

Efficacy of Osteopathic Manipulative Treatment for Low Back Pain in Euhydrated and Hypohydrated Conditions: A Randomized Crossover Trial

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Context: Low back pain (LBP) affects up to 85% of all persons at some time in life and is a condition for which osteopathic manipulative treatment (OMT) has been shown to be beneficial. Measures that can improve the efficacy of OMT would further benefit patients; one such measure, hydration status, was explored in this study.

Objective: To determine whether there is a relationship between a patient's hydration status before OMT for LBP and the outcome of that treatment.

Design: A randomized, single-blind crossover study conducted from March to December 2010.

Setting: Outpatient academic center.

Participants: Eight women and 11 men with LBP of 1 to 12 months duration.

Interventions: Both euhydrated and hypohydrated conditions were achieved in each participant by modifying water consumption for 36 hours before OMT sessions. Participants received 2 sessions of OMT, each in a different hydration condition and with a 1-week washout period in between.

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Main Outcome Measures: Pre- and posttreatment visual analog scale scores for pain, number and severity of somatic dysfunction as scored on the somatic dysfunction severity scale, and number of asymmetric landmarks found on the osteopathic standing structural examination.

Results: Improvements in total and severe number of lumbar somatic dysfunction (*P*=.001 and *P*=.013, respectively) and number of asymmetric landmarks on standing structural examination (*P*=.002) were found to be greater in the euhydrated vs the hypohydrated condition. Participants had a mean of 2 fewer areas of posttreatment somatic dysfunction when euhydrated than when hypohydrated, and they had a mean decrease of 2 asymmetric landmarks on the standing structural examination when euhydrated but none when hypohydrated. Osteopathic manipulative treatment improved self-reported pain immediately after treatment regardless of hydration status.

Conclusion: Outcome measures improved for all participants, with greater improvement observed after participants were treated in the euhydrated condition than when in the hypohydrated condition. It is reasonable for clinicians to recommend that patients increase their hydration to optimize treatment.

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A s early as the 1870s, Andrew Taylor Still, MD, DO, theorized that osteopathic manipulative treatment (OMT) improves blood flow and thus health by allowing the body full opportunity to heal itself.^{1,2} More recently, spinal manipulation has become accepted as a clinically helpful treatment for patients with low back pain (LBP).³⁵ Given that OMT is an effective treatment for patients with back pain and that its effects are elicited through the body's implicit ability to perfuse tissue, the question arises as to whether the body's hydration status affects the efficacy of OMT.

Before discussing the effects of hydration status on human physiology, several terms require defining. *Hypo*-

hydration is defined as reduced total body water. *Euhydration*, or normal body water content, is not a specific point but rather is best represented by a sinusoidal wave that oscillates around an average.⁶ Previous research⁷ indicates that this average euhydration value can be determined by taking the mean of 3 consecutive daily body mass (BM) measurements. Subsequent BM measurements can be compared with this baseline value; a morning body weight within 1% of the baseline indicates euhydration and anything lower indicates hypohydration.⁶⁻⁹ Urine specific gravity (USG), the density of a urine sample relative to that of water, as measured with a refractometer, is another validated method of measuring hydration status.¹⁰⁻¹⁴

Previous studies9-14 have used measures of BM and USG to help quantify the ways in which all physiologic systems in the human body are influenced by hypohydration. The degree of hypohydration dictates the extent of systemic compromise. Hypohydration of up to 5% body weight has been achieved in humans by a variety of methods and with no long-term adverse effects.¹⁵⁻¹⁹ Mild to moderate hypohydration of between 2.5% and 3% can be achieved by water restriction alone.²⁰⁻²² Changes at the level of the muscle tissue have been identified in exercise studies at these levels of hypohydration; they include increased lactate level,9 increased rate of glycogen degradation,^{23,24} elevated muscle temperature,²⁵ and measurable adverse influences on strength, work capacity, performance, and time to exhaustion.9 These findings may be caused by a decrease in blood perfusion of the muscle tissue during the recovery between contractions, secondary to the contracted hypohydrated state of the body.9 Although, to our knowledge, no studies have been published exploring whether such findings are seen after OMT or whether these changes affect treatment outcome, similarities between the effects of exercise and OMT are obvious, particularly for modalities such as muscle energy. Even so, a clinical study that investigates whether and how hydration affects the outcome of OMT is needed.

As LBP is highly prevalent and has been shown to improve with osteopathic care,³⁵ it is a useful condition for investigating the relationship between the efficacy of OMT and hydration status. The cost of back pain in America is in excess of \$85.9 billion annually, higher than that of arthritis (\$80.3 billion) and just below that of cancer (\$89.0 billion); this value represents only health care expenditures and does not include lost earnings or productivity.²⁶ Sixty to seventy percent of all persons are affected by LBP at some time in life,27 with 85% of LBP cases considered nonspecific or biomechanical.28 Low back pain is the second most common reason for visiting a primary care physician.^{29,30} For a condition with such a considerable national and individual toll, any variable that improves the efficacy of OMT could have a considerable effect. The current experimental, randomized, single-blind crossover trial was

designed to determine whether hydration status would affect the efficacy of OMT. We hypothesized that treatment outcomes would be more favorable when patients were in a euhydrated rather than a hypohydrated condition.

Methods Participant Recruitment

The present investigation was a randomized, single-blind crossover study. After obtaining approval from the Midwestern University Institutional Review Board, we recruited 19 study participants with LBP of 1 to 12 months duration from the faculty, students, and staff of Midwestern University in Downers Grove, Illinois.

Participants were included in the study if they had a documented somatic dysfunction of the lumbar spine with or without sacral and pelvic dysfunction and a subjective complaint of LBP of 1 to 12 months duration. Previous studies^{5,30-33} have demonstrated that the majority of primary care patients with LBP show substantial improvement within the first month independent of intervention, making it difficult to demonstrate the value of OMT or any other intervention in patients with acute symptoms. For this reason, 1 month was used as the lower limit. The upper limit of 12 months was selected so that inclusion criteria would not be too narrow and study results would be applicable to more patients with LBP, including those with sub-acute LBP (6-12 weeks duration) and those in the first months of chronic LBP.

Exclusion criteria included previously diagnosed musculoskeletal diseases, nerve root compression or any other findings of frank neurologic signs during physical examination, history of spinal injuries or operations, malignant tumor, scoliosis, a systemic inflammatory disorder, uncontrolled diabetes, urinary tract infection at baseline, and pregnancy.

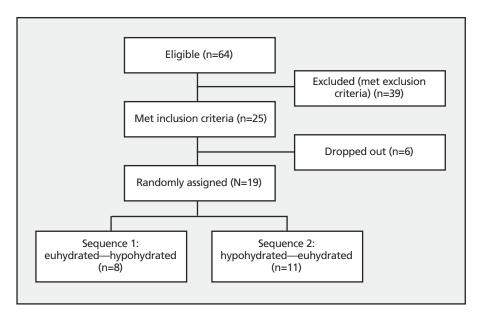
Figure 1 illustrates the flow of participants in the study. At the baseline visit, written informed consent was obtained and participants were randomly assigned to 1 of 2 treatment sequences, according to the crossover study protocol (*Figure 2*). The assignments were generated by a computer and dispersed at the baseline visit.

Power Analysis

Sample size calculation was based on the outcome measure of self-reported pain. A power analysis was performed, and a sample of 18 persons was determined adequate to detect a 15-mm change on a 100-mm visual analog scale (VAS)³⁴ for pain, assuming a power of 80% and an α value of .05.

Treatment

After the baseline visit, when eligibility was established and the treatment sequence was assigned, study participants recorded BM measurements and collected urine



samples for 3 consecutive mornings. This period constituted the first 3 days of the treatment sequence. After a 36-hour period of altered hydration (last 12 hours of day 3, day 4), the first treatment occurred on day 5. On the day of treatment, participants collected their fourth BM and urine samples. They also completed the VAS and had their structural asymmetries and somatic dysfunctions recorded by physician B (R.E.K.) before and after the treatment. The sequence was repeated in the alternate hydration condition, with a washout period of 7 days and a total study involvement of 15 days (*Figure 2*).

All participants received OMT from physician A (K.P.H.), who was blinded to their hydration condition. Osteopathic manipulative treatment involves a dynamic interaction that changes from instant to instant, with the physician modifying treatment according to patient response. Therefore, in keeping with previous findings on OMT and LBP,⁵ the OMT sessions were individualized to each participant and involved any of the following OMT techniques: muscle energy, Still, thrust, counterstrain, articulation, soft-tissue, and myofascial release. There were no limits or restrictions on the number or type of techniques used. Treatments lasted approximately 30 minutes.

Hydration Measures

For the 36 hours immediately preceding treatment in the hypohydrated condition, participants were instructed to discontinue liquid consumption and decrease liquid-rich food consumption, as in a previous study.²⁰ For the 36 hours immediately preceding treatment in the euhydrated condition, participants were instructed to increase water consumption and monitor urine output for pale color. Euhydration and hypohydration levels were determined by (1) BM measurements and (2) USG readings obtained with a digital refractometer. A USG reading of 1.0200 or

Figure 1. Participant flow.

less was considered to indicate euhydration; a USG reading of more than 1.0200, hypohydration.^{935:38} Participants collected their urine samples in sterile collection cups on the morning of 3 consecutive days and kept the samples in a refrigerator until the day of treatment, when the samples were evaluated with a digital refractometer and the mean value recorded as their baseline. Participants were given a digital scale that measured in increments of 0.2 lb

to record their baseline and day-of-treatment weights. Previous studies have established that BM fluctuates by 0.2% to 1% during the course of an average day; thus, the present study defined the hypohydration condition as a decrease in BM by more than 1% from the 3-day mean.^{6-8,39,40} The recorded baseline weights and urine samples were given to the principal investigator at each of the 2 treatment appointments. Participants were considered euhydrated or hypohydrated if they met the BM or USG criterion for either condition.

Outcome Measures

Musculoskeletal dysfunctions involve a complex interaction of physiologic, psychological, and social factors that are difficult to evaluate using conventional biomedical methods³⁴; moreover, OMT techniques often generate results that require more sensitive outcome measures than are currently available. Given these challenges, 4 subjective outcome measures were chosen: (1) total number of somatic dysfunctions, (2) number of severe somatic dysfunctions, (3) number of asymmetric landmarks on the standing structural examination, and (4) self-reported pain on a 100mm VAS. Somatic dysfunction measures were recorded before and after treatment by physician B, who was blinded to the participant's hydration condition and to physician A's diagnosis and treatment. There was a washout period of 7 days between treatments so that outcome measures would more accurately reflect each treatment in isolation rather than treatment sequence.

The somatic dysfunction severity scale is a 4-point scale, as used in the Outpatient Osteopathic SOAP Note Form Series distributed by the American Academy of Osteopathy.⁴¹ The severity scale represents findings from the osteopathic palpatory examination, including tissue texture changes, joint asymmetry, altered range of motion,

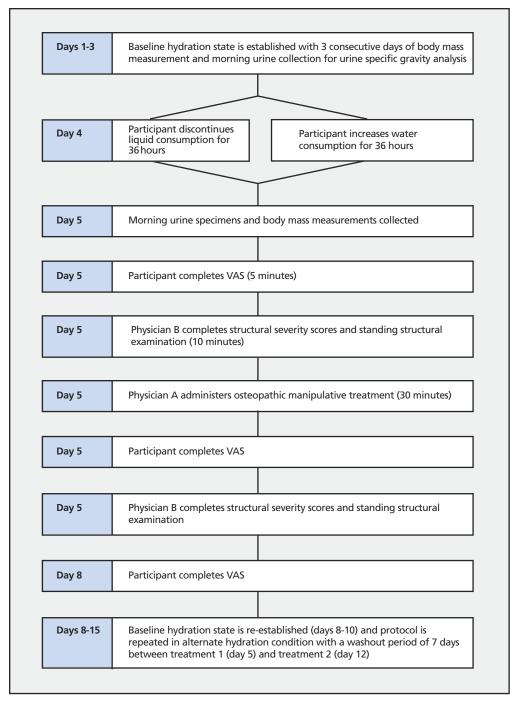


Figure 2. Treatment sequence protocol. Abbreviation: VAS, visual analog scale.

and tenderness.^{42,43} A score of 0 represents no somatic dysfunction; 1, mild dysfunction; 2, moderate dysfunction; and 3, severe dysfunction. In the present study, the total somatic dysfunction severity score was defined as the sum of the severity scores for each of 7 structures (5 lumbar vertebrae, psoas, and sacrum). The severe somatic dysfunction severity score was defined as the sum of moderate and severe dysfunctions (scores 2 and 3). Although they used a 3-point rather than a 4-point severity scale, Snider et al⁴³ used a similar method and provided considerable detail on rating somatic dysfunction.

The standing structural examination included 8 landmarks (occipital condyles, acromion process, inferior angle of the scapula, iliac crest, femoral head, patella, lateral

malleolus, medial arch of the feet) and has been discussed in detail elsewhere.^{44,45} The VAS is 1 of the most commonly used disability inventories and is most effective in assessing change within an individual.³⁴ Participants rated their current pain on the 100-mm VAS before, immediately after, and 3 days after treatment.

Data Analysis

Data were collected on paper forms, which were then transferred to Microsoft Excel spreadsheets (Microsoft Corporation, Redmond, Washington) for data management and then statistical software for analysis. The SPSS statistical software (version 17.0; SPSS Inc, Chicago, Illinois) was used for all analyses. Descriptive statistics were compiled for participants' sex, age, and duration of LBP in months; χ^2 and t tests were used to examine these differences, as well as the hydration status, between the 2 treatment sequences. Nonparametric analysis was used to analyze measures owing to the distribution of the data and underlying constructs. The Wilcoxon signed rank test for related samples was used to compare outcome measures before and after treatments in both the euhydrated condition and the hypohydrated condition. The Wilcoxon signed rank test was used to determine differences in the magnitude of change in somatic dysfunction severity scores, number of asymmetric landmarks, and VAS score between the 2 hydration conditions.

Results

Of the 19 participants who were recruited for the present study, 8 were in sequence 1 (euhydrated for the first treatment, hypohydrated for the second) and 11 in sequence 2 (hypohydrated and then euhydrated). Their mean (standard deviation [SD]) age was 30 (10) years (range, 22-55 years), and the mean (SD) duration of their LBP was 5.4 (0.9) months. There were no statistically significant demographic differences between the 2 treatment sequence groups (*Table 1*). There were no differences in the 4 outcome measures (ie, total and severe somatic dysfunction severity scores, self-reported pain, and structural asymmetry) when they were adjusted for the duration of LBP; outcomes were similar regardless of whether participants had LBP for 1 or 12 months.

Hydration Status

The mean BM change from the baseline hydration state was statistically significant for both euhydrated and hypohydrated conditions (P<.001 for each), as was the mean change from the baseline USG reading (P=.011 for euhydrated; P=.019 for hypohydrated). Thus, the data indicate that participants were in fact at an increased level of hydration for their euhydrated treatments and a decreased level of hydration for their hypohydrated treatments. Comparisons of the 3-day mean BM and USG values before treat-

Table 1.
Efficacy of Osteopathic Manipulative Treatment
for Low Back Pain in Euhydrated and Hypohydrated
Conditions: Characteristics of Participants (N=19)

Characteristic	Sequence 1 ^a	Sequence 2 ^a	P Value
Sex, No.			
Male	7	4	.658
Female	4	4	
Age, mean (SD), y	31.5 (12.1)	27.1 (5.5)	.303
Duration of LBP, mean (SD), mo	5.9 (4.3)	4.7 (3.7)	.545

^a In sequence 1, patients were euhydrated for the first treatment and hypohydrated for the second; in sequence 2, they were hypohydrated for the first treatment and euhydrated for the second.

Abbreviations: LBP, low back pain; SD, standard deviation.

ment sessions for the 2 hydration conditions showed no statistically significant differences (*Table 2*). Thus, participants had a consistent baseline hydration status during the 2 phases of the study. Although all participants achieved adequate euhydration or hypohydration levels as shown by either BM (threshold, 1% BM loss) or USG (threshold, 1.0200) criteria, only 7 participants met both measures for both hydration conditions. Interestingly, there were 7 instances out of the 38 total treatments in which participants had baseline USG readings that met the definition of hypohydration.

The total number of somatic dysfunctions, on a scale of 0 to 3, was recorded for the 5 lumbar vertebral units, psoas, and sacrum. The number of severe somatic dysfunctions, including only those which scored a 2 or 3, was also recorded. The findings for each level of the spine are reported in *Table 3*. In the euhydrated condition, a severe finding persisted after treatment in 1 participant; in the hypohydrated condition, at least 1 severe finding persisted after treatment in 13 participants. Sacral dysfunction, followed by psoas and L1 dysfunction, were the most common pretreatment findings, regardless of hydration condition.

Somatic Findings

Differences were found between pretreatment and posttreatment somatic findings based on the 4-point scale used to evaluate somatic dysfunction in the lumbar, psoas, and sacral regions regardless of hydration condition. Participants in the euhydrated condition had a mean (SD) posttreatment improvement of 3.2 (1.1) total areas of somatic dysfunction out of 7 possible areas (*Table 4*). Participants in the hypohydrated condition had a mean (SD) posttreatment improvement of 1.2 (0.8) total areas of somatic dysfunction. Although participants showed improvement in both conditions, their mean posttreatment improvement was greater in the euhydrated condition (P=.001). For those

Criterion	Euhydra	ted Condition	Hypohydra		
	Baseline	Treatment Day	Baseline	Treatment Day	P Value
Body mass, lb	162.9 (36.2)	163.2 (36.2) ^b	162.9 (36.6)	161.0 (35.8) ^b	.124
Urine specific gravity	1.0192 (0.0036)	1.0126 (0.0051) ^b	1.0182 (0.0060)	1.0268 (0.0054) ^b	.647
 The differences in body mas not differ significantly betw Statistically significant differ hydrated condition). 	een euhydrated and hyp	ohydrated conditions.			

dysfunctions determined to be severe (scores of 2 or 3), there was a mean (SD) improvement of 2.8 (1.1) areas after treatment in the euhydrated condition and 1.7 (1.1) in the hypohydrated condition; again, the difference was statistically significant. These findings support the hypothesis that OMT has more favorable outcomes for euhydrated than hypohydrated patients.

Self-Reported Pain

The VAS scores showed statistically significant improvement immediately after treatment regardless of hydration status (*Table 4*). Three days after treatment, mean scores showed statistically significant improvement for participants in the euhydrated but not the hypohydrated condition. Even so, the improvements in VAS scores collected 3 days after treatment did not differ significantly between hydration conditions (P=.602).

Structural Asymmetry

Statistically significant posttreatment improvements in the

number of asymmetric landmarks on standing structural examination were observed for participants in the euhydrated condition, with a mean resolution of 2.4 landmarks (*Table 4*). For patients in the hypohydrated condition, there was no statistically significant improvement. This finding further supports the hypothesis that OMT has more favorable outcomes for euhydrated than for hypohydrated patients.

Comments

Regarding hydration status, although all participants achieved adequate euhydration or hypohydration levels according to either BM (threshold, 1% BM loss) or USG (threshold, 1.0200) criteria, only 7 participants met both criteria for both hydration conditions. Although this finding suggests that some participants were not as euhydrated or hypohydrated as desired, it allows the findings to be generalized to a clinical population, where patients alter their hydration status under real-world conditions, not in a laboratory. While a more tightly controlled hydration

state—produced, for example, by having participants run in a heated room to dehydrate them to the same point immediately before treatment—would yield a more narrow range of hypohydration, it would also have less clinical applicability. Osteopathic physicians treat patients in a variety of hydration conditions and the present data suggest that patients in a slightly more hydrated state respond to treatment better than those who are less hydrated.

Although participants in both euhydrated and hypohydrated conditions showed an improvement in the total and severe number of somatic dysfunctions,

an	and Hypohydrated Conditions: No. of Total and Severe Somatic Dysfunctions for Participants by Region ^a						าร	
		Euhydrate	ed Conditi	on	I	lypohydrat	ed Condit	tion
	Pretre	atment	Posttr	eatment	Pretre	atment	Posttr	eatment
Region	Total	Severe	Total	Severe	Total	Severe	Total	Severe
L1	16	11	8	0	17	13	14	8
L2	12	10	5	1	12	9	11	5
L3	9	3	3	0	7	4	3	2
L4	4	2	1	0	2	1	2	1
L5	8	5	1	0	9	5	6	0
Psoas	18	7	2	0	17	11	7	1
Sacrum	19	16	5	0	18	15	15	8

Table 3.

Efficacy of Osteopathic Manipulative Treatment for Low Back Pain in Euhydrated

^a On the somatic dysfunction severity scale, a score of 0 represents no somatic dysfunction; 1, mild dysfunction; 2, moderate dysfunction; and 3, severe dysfunction. Total scores represent all regions scored 1 to 3. Severe scores represent only regions scored 2 or 3.

Table 4.

Efficacy of Osteopathic Manipulative Treatment for Low Back Pain in Euhydrated and Hypohydrated Conditions: Changes in Outcome Measures Within and Between Hydration Conditions (N=19)

	Mean (SD)			
Variable	Euhydrated Condition	Hypohydrated Condition	P Value	
Total Somatic Dysfunctions				
Pretreatment	4.5 (0.9)	4.3 (1.2)		
Posttreatment	1.3 (0.9) ^b	3.1 (1.2) ^b		
Difference	3.2 (1.1)	1.2 (0.9)	.001	
Severe Somatic Dysfunctions				
Pretreatment	2.8 (1.1)	3.1 (1.1)		
Posttreatment	0.5 (0.2) ^b	1.3 (1.2) ^b		
Difference	2.8 (1.1)	1.7 (1.1)	.013	
100-mm VAS Score				
Pretreatment	34.7 (13.8)	34.6 (17.4)		
Immediate posttreatment	21.1 (15.6) ^c	22.6 (9.6) ^b		
Difference	13.7 (11.1)	12.0 (12.4)	.485	
Asymmetric Landmarks				
Pretreatment	4.4 (1.9)	4.0 (2.1)		
Posttreatment	2.0 (1.3) ^b	3.6 (2.0)		
Difference	2.4 (1.6)	0.4 (1.9)	.002	

^a *P* values for difference in magnitude between euhydration and hypohydration conditions. All *P* values are from Wilcoxon signed-ranks test for related samples.

^b P<.001 for difference between pre- and posttreatment values within hydration condition.

^c P<.01 for difference between pre- and posttreatment values within hydration condition.

Abbreviations: SD, standard deviation; VAS, visual analog scale.

the extent of improvement in the euhydrated condition was greater than that in the hypohydrated condition, and this difference was statistically significant. Osteopathic manipulative treatment resulted in a mean improvement of 3 total areas scored on the somatic dysfunction severity scale when participants were euhydrated vs 1 when they were hypohydrated.

The distinction between total and severe scores on the somatic dysfunction severity scale was meant to address the fact that patients could have clinically different presentations that might not be represented by total scores alone. For example, a patient who has 5 areas of somatic dysfunction, each scored as a 1 (mild) in severity, is clinically different to an osteopathic physician than a patient with 2 areas of somatic dysfunction scored as 2 and 3 (more severe), even though both patients have the same total score. Considering the improvement in higher-scoring areas of somatic dysfunction as a separate outcome measure helped elucidate the effects of treatment in clinically different patients with the same total scores. Thus, the data suggest that OMT in the euhydrated condition reduced scores to a statistically significant degree for both the total number of dysfunctions and the "key" lesions, as represented by the severe somatic dysfunction severity scores of 2 and 3.

Osteopathic physicians are trained to assess the symmetry of landmarks as a sign of potential disease and to use their resolution or lack of resolution as indicators of treatment success. Although asymmetries may be structural and not functional, the mean improvement of 2.4 fewer asymmetric landmarks for participants in the euhydrated condition indicates that OMT had a positive effect on those asymmetries that were functional. There was no mean difference in the number of asymmetric landmarks after OMT in the hypohydrated condition.

Osteopathic manipulative treatment is effective at lowering selfreported pain immediately after treatment, regardless of hydration status, possibly indicating that the improvement is so noticeable to patients that their state of hypohydration does not negate the perceived difference after treatment. The differences in self-reported pain 3 days after treatment were not statistically significant between

hydration conditions despite the fact that there was, in fact, a statistically significant change after the euhydrated treatment. This finding may be a result of the small sample, the mild nature of the patients' LBP (mean VAS score at baseline, 35 mm), or the relatively small changes in hydration status (10 of the 19 participants were <1% dehydrated according to BM measures). While the data demonstrate a statistically significant improvement in VAS 3 days after euhydrated treatments, it is possible that these factors prevented this finding from achieving a statistically significant difference from the VAS 3 days after hypohydrated treatments.

The main areas of methodologic weakness in the present study were the size of the study group, subjective and temporal nature of the outcome measures, and lack of a placebo control. This study relied on subjective outcome measures, as reported by both the study physicians and the participants themselves. Although these measures were selected because of the confounding nature of objectively measuring OMT outcomes, and although few previous studies have successfully used objective measures, the subjective measures still pose a weakness. The study participants provided information about pain immediately and 3 days after treatment, but they were not followed up long enough to provide information about functional

changes. The short period of euhydration or hypohydration and the lack of extended follow-up for structural and somatic changes are limitations of this study because trends over time or with repeated sessions could not be addressed. Regarding a control group, the potential for LBP improvement with minimal or no treatment in each hydration status was not addressed, and therefore the effects of hydration status alone on LBP cannot be differentiated from those of hydration status coupled with OMT.

Conclusion

To our knowledge, the present study is the first to systematically investigate the effect of hydration status on a body receiving OMT. Results are generally consistent with those of sports medicine studies on hydration, in that hypohydrated bodies had a less impressive response to an intervention than did euhydrated bodies, although our study used subjective and more clinically relevant outcome measures and the sports medicine studies used objective physiologic measures.⁹²³⁻²⁵ Future research is needed to evaluate the lasting effects of hydration beyond 36 hours or across multiple treatment sessions to elucidate further the relationship between hydration status and the efficacy of OMT.

On the basis of the outcome measures of somatic dysfunction severity scale scores, VAS scores, and asymmetric landmarks on the standing structural examination, it is reasonable to recommend that patients increase their hydration to optimize treatment. This study confirms that OMT improves LBP, regardless of the body's hydration status, and it adds another important layer of knowledge about OMT. While replication and expansion of this study are needed, it provides the framework for clinicians to consider how better hydration practices for their patients may help create an environment in the body that is more receptive to the maximum benefit of OMT.

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