



Effect Sizes for Changes in Health and Well-Being Following Treatment With the One-To-Zero Technique in Individuals With Occipito-Atlantal Joint Dysfunction: A Repeated Measures Study

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ABSTRACT

Objectives: The purpose of this study was to determine effect sizes (ES) for changes in self-reported measures of musculoskeletal pain and dysfunction resulting from the one-to-zero method using a repeated measures study design.

Methods: Twenty participants presenting with articular dysfunction of the occipito-atlantal (C0-C1) complex were treated using the one-to-zero method, a high-velocity low-amplitude thrust administered between the C0-C1 complex before treating other restrictive segments in a cephalocaudal direction. The participants completed online questionnaires using Google Forms that assessed aspects of the biopsychosocial model of pain at baseline and within a week after treatment. The questionnaires included the following: (1) Demographic and Health Behavior Survey; (2) Neck Bournemouth Questionnaire (NBQ) or Neck Disability Index (NDI); (3) Beck Anxiety Index (BAI); (4) Insomnia Severity Index (ISI); and (5) 36-Item Short Form Health Survey (SF-36). Paired *t* test or Wilcoxon signed ranks test was performed, dependent on normality. Cohen's *d* values were calculated for each questionnaire score (0.20 indicative of small; ≥ 0.50 medium; and ≥ 0.80 large ES).

Results: The NDI, NBQ, BAI, and ISI had a large ES (all $d \geq 0.80$). In the SF-36, 4 subscales had a small to near-medium ES, 1 subscale had a medium to near-large ES, and the remaining 2 had a large ES ($d \geq 0.80$). The physical and mental component summary had a large ($d = 0.88$) and small ES ($d = 0.35$), respectively.

Conclusion: The effect sizes suggest the one-to-zero treatment induces change in various aspects of the biopsychosocial model. (J Chiropr Med 2023;22:302-312)

Key Indexing Terms: *Atlanto-Occipital Joint; Manipulation, Chiropractic; Surveys and Questionnaires*

INTRODUCTION

Those with chronic musculoskeletal pain have a higher prevalence of insomnia¹ and anxiety, with increased levels of anxiety in those who experience chronic musculoskeletal pain and insomnia.² State anxiety (eg, psychological and physiological transient reactions) has been correlated with increased levels or intensity of neck pain^{3,4} and neck disability.^{4,5} Individuals with chronic musculoskeletal pain and anxiety have reported poor health-related quality of life

compared to those who do not have anxiety.^{5,6} One study reported an association between severity of neck pain and health-related quality of life, where a greater level of neck pain severity is associated with a poor score in the physical and mental component of the Short Form-36 Health Survey (SF-36).⁷ This may suggest that treatment of musculoskeletal pain could impact the psychosocial manifestations that are observed in those who experience pain and comorbidity of anxiety or insomnia.

Chiropractic care for musculoskeletal pain using spinal manipulation or spinal adjustments (defined as manipulation of dysfunctional vertebral segments⁸) has been shown to change levels of pain severity or disability⁹⁻¹² and clinical outcomes pertaining to the biopsychosocial model of pain.^{9,11,13,14} Studies have shown the Neck Bournemouth Questionnaire (NBQ) is sensitive to changes following chiropractic spinal manipulation of the cervical spine.^{9,11} One study showed that patients' anxiety levels and feelings of depression reduced alongside significant improvements in functionality and quality of life.¹¹ The Neck Disability Index (NDI) has been shown to capture long-term¹⁰ or

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short-term¹² improvements in neck pain and disability in those with a dysfunctional cervical spine. The SF-36 and SF-12 have been used in past studies to capture the effectiveness of chiropractic care on subacute or chronic back and/or neck pain,^{13,14} demonstrated as improvements in the physical and mental health summary scores. The previously-mentioned studies have assessed aspects of pain in the context of the psychosocial model, but there is limited research on the effect of chiropractic care on insomnia.¹⁵ The literature suggests that spinal manipulation may improve pain and clinical outcome measures of the biopsychosocial model for some people; however, there is minimal research on a chiropractic technique called one-to-zero (OTZ) tension adjustment and its effects on outcome measures of health and well-being.

Spinal manipulation of a dysfunction between the occiput (C0) and first cervical vertebra (C1), in addition to thoracic spinal adjustment, referred to as the OTZ method, has only been investigated in a case series design for its effects in a population with frozen shoulder syndrome.¹⁶ This case series demonstrated that this technique may improve range of motion in shoulder abduction and reduce levels of pain in those presenting with frozen shoulder syndrome.¹⁶ However, there is no research on the OTZ method and its effects on outcome measures pertaining to the biopsychosocial model.

To date, there is no research that has documented the subjective changes that have been observed in response to the OTZ method. If effect sizes could be determined, then they could be used to calculate sample size for future longitudinal studies or a randomized controlled trial (RCT). Therefore, the purpose of this repeated measure case series design was to determine effect sizes for changes in pain and disability, psychological wellness, and health-related quality of life in those with an articular dysfunction at the C0-C1 joint complex when treated with the OTZ treatment method.

METHODS

Study Design

This study used a repeated measures design, with each participant acting as their own control. The control session was a second baseline measurement session that occurred 2 to 5 days after the first baseline and was designed to control for the effects of repeating the measures. To minimize bias, participants were not informed that the second baseline was intended to act as a control.

Participants

G-power statistical software was used to calculate the number of participants. Since the effect sizes were unknown, we used a large effect size ($d = 0.8$) and a paired

t test design with 1 group and 2 repeated measures. The calculation for a large effect size, alpha error probability = 0.05, and power ($1-\beta$) of 0.90 (set high to minimize the chance of a type II error) indicated that 19 participants would be needed. To allow for dropouts and/or noncompliance with treatment, 24 participants were recruited.

Twenty-four participants presented to a chiropractic practitioner who routinely implements the OTZ technique into practice based on the screening and presence of C0-C1 joint dysfunction. Participants were deemed eligible if they were a patient at a private chiropractic practice in Toronto, Ontario, between 18 to 65 years of age, and if the OTZ technique was recommended by the chiropractor as part of their treatment plan. Participants who reported having a recent neurological problem were excluded from the study. One participant acquired a concussion that resulted in neurological problems, resulting in study withdrawal because they no longer met the inclusion criteria. Participants were also excluded if they dropped out of the study or if they failed to complete the series of questionnaires administered at baseline and/or post-OTZ method. This exclusion criteria resulted in a sample size of 20, 15 women and 5 men (age: 41.20 ± 12.76).

Ethics

This study was approved and conducted in accordance with Ontario Tech University's Research Ethics Board (file no: 14817). Participants provided informed consent, both in writing and orally.

Treatment: OTZ Chiropractic Method

All participants received the OTZ adjustment on the side that presented with recurrent musculoskeletal problems, followed by the other side if clinically indicated. The adjustment was a high-velocity, low-amplitude thrust that was administered in the direction of maximal restriction along the C0-C1 joint complex.¹⁶ This technique was administered after the chiropractor palpated the upper cervical spine to determine the restriction of the C0-C1 joint complex.¹⁶ The general drive of the thrust was posterior to anterior, lateral to medial, and slightly superior to inferior along the C0-C1 articulation.¹⁶ The first treatment session also included high-velocity, low-amplitude thrusts or mobilization of midthoracic and lumbosacral segments with restricted motion. Subsequent treatment sessions addressed dysfunctional vertebral segments as clinically warranted. The OTZ system starts by addressing C0-C1 joint dysfunction(s), followed by the manipulation of remaining dysfunctional segments within the body.

At the initial visit, the chiropractor asked the participant to define their initial presenting state (considering symptoms, pain severity, and mobility) as a score of 10 out of 10. This numeric pain rating scale assessed improvements

for each participant’s symptoms with respect to their own baseline. At each subsequent treatment session, the participant was asked to score how they were feeling relative to their initial visit. Once the participant indicated that their symptoms improved by ~ 80% (with respect to pain and mobility) compared to their initial visit, the original C0-C1 joint dysfunction was deemed to be corrected. Following this, participants were deemed ready to complete the post-OTZ method measures.

Methods

Participants completed a series of questionnaires online using Google Forms at baseline and within a week of their final treatment (post-OTZ method) to either document and/or measure a variety of health outcome measures (Fig 1 shows experimental flow). The survey included the following:

- (1) Demographic and Health Behavior Survey
- (2) NBQ or NDI
- (3) Beck Anxiety Index (BAI)
- (4) Insomnia Severity Index (ISI)
- (5) SF-36

Demographic and Health Behavior Survey

This survey collected age, biological sex, education, employment status, marital status, perceived physical fitness, current substance abuse, and medicinal consumption for heart health and/or mental health and injuries.

Neck Bournemouth Questionnaire

The NBQ was administered to measure changes in the biophysiological connection to neck pain,^{17,18} as it has been found to be a reliable and valid tool to assess

sensitivity to change in those with non-specific neck pain or chronic neck pain.^{17,18} This questionnaire focuses on the dimension of the biopsychosocial model of pain without considering the impact of neck pain on activities of daily living. The NBQ is composed of 7 items, each rated on an 11-point numerical scale from 0 to 10. Total scores for this questionnaire are calculated by adding the score from each item, generating a total score between 0 and 70 (70 reflecting maximal neck pain/disability). A percent change in scores of 36% or more has been used to determine the minimally clinically significant difference/improvement.¹⁹ The equation provided below was used to determine percent change scores for each individual before comparing the average percent change to 36%.

Percent Change Score

$$= \frac{\text{PostOTZ Method Score} - \text{Baseline Score}}{\text{Baseline Score}} \times 100\%$$

Neck Disability Index

The NDI was administered to evaluate self-rated disability due to neck pain of mechanical origin during activities of daily living, such as pain intensity, personal care, lifting, reading, headaches, concentration, work, driving, sleeping, and recreation.^{20,21} Each item in the NDI was measured on a 6-response Likert scale (0 to 5). The total score was calculated by adding the score from each of the 10 items. A maximum score of 50 and minimum score of 0 could be acquired, with 50 representing maximum neck disability and 0 representing no neck disability. The total score was interpreted as follows: 0 to 4 = no disability; 5 to 14 = mild disability; 15 to 24 = moderate disability; 25 to 34 = severe disability; and >35 = complete disability. The percentage

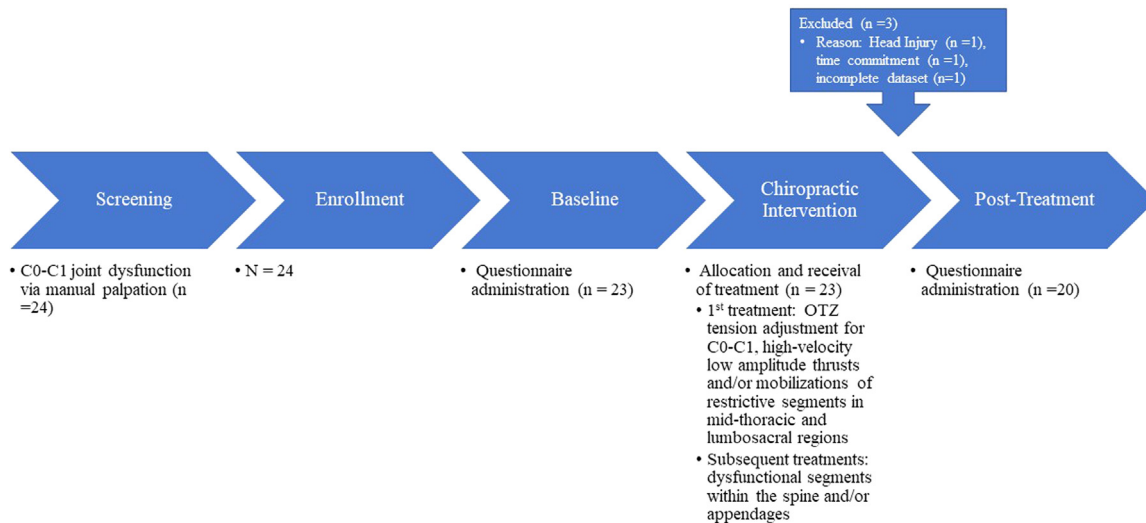


Fig 1. Flowchart of the experimental protocol. OTZ, one-to-zero.

of neck disability was determined by multiplying the total score by 2. Minimum detectable change (90% confidence) of neck disability was found when there was a 5-point or 10%-point change in neck disability. A change of 3.5 points (on a scale out of 50 for individuals with non-specific neck pain) was used to determine the minimally clinically important difference for the sample.²²

Beck Anxiety Inventory

The BAI, a 21-item self-reported inventory, was used to assess anxiety levels²³ because psychosocial factors have been shown to have a strong correlation to variable levels of neck pain.^{3,5,6} Participants were asked to indicate how much they were bothered by each individual symptom during the past month. Each item was rated on a 4-item Likert-type scale and was interpreted as follows: Not at all = 0; Mildly = 1; Moderately = 2; Severely = 3. A grand score was calculated by adding each item's score and interpreted into the following 3 categories: 0 to 21 (low anxiety), 22 to 35 (moderate anxiety), and 36 to 63 (high anxiety). For missing items, the simple mean imputation method was used, where an average score of all values for that individual was inputted for the missing values. This method is generally considered the most unbiased and precise approach for inputting missing items into subscales based on quality of life.²⁴ Total scores and anxiety severity for each participant were then compared, baseline to after treatment.

Insomnia Severity Index

The ISI was used to evaluate patient perception of both nocturnal and diurnal symptoms of insomnia.²⁵ The questionnaire evaluates subjective symptoms of insomnia as well as the degree of concern/distress caused by the difficulties of insomnia.²⁵ The ISI consists of 7 items, which were all scored between 0 to 4 (0 representing no concern/difficulty and 4 representing maximum concern/difficulty). A total score out of 28 was calculated by adding the score of all 7 items. Interpretation of the participant's insomnia severity was represented as follows: 0 to 7 = no clinically significant insomnia, 8 to 14 = subthreshold insomnia, 15 to 21 = clinical insomnia (moderate severity), and 22 to 28 = clinical insomnia (severe). Three versions of this measurement are available (patient, clinician, and significant other); the patient version was used for this present paper.

36-Item Short Form Health Survey

The SF-36 was used to measure generic functional health status in both general and specific populations.²⁶⁻²⁸ The 36-item survey addresses the following 8 health concepts: (1) physical functioning; (2) role limitations due to

physical health; (3) bodily pain; (4) general health; (5) vitality; (6) social functioning; (7) role limitations due to emotional problems; and (8) mental health. The questionnaire creates a multiscore profile through 8 scales alongside a physical and mental component measure derived through norm-based scoring. For each of the 36 items in this questionnaire, participants were required to answer each question from a choice between 2 to 6 possible responses. Original responses given were later transformed to a 0 to 100 scale, 100 representing best possible health (no disability). Item scores were then grouped into 8 different scales. Mean scores were calculated for each of the 8 scales. These scores were then used towards the calculation of 2 aggregate summary scores—the physical component score and the mental component score.

Statistical Analysis

Twenty participants who completed the study were included in the statistical analysis. Shapiro-Wilk Test was used to assess for normality for each score and/or subscale of each questionnaire, except the demographic data. The following data sets were normally distributed at baseline and post-OTZ method: total score of NBQ, anxious and control of neck pain question in NBQ, BAI, ISI, 5 subsections (Bodily Pain, General Health, Vitality, Social Function, and Mental Health), and both component scores of SF-36. For these datasets, a paired sample *t* test was performed. The remaining data sets violated tests of normality, and the Wilcoxon signed-rank test was performed. Since the goal of the feasibility study was to determine effect sizes for each outcome measure, statistical corrections for multiple measurements were not included. Statistical significance was set at $P < .05$. Estimates of effect sizes were reported as Cohen's *d* values, where 0.2 is considered a small effect size, 0.5 reflects a medium effect size, and 0.8 is indicative of a large effect size.^{29,30} All statistical tests were run using SPSS version 26 (IBM Corp.).

RESULTS

Demographic and Health Behavior Survey

Table 1 provides the demographics and characteristics of the 20 participants.

Pain Characteristics

Table 2 provides the clinical characteristics that were experienced with this sample population. The frequency and duration of these symptoms varied between recurrent/ongoing/on-and-off episodes, acute, or chronic. Three participants experienced pain in 1 region of the body, while the remaining experienced pain in various areas of the body.

Table I. Demographic and Characteristics of Sample

Demographic/Characteristics	n	
Biological sex		
Female	15	
Male	5	
Age group		
Age, mean ± SD, y	41.20 ± 12.76	
18-25	4	
26-35	2	
36-45	4	
46-55	10	
56-65	0	
Occupational status		
Part-time	3	
Full-time	16	
Not working	1	
Employment		
Professional	10	
Skilled labor	5	
Non-skilled labor	4	
Not applicable	1	
Marital status		
	Baseline n	Post-OTZ Method n
Married	9	10
Divorced	1	0
Widow/widower	0	0
Single, never married	10	10
Education		
Did not graduate high school	0	0
Graduated high school or trade school	7	6
Attended/attending college or university but does not have qualification	5	7
Received bachelor's degree	7	6
Post-graduate work at a university	1	1

(continued)

Table I. (Continued)

	Baseline n	Post-OTZ Method n
Marital status		
Current substance use (alcohol, drugs, cigarettes)		
No use	5	5
Slight social use	15	15
Great social use	0	0
Abuse	0	0
Severe abuse	0	0
Are you currently taking medications for high blood pressure or heart disease?		
Yes	1	1
No	19	19
Are you currently taking psychotropic drugs (ie, tranquilizers or anti-anxiety medication)?		
Yes	0	0
No	20	20
Have you suffered any traumatic injury?		
Yes	2	0
No	18	20
Perceived physical fitness		
Very fit	0	0
Fit	3	4
Average fitness	10	11
Unfit	7	5

OTZ, one-to-zero.

OTZ Method: Treatment Sessions

At the first treatment session, the OTZ tension adjustment was administered bilaterally for 18 participants and unilaterally for 2 participants. Over the course of the treatments, 6 participants received an additional adjustment unilaterally, while 4 participants received another OTZ adjustment bilaterally. Two participants received a total of 3 OTZ tension adjustments for their unilateral articular dysfunction. The average number of treatments was 10 (range 5-23). Of the 20 participants, 10 individuals received massage therapy in addition to their chiropractic treatment for issues other than their C0-C1 dysfunction.

Table 2. Clinical Characteristics of Individuals With C0-C1 Articular Dysfunction

Clinical Characteristics	No. of Participants
Region of pain	
Neck	12
Shoulder	6
Arm	3
Elbows	0
Upper back	0
Mid-back	2
Low back	12
Hip	3
Leg	2
Knee	3
Ankle	1
Heel	1
Feet	1
Frozen shoulder	1
Headaches	2
Pain exacerbated with poor posture, work/exercise	1
Referred/radiating pain	3
Muscle tightness	3
Numbness of extremities	1
Feeling off/imbalanced	1
Easily fatigued	0
Lack of sleep	2

NBQ and NDI

The NBQ was given with the original questionnaire package at the beginning of the feasibility study. Results from the first 6 participants showed that this questionnaire was limited in deciphering the impact neck pain had on participant's activities of daily living. Given that this study sought to measure effect sizes in order to determine the best outcome measures, the decision was made to replace the NBQ with the NDI, as this questionnaire is more focused on measuring the effect that neck pain has on daily activities. Despite the replacement of the NBQ, 3 questions

from the NBQ pertaining to psychometrics were administered alongside the NDI. Fourteen participants completed the NDI questionnaire, and 20 participants completed the 3 questions from the NBQ.

The Wilcoxon signed rank tests indicated that NDI scores post-OTZ method ($M = 3.29$, $SD = 4.46$) were statistically different from baseline ($M = 13.29$, $SD = 6.27$), with a large effect size ($Z = -3.30$; $P < .001$; $d = 1.36$) (Fig 2). Only 12 out of 14 participants experienced neck pain, and these individuals demonstrated a 14.83 ± 5.31 change in points, meeting the criterion for minimally clinical important difference (>3.5 points) and minimum detectable change (>5 points), indicating a clinically important improvement in neck disability. These participants had a reduction in neck disability of $72.89 \pm 31.55\%$, and with the 2 participants without neck pain (all 14 participants), there was a reduction in neck disability of $76.76 \pm 30.65\%$. The required sample size to show a statistical difference between 2 groups at 2 different time points for an α of .05 and a power ($1-\beta$) of .95 is 8 (4 per group).

Of the 6 participants who completed the NBQ at the beginning of the study, the results from baseline ($M = 34.00$, $SD = 11.85$) and post-OTZ method ($M = 12.33$, $SD = 10.67$) suggest that there was a large effect size ($T_{(5)} = 5.69$; $P = .013$; $d = 2.32$). The average percent change in scores was $66.86\% \pm 29.15\%$ (reduction in biopsychosocial aspects of self-reported neck pain) following the OTZ method, which was greater than 36%, indicating a clinically significant improvement. The required sample size to show a statistical difference between 2 groups at 2 different time points for an α of .05 and a power ($1-\beta$) of .95 is 6 (3 per group).

Table 3 provides the group averages, percent change, statistically significant value, effect size, and required sample of the 20 participants who completed the 3 questions from the NBQ.

Beck Anxiety Index

The results from baseline ($M = 17.15$, $SD = 9.26$) and post-OTZ method ($M = 7.65$, $SD = 5.00$) for the BAI indicates there was a large effect size ($T_{(19)} = 5.39$; $P < .001$; $d = 1.21$). Figure 3 provides a graphical presentation of the interpretation of BAI scores. There was a $52.89\% \pm 33.31\%$ reduction in self-reported anxiety levels following the OTZ method. The required sample size to show a statistical difference between 2 groups at 2 different time points for an α of .05 and a power ($1-\beta$) of .95 is 12 (6 per group).

Insomnia Severity Index

The results from baseline ($M = 10.35$, $SD = 5.41$) and post-OTZ method ($M = 6.45$, $SD = 4.11$) for the ISI indicate there was a large effect size ($T_{(19)} = 3.27$; $P = .002$; $d = 0.73$) (Fig 4). There was a $32.66\% \pm 53.51\%$ reduction

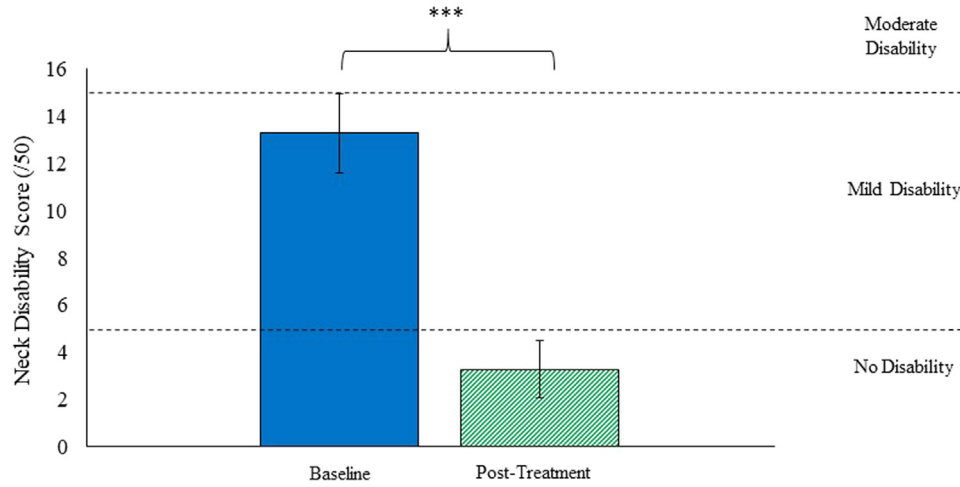


Fig 2. Average neck disability score at baseline (solid blue bar) and following the OTZ treatment (patterned green bar). Error bar represents SD. Asterisk indicates a significant effect of time. ^aP < .001.

Table 3. Group Average Scores at Baseline and Post-OTZ Method Measures of the Psychometric Questions From NBQ

	Baseline	Post-OTZ Method	Percent Change	P Value	d	Required n
NBQ Questions						
Over the past week, how anxious (tense, uptight, irritable, difficulty in concentrating/relaxing) have you been feeling?	4.90 ± 2.40	1.45 ± 1.93	-77.73% ± 28.10%	<.001	1.99	8 (4/group)
Over the past week, how depressed (down-in-the-dumps, sad, in low spirits, pessimistic, unhappy) have you been feeling?	3.40 ± 2.91	0.75 ± 1.61	-80.45% ± 33.51%	<.001	1.01	16 (8/group)
Over the past week, how much have you been able to control (reduce/help) your neck pain on your own?	5.40 ± 2.66	2.10 ± 2.94	-58.29% ± 64.03%	<.001	1.04	16 (8/group)

Note: d (Cohen's, effect size); n (sample size).

NBQ, Neck Bourmemouth Questionnaire; OTZ, one-to-zero.

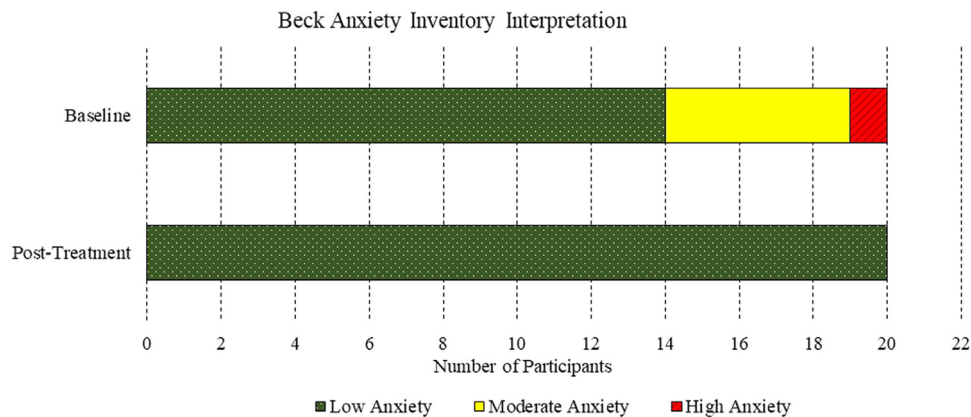


Fig 3. Graphical representations of the BAI interpretation. BAI, Beck Anxiety Index.

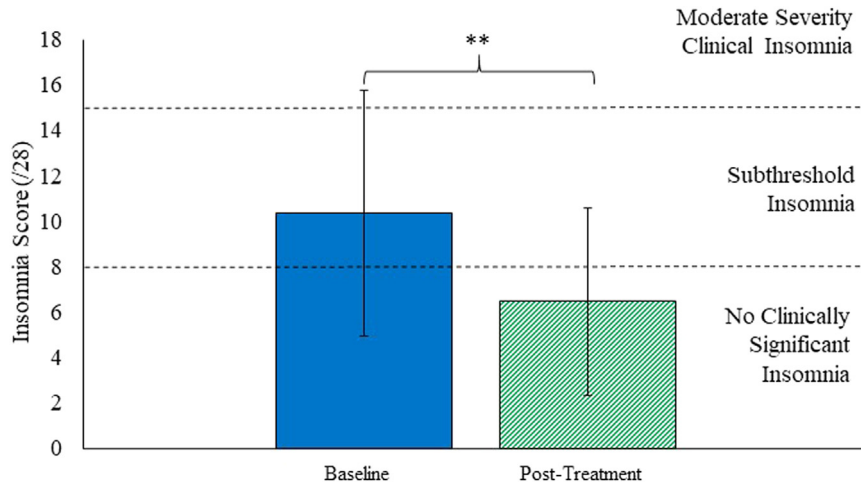


Fig 4. Average Insomnia score of the Insomnia Severity Index at baseline (solid blue bar) and following the OTZ treatment (patterned green bar). Error bar represents SD. Asterisk indicates a significant effect of time. ^aP < .01. OTZ, one-to-zero.

in self-reported severity of insomnia following the OTZ method. The required sample size to show a statistical difference between 2 groups at 2 different time points for an α of .05 and a power $(1-\beta)$ of .95 is 28 (14 per group).

36-Item Short Form Health Survey

The subscales on physical functioning, general health, social functioning, and role limitations due to emotional

problems had a small to near-medium effect size ($0.2 < d < 0.5$). Vitality had a medium to near-large effect size ($0.5 < d < 0.8$). Physical functioning, bodily pain, and mental health had a large effect size ($d > 0.8$). The physical component score had a larger effect size compared to the mental component summary. The change in health status of the SF-36 had a near-medium effect size ($d < 0.5$). Table 4 provides the mean scores at baseline and post-OTZ method, percent improvement, statistical

Table 4. Average \pm SD Scores of SF-36 Subscales at Baseline and Post-OTZ Method

Subscales	Baseline	Post-OTZ method	Percent Improvement	P	d	Required n
Physical functioning	64.96 \pm 29.96	78.61 \pm 29.96	80.29% \pm 176.11%	.043	0.41	80 (40/group)
Role physical	46.25 \pm 39.13	86.25 \pm 27.48	87.22% \pm 124.67%	.002	0.92	18 (9/group)
Bodily pain	41.88 \pm 18.71	71.88 \pm 22.69	94.80% \pm 73.25%	<.001	1.59	8 (4/group)
General health	59.21 \pm 11.21	64.74 \pm 13.89	17.33% \pm 23.72%	.03	0.46	64 (32/group)
Vitality	46.33 \pm 18.66	58.00 \pm 16.76	42.35% \pm 82.89%	.002	0.74	26 (13/group)
Social functioning	69.38 \pm 26.74	76.88 \pm 24.76	24.54% \pm 51.18%	.12	0.27	182 (91/group)
Role emotional	66.67 \pm 43.26	80.00 \pm 33.16	3.13% \pm 34.54%	.14	0.31	138 (69/group)
Mental health	64.60 \pm 15.91	75.20 \pm 13.15	23.04% \pm 26.17%	<.001	1.15	14 (7/group)
Component summary						
Physical	37.22 \pm 11.81	47.13 \pm 8.73	45.99% \pm 56.23%	<.001	0.88	20 (10/group)
Mental	44.57 \pm 11.08	47.44 \pm 9.49	11.23% \pm 32.56%	.074	0.35	110 (55/group)
Change in health status	40.00 \pm 28.56	56.25 \pm 26.75	75.00% \pm 111.64%	.051	0.46	64 (32/group)

Note: d (Cohen's, effect size); n (sample size).

OTZ, one-to-zero; SF-36, 36-Item Short Form Health Survey.

significance between these 2 time points, the effect sizes, and the required sample size.

DISCUSSION

This study demonstrated that the NDI or NBQ, BAI, ISI, and SF-36 were able to capture changes in pain/disability, anxiety, insomnia, and health-related quality of life outcomes following chiropractic care using the OTZ method. The NDI, NBQ, BAI, and ISI had large effect sizes, reflected by a Cohen's *d* greater than 0.8. Four of the subscales from SF-36 had a small to near-medium effect size, 1 subscale had a medium to near-large effect size, and the remaining had a large effect size. The mental component summary score of the SF-36 had a near-medium effect size, while the physical component summary score had a large effect size. Change in health status of the SF-36 had a near-medium effect size.

The improvements in measures of the biopsychosocial model have been postulated to be result of restored function in cranial nerve 11 (CNXI), the spinal accessory nerve, via the C0-C1 joint complex, leading to restored neuromechanical function of the trapezius which is innervated by CNXI.¹⁶ Another possible rationale for these changes could be the association between pain mechanisms or processing, prefrontal cortex processing,^{31,32} sensorimotor integration,^{8,33-35} and/or pain and autonomic reactivity/arousal,^{32,36,37} which are known to occur following high-velocity low-amplitude adjustments.

The study sought to determine effect sizes in order to determine the required sample size to conduct an RCT with 2 groups with a dysfunctional C0-C1 joint complex. According to the effect sizes for the assessment of neck pain and/or disability, a sample of 6 participants (3 per group) and 8 participants (4 per group) are needed for the use of the NBQ and NDI, respectively. Twelve participants (6 per group) are needed for the assessment of changes in state level anxiety, using the BAI. A total of 28 participants (14 per group) are needed for the assessment of changes in insomnia. Based on the individual's subscales and component summary scores within SF-36, a range of sample sizes between 8 (for bodily pain score) and 182 (for social functioning score) are required to see a statistical difference between 2 groups at 2 time points. To measure an overall change in health status of the SF-36, the required sample size is 64 (32 per group).

Limitations

Ten participants received adjunct treatment to address other issues, and it is possible that the effect sizes may reflect the results of combined treatment rather than OTZ alone. As this is a pragmatic trial, the findings cannot be attributed to causation, but the effect sizes reported in this

study can be used to determine sample sizes for future RCT. Additionally, participants had a range of presenting symptoms and some did not have neck pain at all. This makes comparison to clinically significant differences challenging for these measures. However, we have compared the percentile changes for those who did have neck pain to minimal clinically significant differences as reported in the literature for the NBQ and the NDI.

Future Studies

The results from this study suggest further investigation into the OTZ method. The changes in biopsychosocial measures suggested that the OTZ treatment method may potentially impact health and well-being in individuals with an articular dysfunction at the occipito-atlantal joint complex. The NBQ and NDI surpassed the threshold of minimally clinical important difference, suggesting that the OTZ treatment method results in clinically important changes with respect to neck disability and biopsychosocial factors associated with neck pain in those who have neck pain in conjunction with their C0-C1 joint dysfunction. Therefore, for a future RCT, an additional scale questionnaire could be used to capture severity of pain and pain-related disability, such as the chronic pain grade scale. To attribute these changes to the effect of OTZ, further research is required using an RCT, which could be powered based on the effect sizes provided by the current research.

CONCLUSION

This pragmatic quasi-experimental repeated measured study design found the effect sizes of self-reported measures of musculoskeletal pain and dysfunction, specifically aspects of the biopsychosocial model. The effect sizes indicate that the questionnaires used were able to capture changes in pain/disability, anxiety, insomnia, and health-related quality of life outcomes following chiropractic care using the OTZ method.

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CONTRIBUTORSHIP INFORMATION

Concept development (provided idea for the research): H.H., B.M.

Design (planned the methods to generate the results): U.A., H.H., B.M.

Supervision (oversight, organization and implementation): U.A.

Data collection/processing (experiments, organization, or reporting data): U.A., V.B.

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Practical Applications

- This study measured effect sizes for changes in self-reported measures of musculoskeletal pain and dysfunction resulting from the one-to-zero method using a repeated measures study design.
- We found that Neck Disability Index, Neck Bournemouth Questionnaire, Beck Anxiety Index, and Insomnia Severity Index had large effect sizes.
- The effect sizes suggest the one-to-zero treatment induces change in various aspects of the biopsychosocial model.

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