The Working Mechanism of Manual Therapy in Participants With Chronic Tension-Type Headache

Chronic tension-type headache (CTTH) is associated with cervical spine impairments, including restricted range of motion (ROM) of the cervical spine, reduced neck flexor endurance, and greater forward head posture. These associations have led to the development of a biomechanical model for CTTH. According to this conceptual model, cervical dysfunction elicits headache through peripheral or central pain mechanisms; therefore, improvement of cervical dysfunction by physical treatment should reduce headache.

Based on this model, we conducted a randomized clinical trial (RCT) to determine the effectiveness of multimodal manual therapy, including mobilization of the cervical spine, isometric training of neck flexors, and posture correction. A reduction in headache days of 50% or greater was the clinically relevant outcome. A significant difference of 87.5% versus 27.5% in outcome was found in favor of manual therapy, compared to usual care by the general practitioner, in participants with CTTH.

The extent to which specific elements (mobilization, isometric training of neck flexors, or posture correction) contribute to the effectiveness of manual therapy is unknown, and information about the working mechanisms of manual therapy in participants with headache is urgently needed. The biomechanical model mentioned above suggests that increased ROM of the cervical spine, increased neck flexor endurance, and a less pronounced forward head posture may offer potential explanations for the effect of manual therapy in reducing headache frequency. To explore the working mechanism of manual therapy, we investigated whether the above aspects of cervical spine function (cervical ROM, neck flexor endurance, and forward head posture) were mediators of the effect of manual therapy on headache frequency.

METHODS

Participants

For the mediation analyses, we used the combined data obtained from 2 studies, a multicenter, prag-
matic RCT (Netherlands Trial Register, TR 1074) and a parallel multicenter prospective cohort study of participants with CTTH who were recruited from 14 general practices in an urban area near Amsterdam, the Netherlands. From the pragmatic RCT, 82 participants were randomized either to a manual therapy group (n = 41) or to a control group (n = 41) that received usual care from a general practitioner. One hundred four participants who refused randomization because of a preference for manual therapy were entered into the cohort study. Participants in the cohort study fulfilled the same inclusion and exclusion criteria and received identical measurements and manual therapy as participants in the RCT.

To be included in the study, participants had to be between 18 and 65 years of age and to fulfill the criteria for CTTH according to the classification of headaches of the International Headache Society, which defines CTTH as headache occurring at least 15 days per month, on average, for a period of more than 3 months and lasting hours or being continuous in duration. Additionally, the headache had to have at least 1 of the following characteristics: (1) bilateral location, (2) pressing/tightening (nonpulsating) quality, (3) mild or moderate intensity not aggravated by normal physical activity such as walking or climbing stairs, and (4) only 1 of photophobia, phonophobia, or mild nausea, without moderate or severe nausea or vomiting.

Exclusion criteria were rheumatoid arthritis, suspected malignancy or brain tumor, and pregnancy. According to the International Headache Society classification of headache attributed to medication overuse, we excluded participants with an intake of triptans, ergotamines, or opioids on 10 or more days per month or of simple analgesics on 15 or more days per month on a regular basis for at least 3 months. Participants were also excluded if they had received manual therapy in the 2 months before the study or were not able to read and write Dutch.

The selection and informed-consent procedures, baseline and follow-up measurements, and intervention protocol of this study have been previously published. The study protocol was approved by the Medical Ethics Committee of the VU University Medical Center in Amsterdam, the Netherlands.

**Examination**

Baseline measurements included a standardized history of headache, general health, a physical examination carried out by an independent research assistant, and several participant self-report measures. Expectations regarding treatment outcome were measured on a Likert scale ranging from 0 (no result) to 7 (good result).

**Outcome Measures**

As described by Andrasik et al, we defined a 50% or greater reduction in headache days as the clinically relevant outcome (yes, 1; no, 0). To measure frequency of headache days, participants kept a headache diary to report their headaches during 2-week periods before the baseline and follow-up measurements. A 2-week period is sufficient to assess tension-type headache and is recommended for outcome measurement in headache research.

**Potential Mediators**

Cervical ROM was measured with the CROM device (Performance Attainment Associates, Lindstrom, MN) in degrees. The active ROM in all directions (flexion, extension, right and left rotation, and right and left lateroflexion) was examined with the participant in a seated position. The intratester and intertester reliability of this measure have been shown to be good, with intraclass correlation coefficients (ICCs) of greater than 0.80.

Neck flexor endurance was assessed as the isometric strength of the neck flexors and scored as the number of seconds the patient could hold his or her head away from the table when lying on his or her back. This procedure has been described by Harris and colleagues, and 2 studies have reported good to excellent intratester reliability of this test (ICC = 0.82-0.93). Forward head posture was defined as the cranio cervical angle between the horizontal line passing through C7 and the line extending from C7 to the tragus of the ear. This angle was measured using a lateral digital photograph with a digital camera (R707.5; Hewlett-Packard Company, Palo Alto, CA). The photograph was taken with the participant in a seated position. A smaller cranio cervical angle indicates a greater forward head posture (FIGURE 1). The reliability of photographic measurement of the cranio cervical angle is good (ICC = 0.86).

**Interventions**

Manual therapy was applied by 4 manual therapists, who were trained in the treatment protocol in 2 two-hour sessions and received the treatment manual and patient booklets with home exercises. The manual therapists had an average of 10 years of experience, had worked at 3 different locations, and were members of the national association of manual therapists. Manual therapy was restricted to a maximum of 9 sessions (30 minutes each) during a period of 8 weeks, and had 3 goals.

The first goal was mobilization of the cervical and upper thoracic spine in all directions. The therapeutic procedures for these mobilizations consisted of low- and/or high-velocity mobilization and
home exercises. All mobilizations started with active mobilization (hands-off techniques), and, if necessary, the manual therapist proceeded with passive mobilizations (hands-on techniques). In addition to mobilization techniques, soft tissue techniques (muscle stretching and deep muscle frictions) could be used to reduce cervical muscular tension and pain.

The second goal was to train the neck flexor muscles in isometric strength. This training consisted of low-load neck flexor exercises, as described by Jull,\(^2\) using a stabilizer. In case a stabilizer was not available, the participants were instructed to pull their chin in (atlanto-occipital cervical flexion) and to hold this position (isometric contraction) for 10 to 20 seconds, while lying on their back in a horizontal position. These isometric exercises were also instructed in combination with retraction of the cervical spine in a sitting position. Participants were asked to perform these exercises at least twice a day.

The third goal of treatment was postural correction of the head and the cervical and thoracic spines. In an upright sitting position, the manual therapist instructed the participant to straighten the thoracic spine with a simultaneous retraction of the cervical spine. Neck flexor exercises were incorporated in all exercises of postural correction in sitting and standing positions. The manual therapists underlined the importance of this posture correction.

Depending on the participant’s condition and outcome, the manual therapist decided at each session which type of mobilizations or exercises to select for the treatment protocol. Besides posture correction exercises, participants were given advice about their workplace, especially those who performed sedentary work for at least several hours a day. Every participant received a booklet with a full description of all home exercises and written instructions by the manual therapist on type, frequency, and duration of the exercises. The participants were instructed by their manual therapist to continue their exercises after their treatment period, focusing on retraction of the cervical spine and posture correction.

Participants in the control group were provided with usual care by their general practitioners. In 1 meeting, the general practitioners were informed to follow their national clinical guideline for the management of headache.\(^2\) According to this guideline, the general practitioners provided information, reassurance, and advice, and discussed the benefits of lifestyle changes. If necessary, the general practitioners prescribed or changed analgesics or nonsteroidal anti-inflammatory drugs.

**Statistical Analysis**

Descriptive analysis was used to describe and compare the characteristics of participants of the trial and cohort study. Change was assessed as the change in score from baseline to the 8-week follow-up for cervical ROM (the sum of degrees for all directions), neck flexor endurance (seconds), and cranio-cervical angle (degrees).

**FIGURE 2** shows the model used to analyze potential mediation between the independent variable treatment (manual therapy versus usual care), the mediator (cervical ROM or neck flexor endurance or forward head posture), and the dependent variable (50% or greater reduction in headache days).

According to the steps described by Baron and Kenny,\(^3\) three regression analyses were conducted. First, a logistic regression was performed to estimate the effect of manual therapy on outcome, with a 50% or greater reduction in headache days as the dependent variable, so that manual therapy had to be significantly related to a 50% or greater reduction in headache days (total effect, path c). Second, linear regression to estimate the effect of manual therapy on the mediator: manual therapy must be significantly related to the mediator (path a). Third, a logistic regression to regress the dependent variable on both the mediator and the independent variable was performed, so that the mediator had to be significantly related to a 50% or greater reduction in headache days (path b). In this logistic regression, the direct effect (path c’) of manual therapy (manual therapy in the same model as the mediator) on the outcome (50% or greater reduction in headache days) had to be smaller than the total effect (path c).

The mediation effect was estimated by the product-of-coefficients method (path a times path b), and related confidence intervals (CIs) were calculated using bootstrapping techniques (2000 samples).\(^2\) On the basis of the standardized coefficients, we also assessed the proportion of mediated effect: (c – c’)/c × 100%. Analyses were done using SPSS (SPSS Inc, Chicago, IL) and Stata (StataCorp LP, College Station, TX) software.

**RESULTS**

Between June 2007 and March 2009, a total of 204 participants were recruited, and follow-up measurements were completed in September 2009. **FIGURE 3** summarizes recruitment and retention of participants throughout the study. For all included participants (n = 186), the baseline characteristics are described in **TABLE 1**. Baseline characteristics, as well as expectations of treatment outcome, were similar between participants of the cohort study and the RCT. **TABLE 2** includes a description of the mean scores at baseline and 8-week follow-up and the change scores at 8 weeks of the
potential mediators (cervical ROM, neck flexor endurance, and forward head posture), as well as the results for the primary outcome measure (reduction in headache frequency) at 8-week follow-up. Data from 182 participants were available for mediation analysis. The results of the regression analyses are displayed in TABLE 3.

The analysis concerning cervical ROM as a potential mediator showed a significant total effect (path a) of manual therapy (P<.05) compared to usual care on 50% or greater reduction in headache days. Manual therapy was also significantly related to change in cervical ROM (path a). Change in cervical ROM was not significantly related to a 50% or greater reduction in headache days (path b) (0.00; 95% CI: –0.01, 0.01). The direct effect (path c) was not smaller than the total effect (path c) (odds ratio [OR] = 15.3; 95% CI: 6.3, 37.3 versus OR = 15.1; 95% CI: 6.5, 43.8). The results after bootstrapping showed that the mediated effect was not significant and that the proportion of mediated effect was very small.

Concerning neck flexor endurance as a potential mediator, manual therapy was significantly related to change of this variable (path a) in the next regression analyses. Neck flexor endurance was also significantly related to a 50% or greater reduction in headache days (path b) (0.05; 95% CI: 0.02, 0.08). The direct effect of manual therapy on a 50% or greater reduction in headache days (OR = 9.5; 95% CI: 4.3, 25.8) was smaller than the total effect (OR = 15.1; 95% CI: 6.5, 35.9). The mediated effect after bootstrapping was significant (0.13; 95% CI: 0.06, 0.19). The proportion of mediated effect was 24.5%. In other words, the effect of manual therapy on a 50% or greater reduction in headache days partly depended on change in neck flexor endurance.

The mediation analysis for forward head posture showed that manual therapy was significantly related to change of this variable (path a). Forward head posture showed, however, no significant...
relation to a 50% or greater reduction in headache days (path b) (0.05; 95% CI: –0.01, 0.11) and a minor reduction in direct effect (OR = 10.4; 95% CI: 4.1, 26.3) versus the total effect (OR = 11.5; 95% CI: 4.6, 28.8) of manual therapy on a 50% or greater reduction in headache days. The mediation effect (0.03; 95% CI: –0.02, 0.08) was not significant, and the proportion of mediated effect was small.

**DISCUSSION**

**Main Findings**

This study was designed to explore possible working mechanisms in manual therapy, using preselected potential mediators that reflect the goals of manual therapy. We found that increased neck flexor endurance mediated 24.5% of the effect of manual therapy on the reduction in headache days. Cervical ROM and forward head posture did not mediate the effect of manual therapy.

The present study monitored cervical ROM as an indicator of the effect of spinal mobilization consisting of high- and low-velocity thrust techniques and found no mediation effect of cervical ROM on manual therapy in reducing headache days. This finding further supports systematic reviews that have reported inconsistent and inconclusive effectiveness of physical treatments in tension-type headache at mobilization.24,25,26 Considering these results and reported risks of cervical high-velocity thrust mobilization techniques,1 clinicians should reconsider the use of these techniques in participants with CTTH.

The second goal of treatment was to increase neck flexor endurance with a specific training program. Increased neck flexor endurance mediated the effect of manual therapy on headache frequency. Previously, specific training of neck flexors was shown to be effective in reducing the number of headache days in CTTH.28 Specific training of neck flexors appears to be a promising key element of treatment in participants with CTTH. As the results of previous studies indicate that forward head position and decreased neck flexor endurance are associated with CTTH, we hypothesized that improvement of endurance of the neck flexors would contribute to maintaining an upright position of the cervical spine and to supporting the muscular stabilization of the upper cervical segments in this position. An explanation of why this mechanical approach may lead to a reduction of headache frequency may be found in the role of local muscle tenderness and peripheral and central sensitization. Our study, however, was not designed to directly identify which underlying neurological mechanism could explain the effect of neck flexor endurance on reduction in headache days. Therefore, in future research, trigger points or algometry in the cephalic and extracephalic regions should be investigated as treatment mediators of the effect of exercise. Meanwhile, based on our findings, we recommend endurance training of neck flexors in the treatment of patients with CTTH.

The third goal of treatment was to decrease forward head posture by posture correction in sitting and standing positions. The correlation between increased forward head posture and chronic headache is frequently reported in the literature, indicating that forward head posture may be a potential mediator of manual therapy. However, a
### TABLE 3

Mediation Analysis: Results of Logistic and Linear Regression Analysis

<table>
<thead>
<tr>
<th>Mediator/Path, Regression Model</th>
<th>Dependent Variable</th>
<th>Independent Variable</th>
<th>Regression Coefficient*</th>
<th>Odds Ratio*</th>
<th>Mediated Effect†</th>
<th>Proportion of Mediated Effect, %</th>
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</thead>
<tbody>
<tr>
<td>Cervical ROM (n = 178)</td>
<td></td>
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<tr>
<td>Path a, logistic</td>
<td>&gt;=50% reduction in headache days</td>
<td>MT versus UC</td>
<td>2.72 (1.86, 3.75)†</td>
<td>15.1 (6.5, 43.8)</td>
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<tr>
<td>Path b, logistic</td>
<td>Cervical ROM</td>
<td>MT versus UC</td>
<td>19.31 (8.17, 30.45)†</td>
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<tr>
<td>Path c, logistic</td>
<td>&gt;=50% reduction in headache days</td>
<td>MT versus UC</td>
<td>0.00 (-0.01, 0.01)</td>
<td>-0.001 (-0.05, 0.05)</td>
<td></td>
<td>-0.33†</td>
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<tr>
<td>Neck flexor endurance (n = 178)</td>
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<tr>
<td>Path a, logistic</td>
<td>&gt;=50% reduction in headache days</td>
<td>MT versus UC</td>
<td>2.73 (1.84, 3.62)‡</td>
<td>15.3 (6.3, 37.3)</td>
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<tr>
<td>Path b, logistic</td>
<td>Neck flexor endurance</td>
<td>MT versus UC</td>
<td>14.49 (7.5, 21.49)‡</td>
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<tr>
<td>Path c, logistic</td>
<td>&gt;=50% reduction in headache days</td>
<td>MT versus UC</td>
<td>0.05 (0.02, 0.08)‡</td>
<td>0.13 (0.06, 0.19)</td>
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<td>24.5</td>
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<tr>
<td>Forward head posture (n = 143)</td>
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<tr>
<td>Path a, logistic</td>
<td>&gt;=50% reduction in headache days</td>
<td>MT versus UC</td>
<td>2.36 (1.45, 3.27)‡</td>
<td>9.5 (4.3, 25.8)</td>
<td></td>
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</tr>
<tr>
<td>Path b, logistic</td>
<td>Forward head posture</td>
<td>MT versus UC</td>
<td>3.24 (0.46, 6.02)‡</td>
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<tr>
<td>Path c, logistic</td>
<td>&gt;=50% reduction in headache days</td>
<td>MT versus UC</td>
<td>0.05 (-0.01, 0.11)</td>
<td>0.03 (-0.02, 0.08)</td>
<td></td>
<td>6.57</td>
</tr>
</tbody>
</table>

Abbreviations: MT, manual therapy; ROM, range of motion; UC, usual care.

*Values in parentheses are 95% confidence intervals.

†Based on standardized coefficients.

‡Follow-up assessments not available for 8 participants (cervical ROM and neck flexor endurance) and for 43 participants (forward head posture).

The mediated effect was negative due to a positive effect of MT on cervical ROM and a negative effect of cervical ROM on a 50% or greater reduction in headache days.

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Study Limitations

To the best of our knowledge, this is the first study to investigate working mechanisms of the effectiveness of manual therapy in headache using mediation analysis. However, the sample size of the usual care group was small, which limited the statistical power of our analysis. Because of this limitation and to adjust for overoptimism of the mediated effect, bootstrapping was performed. Furthermore, combining data from participants of a cohort and an RCT might have introduced a risk of bias, as cohort participants might have a stronger preference for manual therapy. We therefore compared patient characteristics and expectations regarding treatment outcome at baseline, which were very similar between both groups.

As our analyses could only partly explain the effect of manual therapy, other potential mediators, such as the presence of trigger points and pain sensitivity (see above) or time spent on treatment, could be evaluated as potential mediating variables. In our study, the time spent on treatment differed between the intervention groups due to a larger number of sessions (a mean of 6 versus 2 sessions) and sessions of longer duration (30 versus 10 minutes) with manual therapy compared to usual general practitioner care. To evaluate the mediating effect of time spent on treatment, treatment protocols with identical mobilization or exercise regimes but differences in the duration or number of sessions should be investigated.

CONCLUSION

Increased neck flexor endurance appears to explain part of the working mechanism of manual therapy in participants with CTTH. The effect of manual therapy was not mediated by cervical ROM or forward head posture. We recommend isometric training of neck flexors in physical treatment of participants with CTTH.
**KEY POINTS**

**FINDINGS:** In a multimodule manual therapy treatment for participants with CTH, neck flexor endurance contributed 25% to the total treatment effect of reducing the frequency of headache. Cervical ROM and forward head posture did not influence the total effect of manual therapy.

**IMPLICATIONS:** Because the increase of neck flexor endurance is related to a decrease of headache frequency, isometric training of neck flexors is strongly advised to be part of physical treatment for participants with CTH.

**CAUTION:** The mediation analysis was restricted to participants with CTH; therefore, the results cannot be generalized to other forms of headache.

**REFERENCES**