Dose Optimization for Spinal treatment Effectiveness (The DOSE Study): A randomized controlled trial investigating the effects of high and low mobilization forces in patients with neck pain

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The study was approved by The University of Newcastle Human Research Ethics Committee.

The authors affirm that they have no financial affiliation (including research funding) or involvement with any commercial organization that has a direct financial interest in any matter included in this manuscript.

This trial is registered with the Australian and New Zealand Clinical Trials Registry (http://www.anzctr.org.au/): ACTRN12611000374965.

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Study design: Randomized controlled trial.

Objective: To determine if force magnitude during posterior-to-anterior (PA) mobilization affects immediate and short-term outcomes in patients with chronic non-specific neck pain.

Background: The optimal dose of mobilization to effectively treat patients with neck pain is not known.

Methods: Patients with neck pain of at least 3 months duration (n=64) were randomized to receive a single treatment of PA mobilization applied with 30N or 90N mean peak force (3 sets of 30 seconds) or a placebo (detuned laser) on the spinous process at their painful spinal level. Pressure pain threshold (PPT), pain (visual analogue scale 0-100 mm), cervical range of motion (ROM), and spinal stiffness at the painful spinal level (instrumented measurement, normalized as a percentage of C7 stiffness) were measured before, immediately after, and a mean 4.0 days (SD 1.8) following treatment (follow-up). Repeated measures analysis of covariance and Bonferroni-adjusted post-hoc tests determined group differences for each outcome measure after treatment and at follow-up.

Results: At follow-up, the 90N group had less pain than the 30N group (mean difference 11.3 mm, 95% CI: 0.1, 22.6, P=.048) and lower stiffness than the placebo group (17.5%, 95% CI: 4.2, 30.9, P=.006). These differences were not present immediately after treatment. There were no significant between-group differences in PPT or ROM after treatment or at follow-up.

Conclusion: A specific dose of mobilization, in terms of applied force, appears necessary for reducing stiffness, and potentially pain, in patients with chronic neck pain. Changes were not observed immediately after mobilization, suggesting its effects are not directly mechanical.

Level of evidence: Therapy, level 1b-. *J Orthop Sports Phys Ther 2014;44(3):141-152.*

Key words: *biomechanics, cervical vertebrae, manual therapy, musculoskeletal manipulations, neck*

Approximately 30-50% of adults will experience neck pain over a 12 month period,[27] and many will seek physiotherapy treatment. In treating neck pain, physiotherapists commonly use passive joint mobilization,[31, 41] consisting of manual oscillatory forces applied to the spine.[42] There is some evidence this is effective in treating patients with neck pain when it is combined with exercise,[22, 29] and it appears to be more cost effective than other treatments when societal factors such as lost productivity are considered.[40] However, the optimal dose of joint mobilization is not known and forces applied by therapists vary when performing the same technique,[59] making it difficult to attribute treatment outcomes to a particular technique or dose.

The dose of manual therapy is characterized by the properties of the manual technique applied, the length of time it is applied during a treatment session, and the number and frequency of treatment sessions. The properties of passive joint mobilization include the force magnitude (maximum peak), force amplitude (difference between maximum peak and minimum trough) and direction of the applied force, the oscillation frequency at which the force is applied, and the displacement, or amount of movement occurring during oscillation.[56] There is a nascent body of work of these mechanical properties in terms of patient responses to treatment. Preliminary evidence suggests that there is a critical level of manual force needed to produce a hypoalgesic effect in patients with lateral epicondylalgia following a ‘mobilization with movement’ manual therapy technique at the elbow.[43] There is also some evidence that a higher rate of oscillation increases the sympathoexcitatory effect that occurs following cervical spine mobilizations in asymptomatic individuals.[10] In addition, repeated sets of lumbar mobilization are reported to increase pressure pain thresholds (PPTs) compared to a single set in

asymptomatic individuals.[46] To the contrary, varying the duration, amplitude, or frequency of oscillation of a lumbar mobilization does not influence the change in PPTs.[35, 46, 71] We are unaware of any studies of the effects of specific properties of a spinal mobilization, such as magnitude of force or oscillation frequency, on outcomes in patients with spinal pain.

Systematic reviews of manual therapy for neck pain indicate that research is needed to determine the optimal treatment characteristics and dosages of manual therapy for effectiveness.[22, 23] This randomized controlled trial selects 1 property of mobilization, the magnitude of force, and applies it using 2 standardized force levels to determine if varying the force affects the treatment outcome. The aim was to determine whether the magnitude of force applied during posterior-to-anterior (PA) mobilization affects immediate and short-term treatment outcomes in patients with chronic non-specific neck pain. Specifically, this study investigates whether applying a low or high force PA mobilization, or placebo treatment, results in differences in changes in PPTs, resting pain ratings, cervical range of motion (ROM), or cervical spine stiffness immediately after treatment, and whether these effects are maintained in the short term. This will assist in determining whether a specific dose of mobilization is needed to optimize the treatment of patients with chronic neck pain and provide evidence to guide physiotherapists in their application of mobilization.

METHODS

Study Design

Participants entering the study were randomized into 1 of 3 treatment groups: low force mobilization, high force mobilization, or placebo. Participants attended a single session of treatment in a laboratory setting on The University of Newcastle

(Australia) campus. Measurements were taken prior to and immediately after treatment, and at a follow-up session approximately 4 days later. The study design and participant flow is illustrated in **FIGURE 1**.

Participants

Participants were individuals with chronic non-specific neck pain (of duration greater than 3 months) aged between 18 and 55 years. An upper age limit of 55 years was used to limit the potential of recruiting individuals with degenerative changes possibly affecting the study outcome. Included participants had a minimum resting pain level of 3/10 on a numerical pain rating scale to prevent floor effects and ensure homogeneity. Potential participants were asked the extent their neck pain had interfered with their normal work over the previous 4 weeks, with a selection of 5 Likert-scale options.[70] Eligible participants were those who answered 'moderately,' 'quite a bit,' or 'extremely,' while those who answered 'not at all' or 'a little bit' were excluded. Participants were also excluded if they had upper cervical pain or headache as their primary complaint, or if they had dizziness, a history of trauma related to the neck, surgery to the neck, diabetes, peripheral vascular disease, or referred arm pain past the acromion (ie, radiculopathy). They were also excluded if they had received any form of treatment in the previous 12 weeks that had a hands-on component (eg, physiotherapy, chiropractic, acupuncture, massage). Participants were recruited between April and October 2011 through advertisements in local publications, emails to university staff, and flyers posted around campus where the study was conducted. Interested individuals responding to advertisement were initially screened by telephone.

Participants were assigned through concealed allocation (sealed envelopes) and independent blocked randomization using a random numbers generator to 1 of 3

treatment groups: low or high force PA mobilization, or placebo. One author enrolled patients into the study, while an independent research assistant performed the randomization and prepared the sealed envelopes, which were opened after baseline data collection by the physiotherapist performing the treatments. Participants were treated in a private treatment area and had no knowledge of treatments received by other participants. The study was approved by The University of Newcastle Human Research Ethics Committee. All participants gave informed consent to participate and their rights were protected.

Treatment

A registered physiotherapist with more than 10 years of experience in musculoskeletal (outpatient orthopaedic) physiotherapy selected each participant's most painful spinal level using PA passive joint movement and participant response. A second experienced musculoskeletal physiotherapist (20 years) palpated the selected spinal level and the identification (label) of the level was determined by consensus. Subsequently, the first therapist applied the standardized PA mobilization at either level of force or the placebo treatment. Participants in the active treatment groups received 1 session consisting of 3 sets of 1 minute of PA mobilization applied with the thumbs to the spinous process[42] at the therapist-assessed most painful spinal level. This amount of mobilization is consistent with clinical practice[42] and with previous studies in the cervical spine.[63, 64] The low force treatment group received PA mobilization with a 30N mean peak force, while the high force group received PA mobilization with a 90N mean peak force. Peak forces were measured using load cells fitted to an instrumented treatment table on which the participant lay,[55] and the therapist used real-time feedback via a computer monitor to ensure mean peak force levels remained consistent.[60] Both force levels

were applied with the therapist using the conceptual definition of a grade III mobilization: “large amplitude movement moving into stiffness”.[42] Oscillation frequency was standardized at 1.0 Hz for both force conditions, which is the average frequency physiotherapists use when applying a grade III cervical mobilization.[59] The therapist was also able to monitor their oscillation frequency via the real-time feedback mechanism which provided visual feedback (in the form of flashing colors if outside the target force or oscillation frequency). Force amplitude was expected to be relatively consistent with the magnitude of force applied,[59, 71] though it could also be viewed on the monitor.

The high and low levels of force were selected based on previous published data.[58, 59] Registered physiotherapists who regularly use PA mobilizations apply grade III techniques to the lower cervical spine using a mean peak force of 64.2N (SD 28.6, range 6.0-133.4, excluding 5 outliers confirmed using Grubbs test).[52] The low force of 30N and high force of 90N were selected because they are approximately 1 standard deviation below and above the mean peak force applied by 116 practicing physiotherapists to C7 in a previous study.[59] The high force was expected to be tolerated by the majority of participants, and was high enough to be recognized by most therapists as sufficiently different to the low force of 30N. The low force of 30N is high enough to be considered as ‘moving into stiffness’ in the cervical spine,[57] and low enough to be recognizably different to the high force of 90N. The placebo treatment group received detuned laser for 3 sets of 1 minute. Detuned laser is an acceptable placebo[25, 30] that was plausible in a previous study with patients with cervicogenic pain and dizziness.[48] Though patients were informed that they may receive a placebo intervention, at the time of treatment the treating therapist described all interventions as though they were genuine, including the potential

beneficial and possible adverse effects of either mobilization or laser (the placebo). All patients were told that their intervention was known to be beneficial for some patients with their condition.[3] This was done to blind patients as to whether they received a genuine or placebo treatment.

Outcome measurements

A third physiotherapist with 5 years of experience, and blinded to participant group, performed all measurements. Blinding occurred by removing this therapist from the area while treatments were applied, and instructing participants to refrain from revealing information about the treatment they received to the therapist conducting measurements. The primary outcome was PPT, with secondary outcomes of patient-reported resting pain, cervical ROM, and cervical spine stiffness. At each measurement time point, resting pain was recorded first, followed by ROM, PPT, and then spinal stiffness. This order was selected due to the possible effects of each measurement on the others measured beforehand. To describe the study population and allow comparison with previous research, participants completed the Neck Disability Index (NDI, scored out of 50 points) prior to measurement on the day of treatment. This was repeated at the follow-up session to monitor for changes.[11, 68]

PPT PPT was measured using the J-tech algometer (Tracker Freedom Algometry, J-tech Medical, Salt Lake City, UT). PPT has demonstrated reliability,[47] correlates well with clinical status,[16] and is commonly used to assess immediate treatment effects.[8, 15, 64, 71] Intrarater reliability of PPT measurements is reported to be good between sessions separated by 1 week (intraclass correlation coefficients [ICCs] > 0.87),[47] and ICCs of 0.93 to 0.96 have been reported for repeated PPT tests performed on the same day using the J-tech algometer.[71] Pressure was applied at 4N/s using a 1cm^2 indenter tip, corresponding to 40kPa/s. Participants were instructed to press a

switch at the moment the sensation of pressure from the algometer tip changed to a sensation of discomfort or pain. This stopped the test and the J-tech software recorded a value in N which was subsequently converted to kPa for analysis. Three landmarks were tested in randomized order, as patients with non-specific neck pain are not usually sensitized to pain:[9, 49] (1) adjacent to the spinous process at the treated spinal level (right side) while the participant lay prone, (2) right upper trapezius muscle at the midpoint between C7 and the acromion with the participant in sitting, and (3) right median nerve trunk at the elbow, positioned just medial to the biceps tendon with the elbow in approximately 30 degrees of flexion with the forearm resting on the plinth and the participant sitting. The right side was tested on all participants as previous research has shown that side-to-side differences are insignificant in individuals with non-specific neck pain.[9] Each landmark was tested 3 times with a 10 second rest between tests, and PPT scores were averaged. For analysis, the PPT scores at each of the 3 landmarks, and an overall sum of these, were used. Reliability of PPT testing was examined by calculating ICCs for the triplicate measurements at each landmark at each time point, and standard error of measurement (SEM) was calculated using the SD of the grand mean across time points.[47]

Pain Resting pain was measured at baseline and at follow-up with a 100mm visual analogue scale (VAS) anchored by ‘no pain’ at 0mm on the left and ‘worst pain imaginable’ at 100mm on the right. Participants marked on the VAS their level of resting pain. Participants were also asked to rate their level of comfort/discomfort with the treatment they received by marking a 100mm VAS anchored by ‘very comfortable’ at 0mm on the left and ‘very uncomfortable at 100mm on the right. Any adverse effects from treatment were recorded on patient data sheets. To determine

whether the applied force of the mobilization was acceptable to participants, at the completion of the study they were also asked whether they would be willing to have their assigned treatment again if they were attending physiotherapy.

Cervical ROM Cervical ROM was measured in the sagittal and horizontal planes using a Cervical Range of Motion instrument (CROM, Performance Attainment Associates, Minnesota, IL, USA). The CROM has excellent reported reliability over separate days (ICCs ranging from 0.89 to 0.98).[2] Each movement direction (flexion, extension, right rotation, and left rotation) was repeated 3 times and averaged. Measurements of sagittal and horizontal ROM were randomized to account for any possible effects of movement in one plane on movement in the other. Participants were instructed to move their head as far as possible in each direction. Sagittal ROM was the sum of degrees of flexion and extension. Rotation ROM was the sum of degrees of right and left rotation. Total ROM was the sum of degrees of sagittal and rotation ROM. After measurement in each movement direction, participants were asked to name their most painful movement direction from the 4 directions tested. Degrees of ROM at the first onset of pain in the most painful movement direction were then measured 3 times and averaged.

Spinal stiffness Spinal stiffness was measured with a custom device that applied 5 cycles of standardized oscillatory force at a rate of 1Hz per second. The standardized force was determined by the voltage supplied to the device's motor, which allowed the indenter rod applying the force to move 14 mm against a resistance equal to 70 N.[57] Resistance to the applied force (N) and displacement (in mm), or distance the indenter rod travelled, were recorded simultaneously. The first cycle of applied force was discarded,[44, 50] and stiffness was defined as the slope of the linear portion of the force-displacement curve averaged over cycles 2 through 5

(N/mm).[53, 57] The linear portion was determined by viewing the force-displacement curves across the sample, and selecting a linear range appropriate for all spinal levels measured. Spinal stiffness differs between spinals levels[7, 57, 69] and thus the linear portion of the curve varied slightly between spinal levels. A single force range (15-50N) for calculating stiffness was selected to allow comparisons across the sample, as stiffness differs when calculated for different portions of the force-displacement curve.[37] The stiffness measurement device has satisfactory accuracy and reliability (SEM for C7 measurements is 0.83 N/mm and for C2 is 0.53 N/mm; ICC for repeated measures 0.84, 95% CI: 0.74-0.90), and details about its development and evaluation have been previously reported.[57]

Stiffness was measured first at C7, followed by the participant's painful spinal level. C7 was marked by the same experienced physiotherapist at each occasion of measurement (before and after treatment and at follow-up) using standardized methods.[24, 28, 45] Stiffness at the painful spinal level was normalized as a percentage of stiffness at C7 (as measured at each time point), and this value was used in further analyses. Percentages less than 100% indicated that the painful spinal levels were less stiff than C7.

Data Analysis

Sample size calculations indicated 20 subjects per group were needed (based on detecting a 10% difference in PPT between groups with a variability in that difference score of 8%,[64] 90% power, and alpha = 0.017). PPT was proposed as the primary outcome measure because it was expected to be more sensitive to initial changes following treatment[8, 64, 71] than resting pain (VAS).[32, 33] Data were checked for normality prior to statistical analyses, which were performed per protocol. Descriptive statistics and counts were used to describe the sample. The mean peak mobilization

forces applied to participants in the active treatment groups were averaged across participants in each group to determine if forces were applied at the correct mean peak force level and to calculate the amount of variance in applied force within each group. Participant's comfort levels with the applied treatments were compared using 1-way ANOVA.

Repeated measures analysis of covariance (ANCOVA) with 2 factors, group (high force, low force, and placebo) and time (immediately after treatment and follow-up), were used to determine the effects of treatment on each outcome variable (PPT, pain, ROM, and stiffness) using baseline values as the covariates. A P-value of .05 was considered significant. When the assumption of sphericity was not met, the Greenhouse-Geisser correction was used. For outcome variables with a significant time x group interaction, follow up Bonferroni-adjusted ($P < .017$) post-hoc tests were used to determine differences between the 3 treatment groups (high force versus low force, high force versus placebo, and low force versus placebo) immediately after treatment and at follow-up approximately 4 days later. Cases with missing data were excluded on an analysis by analysis basis. All analyses were performed in IBM SPSS Statistics Version 19.0.

RESULTS

Sixty-four participants entered the study after screening volunteers responding to recruitment advertising (**FIGURE 1**). The most common reasons for exclusion were the participant having had recent hands-on treatment, their neck pain not at least moderately interfering with their normal work, the presence of radiculopathy, and having previous trauma to the neck (most often whiplash). Participant characteristics are described in **TABLE 1**. There were no meaningful differences between the 3

316 treatment groups in baseline characteristics. All participants received the intervention
317 to which they were randomly assigned. Two participants were lost to follow-up, 1 in
318 the high force group and 1 in the placebo group. Data were complete for all other
319 participants for the primary outcome measures with the exception of a single follow-
320 up measurement of spinal stiffness for 1 participant which was missing due to
321 compromised electronic data recording.

322 The average of the mean peak forces applied for each treatment group (recorded
323 across all participants) were 30.8N (95% CI: 30.7, 31.0) for the low force group and
324 88.6N (95% CI: 87.4, 89.8) for the high force group. Participants were less
325 comfortable with the high force mobilization (48.1mm, SD 29.1 on the comfort VAS)
326 compared to the placebo (5.5, SD 9.7) intervention (mean difference 42.5 mm, 95%
327 CI: 24.2, 60.9, $P < .001$). There was no statistical difference in level of comfort with
328 treatment between the high force and low force (35.6, SD 28.2) groups (mean
329 difference 12.4 mm, 95% CI: -5.7, 30.6, $P = .289$). There were no adverse effects
330 from treatment. Follow-up measurement occurred a mean 4.0 days (SD 1.8, range 2-
331 8) after the treatment session, and there were no significant differences between the
332 groups in the number of days between treatment and follow-up. There were no
333 significant differences between groups in NDI at follow-up (mean, SD for low force
334 group 9.7, 4.1; high force group 8.2, 5.0; and placebo group 9.7, 5.7), accounting for
335 baseline NDI scores.

336 **PPT**

337 The time x group interaction for summed PPT was not significant ($F_{3.2,95.1} = 1.41$, $P =$
338 .242), indicating the type of treatment received did not have a significant effect on
339 PPT outcomes over time (**TABLE 2**). However, summed PPT increased across all 3
340 time points for participants as a whole (differences between time points $P \leq .02$).

PPT at individual landmarks were also analyzed separately with no significant time x group interaction, and some improvement overall across time, though this was not consistent across all time points for all landmarks. ICCs and SEMs for PPT were 0.90 (95% CI: .79, .95) and 7.35 kPa, respectively adjacent to the spinous process, 0.85 (95% CI: .72, .94) and 4.67 kPa over the trapezius muscle and 0.78 (95% CI: .53, .91) and 5.48 kPa over the median nerve.

Pain

There was a significant time x group interaction for pain ($F_{3.1,91.1}$ = 4.65, P = .004), with the high force group reporting more pain immediately after treatment than both the low force (mean difference 11.7 mm, 95% CI: 1.9, 21.5, P = .014) or the placebo group (17.9 mm, 7.9, 27.9, P < .001), accounting for pain at baseline (**TABLE 2, FIGURE 2**). Despite this increase in pain, 20 of 21 participants in the high force group reported they would be willing to have this treatment again if they were attending physiotherapy. Conversely, the high force group reported less pain than the low force group at follow-up (mean difference 11.3 mm, 95% CI: 0.1, 22.6, P = .048), but not significantly different to the placebo group (mean difference 7.4 mm, 95% CI: -4.0, 18.8, P = .350, **TABLE 2, FIGURE 2**), accounting for pain at baseline.

Cervical ROM

There were no significant time x group interactions for any ROM variables: sagittal ROM ($F_{3.5,103.5}$ = .23, P = .900), rotation ROM ($F_{4,118}$ = 2.1, P = .086), total ROM ($F_{4,118}$ = .66, P = .623), or degrees until onset of pain in the most painful movement direction ($F_{4,114}$ = .25, P = .907). There were no observable differences between groups in ROM immediately after treatment or at follow-up (**TABLE 2**).

Spinal stiffness

There was a significant time x group interaction for cervical spine stiffness ($F_{4,108}$ = 2.75, P = .032). At follow-up, the high force group was less stiff at their painful spinal level as a percentage of C7 stiffness compared to the placebo group (mean difference 17.5%, 95% CI: 4.2, 30.9, P = .006), but was not significantly different to the low force group (mean difference 9.1%, 95% CI: -4.2, 22.3, P = .293, **TABLE 2, FIGURE 3**), accounting for baseline stiffness. The representative size of the difference between the high force and placebo groups, calculated as 17.5% of the average C7 stiffness in this sample, was 1.5 N/mm. There were no significant differences between groups in spinal stiffness immediately after treatment.

DISCUSSION

To our knowledge, this is the first study to investigate the effects of differences in applied mobilization force on clinical outcomes in patients with chronic neck pain. PPT and cervical ROM following mobilization were not different between groups receiving a either a high force (90N) or low force (30N) mobilization (within the range of commonly applied forces by physiotherapists) or a placebo treatment. A higher mobilization force appeared to be more effective than a lower one in terms of reduced pain at a short-term follow-up approximately 4 days following treatment. However, the lower pain level in the group receiving high force mobilization was not significantly different to the reduced pain observed in a placebo group, suggesting patient expectation played a role in pain outcomes. A high mobilization force also significantly decreased spinal stiffness compared to a placebo at the short-term follow-up, though this decreased stiffness was not significantly different to that occurring with a low force mobilization. Immediately after the application of treatment, patients who received the high force mobilization reported increased pain and had no change in stiffness. This suggests the effect of mobilization may not be

mechanical, as one would expect an immediate change in stiffness. Alternatively, stiffness measurement may be affected by muscle contraction related to pain, as stiffness was less when pain was less. The results of this study suggest that a possible threshold of force may be necessary for reducing the symptoms of chronic neck pain using manual therapy. These results should be viewed with caution, however, as the patients participating in this study reported low disability.

PPT

There were no differences between groups in PPT following treatment in the current study. Similarly, Willett et al[69] found no difference in PPT between groups of asymptomatic subjects receiving different mobilization oscillation frequencies. In patients with whiplash, Sterling et al[62] also reported no difference in PPT between a group receiving a lateral glide mobilization and a placebo group receiving manual contact where the therapist placed their hands on the patient without applying any mobilization force. In contrast to these findings, evidence from many previous studies indicates PPT increases following various manual therapy techniques[15, 39, 65] including cervical spine mobilization,[36] with a meta-analysis of 10 studies concluding a favorable effect on PPT from high velocity thrust manipulations.[13] PPT generally increased over time for all groups in the current study, but did not differ by group. Together these results might suggest the effects of manual therapy on PPT are not related to differences in the properties of the technique applied or a strong placebo effect from detuned laser. Despite the lack of statistical differences in PPT outcomes between groups in the current study, patients in the high force group reported less pain at follow-up than the other groups. This might suggest that there is not a clear link between a person's perception of pain and mechanical hyperalgesia when evaluating the manual therapy parameter of force. PPT may not be a meaningful

measure for a person's pain response immediately after the application of a manual technique, which itself consists of an applied 'pressure' or force.

Pain

At follow-up, there was significantly less resting pain experienced by participants in the high force group compared to the low force group accounting for their baseline pain values. However, pain was not significantly different between the high force and placebo group at follow-up. Patient expectation following the interventions may have played a role in pain responses, as all treatments were presented as genuine.[3] Explanations about the expected outcomes of treatment are known to affect patient pain responses,[5] and laser treatment is known to have a strong placebo effect.[26] Nonetheless, the significantly lower values for pain in the high force group relative to the low force group, together with significantly reduced spinal stiffness in the high force group relative to the placebo group, might suggest a higher applied mobilization force is more effective in this chronic neck pain population, at least in the short-term. The decrease pain at follow-up is in contrast to the significantly higher pain perceived by participants immediately after receiving high force mobilization (**FIGURE 2**).

The point estimates for the mean differences in pain between groups surpass the minimally important clinical difference (MCID) of approximately 9-13 mm.[6, 18, 34] However, the 95% CIs include some values that are less than the MCID, indicating that caution should be exercised when interpreting the differences clinically. A proposed hypothesis that might explain an improvement in pain several days after a treatment that itself was painful is that the treatment stimulated a descending modulation of pain, as in the phenomenon of pain being used to inhibit pain.[67] Despite an increase in resting pain immediately after treatment, participants in the

high force group reported they were willing to receive the same treatment again if they were attending physiotherapy. However, this response may have been influenced by their perceived improvement in symptoms at the time of the follow-up session when they were asked that question. Despite the pain reported immediately after treatment, the clinically desirable reduction of pain and stiffness at follow-up in the high force group suggests a higher mobilization force is more effective for patients with chronic non-specific neck pain. It should be noted that the mean group changes in pain were small and may not be clinically meaningful (≤ 24 mm on a 100mm VAS, **TABLE 2**), although the largest reduction in pain was 70 mm for 1 individual.

Cervical ROM

In the current study there were no significant changes in cervical ROM following mobilization and no differences in ROM between groups receiving either a high or low force mobilization. There are few previous studies reporting cervical ROM measured by a blinded assessor following the application of mobilization or manipulation. Two of these also measured cervical ROM immediately following mobilization, similar to the current study, with one reporting no significant changes in ROM (all pre-post differences less than 3 degrees)[32] and another reporting significant increases of up to approximately 10 degrees.[66] In contrast, other studies that have reported an improvement in cervical ROM following manual therapy have applied a thoracic thrust manipulation[14] and reported changes in ROM at longer follow-up points.[19, 20, 38] A single treatment of mobilization, as occurred in the current study, may not be enough to demonstrate a significant change in cervical ROM. Our data support a mechanism of action that might not be related to immediate or early

mechanical effects, but rather some other mechanism, for example, neurophysiological effects.[4]

Spinal stiffness

There were no significant changes in stiffness for any group immediately after the application of treatment, but participants who received high force mobilization were less stiff at their painful spinal level at the follow-up assessment when compared to placebo (**FIGURE 3**). Several other studies that have measured stiffness in the thoracic or lumbar spine immediately following the application of various manual techniques have also reported no significant changes,[1, 7, 21, 61] though only one of these was in symptomatic patients.[21] This suggests that the mechanism of action of manual therapy may not be mechanical in nature, but instead might relate to the presence of pain, because in the current study, the group that demonstrated decreased stiffness at follow-up was also the group reporting less pain. A possible explanation for our data might be the concept that stiffness measurement does not represent an independent mechanical construct, but rather is a function of the pain experience and accompanying neurophysiological effects in addition to mechanical properties of the deformed soft tissues. However, it should be noted that the established stiffness measurement protocols are designed to control for potentially pain-related phenomena such as breathing,[51] neck position,[54] and muscle contraction.[12, 62]

In contrast to the current study, Fritz et al[17] found a significant decrease in stiffness in the lumbar spine immediately following a thrust manipulation in patients classified as responders, though this decrease was not maintained 3-4 days later.[17] Tuttle et al[66] also reported decreased stiffness immediately following mobilization in the cervical spine, but only when stiffness was measured in specific ranges (< 20N) of

the force-displacement curve.[66] The differences in stiffness between groups in the current study were also small (**TABLE 2**), possibly suggesting that both levels of mobilization force had some effect or that stiffness changes were the result of multiple factors rather than solely due to the mobilization application. The sparse and conflicting evidence for spinal stiffness changes following manual therapy suggests further research is needed, particularly to determine the relationship between spinal stiffness and pain.[53]

Limitations

The results of this study are limited to the short-term effects following the application of a single mobilization treatment to a specific sample of patients with chronic non-specific neck pain. The study was designed this way to investigate the effect of applied force, which is 1 property of mobilization. It is possible that the results might be different if a course of treatment was provided over several sessions, or if different properties of applied force are altered. Specifically, the velocity of applied force (mobilization versus thrust manipulation) has been shown to influence outcomes.[14] Our sample had low disability compared to other manual therapy studies[63, 64] (mean NDI 11.7, SD 4.4, **TABLE 1**), so the results might not apply to patients with more disabling neck pain. The findings may also not relate to patients with previous trauma to their neck or with radiculopathy, as we excluded these from our study. Clinicians commonly tailor their mobilization parameters, modifying the magnitude of applied force based on their assessment of a patient's spinal stiffness and pain. The results may have been different if the therapist was allowed to select a magnitude of force for each participant based on clinical judgment. Lastly, it should be noted that the statistically significant differences observed in this study were small, and may not be clinically meaningful. Furthermore, caution is urged in

concluding that there were no group differences for any statistically non-significant results, as Type II error is a possibility. For example, the observed difference between the high force and placebo group in pain at follow-up and the differences between groups in spinal stiffness at follow-up appear underpowered. Therefore strong conclusions about the possible differences between groups in these outcomes cannot be made.

CONCLUSIONS

This study demonstrates that a higher applied force (90N) during a single application of cervical spine mobilization significantly reduces spinal stiffness in patients with chronic non-specific neck pain at a short-term follow-up (approximately 4 days). A high force mobilization (90N) was also more effective than a lower one (30N) for decreasing resting pain at this short-term follow-up, though decreases in pain were not significantly different to those observed following a placebo intervention, suggesting patient expectation played a role in pain responses. However, the effects observed following a high force mobilization may not all be due to placebo effect as the significant decrease in stiffness in this group tends to suggest a component of mechanical change. There were no observed effects of mobilization on ROM or PPT. Immediately after application of a high force mobilization, participants reported increased pain, however with no significant change in stiffness. These results suggest a possible threshold of force is needed for reducing stiffness, and potentially pain, in patients with non-specific neck pain.

KEY POINTS

Findings: A high mobilization force (90N mean peak force) significantly decreases spinal stiffness at a short-term follow-up of approximately 4 days after treatment, though stiffness was not reduced immediately after treatment. Also at this follow-up, pain was significantly less following a high force (90N) compared with a low force (30N) mobilization, but was not significantly different to that of a placebo treatment.

Implications: A particular threshold of force appears necessary for more effective mobilization treatment, suggesting that specific doses of mobilization should be further investigated.

Caution: These results are limited to patients with chronic non-specific neck pain with relatively low disability.

ACKNOWLEDGEMENTS

This study was supported by a grant from the Physiotherapy Research Foundation of the Australian Physiotherapy Association. The granting body was independent of the research team and had no influence on the study results or reporting. Michele Sterling receives a fellowship from the National Health and Medical Research Council of Australia. The authors would also like to acknowledge physiotherapists Dane P. Fehlberg and Bruce F. Donald for their assistance with data collection and Zoe C. Baldwin for her assistance with participant recruitment and data entry.

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FIGURE CAPTIONS

FIGURE 1. Flow diagram of participants throughout the study.

FIGURE 2. Pain (mm) measured on a 100mm visual analogue scale before and immediately after treatment (low or high force mobilization or placebo), and at short-term follow-up.

FIGURE 3. Spinal stiffness (N/mm) at the painful spinal level, normalized as a percentage of a participant's C7 spinal stiffness, measured before and immediately after treatment (low or high force mobilization or placebo), and at short-term follow-up. Percentages less than 100% indicate that the painful spinal levels were less stiff than C7.

TABLE 1. Participant characteristics (mean, SD or number, percent) at baseline.

Characteristic	Group		
	Low Force (n=21)	High Force (n=22)	Placebo (n=21)
Age (years)	32.1 (11.4)	34.4 (12.5)	33.7 (11.8)
Gender (female)	14 (64)	16 (76)	18 (86)
Neck Disability Index (baseline)*	11.8 (4.2)	11.0 (5.0)	12.2 (4.0)
Length of time with neck pain			
3 to 6 months	3 (14)	1 (5)	1 (5)
6 to 12 months	1 (5)	4 (18)	2 (10)
between 1 and 2 years	4 (19)	5 (23)	3 (14)
more than 2 years	14 (67)	11 (50)	15 (71)
Neck pain interference with normal work over previous 4 weeks			
moderately	15 (71)	13 (59)	14 (67)
quite a bit	6 (29)	8 (36)	7 (33)
extremely	1 (5)	0 (0)	0 (0)
Presence of headache (yes)	13 (62)	11 (50)	16 (76)
Current symptom beliefs			
getting worse	8 (38)	7 (32)	6 (29)
remaining static	13 (62)	10 (45)	10 (48)
getting better	1 (5)	0 (0)	3 (14)
Had time off work due to pain (yes)	4 (19)	2 (9)	8 (38)
Had a worker's compensation claim (yes)	1 (5)	1 (5)	1 (5)
Painful spinal level identified			
C3	2 (10)	0 (0)	1 (5)
C4	6 (29)	8 (36)	6 (29)
C5	5 (24)	7 (32)	4 (19)
C6	6 (29)	2 (9)	4 (19)
C7	3 (14)	4 (18)	5 (24)
T1	0 (0)	0 (0)	1 (5)
PPT (kPA)[†]	558.0 (263.5)	576.6 (273.6)	529.9 (225.5)
Pain (VAS, mm)	33.0 (17.2)	26.6 (21.0)	35.9 (24.4)
ROM (degrees)[‡]	264.5 (41.1)	269.3 (36.8)	258.6 (49.3)
Stiffness (%)[¥]	69.2 (22.8)	74.0 (23.3)	73.7 (24.0)

Abbreviations: VAS, visual analogue scale; ROM, range of motion; PPT, pressure pain threshold
*The Neck Disability Index was scored out of 50 points.
[†]PPT: Sum of the measurements taken adjacent to the painful spinous process (right), mid-trapezius muscle (right), and median nerve trunk at the elbow (right).
[‡]Flexion, extension, and rotation right and left, summed.
[¥]Instrumented stiffness measurement (slope of linear portion of force-displacement curve, N/mm) over the painful spinous process and expressed as a percentage of stiffness measured at C7 at the same time point. Percentages less than 100% indicate that the painful spinal levels were less stiff than C7.

TABLE 2. Results for each time point for each intervention group (low force mobilization, high force mobilization, and placebo of detuned laser), and mean differences between groups (adjusted by baseline value).

	Mean (SD)			Adjusted mean differences[§] (95% CI)		
	Low Force (n=21)	High Force (n=22)	Placebo (n=21)	High force – Low Force	High force – Placebo	Low force – Placebo
Pain (VAS, mm)**						
Baseline	33.0 (17.2)	26.6 (21.0)	35.9 (24.4)	-6.3 (-22.1, 9.5)	-9.3 (-25.3, 6.7)	-3.0 (-18.8, 12.9)
After Rx	27.1 (17.9)	38.9 (22.2)	20.9 (21.2)	11.7 (1.9, 21.5)*	17.9 (7.9, 27.9)*	6.2 (-3.5, 16.0)
Follow-up	26.5 (18.6)	15.2 (14.8)	22.5 (20.3)	-11.3 (-22.6, -0.1)*	-7.4 (-18.8, 4.0)	4.0 (-7.2, 15.1)
ROM (degrees)[†]						
Baseline	264.5 (41.1)	269.3 (36.8)	258.6 (49.3)	4.9 (-27.2, 37.0)	10.8 (-21.6, 43.2)	5.9 (-26.2, 38.0)
After Rx	265.8 (35.2)	271.9 (35.2)	268.7 (48.0)	6.0 (-6.8, 18.8)	3.2 (-9.8, 16.2)	-2.9 (-15.7, 9.9)
Follow-up	275.0 (35.4)	271.7 (39.1)	274.1 (49.6)	-3.4 (-19.9, 13.2)	-2.4 (-19.4, 14.6)	0.9 (-15.6, 17.5)
PPT (kPA)[‡]						
Baseline	558.0 (263.5)	576.6 (273.6)	529.9 (225.5)	18.6 (-173.1, 210.3)	46.7 (-147.2, 240.6)	28.1 (-163.6, 219.8)
After Rx	590.4 (267.1)	637.0 (341.3)	554.2 (290.8)	46.6 (-31.8, 125.0)	82.8 (3.3, 162.3)	36.2 (-42.3, 114.6)
Follow-up	634.0 (265.7)	671.3 (355.0)	629.7 (357.8)	37.3 (-85.1, 159.7)	41.7 (-83.8, 167.2)	4.4 (-118.1, 126.8)
Stiffness (%)**[¥]						
Baseline	69.2 (22.8)	74.0 (23.3)	73.7 (24.0)	4.8 (-13.2, 22.8)	0.3 (-17.9, 18.5)	-4.5 (-22.5, 13.5)
After Rx	81.2 (20.9)	74.8 (23.0)	79.4 (31.6)	-6.4, (-19.8, 7.1)	-4.6 (-18.2, 8.9)	1.8 (-11.7, 15.2)
Follow-up	77.1 (17.4)	68.0 (22.9)	85.5 (26.0)	-9.1 (-22.3, 4.2)	-17.5 (-30.9, -4.2)*	-8.5 (-21.5, 4.5)

Abbreviations: VAS, visual analogue scale; ROM, range of motion; PPT, pressure pain threshold; Rx, treatment.
[†]Flexion, extension and rotation right and left, summed.
[‡]PPT: Sum of the measurements taken adjacent to the painful spinous process (right), mid-trapezius muscle (right), and median nerve trunk at the elbow (right).
[¥]Instrumented stiffness measurement (slope of linear portion of force-displacement curve, N/mm) over the painful spinous process and expressed as a percentage of stiffness measured at C7 at the same time point. Percentages less than 100% indicate that the painful spinal levels were less stiff than C7.
[§]Mean differences from Bonferroni post-hoc tests following one-way analysis of covariance using baseline values as the covariates.
*Difference between groups was significant at the .05 level (Bonferroni adjusted).
**Indicates there were statistically significant time x group interaction effects for this variable

FIGURE 1.

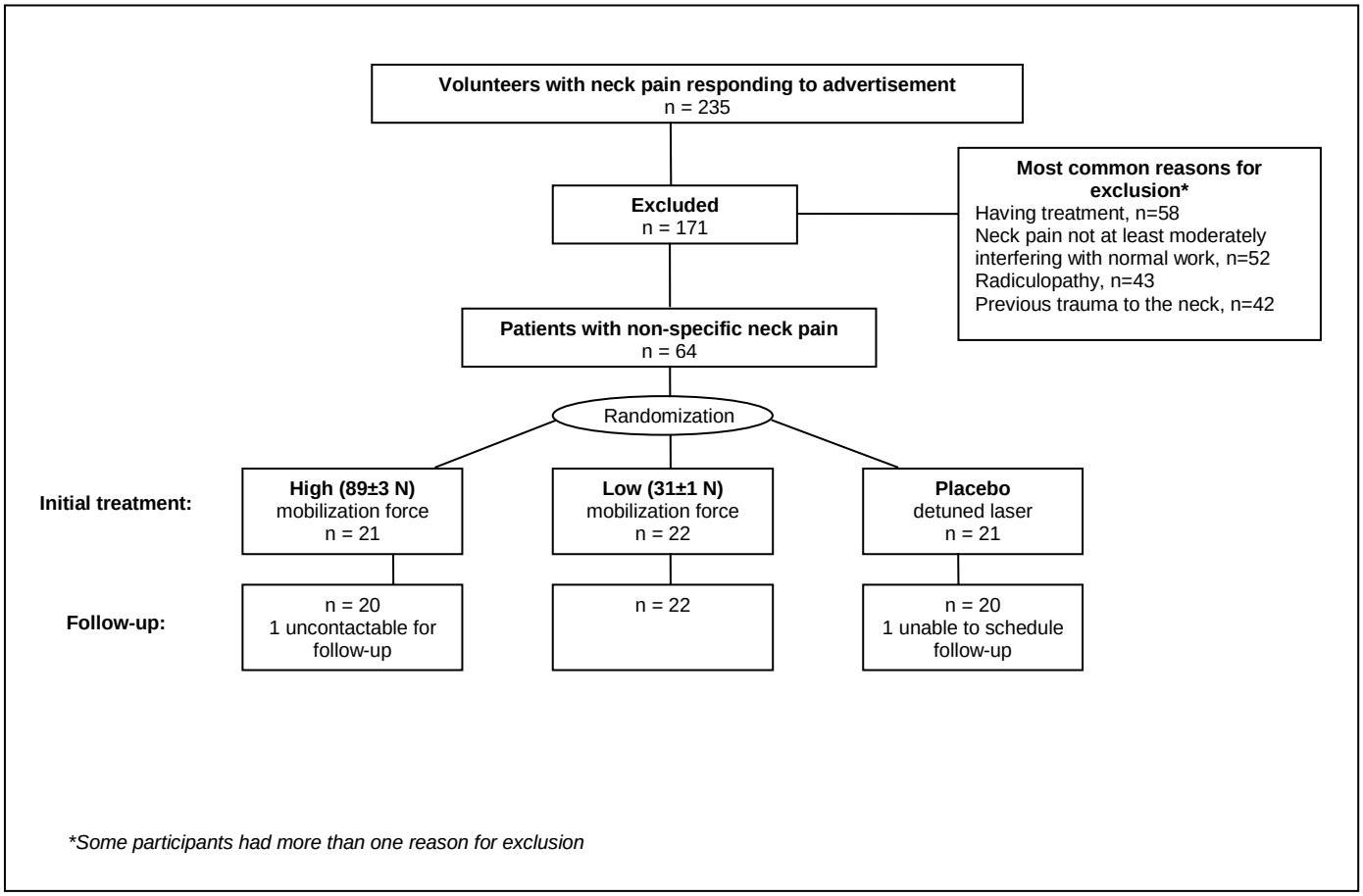
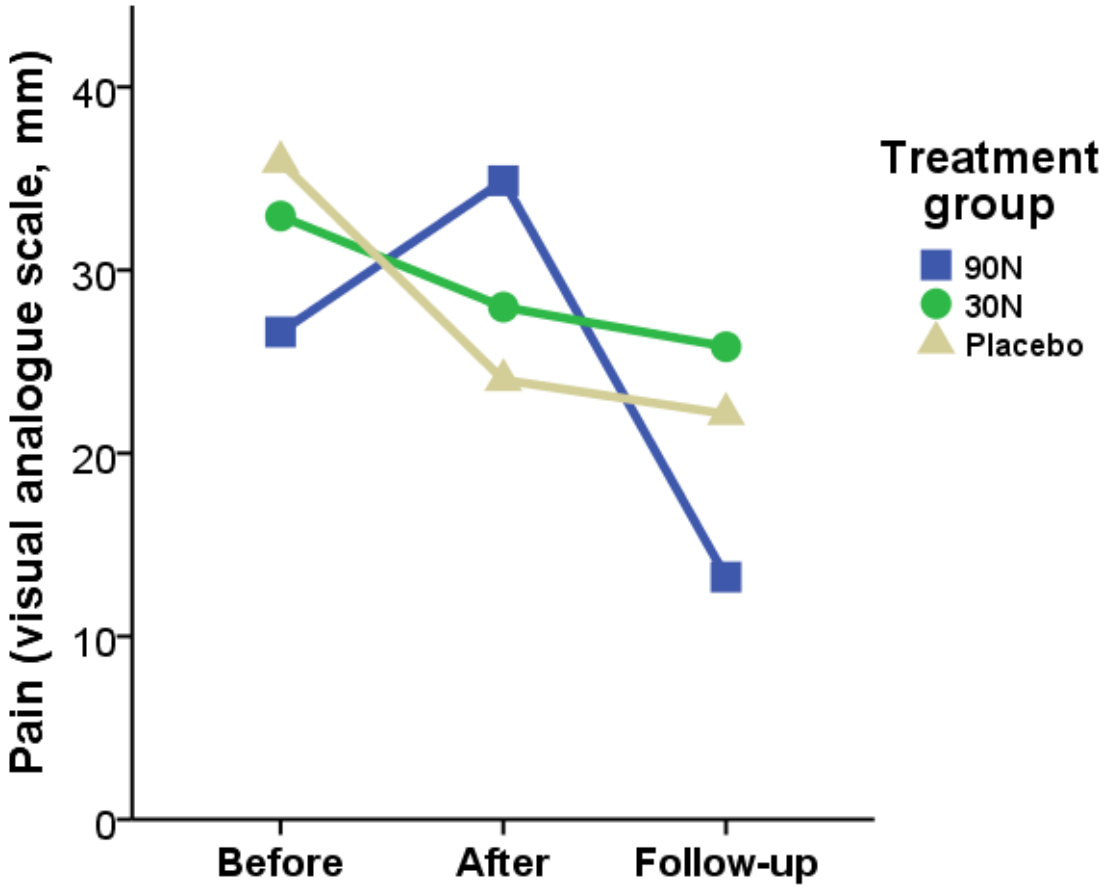
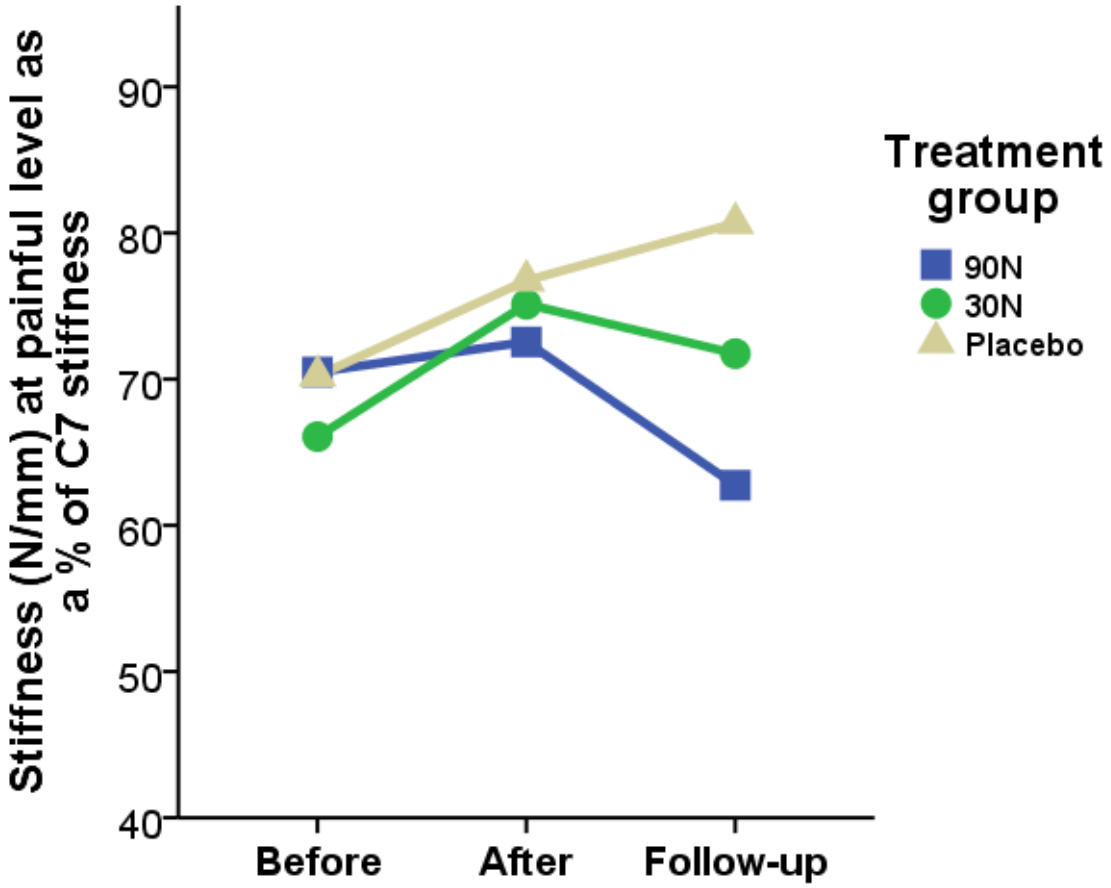

Volunteers with neck pain responding to advertisement
n = 235
Excluded
n = 171
Most common reasons for exclusion*
Having treatment, n=58
Neck pain not at least moderately interfering with normal work, n=52
Radiculopathy, n=43
Previous trauma to the neck, n=42
Patients with non-specific neck pain
n = 64
Randomization
Initial treatment:
High (89±3 N)
mobilization force
n = 21
Low (31±1 N)
mobilization force
n = 22
Placebo
detuned laser
n = 21
Follow-up:
n = 20
1 uncontactable for follow-up
n = 22
n = 20
1 unable to schedule follow-up
*Some participants had more than one reason for exclusion

Figure 2


Pain (visual analogue scale, mm)
40
30
20
10
0
Before
After
Follow-up
Treatment group
90N
30N
Placebo


Stiffness (N/mm) at painful level as a % of C7 stiffness
90
80
70
60
50
40
Before
After
Follow-up
Treatment group
90N
30N
Placebo