RUNNING HEAD: TOMCATT Methods

Care Ally-Assisted Massage for Veterans with Chronic Neck Pain: TOMCATT Results

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ABSTRACT

Purpose

Chronic neck pain (CNP) is prevalent and challenging to treat. Despite evidence of massage's effectiveness for CNP, multiple accessibility barriers exist. The Trial Outcomes for Massage: Care Ally-Assisted vs. Therapist Treated (TOMCATT) study examined a care ally-assisted massage (CA-M) approach compared to a waitlist control prior to a study design modification (WL-C_0).

Methods

CA-M consisted of in-person training for veteran/care-ally dyads to learn a standardized 30-minue massage routine, instructional DVD, and printed treatment manual. Participants were to complete three care ally-assisted massage sessions weekly for 12-weeks. Outcomes collected at baseline, 1-, 3-, and 6-months included validated measures of neck pain severity and associated disability. Linear mixed-model approaches were used for analysis.

Results

Participants (N=203) were 56.7±14 years old, 75% White, 15% female, and 75% married/partnered. Among 102 CA-M participants, 45% did not attend the in-person training and subsequently withdrew from the study and were more likely to be younger (p=0.016) and employed (p=0.004). Compared to WL-C_0, CA-M participants had statistically significant reductions in pain-related disability at 3-months (-3.4, 95%CI=[-5.8, -1.0]; p=0.006) and 6-months (-4.6, 95%CI=[-7.0, -2.1]; p<0.001) and pain severity at 3-months (-1.3, 95%CI=[-1.9, -0.8]; p<0.001) and 6-months (-1.0, 95%CI=[-1.6, -0.4]; p=0.007), respectively.

Conclusion

In this analysis, CA-M led to greater reductions in CNP with disability and pain severity compared to WL-C_0, despite treatment engagement and retention challenges. Future work is needed to determine how to better engage Veterans and their care-allies to attend CA-M training.

Key Words: Veterans, Chronic Neck Pain, Integrative Medicine, Whole Health, Dyad, Partner Massage

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Authors' Contributions

All the authors contributed to the development of this manuscript. NM contributed to study design, data collection, interpretation, and writing. JKD contributed to statistical analysis and writing. EE contributed to study design, data collection, and review. MK contributed to the study design, data collection, and review. JES contributed to statistical analysis and writing. BL contributed to instrumental study support, data collection, and review. TF contributed to instrumental study support, data collection, and review. MM contributed to study design and interpretation of results. MJB was the principal investigator, funding acquisition, study design, results interpretation, and writing.

Abbreviations

BPI – Brief Pain Index

CA-M: care ally–assisted massage

CNP: chronic neck pain

NDI: Neck Disability Index

TOMCATT: Trial Outcomes for Massage: Care Ally–Assisted Versus Therapist-Treated

VA: Veterans Affairs

WL-C: wait-list control

1. Introduction

Neck pain is prevalent, burdensome, and a leading cause of productivity loss and disability worldwide [1, 2]. Of notable concern with neck pain is the potential for an acute episode to develop into a reoccurring or chronic condition. Chronic neck pain (CNP) is particularly prevalent and challenging to treat due in part to its potential to have moderate or greater severity and be combined with comorbidities [3, 4]. Neck pain diagnoses have been reported in up to 67% of Veterans [5] with prevalence dramatically increasing to 96% when diagnoses of stenosis or disk herniation are present [6].

Massage therapy (MT) has demonstrated meaningful impact on musculoskeletal pain generally [7] and specifically for back [8, 9] and neck pain [10, 11].Sherman and colleagues [12, 13] have conducted multiple methodologically rigorous MT trials for CNP. In one trial, patients (N = 64) randomized to 10 weeks of massage were much more likely to meet clinically meaningful improvements for neck pain and disability compared to patients randomized to a pain self-care book [12]. In a larger trial (N = 228), patients who received 60-minute massage sessions, 2 and 3 times a week were more likely to reach clinically meaningful improvements on neck pain disability and pain intensity compared to patients in the control arm [13].

Pain is the primary reason complementary and integrative treatments are used by individuals [14] and neck pain is second to back pain as the most common pain condition for complementary health use [15]. Of the complementary and integrative approaches commonly used for neck pain, massage is one of the most utilized approaches, second after chiropractic [16], and is the most preferred by Veterans [17]. Complementary health approaches are especially popular and in high demand by Veterans with 82% reporting use of at least one complementary therapy and nearly all (99%) willing to try such approaches for pain [17].

Despite the desirability, preference for, and demonstrated effectiveness of massage therapy for various conditions, accessibility barriers such as out-of-pocket costs, treatment availability, or logistical

challenges exist for MT [8, 18, 19]. To circumnavigate MT related accessibility barriers, massage self-care or efforts to train informal caregivers/allies to deliver massage interventions have been developed and researched with promising success, including with Veterans. Self-massage has been examined in many studies for various conditions [20] including for knee pain [21] and fibromyalgia [22], and has demonstrated feasibility and positive impact for CNP [23]. Teaching informal caregivers/allies to provide massage (partner-delivered massage) has often been applied in situations involving people experiencing cancer or other critical illnesses [24], but has also been applied and tested in pediatric [25], obstetrical [26], and relationship support settings [27, 28]. Prior research of caregiver-provided massage for Veterans with cancer showed significant decreases in pain, stress/anxiety, and fatigue [29] as well as depression and cancer-related symptoms [30]. The care ally assisted or self-care massage approach for CNP has not been examined in the U.S. Veterans and is a significant gap in the literature.

2. Methods

2.1. Study Design

The Trial Outcomes for Massage: Care Ally-Assisted vs. Therapist Treated (TOMCATT) study began as a 3-arm, randomized controlled trial of two massage delivery approaches for Veterans with CNP. Neck pain was targeted due to associated condition burden in Veterans and the relative ease to access the neck area by lay-massage people without specific equipment (i.e., a massage table) to deliver massage. Despite robust study recruitment and enrollment efforts, TOMCATT was modified to a 2-arm trial of therapist-delivered massage (TT-M) and waitlist control (WL-C) arms after the study's first 2 years due to challenges with intervention initiation, engagement, and retention in the care ally-assisted massage (CA-M) study arm. This report compares primary and secondary TOMCATT outcomes between CA-M and WL-C arms due to modification.

TOMCATT's methodology has been reported previously, including rationale for removing the study's CA-M arm prior to COVID-19 related disruptions [31]. All participants provided informed consent and

were randomized. This paper focuses on those randomized into the CA-M or WL-C arm prior to the study modification. Participants are indicated as WL-C_0 (the $_0$ indicating this subgroup of the total TOMCATT WL-C participants). TOMCATT was reviewed and approved by the Indiana University Institutional Review Board and VA Research Review Committee and is registered with ClinicalTrials.gov (NCT03100539).

2.2. Eligibility

Veterans could particulate if they were 18 or older, had neck pain for 6 or more months with disability as indicated by a Neck Disability Index score of 10 or higher, did not have massage contraindications, and had a care-ally (spouse, partner, family member, or friend) willing to learn and provide an assisted massage routine during the study period. Care-allies also enrolled in the study and provided informed consent. Care-allies were eligible if their "partnered" veteran was randomized to the care-ally arm, they attended the CA-M training workshop with their veteran partner, and they did not have medical concerns that might interfere with giving a massage.

2.3. Recruitment

Primary care providers within the Roudebush VA Medical Center (Indianapolis, Indiana) and surrounding community-based outpatient clinics provided approval to contact their eligible patients for possible study participation. Potential Veteran participants were identified by an electronic medical record query for specific ICD9 codes for neck pain (721.0-723.9; 2) and a primary care clinic visit in past year. Recruitment letters sent to potentially eligible participants contained an initial screening for neck pain-related disability that were returned by Veterans who wanted to be contacted to assess eligibility and possible participation. Veterans also directly indicated participation interested after learning of TOMCATT through study pamphlets and marketing, acquaintances, and word-of-mouth.

2.4. Randomization

Enrolled Veterans were randomly assigned to one of the three study arms (TT-M, CA-M, WL-C) using stratified block randomization (3 and 6 block sizes). Randomization was stratified by sex (male/female) and occurred after consent, enrollment, and baseline data collection interviews to minimize ascertainment bias.

2.5. Measures

Validated and reliable primary and secondary measures were collected at baseline, 1-month, 3-months, and 6-months for the TOMCATT study. The primary study outcome was neck pain disability and neck pain severity as measured with the Neck Disability Index(NDI) [32, 33] and Brief Pain Inventory (BPI) [34, 35], respectively. Additional secondary outcomes were collected including interference, quality of life, emotional wellbeing, and pain cognitions.

2.5.1. Primary Outcomes

The NDI assesses pain and functioning domains (e.g., sitting, standing, traveling), with each item framed as a "problem right now." The 10 items are scored on a 6-point numeric rating scores of 0 to 5, with 5 being "worst." The total score ranges from 0 to 50, with higher scores representing greater disability from chronic neck pain. The NDI has strong internal consistency (Cronbach's alpha = 0.80) and construct validity [32]. Scoring of the NDI involves summing the score for each item (raw score) with specific scoring intervals to aid interpretation: 0 – 4 = no disability; 5 – 14 = mild; 15 – 24 = moderate; 25 – 34 = severe; and > 34 = complete disability. At least a 5-point change is defined as "clinically meaningful" [13, 32, 36].

The BPI is a validated, condition-adaptable 11-item numeric scales (0-10) assessment with subscales for severity (4-items) and interference (7-items) [34, 35]. The BPI has reliability in patients with arthritis as well as other pain conditions and rates the severity of pain as well as its interference with mood, physical activity, work, social activity, relations with others, sleep, and enjoyment of life [37]. Clinically meaningful change in BPI scores and subscales have been reported as ≥ 30% change [38]. The pain

severity subscale was the second primary study outcome while the BPI interference subscale was a secondary outcome.

2.5.2. Secondary Outcomes

Secondary outcomes included the BPI interference subscale. Of the secondary outcomes, only health related quality of life was collected at all the study intervals: baseline, 1-, 3-, and 6-months, as was collected using the Medical Outcomes Study-Veteran version (SF-36) tool [39] which is reliable and valid and is available in the public domain [40]. The SF-36 measure provides two health composite scores for mental (MCS) and physical (PCS) health and role limitations. Higher scores in the MCS and PCS indicate more positive outcomes.

Psychological symptoms were assessed due to related and evidenced massage impact [41-44]. Depression was assessed with the PHQ-9 which has been validated as a diagnostic measure with excellent psychometric properties (Cronbach's alpha > 0.80) in several studies [45, 46]. Anxiety was measured with the GAD-7 which has demonstrated reliability (alpha = 0.89) and validity (criterion, construct, factorial) as a measure of anxiety in the general population and primary care [47]. Finally, the Pain Catastrophizing Scale, a validated 13-item scale to assess catastrophizing, a pain belief found to be a strong predictor of poor treatment response [48].

2.6. Participant Incentives

Veteran participants were reimbursed $25 per completed outcome assessment at baseline, 1, 3, and 6 months. Care allies received a $50 gift card at the completion of the intervention training session and a complementary massage session at study completion.

2.7. Intervention - Care ally-assisted massage (CA-M)

The CA-M intervention consisted of an in-person training workshop, instructional DVD, and treatment manual. Participants were asked to engage in 3, 30-minute CA-M sessions per week for 3-months. The

CA-M routine's content and general structure was taught during a 3.5-hour training workshop. The instructional DVD included a real-time routine demonstration for participants to access as desired. Study logs were provided for participants to document their weekly massage study. Detailed specifics of the CA-M training and intervention have been described elsewhere [31].

2.7.1. CA-M routine training workshop and materials

Training workshops were comprised of general instruction via lecture, demonstration and supervised massage and self-treatment practice, and a 30-minute supervised practice session of the routine. Training workshop attendees were informed about intervention support materials; specifically, how to use the study DVD and workbook.

2.7.2. CA-M routine

Thirteen progressive components made up the CA-M routine and reflected a logical seated massage treatment progression. CA-M components were 1 to 4 minutes long each with approximately 10 minutes dedicated to self-applied techniques.

2.7.3. CA-M: adherence

Efforts to support adherence and post-training engagement included study personnel contacting Veterans and care allies at 2-weeks, 2-months, and 4-months to inquire about any barriers to home massage (e.g., care ally fatigue or burden, challenges with learning massage techniques and routine, difficulty adhering to 30-minute sessions). Participants were also asked to track their DVD use and record time spent in massage on a log form.

2.8. Waitlist control care group (WL-C)

Participants randomized to WL-C had check-in calls at 2- and 4-months from study personnel staff and completed outcome assessments at baseline, 1-, 3-, and 6-months. Participants continued medical care as normal and were instructed to not begin massage treatment during the 6-month study participation.

2.9. Statistical considerations

Based on the 102 participants in the CA-M arm and the high expected attrition (63%), we expected at least n=37 and n=79, to complete the 3-month time point in CA-M and WL-C_0, respectively. Based on this assumption, there would be 80% power to detect a 0.56 SD difference in mean change in NDI at 3 months between CA-M and WL-C_0 and 97% power to detect a large effect size (ES = 0.8) as defined by Cohen [49] based on a two-sided two-sample t-test with Type I error set at 0.05.

All baseline demographic characteristics were compared between treatment groups (CA-M and WL-C_0) using appropriate tests to verify that randomization achieved balanced groups. All analyses were conducted under the intention-to-treat principle.

All continuous outcomes were analyzed with a constrained longitudinal data analysis (cLDA) [50, 51] model to compare the intervention effects between CA-M and WL-C_0 on change in outcome at the primary 3 month endpoint after adjusting for the stratification variable of gender. The mean change difference from baseline to all timepoints (1, 3, and 6 months) are reported for outcomes along with the associated 95% confidence intervals and p-values. To control the familywise type I error for the number of continuous secondary outcomes, a Šidák adjustment was used to account for the multiple comparisons at a given time point. The mean within-group changes in continuous secondary outcomes are reported similarly with a Šidák adjustment.

For the dichotomous outcomes of clinically meaningful response to NDI (> 5 point decrease) and BPI severity (>30% decrease), logistic regression was used with Generalized Estimating Equation methodology [52] to account for the repeated measures. Odds ratios and associated 95% confidence intervals for clinically meaningful response of CA-M arm relative to WL-C_0 arm are reported at each time point and overall.

Since a large proportion of CA-M participants withdrew prior to receiving the initial intervention training, two sensitivity analyses were conducted to examine robustness of model results. The first was a modified

intention-to-treat (mITT) analysis, by re-running the model for the NDI and BPI for all WL-C_0 participants, but only CA-M participants that received training. The second sensitivity analysis used Multiple Imputation to examine the robustness of model results under the assumption that CA-M participants lost to follow-up were more similar to WL-C_0 in their outcomes trajectory after study drop-out. The reported mixed model is appropriate under the assumption that data are missing-at-random. However, it is plausible those that dropped from the CA-M arm (especially those that did not complete training) would have outcome trajectories like the WL-C_0 participants that received no intervention. All analyses were conducted in SAS V9.4 (SAS Institute, Cary, NC).

3. Results

A total of 203 participants were recruited prior to the TOMCATT study modification. Recruitment and randomization efforts resulted in balanced numbers of participants assigned to each study arm but high attrition in the CA-M arm resulted in uneven data collection at 1-, 3-, and 6-month data collection points (Figure 1).

[Insert Figure 1 about here]

3.1. Sample Characteristics and Baseline Results

The TOMCATT pre-modification cohort consisted of mostly males (85%) of average age 56.7 (SD = 14.0), with approximately 75% White and 21% Black. Participants were mostly employed (44%) or retired (35%) (Table 1). Demographic characteristics did not differ significantly by treatment group. When comparing those with baseline data only vs. those with any follow-up (data not shown), there were no differences in demographic characteristics for those in the WL-C_0 arm; however, for the CA-M arm, those with baseline only were younger (53.8±14.8 vs. 60.6±13.2.; p=.016) and more likely to be employed (61.2% vs. 28.0%; p=.004).

[Insert Table 1]

3.2. Neck Pain with Disability – Primary Outcome Results

For the primary outcome (Table 2, Supplemental Figure 1), participants in the CA-M arm had a significant decrease in NDI at 3 months (mean change (95% CI): -3.3 (-5.3, -1.3); p=.002) and 6 months (mean change (95% CI): -3.5 (-5.5, -1.6); p<.001), whereas, the mean NDI increased for participants in the WL-C_0 arm at both 3 and 6 months, although not significantly. Accordingly, CA-M participants had a significant reduction in NDI compared to the WL-C_0 arm at 3-months (mean change (95% CI): -3.4 (-5.8, -1.0); p=.006) and 6 months (mean change (95% CI): -4.6 (-7.0, -2.1); p<.001).

[Table 2]

3.3. Brief Pain Inventory (*BPI*) *and Other Secondary Outcomes*

A significant decrease was seen in BPI severity within the CA-M arm at 1 month (mean change (95% CI): -0.8 (-1.2, -0.3); p=.007), 3 months (mean change (95% CI): -1.6 (-2.1, -1.1); p<.001) and 6 months (mean change (95% CI): -1.5 (-2.0, -1.0); p<.001), but no significant within-group changes were present in the WL-C_0 arm. Even after adjustment, the CA-M arm demonstrated significant improvement over WL-C_0 in BPI severity at 3 months (mean change (95% CI): -1.3 (-1.9, -0.8); p<.001) and 6 months (mean change (95% CI): -1.0 (-1.6, -0.4); p=.007). Significant improvements were also demonstrated for BPI interference within the CA-M arm at all time points but changes in BPI interference did not significantly differ between treatment arms at any time point. There were no statistically significant within-group or between group mean changes for other secondary outcomes of depression, anxiety, SF-36 mental component score, SF-36 physical component score, or pain catastrophizing (Table 3).

[Table 3]

3.4. Responder Analysis for NDI and BPI

At 3 months, the odds ratio for being a responder based on NDI (> 5-point decrease) for CA-M relative to WL-C_0 did not quite meet the threshold for statistical significance, OR (95% CI) = 2.5 (1.0, 6.5); p=.056 (Supplemental Table S1, Figure 2). However, the repeated measures analysis indicated an overall significant association for NDI response (OR (95% CI), CA-M vs. WL-C_0: 2.0 (1.0, 4.0); p=.046). For BPI severity (>30% decrease) (Supplemental Table S1, Figure 2), the CA-M arm was more likely to demonstrate a clinically meaningful response compared to the WL-C_0 arm at 3 months (OR (95% CI): 3.9 (1.6, 9.4); p=.003), 6 months (OR (95% CI): 3.1 (1.3, 7.9); p=.014), and overall (OR (95% CI): 2.7 (1.5, 5.0); p=.001).

[Figure 2]

3.5. Sensitivity Analysis

Results from the mITT analysis, which includes the subset of CA-M participants that received intervention training and all WL-C_0, participants are reported in Supplemental Table S2. The between-group mean change in NDI at follow-up time points were nearly identical to original model results. The 95% confidence intervals were slightly wider with the reduced sample size but showed statistical significance with p- values similar to reported results.

Figure 3 presents the results of the second sensitivity analysis using multiple imputation. The estimated mean change in NDI and associated 95% CI at follow-up time points by treatment group are similar between the reported model and the model using multiple imputation. From the model estimates obtained by combining estimates over imputations (Supplementary Table S3), the results indicate that even under this worst-case scenario, the CA-M arm demonstrated improvement over WL-C_0 in NDI at both 3 months (mean change (95% CI): -1.6 (-3.8, 0.8); p=.167) and 6 months (mean change (95% CI): -2.1 (-4.2, -0.1); p=.043), although significance was only maintained at the 6 month time point.

[Figure 3]

4. Discussion

The TOMCATT study is the first randomized controlled trial in Veterans to examine massage therapy's impact on CNP. A novel feature of TOMCATT was the original plan to examine the effectiveness of two massage treatment delivery approaches, therapist applied, and care-ally assisted, against a waitlist control. A high attrition rate in the CA-M arm led to the design modification decision to remove the CA-M study arm. This analysis demonstrates that CA-M provided a reduction in neck pain with disability and pain severity compared to WL-C_0, even if data from non-engaged participants washed away some of the effect. Given the high attrition in the CA-M arm, developing delivery strategies to target those more likely to engage will be key to incorporate partnered massage as an evidence-based approach to CNP management.

Partnered massage uptake from other studies in Veterans demonstrated similar challenges as seen in TOMCATT. For example, in Kozak's study only 11 of the 27 dyads (59% attrition) completed the 8-week intervention [29]. In contrast, attrition was much less in a trial of non-Veterans (4% in intervention are; 2% total) [30]. Relative to the Kozak study [29], TOMCATT had less attrition in its CA-M arm yet the decision was made to modify the design and discontinue that study arm. However, the Kozak study's quasi-experimental design, feasibility goal, short recruitment period (6-months), and succinct intervention training (self-directed DVD and printed materials) likely provided less resource burden to the research team.

Other dyad-based massage approaches have had more successful uptake when the intervention was reciprocal or when strong partner "buy-in" was present. The Mission Reconnect pilot study examined a self-directed program of integrative therapies, which included massage therapy, to promote post-deployment reintegration. Thirty-eight (88%) and 32 (74%) of the pilot study's 43 consented dyads began the intervention and completed the final data collection point, respectively. The partner delivered massage in Mission Reconnect was reciprocal with data collection and intervention engagement focused equally on the Veteran and non-Veteran dyad partner [53]. When examined in a larger, post-9/11 Veteran cohort, 160 dyads randomized to a Mission Reconnect affiliated study arm (2 of 4 possible study arms) had only

2% attrition during the 16-week study [54]. A potential explanation of the study's excellent retention is that all participants received at least 90-minutes of quality human contact with the intervention (or data collection for those in the waitlist control) launch. While the CA-M intervention was carefully planned and developed, the 3-4.5 hour in-person intervention training may have seemed less appealing for participants; particularly given care-allies for the TOMCATT study were secondary participants. Mission Reconnect was designed and had recruitment incentives specifically for partners as well as Veterans within the dyad. Another Mission Reconnect study is examining the mobile and web-based program for dyads with Veterans experiencing chronic pain and posttraumatic stress disorder and their partners [55]. Of the 364 dyads consented in this multi-site study, 267 dyads activated the protocol which accounts for a 27% attrition [56]. Several reasons were reported for drop-outs including loss of partner "buy-in" (8%), unrelated health challenges (24%), and difficulties with remote study procedures (34%) [56].

In the CA-M vs. WL-C_0 TOMCATT sub-analysis, younger Veterans and those who were employed were significantly less likely to initiate the intervention through CA-M training attendance. This lack of intervention uptake may suggest time involved and schedule conflicts were significant barriers. Such barriers may not be limited to dyad-based massage approaches as similar findings have been found in therapist-applied massage interventions for chronic musculoskeletal pain. Elder eta al examined massage therapy treatment in a chronic back pain population with methodology intended to decrease access barriers such as treatment location and out-of-pocket expense [8]. Interventions were delivered at no cost to study participants by community-based massage therapists in their clinics near where participants lived or worked. Participants were able to schedule up to 10, 1-hour massage sessions within a 12-week timeframe per their schedule convenience and individualized treatment plan. Younger age predicted non-compliance or withdrawal from the study suggesting those with early adulthood lives and related demands (e.g., early career, hourly work, school, or family care needs) may find making time for massage therapy interventions challenging [8]. This analysis of TOMCATT data reinforces the potential for life-demands faced by younger adults to interfere with participation in partnered massage interventions.

Challenges to CA-M participant retention and the need to remove the CA-M study arm likely reflects engagement issues rather than intervention effectiveness. Consideration is needed as to how best to target and deliver this relatively low-cost potentially high yield intervention approach. This analysis incorporated a rigorous sub-study analysis to complement the original, intention to treat approach as initially designed. A conservative sensitivity analysis was conducted due to the disproportionate number of participants in the treatment arm that did not initiate the intervention and therefore only contributed baseline data in the model. In addition, a robust responder analysis examined clinically meaningful outcomes and differences. Analysis demonstrated significant improvement in neck pain with disability, pain severity, and pain interference at 3- and 6-months for Veterans with CNP in the CA-M arm compared to WL-C_0 and these findings were reinforced with sensitivity analysis. While more research is needed to identify and target those most likely to engage in CA-M training and treatment, prior dyad research in Veterans point to the potential importance of reciprocated interventions as well as partner focused appeal and recruitment/engagement efforts [30, 54].

Massage accessibility challenges was a strong motivator to examine care ally-assisted massage for CNP in Veterans; the rationale being that while effective, massage therapy is largely inaccessible due to high out-of-pocket costs. Care ally-assisted approaches have been effective in Veteran [29, 54] and civilian [23, 26, 57, 58] populations and was expected also demonstrate effective for managing CNP. The care ally-assisted massage protocol and training seminar was specifically designed to be easy to apply and bridge a cost-inhibitive accessibility gap for Veterans to massage. Since the launch of TOMCATT, policies such as Directive 1137 within the Veteran's Administration have changed such that therapist-provided massage therapy is now included in the health benefits package for Veterans improving access to massage therapy [59]. The extent to which Veterans will access and utilized massage therapy for musculoskeletal pain through the Directive 1137 initiative is unclear and CA-M could still address accessibility challenges for Veterans in rural or less massage therapist available environments.

Conclusion

Care-ally assisted massage demonstrated greater reductions in CNP-related disability and pain severity compared to waitlist control, despite treatment engagement and retention challenges. Given the various access barriers to effective chronic pain management faced by Veterans, novel application approaches with demonstrated benefit should be incorporated into recommended options, especially for those more likely to engage in social and pro-active self-care approaches. Future work is needed to determine how to effectively design and deliver dyad-focused massage interventions, engage Veterans and their care-allies to attend training, and incorporate self-care strategies into chronic pain management.

5. References

1. Kazeminasab, S., et al., *Neck pain: global epidemiology, trends and risk factors.* BMC Musculoskelet Disord, 2022. **23**(1): p. 26.
2. Safiri, S., et al., *Global, regional, and national burden of neck pain in the general population, 1990-2017: systematic analysis of the Global Burden of Disease Study 2017.* BMJ, 2020. **368**: p. m791.
3. Goulet, J.L., et al., *The musculoskeletal diagnosis cohort: examining pain and pain care among veterans.* Pain, 2016. **157**(8): p. 1696-1703.
4. Higgins, D.M., et al., *Gender Differences in Demographic and Clinical Correlates among Veterans with Musculoskeletal Disorders.* Womens Health Issues, 2017. **27**(4): p. 463-470.
5. Dobscha, S.K., et al., *Rationale, design, and baseline findings from a randomized trial of collaborative care for chronic musculoskeletal pain in primary care.* Pain Med, 2008. **9**(8): p. 1050-64.
6. Boakye, M., et al., *Health-related quality-of-life status in Veterans with spinal disorders.* Qual Life Res, 2013. **22**(1): p. 45-52.
7. Crawford, C., et al., *The impact of massage therapy on function in pain populations—A systematic review and meta-analysis of randomized controlled trials: Part I, patients experiencing pain in the general population.* Pain Medicine, 2016: p. pnw099.
8. Elder, W.G., et al., *Real-World Massage Therapy Produces Meaningful Effectiveness Signal for Primary Care Patients with Chronic Low Back Pain: Results of a Repeated Measures Cohort Study.* Pain Medicine, 2017.
9. Miake-Lye, I.M., et al., *Massage for Pain: An Evidence Map.* J Altern Complement Med, 2019. **25**(5): p. 475-502.
10. Cook, A.J., et al., *Randomized clinical trial assessing whether additional massage treatments for chronic neck pain improve 12- and 26-week outcomes.* Spine J, 2015. **15**(10): p. 2206-15.
11. Wang, S.Q., A.Y. Jiang, and Q. Gao, *Effect of manual soft tissue therapy on the pain in patients with chronic neck pain: A systematic review and meta-analysis.* Complement Ther Clin Pract, 2022. **49**: p. 101619.
12. Sherman, K.J., et al., *Randomized trial of therapeutic massage for chronic neck pain.* Clin J Pain, 2009. **25**(3): p. 233-8.
13. Sherman, K.J., et al., *Five-week outcomes from a dosing trial of therapeutic massage for chronic neck pain.* Ann Fam Med, 2014. **12**(2): p. 112-20.
14. Eisenberg, D.M., et al., *Perceptions about complementary therapies relative to conventional therapies among adults who use both: results from a national survey.* Ann Intern Med, 2001. **135**(5): p. 344-51.
15. Barnes, P.M., B. Bloom, and R.L. Nahin, *Complementary and Alternative Medicine Use Among Adults and Children: United States, 2007*, in *National Health Statistics Reports*. 2008, National Center for Health Statistics: Hyattsville, MD.
16. Wolsko, P.M., et al., *Patterns and perceptions of care for treatment of back and neck pain: results of a national survey.* Spine (Phila Pa 1976), 2003. **28**(3): p. 292-7; discussion 298.
17. Denneson, L.M., K. Corson, and S.K. Dobscha, *Complementary and alternative medicine use among veterans with chronic noncancer pain.* J Rehabil Res Dev, 2011. **48**(9): p. 1119-28.
18. Munk, N., T. Kruger, and F. Zanjani, *Massage therapy usage and reported health in older adults experiencing persistent pain.* J Altern Complement Med, 2011. **17**(7): p. 609-16.
19. Giannitrapani, K.F., et al., *Barriers to Using Nonpharmacologic Approaches and Reducing Opioid Use in Primary Care.* Pain Med, 2018. **19**(7): p. 1357-1364.

20. Nemati, D., et al., *Massage Therapy as a Self-Management Strategy for Musculoskeletal Pain and Chronic Conditions: A Systematic Review of Feasibility and Scope.* Journal of Integrative and Complementary Medicine, 2023.
21. Atkins, D.V. and D.A. Eichler, *The effects of self-massage on osteoarthritis of the knee: a randomized, controlled trial.* Int J Ther Massage Bodywork, 2013. **6**(1): p. 4-14.
22. Kalichman, L., *Massage therapy for fibromyalgia symptoms.* Rheumatol Int, 2010. **30**(9): p. 1151-7.
23. Munk, N., et al., *Trigger point self-care for chronic neck pain: pilot and feasibility.* Advances in integrative medicine, 2021. **8**(1): p. 9-16.
24. Jagan, S., T. Park, and E. Papathanassoglou, *Effects of massage on outcomes of adult intensive care unit patients: a systematic review.* Nursing in Critical Care, 2019. **24**(6): p. 414-429.
25. Ullsten, A., M. Andreasson, and M. Eriksson, *State of the art in parent-delivered pain-relieving interventions in neonatal care: a scoping review.* Frontiers in Pediatrics, 2021. **9**: p. 170.
26. Hall, H., et al., *Maternal mental health and partner-delivered massage: A pilot study.* Women and Birth, 2021. **34**(3): p. e237-e247.
27. Naruse, S.M., P.L. Cornelissen, and M. Moss, *'To give is better than to receive?'Couples massage significantly benefits both partners' wellbeing.* Journal of Health Psychology, 2018. **25**: p. 10-11.
28. Naruse, S.M. and M. Moss, *Positive Massage: An Intervention for Couples' Wellbeing in a Touch-Deprived Era.* Eur J Investig Health Psychol Educ, 2021. **11**(2): p. 450-467.
29. Kozak, L., et al., *A feasibility study of caregiver-provided massage as supportive care for Veterans with cancer.* J Support Oncol, 2013. **11**(3): p. 133-43.
30. Collinge, W., et al., *Touch, Caring, and Cancer: randomized controlled trial of a multimedia caregiver education program.* Supportive Care in Cancer, 2013. **21**: p. 1405-1414.
31. Munk, N., et al., *Therapist-Delivered Versus Care Ally–Assisted Massage for Veterans With Chronic Neck Pain: Protocol for a Randomized Controlled Trial.* JMIR Research Protocols, 2022. **11**(9): p. e38950.
32. Vernon, H. and S. Mior, *The Neck Disability Index: a study of reliability and validity.* Journal of manipulative and physiological therapeutics, 1991. **14**(7): p. 409-415.
33. Youdas, J.W., J.R. Carey, and T.R. Garrett, *Reliability of measurements of cervical spine range of motion—comparison of three methods.* Physical therapy, 1991. **71**(2): p. 98-104.
34. Cleeland, C. and K. Ryan, *Pain assessment: global use of the Brief Pain Inventory.* Annals of the Academy of Medicine, Singapore, 1994. **23**(2): p. 129-138.
35. Tan, G., M.P. Jensen, J.I. Thornby, and B.F. Shanti, *Validation of the Brief Pain Inventory for chronic nonmalignant pain.* J Pain, 2004. **5**(2): p. 133-7.
36. Vernon, H., *Assessment of self-rated disability, impairment, and sincerity of effort in whiplash-associated disorder.* Journal of Musculoskeletal Pain, 2000. **8**(1-2): p. 155-167.
37. Cleeland, C.S., *The brief pain inventory user guide.* Houston, TX: The University of Texas MD Anderson Cancer Center, 2009: p. 1-11.
38. Atkinson, T.M., et al., *The Brief Pain Inventory and its "pain at its worst in the last 24 hours" item: clinical trial endpoint considerations.* Pain medicine, 2010. **11**(3): p. 337-346.
39. CA, M., W. JE, and R. AE, *The MOS 36-Item Short-Form Health Survey (SF-36): II. Psychometric and clinical tests of validity in measuring physical and mental health constructs.* Med. Care, 1993. **31**(3): p. 247-263.
40. Kazis, L.E., et al., *Dissemination of methods and results from the veterans health study: final comments and implications for future monitoring strategies within and outside the veterans healthcare system.* The Journal of ambulatory care management, 2006. **29**(4): p. 310-319.

41. Ghesquiere, A., K. Wyka, M. Smith, and J.S. Kutner, *Associations between psychological symptoms and treatment outcomes of a massage therapy intervention: secondary analyses of a randomized controlled trial.* Complementary Therapies in Medicine, 2019. **46**: p. 116-122.
42. Mitchinson, A., C.E. Fletcher, and E. Trumble, *Integrating Massage Therapy Into the Health Care of Female Veterans.* Federal Practitioner, 2022. **39**(2): p. 86.
43. Rapaport, M.H., et al., *Six versus twelve weeks of Swedish massage therapy for generalized anxiety disorder: Preliminary findings.* Complementary therapies in medicine, 2021. **56**: p. 102593.
44. Serfaty, M., et al., *The ToT study: helping with Touch or Talk (ToT): a pilot randomised controlled trial to examine the clinical effectiveness of aromatherapy massage versus cognitive behaviour therapy for emotional distress in patients in cancer/palliative care.* Psycho-Oncology, 2012. **21**(5): p. 563-569.
45. Carroll, H.A., et al., *Establishing reliability and validity for mental health screening instruments in resource-constrained settings: systematic review of the PHQ-9 and key recommendations.* Psychiatry research, 2020. **291**: p. 113236.
46. Kroenke, K., R.L. Spitzer, and J.B. Williams, *The PHQ-9: validity of a brief depression severity measure.* Journal of general internal medicine, 2001. **16**(9): p. 606-613.
47. Spitzer, R.L., K. Kroenke, J.B. Williams, and B. Löwe, *A brief measure for assessing generalized anxiety disorder: the GAD-7.* Archives of internal medicine, 2006. **166**(10): p. 1092-1097.
48. Sullivan, M.J., S.R. Bishop, and J. Pivik, *The pain catastrophizing scale: development and validation.* Psychological assessment, 1995. **7**(4): p. 524.
49. Cohen, J., *Statistical power analysis for the behavioral sciences*. 2nd ed. 1988, Hillsdale, N.J.: L. Erlbaum Associates. xxi, 567 p.
50. Liu, G.F., et al., *Should baseline be a covariate or dependent variable in analyses of change from baseline in clinical trials?* Statistics in medicine, 2009. **28**(20): p. 2509-2530.
51. Coffman, C.J., D. Edelman, and R.F. Woolson, *To condition or not condition? Analysing 'change'in longitudinal randomised controlled trials.* BMJ open, 2016. **6**(12): p. e013096.
52. Liang, K.-Y. and S.L. Zeger, *Longitudinal data analysis of continuous and discrete responses for pre-post designs.* Sankhyā: The Indian Journal of Statistics, Series B, 2000: p. 134-148.
53. Collinge, W., J. Kahn, and R. Soltysik, *Promoting reintegration of National Guard veterans and their partners using a self-directed program of integrative therapies: a pilot study.* Military medicine, 2012. **177**(12): p. 1477-1485.
54. Kahn, J.R., W. Collinge, and R. Soltysik, *Post-9/11 veterans and their partners improve mental health outcomes with a self-directed mobile and web-based wellness training program: a randomized controlled trial.* Journal of medical Internet research, 2016. **18**(9): p. e255.
55. Haun, J.N., et al., *A mobile and web-based self-directed complementary and integrative health program for veterans and their partners (mission reconnect): protocol for a mixed-methods randomized controlled trial.* JMIR Research Protocols, 2019. **8**(5): p. e13666.
56. Haun, J.N., et al., *Mobile and Web-Based Partnered Intervention to Improve Remote Access to Pain and Posttraumatic Stress Disorder Symptom Management: Recruitment and Attrition in a Randomized Controlled Trial.* Journal of Medical Internet Research, 2023. **25**: p. e49678.
57. Kempson, D. and V. Conley, *Family caregiver provided massage for rural-dwelling chronically Ill persons.* Home Health Care Management & Practice, 2009. **21**(2): p. 117-123.
58. Vahedian-Azimi, A., et al., *Effect of massage therapy on vital signs and GCS scores of ICU patients: a randomized controlled clinical trial.* Trauma monthly, 2014. **19**(3).
59. Whitehead, A.M. and B. Kligler, *Innovations in care: complementary and integrative health in the Veterans health administration whole health system.* Medical Care, 2020. **58**: p. S78-S79.

545 **Figure 1.** TOMCATT Flow-Diagram

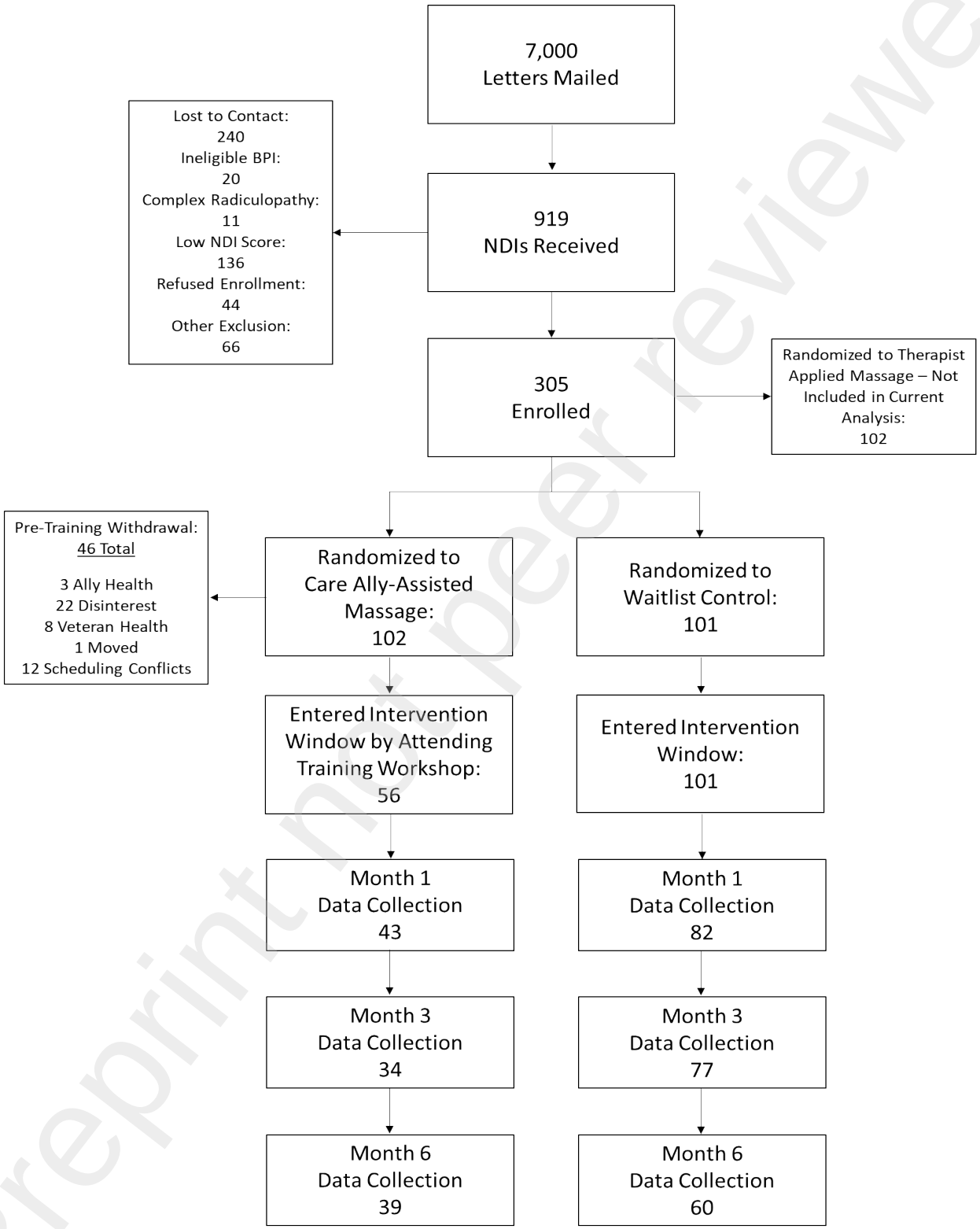

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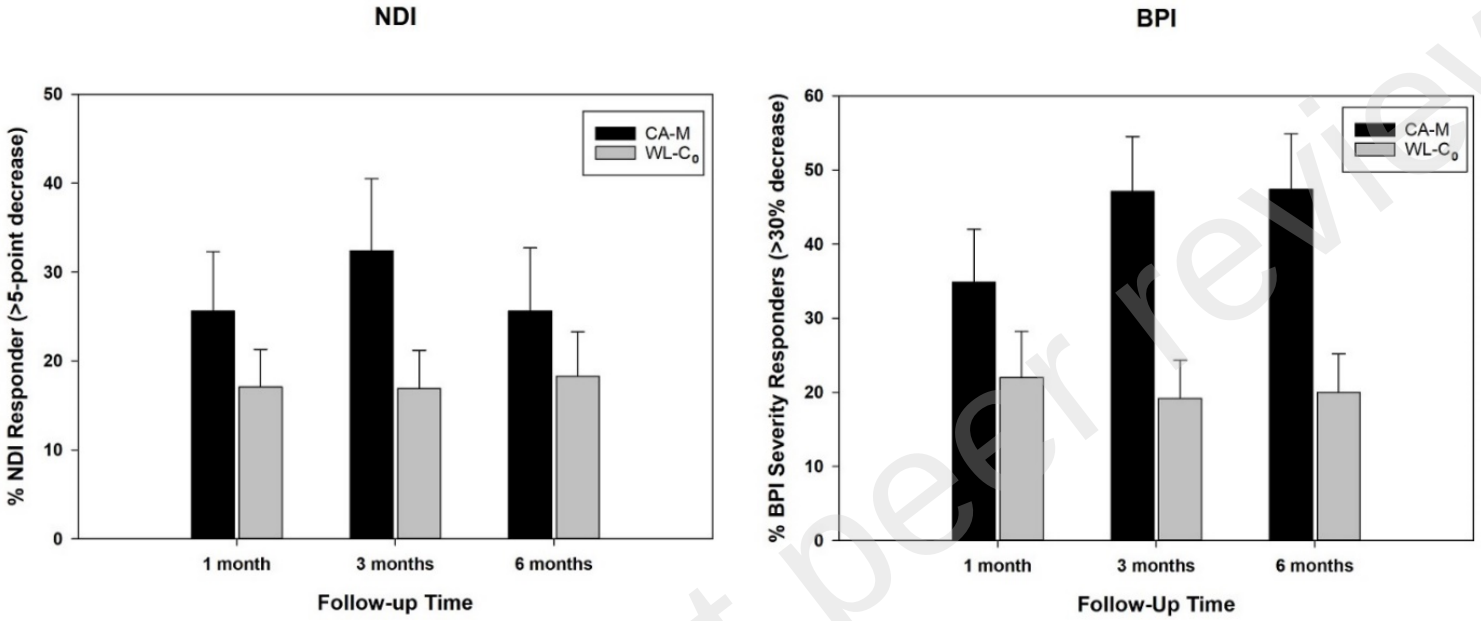
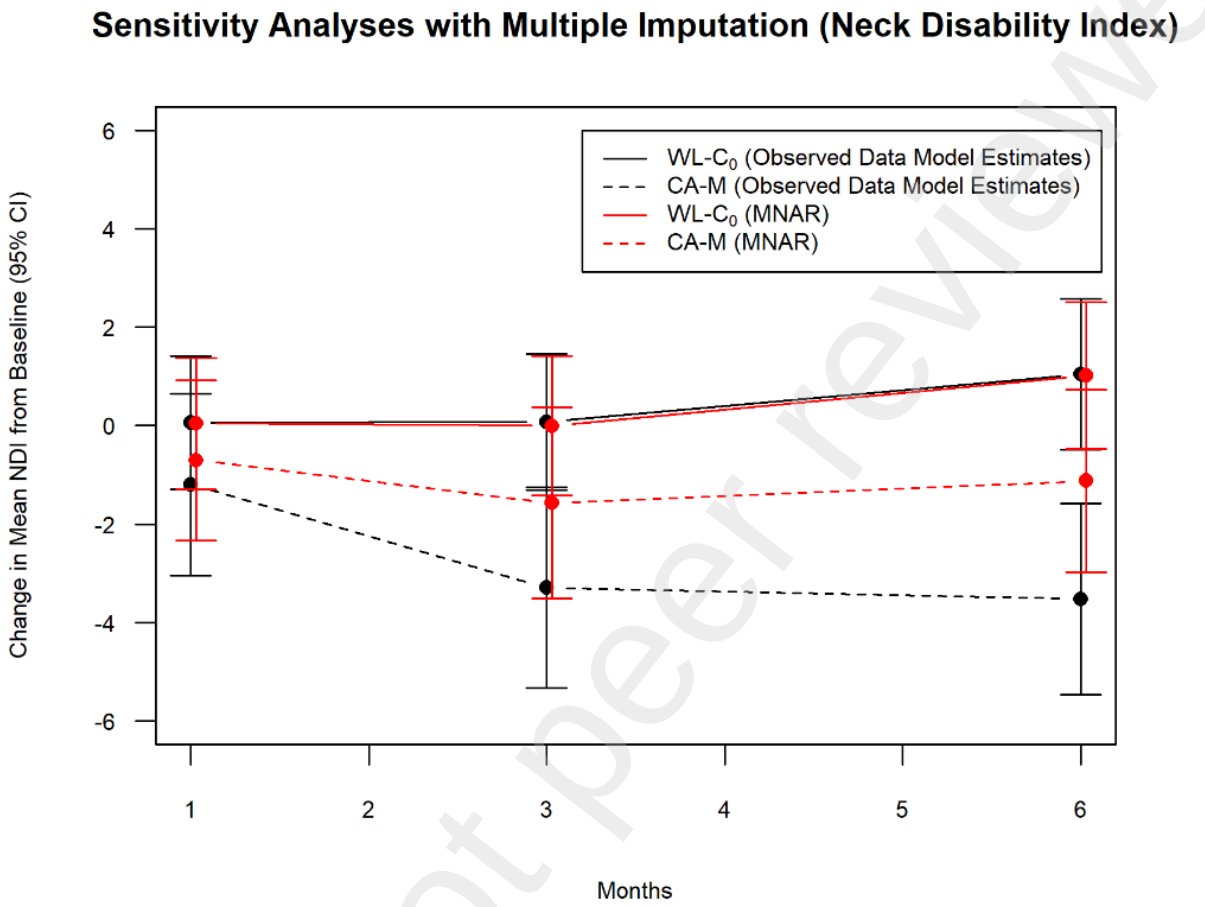
Figure 2. Clinically meaningful change in Neck Disability Index (NDI) and Brief Pain Inventory (BPI) Severity scores across time.



Note: Group populations proportion meeting criterial for responder with standard error bars.

552 **Figure 3.** Sensitivity analysis for clinically meaningful change in Neck Disability Index (NDI) scores
553 across time.



554 Sensivitity - MNAR assuming intermittent missing are Missing-at-Random, control-based imputation for missing follow-up values

555

Table 1. Baseline characteristics for overall sample and by study arm

	Overall (n=203)	WL-C_0 (n=101)	CA-M (n=102)	p-value
Age, Mean (SD)	56.7 (14.0)	56.1 (13.6)	57.2 (14.3)	.550
Education, n (%)				
≤HS	44 (22.1)	22 (22.0)	22 (22.2)	.995
Tech/Business/Associates	90 (45.2)	45 (45.0)	45 (45.5)	
≥Bachelors	65 (32.7)	33 (33.0)	32 (32.3)	
Race,¥ n (%)				
White	150 (75.0)	73 (72.3)	77 (77.8)	.513
Black	41 (20.5)	22 (21.8)	19 (19.2)	
Other	9 (4.5)	6 (5.9)	3 (3.0)	
Hispanic¥ n (%)	5 (2.7)	4 (4.3)	1 (1.1)	.368
Female, n (%)	29 (14.7)	14 (14.0)	15 (15.3)	.795
Marital Status n (%)				
Married/partnered	150 (75.4)	73 (73.7)	77 (77.0)	.593
Non-partnered	49 (24.6)	26 (26.3)	23 (23.0)	
Employment, n (%)				
Employed	88 (44.2)	44 (44.0)	44 (44.4)	.532
Retired	70 (35.2)	32 (32.0)	38 (38.4)	
Unable	22 (11.1)	14 (14.0)	8 (8.1)	
Other	19 (9.6)	10 (10.0)	9 (9.1)	
Income,¥ n (%)				
Comfortable	101 (50.5)	44 (43.6)	57 (57.6)	.233
Just enough	77 (38.5)	43 (42.6)	34 (34.3)	
Not enough	14 (7.0)	9 (8.9)	5 (5.1)	
Don't Know/refused	8 (4.0)	5 (5.0)	3 (3.0)	

Notes: Values are means (standard deviations) for continuous variables and frequencies (percentages) for categorical variables. P-values are from Student's t-tests, Wilcoxon rank-sum tests, and Chi-Square (using Fisher's when expected cell counts are small, marked with a ¥) tests, respectively. Frequencies may not add to column totals due to missing data.

562

563 **Table 2.** Neck Disability Index (NDI) mean scores at each timepoint and within treatment group and between group differences from baseline .

NDI										
	CA-M		WL-C_0		Change in CA-M (from baseline)		Change in WL-C_0 (from baseline)		Change in CA-M vs. Change in WL-C_0	
	N	Mean (Std)	N	Mean (Std)	Mean (95% CI)	p-value	Mean (95% CI)	p-value	Mean (95% CI)	p-value
Baseline	102	18.3 (7.9)	101	20.6 (8.2)						
1 month	43	18.1 (8.5)	82	20.8 (9.1)	-1.2 (-3.0, 0.7)	p=.204	0.1 (-1.3, 1.4)	p=.933	-1.3 (-3.5, 1.0)	p=.270
3 months	34	15.1 (8.7)	77	20.7 (8.6)	-3.3 (-5.3, -1.3)	p=.002	0.1 (-1.3, 1.5)	p=.916	-3.4 (-5.8, -1.0)	p=.006
6 months	39	14.9 (8.3)	60	21.5 (10.0)	-3.5 (-5.5, -1.6)	p<.001	1.0 (-0.5, 2.6)	p=.181	-4.6 (-7.0, -2.1)	p<.001

564 *Notes:* Values are raw means (standard deviations) for non-change at each time point, with sample sizes for non-missing scores. Change values are adjusted
565 means (95% confidence intervals) from cLDA models, adjusted for gender.

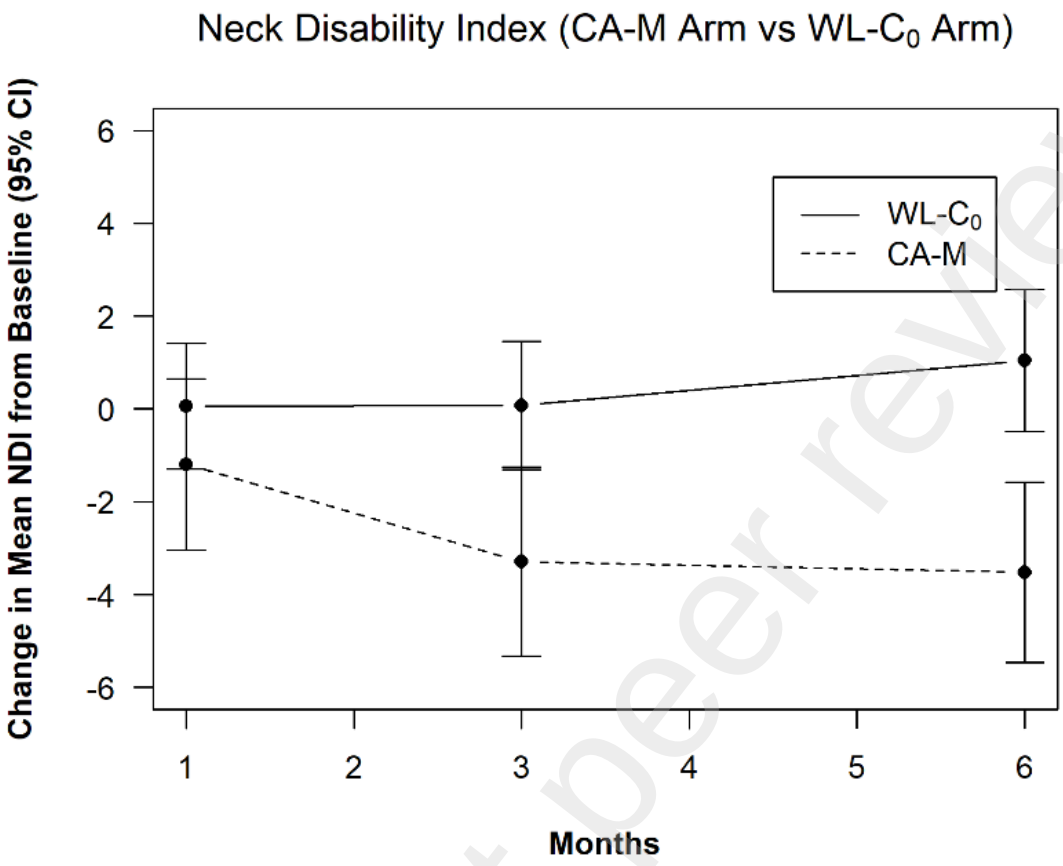
566

Table 3. BPI and other secondary outcome mean scores at each timepoint and within treatment group and between group differences from baseline.

	CA-M		WL-C_0		Change in CA-M (from baseline)		Change in WL-C_0 (from baseline)		Change in CA-M vs. Change in WL-C_0	
	N	Mean (Std)	N	Mean (Std)	Mean (95% CI)	p-value	Mean (95% CI)	p-value	Mean (95% CI)	p-value
BPI Severity										
Baseline	102	6.0 (1.9)	101	6.2 (1.7)						
1 month	42	5.5 (1.7)	82	6.0 (1.9)	-0.8 (-1.2, -0.3)	P=.007	-0.3 (-0.6, 0.1)	p=.544	-0.5 (-1.1, 0.0)	p=.322
3 months	34	4.6 (2.1)	78	5.9 (1.9)	-1.6 (-2.1, -1.1)	P<.001	-0.3 (-0.6, 0.1)	p=.601	-1.3 (-1.9, -0.8)	P<.001
6 months	37	4.5 (2.4)	60	5.7 (1.7)	-1.5 (-2.0, -1.0)	P<.001	-0.5 (-0.8, -0.1)	p=.100	-1.0 (-1.6, -0.4)	P=.007
BPI Interference										
Baseline	102	4.3 (2.3)	101	4.6 (2.3)						
1 month	43	3.4 (2.1)	82	4.2 (2.5)	-1.1 (-1.7, -0.6)	P<.001	-0.4 (-0.8, -0.0)	p=.232	-0.7 (-1.4, -0.0)	p=.226
3 months	34	3.1 (2.7)	78	4.1 (2.6)	-1.2 (-1.8, -0.6)	P<.001	-0.4 (-0.9, -0.0)	p=.221	-0.7 (-1.4, -0.0)	p=.291
6 months	38	3.0 (2.6)	60	4.2 (2.6)	-1.2 (-1.8, -0.6)	P<.001	-0.3 (-0.8, 0.1)	p=.655	-0.9 (-1.6, -0.1)	P=.132
PHQ-9										
Baseline	101	7.0 (5.4)	101	7.6 (5.7)						
3 months	34	6.1 (5.9)	76	7.8 (6.3)	-0.3 (-1.8, 1.1)	P=.999	0.6 (-0.4, 1.6)	p=.897	-0.9 (-2.6, 0.8)	p=.927
6 months	37	6.3 (5.6)	60	8.9 (6.6)	-0.3 (-1.7, 1.2)	P=.999	1.2 (0.1, 2.3)	p=.209	-1.5 (-3.2, 0.3)	P=.525
GAD-7										
Baseline	101	5.3 (4.7)	101	5.5 (5.7)						
3 months	34	5.4 (6.0)	77	6.0 (6.0)	0.5 (-0.6, 1.7)	P=.953	0.9 (0.1, 1.6)	p=.192	-0.3 (-1.7, 1.1)	p=.999
6 months	37	5.0 (5.3)	60	6.7 (6.4)	0.3 (-0.9, 1.4)	P=.999	1.0 (0.2, 1.9)	p=.126	-0.8 (-2.2, 0.6)	P=.903
SF-36 MCS										
Baseline	95	47.0 (12.3)	98	47.2 (13.5)						
1 month	42	47.7 (13.2)	77	48.2 (13.1)	2.4 (-0.7, 5.5)	P=.632	1.0 (-1.3, 3.3)	p=.976	1.4 (-2.3, 5.2)	p=.986
3 months	34	51.3 (15.0)	74	46.9 (14.0)	4.6 (1.2, 8.0)	P=.055	-0.7 (-3.0, 1.7)	p=.997	5.3 (1.2, 9.3)	p=.068
6 months	38	49.7 (11.8)	60	44.8 (15.3)	1.9 (-1.3, 5.2)	P=.863	-1.8 (-4.3, 0.7)	p=.712	3.7 (-0.3, 7.9)	P=.394
SF-36 PCS										
Baseline	95	35.6 (7.2)	98	35.6 (7.8)						
1 month	42	34.9 (7.4)	77	34.9 (7.4)	-0.4 (-2.3, 1.4)	P=.999	-1.0 (-2.4, 0.3)	p=.638	0.6 (-1.6, 2.8)	p=.998
3 months	34	35.1 (7.3)	74	34.1 (6.8)	-0.3 (-2.3, 1.8)	P=.999	-1.1 (-2.5, 0.3)	p=.547	0.9 (-1.5, 3.3)	p=.987
6 months	38	35.7 (7.9)	60	35.4 (7.2)	0.6 (-1.4, 2.5)	P=.997	-0.7 (-2.2, 0.8)	p=.965	1.3 (-1.1, 3.7)	P=.922
Pain Catastrophizing Scale										
Baseline	100	13.4 (12.8)	101	13.5 (13.1)						
3 months	33	11.3 (14.3)	76	13.9 (15.0)	-2.2 (-5.6, 1.2)	P=.788	0.5 (-1.7, 2.7)	p=.999	-2.7 (-6.7, 1.3)	p=.751

Notes: Values are raw means (standard deviations) for non-change at each time point, with sample sizes for non-missing scores. Change values are adjusted means (95% confidence intervals) from cLDA models, adjusted for gender, with Sidak adjusted p-values.

571 **Supplementary Figure 1.** Changes in Neck Disability Index (NDI) scores compared to baseline across
572 time.



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Supplemental Table 1. Neck Disability Index (>5-point decrease) and **Brief Pain Inventory Severity Responder** (>30% decrease) **Analysis Results**.

Outcome: NDI Responder						
	CA-M		$WL\text{-}C_0$		CA-M vs. $WL\text{-}C_0$	
	N	Frequency (%)	N	Frequency (%)	OR (95% CI)	p-value
1 month	43	11 (25.6)	82	14 (17.1)	1.7 (0.7, 4.2)	P=.248
3 months	34	11 (32.4)	77	13 (16.9)	2.5 (1.0, 6.5)	P=.056
6 months	39	10 (25.6)	60	11 (18.3)	1.8 (0.7, 4.9)	P=.239
Overall					2.0 (1.0, 4.0)	P=.046
Outcome: BPI Severity Responder						
	CA-M		$WL\text{-}C_0$		CA-M vs. $WL\text{-}C_0$	
	N	Frequency (%)	N	Frequency (%)	OR (95% CI)	p-value
1 month	43	15 (34.9)	82	18 (22.0)	1.7 (0.8, 4.0)	P=.189
3 months	34	16 (47.1)	78	15 (19.2)	3.9 (1.6, 9.4)	P=.003
6 months	38	18 (47.4)	60	12 (20.0)	3.1 (1.3, 7.9)	P=.014
Overall					2.7 (1.5, 5.0)	P=.001

Notes: Values are raw frequencies (%) for being a responder at each time point, with sample sizes for non-missing scores. Odds ratios (95% confidence intervals) from Generalized Estimating Equation logistic regression models for each outcome, adjusted for gender.

Supplementary Table S2. Sensitivity Analysis 1: Neck Disability Index (NDI) and Brief Pain Inventory (BPI) modified Intent To Treat analysis results.

NDI										
	CA-M		WL-C_0		Change in CA-M (from baseline)		Change in WL-C_0 (from baseline)		Change in CA-M vs. Change in WL-C_0	
	N	Mean (Std)	N	Mean (Std)	Mean (95% CI)	p-value	Mean (95% CI)	p-value	Mean (95% CI)	p-value
Baseline	57	18.4 (8.6)	101	20.6 (8.2)						
1 month	43	18.1 (8.5)	82	20.8 (9.1)	-1.3 (-3.1, 0.6)	p=.185	-0.0 (-1.4, 1.3)	p=.958	-1.2 (-3.5, 1.0)	p=.286
3 months	34	15.1 (8.7)	77	20.7 (8.6)	-3.3 (-5.4, -1.3)	p=.002	-0.0 (-1.4, 1.4)	p=.976	-3.3 (-5.7, -0.9)	p=.007
6 months	39	14.9 (8.3)	60	21.5 (10.0)	-3.6 (-5.5, -1.6)	p<.001	1.0 (-0.6, 2.5)	p=.230	-4.5 (-7.0, -2.1)	p<.001
BPI Severity										
	CA-M		WL-C_0		Change in CA-M (from baseline)		Change in WL-C_0 (from baseline)		Change in CA-M vs. Change in WL-C_0	
	N	Mean (Std)	N	Mean (Std)	Mean (95% CI)	p-value	Mean (95% CI)	p-value	Mean (95% CI)	p-value
Baseline	57	6.1 (1.9)	101	6.2 (1.7)						
1 month	42	5.5 (1.7)	82	6.0 (1.9)	-0.8 (-1.3, -0.4)	P=.007	-0.3 (-0.6, 0.0)	p=.491	-0.5 (-1.1, 0.0)	p=.337
3 months	34	4.6 (2.1)	78	5.9 (1.9)	-1.6 (-2.1, -1.1)	P<.001	-0.3 (-0.6, 0.1)	p=.551	-1.3 (-1.9, -0.8)	P<.001
6 months	37	4.5 (2.4)	60	5.7 (1.7)	-1.5 (-2.0, -1.0)	P<.001	-0.5 (-0.8, -0.1)	p=.088	-1.0 (-1.6, -0.4)	P=.007
BPI Interference										
	CA-M		WL-C_0		Change in CA-M (from baseline)		Change in WL-C_0 (from baseline)		Change in CA-M vs. Change in WL-C_0	
Baseline	57	4.3 (2.4)	101	4.6 (2.3)						
1 month	43	3.4 (2.1)	82	4.2 (2.5)	-1.1 (-1.7, -0.6)	P<.001	-0.4 (-0.8, -0.0)	p=.254	-0.7 (-1.4, -0.0)	p=.232
3 months	34	3.1 (2.7)	78	4.1 (2.6)	-1.2 (-1.8, -0.6)	P<.001	-0.4 (-0.9, -0.0)	p=.243	-0.7 (-1.4, 0.0)	p=.307
6 months	38	3.0 (2.6)	60	4.2 (2.6)	-1.2 (-1.8, -0.6)	P<.001	-0.3 (-0.8, 0.1)	p=.679	-0.9 (-1.6, -0.1)	P=.138

Notes: Values are raw means (standard deviations) for non-change at each time point, with sample sizes for non-missing scores. Change values are adjusted means (95% confidence intervals) from cLDA models, adjusted for gender.

Supplementary Table S3. Sensitivity Analysis 2†: NDI results with and without imputation .

	ORIGINAL RESULTS					
	Change in CA-M (from baseline)		Change in WL-C_0 (from baseline)		Change in CA-M vs. Change in WL-C_0	
	Mean (95% CI)	p-value	Mean (95% CI)	p-value	Mean (95% CI)	p-value
Baseline						
1 month	-1.2 (-3.0, 0.7)	p=.204	0.1 (-1.3, 1.4)	p=.933	-1.3 (-3.5, 1.0)	p=.270
3 months	-3.3 (-5.3, -1.3)	p=.002	0.1 (-1.3, 1.5)	p=.916	-3.4 (-5.8, -1.0)	p=.006
6 months	-3.5 (-5.5, -1.6)	p<.001	1.0 (-0.5, 2.6)	p=.181	-4.6 (-7.0, -2.1)	p<.001
	RESULTS UNDER MNAR USING MULTIPLE IMPUTATION†					
	Change in CA-M (from baseline)		Change in WL-C_0 (from baseline)		Change in CA-M vs. Change in WL-C_0	
	Mean (95% CI)	p-value	Mean (95% CI)	p-value	Mean (95% CI)	p-value
Baseline						
1 month	-0.7 (-2.3, 0.9)	p=.397	0 (-1.3, 1.4)	p=.946	-0.7 (-2.8, 1.3)	p=.467
3 months	-1.6 (-3.5, 0.4)	p=.112	0 (-1.4, 1.4)	p=.998	-1.6 (-3.8, 0.7)	p=.167
6 months	-1.1 (-3.0, 0.7)	P=.234	1.0 (-0.5, 2.6)	p=.182	-2.1 (-4.2, -0.1)	P=.043

†Change values are adjusted means (95% confidence intervals) from cLDA models. Two-stage multiple imputation was used where intermittent missing was first imputed (M=25) to obtain monotone missing data pattern assuming data are missing-at-random and missing follow-up data was then imputed once for each dataset based on regression models using only the WL-C_0 group. *MNAR=missing not at random.