TOMCATT Study Trial Outcomes for Massage: Care-Ally Assisted Vs. Therapist Treated

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Disclosures - Bair

- 1. Research funding:
 - VA HSR, VA CSP, VA CSRD, NEA
- 2. Affiliations
 - VA Center for Health Information & Communication
 - Indiana University School of Medicine/Regenstrief Institute
- 3. Conflicts of Interest
 - None

Disclosures - Munk

- 1. Research funding:
 - None Currently
- 2. Affiliations
 - -ARCCIM Fellow
 - -Massage Therapy Foundation Board of Trustee
 - NOT a federal or VA employee
- 3. Conflicts of Interest
 - -No businesses or related holdings







Objectives

- Background, Context, and Significance
- Original & Overarching Methodology
- Disruptive Encounters
- Design Modification
- Results
 - Care-Ally Assisted Massage (pre-modification)
 - -Therapist Delivered Therapeutic Massage
- Clinical Implications & Discussion



Background, Significance, & Context

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Neck Pain

- 4th leading cause of disability
- function, QoL, emotional well-being
- Economic and care utilization
- Rx and PT = limited benefit
- Effective non-pharmacological approaches needed
- demand for complementary integrative approaches

	~ Prevalence
3-months	15%
12-months	30-50%
U.S. Veterans	67%
Veterans w/ cervical diagnosis	96%

Massage Therapy for Neck Pain

Massage therapy (MT) is effective for musculoskeletal pain



Clin J Pain. Author manuscript; available in PMC 2010 March 1.

Published in final edited form as: Clin J Pain. 2009; 25(3): 233–238. doi:10.1097/AJP.0b013e31818b7912.

Randomized Trial of Therapeutic Massage for Chronic Neck Pain

Karen J. Sherman, PhD, MPH^{1,2}, Daniel C. Cherkin, PhD^{1,3}, Rene J. Hawkes, BS¹, Diana L. Miglioretti, PhD^{1,4}, and Richard A. Deyo, MD, MPH⁵

- Demand & Barriers
 - Perceptions
 - MT access / accessibility
 - Cost
- Integrative medicine at the VA & Massage specific



HHS Public Access

Author manuscript

Spine J. Author manuscript; available in PMC 2016 October 01.

Published in final edited form as: Spine J. 2015 October 1; 15(10): 2206–2215. doi:10.1016/j.spinee.2015.06.049.

Randomized clinical trial assessing whether additional massage treatments for chronic neck pain improve 12- and 26-week outcomes

Andrea J. Cook, PhD^{a,b,*}, Robert D. Wellman, MS^a, Daniel C. Cherkin, PhD^{a,c}, Janet R. Kahn, PhD^d, and Karen J. Sherman, PhD^{a,e}

Study Aims

- Compare the effects of two massage interventions (CA-M: caregiverassisted massage and TT-M: therapist-treated massage) vs. control on pain-related disability
- Compare the effects of two massage interventions vs. control on secondary outcomes, including pain severity, health-related quality of life, depression, anxiety, and stress
- Examine the <u>implementation potential</u> of both massage interventions, including facilitators and barriers, treatment and adherence, and intervention costs.

General Study Timeline

2016 Funding Awarded 2017 Study Launched

Original Design & Methodology

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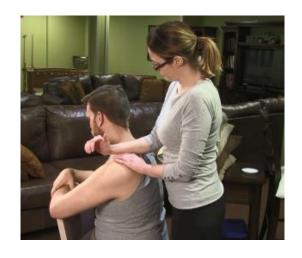
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Original TOMCATT Design





- 5-year, 3-armed study: CA-M, TT-M, WL-C
- Care-Ally assisted massage: 3.5-hr group training workshop,
 30-minute routine, three treatments/week for 12 weeks
- Therapist applied massage: twice weekly, 1-hour massages at the VA for 12 weeks



Participants & Data Collection

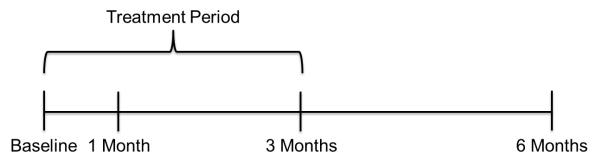
Eligibility & Exclusion

- Medical appointment in past year
- Neck pain for ≥ 6 months
- Neck Pain & Disability Index ≥ 10
- No complexity or contraindications

Recruitment Efforts

- Systematic Mailings
- Word of Mouth
- Clinic Recruitment

Assessment Timeline



Measures

- Neck Pain & Disability Index (NDI)
- Secondary
 - Brief Pain Inventory (BPI)
 - Severity
 - Interference
 - Emotional & Mental Health/Wellbeing

Clinical Meaningful Differences

Neck Disability Index (NDI)

– Neck Pain w/ Disability

Brief Pain Index (BPI) – Neck Pain Severity (Interference and otherwise separate)

NDI – Neck Pain w/ Disability

 ≥ 5-point change = clinically meaningful chance

BPI – Pain Severity & Interference

• ≥ 30% change

CA-M Intervention

- Dyad Group Training & Workshop
 - 3-3.5 hour training
 - Support Materials
 - Training PowerPoint
 - Routine Breakdown
 - DVD & Supplies
- Dose
 - 3 care-ally assisted massage sessions per week for 12 weeks
 - Self-report logs

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Caregiver-Assisted
Massage for Veterans
with Neck Pain
Training Workshop

Niki Munk, PhD, LMT Erica Evans, CMT

ROUTINE PART	Time Allotment (minutes)	Do until (time)	Veteran Activity	Care Ally Activity
Grounding	1	29:00	Deep breathing, grounding, centering (self)	Deep breathing, grounding, centering (self)
Lymph Address	2	27:00	Self-provided lymph drainage	Observing/Applying to self
Range of Motion (ROM)	1	26:00	Head, neck, shoulder, and upper back movement	Neck, arms, wrists, hands, shoulders
Check-in/Initial Connection	1	25:00	Receive and provide feedback	Laying on hands, make connection, assessing tissue with gentle touch
Stretching	3	22:00	Receive and Apply	Apply
Warming of Neck Tissue	2	20:00	Receive – give feedback	Gliding strokes to neck, shoulders
Specific Neck Work	3	17:00	Receive – give feedback	Add kneading and point work
Back work & Abs	4	14:00	Receive – give feedback & apply ab work	Compression, point work, gliding strokes, Upper – Lower Back
Shoulders, Neck, Scalp	3	11:00	Receive – give feedback	Add scalp, shoulders, and neck
Arms and Pecs	3	8:00	Receive – give feedback	Apply to both sides through hands
Back, Shoulders, Neck, Scalp	3	5:00	Receive – give feedback	Final specific work and additional attention items
Veteran Applied Specific Work	4	1:00	Deep back of the neck and front of the neck work	Observe and/or self-apply
Final "sweep" and closure	1	0	Receive	Compression, effleurage, tissue movement/closure

TOMCATT Supplemental Training DVD MAIN MENU

- Massage Routine Demonstration Only
- Introduction, Study Logistics, and Contact Information
- Set-up and Positioning Reminders and Demonstration
- Stroke Reminders and Demonstration
- Self Care Reminders and Demonstration (Veterans and Allies)
- PLAY ALL



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Specific Neck Work - 3 min.

Finish at 17:00

17:42

Next: Back and Abdominals - 4 minutes

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Veteran Applied Specific Point Work - 4 min. Finish at 1:00

To do:

- -back of the neck, "Little Muscles"
- -SCM
- -Scalenes
- -pinchy fingers on shoulder tops

01:36

Next: Final Sweep & Closure-1 minute

TT-M Intervention

Dose – up to 24 sessions

- 60-minute, hands-on
- 2 / week
- 12 weeks

Delivery Descriptors

- Licensed massage therapists
- Within the Roudebush VA Hospital
- Tailored treatment protocol
- Timed PowerPoint

- 1. Warm-Up & Assessment
 - Range of Motion (3min)
 - Lymph Drainage (2-4min)
 - Tissue Warming (1-3min)
- 2. Neck Work (13-22min)

- 3. Compensatory (15-24min)
- 4. Integration I (7-15min)
- 5. Neck Work II (6-10min)
- 6. Integration II (2-5min)
- 7. Closure (1-2min)



General Study Timeline

2016 Funding Awarded

2017 Study Launched

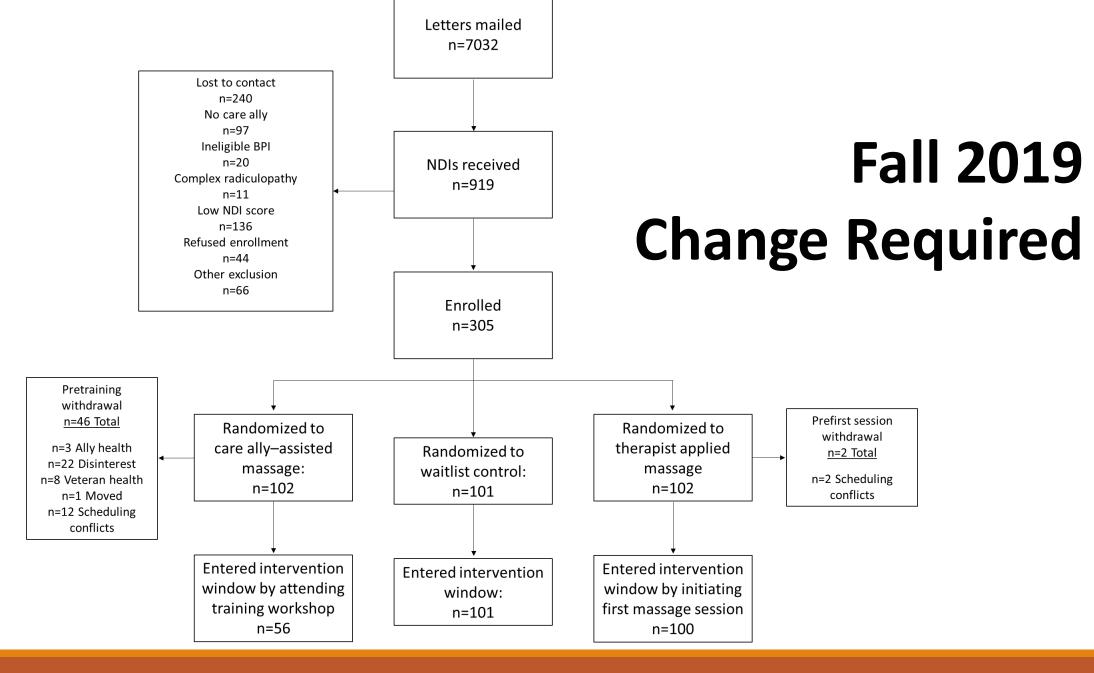
Nov. 2019 Modified to 2-arms

COVID Challenges 3/2020-2/2022

March 2023 Completed

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COVID-19 Impact



Results: CA-M vs. Waitlist Control

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Participant Flow & Characteristics

Participant recruitment began in May 2017 resulting in N=203 participants randomized to CA-M or WL- C_0 prior to the design modification (11/2019).

- Participants evenly distributed across arms, mostly male (85%),
 White (75%), partnered (75%), financially secure (50%-85%), and employed (44%) or retired (35%)
- No characteristic differences existed between arms
- Participants who did not attend training, and withdrew after baseline, were more likely to be younger (53.8±14.8 vs. 60.6±13.2; p=0.016) & employed (61.2% vs. 28.0%; p=0.004)

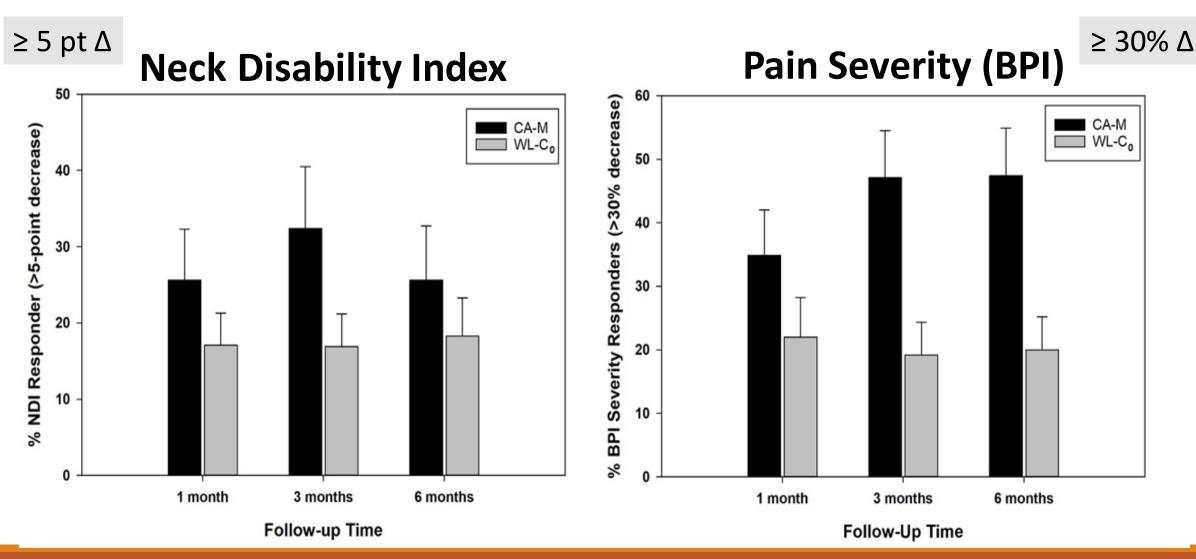
Results: Neck Pain with Disability Change

Primary Outcomes										
	Neck Pain with Disability (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)	0.204	0.1 (-1.3, 1.4)	0.933	-1.3 (-3.5, 1.0)	0.270
3 months	34	15.1 (8.7)	77	20.7 (8.6)	-3.3 (-5.3, -1.3)	0.002	0.1 (-1.3, 1.5)	0.916	-3.4 (-5.8, -1.0)	0.006
6 months	39	14.9 (8.3)	60	21.5 (10.0)	-3.5 (-5.5, -1.6)	<0.001	1.0 (-0.5, 2.6)	0.181	-4.6 (-7.0, -2.1)	<0.001

Results: Neck Pain Severity Change

Secondary Outcomes										
	Pain Severity (BPI)									
CA-M WL-C ₀ Change in CA-M (from baseline)						Change in (from bas	•	Change in C Change in		
	N	Mean (Std)	N	Mean (Std)	Mean (95% CI)	p- value	Mean (95% CI)	p- value	Mean (95% CI)	p-value
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)	0.007	-0.3 (-0.6, 0.1)	0.544	-0.5 (-1.1, 0.0)	0.322
3 months	34	4.6 (2.1)	78	5.9 (1.9)	-1.6 (-2.1, -1.1)	<0.001	-0.3 (-0.6, 0.1)	0.601	-1.3 (-1.9, -0.8)	<0.001
6 months	37	4.5 (2.4)	60	5.7 (1.7)	-1.5 (-2.0, -1.0)	<0.001	-0.5 (-0.8,-0.1)	0.100	-1.0 (-1.6, -0.4)	0.007

Clinically Meaningful Change & Differences



CA-M Related Results & Implications

- Care-ally assisted massage (CA-M) led to greater reductions in CNPrelated disability and pain severity compared to waitlist control, despite treatment engagement and retention challenges.
- Retention challenges likely reflects engagement issues rather than intervention effectiveness.
- Prior partner massage uptake success in prior Veteran studies did not convey to the CNP population.
- More research is needed to determine those most likely engage in CA-M training and treatment and how to target those populations with CA-M approaches.

Results: TT-M vs. Waitlist Control

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Modified Specific Aims:

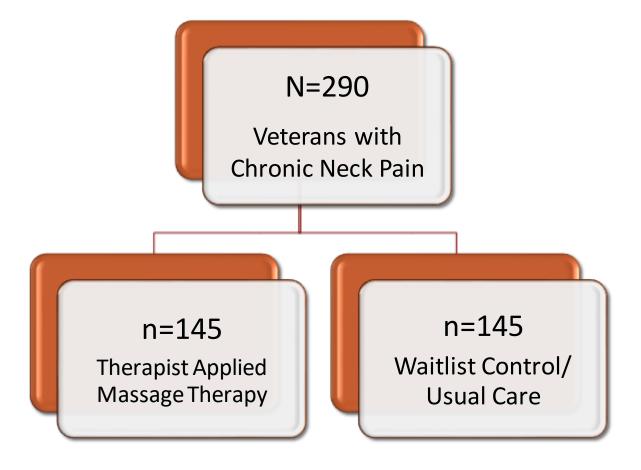


Design

- Randomized Control Trial
- 2-Arms
- Stratified: Male / Female

Compare therapist-treated massage vs. control on *pαin*related disability and secondary outcomes, including *pain severity*, health-related quality of life, depression, anxiety, and stress.

Demographics



- Mean Age = 55.8 years (±13.7)
- Race
 - White = 197 (70.6%)
 - Black = 66 (23.7%)
- Hispanic = 12 (4.6%)
- Female = 42 (14.5%)
- Partnered = 172 (62.6%)
- Employment
 - employed = 128 (46.4%)
 - retired = 92 (33.3%)
 - unable = 32 (11.6%)
- Income
 - comfortable = 147 (52.7%)
 - just enough = 101 (36.2%)
 - not enough = 25 (9.0%)
- Comorbidity Median = 3 (0-8)

Differences in Primary Outcome: Neck Pain & Disability

Neck Disability Index (NDI)							
	TTM WLC			WLC			
	Ν	Mean (Std)	Ν	Mean (Std)			
Baseline	145	20.3 (7.7)	145	20.5 (8.5)			
1 month	109	18.7 (8.4)	114	21.1 (9.2)			
3 months	86	17.0 (8.6)	107	21.2 (9.0)			
6 months	76	18.5 (8.3)	83	21.6 (9.8)			

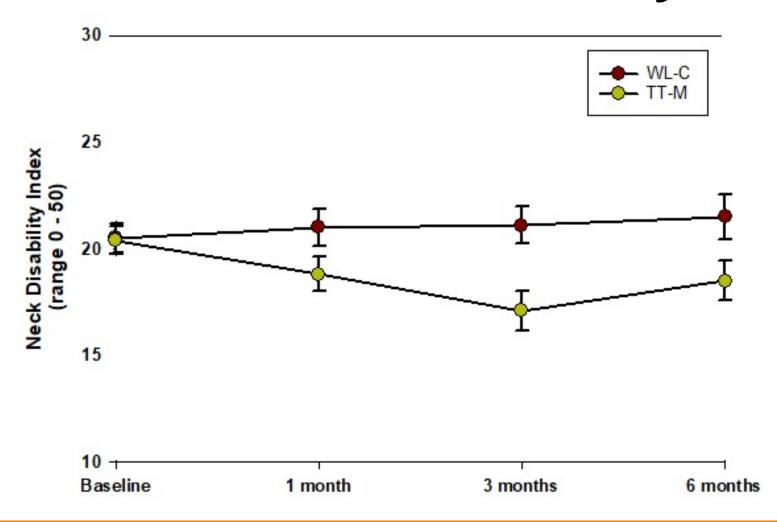
Changes in Neck Disability Index (NDI)									
	Change in TTM		Change in	WLC	Change in TTM vs. Change				
	(from baseline)		(from baseline)		in WLC				
	Mean (95% CI)	p-value	Mean (95% CI)	p-value	Mean (95% CI)	p-value			
Baseline									
1 month	-1.7 (-2.9, -0.5)	.004	0.5 (-0.7, 1.6)	.408	-2.2 (-3.8, -0.6)	.007			
3 months	-2.7 (-4.0, -1.4)	<.001	0.4 (-0.7, 1.6)	.466	-3.1 (-4.8, -1.4)	<.001			
6 months	-0.8 (-2.1, 0.5)	.237	0.9 (-0.4, 2.2)	.172	-1.7 (-3.5, 0.1)	.065			

Differences in Primary Outcome: Neck Pain & Disability

Neck Disability Index (NDI)							
		TTM	WLC				
	N	Mean (Std)	N	Mean (Std)			
Baseline	145	20.3 (7.7)	145	20.5 (8.5)			
1 month	109	18.7 (8.4)	114	21.1 (9.2)			
3 months	86	17.0 (8.6)	107	21.2 (9.0)			
6 months	76	18.5 (8.3)	83	21.6 (9.8)			

	Changes in Neck Disability Index (NDI)								
		Change in T	ITM	Change in	WLC	Change in TTM vs. Change			
		(from baseline)		(from baseline)		in WLC			
		Mean (95% CI)	p-value	Mean (95% CI)	p-value	Mean (95% CI)	p-value		
E	Baseline								
1	month	-1.7 (-2.9, -0.5)	.004	0.5 (-0.7, 1.6)	.408	-2.2 (-3.8, -0.6)	.007		
3	months	-2.7 (-4.0, -1.4)	<.001	0.4 (-0.7, 1.6)	.466	-3.1 (-4.8, -1.4)	<.001		
6	months	-0.8 (-2.1, 0.5)	.237	0.9 (-0.4, 2.2)	.172	-1.7 (-3.5, 0.1)	.065		

Differences in Primary Outcome: Neck Pain & Disability



Differences in Secondary Outcome: Neck Pain Severity

Brief Pain Inventory (BPI) Severity								
		TTM	WLC					
	N	Mean (Std)	N	Mean (Std)				
Baseline	145	6.1 (1.7)	145	6.2 (1.8)				
1 month	109	5.1 (1.9)	114	6.0 (2.0)				
3 months	87	4.5 (2.0)	109	6.0 (1.9)				
6 months	76	4.7 (2.2)	82	5.7 (1.9)				

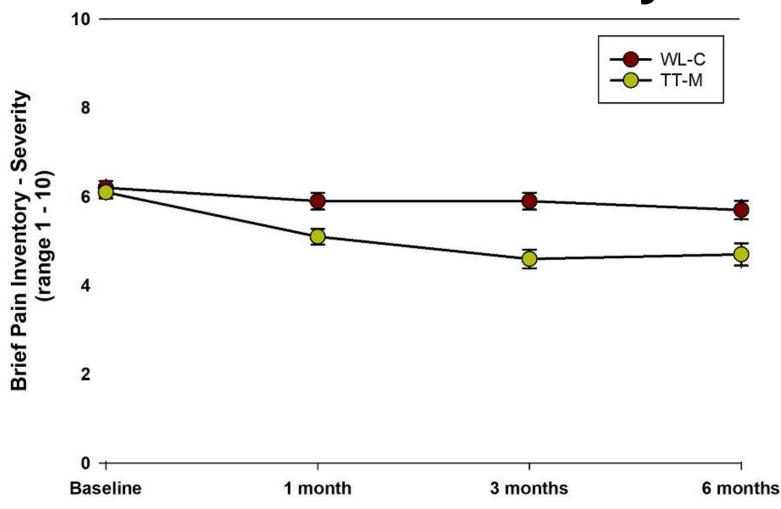
Changes	Changes in Brief Pain Inventory (BPI) Severity									
	Change in TTM (fro	m Change in WL	.C (from	Change in TTM vs. Change						
	baseline)	baselin	e)	in WLC						
	Mean (95% CI) p-va	alue Mean (95% CI)	p-value	Mean (95% CI)	p-value					
Baseline										
1 month	-1.0 (-1.3, -0.7) <.00	1 -0.2 (-0.5, 0.0)	.509	-0.8 (-1.2, -0.4)	.001					
3 months	-1.5 (-1.8, -1.2) <.00	1 -0.2 (-0.5, 0.1)	.824	-1.3 (-1.7, -0.9)	<.001					
6 months	-1.2 (-1.6, -0.9) <.00	1 -0.4 (-0.7, -0.1)	.155	-0.8 (-1.3, -0.4)	.003					

Differences in Secondary Outcome: Neck Pain Severity

Brief Pain Inventory (BPI) Severity								
		TTM		WLC				
	N	Mean (Std)	Ν	Mean (Std)				
Baseline	145	6.1 (1.7)	145	6.2 (1.8)				
1 month	109	5.1 (1.9)	114	6.0 (2.0)				
3 months	87	4.5 (2.0)	109	6.0 (1.9)				
6 months	76	4.7 (2.2)	82	5.7 (1.9)				

C	Changes in Brief Pain Inventory (BPI) Severity									
		Change in TTM	/I (from	Change in WL	C (from	Change in TTM vs. Change				
		baseline)		baseline)		in WLC				
		Mean (95% CI)	p-value	Mean (95% CI)	p-value	Mean (95% CI)	p-value			
В	aseline									
1	month	-1.0 (-1.3, -0.7)	<.001	-0.2 (-0.5, 0.0)	.509	-0.8 (-1.2, -0.4)	.001			
3	months	-1.5 (-1.8, -1.2)	<.001	-0.2 (-0.5, 0.1)	.824	-1.3 (-1.7, -0.9)	<.001			
6	months	-1.2 (-1.6, -0.9)	<.001	-0.4 (-0.7, -0.1)	.155	-0.8 (-1.3, -0.4)	.003			

Differences in Secondary Outcome: Neck Pain Severity



Differences in Primary Outcome: Neck Pain & Disability

Neck Disability Index (NDI)					
		TT-M	WL-C		
	N	Mean (Std)	N	Mean (Std)	
Baseline	145	20.3 (7.7)	145	20.5 (8.5)	
1 month	108	18.7 (8.4)	115	21.1 (9.2)	
3 months	86	17.0 (8.6)	108	21.2 (9.0)	
6 months	76	18.5 (8.3)	84	21.6 (9.8)	



NDI Interpretation

0 to 4 = no disability

5 to 14 = mild

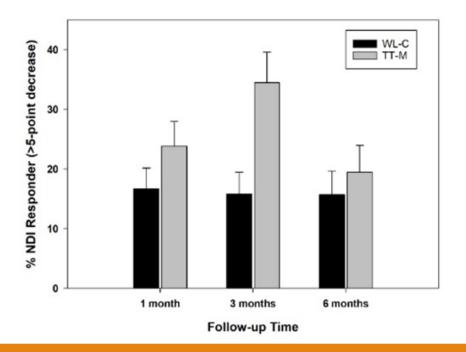
15 to 24 = moderate

25 to 34 = severe

Above 34 = complete

Fairbank, 1980

Differences in Primary Outcome: Neck Pain & Disability

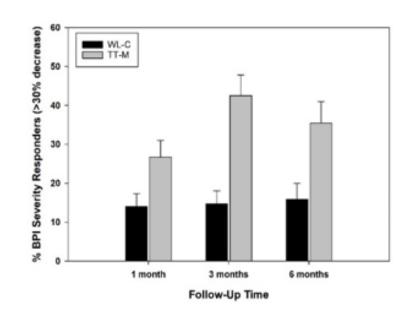


Clinically
Meaningful
Change: ≥ 5

Outcome: NDI Responder						
	TT-M		WL-C		TT-M vs. WL-C	
	N	Frequency (%)	N	Frequency (%)	OR (95% CI)	p-value
1-month	109	26 (23.9)	114	19 (16.7)	1.6 (0.8, 3.0)	P=.186
3-months	87	30 (34.5)	107	17 (15.9)	2.8 (1.4, 5.5)	P=.003
6-months	77	15 (19.5)	83	13 (15.7)	1.3 (0.6, 3.0)	P=.499
Overall					1.9 (1.1, 3.1)	P=.014

Differences in Secondary Outcome: Neck Pain Severity

Neck Pain Severity (BPI)					
		TT-M	WL-C		
		Mean		Mean	
	N	(Std)	N	(Std)	
Baseline	145	6.1 (1.7)	145	6.2 (1.8)	
1 month	109	5.1 (1.9)	114	6.0 (2.0)	
3 months	87	4.5 (2.0)	109	6.0 (1.9)	
6 months	76	4.7 (2.2)	82	5.7 (1.9)	



Clinically
Meaningful
Change: ≥ 30%

Outcome: BPI Pain Severity Responder						
	TT-M		WL-C		TT-M vs. WL-C	
	N	Frequency (%)	N	Frequency (%)	OR (95% CI)	p-value
1-month	109	29 (26.6)	114	16 (14.0)	2.2 (1.1, 4.4)	P=.021
3-months	87	37 (42.5)	109	16 (14.7)	4.3 (2.2, 8.5)	P<.001
6-months	76	27 (35.5)	82	13 (15.9)	3.0 (1.4, 6.3)	P=.005
Overall					3.1 (1.9, 4.9)	P<.001

Section 1 – PAIN INTENSITY

I have no pain at the moment.

The pain is very mild at the moment.

The pain is moderate at the moment.

The pain is fairly severe at the moment.

The pain is very severe at the moment.

The pain is the worst imaginable at the moment.





Section 8 - DRIVING

 I can drive my car without any neck pain.
 I can drive my car as long as I want, with slight pain in my neck.
 I can drive my car as long as I want, with moderate pain in my neck.
 I can't drive my car as long as I want, because of moderate pain in my neck.
 I can hardly drive at all, because of severe pain in my neck.
I can't drive my car at all.

NDI: What CNP with Disability Looks Like...

Severe neck pain with disability: NDI = 25

- Pain described as very severe.
- Cannot lift or carry weights.
- Cannot do any work at all.
- Can drive if I want but with moderate neck pain.
- Cannot do any recreation activities at all.

NDI: What Clinical Benefit Looks Like...

Starting with NDI=25 with 12pt Δ and 48% improvement; Δ from severe to mild

- Pain described as <u>very severe</u> to <u>moderate</u>.
- Cannot lift or carry weights to can lift heavy objects if conveniently positioned.
- Cannot do <u>any</u> work at all to *cannot do my <u>usual</u> work*.
- Sleep mildly disturbed to *I have no trouble sleeping*.
- Can drive but with moderate neck pain to can drive with slight neck pain.
- Cannot do any recreation activities at all to able to engage in all recreation with some pain.

NDI: What Clinical Benefit Looks Like...

Starting with NDI=23 with 10pt Δ and 43% improvement; moderate to mild

- Can lift light objects if conveniently positioned to can lift heavy objects if conveniently positioned.
- <u>Cannot drive</u> as I'd like due to <u>moderate neck pain</u> to <u>can drive</u> as I'd like with <u>slight neck pain</u>.
- Sleep is greatly disturbed (3-5 sleepless hrs) to sleep is mildly disturbed (1-2 sleepless hrs).
- <u>Can hardly do any</u> recreational activities due to pain to <u>engage in all recreation</u> without neck pain.

TT-M Related Results & Take-Aways

- Massage well received and well tolerated
- Comparable to other CNP clinical benefits from massage & reinforces prior findings
- Population differences: Veterans had worse baseline measures and may require higher dosing or prolonged treatment
- Most pronounced impact at treatment series end
- Massage therapy part of Veteran health benefits
- Next Steps: Booster and tapered session approaches

Thank You!



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Questions?

Study Team

Matt Bair MD (PI)

Joanne Daggy (Statistical Lead)

Erica Evans (RA, LMT)

Trevor Foote (Lead LMT)

Amanda Fromer (Study Coordinator)

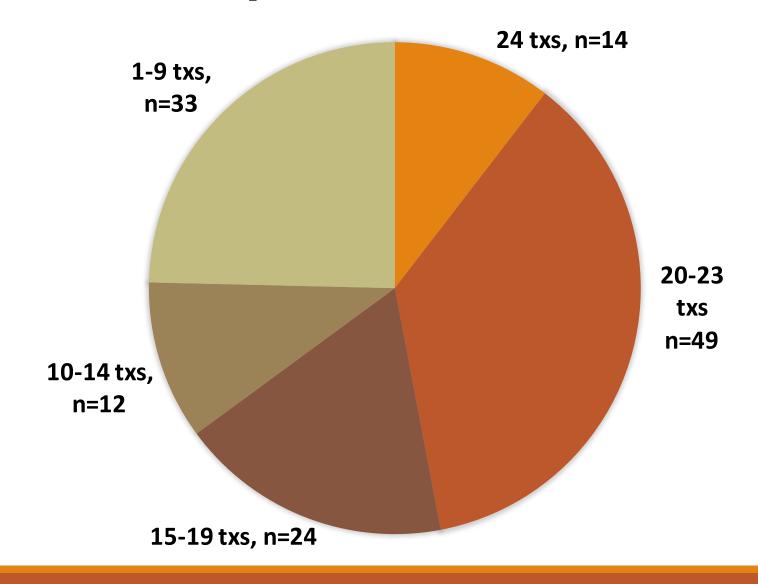
Mikayla Garner (Study Coordinator)

Matt Kline (Study Coordinator, RA)

Niki Munk PhD (Co-I, MOB lead)

James Slaven (Statistician)

TT-M Compliance: 24 treatments (txs)



7:30 In

Hands-On Check-in/Tissue Warming

1-3 Minutes Total

30 Seconds

15 Seconds

5 Seconds

52:30 Left

Neck Work I

13.5 – 20.5 Minutes

- Friction to base of skull
- Long strokes down lamina
- Slow friction, anterior neck
- Slow friction, scalenes
- Deeper longitudinal stripping
- Tx scar tissue if appropriate
- Eff. & Pet., traps, paraspinals
- Stretching
- Myofascial
- Trigger point work

13-23 Minutes Total

43:30 In

16:30 Left

Compensatory / Addit. Work

- Areas
 - Shoulders
 - Arms
- 15-24 Back
- Minutes Hips
 - Total Legs
 - Orientation
 - Supine
 - Prone
 - Side-Lying

Integration I

- Craniosacral
- Stretching
- Rocking
- Long, Slow, Gliding Strokes
- Other items w/in protocol

6-14

Minutes Total

7:30

Neck Work II

- Friction
- Long strokes
- Slow friction
 - anterior neck
 - scalenes
- Stripping
- Tx scar tissue
- Eff. & Pet.
 - Traps
 - paraspinals
- Stretching
- Myofascial
- Trigger point work

6-14 inutes Total

Minutes Total

9:30

13:30

1:30

58:00 In

2:00 Left

Integration II

Final sweep

· Stretching

Craniosacral

Holding

Rocking

1-2

Long, Slow, Gliding Strokes

Minutes Total

Completion

Other items w/in protocol

2-6 Minutes Total

1:00

2:00

59:30 In 0:30 Left

Completion

- · Final sweep
- Holding

1-2 Minutes Total

> 15 Seconds 5 Seconds

0:30