

TRIAL OUTCOMES FOR MASSAGE, CARE ALLY-ASSISTED VS THERAPIST-TREATED (TOMCATT): CHALLENGES & EARLY FINDINGS

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**VA HSR&D Cyberseminar-Complementary and
Integrative Health**

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Why study neck pain?

- **Neck pain is common**
 - **30%-50% - 12-month prevalence**
 - **Even more common in Veteran**
- **Disabling**
 - **4th most common cause in US**
- **Reduces function, quality of life, and is associated with depression/anxiety**

Treatment Options

- **Medications and physical therapy – most commonly used treatments**
- **Limited evidence of treatments – relative to low back pain**
- **NSAIDs and opioids – side effects, controversies**
- **Physical therapy – helpful for some**

**“THE NEED FOR NONDRUG
TREATMENT OPTIONS (FOR
PAIN) IS A SIGNIFICANT AND
URGENT PUBLIC HEALTH
IMPERATIVE.”**

Dr. Josephine Briggs: Director Emeritus of the National
Center for Complementary and Integrative Health
(NCCIH)

VA Context for study

- **Reduce reliance on pharmacological treatment of pain**
- **Opioid Safety Initiative (2012)**
 - **High dose opioids, concomitant opioids and benzodiazepines**
 - **Safer alternatives for treating chronic pain**
 - **VA facilities encouraged to improve access to CIH approaches**

Need for effective and safe treatments

- **High demand for CIH approaches**
- **30% of US adults use CIH approaches**
- **Pain is the main reason**
- **Back pain #1, neck pain #2 reason for use**
- **Chiropractic #1, massage #2 modality used**

Evidence for massage in neck pain

- **Massage reduced pain and/or disability > usual medical care, physical therapy, or no treatment.**
- **Effective in short-term, but long-term benefits?**
- **Overall quality of most massage trials rated poor**
- **Sherman and colleagues have set standard for massage**

Sherman studies

- **N = 64, massage (10 weeks) improved neck pain disability > compared to patients randomized pain self-care book**
- **N = 228, 60-min massage sessions, 1-3 x's/week reached clinically meaningful improvements more than control**
- **F/u study – “booster doses” improved neck disability and pain at 12 wks, non-significant changes at 26 wks**

Theorized massage mechanisms

- **Increased local blood circulation**
- **Improved muscle tone**
- **Increased joint flexibility**
- **Heightened relaxation response**
- **Changes in neuroendocrine and inflammatory biomarkers implicated in pain generation and sensitivity**

Access challenges to massage

- **Costly (~\$60/hour), can vary by region, setting, and therapist training**
- **Typically, out-of-pocket expense**
- **Not affordable to most Veterans**
- **Massage therapy is offered at few VAMC's**
- **Limited cost-effectiveness study of massage**

Caregiver-delivered massage to improve access

- **Tested previously in pediatric, obstetrical, and long-term care settings for dementia.**
- **Kozak et al showed feasibility of caregiver-given massage in 27 caregiver-Veteran dyads**
- **Decreased pain, stress/anxiety, and fatigue in Veterans with cancer**

Caregiver-delivered massage to improve access

- **Collinge and colleagues**
 - **97 patient/caregiver dyads**
 - **Massage intervention vs. attention control**
- **Decreased pain, depression, and other cancer-related symptoms**
- **Caregivers also benefitted from doing hands-on massage**
- **No previous studies in Veterans with chronic pain**

Rationale

- **High prevalence and significant disability from chronic neck pain**
- **Largely neglected condition in Veterans**
- **Chronic pain associated w/ ↓ satisfaction with VA care**
- **Only 28% Veterans report very good or excellent pain treatment effectiveness**
- **Massage is highly preferred by Veterans**
- **VA facilities are being mandated to reduce reliance on opioids and increase access to complementary approaches**

Primary Aim (Initially)

- **To compare the effects of two massage interventions (caregiver-assisted massage and therapist-treated massage) vs. waitlist control on pain-related disability**

Secondary Aims

- **To compare the two massage interventions vs. control on secondary outcomes, including pain severity, health-related quality of life, depression, anxiety, and stress**
- **To examine the implementation potential of both massage interventions, including facilitators and barriers, treatment and adherence, and intervention costs**

TOMCATT Trial Design (initial)



Setting

- **6 primary care clinics at Roudebush (Indianapolis) VA Medical Center**
- **Surrounding community-based outpatient clinics**

Participants – initial recruitment goal

- **N = 468 Veterans with chronic neck pain**

Eligibility

- **Chronic neck pain \geq 6 months**
- **Neck Disability Index (NDI) score \geq 10 (moderate)**
- **Access to working phone**
- **Have “care-ally”/caregiver $>$ 18 (spouse, partner, family member, or friend) willing to learn and provide massage therapy during the study period**

Exclusion Criteria

- **Neck pain due to vertebral fracture or metastatic cancer**
- **Complex neck pain (whiplash)**
- **Any professional massage therapy w/in last 6 months**
- **Contraindication to massage**
- **Active suicidal ideation**
- **Moderately severe cognitive impairment**
- **Medical complexity**
- **Pending neck surgery**
- **Involved in ongoing pain trial**

Care-Ally assisted massage (CA-M)

- **3.5-4 hour group training workshop**
 - **Held 2-3 X's/month - up to 6 participant dyads**
 - **Developed by Niki Munk, PhD, LMT and Erica Evans, CMT**
- **Instructed on 30-minute massage routine**
- **Recommended delivering 3 times per week X 12 weeks**

Care-Ally Assisted Massage Training Workshop Components

- **General instruction on massage, communication approach, safety, chronic neck pain, and trigger points that may exacerbate neck pain**
- **Massage technique demonstration and supervised practice**
- **Specific self-care routine components and individualized trigger point care**
- **Care ally-assisted massage routine demonstration and practice**
- **Questions, study activity log instruction, closure, and wrap-up**

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

- Acknowledgments



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



**Specific Neck Work
- 3 min.**

Finish at 17:00

17:42

**Next: Back and Abdominals -
4 minutes**

Care- Ally Weekly Logs

Daily Log

Please indicate what study activity was specifically completed for your chronic neck pain per day.



Name: _____ Week 1: ____ / ____ / ____ thru ____ / ____ / ____

	Sun.	Mon.	Tues.	Wed.	Thurs.	Fri.	Sat.
Check days you used the DVD	<input type="checkbox"/>						
Check days the full 30-minute routine was completed	<input type="checkbox"/>						
Total minutes of treatment/self-care per day:							
Ally assisted items completed - not full routine							
Stretches	<input type="checkbox"/>						
Neck Routine	<input type="checkbox"/>						
Shoulder Routine	<input type="checkbox"/>						
Back Routine	<input type="checkbox"/>						
Arm Routine	<input type="checkbox"/>						
Pecs Routine	<input type="checkbox"/>						
Head Routine	<input type="checkbox"/>						
Self-care items completed – not full routine							
Grounding/deep breathing/meditation	<input type="checkbox"/>						
2-minute lymph drainage protocol	<input type="checkbox"/>						
Range of motion (neck, shoulders, etc.)	<input type="checkbox"/>						
Self-applied neck stretches	<input type="checkbox"/>						
Specific point work- Front of the neck	<input type="checkbox"/>						
Specific point work- Back of the neck	<input type="checkbox"/>						
Notes: Use this space to note anything that may have contributed to your neck pain or treatment experience							

Therapist-treated massage (TT-M)

- **Therapist applied massage**
 - **Certified / licensed massage therapists**

- **Two, 1-hour massage sessions weekly**

- **Delivered at RVAMC X 12 weeks**

Wait-list control

- **Check-in calls at 2 and 4 months**
- **Undergo outcome assessments at baseline, 1, 3, and 6 months**
- **Continue usual medical care**
- **Offered massage sessions after 6-month outcome assessment**

Primary Outcome

- **Outcome assessments: Baseline, 1, 3, and 6 months**
- **Neck Disability Index (NDI) total score**
- **Compare each massage arm to WLC on change and absolute scores at 3-months (immediate post-treatment)**

Neck Disability Index

This questionnaire has been designed to give us information as to how your neck pain has affected your ability to manage in everyday life. Please answer every section and **mark in each section only the one box that applies to you**. We realise you may consider that two or more statements in any one section relate to you, but please just mark the box that most closely describes your problem.

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 2: Personal Care (Washing, Dressing, etc.)

- I can look after myself normally without causing extra pain
- I can look after myself normally but it causes extra pain
- It is painful to look after myself and I am slow and careful
- I need some help but can manage most of my personal care
- I need help every day in most aspects of self care
- I do not get dressed, I wash with difficulty and stay in bed

Section 3: Lifting

- I can lift heavy weights without extra pain
- I can lift heavy weights but it gives extra pain
- Pain prevents me lifting heavy weights off the floor, but I can manage if they are conveniently placed, for example on a table
- Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned
- I can only lift very light weights

Office Use Only

Name _____

Date _____

- I cannot lift or carry anything

Section 4: Reading

- I can read as much as I want to with no pain in my neck
- I can read as much as I want to with slight pain in my neck
- I can read as much as I want with moderate pain in my neck
- I can't read as much as I want because of moderate pain in my neck
- I can hardly read at all because of severe pain in my neck
- I cannot read at all

Section 5: Headaches

- I have no headaches at all
- I have slight headaches, which come infrequently
- I have moderate headaches, which come infrequently
- I have moderate headaches, which come frequently
- I have severe headaches, which come frequently
- I have headaches almost all the time

Section 6: Concentration

- I can concentrate fully when I want to with no difficulty
- I can concentrate fully when I want to with slight difficulty
- I have a fair degree of difficulty in concentrating when I want to
- I have a lot of difficulty in concentrating when I want to
- I have a great deal of difficulty in concentrating when I want to
- I cannot concentrate at all

Section 7: Work

- I can do as much work as I want to
- I can only do my usual work, but no more
- I can do most of my usual work, but no more
- I cannot do my usual work
- I can hardly do any work at all
- I can't do any work at all

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

Section 9: Sleeping

- I have no trouble sleeping
- My sleep is slightly disturbed (less than 1 hr sleepless)
- My sleep is mildly disturbed (1-2 hrs sleepless)
- My sleep is moderately disturbed (2-3 hrs sleepless)
- My sleep is greatly disturbed (3-5 hrs sleepless)
- My sleep is completely disturbed (5-7 hrs sleepless)

Section 10: Recreation

- I am able to engage in all my recreation activities with no neck pain at all
- I am able to engage in all my recreation activities, with some pain in my neck
- I am able to engage in most, but not all of my usual recreation activities because of pain in my neck
- I am able to engage in a few of my usual recreation activities because of pain in my neck
- I can hardly do any recreation activities because of pain in my neck
- I can't do any recreation activities at all

Score: ___/50 **Transform to percentage score x 100 =** %points

Scoring: For each section the total possible score is 5: if the first statement is marked the section score = 0, if the last statement is marked it = 5. If all ten sections are completed the score is calculated as follows:

Example: 16 (total scored)

50 (total possible score) x 100 = 32%

If one section is missed or not applicable the score is calculated: 16 (total scored)

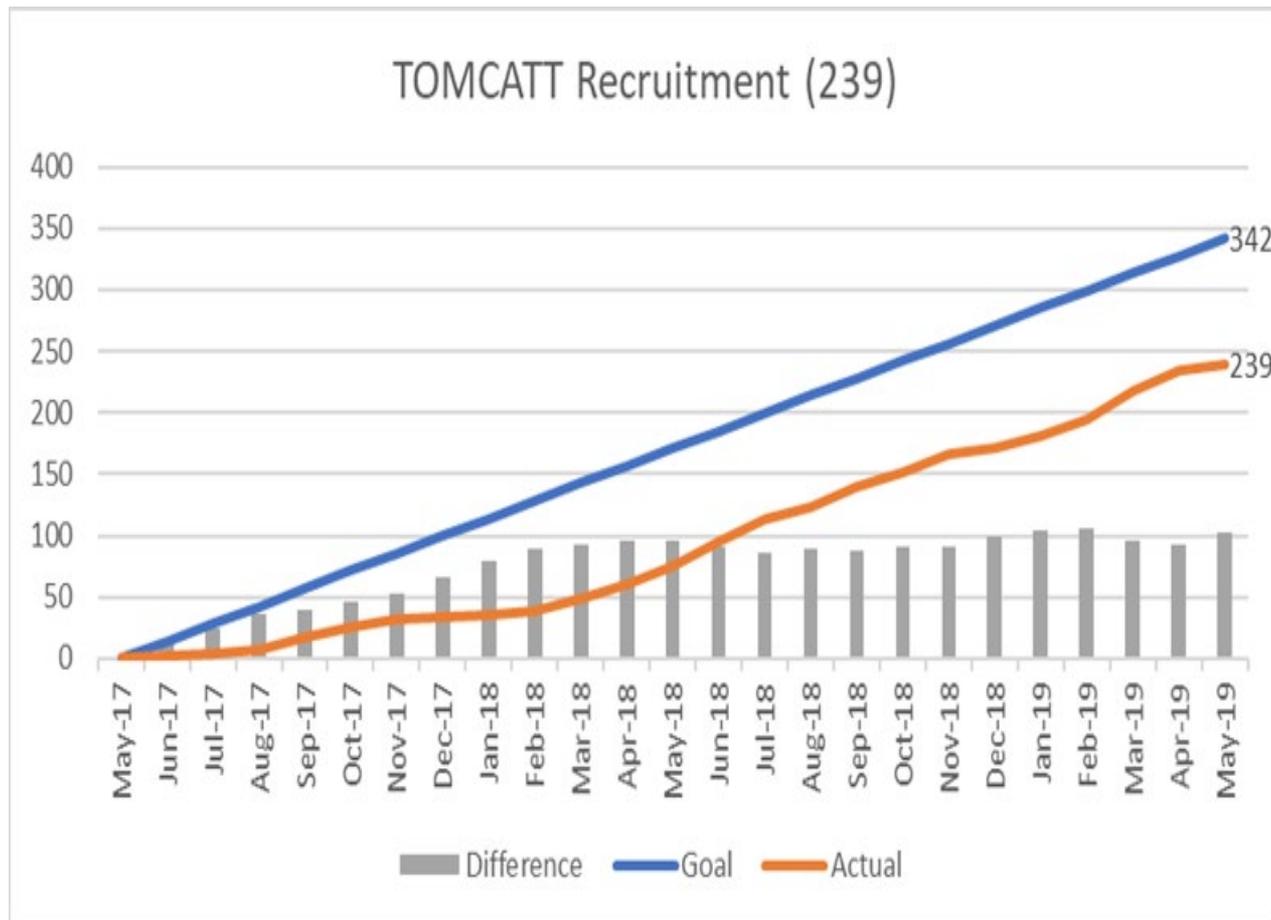
45 (total possible score) x 100 = 35.5%

Minimum Detectable Change (90% confidence): 5 points or 10 %points

Secondary outcomes

- **Pain intensity (Brief Pain Inventory-BPI)**
- **Pain interference (BPI)**
- **Health-related quality of life**
- **Depression**
- **Anxiety**
- **PTSD**
- **Sleep**
- **Stress**
- **Pain beliefs**

Recruitment challenges



Recruitment challenges

- **Start-up delays**
- **Difficulties hiring study personnel**
- **Hiring-freeze**

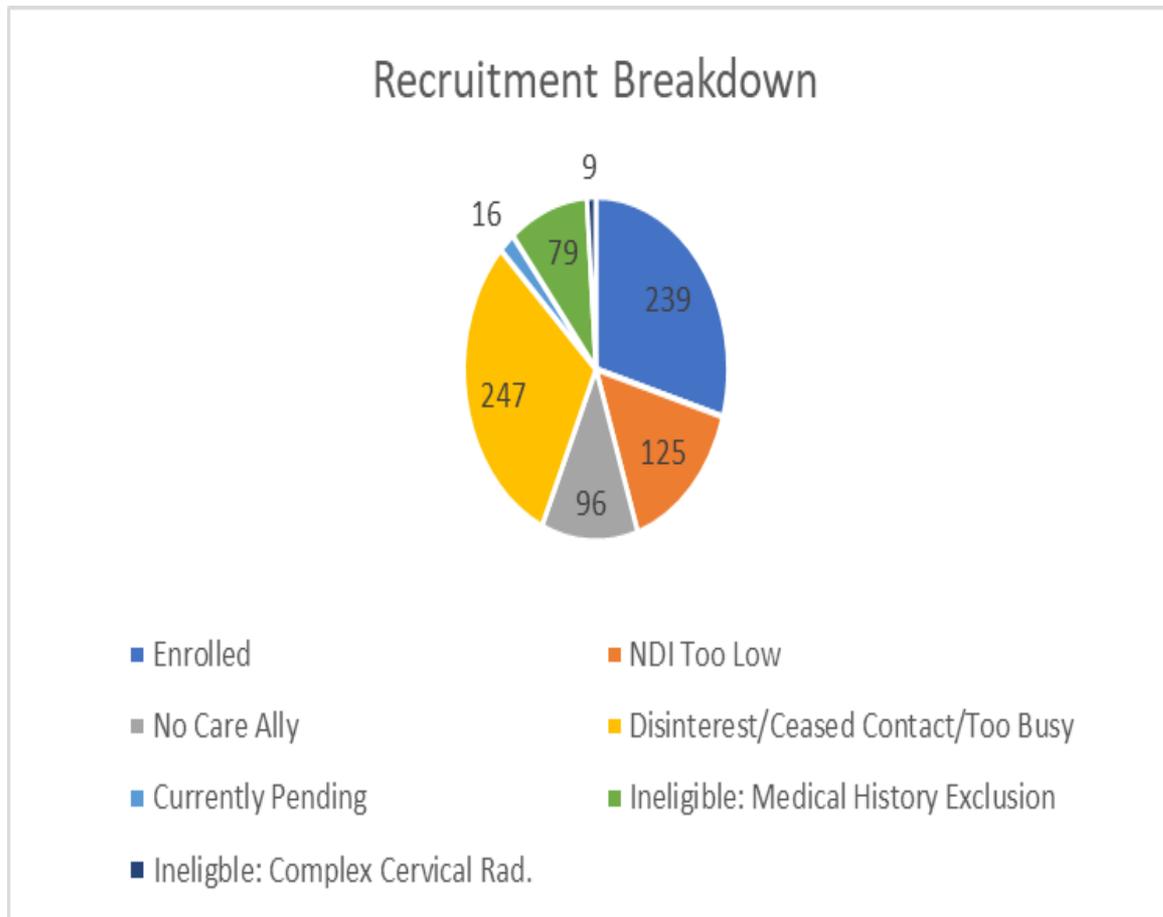
Efforts to boost recruitment

- **Broadened eligibility criteria (lowered NDI score, eliminated BPI)**
- **Approved to send out email blast to Veterans and families**
- **Updated study brochure (MESSAGE STUDY)**
- **Focused on recruiting married Veterans**
- **Added research assistant to recruit in evenings**

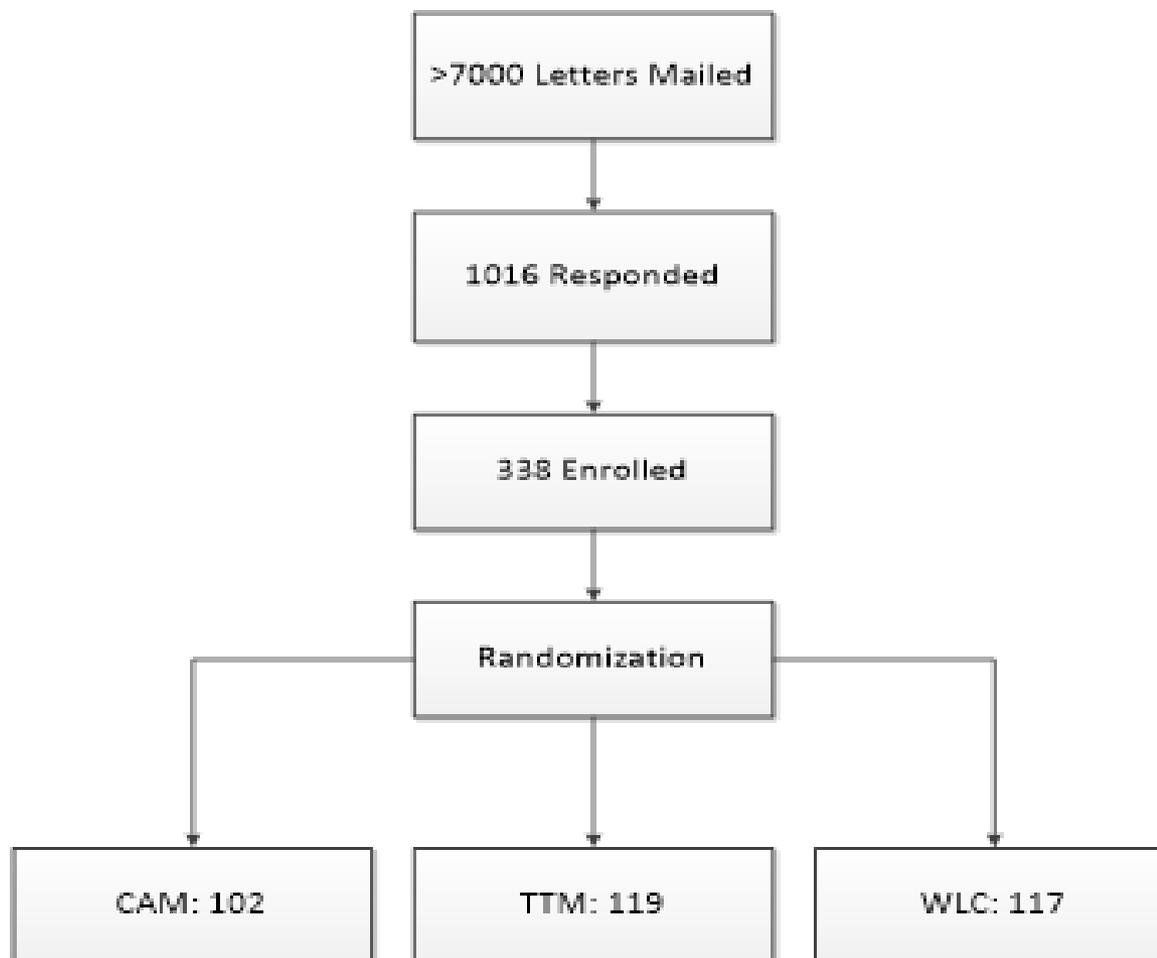
Efforts to boost recruitment

- **Added capacity to deliver Saturday massages and Care-ally training workshops**
- **Presented in person to community-based outpatient clinics and their providers**
- **Distributed brochures to Veteran Services Organizations**
- **Added free massage for Veteran participant in CAM**
- **All TTM Veterans to volunteer to be a care ally for a potential participant who did not have one**

Recruitment breakdown



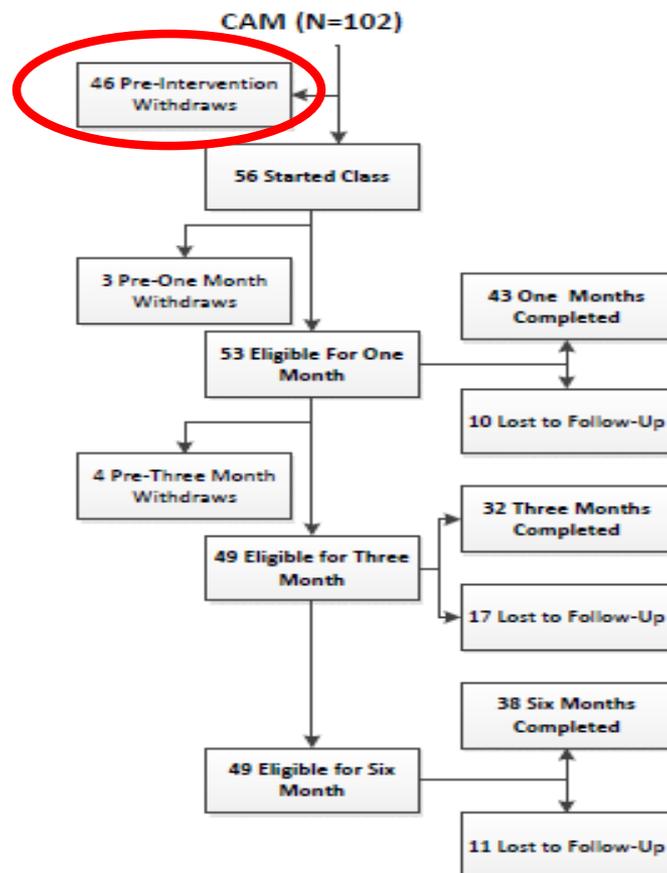
Recruitment Summary



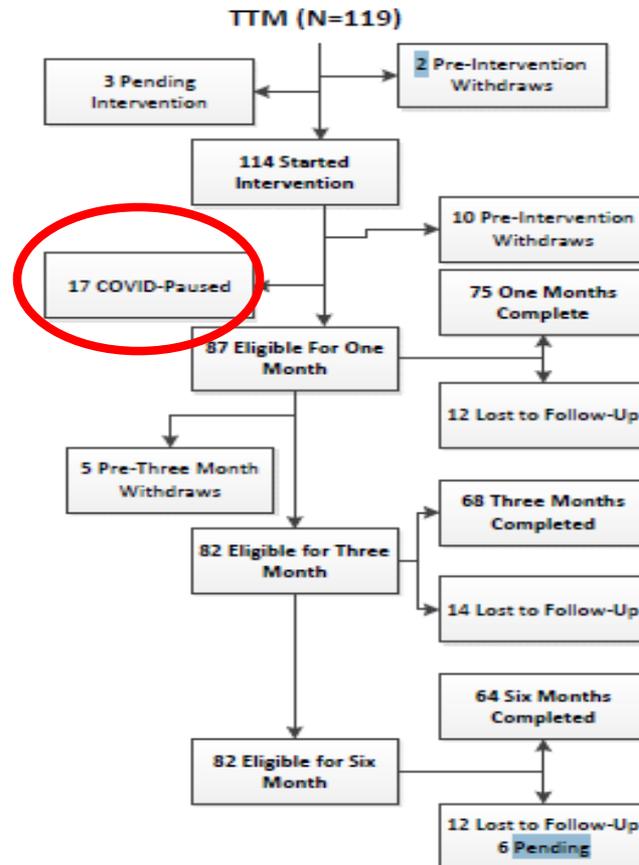
Initial Sample size and power

- **N = 396 (132 per arm) at 3-months**
- **Assumed 15% attrition we needed N = 468 (156 per arm)**
- **80% power to detect a 0.4 SD difference in change scores from baseline in NDI between treatment groups**
- **Type I error set at 0.017 for the 3 comparisons of interest**

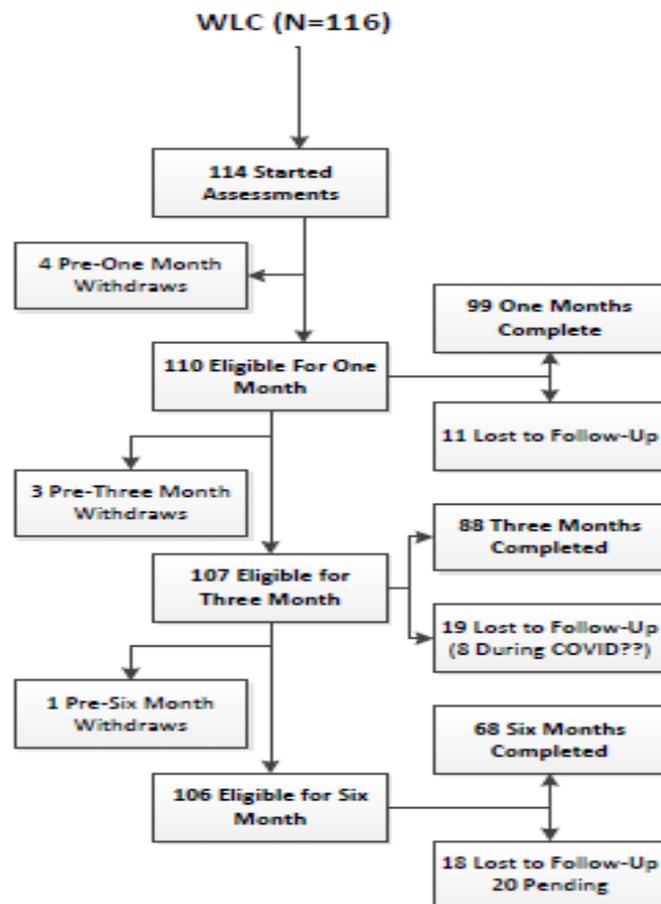
Care-ally flow



Therapist-treated massage



Waitlist Control



Attrition Problems

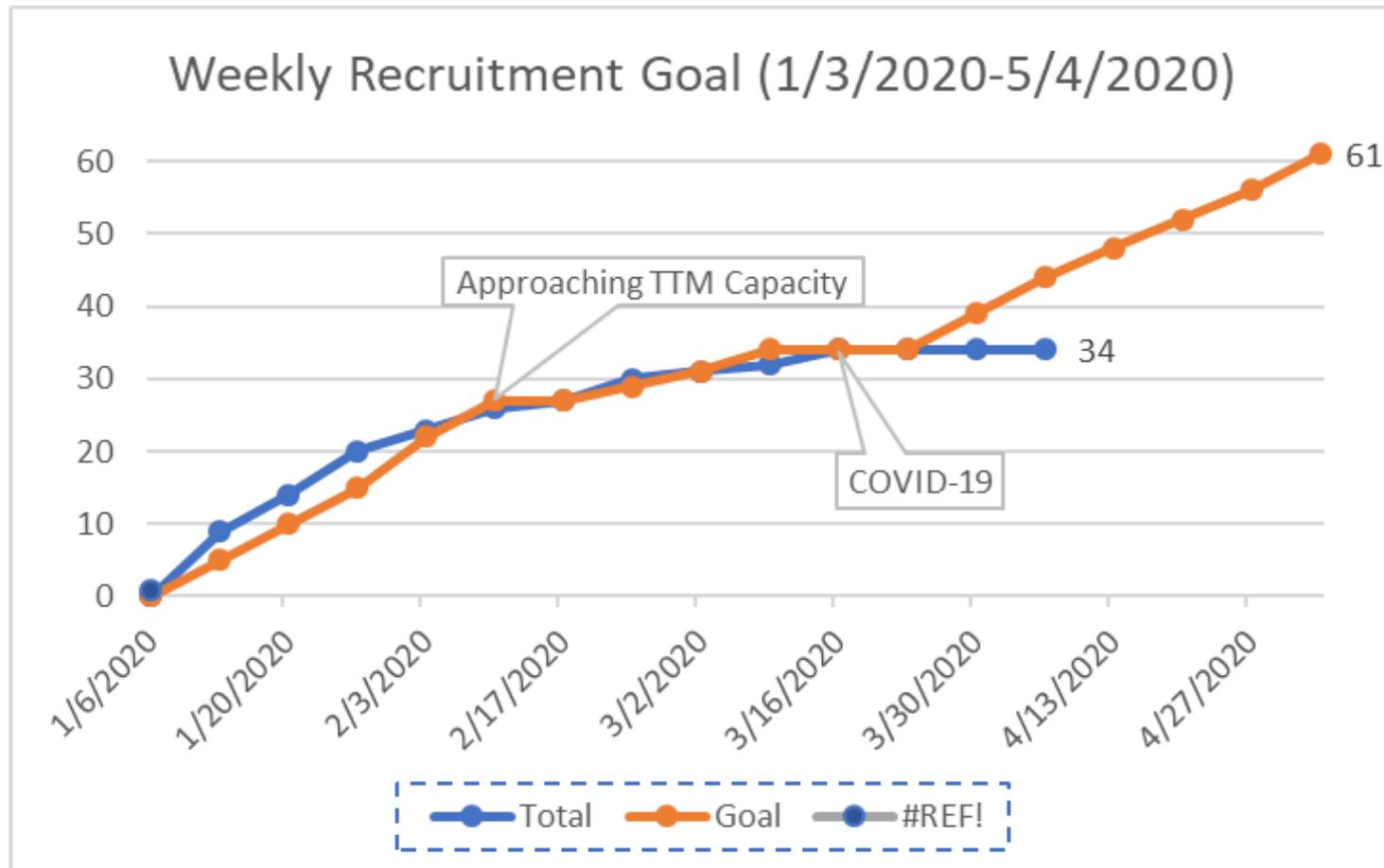
- Higher attrition than expected
 - 98 TTM patients enrolled, 71 have 3 Month follow-up
(27/98 = 27.6% attrition)
 - 98 CAM patients enrolled, 36 have 3 Month follow-up
(62/98 = 63.2% attrition)
 - 99 WLC patients enrolled, 79 have 3 Month follow-up
(20/99 = 20.2% attrition)

**IS CARE-ALLY DELIVERED
MESSAGE FEASIBLE?**

Major Project Modification

- **Proposed dropping care-ally arm**
- **Modify to 2-arm trial (TT-M vs. WLC)**
- **Approved 11/1/2019**
- **Modified sample size calculation and analysis plan**

Post-project modification



COVID-19 IMPACT

COVID-19 Impact

- **Indiana University restricted on-campus research activities to only those of an essential nature (3/23/20)**
- **Non-essential, on-campus research operations began to reopen with the necessary safety precautions in place (6/1/20)**
- **TOMCATT team continued research activities that can be done virtually (outcome assessments, interviews, chart reviews)**
- **Close contact between massage therapist and patients – unique challenges**

COVID-19 Impact

- **RVAMC clinical activities pivoted to almost entirely tele-medicine delivered care**
- **Consulted clinical leaders (PT, OT, chiro)**
- **Consulted massage researchers across US**
- **Reviewed guidelines from massage therapy organizations**
- **Multiple internal discussions with TOMCATT team**

COVID-19 Impact

- **Followed state/local metrics of COVID infectivity rates**
- **Considered other study locations**
- **Study staff became vaccinated**
- **Restart incrementally – target the Veteran employees enrolled**
- **Finish up those already in involved – finish recruitment**

**SECONDARY ANALYSIS:
CARE-ALLY VS. WLC
(BEFORE MODIFICATION)**

Sample characteristics

- **Mean age:** 55.0 (sd = 13.1) years old
- **Sex:** 79.0% men
- **Employment:** 44.8% employed, 33.3% retired, 13% unable
- **Race:**
 - 71.9% White
 - 24.0% Black
- **Marital status**
 - 61.5% married, 28.1% divorced

Neck Disability Changes

	CAM		WLC	
	N	Mean (Std)	N	Mean (Std)
Baseline	99	18.4 (8.0)	100	20.6 (8.2)
1 month	43	18.1 (8.5)	82	20.8 (9.1)
3 months	33	15.3 (8.8)	76	20.9 (8.5)
6 months	39	14.9 (8.3)	59	21.8 (9.9)

Within group changes on NDI

	Change in CAM (from baseline)		Change in WLC (from baseline)	
	Mean (95% CI)	p-value	Mean (95% CI)	p-value
Baseline				
1 month	-1.10 (-2.92, 0.71)	p=.233	0.24 (-1.10, 1.58)	p=.725
3 months	-3.08 (-5.10, -1.06)	p=.003	0.26 (-1.12, 1.65)	p=.709
6 months	-3.19 (-5.08, -1.31)	p=.001	1.13 (-0.40, 2.65)	p=.147

Between group change on NDI

	Change in CAM vs. Change in WLC	
	Mean (95% CI)	p-value
Baseline		
1 month	-1.34 (-3.54, 0.86)	p=.231
3 months	-3.34 (-5.73, -0.94)	p=.006
6 months	-4.32 (-6.70, -1.95)	p<.001

Changes in Brief Pain Inventory

	CAM		WLC		Change in CAM vs. Change in WLC	
	N	Mean (Std)	N	Mean (Std)	Mean (95% CI)	p-value
Baseline	99	5.0 (2.0)	100	5.2 (1.9)		
1 month	43	4.2 (1.8)	82	4.8 (2.2)	-0.66 (-1.22, -0.10)	p=.021
3 months	33	3.7 (2.3)	77	4.8 (2.2)	-0.88 (-1.49, -0.27)	p=.005
6 months	38	3.5 (2.3)	59	4.8 (2.2)	-1.08 (-1.69, -0.47)	p<.001

Limitations

- **Attrition**
- **Conducted at a single medical center**
- **Generalizability**
- **Significant pause in intervention delivery due to COVID**

Conclusions

- **TOMCATT innovative design – understudied chronic pain condition**
- **Recruitment challenges**
 - **Dyadic research is hard**
- **Feasibility of caregiver-delivered massage?**

Conclusions

- **Unique impact of COVID on TOMCATT**
- **Secondary analysis – CAM more effective than WLC**
- **Analytical challenges**
- **Restart and finish up recruitment/enrollment**
 - **Risk mitigation plan approved**

Thank you!

- **Funding from VA HSR&D (IIR 15-333)**
- **TOMCATT Study Team**
 - **Matt Kline**
 - **Niki Munk**
 - **Brian Laws**
 - **Erica Evans**
 - **Stephanie McCalley**
 - **Joanne Daggy**
 - **James Slaven**
 - **Trevor Foote**
 - **Asli Flederjohn**
 - **Marianne Matthias**
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 - **Kathy Snow**

QUESTIONS?

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Thank you for attending