Yoga for Chronic Pain in Veterans and Military Personnel

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Acknowledgements

- **VA Rehabilitation Research & Development, NCCIH, VA Cooperative Studies Program, NMCSD**

- Sunita Baxi, MD, Mercedes Dashefsky, NP
- Laura Schmalzl, PhD
- Adhana McCarthy, MPA
- Camilla Sinclair, RYT,
- Danielle Casteel, MA
- Meghan Maiya, MA, Debora Goodman, Neil Yetz, BA
- Morgan Jones, Carol Hafey, Symone McKinnon, MA
- Co-investigators: Drs. Bormann, Atkinson, Chang, Liu, Wetherell, Ayers, Rutledge, Lang, Weingart

Overview

Brief Background

VA RCT – Yoga for Veterans with cLBP

NCCIH – R34 – 2 Types of Yoga for Military Personnel with cLBP and cNP

VA CSP # 2009 – SCEPTER Trial

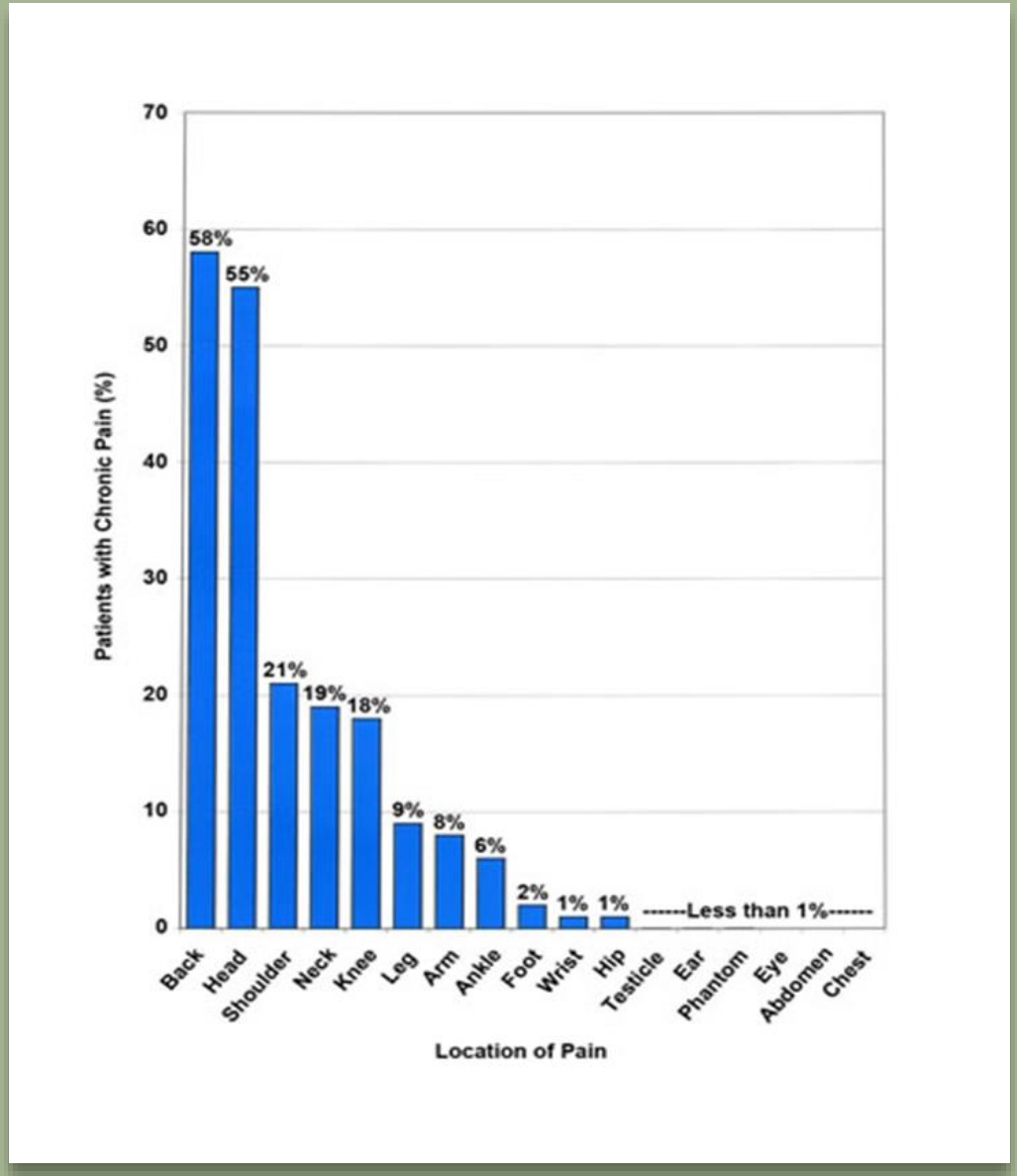
VA RR&D SPIRE – Pilot RCT of Yoga + Mantram for Chronic Pain in Vets w/ PTSD

Background

- CLBP & CNP are highly prevalent conditions that also result in:
  - functional impairment
  - psychological symptoms
  - Lower quality of life
  - higher health care costs

Veterans and chronic pain

- Veterans experience higher rates of chronic pain[1] and co-occurring conditions
- Pain medication - primary treatment for many in VA[2], often ineffective and serious side effects



[1]Lew et al. Prevalence of chronic pain, …. *J Rehabil Res Dev*. 2009.
[2]Outcalt SD, et al. Health Care Utilization…Veterans with Pain and PTSD, Pain Medicine, 2013.

Patanjali's 8 Limbs of Yoga

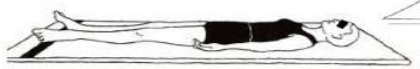
things you do — *things that happen to you*

1	2	3	4	5	6	7	8
Yamas	Niyamas	Asana	Pranayama	Pratyahara	Dharana	Dhyana	Samadhi

restraints	*observances*
1 **Ahimsa** *non-harming*	1 **Soucha** *cleanliness*
2 **Satya** *non-lying*	2 **Santosha** *contentment*
3 **Asteya** *non-stealing*	3 **Tapas** *zeal for yoga*
4 **Brahmacharya** *of Brahma*	4 **Svadyaya** *self-study*
5 **Aparigraha** *non-hoarding*	5 **Ishvarapranidhana** *surrender*

pose

breath



withdrawal of the senses

intense focus

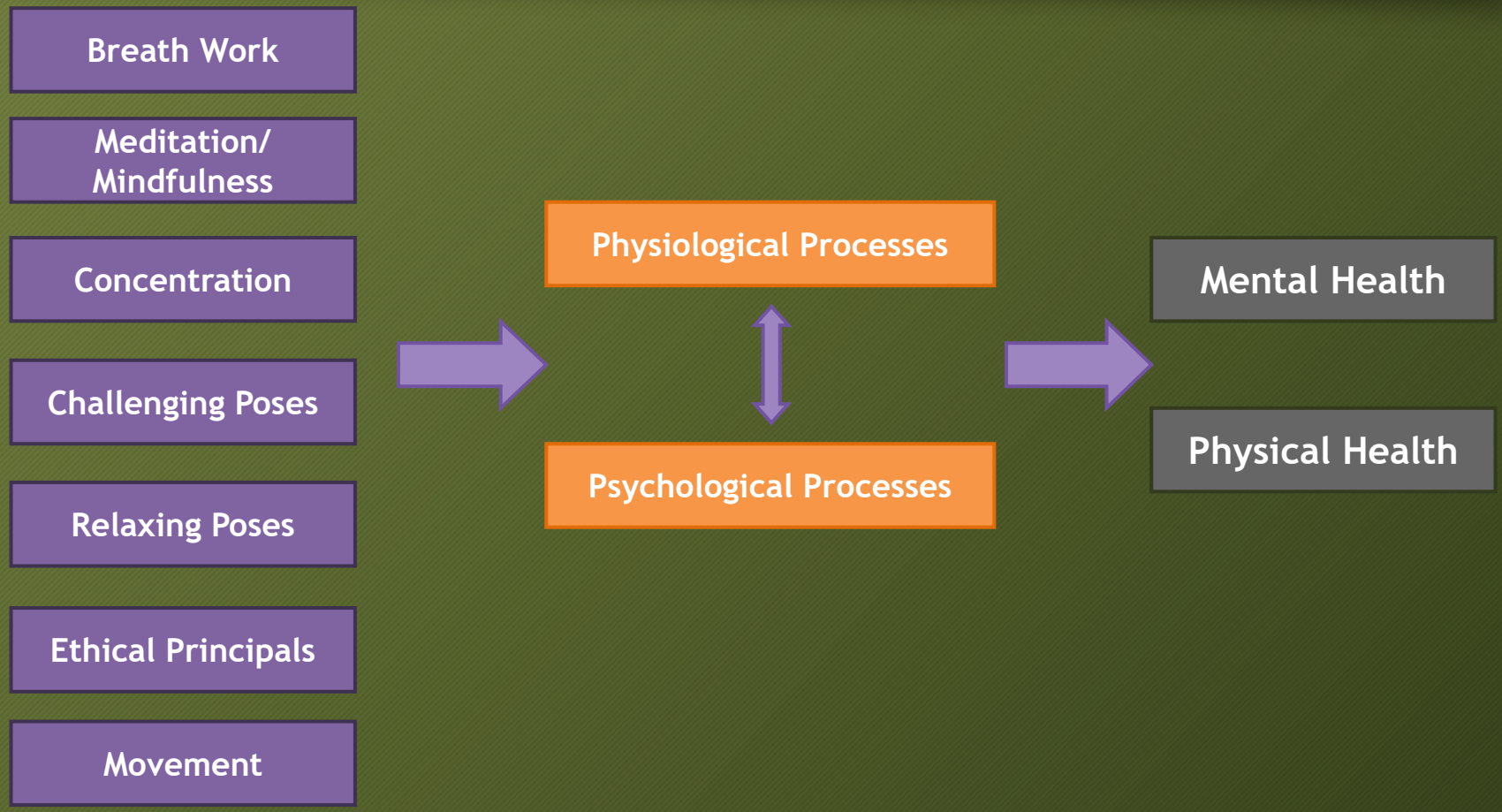
state of meditation

state of oneness

Modern Yoga

- "Traditional" yoga has been transformed
  - Greater emphasis on postures and movement
  - Less of a spiritual emphasis
  - Yoga is used to treat various health conditions – e.g. Yoga therapy – individualized yoga treatment by therapists with additional medical training

Yoga - postures, breathwork, and directed attention (movement)



Heterogeneity of Yoga

Yoga Research on CLBP and CNP

- RCTs
  - Sherman (2011, n = 228); Tilbrook (2011, n = 313) – found yoga better than self-care for reducing disability; Sherman - reductions in pain & medication use (not better than stretching)
  - Cramer (2013, n = 51) – less neck pain, less disability, better QOL in yoga group compared to exercise.
  - Dunleavy (2016, n = 56) – lower NDI scores for yoga and pilates compared to control.
- Conducted in community HMO settings, mostly women, potentially hard to generalize to military populations

Yoga for Veterans with CLBP

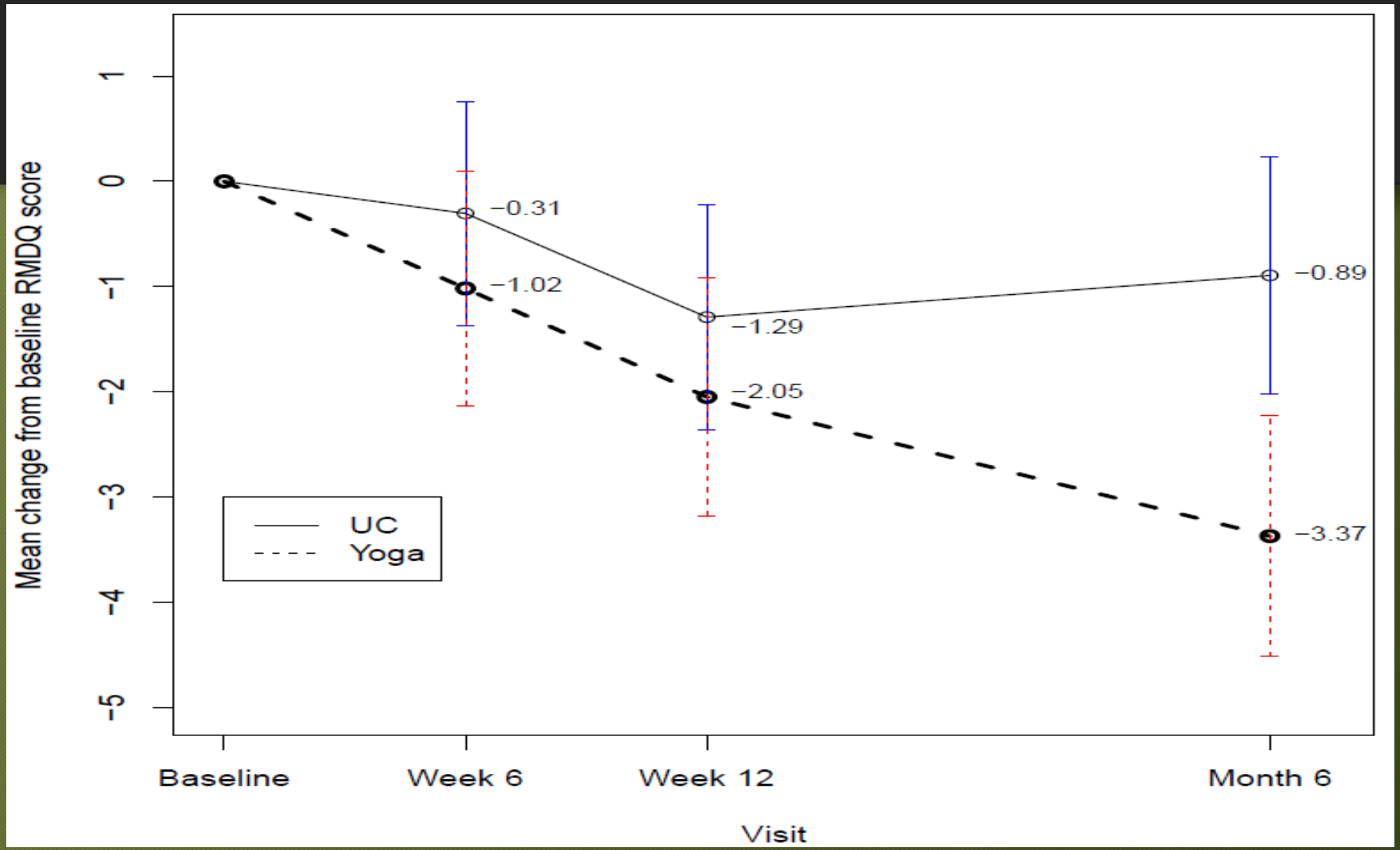
- VA funded study of 150 VA patients w/ CLBP
- Randomized to either
  - Yoga
  - Delayed treatment receiving usual care
- Hatha Yoga with modifications, certified instructor
- 2x weekly, 60-minutes, regular home practice
- Assessments at baseline, 6-weeks, 12-weeks, and 6-months

Yoga for cLBP

Results

- No SAEs
- Yoga group had larger decreases in disability and other outcomes (pain, fatigue, QOL)
- Decreases in pain and disability were small to moderate, but occurred despite:
  - lower than optimal attendance
  - a more impaired population
  - decreased use of opiates and other pain treatments

Groessl et al. Yoga for Military Veterans with Chronic Low Back Pain: A Randomized Clinical Trial. *Am J Prev Med. 2017;53(5):599 608.*
Groessl et al. Secondary Outcomes from a Randomized Controlled Trial of Yoga for Veterans with Chronic Low Back Pain. *IJYT. 2020;30(1):69 76.*


Mean change from baseline RMDQ score
1
0
-1
-2
-3
-4
-5
−0.31
−1.02
−1.29
−2.05
−0.89
−3.37
UC
Yoga
Baseline
Week 6
Week 12
Month 6
Visit

Opiate Pain meds (p < 0.001)

Variable	Baseline	6 weeks	p	12 weeks	p	6-month	p
Narcotic Pain Medication							
Yoga (n=75)	19%	11%		12%		9%	
Usual Care (n = 75)	21%	12%		11%		7%	
Total Sample (n =150)	**20%**	**11%**	**0.007**	**11%**	**0.007**	**8%**	**< 0.001**
Other Medical Treatments for pain							
Yoga	56%	44%		44%		39%	
Usual Care	47%	44%		47%		37%	
Total Sample (n =150)	51%	44%	0.070	45%	0.137	38%	0.001
Self-help pain treatments							
Yoga	76%	71%		71%		68%	
Usual Care	72%	75%		69%		60%	
Total Sample (n =150)	74%	73%	0.744	70%	0.334	64%	0.020

Discussion

Variable	Sherman(2011) (n = 228)	Tilbrook(2011) (n = 313)	current study (n = 150)
Age	48.4	46.3	53.4
Women	64%	70%	25%
Non-White	13%	-	51%
College grads	62%	58%	54%
Not employed	13%	5-13%	21- 35%
Homeless (5 yrs)	-	-	18%
Back pain - Years	10.8	10.0	15.0
RMDQ baseline	9.1	7.8	9.9
Narcotic meds	7%	-	20%
Attend rate	67%	60%	53%

RMDQ – 30% decrease*

*Ostelo RW, et al. *Spine (Phila Pa 1976). 2008;33(1):90 94.*

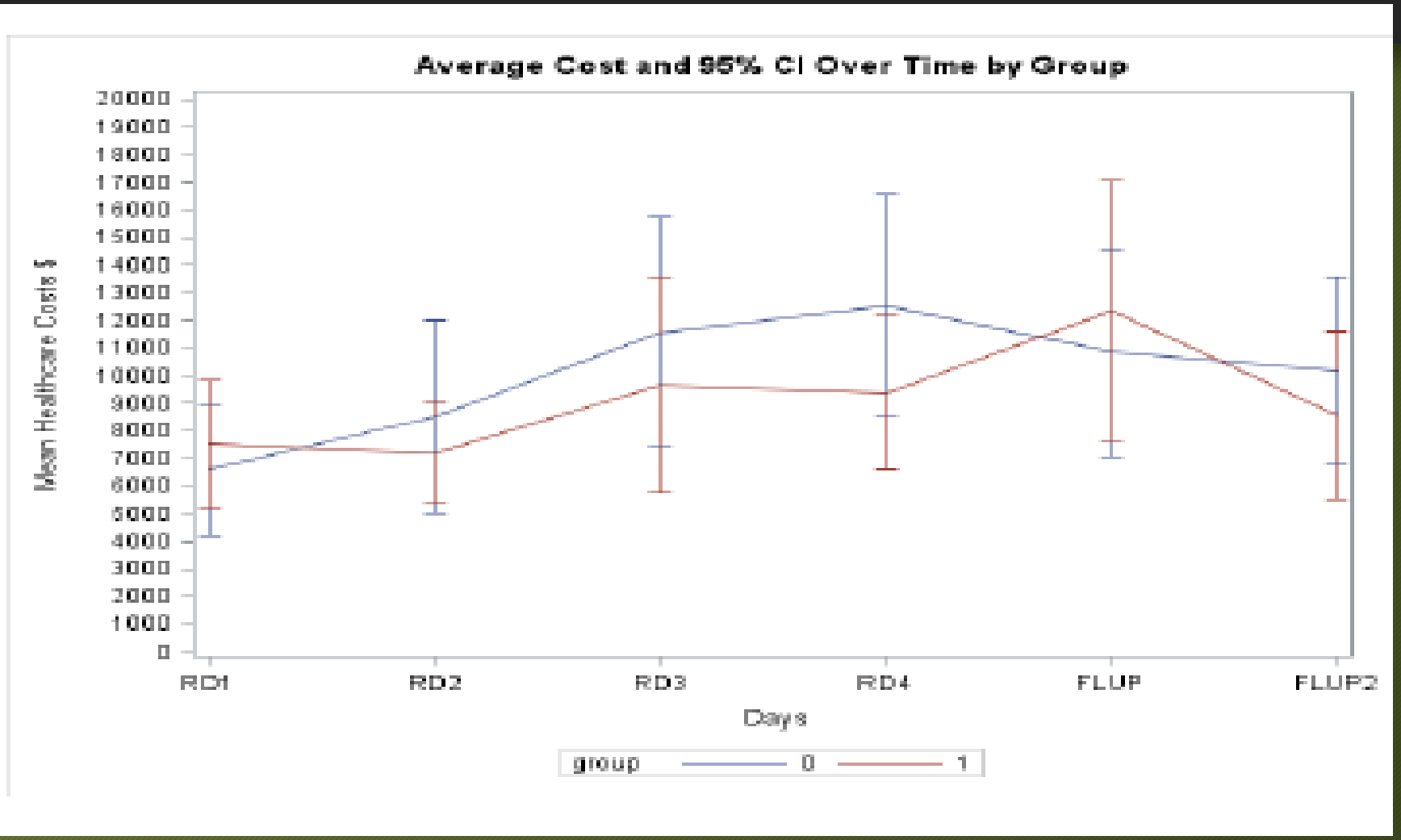
Study	6-weeks	12-weeks	6-months	12-months
Sherman, 2011				
Yoga (n=92)	55	75*	66*	-
Stretching (n=91)	58	71*	72*	-
Self-Care (n=45)	49	45	55	-
Cherkin, 2017	(4-weeks)	(8-weeks)		
MBSR (n=116)	35	47	61*	69*
CBT (n=112)	25	52*	58*	59
Usual Care (n=113)	27	35	44	49
Groessl, 2017				
Yoga (n=75)	33	44	57*	-
Usual Care (n=75)	21	33	24	-

Cost-Effectiveness of Yoga for Veterans with Chronic Low Back Pain

- Effectiveness measures:
  - % clinically improved on RMDQ
  - QALYs derived from EQ-5D
- 12-month time horizon
- Health care system perspective
- Actual intervention costs - tracked
- Healthcare costs - VA medical records
- Sensitivity analyses - scenario comparing ongoing yoga to existing physical therapy

Groessl et al. Cost effectiveness of Yoga for Chronic Low Back Pain in Veterans. *Med Care. 2020;58 Suppl 2 9S:S142 S148.*

Health Care costs (p = 0.59)



Incremental cost-effectiveness

- The net cost of yoga $465/person resulted in 25 more clinically improved participants and 0.04 QALYs
- Incremental cost-effectiveness ratios (ICERs) were
  - $1,395 per clinically improved participant
  - $11,625/QALY.

Cost Scenario

TABLE 3. Estimated Costs of Yoga Sessions Compared With Physical Therapy

Item	Provider	Units	Time (h)	Unit Cost	Total Cost/Participant
Yoga					
Yoga sessions (10 people/class)	Yoga instructor	12/10 people	1.50	$27.87/h	50
Yoga mat		1		$15	15
Overhead/indirect costs (69% of personnel costs)					35
Total costs of intervention					100
Physical therapy					
Physical therapy (1-on-1)	PT	8/1 person	1.0	$45.84/h	367
Transportation					
Overhead/indirect costs (69% of personnel costs)					253
Total costs of intervention					620

OPTYM Study
Importance and Objectives

- Combine cLBP and cNP
- Compare different types of yoga

Objectives

- R34 – NCCIH - Feasibility/acceptability of conducting a yoga RCT among active-duty military personnel
- Preparation for a larger study

Study Design

- Recruit - 50 active-duty personnel with CLBP/CNP.
- Randomize to either Hatha yoga or Restorative yoga
  - 60 min. 1-2x weekly for 12 weeks
  - Choice of 3 class times (1 at NMCSD)
- Examine feasibility through measures of recruitment, retention, attendance, safety, satisfaction
- Outcome assessments at baseline, 12-weeks, 6-months

Hatha Yoga

- Adapted for CLBP/CNP – (Iyengar, Viniyoga)
- Poses demonstrated by instructor
- Movement between poses with slow, deep breaths
- Brief meditation

Restorative Yoga

- emphasizes relaxation
- has little movement, non-strenuous
- sessions typically include 5-7 poses
- mostly done lying down, eyes often closed
- bolsters and blankets used for comfort and warmth
- instructor provides dialogue on breathing techniques or guided imagery

Feasibility Results

- IRB with US Navy took 11 months
- Recruitment
  - Cohort 1 – took almost 6 months
  - Cohort 2 – 3-4 months
- Retention – 86% at 12-weeks, 80% at 6-months
- Attendance - Stopped yoga (n=12) or low attendance (≤ 3 classes; n=5)
- Adverse Events – NO SAEs

Feasibility Results - Satisfaction

Program Evaluation	Hatha (mean, n=20)	Restorative (mean, n=19)	% Agree /Strongly Agree	% Disagree /Strongly Disagree
Enjoyed participating	4.75	4.68	92.3%	0%
Liked instructors	4.65	4.79	92.3%	0%
Would like to continue yoga	4.70	4.68	92.3%	0%
Experienced health benefits	4.15	4.42	74.3%	0%
Class duration was sufficient	4.10	4.47	82.1%	5.1%
Yoga met expectations	4.10	4.42	80.0%	0%
Availability of class locations	3.86	4.15	68.3%	9.8%
Study length was sufficient	3.75	4.05	64.1%	15.4%
Common bond w/others	3.85	3.74	66.7%	7.7%
Availability of class times	3.62	3.72	58.5%	24.4%

Feasibility Results - Outcomes

Outcome	Hatha Yoga (Week 0)	Hatha Yoga (Week 12)	Restorative Yoga (Week 0)	Restorative Yoga (Week 12)	Pre-post Cohen's d H	Pre-post Cohen's d R
RMDQ	10.8(5.2)	10.1(6.3)	10.0(5.6)	7.6(6.1)	0.12	0.41
NDI	14.3(9.3)	14.0(10.7)	12.1(9.0)	10.0(8.9)	0.03	0.24
BPI-PS	4.7(1.7)	4.0(2.3)	4.7(1.8)	3.7(1.9)	0.33	0.51
BPI -PI	4.2(2.2)	3.9(2.4)	4.0(2.4)	3.2(2.5)	0.16	0.34
PROMIS-PI	9.8(1.7)	9.0(2.4)	9.5(2.3)	8.6(2.5)	0.39	0.40
SF12-PH	33.1(7.3)	37.0(8.1)	36.5(10.5)	39.2(9.6)	0.51	0.28
SF12-MH	47.1(11.6)	45.2(12.5)	49.5(9.5)	47.2(10.6)	-0.16	-0.24
FSS	4.0(1.4)	4.4(1.6)	4.0(1.5)	3.8(1.6)	-0.25	0.10

cLBP Vs cNP- Outcomes

	Back pain only (n=21) (mean change)	Neck pain (n=21) (mean change)
RMDQ	-2.8 (d = .57)	-0.3 (d = .05)
BPI-PS	-1.3 (d = .74)	-0.3 (d = .15)
NDI	-1.6 (d = .22)	-0.8 (d = .15)
BPI -PI	-1.1 (d = .68)	-0.1 (d = .05)
PROMIS-PI	-1.3 (d = .62)	-0.4 (d = .21)
SF12-PH	4.9 (d = .80)	1.8 (d = .24)
SF12-MH	-2.4 (d = - .20)	-2.0 (d = - .17)
FSS	0.2 (d = -.13)	0.1 (d = - .03)
Mean effect size - d	**0.41**	**0.08**
Sessions attended	5.9	7.0

Chronic Neck Pain- Outcomes

Neck Pain	Hatha (n=11) (mean change)	Restorative(n=10) (mean change)
RMDQ	1.4 (d = -.22)	-2.1 (d = .52)
BPI-PS	-0.1 (d = .07)	-0.5 (d = .24)
NDI	-0.6 (d = .12)	-1.0 (d = .17)
BPI-PI	0.2 (d = -.08)	-0.4 (d = .21)
PROMIS-PI	-0.4 (d = .30)	-0.5 (d = .18)
SF12-PH	1.7 (d = .42)	1.9 (d = .19)
SF12-MH	-3.4 (d = -.27)	-0.4 (d = -.03)
FSS	0.8 (d = -.50)	-0.7 (d = .45)
Mean effect size - d	**-0.02**	**0.24**
Sessions attended	6.1	7.8

Conclusions

- Feasibility was established, challenges to be addressed.
- Firm conclusions on outcomes should be avoided
- Neck pain may respond differently than cLBP to some types of yoga
- Restorative yoga may be more appealing to those with stressful and busy lives
- Future direction – Multisite trial – add more elements for neck pain

SCEPTER TRIAL (Sequential and Comparative Evaluation of Pain Treatment Effectiveness Response)

- VA Cooperative Studies Program - CSP #2009
- Details were presented by Matthew J. Bair, MD, MS HSR&D Cyberseminar on 11-05-2019
- David Clark, MD and Matt Bair, MD, MS are PIs
- Study has been delayed – but on target to launch later this year

SCEPTER Participants and Sites

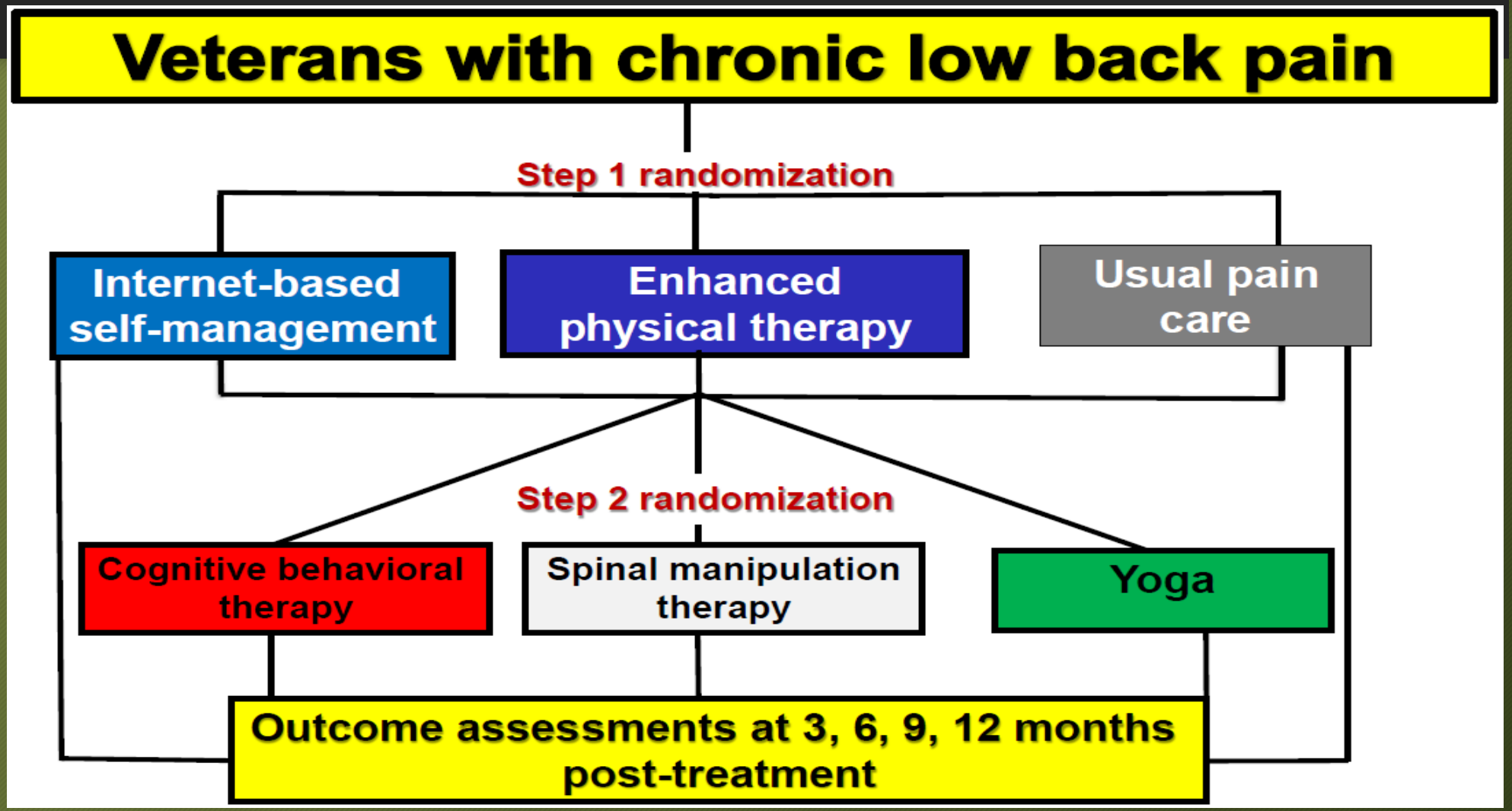
N = 2529 Veterans

Moderate to severe CLBP

20 VA Medical Centers nationally

Study duration = 6 years

SCEPTER Study Design



Key Impacts

- Trial of guideline-concordant therapy (especially for stepped-care options Phase 1)
- Comparative effectiveness data
- Outcomes beyond pain and function
  - Anxiety/Mood, Sleep, QOL
- Predictors of responsiveness
- Incorporates treatment preferences into design
- Implementation and cost-effectiveness data

Yoga + Mantram Repetition for Pain and PTSD

- Veterans with PTSD are:
  - more likely to report the presence of chronic pain
  - report greater pain severity and pain-related disability
  - Increased risk for substance use disorders

Yoga + Mantram Repetition for Pain and PTSD

Mind-body interventions like MBSR, MR, meditation, and yoga can address both pain and PTSD symptoms

Mantram Repetition – Evidence-based intervention developed in VA (Dr. Bormann). Participants choose a spiritual or meaningful phrase to repeat regularly

Adding MR to Yoga provides a portable tool that can be more easily practiced in some settings

Yoga + Mantram Repetition for Pain and PTSD

VA RR&D – Feasibility RCT

32 participants randomized to either Yoga + MR or to Veteran.Calm (relaxation)

12-week interventions, assessments

Yoga + Mantram Repetition for Pain and PTSD

- Significant Delays – COVID
- Recruiting – 1st cohort of 16 being screened
- More to come

Summary

- Non-Pharmacological options for chronic pain are now first-line treatments
- Research supports yoga as an effective and cost-effective option for veterans with chronic pain
- Response to yoga may vary by type of chronic pain and type of yoga
- How can the benefits of yoga best be shared with our Veterans with chronic pain?