



Strength and Awareness in Action: A Feasibility Study of Yoga for Post-Acute TBI Headaches

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Disclaimer

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Acknowledgements:

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Poll Question

Which of the following best describes what you do for work?

- 1) Mental Health Clinician
- 2) Physical Medicine and Rehabilitation Professional
- 3) Researcher
- 4) Policy Maker
- 5) Educator
- 6) Yoga Instructor
- 7) Other



Whi A

Traumatic Brain Injury - A bolt or jolt to the head or a penetrating head injury that disrupts the function of the brain. Not all blows or jolts to the head result in a TBI. The severity of such an injury may range from "mild" (a brief change in mental status or consciousness) to "severe" (an extended period of unconsciousness or amnesia) after the injury.

A TBI can result in short- or long-term problems with independent function.



Mild TBI – American Congress of Rehabilitation Medicine

Traumatically induced disruption of brain function that results in loss of consciousness of less than 30 minutes duration **or** in an alteration of consciousness manifested by an incomplete memory of the event **or** being dazed and confused.



Mild TBI Symptoms

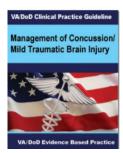
Thinking/ Remembering	Physical	Emotional/ Mood	Sleep
Difficulty thinking clearly	Headache Fuzzy or blurry vision	Irritability	Sleeping more than usual
Feeling slowed down	Nausea or vomiting (early on) Dizziness	Sadness	Sleep less than usual
Difficulty concentrating	Sensitivity to noise or light Balance problems	More emotional	Trouble falling asleep
Difficulty remembering new information	Feeling tired, having no energy	Nervousness or anxiety	



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Headaches are common physical symptoms after mTBI occurring in 30-90% of individuals following TBI (mild, moderate, or severe).[47,48] The International Classification of Headache Disorders- 2nd edition defines posttraumatic headaches as secondary headache disorders that start within seven days after head trauma.[49] Posttraumatic headaches are commonly classified as migraine headaches, tension-type headaches, mixed tension/migraine headaches or cervicogenic headaches. The normal recovery of posttraumatic headaches following concussion is usually rapid (hours to days) with most headaches resolving within three months. However, in some cases, headaches may last longer and are referred to as persistent posttraumatic headaches.[50]







INVITED REVIEW

Characteristics and Treatment of Headache After Traumatic Brain Injury

A Focused Review

ABSTRACT

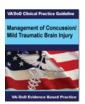
Lew HL, Lin P-H, Fuh J-L, Wang S-J, Clark DJ, Walker WC: Characteristics and treatment of headache after traumatic brain injury: A focused review. Am J Phys Med Rehabil 2006;85:619 – 627.

Headache is one of the most common complaints in patients with traumatic brain injury. By definition, headache that develops within 1 wk after head trauma (or within 1 wk after regaining consciousness) is referred to as posttraumatic headache (PTH). Although most PTH resolves within 6–12 mos after injury, approximately 18–33% of PTH persists beyond 1 yr. We performed a systematic literature review on this topic and found that many patients with PTH had clinical presentations very similar to tension-type headache (37% of all PTH).

Although there is no universally accepted protocol for treating PTH, many clinicians treat PTH as if they were managing primary headache. As a result of the heterogeneity in the terminology and paucity in prospective, well-controlled studies in this field, there is a definite need for conducting double-blind, placebo-controlled treatment trials in patients with PTH.

Key Words: Brain Injuries, Headache, Posttraumatic Headache, Traumatic Brain Injury

18-33% of PTH persist beyond a year



The overall evidence for the treatment of posttraumatic headaches neither supports nor refutes the effectiveness of current management strategies and the clinician must use best clinical judgment in treating headaches while weighing benefits and possible risks.

Recommendation

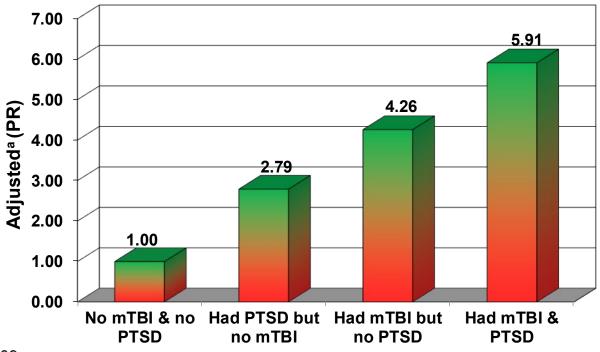
- 11. We suggest that the treatment of headaches should be individualized and tailored to the clinical features and patient preferences. The treatment may include:
 - Headache education including topics such as stimulus control, use of caffeine/tobacco/alcohol and other stimulants
 - b. Non-pharmacologic interventions such as sleep hygiene education, dietary modification, physical therapy (PT), relaxation and modification of the environment (for specific components for each symptom, see Appendix B: Clinical Symptom Management)
 - c. Pharmacologic interventions as appropriate both for acute pain and prevention of headache attacks



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Symptom-Exposure: Headache (n = 204)



Brenner et al., 2009







Poll Question

I practice yoga:

- 1) 6 or 7 times a week
- 3-5 times per week
- 3) 2 times per week
- 4) 1 time per week
- 5) A few times per month
- 6) A few times per year
- 7) I don't practice yoga





Background







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Issues in Yoga Therapy

The Use of Yoga in Specialized VA PTSD Treatment Programs

Daniel J. Libby, PhD, RYT, 1,2,3,4 Felice Reddy, MA, ² Corey E. Pilver, PhD, ³ & Rani A. Desai, PhD, MPH 1,2,3

- 1. Office of Academic Affiliations, Advanced Fellowship Program in Mental Illness Research and Treatment, Department of Veterans Affairs (MIRECC)
- 2. VA Connecticut Healthcare System, West Haven (VACHS)
- 3. Evaluation Division. National Center for PTSD (NCPTSD)
- 4. Veterans Yoga Project, Newington, CT

Abstract

Background: Posttraumatic stress disorder (PTSD) is a chronic, debilitating anxiety disorder that is highly prevalent among U.S. military veterans. Yoga, defined to include physical postures (asana) and mindfulness and meditation, is being increasingly used as an adjunctive treatment for PTSD and other psychological disorders. No research or administrative data have detailed the use of these services in Department of Veterans Affairs' (VA) 170 PTSD treatment programs. Methods: One hundred twenty-five program coordinators or designated staff completed an 81-tiem survey of their program's use of complementary and alternative medicine modalities in the past year. This report describes data from a subset of 30 questions used to assess the prevalence, nature, and context of the use of yoga, mindfulness, and meditation other than mindfulness practices. Results: Results revealed that these practices are widely offered in VA specialized PTSD treatment programs and that there is great variability in the context and nature of how they are delivered. Conclusions: Understanding how yoga is used by these programs may inform ongoing efforts to define and distinguish yoga therapy as a respected therapeutic discipline and to create patient-centered care models that mindfully fulfill the unmet needs of individuals with mental health issues, including veterans with PTSD.

Key Words: Yoga, PTSD, yoga therapy, mental health

than mindfulness instruction offered to veterans with PTSD in VA specialized PTSD treatment programs across the United States Yoga mindfulness and meditation instruction are widely available, and there is considerable variability in the nature and the context in which instruction is offered. More and better education of mental health clinicians and administrators is needed in terms of training and skills of yoga therapists. Limited funding and lack of trained staff were the most frequently cited barriers to offering yoga, which may create an opportunity for properly trained yoga therapists to volunteer their services to veterans needing treatment. There is a pressing need for scientific research examining the efficacy of voga practices for veterans with PTSD. Positive findings from empirically rigorous studies of the effectiveness of yoga therapy may stimulate funding for yoga therapists to be included on interdisciplinary teams providing treatment to veterans with PTSD and other mental health disorders.



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REVIEW ARTICLE

A Systematic Review and Meta-analysis of Yoga for Low Back Pain

Holger Cramer, MSc, Romy Lauche, PhD, Heidemarie Haller, MSc, and Gustav Dobos, MD

Objectives: To systematically review and meta-analyze the effectiveness of yoga for low back pain.

Methods: MEDLINE, the Cochrane Library, EMBASE, CAMBASE, and PsycINFO, were screened through January 2012. Randomized controlled trials comparing yoga to control conditions in patients with low back pain were included. Two authors independently assessed risk of bias using the risk of bias tool recommended by the Cochrane Back Review Group. Main outcome measures were pain, back-specific disability, generic disability, health-related quality of life, and global improvement. For each outcome, standardized mean differences (SMD) and 95% confidence intervals (CI) were calculated.

Results: Ten randomized controlled trials with a total of 967 chronic low back pain patients were included. Eight studies had low risk of bias. There was strong evidence for short-term effects on pain (SMD = -0.48; 95% CI, -0.65 to -0.31; P<0.01), backspecific disability (SMD = -0.59; 95% CI, -0.87 to -0.30; P<0.01), and global improvement (risk ratio = 3.27; 95% CI, 1.89-5.66; P<0.01). There was strong evidence for a long-term effect on pain (SMD = -0.33; 95% CI, -0.59 to -0.07; P=0.01) and moderate evidence for a long-term effect on back-specific disability (SMD = -0.35; 95% CI, -0.55 to -0.15; P<0.01). There was no evidence for either short-term or long-term effects on health-related quality of life. Yoga was not associated with serious adverse events.

Discussion: This systematic review found strong evidence for short-term effectiveness and moderate evidence for long-term effectiveness of yoga for chronic low back pain in the most important patient-centered outcomes. Yoga can be recommended as an additional therapy to chronic low back pain patients.

Key Words: low back pain, yoga, complementary therapies, metaanalysis, review

(Clin J Pain 2013;29:450-460)



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Review

Effects of yoga exercises for headaches: a systematic review of randomized controlled trials

SANG-DOL KIM, RN, PhD1)

J. Phys. Ther. Sci. 27: 2377–2380, 2105

Abstract. [Purpose] To assess the evidence for the effectiveness of yoga exercises in the management of headaches. [Subjects and Methods] A search was conducted of six electronic databases to identify randomized controlled trials (RCTs) reporting the effects of yogic intervention on headaches published in any language before January 2015. Quality assessment was conducted using the Cochrane risk of bias tool. [Results] One potential trial was identified and included in this review. The quality critical appraisal indicated a moderate risk of bias. The available data could only be included as a narrative description. Headache intensity and frequency, anxiety and depression scores, and symptomatic medication use were significantly lower in the yoga group compared to the control group. [Conclusion] There is evidence from one RCT that yoga exercises may be beneficial for headaches. However, the findings should be interpreted with caution due to the small number of RCTs. Therefore, further rigorous methodological and high quality RCTs are required to investigate the hypothesis that yoga exercises alleviate headaches, and to confirm and further comprehend the effects of standardized yoga programs on headaches.

Key words: Headaches, Yoga exercises

(This article was submitted Feb. 19, 2015, and was accepted Mar. 17, 2015)



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Complementary Therapies in Clinical Practice





Combination of Ayurveda and Yoga therapy reduces pain intensity and improves quality of life in patients with migraine headache



Vasudha M. Sharma^{a,*}, Manjunath N.K.^a, Nagendra H.R.^a, Csaba Ertsey^b

ABSTRACT

Objectives: To Understand the efficacy of Ayurveda and Yoga in the management of Migraine Headache. Methods: 30 subjects recruited to Ayurveda and Yoga (AY) group underwent traditional Panchakarna (Biopurificatory process) using therapeutic Purgation followed by Yoga therapy, while 30 subjects of Control (CT) group continued on symptomatic treatment (NSAID's) for 90 days. Body constitution questionnaire was administered to both groups. The outcome measures included Symptom check list, Comprehensive Headache related Quality of Life Questionnaire and Visual Analogue Scale.

Results: Forty-six (76.6%) out of 60 subjects belonging to both groups had Pitta based body constitution. Following 90 days of intervention the AY group showed significant reduction in Migraine symptoms including pain intensity (p < .001) and improvement in Headache related Quality of Life (p < .001). The CT group showed no significant change (p > .05).

Conclusion: Traditional Ayurveda along with Yoga therapy reduces symptoms, intensity of pain and improves Quality of life in Migraine patients.



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^b Department of Neurology, Faculty of Medicine, Semmelweis University Budapest, 1083 Hungary



TBI and Yoga: PubMed = 5 (May 2019)

- Functional Medicine Approach to Traumatic Brain Injury.
- Richer AC.

Med Acupunct. 2017 Aug 1;29(4):206-214. doi: 10.1089/acu.2017.1217.

PMID: 28874921 Free PMC Article

Similar articles

- Feasibility and results of a case study of yoga to improve physical functioning in people with chronic
- 2. traumatic brain injury.

Schmid AA, Miller KK, Van Puymbroeck M, Schalk N.

Disabil Rehabil, 2016;38(9):914-20, doi: 10.3109/09638288,2015.1062927, Epub 2015 Jul 24,

PMID: 26208245

Similar articles

- Systematic Review of Yoga and Balance: Effect on Adults With Neuromuscular Impairment.
- Green E, Huynh A, Broussard L, Zunker B, Matthews J, Hilton CL, Aranha K.
 Am J Occup Ther. 2019 Jan/Feb;73(1):7301205150p1-7301205150p11. doi: 10.5014/ajot.2019.028944.

PMID: 30839270

Similar articles

- Respiratory, physical, and psychological benefits of breath-focused yoga for adults with severe
- 4. traumatic brain injury (TBI): a brief pilot study report.

Silverthorne C. Khalsa SB. Gueth R. DeAvilla N. Pansini J.

Int J Yoga Therap. 2012;(22):47-51.

PMID: 23070671 Similar articles

- Relax while you rehabilitate: A pilot study integrating a novel, yoga-based mindfulness group
- 5. intervention into a residential military brain injury rehabilitation program.

Combs MA, Critchfield EA, Soble JR.

Rehabil Psychol. 2018 May;63(2):182-193. doi: 10.1037/rep0000179. Epub 2018 Mar 12.

PMID: 29528664

Similar articles



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Strength & Awareness in Action for TBI (SAA-TBI)



Yoga =

physical postures

breath awareness

exercises

mindfulness meditation





Key Terms

Conceptual Terms	Operational Definitions
Acceptability	Acceptability refers to the suitability of an intervention from the perspectives
	of participants and/or facilitators.6
Adherence	Adherence is operationalized as the yoga instructors' ability to comply with
	delivering the key elements of the SAA-TBI manual during yoga sessions.
Ecological Momentary	EMA is defined as daily sampling procedures to evaluate activities, barriers and
Assessment (EMA)	facilitators to participation, fulfillment, pain, symptoms and home yoga practice (p. 321). ^{7,8}
Enhanced Treatment	ETU is described as enhanced secondary to participating in study assessment
As Usual (ETU)	procedures
Feasibility	Feasibility is defined as ease of implementation. ⁶
	ROCKY MOUNTA
	MIDEC

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Current Study

The specific aims of the proposed study are to evaluate:

- 1) the **feasibility of design elements** of an SAA-TBI intervention trial (i.e., exercise run-in design, recruitment strategy, participant retention, and ecological momentary assessment [EMA] procedures will be measured by participant accrual, attendance, retention, and homework completion, as well as the proportion of days during which data was collected regarding EMA.)
- 2) the **acceptability** of the intervention
- 3) variability estimates for candidate proximal/distal outcomes





Inclusion Criteria

- History of mTBI per the Ohio State University TBI-ID
- History of PCH pain (TTH, migraine, or mixed), with onset of pain or increase in previous headache pain having occurred within one month of mTBI as determined by structured examination using criteria outlined in the International Classification of Headache Disorders-3 beta (ICHD-3 beta)
- Duration of PCH pain being greater than one year as determined by structured medical examination
- Score of >56 on the Headache Impact Test-6 (HIT-6)60; 5) Medical clearance by study physicians to participate in yoga protocol
- Age between 18 and 50





SAA-TBI

- Originally designed for Veterans with histories of psychological distress using a trauma-informed yoga approach
 - Current intervention modified to address mechanisms that maintain PCH
- 8 weeks, 16 sessions
 - One theme per week
 - Different vinyasa flows each week
 - PCH & mindfulness language woven throughout sessions

"Yoga can teach us that sensations and feelings are constantly shifting and changing--that whatever is felt is time limited."



Sessions

Session(s)	Title	Goal(s)	Theme(s)
2	Interconnection of mind, body and breath.	Introduce participants; explain the rationale for yoga; introduce mindfulness, breathing and movement exercises. Use movement, breath and attention training to calm the body and mind.	Breath and movement exercises can calm and focus the body and mind.
3 4	How do you live in your body?	Learn about the relationship between physical sensation and emotional and mental functioning.	Physical sensation affects our outlook and emotions. When we can shift physical sensation with breath and movement, we can also shift our feelings and outlook.
5	The changing nature of feelings and sensations.	Experience the shifting, changing nature of emotions and physical sensations to increase distress tolerance.	Whatever is felt is time-limited, making challenging feelings easier to bear.
7 8	Present moment awareness.	Learn that the only moment we can directly work with is the present moment.	Living fully within each breath, each movement, impacts present moment experience.
9 10	Reactivity vs. responsivity.	Learn how to become less reactive and more responsive by calming the body-mind with breath and movement.	Developing calm in the body- mind and practicing restraint decreases reactivity and increases responsivity.
11 12	Noticing and stepping out of stories.	Notice, clarify and then step out of old narratives to shift and change.	Noticing and stepping out of habitual storylines can allow one to experience the present more fully.
13	Welcoming in all aspects of experience.	Learn how to open to more of one's experience to live fully.	When we armor ourselves against pain, we numb ourselves to all feelings, including joy.
15 16	Maintaining balance through attunement.	Learn how to find strength and balance by continually tuning into and responding to the shifting needs of the moment.	Health and balance are not static achievements; attunement to the present moment allows us to find balance.

Cueing the Mindfulness Skill:

"As you remain seated, inhale and sweep your arms to the sky, feel your palms approach and meet, trace the midline, feel the full weight of your thumbs on your forehead, nose, lips and heart center. Remaining seated, fold forward and press your palms into the earth. Commit to remaining mindfully aware of your breath and your body as we flow through postures."

Posture Practice:

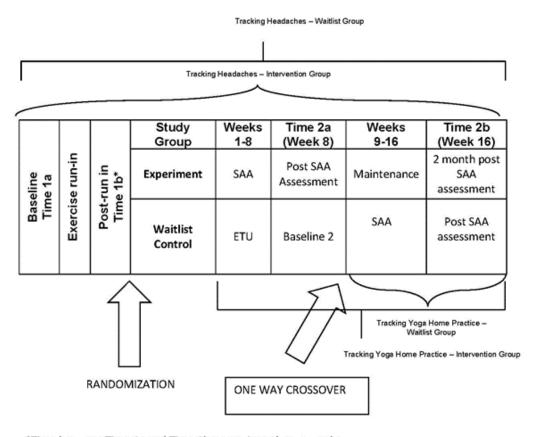
Opening Warm-up:

- 1. Shoulder shrug x 3 "we hold so much tension in our shoulders which can exacerbate headaches; let's see if we can shift it a bit. As you inhale draw your shoulders towards you ears, as you exhale, release"
- 2. Shoulder rolls x 3, backward
- 3. Shoulder rolls x3, reverse the direction, forward
- 4. Child's Pose "know that you can always come back to this pose whenever you need to rest"
- 5. Table
- Cat/Cow x 3 "draw into your strength as you draw your lower ribs in, connect with what is directly in front of you as you reach your heart forward"
- 7. High Plank
- 8. Low Plank
- 9. Cobra x 3



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^{*}Time between Time 1a and Time 1b approximately two weeks



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Exercise Run-In

Physical Poses Only

Resting Pose

Inverted V

Squat

Lunge One

Lunge Two

Balance

Theme
Breathing Exercises
Mindfulness
Yoga Language
PCH Language





Ecological Momentary Assessment (EMA) & Daily Tracking

- Headache Tracking
- Daily activities
- Yoga Tracking

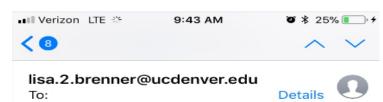












Daily Surveys

Today at 7:00 AM

Hello,

This is Lisa from the Yoga Study at the VA - I am writing to remind you to complete your surveys for this week. If you have any questions about the study you can call me at 303-399-8020 x7095.

Please follow the link below to complete your daily surveys.

Thank you very much, Lisa Brenner

You may open the survey in your web browser by clicking the link below:

Thursday EMA Tracking Form

If the link above does not work, try copying the link below into your web browser:

https://redcap.ucdenver.edu/surveys/?s=oay76BKGwP

This link is unique to you and should not be forwarded to others.

Headache Tracking Form for Wednesday Please use the form below to record your daily headaches:	Resize font: □ □
Headache: Check if you had a headache on Wednesday:	Yes No reset
What time did the headache start on Wednesday	02:00 PEM
What time did the headache end on Wednesday	10:00 PEM
Duration of headache:	08:00 PtM
Check the pain level for the headache	MildModerateSeverereset
Check if you took any medication for your headache	Yes No reset
List the meds you took for your headache and how much and how often	Ibuprofen 400mg, once at 2:30 and again at 6:30
	Expand
Submit Save & Return Later	

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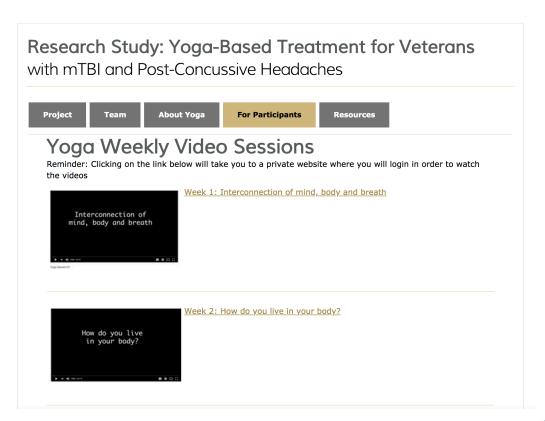
Data Collection Instrument	Week 1	Week 2	Exercise Run-In	Time 1b	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10
Contact Information												
Randomization												
Monday EMA Tracking Form (survey)	Ø	0					0	0	②	0	•	Ø
Monday Headache Tracking Form (survey)	②	0			0	0	0	0	•	0	•	②
Monday Yoga Tracking Form (survey)								0	•		•	②
Tuesday EMA Tracking Form (survey)	0	0			•	0	•	0	•	0	•	0
Tuesday Headache Tracking Form (survey)	0	0			•	0	•	0	•	0	•	0
Tuesday Yoga Tracking Form (survey)							•	0	•	0	•	0
Wednesday EMA						_	<u>~</u>		<u>~</u>		_	



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Home Practice

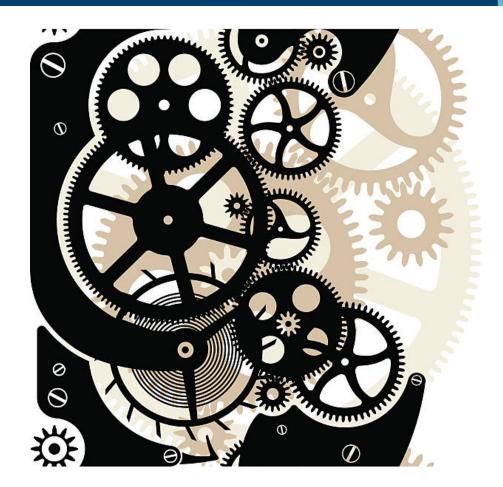




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Feasibility







Feasibility of Enrollment: SAA-TBI Intervention

- 14-20 participants per wave
- <u>></u>4 females or proceed all male waves

Exercise

Run-In

2 weeks

- Yoga-Now
- Yoga-Wait

Randomization

2 weeks

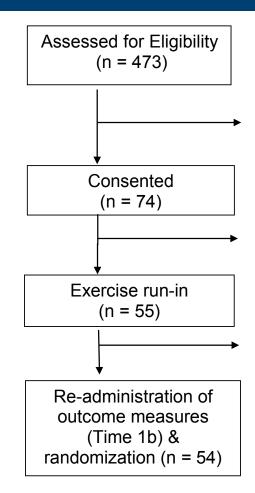
Yoga Sessions

2-4 weeks

- Barriers to scheduling
- Location
- Time of session



Enrollment



Excluded (n=375)

☐ Not meeting inclusion criteria (n=190)

☐ Declined to participate (n=183)

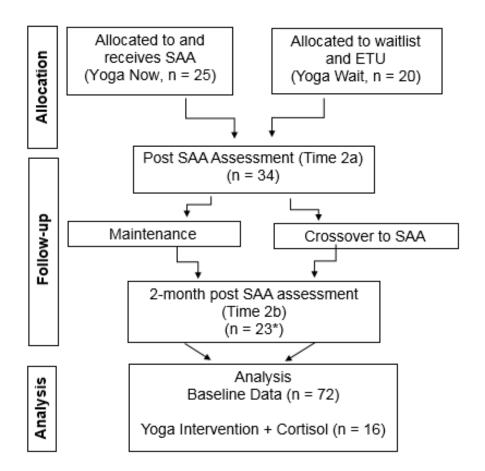
☐ Other reasons (n=2)

Lost to Follow post-Baseline (n = 10)

Discontinued due to physicality (n = 1)



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Sample Characteristics	Mean (SD) or Median (Range)	N (%)
Age	38.1 (6.9)	
	36.5 (27, 51)	
Sex		
Female		13 (18%)
Male		59 (82%)
Intersex		0 (0%)
Racial Background		
Caucasian		58 (81%)
Black or African American		5 (7%)
Native American/Alaskan Native		0 (0%)
Asian		0 (0%)
Pacific Islander		0 (0%)
Multiracial		2 (3%)
Other		7 (10%)
Hispanic/Latino		19 (26%)
Highest Level of Education		
High School Diploma or Equivalent		4 (6%)
Some College		26 (36%)
Associate's		11 (15%)
Bachelor's		19 (26%)
Master's		12 (17%)
Relationship Status		
Married		32 (44%)
Divorced/Separated		10 (14%)
Cohabitating		7 (10%)
Single		23 (32%)
Widowed		0 (0%)
Employment Status		
Full-Time		37 (51%)
Part-Time		6 (8%)
Unemployed, seeking		6 (8%)
Unemployed, not seeking		16 (22%)
Retired		7 (10%)
Student		
Full-Time		18 (25%)
Part-Time		4 (6%)
No		50 (69%)



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Baseline (1a) Interviews		
OSU	Median (Range)	
Count of TBIs	3 (1, 13)	
SCID	Lifetime (N/%)	Current (N/%)**
Mood Disorders		
Bipolar I Lifetime	4 (6%)	1 (1%)
Bipolar II Lifetime	0 (0%)	0 (0%)
MDD	47 (65%)	10 (14%)
Substance Use Disorders		
Alcohol	45 (63%)	2 (3%)
Cannabis	8 (11%)	3 (4%)
Stimulants/Cocaine	5 (7%)	0 (0%)
Opioids	5 (7%)	0 (0%)
Anxiety Disorders		
Panic	2 (3%)	2(3%)
Agoraphobia	0 (0%)	0 (0%)
Social Anxiety	0 (0%)	0 (0%)
Generalized Anxiety	6 (8%)	5 (7%)
PTSD	55 (76%)	23 (32%)

Headache Impact Test (HIT-6)

63.4 (6.1)



MAN AND

Beliefs About Yoga Scale	Mean (SD)	Alpha
Expected Benefits Factor (items: 1, 3, 4, 7, 11)	27.0 (3.8)	0.76
Expected Discomfort* (items: 5, 9, 10)	14.7 (3.7)	0.73
Expected Social Norms*** (items: 2, 6, 8)	14.5 (3.4)	0.63
Total Score**	56.2 (8.6)	0.81

^{*}N=71; **N=68; ***N=64



Development of the Beliefs About Yoga Scale

Stephanie J. Sohl, PhD1, Julie B. Schnur, PhD2, Leslie Daly, MS2, Kathryn Suslov, MD2, and Guy H. Montgomery, PhD²

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Abstract

Beliefs about yoga may influence participation in yoga and outcomes of yoga interventions. There is currently no scale appropriate for assessing these beliefs in the general U.S. population. This study took the first steps in developing and validating a Beliefs About Yoga Scale (BAYS) to assess beliefs about yoga that may influence people's engagement in yoga interventions. Items were generated based on previously published research about perceptions of yoga and reviewed by experts within the psychology and yoga communities, 426 adult participants were recruited from an urban medical center to respond to these items. The mean age was 40.7 (SD = 13.5) years. Participants completed the BAYS and seven additional indicators of criterion-related validity. The BAYS demonstrated internal consistency (11 items; $\alpha = 0.76$) and three factors emerged: expected health benefits, expected discomfort, and expected social norms. The factor structure was confirmed: γ^2 (41, n = 213) = 72.06, p < .001; RMSEA = .06, p = .23. Criterion-related validity was supported by positive associations of the BAYS with past experiences and future intentions related to yoga. This initial analysis of the BAYS demonstrated that it is an adequately reliable and valid measure of beliefs about yoga with a three-factor structure. However, the scale may need to be modified based on the population to which it is applied.

yoga; mind-body therapies; health; self-efficacy; behavior change; social norms





Attendance

	N (%)	Mean (SD) and Median
All Waves Yoga Session	attending at	(range)
Attendance	least one	Among those attending at
	session	least one session
Waves 1-5 [16 sessions	22/20/020/\	7.6 (4.9)
available]	23/28 (82%)	6 (1, 16)



No Maria



Attendance: 16 In Person Sessions

By Wave / Arm	N (%) attending at least one session	Mean (SD) and Median (range) Among those attending at least one session
Wave 1 Yoga-Now	3/3 (100%)	10.3 (7.4) 13 (2, 16)
Wave 1 Yoga-Wait	3/4 (75%)	7.3 (6.8) 5 (2, 15)
Wave 2 Yoga-Now	1/2 (50%)	2 (-) 2 (2, 2)
Wave 2 Yoga-Wait	3/3 (100%)	4.7 (3.2) 6 (1, 7)
Wave 3 Yoga-Now	1/2 (50%)	11 (-) 11 (11, 11)
Wave 3 Yoga-Wait	3/3 (100%)	8.7 (3.1) 8 (6, 12)
Wave 4 Yoga-Now	1/2 (50%)	5 (-) 5 (5, 5)
Wave 4 Yoga-Wait	3/3 (100%)	7.7 (6.7) 6 (2, 15)
Wave 5 Yoga-Now	2/3 (67%)	4 (4.2) 4 (1, 7)
Wave 5 Yoga-Wait	3/3 (100%)	8.3 (4.7) 10 (3, 12)





Feasibility of Enrollment: SAA-TBI Intervention

- 14-20 participants per wave
- >4 females or proceed all male waves

Baseline Visits
2 months

Run-In
2 weeks

- Yoga-Now
- Yoga-Wait

Randomization

2 weeks

Do both yoga sessions need to be in person?

Yoga Sessions

2-4 weeks

- Barriers to scheduling
- Location
- Time of session





Attendance: 7/8 In Person Sessions

By Wave / Arm	N (%) attending at least one session	Mean (SD) and Median (range) Among those attending at least one session
Wave 6 Yoga-Now [7 sessions due to weather]	4/5 (80%)	4.75 (0.96) 4.5 (4, 6)
Wave 6 Yoga-Wait [8 sessions]	4/4 (100%)	6.5 (1.3) 6.5 (5, 8)
Wave 7 Yoga-Now [8 sessions]	8/8 (100%)	3.9 (2.6) 3.5 (1, 8)





Yoga Home Practice

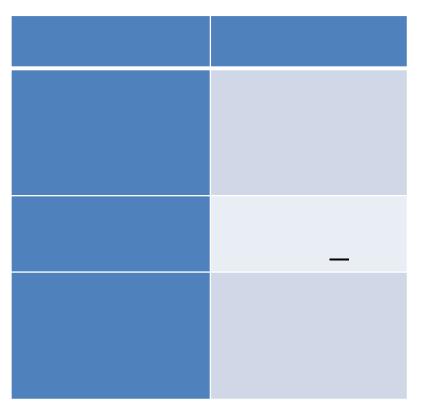
Yoga Practice	N/%
Wave 6 & 7: All participants that used the videos at least once	13/15 (87%)
(item 1 and/or 2 on yoga survey)*	
	6/15 (40%)
	Mean (SD) percent of
Wave 6 & 7: All participants	weeks viewing**
that used the videos at least	66% (40.7)
weekly (item 1 on yoga survey)	Median (range) for
	percent**
	88% (0, 100)



A MANA



Acceptability – Client Satisfaction Questionnaire





http://www.csqscales.com/



A WALL



Measure	Domain (Time to Complete by Participant)	Time 1a	Time 1b	Time 2a &2b	During SAA-TBI	
Inclusion/Exclusion						
Ohio State University TBI-Identification Method (OSU TBI-ID)	TBI history/Post-concussive headaches (20)	Х		X*		
Headache Impact Test (HIT-6)	Headache impact (5)	X	Х	Х	X	
Medical Clearance Form/Medical Examination	Medical history	X				
Group Profile						
Demographic Questionnaire	Demographics (5)	X				
Structured Clinical Interview for DSM-5, Research Version (SCID-5)	Axis I diagnoses (30)	х				
Clinician Administered PTSD Scale-5 (CAPS-5)	PTSD diagnosis (30)	Х				
Complementary, Alternative, and Conventional Medicine Attitudes Scale (CACMUS)	Attitudes and CAM use patterns (10)	X				
Feasibility						
Client Satisfaction Questionnaire (CSQ)	Satisfaction with intervention (5)			Х		
Narrative Evaluation of Intervention Interview (NEII)	Participant feedback regarding the intervention (10)			X		
Reasons for Termination (Client and Yoga Instructor) versions RT- C/RT-C)	Reasons for termination (5)			x		
Yoga Tracking Forms	Daily yoga practice (1)				Ongoing	
Yoga Fidelity Checklist [S]	Fidelity				Ongoing	
Attendance Records [S]	Attendance				Ongoing	
Candidate Outcomes						
Headache Tracking Form (HTF)	Headache days per week, headaches per day, duration, severity, and treatment response					
PROMIS Modules (Neuro-QoL)	Sleep; Depression; Anxiety; Pain (Intensity and Interference); Physical function; Social roles and activities; Satisfaction and ability to participate (15)	х	×	X		
Short Form McGill Pain Questionnaire (SF-MPQ)	Pain intensity (5)	Х	Х	Х		
Brief Pain Inventory (BPI)	Pain interference (5)	X	Х	Х		
International Physical Activity Questionnaire (IPAQ)	Physical activity (10)	X	Х	Х		
Perceived Stress Scale (PSS)	Perceived stress (5)	X	Х	Х		
K Scale: Survey of Headache Impact	Avoidance of pain-related disability (5)	Х	Х	Х		
Neurbehavioral Symptom Inventory (NSI)	Post-concussive symptoms (5)	X	Х	Х		
Heart Rate Variability (HRV)	Vagal nerve tone autonomic nervous (20)	Х	X	Х		
Short Form Health Survey (SF-36)	Quality of life (10)	X	X	Х		
Ecological Momentary Assessment (EMA)	Post-concussive symptoms (3)	Х	Х	Х		
Pedometry	Physical activity (1)	X	X	X		
Distress Thermometer	Distress (1)				At the beginning and end of each yoga session	
Potential Confounder						
Expectancy and Credibility Scale	Participant perception (5)	Х	Х	Х		



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Complete Cortisol Collection Timeline

Time la			Weeks 1-8	Time 2a	Time 2b
Baseline	Pre-Yoga PM	Pre-Yoga AM	Pre-Yoga and Post-Yoga Sessions	Post SAA Assessment	Approx. 2-months post- SAA assessment

Time 1a	Pre-Yoga PM	Pre-Yoga AM	Yoga Session #1	Yoga Session #3	Yoga Session #5	Yoga Session #7	Yoga Session #9	Yoga Session #11	Yoga Session #13	Yoga Session #15	Time 2a	Time 2b
Baseline				Pre-Yoga and Post-Yoga Session						Post SAA	Approx. 2- months post- SAA	

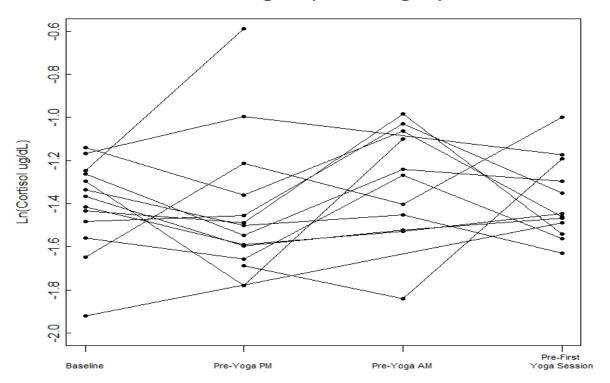




N. A. W.

Cortisol

Pre-Yoga Ln(Cortisol ug/dL)







Questions?

- Is the study design feasible?
 - For whom?
 - Using data to identify those most likely to participate?
 - Sample size recruitment
- Was the intervention acceptable?
 - For whom?
- Candidate outcomes
- Next steps?







SAA Team



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Research Study: Yoga-Based Treatment for Veterans with mTBI and Post-Concussive Headaches

Project

Team

About Yoga

For Participants

Resources

http://www.ucdenver.edu/academics/colleges /medicalschool/departments/pmr/Research/P ages/yoga.aspx



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