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## Strength and awareness in action: Feasibility of a yoga-based intervention for post-acute mild TBI headaches among veterans

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### ABSTRACT

**Background:** Mild traumatic brain injury (mTBI) is a signature injury sustained by Veterans during recent conflicts. For some, mTBI/concussion is associated with disabling symptoms, including post-concussive headaches (PCH). However, there are limited evidence-based treatments for persistent PCH.

**Objective:** Investigators assessed the feasibility of design elements of a yoga-based interventional trial for PCH among Veterans, as well as the acceptability of the intervention.

**Methods:** This randomized controlled acceptability and feasibility trial was implemented using a waitlist-control design. Design elements of interest included: an exercise run-in class; recruitment and retention strategies; and, ecological momentary assessment (EMA) modalities to track headaches and yoga practice. Veteran satisfaction regarding the intervention was also evaluated. A descriptive analysis was conducted on candidate outcomes including PCH, post-concussive symptoms, pain, and daily functioning.

**Results:** Twenty-seven participants (out of 70 consented and eligible after Study Visit 1) completed each evaluation timepoint and regularly attended yoga sessions, with 89% of these Veterans reporting moderate to high levels of satisfaction with the intervention at study completion. Qualitatively, participants endorsed improvements in headaches, chronic pain, and mood. Feasibility results were mixed. Initial feasibility criterion regarding yoga attendance was not met; however, modifications, such as expansion to an additional clinic site and reduction of in-person yoga sessions with increased encouragement to use study-created online yoga videos improved feasibility of the study design. Participants most frequently used mobile and web-based EMA modalities to track yoga practice.

**Conclusions:** Although challenges with feasibility of the study design elements were noted, results suggested acceptability of the yoga-based intervention for Veterans with persistent PCH. Additional exploration regarding the frequency and modality of yoga delivery (e.g., in-person, telehealth) is warranted.

**Impact:** Veterans found the yoga-based intervention acceptable, however exploration of novel modalities of intervention delivery will likely be necessary to enhance the feasibility of intervention implementation during future trials.

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## 1. Introduction

Mild traumatic brain injury (mTBI) is one of the most common injuries sustained by Veterans from recent conflicts. For some, such injuries are associated with disabling post-concussive symptoms (PCS), including post-concussive headaches (PCH). An estimated 11%–23% of those who served in Iraq or Afghanistan have a history of mTBI, with around 7% reporting persistent PCS (e.g., headaches, cognitive challenges, and emotional distress) [1]. PCH pain is the most frequently reported chronic symptom by Soldiers with a history of deployment-related mTBI [2]. PCHs are notoriously resistant to medication alone, and are associated with increased muscle tension, avoidance of physical activities, and pain-related anxiety. Thus, investigating the acceptability and feasibility (ease of implementation) of novel treatments to mitigate PCH symptoms and improve symptom management is warranted.

Research supports the use of non-pharmacological treatments for persistent PCH [3–5]. For example, within the Veterans Affairs/Department of Defense Clinical Practice Guideline (CPG) for the Management of Concussion and mTBI [6] the use of “education on lifestyle modifications, PT [physical therapy] [and] integrative medicine techniques (e.g., acupuncture, relaxation therapy, mindfulness training)...” (p.30) for treatment of PCH are recommended. Specifically, non-pharmacological management strategies for PCH that focus on: regulation of the autonomic nervous system (ANS) via physical activity/breathing exercises; release of muscular tension; and, mindfulness and acceptance strategies are supported by existing research and theory. However, there is a dearth of standardized non-pharmacological evidence-based (EB) treatments for PCHs that focus on these active ingredients (e.g., regulation of the ANS, reduction of muscular tension, mindfulness).

Yoga is a complementary and integrative health intervention that may target PCH pain by releasing muscular tension and regulating the ANS via physical activity, breathing exercises, and mindfulness and acceptance strategies. With these foci, yoga maps well onto the clinical management strategies recommended for PCH. Mindfulness skills have also been associated with building resilience during stress, allowing one to better cope with physical discomfort, and decrease anxiety, depression, and reactivity [7]. In fact, yoga has shown promising results in treating different types of chronic conditions (e.g., low back pain) [8].

Despite these promising findings, existing studies of yoga for chronic conditions have several methodological limitations, including significant variations in dose, duration, lack of standardized protocols, unclear inclusion/exclusion criteria, limited measurement of fidelity and adherence, and inadequate comparison/control groups to name a few [9,10]. Moreover, no studies have rigorously tested the use of yoga for PCH. Although more large scale efficacy studies are needed, important first steps are to: determine whether Veterans with PCHs find a structured yoga-based intervention acceptable; and, identify barriers and facilitators to implementing specific aspects of the study design, including recruitment, retention, intervention delivery, and data collection procedures (feasibility). These steps are especially important as yoga-based interventions may require different demands on participants compared to other conventional treatments for PCH (e.g., medications), such as the need to travel to and attend classes [11], and engage in physical activity. Therefore, the primary aim of the randomized, controlled trial was to evaluate the acceptability and feasibility of a yoga intervention, *Strength and Awareness in Action: an Intervention for Post-Acute TBI Headaches* (SAA-TBI). Herein, acceptability [12] is defined as the satisfaction with the intervention from the participants’ perspective.

In alignment with guidance provided by Areán & Kraemer [13], feasibility focused on the ease of implementation of study design elements including: participant recruitment, retention, and participation; utility of the exercise run-in session; and, data collection procedures (ecological momentary assessment; EMA). Feasibility criteria as suggested by

Thabane and colleagues [14] are as follows: “(i) Stop - main study not feasible; (ii) Continue, but modify protocol – feasible with modifications; (iii) Continue without modifications, but monitor closely – feasible with close monitoring; and (iv) Continue without modifications – feasible as is” (p.5). Based on previous research regarding clinical trials and information from the initial pilot of the SAA intervention, a priori criterion for continuing without modifications (feasible as is) was: at least 50% of those initially randomized (post-exercise run-in, Study Visit 2) completing 75% of sessions. If this criterion is not met, determination of feasibility should include review of individual and combinations of all aspects of feasibility (e.g., participant accrual and retention). In addition, an exploratory aim of this study was to explore changes on validated measures of PCH, post-concussive symptoms, pain, and psychosocial functioning over the course of the yoga trial.

## 2. Methods

### 2.1. Participants

Participants were U.S. military Veterans receiving care at a mountain state Veterans Affairs Medical Center (VAMC). Recruitment strategies included presentations to clinical providers across rehabilitative, mental health, and primary care services located within the VAMC and associated VA community-based outpatient clinics (CBOCs). Flyers were posted at the local VAMC and surrounding CBOCs, as well as community-based Veteran organizations, (e.g., Veteran Service Organizations), and local Vet Centers. Veterans who had participated in previous research with existing consent to be contacted for future studies were mailed flyers and study contact information. Additionally, we identified Veterans with International Classification Disease (version 9 or 10) codes of interest for TBI (e.g., S06) and mailed an initial invitation with the flyer and a refusal response card. Veterans who contacted the study team were screened for possible enrollment into the study.

Veterans who contacted the study team were provided with a detailed description of the study, including procedures and duration of study involvement. If Veterans expressed interest in continuing with the screening, basic demographic information regarding the following inclusion criteria were obtained prior to scheduling the Baseline visit (Study Visit 1).

Veterans were included if: 1) they reported a history of mTBI per the Ohio State University Traumatic Brain Injury-Identification Method (OSU TBI-ID) [15]; 2) they reported a history of persistent (lasting at least 1 year) PCH pain (tension type headache, migraine, or mixed), with onset of pain or increase in headache pain having occurred within 1 month of mTBI as determined by structured examination using the International Classification of Headache Disorders-3 beta (ICHD-3 beta) [16] criteria; 3) they duration of PCH pain lasted >1 year as determined by structured medical examination [3,17]; 4) they reported a score of >49 on the Headache Impact Test-6 (HIT-6) [18]; 5) they received medical clearance by study providers to participate in the yoga protocol; 6) they were between 18 and 55 years of age; and, 7) they were able to provide informed consent. Participants were excluded if they: 1) met criteria for active psychosis or substance dependence, excluding Cannabis (as Cannabis was legal in the state where the trial occurred), as determined by structured clinical interview (during Study Visit 1); 2) reported inability to participate in yoga without significant posture modification; 3) reported a consistent yoga practice (two or more times weekly); or, 4) were participating in an interventional study aimed at addressing pain-related symptoms at the local VAMC.

### 2.2. Procedures

Institutional review board approval was obtained. Data collection occurred between 2017 and 2019. Study participation included completion of 5 study visits and attending the SAA-TBI (yoga) intervention.

See Fig. 1 for the original Study Procedure Timeline. During visits 1, 3, 4 and 5 Veterans completed clinical interviews, self-report measures (including the HIT-6 and exploratory candidate outcome measures), procedures to collect data regarding heart rate variability, and in some cases provided salivary cortisol samples. Veterans were compensated for these visits. Not all data are presented below, though daily headache impact and exploratory candidate outcome data are presented in the Supplementary appendix. After enrolling in the study (completion of Study Visit 1), Veterans were asked to complete EMA via their modality of choice (text message, web-based, or pen-and-paper formats). EMA sampled activities, barrier and facilitators to activity participation, neurobehavioral and pain symptoms, daily headaches and if medication was taken to treat headaches (binary yes/no response), and home yoga practice (during the active yoga phase). Participants received compensation for EMA (\$5 weekly compensation for completing surveys at least 4 out of 7 days).

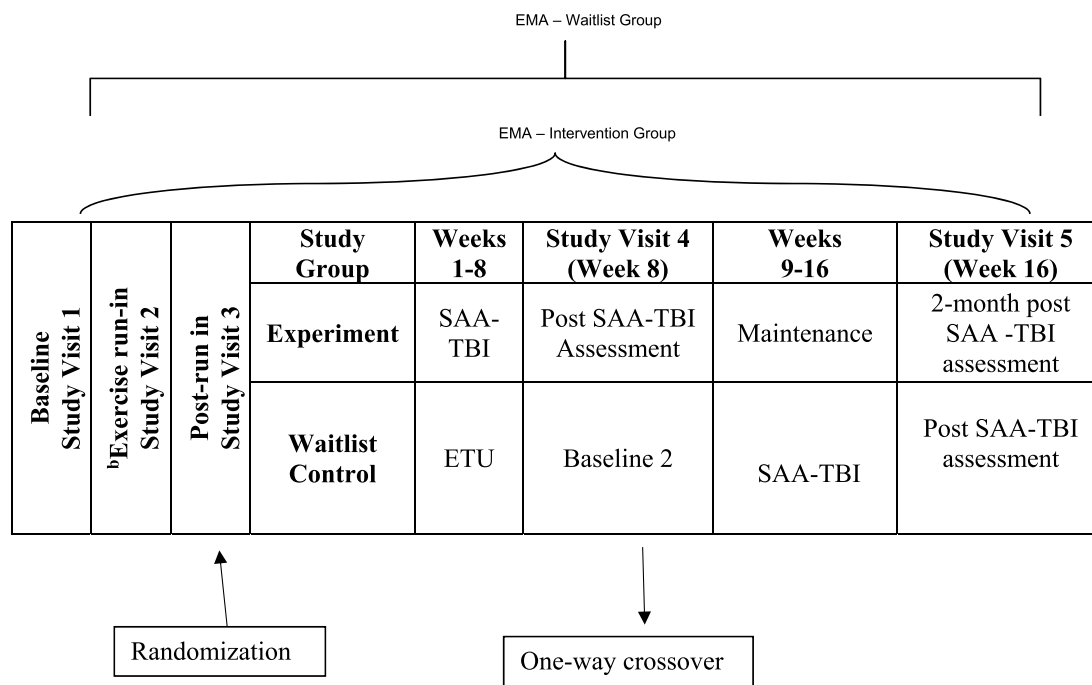
An exercise run-in orientation session (physical poses only) was conducted during Study Visit 2. Findings from a previous pilot study (unpublished) suggested that Veterans' lack of familiarity and comfort with yoga postures may have led to participant attrition following the first yoga session. Thus, the exercise run-in session was included in the current study to increase Veterans' familiarity with yoga and yoga poses with the intention to increase retention. During the exercise run-in, no mindful instruction, breath or meditative practices were presented. Following the run-in, participants completed Study Visit 3 and were provided the opportunity to continue or discontinue study participation. Those who continued were block randomized (1:1) and stratified by gender to two groups, SAA-TBI or waitlist enhanced treatment as usual (ETU; participants randomized to the ETU group received enhanced treatment which consisted of completing surveys over the duration of the entire study period and additional contact/study visits with the study team. ETU did not include additional treatments or interventions specific to headaches). All attempts were made to complete the exercise

run-in (Study Visit 2) within approximately two weeks of enrollment into the trial (Study Visit 1). The 1:1 block randomized waitlist control experimental design was used to determine if those initially allocated to the delayed-start group would remain in the study long enough to be provided the opportunity to participate in the yoga intervention.

Six waves of participants were randomized as noted above. Those allocated to SAA-TBI began the 8-week SAA-TBI yoga intervention immediately, and the ETU delayed-start group started approximately 8 weeks post (see Fig. 1). A seventh cohort was not randomized and all participants in this seventh cohort were invited to start SAA-TBI immediately. All participants were invited to complete Study Visit 4 which occurred within approximately 2 weeks of the SAA-TBI group completing the intervention, and prior to the ETU group receiving the intervention. Study Visit 5 occurred within two weeks of all participants in a respective wave (SAA-TBI and ETU groups) completing the SAA-TBI intervention.

### 2.3. SAA-TBI intervention

A manualized yoga protocol based on mindful, trauma-informed yoga with an emphasis on poses designed to release head, neck, and shoulder tension was used, with a total of 16 yoga sessions building upon one another over the 8 weeks. Key session components included: verbal check-ins (to build conscious awareness of the interconnection between breath patterns, physical sensations and mood); introduction of a mindfulness theme; brief guided mindfulness meditation and breathing exercises; active posture practice; cooling down postures; guided final relaxation; verbal check-outs (to build non-judgmental awareness of how breath patterns, physical sensations and mood may or may not have shifted with practice); and, homework reminders to facilitate both yoga practice outside of sessions and the use of online yoga videos created for this study. The yoga instructors for this study assisted



<sup>a</sup>Participants in Wave 7 were all allocated to the SAA-TBI Experimental Group, no participants were assigned to the Waitlist Control Group.

<sup>b</sup>Time between Study Visit 1 and Study Visit 2 was approximately two weeks.

Fig. 1. Original study procedure timeline for waves 1-6a.

with the creation of 8 online yoga videos using the even-numbered yoga sessions in the SAA-TBI manual, which were available via a password-protected website to participants allocated to the intervention. Instructor adherence was ascertained by a 20% fidelity check of the audiotaped yoga sessions.

Initially, a total of 16 yoga (75 min) group sessions were offered to participants twice weekly over the course of 8 weeks. Adaptations during the study (Wave 6) resulted in offering a total of 8 weekly yoga sessions for later groups, with emphasized encouragement to use the yoga videos between in-person sessions. During in-person sessions, yoga mats were available, and yoga blocks and bolsters were provided to assist with modifications and/or promote comfort.

## 2.4. Measures

### 2.4.1. Sample characteristics

Sample characteristics were obtained using the *Rocky Mountain MIRECC Demographics Form*. The *OSU TBI-ID* [15], a structured clinical interview, was used to establish lifetime history of mTBI at Study Visit 1 [19]. Impact of current PCH pain on daily life was obtained with the *HIT-6* [18], a 6-item self-report measure. Scores on the HIT-6 range from 36 (no impact) to 78 (severe impact) of headaches on daily life. The HIT-6 [18] was used to establish initial PCH inclusion criteria and was also re-administered at all study visits and at the end of each attended yoga session. The study team created a medical examination and review form to document medical or physical contraindications to participating in yoga and to confirm PCH onset following mTBI event(s) using ICHD-3 beta [16] criteria. The *Structured Clinical Interview DSM-5 Research Version (SCID 5)* [20], a semi-structured interview, was used to gather Axis I psychiatric diagnoses at Study Visit 1.

### 2.4.2. Acceptability & feasibility

Acceptability was measured using the Client Satisfaction Questionnaire (CSQ-8)<sup>21</sup>, an 8-item self-report measure regarding satisfaction with the intervention. The a priori criterion for satisfaction with the intervention was  $\geq 70\%$  of participants scoring  $\geq 24$  on the CSQ-8 [21]. A Distress Thermometer [22], a commonly used single item measure of distress in the present moment rated on a scale of no distress (0) to extreme distress (10), was administered pre- and post-yoga for participants who attended yoga sessions. A semi-structured qualitative interview, the Narrative Evaluation of Intervention Interview (NEII) [23] was used to identify illustrative quotes related to participants' experience with the yoga intervention.

Recruitment, accrual, retention, and attrition were recorded using study tracking logs. The study team developed the EMA surveys as a means of tracking yoga practice, daily headaches, and if they took a medication for the headache (yes/no response). Frequency and duration of daily yoga practice, as well as any additional breath work, meditation, poses, or guided practice (e.g., use of yoga videos) was added to the daily EMA surveys when the participant was attending the yoga sessions.

## 2.5. Data analysis

### 2.5.1. Quantitative analyses

Data pertaining to sample characteristics, satisfaction, feasibility, and the change in exploratory candidate outcomes over time were summarized using means and standard deviations; medians and ranges; and N and percent with associated 95% confidence intervals (CI), as appropriate.

### 2.5.2. Qualitative analyses

The first author reviewed all qualitative interviews for thematic content related to satisfaction with the SAA-TBI intervention. Illustrative quotes to elucidate quantitative findings were identified and a select few are presented.

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## 3. Results

### 3.1. Baseline sample characteristics (N = 70 consented and eligible after study visit 1)

Sample characteristics are presented in Table 1. The sample was predominantly male (81%), of Caucasian race (80%), with a mean age of 38.2 (SD = 6.9). The median number of mild TBIs reported was 3 (range 1–13). Mean score of current impact of headaches related to a prior mTBI was 63.5 (SD = 5.8), indicating substantial to severe impact of headaches on daily life. Most common psychiatric diagnoses were lifetime history of alcohol use disorders (63%), major depressive disorder (67%), and post-traumatic stress disorder (PTSD, 76%). Ap-

**Table 1**  
Sample characteristics.

Characteristic	Baseline (n = 70)	All Assigned (SAA/ETU) (n = 54)
	N (%)	N (%)
Age, M (SD)	38.2 (6.9%)	38.4 (7.1%)
Gender		
Male	57 (81.4%)	42 (77.8%)
Female	13 (18.6%)	12 (22.2%)
Race		
Caucasian/White	56 (80.0%)	42 (77.8%)
Black or African American	5 (7.1%)	4 (7.4%)
Multiracial/Other	9 (12.9%)	8 (14.8%)
Hispanic/Latino	19 (27.1%)	16 (29.6%)
Military Branch <sup>a</sup>		
Army - Active	43 (61.0%)	35 (65.0%)
Army - Reserve/NG <sup>b</sup>	19 (27.1%)	17 (31.5%)
Air Force - Active/NG/Reserve	8 (11.4%)	5 (9.3%)
Marines - Active/Reserve	15 (21.4%)	11 (20.4%)
Years of Active Service M (SD)	6.6 (4.3%)	6.7 (4.5%)
Years of Reserve Service M (SD)	2.6 (5.1%)	3.1 (5.6%)
Service Era <sup>c</sup>		
Post-Vietnam/Peacetime	3 (4.3%)	3 (5.6%)
Desert Storm/Desert Shield	16 (22.9%)	13 (24.1%)
OEF/OIF/OND	64 (91.4%)	50 (92.6%)
Number of Deployments <sup>d</sup> Median (Range)	2 (0–11)	2 (0–11)
Number of Combat Tours Median (Range)	1.5 (0–9)	1.8 (0–9)
Highest Level of Education		
High School Diploma or Equivalent	4 (6.0%)	2 (4.0%)
Some College	24 (34.0%)	17 (31.0%)
Associate's/Bachelor's	30 (42.9%)	25 (46.0%)
Master's	12 (17.1%)	10 (18.5%)
Employment Status		
Full-Time	37 (52.9%)	30 (55.6%)
Part-Time	5 (7.1%)	5 (9.3%)
Unemployed	21 (30.0%)	13 (24.1%)
Retired	7 (10.0%)	6 (11.1%)
Student		
Full-Time	16 (22.9%)	12 (22.2%)
Part-Time	4 (5.7%)	3 (5.6%)
No	50 (71.4%)	39 (72.2%)
Relationship Status		
Married	32 (45.7%)	25 (46.3%)
Divorced/Separated	10 (14.3%)	8 (14.8%)
Cohabiting	6 (8.6%)	6 (8.6%)
Single	22 (31.4%)	15 (27.8%)

<sup>a</sup> Participants may have served in more than one military branch.

<sup>b</sup> NG = National Guard.

<sup>c</sup> Participants may have served multiple eras.

<sup>d</sup> N = 69.



proximately 1/3 of the sample met criteria for a current diagnosis of PTSD.

### 3.2. Acceptability

Data regarding participants' satisfaction with the intervention was collected at their final yoga session and again at the final study visit. Participants were invited to complete the final Study Visit 5 regardless of their attendance at yoga sessions. All participants who completed a CSQ-8 at a final yoga session ( $n = 19$ ) reported satisfaction with the intervention. All participants who attended Study Visit 5 (final visit,  $n = 27$ ) reported mean satisfaction of 28.9 ( $SD = 3.5$ ) and median of 30 (range 20–32) with 89% ( $n = 24$ ) participants rating satisfaction  $\geq 24$  (95% CI: 71%, 98%). The median percent of yoga sessions attended for the 27 participants was 62.5% (range 6.3%–100%). Of the 12 participants assigned to the SAA-TBI group and who attended the final study visit, a mean satisfaction of 28.8 ( $SD = 3.7$ ) and median of 30.5 (range 23–32) was reported. Ten participants (83%) in the SAA-TBI group rated satisfaction  $\geq 24$  (95% CI: 52%, 98%). The median percent of yoga sessions attended for these 12 participants was 65.6% (range 12.5%–100%). Fifteen participants assigned to the ETU group and who attended the final study visit reported a mean satisfaction of 28.9 ( $SD = 3.5$ ) and a median of 30 (range 20–32). Fourteen participants (93%) in the ETU group rated satisfaction  $\geq 24$  (95% CI: 68%, 100%). The median percent of yoga sessions attended for these 15 participants was 62.5% (range 6.3%–100%). Additionally, participants ( $n = 7$ ) in the final two waves (reduced in-person yoga sessions) who completed the CSQ-8 at the final study visit reported high levels of satisfaction ( $M = 29.1$ ,  $SD = 3.4$ ; Median = 30 (23–32)). Lastly, change in subjective level of distress pre- and post-yoga attendance was collected for 39 participants who attended at least one yoga session. The average number of sessions at which the distress thermometer was collected was 6.2 ( $SD = 4.1$ ) with a median of 6 (range 1–16). Level of distress lowered on average 1.37 points ( $SD = 1.04$ ; 95% CI: 1.71, –1.03) with a median change of –1.38 points (range –4 – 1).

Qualitative results further supported Veterans' satisfaction with the yoga intervention. One Veteran stated, "I had taken yoga before, but I hadn't really experienced it or enjoyed it as I did with this." Another noted, "it was very satisfying, it gave me the knowledge and ability to do the poses I wasn't able to do before...it was awesome." Many participants described benefits obtained from participating in the intervention such as improvements with headaches, mood, and pain. One Veteran summed it up by saying "it gave me life application steps to better overcome or deal with anger outbursts, headaches, anxiety, nervousness, depression. So instead of internalizing everything I was able to calm myself down and assess what was going on." Another stated "I plan to continue some sort of yoga program because I had a significant change in pain and decrease in headaches and that was, by itself, enough to keep me practicing yoga."

## 4. Feasibility of study design elements

### 4.1. Recruitment, retention, & exercise run-in

Recruitment and retention rates are presented in Fig. 2. Although many Veterans expressed interest in the study ( $n = 480$ ), slightly less than half declined after learning more about the study, and 51% were ineligible. Veterans that declined participation ( $n = 190$ ) reported the following reasons: distance to clinic (45%); lack of time (37%); not interested in yoga (3%); or, other/unknown (15%). Primary ineligibility reasons included: no history of TBI; PCH pain  $< 56$  on the HIT-6; and, age. Due to recruitment challenges, we lowered the HIT-6 score from  $> 56$  to  $> 49$  and increased the upper age limit from 50 to 55. Decreasing the HIT-6 score criteria resulted in an additional 6 (out of 198) interested and eligible Veterans being enrolled. After increasing the age

limit, 21 interested eligible Veterans were identified (out of 198). Of these 21, only 2 additional participants were consented; 7 were not interested, 3 denied history of TBI, 3 denied current PCH, 1 reported a moderate/severe TBI, 1 was engaged in yoga practice more than twice a week, and 4 were lost to follow-up.

Overall, 75 participants were consented and 5 were found to be ineligible during the initial study visit. Approximately 79% enrolled and eligible participants completed the exercise run-in ( $n = 55$ ), and only 1 participant was lost to follow-up post-exercise run-in. Fifty-four participants were assigned to the SAA-TBI ( $n = 29$ ) or ETU ( $n = 25$ ) group.

### 4.2. Group assignment, attendance, and retention

**SAA-TBI Group.** Examining the participants assigned to SAA-TBI, 20 (69%) attended at least 1 yoga session and 14 (70%) who attended at least 1 yoga session completed Study Visit 4. However, only 5 (17%) attended at least 75% of sessions (95% CI: 5.9%, 35.8%). Twelve participants (41%) assigned to SAA-TBI group completed the final study visit.

**ETU Group.** Of the participants assigned to the ETU group, 19 (76%) attended at least 1 yoga session and these participants plus 1 participant who did not attend a yoga session completed Study Visit 4. Seven (28%) attended at least 75% of sessions (95% CI: 12.1%, 49.4%). Fifteen participants (60%) assigned to the ETU group completed Study Visit 5.

Overall, 12 (22%) participants attended at least 75% of sessions (95% CI: 12.0%, 35.6%), which did not meet the feasibility criterion (i.e., 50% completing 75% of sessions). Additional attendance data are shown in Table 2.

### 4.3. Strategies implemented to increase feasibility

Adaptations to improve retention occurred as the study progressed. As noted above, the first 5 waves had 16 in-person yoga sessions (over 8 weeks). This was adapted to 8 weekly in-person yoga sessions for the final 2 yoga waves. In addition, wave 6 was conducted at a CBOC to include Veterans that were interested in participating in the intervention yet not interested in driving to the metropolitan VAMC. After this change, the percent of participants attending at least 75% of yoga sessions almost doubled, from 17% to 33%. Participants in wave 7 were all allocated to SAA-TBI due to study time constraints. Another strategy to improve feasibility of SAA-TBI was staff encouragement of participants' use of the online yoga videos for their home practice, and those enrolled in waves 6 and 7 were specifically asked to use the online yoga videos each week following their in-person yoga session. Study staff monitored participants' reported use of the videos via EMA surveys and contacted individuals by telephone if weekly yoga practice was not endorsed to encourage practice or to help solve any barriers related to practicing yoga. Participants in the first 5 waves minimally used the videos. Session 2 and 6 were most widely watched in this group with a total of 8 and 7 views, respectively, with an average watch time of just over an hour. Participants in waves 6 and 7 viewed videos more frequently with an increase in watch time. Session 2 was viewed 26 times, and sessions 4 and 12 were watched 13 times.

### 4.4. Ecological momentary assessment (EMA) & exploratory outcomes

Although participants were offered EMA surveys via modality choice (web-based, text message, or paper-and-pencil), most of the participants selected web-based modality. On average, participants completed about 2/3 of the number of surveys they received during the SAA-TBI intervention and during their control period. Candidate outcomes are presented in the Supplementary appendix.

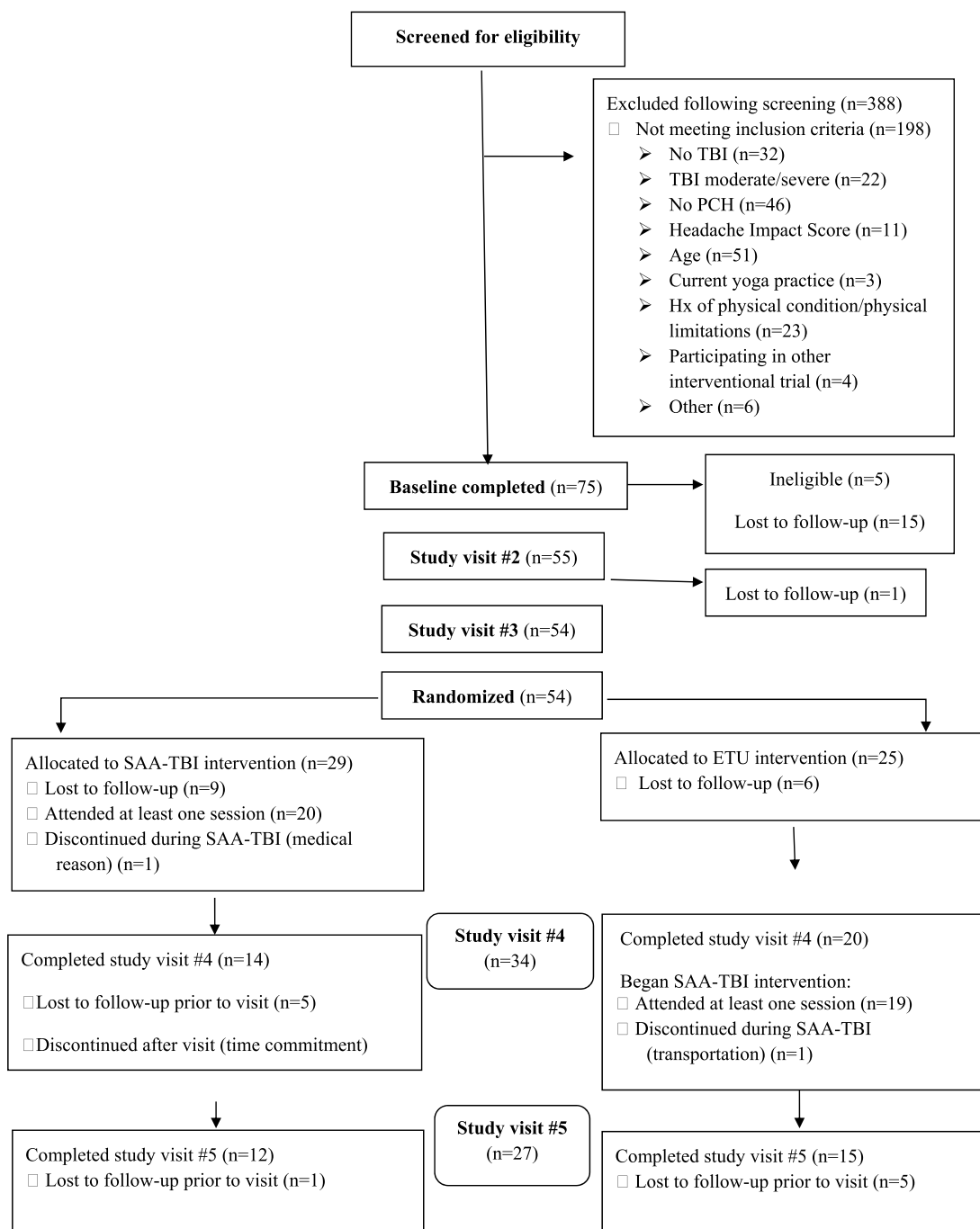


Fig. 2. CONSORT Enrollment diagram.

### 5. Discussion

The present study's results support the acceptability of the manualized 8-week group yoga intervention for Veterans with PCH. Overall, Veterans with mTBI and persistent PCH, regardless of wave, group assignment, or number of sessions attended, were satisfied with the SAA-TBI yoga intervention which supports acceptability of yoga for individuals with PCH. Further, participants who attended at least one session reported a decrease in level of distress pre-to post-yoga session, suggesting that participants engaged in yoga may experience both short-term benefits, facilitating additional retention in the trial, and long-term benefits of reducing PCH and improving symptom management. Additional research is needed to determine which individuals may be drawn to, or benefit from, this type of intervention.

Results regarding the feasibility of the study design elements of this intervention were mixed. Per our feasibility criterion, we did not successfully meet the 50% of participants attending at least 75% of the session, therefore, as planned we implemented modifications to improve feasibility [14]. The following lessons learned may help improve implementation of future efficacy trials to establish an evidence-base for yoga interventions in this population.

#### 5.1. Recruitment & enrollment

Although many Veterans expressed interest in the study, over half were not eligible due to the study-specific inclusion criteria. Changes to inclusion criteria slightly increased enrollment. Importantly, almost half of Veterans expressing initial interest declined to enroll due to dis-

**Table 2**  
SAA-TBI intervention attendance.

	All (N = 36)	SAA-TBI Group (N = 16)	ETU Group* (N = 20)
<b>A Priori 16 Sessions</b>	Mean (SD) and Median (range); or N (%) and 95% CI		
<b>Proportion Completing</b>	6 (16.7%)	2 (12.5%)	4 (20%)
<b>≥75% of Sessions</b>	(6.4%, 32.8%)	(1.6%, 38.4%)	(5.7%, 43.7%)
<b>Number of Sessions</b>	4.6 (5.2)	3.6 (5.3)	5.5 (5.1)
<b>Proportion of Sessions</b>	2 (0,16)	0.5 (0, 16)	5.5 (0,15)
	0.30 (0.33)	0.22 (0.33)	0.34 (0.32)
	0.13 (0,1)	0.03 (0,1)	0.34 (0,0.94)
<b>A Priori 8 Sessions</b>	Mean (SD) and Median (range); or N (%) and 95% CI		
<b>Proportion Completing</b>	6 (33.3%)	3 (23.1%)	3 (60%)
<b>≥75% of Sessions</b>	(13.3%, 59.0%)	(5.0%, 53.8%)	(14.7%, 94.7%)
<b>Number of Sessions</b>	4.2 (2.6)	3.8 (2.4)	5.2 (3.1)
<b>Proportion of Sessions</b>	4.5 (0,8)	4 (0,8)	6 (0,8)
	0.53 (0.33)	0.48 (0.30)	0.65 (0.39)
	0.56 (0,1)	0.50 (0,1)	0.75 (0,1)

\*ETU Group had 15 sessions due to adverse weather; ~The final SAA-TBI group randomized all participants (n = 7) to SAA-TBI.

tance to the study site and the time commitment needed. Modifications implemented during the study to reduce the number of weekly yoga sessions may have increased participation in the study. An additional modification was the expansion to another clinic location for completion of study visits and yoga sessions. Distance to the original clinic location was a barrier observed during the trial, and expansion to an additional clinic site improved recruitment and retention. Future trials will benefit from including multi-site locations to increase recruitment, providing a variety of yoga session offerings per week for drop-in attendance, involving healthcare providers who may have increased contact with individuals with PCH to increase referrals to the study, and increasing community advertisements such as by leveraging the use of technology (e.g., social media, ads, etc.) or partnerships with community fitness centers. Limited staff secondary to the study budget, scheduling the in-person study visits, and timely start of the waves of groups (SAA-TBI and ETU groups) contributed to further enrollment challenges in the current study.

## 5.2. Retention

Retention of participants initially presented challenges, however, modifications reduced attrition. The exercise run-in, the design element intended to expose participants to the physical nature of yoga and facilitate withdrawal prior to randomization and prevent dropout later in the trial, demonstrated limited utility as only one participant dropped out following this session. Thus, removing the exercise run-in could result in earlier randomization and beginning of the yoga intervention, potentially improving retention. Dropout was observed later in the course of the SAA-TBI intervention most frequently due to participation barriers (e.g., arranging childcare, work schedules, transportation). Even for the participants completing the entire study, several Veterans commented on these participation barriers impacting complete attendance in the trial.

In response to participation barriers, we implemented modifications such as reducing in-person yoga sessions from an initial 16 (twice weekly) to 8 (once weekly) sessions with increased encouragement of participants' at-home yoga practice. We also added another clinic site to conduct study visits and yoga sessions in a latter wave. In fact, we

found the median number of attended sessions was higher for those in waves with reduced number of in-person yoga sessions (8 sessions) as compared to those who completed the original 16 in-person yoga session. Although we are not aware of any yoga clinical trials for headache pain for adults reporting attendance rates, prior RCTs on chronic low back pain have shown that 60–70% of participants attended at least half of 12 yoga sessions held once weekly [24,25], and another RCT reported significantly lower adherence rates for a twice weekly yoga intervention [26]. This supports the idea that yoga sessions held once per week may reduce attrition. Most importantly, satisfaction with the intervention remained high even with the reduction of in-person sessions. We are not aware of current guidelines for frequency and duration of yoga on the impact of PCH, though a recent systematic review and meta-analysis on yoga for treating headaches found evidence of short-term efficacy of yoga for headaches even when frequency and duration of yoga practice ranged across studies [27]. That is, this analysis reported on yoga programs ranging from 6 to 16 weeks, session duration ranging from 30 to 75 min, with frequency of one session per week up to five weekly sessions. Similarly, prior literature on yoga for pain and pain-associated disability has shown favorable effects in as short as six weeks [28], and up to as many as 24 weeks [29]. Results from our trial support the acceptability and feasibility of once weekly yoga sessions at 75 min each, supplemented with at-home yoga practice. However, this trial was not designed to determine the long-term benefits and efficacy of yoga for PCH.

Another successful modification was associated with emphasis on using the online yoga videos. When we reduced the yoga sessions to once per week, we implemented additional yoga tracking procedures via EMA surveys and called participants to encourage video use if EMA surveys did not reflect weekly practice. Thereafter, yoga video use increased, demonstrating feasibility of at-home yoga practice to supplement in-person sessions. Future investigation of the use and feasibility of online yoga videos as a comparator condition to face-to-face yoga sessions or telehealth integration to conduct yoga sessions is warranted. To our knowledge, only two studies have explored the use, and acceptability, of telehealth to deliver yoga [30,31]. Schulz-Heik et al. [30] reported Veterans' high levels of satisfaction with telehealth yoga and this was comparable to Veterans who attended in-person yoga sessions. Selman et al. [31] qualitatively assessed and found acceptability of a tele-yoga intervention for individuals with heart failure and chronic obstructive pulmonary disease.

Feasibility of web-based EMA procedures was demonstrated. Participants in this sample preferred web-based surveys to track their yoga practice and daily symptoms. Prior research has demonstrated that home practice is essential for yoga to be effective [32–35] but most studies do not report on participant home practice [36]. Results from our study support the use of EMA procedures to track yoga home practice, providing the field with data regarding adherence to yoga practice over time. Specifically, our modification of using EMA to facilitate study team contact to encourage participants to engage in yoga home practice improved adherence. Although we do not know if the participants completed surveys using their smartphones, text messages or emails with embedded web-based survey links were the primary modes of survey delivery. In a Pew Research Center Mobile Fact Sheet [37], 81% of Americans own and use a smartphone, and prior research has demonstrated that individuals currently receiving mental health services are amenable to using smartphone technology to track their health [38,39]. Further, our findings are supported by prior research of Veterans' positive attitudes and interest in using technology for healthcare and symptom tracking purposes [40]. Future trials may benefit from implementing web-based procedures to complete study assessments, thereby decreasing participation barriers and increasing participant study completion.

Although evaluation of symptom reduction was not the aim of this study, many Veterans qualitatively expressed benefits of their participa-

tion in the SAA-TBI intervention, primarily noting decreased headache frequency and intensity and improvements in pain and overall mood. Results also suggest that the impact of daily headaches, as assessed by the HIT-6, reduced from Study Visit 3 to Study Visit 4. Although we assessed frequency of headache and medication taken for headaches, we did not clearly ascertain the type of medication (e.g., NSAIDs). As such, it is recommended that future trials clearly document and track use of participant medications and reason for primary use of such medications (i.e., pain, headaches, etc.) at baseline and multiple timepoints throughout an intervention. Literature has emphasized the importance of understanding meaningful improvements in patient-reported outcomes beyond variables such as reduction in frequency of headache days [41,42]. Data from the exploratory candidate outcomes also support the potential for improvements in pain and mood; however, future trials should be adequately powered to detect meaningful effect sizes and clinically significant changes.

## 6. Conclusions

In summary, Veterans with PCH found this yoga intervention to be highly satisfactory, demonstrating acceptability. Modifications throughout the study improved feasibility of recruitment, retention, and participation. Our identification of several key elements to promote feasibility of yoga interventions is intended to promote future success of larger trials, thereby contributing to an evidence-base of such interventions in clinical management of PCH. Furthermore, identifying what is feasible will also improve the cost-effectiveness and accessibility of yoga trials. As such, future trials will benefit from investigating the frequency and modality of yoga delivery (e.g., in-person, video, telehealth) to promote accessible, cost-effective and evidence-based yoga treatments.

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## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.conctc.2021.100762>.

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