Management of Posttraumatic Headache

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Objectives

- Review the diagnostic criteria for posttraumatic headache (PTH) and how existing ICHD-3 criteria conform to common PTH clinical presentation.
- Examine the research on the effectiveness of “usual care” treatments for PTH.
- Discuss preliminary outcomes of a clinical trial targeting a novel, non-pharmacological intervention for PTH.

Background on PTH

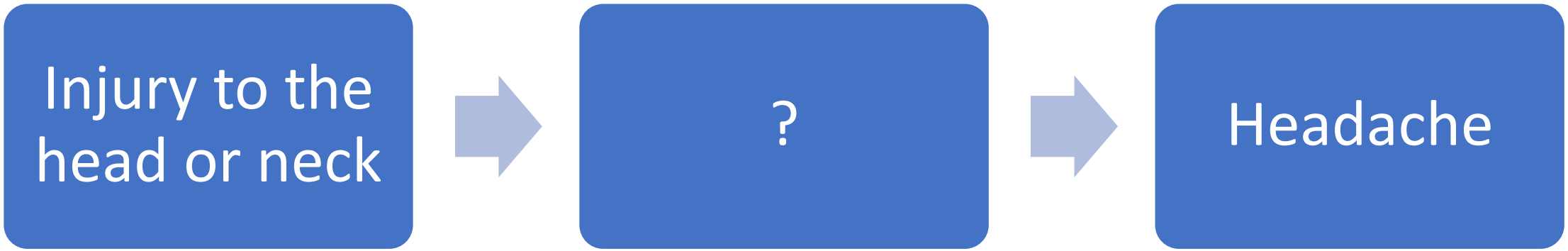
- Headache attributable to an injury to the head or neck
- A very common TBI comorbidity
  - Variable estimates of prevalence
    - 81-97% of military service members report headache after head injury
- PTH is at high risk for persistence in military veterans
  - 60-65% of veterans who develop PTH report persistent headache
- Many regard PTH as the most disabling persistent post-concussive symptom

Wenger et al., 2018; Lindquist et al., 2017; Holtkamp et al., 2016; Leung et al., 2016

What is PTH?

Objective 1: Review the diagnostic criteria for posttraumatic headache and how existing ICHD-3 criteria conform to common PTH clinical presentation.

OBJ 1: Diagnostic criteria for PTH



OBJ 1: Diagnostic Criteria for PTH

- Secondary Headache

- A new headache occurs for the first time (*de novo headache*) in close temporal relation to trauma or injury to the head and/or neck.
- A pre-existing headache is made chronic or significantly worse in close temporal relation to trauma or injury to the head and/or neck.

https://ichd-3.org/5-headache-attributed-to-trauma-or-injury-to-the-head-andor-neck/

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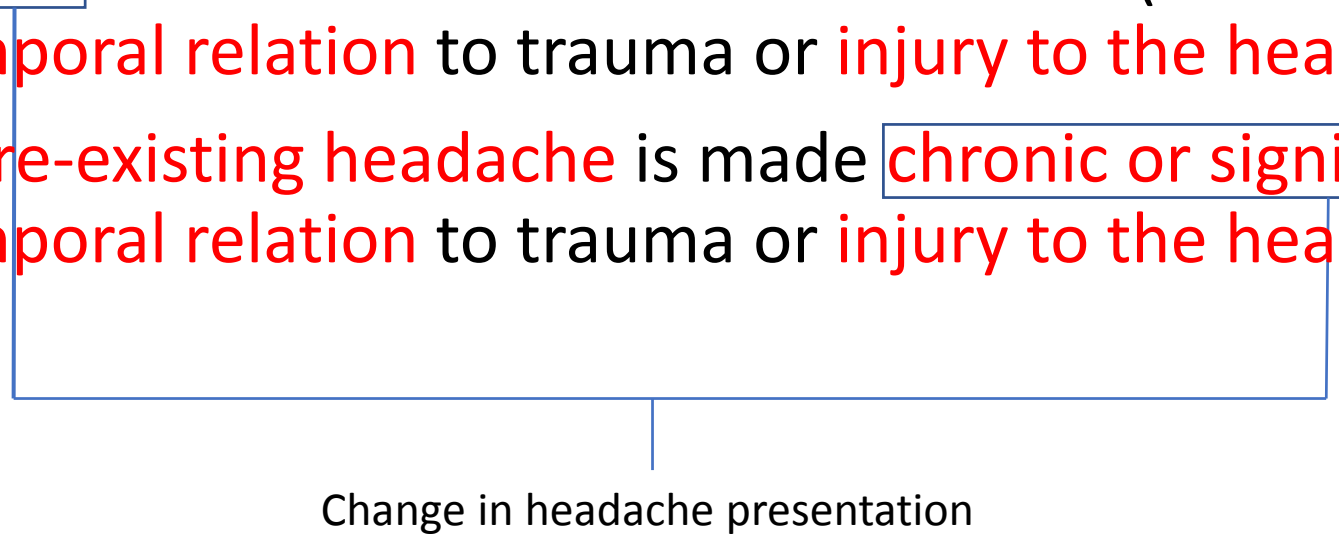

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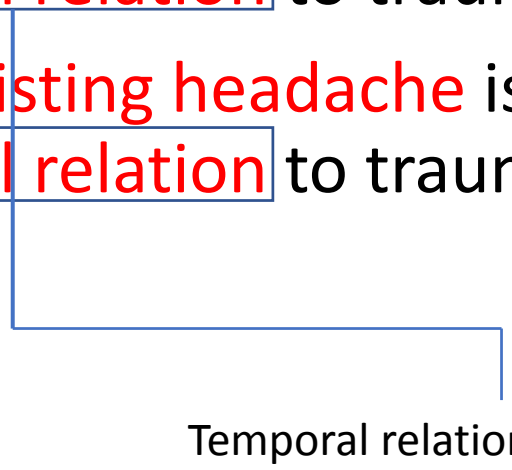
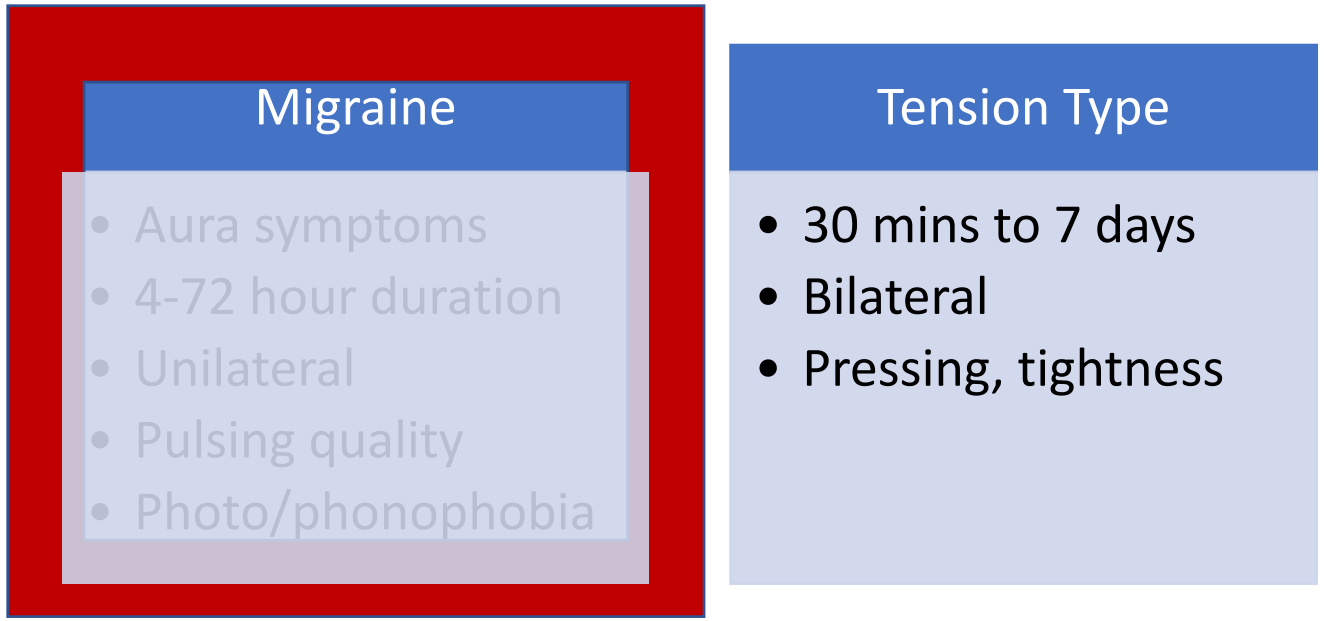


OBJ 1: Diagnostic Criteria for PTH

- Change in headache presentation

- PTH has no defining clinical characteristics
- Often misclassified based on resemblance to primary headache



OBJ 1: Diagnostic Criteria for PTH

- Do clinical characteristics matter?

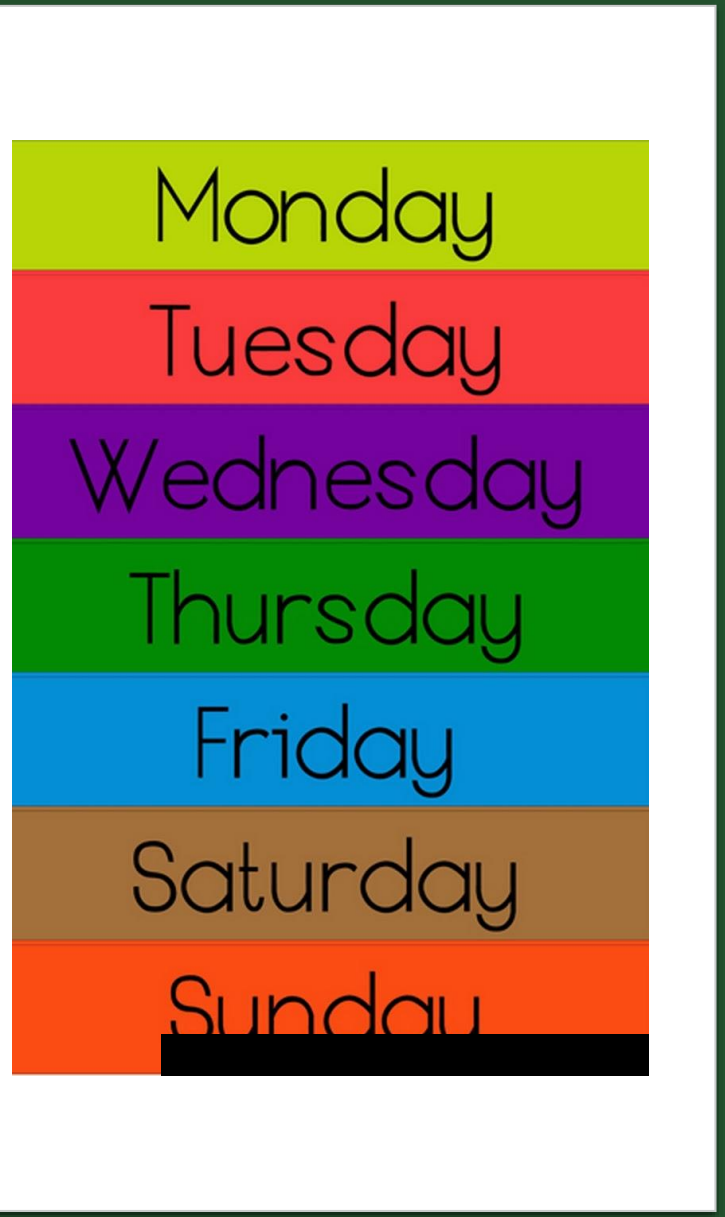
Presenting symptoms may signal treatments used for similar primary headache

Imaging studies show that the underlying brain structure of migraine and PTH with migraine symptoms is different

Schwedt et al., 2017

OBJ 1: Diagnostic Criteria for PTH

- Temporal relationship between change in headache presentation and head and/or neck injury
- Per ICHD-3: “headache must be reported to have developed within 7 days following trauma or injury, or within 7 days after regaining consciousness and/or within 7 days after recovering the ability to sense and report pain.”
- Why a week?



OBJ 1: Diagnostic Criteria for PTH

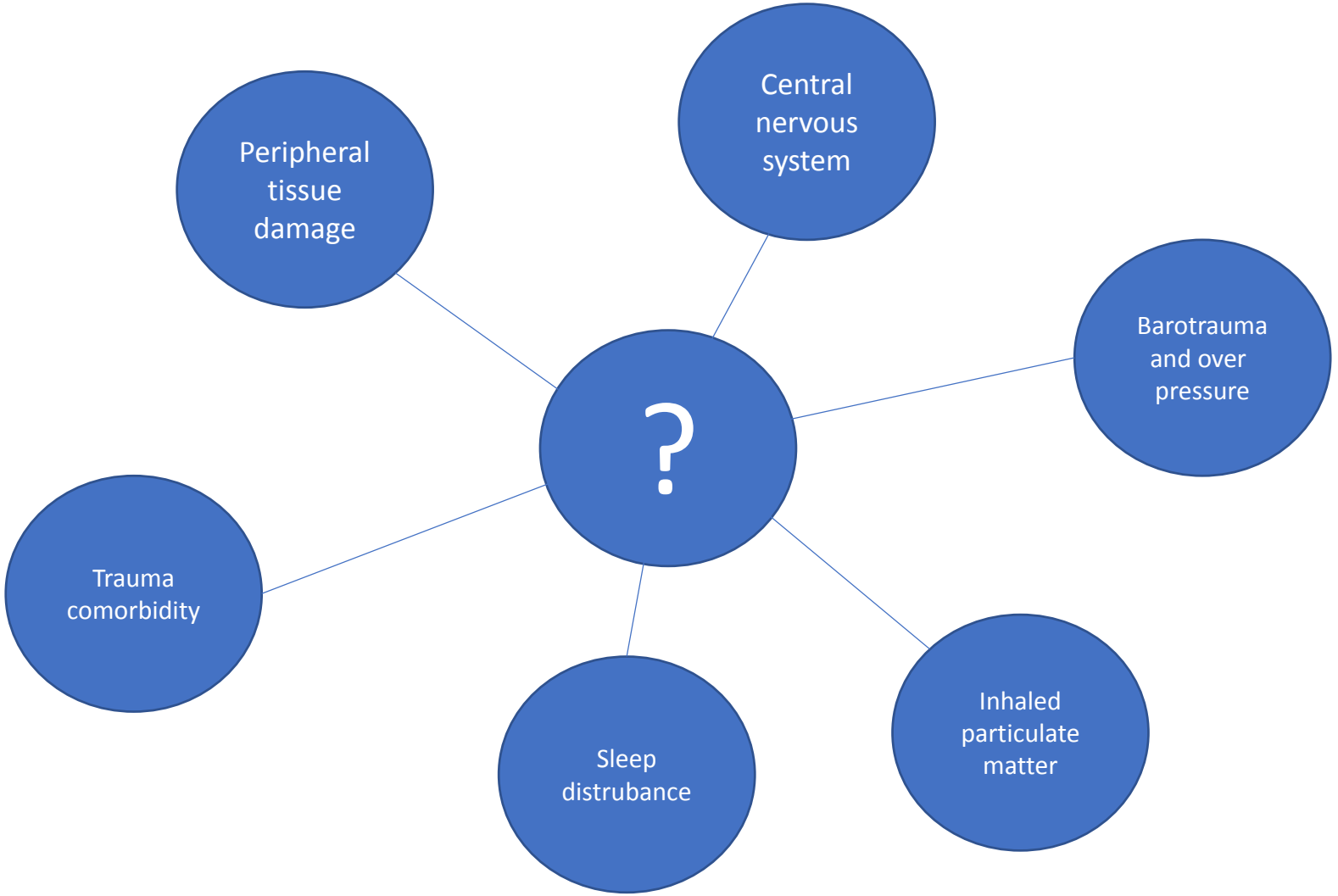
- Per ICHD-3: “Although this 7-day interval is somewhat arbitrary, and some experts argue that headache may develop after a longer interval in a minority of patients, there is not enough evidence at this time to change this requirement.”

OBJ 1: Diagnostic Criteria for PTH

- PTH in veterans is…

- A new or worsened/more frequent headache
- Often resembles migraine but is mechanistically different
- Starting within 7 days of an injury or trauma to the head and/or neck

OBJ 1: Potential mechanisms of military PTH



Defrin, 2014

OBJ 1: Potential mechanisms of military PTH

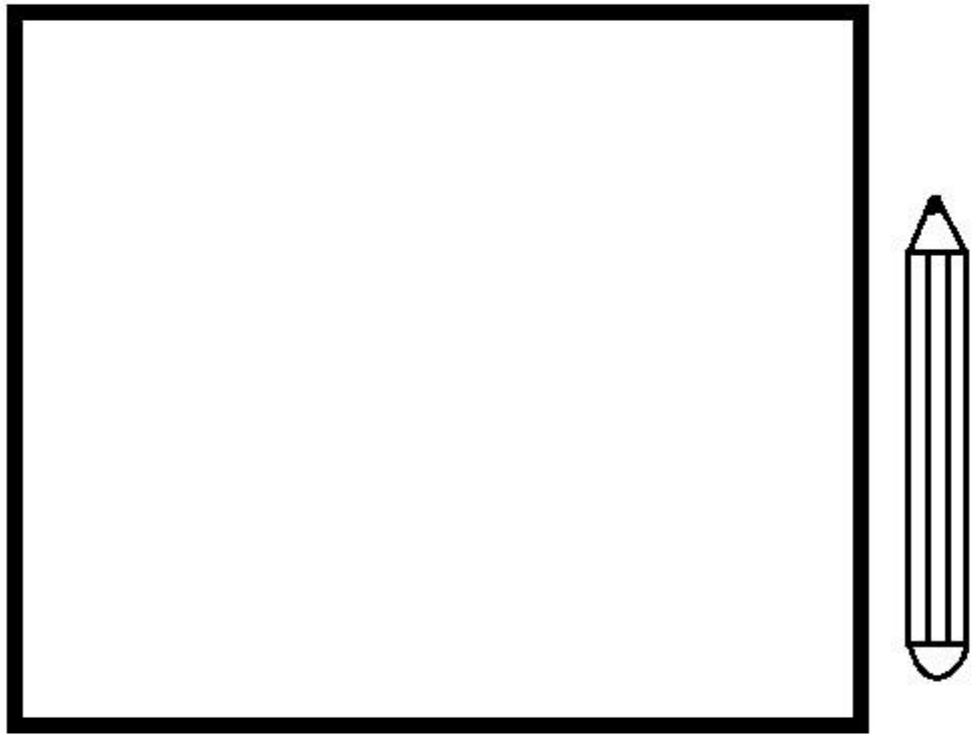
- A word about PTSD

- PTSD commonly co-occurs with PTH
- Some suggest that PTH may be caused by PTSD rather than TBI due to the high comorbidity
  - We'll get back to this later
- Regardless, PTSD symptoms likely affect PTH symptoms and treatment outcomes

Existing PTH Treatments

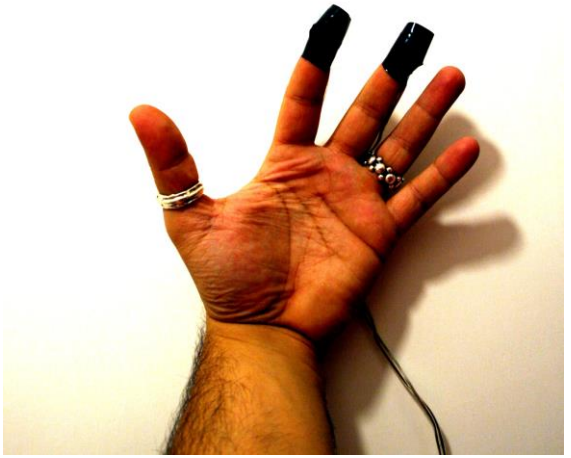
Objective 2: Examine the research on the effectiveness of “usual care” treatments for PTH.

Well-Supported treatments specifically targeting PTH



PTH treatments with some research support

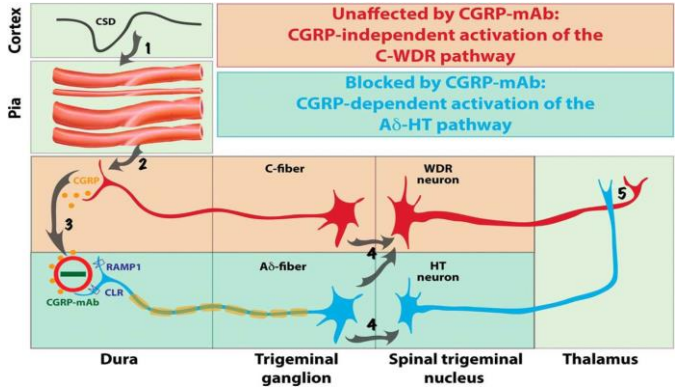
- Non-pharmacological interventions
  - Biofeedback
  - Cognitive and behavioral therapies
  - Relaxation and stress management
  - Acupuncture
  - Physical Therapy



Fraser et al., 2017

PTH treatments with some research support

- Pharmacological interventions
  - Botox – small sample studies
    - Return to duty, disability, use of other medications for HA control
  - Delta opioid receptor agonists (SNC80) – mouse models
    - Studied in the context of multiple headache etiologies
  - Metoclopramide + diphenhydramine – one study of acute PTH in ED
    - Headache intensity and frequency
  - Calcitonin gene-related peptide (CGRP) monoclonal antibody – mouse models
    - Primary indication for migraine



Melo-Carillo et al., 2017; Bree & Levy, 2018; Friedman et al., 2018; Moye et al., 2019; Hack & Eliasen, 2018

PTH treatments with some research support

- Time
  - A lot of acute PTH will abate on its own within three months… but up to 40-60% will persist and most of those that persist will do so beyond one year.

Which existing treatments should we use?

- International Headache Society recommends non-pharmacological interventions as a good starting place because of:
  - Broad treatment targets that could extend to psychiatric comorbidity
  - Low associated risk
- Pharmacological interventions for similarly phenotyped primary headache
  - Abortive and prophylactic medication for migraine have shown some promise in small research studies, but more research is needed
  - Side effects of medication may decrease enthusiasm for use (inclu. MOH)
- Reassurance, communication and education

A Clinical Trial of Non-pharmacological Intervention for Chronic PTH

Obj 3: Discuss preliminary outcomes of a clinical trial targeting a novel, non-pharmacological intervention for PTH.

Randomized Clinical Trial of Cognitive-Behavior Therapy for Comorbid PTSD and Headache

Program: FY12 PH/TBI Research Program, **Award Number:** W81XWH-12-PHTBI-CAP

PI: Donald McGeary, PhD **Org:** UTHSCA

Study Aims

- Evaluate the effectiveness of a non-medication, clinic-based cognitive behavioral intervention (CCBT) for posttraumatic headache (PTH)
- Evaluate the relationship of post-concussive cognitive symptoms and posttraumatic stress symptoms to primary treatment outcomes
- Evaluate whether biomarkers/imaging predict PTHA treatment outcomes

Approach

Conduct a 3-group randomized clinical trial of the efficacy of: (1) a 6-week Clinic-based Cognitive Behavioral Therapy for headache (CCBT), (2) a 6-week Cognitive Processing Therapy (CPT), and (3) a 6-week treatment-as-usual (TAU) regimen for the treatment of chronic PTH in military personnel and veterans.

Timeline and Cost

Activities	FY	14	15	16	17	18	19	20
Manage research funds								
Human Subjects Research Regulatory Review & Approval								
Personnel Management								
Participant Recruitment, Treatment, Assessment, and Monitoring								
Data analysis and dissemination of findings								
Estimated Budget ($K)	**VA**		**346**	**377**	**326**	**326**	**326**	**0**
	DoD	**193**	**282**	**291**	**299**	**308**	**0**	**0**

Proposed Timeline Actual Timeline

Goals/Milestones

FY14 Goals

☑ Complete budget negotiations for DoD funding
☑ Clear the JIT requirements for VA funding
☑ Train staff & Database Development
☑ Recruit first participant
☑ Continue participant recruitment, treatment, data collection

FY15 – 17 Goals

☑ Continue participant recruitment, treatment, data collection

FY18 Goals

☑ Complete participant recruitment, treatment, data collection

FY19-20 Goals

☑ Conduct data analyses
☐ Disseminate findings through presentations & publications

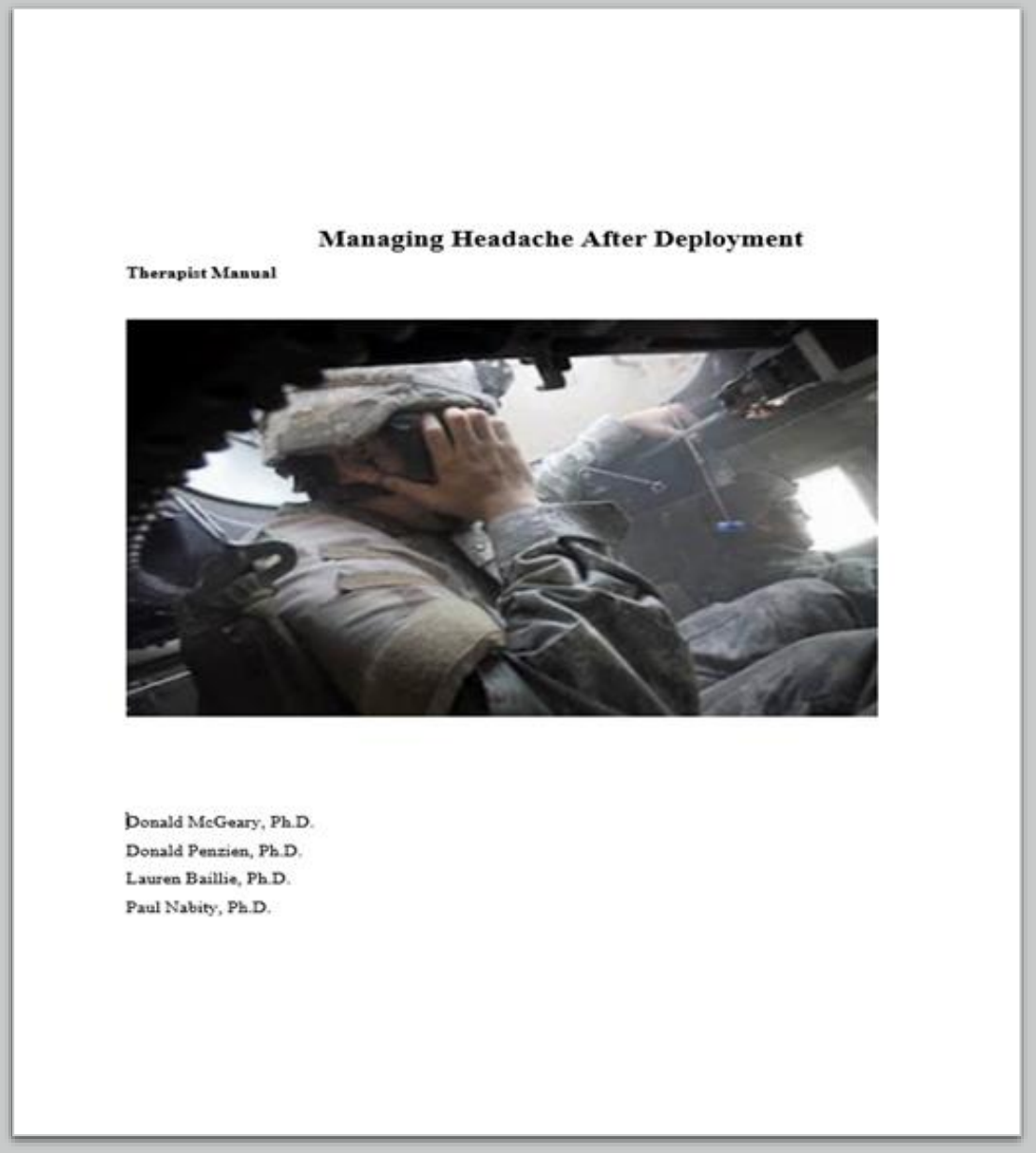
Collaborators at STVHCS

- Carlos Jaramillo, MD, PhD
- Blessen Eapen, MD
- Cindy McGeary, PhD
- Paul Nabity, PhD

- Consortium to Alleviate PTSD

Combined Cognitive Behavioral Therapy for PTH (CCBT)

- 8 sessions based on a manualized intervention for migraine
- 30-45 minutes per session
- Treatment delivered by:
  - Licensed Psychologists
  - Unlicensed postdoctoral fellows
  - Unlicensed predoctoral interns
- Modules covered:
  - Biofeedback-assisted stress reduction
  - Behavioral management of headache symptoms
  - Problem-solving and cognitive therapy for distress
  - Activity engagement



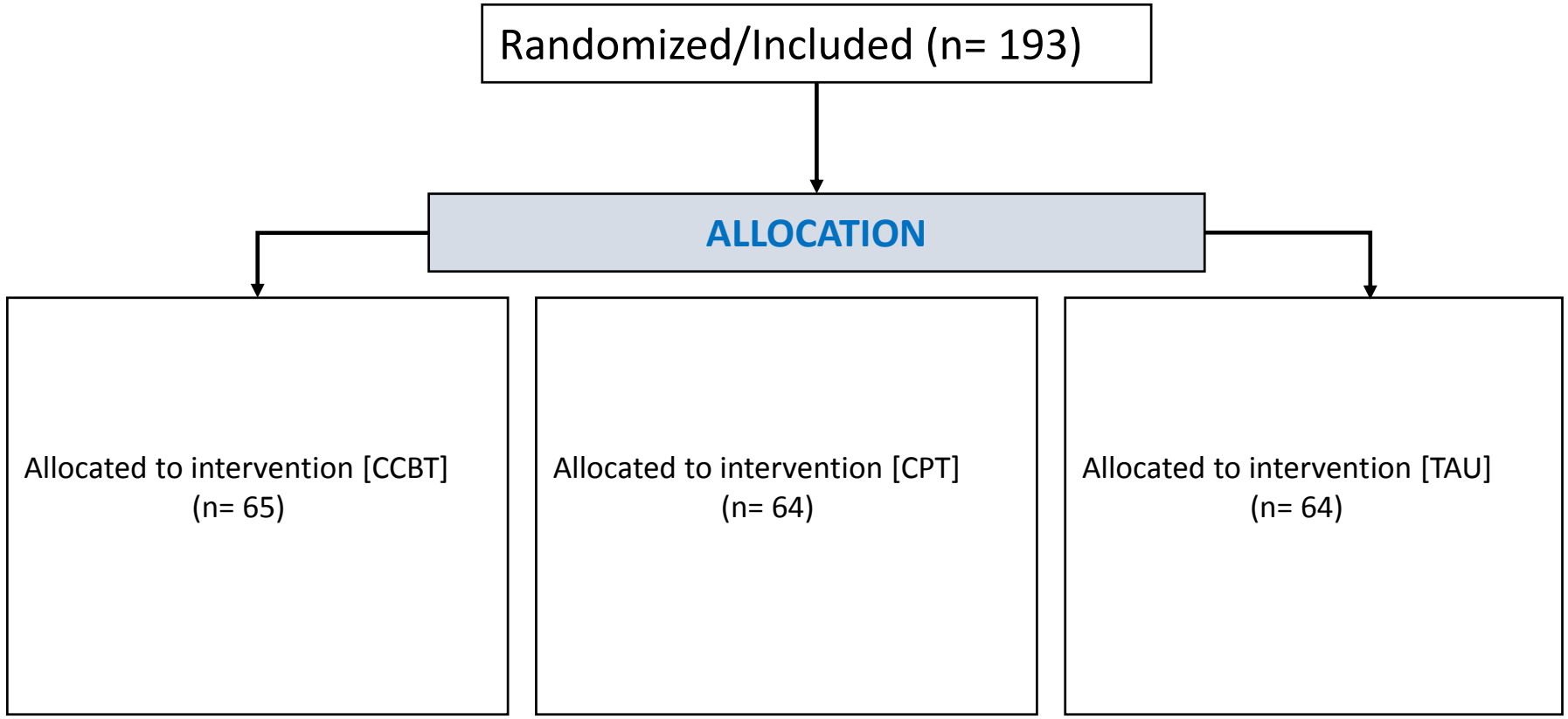
Managing Headache After Deployment

Therapist Manual

Donald McGeary, Ph.D.
Donald Penzien, Ph.D.
Lauren Baillie, Ph.D.
Paul Nabity, Ph.D.

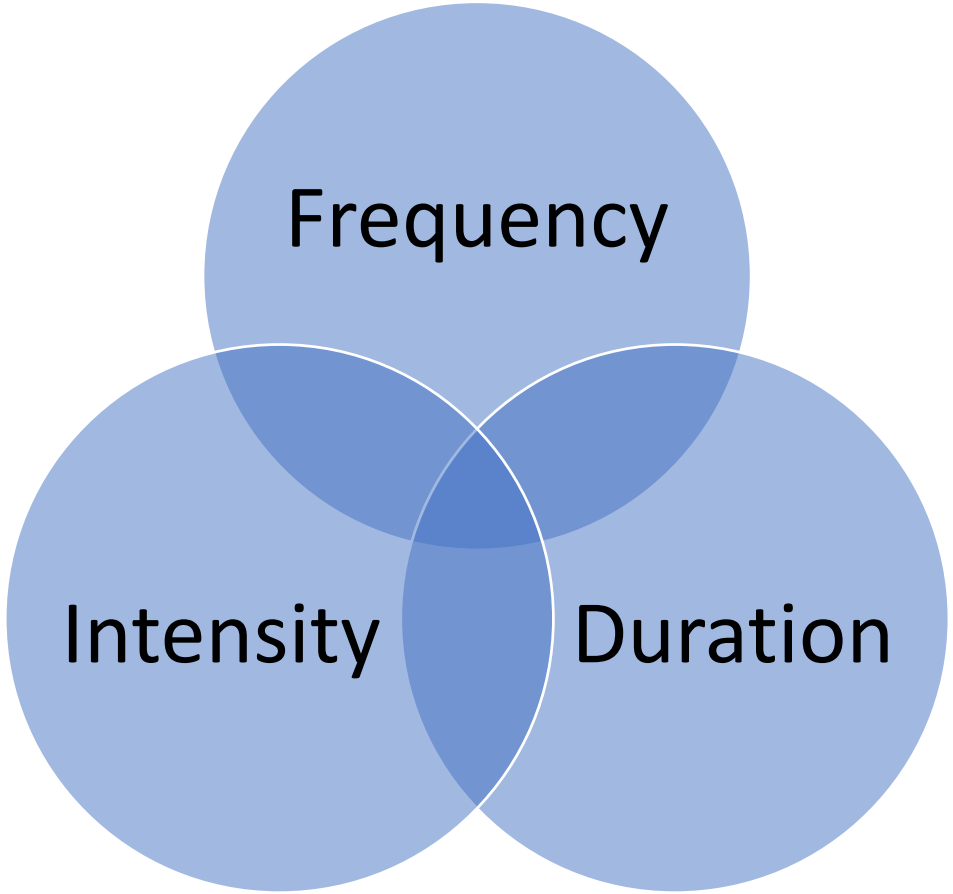
McGeary - Randomized Clinical Trial of Cognitive-Behavior Therapy for Posttraumatic Headache Project

CONSORT Flowchart as of 30 June 2019 (FINAL)



Assessment in Headache Research

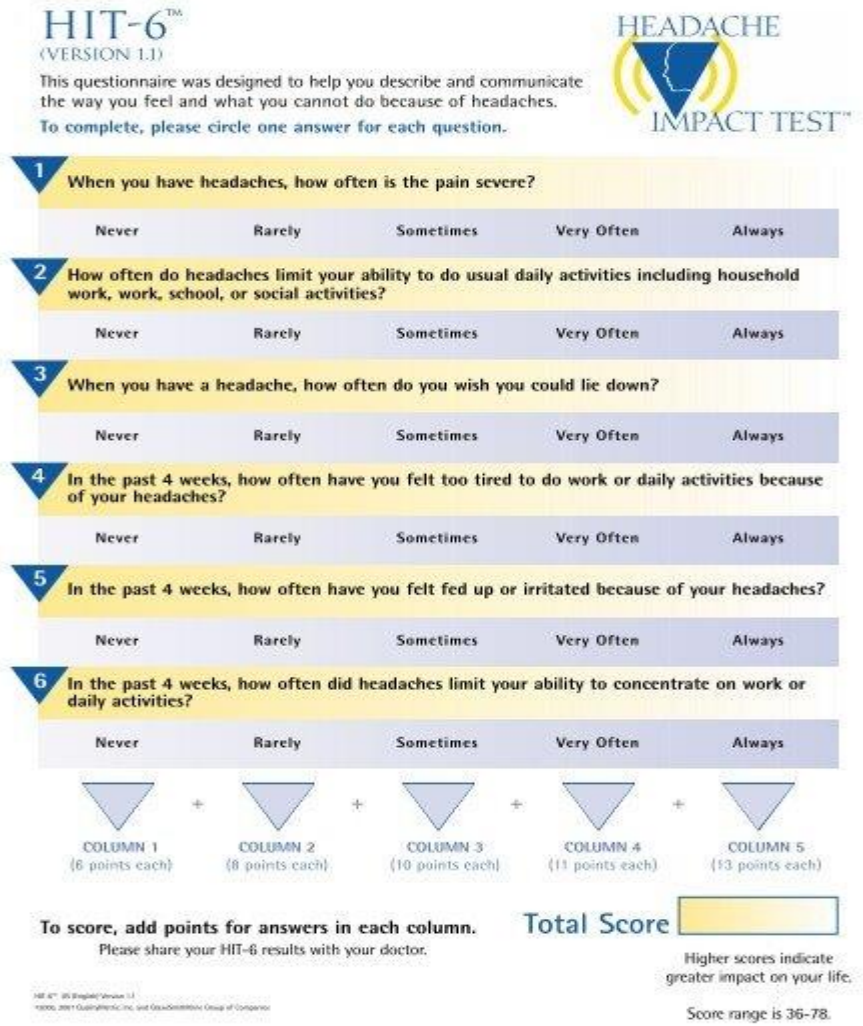
Headache Index



Headache Ratio

Assessment in Headache Research

Headache Disability



HIT-6™
(VERSION 1.1)

HEADACHE IMPACT TEST™

This questionnaire was designed to help you describe and communicate the way you feel and what you cannot do because of headaches.

To complete, please circle one answer for each question.

1 When you have headaches, how often is the pain severe?

Never | Rarely | Sometimes | Very Often | Always

2 How often do headaches limit your ability to do usual daily activities including household work, work, school, or social activities?

Never | Rarely | Sometimes | Very Often | Always

3 When you have a headache, how often do you wish you could lie down?

Never | Rarely | Sometimes | Very Often | Always

4 In the past 4 weeks, how often have you felt too tired to do work or daily activities because of your headaches?

Never | Rarely | Sometimes | Very Often | Always

5 In the past 4 weeks, how often have you felt fed up or irritated because of your headaches?

Never | Rarely | Sometimes | Very Often | Always

6 In the past 4 weeks, how often did headaches limit your ability to concentrate on work or daily activities?

Never | Rarely | Sometimes | Very Often | Always

COLUMN 1 (6 points each) + COLUMN 2 (8 points each) + COLUMN 3 (10 points each) + COLUMN 4 (11 points each) + COLUMN 5 (13 points each)

To score, add points for answers in each column.
Please share your HIT-6 results with your doctor.

Total Score

Higher scores indicate greater impact on your life.

Score range is 36-78.

Demographics

Demographics at Baseline	% or (mean ± SD)
Age in years (mean ± SD)	39.69 ± 8.42
Gender: percent male	86.98%
Military Status Percent active duty Percent veteran	 0.52% 99.48%
CAPS-5 total score (mean ± SD)	33.24 ± 9.39
Headache Impact Test-6 (HIT-6)	65.78 ± 5.64

The Diagnostic Criteria for PTH May Need Revision

- The 7-day headache onset latency criterion for PTH is arbitrary and meaningless.
- Less than 40% of veterans report headache onset within 7 days on head injury, so we set our onset definition at 3 months.
- HCoE Collaboration.

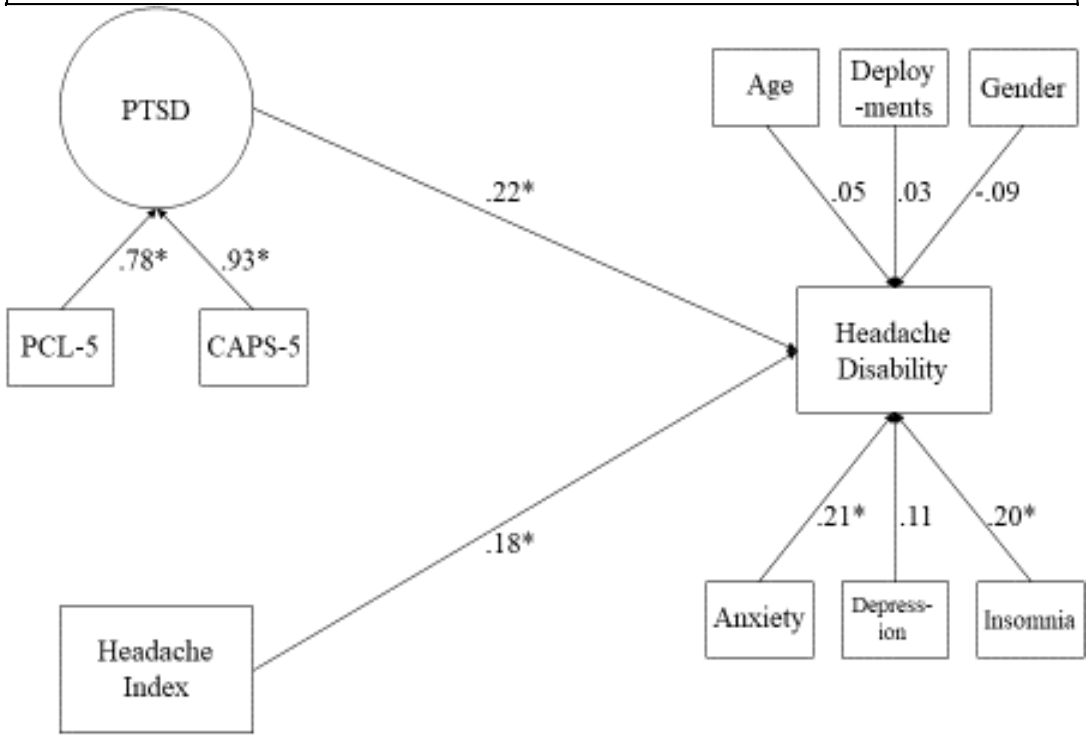
Comparison of headache and clinical comorbidity symptoms for PTH with onset ≤7 days versus onset > 7 days. (baseline data from 258 veterans)

Variable	7-Day Onset	> 7-Day Onset	p
Headache			
Laterality	74% unilateral	76% unilateral	.675
Quality	46% pulsing	56% pulsing	.237
Frequency	13.1 per year	12.4 per year	.815
Intensity	6.8 / 10	6.5 / 10	.368
Comorbidities			
PTSD	PCL5=45.0	PCL5=44.1	.710
Depression	PHQ9=15.5	PHQ9=16.5	.194
Anxiety	GAD7=13.8	GAD7=14.2	.516
Insomnia	ISI=18.8	ISI=18.5	.816

Laterality=headache sidedness; Quality=quality of headache; PCL5=PTSD checklist, 5th Edition; PHQ9=Patient Health Questionnaire, 9 Item; GAD7= Generalized Anxiety Disorder, 7 Item; ISI=Insomnia Severity Index

PTSD is a Big Part of HA Disability

Relationship between headache and psychiatric symptoms controlling for demographics in 258 veterans with chronic PTH in our CAP study.



- PTSD is an undeniable contributor to headache disability, so effective treatment must account for it.

Preliminary PTH Disability outcomes (HIT-6)

No change in disability through 6 months post-treatment

One-fold clinically significant improvement

Three-fold clinically significant improvement

Preliminary PTSD outcomes (PCL-5)

No change in PTSD through 6 months post-treatment

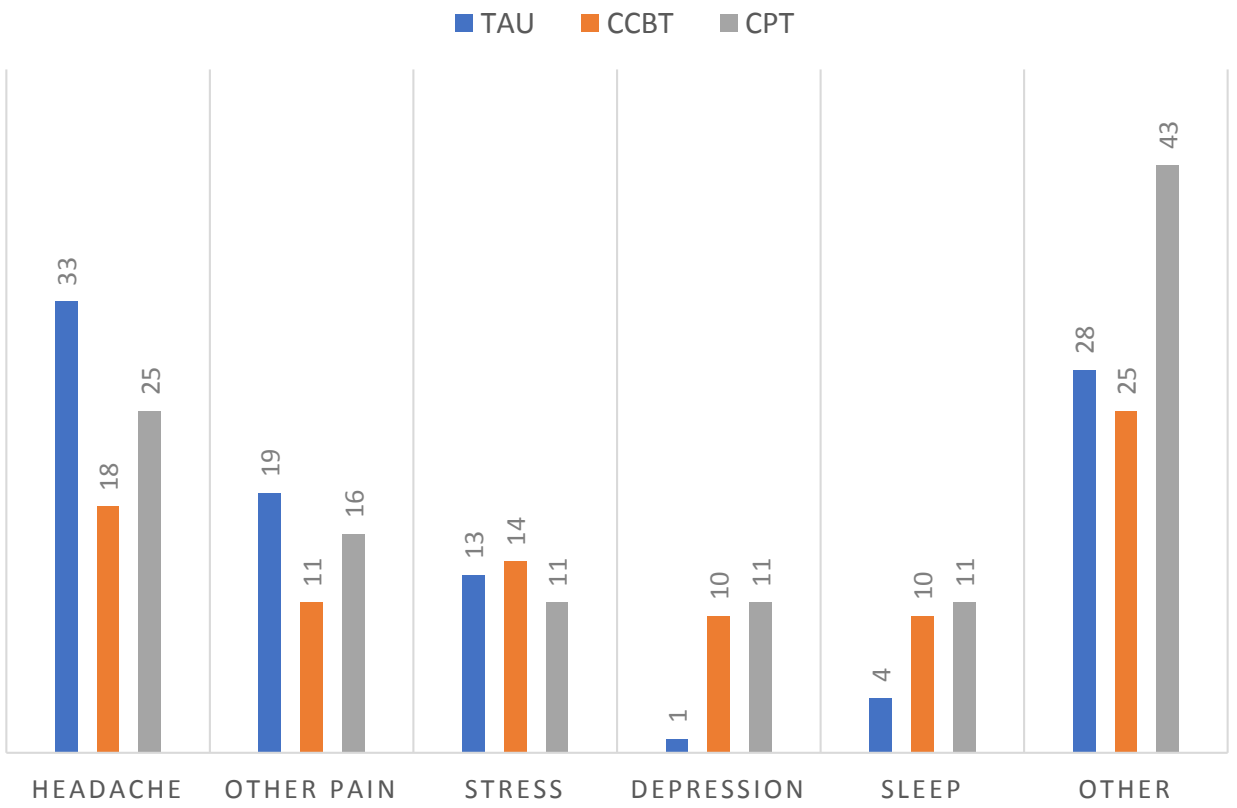
17-point decrease in PCL-5 scores

17-point decrease in PCL-5 scores

Most Common Reasons for Dropout

TAU (10%)	CPT (25%)	CCBT (15%)
• Difficulty traveling due to disability • Treatment in this arm not helping with headache or PTSD	• CPT caused adverse reactions • Not enough focus on headache – too much PTSD • New problems developed	• Could not travel or relocated • Too much time needed for participation (assessment)

Adverse Events



Study Conclusions

- The 7-day latency definition for PTH should be expanded to at least three months.
- PTSD is an important part of disability associated with headache and should be addressed as part of treatment.
- A manualized, non-pharmacological intervention for PTH can significantly improve both PTH and PTSD concurrently.
  - Note: This is a large RCT, but more work should be done to generalize this finding
    - PLANNED MULTISITE TRIAL
- A manualized PTSD intervention improved headache and PTSD, but headache improvements were less than those for CCBT.

Questions?

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