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Combination of two complementary and integrative health (CIH) therapies for improving symptom domains of Gulf War Illness

Results from a randomized controlled trial

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Disclosures

Conflict of Interest

- The presenters report no conflicts of interest.

Disclaimer

- The opinions presented in this presentation are those of the presenters and do not reflect the views of any institution/agency of the U.S. government or the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc.

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Overview of Today's Webinar

- Brief overview of WRIISC
- History of integrative health at WRIISC
- GW-CIH Study
 - Methods
 - Results
- Conclusion

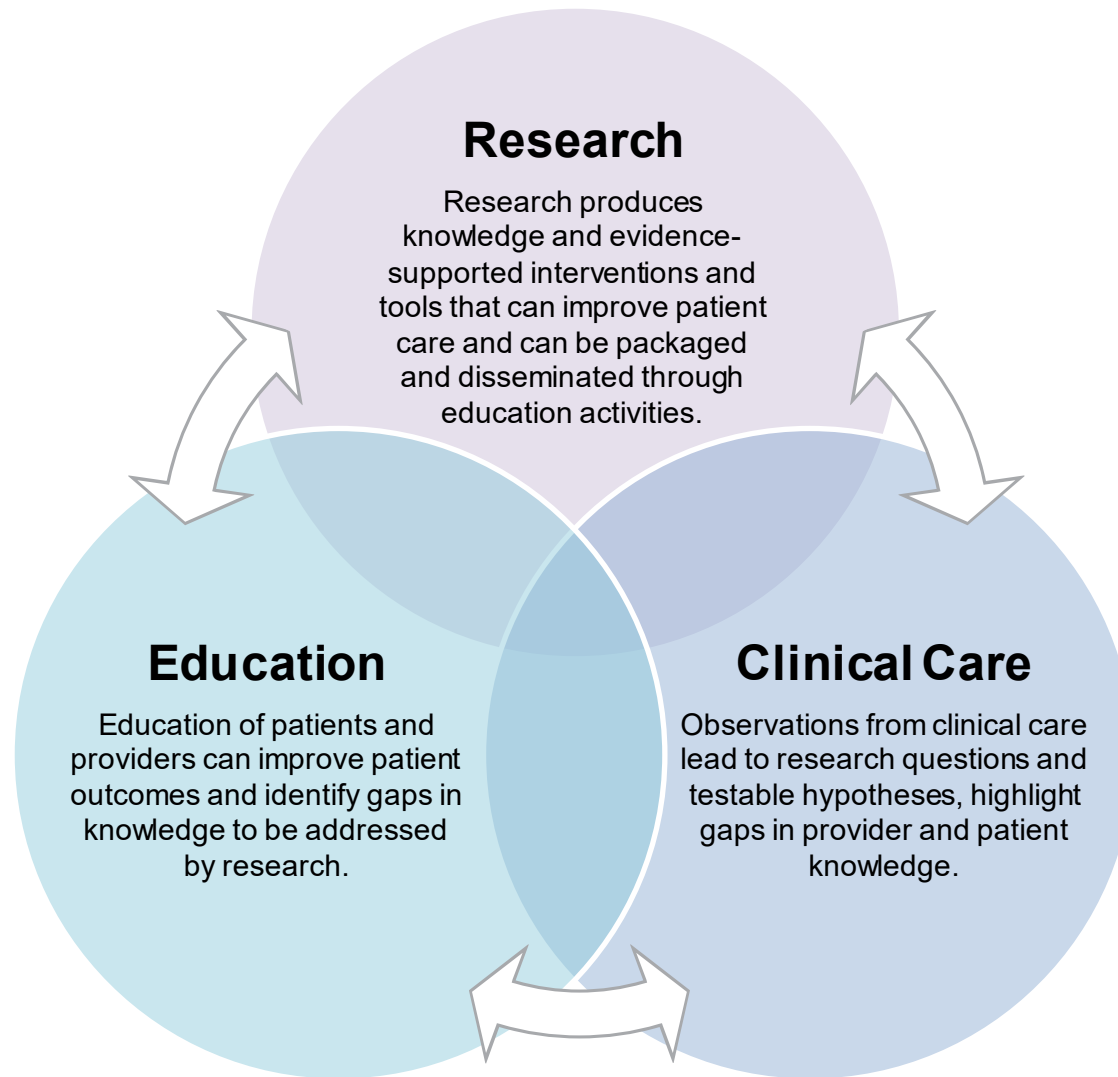


History of the WRIISC

- WRIISC is a National VA Post-Deployment Health Resource (Public Law 105-368).
- The WRIISC develops and provides post-deployment health expertise to Veterans and their health care providers through clinical programs, education and risk communication, and research.
- The first two WRIISC sites were established in 2001; one in Washington, DC, the other at the East Orange, NJ. A third WRIISC site, to provide wider coverage and easier access for Veterans, was authorized and became operational in Palo Alto, CA in 2008.



WRIISC - Translational Model





Background on Gulf War

- Many veterans of the Gulf War (GW) reported a myriad of symptoms that began during or shortly after the war ended
 - Symptoms include but are not limited to fatigue, musculoskeletal pain, sleep disturbance, and cognitive dysfunction
 - Classified as a chronic multisymptom illness (CMI) often referred to as Gulf War Illness (GWI)
- Standard medical approach may benefit from introduction of CIH approaches to enhance positive outcomes



Integrative Health

CSR&D Merit Grant 2015

CIH for Sleep, Health Functioning, and Quality of Life in Veterans with Gulf War Veterans Illnesses

The Future of the IHW Program

will include an increase in evidence based service provision, provider training programs, and web based toolkits for developing CIH lessons learned

OPCC award

to expand CIH services and research. National credentialing of CIH service providers is now available. Hospital wide research protocol is approved.

2013 - Institute of Medicine

Report identifies CIH services for Gulf War Veterans.
VA & DoD Research Initiatives (CSRDI) for Gulf War includes CIH research initiatives.
VA/DoD clinical practice guidelines for CMI will include non pharma

WRIISC starts offering clinical and wellness services, which develops out of WRIISC difficult to treat/diagnose chronically ill patients. (2007)

Satisfaction data is collected, results show improvement in multiple body systems (2010)

Acupuncture and Sleep RCT

provides evidence on the utility of acupuncture. Results are published and CIH services expand

2012 – IHW clinic begins

Providers can now submit consults to refer Veterans for CIH. Pilot Study begins to collect data on physical outcomes, mental health, and patient satisfaction

FY13 – 740 consults submitted, 328 enrolled. Pilot study (N 226) results published and data presented nationally.

OPCC award

to expand CIM services

Online resources launched.

Research findings & implications disseminated through national teleconference.

IHW becomes hub for expansion of integrated health at the DCVAMC.





Evaluation of Patient Experiences

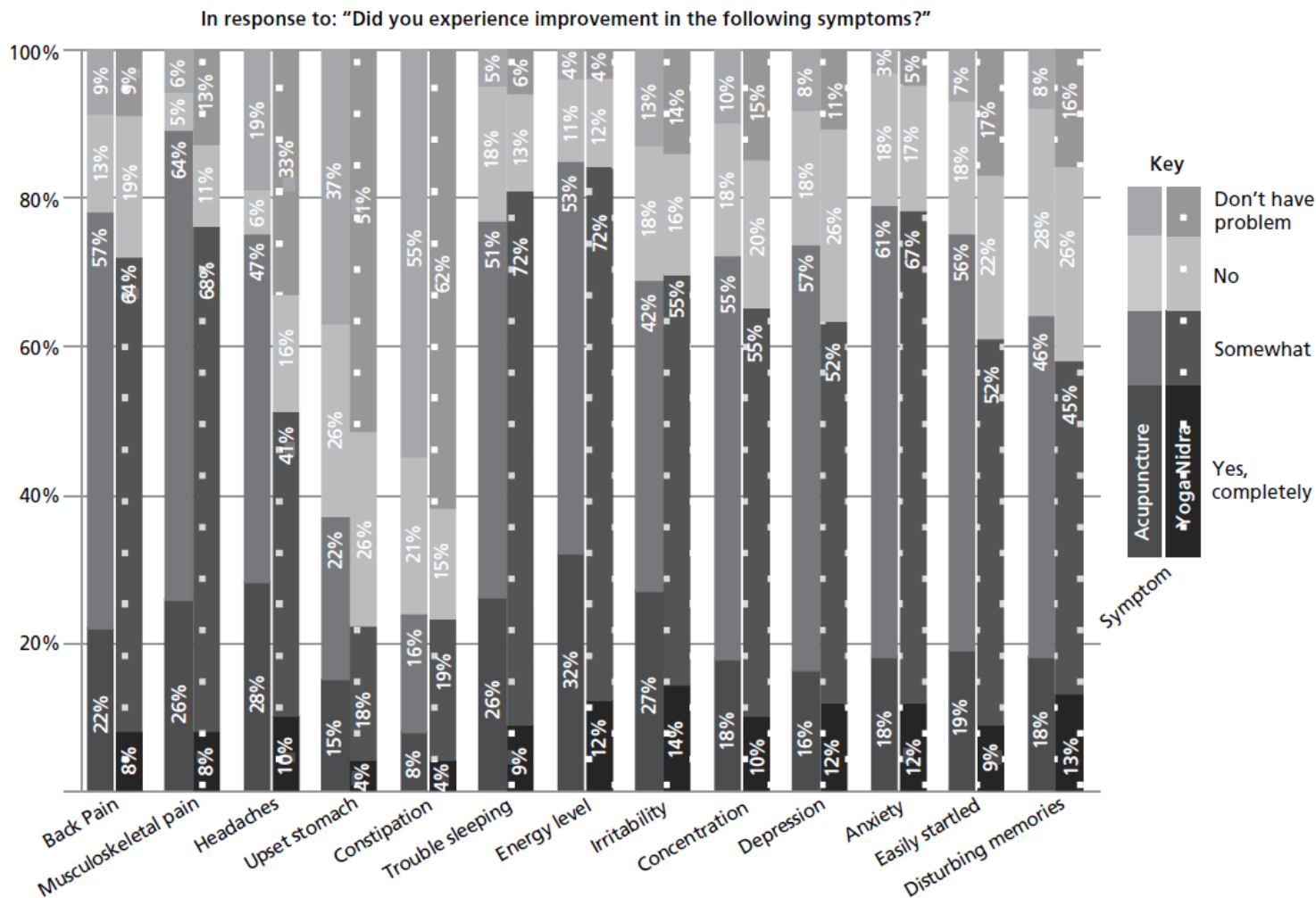


Figure 1 Total: acupuncture (n=118) and iRest Yoga Nidra (n=186) satisfaction data.

Hull A, Reinhard M, Mccarron K, et al. Acupuncture and meditation for military veterans: first steps of quality management and future program development. *Glob Adv Heal Med.* 2014;3(4):27-31. doi:10.7453/GAHMJ.2013.050



Aims

- To examine the effectiveness of a combining mindfulness meditation (iRest® Yoga Nidra) and auricular acupuncture compared to an active control group receiving GW Health Education (GWHE) program.
 - Hypothesis: the combined approach would prove to be more effective in improving health-related functioning and multiple symptom domains of GWI (e.g., pain, fatigue) as compared to an active control group.

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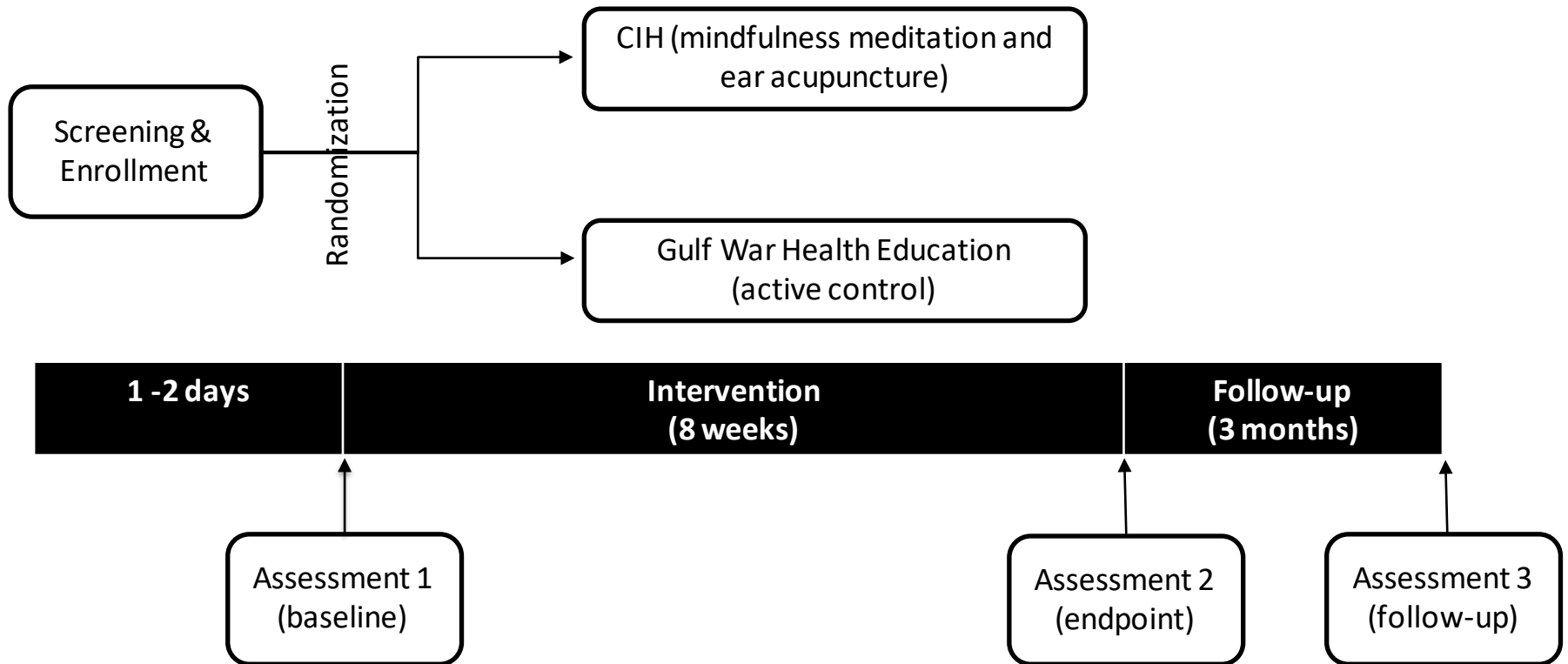


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Methods



Methods – Study Design





Participants

Inclusion Criteria

- U.S. Veteran who was deployed to the 1990-1991 Gulf War
- Met the CDC case definition for chronic multisymptom illness
 - Symptom domains: fatigue, musculoskeletal, and/or mood/cognition

Exclusion Criteria

- Current substance dependence
- Current psychotic symptoms or bipolar disorder
- Current suicide ideation or recent suicidal attempt
- Hearing loss that would prevent participation in a group intervention
- Current involvement in meditation or acupuncture



Group Interventions

CIH group

- Length: 8 weeks
- Group setting
- Received a combination of iRest[®] and ear acupuncture
 - Administered one after the other in the same room (80-90 min session)

GWHE (active control) group

- Length: 8 weeks
- Group setting
- Received 60-min education session
- Health topics selected based on the clinical and research experience of WRIISC-DC staff



CIH Group: Integrative Restoration (iRest®) Yoga Nidra Meditation

10-stage practice

- 1) Intention
 - 2) Heartfelt desire
 - 3) Inner resource
 - 4) Body sensing
 - 5) Breath sensing
 - 6) Feelings and emotions
 - 7) Beliefs
 - 8) Well-being
 - 9) Witnessing and pure awareness
 - 10) Integration
-

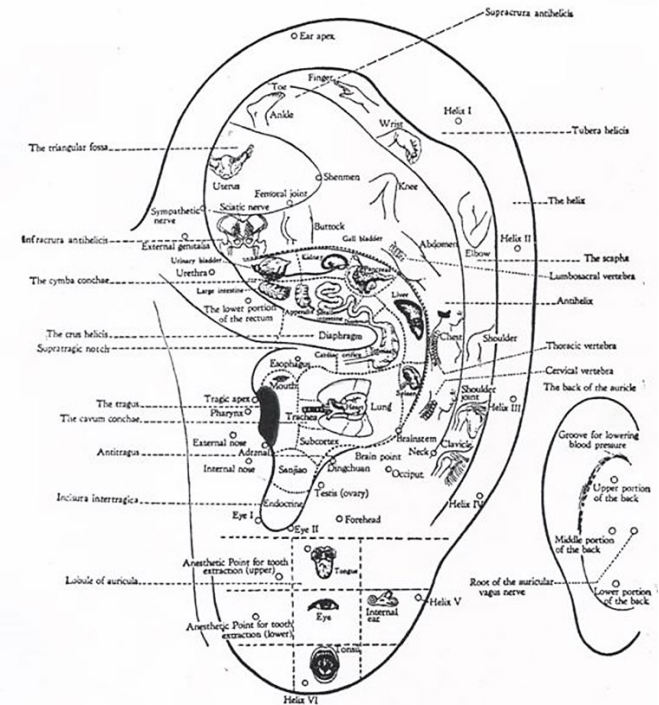
- Guided mindfulness meditation practice
- Standardized iRest® scripts
- Duration: ~20 – 30 minutes



Auricular Acupuncture

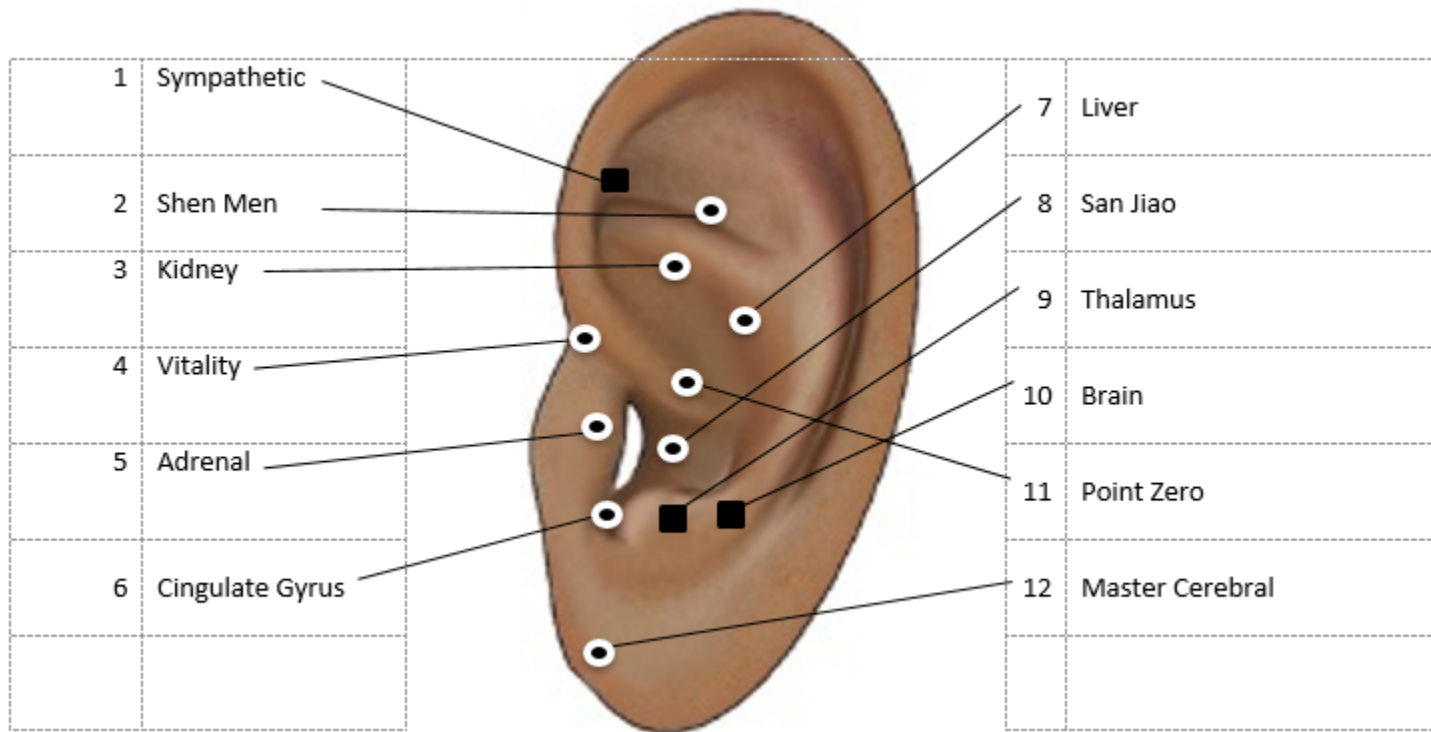
Convenient treatment for GWI:

1. External ear is easily accessible and suitable for a group setting
2. Acupuncture points on the external ear represent the whole body, mind, emotions, and spirit
3. Cost effective
4. Patients can be treated while fully clothed
5. Auricular acupuncture is easily replicated in both clinical and research settings and can even be taught to allied health personnel relatively easily.





CIH Group: Auricular Acupuncture

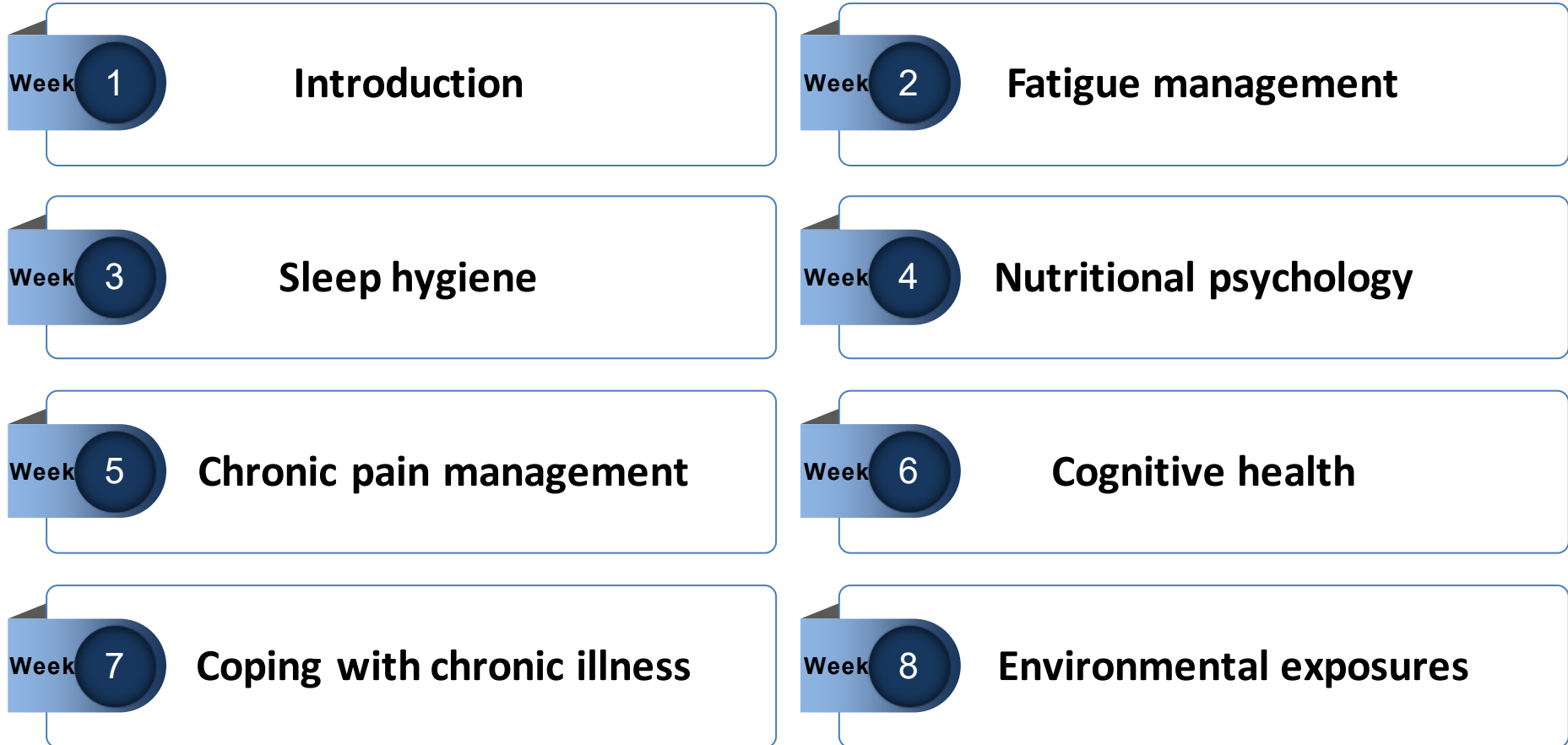


- Semi-standardized treatment (12 pre-determined auricular points)
 - Six points on each ear were selected for treatment
- Duration: ~60 minutes



Gulf War Health Education (Active Control)

Health topics covered each week of intervention:





Health Education Topics

Group Introduction

What Can You Expect From This Group?

- Twenty years after deployment to the Gulf War in 1991, Gulf War Veterans continue to report a higher rate of negative health outcomes than non-deployed Veterans of the same era.
- This includes issues such as:
 - Functional impairment
 - Limitations in daily activities
 - Sleep issues
 - Fatigue
 - Pain
 - Cognitive issues
 - Poorer health-related quality of life
- This group is designed to provide health education related to topics that are relevant for Gulf War Veterans who deployed during 1990-1991.

Coping with Chronic Illness

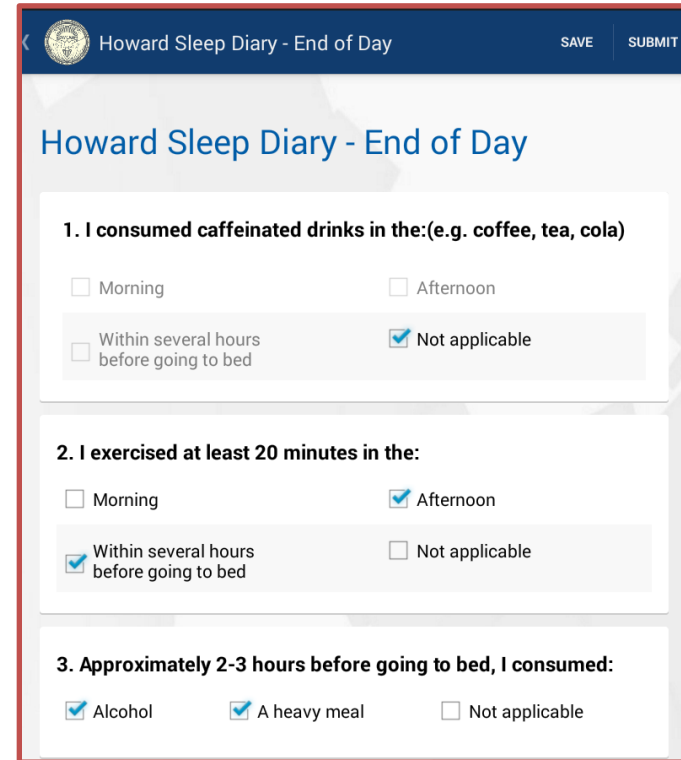
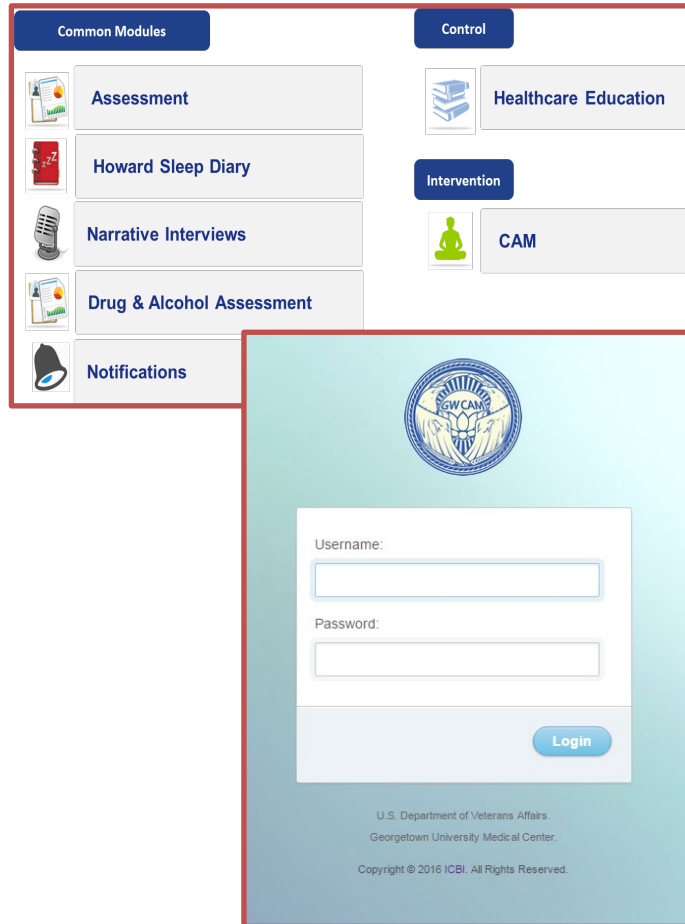
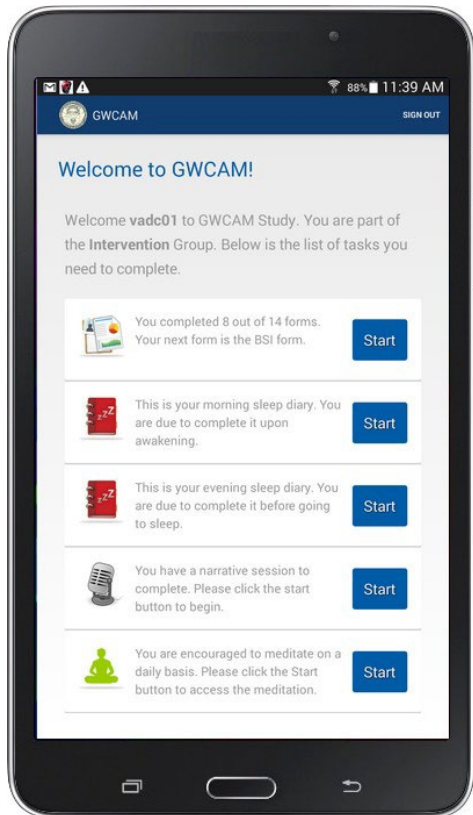


Why can coping with a chronic illness be so difficult?

- When you are ill with bronchitis or the flu, you know you will be feeling better and functioning normally within a week or so.
- A chronic illness is different. A chronic illness may never go away and can disrupt your lifestyle in many ways.
- Chronic Illness refers to any condition that affects your daily living and overall functioning for greater than three months, require some sort of medical device, or cause hospitalization for one month
- Chronic illness can affect our lives in many ways.
 - It can influence our social lives; for example, we may become less sociable because of chronic illness.
 - Chronic illness may also affect our jobs and employment because of disabilities or limitations.
 - Chronic illness can also impact our mood and make us feel sad or down.
 - All of these factors together can also affect us. For example, if you have to stop working because of your chronic illness, you may also become sad and then less sociable.



Methods of Data Collection – Study “App”





Outcomes

Primary

- Health-related functioning (Veterans RAND 36-Item Health Survey)
 - Mental
 - Physical
- Pain interference (PROMIS®)
- Fatigue (PROMIS®)

Secondary

- Pain (SF-MPQ-2)
- Fatigue (MFSI-SF)
- Cognitive Difficulties (Neuro-QOL)
- Depression (PHQ-9)
- PTSD symptoms (PCL-5)
- Subjective distress (PSS)
- Psychological distress (BSI)
- Severity of GW specific symptoms (Kansas Gulf War and Health Questionnaire)

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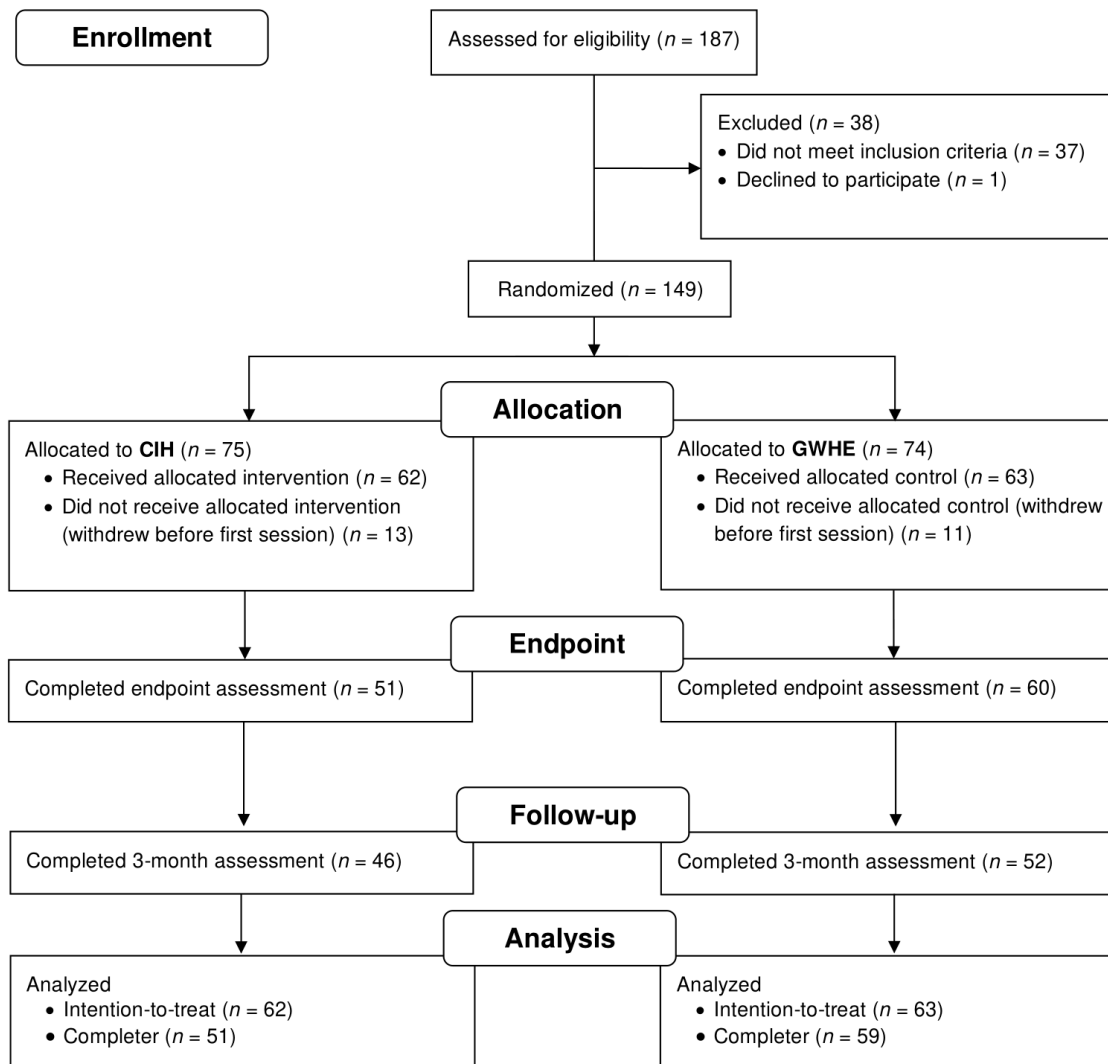


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Results - Baseline



Flow Diagram of Study Enrollment





Results

Characteristic	Overall (n = 149)	Treatment Group	
		CIH (n = 75)	GWHE (n = 74)
Age (years) [M (SD)]	54.31 (7.36)	53.46 (7.15)	55.16 (7.52)
Male [n (%)]	120 (81)	58 (77)	62 (84)
Race [n (%)]			
African American	103 (69)	50 (66)	53 (72)
White	31 (21)	17 (23)	14 (19)
Other	15 (10)	8 (11)	7 (9)
Hispanic ethnicity [n (%)]	5 (3)	4 (5)	1 (1)
Education [n (%)]			
HS/GED	28 (19)	9 (12)	19 (26)
> HS/GED	121 (81)	66 (88)	55 (74)
Married [n (%)]	92 (62)	47 (64)	45 (61)
Employed [n (%)]	82 (55)	40 (53)	42 (57)
Disabled [n (%)]	46 (31)	23 (31)	23 (32)



Five Factor Mindfulness Questionnaire

Proactive Mindfulness

Describing:

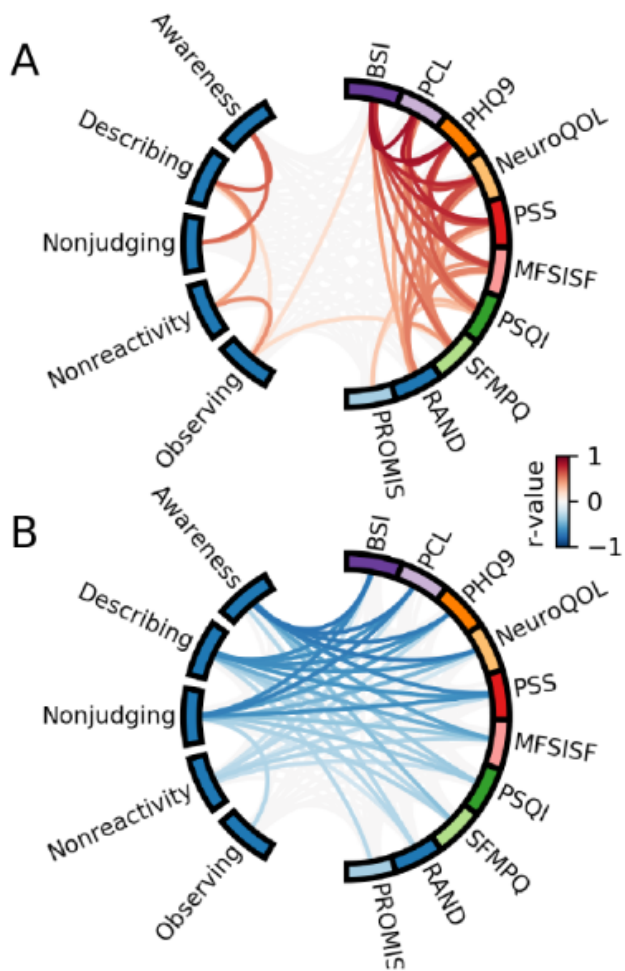
I can easily put my beliefs, opinions, and expectations into words.
Even when I'm feeling terribly upset, I can find a way to put it into words.

Non-judging:

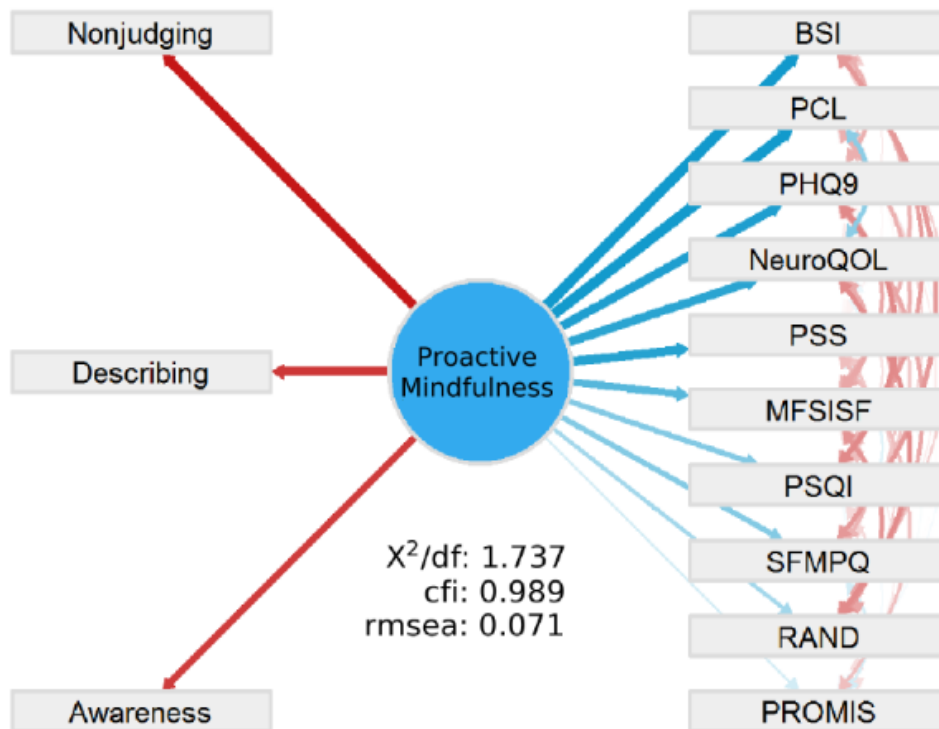
I criticize myself for having irrational or inappropriate emotions. (reverse)
I tell myself I shouldn't be feeling the way I'm feeling. (reverse)

Awareness:

It seems I "run on automatic" without awareness of what I'm doing. (reverse)
I find it difficult to stay focused on what's happening in the present. (reverse)



C Structural Equation Model
Factor 1





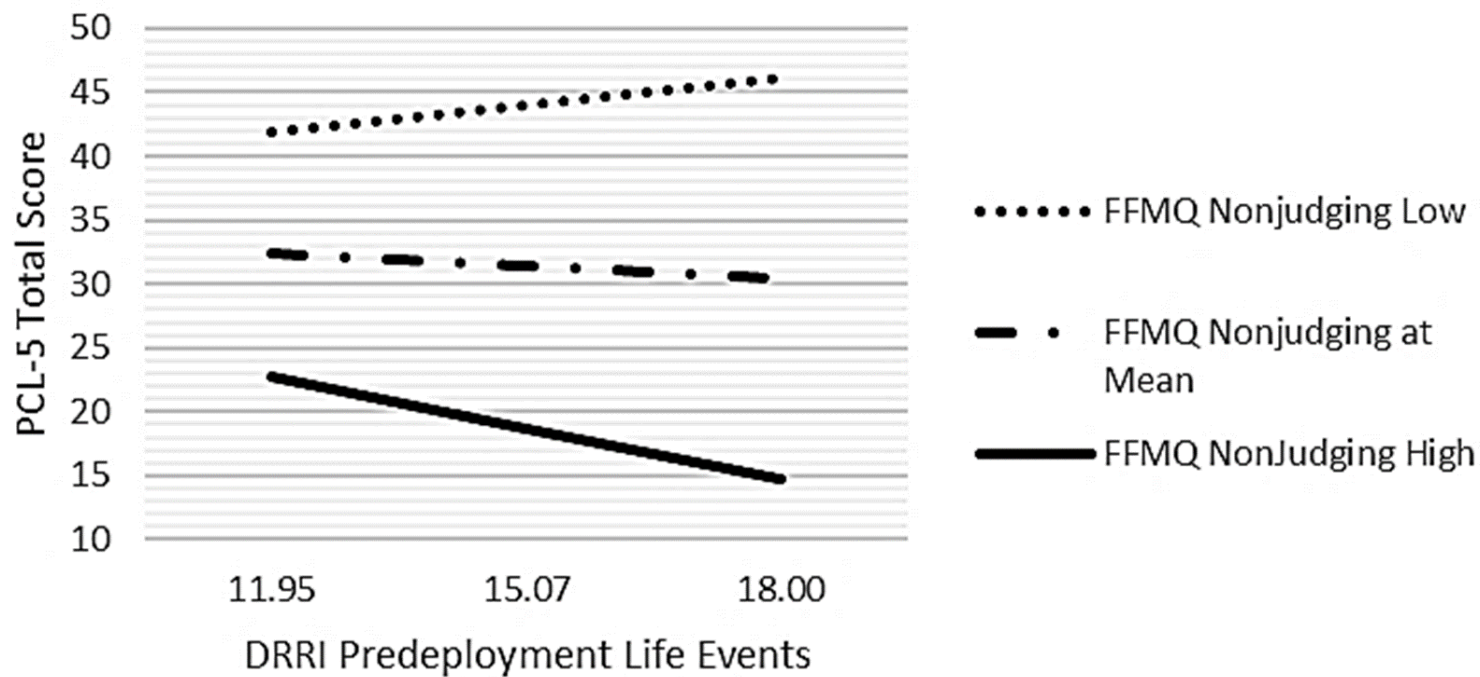
Mindfulness Results

- Facets of dispositional mindfulness related to “proactive” mindfulness were significantly associated with better self-reported health.
- These findings suggest that potential mindfulness treatments that target “proactive” mindfulness can improve the health conditions of Veterans, particularly individuals who suffer from CMI.



PTSD AND MINDFULNESS

FFMQ Nonjudging Moderates the effect of DRRRI Predeployment Life Events on PCL-5 Total Score



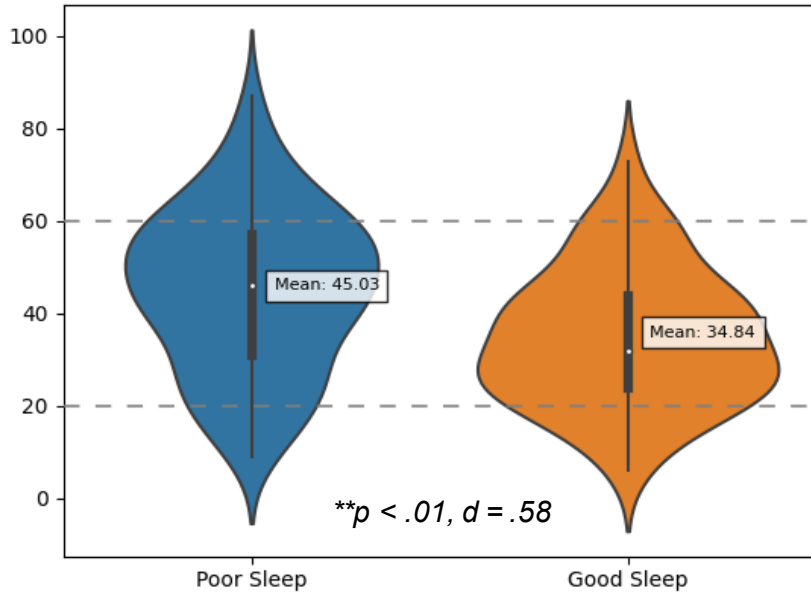


Good vs Poor Sleep Comparison

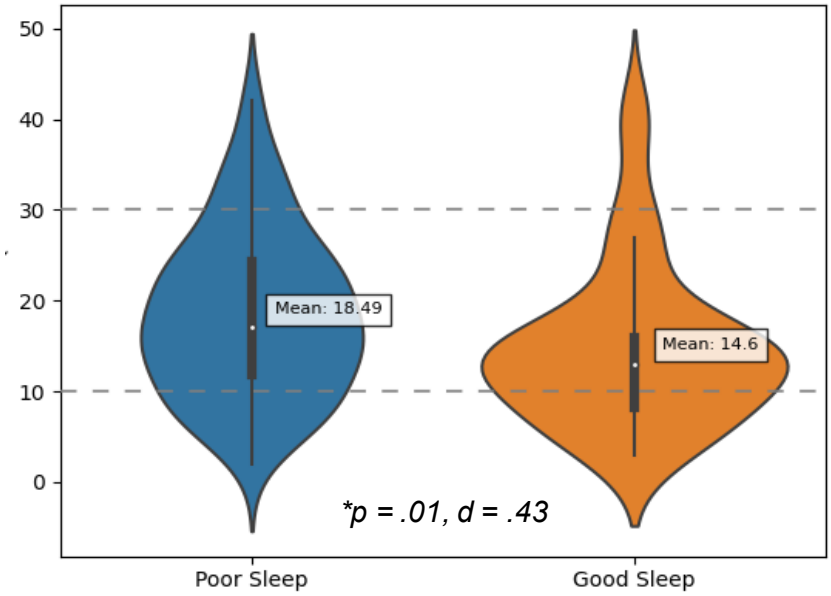
	Good Sleepers. Mean (SD) or % (n=58)	Poor Sleepers. Mean (SD) or % (n=89)	Effect Size (d)	P Value
Neuropsychological Measures				
Kansas Total	34.84 (15.48)	44.61 (17.26)	0.58	<0.01**
VR-36 MCS	46.39 (7.34)	39.11 (7.96)	0.93	<0.01**
VR-36 PCS	38.72 (9.58)	35.88 (9.60)	0.29	0.08
SFMPQ	14.60 (8.81)	18.49 (9.08)	0.43	0.01*
PROMIS Fatigue	17.59 (7.33)	22.97 (7.61)	0.37	<0.01**
PCL 5 Total	21.48 (15.34)	35.58 (20.62)	0.86	<0.01**
PHQ-9	8.26 (2.34)	14.49 (6.82)	0.93	<0.01**
PSS	14.95 (1.92)	20.92 (7.35)	0.81	<0.01**
Neuro QOL	54.45 (15.68)	45.38 (17.84)	0.53	<0.01**

Note. * $p < 0.05$; ** $p < 0.01$

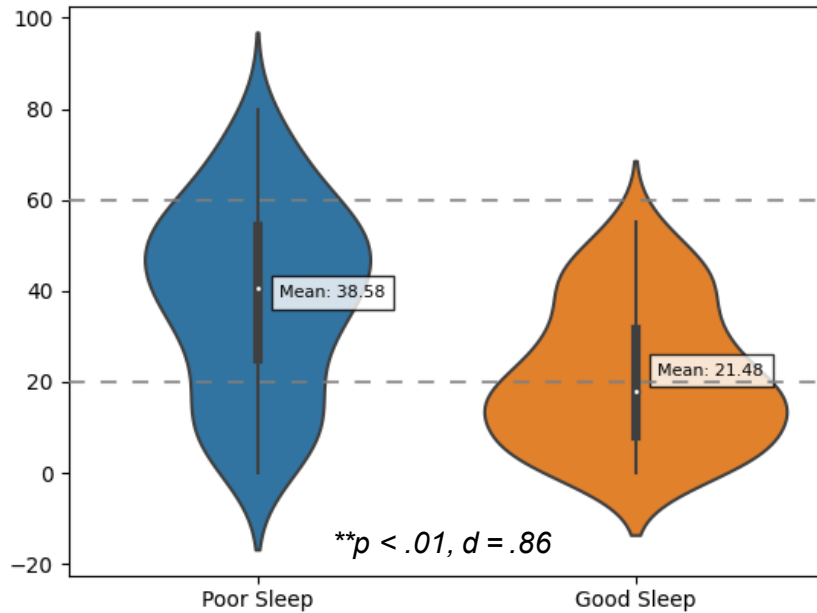
Kansas GW Symptoms



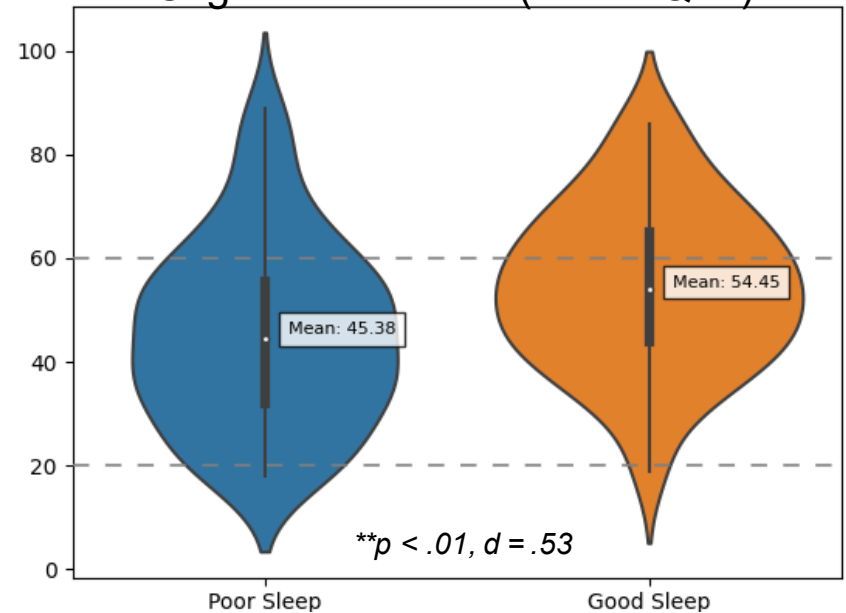
Pain (SFMPQ-2)



PTSD Symptoms (PCL-5)



Cognitive Function (Neuro-QoL)



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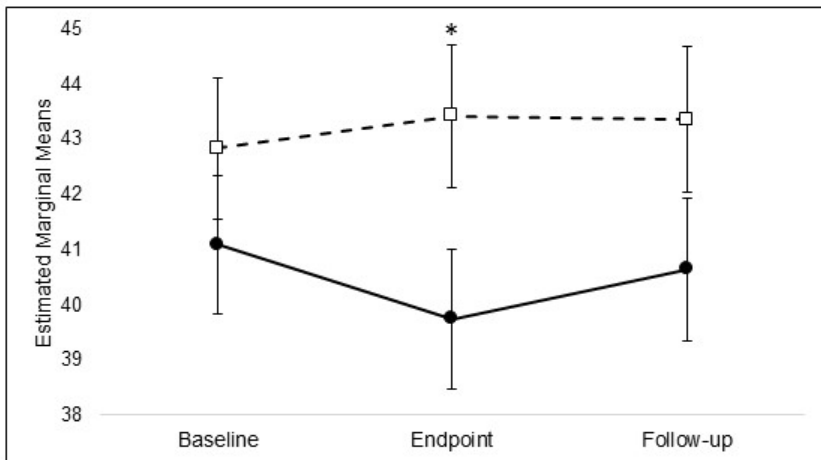
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Results - Intervention

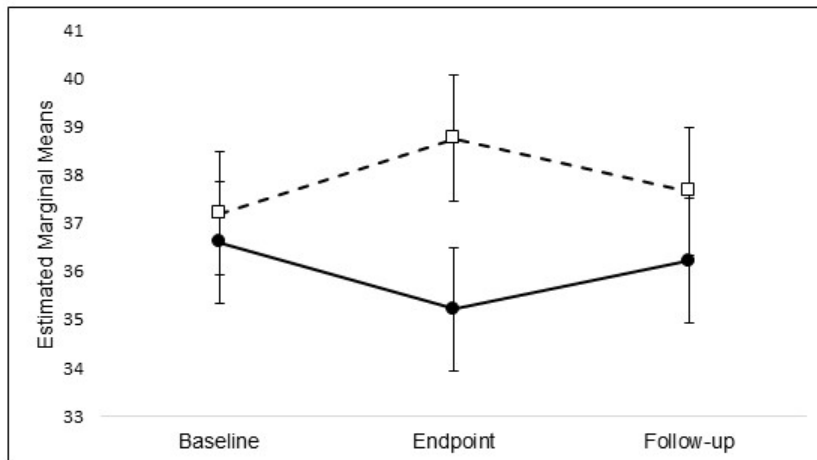


Primary Outcomes

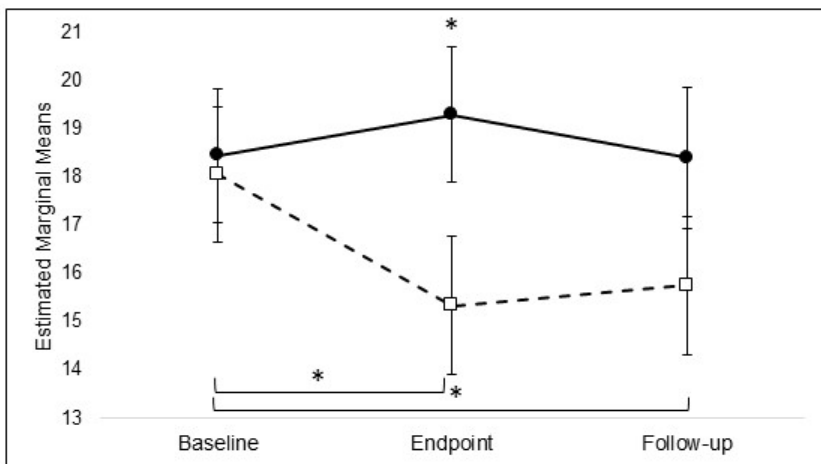
Veterans RAND 36-Item Health Survey - MCS



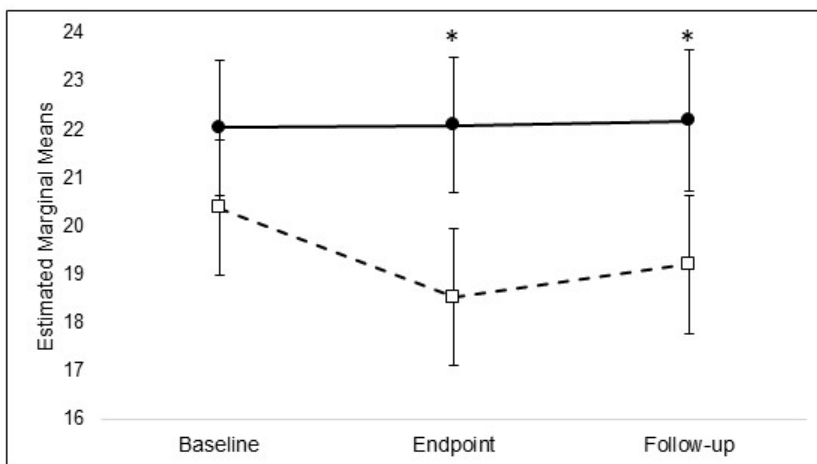
Veterans RAND 36-Item Health Survey - PCS



□ - CIH
● - GWHE



PROMIS® - Pain Interference



PROMIS® - Fatigue

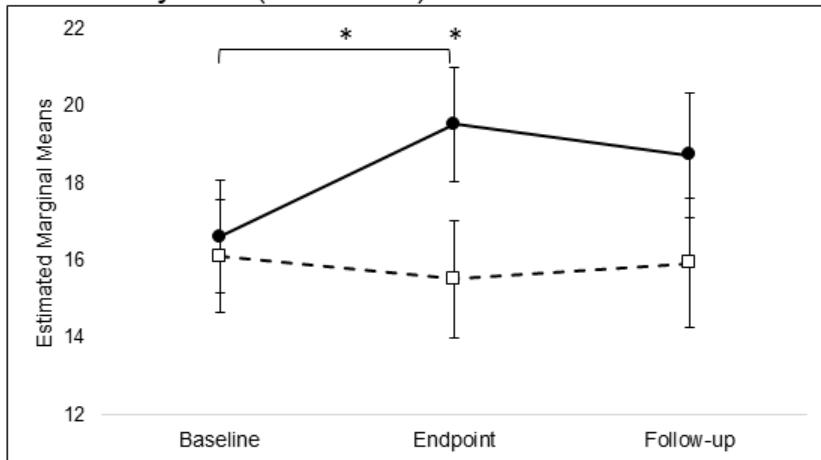
MCS = Mental Component Summary Score; PCS = Physical Component Summary Score

* Indicates statistical significance ($p < 0.05$)

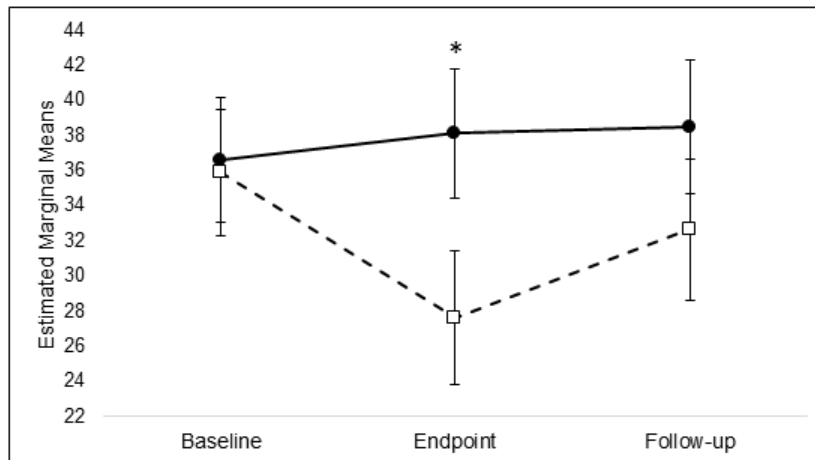


Secondary Outcomes

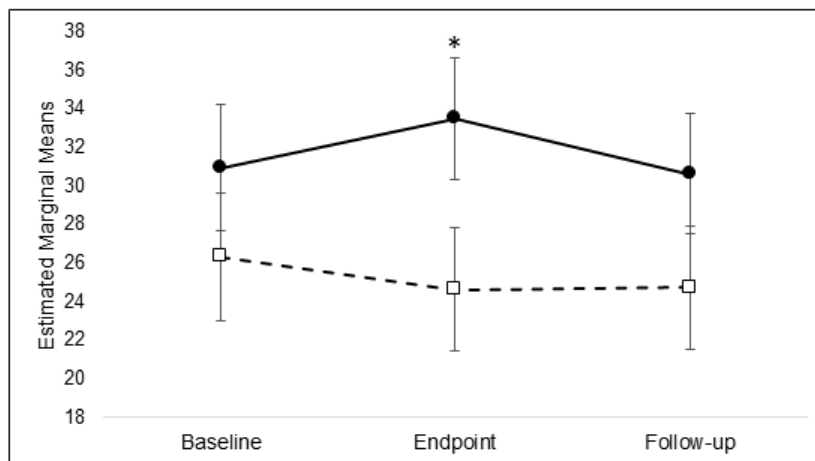
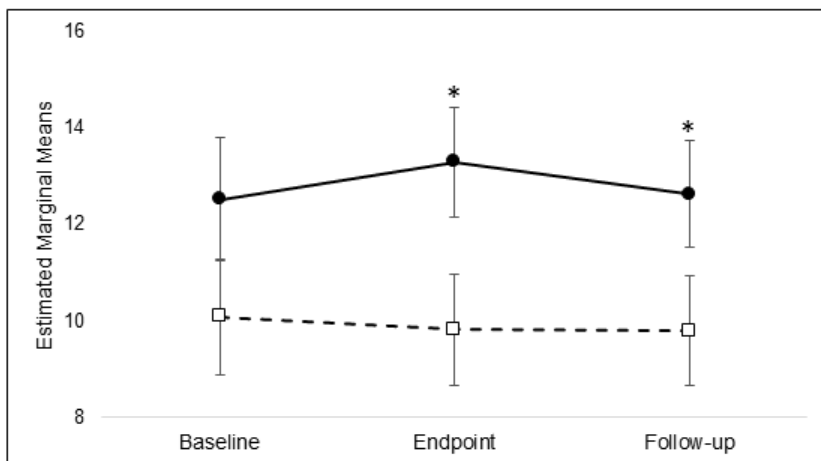
Secondary Pain (SF-MPQ-2)



Secondary Fatigue (MFSI-SF)



□ CIH
● GWHE



Depression (PHQ-9)

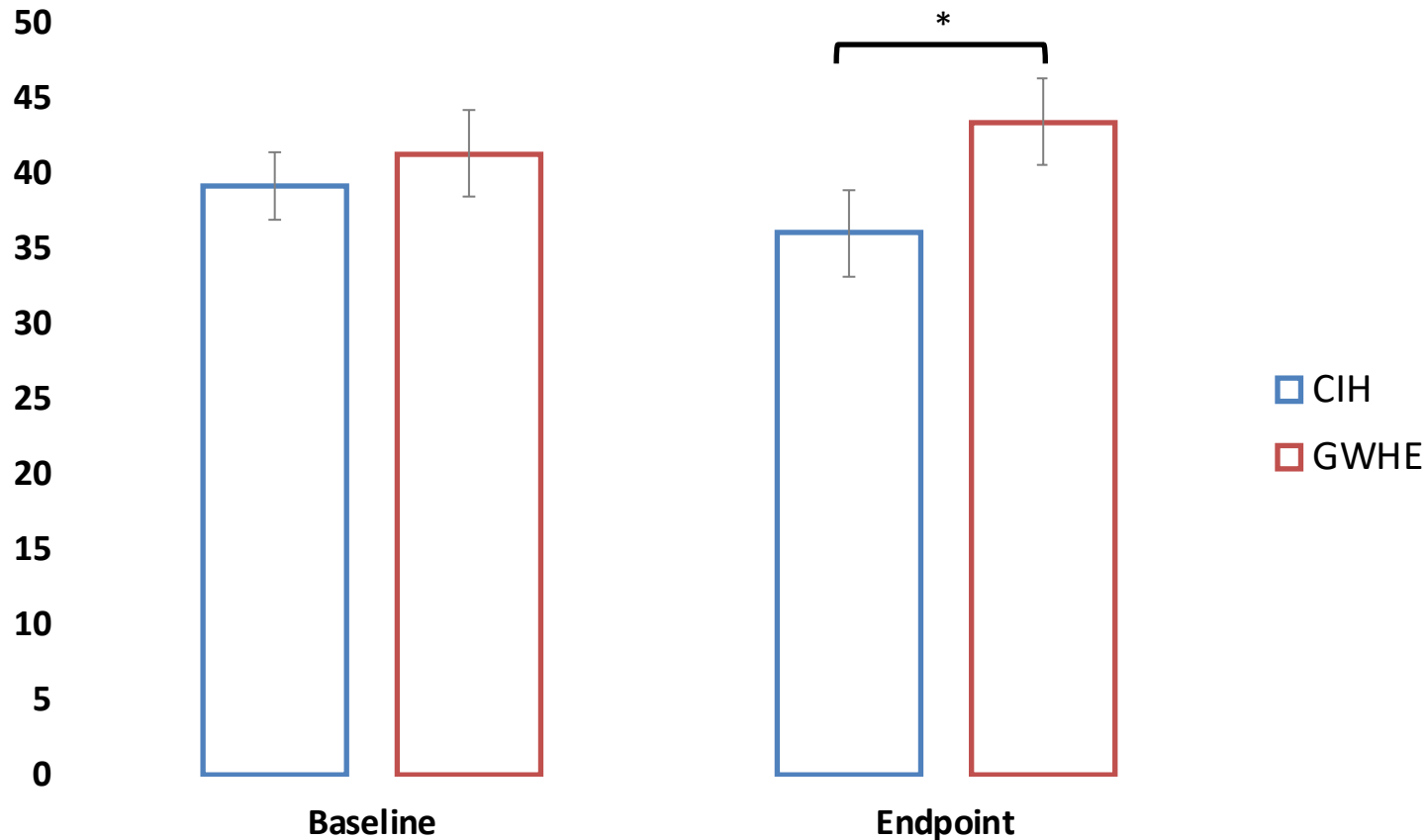
PTSD (PCL-C)

* Indicates statistical significance ($p < 0.05$)



Results

Kansas Gulf War Symptom Severity



* Indicates significant difference ($p < 0.05$)



Satisfaction Results

Percentage who responded 'Agree' or 'Strongly Agree'

	iRest/Acupuncture	GW Health Education
Q1. Easily followed the class instruction	94%	100%
Q2. Relevant to my GWI symptoms	58%	92%

- For iRest/Acu: *'Did you like both classes one after the other?'*
 - 83% reported 'Agree' or 'Strongly Agree'

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Discussion



Discussion

Findings suggest a possible beneficial effect of combining mindfulness meditation and auricular acupuncture in reducing overall symptom severity and individual symptom domains of fatigue, pain, and mood/cognition in Veterans with GWI.



Discussion

- Findings are similar with other GWI studies that used mind-body approaches
 - Improvement in GWI symptoms was reported by another RCT using a mindfulness-based intervention (Nakamura et al., 2017)
 - Reduction in fatigue was observed in Veterans with GWI randomized to a mindfulness-based stress reduction intervention (Kearney et al., 2016)

- Kearney et al. Mindfulness-based Stress Reduction in Addition to Usual Care Is Associated with Improvements in Pain, Fatigue, and Cognitive Failures Among Veterans with Gulf War Illness. *Am J Med.* 2016;129(2):204-214.
- Nakamura et al. Investigating Clinical Benefits of a Novel Sleep-Focused Mind-Body Program on Gulf War Illness Symptoms: A Randomized Controlled Trial. *Psychosom Med.* 2017;79(6):706-718



Conclusion

- When seeing your GW patients, providers can have more confidence in recommendation of most common CIH approaches (meditation and acupuncture) for GW Veterans with ongoing chronic symptoms.



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Original Article



Gulf War Illness: A Randomized Controlled Trial Combining Mindfulness Meditation and Auricular Acupuncture

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and Mary Ann Dutton, PhD³

Background Many Gulf War (GW) Veterans report chronic symptoms including pain, fatigue, and cognitive impairment, commonly defined as Gulf War Illness (GWI). Complementary and integrative health (CIH) therapies may potentially improve multiple symptoms of GWI.

Objective To examine the effectiveness of combining 2 commonly available CIH therapies, mindfulness meditation and auricular acupuncture, in improving health-related functioning and multiple symptom domains of GWI (e.g., pain, fatigue).

Methods This study was a randomized controlled trial in which Veterans with GWI were randomly assigned to either the intervention group (n = 75), wherein they received 2 distinct CIH therapies – mindfulness meditation and auricular acupuncture, or the active control group, wherein they received a

[Gulf War Illness: A Randomized Controlled Trial Combining Mindfulness Meditation and Auricular Acupuncture \(sagepub.com\)](https://sagepub.com)