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TITLE: Effectiveness of Acupressure Treatment for Pain Management and Fatigue Relief in Gulf War Veterans

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14. ABSTRACT This study will provide symptomatic veterans with acupressure treatment and determine its effectiveness in fatigue relief and pain management for GWI disease. We plan to recruit patients who report they have symptoms of GWI through the Department of Veterans Affairs (VA), and randomize them into acupressure group (to receive acupressure treatment) and control group (Reiki). The acupressure treatment will be offered twice per week for 6 weeks. Evaluations will be made before and after treatment, and clinical outcomes will be compared between groups (acupressure group vs control group) and between different stages (before treatment vs. after treatment) within the same group.					
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I. INTRODUCTION

About 25~30% Gulf War veterans suffer Gulf War Illness (GWI), with one or more chronic symptoms (i.e. debilitating fatigue, chronic headache, muscle and/or joint pain, sleeping problems, etc.), lasting six months or longer, in at least two of three categories: fatigue, musculoskeletal pain, and memory and/or mental problems. These symptoms significantly interfere with their motor function and quality of life (QOL), preventing them from doing daily work normally or enjoying social and recreational activities. The etiology of GWI, however, is still elusive currently; hence there is no established conclusive treatment. Veterans with GWI rely on pharmaceutical treatment, physical therapy, and/or nutritional supplements to temporarily alleviate their symptoms, with limited effect. The severity of symptomatic health of veterans with GWI does not change much over time and very few veterans have ever recovered significantly.

This study will provide symptomatic veterans with acupuncture treatment and determine its effectiveness in fatigue relief and pain management for GWI disease. We plan to recruit patients who report they have symptoms of GWI through the Department of Veterans Affairs (VA), and randomize them into acupuncture group (to receive acupuncture treatment) and control group (without acupuncture treatment). The acupuncture treatment, twice per week for 6 weeks, will be offered by licensed acupuncture practitioner, with at least 5 years of clinical experience, who have received 20 hours of training related to symptoms of GWI. Evaluations will be made before and after treatment, and clinical outcomes will be compared between groups (acupuncture group vs. control group) and between different stages (before treatment vs. after treatment) within the same group.

Aim 1 is to investigate the effectiveness of acupuncture for fatigue relief and pain management in veterans with GWI.

Aim 2 is to investigate the relationship between EEG measures, specifically the corticomuscular coherence and power spectra in theta band, and the clinical measures.

II. KEYWORDS

Acupuncture, Reiki, Gulf War Illness, fatigue, chronic headache, musculoskeletal pain, electroencephalography, non-invasive, pain management, quality of life

III. STUDY PROGRESS

The study received continuing renewal approval from Cleveland Clinic IRB and the approval expiration date is 10/18/2017. The study is being conducted at only one site – Cleveland Clinic Foundation. No cost extension of a 12-months of period has been submitted.

Study Advertisements

The online ads has been approved by IRB and placed on contextually relevant sites with content related to Gulf War Veterans/syndrome/illness. Google generates keyword recommendations on what content is most likely relevant to the target, and the ads have been placed within those sites. CCF marketing and study team monitor them for engagement. In order to accelerate recruitment, we also submitted amendment to local IRB to mail the advertisement letters to Gulf War Veterans. The list was purchased by Cleveland Clinic Marketing Services specifically to be used for this research study. The study team will continue to work with the staffs at Cleveland Clinic to screen and enroll subjects.

Number of Subjects

There are totally seven subjects who signed consent form. Among them, four subjects (two for Acupressure, and two for Reiki) completed the study protocol. One subject was withdrawn from the study due to the lack of compliance. The other two subjects withdrew from the study due to personal reasons.

Study findings

Four subjects completed the study protocol (two subjects for Acupressure and two for Reiki). Subjects received Acupressure or Reiki treatments 40 min/day, 2 days/week for 6 weeks. Clinical measurements were performed before, during and after the treatments, which include pain measurement of Brief Pain Inventory (BPI), fatigability measurement of revised Piper Fatigue Scale (rPFS), and short form-36 (SF-36) survey. EEG and EMG data were also collected before, during and after the treatments.

The BPI, rPFS, and SF-36 scores were listed in table 1 for the Acupressure group and Reiki group.

Tests		Acupressure			Reiki		
		Baseline	After	follow up	Baseline	After	follow up
BPI	pain severity	3.84	3.00	4.61	6.67	5.25	6.25
	pain interference	7.34	6.65	7.32	7.21	4.5	5.92
rPFS		7.09	6.39	6.84	4.66	4.57	4.43
SF-36	physical function	25	27.5	22.5	15	20	35
	role limitation due to physical health	0	12.5	0	0	0	0
	role limitation due to emotional health	33.33	33.33	0.00	33.33	83.33	33.33
	Energy/Fatigue	17.5	27.5	20	27.5	32.5	30
	Emotional well being	40	44	38	70	60	68
	Social functioning	37.5	50	43.75	56.25	50	56.25
	Pain	28.75	33.75	22.5	27.5	33.75	33.75
	General health	47.5	40	37.5	32.5	35	37.5

A 6-week Acupressure intervention produced fatigue relief and pain alleviation similar to Reiki in veterans with GWI, indicating that acupressure may be a potential noninvasive therapeutic technology for fatigue relief and pain management in veterans with GWI. The results from the four subjects who have completed the intervention look promising and are indicative of the Acupressure potential for pain management and fatigue relief in veterans with GWI. Pain scale and fatigue scale decreased during the intervention. Continuation of the study will allow us to better understand the efficacy of acupressure for fatigue relief and pain management in veterans with GWI.

Summary of Anticipated and Unanticipated Adverse Effects

N/A

Problem Areas

The initial proposal included Cleveland VA medical center as a recruitment site. However, per Cleveland VA medical center's recommendation, the study needs to recruit subjects only at the Cleveland Clinic. Study subjects will have to visit the Cleveland Clinic two times per week for the intervention. This will limit the number of subjects willing and able to participate in the study. Limited access to Veterans outside Cleveland VA medical center slow down the enrollment. The study team is

working closely with the staff at the Cleveland Clinic to recruit more subjects in the following 12 months.

IV. KEY RESEARCH ACCOMPLISHMENTS

N/A

V. CONCLUSION

The results from the four subjects who have completed the study are very promising and indicative of the Acupressure potential for pain management and fatigue relief for veterans with GWI. Pain scale and fatigue scale decreased during the intervention. Continuation of the study will allow us to better understand the efficacy of acupressure for fatigue relief and pain management in veterans with GWI. The study staffs have gained valuable knowledge related to acupressure and its potential for fatigue relief and pain management in veterans with GWI. This knowledge may lead to further refinement of the protocol as well as advancements in acupressure intervention for veterans with GWI.

VI. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS

N/A

VII. INVENTIONS, PATENTS AND LICENSES

N/A

VIII. REPORTABLE OUTCOMES

Seven subjects (four in the Acupressure group and three in the Reiki group) have been recruited for the study. Of these seven subjects, two have completed the study, one withdrew from the study due to personal reason, and the other four are in various stages of the study. The results from the four subjects who have completed the intervention look promising and are indicative of the Acupressure potential for pain management and fatigue relief in veterans with GWI.

IX. OTHER ACHIEVEMENTS

N/A