

# Effectiveness of Acupuncture in Treating Gulf War Illness

Lisa Conboy, MA MS ScD  
Osher Research Center, Harvard Medical School  
New England School of Acupuncture  
Principal Investigator  
lisa\_conboy@hms.harvard.edu

- Overview of design and methodology
- Preliminary Results
- Next Steps

# Methodology

- Objectives: To find a successful treatment for GWI, by gathering data to better understand: 1) the effectiveness of acupuncture in treating GWI; 2) the mechanisms of this disease.
- Specific Aim: In a sample of veterans with GWI, evaluate the effectiveness of an individualized acupuncture treatment protocol on the volunteers' most distressing GWI symptom.

# Methodology

- Unblinded randomized controlled trial design with a wait-list-control.
- Individualized treatments
- Active group → 6 months of biweekly treatment
- Waitlist group → 2 months of waiting then 4 months of weekly treatments

## Definition: Symptoms in 3 clusters

<b>Cluster A</b> <i>Fatigability</i>	<b>Cluster B</b> <i>Mood &amp; Cognition</i>	<b>Cluster C</b> <i>Musculoskeletal</i>
persistent fatigue 24 hrs or more after exertion	feeling depressed	joint pain/ muscle pain
	feeling irritable	
	feeling worried, tense, or anxious	
	difficulty thinking	
	difficulty concentrating	
	problems finding words	
	problems sleeping	

## How we measure improvement

- Main Outcome: Sf-36
- Fatigability
  - fatigue 24 hours or more after exertion
- Mood and Cognition
  - feeling depressed or
  - feeling irritable or
  - difficulty thinking or concentrating or
  - feeling worried, tense, anxious or
  - problems finding words or
  - problems getting to sleep
- Musculoskeletal
  - joint pain or muscle pain

## How we measure improvement

- The SF-36
- Multidimensional Assessment of Fatigue
- The Profile of Mood States
- Pittsburg Sleep Quality Index
- Measure Your Medical Outcomes Profile
- Beck Anxiety Inventory
- McGill Pain Scale
- Carroll Depression Scale
- Social support, Social Networks, and Stress
- Medication use and Expectations for Treatment
- Blood draw to examine levels of selected markers of inflammation, stress, and immune function

## Measure improvement according to Traditional Chinese Medicine

- Recording
  - TCM symptoms
  - Diagnosis
  - Prognosis
  - Expectations for treatment
  - Alliance with subject
- Measures
  - OM intake-baseline
  - Health History Questionnaire-baseline
  - Monthly progress TCM (baseline and monthly for 6 months of study)

## How TCM Characterizes GWI

- TCM's individualized diagnosis and treatment good for heterogeneous presentation
- Treatment Guided By
  - Literature Review
  - Expert Interviews
  - Exposures to neurotoxicants
- Recommendations
  - TCM Neurology
  - Wei-zhang (Flaccidity Syndrome) – treatment of organophosphate poisoning from TCM perspective
  - Autonomic Nervous System (ANS)
  - Bi Syndrome

## TCM Treatments

Veterans with GWI will receive individualized TCM diagnosis and treatment strategy, directed at their most distressing symptom, and at any additional symptoms, as well as at their root condition, 1-2 x/week x 4-6 months. Full intake will include medical history and exposure to known or suspected neurotoxicants during the war.

Treatments provided by senior practitioners in private offices, may include:

- needling with *de qi* sensation
- warming treatments, e.g., moxibustion, heat lamps
- manual therapies, including tui na, cupping, gua sha
- electroacupuncture, known to be helpful for its analgesic and anti-inflammatory effects
- microsystems - auricular and scalp
- press balls

## TCM Treatments

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Not within the scope of this study, excluded treatments are:

- Chinese Herbal Medicine (CHM)
- Supplements
- This type of Acupuncture is the most commonly used in the US making our results easy to apply. 18,000 practitioners in US.

## Patient Safety

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- An **adverse event** is any negative health change (or side-effect) that happens to a volunteer while he/she is participating in the study.
- Only two AEs were reported

# Practitioner Safety

- Safety issues treating trauma survivors
- Safety Resources
  - **Suicide Prevention Hotline**  
1-800-273-8255 (TALK)
  - **VA Boston**  
24-hour nurse available to provide telephone care for veterans  
1-800-865-3384
  - **National Veterans Helpline**  
1-800-507-4571  
[www.boston.va.gov/](http://www.boston.va.gov/)

# Preliminary Results

- Recruitment
- Main and secondary complaints
- Usability

# Preliminary Results: Recruitment

- Newspaper stories & advertisements, Manpower database (6,000 cards), radio, cable TV, word of mouth (VA, Yellow Ribbon)
- 200 vets started the screening process
- 163 screened
- 101 Enrolled & randomized
- 12 dropouts
  
- 80% White, 10% Black, 10% Other
- Average age 48 years
- Mostly men/women: 7/1

# Preliminary Results

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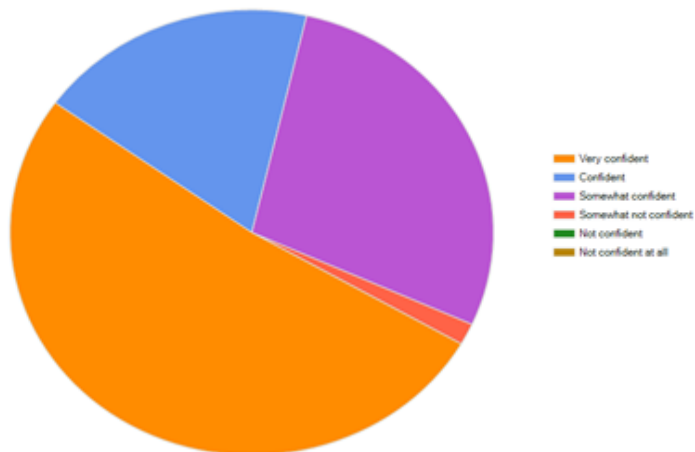


# Main and secondary complaints

- **MYMOP:**  
**Measure Yourself Medical Outcomes Profile** Paterson, J. BMJ. 1996 Apr 20;312(7037):1016-20.
- The MYMOP is cross-validated with the SF-36 and thus should offer comparable results.

# Usability

How confident would you be in recommending acupuncture to a friend or family member?



## Summary

- Almost to target enrollment (might reach n=110)
  - Supplement and Extension to Dec 2012
- Preliminary evidence of treatment effect
  - Primary and secondary symptoms
- Vets are confident recommending acupuncture to loved ones
  - Want to continue with acupuncture

## Next Steps

- Applying CDMPR Investigator-Initiated Research Award
  - 1. Which types of acupuncture work best
    - For which symptoms
    - For which individuals (e.g. IBS)
    - Dose
      - 1x week vs 2x week
      - adherence

## Next Steps

- Applying CDMPR Investigator-Initiated Research Award
  - 2. Detailed treatment protocols
  - 3. Blood subanalyses
    - Within IBS and compare to normals
  - 4. Self-reported exposures
    - Related to reported symptoms
    - Related to TCM dx

**Thank you  
veterans!**

