

ACUPUNCTURE FAQS

What is the purpose of this study?

• To see whether acupuncture can help decrease headaches in Service Members with Traumatic Brain Injury (TBI)

Where does this study take place?

• All study visits are conducted at the TBI Clinic at Fort Belvoir Community Hospital

Who is eligible to participate?

• Previously deployed Service Members with headaches and mild to moderate TBI

What does the study involve?

- Subjects will be randomly assigned to 1 of 3 groups:
 - o Traditional Chinese acupuncture
 - Ear acupuncture
 - Usual care
- Subjects will complete: (1) daily headache diary and (2) questionnaires about their general health, symptoms and health behaviors at baseline, week 6 and week 12.
- Those in the usual care group will continue with their current medical regimen and complete (1) daily headache diary during their 6-week treatment period and (2) questionnaires at week 12. Those who elect to receive 6 weeks of ear acupuncture treatment will do so between weeks 6 and 12.

What are the differences between the three groups?

- Traditional acupuncture group
 - o An acupuncturist will examine and evaluate subjects before inserting thin, sterile stainless steel needles at specific points on their body.
- Ear acupuncture group
 - o An acupuncturist will insert sterile stainless steel needles and an ASP ear needle into various points in subject's outer ear. The ASP is a shorter needle that will stay in the participant's ear for a few days.
- Usual care group
 - o No acupuncture during the 6 week study time period
 - o Continue to receive medical care for headaches and other symptoms
 - Subjects can elect to receive up to 10 ear acupuncture treatments between weeks 6 and 12

How long is this study?

• 12 weeks

What happens during the study visits?

- There are 3 research visits (at baseline, week 6 and week 12) during which participants complete questionnaires. These visits take approximately 60 90 minutes.
- There are 10 acupuncture treatment visits plus an initial assessment over 6 weeks.
 - o Ear acupuncture: 45 minutes/treatment session
 - o Traditional Chinese acupuncture: 60 minutes/treatment session

Are there any risks?

Acupuncture when administered by trained and licensed acupuncturists is relatively safe. However, some possible risks include:

- Expected likely risks: discomfort, slight bleeding and bruising at needle insertion sites
- Ear acupuncture risks: small chance of developing an infection of the outer ear

What are the benefits to participating in the study?

- Acupuncture groups: possible improvement of some symptoms, including headaches; possibility that some may not experience any direct benefit
- Usual care group: no direct benefits, but their participation may help others in the future

Can study participants change their mind about the study?

- Participation is voluntary
- Study participants may withdraw from this study at any time but some testing or period of observation by the investigators may be recommended in order to safely terminate participation

Who can I contact for questions about the study?

- Charmagne Paat, Research Coordinator, 703-299-4841 or
- Ashley Price, Research Coordinator, 703-299-4869 or
- Email acupuncturestudy@siib.org