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Primary Research Interest:	Anesthesiology
Description of Research:	OBJECTIVE: To use auricular PENFS for the treatment of fibromyalgia and to evaluate, using fMRI, the neural substrates of pain changes following the treatments. HYPOTHESIS: PENFS will result in more significant and longer-term improvements in pain and function relative to [standard therapy] for fibromyalgia, and these improvements will correspond to decreased functional connectivity between the insula and default mode network as evaluated by fMRI. METHODS: Subjects who meet study criteria will receive baseline assessments including resting state fMRI, collection of biobehavioural information such as cognitive and psychological assessments on standardized forms, eating, sleeping and drinking habits, [Defense and Veterans Pain Rating Scale (DVPRS), arm curl, 30-s chair stand, and handgrip strength tests] and documented baseline analgesic consumption. Subjects will then undergo randomization to either standard therapy (medication, PT) or PENFS (series of 4, weekly) treatments and assessed for changes in pain and function immediately after treatment, at 1 month and 3 months follow-up without maintenance following the 4-week series. A follow-up fMRI will be obtained to evaluate for long-term changes in functional connectivity within 2 weeks after the final intervention.
Relevance to VA:	BACKGROUND: Fibromyalgia is a chronic pain syndrome that consists of chronic widespread pain, decreased physical function, fatigue, pyschoemotional and sleep disturbances, and various somatic complaints, affecting 5-10 million Americans, with ~1,500 veterans carrying a diagnosis of fibromyalgia seen per year at the Atlanta VAMC alone. It is estimated that fibromyalgia costs the American population over $20 billion/year in lost wages and disability. Initial therapies often include CAM therapies, which are generally considered safe, although their efficacy has not been thoroughly evaluated for fibromyalgia. Thus, non-pharmacologic alternatives require more rigorous scientific investigation for the treatment of fibromyalgia. There is evidence to support the use of percutaneous electrical neural stimulation (PENS) in the treatment of pain conditions, which may have increased effects relative to acupuncture based on systematic reviews. While fMRI data for acupuncture and fibromyalgia exists, no such data exists for PENS treatment. An evolved form of PENS, percutaneous electrical neural field stimulation (PENFS) of the auricle is already used in the military and VA systems for the treatment of chronic pain, but evidence regarding its mechanisms and effects is lacking. If PENFS can provide long-term, clinically significant pain relief, it could decrease the need for opioid analgesics and their associated risks, which is a primary objective of the VA Opioid Safety Initiative.