

Our secondary aim was to compare both methods with usual medical care.

Methods: In a randomized comparative effectiveness trial, we randomized 107 participants with acute and sub-acute low back pain to: 1) usual medical care; 2) manual side-posture manipulation; and 3) mechanical manipulation (Activator). The primary outcome was self-reported disability (Oswestry) at four weeks. Pain was rated on a 0 to 10 numerical rating scale. Pain and disability scores were regressed on grouping variables adjusted for baseline covariates.

Results: Manual manipulation demonstrated a clinically important and statistically significant reduction of disability and pain compared to Activator (adjusted mean difference = 7.9 and 1.3 points respectively, $P < .05$) and compared to usual medical care (7.0 and 1.8 points respectively, $P < .05$). There were no significant adjusted mean differences between Activator and usual medical care in disability and pain (0.9 and 0.5 points respectively, $P > .05$).

Conclusion: Manual manipulation provided significantly greater short-term reduction in self-reported disability and pain compared to Activator and usual medical care. University of Pittsburgh IRB approval: PRO10040327. This work was supported by an award (R00AT004196) from the National Institutes of Health (NIH) National Center for Complementary and Alternative Medicine (NCCAM).

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OA14.02

A Pragmatic-Explanatory Continuum Indicator Summary (PRECIS) Examination of a Recent Study of Massage and Relaxation Therapy Effectiveness

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Purpose: This presentation will discuss the pragmatic methodological approach of a recently completed NIH sponsored study of clinical massage therapy (CMT) and progressive muscle relaxation (PMR). While CMT and PMR have demonstrated efficacy for chronic low back pain (CLBP), their effectiveness in the real world of health care practice is only now being evaluated. Pragmatic studies have been recommended by NIH and the Institute of Medicine to address effectiveness questions.

Methods: Critical discussion among 2 key study team members and 2 outside reviewers analyzed the study protocol for accordance with pragmatic vs. explanatory characteristics developed in the PRECIS tool by Thorpe et al. (2009). Scores for each of 10 domains were used to create an overall visual representation of the extent to which this study reflects a pragmatic research approach.

Results: The visual wagon wheel reflecting the current study's "standing" on the Thorpe model will be presented. The study most strongly reflected a pragmatic approach in the following domains: Eligibility Criteria, Flexibility of Experimental Intervention, Practitioner Expertise, Outcomes, and Participant Compliance. Areas that the current study neutrally reflected a pragmatic approach or reflects more of an explanatory approach included Follow-up Intensity, Analysis of the Primary Outcome, and Practitioner Adherence.

Conclusion: To our knowledge, this is the first CAM related research trail that has retrospectively critiqued its study design

utilizing the PRECIS tool. CAM investigators may utilize this self-critique and the PRECIS tool to develop study designs and prospectively critique the extent to which pragmatic approaches apply. Audience participants will gain understanding of methodologies and techniques of pragmatic studies.

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OA14.03

The Effect of Self-Administered Acupressure on Chronic Pain in Breast Cancer Survivors

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Purpose: There are nearly 3 million breast cancer (BC) survivors in the United States. Chronic pain and sensory disturbances after BC treatment is common, occurring in approximately 50% of patients, and can persist for years. Chronic pain in BC survivors is associated with fatigue, sleep disturbances, mood disorders and decreased quality of life. Current treatments for chronic cancer pain have limited efficacy and/or unacceptable side-effects, and as such there is a tremendous need for new treatments in this area.

Methods: We examined the effect of 6 weeks of the effects of two types of self-administered acupressure (stimulating {SA} and relaxing {RA}) compared to standard of care (SC) in 105 (39 randomized to SA, 33 to RA and 33 to usual care) chronically fatigued BC survivors who reported ≥ 3 on the Brief Pain Inventory's (BPI) average pain subscale and who were from an ongoing randomized clinical trial on acupressure for persistent cancer-related fatigue. The BPI severity and interference pain subscales were used to determine changes in pain. Analysis of variance (ANOVA) was performed on mean differences of changes in pain scales by time and group.

Results: Baseline pain severity scores are 4.6SA, 4.2RA, 4.6 UC (10 point scale) and baseline pain interference scores are 3.0SA, 4.5RA, 4.3UC (10 point scale). There was a significant decrease in pain severity ($p = < 0.01$; $-1.1SA$, $-0.8RA$, $0.03UC$; 10 point scale) and pain interference ($p = < 0.01$; $-1.4SA$, $-1.3RA$, $0.1UC$; 10 point scale) in the combined acupressure group compared to UC.

Conclusion: In this preliminary analysis two types of self-administered acupressure engender a greater analgesic response for clinical pain as compared to UC in fatigued BC survivors. These findings should be interpreted with caution given our small sample size and diverse types of pain. More rigorous studies are recommended.

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OA14.04 LB

Impact of Outpatient Massage on Symptom Expression in Cancer Patients and Caregivers

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Purpose: Massage as a manual therapy has shown benefit for symptomatic relief in cancer patients and their caregivers. We