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Credibility of low-strength static magnet therapy as an attention control intervention for a randomized controlled study of CranioSacral therapy for migraine headaches.

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Abstract

BACKGROUND: Developing valid control groups that generate similar perceptions and expectations to experimental complementary and alternative (CAM) treatments can be challenging. The perceived credibility of treatment and outcome expectancy often contributes to positive clinical responses to CAM therapies, thereby confounding efficacy data. As part of a clinical feasibility study, credibility and expectancy data were obtained from subjects suffering from migraine who received either CranioSacral therapy (CST) or an attention-control, sham, and low-strength magnet (LSSM) intervention.

OBJECTIVE: The objective of this study was to evaluate whether the LSSM intervention generated similar levels of subject credibility and expectancy compared to CST.

DESIGN: This was a two-arm randomized controlled trial.

SUBJECTS: Sixty-five (65) adults with moderate to severe migraine were the subjects of this study.

INTERVENTIONS: After an 8-week baseline, subjects were randomized to eight weekly treatments of either CST (n=36) or LSSM (n=29). The latter involved the use of a magnet-treatment protocol using inactive and low-strength static magnets designed to mimic the CST protocol in terms of setting, visit timing, body positioning, and therapist-subject interaction.

OUTCOME MEASURES: A four-item, self-administered credibility/expectancy questionnaire, based on a validated instrument, was completed after the first visit.

RESULTS: Using a 0-9 rating scale, the mean score for perceived logicality of treatment was significantly less for LSSM (5.03, standard deviation [SD] 2.34) compared to CST (6.64, SD 2.19). Subject confidence that migraine would improve was greater for CST (5.94, SD 2.01) than for LSSM (4.9, SD 2.21), a difference that was not statistically significant. Significantly more subjects receiving CST (6.08, SD 2.27) would confidently recommend treatment to a friend than those receiving LSSM (4.69, SD 2.49).

CONCLUSIONS: Although LSSM did not achieve a comparable level of credibility and expectancy to the CST, several design and implementation factors may have