

Conclusion: This study demonstrates that with visual feedback DCs can successfully deliver prescribed traction forces while treating neck pain patients enabling the capability to conduct force-based dose-response clinical studies.

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P02.29

Massage Effectiveness for Primary Care Patients with Chronic Low Back Pain and Below Normal SF-36v2 Mental Health Scores: Secondary Analysis

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Purpose: The challenging condition of chronic low back pain (CLBP) is often complicated by negative mental health factors. Non-pharmacological approaches to address CLBP alone and in combination with mental health issues are needed. A recently completed NIH funded study examined the effectiveness of clinical massage therapy (CMT) on functional health outcomes for CLBP patients referred to CMT by their PCP regardless of mental health status save psychosis. CMT was found to have significant and clinically meaningful effectiveness for patients (N=85) in the primary outcomes: Oswestry Disability Index, SF-36v2 mental and physical components and pain domain (in review). The purpose this study's secondary analysis is to determine the extent to which participants that began the study below normal in the SF-36v2 mental health component had clinically meaningful change.

Methods: CLBP patients referred by their PCP were assigned to community massage practitioners (CMPs) to receive up to ten, 1-hour CMT sessions over 12-weeks. Individual treatment plans were formulated by study CMPs. Secondary data analyses were conducted examining a subpopulation (n=41) of those beginning the study at below normal (<45) for the SF-36v2 mental health component score.

Results: Mean change for those <norMHC was 8.4 (± 7.6) vs. -1.9 (± 6.6) for the SF-36v2 mental health component score ($p < 0.0001$). 70% (vs. 19%) achieved clinically meaningful improvement (≥ 4.6 change) in the SF-36v2 mental health component score ($p < 0.0001$). Furthermore, 48% of <norMHC, transitioned from below to at or above normal post-intervention. The relationship of mental health scores with other outcomes will be discussed.

Conclusion: While primary study results indicate significant and clinically meaningful outcome for CMT, these secondary analyses suggest striking CMT effectiveness for CLBP patients with below normal mental health component assessments, particularly in regards to their mental health. Stakeholders should consider/utilize CMT as an effective intervention for CLBP patients, particularly those with below normal mental health assessments.

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P02.30

Development and Validation of Instruments to Evaluate Adverse Events After Spinal Manipulation Therapy

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Purpose: Although spinal manipulation therapy (SMT) is used throughout the world, there are no systematic data collection mechanisms in place to monitor and assess adverse events (AE) after SMT. SafetyNet, a multidisciplinary research team, has established a reporting and learning system to fill this void.

Methods: Development and validation occurred in a step-wise fashion: 1) definition of relevant terms (adverse event, seriousness, causality/relatedness, preventability, patient disposition); 2) identification and development of key domains, items, and sub-items (to assess the relationship between exposure and outcome and to be feasible to complete); and 3) assessment of relevant measurement properties (content validity, hypotheses testing, internal consistency, structural validity, cross-cultural validity, criterion validity, responsiveness).

Results: Two provider short forms, a provider long form, and a patient comment form were developed, refined, and pilot tested with 12 providers and 300 patients. Given that terminology differs amongst SMT professions, two provider forms were designed to be profession-specific. The provider long form is designed to be completed for all moderate, serious, or severe patient reported AEs. These forms contain mostly text boxes to allow for narrative descriptions. The patient comment form is two-sided and designed to collect information on satisfaction and potential AEs after the SMT visit from the patient perspective. Pilot testing refined the forms to versions which providers and patients found reasonable to complete, as well as collected necessary information to assess AEs according to the relevant terms.

Conclusion: The development and validation of instruments to evaluate SMT AEs may benefit the SMT research community as well as clinicians and their patients by providing the opportunity for rigorous prospective assessment of potential SMT-related AEs and their risk factors, thus enhancing patient safety and promotion of a safety culture. Placing the instruments in providers' offices for use on consecutive patients is next on the SafetyNet research agenda.

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Influence of the Amount and Duration of Therapeutic Massage for Chronic Neck Pain on 12 and 26 Week Outcomes of Pain and Function

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Purpose: Determine optimal dose (number, frequency, and duration of sessions) of massage for persons with chronic neck pain for use in future effectiveness trials.

Methods: Two-phase randomized trial for persons with chronic non-specific neck pain. Primary randomization of 191 participants to one of 5 groups receiving 4 weeks of massage (30 minutes 2x/ or 3x/week or 60 minutes 1x, 2x, or 3x/week). Secondary randomization occurred 5 weeks after ini-