Official Title:

Efficacy of Chiropractic Spinal Manipulative Therapy in Patients With Primary Chronic Low Back Pain: a Mechanistic Randomized Controlled Trial

NCT number: Not Available

Unique Protocol ID: SMTCLBP

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Statistical analyses

The normal distribution of the data will be verified using the Kolmogorov-Smirnov test. Data deviating from normality will be transformed to obtain a normal distribution before being entered into the data analysis. The two main outcome variables (clinical pain intensity and disability related to low back pain) will be compared between groups (SMT vs. placebo) over time (baseline and session 12) using a mixed analysis of variance. Average pain intensity since the previous treatment visit and in the seven days prior to the initial visit will be the variable used for statistical analyses. With an exploratory objective, the secondary variables (PCS, CSI, BDI-II, GAD scores, PPTs, degree of pain widespreadness, urinary cytokine levels, number and severity of reported adverse effects, presence of leg pain, pain medication use) will be compared between groups (SMT vs placebo) over time (baseline and session 12) using another mixed analysis of variance. To test a priori hypotheses, significant effects will be decomposed using planned comparisons. For the rest of the effects, Tukey's HSD will be used for testing any pair-wise comparisons between group means.

Pearson's product-moment correlation analyses will be carried out to examine the association between primary variables and secondary variables that demonstrate significant effects between groups over time. Subsequently, two multiple regression models will be used to examine the predictors of improvement in clinical pain and disability over time in patients who have received SMT, using secondary variables with a significant association with the primary variables. The secondary variables used for this analysis will be: baseline PCS and CSI score, baseline PPTs in the primary pain region, baseline TNF-α levels, and baseline expectations of pain relief. In addition, in another

regression model, the changes (delta) in these variables (except expectations of pain relief, sinxce is only measured at baseline) throughout the 4 weeks of treatment will be used as predictor variables. This is done to identify the variables most associated with clinical evolution, in order to answer the mechanistic question.

In order to interpret the values obtained in patient groups, they will be compared with reference values obtained from the healthy controls to both CLBP groups. This will allow characterizing the patient groups to determine whether the show increased psychological symptoms, increased pain sensitivity and hyperalgesia as well as increased TNF-alpha levels compared with a reference healthy population. In order to do this, a series of mixed analyses of variance will be performed to examine differences in PPTs, urinary TNF-α levels, PCS, CSI, BDI-II and GAD scores before and after treatment between the three groups (control, SMT and placebo). To test a priori hypotheses, significant effects will be decomposed using planned comparisons. For the rest of the effects, Tukey's HSD will be used for testing any pair-wise comparisons between group means.