Official Title of the study:
The METRIC Study Protocol: an Explanatory Randomized Controlled Trial Investigating the Neurophysiological Mechanisms Underlying the Therapeutic Effects of Spinal Manipulative Therapy for Chronic Primary Low Back Pain

NCT number:
not currently available

Document type:
Statistical Analysis Plan (SAP)

Date of the document:
July 25, 2023

Statistical Analysis Plan

Statistical analysis will be performed by a researcher blind to group allocation (MP). Data will be analyzed using R Studio and packages (Mair & Wilcox, 2020). Descriptive statistics will be reported for all outcome variables.

All results will be expressed as mean ± SD and statistical threshold set at $p<0.05$. Normality will be assessed visually and with the Kolmogorov–Smirnov test. Homogeneity of variance will be assessed using Levene's test and sphericity with the Mauchly's test. Robust statistics will be used for all tests (Mair & Wilcox, 2020).

PRIMARY ANALYSIS

Primary and most secondary outcomes will be analyzed using 3 × 3 mixed ANOVAs, including 3 groups (3 interventions) and 3 time points (baseline, week 4 and week 12). When secondary outcomes are compared between the four groups, 4 × 3 mixed ANOVAs will be used. Significant effects will be decomposed using Tuckey HSD tests. To examine if nociplastic pain processes and other related factors may moderate or contribute to the effects of spinal manipulative therapy on primary outcomes, each secondary outcome will be entered separately as a covariate in a general linear model with the variables described above.

MISSING DATA

Missing data and their causes will be recorded and reported separately for each arm of the study. The intention-to-treat approach will be used for the primary analysis. Maximum likelihood methods will be used to handle missing data. A secondary analysis of the data will be performed using a per-protocol approach. Finally, a sensitivity analysis will be performed to assess the robustness of the conclusions.

REFERENCE

Mair, P., & Wilcox, R. (2020). Robust statistical methods in R using the WRS2 package. *Behav Res Methods*, *52*(2), 464-488. https://doi.org/10.3758/s13428-019-01246-w