

# **Study Protocol with Statistical Analysis Plan**

The effect of additional neurodynamic intervention  
in patients with chronic ankle instability

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**Background:** Chronic ankle instability (CAI) is characterized by pain, repeated sprains and giving way. Approximately 40% of acute ankle sprain would develop into chronic ankle instability. Recently, the pathomechanical impairment, sensory-perceptual impairment and motor-behavioral impairment have been documented in the chronic ankle instability model. Previous research revealed that compared to the control subjects, people with CAI had lower pressure pain threshold (PPT). This increased mechanosensitivity of the neural tissues around the ankle might account for pain and dysfunction in people with CAI. Pahor et al., indicated that in subjects following ankle inversion sprain there is greater restriction of knee extension on the injured side compared to non-injured side in the slump test with the ankle plantar flexion and inversion, which may suggest the restriction in mobility of the common peroneal tract. However, the effects of neurodynamic intervention, which addresses the mechanosensitivity problems, in people with CAI are still unclear. **Purpose:** The aim of the study is to investigate the effects of neurodynamic intervention on the mechanosensitivity, balance performance and self-reported function in patients with CAI. **Study design:** A randomized controlled trial design. Single-blinded. **Methods:** Forty subjects between 20-50 with CAI were recruited and randomized into either the exercise only group or the neurodynamic intervention with exercise (neurodynamic) group. The sample size was calculated based on the PPT data of Lorenzo-Sanchez-

Aguilera et al's, which requires 20 subjects in each group to reach a statistical power of 0.8. Both groups were receive 12 interventions within 6-8 weeks. The exercise only group performed balance training, while the neurodynamic group received balance training and neurodynamic intervention for the common peroneal nerve. Outcome measures included demographic data, pressure pain threshold, active knee extension range of motion (ROM) of the slump test with ankle plantarflexion and inversion (AKEOST), hamstrings flexibility, ankle range of motion, Y balance test and foot and ankle ability measure (FAAM). All data were assessed and collected before and after 12 interventions. **Statistics analysis:** Two-way repeated measures analysis of variance (ANOVA) was used to examine the intervention effect with the alpha level set at 0.05.

