Title: ELECTRICAL STIMULATION AS AN ADJUNCTIVE THERAPY TO ACCELERATE WOUND HEALING IN PEOPLE WITH PERIPHERAL ARTERIAL DISEASE AND PLANTAR ULCERS ¿ A RANDOMIZED CONTROLLED TRIAL

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Statistical analysis plan
Continuous data were reported with mean ± standard deviation (SD). Categorical data were presented as count (%). Shapiro-Wilk test was conducted to identify the normal distribution of continuous variables. One-way ANOVA for normally distributed variables or Mann-Whitney U test for non-normally distributed variables was used to estimate differences of mean between control and intervention groups. χ2 test was used to determine significant level between the groups for categorical variables. The effect size was measured using OR and 95% CI for categorical variables, and Cohen's d to discriminate the difference of primary and secondary outcomes between groups. Outcome changes were assessed over time compared to BL within (ie, time effect) and between (ie, time×group effect) groups using linear mixed model for normally distributed outcome and generalized estimating equations for non-normally distributed outcome with adjustment for potential confounders. Least significant difference method was used for multiple pairwise comparisons. Pearson and Spearman correlation analysis were performed to assess the relationship between wound or demographics/clinical characteristics, and vascular outcomes. The level of statistical significance was set at $P < .050$. To detect changes in perfusion in individuals with marked limb ischemia, a sub-analysis of patients with moderate to severe peripheral arterial disease (PAD) (ABI < 0.8 or > 1.4 at BL)24 was performed. To detect associated risk comorbidities influencing wound healing in those healers (defined as ≥50% of area reduction)25 vs non healers under E-stim, a sub-analysis in the IG was also performed.