Research Title: Effect of Tele-rehabilitation on Nonspecific Chronic Low Back Pain in the Black Population: A Randomized Controlled Trial

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Statistical Analysis Plan

The sample size calculation was based on a previous study [1] where the minimum clinically important difference in subjects was estimated to be at least 2 points on the Numeric Pain Rating Scale (NPRS) [2,3]. In this study, the sample size was calculated using the G*Power 3.1.9 [4] program, with an estimated standard deviation of 1.08, a large effect size (0.8) [5], a statistical power of 95% (probability of type 1 error β) and α of 0.05. The study will require 84 participants. However, an additional 20% of participants will be added for possible sample loss, totaling 102 participants.

All dropouts during the study will be monitored, and the respective reasons for withdrawal will be recorded. All randomized participants will be included in the analysis regardless of whether they complete the intervention or not (where we will use intention-to-treat principles).

A descriptive statistic will be used to present the sociodemographic data and clinical characteristics of the participants. The Kolmogorov-Smirnov test will be utilized to test the normality of the data. For continuous variables with normal distribution (parametric), they will be presented as means and standard deviations, and for non-normal distribution (non-parametric), they will be presented as medians and interquartile ranges. Inferential statistical analysis will be conducted according to the intention-to-treat principle.

An analysis of variance (ANOVA) will be used to examine the effect of treatment, time (pre and post-treatment, 3 and 6 months follow-up), and the interaction between groups (GAG and CG) versus time. If differences between groups are identified, Tukey's multiple comparison test will be performed. For parametric data, paired t-test will be used for within-group comparisons (comparing baseline with follow-ups). The non-parametric statistical test, Wilcoxon's t-test, will be used if the data are not normally distributed. All statistical analyses will be performed using SPSS (IBM Co, Armonk, New York, USA) for Windows, V.19.0. The confidence interval will be set at 95%, and the significance

level will be defined at 5%. Additionally, to verify the magnitude of differences between interventions, the effect size (Cohen's d) will be calculated [7].

Generalized Estimating Equation models, specifically with a first-order autoregressive structure, will be used to assess the differential change in the primary outcome variable (pain intensity) and secondary outcome variables (functional capacity, quality of life, trait-state anxiety, belief, and fear avoidance) between the 2 groups at 3 and 6 months compared to baseline for both outcomes. Completers and non-completers will be compared to check for differences in sociodemographic and clinical characteristics.

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