Study Protocol Cover Page

Official Title of the Study : Effects of Craniosacral Therapy in Primary Caregivers of Individuals With Special Needs

NCT Number:

Title: Study Protocol

Document Date: January 20, 2026

Sponsor / Institution: Istanbul Rumeli University

Confidentiality Statement: This document contains confidential information. Participants' names or personal identifiers are not included.

Brief Description: This study aims to evaluate the effects of craniosacral therapy on pain, body awareness, depression, and quality of life in primary caregivers of individuals with special needs.Primary caregivers often experience physical and psychological burden due to long-term caregiving responsibilities. Craniosacral therapy is a non-pharmacological, manual therapy approach that may help reduce pain, improve body awareness, and support overall well-being.In this study, eligible primary caregivers will be assigned to either a craniosacral therapy group or a control group. The intervention group will receive craniosacral therapy sessions, while the control group will receive no therapeutic intervention during the study period. Outcome measures related to pain, body awareness, depression, and quality of life will be assessed before and after the intervention.The results of this study may contribute to a better understanding of the potential benefits of craniosacral therapy for improving the physical and psychosocial health of primary caregivers of individuals with special needs.

Statistical Cover Page

Document Title: Statistical Analysis Plan

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Brief Description: Statistical analyses will be conducted using appropriate statistical software (SPSS). Continuous variables will be summarized as mean ± standard deviation or median (interquartile range), and categorical variables as frequencies and percentages. Normality will be assessed using the Shapiro–Wilk test. Statistical significance will be set at $p < 0.05$ (two-sided).

Baseline characteristics of the intervention and control groups will be compared descriptively using independent samples t-tests or Mann–Whitney U tests for continuous variables and chi-square tests for categorical variables.

Primary outcomes (pain intensity, body awareness, depression, and quality of life) will be analyzed by evaluating within-group changes from baseline to post-intervention using paired t-tests or Wilcoxon signed-rank tests. Between-group differences in change scores will be analyzed using independent samples t-tests or Mann–Whitney U tests.