

Cover Page for Statical Analysis Plan

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NCT Number:	Not yet
Official Title of Study:	Effects of Carbohydrate Counting Training Versus Standard Nutritional and Medical Therapy on Glycemic Control and Sarcopenia in Type 2 Diabetes: A Randomized Controlled Trial
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Statistical Analysis Plan

Sample Size, Randomization and Formation of Groups

A power analysis was conducted to determine the number of participants to be included in the study. In order to exceed the 80% power level, it was determined that the study should be conducted with 50 individuals (25 participants in the training and 25 participants in the control group), at a significance level was set at 5% with an effect size of 0.518 ($df=41$; $t=1.683$) [1].

Statistical Analyses

The statistical analysis of the data obtained from the study was evaluated using the IBM SPSS Statistics (version 22.0) package program. In order to evaluate the suitability of the data for normal distribution, One-Sample Kolmogorov-Smirnov test was conducted and kurtosis and skewness of the data was evaluated. Independent sample t-test was used to compare two independent groups among with normal distribution, dependent sample t-test and mixed design ANOVA were used to compare repeated measurements between two independent groups. All data have been provided with mean \pm standard deviation (mean \pm SD). Mann-Whitney U test was used to compare data not showing normal distribution, and Wilcoxon test and Friedman test were used for repeated measurements between two groups. Categorical variables were compared using chi-square test and Fisher's exact chi-square test, and these data were shown with frequency (n, %) values. The significance level between the data was accepted as $p=0.05$. The graphical representations of the data were evaluated using the GraphPad Prism (version 9.3.0) package program.

Reference

1. Christensen MB, Serifovski N, Herz AMH, Schmidt S, Hommel E, Raimond L, et al.
Efficacy of Bolus Calculation and Advanced Carbohydrate Counting in Type 2 Diabetes:
A Randomized Clinical Trial. *Diabetes Technol Ther.* 2021;23(2):95-103.