STATISTICAL ANALYSIS

Frequencies and percentages, as well as descriptive statistics, were reported for variables consisting of anthropometric, dietary, and metabolic-biochemical characteristics. For quantitative variables, the Shapiro Wilk test was used to establish the normality of the distribution.

To determine the difference in the controlled attenuation parameter, as determined by hepatic elastography, at baseline and after 12 weeks of treatment with flaxseed compared to the control group, a paired T-test or Wilcoxon signed-rank test was used for the before-and-after measurements, according to the variable distribution. An independent samples T-test or Mann-Whitney U test was used to establish the differences between the groups.

To establish whether there is a difference in anthropometric, dietary, metabolic, and biochemical values at baseline, 6, and 12 weeks of flaxseed treatment compared to the control group, repeated measures ANOVA or Friedman's test was used for quantitative variables. For qualitative variables, a chi-squared test or Fisher's exact test was used, depending on the variable frequency. Statistical significance was considered at a p-value of **The IBM SPSS Statistics 31 software package and R Software were used**. In the event that a patient drops out of the study, this will be reported, and the data will be analyzed by intention-to-treat.

Sample size

The sample size was calculated using the OpenEpi calculator, based on the findings of Yari et al. (1), who analyzed the efficacy of flaxseed on non-alcoholic fatty liver disease (the previous nomenclature for metabolic associated steatotic liver disease). They reported that the Steatosis Score after the intervention was 288.73 ± 50.06 in the control group and 259.62 ± 38.48 in the flaxseed intervention group, representing a difference of 29.11. Using a two-sided alpha of 0.05 and a power of 80%, a sample size of 37 patients per group was obtained. Considering a 10% dropout rate, this was increased to 41 patients per group, for a total of **82** patients.

1. Yari Z, Cheraghpour M, Alavian SM, Hedayati M, Eini-Zinab H, Hekmatdoost A. The efficacy offlaxseed and hesperidin on non-alcoholic fatty liver disease: an open-labeled randomized controlled trial. Eur J Clin Nutr. 2021;75(1):99-111.