

- **Document Date:** August 1, 2025 (Placeholder – replace with actual date of last protocol/SAP update or approval, e.g., ethics committee approval date)
  - **Month:** August
  - **Day:** 1
  - **Year:** 2025
- **Document Type:** Study Protocol with Statistical Analysis Plan

- **Description:**

The Study Protocol with Statistical Analysis Plan (SAP) describes the randomized controlled trial conducted at Van University Hospital, Turkey, from February to August 2025. The protocol includes:

- **Study Design:** Parallel group, pre-test/post-test randomized controlled trial with 171 caregivers (80 intervention, 91 control).
- **Objectives:** To evaluate the effect of a structured educational intervention on caregivers' psychological well-being, Mediterranean diet adherence, and family health.
- **Intervention:** 30–45-minute education sessions delivered to 4–5 participants by a certified practitioner, covering self-efficacy, stress management, healthy lifestyle behaviors, and nutrition.
- **Data Collection:** Measurements at baseline (t0), post-intervention (t1), and 6 weeks post-intervention (t2) using validated scales.
- **Statistical Analysis Plan:** Data analyzed using SPSS-25 with ki-kare tests, dependent t-tests, Pearson correlation, and Cohen's d effect size. Normality assessed via skewness/kurtosis. Significance set at  $p < 0.05$ .
- **Ethical Considerations:** Approved by X University Health Sciences Research and Publication Ethics Committee, compliant with the Helsinki Declaration. The document is in English, PDF/A format, with a cover page including the official title ("Effect of Education Provided to Relatives of Chemotherapy Patients on Family Health, Nutrition, and Psychological Well-Being"), Ethical approval was obtained from the Scientific Research and Publication Ethics

Committee of a university (approval number: 182158, approval date: 10/02/2025). Institutional approval was then obtained from the hospital where the research was conducted. As the protection of individual rights was necessary in the research, the Helsinki Declaration of Human Rights was adhered to throughout the study. No participant names are included.