10.04.2026

RESEARCH PROTOCOL

Official Title:

THE EFFECT OF A PATIENT EDUCATION PROGRAM ON VITAMIN D LEVELS AND HEALTH BELIEFS REGARDING VITAMIN D USE

Brief Title:

'The effect of a patient education program on vitamin D levels and health beliefs regarding vitamin D use'

Principal Investigator: Asst. Prof. Özge ÜÇÜNCÜ KTU Faculty of Medicine, Department of Internal Medicine, Division of Endocrinology and Metabolism

Research Team:

- Prof. Dr. Mustafa KOÇAK (Methodology & Coordination)
- Asst. Prof. Özge ÜÇÜNCÜ (Methodology & Writing)
- Asst. Prof. Mefküre DURMUŞ (Methodology & Data Analysis)
- Res. Asst. Pharm. Sena USTAÖMER (Methodology & Data Collection)

Institutions:

- Karadeniz Technical University (KTU) Faculty of Medicine
- Karadeniz Technical University (KTU) Faculty of Pharmacy

Date of Protocol: April 2026

Study Status: Academic Research / Prospective

- **NCT Number:** Not yet.
- **Protocol Number:** [2025/257]
- **Ethics Committee Approval Number:** [2025/257]
- **Ethics Committee Name:** Karadeniz Technical University, Faculty of Medicine, Scientific Research Ethics Committee

1. General Description of the Research/Thesis

1. a. Title of the Research/Thesis: The Effect of a Patient Education Program on Vitamin D Levels and Health Beliefs Regarding Vitamin D Use

1. b. Principal Investigator: Asst. Prof. Özge ÜÇÜNCÜ

1. c. Research Team:

1. Prof. Dr. Mustafa KOÇAK / KTU Faculty of Medicine / Dept. of Internal Medicine / Division of Endocrinology and Metabolism
2. Asst. Prof. Özge ÜÇÜNCÜ / KTU Faculty of Medicine / Dept. of Internal Medicine / Division of Endocrinology and Metabolism
3. Asst. Prof. Mefküre DURMUŞ / KTU Faculty of Pharmacy / Dept. of Clinical Pharmacy
4. Res. Asst. Pharm. Sena USTAÖMER / KTU Faculty of Pharmacy / Dept. of Clinical Pharmacy

1. d. Nature of the Study:

- **d.1:** Prospective
- **d.2:** Interventional
- **d.3:** Analytical Research (Randomised Controlled Trial)

1. e. Status of the Research: Academic Research

1. f. Multi-center Status: The research is a single-center study

1. g. Informed Consent: Informed Volunteer Consent Form (IVCF) is attached

1. h. Declaration: The study processes will be conducted in accordance with the principles of the Declaration of Helsinki and Good Clinical Practice (GCP) guidelines

1.i. Academic Contributions of the Team:

- Prof. Dr. Mustafa KOÇAK: Methodology, coordination
- Asst. Prof. Özge ÜÇÜNCÜ: Methodology, writing, and proofreading
- Asst. Prof. Mefküre DURMUŞ: Methodology, data analysis, writing, and proofreading
- Res. Asst. Pharm. Sena USTAÖMER: Methodology, data collection, data analysis, writing, and proofreading

2. Technical Information Regarding the Research

2. a. Aim and Hypotheses:

- **Aim:** To evaluate treatment adherence in individuals with Vitamin D levels < 30 ng/mL, identify adherence problems, and determine the role of patient education services in resolving these issues.

- **Hypothesis:** Patient education services increase adherence to Vitamin D treatment and result in a statistically significant difference in achieving the target serum 25(OH) vitamin D range (30-50 ng/mL) at the end of 6 months.

2. b. Scientific Contribution: The study addresses gaps in the literature where patient monitoring services are insufficient and online surveys often lead to selection bias. Unlike traditional methods, this study uses a randomized controlled design, providing structured face-to-face education, informative brochures, and monthly follow-up calls to assess adherence and Vitamin D levels.

2. c. Literature Background: Vitamin D deficiency is a global public health issue affecting nearly 1 billion people. This study builds on findings that pharmacist/health professional counseling can significantly improve patient knowledge scores and increase serum Vitamin D levels (e.g., 7-10 ng/mL increase over 12 weeks).

2. d. Study Location and Permissions: The study will be conducted at the KTU Faculty of Medicine, Division of Endocrinology and Metabolism. Permissions from the Division and the Chief Physician of Farabi Hospital are obtained.

2. e. Methodology:

- **Study Design:** Randomized controlled prospective study.
- **Inclusion Criteria:** Female patients aged 18 and over, Vitamin D levels < 30 ng/mL, providing written consent.
- **Exclusion Criteria:** Males, under 18, those not providing consent, Vitamin D levels > 30 ng/mL, and patients who have undergone gastric bypass or bariatric surgery.
- **Sample Size:** Based on an effect size of 0.25 and 90% power, a minimum of 58 patients (29 per group) will be included, accounting for a 25% dropout rate.
- **Parameters to be Monitored:** Vitamin D Health Belief Scale scores, Serum 25(OH) Vitamin D, PTH, Calcium, Albumin levels, and Medication Possession Ratio (MPR) percentages.
- **Statistical Analysis:** SPSS 23.0 will be used. Normal distributions will be analyzed with Paired t-tests, and non-normal distributions with Wilcoxon signed-rank tests. ANCOVA will be used to evaluate variables like age and MPR on Vitamin D changes.

2. f. Research Schedule:

1. **Ethical Approval:** Sept 2025 - Oct 2025
2. **Patient Enrollment & Initial Scale Application:** Oct 2025 - April 2026
3. **Education Intervention:** Oct 2025 - April 2026
4. **Post-Education Evaluation (Monthly MPR & 6th Month Scale):** April 2026 - Oct 2026
5. **Data Analysis & Finalization:** Oct 2026 - Nov 2026

2. g. Budget: No budget is required for the materials used in the research process.