STUDY PROTOCOL

Official Title: The Effect of Game-Based Education on Treatment Adherence and Anxiety Levels in Type 2 Diabetic Patients Initiated on Insulin Therapy

NCT ID: Not Yet Assigned

Unique Protocol ID: 352-352-10

Document Date: September 25, 2025

Sponsor / Responsible Party: Tınaztepe University

Principal Investigator: Assist. Prof. Gönül Düzgün

1. STUDY SUMMARY

Background

Diabetes mellitus, especially Type 2 Diabetes Mellitus (T2DM), is a growing public health problem worldwide. Individuals newly initiated on insulin therapy often experience increased anxiety and decreased treatment adherence. Game-based educational methods have been shown to improve motivation, reduce anxiety, and enhance learning. This study evaluates the effect of a specially designed board game, "Let's Learn Diabetes," on treatment adherence and anxiety levels.

Objective

To determine whether game-based education improves treatment adherence and reduces anxiety levels in patients with Type 2 Diabetes who have recently started insulin therapy.

Hypotheses

- H1: Game-based diabetes education will significantly improve treatment adherence levels.

- H2: Game-based diabetes education will significantly reduce anxiety levels.

2. STUDY DESIGN

This is a randomized controlled trial (RCT) with pre-test and post-test measures.

- Groups:Intervention group (game-based education) and Control group (traditional education).

- Duration:1 month of active intervention followed by a 1-month follow-up.

- Randomization:Participants will be randomly assigned to either the intervention or control group.

3. STUDY POPULATION

Inclusion Criteria:

- Age between 40-65 years.

- Diagnosed with Type 2 Diabetes for at least 1 year.

- Initiated insulin therapy within the last 3 months.

- No diagnosed mental health disorders.

- Voluntary participation with signed informed consent.

Exclusion Criteria:

- Age below 40 or above 65 years.

- On insulin therapy for more than 3 months.

- Mental or psychological comorbidities.

- Declining to participate or incomplete participation in all four sessions.

Study Site

Uşak Training and Research Hospital Diabetes Education Unit and Diabetes School.

4. SAMPLE SIZE

The sample size was calculated using G*Power 3.1.9.2 at a 95% confidence level, effect size 0.768, and power of 85%.

- Minimum required per group: 32 participants

- Total sample size: 72 participants (36 in each group)

5. STUDY PROCEDURES

Intervention Group:

- Participants will attend four 2-hour game-based education sessions, once per week for 1 month.

- Game sessions will be conducted using the "Let's Learn Diabetes" board game, which includes three difficulty levels.

Control Group:

- Participants will receive traditional diabetes education through lectures and presentations for the same duration.

Follow-up:

- Post-test measurements will be collected one month after completion of the intervention.

6. OUTCOME MEASURES

Primary Outcomes:

1. Anxiety level measured by Beck Anxiety Scale (BAS).

2. Treatment adherence measured by the Patient Compliance Scale for Type 2 Diabetes Mellitus Treatment.

Secondary Outcomes:

- Sub-dimension scores of the treatment adherence scale, including emotional factors, knowledge factors, lifestyle changes, and diet-related factors.

7. DATA COLLECTION

Data will be collected at two time points:

Pre-test: Before the first intervention session.

Post-test: After the final session.

Instruments:

- Beck Anxiety Scale (BAS)

- Patient Compliance Scale for Type 2 Diabetes Mellitus Treatment

8. STATISTICAL ANALYSIS

- Statistical analyses will be conducted using SPSS version 25.0.

- Descriptive statistics: mean, standard deviation, frequency, and percentage.

- Independent t-tests will be used for between-group comparisons.

- Paired t-tests for within-group comparisons.

- Pearson correlation for relationships between anxiety and adherence.

- Significance level set at $p<0.05$.

- Cronbach's alpha will be used to assess the reliability of scales.

9. ETHICS

The study complies with the Declaration of Helsinki. Ethical approval was obtained from the Uşak University Non-Interventional Clinical Research Ethics Committee (Decision Number: 352-352-10). Written informed consent will be obtained from all participants.

10. STUDY TIMELINE

- Recruitment: May 2024 - October 2024

- Intervention: October 2024

- Data Collection: November 2024

- Analysis and Reporting: December 2024 - March 2025

INFORMED CONSENT FORM

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Dear Volunteer / Legal Representative,

You are invited to participate in a study conducted to evaluate the effect of game-based education on treatment adherence and anxiety levels in individuals with Type 2 Diabetes Mellitus who have recently started insulin therapy. Before you decide to participate, it is important that you understand the purpose of the study, the procedures involved, potential benefits, and any possible risks or discomforts. Please read this form carefully and feel free to ask questions.

Participation is completely voluntary . You may refuse to participate or withdraw from the study at any time without any penalty or loss of benefits.

Purpose of the Study

The aim of this study is to examine whether a specially designed game-based education program called "Let's Learn Diabetes" can improve treatment adherence and reduce anxiety levels among Type 2 Diabetes patients who are newly initiated on insulin therapy.

Study Procedures

- The study will take place at the Uşak Training and Research Hospital Diabetes Education Unit and Diabetes School .

- Participants will attend four educational sessions , once per week, each lasting approximately two hours .

- The intervention group will participate in interactive game-based sessions, while the control group will receive standard education through lectures.

- Follow-up measurements will be conducted one month after the final session.

Potential Risks and Discomforts

This study involves only educational interventions. There are no known physical or psychological risks associated with participation.

Potential Benefits

- Participation may improve your diabetes self-management skills and reduce anxiety.

- On a societal level, this research may contribute to the development of innovative educational strategies that reduce diabetes-related healthcare costs.

Confidentiality

Your personal information will remain confidential. All data will be coded and anonymized. In any publication or presentation, your identity will not be disclosed

Rights Regarding Participation

- Your participation is entirely voluntary.

- You may withdraw at any time without affecting your medical care or legal rights.

- If new findings arise during the study that may influence your decision to continue, you will be informed promptly.

Contact Information

For questions or to report any issues, you may contact the research team 24/7:

- Diabetes Education Nurse: Esin Erdem – +90 505 624 8353

- Principal Investigator: Assist. Prof. Gönül Düzgün – +90 544 779 35 97

Consent and Signatures

By signing below, you acknowledge that you have read and understood the information provided, had the opportunity to ask questions, and voluntarily agree to participate in this study.

Role	Name & Surname	Signature	Date
Volunteer / Legal Representative			
Researcher (Diabetes Nurse)			
Witness			

Ethics Approval: This study was approved by the Uşak University Non-Interventional Clinical Research Ethics Committee (Decision Number: 352-352-10).

STATİSTİCAL ANALYSİS PLAN

STATISTICAL ANALYSIS PLAN (SAP)

- Intention-to-Treat (ITT): Includes all randomized participants who completed at least one session.

- Per-Protocol (PP): Includes only participants who completed all four sessions.

DATA MANAGEMENT

- Data will be entered and stored securely with anonymized participant IDs.

- Data quality checks will be performed to identify inconsistencies or missing data.

- Missing data will be handled using listwise deletion for final analyses.

STATISTICAL SOFTWARE

All analyses will be conducted using **SPSS version 25.0**.

DESCRIPTIVE ANALYSIS

- Continuous variables: Mean ± Standard Deviation (SD), Minimum, Maximum.

- Categorical variables: Frequencies and Percentages.

STATISTICAL METHODS

Baseline Comparisons

- Independent samples t-test for continuous baseline characteristics (e.g., age, baseline anxiety).

- Chi-square test for categorical variables (e.g., gender, marital status).

Primary Outcome Analyses

- Within-group analysis: Paired t-test comparing pre-test and post-test scores for anxiety and adherence.

- Between-group analysis: Independent t-test comparing post-test mean differences between intervention and control groups.

Secondary Outcome Analyses

- Pearson correlation to examine relationships between anxiety levels and sub-dimensions of treatment adherence.

- Subgroup analyses by demographic factors (age, gender, education level).

Reliability Testing

- Cronbach’s alpha will be calculated for all scales to ensure internal consistency (>0.70 acceptable).

NORMALITY AND ASSUMPTIONS

- Normality will be assessed using Kurtosis and Skewness statistics.

- Homogeneity of variances will be checked using Levene's test.

- If assumptions are violated, non-parametric equivalents (Mann-Whitney U test, Wilcoxon Signed-Rank test) will be applied.

SIGNIFICANCE LEVEL

- All statistical tests will be two-tailed, with a significance threshold of $p < 0.05$.

HANDLING DROPOUTS

- Participants who miss one or more intervention sessions will be excluded from the Per-Protocol analysis but included in the Intention-to-Treat analysis if they completed pre-test measurements.

REPORTING

- Results will be presented in tables and graphs with exact p-values, 95% confidence intervals, and effect sizes where appropriate.

- CONSORT flow diagram will be included to demonstrate participant flow.

ETHICAL CONSIDERATIONS

The study was approved by the Uşak University Non-Interventional Clinical Research Ethics Committee (Decision Number: 352-352-10). Data privacy will be strictly maintained following the Declaration of Helsinki.

TIMELINE FOR ANALYSIS

- Data Cleaning and Preparation: November 2024

- Statistical Analysis: December 2024

- Final Reporting: January - March 2025