Official Title:

The Effect of a Digital Self-Management Education and Support Program on Self-Management, Glycemic Control, and Distress in Young Adults With Type 2 Diabetes Mellitus

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Study Protocol

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Note: At the time of document preparation and initial submission to ClinicalTrials.gov, an NCT number has not yet been assigned to this study.

5. Detailed Description

Detailed Description:

Type 2 diabetes mellitus (T2DM) is increasingly being diagnosed in young adults, who often face unique psychological, social, and lifestyle challenges that can negatively affect diabetes self-management, glycemic control, and quality of life. Inadequate self-management behaviors, suboptimal glycemic control, and high levels of diabetes-related distress in this age group increase the risk of acute complications and early onset of chronic complications. Evidence-based diabetes self-management education and support (DSMES) is essential to empower individuals with T2DM to manage their condition effectively. However, traditional face-to-face education programs may be limited by accessibility, time constraints, and lack of continuity, particularly for young adults who are working, studying, or living in different locations.

Digital health interventions, including mobile and web-based platforms, provide an opportunity to deliver flexible, interactive, and personalized DSMES. Nurse-led digital interventions can combine clinical expertise with ongoing support, thereby enhancing engagement, adherence, and behavior change. This study has been designed to evaluate the effect of a comprehensive, nurse-led digital DSMES program on self-management, glycemic control, and diabetes distress in young adults with T2DM.

Study Design

This study is a single-center, parallel-group, randomized controlled trial with an intervention group and an active control group. The trial will be conducted at Van Regional Training and Research Hospital, Endocrinology and Metabolism Diseases Outpatient Clinic (Van, Türkiye). A total of 72 participants diagnosed with T2DM, aged between 18 and 45 years, who meet the eligibility criteria and provide informed consent, will be included. The planned study duration is 24 months, including preparation, recruitment, intervention, follow-up, data analysis, and reporting. The intervention period for each participant is 12 weeks.

Participants

Inclusion criteria include: (1) diagnosis of type 2 diabetes mellitus, (2) age 18–45 years, (3) ability to communicate in Turkish, (4) literacy, (5) access to the internet and ability to use a smartphone, tablet, or computer, (6) no severe physical or mental health condition that would prevent participation, and (7) willingness to provide informed consent and participate in digital follow-up.

Exclusion criteria include: (1) presence of advanced diabetic retinopathy with severe visual impairment that prevents use of digital tools, (2) diagnosis of type 1 diabetes or gestational diabetes, (3) refusal to share necessary information for the study, and (4) participation in another structured DSMES program that could interfere with the intervention.

Withdrawal criteria include: (1) participant request to withdraw at any time, (2) inability to complete follow-up assessments, (3) interruption of internet access or digital communication for more than two weeks, (4) failure to start the program within four weeks after enrollment or participation in less than 50% of the planned intervention, (5) initiation of GLP-1 receptor agonist therapy during the study period, and (6) any new health condition deemed by the investigator to make continued participation inappropriate.

Randomization and Blinding

After baseline assessment, participants will be randomized in a 1:1 ratio to the intervention or active control group using stratified block randomization. Stratification will be based on baseline HbA1c levels (6.5–9% and > 9%) to ensure balanced glycemic status across groups. The randomization list will be generated by an independent researcher. Participants will not be explicitly informed of their group allocation (single-blind design); however, due to the nature of the intervention, the research team delivering the DSMES program cannot be blinded.

Intervention Group: Nurse-Led Digital DSMES Program

Participants in the intervention group will receive a 12-week nurse-led digital DSMES program delivered through a dedicated digital platform. The program is structured according to the ADCES7™ self-care behavior framework (healthy coping, healthy eating, being active, monitoring, taking medication, problem solving, and reducing risks). Key components of the program include:

1. Structured Digital Education Modules: Educational content on T2DM pathophysiology, treatment, self-monitoring, nutrition, physical activity, medication adherence, complication prevention, and psychosocial coping strategies, presented in user-friendly language with visual aids.

2. Interactive Self-Monitoring Tools: Digital forms and tracking cards that allow participants to record glycemic values (fasting and postprandial glucose), HbA1c (when available), blood pressure (if applicable), and self-care behaviors related to the ADCES7™ domains. Participants will receive automated reminders to encourage regular data entry.

3. Nurse-Led Individualized Counseling and Support: Regularly scheduled synchronous and asynchronous communications (such as messaging or calls) with a nurse trained in diabetes education. The nurse will review participants' data, provide tailored feedback, reinforce educational messages, support goal-setting and problem solving, and offer motivational encouragement.

4. Digital Support and Chatbot: A chatbot or FAQ component to provide quick answers to common questions about diabetes management, medication use, hypoglycemia management, and lifestyle behaviors, supplementing nurse support.

5. Multidisciplinary Collaboration (as needed): When necessary, participants may be guided to consult their physician, dietitian, or psychologist for issues identified during the digital follow-up. The nurse will facilitate communication and encourage participants to seek appropriate in-person or telehealth services.

Participants in the intervention group will be encouraged to engage with the platform regularly, follow the educational modules according to the suggested schedule, record their data, and communicate with the nurse as needed.

Active Control Group: Standard Digital Education

Participants in the active control group will be provided with access to the standard Type 2 Diabetes Education Brochure prepared by the Turkish Ministry of Health in PDF format via the digital platform. They will also be able to enter their basic glycemic data into the system. However, they will not receive individualized nurse-led digital counseling, structured DSMES modules based on ADCES7™, or chatbot-based interactive support. This design allows comparison of the comprehensive nurse-led digital DSMES program with standard digitally delivered education materials.

Outcome Measures

Primary and secondary outcomes will be assessed at baseline (pre-intervention) and at the end of the 12-week intervention.

Primary Outcomes:

1. Self-Management: Assessed using the Type 2 Diabetes Self-Management Scale, which evaluates key aspects of diabetes self-care behaviors.
2. Glycemic Control: Assessed by HbA1c levels obtained from laboratory records.

Secondary Outcomes:
1. Diabetes Distress: Measured using the Diabetes Distress Scale.
2. Additional Glycemic Parameters: Fasting plasma glucose and postprandial plasma glucose values.
3. Self-Management Behaviors: Assessed using the ADCES7™ Self-Management Behaviors Assessment Form and the Type 2 Diabetes Personal Behavior Goal Tracking Card.
4. Metabolic Parameters: Documented with the Type 2 Diabetes Metabolic Parameter Tracking Form and Metabolic Parameter Goal Tracking Card.
5. Usability and Acceptability of the Digital DSMES Program: Assessed using the Mobile Application Usability Scale (MAUS) among participants in the intervention group.

Ethical Considerations

The study protocol has been reviewed and approved by the Akdeniz University Faculty of Medicine Clinical Research Ethics Committee (Approval No: TBAEK-1079) and by the relevant institutional authorities at Van Regional Training and Research Hospital. All participants will be informed about the purpose, procedures, potential risks, and benefits of

the study and will provide informed consent before enrollment. Participation is voluntary, and participants may withdraw from the study at any time without any impact on their routine medical care.

Data confidentiality and privacy will be strictly protected. Personal data and clinical information will be stored securely and used only for research purposes in accordance with applicable ethical and legal regulations. The study involves a behavioral and educational intervention considered to be low risk. Adverse events related to the intervention are not expected; however, any unexpected problems will be documented and managed according to institutional policies.

Expected Contribution

It is anticipated that the nurse-led digital DSMES program will significantly improve diabetes self-management behaviors, enhance glycemic control, and reduce diabetes-related distress in young adults with T2DM compared with standard digital education alone. The results of this study may provide evidence to support the integration of nurse-led digital DSMES into routine care for young adults with T2DM, contribute to the development of innovative education models in diabetes nursing, and inform health policy and clinical practice regarding the use of digital health technologies in chronic disease management.