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A Mobile Application Designed for Adults at Risk of Developing Diabetes: A Study Protocol for a Randomized Controlled Trial

Diyabet Riski Olan Erişkinlere Yönelik Olarak Mobil Uygulama Geliştirilmesi: Randomize Kontrollü Çalışma Protokolü

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ABSTRACT

Objective: The primary aim of this study is to develop a prediabetes mobile application (PREDIABE-T^{R}) designed in Turkish containing information and advice for individuals at risk of developing diabetes; the secondary aim is to determine whether the use of this application can make a difference in the participants' eating according to the Mediterranean diet plan, or in their physical activity and other diabetes-related metabolic parameters.

Methods: The adults in the experimental group will be using the PREDIABE-T^{R} mobile application for a period of 6 months. The application consists of a pedometer, a diet diary, and sections on diabetes risk, an instructor and a body mass index calculator. Individuals can use the mobile app to contact a public health nurse or academic on a 24/7 basis. Public health nursing can thus perform a consulting role within this framework. Over the same period, the control group will use the Turkish Nutrition Guide and the Diabetes Checklists mobile application distributed by the Turkish Ministry of Health. At the end of the six-month period, a review will be made of the diabetes metabolic data, physical activity levels and the Mediterranean diet eating behaviors.

Results: The benefits of interventions to promote a healthy lifestyle are evident in terms of preventing a transition from prediabetes to diabetes and maintaining present status.

ÖZ

Amaç: Bu çalışmanın birincil amacı diyabet riski olan bireylerde sağlıklı beslenme, fiziksel aktivite yapılması gibi bilgilendirme ve öğütler içeren Türkçe geliştirilmiş bir prediyabet mobil uygulama (PREDIABE-T^{R}) geliştirilmesi, ikincil amacı ise kullanımının katılımcıların Akdeniz tipi beslenme, fiziksel aktivite ve diyabete ilişkin metabolik parametrelerinde değişim yaratıp yaratmayacağını belirlemektir.

Yöntemler: Deney grubunda yer alan erişkinlere 6 ay boyunca PREDIABE-T^{R} mobil uygulaması kullandırılacaktır. Mobil uygulama adımsayar, beslenme takibi, diyabet riski, bilgilendirme ve beden kitle indeksi hesaplama bölümlerinden oluşmaktadır. Bireyler mobil uygulama aracılığıyla 7/24 araştırmacı olan halk sağlığı hemşiresi ve akademisyen ile iletişim kurabilmektedir. Bu çerçevede halk sağlığı hemşireliği danışmanlık rolü yerine getirilebilmektedir. Kontrol grubu ise aynı süreçte Sağlık Bakanlığı'nın Türkiye Beslenme Rehberi ve Diyabet Kontrol Listeleri mobil uygulamasını kullanacaktır. Altı aylık süreç sonunda her iki grubun da diyabet metabolik değerleri, fiziksel aktivite düzeyleri, Akdeniz tipi beslenme davranışları incelenecektir.

Bulgular: Prediyabetik dönemden diyabete geçiş sürecinin engellenmesinde ve mevcut durumun korunmasında sağlıklı yaşam tarzı müdahalelerinin yararlı rolü ortadadır.

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ABSTRACT

Conclusion: This study describes the effect of the use of a mobile application by individuals with prediabetes on metabolic parameters. If reductions can be achieved in metabolic parameters (such as HbA1c), it can be concluded that the mobile app is effective.

Keywords: Mediterranean diet, metabolic variables, mobile application, physical activity, prediabetes

ÖZ

Sonuç: Bu çalışma prediyabetli bireylerde mobil uygulama kullanımının metabolik parametreler üzerine etkisini yansıtmaktadır. Eğer metabolik parametrelerde (A1C gibi) düşme sağlanırsa mobil uygulama etkindir sonucu ortaya çıkacaktır.

Anahtar Sözcükler: Akdeniz tipi beslenme, metabolik değişkenler, mobil uygulama, fiziksel aktivite, prediyabet

Introduction

The "prediabetic" stage that is the interval leading to manifest diabetes from normal glucose metabolism is observed to switch into Type 2 diabetes in 5-10% of individuals each year (1). According to the data of the 10th Edition of the International Diabetes Federation (IDF) Diabetes Atlas, the prevalence of Impaired Glucose Tolerance (IGT) is 541 million (10.6%) while this rate corresponds to 319 million (6.2%) for Impaired Fasting Glucose (IFG). It is expected that these rates will reach 730 million (11.4%) for IGT and 441 million (6.9%) for IFG in 2045. While the incidence of prediabetes increases with age, it is estimated that there will be a pronounced rise in this rate in the next two decades. Projections for 2045 foresee that the prevalence of IFG will increase in all age groups and that in particular, IGT will display a rise in the young adult (<45 years) and older adult (70 years) populations (2). The data of Türkiye's Nutrition and Health Survey for 2017 reveal that the percentage of IFG, defined as fasting serum glucose level of 100-125 mg/dL, is 16.3% among individuals aged 15 and above, and 27.3% among those aged 19 years and above in Türkiye. The prevalence of IFG in individuals aged 15 and above is 15.9% among women and 16.8% among men (3).

There are a number of studies that have been conducted in Türkiye assessing various complications and variables related to prediabetes (4). We found in the accessible resources in the Turkish literature that there are a few studies on mobile applications designed to monitor individuals with diabetes (5), and others that evaluate the effect of such applications (5), but we have not found any research published on a Turkish mobile app for individuals with prediabetes or about the effect of such an app on metabolic variables. The aim of this study is to determine whether participants at risk of diabetes making use of a prediabetes mobile application (PREDIABE-T^{R}) designed in Turkish to inform and advise about healthy eating and physical exercise can record a difference in their implementation of the Mediterranean diet, their engaging in physical activity and in other diabetes-related metabolic parameters.

Hypotheses

Our hypotheses were formulated in line with population – intervention – comparison – outcome - study; significance was set at 0.05 (6). In addition to standard applications, the intervention group will be using the PREDIABE-T^{R} mobile app. The control group will only use standard applications. In this context, our research hypotheses are the following:

H1a: When compared with the control group, the eating behaviors with regard to adopting the Mediterranean diet of prediabetic adults using the PREDIABE-T^{R} app will be at a higher level.

H1b: When compared with the control group, the physical activity (MET, number of steps) of prediabetic adults using the PREDIABE-T^{R} app will be at a higher level.

H1c: When compared with the control group, the metabolic parameters (HbA1c, IFG, IGT) of prediabetic adults using the PREDIABE-T^{R} app will be at lower levels.

H1d: When compared with the control group, prediabetic adults using the PREDIABE-T^{R} app will lose more weight.

Methods

Study Design

This study protocol was drawn up for a single center, single-blind (participant), pretest-posttest, follow-up, parallel group (1:1 ratio) randomized controlled trial (Figure 1). The study protocol was prepared on the basis of the following standard protocol items: Recommendations for Interventional Trials (SPIRIT) guidelines (7) and the Consolidated Standards of Reporting Trials, Non-pharmacological Treatment Interventions Checklist (CONSORT-NPT) (8). The study was registered on ClinicalTrials.gov on NCT05592288.

Study Setting and Population

This study will be carried out at the Yıldırım Beyazıt Family Health Center (FHC) no. 9, a facility in the city of Kütahya, in western Türkiye. No. 9 is an FHC that addresses a large city population and where 5 physicians and 5 midwives work. The target sample will consist of prediabetic adults. The study will be conducted in the FHC between March and June 2024.

Sample Size Determination

The study population will consist of adults of the ages 40-65 who have received a diagnosis of prediabetes and are registered at the Yıldırım Beyazıt FHC no. 9. The sample size determined by

power analysis was based on calculations made with the G*Power program that were used in a similar study. Effect size was 0.666 (9); level of significance, 0.05; confidence interval limit 95%; testing power, 90%. The optimal number of participants calculated in the two-way hypothesis review was found to be 49 for each group. In previous studies (9), the size was increased by 10% to allow for losses. Ultimately, the decision was to enroll 59 participants in each group.

Inclusion Criteria

- Individuals to be included will be those who: are prediabetic (IFG=100-125 mg/dL-mmol/L, HbA1c=5.7-6.4% or IGT=140-199 mg/dL-mmol/L),

- are active Android/IOS cell phone users,

- are not pregnant or have any malignancy,

- have no hearing or vision impairment,

- are at least primary school graduates and fluent in Turkish.

Exclusion Criteria

- Individuals who have a diagnosis of diabetes or are using an insulin pump or oral antidiabetic agents,

- have vision impairment,

- are pregnant,

- have any condition that precludes engaging in physical activity,

- have psychiatric issues or problems with communicating, will be excluded.

Randomization

The stratified block randomization (1:1) will be used to attain objectivity in assigning individuals to the experimental group that will be using the mobile app and to the controls who will be following routine practices (10). The variable "gender" will be used as the control variable in the stratified block randomization (Figure 1).

Blinding and Preventing Bias

The researchers cannot be blinded in this study since they were the parties to develop the application and will be involved in the training. On the other hand, the participants can be blinded because they are to be using either the PREDIABE-T^{R} app or the Türkiye Nutrition Guide. In order to prevent bias, the collection of the randomized assignment data will be handled by a researcher who is not actively involved in the study; this researcher will submit the data in opaque envelopes to the implementing researcher.

Intervention Group

PREDIABE-T^{R} Mobile App Group

Prediabetic individuals 40 years of age and over will be asked to use the PREDIABE-T^{R} mobile app. The researcher will demonstrate how the application can be downloaded to the participants' phones and how to use it. Before the PREDIABE-T^{R} app is sent out to the participants, its content will be reviewed for suitability and content validity by health professionals and experts in health communications, informatics, and social media. The mobile app will be used and the process monitored for a period of 6 months. Each week, healthy eating and physical activity messages will be sent over the mobile app and a daily step count will be announced. Education about prediabetes, the risk of diabetes, the calculation of the body mass index (BMI), as well as other motivating self-evaluation tools and notifications will be sent out via the PREDIAB-T^{R} mobile app. The adherence of the experimental group to the intervention will be assessed in the software and encouraging messages will be sent out to ensure continued use of the app. For example: Bracelets inscribed with "Congrats! You've reached your daily steps goal!" or "Keep Active, Keep Protected from Diabetes!" will be distributed as gifts. If requested, the researcher will come to the FHC one day every week to meet with the participants.

The application consists of a total of 3 parts and 4 modules (Figure 2).

- Module 1: Personal Data

Containing data on the participant's age, gender, telephone number, email and perception of his/her health (bad, so-so, good, very good).

- Module 2: Medical History of the Participant

In this module, the participants tick the items that apply to themselves or their first-degree relatives by marking the conditions in their medical history that may increase the risk of prediabetes. Additionally, in line with the recommendations of the Turkish Association of Endocrinology and Metabolism, this module contains the Finnish Diabetes Type-2 Risk Score (FINDRISK) which assesses an individual's risk of diabetes (11).

- Module 3: Healthy Lifestyle Behaviors

The sub-sections of the module are devoted to nutrition, height-weight-BMI and physical activity.

Nutrition

Users can enter the foods they eat into the application and are informed of the benefit/harm of these foods with a red/green light alert (12). The weight-to-height risk table of the Turkish Diabetes Foundation has been added to the BMI section, where additionally, individuals can automatically calculate their BMI according to the entered. Furthermore, this section will also provide users with 14 recommendations from the Mediterranean Diet Adherence Screener (MEDAS).

Physical Activity

Healthcare providers emphasize at every opportunity the importance of engaging in regular physical activity during the transition from prediabetes to diabetes (13). Physical activity will be followed up with a step-count and a scheduling of the recommended physical activity the participant should engage in during the week. A gold star icon will be sent to app users when they satisfy their physical activity requirement. At the end

of the study, those who have collected 18 or more gold stars will be gifted bracelets inscribed with "Keep Active, Keep Protected from Diabetes!"

- Module 4: Communications

This module will allow users to send direct messages to the researcher, 24/7 for any information they may need.

Notifications

This section contains information based on the guidelines of the IDF, the American Diabetes Association, the Turkish Ministry of Health, Association of Turkish Dieticians, the Turkish Diabetes Foundation, Turkish Diabetes Society, and the Turkish Diabetes Nursing Association on the signs and symptoms of diabetes and prediabetes, diagnosis, treatment, complications, nutrition, physical activity, BMI monitoring and the normal BMI range. The section is designed to inform users about the content of the guidelines and raise awareness and knowledge levels about diabetes.

Safety

This section contains the data and passwords users will use to access the system.

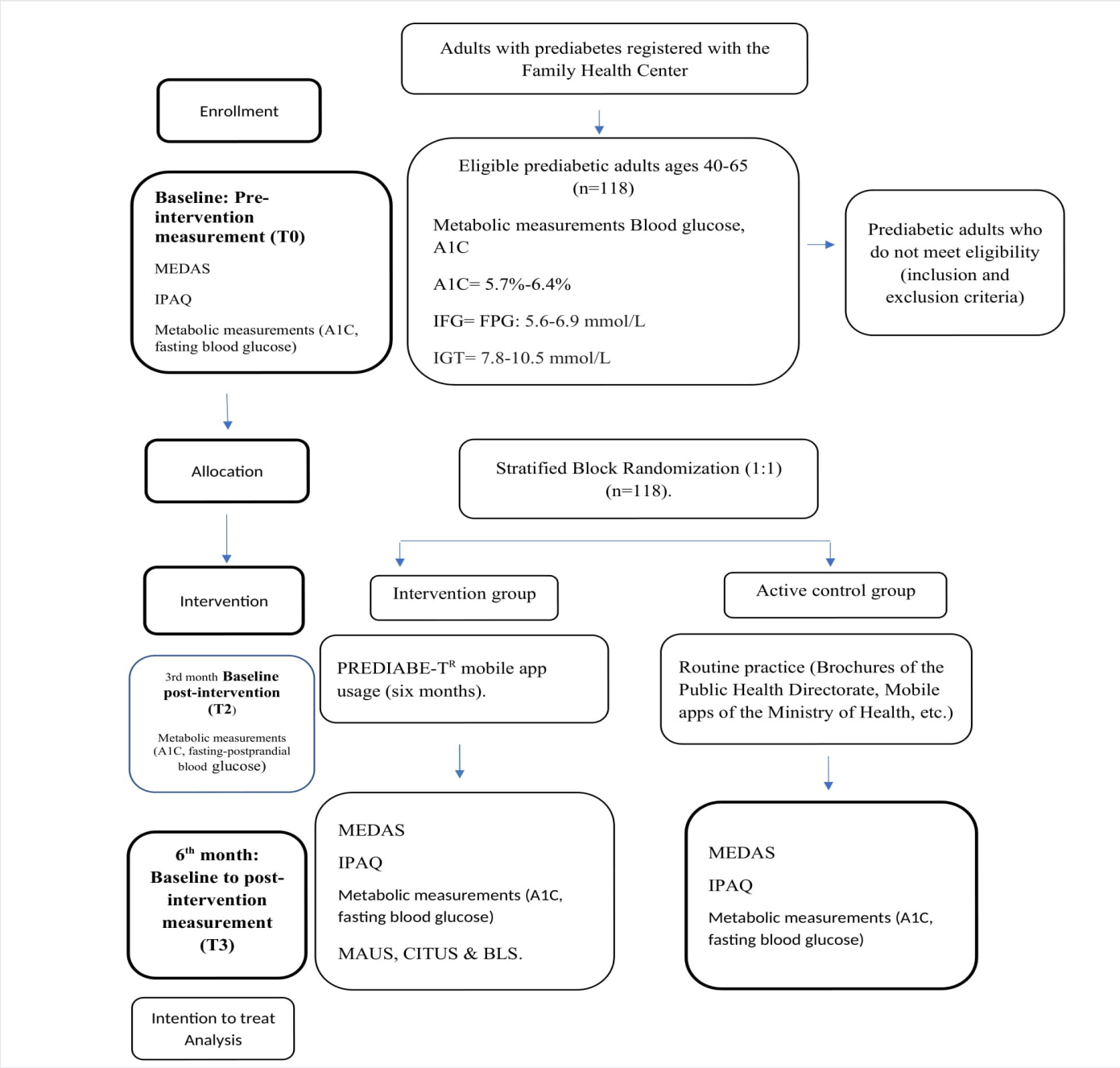

Figure 1. Research flow chart

Figure 2. Prediabetes mobile application draft

Active Control Group

Besides the routine health monitoring of the active controls, this group will be instructed in how to download and use the Ministry of Health's Türkiye Nutrition Guide Mobile Application.

Data Collection

Data will be collected on the individuals' sociodemographic features, gender, age, education, profession and medications they are taking. Their diabetes risk will be measured by means of the FINDRISK. The data collection form will be filled out on the basis of self-reporting. FINDRISK was developed in 1987 by Tuomilehto and Lindström to identify individuals at risk of Type-2 diabetes mellitus without laboratory testing (14). The Turkish validity and reliability study for FINDRISK was performed by Etbaş Demirağ (15) in 2016. The participants' metabolic measurements will be taken by a researcher using the Accu-Chek® Performa Nano device from a capillary blood sample; HbA1c values will be retrieved from FHC records.

Outcome Criteria

The expected primary outcome is a change in the adherence to the Mediterranean diet, physical activity levels and in the prediabetes metabolic values of the adults. The secondary outcome is a change in the adults' ability to achieve weight loss.

Primary Outcome Criterion

Mediterranean Diet Adherence Screener

The Turkish validity and reliability studies for MEDAS, which was originally developed in 2012 by Martínez-González et al. (16), were performed by Pehlivanoglu Ozkan et al. (17) in 2020. MEDAS consists of 14 questions. Each question is scored 1 or 0 points, depending on consumption. A total score of 7 or above indicates that the individual is adhering to the Mediterranean diet at an acceptable rate; a score of 9 or above indicates strict adherence. Cronbach's alpha coefficient for the scale is reported to be 0.829.

International Physical Activity Questionnaire

The International Physical Activity Questionnaire (IPAQ)-Short Form was developed in 1996 by Booth in order to identify the risk factors of inactivity and physical activity levels in prediabetic patients. The Turkish version of the IPAQ-Short Form consisting of 7 questions will be used. The Turkish validity and reliability studies for this questionnaire were conducted by Saglam et al. (18).

Metabolic Measurements

The participants' HbA1c, fasting blood glucose-postprandial blood glucose (whichever is appropriate for the individual) values will be measured.

The HbA1c measurement represents a 3-month mean value (19). The HbA1c testing does not require fasting conditions. The blood sample can be taken at any time of day (20). Over the period of the study, the HbA1c level the participant has obtained from being tested at any health facility will be taken from the personal health system records.

Blood Glucose Measurement: The researcher will measure the participants' blood glucose with a Roche Accu-Chek® Performa Nano device (21). A minimum eight-hour fasting period will be taken as a criterion for fasting blood glucose (22); a postprandial blood glucose test will be administered 2 hours after a meal.

Secondary Outcome Criterion

Height-weight Measurement and Body Mass Index

The researcher will measure the individuals' height and weight with calibrated devices. BMI will be calculated with the formula: Weight (kg)/height (m^2) (23).

Mobile App Usability and Usage Assessment Scale

Three measures developed by Hoehle et al. (24) to assess the usability and usage of a mobile application will be used. The validity and reliability study for the scales was performed by Güler (25).

Mobile Application Usability Scale

This is a measure used to assess and understand how the mobile app can be improved and how it may be made more user-friendly. The scale is a 7-point Likert-type and has a total of 40 items (1= definitely disagree, 7= completely agree). Cronbach's alpha coefficient for the scale is reported as 0.80-0.94 (25).

Continued Intention to Use Scale

This measure was developed to assess how eager individuals are to use the app. It comprises a total of 6 items and is a 7-point Likert-type (1= definitely disagree, 7= completely agree). There are no reversely scored items on the scale. Cronbach's alpha coefficient for the scale is reported as 0.90 (25).

Brand Loyalty Scale

This scale was developed to determine the extent of individuals' loyalty to the mobile app. It comprises a total of 5 items and is a 7-point Likert-type (1= definitely disagree, 7= completely agree). There are no reversely scored items on the scale. Cronbach's alpha coefficient for the scale is reported as 0.86 (25).

Validity-reliability

The study protocol was drawn up based on the SPIRIT (7) and CONSORT-NPT (8) guidelines. Randomization and blinding will reduce bias in the results. The measuring instruments used in this study are valid and reliable (15,17,18,25).

Ethics Statement

Ethical approval for the conduct of the study was obtained from Akdeniz University Faculty of Medicine Clinical Studies Ethics Committee (decision no.: KAEK-192, date: 16.03.2022) and institutional approval from the Kütahya Provincial Health Directorate (no.: 2022/47, date: 30.05.2022). Additionally, the written informed consent of the individuals to be included in the study will be collected. The study was conducted in compliance with the ethical principles of the Declaration of Helsinki.

Statistical Analysis

The data will be analyzed with the SPSS (Statistical Package for the Social Sciences) 23.0 package program licensed by Akdeniz University Faculty of Medicine Department of Biostatistics. The G*Power 3.1 program was used in determining sample size. Intention to Treat analysis will be employed for the analysis of lost data. Descriptive statistics will be defined by means and standard deviation. Numbers, percentage distribution, the chi-square and t-test will be used to identify homogeneous groups. To test normality, skewness and kurtosis values will be taken as a basis for the Shapiro-Wilk test. The one-way ANOVA, two-way ANOVA and ANCOVA tests will be used for dependent and independent groups. Non-parametric equivalents of correlation and regression analyses will be considered in the non-parametric analysis.

Discussion

This study will investigate the efficacy of a mobile application developed under the leadership of public health nursing staff on metabolic factors such as HbA1c and on physical activity and nutrition. Each message sent to the participants via the app will be evaluated on an individual basis. This strategy will have a potential key role in the development of healthy lifestyle applications in the long term. The control group will be asked to use the Diabetes Checklists and the Turkish Nutrition Guide of the Ministry of Health (26,27). The experimental group in the same study will use the PREDIABE-T^{R} mobile app and the metabolic factors, physical activity levels and Mediterranean diet nutritional behaviors of both groups will be compared. This course of action was planned in the light of current studies (28).

In the development stage of the mobile app, it was designed for use within the healthcare system of the Ministry of Health. Furthermore, it is important that the mobile app will be used for a period of six months, which will provide a time frame to determine the shortcomings of the app. Since the mobile app is free of charge, it can be used on a wide scale by nurses (28). The app can also be considered a facilitating alternative to face-to-face examinations, consultations, and follow-ups over the course of the current pandemic. It therefore opens the door to early diagnosis for individuals with prediabetes (29). The research is a randomized study of experimental design. The evidential level of the results to be obtained will be high. The developed mobile app will consequently offer individuals with prediabetes, socially disadvantaged groups, and health personnel an instrument that can be conveniently and safely employed. At the end of the study, this mobile application will be integrated into the Google Play Store database.

Study Limitations

The limitations of the study include the inclusion of individuals aged 40-65 years, prediabetic, using only Android mobile phones, without visual and hearing problems, with a minimum primary education level, who came to Kütahya City Center Family Health Center No. 9, the technical features of the mobile application, and the limitation of monitoring individuals for six months.

Conclusion

This study describes the effect of the use of a mobile application by individuals with prediabetes on metabolic parameters. If reductions can be achieved in metabolic parameters (such as HbA1c), it can be concluded that the mobile app is effective. In this context, information about this application will be sent out to administrators and policy-makers to ensure that more people make use of the app, thereby supporting communities in protecting and improving public health. This study is the first to elaborate on the role of public health nurses in prediabetes and preventive health.

Ethics

Ethics Committee Approval: Ethical approval for the conduct of the study was obtained from Akdeniz University Faculty of Medicine Clinical Studies Ethics Committee (decision no.: KAEK-192, date: 16.03.2022).

Informed Consent: Written informed consent was obtained from the individuals to be included in the study.

Footnotes

Authorship Contributions

Concept: İ.T., S.G., Design: İ.T., S.G., Data Collection or Processing: İ.T., S.G., Analysis or Interpretation: İ.T., S.G., Literature Search: İ.T., Writing: İ.T.

Conflict of Interest: No conflict of interest was declared by the authors.

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