The Impact of a Mobile Application Designed for Adults at Risk of Developing Diabetes on Following the Mediterranean Diet Plan, Physical Activity and Metabolic Parameters: a Study Protocol for a Randomized Controlled Trial

Abstract

Aim: The aim of this study is to determine whether a prediabetes mobile application (PREDIABE-T^{R}) designed in Turkish to inform and advise individuals at risk of developing diabetes about healthy eating and physical exercise 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: A total of 120 adults at risk of developing diabetes will be assigned into an experimental and a control group by means of Stratified Permuted Block Randomization. The adults in the experimental group will be using the PREDIABE-T^{R} mobile application for a period of 6 months. 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. At the same time, an assessment will be made of the control group's use of the mobile application with the help of the Mobile Application Usability Scale (MAUS)**.** Statistical data will be analyzed using the SPSS program.

Discussion: 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. The current novel coronavirus (Covid-19) pandemic has clearly shown the advantages of and necessity for remote interventions. In this study, we will attempt to determine whether or not the use of the PREDIABE-T^{R} mobile application can promote a healthy lifestyle and achieve a reduced risk of diabetes.

Impact: This study will serve to provide evidence of the practicality, acceptability and cost effectiveness of various applications (such as mobile apps) that can be an alternative to face-to-face consultation and other medical practices. This alternative can be suggested to policy- and decision-makers. Such applications can also be considered preventive strategies.

Trial Registration: (ClinicalTrials.gov identifier).

Protocol version:

Keywords: Diabetes risk, prediabetes, mobile application, physical activity, Mediterranean Diet, metabolic variables.

INTRODUCTION

The "prediabetic" stage that is the interval leading to manifest diabetes from normal glucose metabolism is observed to transition into Type 2 diabetes in 5%-10% of individuals each year (Tabak et al., 2012; Turkish Ministry of Health, Türkiye Diabetes Program 2015-2020). It was reported in the United States that there were over 88 million people with prediabetes in 2020. This means that one out of every three Americans has prediabetes. More importantly, eight out of every ten adults are unaware that they have prediabetes (Centers for Diseases Control and Prevention-CDC, 2020). The frequency of prediabetes is reported in the "Turkish Survey on the Epidemiology of Diabetes" (TURDEP-II-2010) as 28.7% (Turkish Ministry of Health, Türkiye Diabetes Program 2015-2020). It can be seen in Türkiye that in the past 12 years, there has been an increase of 106% in prediabetes when compared with the TURDEP-I report (Satman et al., 2013). According to TURDEP data, three out of every 10 adults have prediabetes and over time, there continues to be a remarkable progressive increase in the number of individuals with the condition.

There are a number of studies that have been conducted in Türkiye assessing various complications and variables related to prediabetes (Avishovi, 2019; Demirel, 2019). 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 (Kılıç, 2018; Orhan, 2018; Timurtaş, 2019), and others that evaluate the effect of such applications (Kılıç, 2018; Orhan, 2018), 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 PICOS (Population-Intervention-Comparison-Outcome-Study); significance was set at 0.05 (Higgins et al., 2019). 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 (A1C, Impaired Fasting Glucose-IFG, Impaired Glucose Tolerance-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 (Fig.1). The study protocol was prepared on the basis of the following Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (Chan et al., 2013) and the Consolidated Standards of Reporting Trials, Non-Pharmacological Treatment Interventions Checklist (CONSORT-NPT) (Boutron et al., 2017). The study was registered on ClinicalTrials.gov on XXX with the ID XXXX.

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 Kutahya, 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 January and July 2023.

Sample size determination

The study universe will consist of adults of the ages 45-65 who have received a diagnosis of prediabetes and are registered at the Kütahya FHC No. 9. The sample size determined by power analysis is based on calculations made with the G-Power program that were used in a similar study. Effect size is 0.666 (Chen et al., 2015, Everett et al., 2018); 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 (Chen et al., 2015; Zhang et al., 2017), the size was increased by 10% to allow for losses. Ultimately, the decision was to enroll 60 participants in each group.

Inclusion criteria

- Individuals to be included will be those who: are prediabetic (Impaired Fasting Glucose-IFG=100-125 mg/dl-mmol/L, A1C=5.7%-6.4% or Impaired Glucose Tolerance-IGT=140-190 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,

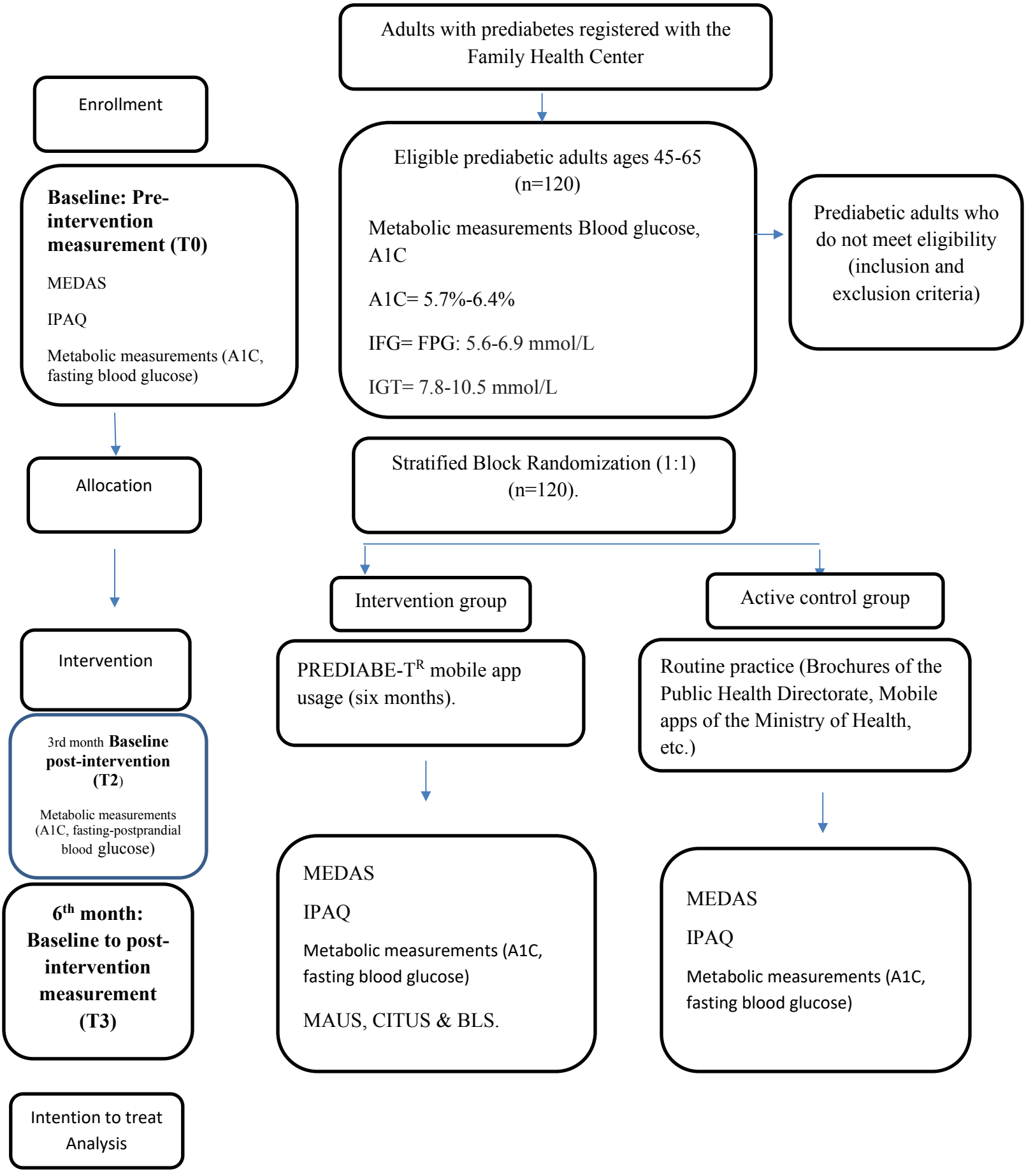
- are pregnant,
- have any condition that precludes engaging in physical activity,
- have psychiatric issues or problems with communicating, will be excluded.

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 (Brugnara et al., 2016; Kautzky-Willer et al., 2016; Kautzky-Willer et al., 2019). The variable **"gender"** will be used as the control variable in the stratified block randomization.

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.

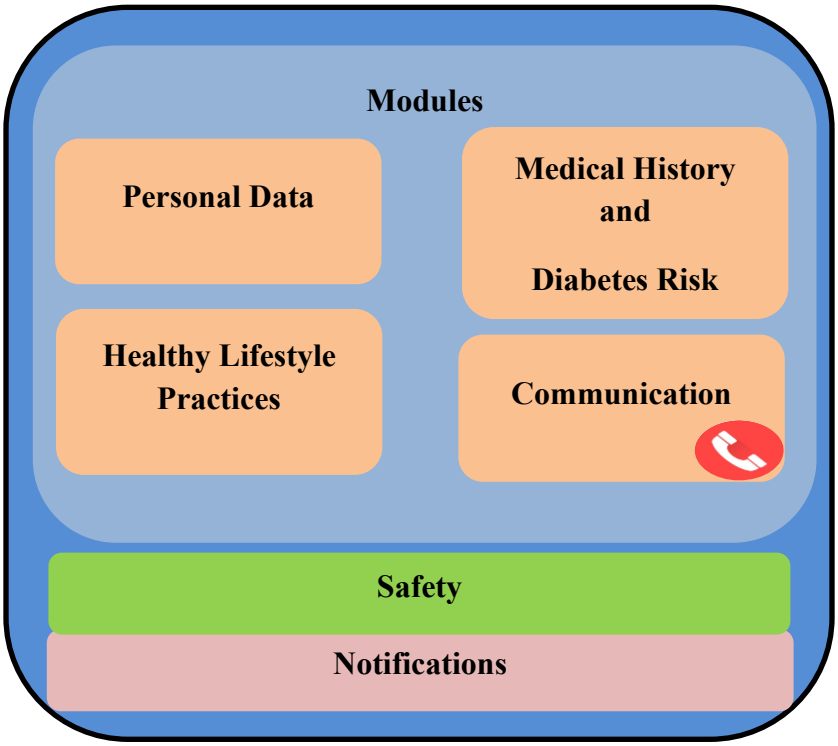

Adults with prediabetes registered with the Family Health Center
Enrollment
Eligible prediabetic adults ages 45-65 (n=120)
Metabolic measurements Blood glucose, A1C
A1C= 5.7%-6.4%
IFG= FPG: 5.6-6.9 mmol/L
IGT= 7.8-10.5 mmol/L
Prediabetic adults who do not meet eligibility (inclusion and exclusion criteria)
Baseline: Pre-intervention measurement (T0)
MEDAS
IPAQ
Metabolic measurements (A1C, fasting blood glucose)
Allocation
Stratified Block Randomization (1:1) (n=120).
Intervention group
Active control group
Intervention
PREDIABE-T^R mobile app usage (six months).
Routine practice (Brochures of the Public Health Directorate, Mobile apps of the Ministry of Health, etc.)
3rd month Baseline post-intervention (T2)
Metabolic measurements (A1C, fasting-postprandial blood glucose)
MEDAS
IPAQ
Metabolic measurements (A1C, fasting blood glucose)
MAUS, CITUS & BLS.
MEDAS
IPAQ
Metabolic measurements (A1C, fasting blood glucose)
6th month: Baseline to post-intervention measurement (T3)
Intention to treat Analysis

Intervention Group

PREDIABE-T^{R} mobile app group

Prediabetic individuals 45 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, 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 (TEMD, 2020).

- **Module 3: Healthy lifestyle behaviors**

  The sub-sections of the module are devoted to nutrition, height-weight-body mass index (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. 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 height and weight data (https://www.turkdiab.org/diyabet-hakkinda-hersey.asp?lang=TR&id=59, Access Date: 9 January 2022). Furthermore, this section will also provide users with 14 recommendations from the Mediterranean Diet Adherence Screener-MEDAS.

  Physical Activity

  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!"

  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 International Diabetes Federation (IDF), the American Diabetes Association (ADA), 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.

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.

Brochures of the Public Health Directorate on healthy nutrition, physical activity, chronic illnesses, and screening.

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 Finnish Diabetes Type-2 Risk Score (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 (Lindström et al., 2003). The Turkish validity and reliability study for FINDRISC was performed by Etbaş Demirağ in 2016 (Etbaş Demirağ, 2016). The participants' metabolic measurements will be taken by a researcher using the

Accu-Chek® Performa Nano device from a capillary blood sample; A1C 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-MEDAS)

The Turkish validity and reliability studies for MEDAS, which was originally developed in 2012 by Martínez-González et al., were performed by Özkan Pehlivanoğlu et al. in 2020 (Martínez-González et al., 2008; Özkan Pehlivanoğlu et al., 2020). MEDAS consists of 14 questions (León-Muñoz et al., 2012). Each question is worth 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 (IPAQ)

The IPAQ International Physical Activity Questionnaire-Short Form was developed in 1996 by Booth in order to identify the risk factors of inactivity and physical activity levels in prediabetes. 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. (Öztürk, 2005; Saglam et al., 2010).

Metabolic Measurements

The participants' A1C, fasting blood glucose-postprandial blood glucose (whichever is appropriate for the individual) values will be measured.

The **A1C Measurement** represents a 3-month mean value (Block et al., 2015; McLeod et al., 2020; Toro-Ramos et al., 2020). The A1C testing does not require fasting conditions. The blood sample can be taken at any time of day (TEMD, Diabetes Mellitus Complications Diagnosis, Treatment and Monitoring Guidelines, 2018). Over the period

of the study, the A1C result 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 (www.rochediagnotics.com.tr, Access Date: 4 May 2022). A minimum eight-hour fasting period will be taken as a criterion for fasting blood glucose (ADA, 2020); 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) (TEMD, Obesity Diagnosis and Treatment Guidelines, 2019).

Mobile App Usability and Usage Assessment Scale

Three measures developed by Hoehle et al. (2016) 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 (2019).

Mobile Application Usability Scale-MAUS

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 (Güler, 2019).

Continued Intention to Use Scale-CITUS

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 (Güler, 2019).

Brand Loyalty Scale-BLS

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 (Güler, 2019).

Ethical Considerations in the Study

Ethical approval for the conduct of the study was obtained from Akdeniz University Faculty of Medicine Clinical Studies Ethics Committee (Date: 16.03.2022, No. KAEK-192) and institutional approval from the Kütahya Provincial Health Directorate (Date: 30.05.2022, No. 2022/47). 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. It was registered on ClinicalTrials.gov on **XXXXX).**

Validity-Reliability

The study protocol was drawn up based on the SPIRIT (Chan et al., 2013) and CONSORT-NPT (Boutron et al., 2017) guidelines. Randomization and blinding will reduce bias in the results. The measuring instruments used in this study are valid and reliable (Block et al., 2015; Etbaş Demirağ, 2016; Güler, 2019; McLeod et al., 2020; Özkan Pehlivanoğlu et al., 2020; Saglam et al., 2010; Toro-Ramos et al., 2020).

Data 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 (ITT) 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 A1C 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 (Republic of Turkiye, Ministry of Health, Public Health Directorate). 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 (Abbate et al., 2021; Fischer et al., 2016; Ramachandran vel al., 2013).

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 (Abbate et al., 2021). 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. 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.

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 A1C), 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.

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