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MedDietAgent: testing a smartphone app that helps people match their everyday food choices to the Mediterranean diet

Submission date 22/09/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 25/09/2026	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 25/09/2026	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

The Mediterranean diet is recommended in Greece as the basis of healthy eating, but following it consistently in everyday life is difficult, and people are often unaware of how far their daily food choices drift from what is recommended. This is particularly important for people living with type 1 diabetes, high blood pressure or abnormal blood fats, for whom what they eat directly affects how well their condition is controlled. Participants in this study were given a baseline eating pattern to follow: the Mediterranean diet as recommended in Greece, with the balance of protein, carbohydrate and fat set within the ranges accepted in international dietary guidelines at the time. MedDietAgent is a smartphone app developed to help people keep to such a pattern. It lets people record what they eat by typing, speaking, or taking a photograph of their meal, works out the nutritional content automatically, and suggests personalised changes. This study looked at whether the app helps people bring their everyday food choices closer to the Mediterranean diet, whether it is easy to use, and how accurate its automatic calculations are.

Who can participate?

Adults aged 18 to 67 years who own an Android smartphone and are able to use it. Healthy adults could take part, as could adults with type 1 diabetes who count carbohydrates and use a continuous glucose monitor, adults with high blood pressure diagnosed at least six months earlier, and adults with abnormal blood fats diagnosed at least 3 months earlier. People with a significant psychiatric condition, a food intolerance restricting their diet, heart, kidney or liver failure, or an active cancer could not take part.

What does the study involve?

Participants were given dietary advice based on the Mediterranean diet, tailored to their own energy needs and health, and were trained to use the app. The study ran in two parts. In the first part, lasting 4 weeks, participants used an early version of the app that recorded meals and displayed their nutritional content. In the second part, lasting at least 8 weeks, they used an updated version that could also recognise meals from photographs or spoken descriptions and that offered personalised dietary suggestions. Before the study and at the end of each part,

participants attended a clinical check-up with measurements of weight, vital signs and blood pressure, and gave a blood sample for laboratory tests. Participants with diabetes also shared their continuous glucose monitoring data, and participants with high blood pressure recorded their blood pressure at home each morning and evening. At the end of the study, participants filled in questionnaires about how easy the app was to use.

What are the possible benefits and risks of participating?
There were no direct benefits to participants. Participation was expected to contribute to understanding how diet, lifestyle and artificial intelligence interact in diabetes, high blood pressure and high cholesterol. Participation involved no cost or burden to participants and no risks. Taking part was entirely voluntary, and participants could withdraw at any time without giving a reason and could ask for their data to be deleted.

Where is the study run from?
"Attikon" University General Hospital (Greece)

When is the study starting and how long is it expected to run for?
November 2021 to February 2024

Who is funding the study?
The study was co-financed by the European Regional Development Fund of the European Union and Greek national funds through the Operational Programme Competitiveness, Entrepreneurship and Innovation, under the call RESEARCH - CREATE - INNOVATE (project code T2EDK-03185)

Who is the main contact?
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National project registry code (MIS)
5131362

University research project number
EKPAR01-0029021

Funding programme project code (Greece 2.0 / EPAnEK, RESEARCH - CREATE - INNOVATE)
T2EDK-03185

Study information

Scientific Title
Evaluation of the MedDietAgent context-aware mobile application for harmonising individual dietary choices with the Mediterranean diet in healthy adults and in adults with type 1 diabetes mellitus, arterial hypertension or dyslipidaemia: a two-phase, single-arm, single-centre study

Acronym
MedDietAgent

Study objectives
1. To assess whether the MedDietAgent mobile application helps participants harmonise their everyday dietary choices with a prescribed baseline dietary pattern, namely the Mediterranean diet as set out in the Greek national food-based dietary recommendations, with a macronutrient distribution consistent with the Acceptable Macronutrient Distribution Ranges of the dietary guidelines in force at the time of the study.
2. To collect observational dietary and clinical data suitable for training and testing the machine learning models underlying the application (Phase A).
3. To evaluate prospectively the usability and effectiveness of the resulting system and to validate the accuracy of its algorithmic output (Phase B).

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 08/12/2021, Scientific Council of "Attikon" University General Hospital, acting on the favourable opinion of the hospital's Bioethics and Deontology Committee (Rimini 1, Chaidari, Athens, 124 62, Greece; +30 (0)210 583 1255; secr.bppk@yahoo.gr), ref: EBD639/25-11-2021

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Dietary behaviour and adherence to the Mediterranean diet in healthy adults and in adults with type 1 diabetes mellitus, arterial hypertension or dyslipidaemia

Interventions
All participants were trained in the use of the MedDietAgent smartphone application (Android) before the start of the study and received a dietary intervention based on the principles of the Mediterranean diet, tailored to their individual energy requirements and clinical profile. The prescribed baseline combined the food-group structure of the Greek national dietary recommendations for the Mediterranean diet with a macronutrient distribution consistent with the Acceptable Macronutrient Distribution Ranges of the dietary guidelines in force at the time of the study. It specified 10-35% of daily energy from protein, 45-65% from carbohydrate and 20-35% from total fat, with saturated fat below 10% and sugars below 18% of total energy, a daily fibre intake of 22-28 g for women and 28-34 g for men, sodium below 2300 mg/day and below 1500 mg/day for participants with hypertension, and prescribed minimum daily servings of fruit, vegetables and dairy products.

In Phase A, lasting 4 weeks, participants used version 1 of the application, which allowed meals to be logged by text search against a food composition database and displayed the meal history and its nutritional composition. In Phase B, lasting at least eight weeks, participants used version 2, which additionally allowed meals to be logged automatically by photographing the food or describing it in natural speech, and which delivered personalised dietary recommendations generated by a machine learning system on the basis of the individual's energy requirements, dietary preferences, personalised dietary plan and the nutritional history of meals already consumed.

Before the start of the study and on completion of each phase, every participant underwent clinical assessment with recording of anthropometric characteristics, medical history and vital signs, and venous blood sampling for biochemical and protein laboratory analysis in order to measure the degree of regulation of their metabolic parameters. Genetic determinations related to hypertension, dyslipidaemia and obesity were also performed. Participants with type 1 diabetes additionally supplied continuous glucose monitoring data and participants with hypertension supplied daily morning and evening home blood pressure readings throughout the study period. On completion of the study, participants completed structured questionnaires assessing the usability of the application.

The study had a single arm. All participants followed the same sequence of Phase A and Phase B, so no allocation, randomisation or masking procedure was applied and no control group was used. The total duration of the intervention and of follow-up was at least twelve weeks per participant.

Intervention Type
Behavioural

Primary outcome(s)
1. Concordance of daily dietary intake with the prescribed baseline dietary pattern measured using the daily dietary records logged by each participant in the MedDietAgent mobile application, assessed across eleven nutritional parameters: total daily energy intake; protein, carbohydrate, total fat, saturated fat and sugars expressed as percentages of daily energy; fibre and sodium expressed as densities per 1000 kcal; and daily servings of fruit, vegetables and dairy products, each compared against the targets prescribed to that participant at enrolment, measured at baseline (enrolment), the end of Phase A (week 4) and the end of Phase B (week 12 or later), with dietary intake recorded continuously throughout both phases

Key secondary outcome(s)
1. Body weight and body mass index measured using body weight and height at clinical assessment at baseline (enrolment), the end of Phase A (week 4) and the end of Phase B (week 12 or later)

2. Glycaemic control measured using glycated haemoglobin (HbA1c) and fasting plasma glucose measured in venous blood at baseline (enrolment), the end of Phase A (week 4) and the end of Phase B (week 12 or later)

3. Lipid profile measured using total cholesterol, HDL, LDL, triglycerides, apolipoprotein A1, apolipoprotein B and lipoprotein(a) measured in venous blood at baseline (enrolment), the end of Phase A (week 4) and the end of Phase B (week 12 or later)

4. Blood pressure measured using office blood pressure recorded at clinical assessment and, in participants with arterial hypertension, morning and evening home blood pressure readings at baseline (enrolment), the end of Phase A (week 4) and the end of Phase B (week 12 or later), with home readings recorded daily throughout both phases

5. Participant engagement with dietary self-monitoring measured using the number of days on which a dietary record was logged in the MedDietAgent application and the proportion of days logged over each participant's tracking window at the end of Phase A (week 4) and the end of Phase B (week 12 or later), computed from records logged continuously throughout both phases

6. Usability of the MedDietAgent application measured using structured usability questionnaires completed by participants at the end of Phase B (week 12 or later)

7. Accuracy of the automated nutritional decomposition of logged meals measured using comparison of the nutritional values generated automatically by the application against the reference food composition database at the end of Phase A (week 4) and the end of Phase B (week 12 or later), assessed against records logged continuously throughout both phases

8. Glycaemic variability in participants with type 1 diabetes mellitus measured using continuous glucose monitoring data supplied by participants, including time in range, at the end of Phase A (week 4) and the end of Phase B (week 12 or later)

Completion date
06/02/2024

Eligibility

Key inclusion criteria
1. Aged 18 to 67 years
2. Able to use a smartphone and in possession of an Android device
3.1. Healthy adults, or
3.2. Participants with type 1 diabetes mellitus (n = 30): diagnosis established for at least 6 months, trained in carbohydrate counting, and using a continuous glucose monitoring system, or
3.3. Participants with arterial hypertension (n = 10): diagnosis established for at least 6 months, and recording morning (on waking) and evening (before retiring) blood pressure daily, or
3.4. Participants with dyslipidaemia (n = 10): diagnosis established for at least 3 months
4. Participants with hypertension or dyslipidaemia may also have diabetes

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
67 Years

Sex
All

Total final enrolment
50

Key exclusion criteria

1. Presence of significant psychological or psychiatric syndromes
2. Food intolerance restricting the diet, such as coeliac disease
3. Cardiac, renal or hepatic failure
4. Active malignancy

Date of first enrolment
20/07/2023

Date of final enrolment
20/10/2023

Locations

Countries of recruitment
Greece

Study participating centre
"Attikon" University General Hospital 2nd Department of Propaedeutic Internal Medicine
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Sponsor information

Organisation
University General Hospital Attikon

ROR
https://ror.org/03gb7n667

Funder(s)

Funder type

Funder Name
European Regional Development Fund (ERDF) of the European Union and Greek national funds through the Operational Programme Competitiveness, Entrepreneurship and Innovation (EPAnEK), RESEARCH - CREATE - INNOVATE (T2EDK-03185)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request. Participant data were anonymised so that individual identities cannot be disclosed to third parties, and identities are not disclosed in any publication or presentation arising from the study.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			22/09/2026	No	Yes