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# Assessing the effectiveness of the Greenhabit method (mHealth) for lifestyle modification in diabetes

**Submission date**
20/05/2021

**Recruitment status**
No longer recruiting

**Registration date**
22/05/2021

**Overall study status**
Completed

**Last Edited**
29/01/2025

**Condition category**
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Diabetes is a long-term disease of high blood sugar levels that lead to blood vessel complications over time. For patients with type 2 diabetes, management initially focuses on lifestyle changes that include daily physical activity, weight control, healthy diets, and the use of oral medications on occasion. The management of these risk factors leads to improved health and prevents the possible complications associated with this disease. Today, advances in digital health technology, especially mobile smartphone technology (apps) could allow greater control of diabetes and other chronic diseases. The Greenhabit app is an application for smartphones. This application aims to improve the lifestyle and dietary habits of people with type 2 diabetes through learning that lasts 12 weeks (3 months). The app is available in Spanish and can be downloaded from the Apple App Store (iOS operating system; Apple Inc.) and the Google Play Store (Android operating system; Google). The application is presented as a journey in which each day the participant, in a personalized way, will be faced with new challenges with the objective of improving their lifestyle. To advance in the game, the participant must try to pass the trials, all of them aimed at improving lifestyle: diet, physical exercise, and mental state (positivity, depression, energy).

Who can participate?
Older adults between 18 and 75 years old, with a recent diagnosis of diabetes (less than 2 years of treatment), who can write and speak Spanish, who have a smartphone and can use the Greenhabit application and finally, who have not undergone or plan bariatric surgery during the study period.

What does the study involve?
Participants are randomly allocated into two groups. The intervention group participants receive instructions and written material with information on seasonal Mediterranean foods, shopping lists, weekly meal plans and cooking recipes for a typical week. Participants will also be able to access a mobile application (Greenhabit), available in Spanish, through their smartphone. This app will help them change their lifestyle through challenges and personalized recommendations. This app has a maximum duration of 3 months. In addition, the intervention

group receive as part of the nutritional education a Greenhabit box with a book, a bottle and some rewards that they will win in the game.
The control group receive instructions and written material with information on seasonal Mediterranean foods, shopping lists, weekly meal plans and cooking recipes for a typical week. The follow-up will be 3 months.
Participants will have a total of three visits: initial, 6 weeks, and 3 months. Each visit will not take more than 60-80 minutes. All participants will have an interview with the dietitian at the beginning of the study and at 3 months (end of the study) in which they will receive instructions and written material with information on seasonal Mediterranean foods, shopping lists, weekly meal plans and recipes, cooking for a typical week. Additionally, individual interviews will include a food frequency questionnaire and personalized recommendations for making changes to the participant's diet to achieve a personalized goal. Also, information on educational level, lifestyle, tobacco habit, medical history and medication will be collected. In both groups (intervention and control group), participants will be encouraged to increase their intake of vegetables (two or more servings per day), fresh fruit (three or more servings per day), legumes, nuts, fish or shellfish (three or more servings per week), and use olive oil for cooking and seasoning. Energy restriction will not be specifically advised in either group, and physical activity will be promoted in both groups.
At the beginning of the study and at 4, 8 and 12 weeks, all participants must complete a series of questionnaires to evaluate different aspects of quality of life such as energy, happiness, positivity, social aspects and relationship with work. These questionnaires will be completed in person by the control group and self-reported by the intervention group through the app itself. In addition, the nutritionist will perform weight, height, waist, hip and blood pressure measurements. These visits will take no more than 45-60 minutes. In these same weeks, the study nurse will call participants to go in the morning (around 8 a.m.) to perform a basic analysis. It will not take more than 20 minutes.

What are the possible benefits and risks of participating?
This study will show how mobile applications can help to modify an individual's lifestyle, making them more aware of their disease. In addition, it will allow the participants to have better control of blood pressure, blood glucose levels, lipids and body weight. Also, it will help them better control stress, anxiety and sadness and improve their relationship with their environment (work, family, friends). Therefore, their physical and mental health will improve. In addition, the study can help participants to better understand their state of health, although it is also possible that they will not obtain any direct benefit from participating. However, it is likely that some of the information obtained may benefit other patients in the future and may contribute to a better understanding of the effect of this intervention on diabetes control.

Where is the study run from?
Hospital Clínic de Barcelona (Spain)

When is the study starting and how long is it expected to run for?
May 2020 to December 2021

Who is funding the study?
EIT Digital (Spain)

Who is the main contact?
1. Dr Ramon Estruch, restruch@clinic.cat
2. Dr Rosa Casas, Casas1@clinic.cat

# Contact information

### Type(s)
Scientific

### Contact name
Dr Ramon Estruch

### ORCID ID
http://orcid.org/0000-0003-1260-4445

### Contact details
Department of Internal Medicine
Hospital Clinic
Villarroel, 170
Barcelona
Spain
08036
+34 (0)93 2275745
restruch@clinic.cat

### Type(s)
Scientific

### Contact name
Dr Rosa M. Casas

### ORCID ID
http://orcid.org/0000-0002-0211-9166

### Contact details
Medical School (University of Barcelona)
CELLEX laboratories
Internal Medicine lab
Planta 4B-Dpto. 4
C/Casanova 143
Barcelona
Spain
08036
+34 (0)932275400 ext. 2907
rcasas1@clinic.cat

# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers
Greenhabit (21105)

# Study information

### Scientific Title
The efficacy of the Greenhabit method (mHealth) for lifestyle modification in diabetes mellitus

### Acronym
Greenhabit

### Study objectives
App-enabled, self-managed and prescribed preventive interventions effectively reduce type 2 diabetes mellitus (T2DM) and cardiovascular risk factors (including blood pressure [BP] measurements, lipid profile), glucose metabolism parameters (glucose concentrations, HbA1c, Homeostatic Model Assessment [HOMA] index), body weight and adiposity parameters, as well as anxiety and depression. In addition, it improves health-related quality of life (HRQoL) and increases adherence to preventative treatments compared to a control group.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 19/04/2021, Institutional Review Board of the Hospital Clinic of Barcelona (Hospital Clínic De Barcelona, Villarroel, 170 – 08036 Barcelona, Spain; +34 (0)93 227 54 00; CEIC@clinic.cat), ref: HCB/2021/0061

### Study design
Randomized interventional controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Home

### Study type(s)
Quality of life

### Participant information sheet
See additional file ISRCTN13456652_PIS_v3_19Mar21 (added 01/06/2021)

### Health condition(s) or problem(s) studied
Improving health and preventing the appearance of possible complications associated with diabetes through changes in lifestyle and dietary pattern

## Interventions
A total of 120 participants will be randomised into two treatment groups (60 individuals per group). The randomization will be carried out by assigning them consecutively by means of sealed envelopes, which have been prepared following a table of random numbers generated by a computer.

Interventional group: 60 participants will receive instructions and written material with information on seasonal Mediterranean foods, shopping lists, weekly meal plans, and cooking recipes for a typical week. Participants will have also access to a smartphone application to access a lifestyle program (Greenhabit) through which they will receive personalized recommendations and education about healthy lifestyles for 3 months.

Control group: 60 participants will receive instructions and written material with information on seasonal Mediterranean (slow carb) foods, shopping lists, weekly meal plans, and cooking recipes for a typical week.

The follow-up will be for 3 months.

## Intervention Type
Behavioural

## Primary outcome measure
1. Glucose and glycated haemoglobin measured using glucose oxidase method at baseline, 1, 2 and 3 months
2. Lipid metabolism measured using enzymatic procedures at baseline, 1, 2 and 3 months
3. Weight recorded with participants in light clothing without shoes or accessories, using a high-quality calibrated scale at baseline and each week for 3 months
4. Waist circumference measured midway between the lowest rib and the iliac crest at baseline and each week for 3 months
5. Height measured with a wall-mounted stadiometer at baseline
6. BMI calculated as weight (kg) divided by the square of height (m2) at baseline, 1, 2 and 3 months
7. Stress relief and dealing with psychological issues measured at baseline, 1, 2 and 3 months, through different validated tests:
7.1. The 14-item dietary screening questionnaire
7.2. The International Physical Activity Questionnaire (IPAQ)
7.3. The Spanish version and the Short Form-36 Health Survey (SF-36)
7.4. The Hospital Anxiety and Depression Scale (HADS)
7.5. The ‘Life Orientation Test’ (LOT)
7.6. The Duke-UNK functional social support questionnaire (DASI)

## Secondary outcome measures
1. Stress relief and quality of life measured through different validated tests:
1.1. Energy measured using the 14-item dietary screening questionnaire, the International Physical Activity Questionnaire (IPAQ), the Spanish version and the Short Form-36 Health Survey (SF-36), at baseline, 1, 2 and 3 months
1.2. Happiness measured using the Hospital Anxiety and Depression Scale (HADS) at baseline, 1, 2 and 3 months
1.3. Positivity measured using the ‘Life Orientation Test’ (LOT) at baseline, 1, 2 and 3 months
1.4. Social support measured using the Duke-UNK functional social support questionnaire (DASI) at baseline, 1, 2 and 3 months

1.5. Work-life balance measured using the Short Form-36 Health Survey (SF-36), at baseline, 1, 2 and 3 months
2. Physical activity measured using the International Physical Activity Questionnaire (IPAQ), Spanish version at baseline, 1, 2 and 3 months

### Overall study start date
06/05/2020

### Completion date
31/12/2021

## Eligibility

### Key inclusion criteria
1. Patients with a recent diagnosis of diabetes* (<2 years treatment)
2. Able to write and speak the Spanish language
3. Own a smartphone
4. Able to use the Greenhabit App
5. Age 18-75 years
6. Have not undergone or planned bariatric surgery during the trial period.

*HbA1c >6.5 percent or fasting plasma glucose (FPG) >126 mg/dl twice, or a 2-hour plasma glucose value after a 75-g oral glucose tolerance test >200 mg/dl.

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
75 Years

### Sex
Both

### Target number of participants
120

### Key exclusion criteria
1. Subjects diagnosed with type 1 diabetes (insulin-dependent), gestational diabetes, maturity-onset diabetes of the young and maternal inherited diabetes and deafness
2. Subjects with any serious chronic disease, alcoholism or other drug addiction, or gastrointestinal diseases that prevent an adequate diet
3. Those who take vitamins or nutritional supplements during the month prior to the study
4. Pregnancy

**Date of first enrolment**
06/09/2021

**Date of final enrolment**
30/12/2021

# Locations

**Countries of recruitment**
Spain

**Study participating centre**
**Hospital Clínic of Barcelona**
C/Villarroel 170
Barcelona
Spain
08036

# Sponsor information

**Organisation**
Consorci Institut D'Investigacions Biomediques August Pi I Sunyer

**Sponsor details**
Carrer del Rosselló, 149
Barcelona
Spain
08036
+34 (0)932275400 ext. 2907
rcasas1@clinic.cat

**Sponsor type**
Research organisation

**Website**
https://www.clinicbarcelona.org/idibaps

**ROR**
https://ror.org/054vayn55

# Funder(s)

**Funder type**

Other

**Funder Name**
EIT Digital

# Results and Publications

### Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

### Intention to publish date
31/12/2022

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Ramon Estruch (restruch@clinic.cat) and Dr Rosa Casas (Casas1@clinic.cat).

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | version v3 | 19/03/2021 | 01/06/2021 | No | Yes |
| Protocol file | version v3 | 19/03/2021 | 01/06/2021 | No | No |
| Results article | | 22/01/2025 | 29/01/2025 | Yes | No |