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Help for comprehensive diabetes self-management (Ayuda para el automanejo Integral de la Diabetes MEllitus)

Submission date
30/04/2026

Recruitment status
Recruiting

Registration date
06/05/2026

Overall study status
Ongoing

Last Edited
03/06/2026

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

The World Health Organization (WHO) estimates over 346 million people worldwide have diabetes, and this could more than double by 2030 if no action is taken. Heart disease is the leading cause of death, killing 17.9 million people each year.

Healthcare providers struggle to meet the ongoing needs of people with chronic illnesses. Regular follow-ups are important to prevent long-term complications. Many studies show poor treatment adherence due to negative attitudes toward diabetes and heart disease risk factors and low health literacy. One solution is promoting self-care, defined by the WHO as the ability to maintain health and manage illness with or without professional support. Self-care includes habits, lifestyle choices, and tools like diagnostics and digital apps.

For people with diabetes, seven key self-care behaviors predict good outcomes and can apply to heart disease: healthy eating, exercise, blood sugar monitoring, medication adherence, problem-solving, coping skills, and risk reduction. Digital health tools (apps, glucose monitors, insulin pumps, and wearables like Fitbits) are increasingly used for chronic disease self-management. Studies on digital tech for diabetes have had mixed results: some show positive effects, others less conclusive. But due to rapid tech advances, many studies quickly become outdated. Variations in study design and tools have made it hard to measure digital tech's true impact. Meanwhile, diabetes and heart disease keep rising; obesity is a major driver.

Now, with AI and big data, new tools could boost self-management. For example, AI-powered personalized diets using blood glucose predictors improved blood sugar more than the Mediterranean diet in a pilot study of 23 patients. A 6-month personalized diet further improved metabolic health.

The EU launched JACARDI, a joint action with 21 countries, to tackle heart disease and diabetes through 142 pilot studies covering the entire patient journey, from awareness and prevention to ongoing care. Our pilot under JACARDI focuses on diabetes self-management using new tech to provide physical activity tools, plus nutrition and medication support. Our hypothesis is that using this tool will improve patients' disease knowledge, leading to better blood sugar control and quality of life.

Who can participate?
Participants must be over 18 years of age and have a diagnosis of diabetes mellitus and at least one other vascular risk factor such as high blood pressure, dyslipidaemia or obesity, or an established vascular disease such as angina or stroke, with the ability to use a smartphone and limited skills in diabetes self-management.

What does the study involve?
The intervention focuses on helping people with diabetes manage their condition on their own, using new technologies and devices that give patients more control over their health. Participants will be randomly assigned to one of two groups: an intervention group or a control group. Both groups will be followed for 14 weeks after joining the study. The clinical intervention will be based on standard medical practice. Additionally, every participant will be given a glucose sensor for continuous monitoring (Libre 3, Abbott) and a smartwatch to track physical activity.
The pilot study focuses specifically on developing a physical activity program that is tailored to each person's abilities in the intervention group. This program will also include nutritional advice and medication management, which will be provided through an app for the intervention group. Participants in the control group will receive the exercise program and nutritional advice in a printed booklet.

What are the possible benefits and risks of participating?
The study aims to improve the metabolic control of diabetes by training patients in self-management of their condition. Therefore, participants will benefit from the availability of digital tools that will help them improve their lifestyles. Through an app, they will be able to follow a personalized physical activity program, view videos on healthy eating, record their medication to receive reminders, and monitor their glucose levels and step count.
The risks are minimal and stem from the potential for malfunction of the applications used. The study is low-intervention, and participants are not exposed to new medications or untested medical devices.

Where is the study run from?
The study is being conducted in medical centers in the Extremadura region of Spain.

When is the study starting and how long is it expected to run for?
February 2026 to September 2026

Who is funding the study?
The study is funded by the European Union through the EU4Health 2021-2027 program under Grant Agreement 101126953.

Who is the main contact?
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Contact information

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Additional identifiers

Protocol serial number
156-2024

Study information

Scientific Title
Will a new digital tool be able to improve self-management among people having diabetes? A randomized clinical trial

Acronym
AID-ME

Study objectives
Based on the use of the diabetes self-management tool:

Primary:
To decrease glycosylated hemoglobin in the intervention arm by more than 0.5% compared to the control arm

Others:
1. Improve self-management capacity in the intervention branch, mainly focused on aspects related to diet, physical activity and therapeutic adherence. Variations at the beginning and end of follow-up will be considered using different tests designed for this purpose.

2. Assess whether there are differences in glycemic variability between the control and intervention branches
3. Assess whether there are differences in weight and body composition between the control and intervention branches
4. Assess the presence of frailty and whether the condition changes after the intervention
5. Assess the presence of obesity and whether this condition changes after the intervention
6. Assess the usefulness of using devices (wearables) in the process of self-management of the disease
7. Assess the usefulness of using apps based on artificial intelligence in the process of self-management of the disease

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 23/01/2025, Cáceres Drug Research Ethics Committee (Hospital San Pedro de Alcántara Planta baja Ronda de San Francisco s/n, Cáceres, 10002, Spain; +34 (0)927 256814; ceic.caceres@salud-juntaex.es), ref: 156-2024

Study design
Multicenter low-interventional double-arm non-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy, Safety

Health condition(s) or problem(s) studied
Diabetes mellitus

Interventions
Control arm:
Continuous glucose monitoring (Libre3 Abbott), smartwatch Samsung Galaxy (watch 7) and written lifestyle advice

Intervention arm:
The same as the control arm, and a digital tool (adapted from mKinetikos) with ability to integrate data from continuous glucose monitoring, a smartwatch, scheduled videos of health diet advices, motivational and physical activity, treatment schedule related warnings and a chat to bidirectionally communicate with healthcare workers

At each enrollment session at each center, prior to the enrollment day, the selected and scheduled participants, ordered alphabetically by the first letter of their surname, will be randomly assigned a number. Once the number is assigned, in a second randomization process, half of these numbers will be assigned to the intervention arm and the other half to the control arm. If the number of scheduled patients is odd, more or fewer participants will be assigned to each arm at each enrollment center throughout the period, in order to obtain two arms with a similar number of participants.

The total duration of intervention and follow-up will be 14 weeks.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
mKinetikos (modified from the original app)

Primary outcome(s)
Glycosylated hemoglobin measured in a sample of peripheral blood at the beginning and after 14 weeks of follow-up

Key secondary outcome(s)
1. Self-management capacity, mainly focused on aspects related to diet, physical activity and therapeutic adherence, measured using DSMQ-R and Diabetes Self-Care Activities (DSCA) at the beginning and after 14 weeks of follow-up
2. Glycemic variability measured by continuous glucose monitoring (Freestyle Libre 3) during 14 weeks of follow-up
3. Weight and body composition: BMI, fat mass, skeletal muscle mass measured with Tanita BC-545 at the beginning and after 14 weeks of follow-up
4. The presence of frailty and whether the condition changes after the intervention, measured using Fried test before and after 14 weeks of follow-up
5. The presence of obesity and whether this condition changes after the intervention, measured using the WHO classification of obesity, changes in percentages by class before and after 14 weeks of follow-up
6. The usefulness of using devices (wearables) in the process of self-management of the disease, assessed using the System Usability Scale (SUS) and the mHealth App Usability Questionnaire (MAUQ) at the beginning and after 14 weeks of follow-up

Completion date
30/09/2026

Eligibility

Key inclusion criteria
1. Patients over 18 years of age
2. Diagnosis of diabetes mellitus (DM): made according to guidelines and with a baseline glycosylated hemoglobin (at the beginning of the study) above 7.5%
3. At least one known vascular risk factor (high blood pressure, dyslipidemia, smoking, obesity or chronic kidney disease) or established vascular disease (coronary disease, cerebrovascular disease or peripheral arterial disease)
4. Ability to use a smartphone-type mobile device
5. Having signed informed consent (by patient or representative)
6. Score equal to or less than six points on the Diabetes Self-Management Questionnaire - Revised (DSMQ-R) questionnaire

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
90 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Patients with DM but without other risk factors or associated established vascular disease
2. Score greater than six points on the DSMQ-R questionnaire
3. Patients with neurological diseases or tumors in advanced stages, who are unable to adequately carry out a basic physical activity program
4. Patient participating in a clinical trial of pharmacological intervention

Date of first enrolment
02/02/2026

Date of final enrolment
25/07/2026

Locations

Countries of recruitment
Spain

Study participating centre
Unidad de Investigacion de Villaueva de la Serena.
Calle Sierra Nevada 10
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Study participating centre
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Study participating centre
Hospital Virgen del Puerto
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Study participating centre

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Sponsor information

Organisation
FUNDESALUD

Organisation
JACARDI (Joint Action on Cardiovascular diseases and diabetes)

Funder(s)

Funder type
Not defined

Funder Name
EU4Health

Alternative Name(s)
L'UE pour la santé, EU za zdravlje, ЕС в подкрепа на здравето, UE pela Saúde

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from FundeSalud (contacto@fundesalud.es) and after permission from FundeSalud of general coordination of JACARDI.

Applications must include a summary justifying the objectives for which the data will be used, the analyses to be performed, and the variables required for the work. Upon approval of the data transfer, a commitment to the use of the anonymized data will be required.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			03/06/2026	No	No