ISRCTN62063346 https://doi.org/10.1186/ISRCTN62063346

CARE4DIABETES - Reducing the burden of non-communicable diseases by providing a multi-disciplinary lifestyle treatment intervention for type 2 diabetes

Submission date
21/01/2025

Recruitment status
No longer recruiting

Registration date
25/02/2025

Overall study status
Completed

Last Edited
25/03/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Type 2 Diabetes Mellitus (T2DM) is a major health issue in many countries. The CARE4DIABETES study aims to help EU countries reduce diabetes risk factors through a lifestyle treatment based on a successful Dutch program called Reverse Diabetes2Now.

Who can participate?
Participants must be 20-80 years old, diagnosed with T2DM, taking diabetes medication, and have a BMI of 25-40 kg/m². They should be able to use digital devices and be committed to making lifestyle changes. Participants should not have severe comorbidities like COPD, kidney or heart failure, have had bariatric surgery, have an eating disorder, or be pregnant or planning to become pregnant during the 12-month study period.

What does the study involve?
The study involves an initial 6-month phase where a team of experts works with groups of 20 people with T2DM. Participants receive counseling on nutrition, physical activity, sleep, and stress management, biometric information, and cooking classes. They also use a digital platform for personal advice and medical follow-up on their medication. The next 6 months focus on maintaining these changes.

What are the possible benefits and risks of participating?
Participants may benefit from improved health and better management of their diabetes through lifestyle changes. However, the study does not have a control group, and different cultural contexts in various European settings might affect the results.

Where is the study run from?
The study is conducted in 22 locations across 12 countries: Belgium, Bulgaria, Finland, Greece, Hungary, Italy, Malta, Poland, Portugal, Slovakia, Slovenia, and Spain.

When is the study starting and how long is it expected to run for?
The study started in February 2023 and is expected to run until January 2026.

Who is funding the study?
The study is funded by the European Commission under the EU4H-2021-C4D-08.1 program, Grant Agreement 101082427.

Who is the main contact?
Dr. Marta Maria Pisano González, martamaria.pisanogonzalez@asturias.org

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Marta María Pisano González

ORCID ID
https://orcid.org/0000-0002-6485-9370

Contact details
C/Ciriaco Miguel Vigil 9
Oviedo. Asturias
Spain
33006
+34 696197060
martamaria.pisanogonzalez@asturias.org

Additional identifiers

Protocol serial number
EU4H-J2021-JA2-IBA-101082427, GA 101082427

Study information

Scientific Title
In patients with Type 2 diabetes, how does a multidisciplinary lifestyle intervention compared to other approaches affect patients' well-being and quality of life, reduce healthcare-associated costs, and promote capacity building of health systems towards more innovative and integrated interventions based on lifestyle changes?

Acronym
CARE4DIABETES Joint Action

Study objectives
Non-communicable diseases (NCDs), such as type 2 diabetes (T2D), represent major causes of disability, ill-health, health-related retirement, and premature death in the EU and cause a considerable social and economic impact. The European project Care4Diabetes Joint Action (C4D) will foster transfer and implementation of an innovative practice that has the potential to

reduce the health burden of T2D by increasing the quality of life and extending life expectancy and decrease the cost of usual T2D management, including medications and/or improve the outcomes for a given investment.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 11/10/2023, Comité De Ética De La Investigación Con Medicamentos Del Principado De Asturias (Hospital Universitario De Asturias. Avd/ Roma S/n, Oviedo, 33011, Spain; +34 985107927; ceim.asturias@asturias.org), ref: 2023.244

2. Approved 27/12/2023, Komisija Za Deontološka in Etična Vprašanja - KDEV (Trubarjeva cesta 2, Ljubljana, 1000, Slovenia; +386 1 2441 400; info@nijz.si), ref: 631-21/2023-11 (013)

3. Approved 13/11/2023, Bioethics Committee at Medical University of Warsaw (Żwirki i Wigury 61, Warsaw, 02-091, Poland; +48 22 57 20 303; komisja.bioetyczna@wum.edu.pl), ref: KB/270 /2023

4. Approved 24/10/2023, CEN (Comitato Etico Nazionale) (Viale Regina Elena 299, Rome, 00161, Italy; +39 06 49904022; segreteria.comitatoetico@iss.it), ref: 48519

5. Approved 21/09/2023, Ethics Comittee of General Alexandra Hospital (Vassilisis Sofias 80 , Athens, 11528 , Greece; +30 213 216 2653 ; grafeio.poiotitas@hosp-alexandra.gr), ref: 668/12-09-2023

6. Approved 17/02/2024, APDP local EC (Rua Rodrigo da Fonseca, 1, Lisbon, 1250-189, Portugal; +351 213816101; comissaoetica@apdp.pt), ref: 41/2024

7. Approved 06/02/2024, Gabinete de Projetos de Investigação Centro Académico Clínico ICBAS-CHUdS (Largo Prof. Abel Salazar, Porto, 4099- 001, Portugal; +351 222 077 500 | Ext: 1429; secretariado.etica@chporto.min-saude.pt), ref: 011-24 (010-DEFI/010-CE)

8. Approved 29/04/2024, Comissão de Ética para a Saúde da ARSLVT (Av. Estados Unidos da América, 75-77, Lisbon, 1749- 096, Portugal; +351 21 842 52 03; etica@arslvt.min-saude.pt), ref: 131/CES/INV/2023

9. Approved 16/01/2024, Comissão de Ética da ULS Baixo Alentejo (Rua Dr. António Fernando Covas Lima, Beja, 7801- 849, Portugal; +351 284 310 200; geral@ulsba.min-saude.pt), ref: EDOC /2023/5239

10. Approved 15/01/2024, Comissão de Ética da ARS Algarve (E.N.125 Sítio das Figuras, Lote 1, 2º andar, Faro, 8005- 145, Portugal; +351 284 310 200; ces@arsalgarve.min-saude.pt), ref: -

11. Approved 07/01/2025, Medical Research Council (Egészségügyi Tudományos Tanács) (Báthory u. 10, Budapest, 1054, Hungary; +36 1 795-5639; tukeb@bm.gov.hu), ref: -

Primary study design
Interventional

Study design
Quasi-experimental prospective multicenter study

Study type(s)
Other, Prevention, Quality of life

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus (T2DM)

Interventions
In the project all the eligible participants will be provided with a lifestyle intervention based on the Reverse Diabetes2 Now (R2N BP.) There is a maximum of 20 participants per group. The total number of people involved in the intervention will be 860 across 12 countries.
The intervention will be carried out in two rounds: First round (January-March 2024 to January-March 2025) with 340 participants and second round (October-December 2025 to October-December 2026) with 520 participants. All participants will receive the same intervention, in one of its modalities (face-to-face or virtual).
Each country will establish its own modalities when it comes to the online community, such as developing an ad hoc platform, embedding it into existing digital platforms of the national /regional health systems, or using social media tools, etc. This digital environment will favour knowledge and experience sharing, facilitate exchanges, and increase motivation and commitment of the patients by learning from peers. Patients will be able to consult background information, recipes, and tips shared by the community.

In CARE4DIABETES project, Reverse Diabetes2 Now is a 1-year lifestyle treatment and consists of two phases : a six-month intensive phase and an after-care phase of six-months. In order to start the program participants are referred to the program by their health professional. After a medical screening to determine if participants meet the inclusion and exclusion criteria participants can start the program.
During the first six months of the program five group-based program days are organized. After 1, 3 and 6 months there are ‘return days’. Every program day participants receive presentations and workshops (e.g., cooking workshop, exercise workshop, coach sessions around the four pillars of the program: nutrition, exercise, relaxation and sleep). On the first return day participants are invited to bring a relative or friend to get acquainted with the program so they can support the participant at home.
The intervention will be carried out by a multidisciplinary team that will take on different roles to meet the objectives of the intervention: nurse, nutritionist, coach and coordinator role.
To maximise the results of the implementation, the consortium has decided to adopt the approach of the Deming / Plan-Do-Study-Act (PDSA) cycles to support the evidence-based adaptations of the primary pilot action plans and to monitor the pilot implementation in different stages and enable continuous improvement. Phase I and II pilot actions will be implemented on a total number of 860 type 2 diabetes patients.

Intervention Type
Behavioural

Primary outcome(s)
1. Height is measured using a stadiometer at enrolment, 6 months, and 12 months
2. Weight is measured using a calibrated scale at enrolment, 6 months, and 12 months
3. BMI is calculated using height and weight measurements at enrolment, 6 months, and 12 months
4. Waist circumference is measured using a tape measure at enrolment, 6 months, and 12 months
5. Blood pressure is measured using a sphygmomanometer at enrolment, 6 months, and 12

months
6. Serum lipids (total cholesterol, HDL, LDL, triglycerides) are measured using a laboratory test at enrolment, 6 months, and 12 months
7. HbA1c is measured using a laboratory test at enrolment, 6 months, and 12 months
8. Medication for diabetes is recorded using medical records/interviews at enrolment, 6 months, and 12 months
9. Medication for blood pressure and lipids is self-reported using a questionnaire at enrolment, 6 months, and 12 months
10. Quality of life is measured using the EQ-5D-5L questionnaire at enrolment, 6 months, and 12 months
11. Perceived health is measured using a Likert scale question at enrolment, 6 months, and 12 months
12. Fatigue is measured using a Likert scale question at enrolment, 6 months, and 12 months
13. Sleep problems are measured using a Likert scale question at enrolment, 6 months, and 12 months
14. Physical activity (aerobic and muscle-strengthening) is measured using a self-report questionnaire at enrolment, 6 months, and 12 months
15. Diet is measured using a short food frequency questionnaire and Healthy Diet Index at enrolment, 6 months, and 12 months
16. Self-efficacy is measured using validated questions at enrolment, 6 months, and 12 months
17. Satisfaction in intervention is measured using NPS and additional questions at enrolment, 6 months, and 12 months

Key secondary outcome(s)
1. Age is measured using a questionnaire at baseline
2. Sex is measured using a questionnaire at baseline
3. Diabetes duration is measured using a questionnaire at baseline
4. Immigrant background is measured using a questionnaire at baseline
5. Highest level of education is measured using a questionnaire at baseline
6. Income adequacy is measured using a Likert scale question at baseline
7. Family status is measured using a questionnaire at baseline
8. Employment status is measured using a questionnaire at baseline
9. Present smoking is measured using a questionnaire at baseline
10. Alcohol consumption is measured using a questionnaire at baseline
11. Special diet is measured using a questionnaire at baseline

Completion date
31/01/2026

Eligibility

Key inclusion criteria
1. Age 20-80 years
2. T2DM treated with medication (oral or injected medicines or insulin)
3. T2DM duration 1-10 years
4. BMI 25-40 kg/m²
5. No COPD or kidney or heart failure diagnosis
6. No bariatric surgery (self-reported/medical record)
7. No eating disorder (self-reported/medical record)
8. No pregnancy (self-reported/medical record)
9. Committed to make lifestyle changes to control T2DM

10. Ability to use necessary digital devices
11. Access to internet
12. Sufficient language skills to take part in the program
13. Possibility to take part in the program as provided (schedule, location)
14. Willingness to measure glucose at home

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
860

Key exclusion criteria
1. Severe COPD
2. Bariatric surgery
3. Kidney failure
4. Heart failure
5. Pregnancy or planning to get pregnant during coming 12 months (self-report)
6. Eating disorder, with symptoms during the past 5 years (self-reported diagnosis)

Date of first enrolment
17/02/2023

Date of final enrolment
31/01/2025

Locations

Countries of recruitment
Belgium

Bulgaria

Finland

Greece

Hungary

Italy

Malta

Poland

Portugal

Slovakia

Slovenia

Spain

Study participating centre
VICEPRESIDENCIA SEGUNDA Y CONSEJERIA DE SANIDAD Y SERVICIOS SOCIALES - JUNTA DE EXTREMADURA (JUNTAEX)
Av. de las Américas, 2
Mérida
Spain
06800

Study participating centre
Medical University of Warsaw (MUW)
Żwirki i Wigury 61
Warsaw
Poland
02-091

Study participating centre
National Health Fund (NFZ)
Rakowiecka 26/30
Warsaw
Poland
02-528

Study participating centre
ISS (BEN)
Viale Regina Elena 299
Rome

Italy
0161

Study participating centre
AOUP (AE)
Via Roma 67
Pisa Italy
Italy
56126

Study participating centre
ASLROMA2 (AE)
Via Brighenti 23
Rome
Italy
00159

Study participating centre
FPG (AE)
Largo Francesco Vito 1
Rome I
Italy
168

Study participating centre
General Alexandra Hospital (ALEXANDRA)
Vassilisis Sofias 80
Athens
Greece
11528

Study participating centre
Centro Hospitalar Universitário de Santo António (ULS de Santo António)
Largo Prof. Abel Salazar ·
Porto
Portugal
4099-001

Study participating centre

ACeS Estuário do Tejo (ULS Estuário do Tejo)
Rua Francisco José Lopes S/n
Alenquer
Portugal
2580-393

Study participating centre
ULS Baixo Alentejo
Rua da Rainha Dona Amélia
Beja
Portugal
7800-528

Study participating centre
ACeS Sotavento (ULS Algarve)
Estrada de Santa Luzia
Tavira
Portugal
8800-534

Study participating centre
National Center for Public Health and Pharmacy
Albert Flórián út 2-6.
Budapest
Hungary
1097

Study participating centre
Sciensano
Rue Juliette Wytsman 14
Ixelles
Belgium
1050

Study participating centre
Maison du diabète
Avenue de France 6
Merche-en-Famenne
Belgium
6900

Study participating centre
RML - UOAD
Rue du Houisse 19
Ciney
Belgium
5590

Study participating centre
Servicio de Salud del Principado de Asturias (SESPA)
Plaza El Carbayón 1-2 8
Oviedo
Spain
33001

Study participating centre
Fundación para el Fomento en Asturias de la Investigación Científica Aplicada y la Tecnología. FiCYT
Calle Noval 11, 1C
Oviedo
Spain
33011

Study participating centre
Consejería de Salud del Principado de Asturias(CSPA)
Calle Ciriaco Miguel Vigil 9
Oviedo, Asturias
Spain
33005

Sponsor information

Organisation
Consejería de Sanidad del Principado de Asturias (CSPA)

Funder(s)

Funder type
Government

Funder Name
European Commission

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date. All data shared during or after the project execution will be anonymized and agroupated.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		19/03/2025	25/03/2025	Yes	No
Protocol file			22/01/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes