Co-funded by
the Health Programme
of the European Union

Project title: Care 4 Diabetes, Reducing the burden of non-communicable diseases by providing a multidisciplinary lifestyle treatment intervention for type 2 diabetes (version 1.0)

INDEX

List of Acronyms

BP: Best Practice

C4D: Care4Diabetes Joint Action

EU: European Union

GDPR: General Data Protection Regulation

GP: General Practitioners

HbA1c: Glycated haemoglobin

NCDs: Non-communicable diseases

T2D: Type 2 Diabetes

RD2N: “Reverse Diabetes2 Now”

VL: Voeding Leeft

WHO: World Health Organization

WP: Work Package

1. General Presentation

1.1 General presentation of the study

Title of the study:
Care 4 Diabetes (C4D), Reducing the burden of non-communicable diseases by providing a multidisciplinary lifestyle treatment intervention for type 2 diabetes.
Type of Study: Quasi-experimental implementation trial conducted in concert in 12 countries.
Time of the project: 3 years.
Biological sampling and collection: yes.
Co-Funding: EU4H-2021-C4D-08.1 the project CARE4DIABETES has received funding from the European Commission under GA 101082427.

(Project budget: 5m €).

1.2 Administrative Structure

Coordinator Team
Principality of Asturias Regional Ministry of Health (CSPA), Asturias Regional Health Service (SESPA) and the Foundation for the Promotion of Applied Scientific Research and Technology (FICYT) in Asturias.
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1.3 Investigative and Collaborative Teams

Name	Structure	Team no.	Status in the study*
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Isabel Diez Valcarce	SESPA	2	Coordination team
Cristina Fernández García	SESPA	3	Coordination team
Mónica López Ventoso	SESPA	4	Coordination team
Maria Jesús Rodríguez Nachón	CSPA	5	Coordination team
Inés Rey Hidalgo	FICYT	6	Coordinator team
Raquel Ochoa	FICYT	7	Coordinator team
Antonio Merayo	FICYT	8	Coordinator team
Maria González	FICYT	9	Coordinator team
Victoria Amaya García Fueyo	SESPA	10	Coordinator team
Lucía Fernandez Ron	SESPA	11	Coordinator team
Maria Antonia Herrero Jabonero	SESPA	12	Coordinator team
Alfonso Alonso Fachado	SERGAS	13	Beneficiary entity
Blanca Cimadevilla	SERGAS	14	Beneficiary entity
Silvia Suarez Luque	SERGAS	15	Beneficiary entity
Carolina Muñoz Ibáñez	SERGAS	16	Beneficiary entity
Luis Alberto Vázquez Salví	SCS	17	Beneficiary entity
Paloma González Álvarez	IDIVAL	18	Beneficiary entity
Yolanda Tomé	JUNTAEXT	19	Beneficiary entity
Bernardino Morillo	FUNDESALUD	20	Beneficiary entity
Elisabeth García	FUNDESALUD	21	Beneficiary entity
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Lucía Lasilla	GAIAP	24	Associated entity
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María Asunción Martínez Brocca	SAS	27	Beneficiary entity
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Nuria Prieto	Ministry of Health	29	

1.4 CARE4DIABETES European partners

Nº	Participating organization	Acronym	Country
Coordinator			
1	Foundation for the Promotion of Applied Scientific Research and Technology in Asturias	FICYT	Spain
2	Principality of Asturias Regional Ministry of Health	CSPA	Spain
3	Principality of Asturias Health Service	SESPA	Spain
Competent Authorities			
4	Sciensano	Sciensano	Belgium
5	Ministry of Health Republic of Bulgaria	MoH BG	Bulgaria
6	Finnish Institute for Health and Welfare	THL	Finland
7	1st Regional Healthcare Authority of Attica	1st YPE ATTICA	Greece
8	National Public Health Center of Hungary	NPHC	Ireland
9	Italian National Institute of Health	ISS	Italy
10	Ministry for Health of Malta	MFH	Malta
11	Polish National Health Fund	NFZ	Poland
12	Directorate General of Health of Portugal	DGS	Portugal
13	Slovakia: Ministry of Health of the Slovak Republic	MoH SR	Slovakia
14	National Institute of Public Health of Slovenia	NIJZ	Slovenia
Affiliated Entities			
15	The Cantabria Health Service	SCS	Spain
16	Valdecilla Biomedical Research Institute	IDIVAL	Spain
17	Galicia Regional Ministry of Health	SERGAS	Spain
18	Extremadura Regional Ministry of Health	JUNTAEX	Spain
19	Foundation for Research and Training of Health Professionals of Extremadura	FUNDESALUD	Spain
20	Andalucía Regional Ministry of Health	SAS	Spain
21	Andalusian Public Foundation Progress and Health	FPS	Spain
22	Regional Health Inspectorate Blagoevgrad	RHI	Bulgaria

23	Finnish Diabetes Association	FDA	Finland
24	The General Hospital Elena Venizelou-Alexandra	ALEXANDRA	Greece
25	Territorial Health Agency of the National Health Service	ASL ROMA 2	Italy
26	The University Hospital Gemelli	FPG	Italy
27	The Public Health University Hospital of Pisa	AOUP	Italy
28	Medical University of Warsaw	MUW	Poland
29	The Competent Authority will involve one AE - the Association of Diabetes Patients of Portugal	APDP	Portugal
30	General Hospital Novo Mesto	SB-NM	Slovenia
Associated Entity			
31	The regional Primary Care Research Institute on chronic diseases. Aragón.	GAIAP	Spain

2. Abstract

Title:
Care4Diabetes, Reducing the burden of non-communicable diseases by providing a multidisciplinary lifestyle treatment intervention for type 2 diabetes.
Rationale:

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.

Context:

The focus will be on tangible transnational activities with a potential to trigger diabetes related policies in Member States with the prospective to improve health and socio-economic outcomes.

Objectives:

The overarching objective of the C4D is to improve and foster health in the European Union (EU) Member States by reducing the burden of T2D and related risk factors, both at societal and personal level, through transfer and implementation of an effective lifestyle treatment and training program. This will be pursued by creating a deep comprehension of the Best Practice (BP) “Reverse Diabetes2 Now” (RD2N), conducting context analysis where the pilot actions will be implemented, monitoring and evaluating system in place to provide details on impact on health and socioeconomic aspects, orienting sustainable practices for a long term vision, and engaging policymakers and stakeholders included in a dissemination and communication strategy over the 36months duration of the project.

Methodology:

Type of Study: Quasi-experimental implementation trial conducted in concert in 12 countries.

General objective: C4D aims to implement and pilot interventions that emulate BP “Reverse Diabetes 2 Now” and evaluate the processes as well as the outputs and outcomes (pre-post measurements) of the implementation using the knowledge and methodologies of implementation science.

Intervention: Up to 120 healthcare professionals (up to 10 per pilot country) will be directly trained by Dutch BP owner for pilot actions in their countries. A total of 860 people with type 2

diabetes are expected to be recruited to the pilots. The C4D will follow the best practice's overall approach and adjust features considering the country-specific guidelines, contexts and needs. This will be outlined in the implementation plans delivered by each country in the preparation phase. Intervention consists of a 6-month initial phase to introduce lifestyle changes and a 6-month follow-up phase to support the sustainability of the changes over time. Evaluation and sustainability elements will be part of the project from early steps, including a dissemination strategy to ensure the awareness and participation of stakeholders and policymakers.

Expected results: The expected outcomes are to improve patients' diabetes management, well-being and quality of life, potentially reduce diabetes medication and healthcare associated costs, and to promote capacity building of health systems towards more innovative and integrated T2D interventions based on lifestyle changes.

2.1 Resumen (Español)

Título: Care4Diabetes, Reducción de la carga de las enfermedades no transmisibles mediante una intervención multidisciplinar de tratamiento del estilo de vida para la diabetes de tipo 2.

Justificación: Las enfermedades no transmisibles (ENT), como la diabetes de tipo 2 (T2D), representan las principales causas de discapacidad, mala salud, jubilaciones por enfermedad y muerte prematura en la UE y causan un considerable impacto social y económico. El proyecto europeo Care4Diabetes Joint Action (C4D) fomentará la transferencia y aplicación de una práctica innovadora que tiene el potencial de reducir la carga sanitaria de la T2D mediante el aumento de la calidad de vida y la prolongación de la esperanza de vida, disminuyendo el coste de la gestión habitual de la T2D, incluidos su gasto farmacéutico o las líneas presupuestarias designadas a esta enfermedad y sus consecuencias.

Contexto: La atención se centrará en actividades transnacionales medibles con potencial para desencadenar nuevas políticas relacionadas con la diabetes en los Estados miembros con la perspectiva de mejorar la salud y los resultados socioeconómicos en esos contextos.

Objetivos: El objetivo general de la C4D es mejorar y fomentar la salud en los Estados miembros de la Unión Europea (UE) reduciendo la carga de la T2D y los factores de riesgo relacionados, tanto a nivel social como personal, mediante la transferencia y aplicación de un programa eficaz de tratamiento y formación sobre estilos de vida. Para ello, se profundizará en el conocimiento sobre la Buena Práctica (BP) "Reverse Diabetes2 Now" (RD2N), se llevará a cabo un análisis del contexto en el que se implementarán las acciones piloto, se establecerá un sistema de seguimiento y evaluación para proporcionar detalles sobre el impacto en la salud y los aspectos socioeconómicos, se orientarán las prácticas para asegurar su perdurabilidad a largo plazo y se implicará a los responsables políticos y a otros interlocutores interesados. Se acompañará de una estrategia de difusión y comunicación a lo largo de los 36 meses de duración del proyecto.

Metodología:

Tipo de estudio: Ensayo de intervención cuasi-experimental realizado de forma simultánea en 12 países.

Objetivo general: El C4D pretende poner en marcha y pilotar intervenciones que emulen la BP "Reverse Diabetes 2 Now" y evaluar los procesos así como los resultados y utilidad (mediciones pre-post) de su adopción utilizando los conocimientos y metodologías de la ciencia de la implementación.

Intervención: Hasta 120 profesionales sanitarios (un máximo de 10 por país piloto) serán formados directamente por el propietario holandés de la BP para llevar a cabo acciones piloto en sus países. Se espera reclutar a un total de 860 personas con diabetes tipo 2 para los programas piloto. La C4D seguirá el enfoque general de las mejores prácticas y ajustará sus características teniendo en cuenta las directrices, contextos y necesidades específicos de cada

país. Esto se indicará en los planes de ejecución que cada país presente en la fase de preparación. La intervención consiste en una fase inicial de 6 meses para introducir cambios en el estilo de vida y una fase de seguimiento de 6 meses para apoyar la sostenibilidad de los cambios a lo largo del tiempo. Los elementos de evaluación y sostenibilidad formarán parte del proyecto desde las primeras etapas, incluida una estrategia de difusión para garantizar la concienciación y participación de las partes interesadas y los responsables políticos.

Resultados previstos: Los resultados esperados son mejorar el control de la diabetes, el bienestar y la calidad de vida de estos pacientes, reducir potencialmente la medicación que usan para tratar la enfermedad y los costes asociados a la atención sanitaria derivada, promoviendo intervenciones más innovadoras e integradas para la T2D dentro de los sistemas sanitarios, basadas en cambios en el estilo de vida.

3. Background

Prevalence of T2D is increasing in Europe due to increases in overweight and obesity, unhealthy diet, ageing, and physical inactivity. If diabetes is not managed correctly, patients are likely to become progressively ill and debilitated. Over time, the disease can damage the heart, blood vessels, kidneys, eyes, and nerves. 50% of people with diabetes die of cardiovascular disease and 10-20% die of kidney failure [1]. Overall, diabetes leads to high costs sustained by governments, and it represents 10% of the global health expenditure. Appropriate interventions are indispensable measures to reduce the health and economic burden of T2D: and its associated complications.

A cornerstone for effective T2D management is a healthy lifestyle, which includes a balanced diet, regular physical activity, not smoking, maintaining a healthy body weight, good mental health including good sleep habits and relaxation techniques practices [2].

The selected best practice for Care4Diabetes is the "RD2N". It is an evidence-based and reimbursed Dutch lifestyle treatment and training Programme for T2D, developed, and promoted by the Dutch Foundation Voeding Leeft (VL) [3].

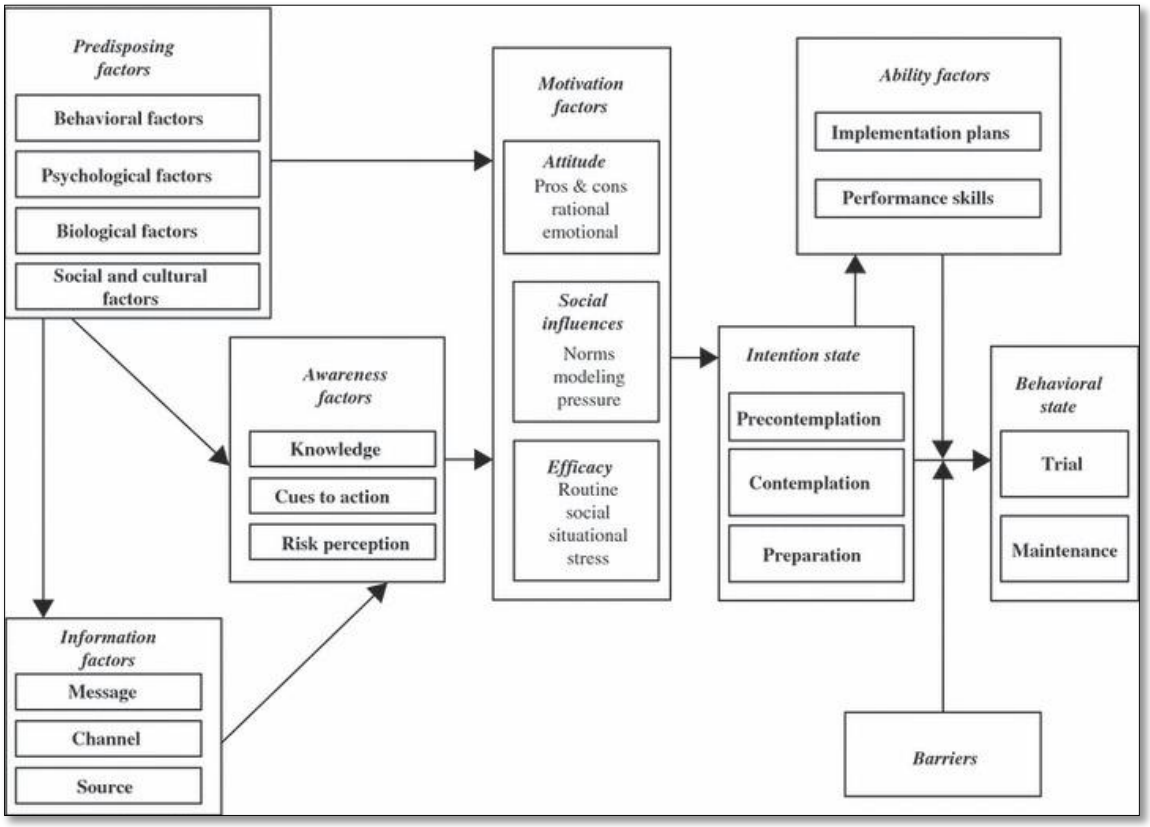
The rationale behind this program - hereafter defined as "best practice" lies in the implementation of effective lifestyle treatment and training program, which can bring improved quality of life in people with T2D and healthier blood glucose levels with potential lower medication consumption.

The RD2N is a multicomponent lifestyle intervention for T2D developed since 2014 by VL in their efforts to change participants' lifestyle to remedy their disease.

The goal of the Reverse Diabetes2 Now program is to improve health through the targeted use of nutrition, exercise, relaxation and sleep with medical supervision to safely reduce medication use.

The programme is based on the 'Integrative Model for explaining motivational and behavioural change' (I-Change model) [4], shown in figure 1 . According to this model a person can change their behaviour if there is awareness of the problem (behaviour), motivation, intention and willingness to change, if the person has sufficient skills and if (potential) barriers have been reduced. In addition, a person should have access to the right information. During the programme, the underlying principles of behavioural change are taken into account for all four core elements: nutrition, exercise, relation and sleep, in order to create a solid foundation for sustainable change. The participants learn by using their head (knowledge), their heart (experience) and their hands (doing) to make the required changes.

Figure 1. 'Integrative Model for explaining motivational and behavioral change' (I-Change model). Hein de Vries 2017.



RD2N is a 6-month group programme using biometric feedback for personalised advice pertaining to the full range of lifestyle factors involved in the T2D pathogenesis

The novelty of the programme lies in its multicomponent character. This includes providing skills rather than just knowledge of nutrition and lifestyle, in its individual approach using biometric feedback, and its use of a group-based approach. In addition, the programme uses a dynamic and practice approach and therefore is continuously updated as insights on T2D develop over time.

C4D is highly **relevant to the call's objectives** and the EU4H Programme, which sets as one of their key priorities the decrease in the impact of NCDs on individuals and society. C4D will aim to reduce T2D burden, as well as raise awareness and acceptance on improved and more innovative related lifestyle interventions, in line with EU policy framework and the Action Plan for Prevention and Control of NCDs in the World Health Organization (WHO) EU Region 2016-2025 [5].

The consortium, composed of beneficiary and associated organisations of 12 Member States, will give feedback and guidance on the progress of the C4D. Results and conclusions from the BP implementation in different EU contexts will allow the production of guidelines for transferability of the intervention in the EU to guide next-generation initiatives for diabetes.

CARE4DIABETES will support cross-national collaboration of Member State implementers together with EU decision-makers.

4. Methods

4.1 Project objectives

Overarching objective

The overarching objective of the CARE4DIABETES is to improve and foster health in the EU Member States by reducing the burden of T2D and related risk factors, both at societal and personal level, through effective lifestyle treatment and training programmes. 12 countries will be involved in the process of transferring and implementing the intervention. Results and conclusions from the best practice implementation in different EU contexts will allow the production of guidelines for transferability of the intervention in the EU.

Specific objectives

- Thorough understanding about the best practice RD2N and its transferability and sustainability supporting factors
- Thorough understanding of national/regional contexts (and main stakeholders) in which the best practice is intended to be implemented.
- Enhanced lifestyle counselling knowledge and skills among healthcare professionals involved in the project pilots.
- Lifestyle intervention model for T2D patients transferred, piloted, evaluated and adjusted in each implementing country
- Improved lifestyle, quality of life and levels of glycaemic control and reduction in use of glucose-lowering medication among T2D participants.
- Lifestyle intervention model for T2D patients integrated into local/regional/national health care services

4.2 Reverse Diabetes2Now organization and content

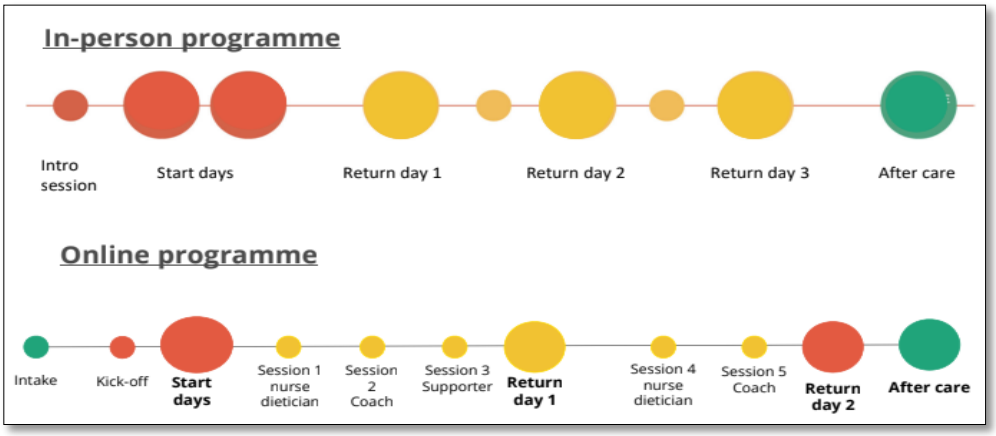
4.2.1 Reverse Diabetes 2 Now phases

All the eligible participants will be provided with a lifestyle intervention based on the R2N BP. There is a maximum of 20 participants per group.

In C4D project, Reverse Diabetes2 Now is a 1-year lifestyle treatment and consists of two phases (see figure 2 for a schematic overview): a six-month intensive phase and an after-care phase of six-months. In order to start the programme participants are referred to the programme by their health professional. After a medical screening to determine if participants meet the inclusion and exclusion criteria participants can start the programme.

During the first six months of the programme five group-based programme days are organized. After 1, 3 and 6 months there are 'return days'. Every programme day participants receive presentations and workshops (e.g., cooking workshop, exercise workshop, coach sessions around the four pillars of the programme: nutrition, exercise, relaxation and sleep). On the first return day participants are invited to bring a relative or friend to get acquainted with the programme so they can support the participant at home.

Figure 2. Schematic overview for participants to RD2N intervention



INTENSIVE FASE (FASE I)

Two approaches are used in R2N practice, face-to-face or online.

The face-to-face version of the training will start with a two-day retreat. Three other one-day face-to-face sessions will be scheduled: after one month, three months and at six months to reinforce knowledge.

The online version foresees more frequent sessions: a minimum of six sessions, four of them of at least half a day. Demographic circumstances (such as population dispersion) will be taken into account to facilitate access to training for a part of the population that would otherwise not be able to participate. As well as those who have availability and preference for this modality will participate. The content will be the same as that foreseen for the face-to-face sessions, but adapted to this modality.

This chapter should describe the practice as it is conducted in VL. In C4D, the piloting partners will adopt-adapt-abandon-adapt as appropriate for their circumstances.

First two programme days:

In the face-to-face intervention of R2N practice, the first two days are intensive meeting days and all participants stay overnight together with the professionals who carry out the R2N intervention.

To ensure participant safety, Reverse Diabetes2 Now works with a specialized multidisciplinary team of professionals including an experienced diabetes nurse, medical doctor, a dietician, a coach and a programme coordinator. Due to often complex multimorbidity of participants a medical team including experienced nurses, general practitioners and an internal medicine specialist is available for medical support.

During the first two days, the glucose level in the blood is measured regularly: before breakfast,1,5/2 hours after breakfast, before luch,1,5/2 hours after luch, after dinner,1,5/2 hours after dinner, and prior to sleep.

and the medication is immediately adjusted if necessary. Measuring blood glucose levels after meals during the day also provides regular biometric feedback to the participants. medical doctors, endocrinologist, diabetologist or experienced diabetes nurses or nurse practitioners under clinical protocol are responsibles for reducing participants' medication in collaboration with the participants' own doctor. During the first six months the multidisciplinary team has intensive contact with the participant and the participants' own doctor to ensure medical safety and prevent dysregulation of glucose levels.

Intensive phase after start 2 days:

In R2N, the intensive phase lasts six months. After the first two programme days the nurse practitioner further reduces participants' medication based on biometric feedback (blood glucose levels measured by the participants, glycated haemoglobin (HbA1c) levels, weight and waist circumference) based on national protocols for reducing diabetes medication. The dietician supports participants in changing their eating pattern and explains the physiology of metabolic syndrome and diabetes type 2 to the participants. The coach helps participants to achieve sustainable behaviour change by learning how to set goals, to create awareness and how to deal with setbacks and life events. The pilot coordinator is responsible for the practical organisation of the programme and is the primary point of contact for participants.

Online Platform

In R2N, the participants have access to an online community for the entire programme where they can contact other group members and the support team to share experiences or ask questions. In addition, the participants have access to recipes, videos, background information, challenges, etc. that facilitate their improvement process.

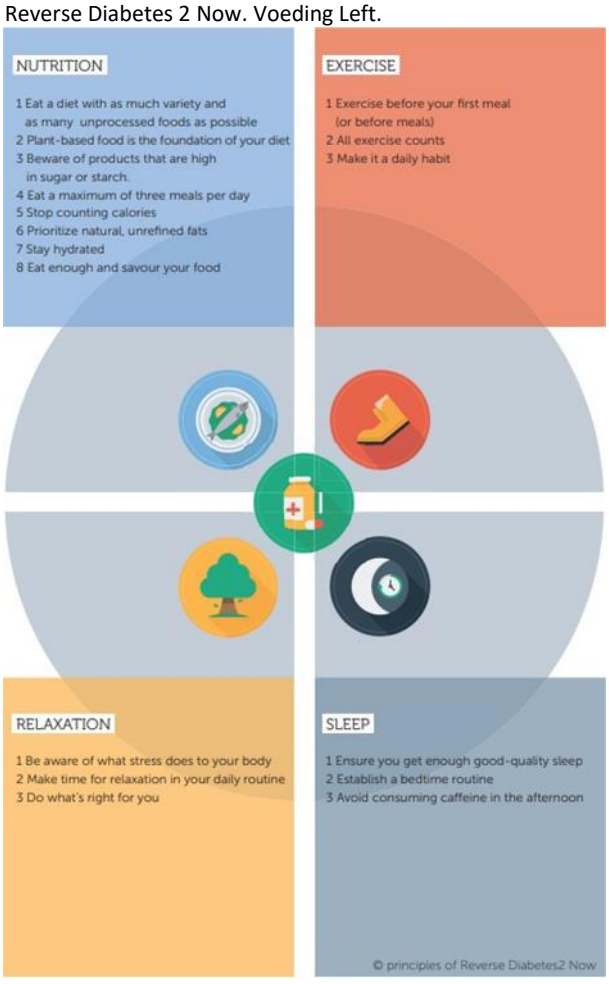
AFTER CARE FASE (FASE II)

After the first six intensive months there is an 'after care' period of 6 months. In R2N, the participants can participate in optional activities in order to improve their improvement process or to get additional support if they have a setback. The activities include presentations to refresh participants' knowledge, questions and answers sessions, coach sessions and inspiring in-depth webinars about the four pillars of the programme (nutrition, exercise, relaxation and sleep). The participants have access to the online community during the aftercare phase.
Most activities are performed in groups during the programme days, but there is room for individual coaching by the team members as well.

4.2.2 Reverse Diabetes 2 Now core elements

The Reverse Diabetes2 Now programme is divided into four core elements: nutrition, exercise, relation and sleep. For each core element several principles have been developed (see Figure 3).

Figure 3: Main elements of Reverse Diabetes 2 Now. Voeding Left.



Nutrition
In R2N, the principles of the dietary pattern are based on the 2015 nutritional guidelines of the Dutch Health Council (Gezondheidsraad) [7], based in international scientific publications, Mediterranean diet and prior experience with the target group.
Group presentations are given by the dietician providing in-depth information about what type of nutrition is most suitable for people with type 2 diabetes and why this is the case. The goal is

to make participants understand what food choices are suitable for them. Participants complete a lifestyle history, to receive information about participants' daily nutrition, exercise, quality of sleep, stress, medication use and measured blood glucose levels). Based on this lifestyle history the diabetes nurse or nurse practitioner and dietician provide individual feedback to the participants. Participants receive a participant's book with background information and follow a 30-day menu with recipes for breakfast, lunchand dinner.

Exercise

The importance of everyday physical activity is emphasized during the programme in R2N. Participants are encouraged to move more at home (e.g., having a walk before lunch, walking or cycling for errands or taking the stairs more often) [8][9]. During the programme days the coach helps participants identify opportunities to embed exercise into their daily life. During the programme daysseveral moving exercises are practiced and the effect is measured by monitoring the blood glucose levels before and after exercising.

Relaxation

All programme days start with a relaxation exercise guided by the coach. During each programme day there is a coaching session to raise awareness of behavioural patterns and obstacles and dealing with stress is a central component. In addition, participants discuss and set goals.

Sleep

The importance and physiology of sleep is explained by the diabetes nurse or nurse practitioner and the dietician. The relationship between sleep and the other pillars is explained and information and advice is shared on how to improve sleep.

This chapter gives an overview of the practice of the VL. In all pilots, good practice will need to be adapted and adjusted, as well as adapted to the available health resources and existing diabetes treatment protocols in the health authorities of each partner involved.

4.2.3 Multidisciplinary team

Each pilot intervention, for a maximum of 20 participants and a minimum of 12 participants, will be conducted by a multidisciplinary team including the roles shown in Table 1.

Up to 120 healthcare professionals, organised in multi-disciplinary local teams, will be directly trained by the best practice owner VL. These trained professionals will train additional personnel, if needed for local pilot actions.

Table 1. Roles and functions of the intervention team

ROLE	RESPONSIBILITIES in R2N practice*

Dietician or equivalent	• Physiological explanation of the metabolic disturbance of type 2 diabetes (insulin resistance) • Guidance for participants in changing eating habits
Nurse or General Practitioner	• Safe process guidance for individual participants • Individual and group guidance on reduction of medication and reversing type 2 diabetes • Manage patient record and registration • Contact with the lead practitioner of the participant
Coach/facilitator or equivalent	• Create a safe setting for the individual and the group • Activate and monitor group dynamics • Guidance in awareness and behavioral change • Guide to activation and integration of sustainable behavior
Pilot coordinator	• Quality assurance • Practical organisation of the program • Communication with patients • Administration patients and keeping overview of progress

*The responsibility division may be changed to suit local settings and organization of work.

4.3 C4D Preparatory actions

During the **preparatory phase**, the Dutch entity will be in charge of sharing their approach and experiences necessary for the development of the pilot projects. It will train the professionals through training of trainers, provide the necessary materials and guidelines in the common language of the project (English), as well as advice and ensure that it is adapted to the original practice, respecting and aligning with local guidelines, practices, roles of professionals and required local languages:

a) In-depth review of the best practice, **context analysis** and stakeholder engagement. This first task will allow the consortium an in-depth understanding to describe RD2N, as well as review national/regional contexts and define key stakeholders to engage. A detailed description on how it was implemented step-by-step (resources and capabilities required, barriers and facilitators, how problems were solved etc.) will follow and core features, context characteristics using the SCIROCCO Maturity Model [10], and the implementation process based on CFIR [11], will be analysed.
b) **Training the trainers**: VL will organise the "train-the-trainers" training of local healthcare staff that will be implementing the pilot actions. Each local team will be multidisciplinary, including pilots' coordinators, nutritionist/dieticians, GPs/internists,

nurses, and, if applicable, coaches (or comparable figures). At the beginning of the task, up to 8-10 healthcare professionals per pilot country will receive the train-the-trainers action in English by VL. The training courses will be divided per country cluster. Following recommendations on VL, 4-5 countries will compose each cluster. The training will include transfer of knowledge by several experts´ presentations. Additionally, participants will practice by doing several exercises, have assignments, and conduct reflection assignments. The training will last 3 months.

When applicable, professionals trained by the best practice owner VL will become "replicators" by training further staff that might be needed to implement the action at national/regional level. During the whole task, VL will support by the coordinator team, coaching individual countries. The training actions will be continuously monitored for improvement. Satisfaction and opinions for evaluation and fine-tuning purposes will be collected from healthcare participants. The assessment of the first cluster training will serve to correct any potential major bottlenecks and fine-tuning the next training. Healthcare professionals will receive a certificate upon completion of the training, which will give them the capacity to train other health professionals in their country.

c) **Adaptation of materials:** Pilot local teams will not just translate but to adapt original materials to their own health, social and cultural context, following the treatment and nutritional guidelines used in the country. The material includes presentations and guidelines. Example recipe videos, podcasts, animations, etc can also be made available in English by VL, and individual countries can determine whether these are required in the local context.

4.4 PDSA cicle

To ensure compliance with the objectives of the good practice, as well as its sustainability, the Deming cycle (Plan-Do-Study-Act (PDSA)) will be applied in the intensive training phase (Phase I) of the pilots.

In Phase I , 340 patients will be involved from month 12 to month 18 (both included). While these groups of patients, after month 6, will move on to the follow-up phase (Phase II), the full PDSA cycle will have been completed in its intensive phase, and will be analysed in each pilot.

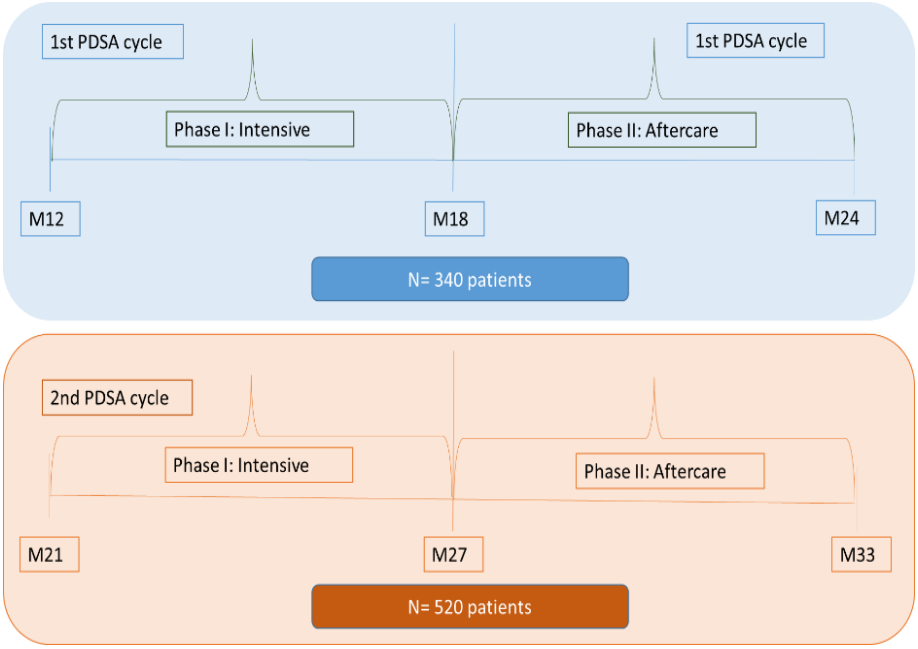
The consortium will use three months of the first PDSA cycle, from M19 to M21 inclusive, to evaluate the results and outline the necessary corrections and adjustments. This approach will allow initial conclusions and recommendations for improvement to be drawn, which will be applied in the second round of intervention with the second group of patients who will start the intensive phase in month 22.

This second round of Phase I intervention, in parallel with a PDSA, will involve a larger number of patients (520) and will run from M22 to M27. Like Phase I, Phase II pilot post-treatment actions will be implemented in 860 patients. The first group of patients (340) will conduct their Phase II activities between M19 and M24, in parallel with a PDSA cycle for evaluation purposes.

The Phase II pilot activities of the second group of patients (520) will run from M28 to M33. The consortium will not apply the PDSA approach to the second round of Phase II intervention, due to the time constraints of the JA duration.

The different phases and groups can be seen in the figure 4:

Figure 4: Timeline of JA interventions with patients in parallel with PDSA cycles



4.5 Study design and selection of study population

Quasi-experimental implementation trial conducted in concert in 12 countries.

4.5.1 Study population

Person between 20 and 80 years old with type 2 diabetes.

4.5.2 Inclusion criteria

- To have diagnosed type 2 diabetes for at least 1 year but no more than 10 years
- Presently using medication (oral or injectable drugs or insulin) to treat T2D
- Being between 20 and 80 years of age
- Body Mass Index (BMI) between 25 and 40
- Motivation for lifestyle change

- Ability to take part in the intervention: measure their glycaemic levels, satisfactory digital skills and access to internet, possibility to take part in the group intervention (face-to-face or online, as appropriate)

4.5.3 Exclusion criteria

- Severe Chronic Obstructive Pulmonary Disease (COPD)
- Bariatric surgery
- Kidney failure
- Pregnancy (self-report)
- Eating disorders (self-reported diagnosis)

4.5.4 Recruitment procedure

Pilot participants will be recruited following methodology that is most feasible in each participating country/area, in line with the national ethical regulations. For example, local health care team may identify T2D patients that are likely to be eligible form health care records and contact them directly, or advertisements may be posted in the health care facilities or social media platforms.

The patients deemed eligible will be invited for baseline visit, during which the procedure to obtain informed consent will be conducted.

4.5.5 Number of subject

The total number of people involved in the intervention will be 860 across 12 countries.

The distribution according to member countries and intervention groups is shown in table 2:

Table 2: Distribution of the sample population by country

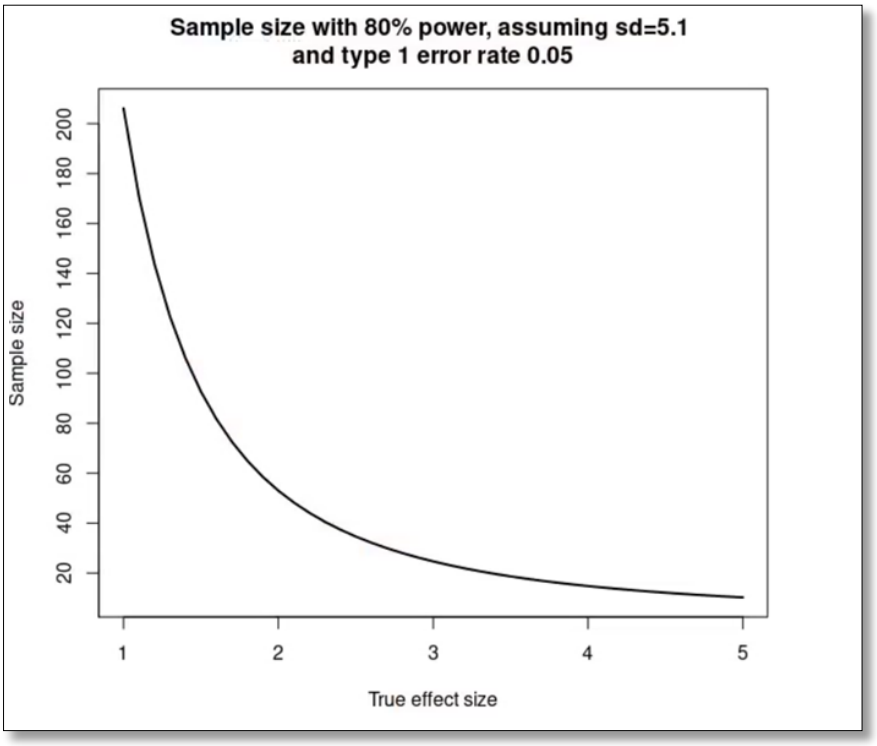
Country	***Areas of implementation***	***Responsible partners for implementation***	***Min. no of patients to recruit***
Spain	Asturias, Cantabria, Galicia, Andalucía, Extremadura, Aragón	CSPA (CA)-SESPA, SCS-IDIVAL, SERGAS, SAS-FPS, JUNTAEX (AEs), GAIAP (AP)	360 (120 1st intervention round + 240 2nd intervention round)
Belgium	Wallonia	Sciensano (CA)	40 (20+20)
Bulgaria	Blagoevgrad	RHI (AE), supported and coordinated by MoH BG (CA)	40 (20+20)
Finland	Country level possibly	FDA (AE), under the coordination of THL (CA)	40 (20+20)
Greece	Attica (incl. Athens)	ALEXANDRA (AE), under the coordination of 1st YPE ATTICA	60 (20+40)

Hungary	Central Hungary	NPHC (CA)	40 (20+20)
Italy	Lazio Region and Tuscany Region	ASL ROMA 2, FPG, AOUP (AEs), under the coordination of ISS (CA)	60 (20+40)
Malta	Country level	MFH	40 (20+20)
Poland	Mazovian district	NFZ (CA) and WMU (AE)	40 (20+20)
Portugal	Lisbon & Tagus Valley Region and Alentejo Region	DGS (CA) and APDP (AE)	60 (20+40)
Slovakia	Country level possibly	MoH SR supported by externally concreted patients' organisations (see budget)	40 (20+20)
Slovenia	South-East Region	SB-NM (AE), under coordination of NIJZ (CA)	40 (20+20)
***TOTAL NO OF PATIENTS*:** **860 (340 1st intervention round; 520 2nd intervention round)**			

Each piloting country will thus enrol at least 40 people. C4D is a quasi-experimental pilot trial aiming to transfer and implement a BP intervention that has already been evaluated thoroughly; therefore no formal statistical hypothesis or sample size calculation is necessary.

However, based on the 6-month body weight reduction results from the original BP, with standard deviation of 5.1 kg (figure 5), we can estimate that the sample size within each piloting country is sufficient for a paired sample t-test (power of 80%, type 1 error rate 0.05), assuming the true effect size (mean reduction in body weight) is 2,3 kg.

Figure 5: Sample size in Care4Diabetesv with 80% power.



4.6 Pilot evaluation and data measures

The evaluation of the pilots will focus on the effects of the intervention on participating individuals' clinical and behavioural characteristics, quality of life, and satisfaction in the intervention. In addition, we will evaluate the implementation processes, and the experiences of the health care professionals involved with the pilot implementation.

Data on background characteristics as well as the baseline measurements (including laboratory tests) will be collected within the month prior to the beginning of the pilot intervention phase (after informed consent has been obtained).

Table 3 lists the background parameters and Table 4 the variables to be evaluated as well as the measurements' timetable.

Table 3. Background clinical and demographic parameters

Background parameters	Unit/Categories
Age	years
Sex	male/female/other
Ethnicity (if applicable)	1) birth country 2) mothers birth country 3) fathers birth country
Educational level	basic/middle/high

Income adequacy	Does your household have enough money to meet your needs? 1 = completely; 2 = mostly; 3 = moderately; 4 = a little; 5 = not at all.
Household status	Tick all that apply: 1) living alone 2) living with a partner 3) under-aged children living in the household 4) other adults living in the household
Employment status	working/unemployed/retired/homemaker/student
Present smoking	non-smoker/occasional smoker/daily smoker
Alcohol	number of units per week
Special diet	no special diet/vegetarian/vegan/no meat/no fish/other, what?

By collecting data on the participants' background characteristics such as educational level, age, and sex, and by comparing it to the local population with diabetes, we can evaluate the possible reach and coverage of the piloted intervention. This will facilitate the evaluation of economic impact of the intervention if scaled-up.

Table 4. Clinical and behavioural measurements during the pilots

Evaluation measurements	Baseline	6 months	12 months
Height (m)	x		
Weight (kg)	x	x	x
-->BMI (kg/m^2)	x	x	x
Waist circumference (cm)	x	x	x
Blood pressure (mmHg)	x	x	x
Serum lipids (total cholesterol, HDL, LDL, trigly; mmol/L)	x	x	x
HbA1c (mmol/mol)	x	x	x
Medication (diabetes, blood pressure, lipids)	x	x	x
Quality of life (EQ5D5L)	x	x	x
Perceived health (Likert scale question)	x	x	x
Fatique (SMRC questionnaire)	x	x	x
Sleep (SMRC questionnaire)	x	x	x
Physical activity (SMRC questionnaire, adapted)	x	x	x
Diet (Diet Assessment Questionnaire (DQI), Diabetes Self-Report Questionnaire (DSMQ)	x	x	x
Satisfaction in intervention (Voeding Left questionnaire, adapted)		x	x

Primary outcome indicators are change in HbA1c and change in diabetes medication from baseline to month 6 and month 12.

Secondary outcome indicators are program adherence, and program appreciation, as well as changes in quality of life (EQ5D5L), body weight, BMI, waist circumference, blood lipids, blood pressure, diet, physical activity, fatigue, sleep, and perceived health.

4.7 Pilot process, outcome, and cost evaluation

The pilots' processes and outcomes will be evaluated following the RE-AIM framework [12], the contents of which are shown in table 5.

Table 5. Process data collection

	Process indicator (based on RE-AIM framework)
REACH	
Inclusion	Activities/procedures to attract possible participants
	Number of patients screened for eligibility
Exclusion	Number of patients excluded (per exclusion criterion)
Background characteristics	Characteristics of participants compared to non-participants or to target population
EFFECTIVENESS	
	Number of sessions/hours of intervention organized
	Number of intervention sessions/hours of intervention attended by each participant
	Attrition (%)
	Outcome measures (%) completed at each timepoint
ADOPTION	
	Characteristics of settings participating compared to non-participants
	Number (and %) of staff participating
	Characteristics of staff participants vs. typical staff
IMPLEMENTATION	
	Adaptations made to intervention (Phase 1)
	Cost of intervention
	Consistency of implementation across staff/settings
MAINTENANCE	
	Outcome measures at 12 months
	Adaptations made to intervention (Phase 2)
	Model integration to the organization

The costs of the pilot will be collected following methodology that will be provided in the Evaluation Protocol. Briefly, the project will look at intervention costs against benefits of the

practice. Implementation costs that could be considered, among others, can be broken into several categories including labour (e.g., the cost of training staff to deliver the intervention), capital (one-off costs of setting up and running the intervention, e.g. building the online platform), administrative (e.g., the cost of promoting the intervention to eligible participants), consumables (e.g., other materials, tools, goods needed for the intervention implementation) and overhead costs.

4.8 Data processing

Each pilot will retain and store their data set containing the answers from individual partners, following their national rules and regulations. Data management and ethics compliance of activities will be ensured. A FAIR Data management plan will be released and periodically updated upon progress. The Data Protection Officer of CSPA will coordinate this activity to ensure that the General Data Protection Regulation (GDPR) is followed. The pilot implementers will collect a variety of data (indices on health, lifestyles and socio-economic status). Sensitive data collection and process will be in line with GDPR rules and national requirements. Guidance on ethical oversight and analyses will be provided, dealing with ethical values, moral principles and social rules from the basics of social life to national laws, with a holistic approach: patients, healthcare professionals, carers or others.

The consortium will comply with the Regulation (EU) 2016/679 -General Data Protection Regulation (GDPR) and ethics procedures.

Each pilot implementer will process its own data and provide aggregated data (mean±std and response distributions, as appropriate, see Table 4 for parameters) to WP3 following the methodology that will be described in detail in the Evaluation Protocol. Based on this aggregated data, WP3 will calculate weighted means and confidence intervals for the consortium level data.

In addition, pilot implementers within a country are allowed to compile their joint research data set in order to conduct their own analyses.

Table 6 shows the procedures, types, formats and sources of information for data collection in C4D.

Table 6. Description, preservation, storage and share, and responsibilities

Dataset reference name: C4D	Data collection procedures; nutrition best practice paper; marketing approaches for healthier nutrition.
Dataset description	
General description	
Data and information from pilot implementers will be regularly collected by implementers following local regulations on data safety and data security. The implementers will provide group-level means / proportions and other aggregated data to WP3 to keep track of Key Performance Indicators (KPIs) collected in the Grant Agreement.	

Origin, nature and scale of data	
In parallel with Phase I and II, collect all needed quantitative and qualitative data to allow assessment of the pilot actions. Take stock of the results and perform a final assessment analysis on the health and socio-economic impact of the best practice in pilot Member States.	
Data format	
Data and metadata will be made available as database formats or spreadsheets.	
Period of preservation	
All the data analysis will be preserved during 5 years after the publication of the results.	
Data storage and back up	
Extracted and aggregated data will be preserved during 5 years after the publication of the results. Aggregated data will be stored at the premises of the partners responsible for their collection and uploaded on the project SharePoint on Teams, restricted to consortium partner's access.	
Data sharing	
Each pilot implementer will store their data following national regulations. Aggregated data and metadata will be made available as database formats or spreadsheets which will be shared in a SharePoint site with the whole consortium.	
Partners' responsibilities	
Data collector	All project partners
Contact partner	THL
Partner in charge of the data storage	All project partners

4.9 Data security

The datasets will be stored in the storage system of the implementing partner. Each partner is responsible for ensuring that the data is stored securely and fully compliant with EU data protection legislation and national legislation.

Ensuring the custody of a database in compliance with European and Spanish data protection laws involve implementing a series of technical and organizational measures aimed at guaranteeing the security and confidentiality of personal data contained within it. Therefore, each partner's database in C4D will have:

- Restricted access: Only authorized personnel should have access to the database. Specific permissions and roles will be assigned exclusively for researchers.
- Encryption: Sensitive data will be encrypted to ensure that only authorized personnel can access it.

- Backups: Daily backups are performed on CSPA servers to prevent data loss and ensure secure storage.
- Activity records (RAT): The Data Processing Record will be completed and made public with its informative duty in two layers: the first layer with basic information and the second layer with more detailed information on the project.
- Risk analysis: To establish security and control measures to guarantee the rights and freedoms of individuals, a risk analysis will be performed. This analysis is particularly necessary in C4D due to the existence of sensitive data such as biometric measurements.

5.Expected Results and Benefits

The final aim of the CARE4DIABETES will be to reduce negative impacts of type 2 diabetes on society by increasing lifestyle training interventions available across the participating Member States with proven favourable effect on patients' quality of life and in achieving blood glucose treatment targets and/or medication reduction, with accompanying sustainability action plans that will support their further use after JA ends and their uptake into other clinical settings in the Member States.

At least 860 type 2 diabetes patients involved in the Phase I and Phase II pilot actions across 12 countries. The key long-term expected impacts of CARE4DIABETES are to:

● Reduce type 2 diabetes' health and costs burden on health care systems.

● Increased patients' durable healthy lifestyles with positive health outcomes and good levels of quality of life to avoid worsening of disease complications

● Promote healthier blood glucose levels adjusting medication when feasible.

● Improve secondary outcomes indicators: program adherence, and program appreciation, as well as changes in quality of life (EQ5D5L), body weight, BMI, waist circumference, blood lipids, blood pressure, diet, physical activity, fatigue, sleep, and perceived health.

6. Schedule

The project has started in February 2023 and will last 3 years.
The most relevant dates are:

- Regulatory Authorities approval: Prior to the recruitment of participants (M0 – M6)

- Inclusion period: 6 months (only start after ethical approval)
- Pilots' implementers start- first patient in: M12 (February 2024)
- Follow-up duration: 12 months
- Data analysis: 3 months
- Time of the study: 36 months (M0 – M36)

In tables 7, 8 and 9 you can see more detailed key tasks and the months of their realisation.

Table 7. Schedule of the main tasks of the 1st year

C4D Ms	1	2	3	4	5	6	7	8	9	10	11	12
calendar	2	3	4	5	6	7	8	9	10	11	12	1
CARE4DIABETES Pilot activities summary												
Context analysis review and stakeholder engagement report (M2-M3)		P	P									
Implementation plan of the pilot country for Phase I and Phase II (M4-M9)				P	P	P	P	P	P			
P1 for Phase I (M2 -M11) and phase II (M2-M11)				x	x	x	x	x	x	x	x	
Ethical approval received										x		
Digital tool in place (portal or similar, for pilots with web-based approach alone or in addition to F2F)											x	
Patients recruited (pts group A M11, pts group B M20)											x	
Materials for Phase I and Phase II adapted and available											x	
C4D practices teams trained											x	
Monitoring system to follow the results and experiences of all D phases in place											x	
D1 Phase I, pts group A (M12-M17), D1 Phase II, pts group A (M18-M23)												D
S1+A1+P2 Phase I pts group A (M18-M20)												
S1+A1+ P2 Phase II, pts group A (M24-M26)												
Patients recruited (pts group B M20)												
D2 Phase I, pts group B (M21-M27), D2 Phase II, pts group B (M27 - M32)												
S2+A2+P3 Phase I, pts group B (M28-M29)												
Final reporting from implementation experience (SQUIRE 2.0) &outcome and impact analysis (M33)												
Sustainability plan including action plans for 1-2 years after JA is over (M34)												

Table 7. Schedule of the main tasks of the 2 nd year

C4D Ms	13	14	15	16	17	18	19	20	21	22	23	24
calendar	2	3	4	5	6	7	8	9	10	11	12	1
CARE4DIABETES Pilot activities summary												
Context analysis review and stakeholder engagement report (M2-M3)												
Implementation plan of the pilot country for Phase I and Phase II (M4-M9)												
P1 for Phase I (M2 -M11) and phase II (M2-M11)												
Ethical approval received												
Digital tool in place (portal or similar, for pilots with web-based approach alone or in addition to F2F)												
Patients recruited (pts group A M11, pts group B M20)												
Materials for Phase I and Phase II adapted and available												
C4D practices teams trained												
Monitoring system to follow the results and experiences of all D phases in place												
D1 Phase I, pts group A (M12-M17), D1 Phase II, pts group A (M18-M23)	D	D	D	D	D	D	D	D	D	D	D	
S1+A1+P2 Phase I pts group A (M18-M20)						SAP	SAP	SAP				
S1+A1+ P2 Phase II, pts group A (M24-M26)												SAP
Patients recruited (pts group B M20)								x				
D2 Phase I, pts group B (M21-M27), D2 Phase II, pts group B (M27 - M32)									D	D	D	D
S2+A2+P3 Phase I, pts group B (M28-M29)												
Final reporting from implementation experience (SQUIRE 2.0) &outcome and impact analysis (M33)												
Sustainability plan including action plans for 1-2 years after JA is over (M34)												

Table 8. Schedule of the main tasks of the 3rd year

C4D Ms	25	26	27	28	29	30	31	32	33	34	35	36
calendar	2	3	4	5	6	7	8	9	10	11	12	1
CARE4DIABETES Pilot activities summary												
Context analysis review and stakeholder engagement report (M2-M3)												
Implementation plan of the pilot country for Phase I and Phase II (M4-M9)												
P1 for Phase I (M2 -M11) and phase II (M2-M11)												
Ethical approval received												
Digital tool in place (portal or similar, for pilots with web-based approach alone or in addition to F2F)												
Patients recruited (pts group A M11, pts group B M20)												
Materials for Phase I and Phase II adapted and available												
C4D practices teams trained												
Monitoring system to follow the results and experiences of all D phases in place												
D1 Phase I, pts group A (M12-M17), D1 Phase II, pts group A (M18-M23)												
S1+A1+P2 Phase I pts group A (M18-M20)												
S1+A1+ P2 Phase II, pts group A (M24-M26)												
Patients recruited (pts group B M20)												
D2 Phase I, pts group B (M21-M27), D2 Phase II, pts group B (M27 - M32)	D	D	D	D	D	D	D	D				
S2+A2+P3 Phase I, pts group B (M28-M29)			SAP	SAP	SAP							
Final reporting from implementation experience (SQUIRE 2.0) &outcome and impact analysis (M33)									x			
Sustainability plan including action plans for 1-2 years after JA is over (M34)										x		

D=do
S=study
A=act
Phase I=intensive programme
Phase II=aftercare

7. Ethical aspects

7.1 Participant information sheet and informed consent

The Participant information sheet and informed consent has been reviewed by CSPA Data Protection Officer.

Each country/partner will fulfil requested needs dictated by their own Ethics Committees to implement the pilot actions in compliance with the HORIZON EU ethical standards.

The participant information sheet is designed to provide potential participants with information about the study and their role in it, while the informed consent form is a legal document that explains the risks and benefits of participation and the participant's rights.

The main elements included are:

- Purpose and nature of the study clear and concise explanation of the research question and purpose, the methods and procedures involved in the study, and the possible outcomes.
- Participant eligibility: who can participate in the study.
- Risks and benefits: possible risks or discomforts that participants may experience as a result of participating in the study, as well as possible benefits.
- Confidentiality: Both the information sheet and the informed consent form explain how the participant's privacy and confidentiality will be protected, including who will have access to their data and how it will be stored.
- Voluntary participation: Both documents emphasise that participation in the study is voluntary and that the participant may withdraw at any time without penalty or consequence.
- Contact information: The information sheet includes the name and contact information for the researcher or study team, which participants can use to ask questions or raise concerns.
- Signature: The informed consent form should include a line for the participant's signature, indicating that they have read and understood the information provided and consent to participate in the study.
- Data transfer: Cross-country transfer of anonymised and aggregated data is envisaged.

Both documents have been reviewed by the DPO and comply with all applicable guidelines.

The generic participant information sheet and the informed consent form are shown in annexes 1 and 2.

The signed consent of the participants will be collected by C4D partners at country level - the investigator or co-investigators as well as by qualified persons after they have been informed of the objectives and the procedures of the C4D. Signed informed consent from the participant will be collected during the inclusion visit prior the start of the intervention programme. Information about this study will be given by the investigator or co-investigators as well as by qualified persons. The participant will receive a copy of the information document and after a sufficient period of reflection, it will be proposed to the participant to sign a consent. One copy will be kept by the subject, one copy will be kept by the investigator.

The information sheet and the consent procedures requested from participants to enter in the project activities and measures to ensure that data collection and storage follow the GDPR and additional national regulations if applicable.

The legislation and treaties on ethics that are taken into account in the Care4Diabetes project are as follows:

7.2 International ethical guidelines

Declaration of Helsinki, which sets out the principles for medical researchers to guide the ethical conduct of research involving human participants and specifically addresses protections for study participants with regard to the risks, burdens, and benefits of participating in studies as well as participants' rights to privacy, confidentiality, and informed consent.

Universal Declaration on Bioethics and Human Rights, which provides ethical guidelines concerning medicine, life sciences and technologies applied to human beings. It protects the interest and welfare of individuals, which are priorities over the sole interest of science or society. With regard to individuals' participation in research, it provides that benefits regarding individuals participating in research must be maximized and harm must be minimized.

7.3 Research ethics and data protection in the EU

European Convention on Human Rights (ECHR), signed in Rome in 1950 and come into force in 1953, is an international treaty to protect human rights and fundamental freedoms in Europe.

Charter of Fundamental Rights of the European Union, defining the concept of fundamental human rights and providing the framework to guide ethics related policy development and implementation at European policy level, as well as in the Member States.

General Data Protection Regulation, entered into force in 2018. This regulation updates and modernizes the principles of the 1995 Data Protection Directive, it sets out the rights of the individual and establishes the obligations of those processing and those responsible for the

processing of the data. It also outlines the methods for ensuring compliance as well as the scope of sanctions for those in breach of the rules.

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9. Annex

Annex1. Participants Information Sheet

GENERIC PARTICIPANTS INFORMATION SHEET

TITLE OF THE STUDY: CARE 4 DIABETES: REVERSE DIABETES 2 NOW : Reducing the burden of non-communicable diseases by providing a multi-disciplinary lifestyle treatment intervention for type 2 diabetes.

MAIN INVESTIGATOR: Marta Pisano González, PhD

CENTER: General Directorate of Care, Humanization and Socio-Health Care of the Principality of Asturias. Ministry of Health (CSPA).

This document aims to provide you with information about a research study in which you are invited to participate. This study was approved by Research Ethics Committee of the Principality of Asturias (CEIM) with the number xxx.

If you choose to participate in it, you should receive personalized information from the researcher, read this document beforehand and be able to ask all questions you need to understand the details of the study. If you wish, you can take the document with you and consult it with other people. You can take the time necessary to decide whether to participate or not.

Participation in this study is completely voluntary. You can decide not to participate or, if you agree to do so, change your mind by withdrawing the consent at any time without giving explanations. We assure you that this decision will not affect the health care to which you are entitled.

What is the purpose of the study?

The main objective of CARE 4 DIABETES is to enhance the autonomy of patients with type 2 diabetes in the control of their disease, improving their lifestyle by increasing their physical activity, a diet adapted to their needs, promoting rest and encouraging the use of relaxation techniques.

Why am I being offered to participate?

You are invited to participate because you have type 2 diabetes and belong to a population group with certain characteristics.

What does my participation consist of?

Those who wish to participate in the study will undergo an intensive 6-month program of education and training in physical exercise, nutrition adapted to their needs, medication adjustment, relaxation techniques and promotion of rest.

The program will be carried out in groups of 15-20 people and may take place in face-to-face or virtual format depending on the previous selection and will be given by a multidisciplinary team of professionals.

The face-to-face training will entail an initial two-day, overnight, coexistence intervention, followed by three other one-day sessions in the following months.

The online training will consist of at least 6 sessions.

After this initial intensive intervention, you will participate in a follow-up intervention to reinforce and strengthen the new habits acquired during the first one.

Will participating in the study cause me any inconvenience or discomfort?

In the case of online training, one disadvantage of participating in the study is the time required to complete the training sessions.

In the case of face-to-face training, in addition to the time required to participate in the sessions, there will be a two-day coexistence with an overnight stay.

In both cases, glucose measurement tests and other specific medical parameters will be performed.

Will I receive any benefit?

Participants are expected to acquire healthy habits and improve their lifestyle and, where possible, reduce medication safely.

Will I receive the information obtained from the study?

If you wish, you will be given a summary of the study results.

Will the results of this study be published?

The study results will be sent to scientific journals for dissemination, but no data will be transmitted that could lead to the identification of the participants.

How will the confidentiality of my data be protected?

The processing, communication and transfer of data will be carried out in accordance with the provisions of the Organic Law 3/2018 and, in accordance with the General Data Protection Regulation, Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.

You can ask at any time what data is being stored (right of access), who is using it and for what purpose; you can request a copy of your personal data for your own use or to transmit it to other

persons (portability). You can correct personal data provided by you and limit the use of data that is incorrect (right of correction and deletion). To do so, you should contact the Directorate General for Care, Humanization and Social and Health Care of the Regional Ministry of Health by sending an e-mail to dgcuidados@asturias.org.

Only the research team and the health authorities, who have the duty to maintain confidentiality, will have access to all the study data collected. Information that could be transferred to third parties (other countries, for example) will be anonymized and protected, and, in no case, will host data by which participants can be identified, in compliance with the European Regulation 2016/679.

Your data will be collected in encrypted form, which means that they have a code by which the research team can know to whom they belong.

The person responsible for the custody of the data is the person in charge of the file and data processing. The information collected will be kept for 5 years after the publication of the results.

Are there economic interests in this study?

This research is promoted by the Ministry of Health from Asturias with funds provided by the Horizon Europe Framework Program of the European Union under the Grant Agreement GA 101082427.

The principal investigator will not receive specific retribution for the dedication to the study. You will not be paid for participating in it.

How to contact the research team of this study?

You can contact Marta Pisano González and coordination team at phone number 985668534 or mail dgcuidados@asturias.org, C4D_WP1@ficyt.es

For more information, see the study website: https://c4djointaction.eu/

Thank you very much for your help!

Annex2. Informed consent

CERTIFICATE OF CONSENT FOR PARTICIPATION IN THE RESEARCH STUDY: CARE4DIABETES

I,……

- Read the participant information sheet of the above mentioned study that was given to me, and I was able to ask all the questions about the study.
- Understand that my participation is voluntary, and that I can withdraw from the study whenever I want, without having to give explanations and without this having an impact on my medical care.
- Agree to the use of my data in the conditions detailed in the participant information sheet.
- Freely give my consent to participate in this study.

Signature of participant: Signature of investigator:

Name and surname: Name and surname:

…… ……

Date: …/…/20… Date: …/…/20…

FORMULATION OF REVOCATION OF INFORMED CONSENT

CARE4DIABETES PROJECT

I,……

I inform you of my decision to withdraw from this study.

Name and surname: Name and surname:

…… ……

Date: …/…/20… Date: …/…/20…

Please, leave blank

Participant number:
.....