







Reducing the burden of noncommunicable diseases by providing a multidisciplinary lifestyle treatment intervention for type 2 diabetes

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- Worldwide, around 537 million people have diabetes.
- In Malta, approx. 34,000 people have diabetes 40,000 people by 2025.
- This global increase in the prevalence of diabetes obesity, poor diet, lack of physical activity, together with a hereditary component.
- When looking at the nutrition component, we see that diets in developed countries have undergone major changes in the last few decades.
- Countries have shifted away from the Mediterranean diet and instead, opted for a more Westernised 'modern' diet,
  - high intake of ready-made and processed foods, such as refined carbohydrates
  - SSBs
  - processed meat.
- The amount of physical activity has drastically reduced.
- Stress and lack of sleep have increased.
- In the Care4Diabetes (C4D) programme we promote going back to **eating wholesome, unprocessed foods** as much as possible. This is in addition to **physical activity** in our daily routine, **adequate sleep and relaxation**.





- The objective of the 'Care4Diabetes' lifestyle programme is to improve the health and well-being of people affected with type 2 diabetes through the implementation of an intensive educational programme.
- The C4D pilot programme is based on a Dutch practice, Reverse Diabetes 2 Now, developed by NGO Voeding Leeft (VL) and awarded best practice by the European Union.
- Together with a MDT, work on changing the habits of individuals affected by type 2 diabetes and offer treatment possibilities based on proven "good practice" that has been recognized by the relevant European bodies.
- C4D will make it possible to reinforce the implementation of non-medical, lifestyle changes within the health care system while being under the care of a team of healthcare professionals.
- The transferability of this best practice will provide an excellent insight for the implementation of a sustainable, multidisciplinary programme for Malta.



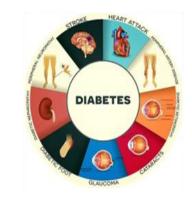


#### MANAGEMENT OF DIABETES IN MALTA









**10%** of the population over the age of 18 have diabetes.

**Diabetes Clinic** in the main general hospital to cater for persons with diabetes.

A shared care
programme was
developed with the
health centres to offer
care and support for
persons with
uncomplicated Type 2
diabetes.

Managed by **MDT** of healthcare professionals: Doctors, Nurses, Podiatrists, and Ophthalmologist.

The high rate of diabetes among the Maltese population calls for immediate action to reduce complications and for improved quality of life.





#### WHY DID MALTA DECIDE TO PARTICIPATE?

- Despite having a diabetes centre and medical care within reach, the prevalence of diabetes is still high and rising.
- It is time to think outside the box and focus on other things that could improve the situation.
- Improve our dietary habits bread, pastries (pastizzi), high salt, processed food.
- Emphasise the importance of physical activity.
- To target the importance of relaxation, stress reduction and sleep, and reduce diabetes distress.
- To promote a health systems that is more inclined towards lifestyle changes and not medications alone.
- To engage policymakers and stakeholders in a dissemination and communication strategy for sustainability.





# CARE4DIABETES JOINT ACTION

- A lifestyle modification programme based on 4 pillars; Nutrition, Exercise, Relaxation and Sleep.
- Multidisciplinary Team Project coordinator (Nutritionist), General Practitioner, Diabetes Practice Nurse, Dietitian,
   Psychologist and Psychotherapist.
- It provides skills rather than just knowledge on nutrition and lifestyle, while providing individualised and group-based approach.
- Collaboration with 12 EU member states, approx. 860 participants.
- Duration of project: 36 months.
- 7 work packages.
- Kick-off February 2023 in Asturias, Spain; and second General Meeting February 2024 in The Hague, Amsterdam.





- 2 pilot studies with 20 participants in each pilot total of 40 participants.
- 6 months face-to-face programme and 6 months aftercare phase (online).
- Medical screening will determine if participants meet the selection criteria.
- Under the care of an Endocrinologist or their private General Practitioner.
- Face-to-face training will take place at a venue in Gozo outside hospital grounds awarding stage of tender.
- Regular measurements of blood glucose (pre and post prandial), BMI, Waist Circumference, HbAIc and BIA.
- Participants have 6 group-based programme days;







### THE PROGRAMME – INITIAL STAGES

- Reached out to the local general hospital and Primary Health Care for the implementation of the project.
   Unable to assist.
- Gozo General Hospital (GGH) ready to support us in this project.
- Approval sought from Director of GGH and Professional Leads (MDT).
- Data protection officers and Ethical approval received.

#### KUMITAT DWAR L-ETIKA FIS-SAHHA

Direttorat ta' I-Informazzjoni fuq is-Sahha u Rićerka 95, Telghet Guardmangia, Pieta' PTA 1313 Malta

Our Ref: HEC18/23 Your Ref:

#### HEALTH ETHICS COMMITTEE

Directorate for Health Information & Research 95, Guardamangia Hill, Pieta' PTA 1313 Malta

Tel: (+356) 25599000 Email: hec@gov.mt

Date: 5th March 2024

Dear Dr Mariella Borg Buontempo & Ms Glorianne Busuttil,

The Health Ethics Committee has recently reviewed your application for ethical approval for the project outlined below. Your proposal is deemed to be ethically sound. It is also deemed to be in line with the General Data Protection Regulation.

Approval Number	HEC18/23
Project Title	Implementing the 'Care4Diabetes' programme in Malta - Reducing the burden of
	noncommunicable diseases by providing a multidisciplinary lifestyle treatment
	intervention for type 2 diabetes (T2D)
Approval Date	5th March 2024
HEC Decision	Approved





### CARE4DIABETES – TRAIN THE TRAINER

#### For who?\*



Nurse practitioner + General practitioner: Advice on safely reducing medication and reversing T2D



Dietician: Explain the physiology of metabolic disruption in T2D and insulin resistance



Coach: Increase awareness around patient's current lifestyle and facilitate behaviour change



Program coordinator: Participant administration and progress tracking and pilot coordination.

# Dates of the training sessions

Startday 1: 27.9.23
Startday 2: 28.9.23
Return day: 12.10.23
Return day: 2.11.23
Return day: 30.11.23

All sessions will be online from 10 AM - 4 PM. Dates of to Meet ups tbd.

It is important to attend all the sessions.

#### Timeschedule of the program







<sup>\*</sup>see the detailed job descriptions

#### RECRUITMENT OF PARTICIPANTS FOR ROUND A

- Participants were conveniently selected for the study while attending for their hospital appointment with the collaborating Endocrinologist at Gozo General Hospital (GGH).
- Various reminders sent to the Endocrinology team and meetings on site.
- Prospective participants kept motivated through calls and offering educational material available at Health Promotion and Disease Prevention Directorate (HPDP).
- Outreaches and social media posts during 'World Diabetes Day 2023'.
- Giving information about diabetes + educational material for home.
- Blood glucose measurements during outreaches organised by HPDP.





### **OUTREACH ACTIVITIES AND SOCIAL MEDIA ENGAGEMENT**











### **OUTREACH ACTIVITIES AND SOCIAL MEDIA ENGAGEMENT**











### RECRUITMENT OF PARTICIPANTS FOR ROUND A

- Total number of participants recruited: 20
- Difficulties encountered during recruitment
  - Limited number of clients fit in the eligibility criteria of the study due to medications
  - Lack of motivation
  - Lack of digital skills
  - Limited to one Consultant





#### **INCLUSION CRITERIA**

- Diagnosed with type 2 diabetes for at least one year but no more than 10 years.
- Presently using oral medication to treat T2D low complex.
- Adults between 20 and 80 years of age.
- Body Mass Index (BMI) between 25 and 45 kg/m<sup>2</sup>.
- Increased abdominal circumference
   (men greater than 102cms and women 88cms).

- Ability to use digital devices.
- Access to internet.
- Sufficient language skills to take part in the programme.
- Possibility to take part in the program as provided (schedule, location).
- Committed/motivated to make lifestyle changes to control diabetes.
- Willingness to measure blood glucose at home.





#### **EXCLUSION CRITERIA**

- Severe COPD (GOLD III/IV).
- Presence of eating disorder (bulimia nervosa or binge eating disorder).
- Type 2 diabetes mellitus managed through insulin.
- SGLT2 inhibitor that cannot/should not be stopped.
- Heart failure in NYHA class III and IV and MI.
- Renal insufficiency with an eGFR <30.</li>
- Age over 80 years and children.

- Illiterate.
- Vegan diet.
- Bariatric surgery gastric bypass/ sleeve/ mini-gastric bypass.
- Insufficient motivation.
- Pregnancy or planned pregnancy within six months after the start of the programme.
- BMI >45.
- Individuals who are non-Maltese speaking.





#### CONTENT OF THE PROGRAMME

- Participants will be given a participant's booklet in either Maltese or English.
- A set of recipes (under construction) will be available online and printed.
- Other educational material will be created and distributed.
- Add Ons
  - Physical activity classes
  - Bio-impedance analyser
  - Smoking cessation talk should the need arises.





#### DIGITAL PLATFORM

- Malta will be using the digital platform hosted by the Italian partners ISS.
- Platform will remain in the English language and will have content in both Maltese and English.
- It will serve as a community platform
  - health records.
  - communication with the MDT and other participants of the study.
  - videos and supportive material.
- If the need arises, we might include Closed Facebook Group and/or WhatsApp Group.
- Family members might be involved in all sessions for communication and support.





#### INTERVENTION

- Dates: June 2024 (change in Ministry and procurement issues).
- Venue and city: Gozo exact location tbd.
- Number of T2D participants enrolled: 20.
- Number of trainers: 7.
- Overnight stay: still to be determined.
- Monitoring of glucose levels: Glucose strips.
- Other important details: Blood glucose machine and few strips are supplied by the hospital. Blood lancets, lancing device and further strips will be supplied during the programme.







Participants' Handbook



Stand-up Banner

- Various leaflets under construction
  - Type 2 diabetes General info
  - Diabetes and eye care
  - Diabetes and oral health
  - Diabetes and heart health
  - Diabetes and care of the kidneys
  - Diabetes and foot care
  - Diabetes and physical activity
- Recipe book in the final stages.
- Participants' booklet printed.
- Information videos under construction.





### **EFFECTIVENESS OF PROGRAMME**



Assessed through health screening results during the study; blood glucose measurements, BMI, BIA and blood results.



Evaluation form after each session to participants and tutors.



Review again after each session – PDSA – amend for second pilot.



QoL assessed through EuroQol (5Q5D5L).



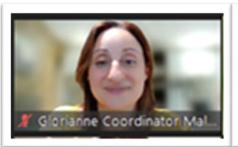


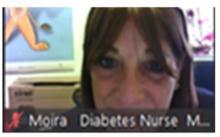
#### **HOW CAN PARTICIPANTS REACH US?**

- Glorianne Busuttil (Project Coordinator) and the coordination team on telephone number 2326 6139 or on <a href="mailto:care4diabetes.hpdp@gov.mt">care4diabetes.hpdp@gov.mt</a> and the Digital Platform.
- Nutrition Helpline 8007 3307.
- For further information, we invite them to visit the Health Promotion and Disease Prevention Directorate website hpdp.gov.mt and that of the study: https://c4djointaction.eu/



















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# **QUESTIONS?**

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