

Effects of education to self-care on the psychological and epigenetic profiles of people with type 2 diabetes

Submission date 25/01/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/03/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 21/08/2020	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Patients with T2DM often take drugs specifically designed for their condition but need to learn how best to cope with the challenges imposed on everyday life by their chronic disease, such as choosing appropriate foods, performing adequate physical activity and self-administering complex therapies. They need to switch to a lifestyle that works with their medication in preventing the long-term complications of their disease. Among published lifestyle intervention models, GC, which is a structured clinical-pedagogic model developed in our department since 1996, is effective in helping people with diabetes, changing their lifestyle for the better. GC is now one of the oldest of such approaches in use, with a large number of patients cared for so far, cost-effective and applicable to other clinics and chronic diseases. Observations accumulated over nearly 20 years of experience suggest that the pathways through which GC improves control of diabetes may go far beyond teaching healthy lifestyles and involve deeper mechanisms, including the resetting of psychological traits and the functioning of our body's archives contained in the cell DNA. In this study we will use GC as an experimental model to modify the patient-related environment and investigate its neuropsychological and epigenetic effects in people with T2DM.

Who can participate?

People with T2DM, aged 40-70 years old, who have not received group care

What does the study involve?

Patients attending a diabetes clinic in Turin (Italy) will be randomly allocated to GC or to continue their usual care. GC will consist of seven 1-hour sessions at 3 months apart and the cycle will be repeated every 2 years.

What are the possible benefits and risks of participating?

The possible benefits are useful insights that will help patients and will help doctors to improve the implementation of GC and ease the burden of diabetes and other chronic diseases.

Where is the study run from?
Laboratory of Clinical Pedagogy (Italy)

When is the study starting and how long is it expected to run for?
February 2015 to March 2019

Who is funding the study?
Ricerca Finalizzata del Ministero della Salute Repubblica Italiana (Italy)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
NeuroPsychological and EpiGenetic effects of structured group cAre for Self-management edUcation in patients with type 2 diabeteS

Acronym
PEGASUS

Study objectives

To verify that the well established clinical and psychological improvements produced by group care (GC), an innovative self-management education model for type 2 diabetes mellitus (T2DM), represents an environmental change sufficient to modify epigenetic mechanisms controlling genes involved in intermediate metabolism

Ethics approval required

Old ethics approval format

Ethics approval(s)

Comitato Etico Interaziendale A.O.U. San Giovanni Battista di Torino - A.O. C.T.O./Maria Adelaide di Torino" (Joint Ethics Committee of the San Giovanni Battista di Torino and A.O. C.T.O./Maria Adelaide di Torino hospitas in Turin, Italy), 07/03/2011, serial no. CEI/177

Study design

Randomised controlled single-centre study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Available in Italian

Health condition(s) or problem(s) studied

1. T2DM is characterised by increased circulating blood glucose levels that require constant attention to appropriate lifestyle behaviours to prevent the onset of long-term complications.
2. Group self-management education is proven to be effective in achieving good control of blood glucose and reduce the risk of complications.

Interventions

GC-naïve patients attending a diabetes clinic in Turin (Italy) with T2DM for at least 1 year will be randomly allocated to GC or to continue usual care:

1. The systemic approach to GC includes seven 1-hour sessions held 3 months apart and the cycle is repeated every 2 years.
2. The curriculum covers burden of overweight, choosing food and meal planning, physical exercise, monitoring and improving metabolic control, smoking cessation, taking medication properly and preventing complications.
3. Education is mostly through group work, hands-on activities, problem-solving, real-life simulations and role playing.
4. One to two members of the team (doctor, educator or psychologist) act as facilitators in groups of up to 10 patients, who remain in the same groups over time.
5. Patients in the control arm will receive standard care in the form of one-to-one consultations

with the doctor and yearly checks/refreshment of their knowledge of diabetes.

6. Both arms will receive yearly screening for complications.

7. All clinical activities will be carried out in the Laboratorio di Pedagogia Clinica at the San Giovanni Antica Sede Hospital in Turin (Italy), affiliated with the main Città della Salute e della Scienza di Torino (Italy).

8. Questionnaire administration and blood sample processing will be done by qualified collaborators.

9. Once stocked, specimens will be sent to laboratories of a hospital in Turin for routine clinical tests and to the Genetics of Diabetes Laboratory of Naples Federico II University (Italy) for epigenetic analyses.

Intervention Type

Behavioural

Primary outcome measure

1. Measurements of psychological profile with questionnaires translated into and validated in Italian:

1.1. Rosenberg Self Esteem Scale

1.2. Hospital Anxiety and Depression Scale

1.3. Locus of Control questionnaire

1.4. Diabetes Quality of Life questionnaire

2. Epigenetic profile of differentially methylated regions of DNA and histones across the genome

These outcomes were measured at months 0 and 24.

Secondary outcome measures

1. Glycated haemoglobin, measured at months 0, 3, 6, 9, 12, 15, 18, 21 and 24

2. Total cholesterol, measured at months 0, 12 and 24

3. High-density lipoprotein cholesterol, measured at months 0, 12 and 24

4. Low-density lipoprotein cholesterol, measured at months 0, 12 and 24

5. Triglycerides, measured at months 0, 12 and 24

6. Serum creatinine, measured at months 0, 12 and 24

7. Blood pressure, measured at months 0, 3, 6, 9, 12, 15, 18, 21 and 24

8. Bodyweight, measured at months 0, 3, 6, 9, 12, 15, 18, 21 and 24

9. Progression of retinopathy, measured at months 0, 12 and 24

10. Microalbuminuria, measured at months 0, 12 and 24

11. Symptoms of neuropathy, measured at months 0, 12 and 24

Overall study start date

01/02/2015

Completion date

31/03/2019

Eligibility

Key inclusion criteria

1. GC-naive patients attending the diabetes clinic in Turin (Italy)

2. T2DM for at least 1 year

3. Aged 40-70 years old

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

60

Key exclusion criteria

1. Current insulin treatment
2. Psychiatric conditions
3. Use of drugs affecting psychological functioning
4. Presence of diseases with reduced life expectancy
5. Planning pregnancy

Date of first enrolment

01/02/2015

Date of final enrolment

30/04/2015

Locations**Countries of recruitment**

Italy

Study participating centre

Laboratory of Clinical Pedagogy

Department of Medical Sciences

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Sponsor information**Organisation**

Department of Medical Sciences

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Sponsor type

University/education

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ROR

<https://ror.org/048tbm396>

Funder(s)

Funder type

Research council

Funder Name

Ricerca Finalizzata del Ministero della Salute Repubblica Italiana (Italy)

Results and Publications

Publication and dissemination plan

1. Communication of results at scientific meetings
2. Analysis and publication of data in top peer-reviewed academic journals and eventually lay press, at completion of trial and according to the results obtained

Intention to publish date

30/11/2019

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.

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?
Results article	results	30/10/2020	21/08/2020	Yes	No

