

# The effect of nutritional intervention on the health of patients affected by type 2 diabetes mellitus in Naples, Italy

<b>Submission date</b> 22/08/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 10/09/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/10/2018	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Type 2 diabetes (T2D) is associated with a diminished quality of life. Changing dietary habits is an absolute priority, as well as implementing nutritional motivational programs. This longitudinal study is part of a health promotion intervention sponsored by the National Center for Prevention and Control of Diseases of the Italian Ministry of Health. It aimed to evaluate possible changes in food habits and health perception in a sample of individuals with T2D before and after a 9 month nutritional motivational program.

### Participants

In the preliminary phase of the study (3 months), physicians and diabeticians of Naples city (ASL Na2 Nord and ASL Na1 Centro) identified patients who were eligible and invited them to participate in the investigation. Eligibility criteria were being between 50 and 70 years old, living in the community, having been diagnosed with T2D at least 1 year prior, absence of major complications of diabetes. All participants were informed about the purpose of the study and the use of resulting data, and signed an informed consent for being included in the intervention. Participants joined the study groups on a voluntary basis. Individuals who decided to take part in the nutritional motivational program formed the intervention group (IG) while recruited patients who decided not to follow the program were included in the control group (CG).

### The study

Anthropometric parameters (BMI, waist measurement, hip measurement) and endocrinal-metabolic data (blood pressure, heart rate, glycaemia, HbA1c, total cholesterol, HDL, LDL, triglycerides, creatinine) were assessed before and after the intervention. Dietary habits were also evaluated.

The intervention lasted 9 months. The nutritional program was structured in quarterly group meetings conducted by a trained nutritionist, who discussed with patients the role of diet in diabetes control, Mediterranean diet benefits, healthy food choices, and how to manage their own nutrition through an adequate daily distribution of meals, using photo books containing examples of meals, as well as to learn a correct interpretation of food labels. Detailed information about how to prevent and manage hypoglycemia was given.

### Possible benefits and risks of participating

A nutritional motivational intervention may be useful in improving dietary habits and health status of patients with T2D. We hope that a similar intervention will be applied in Campania and in other Italian regions.

There were no adverse events associated with this trial.

### Where is the study run from?

This study is part of a health promotion intervention sponsored by the National Center for Prevention and Control of Diseases of the Italian Ministry of Health. About 30 physicians and diabeticians of Naples city (ASL Na2 Nord and ASL Na1 Centro) identified patients who were eligible and invited them to participate in the investigation.

### When is the study starting and how long is it expected to run for?

The study started on 01/01/2012, and ended on 01/10/2014.

### Financial Support

This work was supported by the National Center for Prevention and Control of Diseases of the Italian Ministry of Health (CCM funding, 2012) and by the University of Naples Parthenope (funding for competitive research, 2016).

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## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

CUP:B29E12001850001

## **Study information**

### **Scientific Title**

The Role of Nutrition Education in Treatment and Improvement of the quality of life of patients affected by Type 2 Diabetes mellitus

### **Acronym**

RNETIpatT2D

### **Study objectives**

The health and quality of life of patients with type 2 diabetes will improve if they participate in a nutritional education intervention, but not if they do not participate in this intervention.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics committee: Università degli Studi della Campania "Luigi Vanvitelli" – Azienda Ospedaliera Universitaria "Luigi Vanvitelli" – AORN "Ospedale dei Colli", Naples. Approval date: 21/03/2018. Reference number: N. Prot. 224/2018

### **Study design**

Single-centre non-randomised study

### **Primary study design**

Interventional

### **Secondary study design**

Non randomised study

### **Study setting(s)**

Community

### **Study type(s)**

Quality of life

### **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

### **Health condition(s) or problem(s) studied**

type 2 diabetes mellitus

## **Interventions**

Participants joined the study groups on a voluntary basis. Individuals who decided to take part in the nutritional motivational program formed the intervention group (IG) while recruited patients who decided not to follow the program were included in the control group (CG). The nutritional program lasted 9 months and was structured into quarterly group meetings conducted by a trained nutritionist. The meetings discussed the role of diet in diabetes control, Mediterranean diet benefits, healthy food choices, daily meal distribution. Participants were shown photo books containing examples of meals, learnt how to interpret food labels and were given detailed information about preventing and managing hypoglycemia.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

1. Dietary habits and behaviours were measured using a questionnaire pre-intervention, at time 0, and post-intervention at 9 months
  - 1.1. Daily consumption of food
  - 1.2. The types of food eaten at breakfast, lunch, dinner and snacks
2. Anthropometric parameters were measured pre-intervention, at time 0, and post-intervention at 9 months
  - 2.1 BMI (kg/m<sup>2</sup>) was calculated using weight and height measurements
  - 2.2. Waist circumference
  - 2.3. Hip circumference
3. Endocrinal-metabolic parameters were measured pre-intervention, at time 0, during intervention at months 3 and 6 and post-intervention at 9 months.
  - 3.1. Blood pressure
  - 3.3. Glycaemia was measured using a fasting blood test
  - 3.4. HbA1c was measured using a fasting blood test
  - 3.5. Total cholesterol was measured using a fasting blood test
  - 3.6. HDL was measured using a fasting blood test
  - 3.7. LDL was measured using a fasting blood test
  - 3.8. Triglycerides was measured using a fasting blood test
  - 3.9. Creatinine was measured using a fasting blood test

## **Secondary outcome measures**

Secondary outcomes were measured using the results of a questionnaire reporting daily food consumption at 0 and 9 months post-intervention and calculated using the dietary anamnesis software WinFood7

1. Average daily amount of food consumed
2. Average daily calories consumed
3. Distribution into micro and macro nutrients
4. Caloric breakdown between meals

## **Overall study start date**

01/01/2012

## **Completion date**

01/10/2014

# Eligibility

## Key inclusion criteria

1. between 50 and 70 years old
2. living in the community
3. diagnosed with type 2 diabetes at least 1 year prior

## Participant type(s)

Patient

## Age group

Senior

## Sex

Both

## Target number of participants

512

## Key exclusion criteria

major complications of diabetes

## Date of first enrolment

01/12/2013

## Date of final enrolment

31/08/2014

# Locations

## Countries of recruitment

Italy

## Study participating centre

ASL Napoli 1 Centro

Naples

Italy

80100

# Sponsor information

## Organisation

National Center for Prevention and Control of Diseases of the Italian Ministry of Health (CCM funding, 2012)

**Sponsor details**

Viale Giorgio Ribotta, 5  
Rome  
Italy  
00144  
+39 06 5994 2878  
segr.dgprev@sanita.it

**Sponsor type**

Government

**Website**

<http://www.ccm-network.it/home.html>

**ROR**

<https://ror.org/00789fa95>

## Funder(s)

**Funder type**

Not defined

**Funder Name**

National Center for Prevention and Control of Diseases of the Italian Ministry of Health (CCM funding, 2012)

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

01/09/2018

**Individual participant data (IPD) sharing plan**

The datasets generated during the current study will be available upon request to Valeria Di Onofrio ([valeria.dionofrio@uniparthenope.it](mailto:valeria.dionofrio@uniparthenope.it)). Individual patient data, respecting anonymity, will be available for six months, upon formal request by any interested parties.

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>		03/09/2018	13/09/2018	No	No

[Results article](#)

results

17/10/2018

Yes

No