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

Submission date
22/08/2018

Recruitment status
No longer recruiting

Registration date
10/09/2018

Overall study status
Completed

Last Edited
23/10/2018

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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).

Main contact:
Valeria Di Onofrio
Researcher of General and Applied Hygiene
University of Naples “Parthenope”
Department of Science and Technology
Business District, Block C4, 80143, Naples, Italy.
Tel. +39 0815476542
e-mail: valeria.dionofrio@uniparthenope.it

Contact information

Type(s)
Scientific

Contact name
Dr Valeria Di Onofrio

ORCID ID
https://orcid.org/0000-0001-9398-3496

Contact details
Business District, Block C4
Naples
Italy
80143
+ 39 081 547 65 42
valeria.dionofrio@uniparthenope.it

Additional identifiers

Protocol serial number
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

Study type(s)
Quality of life

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(s)

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/m2) 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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Senior

Sex
All

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)

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

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). 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?
Results article	results	17/10/2018		Yes	No
Basic results		03/09/2018	13/09/2018	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes