An intense nutritional training program for obese patients with type 2 diabetes mellitus: a randomised controlled two-year intervention study

Submission date	Recruitment status	Prospectively registered
07/09/2005	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
10/02/2006	Completed	Results
Last Edited	Condition category	Individual participant data
14/10/2009	Nutritional, Metabolic, Endocrine	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives

To test the hypothesis that an intense nutritional training program (diet, knowledge about diabetes, physical activities and other lifestyle factors) can lead to reduced costs for medication, compared to the standard treatment for diabetes. Furthermore, the impact of the two therapies on the quality of life and differences in the compliance and satisfaction with the respective therapy will be investigated.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by Physicians' Chamber North Rhein on 19/09/2001, reference number 2001193

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Type 2 diabetes mellitus

Interventions

Intense nutritional training program versus usual care

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Costs for diabetes medication in Euro
- 2. Cost efficiency to achieve therapy objectives
- 3. Fasting blood sugar 80-120 mg/dl
- 4. HbA1c <6.5 %
- 5. Blood pressure <140/85 mmHg
- 6. Triglyceride <150 mg/dl
- 7. High density lipoprotein-cholesterol >45 mg/dl
- 8. Low density lipoprotein-cholesterol <115 mg/dl

Secondary outcome measures

- 1. Quality of life
- 2. Differences in compliance
- 3. Satisfaction with the respective therapy

Overall study start date

01/12/2002

Completion date

01/07/2005

Eligibility

Key inclusion criteria

- 1. Type 2 diabetes mellitus (the diagnosis must be made at least six months before inclusion in the study)
- 2. Body Mass Index (BMI) >27
- 3. Aged between 35 and 70 years
- 4. Medication with at least two anti-diabetic drugs and/or antihypertensive drugs and/or lipid-lowering drugs
- 5. Informed consent

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

160

Key exclusion criteria

- 1. Creatinine >2.0 mg/dl
- 2. Transaminase (>3 times higher than normal)
- 3. Alcohol or drug abuse
- 4. Severe psychiatric disorders
- 5. Eating disorders

Date of first enrolment

01/12/2002

Date of final enrolment

01/07/2005

Locations

Countries of recruitment

Germany

Study participating centre Klinik für Ernährungsmedizin

München Germany 81675

Sponsor information

Organisation

German Research Foundation (Deutsche Forschungsgemeinsschaft) (DFG) (Germany)

Sponsor details

Kennedyallee 40 Bonn Germany 53175 +49 (0)228 8851 postmaster@dfg.de

Sponsor type

Research organisation

Website

http://www.dfg.de/

ROR

https://ror.org/018mejw64

Funder(s)

Funder type

Research organisation

Funder Name

German Research Foundation (DFG) (Germany)

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration