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

Submission date
07/09/2005

Recruitment status
No longer recruiting

Registration date
10/02/2006

Overall study status
Completed

Last Edited
14/10/2009

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

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

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
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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 plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration