

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	<input type="checkbox"/> Prospectively registered
Registration date 10/02/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/10/2009	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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 Forschungsgemeinschaft) (DFG) (Germany)

ROR

<https://ror.org/018mejw64>

Funder(s)

Funder type

Research organisation

Funder Name

German Research Foundation (DFG) (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration