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Individualised Tuebingen Lifestyle Intervention Program

Submission date	Recruitment status	[X] Prospectively registered
25/02/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/04/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/04/2010	Nutritional, Metabolic, Endocrine	[ ] 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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72076

Additional identifiers

Protocol serial number
IGT Trial 01

Study information

Scientific Title
An individualised lifestyle intervention program for the identification of prediabetic subjects with high risk phenotype: a non-randomised controlled interventional study

Acronym
iTULIP

Study objectives
Identification of prediabetic subjects with high risk phenotype (fatty liver/insulin resistance or beta cell failure) for future lifestyle intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Tübingen Ethics Committee approved on the 10th January 2003 (ref: 422/2002)

Primary study design
Interventional

Study design
Non-randomised controlled interventional study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Diabetes

Interventions
Control arm:
1. Aimed weight reduction greater than 5%
2. Fat intake less than 30% of calories
3. Saturated fat intake less than 10% of calories
4. Fibre intake greater than 15 g/1000 kcal
5. Recommended physical activity greater than 3 hours/week
Six sessions in one year.

Intervention arm:
1. Aimed weight reduction greater than 5%
2. Fat intake less than 30% of calories
3. Saturated fat intake less than 10% of calories
4. Fibre intake greater than 15 g/1000 kcal
5. Supervised physical activity 8 hours/week
12 session in one year.

Total duration of intervention is 12 months. Follow-ups at 6 and 12 months. Phenotyping (oral glucose tolerance test [OGTT], magnetic resonance imaging [MRI] and magnetic resonance spectroscopy [MRS]) performed at baseline, 6 and 12 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Glucose tolerance, measured at 6 months and 12 months

Key secondary outcome(s)
Measured at 6 months and 12 months:
1. Beta cell function
2. Insulin sensitivity
3. Liver fat content

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Men and women aged 18 - 75 years
2. Family history of diabetes (first degree relative)
3. Impaired glucose tolerance
4. Body mass index (BMI) greater than 27 kg/m^2
5. Prior gestational diabetes

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
All

Key exclusion criteria
1. Aged below 18 years
2. Serious diseases, e.g., incurable cancer, untreated psychiatric disorders
3. Pregnancy

Date of first enrolment
01/06/2010

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Germany

Study participating centre
Otfried-Müller Straße 10
Tübingen
Germany
72076

Sponsor information

Organisation
University Hospital Tuebingen (Universität Tübingen) (Germany)

ROR
https://ror.org/00pjgxh97

Funder(s)

Funder type
Government

Funder Name
Federal Ministry for Education and Research (Bundeministerium für Bildung und Forschung [BMBF]) (Germany) (ref: DLR01GI0925)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration