

Individualised Tuebingen Lifestyle Intervention Program

Submission date 25/02/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 29/04/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/04/2010	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

Contact name
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Contact details
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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)

Study design

Non-randomised controlled interventional study

Primary study design

Interventional

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/m²
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