

# Individualised Tuebingen Lifestyle Intervention Program

<b>Submission date</b> 25/02/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 29/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 29/04/2010	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<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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Germany  
72076

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

**Secondary study design**

Non randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Prevention

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**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 measure**

Glucose tolerance, measured at 6 months and 12 months

**Secondary outcome measures**

Measured at 6 months and 12 months:

1. Beta cell function
2. Insulin sensitivity
3. Liver fat content

**Overall study start date**

01/06/2010

**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<sup>2</sup>
5. Prior gestational diabetes

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

75 Years

**Sex**

Both

**Target number of participants**

1000

**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)

**Sponsor details**

c/o Prof. Dr. med. H.U. Häring

Otfried Müller Straße 10

Tübingen

Germany

72076

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.medizin.uni-tuebingen.de/>

**ROR**

<https://ror.org/00pjgxx97>

## **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**

**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