

# 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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**Contact details**  
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Tübingen  
Germany  
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/m<sup>2</sup>
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/00pjgxb97>

## 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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes