

# Prevention of pre-diabetes in adults

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<b>Registration date</b> 04/10/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 04/10/2013	<b>Condition category</b> 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

### Background and study aims

This study focuses on the negative emotions that play an important role in the development of type 2 diabetes mellitus (T2DM) and its complications. Drug therapy, psychological therapy and psychological health education are used in this study to improve the patients blood glucose levels. We are looking for the right scheme for the prevention and management of pre-diabetes and T2DM. We are also looking for some psychological indicators which would be an early warning for T2DM.

### Who can participate?

Individuals seeing a doctor in the participating hospitals in China.

### What does the study involve?

Participants are randomly assigned to one of five groups: the control group (conventional diabetes education only), the metformin group, the psychological treatment group, the anti-depressant group, or the psychological health education group. Participants receive the respective treatments according to the group to which they belong; all participants also receive conventional diabetes education. All subjects are interviewed and take an oral glucose tolerance test (OGTT) at the beginning of the study and are followed up after 1 and 2 years of the study.

### What are the possible benefits and risks of participating?

In addition to helping the participants improve negative emotion and lower their blood glucose, the project helped the hospitals and government provide the right scheme for the prevention and management of pre-diabetes and T2DM. There was no significant risk to participants of the study.

### Where is the study run from?

This study is run from six hospitals in China.

### When is the study starting and how long is it expected to run for?

The study started in May 2011 and ends in July 2014.

### Who is funding the study?

The study is funded by the National Key Technology R&D Program.

Who is the main contact?

Prof. Xueli Sun

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## Contact information

### Type(s)

Scientific

### Contact name

Prof Sun Xueli

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

Project No: 2009BAI77B06 (the National Key Technology R&D Program)

## Study information

### Scientific Title

Early identification and intervention on psychological problems in people in pre-diabetes

### Study objectives

To evaluate the effectiveness of an intervention on negative emotions in pre-diabetic individuals that aimed to slow down and even reverse the development process from pre-diabetes to type 2 diabetes (T2DM). To explore the optimized scheme for early prevention, and identify psychological early warning indicators for this process.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Institutional Ethics Committee of Sichuan University, 21/12/2010, ref: 72

**Study design**

Multi-center randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**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**

Pre-diabetes in adults

**Interventions**

500 subjects were randomly allocated to one of five groups:

Group 1: conventional diabetes education (blank control)

Group 2: conventional diabetes education + metformin

Group 3: conventional diabetes education + cognitive-behavioral group therapy

Group 4: conventional diabetes education + antidepressant (Seroxat)

Group 5: conventional diabetes education + psychological health education

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

1. Changes of indicators of the oral glucose tolerance test and glycated hemoglobin reflecting the function of glycometabolism
2. Numerous neuroendocrine indicators reflecting the function of the hypothalamic-pituitary-adrenal axis and the hypothalamic-pituitary-thyroid axis
3. Numerous psychological tests reflecting personality, coping style, social support, emotion, life satisfaction and alexithymia

Outcome measures were assessed at baseline (T0) before the intervention, reassessed at 1 year and 2 years after the intervention, and then analyzed the psychological warning indicator of psychosomatic disease and optimization scheme for prevention of psychosomatic disease such as T2DM.

**Secondary outcome measures**

1. To explore the psychological characteristics of pre-diabetes in Chinese adults, including personality, coping style, social support, emotion, life satisfaction and alexithymia
2. The relationship between those psychological indicators and neuroendocrine indicators or glycometabolism
3. At the end of study, a warning scale for T2DM should be designed and can be applied in practice

**Overall study start date**

01/05/2011

**Completion date**

31/07/2014

## Eligibility

**Key inclusion criteria**

1. Aged 30-70 years
2. Fasting plasma glucose after a 75-g oral glucose tolerance test  $>5.6$  mmol/L,  $<7.0$  mmol/L; or 2 h after a 75-g oral glucose tolerance test  $>7.8$  mmol/L,  $<11.1$  mmol/L
3. Glycated hemoglobin  $<8.0\%$

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

A total of 500 subjects were enrolled in the programme

**Key exclusion criteria**

1. Those eligible students who refused to participate
2. Women who were pregnant during the study, planning to get pregnant or lactating
3. People with type 1 diabetes or confirm there has significant clinical complications
4. Having acute myocardial infarction, unstable angina or heart failure within 3 months before screening
5. Using drugs which significantly affect the metabolism of sugar within 4 weeks before screening
6. Having a clinical diagnosis for malignant tumors and treatment within 5 years before screening
7. Having severe mental disorder or suicidal tendencies

**Date of first enrolment**

01/05/2011

**Date of final enrolment**

31/07/2014

# Locations

## Countries of recruitment

China

## Study participating centre

28th Dianxin South road, Psychological Center

Chengdu

China

610041

# Sponsor information

## Organisation

Ministry of Science and Technology of The People's Republic of China (China)

## Sponsor details

B15th Fuxing road Beijing

Beijing

China

100862

bzxx@most.gov.cn

## Sponsor type

Government

## Website

<http://www.most.gov.cn/bszn/index.htm>

## ROR

<https://ror.org/027s68j25>

# Funder(s)

## Funder type

Government

## Funder Name

This project was funded by the National Key Technology R&D Program (2009BAI77B06).

# 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