ISRCTN86375169 https://doi.org/10.1186/ISRCTN86375169

Prevention of pre-diabetes in adults

Submission date	Recruitment status	[ ] Prospectively registered
02/09/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/10/2013	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/10/2013	Nutritional, Metabolic, Endocrine	[ ] 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
sunxueli58@163.com

Contact information

Type(s)
Scientific

Contact name
Prof Sun Xueli

Contact details
28th Dianxin South road, Psychological Center
West China Hospital
Sichuan University
Sichuan
Chengdu
China
610041
sunxueli58@163.com

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 2conventional 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