# Prevention of diabetes using eCROPS (educating doctors and electronic supports, Counseling diabetes prevention, Recipe for lifestyle modification, Operational toolkit, Performance-based reimbursement for doctors and Screening service)

Submission date	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered		
06/05/2013		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
21/05/2013	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
03/04/2014	Nutritional, Metabolic, Endocrine			

# Plain English summary of protocol

Background and study aims

Pre-diabetes is an intermediate stage in the development of diabetes. In China, over 14% of people are affected with pre-diabetes and one to three quarters of them will be affected with diabetes in 10 years. It is well established that the risk of diabetes can be decreased substantially by a whole range of proven guidelines, protocols and methodologies. Unfortunately, most proven methods are seldom used in daily practice and this is especially true in resource-poor rural China. This project aims at developing and evaluating an educative counseling package in preventing diabetes.

# Who can participate?

Villagers, over 40 years of age, who have lived in the selected villages for over 6 months can participate in the study.

# What does the study involve?

The villages are randomly allocated to one of 7 groups. Group 0 consisting of 3 villages receives an initial counseling package called preliminary eCROPS and the rest of the 6 groups of villages receive an advanced counseling package called refined eCROPS. Plasma glucose (every 12 months), body weight (monthly) and blood pressure (monthly) are measured for each group before and after counseling. The measures are documented for 6 years and the results are analysed for lower incidence of progression into diabetes, decreased body mass index, blood pressure, and increased service use and involvement in healthy dietary and physical activities among pre-diabetics compared to those before counseling and lifestyle education.

What are the possible benefits and risks of participating? Anticipated benefits:

- 1. Improved knowledge about diabetes, prevention, and health services from the village doctors
- 2. Early diagnosis of pre-diabetes, diabetes, potential detection of high blood pressure and other conditions
- 3. A small gift, given at initial assessment and a villager-friendly educational calendar, for promoting diabetes-related lifestyle modifications, given before the start of each follow-up year. Potential risks and discomforts:
- 1. Mild pain
- 2. Potential loss of privacy if diagnosed with diabetes or pre-diabetes condition
- 3. Time taken for the assessment and follow-up (about 1 hour each)

Where is the study run from?

Approximately 75 village clinics take part in the study and their names are determined at random.

When is the study starting and how long is it expected to run for? June 2013 to May 2019.

Who is funding the study? Natural Science Foundation of China and Lu'an Center for Diseases Control (China)

Who is the main contact? Dr Rui Feng xiao816meng@sina.cn

# Contact information

## Type(s)

Scientific

#### Contact name

Prof Debin Wang

#### Contact details

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# Additional identifiers

**Protocol serial number** N/A

# Study information

Scientific Title

Integrated and sustainable prevention against diabetes in rural China: Lu'an eCROPS demonstration project

## Acronym

eCROPS

## **Study objectives**

This project aims at devising and evaluating an educative counseling package in preventing diabetes. Bringing the best interventions into practice, integrated with routine services, may be effective and sustainable in preventing diabetes.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Anhui Medical University Biomedical Ethics Committee; 26th February, 2013; Reference number: 20131162

## Study design

Quasi cluster randomized controlled trial using batched implementation strategies

## Primary study design

Interventional

# Study type(s)

Prevention

## Health condition(s) or problem(s) studied

Diabetes

#### **Interventions**

eCROPS: The villages are recruited in 7 blocks within 7 consecutive years respectively. Block 0 (control) involves 3 villages and provides an opportunity for piloting and refining primitive intervention methodologies and protocols. The following 6 blocks consist of 12 villages each and serve as intervention arm.

## **Intervention Type**

Other

#### **Phase**

Not Applicable

## Primary outcome(s)

Fasting glucose: For each block, measurement is taken at baseline and every 12 months (for plasma glucose) or monthly (for body weight and blood pressure) after baseline.

# Key secondary outcome(s))

6 years of consecutive measures and detection of lower incidence of progression into diabetes, decreased body mass index and blood pressure, and increased service use and involvement in healthy dietary and physical activities among pre-diabetics receiving the experimental intervention compared to those at baseline or in the delayed-intervention control condition.

## Completion date

31/05/2019

# **Eligibility**

## Key inclusion criteria

- 1. Men and women who are over 40 years and live in the selected villages for over 6 months in a year are eligible for baseline and biannual follow up screening
- 2. Villagers with a fasting glucose of 5.6<6.9 mmol/l, who are not currently being treated with oral hypoglycemic medication or insulin, are treated as priority intervention group

## Participant type(s)

**Patient** 

## Healthy volunteers allowed

No

## Age group

Adult

## Sex

All

## Key exclusion criteria

- 1. Those with a baseline fasting glucose of 6.1-6.9 mmol/l but are confirmed as diabetic
- 2. Those with a fasting glucose of 5.6-6.9 mmol/l but are on treatment with oral hypoglycemic medication or insulin

## Date of first enrolment

01/06/2013

## Date of final enrolment

31/05/2019

# Locations

## Countries of recruitment

China

# Study participating centre 81, Meishan Road, Anhui Medical University

Hefei China

230032

# Sponsor information

# Organisation

Natural Science Foundation of China (China)

## ROR

https://ror.org/01h0zpd94

# Funder(s)

# Funder type

Government

## **Funder Name**

Natural Science Foundation of China and Lu'an Center for Diseases Control (China)

# **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?		
Results article	results	01/04/2014	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes