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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
06/05/2013

Recruitment status
No longer recruiting

Registration date
21/05/2013

Overall study status
Completed

Last Edited
03/04/2014

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
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
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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/06/2013

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

Age group
Adult

Sex
Both

Target number of participants
6840

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
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230032

Sponsor information

Organisation
Natural Science Foundation of China (China)

Sponsor details
83 Shuangqing Road, Haiding District, Beijing
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Sponsor type
Government

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2014		Yes	No