

Prevention of cancers using eCROPS-CA (electronic supports and supervision, Counseling behavior prevention, Recipe for objective behaviors, Operational toolkit, Performance-based incentives for doctors, and Screening and assessment)

Submission date 04/05/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/05/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/01/2016	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Effective cancer prevention depends on a sustained individual effort to practice protective behaviors and avoid risk factors, which requires personalized support. However, current prevention mainly relies on strategies targeting the general population or, at most, selected specific groups, with limited attention being paid to individualized approaches. This aim of this study is to test a new behavior intervention package called eCROPS-CA.

Who can participate?

Men and women at high risk of cancer who are over 35 years old and living in one of the 36 administrative villages randomly sampled from nine counties in Anhui province, China.

What does the study involve?

Participants are randomly allocated into either the intervention group or the delayed intervention group. The intervention group receives the eCROPS-CA behavior intervention package for 5 years and will undergo a baseline evaluation at the start of the study and 10 semi-annual follow-up evaluations. The delayed intervention group does not receive eCROPS-CA but will undergo the baseline and follow-up evaluations.

What are the possible benefits and risks of participating?

The anticipated benefits are improved knowledge about cancers, prevention, and health services from the village doctors, improved lifestyle, and early diagnosis of cancer and cancer-related conditions. Potential risks and discomforts include potential loss of privacy if diagnosed with cancers or cancer-related conditions, and the time taken for the assessment and follow-up (about 1 hour each).

Where is the study run from?

36 village clinics in Anhui province, China will 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?

The study will run from May 2014 to April 2019.

Who is funding the study?

Natural Science Foundation of China and Center for Cancer Control Collaboration of Anhui Medical University (China).

Who is the main contact?

Dr Jing Chai

jingchai82@sina.com

Contact information

Type(s)

Scientific

Contact name

Prof Debin Wang

Contact details

81 Meishan Road

Anhui Medical University

Hefei

China

230032

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

eCROPS-CA: a systematic approach toward effective and sustainable cancer prevention in rural China

Acronym

eCROPS-CA

Study objectives

This project aims at demonstrating that eCROPS-CA is effective in preventing cancers, and high-risk individuals in the intervention arm will, compared to those in the control condition, show a lower incidence of cancers, improved biophysical indicators, increased service use and involvement in protective behaviors. A secondary objective is to establish a sustainable mechanism, in which participating village doctors maintain continuous momentum integrating cancer prevention with routine medical service ever since initiation of this project in resource-poor rural China.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Anhui Medical University Biomedical Ethics Committee, 01/03/2014, ref. 20140271

Study design

Quasi cluster randomized controlled trial using equal intervention and delayed intervention arms

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

GP practice

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

Nine common cancers (trachea/bronchus/lung cancer, stomach cancer, colon/rectum/anus cancer, liver cancer, esophagus cancer, breast cancer, pancreas cancer, lymphoma cancer, and bladder cancer)

Interventions

The study recruits 36 administrative villages from nine counties in Anhui province, China and assigns them into equal intervention and delayed intervention arms. The intervention arm receives baseline and 10 semi-annual follow-up evaluations plus 5 years of eCROPS-CA. The delayed intervention arm receives only the baseline and follow-up evaluations.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Diagnosis of nine common cancers surveyed every 6 months after project initiation.

Secondary outcome measures

1. Cancer-related knowledge, attitudes and practices
2. Cancer-related biophysical indicators, e.g., hypertension, gastritis, pre-diabetes/diabetes
3. Intervention compliance

Secondary outcome measure(s) will be measured using structured questionnaires (for objective behaviors and service use), scales (for body weight and height), sphygmomanometer (for blood pressure) and tests (for blood glucose and other easy biological indicators) at baseline and every 6 months after baseline for 5 years.

Overall study start date

01/05/2014

Completion date

30/04/2019

Eligibility**Key inclusion criteria**

Men and women who:

1. Are over 35 years old
2. Live in the selected villages for over 6 months per year
3. Meet rapid risk assessment score (≥ 70) and detailed risk assessment score (≥ 80) threshold

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

4320

Key exclusion criteria

Villagers who have already diagnosed with cancer and mental illness or serious illness or disability are excluded.

Date of first enrolment

01/05/2014

Date of final enrolment

30/04/2019

Locations

Countries of recruitment

China

Study participating centre

Anhui Medical University

Hefei

China

230032

Sponsor information

Organisation

Natural Science Foundation of China (China)

Sponsor details

83 Shuangqing Road

Haiding District

Beijing

Beijing

China

100000

Sponsor type

Research organisation

ROR

<https://ror.org/01h0zpd94>

Funder(s)

Funder type

Research organisation

Funder Name

National Natural Science Foundation of China

Alternative Name(s)

Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, , National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhùi, NSFC, NNSF, NNSFC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

China

Funder Name

Anhui Medical University - Center for Cancer Control Collaboration (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	08/04/2015		Yes	No
Results article	results	12/10/2015		Yes	No