

Risk reduction intervention of cardiovascular disease in China

Submission date 12/10/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 19/10/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/07/2021	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Cardiovascular disease (CVD, disease of the heart and/or blood vessels) remains one of the main causes of death worldwide. One of the main factors contributing to CVD is raised blood pressure (hypertension), which is responsible for 5 in 10 deaths from coronary heart disease and 6 in 10 deaths from stroke. China has more than 160 million hypertensive patients, and the death rate for stroke is 4-6 times higher than Japan and the USA, while the amount of stroke and hypertension sufferers is far higher in rural areas (country) compared with urban areas (cities). In 2010, an initial study was conducted in two township hospitals of Zhejiang Province, China to understand the latest situation of CVD control and explore the feasibility of a program to lower the risk of CVD. Based on the feedback of this study, we propose to develop and test a package of cardiovascular risk reduction programs in Zhejiang China. The aim of this study is to explore the effectiveness and cost-effectiveness of a comprehensive CVD risk reduction program.

Who can participate?

Adults aged 50-74 years who have high blood pressure and live in the study area.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group continue to receive standard care for the duration of the study. Those in the second group take part in the CVD risk reduction program. This involves being prescribed a combination of drugs, including anti-hypertensives (drugs which lower blood pressure), low dose aspirin (Which thins the blood and prevents blood clots, lowering the risk of stroke) and a statin (which lowers cholesterol). Participants also receive support for taking their medication properly, attending appointments and making healthy lifestyle changes; and health education (including advice on smoking cessation, reduction of salt, sugar and oil in their diet, and physical exercise). The number of participants to have a CVD event (such as heart attack or stroke) is collected from Zhejiang provincial CVD surveillance system and double checked by interviewing patients at 12, 24 and 36 months. A sampling survey is also conducted at the start of the study and then after 12, 24 and 36 months to find out more about the patients' background, lifestyle and health.

What are the possible benefits and risks of participating?

Participants may benefit from a lower risk of developing CVD. Risks of participating are very low

as the doses of drugs used will be modified on an individual basis. Any negative side effects of the drugs will be closely monitored by family doctors and village doctors.

Where is the study run from?

All township hospitals in 3 counties of Zhejiang province, apart from the hospital that took part in the pilot study (China)

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

March 2012 to December 2017

Who is funding the study?

1. Comdis Health Services Delivery Research Consortium (UK)
2. Zhejiang Provincial Centre for Disease Control and Prevention (China)

Who is the main contact?

Professor Xiaolin Wei
xiaolin.wei@utoronto.ca

Contact information

Type(s)

Scientific

Contact name

Prof Xiaolin Wei

Contact details

Dalla Lana School of Public Health, University of Toronto
582-155 College Street
Toronto
Canada
M5T 3M7
+1 416 978 2020
xiaolin.wei@utoronto.ca

Type(s)

Scientific

Contact name

Dr Min Yu

Contact details

No. 3399
Binsheng Road
Binjiang District
Hangzhou
China
310051
+86 0571 87115005
myu@cdc.zj.cn

Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Cardiovascular disease risk reduction in China: a pilot and clustered randomized controlled trial in Zhejiang

Study objectives

This systematic cardiovascular disease (CVD) risk reduction programme can reduce CVD events of the population in the intervention group compared with the usual care; the programme is cost effective, friendly to implement and scale up.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. University of Leeds Research Ethics Committee, 08/10/2012, ref: HSLTLM/12/010
2. Ethics Committee of Zhejiang Provincial Centre for Disease Control and Prevention, 18/06/2012

Study design

Prospective open-labeled cluster randomised controlled trial with blinded data analysis

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Cardiovascular diseases

Interventions

Interventions as of 29/07/2016:

1. Prescribing a combination of drugs: anti-hypertensives, low dose aspirin and a statin;
2. Adherence support on drug compliance, attendance at appointments and healthy lifestyle change;
3. Health education: advice on smoking cessation, reduction of salt, sugar and oil in their diet, and physical exercise.

Previous interventions as of 06/12/2012:

1. Prescribing a combination of drugs: anti-hypertensives, low dose aspirin and a statin
2. Adherence support for drug compliance, attendance and healthy lifestyle change
3. Health Education: smoking cessation, salt, sugar and oil reduction
4. Community-based health intervention:
 - 4.1. Banners and chalked messages

4.2. Peer education by residents with CVD risk

5. Implementation strategies, embedded within the primary care delivery system

The intervention will be designed as job descriptions of family doctors and implemented within the primary care delivery system in Zhejiang China

Previous interventions until 06/12/2012:

1. Health Education: smoking cessation, salt, sugar and oil reduction
 2. Proven Drugs: anti-hypertensive's, low dose aspirin, folic acid and a statin
 3. Adherence support for drug compliance, attendance and healthy lifestyle change
 4. Implementation strategies, embedded within the primary care delivery system
- The intervention will be designed as job descriptions of family doctors in the rural areas and implemented within the primary care delivery system in rural Zhejiang China

Intervention Type

Mixed

Primary outcome(s)

Current primary outcome measure as of 06/12/2012:

The major CVD event rates of the residents in study areas

Previous primary outcome measure until 06/12/2012:

The percentage of end events in CVD morbidity and mortality

Key secondary outcome(s)

Current secondary outcome measures as of 29/07/2016:

1. Mean systolic and diastolic blood pressures of participants
2. Time to the first reported CVD event, mortality, and morbidity of CVD events during the trial period of 36 months
3. Mean change in glycated hemoglobin (HbA1c)
4. Mean change in serum TC and low density lipoprotein
5. Adherence to booked appointments, using the denominator of all participants registered, including defaulters
6. Self-reported adherence to drugs and healthy lifestyle change, for example, smoking cessation rates (for participants who smoke at randomization, the percentage who smoke less than one cigarette a week at 24 months after randomization)
7. Cost-effectiveness
8. Feasibility measures

Previous secondary outcome measures until 06/12/2012:

1. Mean systolic and diastolic blood pressure
2. CVD risk scores
3. Prescription rate of intervention drugs
4. Serum total cholesterol, low density lipid cholesterol (LDL)
5. Smoking cessation rates
6. Adherence to booked appointments and self-reported adherence to healthy lifestyle change and drugs

Completion date

31/12/2017

Eligibility

Key inclusion criteria

Inclusion criteria as of 29/07/2016:

Township hospitals:

1. Have family doctors who provide care according to the essential public health tasks requested by the government and who agree to follow the allocated treatment
2. Are willing to participate in the trial or pilot study

High CVD risk subjects:

1. Adults aged 50-74 years who have provided informed consent
2. Have been diagnosed as hypertension with a calculated 10-year CVD risk of 20% or higher, or have a recorded medical history of diabetes
3. Hold permanent residency in the study area

Previous inclusion criteria as of 06/12/2012:

Township hospitals:

1. Have family doctors who provide care according to the essential public health tasks requested by the government and who agree to follow the allocated treatment
2. Are willing to participate in the trial or pilot study

High CVD risk subjects:

1. Adults aged 60 years and above who have provided informed consent
2. Hold permanent residency in the study area
3. Have a calculated 10-year CVD risk of 20% or higher
4. Have a recorded medical history of diabetes, hyperlipidaemia, coronary heart disease, ischaemic or haemorrhagic cerebro-vascular disease, or peripheral vascular disease.

Previous inclusion criteria until 06/12/2012:

Township hospitals:

1. Located in rural Zhejiang
2. Have family doctors who provide care according to the essential public health tasks requested by the government and who agree to follow the allocated treatment
3. Are willing to participate in the trial or pilot study

High CVD risk subjects:

1. Adults aged 40-74 years who have provided informed consent
2. Hold permanent residency in the study area
3. Have a calculated 10-year CVD risk of 20% or higher, including those having a recorded medical history of hypertension (>140/90)
4. Diabetes, hyperlipidaemia, coronary heart disease, ischaemic or haemorrhagic cerebro-vascular disease, or peripheral vascular disease, or those without CVD symptoms.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

28130

Key exclusion criteria

Current exclusion criteria as of 06/12/2012:

1. People with known mental illnesses or other severe diseases or disabilities which mean they cannot communicate with township doctors well or regularly
2. Those not living in the community or will move away in the next two years
3. People who have shown serious adverse effects to the recommended drugs
4. Patients who decline to participate in the trial will be excluded

Previous exclusion criteria until 06/12/2012:

1. People with known mental illnesses or other severe diseases or disabilities which mean they cannot communicate with township doctors well or regularly
2. Those not living in the community or will move away in the next three years after recruitment
3. People who have shown serious adverse effects to the recommended drugs
4. Pregnant or breastfeeding women
5. Patients who decline to participate in the trial will be excluded

Date of first enrolment

01/09/2013

Date of final enrolment

31/05/2014

Locations

Countries of recruitment

China

Study participating centre

Dongguan community health center

No.5 Hospital Road

Dongguan Street

Shangyu District

Shaoxing

China

312352

Study participating centre

Gaibei Township Hospital

Sihe Village

Gaibei Town

Shangyu District

Shaoxing

China
312369

Study participating centre
Tangpu Township Hospital
Xin Street
Yangpu Town
Shangyu District
Shaoxing
China
312364

Study participating centre
Changtang Township Hospital
No.37 Changtangshang Street
Changtang Town
Shangyu District
Shaoxing
China
312352

Study participating centre
Zhangzhen Township Hospital
No.30 Huayuan Road
Zhangzhen Town
Shangyu District
Shaoxing
China
312363

Study participating centre
Fenghui Township Hospital
Dongmen Community
Fenghui Town
Shangyu District
Shaoxing
China
312361

Study participating centre

Yonghe Township Hospital

Yonghe village
Shangyu District
Shaoxing
China
312371

Study participating centre

Caoe Community Health Center

No.301 Lianfeng Road
Shangyu District
Shaoxing
China
312352

Study participating centre

Lingnan Township Hospital

Fengshuping Village
Daoxu Town
Shangyu District
Shaoxing
China
312379

Study participating centre

Dingzhai Township Hospital

No.111 Xiayi Road
Shangzhai Town
Dingzhai County
Shangyu District
Shaoxing
China
312373

Study participating centre

Xiaoyue Township Hospital

No.134 Yuedong Road
Xiaoyue Town
Shangyu District
Shaoxing
China
312367

Study participating centre
Chenxi Township Hospital
Damiao,Chenxi County
Shangyu District
Shaoxing
China
312362

Study participating centre
Shangpu Township Hospital
.Shangpu Village
Shangpu Town
Shangyu District
Shaoxing
China
312375

Study participating centre
Lianghu Township Hospital
Lianghu Nerghborhood Committee
Lianghu Town
Shangyu District
Shaoxing
China
312399

Study participating centre
Songxia Township Hospital
No.328 Baisong Road
Songxia Town
Shangyu District
Shaoxing
China
312365

Study participating centre
Xietang Township Hospital
Jinsheng Street
Donglian Village
Xietang Town
Shangyu District

Shaoxing
China
312369

Study participating centre
Baiguan Community Health Center
No.137 Mid Renmin Road
Baiguan Street
Shangyu District
Shaoxing
China
312399

Study participating centre
Yiting Township Hospital
Xinyiting Village
Yiting Town
Shangyu District
Shaoxing
China
312353

Study participating centre
Xiaguan Township Hospital
No.28 Shuren Road
Xiaguan Town
Shangyu District
Shaoxing
China
312351

Study participating centre
Sanjie Township Central Hospital
No.60 Qingchun Road
Sanjie Town
Shengzhou
Shaoxing
China
312452

Study participating centre

Tongyuan Township Hospital

Gangxia Village
Tongyuan County
Shengzhou
Shaoxing
China
312471

Study participating centre

Xiawang Township Hospital

No.1 Fupai Road
Xiawang Village
Xiawang Town
Shengzhou
Shaoxing
China
312454

Study participating centre

Sanjiang Community Health Center

No.32 Shangtang South Road
Sanjiang Street
Shengzhou
Shaoxing
China
312499

Study participating centre

Shihuang Township Hospital

No.1 Zhenxi Road
Shihuang Town
Shengzhou
Shaoxing
China
312471

Study participating centre

Shanhu Community Health Center

No.23 Donghou Street
Shengzhou
Shaoxing
China
312432

Study participating centre
Xianyan Township Hospital
Xianyan Village
Xianyan Town
Shengzhou
Shaoxing
China
312459

Study participating centre
Lushan Community Health Center
No.143 Changan Road
Shengzhou
Shaoxing
China
312499

Study participating centre
Gulai Township Hospital
No.43 Wenwei Road
Shengzhou
Shaoxing
China
312472

Study participating centre
Beizhang Township Hospital
Beizhang Village
Beizhang Town
Shengzhou
Shaoxing
China
312458

Study participating centre
Pukou Community Health Center
No.3 Wenhua Road
Pukou Street
Shengzhou
Shaoxing

China
312451

Study participating centre
Ganlin Township Central Hospital
No.2 Damiao Road
Shengzhou
Shaoxing
China
312464

Study participating centre
Wangyuan Township Hospital
No.289 Wnagyuuan Village
Wangyuan County
Shengzhou
Shaoxing
China
312472

Study participating centre
Jinting Township Hospital
Jinxi Village
Jinting Town
Shengzhou
Shaoxing
China
312458

Study participating centre
Guimen Township Hospital
Guimen Village
Guimen County
Shengzhou
Shaoxing
China
312466

Study participating centre
Zhuxi Township Hospital
Zhuxi Village

Zhuxi County
Shengzhou
Shaoxing
China
312472

Study participating centre
Linan Township Hospital
Xiaye Village
Linan County
Shengzhou
Shaoxing
China
312465

Study participating centre
Huangyi Township Central Hospital
Huangze Town
Shengzhou
Shaoxing
China
312455

Study participating centre
Yahuang Township Hospital
Yahuang Village
Yahuang County
Shengzhou
Shaoxing
China
312471

Study participating centre
Chongren Township Central Hospital
Lingtang Road
Chongren Town
Shengzhou
Shaoxing
China
312473

Study participating centre
Changle Township Central Hospital
Changle Town
Shengzhou
Shaoxing
China
312467

Study participating centre
Huangshan Township Hospital
No.291 Xiashi Village
Huangshan Town
Zhuji
Shaoxing
China
311809

Study participating centre
Chenzhai Township Hospital
Chen Residence
Chenzhai Town
Zhuji
Shaoxing
China
311823

Study participating centre
Zhibu Township Hospital
Zhibu Village
Zhibu Town
Zhuji
Shaoxing
China
311827

Study participating centre
Jiangzao Township Hospital
Jiangzao Village
Jiangzao Town
Zhuji
Shaoxing
China
311822

Study participating centre
Zhaojia Township Hospital
Zhaoyi Village
Zhaojia Town
Zhuji
Shaoxing
China
311819

Study participating centre
Ruanshi Township Hospital
No.142 Nanbin Road
Ruanshi Town
Zhuji
Shaoxing
China
311826

Study participating centre
Wuxie Township Hospital
No.19 Wuxie Road
Wuxie Town
Zhuji
Shaoxing
China
311807

Study participating centre
Jiyang Community Health Center
No.98 Zhugong Road
Zhuji
Shaoxing
China
311899

Study participating centre
Lipu Township Hospital
No.102 Shuidong Road
Lipu Town
Zhuji

Shaoxing
China
312300

Study participating centre
Paitou Community Health Center
Paitou Town
Zhuji
Shaoxing
China
311825

Study participating centre
Lingbei Township Hospital
No.110 Zhuyuanfang
Lingbei Town
Zhuji
Shaoxing
China
311823

Study participating centre
Ciwu Township Hospital
No.13 Xiusong Road
Ciwu Town
Zhuji
Shaoxing
China
311815

Study participating centre
Jieting Township Hospital
Jieting Village
Jieting Town
Zhuji
Shaoxing
China
311805

Study participating centre

Caota Township Hospital

No.30 Fuzhou East Road

Cao Tower Town

Zhuji

Shaoxing

China

311812

Study participating centre

Huandong Community Health Center

No 580 Ji East Road

Zhuji

Shaoxing

China

311899

Study participating centre

Donghe Township Hospital

Dongyi

Donghe Town

Zhuji

Shaoxing

China

311833

Study participating centre

Taozhu Community Health Center

No.317 County Road

Zhuji

Shaoxing

China

311899

Study participating centre

Datang Township Hospital

Qingfang North Road

Datang Town

Zhuji

Shaoxing

China

311801

Study participating centre
Majian Township Hospital
No.5 Majian Town
Zhuji
Shaoxing
China
311803

Study participating centre
Anhua Township Hospital
Xin Street Development Area
Anhua Town
Zhuji
Shaoxing
China
311821

Study participating centre
Yingdian Community Health Center
No.7 Jiankang Road
Yingdianjie Town
Zhuji
Shaoxing
China
311817

Study participating centre
Dongbaihu Township Hospital
Chencai Village
East Baihu Town
Zhuji
Shaoxing
China
311818

Study participating centre
Wangjiajing Township Hospital
No.50 Shinan Road
Wnagjiajin Town
Zhuji

Shaoxing
China
311813

Study participating centre
Shanxiahu Township Hospital
Licha Road
Shanxiahu Town
Zhuji
Shaoxing
China
311804

Study participating centre
Diankou Township Hospital
Diankou Township Hospital
No.16 Zhenganxi Road
Zhuji
Shaoxing
China
311835

Study participating centre
Fengqiao Township Hospital
Youyi Plaza Zone
Fengqiao Town
Zhuji
Shaoxing
China
311811

Study participating centre
Tongshan Township Hospital
.No.2 Xin Street
Tongshan Town
Zhuji
Shaoxing
China
311808

Sponsor information

Organisation

University of Leeds

ROR

<https://ror.org/024mrxd33>

Organisation

Zhejiang Provincial Center for Disease Control

Funder(s)

Funder type

University/education

Funder Name

Comdis Health Services Delivery Research Consortium

Funder Name

Zhejiang Provincial Center for Disease Control

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/08/2017	26/02/2021	Yes	No
Results article		01/07/2021	05/07/2021	Yes	No
Protocol article	protocol	25/10/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes