

# Risk reduction intervention of cardiovascular disease in China

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

### Type(s)

Scientific

### Contact name

Prof Xiaolin Wei

### Contact details

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# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### 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

## 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 measure

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

### Secondary outcome measures

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

**Overall study start date**

01/03/2012

**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

#### Age group

Adult

#### Sex

Both

#### Target number of participants

30,000

#### 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  
Zhujia  
Shaoxing  
China  
311815

**Study participating centre**  
**Jieting Township Hospital**  
Jieting Village  
Jieting Town  
Zhujia  
Shaoxing  
China  
311805

**Study participating centre**  
**Caota Township Hospital**  
No.30 Fuzhou East Road  
Cao Tower Town  
Zhujia  
Shaoxing  
China  
311812

**Study participating centre**  
**Huandong Community Health Center**  
No 580 Ji East Road  
Zhujia  
Shaoxing  
China  
311899

**Study participating centre**  
**Donghe Township Hospital**  
Dongyi  
Donghe Town  
Zhujia

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 Zhengnanxi Road  
Zhuji  
Shaoxing  
China  
311835

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

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

## **Sponsor information**

**Organisation**  
University of Leeds

**Sponsor details**  
101 Clarendon Road  
Leeds  
United Kingdom  
LS2 9LJ

**Sponsor type**  
Research organisation

**Website**  
<http://www.leeds.ac.uk/>

**ROR**  
<https://ror.org/024mrx33>

**Organisation**  
Zhejiang Provincial Center for Disease Control

**Sponsor details**

No. 3399  
Binsheng Road  
Binjiang District  
Hangzhou  
China  
310051

**Sponsor type**

Government

**Website**

<http://www.cdc.zj.cn/>

## **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**

**Publication and dissemination plan**

Planned publication of five papers in in high-impact peer reviewed journals:

1. Baseline evaluation of medication adherence (to be published during the trial)
2. Interim analysis of secondary outcomes (to be published during the trial)
3. Qualitative paper on process evaluation of the trial (to be published about one year after the trial end)
4. Paper on costing study (to be published about one year after the trial end)
5. Paper on final outcomes of the trial (to be published about one year after the trial end)

**Intention to publish date**

31/12/2017

**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?
<a href="#">Protocol article</a>	protocol	25/10/2013		Yes	No
<a href="#">Results article</a>	results	16/08/2017	26/02/2021	Yes	No
<a href="#">Results article</a>		01/07/2021	05/07/2021	Yes	No