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Blood pressure control program in China

Submission date	Recruitment status	[ ] Prospectively registered
23/12/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/01/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/01/2018	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The disease burden of hypertension (high blood pressure) in China has been increased rapidly, and long-term effective prevention strategies are needed to prevent and control hypertension in China. This is a 2-year community-based study in two communities in Shanghai, China with the support of the local government. The aim of this study is to find out whether a community-based comprehensive intervention strategy of blood pressure control is effective.

Who can participate?
People aged 35 to 74 living in two selected communities in China

What does the study involve?
All participants in the intervention community receive comprehensive interventions, including health education and lifestyle interventions, including reducing intakes of dietary sodium, decreasing body weight, and increasing physical activity. In addition, the hypertensive patients in the intervention community are managed with hypertensive drug treatment to control blood pressure and followed up by the community physicians regularly. Participants in control community do not receive any intervention provided by the investigators of this study.

What are the possible benefits and risks of participating?
The participants would not have any direct benefit from the study, but the study may contribute to the prevention and control of blood pressure in China. When the participants had physical examinations, they may feel uncomfortable. For example, sphygmomanometer cuff inflation for blood pressure measurement may cause discomfort. In addition, the participants may feel short-term discomfort when blood is drawn. There is a small possibility of infection, excessive bleeding, clotting or fainting. If the participants are injured as a result of participating in this study, medical treatment is provided by the researchers.

Where is the study run from?
1. Bansongyuan Community (China)
2. Nanjing East Road Community (China)

When is the study starting and how long is it expected to run for?
May 2007 to December 2010

Who is funding the study?
National Science and Technology Support Projects for the Eleventh Five-Year Plan of China

Who is the main contact?
Dr Tao Wu

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A community-based non-randomized controlled intervention program for blood pressure control in China

Study objectives
The community-based comprehensive intervention strategy of blood pressure control is more effective in the intervention group compared to the control group without interventions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of Peking University Health Science Center, 01/01/2007

Study design
Community-based non-randomized controlled intervention program

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
The study was a non-randomized controlled intervention program, and two well-organized communities, in which the population was relatively stable and health records of the participants were accessible, were selected as our survey sites.

All participants in the intervention community received health education to improve hypertension-related knowledge. Lifestyle interventions including reducing intakes of dietary sodium, decreasing body weight, and increasing physical activity were offered to all participants in the intervention community. Whole community fitness program was launched in the intervention community to encourage residents to participate in physical exercise. Also, cardiovascular and cerebrovascular diseases specialists provided on-site counseling and guidance on healthy lifestyle. In addition, the hypertensive patients in the intervention community were managed to have hypertensive drug treatment to control blood pressure and followed up by the community physicians regularly. Participants in control community did not receive any intervention provided by the investigators of this project. The total duration of the intervention and follow-up was 2 years.

Intervention Type
Behavioural

Primary outcome measure
Systolic blood pressure, measured by trained staff using a conventional mercury sphygmomanometer and appropriately sized cuffs after a 5-minute rest in the seated position, at baseline and the endpoint of the study

Secondary outcome measures
Diastolic blood pressure, measured by trained staff using a conventional mercury sphygmomanometer and appropriately sized cuffs after a 5-minute rest in the seated position, at baseline and the endpoint of the study

Overall study start date
01/05/2007

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Aged 35 to 74 years
2. With local registered residence
3. Living in the community for more than five years
4 Being able to sign the written informed consent

Participant type(s)
All

Age group
Adult

Sex
Both

Target number of participants
18,528

Key exclusion criteria
Unable to sign the written informed consent

Date of first enrolment
01/06/2007

Date of final enrolment
01/10/2007

Locations

Countries of recruitment
China

Study participating centre
Bansongyuan Community
Shanghai
China
200000

Study participating centre

Nanjing East Road Community
Shanghai
China
200000

Sponsor information

Organisation
Ministry of Science and Technology of the People's Republic of China

Sponsor details
B15, Fuxing Road
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Sponsor type
Government

ROR
https://ror.org/027s68j25

Funder(s)

Funder type
Government

Funder Name
National Science and Technology Support Projects for the Eleventh Five-Year Plan of China (grant number 2006BA101A01)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
19/03/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available. The decision was attained by all parties involved in the study. The dataset is kept by specialized data analysts under the supervision of principal investigators of the study.

IPD sharing plan summary

Not expected to be made available