

# An integrative program on the population at risk for high blood pressure (hypertension)

<b>Submission date</b> 27/07/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 02/08/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/12/2022	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The population at risk for hypertension (high blood pressure) has a doubling risk of developing hypertension, and higher illness and death attributable to cardiovascular and cerebrovascular diseases, compared to individuals who are not at risk. Several studies have evaluated the effects of community-based integrative interventions to manage the population at risk for hypertension, including self-monitoring of blood pressure (BP), dietary adjustments, and regular exercises. In China, high-quality evidence is lacking regarding the effects of community-based integrative interventions on the population at risk for hypertension. This study aimed to evaluate the effectiveness of a community-based integrative program in reducing hypertension incidence among the population at high risk for hypertension in Shanghai, Eastern China.

### Who can participate?

Adults aged between 18 and 80 years identified as individuals at risk for hypertension with no previous history of hypertension diagnosis or use of anti-hypertensive medication.

### What does the study involve?

Participants were randomly divided into two groups (the intervention group and the control group). The intervention group received an integrative program that includes health education, physician follow-up, and self-management. The control group received usual care only. All patients were followed up for one year. Questionnaires were used to investigate risk factors, knowledge, attitudes, and behaviors regarding hypertension prevention for all participants at baseline and follow-up. BP was measured for all participants at baseline and follow-up.

### What are the possible benefits and risks of participating?

The researchers did not think that taking part has any major risks. The possible benefits of this study included lower hypertension incidence and improvement in hypertension-related knowledge, attitudes, and behaviors.

### Where is the study run from?

Six neighbourhood blocks in Changning District of Shanghai (China)

When is the study starting and how long is it expected to run for?  
January 2018 to December 2021

Who is funding the study?  
The National Natural Science Foundation of China

Who is the main contact?  
Dr Chengyue Li  
lichengyue@fudan.edu.cn

## Contact information

**Type(s)**  
Principal investigator

**Contact name**  
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## Additional identifiers

## Study information

**Scientific Title**  
Effectiveness of an integrative program on reducing hypertension incidence among the population at risk for hypertension

**Study objectives**  
The integrative program can improve the level of hypertension-related knowledge, attitudes, and behaviors, and can be effective in delaying the development of hypertension in high-risk populations.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

Approved 03/03/2017, Fudan University School of Public Health Institutional Review Board (130 Dong'an Road, Shanghai 200032, China; +86 (021) 54237051; no email provided), ref: IRB #2017-TYSQ-03-10.

## **Study design**

Cluster-randomized intervention trial

## **Primary study design**

Interventional

## **Study type(s)**

Prevention

## **Health condition(s) or problem(s) studied**

Population at risk for hypertension

## **Interventions**

The researchers conducted a community-based randomized intervention trial among the population at risk for hypertension. They selected community A in Changning District of Shanghai, located in the Eastern Region of China, as the study setting. For the interventions, the randomization process was performed as follows: first, 6 neighbourhood blocks were randomly selected from the 17 neighbourhood blocks in community A for inclusion in the study, by using a computer-generated random number. Three blocks were randomized as the intervention group and the other three were treated as the control group. One lane was randomly selected from each sampled neighbourhood block by using a computer-generated random number to recruit the participants, with approximately 300 to 400 residents in each lane.

The study was implemented in October 2019-October 2020. The intervention group was managed through the integrative intervention, and the control group received usual care (i.e., the general practitioners followed up with patients and queried their BP levels, and lifestyles via phone every 6 months). The integrative program consisted of three sections: health education, physician follow-ups, and self-management. The training was provided to all general practitioners (GPs) and staff involved in the intervention group, including the intervention measures for high-risk individuals, the intervention contents, the implementation procedures, and rules for filling out the tables regarding the intervention process. Before the intervention, health education lecture schedules, self-management cards, and health education leaflets were allocated to individuals in the intervention group, and an online group chat using social media (WeChat, Tencent Co. Ltd, China) was also created.

All recordings and documents of the management process were employed to ensure that assessment and intervention procedures were standardized across the study sites and all participants. The activities of the interviews, physical assessment procedures, and program implementation were routinely supervised and monitored by senior researchers.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

Incidence of hypertension measured based on BP readings obtained by the automated validated Omron electronic sphygmomanometer among participants in the two groups at baseline and 1-year follow-up.

### **Key secondary outcome(s)**

Changes in hypertension-related knowledge, attitude, behavior (KAB) measured using a structured questionnaire for participants in the two groups at baseline and 1-year follow-up.

### **Completion date**

31/12/2021

## **Eligibility**

### **Key inclusion criteria**

1. Permanent residents aged 18-80 years of the sampled lane (excluding those who leave this lane for more than half a year)
2. Identified as individuals at risk for hypertension, with a total risk score of more than 20 based on our screening tool
3. Informed consent and willingness to participate in this study
4. No previous history of hypertension diagnosis or use of anti-hypertensive medication
5. With good cognitive function and physical condition

### **Participant type(s)**

Other

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Lower age limit**

18 years

### **Upper age limit**

80 years

### **Sex**

All

### **Total final enrolment**

607

### **Key exclusion criteria**

1. Those with a history of severe mental illness or poor compliance
2. Not identified as individuals at risk for hypertension, with total risk score less than 20 based on our screening tool
3. With a previous history of hypertension diagnosis or use of anti-hypertensive medication

**Date of first enrolment**

01/10/2019

**Date of final enrolment**

30/10/2020

## Locations

**Countries of recruitment**

China

**Study participating centre**

**Changning District Xinhua Street Community Health Service Center**

1467 Huashan Road

Changning District

Shanghai

China

200052

## Sponsor information

**Organisation**

Fudan University

**ROR**

<https://ror.org/013q1eq08>

## Funder(s)

**Funder type**

Government

**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

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets will be available upon request from Chengyue Li (lichengyue@fudan.edu.cn)

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		17/12/2022	19/12/2022	Yes	No
<a href="#">Basic results</a>		02/09/2022	02/09/2022	No	No
<a href="#">Protocol file</a>		31/07/2022	01/08/2022	No	No