

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

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

ORCID ID
<https://orcid.org/0000-0001-5829-5129>

Contact details
Department of Health Policy and Management
School of Public Health
Fudan University
130 Dong'an Road
Shanghai
China
200032
+86-21-33561022
lichengyue@fudan.edu.cn

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

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?
Results article		17/12/2022	19/12/2022	Yes	No
Basic results		02/09/2022	02/09/2022	No	No
Protocol file		31/07/2022	01/08/2022	No	No