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

Submission date 27/07/2022	Recruitment status No longer recruiting	[] Prospectively registered[X] Protocol
Registration date 02/08/2022	Overall study status Completed	[_] Statistical analysis plan[X] Results
Last Edited 19/12/2022	Condition category Circulatory System	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 intervention 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

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers 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

Secondary study design Cluster randomised trial

Study setting(s) Community

Study type(s) Prevention

Participant information sheet

The participant information sheet is not available in web format, please use the contact details to request a participant information sheet: Chengyue Li (lichengyue@fudan.edu.cn).

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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/01/2018

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

Age group Mixed

Lower age limit 18 Years

Upper age limit

80 Years

Sex Both

Target number of participants 280 for both the intervention and control groups

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

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Sponsor type University/education

Website http://www.fudan.edu.cn/en/

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 Wěiyuánhuì, NSFC, NNSF, NNSFC

Funding Body Type Government organisation

Funding Body Subtype National government

Location China

Results and Publications

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

Intention to publish date 01/12/2022

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