ISRCTN74154693 https://doi.org/10.1186/ISRCTN74154693

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

Submission date
27/07/2022

Recruitment status
No longer recruiting

Registration date
02/08/2022

Overall study status
Completed

Last Edited
19/12/2022

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
http://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

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

Sponsor details
School of Public Health
130 Dong'an Road, Xuhui District

Shanghai
China
200032
+86-021-54237051
gwkyb@fudan.edu.cn

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