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Financial incentives for hypertension control in China (FIHCC study)

Submission date
23/04/2019

Recruitment status
No longer recruiting

Registration date
16/05/2019

Overall study status
Completed

Last Edited
10/06/2024

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Hypertension, a major risk factor for cardiovascular disease (CVD) and premature death, has been a leading public health problem worldwide. How to make hypertensive patients positively change unhealthy lifestyles and promote their regular medication is an important problem that needs to be addressed in current hypertension control. Financial incentives have been explored in smoking, weight loss, and diabetes and confirmed that it can significantly increase the rates of smoking cessation, promote obese participants lost significantly more weight, and improve self-monitoring rates of blood pressure (BP), blood glucose and weight in diabetic patients. Therefore, the aim of this study is to explore whether financial incentives will improve hypertension control among community-based uncontrolled hypertensive patients in China.

Who can participate?
Adults aged 35 - 75 years who have uncontrolled hypertension

What does the study involve?
Interested subjects should complete a screening questionnaire on the web first, and then the researchers will contact the potential subjects and confirm them at the recruitment location. Subjects who meet the inclusion criteria will be required to sign an informed consent. Participants will be randomized to the intervention and control group. The control group will be provided with patient education and can communicate with the researcher through the mobile at any time. The participants of the intervention group will be provided with patient education but also receive financial incentives. Financial incentives include the rewards for self-measurement of BP and the participants whom BP values were decreased by 10 mmHg relative to baseline or achieve hypertension control (BP < 140/90 mmHg). The intervention lasts one year in total and the study lasts three years in total. The researchers will collect data at baseline, months 1, 3, 6, and 12. Data collection locations are carried out at hospitals in the regional centers. The data was obtained by standardized questionnaires and measurement.

What are the possible benefits and risks of participating?
The results of this study will help improve the control rate of hypertension and lower blood

pressure levels in urban communities. Because of lowering blood pressure, you may further reduce the chance of stroke recurrence, coronary heart disease and heart failure. All participants will be asked to complete questionnaires, which may be psychologically uncomfortable.

Where is the study run from?
The FHICC study is being run by Shengjing Hospital of China Medical University, Fushun Mining General Hospital of Liaoning Health Industry Group, Dandong Central Hospital, Anshan Central Hospital, Fuxin Mining General Hospital of Liaoning Health Industry Group and Fenyang Hospital of Shanxi Medical University and Shengjing Hospital of China is the lead center.

When is the study starting and how long is it expected to run for?
January 2019 to July 2021

Who is funding the study?
Investigator-initiated and funded

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Financial incentives for hypertension control among community-based hypertensive populations: a multi-center, randomized controlled trial

Acronym
FIHCC

Study objectives
Compared to control group, the financial incentives will lower systolic and diastolic BP among hypertensive patients over an 12-month period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/03/2019, Shengjing Hospital of China Medical University Medical Ethics Committee (Shengjing Hospital of China Medical University, 36 SanHao Street, Heping District, Shenyang, 110004, China; 86-24-96615-10027; wangh3@sj-hospital.org), ref:2019PS397K

Study design
Multi-center open randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
We will recruit 400 eligible subjects and assign the subjects 1:1 to the intervention and control groups by block randomization, with 200 in each group.
Participants in control group will receive interactive management of mobile devices, including:
1. Patient education: researchers will send relevant knowledge of hypertension prevention and treatment at the beginning of each month in the WeChat group, including the definition and severity of hypertension, methods of correctly measuring BP, lifestyle prevention, the types and selection of antihypertensive drugs, the harms of hypertension complications.
2. Communication: If the patients have any questions during the intervention and follow-up, they can communicate with the researcher through the mobile at any time, and the researcher will answer their questions.
The participants of the intervention group will implement financial incentives on the basis of control group, and the specific measures include two parts:
1. Participants were encouraged to self-measure BP once a week and record the condition of antihypertensive medications, and the rewards of 5 yuan (red envelope) were received as they record the results accurately and completely every week.
2. At the follow-up months 1, 3, 6, and 12, researchers measured participants BP and gave a reward of 50 yuan or equivalent gift (shopping cards, phone bills, cooking oil, etc.) to the patients whom BP values were decreased by 10 mmHg (compared to baseline BP values) or achieve the control criteria (SBP/DBP <140/90 mmHg).
The study will last one year in total and researchers will collect data at baseline, months 1, 3, 6, and 12.

Intervention Type
Behavioural

Primary outcome(s)
Systolic blood pressure at the baseline and after 1, 3, 6, and 12 months

Key secondary outcome(s))
1. Diatolic blood pressure measured using blood pressure monitors at the baseline, and after 1, 3, 6 and 12 months
2. The proportion of hypertension control (BP <140/90 mmHg) at 1, 3, 6, and 12 months
3. Medication adherence at the baseline, and after 1, 3, 6, and 12 months
4. Body mass index assessed by dividing weight in kg by height in metres at the baseline, and after 1, 3, 6, and 12 months
5. Physical activity at the baseline, and after 1, 3, 6, and 12 months
6. Counseling frequency at the baseline, and after 1, 3, 6, and 12 months
7. Counseling content at the baseline, and after 1, 3, 6, and 12 months
8. Number of steps in WeChat at the baseline, and after 1, 3, 6, and 12 months
9. Pulmonary function at the baseline and after 12 months
10. Pulse wave velocity at the baseline and after 12 months
11. Ankle brachial index at the baseline and after 12 months
12. Cost-effectiveness

Completion date
01/07/2021

Eligibility

Key inclusion criteria

1. Aged 35 - 75 years
2. Uncontrolled hypertensive patients (SBP/DBP ≥ 140/90mmHg)
3. Have WeChat and use skillfully
4. Local residents, who live in local places for more than 12 months
5. Voluntarily joined and signed informed consents

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
35 years

Upper age limit
75 years

Sex
All

Total final enrolment
207

Key exclusion criteria
1. Pregnant women or women who are planning to become pregnant in the next year
2. Plans to move from the neighborhood in the next year
3. Malignant tumors or severe liver, kidney dysfunction
4. Can not be proficient in using WeChat
5. Secondary hypertension patients
6. Disagree to participate in the study or cannot give the informed consent

Date of first enrolment
01/08/2019

Date of final enrolment
27/03/2021

Locations

Countries of recruitment
China

Study participating centre

Shengjing Hospital of China Medical University
China
110004

Study participating centre
Fushun Mining General Hospital of Liaoning Health Industry Group
China
113008

Study participating centre
Dandong Central Hospital
China
118000

Study participating centre
Anshan Central Hospital
China
114001

Study participating centre
Fuxin Mining General Hospital of Liaoning Health Industry Group
China
123099

Study participating centre
Fenyang Hospital of Shanxi Medical University
China
032200

Sponsor information

Organisation
Shengjing Hospital of China Medical University

ROR
https://ror.org/0202bj006

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/07/2022	22/07/2022	Yes	No
Protocol article		03/02/2020	10/06/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes