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Effectiveness of community intervention program

Submission date
04/08/2013

Recruitment status
No longer recruiting

Registration date
09/08/2013

Overall study status
Completed

Last Edited
09/08/2013

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
We are interested in finding out about what can be done to improve knowledge, control and management of high blood pressure. We know from previous studies that reducing salt intake, increasing exercise, managing negative emotion and taking medication can control high blood pressure. But there are many things we still dont know, for example who benefits the most. In this study we want to see if we can find out more about this through community-based activities.

Who can participate?
You can participate if you are aged 35 or over and your blood pressure level is more than 140/90 mm Hg or you have history of high blood pressure and currently is normal when you take medication, and you live in the area we are studying. You should also respond to the preliminary information about the project.

What does the study involve?
Participants will be randomly allocated to one of two groups: control group (usual care) and intervention group (will be participating in the education class). During the study, you will be asked to complete and return a questionnaire asking for a few personal details. You will then be invited to participate in a education class for six sessions. The group will meet once a week for 6 weeks. During this time we will ask you to fill in three short questionnaires about your health and return them to us by post in a pre-paid envelope. We will also measure your height, weight, blood pressure and blood cholesterol and sugar level. We will ask you to do this at the start of the research, then 6 months later (at the end of the doctors consultation sessions) and a further 6 months after that. We may also ask if we can talk to you on the telephone or at a place convenient to you around the third time you fill in the questionnaires. This will allow you to tell us about your health in your own words and what you think about any activities you have taken part in. After the final questionnaires have been completed, everyone will be able to join a education group if they wish.

What are the possible benefits and risks of participating?
The study will help us to understand whether community-based activities help people with high

blood pressure feel better and to know who benefits the most. This means that in future individuals can be referred by professionals to the right sort of activities to help improve their health. There are no risks of participating in the project.

Where is the study run from?
The study will be conducted in 36 communities in Fangshan District, Beijing, China.

When is the study starting and how long is it expected to run for?
The study started in February 2011 and ran till February 2012.

Who is funding the study?
This study is funded by Griffith University in Australia, Fangshan District Center for Disease Control and Prevention, Beijing, China; Peking University, China, and Bureau of Health, Fangshan District, Beijing, China.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Improved hypertension awareness, control and management with low-cost interventions in a rural Chinese environment of rural community medical center-led care: a cluster-randomised trial

Study objectives
A community based intervention program is effective in improving the hypertension awareness, monitoring and management of patients with hypertension in rural China.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Fangshan District Center for Disease Control and Prevention Research Board has approved the study

Study design
Cluster randomised control trial

Primary study design
Interventional

Study type(s)
Prevention

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

Interventions
All physicians in all groups participated in a one day training session on hypertension self-management skills, communication skills with patients with hypertension through telephone counselling and how to follow up the skills that they learned from the training sessions on a regular basis until 12 months after the intervention program is completed. Subsequently, all physicians are trained on how to establish a treatment plan with hypertensive patients. Such plan constituted the background intervention in all study groups. Plans were set up by the physicians for each newly detected patient with hypertension enrolled into the trial. The process includes four sequential steps:
1. An in-depth counselling on the chronic nature of the disease, the importance of a long-term care in changing lifestyle, regular exercise, diet and salt control
2. Establish trust with patients for long-term care in the current facility
3. The identification of possible obstacles in the patients psychosocial condition that might interfere with a longterm care
4. A formal commitment signed by patient and physician, in which patients commit to do their best to adhere to follow-up schemes and physicians commit to do their best to provide good care.

Group 1 served as a control group, with no additional interventions.
Group 2, intervention group, in addition to the treatment plan, patients were offered the six sessions of training classes and subsequently regular phone call and home visit by physicians with free cost. Intervention group participants received a risk based multifactorial hypertension prevention program including exercise intervention, health education in providing knowledge of hypertension, along with medication compliance review, hypertension monitoring and control training. The community intervention program was a series of small group, supervised activities consisting of six training sessions led by community centre doctors and group leader in the following content: (1) awareness of hypertension; self management skills, goal setting and action plan designing; how to increase confidence in hypertension
control, methods to deal with stress, anger and worries; negative emotion management, management of tiredness; relaxation skills; improving communication skills, problem solving skills, exercise, healthy diet, quit smoking, weight control, mediation use, blood pressure self-

monitoring, and compliance to medical advice from doctors. After baseline assessment, eligible participants were randomly allocated into the intervention group and control group stratified by age and gender. All randomisations were concealed through computerised random number generator or sealed numbers in envelops depending on the regular practice pattern of each community medical centre.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Blood pressure

Key secondary outcome(s))
1. A structured questionnaire with 17 questions covering common risk factors was administered to test the participants knowledge, awareness, hypertension control and management. Hypertension knowledge questions included patients knowledge of exercise, salt intake, blood pressure level, smoking and stress.
2. Health behavior questions included smoking, alcohol intake, exercise, fruit and vegetable intake.
3. Hypertension management including medication compliance, and blood pressure monitoring and control and regulation through exercise, psychological stress management, and medication.

1.Hypertension knowledge was developed for this study to be appropriate to rural area patients level of understanding in China. The hypertension knowledge questions consisted of nine questions including awareness of hypertension diagnosis criteria, understanding causes of hypertension relating to healthy diet and less salt intake, moderate exercise level, anger control, and medication adherence. The structure of the questions and validity were analysed by confirmatory factor analysis. The overall structure of the questions had a good modle fit.
2. Health behavior scale consists of four questions including smoking, alcohol, diet and salt control, and exercise after confirmation factor analysis was conducted. The confirmatory factor analysis demonstrates that the four questions have a good model fit with fit indices are within the acceptable range.
3. Control and management of high blood pressure methods: weekly monitoring blood pressure, medication use, exercise and diet control.

Completion date
01/02/2012

Eligibility

Key inclusion criteria
Subjects were enrolled if one of the following inclusion criteria were fulfilled:
1. had blood pressure more than 140/90
2. had family of hypertension
3. they were registered in the community medical centre, not staying in the hospitals

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
People with hypertension who had the following conditions were excluded from the study:
1. People who had severe neurological and psychiatric diseases, serious complications and comorbidities such as stroke and diabetes, cancer, and had chemotherapy in the last six months
2. Aged less than 35 years
3. People who did not want to comply to the program protocol
4. People attending other intervention programs, and/or having physical limitations to prohibit them to attend the regular activities.

Date of first enrolment
01/02/2011

Date of final enrolment
01/02/2012

Locations

Countries of recruitment
Australia

China

Study participating centre
Jing Sun
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Sponsor information

Organisation
Griffith University (Australia)

ROR
https://ror.org/02sc3r913

Funder(s)

Funder type
Government

Funder Name
Fangshan Bureau of Health, Beijing, China

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes