

Keep Moving toward Healthy Heart and Healthy Brain

Submission date 03/02/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/02/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/03/2023	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

More than 50% of senior Chinese suffer from hypertension (high blood pressure) and this number is growing along with the rapid economic growth in China. Therefore, the prevention of high blood pressure related consequences, particularly heart attack and stroke, becomes a number one priority for chronic disease prevention. To control high blood pressure, the Wuhan Center for Disease Prevention and Control established the Community-Based Hypertension Control Program (CBHCP) in 2006 to deliver a drug-treatment program. This strategy emphasizes drug treatment to low blood pressure without considering physical activity. Scientific evidence from diverse sources indicates that physical activity can be a promising and cost-effective measure for blood pressure control to reduce many life-threatening consequences, including heart attack and stroke. Based on a community-based program, this study is devised to test the effectiveness of a physical activity training program, 'Keep Moving Toward Healthy Heart and Healthy Brain' (KM2H2), in controlling high blood pressure and reducing risk for heart attack and stroke. To ensure feasibility and sustainability, the study focuses on the physical activities commonly practiced by old people in China, including jogging, quick walking, slow running, group-dancing and cycling.

Who can participate?

Patients aged 55 and over diagnosed by a doctor as hypertensive, currently on hypertensive medication, and able to safely participate in moderate or higher levels of physical activity.

What does the study involve?

Participants are randomly assigned to receive either KM2H2 or the standard CBHCP care. Participants will attend two lectures at community health centers regarding high blood pressure and its consequences, with emphasis on physical activities as an important approach for prevention. After the two lectures, participants will be followed-up twice. The first follow-up, a week after the lecture, is a one-on-one psychological counseling session to encourage safe and appropriate physical activities and to solve issues confronted in engaging in physical activities. One week later, the participants are followed up again through a researcher-guided small group session (8-10 patients) to exchange skills and experience in physical activities for blood pressure control and to foster social and emotional support among the participants. The counseling and small group sessions are repeated one month later to end the intervention. Boosters are

arranged at three months post-intervention delivered also through one-on-one counseling and small group activities. During the course of the study, participants are asked to complete three surveys, one before the intervention and two at 3 and 6 months after the intervention. During each of these surveys, participants are interviewed by trained investigators regarding their medical conditions and physical activities. Participants will also provide blood samples to measure blood sugar and fat and blood pressure will be measured.

What are the possible benefits and risks of participating?

Participants may benefit from participating in the study in several ways. They may build a good habit for exercise, they may gain better control of their high blood pressure, and they may also reduce the risk of heart attack and stroke. No significant risk is anticipated with the safety measures for physical activities as the research study emphasized. In case an accident happens because of participation in this study, participants are warranted priority to access care at all levels from the local community health centers to the tertiary level hospitals in Wuhan.

Where is the study run from?

Wuhan Center for Disease Prevention and Control (China).

When is the study starting and how long is it expected to run for?

April 2011 to November 2011

Who is funding the study?

Wuhan Centers for Disease Prevention and Control and Hong Kong Polytechnic University (China)

Who is the main contact?

Dr Jie Gong

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Contact information

Type(s)

Scientific

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EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information**Scientific Title**

A physical activity enhancement program KM2H2 for secondary prevention of hypertension among old adults

Acronym

KM2H2

Study objectives

Senior hypertensive patients can be motivated to participate in physical activity and a moderate level of physical activity has a significant effect to reduce the life-threatening consequences of hypertension, particularly the incidence of heart attack and stroke.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. University of Florida IRB, 07/14/2014, ref: IRB201400518
2. Wuhan CDC, 03/15/2010, ref: WHN.IRB30124
3. Hong Kong Polytech, 08/26/2010, ref: HKT_IRB2010C1032

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Hypertension

Interventions

The study participants (n=450) from 12 community health centers were randomly assigned to receive either KM2H2 (n=232) or the standard care (n=218).

The KM2H2 intervention include six sessions, plus two booster sessions. The first session covers basic knowledge about hypertension and motivation of physical activity, the second session is for physical activity training, the third session is one-on-one counseling, and the fourth session is small group activity. These four sessions are delivered on a weekly basis. Sessions three and four are repeated once to complete the intervention. The intervention program is based on an extended Transtheoretical Model to incorporate the Model of Personalized Medicine for individualized counseling and the Social Capital Theory for small group activities.

Intervention Type

Behavioural

Primary outcome measure

1. Levels of physical activity measured using the a verified survey questionnaire
 2. Incidence of heart attack and stroke determined with medical records
 2. Blood pressure assessed following the standard protocol of the American Hypertension Association
- Measured at baseline and the two follow-ups 3 months and 6 months post-intervention

Secondary outcome measures

Blood fats and sugar (total cholesterol, HDL, LDL) were measured using the standard methods at the Biochemistry Laboratory at Wuhan CDC at baseline and the two follow-ups 3 months and 6 months post-intervention

Overall study start date

20/04/2011

Completion date

28/11/2011

Eligibility

Key inclusion criteria

1. Aged 55 and above
2. Diagnosed by a doctor as hypertensive (SBP greater or equal 140 mmHg and DBP greater or

equal 90 mmHg)

3. Currently on hypertensive medication

4. Able to participate in moderate or higher levels of physical activity safely

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

450

Key exclusion criteria

1. Significant physical and other medical conditions preventing from participating in physical activities

2. Failure in physical activity safety screen test

2. Obvious EKG abnormalities

Date of first enrolment

20/04/2011

Date of final enrolment

08/06/2011

Locations

Countries of recruitment

China

Study participating centre

Wuhan Center for Disease Prevention and Control

24 Jiang-Han-Bei-Lu Road

Wuhan

China

430022

Sponsor information

Organisation

Wuhan Center for Disease Prevention and Control

Sponsor details

24 N. Jian-Han-Bei-Lu Road
Wuhan
China
430022

Sponsor type

Government

Funder(s)**Funder type**

University/education

Funder Name

Wuhan Centers for Disease Prevention and Control

Funder Name

Hong Kong Polytechnic University

Alternative Name(s)

The Hong Kong Polytechnic University, , Hong Kong PolyU, Government Trade School, Hong Kong Technical College, Hong Kong Polytechnic, PolyU, HKPU

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Hong Kong

Results and Publications**Publication and dissemination plan**

Publish the study findings, apply for new funding for phase 3 trial.

Intention to publish date**Individual participant data (IPD) sharing plan**

Not provided at time of registration

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2015		Yes	No
Results article	30-month results	02/01/2018		Yes	No
Protocol article			08/03/2023	Yes	No