

A randomised trial of a brief cognitive-behavioural, manualised, self-management programme for hypertension delivered in a cardiac patient club in Shanghai

| | | |
|--|---|---|
| Submission date 14/08/2007 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 22/08/2007 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 10/01/2020 | Condition category Circulatory System | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Feng Xue

Contact details

Postgraduate Area
2nd Floor
Hull York Medical School (HYMS) Building
University of York
Heslington
York
United Kingdom
YO10 5DD
-
fx101@york.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A randomised trial of a brief cognitive-behavioural, manualised, self-management programme for hypertension delivered in a cardiac patient club in Shanghai

Study objectives

Patients recruited from an anti-hypertensive club who are shown how to use a cognitive-behavioural self-management manual together with brief group facilitation, will demonstrate similar levels of blood pressure, self-efficacy, behavioural change and quality of life at follow-ups when compared to patients given written information alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Department of Health, Sciences Research Governance Committee at the University of York approved this study on 5 January 2005.

Study design

Pragmatic randomised controlled trial.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Hypertension

Interventions

Intervention group: A self-management manual (the Hypertension Manual) plus four educational sessions (in small groups)

Control group: Written information alone

The topics covered in the educational sessions included the following:

1. Basic knowledge of hypertension
2. Goal setting
3. Self-monitoring of blood pressure
4. Physical activity (demonstration of exercises)
5. Dietary advice
6. Calculating BMI
7. Food energy calculation

The booklet provided to the control group covered:

1. Basic knowledge on hypertension, including cardiovascular anatomy, definition and classification of hypertension, and how to measure blood pressure
2. Preventive knowledge on hypertension, including the implications of life style changes and a self-assessment tool for cardiovascular risks
3. Clinical knowledge on hypertension, including symptoms and signs of hypertension, anti-hypertensive medication and compliance with taking drugs

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Systolic and diastolic blood pressure at 1 month and 4 months after the end of treatment.

Secondary outcome measures

The following were assessed at 1 month and 4 months after the end of treatment:

1. Blood total cholesterol
2. Urinary sodium and potassium
3. Body mass index
4. Waist circumference
5. Self-efficacy
6. Physical activity
7. Dietary behaviour
8. Quality of life

Overall study start date

01/09/2004

Completion date

30/11/2005

Eligibility

Key inclusion criteria

Clinician diagnosed primary hypertension defined as having systolic Blood Pressure (BP) >140 mmHg or diastolic BP >90 mmHg recorded in their medical records. An age criterion is adopted restricting recruitment to those aged 18 to 69 years because the physical activity questionnaire used is only valid in this range.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

140

Total final enrolment

140

Key exclusion criteria

1. Secondary forms of hypertension
2. Target organ damage and/or diabetes
3. Use of weight-loss medications
4. Congestive heart failure
5. Angina
6. Life-threatening co-morbidity (e.g. carcinoma, terminal liver or renal failure)
7. Disability that would prevent participation in a walking exercise regime
8. Inability to read or communicate in Chinese, and/or a history of reduced cognitive ability

Date of first enrolment

01/09/2004

Date of final enrolment

30/11/2005

Locations**Countries of recruitment**

China

England

United Kingdom

Study participating centre**Postgraduate Area**

York

United Kingdom

YO10 5DD

Sponsor information

Organisation

University of York

Sponsor details

Heslington

York

England

United Kingdom

YO10 5DD

-

jah14@york.ac.uk

Sponsor type

University/education

Website

<http://www.york.ac.uk>

ROR

<https://ror.org/04m01e293>

Funder(s)

Funder type

Charity

Funder Name

Great Britain-China Educational Trust (UK)

Funder Name

Henry Lester Trust Limited (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 06/05/2008 | 10/01/2020 | Yes | No |