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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

Registration date
22/08/2007

Overall study status
Completed

Last Edited
10/01/2020

Condition category
Circulatory System

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 faciliatation, 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
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Sponsor information

Organisation
University of York

Sponsor details
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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