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Investigating the effectiveness of a pre-operative education intervention on reducing anxiety and improving recovery among Chinese cardiac patients

Submission date
02/11/2009

Recruitment status
No longer recruiting

Registration date
30/11/2009

Overall study status
Completed

Last Edited
30/11/2009

Condition category
Mental and Behavioural Disorders

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

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
Investigating the effectiveness of a pre-operative education intervention on reducing anxiety and improving recovery among Chinese cardiac patients: a two-arm randomised controlled trial taking place in two centres

Study objectives
Compared with usual care, participants who receive the pre-operative education intervention will show reduced anxiety and depression, reduce reported pain, reduce hospital admission, and reduce length of time in intensive care unit.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The First Affiliated Hospital of Henan Science and Technology University - University Teaching and Research Committee approved on the 15th January 2009
2. Luoyang City Central Hospital approved on the 8th January 2009

Study design
Two-arm multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Anxiety in elective cardiac surgery

Interventions
Intervention: a structured leaflet based education intervention that includes:
1. A leaflet designed for Chinese cardiac patients and their families
2. 15 minute face-to-face oral explanation and opportunity to ask questions
3. Family in attendence if requested

Control: routine care

This form of intervention will take no more than 20 minutes and the total duration of follow-up for the two arms is 7 days following surgery.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Anxiety measured by the Hospital Anxiety & Depression Scale at baseline and 7 days after surgery

Secondary outcome measures
1. Depression measured by the Hospital Anxiety & Depression Scale at baseline and 7 days after surgery
2. Pain measured by the Brief Pain Inventory at baseline and 7 days after surgery
3. Time to discharge from intensive care unit following surgery
4. Time to discharge from hospital following surgery

Overall study start date
30/11/2009

Completion date
30/05/2010

Eligibility

Key inclusion criteria
1. Aged 18 years and over, either sex
2. Admission for any form of elective cardiac surgery at either of the two hospitals
3. Able to speak, read and write Chinese

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
125

Key exclusion criteria
1. Unable to give informed consent
2. Emergency cases
3. Previous cardiac surgery

Date of first enrolment
30/11/2009

Date of final enrolment
30/05/2010

Locations

Countries of recruitment
China

England

United Kingdom

Study participating centre
School of Nursing, Midwifery & Physiotherapy
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details
Research Innovation Services
Kings Meadow Campus
Lenton Lane
Nottingham
England
United Kingdom
NG7 2NR

Sponsor type
University/education

Website
http://www.nottingham.ac.uk/

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
University/education

Funder Name
University of Nottingham (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
The First Affiliated Hospital of Henan Science and Technology University (China)

Funder Name
Luoyang City Central Hospital (China)

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