ISRCTN60618114 https://doi.org/10.1186/ISRCTN60618114

The development and feasibility of an intervention to reassure patients about test results in rapid access chest pain clinic

Submission date 27/05/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/05/2011	**Overall study status** Completed	
Last Edited 06/10/2014	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Gill Furze

Contact details
Coventry University
Room 309, Richard Crossman Building
Priory Street
Coventry
United Kingdom
CV1 5FB

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
9810

Study information

Scientific Title
The development and feasibility of an intervention to reassure patients about test results in a rapid access chest pain clinic

Study objectives
The study has two parts:
1. In the first part (the development phase), an intervention will be developed with input from experts, patients and clinic staff. The intervention will be a brief (10 - 15 mins) face-to-face discussion delivered by a nurse to patients attending rapid access chest pain clinic (RACPC) that will explain to the patients the tests they are going to undergo in RACPC, the possible test results they may get, and what the possible treatments may be for the different test results. This discussion will take place before the patients undergo their test in RACPC and the aim of the intervention is to increase patients reassurance with their test results and ensuing treatment. A focus group of ten previous RACPC patients will be setup to gain their views on the draft intervention. The final draft intervention will be tested in ten patients in RACPC before being finalised.

2. (The pilot trial phase) we will undertake a pilot randomised controlled trial (RCT) with 120 patients in RACPC. The two-arm study will compare the intervention (face-to-face discussion developed in the first part of the study) PLUS usual care (a written leaflet giving the same information - tests that may be undertaken in RACPC, results and potential ensuing treatments) VERSUS usual care alone. The pilot RCT will inform the design of a future multicentre trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC approval date 15/12/2010, ref: 10/H1014/82

Study design
Randomised, interventional, observational qualitative trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Cardiovascular disease

Interventions
1. Nurse-facilitated intervention: a brief (10 - 15 mins) face-to-face discussion delivered by a nurse to patients attending rapid access chest pain clinic (RACPC) that will explain to the patients the tests they are going to undergo in RACPC, the possible test results they may get, and what the possible treatments may be.
2. Follow up length: 6 month(s)
3. Study entry: single randomisation only

In the first stage of the study, ten participants will be recruited for the focus group and ten participants will be recruited for testing each draft of the intervention. For the pilot RCT, we propose to recruit 120 participants (60 per group).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Patient reported reassurance
2. Timepoint(s): 1 month and six months

Secondary outcome measures
No secondary outcome measures

Overall study start date
30/03/2011

Completion date
30/06/2012

Eligibility

Key inclusion criteria
Applies to the developmental phase and the pilot study:
1. All patients attending RACPC for assessment of new-onset, non-urgent chest pain
2. Able to read written English
3. Able to comprehend spoken English
4. Aged 18 years and over
5. Able and willing to give informed consent
6. Target gender: male & female
7. Lower age limit 18 years

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 140; UK Sample Size: 140;

Key exclusion criteria
Pilot study only:
1. Previously diagnosed cardiac pathology
2. No symptoms of chest pain
3. Undertaking the stress test as part of a pre-surgical medical examination
4. Pregnant
5. Currently involved in a research study
6. Severe documented psychiatric disorder (psychosis/bipolar disorder)
7. Life threatening co-morbidities

Date of first enrolment
30/03/2011

Date of final enrolment
30/06/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Coventry University
Coventry
United Kingdom
CV1 5FB

Sponsor information

Organisation
University of York (UK)

Sponsor details
Department of Health Sciences
York Trials Unit
Area 4
Sebohm Rowntree Building
Heslington
York
England
United Kingdom
YO10 5DD

Sponsor type
University/education

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

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

Funder Name
NIHR Research for Patient Benefit Programme (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	04/10/2014		Yes	No