

A randomised controlled trial of an intervention to improve communication with patients suffering acute chest pain

Submission date 20/10/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/11/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/03/2009	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Miss Jane Arnold

Contact details
MCRU
Regent Court
30 Regent Street
Sheffield
United Kingdom
S1 4DA
+44 (0)114 2220882
j.a.arnold@sheffield.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Study objectives

Chest pain from suspected heart disease is a common cause for emergency hospital attendance. The Chest Pain Unit (CPU) has been developed to provide rapid and accurate diagnostic assessment for patients with acute chest pain. A recent randomised controlled trial has shown that, compared to routine care, CPU care leads to improved patient quality of life and satisfaction, and reduced hospital admissions.

Hypothesis:

Does provision of a written factsheet to patients suffering an episode of acute chest pain reduce subsequent symptoms of anxiety?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 03/03/2009: Approved by North Sheffield Local Research Ethics Committee

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Acute chest pain

Interventions

Chest pain from suspected heart disease is a common cause for emergency hospital attendance. Despite receiving a thorough investigation, many patients report anxiety, poor health and concerns regarding poor communication after their hospital attendance. Written factsheets have been shown to improve communication in the outpatient setting. This study will adapt these factsheets to the emergency setting and formally test them. We will give factsheets to

some patients, but not others, and then compare levels of anxiety, health, chest pain symptoms, satisfaction with care, and attempts at lifestyle change. If the factsheets are beneficial for patients, we will recommend their widespread use.

During the initial four months of the evaluation fifteen to twenty semi-structured face-to-face interviews will be undertaken with patients who have recently undergone diagnostic assessment on the CPU. Patients assessed on the CPU will be given the factsheet relevant to their condition following diagnostic evaluation and verbal communication with medical and nursing staff. Appropriate individuals will be identified and invited to participate in the study.

The interview will focus on identifying misunderstandings, inappropriate advice, and potential areas for improvement. Following analysis of the transcripts the factsheets will be adapted to take into account feedback from the interviews and ensure that they are appropriate for use in the emergency setting.

Phase 2: Evaluation of the factsheets

The specific hypotheses outlined in the aims will be tested in a randomised controlled trial. Consecutive patients with acute chest pain who are managed on the CPU will be invited to participate in the trial. Eligible patients will be asked to provide written, informed consent. After providing consent each patient will be randomly allocated to receive either standard verbal advice or verbal advice augmented with the written factsheet.

Follow-up:

One month after attendance all participants will be sent a postal questionnaire consisting of the Hospital Anxiety and Depression Scale (HADS), the SF-36 health-related quality of life survey, the Group Health Association of America (GHAA) Consumer Satisfaction Survey, and a brief questionnaire asking:

1. Severity and duration of any chest pain related symptoms
2. Any attempts at lifestyle change (smoking cessation, dietary change and exercise)
3. Specific questions testing the patients knowledge of their complaint
4. Whether the patient sought information about their complaint from other sources

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The primary outcome will be score on the anxiety scale of the Hospital Anxiety and Depressions Scale (HADS).

Secondary outcome measures

1. HADS depression score
2. 36-item Short Form health survey (SF-36) scores
3. Patient satisfaction
4. Proportion with persistent chest pain at one month
5. Proportion who have attempted/succeeded in smoking cessation
6. Dietary change or increased exercise
7. A 'knowledge score' regarding their complaint

Planned subgroup analyses will compare outcomes for the following subgroups:

1. Patients with a final diagnosis of angina
2. Patients with an uncertain diagnosis
3. Patients with benign (non-cardiac) chest pain

Overall study start date

15/11/2005

Completion date

14/11/2007

Eligibility

Key inclusion criteria

All patients presenting to the Emergency Department with acute chest pain who are subsequently managed on the Chest Pain Unit (CPU) will be eligible for inclusion in the study: phase 1 and 2.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Phase 1: 15 - 20; Phase 2: 350 intervention, 350 control

Key exclusion criteria

Patients who are unable to read or understand the trial will be excluded.

Date of first enrolment

15/11/2005

Date of final enrolment

14/11/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

MCRU
Sheffield
United Kingdom
S1 4DA

Sponsor information

Organisation

The University of Sheffield (UK)

Sponsor details

New Spring House
231 Glossop Road
Sheffield
England
United Kingdom
S10 2GW

Sponsor type

University/education

ROR

<https://ror.org/05krs5044>

Funder(s)

Funder type

Charity

Funder Name

The Health Foundation (UK) - Leading practice through research award scheme (ref: 577/3869)

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	26/02/2009		Yes	No