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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/11/2005	**Overall study status** Completed	
Last Edited 03/03/2009	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
109232

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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
MCRU
Sheffield
United Kingdom
S1 4DA

Sponsor information

Organisation
The University of Sheffield (UK)

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

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