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## Information sheets for patients with acute chest pain: randomised controlled trial

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## Information sheets for patients with acute chest pain: randomised controlled trial

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### ABSTRACT

**Objectives** To determine whether providing an information sheet to patients with acute chest pain reduces anxiety, improves health related quality of life, improves satisfaction with care, or alters subsequent symptoms or actions.

**Design** Single centre, non-blinded, randomised controlled trial.

**Setting** Chest pain unit of an emergency department.

**Participants** 700 consecutive patients with acute chest pain and no clear diagnosis at initial presentation.

**Interventions** After a diagnostic assessment patients were randomised to receive either standard verbal advice or verbal advice followed by an information sheet.

**Main outcome measures** The primary outcome was anxiety (hospital anxiety and depression scale). Secondary outcomes were depression (hospital anxiety and depression scale), health related quality of life (SF-36), patient satisfaction, presentation with further chest pain within one month, lifestyle change (smoking cessation, diet, exercise), further information sought from other sources, and planned healthcare seeking behaviour in response to further pain.

**Results** 494 of 700 (70.6%) patients responded. Compared with those receiving standard verbal advice those receiving advice and an information sheet had lower mean hospital anxiety and depression scale scores for anxiety (7.61 v 8.63, difference 1.02, 95% confidence interval 0.20 to 1.84) and depression (4.14 v 5.28, difference 1.14, 0.41 to 1.86) and higher scores for mental health and perception of general health on the SF-36. The information sheet had no significant effect on satisfaction with care, subsequent symptoms, lifestyle change, information seeking, or planned actions in the event of further pain.

**Conclusions** Provision of an information sheet to patients with acute chest pain can reduce anxiety and depression and improve mental health and perception of general health but does not alter satisfaction with care or other outcomes.

**Trial registration** Current Controlled Trials  
ISRCTN85248020.

### INTRODUCTION

Chest pain is responsible for around 700 000 emergency department attendances each year in England

and Wales.<sup>1</sup> Many of these patients have no immediately obvious cause for their pain and require diagnostic assessment, the results of which need to be carefully communicated to the patient. Despite thorough diagnostic assessment many patients have further episodes of chest pain, often associated with anxiety and uncertainty about diagnosis.<sup>2-4</sup> This can have an important impact on quality of life.<sup>4</sup>

Written information could help to tackle problems with communication. Information sheets have been developed for use in the cardiology outpatient setting and used to assist with communication.<sup>5</sup> We have adapted these information sheets for use by patients with acute chest pain in the emergency department by undertaking 30 semistructured face to face interviews to explore patients' perceptions of the information sheets.<sup>6</sup> Further refinement led to four separate information sheets for patients in the following categories after diagnostic assessment: definite angina, definite benign non-cardiac chest pain, uncertain cause requiring further cardiology investigation, and uncertain cause suitable for expectant ("wait and see") management (see web extra appendices).

We determined whether provision of an information sheet could improve care for patients who had received diagnostic assessment for acute chest pain. Specifically, we determined whether the information sheet would reduce anxiety, improve health related quality of life and satisfaction with care, and alter subsequent symptoms of chest pain, lifestyle, information seeking behaviour, and planned actions in the event of further pain.

### METHODS

We undertook a non-blinded randomised controlled trial to compare verbal advice alone with verbal advice augmented with an information sheet in patients assessed for acute chest pain. The trial was carried out in the emergency department of a 1100 bed urban teaching hospital. Specialist chest pain nurses provided rapid diagnostic assessment for acute coronary syndrome using biochemical cardiac marker testing (creatin kinase MB(mass) levels at baseline and at least two hours later, and troponin I levels at least six hours after worst symptoms) and exercise treadmill

testing for selected cases. Emergency doctors were responsible for overseeing decision making, whereas the chest pain nurses were responsible for diagnostic testing and treatment. The doctor typically communicated the main diagnostic impression and outlined the management plan to the patient. The chest pain nurses then provided more detailed information and undertook further communication.

We planned to recruit 700 consecutive patients who had been investigated for suspected acute coronary syndrome. Patients were investigated if they had chest pain of possible cardiac origin, were aged over 25, had no changes for acute coronary syndrome on a diagnostic electrocardiogram, had no suspected life threatening non-cardiac disease, and did not have known coronary heart disease presenting with recurrent or prolonged episodes of cardiac-type chest pain.

Eligible patients were identified by the chest pain nurses, who excluded patients who had previously participated in the trial and those who were unable to read or comprehend the trial documentation. After providing written, informed consent the patients were randomly allocated to receive either standard verbal advice or verbal advice followed by an information sheet relevant to their diagnosis at discharge. Allocation was determined by a block randomisation sequence, with variable block length and stratified by the four different information sheets, that was generated by the Sheffield Clinical Trials Research Unit. Randomisation was implemented using consecutively numbered, sealed, opaque envelopes with corresponding numbered consent forms. The chest pain nurses were unaware of allocation until after the patient was recruited to the trial. The nurses confirmed recruitment

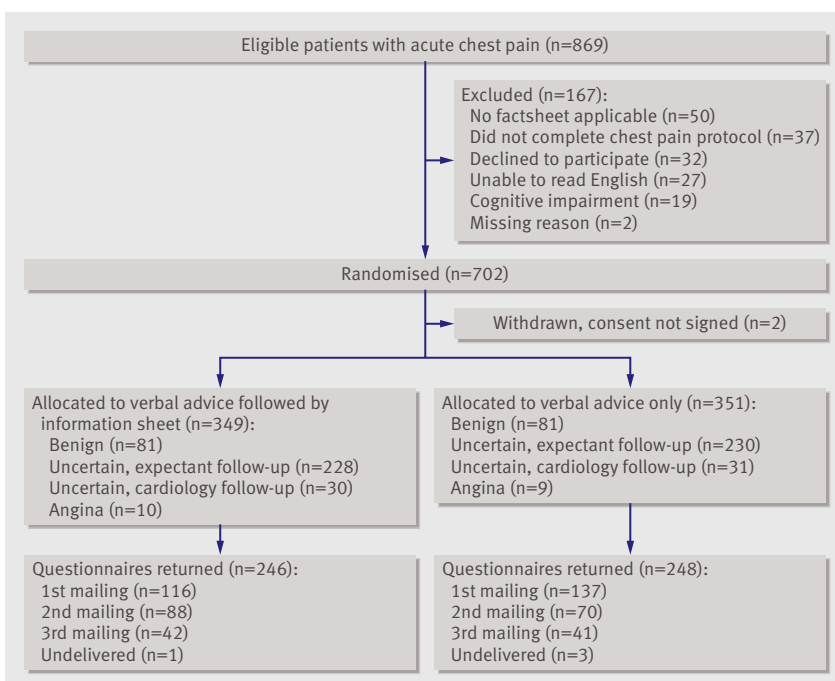
of each patient by telephone to the lead investigator (JA), who accounted for all envelopes.

Intervention took place after diagnostic assessment was complete and the patient's management plan had been formulated. On the basis of the diagnostic information obtained, the chest pain nurses decided which of the four information sheets was most appropriate for each patient. This decision was recorded before randomisation. After randomisation, patients in both the intervention and the control groups received standard verbal advice from the chest pain nurses. After advice, patients allocated to the intervention group were given the appropriate information sheet to read and take away. The chest pain nurses answered any queries about the information but did not talk through the sheet with the patients.

We collected basic data on all enrolled patients, including sex, age, ethnic origin, and risk factors for coronary heart disease. One month after recruitment all patients were sent a questionnaire by post consisting of the hospital anxiety and depression scale, the SF-36 health related quality of life survey, a patient satisfaction survey, and a brief questionnaire asking about severity and duration of any symptoms related to chest pain, any attempts at lifestyle change (smoking cessation, dietary change, and exercise), whether the patient sought information about their symptoms from other sources, and what actions the patient would take in the event of further chest pain. Questionnaires were resent to non-responders at six and eight weeks. Once responses had been received all participants in the control group were sent a copy of the information sheet most appropriate to their discharge diagnosis.

The primary outcome was scores on the anxiety subscale of the hospital anxiety and depression scale. Secondary outcomes included the depression score on the hospital anxiety and depression scale; SF-36 scores; patient satisfaction; presentation with further chest pain within one month; attempted smoking cessation, dietary change, or increased exercise; seeking further information from a variety of sources; and planned healthcare seeking behaviour in response to further pain.

The hospital anxiety and depression scale comprises a self screening questionnaire with 14 questions, which was developed and validated for measuring symptoms of anxiety and depression in the outpatient setting.<sup>7</sup> It produces scores on two subscales (anxiety and depression) ranging from 0 to 21. Scores of 0-7 indicate no depression or anxiety, 8-10 indicate mild symptoms, 11-14 indicate moderate symptoms, and 15-21 indicate severe symptoms. The SF-36 is a self screening questionnaire consisting of 36 questions about health related quality of life.<sup>8</sup> It produces scores between 0 and 100 for eight dimensions of quality of life, where 0 is the lowest quality of life and 100 the highest. The patient satisfaction survey was developed from the Group Health Association of America consumer satisfaction survey<sup>9</sup> and consists of 12 questions relating to different aspects of care, each with a five point Likert scale response allowing ratings of poor (1 point), satisfactory



Patient flow through trial

**Table 1** | Baseline characteristics of patients with acute chest pain randomised to receive verbal advice followed by an information sheet (intervention) or verbal advice alone. Values are numbers (percentages) unless stated otherwise

Variables	Intervention group (n=349)	Control group (n=351)	Total (n=700)
Mean (SD) age (years)	48.3 (11.8)	48.9 (11.2)	48.6 (11.5)
Men	214 (61)	217 (62)	431 (61.6)
Diagnostic group receiving information sheet:			
Benign non-cardiac chest pain	81 (23)	81 (23)	162 (23)
Chest pain uncertain, no follow-up	228 (65)	230 (66)	458 (65)
Chest pain uncertain, referred to cardiology	30 (9)	31 (9)	61 (9)
Angina	10 (3)	9 (3)	19 (3)
Risk factors:			
Smoker	78 (22)	101 (29)	179 (25)
Former smoker	64 (18)	50 (14)	114 (16)
Diabetes	20 (6)	20 (6)	40 (6)
Hypertension	76 (22)	84 (24)	160 (23)
Hyperlipidaemia	63 (18)	73 (21)	136 (19)
Family history	140 (40)	142 (40)	282 (40)
Previous history of coronary heart disease	10 (3)	10 (3)	20 (3)

(2), good (3), very good (4), and excellent (5). It has been used in patients with acute chest pain.<sup>10</sup> The remaining questions on the survey were designed for this study and piloted on appropriate patients to ensure basic comprehensibility.

We planned to recruit 700 participants (350 in each arm) over 15 months and anticipated a 70% response rate to the questionnaire, giving usable data for around 500 patients. This would provide 80% power to detect a one point change in the anxiety score on the hospital anxiety and depression scale ( $\alpha$  0.05) assuming a standard deviation of four points.<sup>10 11</sup>

SPSS version 15 was used to analyse data. We analysed all available cases as randomised using  $\chi^2$  tests to compare dichotomous outcomes, *t* tests to compare continuous outcomes, and Kruskal Wallis tests to compare ordered categorical outcomes—that is, categorised scores on the hospital anxiety and depression

**Table 2** | Comparison of anxiety and depression by score categories (not scores) on hospital anxiety and depression scale (HADS) in patients with acute chest pain randomised to receive verbal advice followed by an information sheet (intervention) or verbal advice alone. Values are numbers (percentages) unless stated otherwise

HADS subscales	Control group	Intervention group	P value*
Anxiety:			
None (0-7)	103 (43.5)	130 (54.6)	0.009
Mild (8-10)	48 (20.3)	42 (17.6)	
Moderate (11-14)	53 (22.4)	47 (19.7)	
Severe (15-21)	33 (13.9)	19 (8.0)	
Depression:			
None (0-7)	172 (72.6)	190 (80.2)	0.026
Mild (8-10)	29 (12.2)	31 (13.1)	
Moderate (11-14)	29 (12.2)	13 (5.5)	
Severe (15-21)	7 (3.0)	3 (1.3)	

A few patients did not complete all elements of the HADS so a score could not be calculated. P values differ from those reported in text: analysis in text compares mean HADS scores using a *t* test.

\*Kruskal Wallis test.

scale. The confidence interval for the number needed to treat was calculated using the Newcombe method, as implemented by confidence interval analysis software (BMJ Books, London). We considered a two tailed P value of <0.05 as statistically significant. No interim analyses were planned or undertaken.

## RESULTS

Between May 2006 and September 2007, 700 patients (349 intervention, 351 control) were recruited to the study (figure). An additional 167 patients (mean age 56.9 years, 89/167 (53%) men) were also considered during this period: 32 declined participation, 19 had cognitive impairment and were unable to provide informed consent, 27 did not understand written English, 37 were either admitted for inpatient care or did not complete the chest pain unit's protocol, and details were missing for two. A further 50 patients were willing to join the trial but were excluded because the chest pain nurses thought that none of the information sheets was appropriate to their diagnosis. Also, four patients who agreed to participate had to be withdrawn before randomisation because of a sudden change in either their condition or the doctor's opinion.

The study population had a mean age of 48.6 years, and 61.6% (431/700) were men (table 1). Information sheets were deemed suitable for 19 patients with a diagnosis of angina (mean age 69, 58% men), 162 with a diagnosis of definite benign non-cardiac pain (mean age 43, 65% men), 61 with a diagnosis of uncertain cause requiring further cardiology investigation (mean age 52, 49% men), and 458 with a diagnosis of uncertain cause suitable for expectant management (mean age 49, 62% men).

The patients were sent a questionnaire by post one month after recruitment; four were subsequently returned as the envelopes were incorrectly addressed. Responses were received from 494 patients (70.6%): 248 (71%) from the control group and 246 (71%) from the intervention group.

Scores for anxiety and depression on the hospital anxiety and depression scale were both lower in the intervention group: anxiety 7.61 versus 8.63 (difference 1.02, 95% confidence interval 0.20 to 1.84,  $P=0.015$ ), depression 4.14 versus 5.28 (1.14, 0.41 to 1.86,  $P=0.002$ ). On the anxiety subscale, intervention was associated with a shift from mild or moderate anxiety to no anxiety, whereas on the depression subscale, intervention was associated with a shift towards lower scores among those with no depression and also a reduction in the proportion with moderate depression (table 2). The number needed to treat to avoid one case of anxiety (the number of patients needed to be provided with an information sheet for one patient to move from a score of  $\geq 8$  to a score of  $\leq 7$ ) was 9.0 (95% confidence interval 5.0 to 46.1) and the number needed to treat to avoid one case of depression was 13.1 (6.6 to infinity).

Patients in the intervention group had significantly higher scores for mental health ( $P<0.007$ ) and general health perception ( $P<0.006$ ) on the SF-36 than those in

**Table 3** | Mean (standard deviation) SF-36 scores in patients with acute chest pain randomised to receive verbal advice followed by an information sheet (intervention) or verbal advice alone

SF-36 items	Control group	Intervention group	Difference (95% CI)	P value
Physical functioning	78.6 (23.6)	81.1 (22.9)	2.5 (-1.7 to 6.6)	0.239
Social functioning	76.2 (26.3)	80.0 (24.6)	3.8 (-0.7 to 8.4)	0.095
Role physical	65.1 (41.1)	70.8 (39.3)	5.7 (-1.5 to 12.9)	0.122
Role emotional	65.8 (41.8)	70.8 (38.8)	5.0 (-2.2 to 12.2)	0.172
Mental health	62.9 (22.6)	68.2 (21.1)	5.3 (1.4 to 9.2)	0.007
Energy or vitality	49.6 (23.5)	53.3 (23.0)	3.7 (-0.4 to 7.8)	0.079
Pain index	69.2 (26.1)	72.8 (25.9)	3.6 (-1.0 to 8.2)	0.127
General health perceptions	57.6 (22.7)	63.1 (20.7)	5.5 (1.6 to 9.3)	0.006

the control group (table 3). There was also weak evidence that intervention was associated with higher scores for social functioning (P=0.095) and energy or vitality (P=0.079). Point estimates for all SF-36 dimensions were higher among patients receiving the information sheet.

Both groups had high scores for each dimension of patient satisfaction and there was no evidence that the information sheet was associated with any change in satisfaction with care (table 4). The prevalence of further pain did not differ: 40.4% (97/240) in the intervention group compared with 40.2% (97/241) in the control group (difference 0.2%, 95% confidence interval -9.5% to 8.9%, P=0.970); and there was no difference in the severity of pain experienced: 1.0 on a 0-10 scale in the intervention group compared with 1.1 in the control group (0.1, -0.2 to 0.4, P=0.610).

There were no significant differences in the proportion of patients attempting changes in smoking, diet, or

**Table 4** | Mean (standard deviation) scores\* for satisfaction in patients with acute chest pain randomised to receive verbal advice followed by an information sheet (intervention) or verbal advice alone

Dimension	Control group	Intervention group	Difference (95% CI)	P value
Thoroughness of examinations and accuracy of diagnosis	4.24 (0.86)	4.21 (0.92)	0.04 (-0.12 to 0.19)	0.658
Skill, experience, and training of hospital staff	4.31 (0.72)	4.25 (0.87)	0.06 (-0.08 to 0.20)	0.407
Thoroughness of treatment	4.29 (0.78)	4.33 (0.87)	0.04 (-0.10 to 0.19)	0.550
Explanations about medical procedures and tests	4.16 (0.92)	4.18 (0.94)	0.02 (-0.14 to 0.18)	0.802
Attention given to what you have to say	4.02 (0.93)	4.06 (0.99)	0.04 (-0.13 to 0.21)	0.672
Advice about ways to avoid illness and stay healthy	3.46 (1.22)	3.62 (1.17)	0.17 (-0.05 to 0.38)	0.126
Friendliness and courtesy shown by hospital staff	4.51 (0.71)	4.40 (0.78)	0.11 (-0.02 to 0.24)	0.096
Personal interest in you and your medical problems	4.08 (0.95)	4.08 (0.92)	0.00 (-0.17 to 0.17)	0.997
Respect and attention to privacy	4.19 (0.96)	4.14 (0.97)	0.05 (-0.12 to 0.22)	0.547
Reassurance and support offered by hospital staff	4.11 (0.95)	4.11 (0.97)	0.01 (-0.16 to 0.18)	0.933
Amount of time hospital staff gave you	3.85 (1.03)	3.91 (1.00)	0.06 (-0.12 to 0.23)	0.541
Overall quality of care	3.56 (0.60)	3.52 (0.66)	0.03 (-0.08 to 0.14)	0.566

\*Scores on 1-5 point Likert scale.

exercise: 42.9% (36/84) of smokers in the intervention group attempted to stop compared with 43.0% (43/100) in the control group (0.1%, -14.0% to 14.2%, P=0.984), 69.5% (157/226) in the intervention group attempted to change their diet compared with 70.9% (161/227) in the control group (1.5%, -6.9% to 9.8%, P=0.318), and 65.5% (150/229) in the intervention group attempted to increase their exercise compared with 63.5% (146/230) in the control group (2.0%, -6.7% to 10.7%, P=0.728).

Some patients sought further information on their symptoms from more than one source (table 5). Provision of the information sheet was associated with no significant difference in information seeking from any source. There was no evidence that the information sheet altered planned action in the event of recurrent pain: 57% (134/234 patients) in the intervention groups would call for an emergency ambulance compared with 58% (139/238) in the control group, 24% (56) compared with 23% (54) would attend their general practitioner, 10% (24) compared with 9% (21) would take analgesics, 2% (4) compared with 3% (6) would ignore the pain, and 7% (16) compared with 8% (18) would take another course of action (P=0.937).

## DISCUSSION

Provision of written information to patients with acute chest pain can reduce anxiety and depression and improve mental health and general health perception, but it does not alter the frequency or severity of further pain, plans for changes to lifestyle, subsequent information seeking behaviour, planned actions in response to further pain, or patient satisfaction with care. The differences in scores on the hospital anxiety and depression scale recorded in this study border on being clinically important and may represent worthwhile benefits for patients. As the information sheets are simple to administer and outcomes were on balance positive, we recommend their use in patients receiving diagnostic assessment for acute chest pain.

In making this recommendation several caveats should be borne in mind. The information sheets were developed, validated, and evaluated in English speaking patients in a northern English city with a relatively small ethnic minority population. The sheets may need modification to take into account language, social, and cultural differences between the study setting and other locations. Specialist chest pain nurses administered the information sheets and provided verbal advice, so the sheets should augment rather than replace verbal advice with an experienced clinician.

### Comparison with previous studies

Previous evaluations of written information in the emergency department have produced mixed results. One study<sup>12</sup> found that providing information on the function of the emergency department and times to the evaluation of patients on alternate days was associated with improved patient satisfaction. Another study<sup>13</sup> found that introduction of an information leaflet was associated with improved satisfaction. However,

**Table 5** | Proportions of patients with acute chest pain randomised to receive verbal advice followed by an information sheet (intervention) or verbal advice alone who sought further information. Values are numbers (percentages) unless stated otherwise

Variables	Control group	Intervention group	Difference (95% CI)	P value
General practitioner	123/225 (55.7)	103/223 (46.2)	8.5 (-0.8 to 15.5)	0.073
Hospital	64/196 (32.7)	55/198 (27.8)	4.9 (-4.2 to 13.8)	0.292
Friends or family	53/183 (29.0)	54/188 (28.7)	0.2 (-8.9 to 9.4)	0.960
Books or magazines	46/184 (25.0)	43/186 (23.1)	1.9 (-6.8 to 10.6)	0.672
Telephone advice line	7/173 (4.0)	8/176 (4.5)	0.5 (-4.1 to 5.2)	0.818
Any source	171/240 (71.3)	165/240 (68.8)	2.5 (-5.7 to 10.6)	0.550

patient satisfaction was unchanged in a study<sup>14</sup> that undertook allocation of an emergency department to provision of an information leaflet in two week clusters. Our study found no improvement in satisfaction associated with provision of the information sheet. One possible explanation is that satisfaction levels were high in the control group, with care being rated as “very good” on average, so there was little scope for the information sheet to produce improvement. Alternatively, it is possible that the information sheets were not optimal and that a less clinically focused information sheet or one with a different format would have achieved higher levels of satisfaction and behavioural change.

Information sheets relating to cardiac diagnostic assessment have received little evaluation. A small randomised trial<sup>15</sup> on methods for providing information to outpatients undergoing exercise treadmill testing showed that provision of a written pamphlet resulted in fewer episodes of chest pain over the following month. Higher levels of reassurance were achieved when the pamphlet was combined with a brief discussion about the meaning of normal test results.

Systematic reviews of written information in other conditions have produced mixed findings. One review<sup>16</sup> identified only two trials of written information for patients being discharged from acute hospital settings to home. They showed increased knowledge and improved satisfaction associated with written information for parents of children discharged from children’s hospitals. Another review<sup>17</sup> found that provision of written information on medicines did not generally increase knowledge or improve satisfaction, although this could have reflected the poor quality of the leaflets tested. One study<sup>18</sup> found that provision of information for patients with stroke and their carers using a variety of methods was associated with improved knowledge and satisfaction and a small reduction in depression.

#### Limitations

We were unable to blind patients to treatment group so questionnaire responses may have been influenced by awareness of intervention received. We originally planned to use a postponed informed consent procedure,<sup>19</sup> whereby patients would be asked to consent to having full information withheld about the study (particularly the exact nature of the intervention)

until after follow-up. The ethics committee did not, however, approve this suggestion. There is also potential for contamination between the intervention and control groups by nurses learning the information provided on the information sheet and giving this verbally to the control group. If contamination were a problem we would anticipate that this would attenuate the observed effect of the information sheet. We excluded patients with important comorbidities, cognitive impairment, and inability to understand written English, so the findings may not be generalisable to all patients with chest pain. Finally, just under 30% of the study population did not respond to the questionnaire and thus provided no outcome data. Response rates in the two study arms were almost identical, so there was no evidence of differential responses leading to bias.

#### Unanswered questions and future research

One feature of our evaluation that warrants further comment is that most patients received the information sheet on the basis of a diagnosis of pain of uncertain cause suitable for expectant management. This is a surprising finding and suggests that the diagnostic assessment may not be as decisive as we might like. Alternatively, it may reflect reluctance to categorise patients with a negative diagnostic assessment as having definite non-cardiac pain, particularly when a less decisive option (uncertain cause) is available. A recent study of 8762 patients diagnosed as having benign chest pain in a cardiology clinic<sup>20</sup> found that 2.7% died of coronary heart disease or had an episode of acute coronary syndrome or unstable angina over the following three years. This suggests that it is probably appropriate to admit uncertainty after a negative diagnostic assessment.

Given the potential benefits we have shown from provision of an information sheet for patients with chest pain, further research would be worthwhile to develop and evaluate written information for other conditions that are associated with significant patient anxiety and impaired quality of life. In the case of chest pain, further research is required to adapt information sheets for non-English speaking patients.

#### WHAT IS ALREADY KNOWN ON THIS TOPIC

Acute chest pain is common and often associated with anxiety and impaired quality of life despite a thorough diagnostic assessment

Written information can assist with communication after assessment for acute chest pain

#### WHAT THIS STUDY ADDS

An information sheet for patients with acute chest pain can reduce anxiety and depression and improve mental health and general perception of health

The information sheet did not alter subsequent symptoms, lifestyle change, information seeking, planned actions in the event of further pain, or patient satisfaction

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**Competing interests:** JP has received research grants and honorariums from Servier UK.

**Ethical approval:** This study was approved by the north Sheffield local research ethics committee.

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