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Investigation of growth, development, and factors associated with injury in elite schoolboy footballers: prospective study

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ABSTRACT

Objective To investigate the differences between skeletal and chronological age and to assess the role of maturity status, anthropometric data, and football related variables in explaining injury statistics in elite schoolboy footballers.

Design Prospective study of injuries in schoolboy footballers according to skeletal age.

Setting Premier league football club in England.

Participants 292 schoolboy players (age 9-16) registered at the club.

Interventions Annual x ray film of hand or wrist.

Main outcome measures Data on injury 2001-7. Skeletal age determined with the Fels method. Skeletal age of more than one year above chronological age was classified as an early maturer, within one year as a normal maturer, and more than one year below normal as a late maturer. Injury and hours of training and rates of exposure to match play.

Results Over six years 476 injuries were reported. The mean chronological age (11.74 (SD 2.35) years) and skeletal age defined by x ray picture (12.08 (SD 3.14) years) showed a significant mean difference of −0.344 (95% confidence interval −0.490 to −0.198; t=−4.64, df=280). Analysis of covariance showed that injury incidents did not differ significantly with maturity status after adjusting for training time, playing time, height, and position played (F=$0.3_{2,160}$, P=0.73). General log linear analysis with a Poisson model showed that difference in maturity, playing hours, and training hours collectively explained 48% of the variance in injury incidents. Injury exposure rates differed considerably, with 1.44/1000 hours for training and 10.5/1000 hours for match play.

Conclusion Maturity, defined by the difference between chronological age and skeletal age, plus training and playing hours together predict injury in schoolboy footballers. Injury exposure rates were higher for match play than training, which could have implications for targeting preventative interventions by academy staff. The use of skeletal age measurements to establish accurate "windows of opportunity" for training is more appropriate than the commonly used chronological age. Caution is needed when interpreting differences in injury occurrence as the factors that contribute are often complex.

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INTRODUCTION

Though chronological age is the usual method of dividing children into age related training and competitive groups, this can differ by as much as four years from skeletal age.[1 2] Skeletal age might be a more accurate method of identifying critical periods of development and therefore a more meaningful way of separating players into training groups.

The general consensus is that 10 000 hours of directed and organised coaching over 10 years are needed to reach the highest level in any sport.[3-5] There are specific periods of development where accelerated adaptation to training takes place that maximises the potential of an athlete.[5 6] Prediction of the likelihood and extent of injury in immature elite athletes has been a key goal of preventive medicine for years, but few studies have been carried out on elite youth football players.[7-9]

Skeletal age is said to be the most accurate method of assessing biological maturity[2 7 10] and can give the coach and medical staff an accurate indication of the stage of maturity an athlete has reached. It can show whether the athlete is an early or late developer, an important factor when determining long term development plans and identifying the most appropriate intensity and training protocols.[5 6 10]

We examined the relation between chronological age, skeletal age, and injury in elite youth footballers at Manchester United Football Club (MUFC) Academy.

METHODS

This prospective study entailed repeated measurements over the six years 2001-7. The participants were boys aged 9-16 years from the academy and participation was voluntary; both players and their parents or guardians completed informed consent forms.

All players completed a medical questionnaire and underwent basic medical screening. All consenting players underwent a basic radiograph of the left wrist and hand, which is the most common method to determine skeletal age.[2] This was repeated on an annual basis. We collected data regarding injury, skeletal age, training, and playing hours for every player for the period of time he spent at the academy.

We determined skeletal age using the Fels method, which uses a bone by bone comparison with the addition of ratios between epiphyses and diaphyses.[10] In our study the intraclass correlation coefficient for Fels measurement was 0.998 (95% confidence interval 0.996 to 0.999).

We classified maturity status into three categories: early, normal, or late. Early and late maturers were classified as such if their skeletal age was more than a year older or younger, respectively, than their chronological age. Normal maturers were those with a skeletal age within one year of their chronological age.

RESULTS

Over the six years, 292 players took part (all of the available boys) with an average of 130 players each season. The players were aged 9-16, with an average chronological age of 11.74 (SD 2.35). The average dropout rate for the academy per season was 21.3%.

There were 476 injuries across all the age groups. Of these, 244 occurred during training and 169 during match play, which equated to 2.23 injuries each player per 1000 hours of total exposure to training and match play or 1.44 injuries per 1000 hours training compared with 10.5 injuries per 1000 hours in match play. The other 63 injuries were not related to playing football and were not included in the study. The average number of days lost per season was 1630.8, which is an average of 12.5 injury days per player per season. Boys under 14 were the most vulnerable, with overuse injuries being more common than direct or indirect trauma. Soft tissue injuries were the most common, with the knee joint being the most commonly injured.

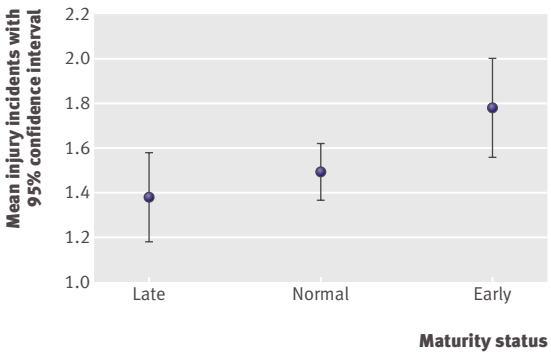
Most (n=282) players underwent x ray examination, fewer than in the injury analysis because of lack of consent for this part of the study or unavailability when x rays were taken. The mean x ray defined skeletal age was 12.08 (SD 3.14) compared with a mean chronological age of 11.74 (SD 2.35); a paired *t* test showed significant mean differences (−0.34 (SD 1.2) 95% confidence interval −0.490 to −0.198; t=−4.64, df=280, P<0.05) indicating that the Fels method overestimates bone age compared with chronological age.

Injury incidents did not differ significantly between categories of maturity status (figure) when we adjusted for mean playing time, mean training time, mean height, and position played (F= $0.3_{2,160}$, P=0.73). Position played, foot dominance, or average height gain were also not determinants of injury occurrence.

Descriptive statistics for 174 boys over six years used in regression analysis

	Minimum	Maximum	Mean (SD)
Maturity difference*	−2.82	3.06	0.50 (1.28)
Playing hours	0	40	19.09 (6.84)
Training hours	32.25	365	202.27 (66.51)
Injury incidents	1	4	1.58 (0.71)

*Chronological age minus skeletal age (years).



Injury incident differences between maturity status

Mean training time, mean match play time, and mean difference in maturity (chronological minus skeletal age) were significantly associated (P<0.05) with mean injury occurrence (t ratio=−2.03 for playing hours, 3.84 for training hours, and −2.65 for chronological minus skeletal age) (table). The percentage of variance explained by these factors combined was high at R^2=48% (t ratio =−4.36, P<0.001).

DISCUSSION

Early maturers had more injuries than late or normal maturers, a finding reported in previous research in youth football, but when we controlled for potential confounding variables this difference was no longer significant. Therefore caution is required in using variables such as maturity status to infer difference in injury incidents.

Previous studies have shown a higher incidence of injury during match play rather than during training,[8] a finding replicated by this study, and this could also be relevant when targeting interventions to reduce injury in elite youth footballers.

The literature regarding long term development of athletes highlights the concept of "windows of opportunity," where accelerated adaptation can be achieved in response to the correct training regimens.[5,6] Skeletal maturity plus training and playing hours are predictive of injury in schoolboy footballers. Measurements of skeletal age may establish accurate "windows of opportunity" facilitating more appropriate training programmes and competitive groups than the commonly used chronological age.

Many players undergoing training in chronologically age defined groups might not benefit optimally from prescribed training regimens because of the large variability of skeletal age, which could be as much as 21 months for 68% of the players. Effective use of the window of opportunity might be achieved by grouping players by skeletal rather than chronological age.

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Ethical approval: This study was approved by Manchester University ethics committee (No 05099) and informed consent was given by parents and boys.

WHAT IS ALREADY KNOWN ON THIS TOPIC

The level of evidence underpinning injury statistics and preventive interventions is weak

Uncertainty exists in defining the extent of the relation between injury and maturity status

Rates of exposure to match play determine incidence of injury more than rates of exposure to training

WHAT THIS STUDY ADDS

Maturity status plus match play and training hours together predict injury in schoolboy footballers

Rate of exposure to match play was associated with a greater incidence of injury than rates of exposure to training

Only two thirds of players were shown to be within the normal maturity category

Injury trends are complex and often multifactorial

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ARTIST (osteoarthritis intervention standardized) study of standardised consultation versus usual care for patients with osteoarthritis of the knee in primary care in France: pragmatic randomised controlled trial

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ABSTRACT

Objective To evaluate the impact of standardised consultations on patients with osteoarthritis of the knee.

Design Open pragmatic cluster randomised controlled trial.

Setting Primary care in France.

Participants 198 primary care rheumatologists, each of whom had to include two consecutive patients who met the American College of Rheumatology criteria for osteoarthritis of the knee.

Interventions Standardised consultation was provided during three goal oriented visits (education on osteoarthritis and treatment management; information on physical exercises; information on weight loss) or usual care.

Main outcome measures Change in body weight and in time spent on physical exercises (Baecke index) at four months.

Results 336 patients were included (154 allocated to standardised consultation and 182 to usual care). Nine patients were excluded because of lack of baseline data (standardised consultation, n=8; usual care, n=1). At four months, taking into account the clustering effect, the decrease in weight was greater in the standardised consultation group than in the usual care group (mean −1.11 (SD 2.49) kg *v* −0.37 (2.39) kg; P=0.007). The physical activity score was higher for the standardised consultation group than for the usual care group (mean 0.20 (0.65) *v* 0.04 (0.78); P=0.013). The standardised consultation and usual care groups did not differ in secondary outcomes, except for global assessment of disease activity (0-10 numeric scale: mean −1.66 (2.26) *v* −0.90 (2.48); P=0.003) and pain level (0-10 numeric scale: mean −1.65 (2.32) *v* −1.18 (2.58); P=0.04).

Conclusions A structured consultation programme for patients with osteoarthritis of the knee resulted in short term improvement in weight loss and time spent on physical activity.

Trial registration Clinical trials NCT00462319.

INTRODUCTION

The guidelines for treatment of osteoarthritis of the knee from the National Institute for Health and Clinical Excellence, and the European League Against Rheumatism recommend non-drug treatments,[1-4] including education of patients, social support, physical exercises, and weight loss.[5] Despite these recommendations, such non-drug treatments are not systematically offered to patients in clinical practice.

Managing a chronic disease such as osteoarthritis requires a modification of patients' behaviour; patients need to be educated about the disease and to understand the purpose of the treatment proposed. However, providing such complex interventions is time consuming and difficult to do in the context of short consultations.[6-8] We tested whether a new standardised

programme of goal oriented visits would give better results in terms of weight management and physical activity than usual care among patients with osteoarthritis of the knee.

METHODS

Design

We designed a multicentre pragmatic cluster randomised controlled trial. The unit of randomisation was care providers, and the unit of analysis was patients.

Participants

We invited rheumatologists to participate by mail. Patients had to meet the following criteria: outpatient aged 45-75 years consulting a rheumatologist, diagnosis of osteoarthritis of the knee, knee pain rated between 30 mm and 70 mm on a numerical scale and necessitating treatment with non-steroidal anti-inflammatory drugs, and body mass index ≥25 and <35.

Allocation sequence generation and concealment

We randomly assigned rheumatologists stratified by region to provide either usual care or standardised consultation. We based allocation on clusters rather than individuals. Rheumatologists recruited patients after knowing the treatment assignment. To limit the risk of selection bias, we asked rheumatologists to include the first two patients who met the selection criteria.

Intervention

A group of rheumatologists and epidemiologists developed and defined the experimental intervention after iterative discussion sessions.[9] We proposed three goal oriented visits. We standardised the content of each visit by providing a description of the content on the case report form.

Experimental intervention—During the first visit (day 0), rheumatologists provided education and advice related to osteoarthritis and its treatment. During the second visit (day 15), they informed patients about how to protect joints and the need for physical exercise. They proposed a progressive exercise regimen consisting of three sessions of 30 minutes a week progressively increased to three sessions of 60 minutes a week of rapid walking or cycling. During the third visit (day 30), rheumatologists educated patients about body weight and its influence on osteoarthritis of the knee and proposed a strategy for losing or maintaining weight. Rheumatologists implemented the US National Institutes of Health guidelines for management of obesity (see bmj.com).[10] We provided patients with written information on osteoarthritis and a booklet to record weight and physical activities each week.

Control group—In France, patients with osteoarthritis of the knee usually visit their rheumatologists every six or 12 months. We asked rheumatologists randomised to the control arm to provide usual care to their patients during three consecutive visits.

Co-interventions—We left the prescription of drugs and other co-interventions to the care providers' decision.

Outcomes

Rheumatologists evaluated all patients during clinical visits at baseline and at days 15, 30, and 120. An independent data collector evaluated long term outcomes and patients' satisfaction and knowledge at 12 months.

Short term outcomes (four months)

We evaluated the primary short term outcomes at four months. These included patients' weight and time spent on physical exercises as measured by the physical exercise in leisure subscale of the Baecke index (0-5 scale).[11-13]

Secondary outcomes evaluated during the follow-up visits to the rheumatologist were pain on movement during the 48 hours before the visit; score on the French-Canadian version of the Western Ontario and McMaster Universities osteoarthritis index (WOMAC) physical function subscale; global assessment of disease activity; and physical and mental scores on the Medical Outcomes Survey short form 12 (SF-12).[14] Patients completed questionnaires in the seven days after the visit. Secondary outcomes evaluated during a phone interview were patients' satisfaction with and knowledge of with their treatment.

Long term outcomes (12 months)

At 12 months, the patients' outcomes collected by phone interview were self reported weight, time spent on physical exercises during the previous three months, pain on movement during the 48 hours before the contact, score on the French-Canadian version of the WOMAC physical function subscale, global assessment of disease activity, and SF-12 score.[14]

Blinding

We could not blind patients and care providers to the intervention allocated, and nor could outcome assessment be blind. Patients were blinded to the study hypothesis.

Statistical methods

Analyses were based on a modified intention to treat; if no baseline data were recorded, we excluded the patients from the analyses. We analysed all outcomes in the framework of a marginal model analysis, comparing changes in means of variables in each group. We adjusted all comparisons for the baseline value and, except for weight, for the baseline value of the body mass index. For primary outcomes, we considered a P value ≤0.025 to be statistically significant.

We did a propensity score analysis. For each patient, we calculated the conditional probability that a patient received a particular treatment on the basis of pre-treatment variables. A propensity score weighted marginal model was fitted to compare groups for each outcome.[15] For each outcome measure, we estimated the intracluster correlation coefficient and derived an approximate 95% confidence interval by using formulas for the balanced case.[16]

RESULTS

Participants

We included and randomised 198 rheumatologists between May 2005 and June 2006; 137 rheumatologists included two patients, and 53 included only one patient. We excluded six rheumatologists (see bmj.com). At four months, data were available for 327 patients—146 in the standardised consultation group and 181 in the usual care group.

The groups were similar at baseline. However, the standardised consultation group had a higher mean body mass index and longer delay from the beginning of pain linked to osteoarthritis of the knee. Patients in the usual care group were more often treated with non-drug treatments. More than 95% of patients in the intervention group and 96% of patients in the control group attended all three consultations.

Outcomes

The table gives the results for the primary and secondary outcome measures at four months. The decrease in measured weight was greater in the standardised consultation group than in the usual care group (mean −1.11 (SD 2.49) kg *v* −0.37 (2.39) kg; P=0.007). The proportion of patients who lost more than 2 kg was 28.1% (41/146) in the standardised consultation group and 16.0% (29/181) in the usual care group (P=0.01).

The increase in time spent on physical exercises was greater in the standardised consultation group than in the usual care group (mean 0.20 (0.65) *v* 0.04 (0.78); P=0.013). When we applied propensity methods in the primary analyses, the differences seen were also significant. The standardised consultation and usual care groups did not differ in secondary outcomes, except for pain (0-10 numerical scale: mean −1.65 (2.32) *v* −1.18 (2.58); P=0.04) and global assessment of disease activity (0-10 numerical scale: mean −1.66 (2.26) *v* −0.90 (2.48); P=0.003). The intracluster correlation coefficients varied from 0.00 to 0.315 according to the outcome measure chosen and are detailed in the table.

Satisfaction

Patients in the standardised consultation group were more likely than those in the usual care group to have obtained information about osteoarthritis of the knee, and the need for regular exercises and to lose weight. Their knowledge about management of osteoarthritis of the knee did not differ substantially from that of the usual care group, except for knowledge about losing weight.

One year follow-up

A total of 235 of the 327 patients completed one year follow-up. The standardised consultation and usual

Mean change between baseline and four months for patients receiving standardised consultation and usual care (n=327)

	Mean	SD	Intracluster correlation coefficient (95% CI)	P value*	P value†
Weight (kg)					
Standardised consultation	−1.11	2.49	0.006 (0.000 to 0.144)	0.007	0.005
Usual care	−0.37	2.39	0.000 (0.000 to 0.101)		
PEL (0-5)					
Standardised consultation	0.20	0.65	0.000 (0.000 to 0.357)	0.013	0.025
Usual care	0.04	0.78	0.244 (0.000 to 0.483)		
Pain (NS 0-10)					
Standardised consultation	−1.65	2.32	0.315 (0.084 to 0.535)	0.041	0.020
Usual care	−1.18	2.58	0.161 (0.000 to 0.383)		
WOMAC physical function subscale (0-100)					
Standardised consultation	−5.74	10.66	0.079 (0.000 to 0.267)	0.199	0.121
Usual care	−4.03	11.35	0.000 (0.000 to 0.184)		
Global assessment of disease status (NS 0-10)					
Standardised consultation	−1.66	2.26	0.008 (0.000 to 0.298)	0.003	0.002
Usual care	−0.90	2.48	0.281 (0.068 to 0.487)		
Body mass index					
Standardised consultation	−0.37	1.14	0.069 (0.000 to 0.204)	0.124	0.095
Usual care	−0.16	0.92	0.000 (0.000 to 0.116)		
SF-12 physical function subscale (n=276)					
Standardised consultation	3.02	6.97	0.000 (0.000 to 0.200)	0.109	0.203
Usual care	1.83	7.39	0.001 (0.000 to 0.276)		
SF-12 mental function subscale (n=276)					
Standardised consultation	0.36	8.91	0.000 (0.000 to 0.177)	0.890	0.665
Usual care	0.86	9.51	0.082 (0.000 to 0.286)		

NS=numerical scale; PEL=physical exercises in leisure subscale of Baecke index; SF-12=Medical Outcomes Study short form 12; WOMAC=Western Ontario and McMaster Universities osteoarthritis index.
*Comparisons were adjusted for baseline value and for baseline value of body mass index for all variables except weight.
†Comparisons were adjusted for baseline value and for baseline value of body mass index for all variables except weight and used a propensity score weight method.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Non-drug treatments, including education of patients, social support, physical exercises, and weight loss, are widely recommended for management of osteoarthritis of the knee

However, such non-drug treatments are rarely proposed to patients in clinical practice

The lack of implementation of these guidelines may be linked to difficulties in providing information to patients on all these important matters during a single consultation

WHAT THIS STUDY ADDS

A programme of three goal oriented standardised consultations was useful for patients with osteoarthritis of the knee

This programme led to increased weight loss and physical activity at four months and improved patients' function and pain at four months and at one year

care groups did not differ in self reported weight (mean −2.85 (4.76) *v* −2.07 (4.37); P=0.20). The proportion of patients who lost more than 2 kg was 44.5% (65/146) in the standardised consultation group and 39.2% (71/181) in the usual care group (P=0.36). The standardised consultation group showed better scores than did the usual care group for physical activity (mean 0.23 (0.72) *v* 0.08 (0.85); P=0.024), pain level (n=145, mean −1.35 (2.48) *v* n=181, −0.86 (2.59); P=0.03), WOMAC function score (n=144, mean −8.67 (12.05) *v* n=176, −5.44 (12.97); P=0.02), global assessment of disease activity (n=146, mean −1.40 (2.56) *v* n=181, −0.51 (2.59); P<0.001) and SF-12 physical component score (n=129, mean 5.23 (8.18) *v* n=147, 2.97 (7.72); P=0.003).

DISCUSSION

With a programme of standardised consultations given by rheumatologists to patients with osteoarthritis of the knee such patients can reduce their body weight, increase the time they spend on physical activity, and show improved pain level and global measures of disease activity at four months compared with patients given usual care. However, disability at four months did not differ between the groups. At 12 months, the two groups did not differ in self reported weight, but the standardised consultation group showed greater improvement in physical activities, pain level, and function than did the usual care group.

Our results have high applicability because we recruited rheumatologists in primary care settings, the inclusion criteria were not too stringent, and the intervention is easy to reproduce. Nurses could help physicians to do this intervention, although the prime effect of advice from a physician as a catalyst for changing patients' behaviour should not be underestimated.[17]

In cluster randomised controlled trials, observations for individual participants in the same cluster tend to be correlated. We controlled for the effect of clusters in the statistical analyses. Nevertheless, such a trial implies risk of selection bias because, for our trial, we randomised rheumatologists to trial arms before they included patients. We used propensity scores to deal with potential confounders and imbalance to confirm our results.

To limit the risk of bias, patients were blinded to the study hypothesis. Furthermore, patients in each arm had the same number of visits. Consequently, the control arm is not really a "usual care" arm. Usually, patients with osteoarthritis visit their rheumatologists every six or 12 months. This modification in visits could favour the usual care group and potentially underestimate the treatment effect.

In terms of clinical relevance of the modifications we saw, the mean weight reduction at four months was limited (approximately 1 kg). However, some consider that a 1 kg weight loss is associated with a 4 kg reduction in knee load per step.[18] In addition, we found no difference in patients' self reported weight loss at one year but a significant improvement in pain and physical function. Such improvement in a large population of patients could have public health implications.[19]

This study has several limitations. Firstly, the baseline data showed a higher mean weight for the standardised consultation than for the usual care group. To take this into account, we did marginal model analyses adjusted for baseline values, as well as propensity score analysis. Secondly, because of partial lack of blinding, and we cannot exclude the possibility that subjective outcomes could be influenced.

Conclusions

Rheumatologists offering a programme of standardised consultations about non-drug treatment for osteoarthritis of the knee could be useful for patients with osteoarthritis of the knee. Such a programme led to weight loss, increased physical activity, and improved pain after four months and improved patients' physical activity, pain, and function at one year. Further studies in different settings are needed to confirm these results.

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Competing interests: None declared.
Ethical approval: Hospital Bichat (Paris) medical research ethics committee; informed consent was obtained from all rheumatologists and patients.

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

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EDITORIAL by Jones and Mountain

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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 seeeking 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

In many patients attending emergency departments the cause of chest pain is not immediately obvious. Diagnostic assessment is therefore required, with the results carefully communicated to the patients. We adapted information sheets developed for use in the cardiology outpatient setting[1] for patients with acute chest pain in the emergency department (see bmj.com).[2] Four sheets were created according to the diagnostic categories of angina, benign non-cardiac chest pain, uncertain cause requiring further cardiology investigation, and uncertain cause suitable for expectant management (see web extra appendices).

We determined the effect of information sheets on anxiety, health related quality of life, satisfaction with care, 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 adults (≥25 years) assessed for acute chest pain in an emergency department. Chest pain nurses provided rapid diagnostic assessment for acute coronary syndrome. Emergency doctors communicated the main diagnostic impression and outlined the management plan to the patient. The chest pain nurses provided more detailed information and undertook further communication.

After providing written, informed consent eligible patients were randomly allocated to receive standard

verbal advice or verbal advice followed by an information sheet relevant to their diagnosis. The chest pain nurses were unaware of allocation until after the patient was recruited.

Intervention took place after diagnostic assessment and formulation of the patient's management plan. The chest pain nurses allocated an information sheet to each patient on the basis of the diagnostic information. Patients in both the intervention and the control groups received standard verbal advice from the nurses. After advice, patients allocated to the intervention group were given an information sheet.

We collected data on sex, age, ethnic origin, and risk factors for coronary heart disease. One month after recruitment the patients were sent a questionnaire comprising the hospital anxiety and depression scale, the SF-36 survey, a patient satisfaction survey, and a questionnaire on severity and duration of any symptoms related to chest pain, attempts at lifestyle change (smoking cessation, dietary change, and exercise), information on symptoms sought from other sources, and planned actions in the event of future chest pain.

The primary outcome was scores on the anxiety subscale of the hospital anxiety and depression scale. This tool comprises two subscales for depression and anxiety (scores 0-7 no symptoms, 8-10 mild symptoms, 11-14 moderate symptoms, and 15-21 severe symptoms). The SF-36 measures health related quality of life[3] (score 0 lowest quality of life to 100 highest quality of life). The patient satisfaction survey relates to different aspects of care and has been used in patients with acute chest pain.[4]

We analysed all available cases as randomised using χ^2 tests to compare dichotomous outcomes, *t* tests to compare continuous outcomes, and Kruskal Wallis tests to compare ordered categorical outcomes. The confidence interval for the number needed to treat was calculated using the Newcombe method (confidence interval analysis software; BMJ Books). We considered a two tailed P value of <0.05 as statistically significant.

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.

RESULTS

Between May 2006 and September 2007, 700 patients (349 intervention, 351 control) were recruited to the study (see bmj.com). The study population had a mean age of 48.6 years, and 61.6% (431/700) were men (see bmj.com). Information sheets were given to 19 patients with angina (mean age 69, 58% men), 162 with benign non-cardiac pain (mean age 43, 65% men), 61 with an uncertain cause requiring further cardiology investigation (mean age 52, 49% men), and 458 with an uncertain cause suitable for expectant management (mean age 49, 62% men).

Overall, 494 patients (70.6%) responsed to a questionnaire one month after recruitment: 248 (71%) in the control group and 246 (71%) in 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 *v* 8.63, difference 1.02 (95% confidence interval 0.20 to 1.84), P=0.015; depression 4.14 *v* 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). The number needed to treat to avoid one case of anxiety 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 (see bmj.com) than those in the control group. 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 in the intervention group.

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 (see bmj.com). There were no significant differences in the proportion of patients attempting changes in smoking, diet, or exercise or in information seeking from any source (see bmj.com). There was no evidence that the information sheet altered planned action in the event of recurrent pain (see bmj.com).

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

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

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[5] 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[6] found that an information leaflet was associated with improved satisfaction. However, patient satisfaction was unchanged in a study[7] that undertook allocation of an emergency department to provision of an information leaflet in two week clusters. Our study found no improvement in satisfaction. One possible explanation is that satisfaction levels were already high in the control group (care was rated as "very good"). Alternatively, it is possible that the information sheets were not optimal in focus or design.

Systematic reviews of written information in other conditions have produced mixed findings. One review[8] identified only two trials of written information for acute patients being discharged home. They showed increased knowledge and improved satisfaction associated with written information for parents of children discharged from hospitals. Another review[9] found that written information on medicines did not generally increase knowledge or improve satisfaction, although this could have reflected the poor quality of the leaflets. One study[10] 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. There is also potential for contamination between the groups by nurses learning the information on the 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 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, although response rates were similar in the study arms.

Given the potential benefits of providing an information sheet for patients with chest pain, further research should develop and evaluate written information for other conditions that are associated with 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.

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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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Naftidrofuryl for intermittent claudication: meta-analysis based on individual patient data

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STUDY QUESTION What is the efficacy and safety of oral naftidrofuryl, a specific vasoactive drug, compared with placebo in improving walking distance in patients with intermittent claudication?

SUMMARY ANSWER Oral naftidrofuryl has a clinically meaningful but moderate efficacy for improving walking distance in patients with intermittent claudication. Its safety profile in oral use is acceptable (only higher prevalence of mainly mild gastric discomfort compared with placebo). Head to head comparison of naftidrofuryl with other products used to treat intermittent claudication is the next stage. In the future, meta-analyses such as ours would be greatly aided by the establishment of, in addition to registries of randomised controlled trials, repositories of data from drug trials available for independent patient data analysis (with due consideration of patient privacy).

EFFICACY OF NAFTIDROFURYL IN TREATING INTERMITTENT CLAUDICATION

	Difference for naftidrofuryl *v* placebo (95% CI)
Ratio of relative improvement in walking distance from baseline value	
Pain-free walking distance	1.37 (1.27 to 1.49)
Maximal walking distance	1.40 (1.19 to 1.63)
Responder analysis (improvement in walking distance of ≥50%)	
Response rate	22.3% (17.1% to 27.6%)
Number needed to treat over 6 months	4.48 (3.62 to 5.85)
Relative benefit	1.75 (1.50 to 2.03)
Odds ratio	2.65 (2.10 to 3.37)

Selection criteria for studies

We searched Medline, International Pharmaceutical Abstracts, Embase, Science Citation Index, and the Cochrane trial registers; checked reference lists of retrieved articles; and approached authors and the manufacturer of naftidrofuryl for additional trial information and individual patient data. Our selection criteria were double blind, randomised controlled trials performed in patients with intermittent claudication receiving oral naftidrofuryl or placebo and with pain-free walking distance as the primary outcome.

We collected individual patient data from electronic data or from case report forms and checked them for data integrity. All randomised patients were analysed on the basis of intention to treat. Treatment efficacy was assessed by the ratio of the geometric mean of relative improvement in the pain-free walking distance for naftidrofuryl compared with placebo. For responder analysis, therapeutic success was defined as an improvement in walking distance of at least 50%. We assessed the safety of oral naftidrofuryl by reviewing the reports of adverse drug reactions in the selected trials, by retrieving published case reports from the literature, and by analysing the latest safety update report from the manufacturer of naftidrofuryl.

Primary outcome(s)

The primary outcome was pain-free walking distance, defined as the distance walked (in metres) during a standardised exercise test before the start of leg pain.

Main results and role of chance

The total number of randomised patients was 1266 (1083 in the main analysis). The ratio of relative improvement in pain-free walking distance for naftidrofuryl compared with placebo was 1.37 (95% confidence interval 1.27 to 1.49, P<0.001). The difference in responder rate was 22.3% (17.1% to 27.6%), and the number needed to treat for symptom relief during six months of treatment was 4.48 (3.62 to 5.85).

Bias, confounding, and other reasons for caution

The question remains whether the data on which we based our meta-analysis can be trusted. We were dependent on the goodwill of Merck Darmstadt, the marketing authorisation holder for naftidrofuryl, for access to the data of studies, mostly funded by the company. We found references and full text of identified studies in the medical literature, but for the individual patient data we had to rely on the permission of Merck, as data were not readily available from the principal investigators. Some studies date from before the rigorous implementation of Good Clinical Practice.

Our meta-analysis was entirely paid for by internal funds from our university, and not by the drug manufacturer, as directed by the Cochrane Collaboration. Merck provided the data without preliminary conditions. The data were subjected to rigorous data integrity checks. Successful comparison of the data in our meta-analysis database with published results provided reassurance in this regard.

Study funding/potential competing interests

The study was funded by the Heymans Institute of Pharmacology (Ghent University, Belgium). PL has performed statistical consultancy for a number of pharmaceutical companies including Merck Darmstadt.

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Inequalities in maternal health: national cohort study of ethnic variation in severe maternal morbidities

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STUDY QUESTION Do ethnic differences exist in the incidence of specific "near miss" maternal morbidities in women giving birth in the United Kingdom?

SUMMARY ANSWER Severe maternal morbidities occurred more than 1.5 times more often among non-white women than in white women, more than twice as often among women of black African or black Caribbean ethnicity, and 1.5 times more often in Pakistani women. This pattern is similar to reported ethnic differences in maternal death rates. These differences may be due to the presence of pre-existing maternal medical factors or to factors related to care during pregnancy, labour, and birth; they are unlikely to be due to differences in age, socioeconomic or smoking status, body mass index, or parity. This highlights to clinicians and policy makers the importance of tailored maternity services and improved access to care for women from ethnic minorities.

Participants and setting

The study took place in all 229 hospitals with consultant led maternity units in the UK and included the entire cohort of women giving birth in the UK.

Design, size, and duration

We used the UK Obstetric Surveillance System (UKOSS) to identify cases of specific severe maternal morbidities (acute fatty liver of pregnancy, amniotic fluid embolism, antenatal pulmonary embolism, eclampsia, and peripartum hysterectomy) occurring in women giving birth between February 2005 and February 2006. In order to calculate the incidence, we estimated denominator births in each ethnic group by using maternity hospital episode statistics. Maternal ethnicity was the main exposure examined. To investigate the potential factors underlying ethnic differences in severe maternal morbidities, we used a logistic regression analysis comparing information about women with severe maternal morbidity with information on comparison women also collected through UKOSS, as national data did not have sufficient information on potential confounders.

Main results and the role of chance

In an estimated cohort of 775 186 women giving birth, we identified 686 women with severe maternal morbidity; 74% of these women were white, and 26% were non-white. The estimated risk of severe maternal morbidity in white women was 80 cases per 100 000 maternities, and in non-white women it was 126 cases per 100 000 (table). Black African women and black Caribbean women had the highest risk. The risk in non-white women remained high after adjustment for differences in age, socioeconomic and smoking status, body mass index, and parity (odds ratio 1.50, 95% CI 1.15 to 1.96).

ESTIMATED RISKS (95% CI) OF SEVERE MATERNAL MORBIDITY IN DIFFERENT ETHNIC GROUPS

Ethnic group	Morbidity risk per 100 000 maternities	Risk difference per 100 000 maternities	Risk ratio
White	80 (73 to 87)	0 (reference)	1.0 (reference)
Pakistani	119 (83 to 165)	39 (0.3 to 79)	1.49 (1.06 to 2.09)
Black African	188 (110 to 301)	108 (18 to 197)	2.35 (1.45 to 3.81)
Black Caribbean	196 (143 to 261)	116 (59 to 172)	2.45 (1.81 to 3.31)
Any non-white	126 (108 to 146)	46 (27 to 66)	1.58 (1.33 to 1.87)

Bias, confounding, and other reasons for caution

Denominator information on maternal ethnicity was estimated from data that covered 75% of the women studied; this method of estimation may slightly underestimate the number of women from ethnic minority groups but is unlikely to affect the estimated relative risks significantly. We did not attempt to collect comprehensive information on all severe maternal morbidities but concentrated on major conditions causing direct maternal death in the UK. Existing evidence suggests that this approach is unlikely to have appreciably affected the estimates of the risk ratio between ethnic groups.

Generalisability to other populations

The results are generalisable to countries with low rates of maternal death, high resource settings, and large ethnic minority populations.

Study funding/potential competing interests

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