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Research

State anxiety improves prediction of pain and pain-related disability after 12 weeks in patients with acute low back pain: a cohort study

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KEY WORDS

Spinal low back pain
Anxiety
Prognostic factor
Risk
Prediction
Psychological



ABSTRACT

Question: Do measures of state anxiety and trait anxiety in people with acute low back pain (ALBP) improve prediction of chronic low back pain (CLBP), defined as pain or pain-related disability at 12 weeks? **Design:** Observational multi-centre prospective cohort study in primary physiotherapy care with measurements at baseline and at 12 weeks of state and trait anxiety, as well as other established prognostic factors for CLBP. **Participants:** People with nonspecific ALBP, aged 18 to 60 years, who had been pain free for ≥ 3 months before their current ALBP, and who were being treated according the Dutch clinical guidelines. **Outcome measures and analysis:** CLBP was defined as a pain score $\geq 3/10$ on the Numerical Pain Rating Scale (primary outcome), and as a pain-related disability score $\geq 19/70$ on the Pain Disability Inventory. Univariate and multivariate logistic regression analyses estimated how the risk of CLBP differed with state and trait anxiety and other established prognostic factors. **Results:** Most (204 of 225) participants completed both assessments. State anxiety was an independent predictor of CLBP, whether defined as pain or pain-related disability at 12 weeks, in contrast to trait anxiety. State anxiety improved the predictive performance of the model, with area under the curve (AUC) increasing from 0.64 (95% CI 0.56 to 0.71) to 0.75 (95% CI 0.68 to 0.82) and Nagelkerke's R^2 increasing from 0.08 to 0.24 for the primary outcome measure, pain. For the secondary outcome measure, pain-related disability: AUC 0.63 (95% CI 0.54 to 0.72) improved to 0.73 (95% CI 0.65 to 0.82) and Nagelkerke's R^2 increased from 0.05 to 0.16. Adding trait anxiety to the prognostic model for pain improved the AUC from 0.64 (95% CI 0.56 to 0.71) to 0.70 (95% CI 0.62 to 0.77) and Nagelkerke's R^2 from 0.08 to 0.15. **Conclusion:** State anxiety in patients with ALBP improved prediction of CLBP, defined as pain and pain-related disability at 12 weeks. [Hallegraef JM, Kan R, van Trijffel E, Reneman MF (2020) State anxiety improves prediction of pain and pain-related disability after 12 weeks in patients with acute low back pain: a cohort study. *Journal of Physiotherapy* 66:39–44]

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Introduction

In primary care physiotherapy, the natural course of acute low back pain (ALBP) is favourable, whereby a reduction in pain and disability can be expected within 4 to 6 weeks.¹ However, recurrence rates within a year are high and the risk of chronic low back pain (CLBP) is substantial.^{1,2} Psychological factors such as depression, distress, negative expectations and somatisation can negatively influence the course of low back pain and treatment outcomes.³ In addition, anxiety may also play a role in the transition of ALBP to CLBP and in the persistence or recurrence of pain.⁴ Anxiety is the anticipation of a future threat, which leads to nervous behaviour, concentration problems, inner agitation and somatic symptoms such as fatigue, worry, restlessness and muscular tension.⁵ 'Trait anxiety' is ever-present and reflects a person's general and long-standing characteristics regarding how they respond to perceived threats; individuals high in trait anxiety react with high 'state anxiety',⁵ which

is a temporary subjective condition that reflects feelings of fear and tension due to physical or perceived threats.^{6,7}

Pain-related anxiety is related to perception of pain and thoughts about the consequences of pain⁸ and is associated with cognitive and somatic anxiety symptoms and pain avoidance behaviour.⁹ Negative emotions such as anxiety and fear increase pain when fear is an active response to a present threat and when anxiety is more defensive and passively oriented.¹⁰ State anxiety or trait anxiety might facilitate the transition from ALBP to CLBP.^{4,8,9} Higher anxiety-related sensations are associated with a decrease in perceived pain tolerance and more severe pain perceptions.¹¹ In patients with chronic pain, trait anxiety has also been found to be associated with pain intensity.^{12,13} Besides anxiety, fear of pain plays a role in fear-avoidance behaviour and pain intensity in people with ALBP.¹⁴ Anxiety and fear of pain are assumed to be related to avoidance behaviour and reduced physical performance.^{13,15} There is evidence that targeting anxiety can reduce pain.¹⁶

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Few studies have investigated the role of state anxiety and trait anxiety in the transition from ALBP to CLBP. State anxiety has been found to be similar between patients with ALBP and those with CLBP, but trait anxiety was significantly higher in CLBP.¹⁵ However, that study included patients in tertiary care and did not specify whether back pain was of specific or non-specific origin. In the current study, we hypothesised that state anxiety and trait anxiety could be predictive of poor outcomes in patients with ALBP.

Therefore, the research question for this observational multi-centre prospective cohort study was:

Do measures of state anxiety and trait anxiety in people with acute low back pain improve prediction of chronic low back pain, defined as pain or pain-related disability at 12 weeks?

Methods

Design

The STROBE statement was used as a guide to report this study, and the study methods and results are reported according to the REMARK checklist.¹⁷ A longitudinal multi-centre prospective cohort study design with two measurement occasions was conducted. Recruitment occurred at 26 primary care physiotherapy practices throughout the Netherlands. The study was a Phase II confirmatory prognostic study to establish the independent prognostic value of state anxiety and trait anxiety in patients with ALBP.^{18,19}

Physiotherapists working in primary care and who were studying a Master of Science degree in Manual Therapy were requested to participate in the study by collecting data on consecutive patients with ALBP. Participation was based on personal commitment; as a consequence, geographically, the centres and practices were spread randomly throughout the Netherlands. All patients with ALBP attended a baseline assessment in the acute stage (< 6 weeks), within 1 week after initial contact, and all self-reported data were collected before history taking and physical examination. Patients were reassessed 12 weeks after baseline assessment for pain and disability. Confidential records were stored in a secure area with limited access. Anonymity and confidential input of data were guaranteed to protect the health status information of the participants. Encoded data were entered in an encrypted electronic database.

Participants

People with ALBP were consecutively included if they were aged 18 to 60 years, reported low back pain of < 6 weeks duration with or without radiating pain, and had been pain-free for at least 3 months before the onset of their current back pain. They were also required to be able to read and understand the Dutch language. People were excluded if they had undergone previous lumbar spinal surgery, experienced any neurological signs in their lower limbs, or were diagnosed with a specific cause of low back pain such as lumbar spinal stenosis, current malignancy, spondyloarthropathy, osteoporosis, spondylolisthesis, major trauma, infection or systemic disease. During follow-up, standard care physiotherapy according to the Dutch clinical practice guideline for low back pain was carried out.²⁰ Prior to participation, the study protocol was explained verbally and in writing to patients, after which patients signed informed consent.

Data collection

Data collection was carried out from January 2016 to March 2016 and January 2017 to March 2017. All self-reported measures were obtained in a separate room prior to physical examination and standard care. Two days before baseline assessment, each participant was contacted by email or telephone as a reminder. Participants were asked to complete blank items in the event of non-completion of questionnaire items. Data from the following questionnaires were

obtained at baseline and at 12 weeks in a standardised sequence: Numeric Pain Rating Scale; State and Trait Anxiety Inventory (STAI); and Pain Disability Inventory.^{21–23}

State and trait anxiety

Levels of state and trait anxiety were measured using the revised STAI scales in the authorised Dutch translation (STAI-Y).^{6,24,25} The STAI-Y is a self-reported questionnaire comprising two subscales of 20 items each. The State Anxiety scale (STAI-S) evaluates the current state of anxiety, asking how respondents feel 'at this moment' using items that measure subjective feelings of tension, nervousness, worry and arousal. The Trait Anxiety scale (STAI-T) evaluates relatively stable aspects of 'anxiety disposition', including general states of tranquillity, confidence and safety. The response items for the STAI-S include: 'not at all', 'somewhat', 'moderately so' and 'very much so'. The STAI-T response options are: 'almost never', 'sometimes', 'often' and 'almost always'. Ten items of each subscale should be reversed and the subsequent summing of the 20 items results in scores ranging from 20 to 80, with higher scores reflecting higher levels of anxiety. Internal consistency (Cronbach's alpha) was measured among Dutch students and reached scores of 0.87 to 0.95 for the STAI-S and 0.85 to 0.94 for the STAI-T. Test-retest reliability in a healthy population showed Pearson correlation coefficients (r_p) for the STAI-T 0.86 and for STAI-S 0.52.²⁵ Construct validity of the STAI is good with r_p 0.73 and r_p 0.85 with the Cattell and Scheier's Anxiety Scale Questionnaire, respectively.²⁶

Known factors adjusted in the model

The following factors were considered as 'known' prognostic factors in the model because there is evidence^{27–31} that they increase the risk of CLBP: pain intensity at onset, assessed with the Numeric Pain Rating Scale, with scores ranging from 0 to 10; pain-related disability measured by the Pain Disability Inventory; duration of low back pain measured as number of days having low back pain; physical workload (classified in four categories: office worker, driver, physically heavy work and healthcare worker); and widespread pain (classified in three categories: lumbosacral region, radiation proximal to the knee and radiation distal to the knee).

Outcome measures

At 12 weeks, pain and pain-related disability were assessed using the Numeric Pain Rating Scale and the Pain Disability Inventory, respectively. The Numerical Pain Rating Scale is a one-dimensional measure of pain intensity in adults. The Pain Disability Inventory is a seven-item ordinal scale to measure the impact of pain on seven domains of functioning on a scale ranging from 0 to 70, where 70 is the most severe score. Test-retest reliability of the Pain Disability Inventory is adequate (ICC 0.76) and the minimum clinically important change is between 8.5 and 9.5 points.^{22,23} To classify CLBP patients as having the outcome pain at 12 weeks, a cut-off for pain was defined as greater than 'very mild' pain that resulted in a pain score $\geq 3/10$ on the Numerical Pain Rating Scale and with the outcome pain-related disability at 12 weeks, a score $\geq 19/70$ on the Pain Disability Inventory.^{31,32}

Data analysis

It was expected to find a prevalence of anxiety of 30% in the ALBP population.²⁴ Using this estimate, the a priori sample size calculation revealed that to ensure the width of the 95% confidence interval would be $\pm 6.9\%$ around a proportion of 30% having anxiety as determined using the STAI scale, at least 170 participants would be required.

Univariate logistic regression analyses were performed to estimate the independent, uncorrected association of state anxiety and trait anxiety with pain and pain-related disability. Subsequently, separate multivariate logistic regression models were produced to estimate

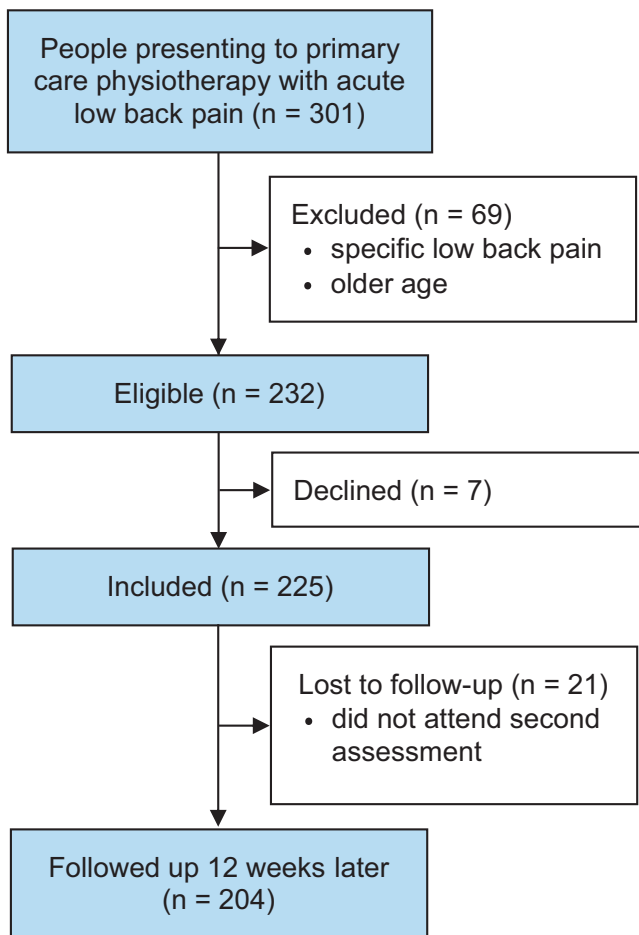


Figure 1. Flow diagram of participants through the study.

the independent contribution of state anxiety and trait anxiety adjusted for the effects of currently known prognostic factors for predicting low back pain status at 12 weeks. These five baseline variables, the 'known' factors (pain intensity, pain-related disability, pain duration, physical work load and widespread pain), were forced into the prognostic model as adjusted irrespective of their univariate association with the outcomes.^{27–30} Associations between state

Table 1
Baseline demographic and clinical characteristics of the study completers, and values 12 weeks after enrolment in the study.

Characteristic	Baseline (n = 204)	12 weeks (n = 204)
Age (y), mean (SD)	41 (12)	
Gender, n female (%)	103 (51)	
Recurrent, n (%)	148 (73)	
Localisation, n (%)		
lumbosacral region	152 (75)	
radiation to proximal knee	42 (21)	
radiation to distal knee	10 (5)	
Workload, n (%)		
office worker	88 (43)	
driver	6 (3)	
heavy physical work	71 (35)	
healthcare worker	35 (17)	
Physically active, n (%)	141 (69)	
Body mass index (kg/cm ²), mean (SD)	24.9 (6.9)	
State anxiety (STAI-S), mean (SD)	35.0 (11.0)	25.9 (14.2)
Trait anxiety (STAI-T), mean (SD)	35.2 (10.5)	27.1 (15.6)
Pain intensity (NPRS 0/10), mean (SD)	6.4 (1.7)	2.2 (2.3)
Greater than 'very mild' pain $\geq 3/10$ NPRS, n (%)		73 (36)
Disability (PDI 0/70), mean (SD)	24.7 (14.7)	8.3 (11.0)
Greater than 'mild' disability $\geq 19/70$ PDI, n (%)		35 (17)

NPRS = Numerical Pain Rating Scale, PDI = Pain Disability Inventory, STAI-S = State and Trait Anxiety Inventory-State, STAI-T = State and Trait Anxiety Inventory-Trait.

Table 2
Univariate regression and multivariate regression analyses of state anxiety for pain at 12 weeks, classified as a Numerical Pain Rating Scale score $\geq 3/10$, adjusted for pain, pain-related disability, duration, physical workload and widespread pain.

Model	Variable	Pain		
		Beta	Odds Ratio (95% CI)	p-value
Unadjusted	State anxiety	0.08	1.1 (1.0 to 1.1)	0.00
Adjusted	State anxiety	0.08	1.1 (1.1 to 1.1)	0.00
	Pain	0.29	1.3 (1.1 to 1.7)	0.01
	Pain-related disability	-0.02	1.0 (1.0 to 1.0)	0.16
	Duration	0.14	1.2 (0.99 to 1.3)	0.06
	Physical workload	0.01	1.0 (0.9 to 1.2)	0.89
	Widespread pain	0.17	1.2 (0.7 to 2.1)	0.58

anxiety and trait anxiety and outcomes were calculated as β coefficients, odds ratios (ORs) with their 95% confidence interval (CI), and p-values. To prevent over-fitting, the total number of variables included in the model was limited to five variables to ensure 10 events per variable.³³

Model fit statistics

To quantify how close predictions were to the actual outcome, the Brier test was used, ranging from 0 to 0.25, whereby a score closer to 0 indicates good performance.^{18,34} Explained variance was calculated applying the standard procedure of Nagelkerke's R^2 . Whether the prediction of the model aligned with the observed probability of developing CLBP was assessed by the Hosmer-Lemeshow goodness-of-fit test, where a larger p-value indicates a better fit.

It was hypothesised that an increase of $\geq 10\%$ chance would be considered clinically relevant for predicting CLBP by adding state or trait anxiety in the prognostic model, adjusted with the five 'known' factors as shown by the area under the Receiver Operating Characteristic (ROC) curve (AUC). Moreover, an AUC ≥ 0.70 would be acceptable.³⁵ It was also hypothesised that explained variance must show improvement > 0.20 when state or trait anxiety is added.

Significance level for the multivariate analysis was set at $\alpha = 0.05$. All analyses were performed using IBM SPSS Statistics v. 25.0.

Results

The flow of participants through the study is shown in Figure 1. Baseline demographic and clinical characteristics of the study participants with complete datasets (n = 204) are presented in Table 1. The normally distributed data showed no floor or ceiling effects. Univariate regression and multivariate regression analyses were performed on state anxiety and trait anxiety for both pain and pain-related disability at 12 weeks, and adjusted for pain, pain-related disability, duration, physical workload and widespread pain.

The adjusted multivariate regression of state anxiety showed an increase of 10% in the probability of developing CLBP with every unit increase in the score on the STAI-S. In addition, pain intensity at onset was also an independent predictor for CLBP with OR 1.3 (95% CI 1.1 to 1.7) and $p = 0.01$ (Table 2).

Table 3
Univariate regression and multivariate regression analyses of state anxiety for pain-related disability at 12 weeks, measured as a Pain Disability Inventory score $\geq 19/70$, adjusted for pain, pain-related disability, duration, physical workload and widespread pain.

Model	Variable	Pain		
		Beta	Odds Ratio (95% CI)	p-value
Unadjusted	State anxiety	0.07	1.1 (1.0 to 1.1)	0.00
Adjusted	State anxiety	0.07	1.1 (1.0 to 1.2)	0.00
	Pain	0.03	1.0 (0.8 to 1.3)	0.80
	Pain-related disability	0.02	1.0 (1.0 to 1.1)	0.14
	Duration	0.03	1.0 (0.9 to 1.2)	0.76
	Physical workload	-0.09	0.9 (0.8 to 1.1)	0.34
	Widespread pain	-0.15	0.9 (0.4 to 1.7)	0.66

Table 4

Univariate regression and multivariate regression analyses of trait anxiety for pain at 12 weeks, classified as a Numerical Pain Rating Scale score $\geq 3/10$, adjusted for pain, pain-related disability, duration, physical workload and widespread pain.

Model	Variable	Pain		
		Beta	Odds Ratio (95% CI)	p-value
Unadjusted	Trait anxiety	0.05	1.1 (1.0 to 1.1)	0.01
Adjusted	Trait anxiety	0.05	1.1 (1.0 to 1.1)	0.01
	Pain	0.29	1.3 (1.1 to 1.6)	0.01
	Pain-related disability	-0.01	1.0 (0.9 to 1.0)	0.24
	Duration	0.15	1.2 (1.0 to 1.3)	0.049
	Physical workload	0.02	1.0 (0.9 to 1.2)	0.83
	Widespread pain	0.17	1.2 (0.7 to 2.0)	0.55

The adjusted multivariate logistic regression of state anxiety showed an increase of 10% in the probability of developing CLBP with every unit increase in the score on the STAI-S. No other independent predictors were identified (Table 3).

The adjusted multivariate logistic regression of trait anxiety showed an increase of 10% in the probability of developing CLBP with every unit increase in the score on the STAI-T. Pain intensity and duration of pain were independent predictors for CLBP (Table 4.)

The adjusted multivariate logistic regression of trait anxiety showed no additional predictive value. No other independent predictors were identified (Table 5).

Model fit statistics

The predictive performance of the model was quantified in terms of overall fit and discrimination. Discrimination with state anxiety added improved into acceptable accuracy for the primary outcome, pain: AUC improved from 0.64 (95% CI 0.56 to 0.71) to 0.75 (95% CI 0.68 to 0.82) and Nagelkerke's R^2 improved from 0.08 to 0.24. Discrimination with state anxiety added improved into acceptable accuracy for the secondary outcome, pain-related disability: AUC improved from 0.63 (95% CI 0.54 to 0.72) to 0.73 (95% CI 0.65 to 0.82) and Nagelkerke's R^2 improved from 0.05 to 0.16. Discrimination with trait anxiety added improved for the primary outcome, pain: AUC improved from 0.64 (95% CI 0.56 to 0.71) to 0.70 (95% CI 0.62 to 0.77) and Nagelkerke's R^2 improved from 0.08 to 0.15. On the secondary outcome, no improvement was detectable. Hosmer and Lemeshow (p -values) varied between 0.22 and 0.94 and Brier scores varied between 0.13 and 0.22.

The ROC curves illustrate the discrimination of the primary and secondary outcomes due to the addition of state anxiety to the model (Figures 2 and 3).

Discussion

This prospective prognostic cohort study found evidence that state anxiety in people with ALBP is an independent predictor of the risk of developing CLBP at 12 weeks, in contrast with trait anxiety. In the multivariate adjusted model, the addition of state anxiety improved discrimination between people at risk or not of developing CLBP in contrast with adding trait anxiety. This suggests that state

Table 5

Univariate regression and multivariate regression analyses of trait anxiety for pain-related disability at 12 weeks, measured as a Pain Disability Inventory score $\geq 19/70$, adjusted for pain, pain-related disability, duration, physical workload and widespread pain.

Model	Variable	Pain		
		Beta	Odds Ratio (95% CI)	p-value
Unadjusted	Trait anxiety	0.03	1.0 (0.9 to 1.1)	0.11
Adjusted	Trait anxiety	0.02	1.0 (0.9 to 1.1)	0.26
	Pain	0.06	1.0 (0.8 to 1.4)	0.61
	Pain-related disability	0.02	1.0 (0.9 to 1.1)	0.09
	Duration	0.02	1.0 (0.9 to 1.2)	0.80
	Physical workload	-0.07	0.9 (0.8 to 1.1)	0.49
	Widespread pain	-0.09	0.9 (0.5 to 1.7)	0.78

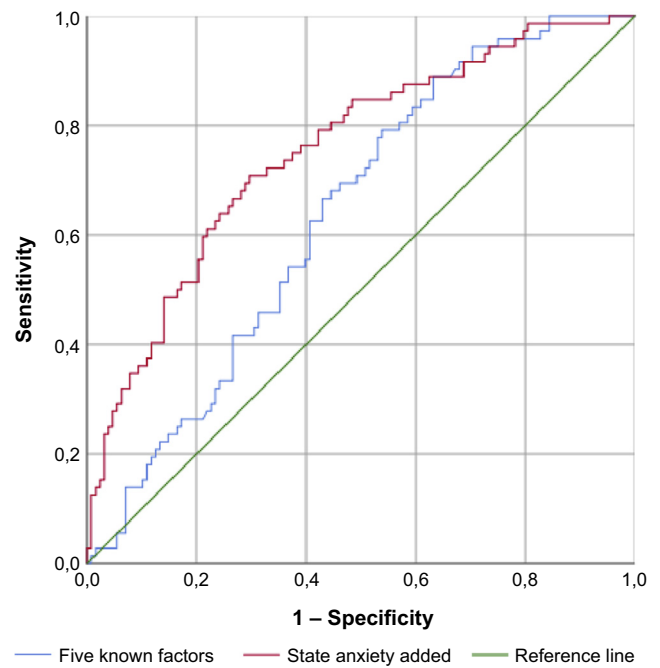


Figure 2. Receiver Operating Characteristic (ROC) curve of state anxiety (red line) to visualise the discriminatory power. The outcome is the primary outcome: pain at 12 weeks.

anxiety, not trait anxiety, is a prognostic factor and may be of additional value in the clinical setting.

Current guidelines for low back pain emphasise that psychological factors, of which anxiety is one, are risk factors for poor prognosis at the acute stage.¹⁹ Although trait anxiety reflects a person's long-standing characteristic, it is remarkable that trait anxiety showed a substantial decrease during the 12-week period in the transition from ALBP to CLBP. This implies that the general characteristics of trait anxiety may be debatable, although in a nonclinical population both state anxiety and trait anxiety scores differed, which was supported by neuroanatomical correlations.³⁶ In addition, mean anxiety scores at baseline were different from values found in other studies and it is

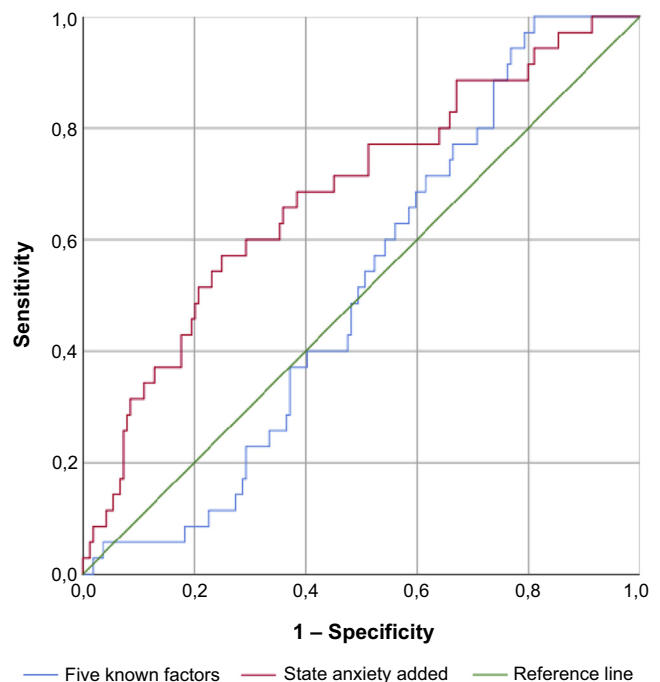


Figure 3. Receiver Operating Characteristic (ROC) curve of state anxiety (red line) to visualise the discriminatory power. The outcome is the secondary outcome: pain-related disability at 12 weeks.

unknown what represents valid anxiety scores in CLBP. Newcomer et al recruited participants from a tertiary care clinic in which trait anxiety was more strongly present than state anxiety.¹⁵ In contrast to the current sample of patients with ALBP, Bean et al found no significant role for state anxiety to predict disability and pain in patients with CLBP.¹⁶ Their study did not distinguish between state anxiety and trait anxiety, and did not measure anxiety at the acute stage.¹⁶ In addition, a systematic review found limited evidence that anxiety is predictive of disability in patients with subacute, non-malignant pain conditions.³⁷

Strengths of this study were: the use of a thoroughly validated instrument for measuring state and trait anxiety, with good discriminant properties and ease of implementation in clinical practice; and the recruitment in primary care with acceptable loss to follow-up. In addition, the sample size and event rate appeared sufficient to allow a maximum of five variables in the model and, consequently, provide stable predictors. However, analysing missing values at baseline showed that pain intensity and disability were 10% and 17% below the mean scores, respectively. In contrast to what was expected, the adjusted prognostic factor effects of state anxiety and trait anxiety were approximately equal to the unadjusted ones. The predictive performance of the prognostic model is quantified in terms of overall measures of fit and discrimination, whereby the increase in the explained variance may be regarded as a relevant scientific and clinical contribution. When focused on state anxiety as a prognostic factor, the explained variance tripled on both primary and secondary outcome measures. In addition, on both outcomes the AUC showed substantial improvement in discriminant capacity by adding state anxiety, which was in contrast to trait anxiety. Nevertheless, a large part of the variance remains unexplained; this should be investigated in further research.

A limitation of the study results is that only complete cases were used and imputation was not used. However, it is debatable whether the bias of imputation would be less than the selection bias that may arise from using only complete cases.¹⁸ Selection bias may have been present, when selection was based on incorrect identification of patients at baseline and during follow-up in patients who had withdrawn. In our study we assumed that these cases were a random selection of the data, although analysing these cases would have been preferable.

The results of this study are in line with recommendations emphasising the need for attention to psychological factors in physiotherapy care.²⁴ Although it requires specific professional skills, evidence exists that patient education can provide reassurance.³⁸ Replication of this study's findings is needed in other multiple independent confirmatory studies to assess the best way of classifying state anxiety and also to investigate the mechanisms that lie behind the construct of state anxiety in nonspecific low back pain, how it is affected, and the role of physiotherapists in the management of these patients in clinical practice. It is recommended that clinicians consider state anxiety as a potential predictor of poor outcome in patients with ALBP. Further research on anxiety as a psychosocial factor and as part of screening instruments in ALBP patients is warranted.³⁹

What is already known on this topic: Several factors contribute to the transition from acute to chronic low back pain. However, the influence of anxiety is unknown.

What this study adds: Patients with acute low back pain presenting in primary care with higher levels of state anxiety have higher risk of developing chronic low back pain and pain-related disability at 12 weeks. Further validation of these findings is warranted. Meanwhile, physiotherapists could consider identifying those patients at-risk, in order to intervene and decrease the risk of chronicity.

Ethics approval: The Medical Ethics Committee (METC) of the University of Groningen reviewed the study procedures and decided

that, within the Dutch regulations, formal ethical approval was not needed. All participants gave written informed consent before data collection.

Competing interests: Nil.

Source(s) of support: Nil.

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Provenance: Not invited. Peer reviewed.

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