

# A Systematic Review of Psychological Factors as Predictors of Chronicity/Disability in Prospective Cohorts of Low Back Pain

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**Study Design.** A systematic review of prospective cohort studies in low back pain.

**Objectives.** To evaluate the evidence implicating psychological factors in the development of chronicity in low back pain.

**Summary of Background Data.** The biopsychosocial model is gaining acceptance in low back pain, and has provided a basis for screening measurements, guidelines and interventions; however, to date, the unique contribution of psychological factors in the transition from an acute presentation to chronicity has not been rigorously assessed.

**Methods.** A systematic literature search was followed by the application of three sets of criteria to each study: methodologic quality, quality of measurement of psychological factors, and quality of statistical analysis. Two reviewers blindly coded each study, followed by independent assessment by a statistician. Studies were divided into three environments: primary care settings, pain clinics, and workplace.

**Results.** Twenty-five publications (18 cohorts) included psychological factors at baseline. Six of these met acceptability criteria for methodology, psychological measurement, and statistical analysis. Increased risk of chronicity (persisting symptoms and/or disability) from psychological distress/depressive mood and, to a lesser extent, somatization emerged as the main findings. Acceptable evidence generally was not found for other psychological factors, although weak support emerged for the role of catastrophizing as a coping strategy.

**Conclusion.** Psychological factors (notably distress, depressive mood, and somatization) are implicated in the transition to chronic low back pain. The development and testing of clinical interventions specifically targeting these factors is indicated. In view of the importance attributed to other psychological factors (particularly coping strategies and fear avoidance) there is a need to clarify their role in back-related disability through rigorous prospective studies. [Key Words: back pain, chronicity, disability, psychology, psychosocial] **Spine 2002;27:E109–E120**

There is increasing acceptance that psychosocial factors play a crucial role in the transition from an acute episode of low back pain (LBP), or a sequence of such episodes, to a chronic back disorder, and that they may also be etiologic factors.<sup>4,33,49</sup> However, to date, there has not been a systematic review critically appraising the scientific evidence relating to individual psychological factors with an emphasis on clinical settings. Although screening for psychosocial risk factors and intervention targeting them, has been implemented with reported success,<sup>59,33</sup> clarification of the evidence may considerably enhance efficacy in both.

The issue is confounded with information from different clinical environments under different health care systems and with different measures of outcome. The quality of the psychological measurements in terms of their psychometric properties, their utility in directing interventions, and their underlying validity needs to be considered. Psychological questionnaires applied to populations experiencing pain have been criticized for their inclusion of criterion contamination (in which items could be measuring either physical or psychological states, but considered to be an indication of only one of these).<sup>17,44,45</sup> The interpretation of questionnaires developed in and for one population (e.g., psychiatric patients) but applied indiscriminately to pain patients is an additional complication.<sup>46</sup> Questionnaires specifically developed as trait measures (stable characteristics) are not sensitive to change.<sup>1,40,65</sup> Furthermore, if it is unclear what a questionnaire is measuring, it becomes difficult to focus interventions aimed at changing the purported concept. The use of different outcome measures to represent chronicity impedes the understanding of underlying mechanisms. Chronicity has been described in terms of persisting symptoms, disability, and work status. Finally, different population sources (clinical and occupational settings) will not necessarily share the same characteristics.

These confounding issues will be duly considered in this review to identify robust correlations between psychological parameters and chronic sequelae of LBP.

## Objectives

This review aims to estimate the strength of evidence from prospective cohort studies suggesting that psychological factors influence the transition to chronicity in LBP patients. The value of these factors to inform screening and interventions will be considered.

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The following questions were addressed, so far as is permitted by the published literature reporting psychological factors as predictors of LBP outcomes:

1. What is the methodologic quality of the evidence?
2. How satisfactorily have psychological factors been measured?
3. Do the findings differ across environments (primary care settings, clinics, and workplace), or in terms of selected outcome measures (occupational *vs.* clinical)?
4. What are the most consistent psychological factors predicting LBP outcomes, and is there evidence that their influence exceeds that from clinical/demographic variables in studies in which these were included?

## ■ Methods

**Scope of the Study.** The selection criteria for inclusion of studies were:

- Prospective cohorts concerning LBP (considered the appropriate route to best evidence for questions about prognosis<sup>50</sup>)
- Subjects with acute or subchronic LBP (as opposed to a specific diagnosis/pathology or chronic symptoms) Measurement of at least one psychological variable at base line (including affect, cognition, anxiety, beliefs, coping, *etc.*)

The following were excluded:

- Retrospective studies
- Studies that included only social, demographic, or clinical variables
- Studies that specifically did not study the transition from acute to chronic
- Studies that investigated psychological factors predicting incidence of back pain
- Studies investigating psychological processes in chronic (more than 3 months) back pain

**Searching.** Electronic database searches of *Medline*, *Amed*, and *Knowledge Finder* were carried out in October 1999, and included various combinations of a variety of keywords (*e.g.*, prospective, back pain, psychological measures, psychological, cohort, longitudinal), with no language restriction, resulting in 176 hits. After excluding papers that did not fit the inclusion criteria, a further electronic search was carried out on author names from successful hits. Hand searching the journal *Spine* from 1982 uncovered 6 further studies. Hand searching the journal *Pain* from 1982 and searches of personal databases did not lead to additional studies. (Full details of the search strategy are available on-request from the authors.)

The papers were scrutinized and assessed for inclusion/exclusion criteria. The selected studies were divided into three groups depending on the research setting: “primary care” (*i.e.*, general practice, state national health surgeries, *etc.* [n = 9]), “clinics” (orthopedic, chiropractic, osteopathic, hospital outpatients, *etc.* [n = 10]), and “workplace” (workforce participants [n = 6]). In total, 25 papers were identified reporting investigation of psychological factors as predictors of the transition from acute to chronic LBP. It was noted that some papers were based on findings from the same sample; these publications have been counted as one study, resulting in 18 indepen-

dent studies overall, but information contained in all 25 papers was included in the assessment process.

**Assessment Protocol.** Two reviewers, each blind to the other’s assessment, coded each paper on the basis of predetermined criteria. One of them specializes in research methods/epidemiology and psychological measurement, whereas the other was a clinician researcher specializing in back pain. They then met to discuss and reach agreement on any differences in coding. A sample of the papers (n = 6, two from each environment) was assessed blindly by a third experienced reviewer. All three reviewers then met to reconcile remaining minor differences. An independent statistician performed the statistical conversion of reported results to effect sizes.

**Criteria for Assessing Prospective Cohorts.** The criteria applied in this review were based on general evidence-based medicine guidelines for prognosis and etiology,<sup>50</sup> guidelines specific to back pain research,<sup>58</sup> and issues specific to psychological measurement in pain.<sup>46,65</sup> These criteria were divided into three sets, and enabled ‘yes/no’ coding according to the presence of each criterion in the published reports. (Full details of the criteria are presented in the Appendix.)

The first set focuses on methodologic merit derived from evidence-based medicine principles, and includes early recruitment, exclusion/inclusion criteria, dropout rate, and comparison of baseline variables between complete sets of data and dropout subjects. The second set focuses on the quality of psychological measurement, and includes multiple instruments and selection of measurement tools developed specifically for this patient population. The third set includes statistical considerations, such as sample size and use of appropriate multi-variable tests together with provision of information enabling the calculation of effect size. In addition, papers were coded for details that provide useful information relevant to the research question, including measurement of outcome on at least two occasions (providing short- and longer-term follow-up),<sup>15</sup> and measurement at a minimum 12-month follow-up.

**Assessment of Criteria.** Each criterion was examined for presence or absence in the study reports. When a clear demarcation could not be applied strictly, a decision based on concordance between independent reviewers was applied. The reviewers’ independent decisions were in concordance 98% of the time. The remaining 2% (6 items) were debated and agreement was achieved. Finally, a summary rating for each domain (methodology, psychological measurement, and statistical analysis) was constructed and is presented under a “star” system:

- \*\*\* *Good*, meets all main criteria
- \*\* *Acceptable*, meets >1 main criterion
- \* *Unacceptable*, meets ≤ 1 main criterion

The studies were then scored for overall methodologic quality on the basis of the number of stars awarded across the three domains (maximum = 9):

- 8–9, high quality
- 6–7, acceptable quality
- 0–5, unacceptable quality

Because the decisions concerning quality are somewhat subjective, even with the utilization of explicit coding criteria, none of the studies were excluded from the analysis, presentation of results, or discussion. The presentation of results for all studies will permit the reader to assess independently the weighting

**Table 1. Summary of the Selected Reports From Prospective Cohorts**

Reference	Country	No. at Follow-up	Main Outcomes	Methodologic Quality	Quality of Psychological Measurement	Statistical Quality	Overall Quality Rating	Short- and Long-term Follow-up	Follow-up at $\geq 12$ Months
Primary care									
Macfarlane et al. <sup>39</sup> Thomas et al. <sup>54</sup>	UK	180	Chronicity	**	***	**	A	+	+
Linton and Hallden <sup>38</sup>	Sweden	137	Accumulated sick leave	*	*	*	U	-	-
Dionne et al. <sup>19</sup> Engel et al. <sup>20</sup> Dionne et al. <sup>18</sup> Von Korff et al. <sup>61</sup> Cherkin et al. <sup>11</sup>	USA	1024	Disability and cost	***	**	***	H	+	+
Klenerman et al. <sup>35</sup>	UK	162	Pain/disability	**	*	*	U	+	+
Clinics									
Haldorsen et al. <sup>28</sup>	Norway	260	Return to work	*	**	**	U	+	+
Burton et al. <sup>8</sup>	UK	186 (56 < 3 wk)	Disability	**	**	**	A	-	+
Gatchel et al. <sup>25</sup>	USA	421 (215 for MMPI)	Return to work	**	**	**	A	+	+
Gatchel et al. <sup>26</sup> Greenough and Fraser <sup>27</sup>	AUS	274	Disability	*	**	**	U	-	+
Cats-Baril and Frymoyer <sup>16</sup>	USA	250	Return to work	**	*	*	U	-	-
Gallagher et al. <sup>24</sup> Bradish et al. <sup>5</sup>	USA Canada	150 62	Return to work Work status, opinion of health status, clinician's opinion of health status	* *	* *	** *	U U	- -	- -
Murphy and Cornish <sup>43</sup> McNeil et al. <sup>42</sup>	USA USA	48 175	Chronicity Medication, work status, pain, patients opinion of improvement	* *	** *	* *	U U	- -	+
Workplace									
Williams et al. <sup>66</sup>	USA	82	Clinical state, comprising disability and distress	**	**	**	A	+	+
Epping Jordan et al. <sup>21</sup> Wahlgren et al. <sup>63</sup> Estlander et al. <sup>22</sup>	Finland	365	Days of pain over 12 mo persistent, contracted, or recovered	*	**	*	U	+	+
Lehmann et al. <sup>37</sup>	USA	55	Time to return to work	**	**	*	U	-	-
Lancourt and Kettelhut <sup>36</sup>	USA	134	Return to work	**	*	**	U	-	-

H = high; A = acceptable; U = unacceptable; + = yes; - = no.

\* good

\*\* acceptable

\*\*\* unacceptable

they might wish to attribute to each study, and also presents a complete picture of current evidence.

## ■ Results

Table 1 displays summary information on the population for each study (country, sample size, outcome measure, and information on the additional criteria). It also

presents the quality ratings for methodology, psychological measurement, statistical analysis, and the overall quality rating.

It was found that outcome was measured according to several different parameters over differing time periods. For the purposes of this review, these variables were taken to represent measures of unfavorable outcome (reflecting persisting pain and/or disability). These mea-

**Table 2. Details of Methodologic Criteria**

Reference	Recruitment Within 3 Weeks of Onset	Inclusion Criteria	Exclusion Criteria	% Loss to Follow-up	Compare Drop-out to Complete on Baseline Variables
<b>Primary care</b>					
Macfarlane et al. <sup>39</sup>	Yes (GHQ measured before onset)	Area bordered by the 12 <sup>th</sup> rib and the gluteal folds, radiation recorded, previous history of LBP recorded	Not reported	44	Yes
Thomas et al. <sup>54</sup> Linton and Hallden <sup>38</sup>	No (acute and subacute)	Back or neck area, multiple pain sites recorded, previous history recorded	Lack of language skills	3	N/A
Dionne et al. <sup>19</sup>	No (4–6 weeks after consultation)	Age 18–75 years, back pain (including thoracic and cervical spine), previous history recorded	Visits to emergency room or walk in clinics, abscess, neoplasm, pregnancy, and alignment problems	16	N/A
Elgel et al. <sup>20</sup> Dionne et al. <sup>18</sup> Von Korff et al. <sup>61</sup> Cherkin et al. <sup>11</sup>	Yes (18% of sample above 3 weeks)	Age 20–69 years, first visit for LBP, radiation recorded	Previous back surgery, systemic or visceral disease, known osteoporosis or corticosteroids, pregnancy, cancer, unexplained weight loss, vertebral fracture, neurologic pathology, litigation involvement, lack of English, substance abuse	10	N/A
Klenerman et al. <sup>25</sup>	Yes (within 1 week of onset)	First episode of benign, musculoskeletal LBP, previous history recorded	Not reported	46	Yes
<b>Clinics</b>					
Haldorsen et al. <sup>28</sup>	No (8–12 weeks)	Back pain (with and without radiation)	Pregnancy, sick leave for 12 weeks and above	1	N/A
Burton et al. <sup>8</sup>	Yes (subgroup of 56 < 3 weeks; analyzed separately)	New occurrence of LBP, recorded radiation, previous history recorded	Serious pathology (organic or neoplastic disease)	26 (52 acute)	Yes
Gatchel et al. <sup>23</sup>	± Yes (all <6 weeks: 54% <2 weeks; tested together)	Lumbar pain syndrome (acute back pain)	Not reported	7	N/A
Gatchel et al. <sup>26</sup> Greenough and Fraser <sup>27</sup>	? (no data on onset of current episode)	Back pain	Fracture of dislocation of the spine, spinal surgery	47	Yes
Cats-Baril and Frymoyer <sup>18</sup>	? (data on employment status only)	Age 18–65 years, new episodes of LBP	Unemployed >3 months	7	N/A
Gallagher et al. <sup>24</sup>	? (no data on onset of current episode)	Currently out of work because of low back pain	More than one previous surgical operation for LBP (half the sample only), unemployment for >18 months (half the sample only)	11	N/A
Bradish et al. <sup>5</sup>	No (<6 months since injury)	Age 18–65 years, low back pain resulting from work-related injury, divided into nonspecific and degenerative change	Prior history of LBP injury or surgery, radiculopathy, spinal instability, spinal fracture, spinal stenosis	30	No
Murphy and Cornish <sup>43</sup>	? (no data on onset of current episode)	Acute LBP	>6 months duration of LBP	7	N/A
McNeil et al. <sup>42</sup>	No (<6 months)	LBP, recorded radiation	Not reported	51	No
<b>Workplace</b>					
Williams et al. <sup>66</sup>	No (6–10 weeks)	Men only, age 18–50 years, first onset back pain (T6 or below) present on a daily basis for 6–10 weeks, recorded radiation, recorded neurologic symptoms	Major medical illness or pain disorder, history of back pain, medication associated with mood, major surgery in previous 12 months, neoplastic disease, osteomyelitis, fractures	35	Yes
Epping Jordan et al. <sup>21</sup> Wahlgren et al. <sup>63</sup> Estlander et al. <sup>22</sup>	? (no data on onset of current episode)	Age below 54 years, LBP, neck and shoulder pain for at least 30 days in previous 12 months, recorded sites and history		19	Yes
Lehmann et al. <sup>37</sup>	± Yes (2–6 weeks)	Age 18–65 years, work absence due to LBP, lumbar problems only, recorded additional pain sites	Tumor, fractures, long-term care, pathology	10	N/A
Lancourt and Kettelhut <sup>36</sup>	? (acute and chronic)	Receiving compensation for low back pain, measured leg pain and prior surgery	Significant nonspinal conditions, limited English	17	N/A

N/A = not applicable; LBP = low back pain.

asures included the Symptom Satisfaction Questionnaire, categorized as “good” or “bad”<sup>11</sup>; ratings on the Roland Disability Questionnaire at 1 or 2 years<sup>8,19</sup>; measurement of persistent back pain by self-report at 1 week, 3 months, and 12 months<sup>34</sup>; sick leave for back pain over 12 months<sup>38</sup>; categorization of patients into no pain, intermittent pain and constant pain through 12 months<sup>35</sup>; work status at 6 months<sup>36</sup>; time to return to work<sup>37</sup>; days off work because of back pain in the past 12

months (measured retrospectively)<sup>22</sup>; and disability and pain.<sup>21,63,66</sup>

In terms of overall quality, two studies were rated as high quality and four were rated as being of acceptable quality.

Table 2 gives details of the coding of the methodologic criteria. Five studies specifically reported interviewing patients within 3 weeks of onset. The study by Thomas et al.<sup>54</sup> included psychological measurement before onset.

**Table 3. Details of Psychological Measurements**

Reference	Psychological Measures	Population for Which Developed	Somatic Items Excluded?	>1 Psychological Measure
<b>Primary care</b>				
Macfarlane et al. <sup>39</sup> Thomas et al. <sup>54</sup> Linton and Hallden <sup>38</sup>	GHQ distress	Community and medical outpatients	Yes: used the 12 item GHQ	Yes
	Single item from CSQ Single item on stress/anxiety Single item on depression	Physical disorders	N/A	Yes
Dionne et al. <sup>19</sup> Elgel et al. <sup>20</sup> Dionne et al. <sup>18</sup> Von Korff et al. <sup>61</sup> Cherkin et al. <sup>11</sup>	SCL-90 somatization SCL-90 depression	Normal and physical illness	No: included vegetative symptoms, energy, effort, and sleep disturbance	Yes
Klenerman et al. <sup>35</sup>	Combined depression/somatic perception, disability and pain	Back pain patients	No: included items on sleep disturbance, and energy No: contained pain and disability ratings	Yes
<b>Clinics</b>				
Haldorsen et al. <sup>28</sup>	MHLC (internal) State/Trait Anxiety EPI	Normal and physical illness Normal and psychiatric Normal and psychiatric	N/A	Yes
Burton et al. <sup>8</sup>	DRAM distress (MSPQ + Zung) FABQ fear avoidance CSQ coping strategies	Pain populations Pain population Physical illness	No: included 7 somatic items N/A N/A N/A	Yes
Gatchel et al. <sup>25</sup> Gatchel et al. <sup>26</sup>	MMPI hysteria MMPI depression MMPI hypochondriasis (measured SCID DSM Axis II, but not reported in results)	Normal and psychiatric Psychiatric diagnosis	No: included somatic items	Yes
Greenough and Fraser <sup>27</sup>	Psychiatric disturbance, combining MSPQ and Zung (i.e., DRAM)	Pain patients	Not reported: ? contained somatic items	Yes
Cats-Baril and Frymoyer <sup>10</sup>	Unspecified psychological factors	?	?	No
Gallagher et al. <sup>24</sup>	MMPI Hy Single items on health locus of control, stress, coping and psychiatric symptoms	Normal, extracted from standardized instruments + authors additions	N/A ? Items not reported	Yes
Bradish et al. <sup>5</sup> Murphy and Cornish <sup>43</sup>	Nonorganic signs MMPI EPI MHLC	Back pain patients Normal Normal Normal	N/A N/A	No No
McNeil et al. <sup>42</sup>	Back Pain Classification Scale as a measure of disturbance	Back pain patients	No: based on pain descriptors	Yes
<b>Workplace</b>				
Williams et al. <sup>66</sup>	Depression (Hamilton and BDI)	Normal and psychiatric	No, contained somatic items	Yes
Epping Jordan et al. <sup>21</sup> Wahlgren et al. <sup>63</sup> Estlander et al. <sup>22</sup>	MSPQ somatic perceptions Zung depression SES self-efficacy	Pain patients Pain patients Normal and physical illness	N/A Not reported: ? contained somatic items N/A	Yes
Lehmann et al. <sup>37</sup>	Job-related stress BDI	Normal Normal and psychiatric	N/A No, contained somatic items	Yes
Lancourt and Kettelhut <sup>36</sup>	Nonorganic signs Single item on coping	Back pain populations ?	N/A N/A	Yes

N/A = not applicable.

Klenerman et al.<sup>35</sup> measured psychological factors within 1 week of presentation, whereas Burton et al.<sup>8</sup> subdivided their sample and separately analyzed patients who were assessed within 3 weeks. Cherkin et al.<sup>11</sup> reported that less than 20% of their sample had a history in excess of 3 weeks, while Gatchel et al.<sup>25,26</sup> measured baseline variables less than 2 weeks from injury in 54% of their sample.

Inclusion criteria were described in most studies, but only a few outlined the criteria for exclusion. Although many studies recorded previous histories of LBP and known confounding variables, it was not always clear how (or if) these variables were entered into the analyses. Of the studies carried out in primary care, all but one<sup>38</sup> measured outcome both in the short-term and a longer term. In contrast, only two of the clinic studies<sup>25,26,28</sup>

measured outcome twice, and four others measured outcome only at 6 months or less.<sup>5,10,24,43</sup> Two workplace studies measured outcome only once (at 6 months or less).<sup>36,37</sup>

Twelve studies achieved 'acceptable' loss to follow-up. There was no substantial difference between environments in this respect, yet studies performed in the USA achieved rather better follow-up proportions than those from other countries. There were four studies that compared baseline factors between patients who completed the follow-up measurements and those who did not. Eleven studies (61%) were considered of acceptable methodologic quality.

The ratings for the quality of psychological measurement are presented in Table 3. The most commonly measured factor was distress (commonly labeled "depres-

**Table 4. Details of Statistical Assessment**

Study	No.*	Outcome	Psychological Factors	Medical or Demographic Factors†	Multivariate Method	Results and Effect Sizes‡	Comments
Primary care Macfarlane et al. <sup>39</sup>	238	Improved vs. not	GHQ	Age, self-rated health, employment characteristics, weight	Yes (logistic regression)		For GHQ, males (n = 97) and females (n = 141) were analyzed separately; for males a low GHQ score (<21), produced an odds ratio of 8.7 when using high GHQ as a reference category; for females, GHQ did not predict better outcome
Thomas et al. <sup>54</sup>	180	Persistent pain vs. not	GHQ	Age, gender	No and yes (logistic regression)	Univariate analysis (adjusted for gender and age) revealed an effect of low GHQ scores with an odds ratio (adjusted for gender and age) of 3.34 for low GHQ scores vs. high	No significant effect of GHQ scores (but wasn't split by gender)
Linton and Hallden <sup>38</sup>	137	Recovered vs. not	Coping, depression, stress	Work type, current pain intensity, belief that one shouldn't work with current pain levels	Yes (discriminant analysis)		Six variables were selected for the final discriminant function analysis of the psychological factors stress and perceived chance of being able to work again were included; both variables had a significant contribution to the analysis, but no precise details are given and variate structure is not described
Dionne et al. <sup>18</sup>	1009	Roland-Morris disability	Somatization, depression	Age, gender, job characteristics, compensation	Yes (multiple regression)	Depression and somatization both predicted disability (both d ≈ 0.206); somatization predicted disability at follow-up (d ≈ 0.206)	Looked at variables that moderate the relationship between education and disability; depression (−19%) and somatization (−31 or −37% for continued disability) had a reducing effect on the β value for education when predicting disability
Dionne et al. <sup>19</sup>	408	Roland-Morris disability	Somatization, depression	Age, gender, pain intensity, chronic pain score, initial RDQ, days in pain, medical visits, education, job characteristics	Yes (multiple regression)	Somatization (d = 0.921) and depression (d = 0.424) predicted 2-year follow-up	Validated model on different sample (n = 644)
Engel et al. <sup>20</sup>	986 and 1058	Cost	Depression	Age, gender, education, chronic pain grade, days in pain, disability pay, diagnosis	Yes (logistic regression)	Depression predicted total cost (d ≈ 0.105); depression predicted back pain cost (d ≈ 0.201) but not after adjustment for other predictors and demographic variables; utilization: depression had no effect after adjustment for demographics and all other predictors except after 8 or more pain medicine fills (d ≈ 0.208)	For total costs the confidence interval for the odds ratio of moderate scores crosses 1, indicating a nonsignificant, or at least unstable, result
Von Korff et al. <sup>61</sup>	1128	Good, fair, or poor outcome	Depression		No (descriptives)		This study had the potential to look at whether depression scores predict membership of groups using discriminant analysis; this analysis was not done
Cherkin et al. <sup>11</sup>	206	Symptom satisfaction	Depression	Age, employment details, back pain history, disability, current back pain details (duration, persistence, bothersomeness)	Yes (logistic regression)	At 7 weeks and 1 year, depression significantly predicted a poor outcome after controlling for other predictors (both d ≈ 0.441)	The strong effect of depression could be due to the outcome measure being subjective and, therefore, influenced by depression
Klenerman et al. <sup>35</sup>	300	Pain/disability composite	Composite variable	Demographic, historical, fear-avoidance	Yes (multiple regression)	Psychosocial composite predicted pain 2–12 months (d = 1.51)	The psychological predictor was a composite measure made up of Zung depression, inappropriate signs and symptoms, somatic perception–MSPQ, 2 measures of disability, and severity of present pain; the unique role of depression and MSPQ cannot be assessed
Clinics Haldorsen et al. <sup>28</sup>	260	Return to work	EPI, STAI, MHLIC	Lateral mobility, finger–floor distance, left Achilles reflex	Yes (discriminant analysis)	Psychological factors alone: nonreturners could be predicted (d = 1.26); returners could not be significantly predicted	When psychological and medical variables were included in the same analysis nonreturners were correctly classified on 77% of occasions; in this final analysis only MHLIC was present
Burton et al. <sup>8</sup>	131	Disability	DRAM, MSPQ, Zung, FABQ, CSQ	Present pain intensity, SLR, root tension signs, duration of episode, age, gender, flexibility measures	Yes (multiple regression + discriminant analysis)	All patients: coping (paying/hoping) (d = 1.09), and MSPQ (d = 0.40); acute patients: coping (catastrophizing) (d = 1.88); coping (paying/hoping) (d = 0.40), and MSPQ (d = 0.59); subchronic: no predictors	Discriminant analysis was used to predict recovered from nonrecovered patients; for all patients 75.4% of cases were correctly classified and the model retained depressive symptoms, coping (praying/hoping), and MSPQ; for acute patients 82.1% of cases were correctly classified and depressive symptoms and coping were retained in the model
Gatchel et al. <sup>25</sup>	324	Return to work	SCID axis I and II, MMPI	Gender, pain and disability analogue scale, compensation	Yes (logistic regression)	Analysis excluding MMPI scales correctly classified 87% of cases; SCID Axis II was retained in the model (this result controls for age, race, and pain intensity) the confidence interval of the odds ratio crossed 1 (0.874–4.415) indicating nonsignificance at P = 0.05; in a second analysis Axis II was still retained as a predictor, but again the confidence interval crossed 1 indicating nonsignificance: CI <sub>95</sub> = 0.930–7.845; MMPI scale 3 (hysteria) was also a predictor with a confidence interval that didn't cross 1 (CI <sub>95</sub> = 1.129–2.802)	
Primary care Gatchel et al. <sup>26</sup>	421	Return to work	SCID I and II, MMPI	Gender, pain and disability analogue scale, compensation	Yes (logistic regression)	Analysis excluding MMPI scales correctly classified 92.8% of cases, but no psychological factors emerged as significant predictors: in a second analysis including MMPI scales 90.7% of cases were correctly classified; MMPI scale 3 (hysteria) was the only psychological predictor retained (odds ratio = 1.521), but the confidence interval crossed 1 (CI <sub>95</sub> = 0.977–2.367) indicating an unstable result	

Table 4 (Continued)

**Table 4. Details of Statistical Assessment**

Study	No.*	Outcome	Psychological Factors	Medical or Demographic Factors†	Multivariate Method	Results and Effect Sizes‡	Comments
Greenough and Fraser <sup>27</sup>	274	WPIS, WDS, ODS	MSPQ, depression composite	Sex, age, social group, employment, compensation	Yes (multiple regression)	Psychiatric disturbance significantly predicted outcome ( $d \approx 0.465$ ), ODS ( $d \approx 0.465$ ), WDS ( $d \approx 0.465$ ), and WPIS ( $d \approx 0.465$ )	Four multiple regression analyses were conducted but not hierarchically; not enough information (e.g., $r^2$ ) to assess the importance of these contributions
Cats-Baril and Frymoyer <sup>10</sup>	250	Working vs. disabled	Psychological factors		Yes (discriminant analysis)		Predictors were items on a questionnaire generated by experts; the unspecified psychological factors did not emerge as a significant predictor of return to work (no statistics were quoted)
Gallagher et al. <sup>24</sup>	150	Working vs. disabled	MMPI, HLC	Age, education, time off work	Yes (ANCOVA, logistic regression)	MMPI (hysteria) predicted return to work ( $d \approx 0.550$ ), as did HLC ( $d \approx 0.388$ ) and the interaction of the two ( $d \approx 0.270$ ); the interaction of the length of time away from work (level 1 = 0–6 months, level 2 = 6–12 months, level 3 = 12+ months) and hysteria was also a significant predictor (both $d \approx 0.550$ )	ANCOVAs didn't look at predicting chronicity, logistic regression predicting work status from various predictors (selected based on partial correlations); age was controlled for in the logistic regression analyses
Bradish et al. <sup>5</sup>	120	Recovery status	None		No (descriptives)		
Murphy and Cornish <sup>43</sup>	48	Chronic vs. acute groups	MMPI, EPI locus of control scale	CMI, MPQ, pain drawing	Yes (discriminant analysis)	Calculating the change in $\lambda$ we see the unique effect of each variable; MMPI-9 (hypomania-impulsive, etc.) was a significant discriminator (change in $\lambda = 0.134871$ ) as was MMPI-7 (psychasthenia-worried, anxious) (change in $\lambda = 0.114846$ )	Eigen values associated with each variable were not reported; 85.4% of cases were correctly classified
McNeil et al. <sup>42</sup>	Up to 175	Rating of improvement, LBPD pain medication, pain intensity, work status			No ( $t$ tests, $\chi^2$ )	Medication outcome: significant association with psychological disturbance using the PBSC ( $d \approx 0.403$ ) and the pain drawing ( $d \approx 0.384$ ), rated improvement by the patient; significant associations with psychological disturbance using both the BPCS ( $d \approx 0.358$ ) and the pain drawing ( $d \approx 0.351$ ); work status: a significant association with psychological disturbance using the BPCS ( $d \approx 0.340$ ) but not using the pain drawing classification ( $d \approx 0.045$ )	Patients were classified as disturbed or nondisturbed based on the BPCS classification (using pain work), and the pain drawing classification; $\chi^2$ analysis was done to look for an association between psychological disturbance and the various outcomes
Workplace Williams et al. <sup>66</sup>	82	Pain, disability, psychological distress	None as predictors	Ethnicity, orthopedic impairment, job satisfaction	Yes (hierarchical regression)		Psychological factors were an outcome and not a predictor
Epping Jordan et al. <sup>21</sup>	78	Pain intensity, disability	BDI	Age, income, ethnicity, pain intensity	Yes (hierarchical regression)	Six-month BDI predicted 12-month disability ( $d = 0.41$ ); 2-month BDI predicted 12-month pain ( $d = 0.55$ ) and 6-month disability ( $d = 0.38$ )	Covariates chosen did not correlate with all outcomes; therefore, nonsignificant predictors were forced into the model before psychological factors; BDI scores were blocked with other nonpsychological factors (e.g., pain intensity)
Wahlgren et al. <sup>63</sup>	76	Improved vs. nonimproved groups	DDS, SIP, BDI		Yes (MANOVA)		Did not look to predict improvement merely to validate a classification strategy based on psychological variables
Lehman et al. <sup>37</sup>	52–55	Return to work	Depression, job stress		No (correlation)	Depression ( $N = 52$ , $d = 0.345$ ) and job stress ( $N = 55$ , $r$ not reported) were not significantly related to return to work; job stress related to job termination ( $d = 0.61$ )	No Bonferroni correction used on the 435 correlations
Estlander et al. <sup>22</sup>	452	Pain vs. recovered	Depression, MSPQ	Age, subjective disability	Yes (blocked logistic regression)	MSPQ-n and Zung were significant predictors of persistent pain when entered in a block with age and subjective disability ( $d$ for block = 0.159); when entered alone, they were not	Subjective disability alone was a significant predictor ( $d = 0.232$ ) and so the significance of the block was due to this variable
Lancourt and Kettelhut <sup>66</sup>	161	Return to work	Coping, verbal magnification, sciatic tension, superficial palpitation	Personal history, family factors, employment characteristics, muscle atrophy, gait, SLR	Yes (discriminant analysis)	Coping ( $d = 0.478$ ), verbal magnification ( $d = 0.644$ ), and sciatic tension ( $d = 0.369$ ) significantly discriminated those who returned to work from those who didn't; superficial palpitation ( $d = 0.313$ ) did not; verbal magnification ( $d = 0.51$ , based on partial $r^2$ ), superficial palpitation ( $d = 0.36$ ), and sciatic tension ( $d = 0.85$ ) had relationships with short-term absence from work ( $\leq 6$ months)	None of the psychological factors had significant relationships with long-term absence from work ( $>6$ months)

SIP = Sickness Impact Profile; EPI = Eysenck Personality Inventory; STAI = State and Trait Anxiety Scale; MHLC = Multiple Health Locus of Control; SCID = Structured Clinical Interview; DDS = Descriptor Differential Scale; SIP = Sickness Impact Profile; DSM = Diagnostic Statistical Manual of Mental Disorders; SLR = straight leg raising.

\* Sample sizes (n) quoted in this table reflect the sample on which statistics relating to psychological factors are based. As such, these values may differ from the total sample sizes reported for the article (because of missing data).

† Only factors used in statistical analyses are listed.

‡ In many cases effect sizes were based on the probability values quoted for a given effect (by first converting to z-values using the table in Field, 2000).<sup>23</sup> Probability values are often rounded up and so the resulting effect sizes are only approximations and reflect a conservative estimate.

sion”); this was measured in six studies using an instrument specific to this population, in three studies using generic instruments, and in one study with a single item. Overall, 11 studies (61%) were considered acceptable in quality of psychological measurement tools.

The assessment of the quality of statistical analysis is given in Table 4. Unlike the previous tables, which group

studies based on the same population sample, the statistical coding was carried out separately for each study. This enabled the calculation of effect sizes for each analysis. Eleven studies provided acceptable statistical information on psychological variables as predictors of chronicity. This information is, however, based on heterogeneous instruments and outcomes, so pooling the

data in a metaanalysis would not be appropriate. In general, there was little consistency in how results were reported across the studies. In particular, the use of discriminate analysis was reported incompletely and, when multiple regression was used, the change in  $R^2$  associated with a particular predictor was not included. Logistic regression tended to be reported rather better, with odds ratios being the commonly quoted statistic.

So the various studies could be compared, effect sizes were computed when possible. In most cases, this was done using the various transformations listed by Rosenthal.<sup>47</sup> Cohen's effect-size statistic ( $d$ ) is measured in standard deviation units,<sup>12,13</sup> and the following arbitrary criteria are given for assessing the magnitude of effect:  $d = 0.2$  (small),  $d = 0.5$  (medium), and  $d = 0.8$  (large). In many cases, the studies provided insufficient detail to calculate these effect sizes.

Table 4 summarizes the statistical assessments. Several studies<sup>5,37,61</sup> did not take a multivariate approach to their analysis, so there was no control for known predictors and the unique relative contribution of psychological factors could not be determined. Some studies<sup>61,63,66</sup> did not identify a relevant outcome from psychological factors, thus limiting their power for prediction of chronicity. In other studies, psychological factors are either unspecified, combined to produce composite scores, or are entered into the model as part of a block in which statistics for the individual components are not calculated or quoted.<sup>10,21,22,35</sup> Several studies, though, did carry out multivariate analyses including demographic and physical variables being entered into the model first, two of which were based on large samples.<sup>11,19</sup>

### Summary of Main Findings

The major findings are based on the six studies that were rated as being of high or acceptable quality on the three main criteria. Methodologic weaknesses in two-thirds of the studies resulted in insufficient evidence being available for the assessment of numerous psychological variables. However, the findings from these studies are represented in the tables and do not contradict the main findings reported below.

### Psychological Distress/Depressive Mood

Because of the properties of measurement instruments used in the studies, it was not possible to differentiate satisfactorily between psychological distress, depressive symptoms, and depressive mood. The term "distress" is adopted in this review to represent a composite of these parameters. The most consistent finding was that distress is a significant predictor of unfavorable outcome, particularly in primary care; the evidence came from two high-quality and two acceptable studies.<sup>11,18,19,21,54</sup> Multivariate analyses in these studies demonstrated that this effect was independent of clinical factors, such as pain and function at baseline. The moderate effect size for distress was similar across these studies ( $d$  approximately 0.4, and odds ratio approximately 3). The combination of depressive symptoms and somatization (Distress and

Risk Assessment Method [DRAM]) was not found to predict clinical outcome in a multivariate analysis in the one acceptable study that studied it, though the depressive symptoms component did significantly discriminate between 'recovered' and 'nonrecovered' patients at 12 months.<sup>8</sup> The four other studies that examined distress had an unacceptable overall quality rating.

### Somatization

One high-quality study and one acceptable study found somatization scales to predict unfavorable outcome. However, they varied in their effect size, ranging from  $d = 0.2$ <sup>18</sup> to  $d = 0.6$ <sup>8</sup> for 1 year follow-up, and  $d = 0.9$  at two year follow-up.<sup>19</sup> The two other studies that examined somatization had an unacceptable overall quality rating.

### Personality

The Minnesota Multiphasic Personality Inventory (MMPI) subscale of hysteria was reported to be a predictor of return to work with an odds ratio of 1.5 in one acceptable study,<sup>25,26</sup> but this result was considered statistically unreliable. The two other studies that examined the MMPI had an unacceptable overall quality rating.

### Cognitive Factors

One acceptable study<sup>8</sup> found subscales from the Coping Strategies Questionnaire to be predictive of unfavorable outcome, where  $d = 1.09$  and  $1.88$  for praying/hoping and catastrophizing, respectively (the latter being related to acute patients). One study of acceptable quality found that fear avoidance was not retained in a multivariable model that included other psychological factors predictive of outcome.<sup>8</sup> The five other studies that examined cognitive factors had an unacceptable quality rating.

## Discussion

The role of psychosocial (as opposed to psychological) factors in the incidence of back pain and their influence on delayed return to work recently have been reviewed comprehensively.<sup>29,55</sup> Although the present review covered some of the same literature, the focus was quite different; it was specifically concerned with the role of psychological factors in the transition from acute presentation to chronicity in LBP. This focus dictated the criteria for determining acceptability of the reviewed studies (methodologic merit, psychological measurement, and statistical considerations).

The methodologic quality of the papers studied was highly variable. Only five studies succeeded in interviewing most of the patients at what can be considered an acute stage, which is essential for establishing a clear timeline between psychological factors at acute stages of LBP and the progression to chronicity. The remaining studies either included a mixture of acute and subchronic patients or recruited just subchronic patients, making their findings considerably more difficult to interpret and shedding only limited light on the primary question. The

recording of inclusion and exclusion criteria was especially variable. On the basis of the information available, though, it seems reasonable to conclude that these cohorts generally represented the heterogeneous group of patients labeled as nonspecific LBP (*i.e.*, they were without detectable pathology and may be considered as a “pain” population). Only 12 studies, most of which were carried out in the USA, achieved an acceptable follow-up rate. These, and the four studies that compared complete baseline data with those lost to follow-up, have the potential to offer useful information. Early recruitment appears to be coupled with high loss to follow-up. This might be related to the fact that many primary care patients consulting with a new onset of simple LBP do not consult again within 12 months<sup>14</sup>; they may be disinclined to return questionnaires about a problem they do not see as relevant to themselves some 12 months later. The high proportion of methodologically unacceptable studies (45%) highlights the danger of drawing conclusions from single reports in the literature.

A wide range of psychological domains was investigated, purportedly covering depression, distress, personality, and cognitive factors. Depression tended to be measured by instruments that evaluated depressive mood rather than clinical depression. They included the modified Zung scale, which was developed specifically for back pain populations. This instrument, when combined with the Modified Somatic Perception Questionnaire, forms the DRAM,<sup>41</sup> which has been shown to perform well in LBP populations. The Beck Depression Inventory<sup>2</sup> has also been used, but this measure was developed originally to measure depression in psychiatric and normal populations, and contains a subsection of somatic items. It is generally accepted that pain patients will tend to endorse the somatic items and inflate their overall score of depression.<sup>65</sup> Findings from studies using the Zung and DRAM can be considered reliable, but studies using the Beck Depression Inventory should be viewed with caution. Two studies utilized generic instruments to measure psychological distress. The General Health Questionnaire (GHQ), has been used widely and validated in clinical populations, and it has a 12-item version that discards somatic items. The Symptom Check List (SCL-90-R)<sup>16</sup> aims to provide a global distress score. Although it has shown poor psychometric properties when applied to pain populations,<sup>6,7,56</sup> it is considered acceptable as an independent subscale in back pain populations.<sup>3</sup> Information from the GHQ and SCL-90-R is useful, with the GHQ weighted higher because of its exclusion of somatic items and superior reliability and sensitivity.

Only one prospective cohort was found in which fear avoidance beliefs were measured directly. The Fear Avoidance Beliefs Questionnaire did not significantly predict outcome in a multivariate model, thus indicating that it does not contain unique predictive qualities independent of other psychological measures already entered into the model. Another study created a composite mea-

sure by adding scores on pain, disability, depression, and somatic perception, which was labeled “fear avoidance.” Although it emerged as a significant predictor of chronicity, it is psychometrically imprecise.

The measurement of cognitions included The Multidimensional Locus of Control<sup>64</sup> and the Coping Strategies Questionnaire.<sup>48</sup> Although these questionnaires are used extensively in the research of pain patients,<sup>57</sup> interpretation of the results is often difficult and the implications for intervention are sometimes obscure.<sup>30,32,66</sup> However, coping strategies were successfully measured in one study,<sup>8</sup> in which it was found that catastrophizing was a significant predictor with a large effect size in acute patients. Personality has been investigated with the MMPI but, because personality is generally considered a steady trait, it is hard to see the utility for interventions.<sup>1</sup>

Overall, psychological measurement in prospective cohorts could be improved by focusing on validated instruments measuring factors that are appropriate to LBP patients and amenable to clinical intervention. However, there are two areas of psychological risk that are surprisingly underrepresented in the current research: fear avoidance and catastrophizing. The limited use of measures of anxiety and fear is surprising because the concept of fear, whether applied specifically to activity or described as anxious mood, is currently a theoretical and research focus.<sup>59,62</sup> Although it is felt that pain-related fear and avoidance appear to be an essential feature of the development of chronicity, the support from prospective studies is currently sparse. However, there is emerging evidence from clinical trials that addressing fear avoidance can have a beneficial influence on outcomes.<sup>9,60</sup> Catastrophizing, broadly described as an exaggerated orientation towards pain stimuli and pain experience,<sup>51</sup> is considered to be a maladaptive coping mechanism. Theoretically, it is of great interest as a risk factor because it has been described as an explanatory construct for variations in pain and depression in chronic pain patients.<sup>31</sup> An overlap between catastrophizing and depression (or emotional distress) might explain why the effect size for catastrophizing was high in the one study that measured it, and why, once entered in the step-wise regression, distress did not appear to significantly predict long-term disability.<sup>8</sup> Unfortunately, the majority of research suggesting that catastrophizing ‘predicts’ disability and pain independently of depression is based on cross-sectional studies,<sup>52</sup> or is based on groups with different disorders. There is clearly a need for prospective studies to clarify the independent properties of the concept of catastrophizing from those that overlap with negative mood or distress.

In summary, distress and somatization are confirmed as having a role in the progression to chronicity in LBP. The role for other psychological factors (notably fear-avoidance beliefs and catastrophizing) was not confirmed by the available evidence, despite support for

their importance from elsewhere. The increasing emphasis on psychological factors in current guidelines,<sup>34,49</sup> which recommend their consideration at an early stage, is supported by these findings, although their recommendations may go a little beyond the current evidence. It is clear that, as yet, a comprehensive picture of the role of psychosocial factors is lacking, thus limiting the potential for optimally targeted interventions. Although there remains a need for further prospective studies to disentangle the various psychological parameters, such as fear avoidance and catastrophizing, there is nevertheless sufficient evidence to justify clinical trials of interventions that address those that are known (or strongly suspected) to be involved in the transition from acute presentation to chronicity in LBP (such as distress and somatization).

### ■ Conclusions

This systematic review of the literature has found evidence for the influence of certain psychological factors in the progression to chronicity in LBP, but the role of others remains uncertain.

There is strong evidence for the role of psychological distress/depressive mood in the transition from acute to chronic LBP. The effect size was moderate, but exceeded that of physical clinical factors measured in the same samples.

There is moderate evidence for the role of somatization, but the effect size was found to be variable.

The evidence for fear/anxiety is surprisingly scarce; the single acceptable study that included fear-avoidance found it had no significant predictive power when analyzed together with other parameters.

There is limited evidence for the role of cognitive factors, coming from just one acceptable study. Concepts such as coping strategies, with special emphasis on catastrophizing, appear to be more predictive than locus of control.

The evidence for the role of a dysfunctional personality is limited to one acceptable study showing an influence on work loss. The implications for interventions are at best questionable.

Overall, this review suggests that psychological factors play an important role in the transition to chronicity in LBP, and that they may contribute at least as much as clinical factors. The present authors believe that the findings constitute a strong indication for the development and testing of clinical interventions specifically targeting psychological distress/depressive mood and, arguably, somatization, but other parameters, such as fear avoidance and catastrophizing, deserve consideration. However, there remains a need for further research into those factors for which evidence is lacking. Such studies should be conducted on large samples, with careful selection of measurements and efforts to decrease loss to follow-up.

### ■ Key Points

- The evidence implicating psychological factors in the transition to chronicity in LBP has been reviewed systematically by examination of reports from prospective cohorts.
- The quality of evidence was found to be variable, thus limiting the information on numerous potentially important factors.
- Substantial evidence was established for the role of distress/depressive mood and, to a lesser extent, somatization.
- In view of their purported impact, other factors (particularly coping strategies and fear avoidance) deserve further investigation through rigorous prospective studies.

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### ■ Appendix

#### *Methodologic Criteria*

**Early Recruitment.** From a methodologic point of view it is essential to test baseline measurements as close as possible to the onset of a discrete episode to establish possible causal relationships. The criteria considered were: new episode, free from LBP in previous 12 months, and tested within 3 weeks of presentation. In studies in which more than 60% of the sample was interviewed within 3 weeks of onset, this criterion was deemed fulfilled.

**Exclusion and Inclusion Criteria.** Explicit and detailed inclusion and exclusion criteria are necessary to identify which population has been examined, and to enable elimination of, or control for, known confounding variables. To establish risk factors in the transition from acute to chronic LBP, inclusion criteria should state that the primary presentation was for LBP. Because subgrouping, focusing on presence/absence of radiation to the leg, has been considered relevant,<sup>58</sup> the presence of leg pain should be recorded and included in the analysis. Exclusion criteria should be recorded, and should include major pathologies, history of psychiatric disorder, previous spinal surgery, and pregnancy. Other practical exclusion criteria, such as illiteracy, should be stated.

**Drop-Out Rate.** A dropout rate of less than 20% has been suggested as appropriate, along with testing of baseline variables between groups with complete data and those lost to follow-up to reduce sample bias.<sup>50</sup> However, a dropout rate below 20% is particularly difficult to achieve in the sort of cohorts used in the identified studies, and disregarding evidence from these studies would reduce the data set considerably. More weight should, of

course, be given to studies that achieved low dropout rates. The evidence from studies with higher dropout rates was considered acceptable if comparisons of baseline variables did not reveal statistically significant (or substantial) differences between those subjects who completed the study and those who did not.

### Psychological Criteria

**Multiple Psychological Factors Measured at Baseline.** Because various psychological variables are highly correlated, there are theoretical advantages from testing more than one psychological factor, thus enhancing reliability and validity. Furthermore, with consideration for the complexity of human cognitive, emotional, and motivational factors, the present authors believed that more information would derive from the measurement of several psychological factors. This, in turn, may have implications for screening and intervention.

**Appropriate for Back Pain Population.** Psychometric instruments are often developed on a particular patient group, and may not be valid for other groups. The instruments used in the identified studies were checked as thoroughly as possible to determine whether they had been developed or revalidated in back pain populations, or in patients with physical illness in general. The availability of measures of reliability based on these populations was also considered, but the controversy in the current literature regarding commonly used instruments is such that the simpler rule of development or revalidation in pain/illness populations was adopted.

### Statistical Criteria

To assess the unique contribution of any one psychological factor beyond the known (or presumed) effects of other demographic or clinical risk factors, a multivariate analysis should be attempted. The analysis should be conducted hierarchically, with known (or presumed) predictors being entered into the model before the psychological factors are considered.<sup>23</sup> A second consideration relates to the degree to which the analysis informs about the transition from acute to chronic pain. To draw conclusions about predictors of this transition, the outcome variable in the analysis must relate, in some way, to the transition. This might be in the form of a categorical variable (movement from one category to another), a change along some relevant scale (e.g., disability or pain perception), or in terms of behavioral change (e.g., return to work). In summary, the statistical criteria include the following:

- Adjustment for known risk factors. Clinical factors, such as pain, disability, and radiation, together with demographic factors, such as age, sex, and job status (where applicable) should be entered into the multivariate analysis first.
- Multivariate analysis. Hierarchical or step-wise regression analysis or discriminant analysis, providing

full details of variability, adjustment, significant criterion, and numbers included.

- Sample size of more than 300. What constitutes an adequate sample size for modeling multivariate relationships between factors is not universally agreed, but a sample size of 300 has been described as “fair” and a sample size of 500 has been described as “good.”<sup>53</sup>

Some statistical advisors and researchers consider that an arbitrary criterion of 8 subjects for each predictor variable entered in the equation can be considered suitable, but the possibility of bias in smaller studies permits less confidence in the results of the analysis. Studies with more than 300 subjects were given a higher rating.

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