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ORIGINAL REPORT

VALIDITY, INTERNAL CONSISTENCY AND SELF-RATED CHANGE OF THE PATIENT ENABLEMENT INSTRUMENT IN PATIENTS WITH CHRONIC MUSCULOSKELETAL PAIN

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Objective: **Patient enablement reflects patient's understanding of and coping with illness. The aim of this study was to investigate the content validity, construct validity, internal consistency and self-rated change (SRC) of the Patient Enablement Instrument (PEI) in patients with whiplash-associated disorders, cervical radiculopathy and mixed chronic pain treated in different settings.**

Design: **Psychometric analyses.**

Participants: **Patients with disabling non-malignant chronic musculoskeletal pain.**

Methods: **Participants answered questionnaires on disability (Neck Disability Index (NDI) or Functional Rating Index (FRI)), anxiety/depression (*Hospital Anxiety* and Depression Scale; HADS) and general health (EuroQol; EQ-5D). Content validity, construct validity (confirmatory factor analysis), internal consistency and cut-off for SRC were investigated for the PEI after treatment. The SRC value was the receiver operating characteristic (ROC) curve optimal cut-off point.**

Results: **After treatment all items were completed by 516 patients (mean standard deviation (SD) age 45.1 years (SD 10.1), women 75% ($n = 385$)). The 1-factor PEI model had approximate fit to the data. The internal consistency Cronbach's alpha was between 0.878 and 0.929 for the 3 groups. Correlations between the PEI and the NDI/FRI, HADS and EQ-5D were fair to good. The SRCROC for whiplash-associated disorders, cervical radiculopathy and mixed chronic pain groups was 5, 6 and 4 points in the PEI, respectively.**

Conclusion: **The PEI showed fair content validity, construct validity and internal consistency. However, the scale needs further development to improve measurement of change.**

Key words: validity; reliability; primary care; whiplash injury; neck pain; chronic pain; outcome assessment.

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LAY ABSTRACT

Patient enablement reflects patients understanding of and coping with illness. This study investigated measurement properties and minimal important change in the Patient Enablement Instrument (PEI) in patients with whiplash-associated disorders, cervical radiculopathy and mixed chronic pain treated in different care settings. After treatment, all items were completed by 516 patients (mean age 45.1 years (standard deviation 10.1), women 75% ($n = 385$)). Fair measurement properties were found for the PEI for the included groups of patients, indicating that the PEI is suitable for use in patients with chronic musculoskeletal pain. The minimal important change in the PEI for whiplash-associated disorders, cervical radiculopathy and mixed chronic pain groups was 5, 6 and 4 points, respectively, indicating that a study-specific minimal important change should be applied. However, the cale needs further development to improve measurement of changes.

Patient enablement reflects the extent to which a patient can understand and cope with his or her illness (1, 2). The Patient Enablement Instrument (PEI) is a validated consultation outcome measure that was developed for use in primary care (3, 4). The instrument was subsequently used in a number of studies with different populations and settings (5–9), with some studies reporting its validity (3–6, 10, 11) and reliability (1, 3, 6, 10).

Outcomes after different treatment/rehabilitation efforts, especially in chronic pain, sometimes fail to affect traditional outcomes, such as pain and disability. It is important to empower patients and to have strategies to cooperate with and support patients in order to help them regain power over their own lives, accept their current status and future outlook, and help them achieve better health and reach their personal goals (12). Measuring patient enablement might be a valuable complement to a biopsychosocial approach in order to understand the goals of broad interventions for patients with chronic pain. In previously published studies we showed that patients who received specific

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intervention (see intervention description below) had greater enablement than patients in the control group (13, 14). This shows that enablement can mirror the results differently from traditionally used outcome measures. To our knowledge, no studies have investigated the measurement properties of the PEI for this group of patients.

The aim of the study was to investigate content validity, construct validity, internal consistency, and self-rated change (SRC) for the PEI in patients with chronic musculoskeletal pain treated in different settings. Our hypotheses were that the PEI is unidimensional, and that it has fair to moderate relationships with health-related measures, such as disability, mental and general health, and self-reported work ability.

MATERIALS AND METHODS

Design

The study included participants from 3 studies of chronic musculoskeletal disorders: a whiplash-associated disorders (WAD) group, a cervical radiculopathy (CR) group, and a mixed chronic pain (MixCP) group. For the WAD and the CR studies these were secondary analyses of multicentre, prospective, randomized controlled clinical trials (Clinical Trials.gov, number NCT01528579 and NCT01547611, respectively) (15, 16). For the MixCP study this was a prospective pragmatic cohort study. All 3 groups completed questionnaires at baseline. The WAD group completed follow-up questionnaires after a 3-month rehabilitation programme, the CR group 3 months after surgery, and the MixCP group after a 6–8 weeks rehabilitation programme.

Participants and settings

Whiplash-associated disorders group. Participants were recruited from primary care in 6 counties between February 2011 and May 2012. Participants were aged between 18 and 63 years, with whiplash injury grade 2 or 3 in the preceding 6–36 months, and had received neck-specific treatment. Detailed eligibility criteria have been published previously (15).

Cervical radiculopathy group. Participants were recruited from 3 spinal centres and were scheduled for surgery between January 2010 and December 2014. Participants were aged between 18 and 70 years with persistent CR symptoms and verified disc disease for at least 2 months on magnetic resonance imaging (MRI). Detailed eligibility criteria have been published previously (16).

Mixed chronic pain group. The study included consecutive patients aged 18–65 years with a referral for multimodal rehabilitation (MMR) between August 2010 and December 2012. All participants had disabling non-malignant chronic pain with a duration of at least 3 months that was due to musculoskeletal disorders (MSD; according to the ICD-10 (International Classification of Diseases) plus the potential for an active change in their lives. Participants were recruited from 6 healthcare centres in a County Council region in south-east Sweden. All participants were offered MMR by an interdisciplinary team.

Exclusion criteria for participants in all 3 study groups were severe psychiatric disorders, neurological diseases, drug abuse, or insufficient competence in the Swedish language.

Intervention

Whiplash-associated disorders group. For the current study participants who received neck-specific exercises with (NSEB) or without (NSE) a behavioural approach (pain management strategies and goal setting) were included (15, 17). Both groups received information about neck anatomy and the purpose of the exercises. The interventions lasted for 12 weeks and included exercise guided by a physiotherapist twice a week plus home exercises.

Cervical radiculopathy group. For the current study, the surgical procedure included anterior cervical decompression and fusion (ACDF) (14). Initial postoperative care at the spinal centre included advice about posture and ergonomics, information about movements and tasks to avoid, and mobility exercises for the shoulders. At 6 weeks the participants had a routine visit to the surgeon and received instructions about mobility exercises for the neck from a physiotherapist (14).

Mixed chronic pain group. The treatment consisted of an MMR programme based on a biopsychosocial model that considers the individual's somatic, psychological, environmental, and personal characteristics. MMR included, for example, pain education, physical exercise and cognitive behavioural therapy. The interdisciplinary rehabilitation team included different healthcare professions, e.g. an occupational therapist, physiotherapist, physician, psychologist, and social worker. Patient interaction in goal-setting was encouraged. The duration of the programme was 6–8 weeks. The treatment comprised group-based sessions complemented by individual treatment sessions or counselling, depending on the patient's needs. The sessions were held once or twice a week (range 7–17).

Assessment

The participant-reported questionnaires cover important outcome domains for the evaluation of chronic pain clinical trials, as recommended by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) (18), and are reported in Table I.

Patient enablement: main outcome in the current study. After the treatment period, the PEI was used to measure the patient's perceived change in ability to understand and cope with his or her health issues (4). A minor change was made to the introductory statement of the original PEI to make it more relevant to the specific study. Specifically, "As a result of your visit to the doctor today, do you feel you are …" was changed to "As a result of the treatment for your problem(s), do you feel you are …" followed by the original 6 items (see Table V). The PEI points for much better/much more is 2; better/more is 1; and same, less, or not applicable is 0. Thus, the total score is between 0 and 12 (4), and was calculated only for those participants who answered all 6 questions. A higher score indicates higher enablement. The validity and reliability of the PEI have been found to be acceptable (3, 4, 6, 10). The Swedish version of the PEI shows high internal consistency and moderate to good reliability for a single visit in primary care (19).

Perception of received care. Global perceived effect (GPE) was measured with the question "Compared with before treatment, how would you describe your complaint/problem now …?". For the WAD and CR studies the answer was rated on a 6-point scale that ranged from "complete recovery" to "much worse," and for the MixCP study on a 7-point scale that ranged from "very much improved" to "very much worsened".

Table I. Description of the background and outcome variables in the study groups

	WAD	CR	MixCP
Baseline characteristics			
Age, years	✓	✓	✓
Sex, men/women	✓	✓	✓
Body mass index (BMI): normal weight, BMI < 25; overweight, BMI 25 ≥ BMI < 30; obese, BMI ≥ 30.	✓	✓	✓
Country of origin: Sweden; other Scandinavian; non-Scandinavian	✓		✓
Living conditions: living alone; living with others (e.g. with wife/husband, children, parents, or other adults)	✓	✓	✓
Education: compulsory; high school; university/college; other	✓		✓
Working status: (self-)employed/student, part- or full time; Unemployed; Other	✓	✓	✓
Sick leave, No/Yes	✓	✓	✓
Worries about finances (4-point scale): often/quite often; seldom/not at all worried	✓		✓
Expectations for treatment (4-point scale): full recovery/some improvement; some relief/no expectations at all	✓	✓	✓
Probability of working within 6 months (7-point scale), dichotomized into: very large/large vs moderate to very small.	✓	✓	✓
Outcome measures			
Disability			
Neck Disability Index (NDI) (34). 10 items, each item was scored from 0 (no activity limitations) to 5 (major activity limitations). Transformed into 0–100%; 0%=no disability.	✓	✓	
Functional Rating Index (FRI) (35). 10 items, each item was scored from 0 (no activity limitations) to 4 (major activity limitations). Transformed into 0–100%; 0%=no disability.			✓
Mental health			
Pain Catastrophizing Scale (PCS) (36). Contains 13 items on 5-point scale (0 (not at all) to 4 (always); higher scores indicate higher catastrophizing.	✓		
Self-Efficacy Scale (SES) (37). Contains 20 items on 0–10 point scale (0=not confident at all, to 10=very confident to perform different activities) and generates a total score from 0-200.	✓	✓ (baseline)	
Coping Strategies Questionnaire (38). The catastrophizing subscale comprises 6 items that describe catastrophic thoughts. Total score 0-36, higher score signifies higher level of catastrophizing.		✓	
Hospital Anxiety and Depression Scale (HADS) [29, 30, 31]. 7 items for anxiety (HAD-A), 7 items for depression (HAD-D). Subscale scores range from 0 to 21: 0–7: non-case; 8–10 indicates a possible case; 11 or more indicates a definite case.	✓ (baseline)		✓
Health-Related Quality of Life (HRQoL)			
European Quality of Life instrument (EQ-5D) [32, 33], consists of 2 parts:	✓	✓	✓
1) The EQ-5D (3-L) contains 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.			
Each dimension has 3 levels: no problems, some problems, and extreme problems. The answers on the 5 dimensions are converted into a single EQ-5D index ranging from −0.594 to 1, where 1 indicates optimal health.			
2) The EQ VAS records the respondent's self-rated health on a vertical visual analogue scale that ranges from 0 ("worst possible health state") to 100 ("best possible health state").			
Self-reported current work ability was measured using the wording,	✓	✓	✓
"Current work ability compared with best," from the Work Ability Index (WAI) (39, 40). Score: 0 (completely unable to work) to 10 (best work ability).			

WAD: whiplash-associated disorders; CR: cervical radiculopathy; MixCP: mixed chronic pain.

Ethics

The ethics committee at the Faculty of Health Sciences at Linköping University, Linköping in Sweden approved the WAD study (Dnr 2010/1888-31 and 2011/262-32) (15) and the CR study (Dnr-M126-08 and M126-08 T99-09) (16). For the MixCP study the patients received treatment as usual and completed routine questionnaires for MMR. The questionnaires formed the basis for the Swedish Quality Registry for Pain rehabilitation in primary care (SQRP), which today is part of routine care in 39 rehabilitation/primary care clinics in Sweden. SQRP data is stored with the approval of the National Swedish Data Inspection Agency (permission number 1580-97). The study followed the ethical principles of the Declaration of Helsinki and Swedish law regarding the use of personal information (20, 21). Local health authorities approved the study design and protocol.

In all studies the participants were free to leave the study without explanation with no negative consequences on future treatment. Personal participant details were rendered anonymous before data-entry. There were no commercial interests connected to the studies. Informed written consent was obtained from all participants included in the studies.

Statistical analysis

Power calculation in the WAD (15) and CR (16) studies was performed for the original RCT studies to detect significant effects between treatments. In the current study the number of participants was higher than the proposed minimum requirements of 5 participants per included item to perform factor analysis (22) and sufficient to perform all comparisons

The Student's *t*-test, χ^2 test, and Fisher's exact test were used for within-group and between-group comparisons, as appropriate. Some important psychometric properties of PEI were investigated.

Content validity was investigated using the proportion of participants that had missing responses (23), and that gave "not applicable" responses based on the assumption that they perceived these items/questions not to be relevant (19). Differences were analysed with the χ^2 test.

Using MPlus version 8 (MPlus, Muthén & Muthén, Los Angeles, CA, USA), a confirmatory factor analysis (CFA) was conducted to test the one-factor measurement model of the 6-item PEI. Because of the Likert-type scale, where response categories range from "much better/much more" to "no change" the data were treated as ordered categorical when the model parameters were estimated in MPlus. The CFA was assessed for exact fit with the means and variance-adjusted weighted least squares (WLSMV) χ^2 and approximate fit with standardized root mean square residual (SRMR) according to the guidelines set out in 2018 by Asparouhov & Muthén (24). Specifically, exact fit was concluded if the χ^2 was not significant ($p > 0.05$). Otherwise approximate fit was concluded if the χ^2 test rejects the model ($p < 0.05$), but SRMR ≤ 0.08 and standardized residuals were small ($|r_{res}| < 0.10$ (25)).

Cronbach's alpha (26) was used to measure the internal consistency or internal reliability of the PEI. If 3 studies show Cronbach's alphas between 0.85 and 0.90 this indicates strong evidence for good internal consistency (27).

The relationships between the PEI and other measures were investigated with Spearman's rank correlation ($r_{Spearman}$), using the following coefficients: 0–0.25 none to little; 0.25–0.50 fair; 0.50–0.75 moderate to good; >0.75 very good to excellent (28).

The SRC was estimated by a measure integrating anchor- and distribution-based approaches. The SRC value is the optimal cut-off point of the receiver operating characteristic curve (SRC_{ROC}) (29). The GPE, dichotomized into importantly changed (very much or much improved) or not importantly changed (slightly improved, unchanged, or slightly worsened), was used as the external criterion (anchor). Six participants reported greater deterioration, and were excluded from further analyses, since this number was too small to determine the SRC for deterioration. The Spearman's correlation ($r_{Spearman}$) between the GPE and PEI was used to examine whether the anchor was adequate; a correlation coefficient of at least 0.5 has been recommended (27).

The distribution of the PEI for participants who were importantly improved or not (anchor) was described. The sensitivity and specificity were calculated to determine the ROC cut-off point for each PEI score. To construct the ROC curve, the combination of sensitivity and 1-specificity was plotted for each PEI score. The SRC_{ROC}, defined as the optimal cut-off point, is found on the ROC curve where the sum of the percentages of misclassified participants is lowest (29). Furthermore, positive predictive value (PPV) estimates the proportion of participants who actually had a high PEI score from the total number of participants classified as importantly improved. The negative predictive value (NPV) estimates the proportion of participants that actually had a low PEI score from the total number of participants that were not improved. Values of PPV and NPV that are close 1.00 suggest a higher probability of correctly classifying participants into improved/not improved. Statistical analyses were conducted using IBM SPSS, version 23. The level of significance was set at 0.05. No imputation for missing values was performed.

RESULTS

Participant characteristics

A total of 738 participants answered the questionnaire at the start of the treatment (not shown in Table II). A total of 159 subjects did not answer the questionnaire after treatment (WAD study $n=16$, CR study $n=25$, MixCP study $n=118$, of whom 30 did not complete the treatment, and for 88 participants the reason for non-completion was unknown).

A total of 579 participants answered the questionnaires after treatment and 516 participants completed the Neck Disability Index/Functional Rating Index (NDI/FRI), the GPE item "Compared with before treatment, how would you describe your problems now?", and all items of the PEI after treatment (Table II). Completers were less often living alone than non-completers ($n=108$ (20.9%) vs $n=63$ (28.9%), respectively, $p=0.020$). Completers were less often worried about their finances than non-completers ($n=217$ (54.8%) vs $n=114$ (65.9%), respectively, $p=0.014$). Otherwise there were no significant differences between the groups in participant characteristics (Table II). Completers had lower EuroQol visual analogue scale (EQ-VAS) scores than non-completers (mean (SD) 47.6 (21.0) vs 54.9 (20.9), respectively, $p=0.014$). There were no significant differences between the groups regarding self-reported NDI/FRI, EQ-5D index, Anxiety and Depression (Hospital Anxiety and Depression Scale; HADS), and current work ability.

For the participants who completed the NDI/FRI, the GPE, and all items of the PEI after treatment (Table II), the mean (SD) age was 45.1 (10.1) years, and 385

Table II. Baseline characteristics of the participants who completed the Neck Disability Index (NDI) or Functional Rating Index (FRI), the Global Perceived Effect (GPE), and all items of the Patient Enablement Instrument (PEI) after treatment

	All ($n=516$) *n* (%)	WAD ($n=116$) *n* (%)	CR ($n=115$) *n* (%)	MixCP ($n=285$) *n* (%)
Age, years, mean (SD)	45.1 (10.1)	39.8 (11.2)	48.9 (7.4)	45.7 (9.8)
Sex, women	385 (74.6)	81 (69.8)	67 (58.3)	237 (83.2)
BMI				
Overweight	192 (38.6)	41 (36.0)	54 (47.8)	97 (35.9)
Obese	126 (25.4)	22 (19.3)	23 (20.4)	81 (30.0)
Country of origin				
Sweden	–	105 (91.3)	–	204 (73.6)
Other Scandinavian	–	5 (4.3)	–	4 (1.4)
Non-Scandinavian	–	5 (4.3)	–	69 (24.9)
Living alone	108 (20.9)	26 (22.4)	24 (20.9)	58 (20.4)
Education				
Compulsory	–	7 (6.1)	–	66 (23.3)
High school	–	61 (53.0)	–	162 (57.2)
University/college	–	41 (35.7)	–	55 (19.4)
Other	–	6 (5.2)	–	–
Working status				
(Self-) employed/student, part- or full time	379 (73.9)	108 (93.1)	93 (81.6)	178 (62.9)
Unemployed	86 (16.8)	5 (4.3)	7 (6.1)	74 (26.1)
Other	48 (9.4)	3 (2.6)	14 (12.3)	31 (11.0)
Sick leave (yes) $n=116$, 109, 283	239 (47.0)	13 (12.9)	63 (57.8)	169 (59.7)
Worries about finances often/quite often	217 (54.8)	36 (31.9)	–	181 (64.0)
Expectations for treatment: full recovery/some improvement	356 (69.8)	83 (72.2)	109 (95.6)	164 (58.4)
Probability of working within 6 months: very large or large, $n=-$, 102, 163	208 (57.1)	–	91 (89.2)	117 (45.7)

Data are reported as numbers (percentages) unless stated otherwise.
WAD: whiplash-associated disorders; CR: cervical radiculopathy; MixCP: mixed chronic pain; SD: standard deviation; BMI: body mass index.

Table III. Change and outcome after treatment in self-reported health, work ability and Patient Enablement Instrument (PEI) in the participants who completed the Neck Disability Index (NDI) or Functional Rating Index (FRI), the Global Perceived Effect (GPE), and all items of the PEI after treatment

	All Mean (SD)	WAD Mean (SD)	CR Mean (SD)	MixCP Mean (SD)
Disability				
NDI or FRI baseline (1)	–	32.3 (12.9)	41.8 (14.4)	62.9 (17.6)
NDI or FRI after treatment (2)	–	27.4 (15.3)	28.3 (16.4)	59.5 (21.1)
NDI or FRI change (1–2)	–	–4.9 (10.6)	–13.5 (16.3)	–3.5 (15.7)
Mental health				
Anxiety (HADS) baseline	–	6.9 (4.6)	–	10.1 (5.0)
Anxiety (HADS) after treatment	–	–	–	9.1 (5.0)
Anxiety (HADS) change (1–2)	–	–	–	–0.9 (3.2)
Depression (HADS) baseline (1)	–	4.9 (4.1)	–	7.7 (4.3)
Depression (HADS) after treatment (2)	–	–	–	6.7 (4.2)
Depression (HADS) change (1–2)	–	–	–	–1.0 (3.1)
PCS baseline (1)	–	18.4 (11.1)	–	–
PCS after treatment (2)	–	14.3 (11.2)	–	–
PCS change (1–2)	–	–4.1 (9.3)	–	–
SES baseline (1)	–	153 (33)	129 (37)	–
SES after treatment (2)	–	160 (35)	–	–
SES change (1–2)	–	8 (25)	–	–
CSQ Catastrophising thoughts baseline (1)	–	–	14.6 (7.9)	–
CSQ Catastrophising thoughts after treatment (2)	–	–	8.3 (7.6)	–
CSQ Catastrophising thoughts change (1–2)	–	–	6.3 (9.0)	–
Health				
EQ-5D Index baseline (1)	0.365 (0.340)	0.595 (0.267)	0.412 (0.306)	0.252 (0.327)
EQ-5D Index after treatment (2)	0.486 (0.337)	0.681 (0.225)	0.647 (0.254)	0.344 (0.336)
EQ-5D Index change (1–2)	0.121 (0.284)	0.088 (0.237)	0.234 (0.327)	0.092 (0.274)
EQ VAS baseline (1)	48 (21)	62 (18)	47 (21)	42 (19)
EQ VAS after treatment (2)	57 (23)	67 (19)	69 (21)	48 (21)
EQ VAS change (1–2)	9 (223	5.3 (20)	21 (27)	6 (18)
Self-reported current work ability at baseline (1)	4.4 (2.8)	7.0 (2.1)	4.0 (2.8)	3.6 (2.5)
Self-reported current work ability after treatment (2)	–	7.3 (2.0)	–	4.2 (2.5)
Self-reported current work ability change (1–2)	–	0.3 (1.8)	–	0.6 (1.9)

NDI: 0–100%, FRI: 0–100%, higher value indicates higher disability. WAD: whiplash-associated disorders; CR: cervical radiculopathy; MixCP: mixed chronic pain; HADS: Hospital Anxiety and Depression Scale; PCS: Pain Catastrophizing Scale; SES: Self-Efficacy Scale; CSQ: Coping Strategies Questionnaire; EQ-5D: European Quality of Life 5 Dimensions; VAS: visual analogue scale; SD: standard deviation.

(74.6%) were women. Fifty-five percent of subjects were often or quite often worried about their financial situation, and 49% were on sick leave. Of the participants, 62% reported a small to large improvement in their problems after treatment, 30% reported that their condition had not changed, and 8% reported that they had more problems than before treatment.

The participants improved significantly between baseline vs after treatment in function (FRI), anxiety and depression (HADS), general health (EQ-5D Index and VAS) and self-reported work ability (Table III, all $p<0.001$). For the WAD, CR and MixCP groups the median PEI was 4, 6 and 3, respectively.

Patient Enablement Instrument

Content validity. Most participants did not use the response "not applicable". For all participants, between 5 and 22 (0.9–3.8%) gave a "not applicable" response to at least 1 of the 6 PEI questions. The question most commonly characterized as being not applicable was "able to keep yourself healthy" (Table IV).

For all participants, 6.9% ($n=40/579$) did not answer at least one of the 6 PEI questions, and question 4 "able to keep yourself healthy" had the highest percentage of missing answers (4.7%, $n=27$, Table IV). The highest and lowest missing values were found in question

Table IV. Number of respondents (percentage) in the different studies after treatment who said the Patient Enablement Instrument (PEI) questions were not applicable and missing values

	All $n=579$		WAD $n=131$		CR $n=137$		MixCP $n=311$	
	Not applicable *n* (%)	Missing *n* (%)	Not applicable *n* (%)	Missing *n* (%)	Not applicable *n* (%)	Missing *n* (%)	Not applicable *n* (%)	Missing *n* (%)
Able to cope with life	6 (1.0)	22 (3.8)	4 (3.1)	5 (3.8)	7 (5.1)	7 (5.1)	2 (0.6)	10 (3.2)
Able to understand your illness	10 (1.7)	26 (4.5)	2 (1.5)	7 (5.3)	5 (3.6)	11 (8.0)	3 (1.0)	8 (2.6)
Able to cope with your illness	8 (1.4)	21 (3.6)	1 (0.8)	7 (5.3)	6 (4.4)	6 (4.4)	1 (0.3)	8 (2.6)
Able to keep yourself healthy	22 (3.8)	27 (4.7)	5 (3.8)	7 (5.3)	9 (6.6)	10 (7.3)	8 (2.6)	10 (3.2)
Confident about your health	5 (0.9)	21 (3.6)	1 (0.8)	8 (6.3)	0 (0.0)	6 (4.4)	4 (1.3)	7 (2.3)
Able to help yourself	9 (1.6)	23 (4.0)	1 (0.8)	8 (6.3)	5 (3.6)	9 (6.6)	3 (1.0)	6 (1.9)

WAD: whiplash-associated disorders; CR: cervical radiculopathy; MixCP: mixed chronic pain.

Table V. Confirmatory factor analysis, including all items of the Patient Enablement Instrument (PEI) for all groups

	All ($n=516$) Factor 1	WAD ($n=116$) Factor 1	CR ($n=115$) Factor 1	MixCP ($n=285$) Factor 1
χ^2 test of model fit	64.309	16.856	42.002	37.057
Degrees of freedom (df)	(9)	(9)	(9)	(9)
p-value	<0.001	0.051	<0.001	<0.001
SRMR	0.027	0.031	0.038	0.038
Residual correlations	<0.1	<0.1[a]	<0.1	<0.1[b]
Standardized factor loadings				
PEI1, able to cope with life	0.870	0.813	0.889	0.892
PEI2, able to understand your illness	0.788	0.706	0.855	0.752
PEI3, able to cope with your illness	0.916	0.924	0.932	0.879
PEI4, able to keep yourself healthy	0.880	0.804	0.905	0.891
PEI5, confident about your health	0.895	0.907	0.927	0.821
PEI6, able to help yourself	0.882	0.927	0.907	0.882

[a]Residual correlation PEI2 – PEI4 = 0.128, [b]residual correlation PEI3 – PEI5 = 0.100. WAD: whiplash-associated disorders; CR: cervical radiculopathy; MixCP: mixed chronic pain; SRMR: standardized root mean square residual.

2 "able to understand your illness" (CR group, 8%, $n=11$) and question 6 "able to help yourself" (MixCP group, 1.9%, $n=6$), respectively.

Construct validity. Results showed the 1-factor PEI model had approximate fit to the data for all 4 groups, with (all) χ^2 (9)=64.309, $p<0.001$, SRMR=0.027, (WAD) χ^2 (9)=16.856, $p=0.051$, SRMR=0.031, (CR) χ^2 (9)=42.002, $p<0.001$, SRMR=0.038, and (MixCP) χ^2 (9)=37.057, $p<0.001$, SRMR=0.038, respectively (Table V). Furthermore, all standardized residual correlations were small (<0.10). However, in the WAD group 1 residual correlation was at 0.12 and in the MixCP group 1 residual correlation was at 0.10, but can be considered small. Standardized factor pattern loadings ranged from 0.706 to 0.932.

Internal consistency. For all participants the PEI ($n=516$) had a Cronbach's alpha of 0.907. In the WAD, the CR and the MixCP group the Cronbach's alpha was 0.890, 0.929 and 0.878, respectively.

Correlations between Patient Enablement Instrument and other measures

For all participants the correlations between PEI score and health (EQ-5D Index and EQ VAS) after treatment were moderate ($r_{Sp}=0.507–0.581$, Table VI). For the CR group the correlation between the PEI score and

Table VI. Correlations between the Patient Enablement Instrument (PEI) score after treatment with self-reported health after treatment and changes from baseline to after treatment

	Patient Enablement Instrument							
	All ($n=485–504$)		WAD ($n=113–116$)		CR ($n=108–115$)		MixCP ($n=262–276$)	
Variables	r_{Sp}	*p*-value	r_{Sp}	*p*-value	r_{Sp}	*p*-value	r_{Sp}	*p*-value
Baseline								
Age, years	0.037	0.413	0.126	0.177	–0.082	0.383	0.016	0.795
Sex (men, women)	–0.012	0.790	0.108	0.247	0.035	0.712	0.090	0.135
BMI	–0.070	0.790	0.035	0.713	–0.162	0.087	–0.054	0.382
Country of birth (Sweden, Scandinavian country outside Sweden, non-Scandinavian country)	–	–	0.069	0.464	–	–	–0.103	0.090
Level of education (Compulsory, High school, University/college)	–	–	0.039	0.690	–	–	0.099	0.100
Living alone (yes, no)	–0.022	0.627	–0.172	0.064	–0.053	0.574	0.062	0.304
Disability (NDI or FRI)								
After treatment	–	–	–0.387	<0.001	–0.579	<0.001	–0.383	<0.001
Change from baseline to after treatment	–	–	–0.452	<0.001	–0.554	<0.001	–0.274	<0.001
Anxiety (HADS)								
After treatment	–	–	–	–	–	–	–0.276	<0.001
Change from baseline to after treatment	–	–	–	–	–	–	–0.286	<0.001
Depression (HADS)								
After treatment	–	–	–	–	–	–	–0.335	<0.001
Change from baseline to after treatment	–	–	–	–	–	–	–0.293	<0.001
PCS								
After treatment	–	–	–0.332	<0.001	–	–	–	–
Change from baseline to after treatment	–	–	–0.353	<0.001	–	–	–	–
SES								
After treatment	–	–	0.250	0.008	–	–	–	–
Change from baseline to after treatment	–	–	0.260	0.005	–	–	–	–
CSQ Catastrophizing								
After treatment	–	–	–	–	0.552	<0.001	–	–
Change from baseline to after treatment	–	–	–	–	0.388	<0.001	–	-
EQ-5D index								
After treatment	0.505	<0.001	0.252	0.007	0.543	<0.001	0.432	<0.001
Change from baseline to after treatment	–0.248	<0.001	0.137	0.065	0.209	0.030	0.200	0.001
EQ VAS								
After treatment	0.576	<0.001	0.403	<0.001	0.618	<0.001	0.530	<0.001
Change from baseline to after treatment	0.490	<0.001	0.297	0.001	0.494	<0.001	0.384	<0.001
Self-reported current work ability								
After treatment ($n=103$, 275)	–	–	0.201	0.040	–	–	0.356	<0.001
Change from baseline to after Treatment ($n=93$; 273)	–	–	0.201	0.053	–	–	0.167	0.006

WAD: whiplash-associated disorders; CR: cervical radiculopathy; MixCP: mixed chronic pain; NDI: Neck Disability Index; FRI: Functional Rating Index; HADS: Hospital Anxiety and Depression Scale; EQ-5D: European Quality of Life-5 Dimensions; VAS: visual analogue scale; rSp: Spearman's rho.

Table VII. Patient Enablement Instrument (PEI) median and interquartile range (IQR) scores of participants with chronic pain based on their answers on the Global Perceived Effect (GPE) (anchor)

	Patient Enablement Instrument							
	All participants		WAD		CR		MixCP	
Global perceived effect	*n* = 516 (%)	Median (IQR)	*n* = 116 (%)	Median (IQR)	*n* = 115 (%)	Median (IQR)	*n* = 285 (%)	Median (IQR)
Very much improved/ Completely recovered	14 (2.7)	11 (9–12)	1 (0.9)	11 (11–11)	9 (7.8)	12 (9–12)	4 (1.4)	9 (9–10)
Much improved	105 (20.3)	7 (6–9)	21 (18.1)	8 (6–11)	51 (44.3)	7 (6–10)	33 (11.6)	6 (6–7)
Improved	200 (38.8)	4 (2–6)	55 (47.4)	5 (3–6)	44 (38.3)	4 (2–6)	101 (35.4)	4 (2–6)
Unchanged	154 (29.8)	1 (0–3)	31 (26.7)	2 (1–3)	4 (3.5)	0 (0–2)	119 (41.8)	1 (0–3)
Worsened	31 (6.0)	0 (0–2)	8 (6.9)	0 (0–1)	4 (3.5)	0 (0–1)	19 (6.7)	1 (0–3)
Much worsened	10 (1.9)	0 (0–2)	0 (0.0)		3 (2.6)	0 (0–0)	7 (2.5)	1 (0–3)
Very much worsened	2 (0.4)	1 (0–1)					2 (0.7)	1 (0–1)

IQR: interquartile range; WAD: whiplash-associated disorders; CR: cervical radiculopathy; MixCP: mixed chronic pain.

CSQ catastrophizing after treatment was moderate (r_{Sp}=0.552). All other correlations between PEI and self-reported measures were fair (r_{Sp}=–0.250–0.380), except for none to little correlations between PEI score and the change between baseline and after treatment in the EQ-5D Index and self-reported work ability. In all groups the correlations between PEI score and socio-demographic variables at baseline were none to little.

Self-rated change

All the 516 participants included in the factor analysis had complete data for the PEI and GPE scores. The correlation between the PEI and GPE was good (r_{Sp}=–0.69, p<0.001, Table VII). Ten participants reported a large deterioration and 2 participants a very large deterioration; they were excluded from further analyses, since this number was too small to determine the SRC for deterioration (29). For the WAD, CR and MixCP groups the correlations between the PEI and GPE were r_{Sp}=–0.72, –0.70 and –0.60, respectively.

The SRC_{ROC}, defined as the most optimal ROC cut-off point, was found at a PEI score of 5 points for all participants, and had a sensitivity of 85% and a specificity of 82% (see Figs 1a–d). These findings correspond to a misclassification of 33% of the participants. The positive predictive value (PPV) was 59% and the negative predictive value (NPV) was 95%. The overall model quality was 0.87.

For the WAD group, the SRC_{ROC} was found at a PEI score of 5 points and had a sensitivity of 96% and a specificity of 75%, corresponding to a misclassification of 30% of the participants. The PPV was 47% and the NPV was 99%. The overall model quality was 0.86. For the CR group, the SRC_{ROC} was found at a PEI score of 6 points and had a sensitivity of 85% and a specificity of 69%. These findings correspond to a misclassification of 43% of the participants. The PPV was 76% and the NPV was 80%. The overall model quality was 0.79. For the MixCP group, the SRC_{ROC} was found at a PEI score of 4 points and had a sensitivity of 89% and a specificity of 77%, corresponding to a misclassification of 32% of the participants. The PPV was 40% and the NPV was 98%. The overall model quality was 0.86.

DISCUSSION

The results of this study suggest that the PEI demonstrates fair measurement properties (content validity, construct validity, and internal consistency) in participants with chronic musculoskeletal pain treated in different settings. Higher patient enablement scores were related to better health after treatment and to positive changes in health between baseline and after treatment. The PEI may be a valid outcome measure for use in the long-term management of participants with chronic musculoskeletal pain, although the instrument may need further development (see below).

Content validity of the Patient Enablement Instrument

Only a few patients did not complete the questionnaire, or found the PEI questions "not applicable", suggesting that most patients considered the questions relevant to their condition. This contrasted with another Swedish study in which many patients (39%) consulting a general practitioner (GP) in primary care characterized at least 1 of the questions as not applicable (19). A large study performed in primary care in England (30) found that a larger percentage of patients with longstanding illnesses (53.6% vs 46.0%), or above-average consultation rates (31.1% vs 24.8%) completed the PEI. It is possible that patients who received an intervention over time find the PEI questions more relevant compared with those who completed the questionnaire after consultation with a GP.

Construct validity of the Patient Enablement Instrument

CFA showed the 1-factor PEI model had approximate fit to the data for all 4 groups, with all SRMR values <0.08, and standardized residual correlations were

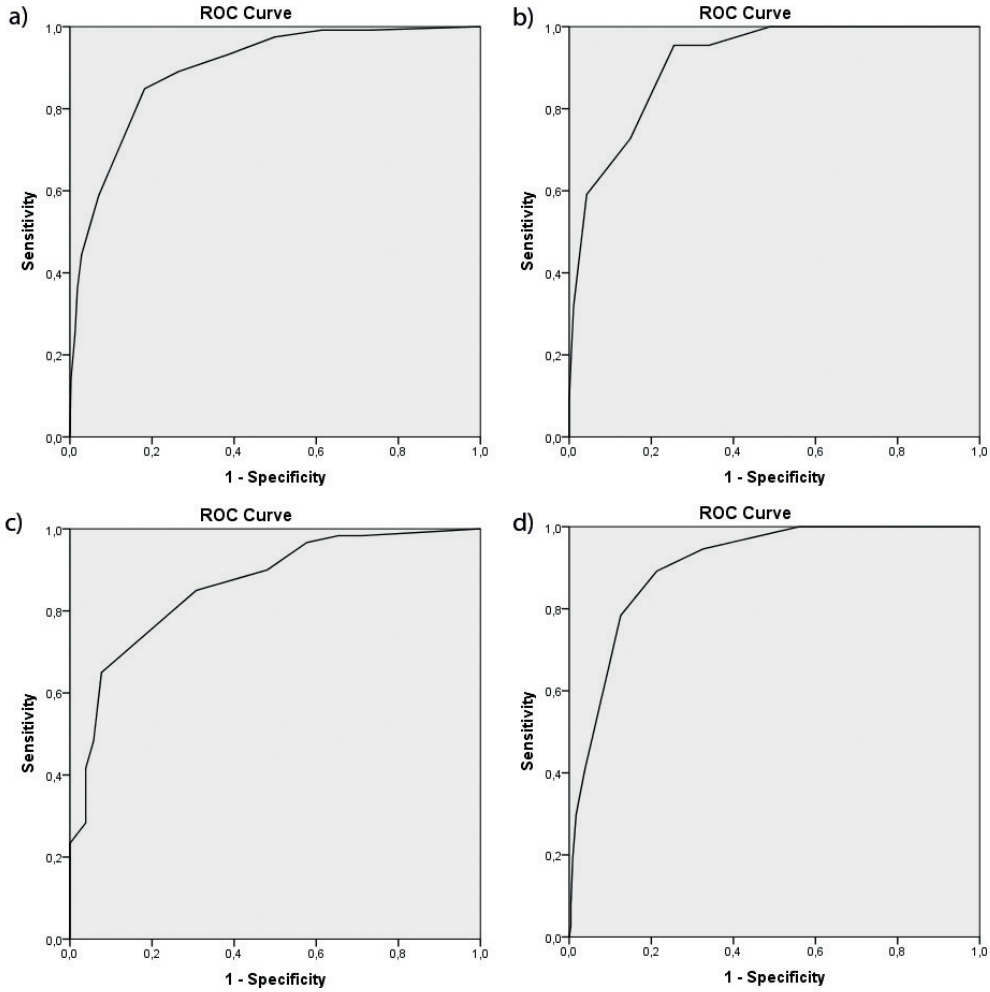

Fig. 1. Receiver operating characteristic (ROC) curve for different cut-off points for the Patient Enablement Instrument (PEI) in different groups. (a) All participants, $n = 504$, area under the curve (AUC) 0.897 (95% confidence interval (95%CI) 0.867–0.928). (b) Whiplash-associated disorders (WAD) group ($n = 116$), AUC 0.914 (CI 0.858–0.970). (c) Cervical radiculopathy (CR) group, $n = 112$, AUC 0.862 (CI 0.794–0.929). (d) Mixed chronic pain (MixCP) group, $n = 276$, AUC 0.914 (CI 0.858–0.970).

small (<0.10, with 2 exceptions that were close to 0.10) (24). This supports the internal construct validity of the PEI. The original authors investigated the construct validity by adding 3 items to the instrument and found the construct validity of the original 6 items to be satisfactory (3). To our knowledge, only 1 study, conducted in Japanese patients with chronic illnesses, found that the PEI consisted of 2 principal factors (6). The first factor comprised questions 1–4, and the second factor comprised questions 5 and 6. However, other studies using factor analysis support the finding that the PEI is unidimensional (10, 11).

Internal consistency of the Patient Enablement Instrument

Cronbach's alpha coefficient for the PEI varied between 0.878 and 0.907, indicating good internal consistency (27). For the original PEI, Cronbach's alpha coefficient was 0.925, and it decreased each time an item from 2 different satisfaction scales was added or when any of the 6 PEI items was removed. This suggests that the 6 original PEI items comprise a unified group of questions that differ from other concepts, such as patient satisfaction (3, 4). Other studies conducted in primary care found Cronbach's alpha values between 0.86 and 0.93 (2, 6, 10, 19), while studies with a PEI that was modified to fit patients with asthma reported values between 0.87 and 0.92 (5, 11), all within suggested alpha limits (27).

Relationship between the Patient Enablement Instrument and other measures

As hypothesized, higher PEI score showed a fair to moderate relationship with better function and mental and general health in all groups with chronic pain after treatment (Table VI). Furthermore, a higher PEI

score was related to a positive change in complaints compared with baseline. Haughney et al. (5) found a fair correlation (0.30) between higher enablement and improvement in asthma-related quality of life after treatment. Ožvačić Adžić et al. (31) found an association between low enablement and poor self-perceived health in patients consulting a GP. These results suggest that a higher PEI score may be related both to better current health and improvement in health over time.

Self-rated change

The SRC of a measure depends on several factors, such as the patient group being studied and the method used to calculate the measure (27). In this study the SRC in perceived enablement for the WAD, CR and MixCP groups were 5, 6 and 4, respectively, illustrating that the SRC may be different for different groups. In patients in primary care, a PEI score ≥ 6 was reported to indicate clinically meaningful "enablement" (32). However, this was an arbitrary judgement by the original authors (3).

Although overall model quality was acceptable; for example, in the model with all participants approximately one-third were misclassified. The GPE, a more generic measure of health effects, correlated moderately with the PEI, justifying its use as an anchor. Furthermore, the PEI was correlated with change in health and disability measures, as well as with the GPE. The PEI had high sensitivity and specificity, but low PPV. As the PPV depends on prevalence this may partly have stemmed from a low proportion of patients who improved (23.6%, $n=119$) compared with those who did not (76.4%, $n=385$). In summary, we suggest a study-specific self-rated important change should be applied. Since it may not be realistic to determine the cut-off for every new population, a score of at least 4 on the PEI is recommended for important self-rated change in perceived enablement in patients with chronic pain. However, due to participant misclassification the instrument must be administered with caution as it may be overly sensitive.

Strengths and weaknesses

The relatively large number of patients included from different healthcare centres, with different chronic musculoskeletal conditions, and treated with different interventions, is a strength of this study, as this might enhance the generalizability of the results. It is also a strength to have a relatively large number of patients in the context of the planned statistical analyses.

In the WAD and MixCP groups the proportion of women was high, making the results less generalizable to men. In the MixCP group a considerable number of patients did not complete the self-reported questionnaire after the treatment period. One reason for this was that a number of patients never finished the treatment, either because they stopped participating in treatment or because the rehabilitation team found a different treatment to be more appropriate. Another reason for this was administrative issues, since the staff was not very experienced in administration of the questionnaires. There were only a few differences between those who did vs did not complete the questionnaires, which might indicate that there was no significant selection bias. However, a better response rate would be preferable.

The PEI measures *change* in enablement, which might be considered a limitation or weakness of the instrument. Patients with less experience and knowledge of their disease might be more likely to improve in enablement (i.e. to have higher PEI scores) than patients who have experienced problems for a longer period of time. In addition, patients might be satisfied with their treatment even if there was no improvement in enablement (13). Another issue is that, since the PEI measures change in enablement, it is not known how "enabled" the patient actually is. Traditionally, the measurement of, for example, the minimal important change is based on the difference between 2 measurements. It is important to mention that in this study the self-rated change is based on 1 measurement with the PEI. It is considered important to investigate responsiveness as a measurement property. Responsiveness is defined as "the ability of an instrument to detect change over time in the construct to be measured." However, the PEI is aimed to measure self-rated change; therefore, assessment of responsiveness was judged not to be appropriate. Further development of the instrument measuring current patient enablement at different time-points might improve the possibility to measure responsiveness. For this, it would also be better to use response options with a larger range (e.g. 0–10) instead of the current limited response options 0–2, leaving little room for change.

A recent publication (33) recommends 10 criteria for evaluating the content validity of patient-reported outcome measures, asking about the relevance, comprehensiveness and comprehensibility of the items, response options, and instructions. This paper investigated only parts of these criteria. The PEI was not originally developed for use in patients with chronic musculoskeletal pain, and further assessment of the content validity is recommended (27, 33).

In conclusion, the PEI showed fair content validity, construct validity, and internal consistency in individual patients with chronic musculoskeletal pain. The estimated SRC values could be used to indicate relevant changes in patient enablement in clinical practice and to guide interpretation of the results of

specific treatments. A study-specific self-rated important change should be applied. Further studies on the meaning of enablement in patients with chronic pain and construction of the PEI are recommended.

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