Original Article

Clinical Prediction for Non-Specific Low Back Pain Who Responded to Specific-Direction Exercises: A Development and Validation

Karoonsupcharoen O, MSc[1], Pattaraarchachai J, ScD[2], Wealusuwan N, MSc[3], Viriyatharakij N, PhD[1]

[1] Department of Physical Therapy, Faculty of Physical Therapy, Srinakharinwirot University, Nakhon Nayok Thailand

[2] Chulabhorn International College of Medicine, Thammasat University, Pathum Thani, Thailand

[3] Physical Medicine and Rehabilitation, Lerdsin Hospital, Bangkok, Thailand

Background: Clinical prediction rules (CPRs) are tools that classify the specific characteristics of patients who improve outcome from specific treatments. The specific-direction exercises are useful for non-specific low back pain (NSLBP) patients, but the predictors of CPRs are still limit.

Objective: To develop and validate CPRs for predicting improvement of outcome of specific-direction exercise in NSLBP.

Materials and Methods: Participant with NSLBP, aged 18 to 65 years, who showed the characteristic of centralization (CEN) or directional preference (DP) in mechanical diagnosis were recruited. The efficacy of specific-direction exercise compared with standard physical therapy within four weeks was first verified. Improvement of the Numeric Pain Scale (NPS) score by at least two points and improvement of the Thai version of the Modified Oswestry Low Back Pain Disability Questionnaire (Thai ODQ) score by at least 20% to 30% were examined. Then, four clinical predictors including current onset of NSLBP, pain area, pain characteristics, and Fear Avoidance Beliefs Questionnaire (FABQ) score were tested for the ability to predict improved outcomes of specific-direction exercise in development and validation phase of CPRs.

Results: NSLBP onset at less than six weeks and physical ability score of 14 points or less FABQ were significant predictors of the cumulative effect of specific-direction exercise, which increased the probability to improve the Thai ODQ score by 20% from baseline from 44.6% to 89.6%. NSLBP onset at less than six weeks was the only predictor that increased the probability of improving the Thai ODQ score by 30% from baseline from 45.2% to 71.9%.

Conclusion: NSLBP onset at less than six weeks and physical ability score of 14 points or less FABQ were predictors of improved disability outcome within four weeks of specific-direction exercise that were supported by the validation phase of CPRs.

Keywords: Clinical prediction rule, Treatment outcome, Mechanical diagnosis and treatment, Specific-direction exercise, Low back pain, Physical Therapy

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Clinical prediction rules (CPRs) are evidence-based tools that combine specific clinical predictors (CPs) to assist the clinician in making decisions for diagnosis, prognosis, and treatment[1,2]. Randomized controlled trial (RCT) is the recommended study design for the development of CPRs for detecting the efficacy of the treatment and identify the CPs associated with outcome improvement[3].

The most common type of back pain is non-specific low back pain (NSLBP), which shows variable symptoms and has a difficult-to-define cause. Therefore, the aim of CPRs is to decrease the variability by matching between subgroup of patients and specific treatment[1]. Specific-direction exercise is one of four specific treatments in the Treatment-Based Classification (TBC) system. TBC was developed by Delitto et al in 1995[4] for treating patients with acute NSLBP. Specific-direction exercise

Correspondence to:

Viriyatharakij N.

Department of Physical Therapy, Faculty of Physical Therapy, Srinakharinwirot University, Rangsit-Nakhon Nayok Road, Ongkharak, Nakhon Nayok 26120, Thailand.

Phone: +66-2-6495000 ext. 27309, **Fax**: +66-37-395438

Email: nitayav@g.swu.ac.th

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is based on the concept of Mechanical Diagnosis and Treatment (MDT)[5], which divides LBP into postural, dysfunction, and derangement syndromes. The efficacy of specific-direction exercise in reducing pain and disability has been shown to be better than that of other treatments for LBP[6,7]. In the decision flow of TBC[8], only centralization (CEN) and directional preference (DP)[9,10] were specified as validated CPs for specific-direction exercise. The current onset[9,11], pain area[9,12], and pain characteristics (intermittent or constant)[12,13] were mentioned as CPs in the derivation phase of CPRs. In the context of MDT, current onset met the requirement as a CP in solving LBP in the acute phase[4]. Pain area represented clinical symptoms found in postural, dysfunction, and derangement syndromes[5]. In addition, the Fear Avoidance Beliefs Questionnaire (FABQ) was demonstrated as a prognostic factor[14]. As self-treatment is a core concept of MDT[5], the FABQ score reflected the participant's compliance to specific-direction exercise and improvement from disability[15]. Defining CPs is the first process in developing CPRs. The validity of each CP and the cumulative effect of all CPs must be clearly analysed for accurate predictive probability through a multivariate analysis in a cohort study. The development of CPRs from validated CPs will allow generalisability in clinical practice.

The present study aimed to develop and to validate the ability of four CPs, including current onset, pain area, pain characteristics, and FABQ score, in predicting the outcome of the specific-direction exercise.

Materials and Methods

Study design

RCT with participant-blinded allocation and prospective cohort study (winner design) were study designs used in CPRs development and validation, respectively.

Study population

Participants were recruited from three physical therapy departments of government hospitals in Thailand between July 2015 and May 2017. Persons with NSLBP, aged between 18 and 65 years, and with the characteristic of CEN or DP were included in the study. Participants with specific LBP or other problems that limited the assessment and treatment procedures of MDT were excluded.

Definition of centralization (CEN) and directional preference (DP)

Definition of CEN is the spinal or referred pain that responds to the position or movement test by eliminating or changing the pain location from distal to proximal. Definition of DP is movement direction that can decrease pain or increase the range of motion without changing the location[5,13].

Procedure

Clinical prediction rules development: The RCT was performed to confirm the efficacy of specific-direction exercise. Then, the CPs related to improving outcomes of specific-direction exercise were verified.

Eligible participants signed the consent forms and were randomly allocated to receive either specific-direction exercise or standard physical therapy. All participants were blinded to their allocation.

The nine physical therapists (PTs) involved in the present study had clinical experiences of at least three years. One PT (Karoonsupcharoen O) managed the specific-direction exercise for the intervention group. The other eight PTs performed the standard physical therapy for the control group.

A standardised physical examination according to the original method reported by McKenzie and May in 2003[5] was conducted by a PT (Karoonsupcharoen O). Then, all participants completed a survey for collecting demographic information and four self-reporting instruments, which were 1) body diagram[16] for localised pain area, 2) Numeric Pain Scale (NPS, 0 to 10) for pain intensity, 3) Thai version of the Modified Oswestry Low Back Pain Disability Questionnaire (Thai ODQ, 0 to 100)[17] for the disability of LBP, and 4) Thai version of the Fear-Avoidance Beliefs Questionnaire (Thai FABQ)[18] for the level of fear of pain and beliefs about the need to change behaviour to avoid pain in persons with LBP[19,20]. The Thai FABQ was composed of a physical activity subscale and a work subscale.

Intervention

Specific-direction exercise (intervention group): The application of the specific-direction exercise and postural adjustment were conducted by one PT (Karoonsupcharoen O) following two steps. First, the PT (Karoonsupcharoen O) assigned the specific direction of treatment for each participant based on the direction of trunk movement or trunk posture shown in the characteristic of CEN or DP. The intensity of the exercise was assigned at 10 times per set and five sets daily. Second, treatment progression was assessed based on a trunk movement test performed consistently twice a week for reassessment of individual response. Participants with better condition or improvement were

subjected to forced progression or forced alternative exercise[5]. The forced progression started from static positions and changed to dynamic motions, whereas the forced alternative exercise modified loading by altering the position, direction, and repetition.

All participants had to perform all assigned exercises at a level of least 50% intensity. Compliance to treatment was assessed by collecting the number of visiting times and the percentage of successive exercise intensities throughout the duration of treatment. A logbook was used to record the number of exercise sessions daily and to confirm the treatment compliance.

Standard physical therapy (control group): Standard physical therapy including passive or active treatment was provided. Each participant received treatment, evaluation, and reassessment from the same PT twice a week throughout the four weeks of the present study. The progression of treatment was adjusted based on each participant's response. The number of visiting times was collected to determine treatment compliance.

Outcome measures

The participants reported two clinical outcomes including NPS score (0 to 10) and Thai ODQ score (0 to 100) at baseline and after four weeks of treatment.

Clinical prediction rules validation: The significant CPs related to improve of outcomes of specific-direction exercise from development phase were then tested of narrow validity. The same methodology in CPRs development was repeated in new participants at the same setting.

Sample size

Clinical prediction rules development: The efficacy of intervention and its non-inferiority to control treatment were determined according to the improvement of disability scores in four weeks. The proportion of improvement in matched treatment was 78%, whereas in unmatched treatment was 60%[21]. At 95% confidence interval (CI), the power was 80% and the non-inferiority ratio was –0.15. The calculated sample size was at least 24 participants for each trial group (ratio 1:1)[22].

Clinical prediction rules validation: For the validation of the ability of the CPs, the expected ratio of the probability of improvement from the intervention by any CPs was approximately 1.5. According to the ethical principles on the benefit for participants with NSLBP, the allocation ratio for the intervention and control groups was defined as 2:1.

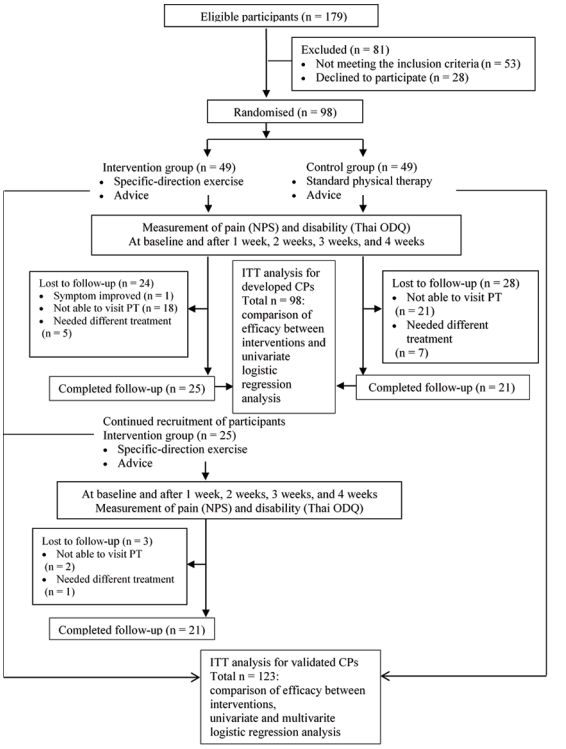

Figure 1. Flow of participants.

NPS=Numeric Pain Scale; Thai ODQ=Thai version of the Modified Oswestry Low Back Pain Disability Questionnaire; ITT=intention to treat; PT=physical therapist; CPs=clinical predictors

Then, further participants were specifically recruited for the intervention group. The expected number of participants completing the four weeks of treatment for the validation CPs was at least 57 participants.

Statistical analysis

Data were analyzed using Stata version 10 (StataCorp, TX, USA). All baseline characteristics of the participants were reported using descriptive statistics and were referenced for the improvement or change at the end of the four weeks. The improvement was determined according to either a decrease in the NPS score by at least two points or a decrease in the Thai ODQ score at 20% and 30%. Comparisons of the efficacy between treatments were analyzed according to relative improvement and 95% CI. Relative improvement was calculated using the same concept of relative risk. The intention-to-treat (ITT) methods were used for data analysis. Missing data were replaced with the last available values of outcomes carried forward.

The univariate binary logistic regression analysis

Table 1. Baseline characteristics of the study participants

Characteristics	RCT		Validation of CPs
	Specific-direction exercise (n = 49)	Standard physical therapy treatment (n = 49)	Specific-direction exercise (n = 74)
	n (%)	n (%)	n (%)
Age (years), Mean (95% CI)	38.7 (35.3 to 42.0)	38.3 (35.1 to 41.5)	37.3 (34.7 to 40.0)
Sex: male	24 (49.0)	22 (44.9)	39 (52.7)
Currently working: yes	42 (85.7)	45 (91.8)	67 (90.5)
Comorbid: yes	14 (28.6)	18 (36.7)	20 (27.0)
Medication use: use	37 (75.5)	41 (83.7)	41 (83.7)
MDT response			
CEN	11 (22.4)	10 (20.4)	19 (25.7)
DP	38 (77.6)	39 (79.6)	55 (74.3)
Pain intensity, Median (95% CI)			
NPS (0 to 5)	4 (3 to 5)	4.5 (4 to 5)	4 (4 to 5)
NPS (6 to 10)	8 (7 to 9)	8 (7 to 9)	8 (7 to 8)
Disability score, Mean (95% CI)			
Thai ODQ	36.2 (31.9 to 40.5)	37.1 (33.3 to 40.9)	34.8 (31.5 to 38.1)
Clinical predictors			
Current onset (weeks), Mean (95% CI)	8.9 (5.0 to 12.8)	10.1 (5.3 to 15.0)	9.2 (6.1 to 12.3)
• <6 weeks	33 (67.3)	28 (57.1)	47 (63.5)
• ≥6 weeks	16 (32.7)	21 (42.9)	27 (36.5)
Painful area			
• Either back or leg	13 (26.5)	10 (20.4)	17 (23.0)
• Both back and leg	36 (73.5)	39 (79.6)	57 (77.0)
Pain characteristic			
• Intermittent only	42 (85.7)	44 (89.8)	65 (87.8)
• Both intermittent and constant	7 (14.3)	5 (10.2)	9 (12.2)
FABQ*			
• Physical activity subscale (score = 24)			
- Mean (95% CI)	15.8 (14.0 to 17.7)	17.6 (16.3 to 18.9)	15.9 (14.4 to 17.3)
- Score ≤14	16 (32.7)	10 (20.4)	24 (32.4)
- Score >14	33 (67.3)	39 (79.6)	50 (67.6)
• Work activity subscale (score = 42)			
- Mean (95% CI)	23.2 (19.8 to 26.6)	23.6 (20.9 to 26.3)	23.1 (20.7 to 25.6)
- Score ≤29	29 (69.0)	33 (73.3)	46 (69.7)
- Score >29	13 (31.0)	12 (26.7)	20 (30.3)

RCT=randomized controlled trial; CPs=clinical predictors; CI=confidence interval; CEN=centralization; DP=directional preference; NPS=Numeric Pain Scale; Thai ODQ=Thai version of the Modified Oswestry Low Back Pain Disability Questionnaire; FABQ=Fear Avoidance Beliefs Questionnaire

* FABQ cut-points: for physical activity, the subscale was score ≤14 or >14[19]; for work, the subscale was score ≤29 or >29[20]

Table 2. Univariate analysis to develop clinical predictors for improvement of the Thai ODQ score by at least 20% and 30% from baseline after 4 weeks of treatment (n = 98 in both groups)

Clinical predictors	Improvement of Thai ODQ score					
	By ≥20% from baseline			By ≥30% from baseline		
	Improved n (%)	Did not improve n (%)	Relative improvement (95% CI)	Improved n (%)	Did not improve n (%)	Relative improvement (95% CI)
Current onset			1.42 (0.98 to 2.05)			1.69 (1.07 to 2.66)
<6 weeks	42 (68.9)	19 (31.1)		39 (63.9)	22 (36.1)	
≥6 weeks	18 (48.6)	19 (51.4)		14 (37.8)	23 (62.2)	
Pain area			1.29 (0.94 to 1.76)			1.54 (1.10 to 2.16)
Either back or leg	17 (73.9)	6 (26.1)		17 (73.9)	6 (26.1)	
Both back and leg	43 (57.3)	32 (42.7)		36 (48.0)	39 (52.0)	
Pain characteristics			0.79 (0.55 to 1.15)			0.68 (0.46 to 1.00)
Intermittent only	51 (59.3)	35 (40.7)		44 (51.2)	42 (48.8)	
Both intermittent and constant	9 (75.0)	3 (25.0)		9 (75.0)	3 (25.0)	
FABQ physical ability subscale (n = 98)			1.38 (1.03 to 1.86)			1.42 (1.00 to 2.02)
Score ≤14	20 (76.9)	6 (23.1)		18 (69.2)	8 (30.8)	
Score >14	40 (55.6)	32 (44.4)		35 (48.6)	37 (51.4)	
FABQ work activity subscale (n = 87)			1.09 (0.73 to 1.63)			1.14 (0.72 to 1.82)
Score ≤29	38 (61.3)	24 (38.7)		34 (54.8)	28 (45.2)	
Score >29	14 (56.0)	11 (44.0)		12 (48.0)	13 (52.0)	

Thai ODQ=Thai version of the Modified Oswestry Low Back Pain Disability Questionnaire; FABQ=Fear Avoidance Beliefs Questionnaire; CI=confidence interval

Relative improvement (relative risk): specific-direction exercise relative to standard physical therapy

Intention-to-treat analysis: specific-direction exercise (n = 49), standard physical therapy (n = 49)

was used to confirm the probability of outcome improvement by each CP. The alpha level for univariate analyses was set at 0.05. Next, the approved CPs from univariate binary logistic regression analysis were validated using multivariate binary logistic regression models. The efficacy of intervention was treated as another CP in the tested models. The probability of outcome improvement from multivariate logistic regression models was calculated using the following probability equation[23]: Probability $(y=1|x) = \text{exponential}(a + b_1x_1 + b_nx_n) / [1 + \text{exponential}(a + b_1x_1 + b_nx_n)]$, where the exponential was 2.71828.

Results

Clinical prediction rules development

Ninety-eight participants met the inclusion criteria and were equally randomized into the two groups of treatments.

Characteristics of participants: There were no significant differences in demographic data, baseline clinical characteristics, and CPs between the groups (Table 1). The flow of participants through the study are shown in Figure 1. At the fourth week, participants who were lost to follow-up from both groups showed no substantial difference of Thai ODQ score between continuing and discontinuing participants, (specific-direction exercise (p=0.106), or standard physical therapy (p=0.452)).

Efficacy of interventions: After the fourth weeks, the results showed no statistically significant difference only in the NPS improvement rate between groups. The participants in the specific-direction exercise group showed statistically significantly higher improvement rates than the control group (35/49 versus 25/49, and 32/49 versus 21/49 at 20% and 30% improvement of Thai ODQ score, respectively). The relative improvement and 95% CI were 1.40 (1.01 to 1.94) and 1.52 (1.04 to 2.23) for 20% and 30% improvement of Thai ODQ score, respectively.

Table 3. Univariate analysis to validate clinical predictors for improvement of the Thai ODQ score by at least 20% and 30% from baseline after 4 weeks of treatment (n = 123 in both groups)

Clinical predictors	Improvement of Thai ODQ score					
	by ≥20% from baseline			by ≥30% from baseline		
	Improved n (%)	Did not improve n (%)	Relative improvement (95% CI)	Improved n (%)	Did not improve n (%)	Relative improvement (95% CI)
Current onset			1.60 (1.14 to 2.24)			1.74 (1.17 to 2.60)
<6 weeks	55 (73.3)	20 (26.7)		49 (65.3)	26 (34.7)	
≥6 weeks	22 (45.8)	26 (54.2)		18 (37.5)	30 (62.5)	
Pain area			1.08 (0.80 to 1.48)			1.31 (0.94 to 1.82)
Either back or leg	18 (66.7)	9 (33.3)		18 (66.7)	9 (33.3)	
Both back and leg	59 (61.5)	37 (38.5)		49 (51.0)	47 (49.0)	
Pain characteristics			0.77 (0.56 to 1.05)			0.73 (0.50 to 1.07)
Intermittent only	66 (60.6)	43 (39.4)		57 (52.3)	52 (47.7)	
Both intermittent and constant	11 (78.6)	3 (21.4)		10 (71.4)	4 (28.6)	
FABQ physical ability subscale (n = 98)			1.33 (1.03 to 1.73)			1.37 (1.00 to 1.87)
Score ≤14	26 (76.5)	8 (23.5)		23 (67.6)	11 (32.4)	
Score >14	51 (57.3)	38 (42.7)		44 (49.4)	45 (50.6)	
FABQ work activity subscale (n = 87)			0.99 (0.72 to 1.37)			1.02 (0.70 to 1.50)
Score ≤29	49 (62.0)	30 (38.0)		43 (54.4)	36 (45.6)	
Score >29	20 (62.5)	12 (37.5)		17 (53.1)	15 (45.9)	

Thai ODQ=Thai version of the Modified Oswestry Low Back Pain Disability Questionnaire; FABQ=Fear Avoidance Beliefs Questionnaire; CI=confidence interval

Relative improvement (relative risk): specific-direction exercise relative to standard physical therapy

Intention-to-treat analysis: specific-direction exercise (n = 74), standard physical therapy (n = 49)

Predictors of specific-direction exercise in development phase: Ninety-eight participants were included in univariate binary logistic regression. The probability of outcome improvement by each CP is shown in Table 2. The results showed a significant relationship between physical ability score of FABQ at 20% improvement of the Thai ODQ score during current onset. Pain area and physical ability score of FABQ were predictor related to 30% improvement of the Thai ODQ score.

Clinical prediction rules validation

Efficacy of interventions: The 67 participants who completed all treatment protocols (46 from specific-direction exercise and 21 from standard physical therapy) are shown in Figure 1. For the specific-direction exercise group and the standard physical therapy group, the average treatment duration (95% CI) was 25.3 (23.7 to 26.9) days and 23.5 (21.2 to 25.8) days, respectively. The median total visiting time (95% CI) was five (five to six) and six (four to seven) times, respectively. No statistically significant differences in both treatment duration (p=0.197) and total visiting time (p=0.242) between groups were found. The average percentage of exercise intensity (95% CI) reported by participants in the specific-direction exercise group was 75.3% (70.8% to 79.7%).

The results still confirmed the efficacy of the specific-direction exercise in improvement of 20% and 30% of Thai ODQ score when compared with standard physical therapy. The participants in the specific-direction exercise group showed statistically significant higher improvement rates over the control group (52/74 versus 25/49, and 46/74 versus 21/49 at 20% and 30% improvement of Thai ODQ score, respectively). The relative improvement and 95% CI were 1.38 (1.01 to 1.88) and 1.45 (1.00 to 2.10) for 20% and 30% improvement of Thai ODQ score, respectively.

Table 4. Probability of improvement in the Thai ODQ score by at least 20% and 30% from baseline according to predictors

Model	Predictors			Improvement (%)	Relative improvement
	Treatment (X_1)	Current onset (X_2)	Physical ability score of FABQ (X_3)		
20% improvement in Thai ODQ score from baseline					
Model 0: $e^{(-0.924)} / 1 + e^{(-0.924)}$	0	0	0	28.4	-
Model 1: $e^{(-0.924+0.709)} / 1 + e^{(-0.924+0.709)}$	1	0	0	44.6	1.57
Model 2: $e^{(-0.924+0.709+1.322)} / 1 + e^{(-0.924+0.709+1.322)}$	1	1	0	75.2	2.64
Model 3: $e^{(-0.924+0.709+1.045)} / 1 + e^{(-0.924+0.709+1.045)}$	1	0	1	69.6	2.45
Model 4: $e^{(-0.924+0.709+1.322+1.045)} / 1 + e^{(-0.924+0.709+1.322+1.045)}$	1	1	1	89.6	3.15
30% improvement in Thai ODQ score from baseline					
Model 0: $e^{(-0.969)} / 1 + e^{(-0.969)}$	0	0	-	27.6	-
Model 1: $e^{(-0.963+0.769)} / 1 + e^{(-0.963+0.769)}$	1	0	-	45.2	1.64
Model 2: $e^{(-0.963+0.769+1.134)} / 1 + e^{(-0.963+0.769+1.134)}$	1	1	-	71.9	2.60

Thai ODQ=Thai version of the Modified Oswestry Low Back Pain Disability Questionnaire; FABQ=Fear Avoidance Beliefs Questionnaire

Probability ($y=1|x$) = exponential ($a + b_1x_1 + b_nx_n$) / [1 + exponential ($a + b_1x_1 + b_nx_n$)], where exponential=2.71828

Probability that event y occurs given x

a=constant value, b=coefficient from multivariate binary logistic regression model

Y, = Improvement of the Thai ODQ score from baseline at the specific cut-point: 1=improved, 0=did not improve

X_1 = Treatment: 1=specific-direction exercise, 0=standard physical therapy

X_2 = current onset: 1=<6 weeks, 0=≥6 weeks

X_3 = FABQ (physical activity score): 1=score ≤14, 0=score >14

Percentage of improvement = probability ×100

Relative improvement (relative risk) = improvement of Model n / improvement of Model 0

Predictors of specific-direction exercise in validation phase: One hundred twenty-three participants were included in the univariate binary logistic regression. The results showed a significant relationship between two CPs (current onset and physical ability score of FABQ) and the improvement of the Thai ODQ score at both defined cut points (Table 3). Difference from development phase, only current onset, and physical ability score of FABQ were predictors to test the cumulative effect for the predicted-to-improve outcome of specific-direction exercise.

The multivariate binary logistic regression analysis results of the testing models are shown in Table 4. The cut-points for 20% and 30% improvement from baseline[21] were defined as the probabilities of outcome improvement for testing the models. Model 0 represented the improvement from standard physical therapy alone, and the improvements were 28.4% and 27.6% for 20% and 30% improvement of Thai ODQ score, respectively. In contrast, Model 1 represented the improvement from specific-direction exercise alone, and the improvements were 44.6% and 45.2%. On the other hand, Model 2 with only current onset as CP showed a probability of improved rate of the Thai ODQ score from 44.6% to 75.2% and 45.2% to 71.9%. In model 4, including two CPs, current onset of less than six weeks and physical ability score of 14 points or less FABQ with at least 20% improvement from baseline showed an increase in the probability of improved NSLBP from 44.6% to 89.6%. Considering relative improvement as a reference to standard physical therapy, improvement of disability outcome of at least 20% from baseline in specific-direction exercise when including the two CPs were increased by 1.57 to 3.15 times. Additionally, improvement of the Thai ODQ scores by at least 30% from baseline in specific-direction exercise when the current onset was less than six weeks presented an increase from 1.64 to 2.60 times relative to standard physical therapy alone.

Discussion

The results also supported that participants with the characteristic of CEN or DP and two validated CPs would improve their disability outcomes after specific-direction exercise. Current onset of NSLBP of less than six 6 weeks and physical ability score of 14 points or less FABQ were the two significant CPs that were found in development and validation phase of CPRS. The cumulative effect from the current onset and physical activity score of FABQ would increase the probability of improving the disability outcome only in the circumstance of at least 20% change from baseline.

The specific-direction exercise uses the MDT principle in detecting abnormal mechanical function of the back, determining which specific direction should be exercised and assigning a specific-direction exercise to reverse the abnormal mechanical function. Therefore, the specific-direction exercise can decrease pain and functional limitation in the acute phase[4]. The present study supported the accuracy of current onset as a CP for the CPRs of specific-direction exercise.

The present study also supported a previous study[24] showing that bio-behavioral factors, including psychophysical and environmental factors, could affect the pathology, pain, and disability of patients. A high score in the physical ability scale of FABQ indicated high fear avoidance levels. A maladaptive emotional response to fear of participants could affect their behaviors in avoiding any physical activity because of excessive fear of pain. Thus, excessive fear of pain might limit all physical activities including treatment exercise. Concurrently, a higher level of physical ability score of FABQ presented lower improvement rates in the present study. In addition, fear of pain may have had less influence when the current onset, which was less than six weeks, because participants had a higher probability to comply with the exercise and decrease their disability. This was supported by the finding that predictive probability of FABQ showed no significant influence when adjusted in the multivariate model for improvement of at least 30%. In summary, a physical ability score of 14 points or less FABQ and current onset of NSLBP were significant predictors for improving the disability outcome by at least 20% from baseline in the specific-direction exercise group.

Four advantages were gained from the present study. First, the CPs were obtained from a prospective design and the efficacy of specific-direction exercise was confirmed using RCT, which is the recommended study design for developing prescriptive CPRs. Second, the large participant numbers in the specific-direction exercise group enhanced the strength of the CPs in the narrow validation phase of CPRs. Third, a previous research specifically recruited patients with LBP in the acute phase[12]. The present study included participants having current onset ranging from the acute to the chronic phase. Therefore, the results could be generalized to both acute and chronic patients with NSLBP who responded to MDT assessment. According to the definition of CEN and DP, a PT can clearly detect symptoms and evidently decide to continue or stop the exercise. This was a recommendation from previous studies[25] that would yield great benefits for both PTs and patients. Thus, the fourth advantage was the clear operational definitions of CEN and DP assessed through the present study.

The present study had some limitations. As the NPS and Thai ODQ scores were self-reported outcomes. The instructions were thoroughly explained by the researcher before data collection. Clear instructions helped in controlling errors from under- or over-estimation of reported conditions that might distort the study outcome. Most of the participants were of working age. The need to take leave from work was an important factor that limited the time to receive treatment for four weeks. However, the score of the Thai ODQ did not show significant differences between participants who completed and did not complete the follow-up.

In conclusion, the current onset of NSLBP and the physical ability score of FABQ were the applicable CPs to prescribe as CPRs for specific-direction exercise in the narrow validation phase. The results can be generalized to patients with NSLBP who have the characteristic of CEN or DP according to the MDT principle. However, the development of CPRs in broad validity and the impact analysis remains an interest for a future study.

What is already known on this topic?

Determination of clinical prediction rules (CPRs) for specific-direction exercise is still limited. Only CEN and DP are characteristic responses mostly use to predict improvement of outcome from specific-direction exercise, but other characteristics have not been reported.

What this study adds?

Other than CEN and DP, the current onset of less than six weeks and the physical ability score of 14 points or less FABQ are significant clinical predictors to improve outcome of specific-direction exercise. The study outcomes were confirmed in the narrow

validation phase of CPRs.

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Conflicts of interest

The authors declare no conflict of interest.

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