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Predictors for future activity limitation in women with chronic low back pain consulting primary care: a two-year prospective longitudinal cohort study

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ABSTRACT

Objectives. To assess if body function, activity, participation, health-related quality of life and lifestyle behavioral factors can predict the future activity limitation in women with chronic low back pain (CLBP) in primary health care (PHC) two years later.

Design. A two-year prospective longitudinal cohort study within PHC.

Settings: Primary health care in south-western Sweden.

Participants: The cohort comprised 130 women with CLBP attending PHC at baseline 2004-2005 and were re-assessed after two years.

Measures. The dependent outcome variable was self-reported activity limitation (Roland Morris disability questionnaire (RMDQ)) at two-year follow-up. Independent predictors at baseline were BMI, smoking, alcohol consumption, sleep quantity and quality, leisure time physical activity, a questionnaire of the clinical manifestation of stress (Stress and Crises Inventory (SCI-93)), pain localisation, pain intensity, fatigue, anxiety, depression, RMDQ, work status, private social support, health-related quality of life and measures of physical performance specified as the six-minute walk test (6MWT) and hand grip strength. Relation between baseline predictors and variation in later self-reported activity limitation RMDQ was analysed using multivariate linear regression.

Results. Ninety-five percent (n=123/130) were followed up after two years. The participants were middle-aged (mean 45 (SD10) years), mostly educated more than 9 years (88%;118/123), mainly living with another adult (76%;93/122) and born in Sweden (90%;111/123). Seventy-nine percent (97/123) were categorized as having work ability at baseline. The final prognostic model including 6MWT, SCI-93 and RMDQ at baseline explained 54% of the variance in self-reported activity limitation (RMDQ) at the two-year follow-up.

Conclusions: Lower physical performance (6MWT), more severe clinical stress symptoms

(SCI-93) and more severe activity limitation (RMDQ) predicted activity limitation (RMDQ) after two years in women with CLBP within PHC. This result suggests that interventions aiming to improve physical capacity and decrease stress are likely to be important for women with CLBP to improve the prognosis.

Key Words: Chronic Pain, Low Back Pain, Primary Health Care, Life Style, Disability Evaluation, Prognostic Factors, Women.

Strengths and limitations of this study

- The main strength of this study is the longitudinal prospective design over two years within primary health care, high long-term follow up (95%), measurements representing all the domains of International Classification of Functioning, Disability and health (ICF) complemented with lifestyle behavioural factors.
- The limitation of this study is that we included only women so the influence of gender can't be analysed.

INTRODUCTION

Non-specific chronic low back pain (CLBP), defined as pain duration longer than three months, is associated with variations of recurrent or persistent pain.[1, 2] CLBP have various impact on body functions, activity and participation in daily life[1-4] and it is a common cause for attending health care.[1]

Non-specific acute low back pain (LBP) is described to have a spontaneous course.[1, 2, 5] However, after one year 63-82% of primary care patients with LBP report to have recurrent LBP and 20-45% impaired function.[6-10] Prognostic factors for the transition from non-specific acute LBP to CLBP has previously been described in personal and socioeconomic areas as well as in all domains of the International Classification of Functioning, Disability and Health (ICF).[6, 9, 11-18] Women seems to have a greater risk for CLBP[6] and when studying prognostic factors it is suggested to assess women separately.[19-21] Previous prognostic models for the transition to CLBP explain 28-51% of variability in the measured outcome.[22] The outcomes, combination of included prognostic factors and statistical analyses often differs between studies, making comparisons or meta-analysis difficult.[18]

Some studies have described similar prognostic factors for persistent CLBP as for the transition from non-specific acute LBP to CLBP.[23, 24] Since the course of non-specific acute LBP and CLBP differs, more knowledge of prognostic factors for varying outcomes in patients with CLBP is warranted.[25] A previous review studying prognostic factors for delayed recovery in CLBP found no association between age, sex and the outcome measure of pain intensity and disability at short-term follow-up (e.g. 6-weeks). Conflicting evidence was found for fear of avoidance as a predictor.[26] At long-term follow-up (e.g. 6 months) no association was found between smoking, pain intensity, fear of avoidance and the dependent variable disability.[26] Conflicting evidence was found for age, sex and physical job demands and the outcome measure of pain intensity and disability. Moreover, conflicting evidence was

found for the association between age, activities of daily living, pain intensity and physical job demand and the outcome return to work.[26] However, recently a study showed that a physical performance test (6-minute walk test), depression and earlier work ability predicted later work ability in women with CLBP.[27]

The knowledge about various prognostic factors for the recovery for patients with CLBP is still insufficient. Moreover, the prognostic value of lifestyle behavioral factors, stress symptoms and physical performance for later activity limitation in CLBP is unknown.

The aim was to assess if body function, activity, participation, health-related quality of life and lifestyle behavioral factors can predict the future variance of self-rated activity limitation in women with CLBP in PHC two years later.

METHODS

Study design

This two-year prospective longitudinal cohort study included women (n=130) with CLBP within PHC.[28] Patients were assessed at baseline and were re-assessed after two years. Predictors for later self-reported activity limitation (Roland Morris disability questionnaire (RMDQ)), was analysed by multivariate linear regression. Independent variables found to be associated with disability in CLBP patients,[27] were complemented with lifestyle behavioural factors including Body Mass Index (BMI), smoking, alcohol consumption, sleep quantity and quality, leisure time physical activity and a questionnaire of the clinical manifestation of stress. Other independent variables related to chronic pain were pain localisation, pain intensity, fatigue, anxiety, depression, work status, private social support health-related quality of life and two measures of physical performance.

Participants were assessed by a trained physical therapist in PHC both at baseline and after two years and included a structured interview, measure of body height and weight, and the two physical performance tests. Participants were asked to fill in a package of self-administrated questionnaires at the assessment and two at home. They were provided with a pre-paid addressed envelope to return questionnaires. If no questionnaires were returned within two weeks, a reminder by telephone was made. The Regional Ethical Review Board in Gothenburg approved the study. Written informed consent was obtained from all patients.

Selection of patients

Female patients were identified by systematic search in medical charts for LBP diagnoses "M545" (ICD-10) at eight PHC clinics in south-western Sweden, a mixture of urban and rural populations, in 2004-2005. All patients who could be contacted, accepting participation and fulfilling the inclusion criteria were invited to enroll in the study. The inclusion criteria were: female patient, low back pain (pain between costal margins and gluteal folds) with or without referred leg pain.[1] Further inclusion criteria were; longer than 12-week's duration of symptoms, not pregnant, no known spinal pathology, no other severe co-morbidity, age between 18 and 60 years, understanding and fluent in Swedish. At the two-year follow-up, all patients included in the cross-sectional study (n=130),[28] who could be contacted and accepting participation were invited to the follow-up, containing the same study protocol as at baseline.

Measurements

The structured interview included questions about age, nationality, education level, family situation, work status, back pain history (onset, duration and symptoms), co-morbidity and pharmacological treatment.

1. Lifestyle behavioural factors

1.1 Body Mass Index (BMI)

Height and weight were assessed for calculating the BMI (kg/m^2).

1.2 Alcohol consumption

For alcohol consumption the Alcohol Use Disorders Identification Test (Audit-C)[29] was used (range 0-12). Higher scores indicate higher alcohol consumption.

1.3 Smoking

Tobacco use was dichotomized into two categories, No smoker or smoker. The category, no smoker required to never been smoking. The category smoker required to previously been a smoker or are reported to be currently smoking.

1.4 Sleep

For sleep quantity and quality two questions was used.[30] "Do you think you get enough sleep?" (range 1-4) and "On the whole, how do you think you sleep?"(range 1-4). Higher score indicate better sleep quantity and quality.

1.5 Stress symptoms

To quantify clinical manifestations of stress symptoms the Stress and Crises Inventory (SCI-93) was used (range 0-140) where higher scores indicate more severe clinical stress symptoms.[31, 32] A total score of ≤38 indicates normal resources for activity and work.[33]

1.6 Physical activity at leisure time

The Leisure Time Physical Activity Instrument (LTPAI) was used to assess the amount of physical activity in leisure time during a typical week.[34] The number of hours spent for light, moderate and vigorous activities was registered and the total number of hours were used.[34]

2. Body function

2.1 Physical performance tests

The 6-minute walk test (6MWT) was used to assess physical performance.[35-37] The distance (meter) is measured while the patient walks up and down a 30 meter corridor for 6 minutes. The participant was instructed to walk as quickly as possible without running.

Hand grip strength was measured with an electronic instrument Grippit®.[38, 39] A sustained voluntary 10-second contraction was measured. The right hand value was used for analyses in the present study.

2.2 Number of pain localisation, pain intensity and fatigue

For pain distribution, a drawing of the body was used for register pain localisations (0-18).[40] Pain intensity and fatigue during the last week was measured on a visual analogue scale 0-100 mm (VAS).

2.3 Distress

The Hospital Anxiety and Depression Scale (HADS), HADS-A was used for assessment of anxiety, (range 0-21) and the HADS-D for depression (range 0-21). Higher scores indicate greater anxiety or depression.[41, 42]

3. Activity limitations

The RMDQ was used for self-reported activity limitation related to LBP. The RMDQ consists of 24 yes/no statements, where higher scores indicate greater activity limitation (range 0-24).[43]

4. Participation

Work status was dichotomized into two categories, work ability or not. The category, work ability required work or study, full or part-time, applying for work, parental leave full or part-time or part-time disability pension. The category no work ability required full-time sick leave or full-time disability pension. Self-reported sick absenteeism has been shown reliable.[44]

5. Environmental factors

The 4-item version of Medical Outcome Study Social Support Survey (MOS-SSS) registered private social support: emotional-informational, tangible, affectionate support and positive social interaction (range 1-5 for each item). Higher scores indicate more support (total range 4-20).[45]

6. Health-related quality of life

The SF-36 short form health survey (SF-36) was used for general health status. The Physical Component Summary score (PCS) and the Mental Component Summary score (MCS) representing an overall health index of physical or mental health (range 0-100) were used.[46-48]

Statistical analysis

Group characteristics are presented as mean and standard deviations (SD), median and 25th and 75th percentile or the number and percentage at baseline. Percentages change for RMDQ

was constructed by subtracting baseline value from two-year follow-up value. The change was divided with baseline and multiplied by 100 to create a percentage change.

Multivariate regressions were used to identify predictors of self-reported activity limitation related to LBP (RMDQ) at the two-year follow-up. Independent variables were age, BMI, smoking, AUDIT-C, sleep quantity and quality, SCI-93, LTPAI, 6MWT, hand grip strength, number of pain localisations, pain intensity, fatigue, HADS-A, HADS-D, RMDQ at baseline, work ability, MOS-SSS, PCS and MCS obtained at baseline. Firstly, the RMDQ at the two-year follow-up was used as dependent variable. Secondly, percentage change was used as dependent variable excluding RMDQ at baseline as an independent variable.

Prior to the multivariate linear regression, the variables were evaluated for the assumptions of multivariate analysis. The dependent variable RMDQ fulfilled the assumption of normal distribution when ranked using Blom's formula.[49] The statistical criteria for the independent variables were 0.05 for entry and 0.10 for removal. Multi-collinearity was checked by the values of Tolerance and VIF.

To enable more meaningful clinical interpretation small units were transformed to larger ones. In 6MWT one meter was transformed to 100 meter, in hand grip strength one Newton was transformed to 50 Newton, in the pain and fatigue scores, one mm was transformed to 10 mm (VAS).

First, Spearman Rank correlation between RMDQ at two years and each of the independent variables at baseline was performed as a sorting mechanism. Secondly, a stepwise multivariate linear regression including the independent variables that had significant correlation to RMDQ in the first step was performed. The same procedure was performed with percentage change in RMDQ as dependent variable.

The level of significance for independent variables remaining in the final model was set to 0.05. The IBM SPSS Windows version 22.0 was used for the statistical analyses.

RESULTS

Ninety-five percent (n=123/130) of the participants included in the cross-sectional study[28] could be followed up after two years (Figure 1). Seven patients could not be assessed at the two-year follow-up, three of them due to pregnancy, an exclusion criteria in the present study. The participants were middle-aged (mean 45 (SD10)), mostly educated more than 9 years (88%; 118/123), mainly living with another adult (76%; 93/122) and born in Sweden (90%; 111/123) (Table 1). Seventy-nine percent (97/123) were categorized as having work ability at baseline. The BMI mean and median values of 27 (SD 5.5) and 26 (25^{th};75^{th} percentile 23; 29) indicates that a significant proportion were overweight (≥ 25 BMI).[50] Seventy-six percent (n=93/123) were currently non-smokers and did not exceed risk consumption of alcohol (Table 2). Only 14% (17/123) reported sleeping certainly enough and 19% (23/121) reported very good sleep quality (Table 2). Body function, activity, participation and quality of life at baseline indicates that these aspects of life varied and several of them were not optimal (Table 2).

Table 1. Group characteristics at baseline (n=123)

Personal data	
Age, years [mean (SD)]	45 (10)
Nationality Swedish [% (n/n)]	90% (111/123)
Symptom duration, years [mean (SD)]	9.6 (8.8)
Education status [% (n/n)]	
≤ 9 years	12% (15/123)
10-12 years	40% (49/123)
> 12 years	48% (59/123)
Social status [% (n/n)]	
Living with an adult	26% (32/122)
Living with an adult and child/children	50% (61/122)
Living alone	12% (14/122)
Living alone with child/children	9.0% (11/122)
Living apart with an adult	3.3% (4/122)
Pharmacological treatment, yes [% (n/n)][a]	
Analgesics	53% (65/123)
Psychotropic drugs	16% (20/123)
Employment Status [% (n/n)]	
Currently working and/or studying	58% (71/123)
Sick-leave, full-time	11% (13/123)
Sick-leave, part-time	8.9% (11/123)
Disability pension, full-time	11% (13/123)
Disability pension, part-time	5.7% (7/123)
Parental leave, full-time	1.6% (2/123)
Parental leave, part-time	1.6% (2/123)
Unemployed, full-time	0.81% (1/123)
Unemployed, part-time	2.4% (3/123)

[a] The use last month registered by yes or no.

Table 2. Lifestyle factors, body function, activity, participation and health related quality of life at baseline (n=123).

Lifestyle behavioral factors	
Body Mass Index (kg/m^2) [a]	27 (5.5) --- 26 (23; 29)
Audit-C (0-12)[b]	2.2 (1.4) --- 2.0 (1.0; 3.0)
Smoking [% (n/n)]	
never smoked	40% (49/123)
previously smoked	36% (44/123)
currently smoking	20% (25/123)
currently snuffing	4% (5/123)
Sleep quantity [% (n/n)][c]	
certainly enough	14% (17/123)
broadly enough	47% (58/123)
some shortage	24% (29/123)
clearly insufficient	15% (19/123)
Sleep quality [% (n/n)][d]	
very good	19% (23/121)
quite good	51% (62/121)
quite bad	21% 25/121)
very bad	9% (11/121)
SCI-93[e]	36 (21) --- 35 (19; 51)
LTPAI, hours per week (n= 122)[f]	7.8 (8.5) --- 6.0 (3.4; 9.0)
Body function	
Pain localizations (0-18)[g]	4.6 (3.2) --- 4.0 (2.0; 6.0)
Pain intensity (VAS 0-100 mm)[h]	45 (27) --- 45 (24; 68)
Fatigue (VAS 0-100 mm)[h]	53 (29) --- 53 (28; 75)
6MWT (meter) (n=121)	572 (86) --- 581 (515; 633)
Hand grip strength (Newton)	232 (76) --- 237 (184; 285)
HADS-A (0-21)[i]	6.4 (4.4) --- 5.0 (3.0; 9.0)
HADS-D (0-21)[i]	4.3 (3.6) --- 3.0 (1.0; 7.0)
Activity (n=121)	
RMDQ (0-24)[j]	8.4 (4.8) --- 7.0 (4.0; 12)
Participation	
Work ability (yes) [% (n/n)]	79% (97/123)
Environmental factors	
Private social support (4-20)[k]	16 (3.5) --- 17 (14; 19)
Health-related quality of life (n=122)	
PCS (0-100)[l]	38 (9.9) --- 39 (31; 47)
MCS (0-100)[l]	46 (13) --- 49 (37; 56)

[a] First figure mean values (standard deviation). Second figure median values (25th; 75th percentile).
[b] The Alcohol Use Disorders Identification Test (AUDIT-C), 3 items. Higher scores reflect higher alcohol consumption (0-12).
[c] One item: "Do you think you get enough sleep?"
[d] One item: "On the whole, how do you think you sleep?"
[e] Stress and crisis inventory (SCI-93). Higher scores indicate more severe clinical stress symptoms (0-140).
[f] The Leisure Time Physical Activity Instrument (LTPAI) assess the total hours of physical activity in leisure time during a typical week.
[g] Self-reported pain locations registered by a figure with predefined body locations (0-18).
[h] Perceived pain intensity, fatigue over the last week rated on a visual analogue scale, VAS (0-100). Higher values indicate more pain, fatigue.
[i] Hospital Anxiety and Depression Scale (HADS). Higher scores indicate more anxiety (0-21) and depression (0-21).
[j] Roland Morris disability questionnaire (RMDQ) indicates disability related to low back pain (0-24) at baseline. Higher scores indicate more severe disability.
[k] Medical outcome study social support survey (MOS-SSS, 4- item scale) reflects private social support ranging from 1-5. Higher scores reflect more perceived support (4-20).
[l] SF-36. The physical component summary score (PCS) (0-100) and mental component summary score (MCS) (0-100).

Two-year follow-up RMDQ status

There was a statistical significant mean decrease of 1.9 points (95% CI, 1.2-2.5) on RMDQ from 8.4 (SD 4.8) at baseline to 6.4 (SD 5.5) at the two-year follow-up ($p< 0.0001$). The percentage decrease in RMDQ was 23 %.

Predictors for activity limitation (RMDQ) at the two-year follow-up

The stepwise multivariate regression analysis showed that the 6MWT, SCI-93 and RMDQ at baseline were the most important predictors explaining 54 % of variance in the RMDQ at the two-year follow-up (Table 3).

There were no significant association between percentage change in RMDQ and any of the independent variables.

Table 3. Prognostic factors at baseline for activity limitation at the later two-year follow-up, using the Roland Morris disability Questionnaire (RMDQ) at two-year follow-up as the dependent variable (n=120).

	Spearman Rank Correlation Correlation with RMDQ at two year			**Stepwise multiple linear regression**[a] Significant independent variables entered in the model. **R^2 = 0.54 for the overall model.**	
	number	**r**	**p-value**	**β (CI 95%)**	**p-value**
Age, years	120	0.067	0.47		
Lifestyle behavioural factors					
Body Mass Index (kg/m^2)	119	0.21	0.021		
Smoker (n=72) --- no smoker (n=48)	120	0.14	0.14		
AUDIT-C (0-12)[b]	118	-0.23	0.011		
Sleep quantity (1-4)[c]	120	-0.34	0.00014		
Sleep quality (1-4)[d]	118	-0.43	<0.0001		
SCI-93[e]	120	0.48	<0.0001	**0.0089 (0.0020 - 0.016)**	**0.012**
LTPAI, (hours per week)[f]	119	-0.11	0.24		
Body function					
Pain localisations (0-18)[g]	120	0.36	0.000052		
Pain intensity 10 mm (VAS 0-100)[h]	120	0.20	0.027		
Fatigue 10 mm (VAS 0-100)[h]	120	0.24	0.0078		
6MWT, 100 meters	118	-0.41	<0.0001	**-0.19 (-0.35 - -0.027)**	**0.023**
Hand grip strength 50 N (Newton)	120	-0.17	0.070		
HADS-A (0-21) [i]	120	0.16	0.089		
HADS-D (0-21) [i]	120	0.37	0.000025		
Activity					
RMDQ at baseline (0-24)[j]	118	0.71	<0.0001	**0.11 (0.071 - 0.14)**	**<0.0001**
Participation					
Work ability (n=95) --- no work ability (n=25)	120	-0.37	0.000026		
Environmental factors					
Private social support (4-20)[k]	120	-0.29	0.0013		
Health-related quality of life					
PCS (0-100)[l]	119	-0.42	<0.0001		
MCS (0-100)[l]	119	-0.28	0.0022		

[a] Roland Morris disability questionnaire (RMDQ) score was transformed to ranked normal score of RMDQ, using Blom's formula. The variables shown, $R^2 = 0.54$.
[b] The Alcohol Use Disorders Identification Test (AUDIT-C), 3 items. Higher scores reflect higher alcohol consumption (0-12).
[c] One item: "Do you think you get enough sleep?". Higher scores indicates better sleep (1-4).
[d] One item: "On the whole, how do you think you sleep?". Higher scores indicates better sleep (1-4).
[e] Stress and crisis inventory (SCI-93). Higher scores indicate more severe clinical stress symptoms (0-140).
[f] The Leisure Time Physical Activity Instrument (LTPAI) assess the total hours of physical activity in leisure time during a typical week.
[g] Self-reported pain locations registered by a figure with predefined body locations (0-18).
[h] Perceived pain intensity, fatigue over the last week rated on a visual analogue scale, VAS (0-100). Higher values indicate more pain, fatigue.
[i] Hospital Anxiety and Depression Scale (HADS). Higher scores indicate more anxiety (0-21) and depression (0-21).
[j] Roland Morris disability questionnaire indicates disability related to low back pain (0-24) at baseline. Higher scores indicate more severe disability.
[k] Medical outcome study social support survey (MOS-SSS, 4- item scale) reflects private social support ranging from 1-5. Higher scores reflect more perceived support (4-20).
[l] SF-36. The physical component summary score (PCS) (0-100) and mental component summary score (MCS) (0-100).

DISCUSSION

This two-year prospective cohort study of women with CLBP attending PHC showed that lower performance in walking capacity (6MWT), more severe clinical stress symptoms (SCI-93) and more severe activity limitation (RMDQ) at baseline predicted more activity limitation (RMDQ) after two years (Table 3). The model with these three predictors explained 54% of the variance in self-reported activity limitation (RMDQ) at the two-year follow-up, which is similar to a previous review of prediction models including various predictors for disability in patients with subacute non-specific LBP.[22]

Strengths and limitations

This study included measurements representing all the domains of ICF[17] complemented with lifestyle behavioural factors, which is considered as a main strength. The follow-up frequency was very high with 95% being followed up.

Prevalence and predictors of chronic pain have been studied in general populations,[21, 40, 51] while the present study assessed women with CLBP consulting PHC, contributing with new knowledge for health care professionals working in PHC. Previous studies found that chronic pain is more common in women, and that women are at greater risk of chronic pain and disability.[6, 40, 51] It has been suggested that women should be assessed separately when studying prognostic factors for LBP,[19, 20] hence the present study included only female patients.

Self-administrated questionnaires are recommended for the assessment of activity limitation in patients with LBP.[52] The present study used RMDQ as the outcome measure at the two-year follow-up. The RMDQ is considered valid, commonly used and recommended in LBP research for monitoring disability.[53, 54] Seventeen statements in the RMDQ are reported

to be linked to the activity component in the ICF.[55, 56] However, self-reports may suffer from the fact that some patients may under or overestimate their limitations and physical performance tests are suggested to complement self-reports.[57] Walk capacity (6MWT) and hand grip strength, semi-objective measures of body function, were therefore included as potential predictors in this study.

There was a statistical significant mean decrease of approximately 2 points on RMDQ during the two-year period. Minimal clinical detectable change in the RMDQ is considered to be 2 to 3 points. Others have suggested a change of 4 to 5 points to be of clinical value.[53]

Predictors for activity limitation (RMDQ) at two-year follow-up

The BMI values corresponded with overweight (mean 27 (SD 5.5)), which is common in patients with chronic pain[28, 58] and might be due to impaired body function, activity limitation and restrictions of participation. A previous one-year follow up study found self-reported weight and height (BMI) as a significant predictor for activity limitation.[59] However, this could not be confirmed in the present study.

Previously or currently smoking was not found as a predictor, which is concordant to a review studying prognostic factors for pain and disability in CLBP.[26] In the present study, hours per week of leisure time physical activity (LTPAI) (mean 7.8 (SD 8.5) was within recommended levels of physical activity[60] which might have been the reason for no prognostic value. A healthy lifestyle behavior, combinations of lifestyles factors, is reported to influences the prognosis of LBP.[21] It could be interesting to combine and categorize various self-reported lifestyles behavioral factors for analyzing their prognostic value for patients with CLBP. However, in the present study the prognostic value of lifestyle behavioral factors were analyzed separately for later self-reported activity limitation in CLBP.

Previous prospective studies of LBP have evaluated body function by measuring spinal motion and muscle strength, showing them to be of poor prognostic value.[11, 61] In the present study, the body function assessed by the 6MWT was of good prognostic value, showing that lower performance in the 6MWT at baseline predicted more severe activity limitation at two-year follow-up. Therefore, the 6MWT is recommended to be included as a complement to standard clinical examination of CLBP. Physical activity is a recommended intervention for patients with CLBP. The 6MWT is easy to perform and provides information of an individual's physical performance. In the future, the 6MWT might be used as a self-administrated assessment tool to promote physical activity and self-management strategies for patients with CLBP. However, the utility of 6MWT as a self-assessment tool needs to be studied further.

More severe clinical stress symptoms (SCI-93), could independently predict more severe activity limitation (RMDQ) at the two-year follow-up (Table 3). The mean score for SCI-93 at baseline was 36 (SD 21) (Table 2), which indicates an increased level of clinical stress symptoms in the group, compared to the reference values.[32, 33] Signs and symptoms in patients with chronic pain are suggested to be associated with prolonged stress,[62] but measurement of clinical stress symptoms is not standard in the clinical assessment of patients with CLBP. Therefore, the SCI-93 could provide valuable information for predicting later activity limitation for these patients. Moreover, questionnaires assessing symptoms severity might stimulate the patient's motivation in using active coping strategies to alleviate their stress responses.[32]

In this study, the prognostic model including the baseline RMDQ, 6MWT, and SCI-93 explained 54% of the variance in activity limitation (RMDQ) at the two-year follow-up (Table 3), which is slightly more compared to findings in a previous review of different prognostic models explaining 28-51% of variance in persisting disability in LBP.[22] Knowledge about

factors that are associated with the probable recovery or not in CLBP can be used to improve the management of patients with CLBP in primary care. The results of this study suggest that interventions aiming to improve physical capacity and decrease stress are likely to be successful in women with CLBP.

CONCLUSION

A walk test (6MWT), clinical stress symptoms (SCI-93) and activity limitation (RMDQ) predicted future activity limitation in women with CLBP within PHC. The prognostic model including these three predictors explained 54% of the variance in self-reported activity limitation (RMDQ) after two years.

Contributors

LN contributed to the design of the study, were responsible for the data collection, participated in the statistical analysis, interpreted the data and drafted the first manuscript. LT contributed to the interpretation of data and revision of manuscript for important content. RG contributed to the design of the study, participated in the statistical analysis, interpreted the data and critically revised all versions of the manuscript. KM contributed to the design of the study, participated in the statistical analysis, interpreted the data and critically revised all versions of the manuscript. All authors read and approved the final manuscript.

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Competing interests

The authors declare that they have no competing interest.

Ethics approval

The Regional Ethical Review Board in Gothenburg approved the study. Written informed consent was obtained from all patients.

Data sharing statement

No additional data are available.

Figure legends

Figure 1. Participants flow.

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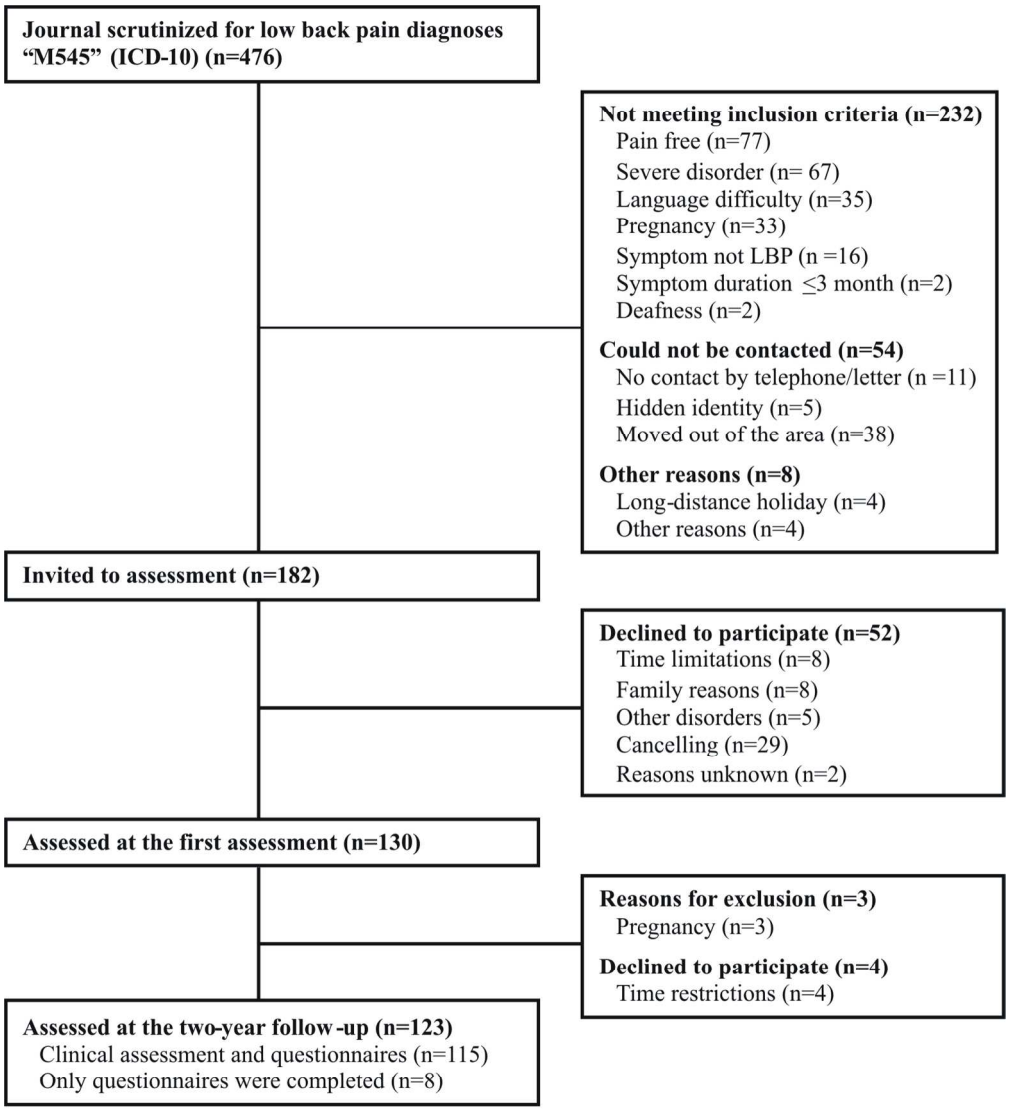

Figure 1. Participants flow.

Figure 1. Participants flow

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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Noted in Title page and Abstract. Pages 1,2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Pages 2,3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Pages 5,6
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 6
Methods			
Study design	4	Present key elements of study design early in the paper	Pages 6,7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 7
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Pages 6,7
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Pages 7-10
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Pages 7-10
Bias	9	Describe any efforts to address potential sources of bias	Page 11
Study size	10	Explain how the study size was arrived at	Page 7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Pages 10,11
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Pages 10,11
		(*b*) Describe any methods used to examine subgroups and interactions	Pages 10,11
		(*c*) Explain how missing data were addressed	Page 12 and Figure 1 (at page 27)

		(*d*) If applicable, explain how loss to follow-up was addressed	Page 12 and Figure 1 (at page 27)
		(*e*) Describe any sensitivity analyses	NA
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Page 12 and Figure 1 (at page 27)
		(b) Give reasons for non-participation at each stage	Page 12 and Figure 1 (at page 27)
		(c) Consider use of a flow diagram	Figure 1 (at page 27)
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 12 and Tables 1,2 at pages 13,14
		(b) Indicate number of participants with missing data for each variable of interest	Tables 1,2 at pages 13,14
		(c) Summarise follow-up time (eg, average and total amount)	Follow-up time is two years, documented throughout the manuscript.
Outcome data	15*	Report numbers of outcome events or summary measures over time	Page 15 and Table 3 at page 16
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Page 11, 15 and Table 3 at page 16
		(*b*) Report category boundaries when continuous variables were categorized	NA
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 17
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Pages 17,18
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Pages 17-20

Generalisability	21	Discuss the generalisability (external validity) of the study results	Pages 17-20
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 21

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Predictors for future activity limitation in women with chronic low back pain consulting primary care: a two-year prospective longitudinal cohort study

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ABSTRACT

Objectives. To assess if body function, activity, participation, health-related quality of life and lifestyle behavioral factors can predict activity limitation in women with chronic low back pain (CLBP) in primary health care (PHC) two years later.

Design. A two-year prospective longitudinal cohort study within PHC.

Settings: Primary health care in south-western Sweden.

Participants: The cohort comprised 130 women with CLBP attending PHC at baseline 2004-2005 and were re-assessed after two years.

Measures. The dependent outcome variable was self-reported activity limitation (Roland Morris disability questionnaire (RMDQ)) at two-year follow-up. Independent predictors at baseline were age, BMI, smoking, alcohol consumption, sleep quantity and quality, leisure time physical activity, a questionnaire of clinical manifestation of stress (Stress and Crises Inventory (SCI-93)), pain localisation, pain intensity, fatigue, anxiety, depression, RMDQ, work status, private social support, health-related quality of life and measures of physical performance specified as six-minute walk test (6MWT) and hand grip strength. Relation between baseline predictors and variation in later self-reported activity limitation (RMDQ) was analysed using multivariate linear regression.

Results. Ninety-five percent (n=123/130) were followed up after two years. The participants were middle-aged (mean 45 (SD10) years), mostly educated more than 9 years (88%;108/123), mainly living with another adult (76%;93/122) and born in Sweden (90%;111/123). Seventy-nine percent (97/123) were categorized as having work ability at baseline. The final prognostic model including 6MWT, SCI-93 and RMDQ at baseline explained 54% of the variance in self-reported activity limitation (RMDQ) at the two-year follow-up.

Conclusions: Lower physical performance, more severe clinical stress symptoms and more

severe activity limitation predicted activity limitation after two years in women with CLBP within PHC. The results can give guidance for interventional trials aiming to improve physical capacity and decrease stress. The impact of the interaction between prognostic factors and interventions on activity limitation, needs further investigation.

Key Words: Chronic Pain, Low Back Pain, Primary Health Care, Life Style, Disability Evaluation, Prognostic Factors, Women.

Strengths and limitations of this study

- The main strength of this study is the longitudinal prospective design over two years within primary health care, high long-term follow up (95%), measurements representing all the domains of International Classification of Functioning, Disability and health (ICF) complemented with lifestyle behavioural factors.
- The limitation of this study is the small sample size and that we included only women which limits the generalizability to men.

INTRODUCTION

Non-specific chronic low back pain (CLBP), defined as pain duration longer than three months, is associated with variations of recurrent or persistent pain.[1, 2] CLBP have various impact on body functions, activity and participation in daily life[1-4] and it is a common cause for attending health care.[1]

Non-specific acute low back pain (LBP) is described to have a spontaneous course.[1, 2, 5] However, after one year 63-82% of primary care patients with LBP report to have recurrent LBP and 20-45% impaired function.[6-10] Prognostic factors for the transition from non-specific acute LBP to CLBP has previously been described in personal and socioeconomic areas as well as in all domains of the International Classification of Functioning, Disability and Health (ICF).[6, 9, 11-18] Women seems to have a greater risk for CLBP[6] and when studying prognostic factors it is suggested to assess women separately.[19-21] Previous prognostic models for the transition to CLBP explain 28-51% of variability in the measured outcome.[22] The outcomes, combination of included prognostic factors and statistical analyses often differs between studies, making comparisons or meta-analysis difficult.[18]

Some studies have described similar prognostic factors for persistent CLBP as for the transition from non-specific acute LBP to CLBP.[23, 24] Since the course of non-specific acute LBP and CLBP differs, more knowledge of prognostic factors for varying outcomes in patients with CLBP is warranted.[25] A previous review studying prognostic factors for delayed recovery in CLBP found no association between age, sex and the outcome measure of pain intensity and disability at short-term follow-up (e.g. 6-weeks). Conflicting evidence was found for fear of avoidance as a predictor.[26] At long-term follow-up (e.g. 6 months) no association was found between smoking, pain intensity, fear of avoidance and the dependent variable disability.[26] Conflicting evidence was found for age, sex and physical job demands and the outcome measure of pain intensity and disability. Moreover, conflicting evidence was

found for the association between age, activities of daily living, pain intensity and physical job demand and the outcome return to work.[26] However, recently a study showed that a physical performance test (6-minute walk test), depression and earlier work ability predicted later work ability in women with CLBP.[27]

The knowledge about various prognostic factors for the recovery in the long-term for patients with CLBP is still insufficient. This study is an extended analysis of the material from the two-year longitudinal cohort study of prognostic factors for work ability in women with CLBP[27]. The present study aim to focus on the prognostic value of lifestyle behavioral factors, stress symptoms and physical performance for future activity limitation using the same material and measurements.

The aim was to assess if body function, activity, participation, health-related quality of life and lifestyle behavioral factors can predict the future variance of self-rated activity limitation in women with CLBP in PHC two years later.

METHODS

Study design

This two-year prospective longitudinal cohort study included women (n=130) with CLBP within PHC.[28] Patients were assessed at baseline and were re-assessed after two years. Predictors for later self-reported activity limitation (Roland Morris disability questionnaire (RMDQ)), was analysed by multivariate linear regression. Independent variables found to be associated with disability in CLBP patients,[27] were complemented with lifestyle behavioural factors including Body Mass Index (BMI), smoking, alcohol consumption, sleep quantity and quality, leisure time physical activity and a questionnaire of the clinical manifestation of

stress. Other independent variables related to chronic pain were pain localisation, pain intensity, fatigue, anxiety, depression, work status, private social support health-related quality of life and two measures of physical performance.

Participants were assessed by a trained physical therapist in PHC both at baseline and after two years and included a structured interview, measure of body height and weight, and the two physical performance tests. Participants were asked to fill in a package of self-administrated questionnaires at the assessment and two at home. They were provided with a pre-paid addressed envelope to return questionnaires. If no questionnaires were returned within two weeks, a reminder by telephone was made. The Regional Ethical Review Board in Gothenburg approved the study. Written informed consent was obtained from all patients.

Selection of patients

Female patients were identified by systematic search in medical charts for LBP diagnoses "M545" (ICD-10) at eight PHC clinics in south-western Sweden, a mixture of urban and rural populations, in 2004-2005. All patients who could be contacted, accepting participation and fulfilling the inclusion criteria were invited to enroll in the study. The inclusion criteria were: female patient, low back pain (pain between costal margins and gluteal folds) with or without referred leg pain.[1] Further inclusion criteria were; longer than 12-week's duration of symptoms, not pregnant, no known spinal pathology, no other severe co-morbidity (e.g. cancer, fracture, stroke, severe psychiatric disorders, mental retardation), age between 18 and 60 years, understanding and fluent in Swedish. At the two-year follow-up, all patients included in the cross-sectional study (n=130),[28] who could be contacted and accepting participation were invited to the follow-up, containing the same study protocol as at baseline.

Measurements

The structured interview included questions about age, nationality, education level, family situation, work status, back pain history (onset, duration and symptoms), co-morbidity and pharmacological treatment.

1. Lifestyle behavioural factors

1.1 Body Mass Index (BMI)

Height and weight were assessed for calculating the BMI (kg/m^2).

1.2 Alcohol consumption

For alcohol consumption the Alcohol Use Disorders Identification Test (Audit-C)[29] was used (range 0-12). Higher scores indicate higher alcohol consumption.

1.3 Smoking

Tobacco use was dichotomized into two categories, No smoker or smoker. The category, no smoker required to never been smoking. The category smoker required to previously been a smoker or are reported to be currently smoking.

1.4 Sleep

For sleep quantity and quality two questions was used.[30] "Do you think you get enough sleep?" (range 1-4) and "On the whole, how do you think you sleep?"(range 1-4). Higher score indicate better sleep quantity and quality.

1.5 Stress symptoms

To quantify clinical manifestations of stress symptoms the Stress and Crises Inventory (SCI-93) was used (range 0-140) where higher scores indicate more severe clinical stress symptoms.[31, 32] A total score of ≤38 indicates normal resources for activity and work.[33]

1.6 Physical activity at leisure time

The Leisure Time Physical Activity Instrument (LTPAI) was used to assess the amount of physical activity in leisure time during a typical week.[34] The number of hours spent for light, moderate and vigorous activities was registered and the total number of hours were used.[34]

2. Body function

2.1 Physical performance tests

The 6-minute walk test (6MWT) was used to assess physical performance.[35-37] The distance (meter) is measured while the patient walks up and down a 30 meter corridor for 6 minutes. The participant was instructed to walk as quickly as possible without running.

Hand grip strength was measured with an electronic instrument Grippit®.[38, 39] A sustained voluntary 10-second contraction was measured. The right hand value was used for analyses in the present study.

2.2 Number of pain localisation, pain intensity and fatigue

For pain distribution, a drawing of the body was used for register pain localisations (0-18).[40] Pain intensity and fatigue during the last week was measured on a visual analogue scale 0-100 mm (VAS).

2.3 Distress

The Hospital Anxiety and Depression Scale (HADS), HADS-A was used for assessment of anxiety, (range 0-21) and the HADS-D for depression (range 0-21). Higher scores indicate greater anxiety or depression.[41, 42]

3. Activity limitations

The RMDQ was used for self-reported activity limitation related to LBP. The RMDQ consists of 24 yes/no statements, where higher scores indicate greater activity limitation (range 0-24). [43]

4. Participation

Work status was dichotomized into two categories, work ability or not. The category, work ability required work or study, full or part-time, applying for work, parental leave full or part-time or part-time disability pension. The category no work ability required full-time sick leave or full-time disability pension. Self-reported sick absenteeism has been shown reliable.[44]

5. Environmental factors

The 4-item version of Medical Outcome Study Social Support Survey (MOS-SSS) registered private social support: emotional-informational, tangible, affectionate support and positive social interaction (range 1-5 for each item). Higher scores indicate more support (total range 4-20).[45]

6. Health-related quality of life

The SF-36 short form health survey (SF-36) was used for general health status. The Physical Component Summary score (PCS) and the Mental Component Summary score (MCS) representing an overall health index of physical or mental health (range 0-100) were used.[46-48]

Statistical analysis

Group characteristics are presented as mean and standard deviations (SD), median and 25th and 75th percentile or the number and percentage at baseline. Percentages change for RMDQ was constructed by subtracting baseline value from two-year follow-up value. The change was divided with baseline and multiplied by 100 to create a percentage change.

To enable more meaningful clinical interpretation small units were transformed to larger ones. In 6MWT one meter was transformed to 100 meter, in hand grip strength one Newton was transformed to 50 Newton, in the pain and fatigue scores, one mm was transformed to 10 mm (VAS).

Spearman Rank correlation between RMDQ at two years and each of the independent variables at baseline was performed to evaluate independent variables and reduce the number of independent variables of interest. This analyse was also performed between RMDQ percentages change and each of the independent variables at baseline. Independent variables with $p<0.20$ were included in next multivariate regression step.

Two forward stepwise multivariate linear regression analysis were performed, one with RMDQ at two years as dependent variable and one with RMDQ percentage change as dependent variable. The independent variables remaining from the first step described above were included.

Prior to the multivariate linear regression, the variables were evaluated for the assumptions of multivariate analysis. The dependent variable RMDQ at two years fulfilled the assumption of normal distribution when ranked using Blom's formula.[49] The statistical criteria for the independent variables were 0.05 for entry and 0.10 for removal. Multi-collinearity was checked by the values of Tolerance and VIF. The final models were adjusted for age as it could be a potential confounding factor, using standard (Enter) multivariate linear regression.

The level of significance for independent variables remaining in the final model was set to 0.05. The IBM SPSS Windows version 22.0 was used for the statistical analyses.

RESULTS

Ninety-five percent (n=123/130) of the participants included in the cross-sectional study[28] could be followed up after two years (Figure 1). Seven patients could not be assessed at the two-year follow-up, three of them due to pregnancy, an exclusion criteria in the present study. The participants were middle-aged (mean 45 (SD10)), mostly educated more than 9 years (88%; 108/123), mainly living with another adult (76%; 93/122) and born in Sweden (90%; 111/123) (Table 1). Seventy-nine percent (97/123) were categorized as having work ability at baseline. The BMI mean and median values of 27 (SD 5.5) and 26 (25^{th};75^{th} percentile 23; 29) indicates that a significant proportion were overweight (≥ 25 BMI).[50] Seventy-six percent (n=93/123) were currently non-smokers and did not exceed risk consumption of alcohol (Table 2). Only 14% (17/123) reported sleeping certainly enough and 19% (23/121) reported very good sleep quality (Table 2). Body function, activity, participation and quality of life at baseline indicates that these aspects of life varied and several of them were not optimal (Table 2).

Table 1. Group characteristics at baseline (n=123)

Personal data	
Age, years [mean (SD)]	45 (10)
Nationality Swedish [% (n/n)	90% (111/123)
Symptom duration, years [mean (SD)]	9.6 (8.8)
Education status [% (n/n)]	
≤ 9 years	12% (15/123)
10-12 years	40% (49/123)
> 12 years	48% (59/123)
Social status [% (n/n)]	
Living with an adult	26% (32/122)
Living with an adult and child/children	50% (61/122)
Living alone	12% (14/122)
Living alone with child/children	9.0% (11/122)
Living apart with an adult	3.3% (4/122)
Pharmacological treatment, yes [% (n/n)][a]	
Analgesics	53% (65/123)
Psychotropic drugs	16% (20/123)
Employment Status [% (n/n)]	
Currently working and/or studying	58% (71/123)
Sick-leave, full-time	11% (13/123)
Sick-leave, part-time	8.9% (11/123)
Disability pension, full-time	11% (13/123)
Disability pension, part-time	5.7% (7/123)
Parental leave, full-time	1.6% (2/123)
Parental leave, part-time	1.6% (2/123)
Unemployed, full-time	0.81% (1/123)
Unemployed, part-time	2.4% (3/123)

[a] The use last month registered by yes or no.

Table 2. Lifestyle factors, body function, activity, participation and health related quality of life at baseline (n=123).

Lifestyle behavioral factors	
Body Mass Index (kg/m^2) [a]	27 (5.5) --- 26 (23; 29)
Audit-C (0-12)[b]	2.2 (1.4) --- 2.0 (1.0; 3.0)
Smoking [% (n/n)]	
never smoked	40% (49/123)
previously smoked	36% (44/123)
currently smoking	20% (25/123)
currently snuffing	4% (5/123)
Sleep quantity [% (n/n)][c]	
certainly enough	14% (17/123)
broadly enough	47% (58/123)
some shortage	24% (29/123)
clearly insufficient	15% (19/123)
Sleep quality [% (n/n)][d]	
very good	19% (23/121)
quite good	51% (62/121)
quite bad	21% 25/121)
very bad	9% (11/121)
SCI-93[e]	36 (21) --- 35 (19; 51)
LTPAI, hours per week (n= 122)[f]	7.8 (8.5) --- 6.0 (3.4; 9.0)
Body function	
Pain localizations (0-18)[g]	4.6 (3.2) --- 4.0 (2.0; 6.0)
Pain intensity (VAS 0-100 mm)[h]	45 (27) --- 45 (24; 68)
Fatigue (VAS 0-100 mm)[h]	53 (29) --- 53 (28; 75)
6MWT (meter) (n=121)	572 (86) --- 581 (515; 633)
Hand grip strength (Newton)	232 (76) --- 237 (184; 285)
HADS-A (0-21)[i]	6.4 (4.4) --- 5.0 (3.0; 9.0)
HADS-D (0-21)[i]	4.3 (3.6) --- 3.0 (1.0; 7.0)
Activity (n=121)	
RMDQ (0-24)[j]	8.4 (4.8) --- 7.0 (4.0; 12)
Participation	
Work ability (yes) [% (n/n)]	79% (97/123)
Environmental factors	
Private social support (4-20)[k]	16 (3.5) --- 17 (14; 19)
Health-related quality of life (n=122)	
PCS (0-100)[l]	38 (9.9) --- 39 (31; 47)
MCS (0-100)[l]	46 (13) --- 49 (37; 56)

[a] First figure mean values (standard deviation). Second figure median values (25th; 75th percentile).
[b] The Alcohol Use Disorders Identification Test (AUDIT-C), 3 items. Higher scores reflect higher alcohol consumption (0-12).
[c] One item: "Do you think you get enough sleep?"
[d] One item: "On the whole, how do you think you sleep?"
[e] Stress and crisis inventory (SCI-93). Higher scores indicate more severe clinical stress symptoms (0-140).
[f] The Leisure Time Physical Activity Instrument (LTPAI) assess the total hours of physical activity in leisure time during a typical week.
[g] Self-reported pain locations registered by a figure with predefined body locations (0-18).
[h] Perceived pain intensity, fatigue over the last week rated on a visual analogue scale, VAS (0-100). Higher values indicate more pain, fatigue.
[i] Hospital Anxiety and Depression Scale (HADS). Higher scores indicate more anxiety (0-21) and depression (0-21).
[j] Roland Morris disability questionnaire (RMDQ) indicates disability related to low back pain (0-24) at baseline. Higher scores indicate more severe disability.
[k] Medical outcome study social support survey (MOS-SSS, 4- item scale) reflects private social support ranging from 1-5. Higher scores reflect more perceived support (4-20).
[l] SF-36. The physical component summary score (PCS) (0-100) and mental component summary score (MCS) (0-100).

Two-year follow-up RMDQ status

There was a statistical significant mean decrease of 1.9 points (95% CI, 1.2-2.5) on RMDQ from 8.4 (SD 4.8) at baseline to 6.4 (SD 5.5) at the two-year follow-up (-23%, $p< 0.0001$).

Predictors for activity limitation (RMDQ) at the two-year follow-up

The stepwise multivariate regression analysis showed that the 6MWT, SCI-93 and RMDQ at baseline were the most important predictors explaining 54 % of variance in the RMDQ at the two-year follow-up (Table 3). A model including age, 6MWT and SCI-93 made statistically significant contribution with adjusted R^2 0.39. However, a model including only RMDQ (with or without addition of age) gave an R^2 of 0.51. Models with 6MTW or SCI-93 alone gave R^2 of 0.20 and 0.25 respectively.

There were no significant association between percentage change in RMDQ and any of the independent variables (Table 4).

Table 3. Prognostic factors at baseline for activity limitation at the later two-year follow-up, using the Roland Morris disability Questionnaire (RMDQ) at two-year follow-up (n=120).

	Spearman Rank Correlation Correlation with RMDQ at two year			**Forward stepwise multivariate linear regression**[a] Independent variables p<0.20 entered in the model, adjusted for age. **R^2 = 0.54 for the overall model.**	
	number	**r**	**p-value**	**β (CI 95%)**	**p-value**
Age, years	120	0.067	0.47	-0.0048 (-0.019 - 0.010)	0.51
Lifestyle behavioural factors					
Body Mass Index (kg/m^2)	119	0.21	0.021		
Smoker (n=72) --- no smoker (n=48)	120	0.14	0.14		
AUDIT-C (0-12)[b]	118	-0.23	0.011		
Sleep quantity (1-4)[c]	120	-0.34	0.00014		
Sleep quality (1-4)[d]	118	-0.43	<0.0001		
SCI-93[e]	120	0.48	<0.0001	**0.0091 (0.0023 - 0.016)**	**0.0088**
LTPAI, (hours per week)[f]	119	-0.11	0.24		
Body function					
Pain localisations (0-18)[g]	120	0.36	0.000052		
Pain intensity 10 mm (VAS 0-100)[h]	120	0.20	0.027		
Fatigue 10 mm (VAS 0-100)[h]	120	0.24	0.0078		
6MWT, 100 meters	118	-0.41	<0.0001	**-0.23 (-0.42 - -0.036)**	**0.020**
Hand grip strength 50 N (Newton)	120	-0.17	0.070		
HADS-A (0-21) [i]	120	0.16	0.089		
HADS-D (0-21) [i]	120	0.37	0.000025		
Activity					
RMDQ at baseline (0-24)[j]	118	0.71	<0.0001	**0.10 (0.068 - 0.14)**	**<0.0001**
Participation					
Work ability (n=95) --- no work ability (n=25)	120	-0.37	0.000026		
Environmental factors					
Private social support (4-20)[k]	120	-0.29	0.0013		
Health-related quality of life					
PCS (0-100)[l]	119	-0.42	<0.0001		
MCS (0-100)[l]	119	-0.28	0.0022		

[a] Roland Morris disability questionnaire (RMDQ) score was transformed to ranked normal score of RMDQ, using Blom's formula. The final model was adjusted for age, using standard (Enter) multivariate linear regression.
[b] The Alcohol Use Disorders Identification Test (AUDIT-C), 3 items. Higher scores reflect higher alcohol consumption (0-12).
[c] One item: "Do you think you get enough sleep?". Higher scores indicates better sleep (1-4).
[d] One item: "On the whole, how do you think you sleep?". Higher scores indicates better sleep (1-4).
[e] Stress and crisis inventory (SCI-93). Higher scores indicate more severe clinical stress symptoms (0-140).
[f] The Leisure Time Physical Activity Instrument (LTPAI) assess the total hours of physical activity in leisure time during a typical week.
[g] Self-reported pain locations registered by a figure with predefined body locations (0-18).
[h] Perceived pain intensity, fatigue over the last week rated on a visual analogue scale, VAS (0-100). Higher values indicate more pain, fatigue.
[i] Hospital Anxiety and Depression Scale (HADS). Higher scores indicate more anxiety (0-21) and depression (0-21).
[j] Roland Morris disability questionnaire indicates disability related to low back pain (0-24) at baseline. Higher scores indicate more severe disability.
[k] Medical outcome study social support survey (MOS-SSS, 4- item scale) reflects private social support ranging from 1-5. Higher scores reflect more perceived support (4-20).
[l] SF-36. The physical component summary score (PCS) (0-100) and mental component summary score (MCS) (0-100).

Table 4. Prognostic factors at baseline for percentage change in the Roland Morris disability Questionnaire (RMDQ) (n=115).

	Spearman Rank Correlation Correlation with percentage change in RMDQ			**Forward stepwise multivariate linear regression**[a] Independent variables p<0.20 entered in the model, adjusted for age. No significant association.	
	number	**r**	**p-value**	**β (CI 95%)**	**p-value**
Age, years	115	-0.11	0.23	-0.0017 (-0.014-0.011)	0.79
Lifestyle behavioural factors					
Body Mass Index (kg/m^2)	114	-0.13	0.18		
Smoker (n=72) --- no smoker (n=48)	115	-0.072	0.44		
AUDIT-C (0-12)[b]	113	0.11	0.23		
Sleep quantity (1-4)[c]	115	0.18	0.054		
Sleep quality (1-4)[d]	113	0.16	0.099		
SCI-93[e]	115	-0.17	0.075		
LTPAI (hours per week)[f]	115	0.13	0.18		
Body function					
Pain localisations (0-18)[g]	115	-0.15	0.10		
Pain intensity 10 mm (VAS 0-100)[h]	115	0.078	0.41		
Fatigue 10 mm (VAS 0-100)[h]	115	-0.046	0.62		
6MWT, 100 meters	113	0.17	0.065		
Hand grip strength 50 N (Newton)	115	0.057	0.55		
HADS-A (0-21)[i]	115	-0.023	0.81		
HADS-D (0-21)[i]	115	-0.11	0.24		
Participation					
Work ability (n=95) --- no work ability (n=25)	115	0.15	0.11		
Environmental factors					
Private social support (4-20)[j]	115	0.14	0.14		
Health-related quality of life					
PCS (0-100)[k]	114	0.029	0.76		
MCS (0-100)[k]	114	0.14	0.13		

[a] Percentage change in RMDQ as dependent variable. The final model was adjusted for age, using standard (Enter) multivariate linear regression.
[b] The Alcohol Use Disorders Identification Test (AUDIT-C), 3 items. Higher scores reflect higher alcohol consumption (0-12).
[c] One item: "Do you think you get enough sleep?". Higher scores indicates better sleep (1-4).
[d] One item: "On the whole, how do you think you sleep?". Higher scores indicates better sleep (1-4).
[e] Stress and crisis inventory (SCI-93). Higher scores indicate more severe clinical stress symptoms (0-140).
[f] The Leisure Time Physical Activity Instrument (LTPAI) assess the total hours of physical activity in leisure time during a typical week.
[g] Self-reported pain locations registered by a figure with predefined body locations (0-18).
[h] Perceived pain intensity, fatigue over the last week rated on a visual analogue scale, VAS (0-100). Higher values indicate more pain, fatigue.
[i] Hospital Anxiety and Depression Scale (HADS). Higher scores indicate more anxiety (0-21) and depression (0-21).
[j] Medical outcome study social support survey (MOS-SSS, 4- item scale) reflects private social support ranging from 1-5. Higher scores reflect more perceived support (4-20).
[k] SF-36. The physical component summary score (PCS) (0-100) and mental component summary score (MCS) (0-100).

DISCUSSION

This two-year prospective cohort study of women with CLBP attending PHC showed that lower performance in walking capacity (6MWT), more severe clinical stress symptoms (SCI-93) and more severe activity limitation (RMDQ) at baseline predicted more activity limitation (RMDQ) after two years (Table 3). The model with these three predictors explained 54% of the variance in self-reported activity limitation (RMDQ) at the two-year follow-up, which is similar to a previous review of prediction models including various predictors for disability in patients with subacute non-specific LBP.[22]

Strengths and limitations

This study included measurements representing all the domains of ICF[17] complemented with lifestyle behavioural factors, which is considered as a main strength. The follow-up frequency was very high with 95% being followed up.

Prevalence and predictors of chronic pain have been studied in general populations,[21, 40, 51] while the present study assessed women with CLBP consulting PHC, contributing with knowledge for health care professionals working in PHC. Previous studies found that chronic pain is more common in women, and that women are at greater risk of chronic pain and disability.[6, 40, 51] It has been suggested that women should be assessed separately when studying prognostic factors for LBP,[19, 20] hence the present study included only female patients.

Each independent variable were analysed in a bivariate analysis. The multivariate model was built by using the independent variables with $p < 0.20$ entered in the model. Physical performance (6MWT) was included in the final model. Knowing that age influences physical

performance, age was included as a potential confounder, even though it was not correlated with RMDQ.

We deployed a sorting mechanism (Spearman's rank correlation) to reduce the problem which may occur when there are few participants relative to the number of independent variables, before doing the multivariate regression. Hence, the number of participants were considered to be sufficient for the final model.

Prior to the multiple regression, the variables were evaluated for assumptions of multivariate analysis including checking for multicollinearity and singularity. The values of Tolerance (0.52-0.74) and VIF (1.3-1.9) were checked indicating low correlation between the independent variables. Moreover, questionnaires total scores was used to avoid singularity.

Self-administrated questionnaires are recommended for the assessment of activity limitation in patients with LBP.[52] The present study used RMDQ as the outcome measure at the two-year follow-up. The RMDQ is considered valid, commonly used and recommended in LBP research for monitoring disability.[53, 54] Seventeen statements in the RMDQ are reported to be linked to the activity component in the ICF.[55, 56] However, self-reports may suffer from the fact that some patients may under or overestimate their limitations and physical performance tests are suggested to complement self-reports.[57] Walk capacity (6MWT) and hand grip strength, semi-objective measures of body function, were therefore included as potential predictors in this study.

The group showed a moderate grade of disability, RMDQ 8.4 (SD 4.8), at baseline which might reflect that the women included were not in acute need for treatment when recruited. There was a statistical significant mean decrease of approximately 2 points on RMDQ during the two-year period. Minimal clinical detectable change in the RMDQ is considered to be 2 to 3 points. Others have suggested a change of 4 to 5 points to be of clinical value.[53]

Predictors for activity limitation (RMDQ) at two-year follow-up

The BMI values corresponded with overweight (mean 27 (SD 5.5)), which is common in patients with chronic pain[28, 58] and might be due to impaired body function, activity limitation and restrictions of participation. A previous one-year follow up study found self-reported weight and height (BMI) as a significant predictor for activity limitation.[59] However, this could not be confirmed in the present study.

Previously or currently smoking was not found as a predictor, which is concordant to a review studying prognostic factors for pain and disability in CLBP.[26] In the present study, hours per week of leisure time physical activity (LTPAI) (mean 7.8 (SD 8.5) was within recommended levels of physical activity[60] which might have been the reason for no prognostic value. A healthy lifestyle behavior, combinations of lifestyles factors, is reported to influences the prognosis of LBP.[21] It could be interesting to combine and categorize various self-reported lifestyles behavioral factors for analyzing their prognostic value for patients with CLBP. However, in the present study the prognostic value of lifestyle behavioral factors were analyzed separately for later self-reported activity limitation in CLBP.

Previous prospective studies of LBP have evaluated body function by measuring spinal motion and muscle strength, showing them to be of poor prognostic value.[11, 61] In the present study, the body function assessed by the 6MWT was of prognostic value, showing that lower performance in the 6MWT at baseline predicted more severe activity limitation at two-year follow-up. Therefore, the 6MWT could be included as a complement to standard clinical examination of CLBP. Physical activity is a recommended intervention for patients with CLBP. The 6MWT is easy to perform and provides information of an individual's physical performance. In the future, the 6MWT might be used as a self-administrated assessment tool to promote physical activity and self-management strategies for patients with CLBP. However, the utility of 6MWT as a self-assessment tool needs to be studied further.

More severe clinical stress symptoms (SCI-93), could independently predict more severe activity limitation (RMDQ) at the two-year follow-up (Table 3). The mean score for SCI-93 at baseline was 36 (SD 21) (Table 2), which indicates an increased level of clinical stress symptoms in the group, compared to the reference values.[32, 33] Signs and symptoms in patients with chronic pain are suggested to be associated with prolonged stress,[62] but measurement of clinical stress symptoms is not standard in the clinical assessment of patients with CLBP. Therefore, the SCI-93 could provide valuable information for predicting later activity limitation for these patients. Moreover, questionnaires assessing symptoms severity might stimulate the patient's motivation in using active coping strategies to alleviate their stress responses.[32] Stress reduction interventions have shown to improve pain acceptance.[63] However, if pain acceptance might mediate the association of stress, physical activity and disability need further investigation.

Studies of prognostic factors for patients with acute LBP report similar predictors as this study to the ones in this study.[64, 65] However, the characteristics of the patients in the study used to derive the predictive model have to be similar to those in whom the model will be used to. Various factors can impact disability in patients with CLBP (> 12 weeks duration) and function and functional demands often differs between women and men. Therefore, women with CLBP were included in this study.

The baseline activity limitation (RMDQ) was the strongest predictor (R^2 0.51) for activity limitation (RMDQ) at two year. The prognostic model including the baseline RMDQ, 6MWT, and SCI-93 explained 54% of the variance in activity limitation (RMDQ) at the two-year follow-up (Table 3), which is slightly more compared to findings in a previous review of different prognostic models explaining 28-51% of variance in persisting disability in sub acute LBP.[22] The 6MWT and SCI-93 may add useful information where the outcome of RMDQ is unavailable.

Knowledge about factors that are associated with the probable recovery or not in CLBP can be used to improve the management of patients with CLBP in primary care. The results of this study can give guidance for interventional trials aiming to improve physical capacity and decrease stress in women with CLBP. The impact of the interaction between prognostic factors and interventions on activity limitation in women with CLBP, needs further investigation.

CONCLUSION

A walk test (6MWT), clinical stress symptoms (SCI-93) and activity limitation (RMDQ) predicted future activity limitation in women with CLBP within PHC. The prognostic model including these three predictors explained 54% of the variance in self-reported activity limitation (RMDQ) after two years.

Contributors

LN contributed to the design of the study, were responsible for the data collection, participated in the statistical analysis, interpreted the data and drafted the first manuscript. LT contributed to the interpretation of data and revision of manuscript for important content. RG contributed to the design of the study, participated in the statistical analysis, interpreted the data and critically revised all versions of the manuscript. KM contributed to the design of the study, participated in the statistical analysis, interpreted the data and critically revised all versions of the manuscript. All authors read and approved the final manuscript.

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Competing interests

The authors declare that they have no competing interest.

Ethics approval

The Regional Ethical Review Board in Gothenburg approved the study. Written informed consent was obtained from all patients.

Data sharing statement

No additional data are available.

Figure legends

Figure 1. Participants flow.

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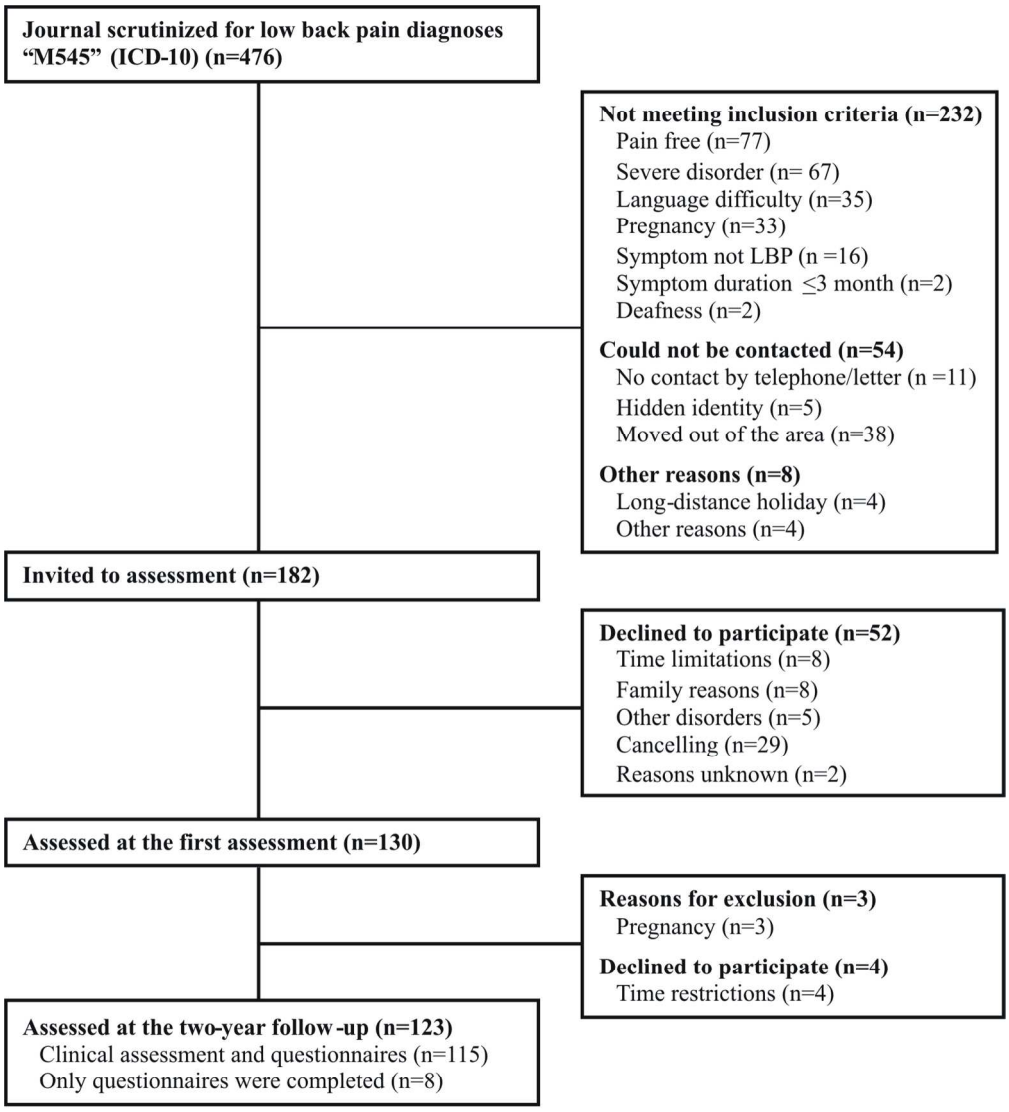

Figure 1. Participants flow.

Figure 1. Participants flow

150x177mm (300 x 300 DPI)

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Noted in Title page and Abstract. Pages 1,2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Pages 2,3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Pages 5,6
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 6
Methods			
Study design	4	Present key elements of study design early in the paper	Pages 6,7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 7
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Pages 6,7
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Pages 7-10
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Pages 7-10
Bias	9	Describe any efforts to address potential sources of bias	Page 11
Study size	10	Explain how the study size was arrived at	Page 7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Pages 10,11
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Pages 11,12
		(*b*) Describe any methods used to examine subgroups and interactions	Pages 11,12
		(*c*) Explain how missing data were addressed	Page 13 and Figure 1 (at page 30)

		(*d*) If applicable, explain how loss to follow-up was addressed	Page 13 and Figure 1 (at page 30)
		(*e*) Describe any sensitivity analyses	NA
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Page 13 and Figure 1 (at page 30)
		(b) Give reasons for non-participation at each stage	Page 13 and Figure 1 (at page 30)
		(c) Consider use of a flow diagram	Figure 1 (at page 30)
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 11 and 13 and Tables 1,2 at pages 14,15
		(b) Indicate number of participants with missing data for each variable of interest	Tables 1,2 at pages 14,15
		(c) Summarise follow-up time (eg, average and total amount)	Follow-up time is two years, documented throughout the manuscript.
Outcome data	15*	Report numbers of outcome events or summary measures over time	Page 16 and Table 3 at page 17, Table 4 at page 18
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Page 11, 16 and Table 3 at page 17, Table 4 at page 18
		(*b*) Report category boundaries when continuous variables were categorized	NA
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 19
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and	Pages 19, 20

		magnitude of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Pages 19-23
Generalisability	21	Discuss the generalisability (external validity) of the study results	Pages 19-23
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 24

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Predictors for future activity limitation in women with chronic low back pain consulting primary care: a two-year prospective longitudinal cohort study

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ABSTRACT

Objectives. To assess if body function, activity, participation, health-related quality of life and lifestyle behavioral factors can predict activity limitation in women with chronic low back pain (CLBP) in primary health care (PHC) two years later.

Design. A two-year prospective longitudinal cohort study within PHC.

Settings: Primary health care in south-western Sweden.

Participants: The cohort comprised 130 women with CLBP attending PHC at baseline 2004-2005 and were re-assessed after two years.

Measures. The dependent outcome variable was self-reported activity limitation (Roland Morris disability questionnaire (RMDQ)) at two-year follow-up. Independent predictors at baseline were age, BMI, smoking, alcohol consumption, sleep quantity and quality, leisure time physical activity, a questionnaire of clinical manifestation of stress (Stress and Crises Inventory (SCI-93)), pain localisation, pain intensity, fatigue, anxiety, depression, RMDQ, work status, private social support, health-related quality of life and measures of physical performance specified as six-minute walk test (6MWT) and hand grip strength. Relation between baseline predictors and variation in later self-reported activity limitation (RMDQ) was analysed using multivariate linear regression.

Results. Ninety-five percent (n=123/130) were followed up after two years. The participants were middle-aged (mean 45 (SD10) years), mostly educated more than 9 years (88%;108/123), mainly living with another adult (76%;93/122) and born in Sweden (90%;111/123). Seventy-nine percent (97/123) were categorized as having work ability at baseline. The final prognostic model including 6MWT, SCI-93 and RMDQ at baseline explained 54% of the variance in self-reported activity limitation (RMDQ) at the two-year follow-up.

Conclusions: Lower physical performance, more severe clinical stress symptoms and more

severe activity limitation predicted activity limitation after two years in women with CLBP within PHC. The results can give guidance for interventional trials aiming to improve physical capacity and decrease stress. The impact of the interaction between prognostic factors and interventions on activity limitation, needs further investigation.

Key Words: Chronic Pain, Low Back Pain, Primary Health Care, Life Style, Disability Evaluation, Prognostic Factors, Women.

Strengths and limitations of this study

- The main strength of this study is the longitudinal prospective design over two years within primary health care, high long-term follow up (95%), measurements representing all the domains of International Classification of Functioning, Disability and health (ICF) complemented with lifestyle behavioural factors.
- The limitation of this study is the small sample size and that we included only women which limits the generalizability to men.

INTRODUCTION

Non-specific chronic low back pain (CLBP), defined as pain duration longer than three months, is associated with variations of recurrent or persistent pain.[1, 2] CLBP have various impact on body functions, activity and participation in daily life[1-4] and it is a common cause for attending health care.[1]

Non-specific acute low back pain (LBP) is described to have a spontaneous course.[1, 2, 5] However, after one year 63-82% of primary care patients with LBP report to have recurrent LBP and 20-45% impaired function.[6-10] Prognostic factors for the transition from non-specific acute LBP to CLBP has previously been described in personal and socioeconomic areas as well as in all domains of the International Classification of Functioning, Disability and Health (ICF).[6, 9, 11-18] Women seems to have a greater risk for CLBP[6] and when studying prognostic factors it is suggested to assess women separately.[19-21] Previous prognostic models for the transition to CLBP explain 28-51% of variability in the measured outcome.[22] The outcomes, combination of included prognostic factors and statistical analyses often differs between studies, making comparisons or meta-analysis difficult.[18]

Some studies have described similar prognostic factors for persistent CLBP as for the transition from non-specific acute LBP to CLBP.[23, 24] Since the course of non-specific acute LBP and CLBP differs, more knowledge of prognostic factors for varying outcomes in patients with CLBP is warranted.[25] A previous review studying prognostic factors for delayed recovery in CLBP found no association between age, sex and the outcome measure of pain intensity and disability at short-term follow-up (e.g. 6-weeks). Conflicting evidence was found for fear of avoidance as a predictor.[26] At long-term follow-up (e.g. 6 months) no association was found between smoking, pain intensity, fear of avoidance and the dependent variable disability.[26] Conflicting evidence was found for age, sex and physical job demands and the outcome measure of pain intensity and disability. Moreover, conflicting evidence was

found for the association between age, activities of daily living, pain intensity and physical job demand and the outcome return to work.[26] However, recently a study showed that a physical performance test (6-minute walk test), depression and earlier work ability predicted later work ability in women with CLBP.[27]

The knowledge about various prognostic factors for the recovery in the long-term for patients with CLBP is still insufficient. This study is an extended analysis of the material from the two-year longitudinal cohort study of prognostic factors for work ability in women with CLBP[27]. The present study aim to focus on the prognostic value of lifestyle behavioral factors, stress symptoms and physical performance for future activity limitation using the same material and measurements.

The aim was to assess if body function, activity, participation, health-related quality of life and lifestyle behavioral factors can predict the future variance of self-rated activity limitation in women with CLBP in PHC two years later.

METHODS

Study design

This two-year prospective longitudinal cohort study included women (n=130) with CLBP within PHC.[28] Patients were assessed at baseline and were re-assessed after two years. Predictors for later self-reported activity limitation (Roland Morris disability questionnaire (RMDQ)), was analysed by multivariate linear regression. Independent variables found to be associated with disability in CLBP patients,[27] were complemented with lifestyle behavioural factors including Body Mass Index (BMI), smoking, alcohol consumption, sleep quantity and quality, leisure time physical activity and a questionnaire of the clinical manifestation of

stress. Other independent variables related to chronic pain were pain localisation, pain intensity, fatigue, anxiety, depression, work status, private social support health-related quality of life and two measures of physical performance.

Participants were assessed by a trained physical therapist in PHC both at baseline and after two years and included a structured interview, measure of body height and weight, and the two physical performance tests. Participants were asked to fill in a package of self-administrated questionnaires at the assessment and two at home. They were provided with a pre-paid addressed envelope to return questionnaires. If no questionnaires were returned within two weeks, a reminder by telephone was made. The Regional Ethical Review Board in Gothenburg approved the study. Written informed consent was obtained from all patients.

Selection of patients

Female patients were identified by systematic search in medical charts for LBP diagnoses "M545" (ICD-10) at eight PHC clinics in south-western Sweden, a mixture of urban and rural populations, in 2004-2005. All patients who could be contacted, accepting participation and fulfilling the inclusion criteria were invited to enroll in the study. The inclusion criteria were: female patient, low back pain (pain between costal margins and gluteal folds) with or without referred leg pain.[1] Further inclusion criteria were; longer than 12-week's duration of symptoms, not pregnant, no known spinal pathology, no other severe co-morbidity (e.g. cancer, fracture, stroke, severe psychiatric disorders, mental retardation), age between 18 and 60 years, understanding and fluent in Swedish. At the two-year follow-up, all patients included in the cross-sectional study (n=130),[28] who could be contacted and accepting participation were invited to the follow-up, containing the same study protocol as at baseline.

Measurements

The structured interview included questions about age, nationality, education level, family situation, work status, back pain history (onset, duration and symptoms), co-morbidity and pharmacological treatment.

1. Lifestyle behavioural factors

1.1 Body Mass Index (BMI)

Height and weight were assessed for calculating the BMI (kg/m^2).

1.2 Alcohol consumption

For alcohol consumption the Alcohol Use Disorders Identification Test (Audit-C)[29] was used (range 0-12). Higher scores indicate higher alcohol consumption.

1.3 Smoking

Tobacco use was dichotomized into two categories, No smoker or smoker. The category, no smoker required to never been smoking. The category smoker required to previously been a smoker or are reported to be currently smoking.

1.4 Sleep

For sleep quantity and quality two questions was used.[30] "Do you think you get enough sleep?" (range 1-4) and "On the whole, how do you think you sleep?"(range 1-4). Higher score indicate better sleep quantity and quality.

1.5 Stress symptoms

To quantify clinical manifestations of stress symptoms the Stress and Crises Inventory (SCI-93) was used (range 0-140) where higher scores indicate more severe clinical stress symptoms.[31, 32] A total score of ≤38 indicates normal resources for activity and work.[33]

1.6 Physical activity at leisure time

The Leisure Time Physical Activity Instrument (LTPAI) was used to assess the amount of physical activity in leisure time during a typical week.[34] The number of hours spent for light, moderate and vigorous activities was registered and the total number of hours were used.[34]

2. Body function

2.1 Physical performance tests

The 6-minute walk test (6MWT) was used to assess physical performance.[35-37] The distance (meter) is measured while the patient walks up and down a 30 meter corridor for 6 minutes. The participant was instructed to walk as quickly as possible without running.

Hand grip strength was measured with an electronic instrument Grippit®.[38, 39] A sustained voluntary 10-second contraction was measured. The right hand value was used for analyses in the present study.

2.2 Number of pain localisation, pain intensity and fatigue

For pain distribution, a drawing of the body was used for register pain localisations (0-18).[40] Pain intensity and fatigue during the last week was measured on a visual analogue scale 0-100 mm (VAS).

2.3 Distress

The Hospital Anxiety and Depression Scale (HADS), HADS-A was used for assessment of anxiety, (range 0-21) and the HADS-D for depression (range 0-21). Higher scores indicate greater anxiety or depression.[41, 42]

3. Activity limitations

The RMDQ was used for self-reported activity limitation related to LBP. The RMDQ consists of 24 yes/no statements, where higher scores indicate greater activity limitation (range 0-24). [43]

4. Participation

Work status was dichotomized into two categories, work ability or not. The category, work ability required work or study, full or part-time, applying for work, parental leave full or part-time or part-time disability pension. The category no work ability required full-time sick leave or full-time disability pension. Self-reported sick absenteeism has been shown reliable.[44]

5. Environmental factors

The 4-item version of Medical Outcome Study Social Support Survey (MOS-SSS) registered private social support: emotional-informational, tangible, affectionate support and positive social interaction (range 1-5 for each item). Higher scores indicate more support (total range 4-20).[45]

6. Health-related quality of life

The SF-36 short form health survey (SF-36) was used for general health status. The Physical Component Summary score (PCS) and the Mental Component Summary score (MCS) representing an overall health index of physical or mental health (range 0-100) were used.[46-48]

Statistical analysis

Group characteristics are presented as mean and standard deviations (SD), median and 25th and 75th percentile or the number and percentage at baseline. Percentages change for RMDQ was constructed by subtracting baseline value from two-year follow-up value. The change was divided with baseline and multiplied by 100 to create a percentage change.

To enable more meaningful clinical interpretation small units were transformed to larger ones. In 6MWT one meter was transformed to 100 meter, in hand grip strength one Newton was transformed to 50 Newton, in the pain and fatigue scores, one mm was transformed to 10 mm (VAS).

Spearman Rank correlation between RMDQ at two years and each of the independent variables at baseline was performed to evaluate independent variables and reduce the number of independent variables of interest. This analyse was also performed between RMDQ percentages change and each of the independent variables at baseline. Independent variables with $p<0.20$ were included in next multivariate regression step.

Two forward stepwise multivariate linear regression analysis were performed, one with RMDQ at two years as dependent variable and one with RMDQ percentage change as dependent variable. The independent variables remaining from the first step described above were included.

Prior to the multivariate linear regression, the variables were evaluated for the assumptions of multivariate analysis. The dependent variable RMDQ at two years fulfilled the assumption of normal distribution when ranked using Blom's formula.[49] The statistical criteria for the independent variables were 0.05 for entry and 0.10 for removal. Multi-collinearity was checked by the values of Tolerance and VIF. The final models were adjusted for age as it could be a potential confounding factor, using standard (Enter) multivariate linear regression.

The level of significance for independent variables remaining in the final model was set to 0.05. The IBM SPSS Windows version 22.0 was used for the statistical analyses.

RESULTS

Ninety-five percent (n=123/130) of the participants included in the cross-sectional study[28] could be followed up after two years (Figure 1). Seven patients could not be assessed at the two-year follow-up, three of them due to pregnancy, an exclusion criteria in the present study. The participants were middle-aged (mean 45 (SD10)), mostly educated more than 9 years (88%; 108/123), mainly living with another adult (76%; 93/122) and born in Sweden (90%; 111/123) (Table 1). Seventy-nine percent (97/123) were categorized as having work ability at baseline. The BMI mean and median values of 27 (SD 5.5) and 26 (25^{th};75^{th} percentile 23; 29) indicates that a significant proportion were overweight (≥ 25 BMI).[50] Seventy-six percent (n=93/123) were currently non-smokers and did not exceed risk consumption of alcohol (Table 2). Only 14% (17/123) reported sleeping certainly enough and 19% (23/121) reported very good sleep quality (Table 2). Body function, activity, participation and quality of life at baseline indicates that these aspects of life varied and several of them were not optimal (Table 2).

Table 1. Group characteristics at baseline (n=123)

Personal data	
Age, years [mean (SD)]	45 (10)
Nationality Swedish [% (n/n)	90% (111/123)
Symptom duration, years [mean (SD)]	9.6 (8.8)
Education status [% (n/n)]	
≤ 9 years	12% (15/123)
10-12 years	40% (49/123)
> 12 years	48% (59/123)
Social status [% (n/n)]	
Living with an adult	26% (32/122)
Living with an adult and child/children	50% (61/122)
Living alone	12% (14/122)
Living alone with child/children	9.0% (11/122)
Living apart with an adult	3.3% (4/122)
Pharmacological treatment, yes [% (n/n)][a]	
Analgesics	53% (65/123)
Psychotropic drugs	16% (20/123)
Employment Status [% (n/n)]	
Currently working and/or studying	58% (71/123)
Sick-leave, full-time	11% (13/123)
Sick-leave, part-time	8.9% (11/123)
Disability pension, full-time	11% (13/123)
Disability pension, part-time	5.7% (7/123)
Parental leave, full-time	1.6% (2/123)
Parental leave, part-time	1.6% (2/123)
Unemployed, full-time	0.81% (1/123)
Unemployed, part-time	2.4% (3/123)

[a] The use last month registered by yes or no.

Table 2. Lifestyle factors, body function, activity, participation and health related quality of life at baseline (n=123).

Lifestyle behavioral factors	
Body Mass Index (kg/m^2) [a]	27 (5.5) --- 26 (23; 29)
Audit-C (0-12)[b]	2.2 (1.4) --- 2.0 (1.0; 3.0)
Smoking [% (n/n)]	
never smoked	40% (49/123)
previously smoked	36% (44/123)
currently smoking	20% (25/123)
currently snuffing	4% (5/123)
Sleep quantity [% (n/n)][c]	
certainly enough	14% (17/123)
broadly enough	47% (58/123)
some shortage	24% (29/123)
clearly insufficient	15% (19/123)
Sleep quality [% (n/n)][d]	
very good	19% (23/121)
quite good	51% (62/121)
quite bad	21% 25/121)
very bad	9% (11/121)
SCI-93[e]	36 (21) --- 35 (19; 51)
LTPAI, hours per week (n= 122)[f]	7.8 (8.5) --- 6.0 (3.4; 9.0)
Body function	
Pain localizations (0-18)[g]	4.6 (3.2) --- 4.0 (2.0; 6.0)
Pain intensity (VAS 0-100 mm)[h]	45 (27) --- 45 (24; 68)
Fatigue (VAS 0-100 mm)[h]	53 (29) --- 53 (28; 75)
6MWT (meter) (n=121)	572 (86) --- 581 (515; 633)
Hand grip strength (Newton)	232 (76) --- 237 (184; 285)
HADS-A (0-21)[i]	6.4 (4.4) --- 5.0 (3.0; 9.0)
HADS-D (0-21)[i]	4.3 (3.6) --- 3.0 (1.0; 7.0)
Activity (n=121)	
RMDQ (0-24)[j]	8.4 (4.8) --- 7.0 (4.0; 12)
Participation	
Work ability (yes) [% (n/n)]	79% (97/123)
Environmental factors	
Private social support (4-20)[k]	16 (3.5) --- 17 (14; 19)
Health-related quality of life (n=122)	
PCS (0-100)[l]	38 (9.9) --- 39 (31; 47)
MCS (0-100)[l]	46 (13) --- 49 (37; 56)

[a] First figure mean values (standard deviation). Second figure median values (25th; 75th percentile).
[b] The Alcohol Use Disorders Identification Test (AUDIT-C), 3 items. Higher scores reflect higher alcohol consumption (0-12).
[c] One item: "Do you think you get enough sleep?"
[d] One item: "On the whole, how do you think you sleep?"
[e] Stress and crisis inventory (SCI-93). Higher scores indicate more severe clinical stress symptoms (0-140).
[f] The Leisure Time Physical Activity Instrument (LTPAI) assess the total hours of physical activity in leisure time during a typical week.
[g] Self-reported pain locations registered by a figure with predefined body locations (0-18).
[h] Perceived pain intensity, fatigue over the last week rated on a visual analogue scale, VAS (0-100). Higher values indicate more pain, fatigue.
[i] Hospital Anxiety and Depression Scale (HADS). Higher scores indicate more anxiety (0-21) and depression (0-21).
[j] Roland Morris disability questionnaire (RMDQ) indicates disability related to low back pain (0-24) at baseline. Higher scores indicate more severe disability.
[k] Medical outcome study social support survey (MOS-SSS, 4- item scale) reflects private social support ranging from 1-5. Higher scores reflect more perceived support (4-20).
[l] SF-36. The physical component summary score (PCS) (0-100) and mental component summary score (MCS) (0-100).

Two-year follow-up RMDQ status

There was a statistical significant mean decrease of 1.9 points (95% CI, 1.2-2.5) on RMDQ from 8.4 (SD 4.8) at baseline to 6.4 (SD 5.5) at the two-year follow-up (-23%, $p< 0.0001$).

Predictors for activity limitation (RMDQ) at the two-year follow-up

The stepwise multivariate regression analysis showed that the 6MWT, SCI-93 and RMDQ at baseline were the most important predictors explaining 54 % of variance in the RMDQ at the two-year follow-up (Table 3). A model including age, 6MWT and SCI-93 made statistically significant contribution with adjusted R^2 0.39. However, a model including only RMDQ (with or without addition of age) gave an R^2 of 0.51. Models with 6MTW or SCI-93 alone gave R^2 of 0.20 and 0.25 respectively.

There were no significant association between percentage change in RMDQ and any of the independent variables (Table 4).

Table 3. Prognostic factors at baseline for activity limitation at the later two-year follow-up, using the Roland Morris disability Questionnaire (RMDQ) at two-year follow-up (n=120).

	Spearman Rank Correlation Correlation with RMDQ at two year			**Forward stepwise multivariate linear regression**[a] Independent variables p<0.20 entered in the model, adjusted for age. **R^2 = 0.54 for the overall model.**	
	number	**r**	**p-value**	**β (CI 95%)**	**p-value**
Age, years	120	0.067	0.47	-0.0048 (-0.019 - 0.010)	0.51
Lifestyle behavioural factors					
Body Mass Index (kg/m^2)	119	0.21	0.021		
Smoker (n=72) --- no smoker (n=48)	120	0.14	0.14		
AUDIT-C (0-12)[b]	118	-0.23	0.011		
Sleep quantity (1-4)[c]	120	-0.34	0.00014		
Sleep quality (1-4)[d]	118	-0.43	<0.0001		
SCI-93[e]	120	0.48	<0.0001	**0.0091 (0.0023 - 0.016)**	**0.0088**
LTPAI, (hours per week)[f]	119	-0.11	0.24		
Body function					
Pain localisations (0-18)[g]	120	0.36	0.000052		
Pain intensity 10 mm (VAS 0-100)[h]	120	0.20	0.027		
Fatigue 10 mm (VAS 0-100)[h]	120	0.24	0.0078		
6MWT, 100 meters	118	-0.41	<0.0001	**-0.23 (-0.42 - -0.036)**	**0.020**
Hand grip strength 50 N (Newton)	120	-0.17	0.070		
HADS-A (0-21) [i]	120	0.16	0.089		
HADS-D (0-21) [i]	120	0.37	0.000025		
Activity					
RMDQ at baseline (0-24)[j]	118	0.71	<0.0001	**0.10 (0.068 - 0.14)**	**<0.0001**
Participation					
Work ability (n=95) --- no work ability (n=25)	120	-0.37	0.000026		
Environmental factors					
Private social support (4-20)[k]	120	-0.29	0.0013		
Health-related quality of life					
PCS (0-100)[l]	119	-0.42	<0.0001		
MCS (0-100)[l]	119	-0.28	0.0022		

[a] Roland Morris disability questionnaire (RMDQ) score was transformed to ranked normal score of RMDQ, using Blom's formula. The final model was adjusted for age, using standard (Enter) multivariate linear regression.
[b] The Alcohol Use Disorders Identification Test (AUDIT-C), 3 items. Higher scores reflect higher alcohol consumption (0-12).
[c] One item: "Do you think you get enough sleep?". Higher scores indicates better sleep (1-4).
[d] One item: "On the whole, how do you think you sleep?". Higher scores indicates better sleep (1-4).
[e] Stress and crisis inventory (SCI-93). Higher scores indicate more severe clinical stress symptoms (0-140).
[f] The Leisure Time Physical Activity Instrument (LTPAI) assess the total hours of physical activity in leisure time during a typical week.
[g] Self-reported pain locations registered by a figure with predefined body locations (0-18).
[h] Perceived pain intensity, fatigue over the last week rated on a visual analogue scale, VAS (0-100). Higher values indicate more pain, fatigue.
[i] Hospital Anxiety and Depression Scale (HADS). Higher scores indicate more anxiety (0-21) and depression (0-21).
[j] Roland Morris disability questionnaire indicates disability related to low back pain (0-24) at baseline. Higher scores indicate more severe disability.
[k] Medical outcome study social support survey (MOS-SSS, 4- item scale) reflects private social support ranging from 1-5. Higher scores reflect more perceived support (4-20).
[l] SF-36. The physical component summary score (PCS) (0-100) and mental component summary score (MCS) (0-100).

Table 4. Prognostic factors at baseline for percentage change in the Roland Morris disability Questionnaire (RMDQ) (n=115).

	Spearman Rank Correlation Correlation with percentage change in RMDQ			**Forward stepwise multivariate linear regression**[a] Independent variables p<0.20 entered in the model, adjusted for age. No significant association.	
	number	**r**	**p-value**	**β (CI 95%)**	**p-value**
Age, years	115	-0.11	0.23	-0.0017 (-0.014-0.011)	0.79
Lifestyle behavioural factors					
Body Mass Index (kg/m^2)	114	-0.13	0.18		
Smoker (n=72) --- no smoker (n=48)	115	-0.072	0.44		
AUDIT-C (0-12)[b]	113	0.11	0.23		
Sleep quantity (1-4)[c]	115	0.18	0.054		
Sleep quality (1-4)[d]	113	0.16	0.099		
SCI-93[e]	115	-0.17	0.075		
LTPAI (hours per week)[f]	115	0.13	0.18		
Body function					
Pain localisations (0-18)[g]	115	-0.15	0.10		
Pain intensity 10 mm (VAS 0-100)[h]	115	0.078	0.41		
Fatigue 10 mm (VAS 0-100)[h]	115	-0.046	0.62		
6MWT, 100 meters	113	0.17	0.065		
Hand grip strength 50 N (Newton)	115	0.057	0.55		
HADS-A (0-21)[i]	115	-0.023	0.81		
HADS-D (0-21)[i]	115	-0.11	0.24		
Participation					
Work ability (n=95) --- no work ability (n=25)	115	0.15	0.11		
Environmental factors					
Private social support (4-20)[j]	115	0.14	0.14		
Health-related quality of life					
PCS (0-100)[k]	114	0.029	0.76		
MCS (0-100)[k]	114	0.14	0.13		

[a] Percentage change in RMDQ as dependent variable. The final model was adjusted for age, using standard (Enter) multivariate linear regression.
[b] The Alcohol Use Disorders Identification Test (AUDIT-C), 3 items. Higher scores reflect higher alcohol consumption (0-12).
[c] One item: "Do you think you get enough sleep?". Higher scores indicates better sleep (1-4).
[d] One item: "On the whole, how do you think you sleep?". Higher scores indicates better sleep (1-4).
[e] Stress and crisis inventory (SCI-93). Higher scores indicate more severe clinical stress symptoms (0-140).
[f] The Leisure Time Physical Activity Instrument (LTPAI) assess the total hours of physical activity in leisure time during a typical week.
[g] Self-reported pain locations registered by a figure with predefined body locations (0-18).
[h] Perceived pain intensity, fatigue over the last week rated on a visual analogue scale, VAS (0-100). Higher values indicate more pain, fatigue.
[i] Hospital Anxiety and Depression Scale (HADS). Higher scores indicate more anxiety (0-21) and depression (0-21).
[j] Medical outcome study social support survey (MOS-SSS, 4- item scale) reflects private social support ranging from 1-5. Higher scores reflect more perceived support (4-20).
[k] SF-36. The physical component summary score (PCS) (0-100) and mental component summary score (MCS) (0-100).

DISCUSSION

This two-year prospective cohort study of women with CLBP attending PHC showed that lower performance in walking capacity (6MWT), more severe clinical stress symptoms (SCI-93) and more severe activity limitation (RMDQ) at baseline predicted more activity limitation (RMDQ) after two years (Table 3). The model with these three predictors explained 54% of the variance in self-reported activity limitation (RMDQ) at the two-year follow-up, which is similar to a previous review of prediction models including various predictors for disability in patients with subacute non-specific LBP.[22]

Strengths and limitations

This study included measurements representing all the domains of ICF[17] complemented with lifestyle behavioural factors, which is considered as a main strength. The follow-up frequency was very high with 95% being followed up.

Prevalence and predictors of chronic pain have been studied in general populations,[21, 40, 51] while the present study assessed women with CLBP consulting PHC, contributing with knowledge for health care professionals working in PHC. Previous studies found that chronic pain is more common in women, and that women are at greater risk of chronic pain and disability.[6, 40, 51] It has been suggested that women should be assessed separately when studying prognostic factors for LBP,[19, 20] hence the present study included only female patients.

The initial decision to collect variables was based on previous studies indicating suitable variables of potential interest. However, this decision led to a large number of variables and a further sorting mechanism was needed before the final multivariate regression model. This sorting mechanism could be done either by further using clinical reasoning and prior

knowledge or by looking at statistical significance. Each of these approaches will have a different risk for bias. Using clinical reasoning and prior knowledge may make us blind to new knowledge that previous studies missed. Using the approach we finally chose, bivariate correlation in Spearman's rank correlation may cause clinically insignificant findings to be put forward.

Hence, each independent variable were first evaluated in this bivariate analysis. Secondly, the multivariate model was built by using the independent variables with $p < 0.20$ in the rank correlation. Physical performance (6MWT) was included in the final model. Knowing that age influences physical performance, age was included as a potential confounder, even though it was not correlated with RMDQ.

The main reason for deploying a sorting mechanism (Spearman's rank correlation) before doing the multivariate regression was to reduce the problem which may occur when there are few participants relative to the number of independent variables. Hence, the number of participants were considered to be sufficient for the final model.

Prior to the multiple regression, the independent variables were also evaluated for assumptions of multivariate analysis including checking for multicollinearity and singularity. The values of Tolerance (0.52-0.74) and VIF (1.3-1.9) were checked indicating low correlation between the independent variables. Moreover, questionnaires total scores was used to avoid singularity.

Self-administrated questionnaires are recommended for the assessment of activity limitation in patients with LBP.[52] The present study used RMDQ as the outcome measure at the two-year follow-up. The RMDQ is considered valid, commonly used and recommended in LBP research for monitoring disability.[53, 54] Seventeen statements in the RMDQ are reported to be linked to the activity component in the ICF.[55, 56] However, self-reports may suffer from

the fact that some patients may under or overestimate their limitations and physical performance tests are suggested to complement self-reports.[57] Walk capacity (6MWT) and hand grip strength, semi-objective measures of body function, were therefore included as potential predictors in this study.

The group showed a moderate grade of disability, RMDQ 8.4 (SD 4.8), at baseline which might reflect that the women included were not in acute need for treatment when recruited. There was a statistical significant mean decrease of approximately 2 points on RMDQ during the two-year period. Minimal clinical detectable change in the RMDQ is considered to be 2 to 3 points. Others have suggested a change of 4 to 5 points to be of clinical value.[53]

Predictors for activity limitation (RMDQ) at two-year follow-up

The BMI values corresponded with overweight (mean 27 (SD 5.5)), which is common in patients with chronic pain[28, 58] and might be due to impaired body function, activity limitation and restrictions of participation. A previous one-year follow up study found self-reported weight and height (BMI) as a significant predictor for activity limitation.[59] However, this could not be confirmed in the present study.

Previously or currently smoking was not found as a predictor, which is concordant to a review studying prognostic factors for pain and disability in CLBP.[26] In the present study, hours per week of leisure time physical activity (LTPAI) (mean 7.8 (SD 8.5) was within recommended levels of physical activity[60] which might have been the reason for no prognostic value. A healthy lifestyle behavior, combinations of lifestyles factors, is reported to influences the prognosis of LBP.[21] It could be interesting to combine and categorize various self-reported lifestyles behavioral factors for analyzing their prognostic value for patients with CLBP. However, in the present study the prognostic value of lifestyle behavioral factors were analyzed separately for later self-reported activity limitation in CLBP.

Previous prospective studies of LBP have evaluated body function by measuring spinal motion and muscle strength, showing them to be of poor prognostic value.[11, 61] In the present study, the body function assessed by the 6MWT was of prognostic value, showing that lower performance in the 6MWT at baseline predicted more severe activity limitation at two-year follow-up. Therefore, the 6MWT could be included as a complement to standard clinical examination of CLBP. Physical activity is a recommended intervention for patients with CLBP. The 6MWT is easy to perform and provides information of an individual's physical performance. In the future, the 6MWT might be used as a self-administrated assessment tool to promote physical activity and self-management strategies for patients with CLBP. However, the utility of 6MWT as a self-assessment tool needs to be studied further.

More severe clinical stress symptoms (SCI-93), could independently predict more severe activity limitation (RMDQ) at the two-year follow-up (Table 3). The mean score for SCI-93 at baseline was 36 (SD 21) (Table 2), which indicates an increased level of clinical stress symptoms in the group, compared to the reference values.[32, 33] Signs and symptoms in patients with chronic pain are suggested to be associated with prolonged stress,[62] but measurement of clinical stress symptoms is not standard in the clinical assessment of patients with CLBP. Therefore, the SCI-93 could provide valuable information for predicting later activity limitation for these patients. Moreover, questionnaires assessing symptoms severity might stimulate the patient's motivation in using active coping strategies to alleviate their stress responses.[32] Stress reduction interventions have shown to improve pain acceptance.[63] However, if pain acceptance might mediate the association of stress, physical activity and disability need further investigation.

Studies of prognostic factors for patients with acute LBP report similar predictors as this study to the ones in this study.[64, 65] However, the characteristics of the patients in the study used to derive the predictive model have to be similar to those in whom the model will be

used to. Various factors can impact disability in patients with CLBP (> 12 weeks duration) and function and functional demands often differs between women and men. Therefore, women with CLBP were included in this study.

The baseline activity limitation (RMDQ) was the strongest predictor (R^2 0.51) for activity limitation (RMDQ) at two year. The prognostic model including the baseline RMDQ, 6MWT, and SCI-93 explained 54% of the variance in activity limitation (RMDQ) at the two-year follow-up (Table 3), which is slightly more compared to findings in a previous review of different prognostic models explaining 28-51% of variance in persisting disability in sub acute LBP.[22] The 6MWT and SCI-93 may add useful information where the outcome of RMDQ is unavailable.

Knowledge about factors that are associated with the probable recovery or not in CLBP can be used to improve the management of patients with CLBP in primary care. The results of this study can give guidance for interventional trials aiming to improve physical capacity and decrease stress in women with CLBP. The impact of the interaction between prognostic factors and interventions on activity limitation in women with CLBP, needs further investigation.

CONCLUSION

A walk test (6MWT), clinical stress symptoms (SCI-93) and activity limitation (RMDQ) predicted future activity limitation in women with CLBP within PHC. The prognostic model including these three predictors explained 54% of the variance in self-reported activity limitation (RMDQ) after two years.

Contributors

LN contributed to the design of the study, were responsible for the data collection, participated in the statistical analysis, interpreted the data and drafted the first manuscript. LT contributed to the interpretation of data and revision of manuscript for important content. RG contributed to the design of the study, participated in the statistical analysis, interpreted the data and critically revised all versions of the manuscript. KM contributed to the design of the study, participated in the statistical analysis, interpreted the data and critically revised all versions of the manuscript. All authors read and approved the final manuscript.

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Competing interests

The authors declare that they have no competing interest.

Ethics approval

The Regional Ethical Review Board in Gothenburg approved the study. Written informed consent was obtained from all patients.

Data sharing statement

No additional data are available.

Figure legends

Figure 1. Participants flow.

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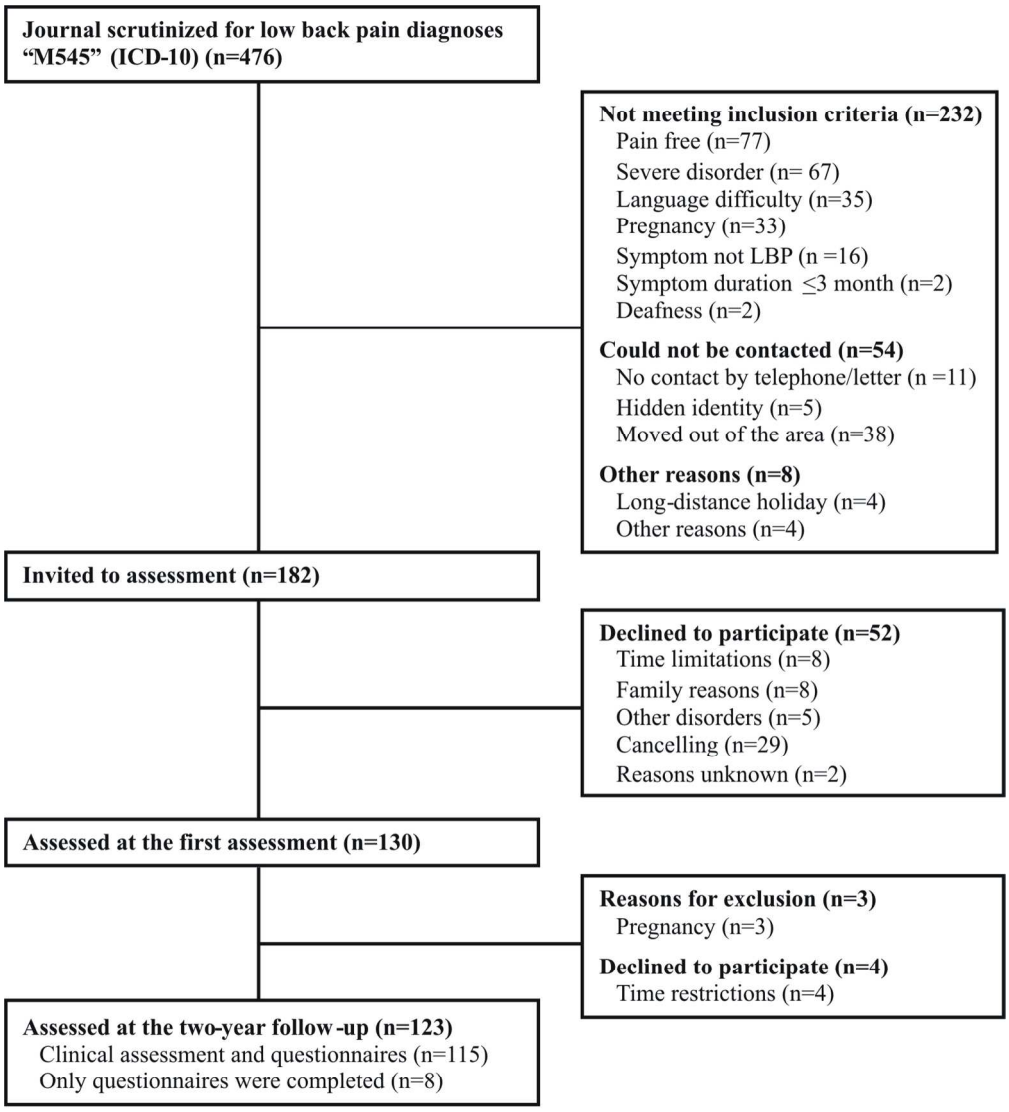

Figure 1. Participants flow.

Figure 1. Participants flow

150x177mm (300 x 300 DPI)

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Noted in Title page and Abstract. Pages 1,2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Pages 2,3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Pages 5,6
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 6
Methods			
Study design	4	Present key elements of study design early in the paper	Pages 6,7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 7
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Pages 6,7
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Pages 7-10
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Pages 7-10
Bias	9	Describe any efforts to address potential sources of bias	Page 11
Study size	10	Explain how the study size was arrived at	Page 7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Pages 10,11
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Pages 11,12
		(*b*) Describe any methods used to examine subgroups and interactions	Pages 11,12
		(*c*) Explain how missing data were addressed	Page 13 and Figure 1 (at page 30)

		(*d*) If applicable, explain how loss to follow-up was addressed	Page 13 and Figure 1 (at page 30)
		(*e*) Describe any sensitivity analyses	NA
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Page 13 and Figure 1 (at page 30)
		(b) Give reasons for non-participation at each stage	Page 13 and Figure 1 (at page 30)
		(c) Consider use of a flow diagram	Figure 1 (at page 30)
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 11 and 13 and Tables 1,2 at pages 14,15
		(b) Indicate number of participants with missing data for each variable of interest	Tables 1,2 at pages 14,15
		(c) Summarise follow-up time (eg, average and total amount)	Follow-up time is two years, documented throughout the manuscript.
Outcome data	15*	Report numbers of outcome events or summary measures over time	Page 16 and Table 3 at page 17, Table 4 at page 18
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Page 11, 16 and Table 3 at page 17, Table 4 at page 18
		(*b*) Report category boundaries when continuous variables were categorized	NA
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 19
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and	Pages 19, 20, 21

		magnitude of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Pages 19-23
Generalisability	21	Discuss the generalisability (external validity) of the study results	Pages 19-23
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 24

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.