Course of disability reduction during a pain rehabilitation program: A prospective clinical study

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Abstract

The aim of this study was to analyze the course of reduction of disability during a pain rehabilitation program (PRP) and factors influencing this course. A prospective cohort study was carried out. All patients with chronic musculoskeletal pain treated in a PRP between March 2010 and December 2010 were eligible for this study. All patients were treated at a University-based rehabilitation center and received an outpatient multidisciplinary PRP. Main outcome measures, Pain Disability Index (PDI), and average pain measured with a numeric rating scale, were measured every 2 weeks during the PRP. To analyze the course of disability, a linear mixed-effect model was applied. One hundred twenty-eight patients participated in the study, of which 20% dropped out during the PRP. Initial PDI ($\beta = 0.8$), treatment week ($\beta = -0.2$), treatment week squared ($\beta = 0.03$), average pain ($\beta = 2.3$), and interaction between initial PDI and treatment week ($\beta = -0.02$) influenced the course of disability during PRP. Disability reduces during the PRP. Initial PDI, treatment week, average pain, and interaction between initial PDI and treatment week influence the course of disability reduction during the PRP. These results could aid in predicting the required duration of a PRP at the start.

Keywords
Chronic pain, disability, Pain Disability Index, Patient Care Team, Rehabilitation
**Introduction**

On the basis of pre and post measurements, it is known that pain rehabilitation programs (PRPs) are effective in disability reduction in patients with chronic musculoskeletal pain (CMP) 1-7. However, the course of disability reduction is unknown. Understanding the course of disability reduction could aid in determining the optimum duration of PRPs. This understanding would benefit patients, clinicians, insurance companies and health care providers because it prevents overtreatment or undertreatment and contributes towards better use of (public) recourses.

A wide diversity of content, composition, and duration of PRPs exist 3,4. In one systematic review, differences in duration were unrelated to differences in outcomes 3. However, in another review it was reported that multidisciplinary PRP of more than 100 h was superior to monodisciplinary treatment, and that multidisciplinary PRP of less than 30 h was not superior to monodisciplinary treatment. Although the authors focused on the content of different PRPs and the review was designed to assess the effect of PRP, they concluded that PRPs of more than 100 h were more effective. The conclusions of these reviews were used to establish guidelines and clinical practice 8,9. However, these conclusions were based only on pre-post assessments. To our knowledge, no studies have analyzed the course of disability reduction during the programs to establish the optimum duration of a PRP. In addition, it is unknown whether the improvements gained with intensive PRPs are worth the expenses 4. Theoretically, if 90% of the improvements are observed in the first half of the PRP, it may be debated whether these 100 h or more, as proposed by Guzman et al 4, are needed.

Because no previous research is available into this specific aspect of PRPs, we hypothesized that there would be several possible courses of reduction of disability (Fig. 1). Line A assumes that the course of disability has a steeper slope at the end of the PRP. This implies that disability decreases most in the last part of the PRP. In contrast, line B assumes a steeper slope at the first half of the PRP. This implies that disability decreases most in the first part of the PRP. Line C implies a linear decrease of disability, and an alternating pattern of decrease and increase during the PRP is hypothesized in line D.

The aim of this study was to analyze the course of reduction of disability during PRP and to analyze factors influencing this course.
Figure 1 Hypothesized courses of reduction of disability during a hypothetical Pain Rehabilitation Program
Line A: the decrease of disability has a steeper slope at the second half of PRP.
Line B: the decrease of disability is steeper slope at the first half of PRP.
Line C: a linear decrease of disability during PRP.
Line D: an alternating pattern of decrease and increase of disability during PRP.

Patients and methods

Study design and setting
A prospective cohort study was carried out with patients with CMP admitted to the outpatient multidisciplinary PRP of the Center for Rehabilitation of the University Medical Center Groningen (UMCG).

The primary aim of this PRP, on the basis of cognitive behavioral principles, was to decrease pain-related disability. The rehabilitation team consists of physicians, occupational therapists, physiotherapists and psychologists. PRP consists of education on differences between nociceptive pain and chronic pain. Patients are counseled to reflect on their own pain management strategies (avoiding pain) and how these strategies could be changed into more healthy management strategies (coping with pain, alternation between physical activity and rest, and to gradually increase functioning). Each patient sets individual treatment goals to create a meaningful life
despite the pain. To achieve these goals, each professional applies specific techniques. Physical therapists apply exercise programs and sports activities, improve patients’ confidence in movement, and reduce pain related fear. Occupational therapists assess current activities and patterns in daily living and educate patients on how these activities can be changed into healthy activity levels and patterns. The psychologists coaches patients in understanding and dealing with the social and emotional impact of pain in daily life, pain beliefs, and barriers for behavior change, and coach patients on how to cope with pain. The rehabilitation physicians are responsible for the medical diagnosis and interventions, and the overall treatment plan. During intake, the rehabilitation team decides whether the patient can be admitted for PRP. PRP consisted of occupational therapy sessions, 30 min, two times a week, physiotherapy sessions, 30-60 min, two times a week, and psychology sessions, 60 min, once a week. The session frequency of occupational therapy and physiotherapy reduced to once a week during the second half of PRP to encourage patients self management among patients. After intake, the rehabilitation physician proposed a duration of 8, 12, 16 or 20 weeks of PRP to the patient on the bases of assessment of the complexity of the physical, social and personal situation of the patient, motivation, and ability to change behavior. The duration in weeks of the PRP could be adapted (increased or reduced) depending on clinical progress. Duration could be increased when additional decrease in disability was expected by lengthening the program. Duration was reduced when treatment goals were achieved earlier than expected, when the patient showed continued lack of progress, or stops the treatment because it did not match patients’ expectations or for reasons not related to the program.

Patients were included for PRP when they were 18 years or more of age, had CMP for more than 3 months, experienced disabilities because of CMP, were not attending any other type of treatment, were willing to participate in a PRP, and had signed an informed consent form. Patients with severe comorbidities, interfering with PRP, such as heart failure, rheumatoid arthritis, psychiatric disorders, and participants with an indication for surgery were not included for the PRP. All patients treated in the PRP of the UMCG from March 2010 until December 2010 were eligible for the study.

At baseline, patient characteristics (age, sex, marital status and employment status) were recorded. The first visit to the PRP (T1) and every uneven treatment week during the program (T2= week 3, T3= week 3 etc), patients filled in the Pain Disability Index (PDI) and a numeric rating scale (NRS) for average pain in the previous week (0 = no pain, 10= unbearable pain). The last assessment was performed during the last visit. Patients were blinded for previous scores. If patients could not be measured at the proposed week, they filled in the questionnaire the next visit.
Main outcome

The PDI measures self-reported disability on seven domains: family/home responsibilities, recreation, social activity, occupation, sexual behavior, self-care, and life-support activity. The patient scores the amount of interference in daily life because of pain for each domain (0 = no interference, 10 = total interference). Total PDI is calculated by adding the scores of all domains [range 0 (no disability) to 70 (extreme disability)]. Internal consistency for the PDI is high (Cronbach’s $\alpha$ = 0.86). Construct validity is supported by a multiple regression analyses showing nine variables to predict the PDI scores ($R=0.74$). Test-retest reliability (1-week interval) is good (intraclass correlation coefficient = 0.91). The minimal clinically important change is 8.5 point. A maximum of two missing items was accepted for the PDI. If more than two items were missing, a sum score was not calculated. When one or two items of the PDI were missing, the mean score of the other items of that patient was calculated. The total score was calculated by replacing the missing item by this calculated mean.

As patients provided written permission to use their clinical data and data were gathered during care as usual, in the Netherlands, approval from a Medical Ethics Committee is not needed.

Statistical analysis

Descriptive statistics were computed for patient characteristics and outcome variables. Means and SDs were used for PDI and pain scores. An independent sample t-test was used to compare means of initial PDI of completers (participants who completed the program) versus noncompleters (participants who dropped out before the program was ended). Q-Q plots were constructed to check the assumptions of normal distribution of initial PDI scores. The duration of PRP was categorized according to the total number of weeks that a patient received treatment. Categories were: ≤ 8, 9 ≤ 12, 13 to ≤ 16 and ≥17 weeks. To analyze the course of disability during PRP and factors influencing this course, a linear mixed-effect model was applied. A linear mixed-model analysis corrects for autocorrelation in data, which occurs in repeated measurements over time within individuals. All available data were taken into account in the analysis, including those of patients with incomplete datasets. Outcomes on the PDI were entered as response variable. Before this analysis, the change in PDI scores during PRP was assessed in a graph to check linearity for applying the appropriate regression model. Possible predictor variables of the course were patient characteristics (age, sex, marital status, and employment status), treatment week (= week of measurement), duration of PRP (in categories), initial PDI score, pain characteristics (average pain in the week before the PDI assessment, pain duration, and pain localization) and completing PRP (yes, no). These variables were entered stepwise in the regression model. Assessment of the graph showed that the change of PDI during PRP allowed a quadratic (treatment week x treatment week) or cubic model (treatment week x treatment week x treatment week). These models were explored by entering variable treatment week$^2$ and treatment week$^3$ in the regression.
Results

A total of 128 patients participated in the study. Mean age of the patients was 41.7 (SD 11.8, range 19-68) years. CMP was categorized as chronic back pain (55%), chronic neck pain (19%) and other types of chronic pain (26%), such as widespread pain, non-specific pain of lower extremities (knee, foot) etc. Patients attended PRP for an average duration of 12.5 (SD 4.0, range 3-23) weeks and received on average 38 (SD 17.1, range 5.5-89.8) contact hours. Thirty-eight percent (n=49) of the patients received the proposed amount of treatment weeks (range ± 1 week). Thirty-seven percent (n=47) received less (including noncompleters) and 13% (n=17) received more than amount of treatment weeks proposed by the rehabilitation physician. The proposed duration was not reported in 12% (n=15) of the cases. Twenty-six (20%) of the 128 patients dropped out during the PRP; they did not complete the program for lack of effect (2%, n=2), unrealistic expectations of the program (3%, n=4), wanting additional diagnostic procedures (2%, n=2), because they believed that the benefits of the program did not weigh against efforts (3%, n=4), treatment was too demanding (3%, n=4) or other reasons (8%, n=10). The majority of noncompleters stopped during the first 8 weeks of PRP. Because of different treatment durations and dropout, the total number of participants decreased from the first to the 27th treatment week (Fig. 2). Baseline characteristics (n= 128) are shown in Table 1. Noncompleters and completers significantly differed on age, marital status, and employment status. The difference in duration of pain of completers versus noncompleters was not significant.

The mean PDI for all patients at T1 (n = 125) was 34.2 (SD 12.0). Mean NRS average pain was 5.6 (SD 1.9). The mean initial PDI was significantly (P=0.013) lower for completers compared to noncompleters [mean difference= 6.6, confidence interval (CI) 1.4-11.7] (Table 2).
Table 1 Baseline characteristics (n=128)

<table>
<thead>
<tr>
<th></th>
<th>All patients/ durations (n=128)</th>
<th>Sorted by duration PRP (weeks)</th>
<th>Completers versus noncompleters (n= 102)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>≤ 8 (n= 21)</td>
<td>Completers (n=21) Noncompleters (n=26)</td>
</tr>
<tr>
<td>Age [mean (SD)]</td>
<td>41.7 (11.8)</td>
<td>45.7 (12.3)</td>
<td>42.0 (13.2)</td>
</tr>
<tr>
<td>Sex (female) [n (%)]</td>
<td>73 (94)</td>
<td>91 (19)</td>
<td>56 (29)</td>
</tr>
<tr>
<td>Married [n (%)]</td>
<td>73 (94)</td>
<td>95 (20)</td>
<td>75 (39)</td>
</tr>
<tr>
<td>Employment status [n (%)]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low back pain</td>
<td>55 (70)</td>
<td>53 (11)</td>
<td>60 (31)</td>
</tr>
<tr>
<td>Neck pain</td>
<td>19 (25)</td>
<td>14 (3)</td>
<td>17 (9)</td>
</tr>
<tr>
<td>Other</td>
<td>26 (33)</td>
<td>33 (7)</td>
<td>23 (12)</td>
</tr>
<tr>
<td>Duration of pain [median (IQR) years]</td>
<td>3.0 (1.5-8.0)</td>
<td>3.0 (1.5-10.0)</td>
<td>3.0 (1.5-7.0)</td>
</tr>
<tr>
<td>Missing [n (%)]</td>
<td>22 (28)</td>
<td>10 (2)</td>
<td>28 (11)</td>
</tr>
</tbody>
</table>

PRP, pain rehabilitation program.  
* P value of difference between completers and noncompleters.
Course of outcome Pain Disability Index scores over time

The mean PDI scores and the mean average pain scores on the previous week over time are shown in Fig. 2. The wide 95% CI at the even treatment weeks and at the tail of the curve (≥17 weeks) can be attributed by the smaller number of patients measured in those weeks (n= shown under the x-axis). From week 17, the number of participating patients decreases to less than 1/3 of the total number of patients at week 1; therefore the 95% CIs become wider and the scores are less precise.

Table 2 Mean PDI and average pain at T1.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total group</th>
<th>Completers</th>
<th>Non-completers</th>
<th>Differences in means (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PDI (0-70)</td>
<td>34.2 (12.0)</td>
<td>32.8 (11.8)</td>
<td>39.4 (11.4)</td>
<td>6.6 (-1.4 to 11.7)</td>
<td>0.013</td>
</tr>
<tr>
<td>Average pain (0-10)</td>
<td>5.6 (1.9)</td>
<td>5.5 (1.9)</td>
<td>5.7 (1.8)</td>
<td>0.2 (-0.6 to 1.0)</td>
<td>0.627</td>
</tr>
</tbody>
</table>

Figure 2 Mean PDI and 95% CI and mean of average pain.

n= Number of available measurements reported per week.

Mixed-effect modeling

The covariance structure was autoregressive heterogeneous, which means that correlations between scores reduced over time. Variables that were entered in the model but did not improve the model significantly were patient characteristics (age, sex, marital status, and employment status), duration of the PRP (≤8, 9 to ≤12, 13 to ≤16, and ≥17 weeks), pain duration, pain localization and interaction between duration of PRP and treatment week. This means that these variables did not influence the course of reduction on PDI over time. Predictor variables that
significantly influenced the model were treatment week, initial PDI score, average pain, and the interaction between initial PDI and treatment week. This means that these variables did influence the course. The model improved significantly by allowing for each patient a random intercept and a random slope for average pain (Table 3). Treatment week² contributed significantly toward the regression equation, treatment week³ did not. This means that the PDI reduces according to a quadratic model over time during PRP, and not according to a cubic model.

Table 3 Results of a linear mixed-model analysis to predict change in Pain Disability Index score during a pain rehabilitation program.

<table>
<thead>
<tr>
<th>Predictor</th>
<th>β</th>
<th>SE  β</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept (Pb)</td>
<td>-5.3</td>
<td>1.9</td>
<td>0.005</td>
</tr>
<tr>
<td>Treatment week</td>
<td>-0.2</td>
<td>0.2</td>
<td>0.174</td>
</tr>
<tr>
<td>Initial PDI</td>
<td>0.8</td>
<td>0.05</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Average pain previous week (Pb)</td>
<td>2.3</td>
<td>0.2</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Time x Initial PDI</td>
<td>-0.02</td>
<td>0.004</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Treatment week x Treatment week</td>
<td>0.03</td>
<td>0.007</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

PDI, Pain Disability Index.

Clinically, this means that treatment week, initial PDI score, average pain, and the interaction between initial PDI and treatment week influence the course of PDI scores during PRP. The coefficients of Table 3 indicate that, for instance, a patient with an initial PDI score of 40 and a score of 6 on average pain in the fourth treatment week will have an average PDI score of 36.3 in the fifth treatment week of the PRP. This can be calculated using the following formula:

\[ \text{PDI} = -5.3 + (-0.2 \times \text{treatment week}) + (0.8 \times \text{initial PDI}) + (2.3 \times \text{average pain}) + (0.03 \times \text{treatment week}^2) + [-0.02 \times (\text{initial PDI} \times \text{treatment week})]. \]

**Discussion**

At group level, disability reduction during PRP occurs following a quadratic model, quite similar to the hypothesized line B in Fig. 1. Reduction in average pain in the previous week precedes decrease of disability. The strength of this influence is 2.3 points on PDI per point pain reduction (Table 3). Hence, a reduction of 1 point on average pain will decrease disability with 2.3 points. The interaction between initial PDI and treatment weeks also influences the course, which means the strength of influence per treatment week on PDI (β=0.02) depends on the initial PDI: a higher initial PDI will lead to a steeper decrease per week compared with a lower initial PDI. The influence of the quadratic factor of treatment week on the course is 0.03: the effect of treatment week on PDI (-0.2 per treatment week) is reduced by the quadratic term of treatment week.
This means that towards the end of the PRP, disability reduction per week becomes smaller (Fig. 1, line B).

The results of this study have provided insight into the course of disability reduction over time. The clinical relevance of this study is two-fold. First, because most of the gain in disability reduction is obtained in the earlier weeks of PRP, the added value of additional PRP toward the end of the program may become trivial. Second, the relevance of knowing which factors influence the course of disability reduction may be that one can on average predict the duration of the PRP if one knows the target reduction of disability. For example, if the target reduction is 8.5 PDI points, the minimal clinically important change 6, the predicted mean duration of the PRP for an ‘average patient’, with an initial PDI of 40 and an average pain score of 6, would be 14 weeks.

This is the first study in which the course of disability during a PRP was analyzed. Most studies have focused on the effect of PRPs based on pre, post, and follow-up measurements, focused on other types of treatments or other groups of participants. 6,15,16. With this study, we have provided a new aspect of research of PRPs: dose of PRP. Within the rehabilitation literature, there is no robust evidence to substantiate dose aspects (duration and contact hours) of PRPs. It appears that dose aspects have been neglected in PRP research. Generalization of the findings of this study may be challenging and calls for replication studies within and outside the Netherlands. The general principle of the course of disability reduction might also apply to PRPs outside the Netherlands. However, dose choices are also influenced by cultural factors and differences between professional teams within and outside the Netherlands. In addition, financial reimbursement will also influence the choice of dose.

Study limitations
This study has some limitations. Some data were missing on PDI items. However, the effects of these missing data were limited because the total score of PDI is used, which represents general (average) disability. For the statistical analyses, the use of a mixed model limited the influence of missing data. In clinical practice, we could not arrange a rigidly fixed measurement time equal for each patient. We had to deal with absence of patients and care as usual was not ready for digitalized versions of the questionnaires to minimize missing data because of absence. Nevertheless, all available data were used in the mixed-effect model. Because of ethical regulations related to digital patient information safety, we could not follow up patients every 2 weeks after PRP. It is advised, however, that future studies focus on the follow-up period also because it is assumed that further progress occurs after completion of the program. Twenty percent of the patients dropped out, but data of all patients, completers and noncompleters, were taken into account for the mixed-model analysis. Noncompleters may be considered a limitation from a statistical point of view. However, in daily clinical care, noncompletion is often
observed. Noncompletion has not been the subject of study. In this study, it appeared challenging for the clinicians to estimate treatment duration before the PRP. As shown in the result section, the actual PRP duration differed from the pretreatment estimated duration. This may be regarded a limitation of this study because this provides variance in total treatment weeks and number of patients per treatment duration, but it underscores the clinical need to know the course of disability reduction and factors predicting this course that could contribute toward more rational estimations of treatment duration.

The major strength of this study is the strong relation to clinical practice, which enhances the external validity: measurements were performed in care as usual and the results of the mixed-model analyses can contribute toward estimate of the duration of PRPs. Also, the heterogeneous group strengthens the results of this study because differences in pain locations did not affect the results and therefore the outcome is generalizable to a broader group of patients with CMP.

Conclusions regarding optimum duration of PRPs cannot be drawn. However, the results of this study show the need for further research on the course of disability and dose aspects of PRPs. Future research could focus on the effect of shortening a PRP on the course of disability reduction or the course of disability after completion of a PRP. It should also focus on the added value of additional PRP (h/weeks) to analyze at which point treatments are no longer beneficial for the patient or no longer cost-effective.

**Conclusion**

From the results of this study, we can conclude that disability reduces according to a quadratic model during PRPs. Initial PDI, treatment week, average pain, and interaction between initial PDI and treatment week influence the course of disability reduction during PRP. These data could aid in clinical practice to predict the duration of the PRP at start. Further research investigating dose aspects of PRPs is needed to aid in the effectiveness and cost-effectiveness of PRPs.

**Acknowledgements**

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References


