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Dose or content? Effectiveness of pain rehabilitation programs for patients with chronic low back pain: A systematic review

Franka P.C. Waterschoot [a,*], Pieter U. Dijkstra [a,b], Niek Hollak [c], Haitze J. de Vries [a], Jan H.B. Geertzen [a], Michiel F. Reneman [a]

[a] Department of Rehabilitation Medicine, Center for Rehabilitation, University Medical Center Groningen, University of Groningen, The Netherlands
[b] Department of Oral and Maxillofacial Surgery, University Medical Centre Groningen, University of Groningen, The Netherlands
[c] Center for Human Movement Sciences, University Medical Center Groningen, University of Groningen, Groningen, The Netherlands

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ABSTRACT

We sought to systematically analyze the influence of dose of pain rehabilitation programs (PRPs) for patients with chronic low back pain (CLBP) on disability, work participation, and quality of life (QoL). Literature searches were performed in PubMed, Cochrane Library, Cinahl, and Embase up to October 2012, using MeSH terms, other relevant terms and free-text words. Randomized controlled trials in English, Dutch, and German, analyzing the effect of PRPs, were included. One of the analyzed interventions had to be a PRP. Outcomes should be reported regarding disability, work participation, or QoL. To analyze dose, the number of contact hours should be reported. Two reviewers independently selected titles, abstracts, and full-text articles on the basis of inclusion and exclusion criteria. Data were extracted and risk of bias was assessed. Effect sizes (ES) were calculated for each intervention, and influence of dose variables was analyzed by a mixed model analysis. Eighteen studies were identified, reporting a wide variety of dose variables and contents of PRPs. Analyses showed that evaluation moment, number of disciplines, type of intervention, duration of intervention in weeks, percentage of women, and age influenced the outcomes of PRPs. The independent effect of dose variables could not be distinguished from content because these variables were strongly associated. Because dose variables were never studied separately or reported independently, we were not able to disentangle the relationship between dose, content, and effects of PRPs on disability, work participation, and QoL.

1. Introduction

Multidisciplinary pain rehabilitation programs (PRPs) are effective in improving daily functioning of patients with chronic low back pain (CLBP) [12,14,30]. Most studies investigating the effects of PRPs focused on the relationship between therapy content and effect. Guidelines for managing CLBP are based on evidence obtained from these studies [1,27]. However, this evidence might be biased.

In a literature search, we could not identify any study analyzing the relationship between dose and effect as a primary objective. Two systematic reviews [14,30] were identified that analyzed dose and effect as a secondary objective. These reviews presented conflicting conclusions on dose effects.

In a review by Guzman et al. [14], 10 randomized controlled trials (RCTs) were included reporting on 12 PRPs. PRPs were divided into 2 categories: daily intensive programs with more than 100 h of therapy, and once- or twice-weekly programs with less than 30 h of therapy. On the basis of that distinction, it appeared that multidisciplinary PRPs of more than 100 h were superior to monodisciplinary treatment, and PRPs of less than 30 h were not. The authors concluded that intensive multidisciplinary PRPs are superior to less intensive multidisciplinary PRPs [14]. These results have been used in guidelines and clinical practice [1,31]. However, it may be debated whether the conclusion regarding dose is valid to support its clinical implications. First, there is an absence of knowledge about PRPs with doses between 30 to 100 h. Second, no distinction was made within intensive and less intensive PRPs, although there was a wide variety within the groups. Less intensive PRPs ranged from 17.5 to 30 h, while intensive PRP ranged from 100 to 280 h. Third, the review [14] was designed to assess the effect of different PRPs on clinically relevant outcomes. All PRPs differed not only in dose but also in content, setting, and number

* Corresponding author. Address: Department of Rehabilitation Medicine, Center for Rehabilitation, University Medical Center Groningen, University of Groningen, PO Box 30.002, 9750 RA Haren, The Netherlands. Fax: +31 505338258.
E-mail address: f.p.c.waterschoot@cvr.umcg.nl (F.P.C. Waterschoot).

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of disciplines involved, which may have confounded the dose aspect of the conclusion. Additionally, the authors discussed whether the improvements gained with intensive PRP were worth the expense.

The review of van Geen et al. [30] also had some limitations. It assessed the long-term effect of PRPs with different contents and doses. Ten studies were included, and a distinction was made between 30 h of training a week or more (intensive therapy) vs less than 30 h of training a week (low-intensive therapy). Both the intensive and low-intensive PRPs showed positive effects. The conclusion in that review was that the dose of the intervention had no substantial influence on the effectiveness of the intervention.

In summary, while many studies provide evidence for effectiveness of multidisciplinary PRP, dose of multidisciplinary PRP to achieve these effects remains unclear. The objective of the current study was to analyze the influence of dose variables on the outcome of PRPs for patients with CLBP.

2. Methods

Publications were retrieved by computer-aided search on PubMed, the Cochrane Library, Cinahl, and Embase up to October 2012. A specific search was developed using MeSH terms and other relevant terms for each database. The PubMed search is described in the Supplement. Refworks was used to store the results of the searches and to remove duplicates.

2.1. Selection of studies

Selection criteria were applied independently by 2 reviewers (FW and NH). The retrieved studies were first selected by title and abstract. Doubtful cases were discussed by the reviewers and included or excluded for full-text analysis by consensus. Full-text reports of studies eligible for inclusion were analyzed. Disagreements were resolved by consensus or when necessary by a third reviewer (HdV).

Studies were selected on the basis of the following inclusion criteria: (1) RCTs written in English, Dutch, or German; (2) the objective was to assess effectiveness of a multidisciplinary PRP for patients with CLBP; PRP was defined as a rehabilitation program on the basis of the biopsychosocial model [33] with 3 or more disciplines providing the program (with or without a medical doctor); (3) total number of contact hours of PRP was described; (4) participants were between 18 and 65 years with disabling nonspecific CLBP for at least 3 months; and (5) outcome variables were described in the domain of disability, work participation, or quality of life (QoL). Studies were excluded if: (1) the multidisciplinary PRP was given in primary care; (2) the objective was to assess effectiveness of only a biomedical intervention; (3) the study included participants who were diagnosed with specific disorders or severe comorbidities interfering with PRP, such as heart failure, rheumatoid arthritis, or psychiatric disorders; and (4) only total duration of PRP was reported.

2.2. Data management

Risk of bias of included studies was assessed according to the Cochrane Back Review Group [5] by 2 reviewers independently (FW and HdV). The criteria are presented in Table 1. Each criterion was scored as positive (Y), negative (N), or unclear (U). The total score was computed by counting the number of criteria scored as positive. Studies with a score of 6 or higher were defined as low risk of bias; a score lower than 6 was defined as high risk of bias. In case of unclear scores, corresponding authors of the studies were contacted by e-mail.

Table 1
Criteria risk of bias analysis.

1	Was the method of randomization adequate?
2	Was the treatment allocation concealed?
	Was knowledge of the allocated interventions adequately prevented during the study?
3	Was the patient blinded to the intervention?
4	Was the care provider blinded to the intervention?
5	Was the outcome assessor blinded to the intervention?
	Were incomplete outcome data adequately addressed?
6	Was the drop-out rate described and acceptable?
7	Were all randomized participants analyzed in the group to which they were allocated?
8	Are reports of the study free of suggestion of selective outcome reporting?
	Other sources of potential bias:
9	Were the groups similar at baseline regarding the most important prognostic indicators?
10	Were cointerventions avoided or similar?
11	Was the compliance acceptable in all groups?
12	Was the timing of the outcome assessment similar in all groups?

Performance bias was analyzed with different items of blinding. The item regarding blinding of care providers for intervention is frequently impossible in nondrug trials. To analyze the influence of lack of blinding of care providers on the judgment of methodological quality, we performed a sensitivity analysis by excluding item 4 of the risk of bias analysis.

A data extraction form was developed and piloted before data extraction. Data were extracted by 2 reviewers independently (FW and HdV). Disagreement was resolved by consensus or, if necessary, by a third reviewer (MR). Data were extracted on general study, participant, and dose characteristics (including total number of contact hours and total duration of the treatment in weeks) and treatment content (including description of treatment, treatment components, and number of disciplines). Reported outcome measures were categorized into disability, work participation, and QoL. The following interventions were distinguished: PRP, no treatment, care as usual (CAU), individual physical treatment, individual psychological treatment, surgery, and multidisciplinary treatment not defined as PRP.

For each intervention, the effect size (ES) was calculated by subtracting the posttreatment mean from the pretreatment mean (for each evaluation moment separately), divided by the pretreatment standard deviation (SD). If the mean change (pretreatment − posttreatment) was reported, ES was calculated by dividing the mean change by the SD of the change. If outcome was reported as a proportion (eg, work participation), ES was calculated according to Hojat et al. [17]. If medians and ranges were reported [3–6], means and SDs were estimated [18]. Because of the small sample sizes of the different interventions, the ES were corrected with Hedges J as described by Borenstein et al. [7].

To analyze the influence of dose variables on ES, a linear mixed effect model was applied by SPSS version 18.0 software. Analyses were applied for all interventions on each outcome category separately. The study of Hellum et al. [15] was the only one comparing effects of PRP with those of surgery. In that study, patients with CLBP were included, but it was not clear whether they had a specific or nonspecific diagnosis. Because of the unique character of that study, the analyses were done twice: with and without this study for outcome categories disability and QoL. ES per intervention was the response variable. Predictor variables were PRP (yes/no), number of disciplines involved in the program, number of contact hours, treatment duration in weeks, type of intervention (no treatment, CAU, surgery, individual physical therapy [exercise], psychological treatment, other multidisciplinary treatment, PRP), evaluation moment (in months), age, percentage of women, and