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### Quality improvement of vocational rehabilitation in patients with chronic musculoskeletal pain and reduced work participation

Beemster, Timo

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# **CHAPTER 7**

Vocational Rehabilitation with or without Work Module for Patients with Chronic Musculoskeletal Pain and Sick Leave from Work: Impact on Work Participation

> T. Beemster C. van Bennekom J. van Velzen M. Frings-Dresen M. Reneman

> > Submitted

## Abstract

#### Purpose

To study the relationship between interdisciplinary vocational rehabilitation with (VR+ program) or without (VR program) additional work module on work participation of patients with chronic musculoskeletal pain and sick leave from work.

#### Methods

A retrospective cohort study was conducted, with data retrieved from care as usual in seven VR centers in the Netherlands. The VR program consisted of multi-component healthcare (physical exercise, cognitive behavioral therapy, education, relaxation). VR+ additional components were case management and workplace visit. The dependent variable was work participation (achieved/not achieved). Independent variables were type of intervention (VR/VR+), demographics, clinical, and work-related (return to work [RTW] expectation, sick leave duration, working status, job strain, and job dissatisfaction). Multivariate logistic regression analyses were applied on discharge and six-months follow-up.

#### Results

Of the 142 patients included, 26% received VR and 74% VR+. Both programs increased work participation at six-months follow-up (VR 80%, VR+ 86%). There were non-significant relationships between type of intervention and work participation on discharge (OR 1.0, p = 0.99) and six-months follow-up (OR 1.3, p = 0.52). RTW expectation was the only significant independent factor in the multivariate model on discharge (OR 2.9, p = 0.00) and six-months follow-up (OR 3.0, p = 0.00).

#### Conclusions

Both programs led to increased work participation. The addition of a work module to the VR program did not lead to significant increase in odds of work participation at discharge and six-months follow-up. This finding was probably due to a lack of contrast between the two programs.

#### Keywords

Chronic pain, observational study, occupational therapy, biopsychosocial, multidisciplinary.

### Introduction

Chronic musculoskeletal pain (CMP) affects quality of life, disability, and work [1, 2]. Workers with CMP have high rates of absenteeism and presenteeism (at work but with decreased productivity), with productivity losses equivalent to 1.6% of Gross Domestic Product for the Netherlands [3]. Thus, the main goal of interventions for patients with CMP and productivity loss from work is to increase work participation. Several reviews have shown that interdisciplinary vocational rehabilitation (VR) programs are effective in realizing this goal [4-6].

There is large variation in the content of VR programs [4-7]. A recent review recommended that effective VR programs should encompass the following three domains: 1. health-focused (i.e., health services intervention subcategories such as graded activity/exercise, cognitive behavioral therapy [CBT], work-hardening), 2. service coordination (i.e., improving communication within the workplace or between the workplace and the healthcare providers), and 3. work modification (i.e., modified duties, modified working hours, supernumerary replacements, ergonomic adjustments, or other worksite adjustments) (Box 1) [4]. The same review also mentioned that a multi-domain intervention including components in at least two of the three domains mentioned, can help reduce lost time from work for CMP-related conditions [4].

The review mentioned above and other studies on this topic mainly consist of RCT studies in which multi-domain programs were compared with usual care [4, 5, 8] or with single component programs from the health-focused domain, such as graded activity/physical exercise [5, 7, 9], or education [5]. Little evidence is available about the additional increase in effect on work participation when components from the work-related domains (i.e., service coordination and work modifications, see Box 1) are added to a multi-component health-focused program. The latter is standard care for patients with CMP in most industrialized countries. However, the evidence concerning this niche is contradictory.

On the one hand, an RCT study conducted in Norway in patients with neck and back pain found no significant differences in work participation between the group who took part in a multidisciplinary program (i.e., multi-components from the health-focused domain) that included work-focused components and a group who only took part in a multidisciplinary program [10]. On the other hand, a retrospective cohort study conducted in Canada showed that a multidisciplinary (i.e., multi-components from the health-focused domain) pain program that included return to work coordination had 3.4 higher odds of a return to work compared with a multidisciplinary program without coordination [11].

In summary, while the evidence on the overall effectiveness of VR is robustly positive, the evidence concerning the content of VR is contradictory. In the present study, we analyzed the difference in work participation of patients who were referred to multi-component health-focused VR program with or without an additional work module in clinical practices in the Netherlands (VR+ and VR respectively).

The research question of this study was: Are patients with CMP who are on sick leave from work more likely to participate in work if they take part in a VR+ program compared with patients who only take part in a VR program? Based on recommendations from various systematic reviews to include work domains in VR to achieve successful work participation [4, 5, 8, 12], we hypothesized that patients who took part in the VR+ program would have higher odds of participating in work compared to patients who only took part in the VR program.

#### Box 1. Intervention components in rehabilitation treatments

Health-focused interventions. These interventions facilitate the delivery of health services to the injured worker either in the workplace or in settings linked to the workplace (e.g., visits to healthcare providers initiated by the employer/workplace). Specific health services intervention subcategories for which evidence synthesis was conducted include; graded activity/ exercise, cognitive behavioural therapy, work hardening and multi-component health-focused interventions (which often included the above elements as well as: medical assessment, physical therapy, psychological therapy, occupational therapy).

Service coordination interventions. These interventions were designed to better coordinate the delivery of, and access to, services to assist RTW within and involving the workplace. Coordination involves attempts to improve communication within the workplace or between the workplace and the healthcare providers. Examples are development of RTW plans, case management and education and training.

Work modification interventions. These interventions alter the organization of work or introduce modified working conditions. Examples are: workplace accommodations such as provision of modified duties, modified working hours, supernumerary replacements, ergonomic adjustments or other worksite adjustments.

**Multi-domain interventions.** These interventions had multiple intervention components and included at least two of the three above intervention domains [e.g., interventions that involved graded activity in the workplace (health-focused domain) in addition to modified working conditions (work modification domain)].

Text obtained from Cullen et al. [4]

### Methods

The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist was used in the design and reporting of this study [13].

#### Design, setting, and procedure

A retrospective cohort study was conducted, with data collected from November 2014 to July 2018 by seven rehabilitation centers located throughout the Netherlands. These seven centers all offered interdisciplinary VR for workers with CMP who were hampered in their work participation. Patients were referred to the VR program by their occupational physician, general physician, rehabilitation physician, medical specialist, or others. Before entering the VR program, patients completed web-based questionnaires (T0) and underwent a multidisciplinary (MD) screening performed by an MD team consisting of a rehabilitation physician, psychologist, physical therapist, and vocational specialist. After the MD screening, the team and patient decided whether a VR+ program was appropriate or not (criteria, see [14]). Before VR+ started, the employer of every patient was asked to reimburse the additional work module (€1200), which was a condition of the patient participating in the VR+ program. VR was reimbursed by the healthcare insurer. Apart from the additional work module, patients of both programs participated as one group. Patients received web-based questionnaires at discharge (T1) and at six-months follow-up (T2). If patients did not complete the T0-2 questionnaires within a week, they received a reminder by email.

#### Participants

Working age individuals (18-65 years) with subacute or chronic musculoskeletal pain and reduced work participation (full or part-time sick leave) who were referred to vocational rehabilitation and who underwent a vocational rehabilitation program (VR+ or VR) between September 2014 and October 2017 participated in this study. Patients were excluded if they had no paid work, if they were not able to complete questionnaires in Dutch, or if they did not grant informed consent. The Medical Ethical Committee of the Academic Medical Center, Amsterdam, the Netherlands, authorized this study and decided that a full application was not required (number W18\_194). Participation in the study was voluntary, all participants provided informed consent, and answers were processed anonymously.

#### Context

When an employee is sick-listed in the Netherlands, both the employee and employer are responsible for the work participation process during the first two years of sick leave. According to the Dutch Gatekeeper Improvement Act, the employer must provide wage replacement and modified work during this twoyear period [15].

#### Interventions

#### Vocational rehabilitation (VR)

The vocational rehabilitation (VR) program was an interdisciplinary group-based program that consisted of multi-components from the health-focused domain. They included general exercise therapy based on principles of graded activity (total ~60 hours; 30 x 2 hours), CBT (total ~7.5 hours; 15 x 0.5 hour), group education (total ~15 hours; 15 x 1 hour), and relaxation (total ~7.5 hours; 15 x 0.5 hour). There were two evaluation moments with the patient: one midevaluation after seven weeks and one end evaluation at discharge. A report from these two evaluation moments was sent to the patient. The MD team consisted of a physician, physiotherapist, and a psychologist. The program lasted fifteen weeks (total ~90 hours) with two 3.5 to 4 hour sessions per week. More information about the content of the VR program can be found in the study protocol paper [16].

#### Vocational rehabilitation + work module (VR+)

The vocational rehabilitation + work module (VR+) program was an interdisciplinary group-based program that consisted of the same health-focused components as the VR program, but was extended with a work module. The work module consisted of case management and a workplace visit (total of ~10 hours), and was executed by an RTW coordinator. The case management involved discussion of work-related problems, the design and discussion of the progress of a work participation plan, and the provision of information about work-related legislation. The company visit included communication between the patient, the RTW coordinator, and the employer with the goal of discussing and resolving barriers to and facilitators of work participation, as well as discussing a work participation plan. A workplace inspection with possible advice for ergonomic adjustment was also part of the workplace visit. There were two evaluation moments with the patient: one mid-evaluation after seven weeks and one end evaluation at discharge. A report of these two evaluation moments was sent

to the patient and his/her employer and occupational physician. If necessary, the evaluation reports were discussed with the employer and/or occupational physician. The MD team consisted of a physician, physiotherapist, psychologist, and an RTW coordinator. The program lasted fifteen weeks (total ~100 hours) with two 3.5 to 4 hour sessions per week. An outline of the content and dosage of the modules of the VR+ program are described in the study protocol paper [16].

#### Measures

#### Dependent variable: work participation

Work participation was assessed using the *working status* item of the *imta Productivity Cost Questionnaire-Vocational Rehabilitation version* (iPCQ-VR) [17]. Working status was assessed with the question: "Are you working full-time at this moment?" with the answer categories: "Yes," "No, I am partly at work," and "No, I am on 100% sick leave." In the case of patients being partly at work, there was an additional question: "How many hours are you working per week at the moment?" For the aim of this study, the *working status* and *hours working per week* items were first converted into a continuous variable of "hours working per week." In a second step, the change in working hours per week was calculated by subtracting working hours per week at T1/T2 from the working hours per week at T0. In a final step, the working hours per week difference was dichotomized into "Achieved work participation" for those who worked at least one hour or more per week at T1/T2 compared to T0, and "Not achieved work participation" for those who worked the same working hours per week or less at T1/T2.

#### Independent variables

The fixed independent variable in this study was **type of intervention** (VR+/VR). The other independent variables selected were potentially associated with or confounders of the outcome of "work participation." The independent variables of this study were clustered into biopsychosocial characteristics [18]: demographic, personality, disorder-related, and work-related. Hereafter, we briefly describe the content and score ranges of the independent variables selected and used in this study. A detailed description and clinometric properties of the questionnaires included can be found elsewhere [16, 17, 19].

#### **Demographic characteristics**

The following demographic characteristics were included: **age** [20-23], **gender** [11, 21-24], and **level of education** [22, 25-28]. Age was dichotomized based on the median. Level of education was divided into three categories: "low" (including primary school, lower vocational education, and lower secondary school), "medium" (including intermediate vocational education and upper secondary school), and "high" (including upper vocational education or university) [25].

#### **Psychological variables**

The following psychological characteristics were used: **job-related illness behavior** [25, 29, 30] and **perfectionism** [25, 29, 30]. These two constructs were measured with two subscales from the Work Reintegration Questionnaire (WRQ), which is a Dutch validated questionnaire [29, 30]. Both subscales consist of multiple statements which are answered on a 4-point Likert scale (1 = disagree, 2 = somewhat agree, 3 = quite agree, 4 = completely agree). The WRQ scales were dichotomized based on norm scores [29]. The illness behavior scale ranges from 10 to 40 and was dichotomized, with scores above 34 referring to high illness behavior. The perfectionism scale ranges from 12 to 48 and was dichotomized, with scores above 39 referring to high perfectionism.

#### **Disorder-related characteristics**

The following disorder-related characteristics were used: **duration of complaints** [11, 31], **pain intensity** [20, 22, 23, 32], **widespread pain** [21, 22, 33], **level of disability** [20, 22, 34, 35], and **perceived health** [22, 23]. Duration of complaints was dichotomized into "subacute" (duration of complaints 3 to 6 months) and "chronic" (more than six months) complaints [31]. Pain intensity was assessed on a 11-point Likert scale, as the mean pain score in the preceding week, where 0 denoted no pain and 10 denoted worst possible pain. Pain intensity was dichotomized into "high pain score" (score of  $\geq$  7) versus "medium/low pain score" (score of  $\leq$  6) [2]. Widespread pain was dichotomized into "yes" or "no." Widespread pain was defined as "yes," if pain in the upper extremities (arm, hand, or wrist), lower extremities (hip, knee, ankle, or foot) and axial skeletal pain (back) was present [36].

Level of disability was measured with the Pain Disability Index (PDI) [37], which is a 7-item questionnaire that measures self-reported pain-related disability. The

PDI measures seven dimensions: family/home responsibilities, recreation, social activity, occupation, sexual behavior, self-care, and life support activity on a 0-10 scale (0 denotes "no disability" and 10 denotes "maximum disability"). Total scores range from 0-70, with higher scores reflecting higher level of disability. The level of disability score was dichotomized based on the median. Perceived health was assessed with a single health status item obtained from the RAND-36 [38, 39]: "What do you think about your health in general?," with five answer categories, ranging from "excellent" to "bad." Perceived health was dichotomized into good health ("excellent," "very good," and "good") and moderate health ("moderate," "bad").

#### Work-related characteristics

The following work-related characteristics were used: **RTW expectation** [22-25, 32, 40-42], sick leave duration [21, 22, 43, 44], working status [20, 22, 35, 45], job strain [27], and job dissatisfaction [24, 46]. RTW expectation was assessed on a 0-10 scale, with patients rating the certainty that they will be working in six months, where 0 represents "Not at all certain" to 10 "Extremely certain." We dichotomized this item into negative RTW expectancy (score 0-5) and positive RTW expectancy (score 6-10). Sick leave duration was assessed with the sick leave long item of the iPCQ-VR questionnaire [17]. We dichotomized this item into long-term sick leave or not ("yes" = absenteeism for six weeks or more; "no" = absenteeism for less than six weeks). The decision to consider a period of six weeks' sick leave in this study was based on Dutch social security legislation [47]. Working status was assessed with the working status item of the iPCQ-VR [17]. We dichotomized this item into "full sick leave" and "part-time sick leave." Job strain and job dissatisfaction were measured with two subscales of the WRQ, which were dichotomized based on norm scores [31]. The job strain scale ranges from 7 to 28 and was dichotomized, with scores above 17 referring to high job strain. The job dissatisfaction scale ranges from 12 to 48 and was dichotomized, with scores above 30 referring to high job dissatisfaction.

#### Statistical analyses

All analyses were performed using SPSS Statistics for Windows, version 23.0 (2015), IBM Corp., Armonk, NY. The analyses were performed in four steps. In the first step, univariate logistic regression analyses were performed for all independent variables, with work participation as the dependent variable. In the second step, multivariate logistic regression was performed. We applied a

forward selection procedure, with type of intervention as the fixed independent (starting) variable in the model and the independent variables with a p-value of  $\leq$  0.10 obtained from the univariate analyses (Step 1). Work participation was the dependent variable. We used a p-value of 0.10 for the forward procedure.

In step three, we examined whether confounding variables were present in the first round of the multivariate regression analyses. If the regression coefficient of the *type of intervention* variable increased or decreased  $\geq$  10%, we considered the independent variable as a confounder. Based on the available evidence, we assumed a priori that RTW expectation [22-25, 32, 40-42], work status [20, 22, 35, 45], and sick leave duration [21, 22, 43, 44] were potential confounders. In the fourth and final step, interaction effects between possible confounders and the dependent variable of work participation were examined using a p-value of < 0.05. Of the final models, model fit was performed based on Hoseman and Lemershow [48]. We report odds ratios, 95% confidence intervals of odds ratios, and p-values. Insight about the relationship between type of intervention and the dependent variable (i.e., work participation) was provided by calculating the proportion of achieved/not achieved work participation and descriptive statistics, separated for type of intervention. We performed the main analyses with complete cases at T0, T1, and T2.

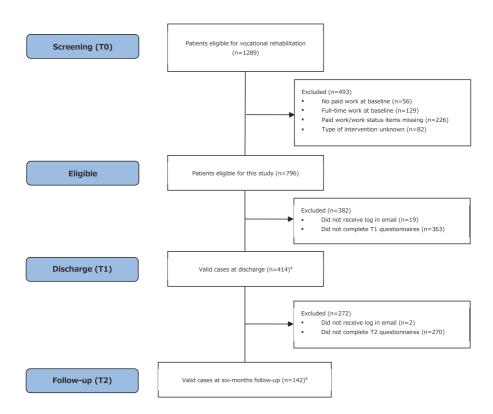
#### Missing data

Based on earlier (interim) analyses, it was expected that a high proportion of missing data due to loss to follow-up would be present in the dataset, especially for the complete cases. The missing data mechanism (i.e., missing complete at random [MCAR] or missing at random [MAR] [49]) was analyzed by conducting a T-test and Little MCAR tests. We also conducted two additional analyses to explore the influence of missing data on the statistical models. The first additional analyses concerned valid cases on discharge. These patients only completed questionnaires at baseline and discharge. The second additional analyses concerned valid cases on six-months follow-up. For these additional analyses, we followed the same procedure as we had done with the complete cases. A priori, we expected no difference between the final models, confounders, or interaction effects between the complete cases and the additional analyses; however, we did expect smaller confidence intervals and, consequently, a greater likelihood that they would reach statistical significance.

### Results

Out of 796 eligible patients, a total of 142 (18%) completed questionnaires at all time points. Of these, 37 (26%) received VR and 105 (74%) VR+. Figure 1 shows a flowchart of the participant inclusion and reasons for dropout. The missing data mechanism for T1 and T2 was missing at random. The sample characteristics of both programs are presented in Table 1.





 $^{a}$ N=414 patients (52%) completed the discharge questionnaires, but not the six-month follow-up questionnaires. Additional analyses were performed on this subgroup.  $^{b}$ N=200 patients (25%) completed the six-month follow-up questionnaires, but not the discharge questionnaires. Additional analyses were performed on this subgroup.

	Complete cases (N=142)		
	VR (N=37)	VR+ (N=105)	
	Mean (SD) or %	Mean (SD) or %	
Age (years), mean	46.7 (11.8)	47.2 (11.4)	
≥ 51 years (%)	53	46	
Gender (% female)	54	65	
Education <sup>a</sup>			
Low	30	21	
Medium	43	41	
High	24	30	
Other	3	9	
Contract (hours/week)	30.9 (11.0)	30.1 (8.8)	
Work status			
Part-time sick leave	51	51	
Full sick leave	49	49	
Sick leave > 6 weeks (% yes)	46	50	
Widespread pain (% yes)	24	15	
Duration of complaints			
< 6 months	24	21	
0.5-1 year	35	26	
1-2 years	16	22	
2-5 years	3	20	
More than 5 years	22	11	
Perceived health (% good)	61	59	
Pain intensity (0-10) <sup>b</sup>	5.6 (2.4)	5.2 (2.2)	
≥ score 7	46	39	
Level of disability (PDI 0-70) <sup>c</sup>	37.7 (10.8)	33.8 (12.3)	
≥ score 37 <sup>d</sup>	49	47	
RTW expectancy (0-10) <sup>e</sup>	5.4 (3.1)	6.8 (2.5)	
Median	5	7	
≥ score 6	47	68	
Job strain (7-28)	14.2 (5.1)	15.8 (5.4)	
≥ score 18	30	33	
Job dissatisfaction (12-48)	24.0 (8.8)	22.3 (7.3)	
≥ score 31	19	13	
Perfectionism (12-48)	35.7 (7.1)	36.1 (6.3)	
≥ score 40	11	5	
Job-related illness behavior (10-40)	32.8 (5.2)	31.5 (6.2)	
≥ score 35	49	39	

Table 1. Baseline characteristics of the study population (complete cases)

SD standard deviation; PDI, pain disability index; RTW, return to work <sup>a</sup>Education category 'other' not taken into account. Therefore, total percentage may deviate from 100% <sup>6</sup> 0=no pain, 10=worst possible pain <sup>c</sup> 0=no disability, 70=maximum disability <sup>d</sup> Median of total sample was 36 <sup>e</sup> 0=not at all certain, 10=extremely certain

#### Work participation

At discharge from vocational rehabilitation, 50% of participants in the VR program and 55% in the VR+ program achieved work participation. At sixmonths follow-up, 56% of participants in the VR program and 69% in the VR+ program had achieved work participation. The mean number of hours working per week and the working status proportions at each time point for both programs are presented in Table 2 and Figure 2. A non-parametric Mann Whitney U-test showed non-significant differences in working hours per week between VR and VR+ at each time point.

**Table 2.** Working hours per week for both intervention programs and for the subgroups that achieved/did not achieve work participation at baseline, discharge, and six-months follow-up

	VR	VR+	Work participation achieved <sup>§</sup>	Work participation not achieved <sup>¥</sup>		
	Working hours: mean (SD)					
Screening (T0)	6.7 (8.7)	8.0 (9.3)	5.8 (8.3)	9.8 (9.7)		
Discharge (T1)	14.2 (13.2)	12.7 (10.4)	18.3 (10.2)	6.6 (8.2)		
Difference T1-T0	6.7 (12.5)*	4.6 (9.9)*	12.5 (8.8)*	-3.3 (4.4)*		
Follow-up 6 months (T2)	18.0 (15.4)	19.8 (14.0)	27.5 (9.2)	3.0 (6.3)		
Difference T2-T0	10.6 (18.3)*	11.7 (14.7)*	20.2 (10.7)*	-5.4 (8.1)*		

VR, vocational rehabilitation; VR+, vocational rehabilitation + work module; SD, standard deviation

<sup>§</sup> participants who worked at least one hour or more per week at T1/T2 compared to T0

\* participants who worked the same working hours per week or less at T1/T2 compared to T0 \* Significant (p < 0.05)

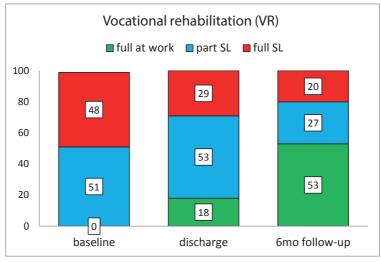
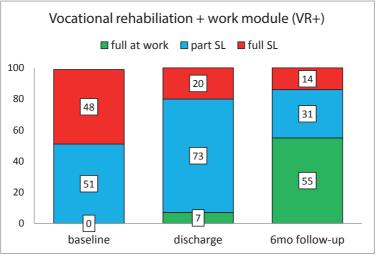


Figure 2. Working status proportions at baseline, discharge, and six-months follow-up

SL, sick leave



SL, sick leave

#### **Regression analyses**

The results of the univariate logistic regression analysis are presented in Table 3. The type of intervention had a non-significant relationship to the achievement of work participation at discharge (OR 1.2, p = 0.62) and six-months follow-up (OR 1.8, p = 0.14). The analyses of confounding variables in the relationship

between type of intervention and work participation are presented in Appendix 1. The results of the final multivariate logistic models are presented in Table 4. The type of intervention was not significantly associated with work participation at discharge (OR 1.0, p = 0.99) or six-months follow-up (OR 1.3, p = 0.52). RTW expectation was the only independent factor at discharge (OR 2.5, p = 0.02) and follow-up (OR 2.8, p = 0.01), and a significant confounder at both time points (Appendix 1). No significant interactions were found (results available upon request).

	_	Di	ischarge	Six-months follow-up		
	Reference category	Complete	e cases (N=142)	Complete	cases (N=142)	
	outogo. y	P-value	OR (CI 95%)	P-value	OR (CI 95%)	
Type of intervention	VR	0.62	1.2 (0.6-2.6)	0.14	1.8 (0.8-3.9)	
Pain intensity	Score 7-10	0.85	1.1 (0.5-2.1)	0.05	<b>2.0 (1.0-4.1)</b> <sup>a</sup>	
Widespread pain	Yes	0.48	0.7 (0.3-1.8)	0.04	2.5 (1.0-6.0) <sup>b</sup>	
Perceived health	Good	0.26	1.5 (0.7-2.9)	0.53	0.8 (0.4-1.6)	
Age	51-65 years	0.65	0.8 (0.4-1.7)	0.92	1.0 (0.5-2.0)	
Gender	Female	0.21	1.6 (0.8-3.1)	0.95	1.0 (0.5-2.1)	
Job-related illness behavior	Score 35-40	0.84	0.9 (0.5-1.8)	0.19	1.6 (0.8-3.2)	
Perfectionism	Score 40-48	0.89	0.9 (0.2-3.5)	0.52	1.6 (0.4-6.1)	
Job strain	Score 18-28	0.10	0.5 (0.3-1.1)	0.49	1.3 (0.6-2.7)	
Job dissatisfaction	Score 31-48	0.06	0.4 (0.1-1.1)	0.19	0.5 (0.1-1.5)	
Sick leave duration	>6 weeks	0.81	1.1 (0.6-2.1)	0.70	1.1 (0.6-2.3)	
Duration of complaints	≤6 months	0.87	0.9 (0.4-2.1)	0.49	0.7 (0.3-1.8)	
RTW expectation	Score 0-5	0.03	2.1 (1.1-4.3)	0.00	3.1 (1.5-6.5)	
Level of disability	Score 37-70	0.34	1.4 (0.7-2.7)	0.09	0.8 (0.9-3.7)	
Education, low	NA	0.11	NA	0.37	NA	
Education, medium	Low	0.16	0.5 (0.2-1.3)	0.34	0.6 (0.3-1.6)	
Education, high	Low	0.67	1.2 (0.5-3.1)	0.79	1.1 (0.4-3.2)	
Working status	Full sick leave	0.04	0.5 (0.3-1.0) <sup>c</sup>	0.19	0.6 (0.3-1.3)	

**Table 3.** Relationship of independent variables with work participation, univariate unadjusted analyses at discharge and six-months follow-up

P-value of  $\leq$  0.10 in bold

<sup>a</sup> original value lower bound: 1.03

<sup>b</sup> original value lower bound: 1.00

<sup>c</sup> original value upper bound: 0.97

#### Additional analyses

Baseline characteristics of the additional analyses on discharge (n=414) and at six-months follow-up (n=200) are presented in Appendix 2. There were no substantial differences between the baseline characteristics of the complete cases and the additional analyses. Regarding the descriptive statistics of the primary outcome, the additional analyses showed the same pattern as the complete cases. Regarding the univariate analyses, the additional analyses revealed different significant variables (p-value  $\leq 0.10$ ) from the complete cases (Appendix 3). The final multivariate regression model of the additional analyses at discharge included working status as a borderline significant factor (p = 0.04, and value 1 not in 95% CI) related to work participation (Appendix 4). In contrast, in the complete cases set, working status was borderline non-significant (p = 0.05, and value 1 in 95% CI) at this time point. The final multivariate regression model of the additional analyses at six-months follow-up included widespread pain as a significant factor related to work participation (Appendix 4).

	Discharge (N=142)		
	Reference category	P-value	OR (CI 95%)
Type of intervention	VR	0.99	1.0 (0.4-2.3)
RTW expectation	Score 0-5	0.02	2.5 (1.2-5.3)
Working status	Full sick leave	0.05ª	0.5 (0.2-1) <sup>b</sup>
Job dissatisfaction	Score 31-48	0.07	0.4 (0.1-1.1)
Job strain	Score 18-28	0.24	0.6 (0.3-1.4)

Table 4. Multivariate analyses with type of intervention (VR+, VR) as fixed variable

P-value of  $\leq$  0.05 in bold

<sup>e</sup> Original value: 0.050

<sup>b</sup> Original value lower bound: 1.001

	Six-months follow-up (N=142	2)	
	Reference category	P-value	OR (CI 95%)
Type of intervention	VR	0.52	1.3 (0.6-3.1)
<b>RTW</b> expectation	Score 0-5	0.01	2.8 (1.3-5.9)
Widespread pain	Yes	0.11	2.2 (0.9-5.5)
Level of disability	Score 37-70	0.34	1.4 (0.7-3.1)

P-value of  $\leq$  0.05 in bold

### Discussion

We hypothesized that patients who received VR+ would have greater odds of achieving work participation compared to patients who received VR. Our hypothesis was not proven. At first sight, the main finding of this study does not appear to be consistent with the strong recommendations of various systematic reviews to include work components to optimize work participation [4, 5, 7, 8, 12, 50, 51].

However, other studies compared multi-domain programs with single-component programs or care as usual [4, 5, 7-9], which complicates comparison of the findings of the present study with them because we compared two multi-component programs. A retrospective cohort study conducted in Canada showed that patients who completed a multimodal pain program that included RTW coordination had 3.4 higher odds of returning to work compared with patients who received the multimodal program without RTW coordination [11]. However, this study did not correct for RTW expectancy.

Based on the present study, and many others [22-25, 32, 40-42], it is clear that RTW expectation is an important confounder in the relationship between an intervention program and a focus on improving work participation. Another RCT study conducted in Norway in patients with neck and back pain showed similar results to our study, namely no significant difference between a group who took part in a multidisciplinary program that included a work focus and a control group who only took part in a multidisciplinary program [10]. One disadvantage of that study, however, was that for the multidisciplinary work-focused group it was not possible to intervene at the workplace due to regulations in Norway. Thus, these results are not directly comparable with those of our study.

In the present study, the proportion of patients at work (full-time or part-time) at six-months follow-up was VR 80% and VR+ 86%. These proportions are slightly higher compared to multi-domain VR described by others, who showed mean work participation proportions of 65%  $\pm$  11% [52-58]. In addition, in the present study, the proportion of patients at work full-time at six-months follow-up was VR 53% and VR+ 55%, which is similar to the full-time work proportions reported in other multi-domain VR studies, namely 52%  $\pm$  16% [59-63]. In summary, the impact on full-time work participation of the present study, which was performed within clinical practice, was similar to other studies in different countries which were performed in a controlled setting.

Within the Dutch social security system, the employer has a mandatory role in offering modified work. All patients in this study had been offered this in some form, including those in the VR group. In practice, therefore, the contrast between VR and VR+ was smaller than suggested, which may provide an additional plausible explanation for the lack of difference between the groups. The results may thus also provide confirmation, rather than mere falsification of the hypothesis, that work modifications are in fact a core element of VR [4]. How the three core elements (Box 1) should be delivered optimally, however, may depend on country-specific system characteristics and further study.

#### Strengths and limitations

One strength of a retrospective study is its observational character, as the researcher is able to observe what actually happens or naturally occurs in practice. This is a great advantage in terms of adaptation for professionals. In addition, in our case, it was possible to correct for many independent (potentially confounding) variables which were clustered a priori based on the biopsychosocial model. This increases knowledge of which factors are important to take into account in research and clinical practice. Based on additional analyses, it was possible to detect the influence of more power on the logistic models. This increased the robustness of our findings.

One limitation of a retrospective cohort design is that the intended intervention is less controllable, which may bias the results. In our case, contamination bias between the two programs could have occurred. Patients from both intervention groups were undertaking rehabilitation together. Patients who only participated in the VR program probably obtained information from patients who completed the VR+ program and from the RTW coordinators during group meetings or coffee breaks. Because 3 out of 4 patients received the VR+ program, the chance of contamination bias, resulting in a lack of contrast, was high.

Selection bias may also have occurred, as the type of program a patient participated in was dependent on the employer's willingness to pay for the additional work module. However, at baseline there were no substantial differences between job dissatisfaction and job strain between the VR+ and VR groups. There were probably other factors which influenced the outcomes of the additional work module. From the beginning, it appeared that the VR+ group would have higher odds of achieving work participation compared to the VR group, due to differences in a number of variables: the VR group was

less educated, had a higher proportion of widespread pain, higher pain scores, higher disability scores, and lower RTW expectancy. However, almost all of the independent variables selected a priori were not included or did not contribute to the final multivariate models. The only significant independent variable (and also confounder) in the final multivariate models at discharge and six-months follow-up was RTW expectation. Because selection bias on RTW expectation did not result in a positive association of VR+ and work participation, we assume that the baseline differences between both VR groups did not introduce bias into the results of this study. One final limitation was a high proportion of loss to follow-up, which negatively influenced the sample size of the complete cases (n=142). However, because the results of the additional analyses with larger samples were similar, we assume our findings were not influenced by low power.

#### Methodological considerations

One methodological consideration with respect to our study concerns the operationalization of the dependent variable of work participation. To detect the influence of our cut-off choice on the reported results, we repeated the univariate and multivariate (if necessary) analyses of the three datasets used in this study. For these additional analyses (not reported; available upon request), we used values ranging from  $\geq 2$  working hours to  $\geq 20$  working hours as the cut off for the achievement of work participation. The results showed the same non-significant relationship between type of intervention and the achievement of work participation was operationally defined as full return to work (yes/no). We conclude that our findings would not differ substantially if full-time at work was the dependent variable.

#### **Clinical implications**

This study found no significant difference between the effects of VR with or without the addition of a work module on work participation at discharge and six-months follow-up. Both programs showed beneficial RTW rates at six-months follow-up, which is an important message for clinical practice. There was a non-significant, but probably clinically relevant, difference on full sick leave rates at six-months follow-up between both groups (VR+ 14%, VR 20%). Patients, professionals, managers, employers, and policymakers should consider whether this difference suggests that it is worthwhile to add a work module to VR. Before a patient starts VR, it might be advisable to discuss with them which work

components have already been performed at their company, or which steps might be expected during the intervention period, and use this information to decide with them whether a work module should be added to VR. Another implication for practitioners is to take RTW expectations into account before the start of an interdisciplinary VR program, since our study showed that patients with positive RTW expectations had three times higher odds of responding successfully after VR (independent of type of program).

#### **Future directions**

In line with the previous point, we recommend that future research should always assess RTW expectations at baseline and correct for this variable during the analyses. Another future direction for research would be to execute return on investment analyses on the added value of work modules when nested in VR. This information is important for those who are asked to reimburse these modules.

## Conclusion

This study found no significant difference between interdisciplinary VR programs implemented with or without an additional work module. Both programs were beneficial in improving work participation of sick-listed employees with CMP. Return to work expectations had a strong and significant relationship to the achievement of work participation.

### **Compliance with Ethical Standards**

#### Funding

No commercial sponsorship was involved in designing or conducting the study.

#### **Conflict of interest**

Author TB, author JvV, author CvB, author MFD, and author MR declare that they have no conflict of interest.

#### **Ethical approval**

All procedures performed were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The Medical Ethical Committee of the Academic Medical Center, Amsterdam, the Netherlands, authorized this study and decided that a full application was not required.

#### Informed consent

Informed consent was obtained from all individual participants included in the study.

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**Appendix 1.** Confounding analyses of the relationship of type of intervention with work participation at discharge and six-months follow-up (executed for complete cases and additional analyses datasets)

#### Complete cases: Discharge (N=142)

	Reference						B change
	category	P-value	OR (CI 95%)	Wald	B unadj.	B adj.	(%)
Job strain	Score 18-28	0.10	0.5 (0.3-1.1)	2.7	0.193	0.146	24
Job dissatisfaction	Score 31-48	0.06	0.4 (0.1-1.0)	3.6	0.193	0.221	-15
<b>RTW</b> expectation	Score 0-5	0.04	2.1 (1.05-4.3)	4.4	0.193	0.005	97
Working status	Full sick leave	0.04	0.5 (0.3-1.0)ª	4.2	0.193	0.206	-7

Confounders in bold

<sup>a</sup> Original value upper limit: 0.97

#### Complete cases: Six-months follow-up (N=142)

	Reference						B change
	category	P-value	OR (CI 95%)	Wald	B unadj.	B adj.	(%)
Pain intensity	Score 7-10	0.06	2.0 (0.8-3.8)	3.5	0.588	0.542	8
Widespread pain	Yes	0.06	2.3 (1.0-5.7)	3.5	0.588	0.518	112
<b>RTW</b> expectation	Score 0-5	0.00	3.0 (1.4-6.3)	8.4	0.588	0.341	42
Level of disability	Score 37-70	0.09	1.8 (0.9-3.7)	2.8	0.588	0.594	-1

Confounders in bold

#### Additional analyses: Discharge (N=414)

	Reference						B change
	category	P-value	OR (CI 95%)	Wald	B unadj.	B adj.	(%)
<b>RTW</b> expectation	Score 0-5	0.00	2.7 (1.8-4.1)	22.8	0.593	0.501	16
Education, low	NA	0.26	NA	2.7	0.593	0.49	17
Education, medium	Low	0.56	1.2 (0.7-1.9)	0.3	NA	NA	NA
Education, high	Low	0.11	1.6 (0.9-2.7)	2.5	NA	NA	NA
Working status	Full sick leave	0.13	0.7 (0.5-1.1)	2.3	0.593	0.571	4

Confounders in bold

#### Additional analyses: Six-months follow-up (N=200)

	Reference category	P-value	OR (CI 95%)	Wald	B unadj.	B adj.	B change (%)
Pain intensity	Score 7-10	0.14	1.6 (0.9-2.9)	2.2	0.464	0.431	7
Widespread pain	Yes	0.04	2.2 (1.1-4.7)	4.4	0.464	0.412	11
Job-related illness behavior	Score 35-40	0.06	1.8 (1.0-3.3)ª	3.6	0.464	0.377	19
<b>RTW</b> expectation	Score 0-5	0.00	3.1 (1.7-6.0)	12.8	0.464	0.231	50
Level of disability	Score 37-70	0.08	1.7 (0.9-3.2)	3.2	0.464	0.383	18

Confounders in bold

<sup>a</sup> Original value lower bound: 0.98

	Discha		Six-months follow-up		
		lyses (N=414)		alyses (N=200)	
	VR (N=109)	VR+ (N=305)	VR (N=51)	VR+ (N=149)	
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	
	or %	or %	or %	or %	
Age (years), mean	47.2 (11.0)	47.3 (10.5)	46.1 (12.1)	47.7 (10.9)	
≥ 51 years (%)	47	45	49	47	
Gender (% female)	54	62	51	65	
Education <sup>a</sup>					
Low	38	21	26	22	
Medium	40	42	46	41	
High	19	31	26	30	
Other	3	6	2	7	
Contract (hours/week) Work status	30.3 (11.5)	30.8 (9.2)	31.9 (10.1)	30.2 (8.9)	
Part-time sick leave	56	48	49	53	
Full sick leave	44	52	51	47	
Sick leave > 6 weeks (%	44	52	51	47	
yes)	44	57	49	50	
Widespread pain (% yes)	21	12	24	17	
Duration of complaints	21	12	27	17	
< 6 months	25	24	28	22	
0.5-1 year	50	53	33	22	
1-2 years	22	19	14	19	
2-5 years	8	19	8	21	
More than 5 years	20	14	18	13	
Perceived health (% good)	55	55	61	60	
Pain intensity (0-10) <sup>b</sup>	5.7 (2.1)	5.2 (2.3)	6.0 (2.2)	5.3 (2.3)	
$\geq$ score 7	45	39	0.0 (2.2) 54	3.3 (2.3) 41	
Level of disability (PDI	45	59	JŦ	71	
0-70) <sup>c</sup>	35.5 (11.0)	35.7 (11.9)	39.9 (10.3)	34.0 (12.4)	
≥ score 37 <sup>d</sup>	43	49	61	46	
RTW expectancy (0-10) <sup>e</sup>	5.5 (3.1)	6.5 (2.6)	5.5 (3.0)	6.7 (2.5)	
Median	5.5 (5.1)	7	5.5 (5.6)	7	
$\geq$ score 6	47	66	45	65	
Job strain (7-28)	14.6 (5.5)	15.2 (5.2)	14.9 (5.1)	15.9 (5.4)	
$\geq$ score 18	31	30	31	35	
Job dissatisfaction (12-48)	24.4 (8.0)	22.9 (7.2)	24.6 (8.5)	22.8 (7.7)	
$\geq$ score 31	2111 (0.0)	15	24	15	
Perfectionism (12-48)	34.6 (6.9)	35.2 (6.2)	36.6 (7.0)	35.8 (6.3)	
$\geq$ score 40	9	55.2 (0.2)	8	55.0 (0.5)	
Job-related illness behavior					
(10-40)	32.5 (5.7)	31.7 (5.8)	33.2 (5.3)	31.6 (5.8)	
$\geq$ score 35	43	39	53	40	

Appendix 2. Baseline characteristics of the additional analyses study samples

SD standard deviation; PDI, pain disability index; RTW, return to work <sup>a</sup>Education category 'other' not taken into account. Therefore, total percentage may deviate from 100%

<sup>6</sup> 0=no pain, 10=worst possible pain <sup>c</sup> 0=no disability, 70=maximum disability <sup>d</sup> Median of total sample of the complete cases was 36 (see Table 1) <sup>e</sup> 0=not at all certain, 10=extremely certain

		Dis	scharge	Six-mor	ths follow-up
		Additio	Additional analyses (N=412)		nal analyses N=200)
	Reference category	P-value	OR (CI 95%)	P-value	OR (CI 95%)
Type of intervention	VR	0.01	1.8 (1.2-2.8)	0.17	1.6 (0.8-3.1)
Pain intensity	Score 7-10	0.11	1.4 (0.9-2.1)	0.10	1.7 (0.9-3.0)
Widespread pain	Yes	0.56	1.2 (0.7-2.0)	0.03	2.3 (1.1-4.8)
Perceived health	Good	0.91	1.0 (0,7-1.4)	0.50	0.8 (0.4-1.5)
Age	51-65 years	0.53	1.1 (0.8-1.7)	0.49	0.8 (0.4-1.5)
Gender	Female	0.43	1.2 (0.8-1.7)	0.94	1.0 (0.6-1.9)
Job-related illness behavior	Score 35-40	0.43	1.2 (0.8-1.8)	0.04	1.9 (1.0-3.4)ª
Perfectionism	Score 40-48	0.29	0.6 (0.3-1.4)	0.45	1.6 (0.5-5.2)
Job strain	Score 18-28	0.97	1.0 (0.7-1.5)	0.83	1.1 (0.6-2.0)
Job dissatisfaction	Score 31-48	0.67	0.9 (0.5-1.5)	0.31	0.6 (0.3-1.5)
Sick leave duration	>6 weeks	0.95	1.0 (0.7-1.5)	0.30	1.4 (0.8-2.5)
Duration of complaints	≤6 months	0.78	0.9 (0.6-1.5)	0.18	0.6 (0.3-1.3)
RTW expectation	Score 0-5	0.00	2.8 (1.9-4.2)	0.00	3.3 (1.8-6.1)
Level of disability	Score 37-70	0.25	1.3 (0.9-1.9)	0.06	1.8 (1.0-3.3) <sup>b</sup>
Education, low	NA	0.14	NA	0.32	NA
Education, medium	Low	0.39	1.2 (0.8-2.0)	0.34	0.7 (0.3-1.5)
Education, high	Low	0.05	1.7 (1.0-2.9)	0.73	1.2 (0.5-2.8)
Working status	Full sick leave	0.09	0.7 (0.5-1.1)	0.28	0.7 (0.4-1.3)

**Appendix 3.** Relationship of independent variables with work participation: univariate unadjusted analyses with additional analyses datasets at discharge and six-months follow-up

P-value of  $\leq$  0.10 in bold

<sup>a</sup> original value lower bound: 1.02
<sup>b</sup> original value lower bound: 0.99

**Appendix 4.** Multivariate analyses with type of intervention as fixed variable (analyses of additional datasets at discharge and six-months follow-up)

	Discharge (N=414)		
	Reference category	P-value	OR (CI 95%)
Type of intervention	VR	0.15	1.4 (0.9-2.3)
RTW expectation	Score 0-5	0.00	2.9 (1.9-4.4)
Education, low	0.29	NA	NA
Education, medium	Low	0.57	1.2 (0.7-1.9)
Education, high	Low	0.13	1.6 (0.9-2.7)
Working status	Full sick leave	0.04	0.6 (0.4-1.0) <sup>a</sup>

P-value of  $\leq$  0.05 in bold NA, not applicable <sup>a</sup> Original value upper bound: 0.97

Six-months follow-up (N=200)			
	Reference category	P-value	OR (CI 95%)
Type of intervention	VR	0.86	1.1 (0.5-2.2)
<b>RTW</b> expectation	Score 0-5	0.00	3.0 (1.5-5.7)
Widespread pain	Yes	0.02	2.7 (1.1-6.3)
Pain intensity	Score 7-10	0.64	0.8 (0.4-1.8)
Job-related illness behavior	Score 35-40	0.24	1.5 (0.8-3.0)
Level of disability	Score 37-70	0.26	1.5 (0.7-3.0)

P-value of  $\leq$  0.05 in bold

