

# Long-term effects of rehabilitation and prevention of further chronification of pain among patients with non-specific low back pain

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## Abstract.

**BACKGROUND:** Psychological factors influence the development and persistence of chronic low back pain (CLBP) and may impair the psychosocial rehabilitation success.

**OBJECTIVE:** To examine the effects of a combined pain competence and depression prevention training compared to the pain competence training alone and as well as the patients' stages of pain on the long-term psychosocial rehabilitation success.

**METHODS:** In this controlled multicentre study with cluster-block randomization, patients with CLBP in different stages of pain (I–III) received either pain competence training (control group, CG;  $n = 255$ ) or combined pain competence and depression prevention training (intervention group, IG;  $n = 271$ ; per protocol). Depressive symptoms (primary outcome), anxiety, somatization, health status, and average pain intensity (secondary outcomes) were assessed up to 12 months of follow-up. Standardised questionnaires were used to record the outcomes, which were filled out by the patients themselves. Analyses after multiple imputation ( $N = 1225$ ) were conducted to validate multi- and univariate analyses of variance.

**RESULTS:** Patients in stage of pain I and II showed significant improvements in depressive symptoms, anxiety, mental health, and average pain intensity at the 12-month follow-up, irrespective from treatment condition.

**CONCLUSIONS:** Multidisciplinary rehabilitation seems to be appropriate for patients with CLBP in stage of pain I and II. However, patients in stage of pain III need more psychological treatments to manage their mental comorbidities.

Keywords: Low back pain, pain chronification, mental disorders, multidisciplinary rehabilitation, Mainz Pain Staging System

## 1. Introduction

Non-specific low back pain is a leading health problem, especially in Western industrial countries [1]. Previous research has provided evidence that psychosocial factors influence the transition from acute to chronic

low back pain (CLBP) and the exacerbation of low back pain [2]. Psychosocial risk factors (yellow flags) are especially emotional responses (e.g., depressive symptoms) and dysfunctional cognitive (e.g., catastrophizing) and behavioural pain coping strategies (avoidance/endurance behaviour) [3–5]. Consequently, there is a need to better understand the relationship between psychosocial and physical aspects to increase knowledge about the process of pain chronification. Therefore, interdisciplinary and multimodal pain management treatments with cognitive-behavioural components were developed, and a biopsychosocial approach

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was applied to these treatments [6,7]. Their short- and mid-term treatment effectiveness among patients with CLBP was demonstrated, showing decreased pain intensity, disability, and pain catastrophizing and increased quality of life (e.g., [8–10]). Furthermore, first long-term improvements in quality of life and daily functioning [11] as well as intake of medication and use of the health care system were reported [12].

With regard to German multidisciplinary orthopaedic rehabilitation, different long-term treatment effects among patients with CLBP have been reported [13–15]. For example, a standardized back school programme [14] and an integrative pain management training without cognitive-behavioural elements [15] could not evoke significant long-term improvements in psychological parameters (e.g., mental quality of life, depression, anxiety), but in somatic outcomes [15]. However, cognitive-behavioural pain management training with an additional depression prevention module showed beneficial long-term effects in depressive symptoms and anxiety [16,17]. For further research, our former treatment was modified to integrate current didactic methods and newly developed psychological treatment elements. Thus, in this modified cognitive-behavioural pain management and depression prevention training, called Debora [18], elements of mindfulness-based interventions as well as group workshops without educators were included. The results showed that Debora significantly improved depressive symptoms and pain self-efficacy among patients with high levels of depressive symptoms at a 12-month-follow-up assessment [19].

Finally, stage of pain among patients with CLBP has been proven to be a significant moderator for rehabilitation outcomes [20]. Thus, subgroups with different stages of pain should be taken into consideration, which have to be evaluated by an objective measure of the chronification process (cf. [21,22]). In German-speaking countries, the Mainz Pain Staging System (MPSS) has been established as a valid and reliable measurement for pain chronification [23]. The MPSS is a diagnosis-independent staging model and comprises a total of four axes that investigate different dimensions of pain based on anamnestic patient data. Hence, the MPSS differentiates three stages of pain (I–III); patients in stage of pain I demonstrate a low level of chronification, and patients in stage of pain III show a high level of chronification. In German studies, psychological symptoms (e.g., depressive symptoms, anxiety), pain-specific parameters (e.g., impairment in daily activities) and inability to work were enhanced with an increasing stage of pain [24]. In addition, former results

suggest that higher stages of pain may interfere with the psychosocial rehabilitation success [20,25,26]. Our combined training Debora is aimed to improve long-term psychosocial rehabilitation outcome among patients in stages of pain I and II but without co-existing mental disorders.

The aim of this study was to examine the 1-year longitudinal effects of Debora and stages of pain on depressive symptoms (primary outcome) as well as anxiety, somatization, health status and average pain intensity (secondary outcomes) in German inpatient multidisciplinary rehabilitation centres. It is expected that patients with CLBP will differ in their long-term psychosocial rehabilitation success dependent on the treatment conditions and stages of pain.

## 2. Methods

### 2.1. Design and procedure

The present study was a randomized controlled trial with cluster-block randomization. Block randomization was realized by having two multidisciplinary orthopaedic clinics perform the control condition and two other clinics simultaneously perform the intervention condition to control seasonal effects. In the context of cluster randomization, each clinic had the same number of control and intervention groups according to an a priori fixed alternating rhythm [27]. Patients were assigned to the clinics by the German Pension Insurance. The project management therefore had no influence on how many patients were assigned to which clinic at which time. In addition, all patients from one week of arrival formed a closed psychological group who participated in either the control or the intervention condition. All psychological interventions and thus also the pain competence and depression prevention training, were conducted by clinical psychologists working on site in the respective cooperation clinic. Additionally, a documentation assistant was employed in each clinic to coordinate the study.

To investigate the long-term rehabilitation outcomes, a  $2 \times 4$  factorial repeated measurements design was realized with *treatment condition* and *stage of pain* as between-subjects factors and *time of assessment* as a within-subjects factor. The first independent factor was *treatment condition*, including one control and one intervention condition. Participants in the control group (CG;  $n = 255$ ) and the intervention group (IG;  $n = 271$ ) underwent pain competence training. In addition,

the IG participated in the combined version of pain competence and depression prevention training [18]. To compensate for the difference in the amount of time, the CG still attended relaxation exercises. According to MPSS [23], the second factor, *stage of pain*, consisted of three groups: stage of pain I ( $n = 126$ ), II ( $n = 270$ ) and III ( $n = 130$ ). The within-subjects factor *time of assessment* consisted of four sample points: pre-rehabilitation ( $t_0$ ), post-rehabilitation ( $t_1$ ) as well as 6 ( $t_2$ ) and 12 months ( $t_3$ ) after rehabilitation.

Recruitment consecutively occurred during the initial physical consultation in four inpatient multidisciplinary clinics in Germany: 'Paracelsus-Klinik an der Gande' in Bad Gandersheim, 'Reha-Zentrum Bad Sooden-Allendorf Klinik Werra' in Bad Sooden-Allendorf, 'Rehabilitationsklinik Auental' in Bad Steben and 'Rehabilitationsklinik Göhren' in Göhren. The patients were informed about the aims, contents and data protection process of the study. Referring to the week of arrival, voluntary patients were allocated to treatment conditions. Allocation was achieved by a randomized Latin square design to control for seasonal effects; the four allocation plans were assigned to the clinics by an independent doctoral student at the Europa-Universität of Flensburg. While the physician determined the stage of pain during an initial consultation, the other data were collected with questionnaires. Data collection pre- and post-assessment occurred before ( $t_0$ ) or at the end of rehabilitation ( $t_1$ ) in the clinics and was accompanied by a documentation assistant. Follow-up assessments ( $t_2, t_3$ ) were sent by regular mail by research assistants of the Europa-Universität Flensburg. The data were collected between October 2014 and December 2015 for the time of assessments before ( $t_0$ ) and at the end ( $t_1$ ) of rehabilitation. Data collection for follow-up assessments 6 ( $t_2$ ) and 12 ( $t_3$ ) months after rehabilitation took place between April 2015 and November 2016. Overall, 526 participants completed the questionnaires at all four assessment points.

Although physicians and nursing staff were blinded to the patients' group assignment, patients and responsible therapists who conducted the pain competence training or the combined training with depression prevention were not. The documentation assistants in the clinics who organised and accompanied the data collections had also knowledge of the assignment of the treatment conditions and were therefore not blinded. In addition, the study management and thus the evaluators of the analyses had the pseudonymised data and the list for linking the ID numbers with the plain names. However, the study data were entered pseudonymously

and subsequently analysed. The statistical variable intervention group/control group was noted in the data sets. The evaluators were therefore not blinded.

This study was approved by the ethical review board of the German Psychological Society (DGPs) and was conducted in accordance with the 1964 Declaration of Helsinki and its later amendments. Written consent was obtained from all individual participants included. Furthermore, the trial was registered with the German Clinical Trial Register DRKS (DRKS00015465). The present study is a secondary analysis within the evaluation of the registered, controlled trial Debora. Therefore, no additional sample size calculation and power analysis was performed for the present analysis, as it is a continuing evaluation within the overall trial Debora. The sample size calculation was calculated before starting the study for the primary outcome 'depression'. Please see the published sample size calculation and power analysis in Linton and Kienbacher [22].

## 2.2. Participants

A total of 526 patients with CLBP were included in the per protocol (PP) analyses. The patients had a mean age of 53.22 years ( $SD = 6.11$ ) and a mean pain duration of 15.11 years ( $SD = 10.72$ ; Table 1). Participants were included if they had a diagnosis of non-specific CLBP lasting at least 6 months (ICD-10: M51, M53, M54), an age between 20 and 65 years at pre-assessment, and fluency in the German language. The exclusion criteria were surgery or an accident in the last 6 months before rehabilitation; somatic diseases inducing back pain, pregnancy, infections, cardiovascular or metabolic diseases affecting rehabilitation; or serious psychiatric disorders.

## 2.3. Treatment conditions

In the context of a German inpatient multidisciplinary orthopaedic rehabilitation programme lasting 3 to 4 weeks, the combined pain competence and depression prevention training 'Debora' was implemented and followed a biopsychosocial approach of CLBP [18]. The aim of the cognitive-behavioural patient training is to reduce biopsychosocial dysfunction among patients with somatic-psychic comorbidity of CLBP and depressive symptoms. Furthermore, long-term attitude and behaviour change through the promotion of patients' self-management skills and empowerment are further aims of the training. To conduct patient training, clinics were a priori provided with prepared presentations and

Table 1  
Participant's baseline characteristics for all stages of pain according to the Mainz Pain Staging System

Variable	<i>p</i> -value	Stage of pain I ( <i>n</i> = 126)	Stage of pain II ( <i>n</i> = 270)	Stage of pain III ( <i>n</i> = 130)	Total sample ( <i>N</i> = 526)
Socio-demographic data					
Age [in years] (mean ± <i>SD</i> )	<i>p</i> = 0.454	52.79 ± 6.45	53.18 ± 5.83	53.74 ± 6.36	53.22 ± 6.11
Gender, female no. (%)	<i>p</i> = 0.010	96 (76.2%)	235 (87.0%)	101 (77.7%)	432 (82.1%)
Family status, married no. (%)	<i>p</i> = 0.033	71 (56.4%)	173 (64.1%)	87 (66.9%)	331 (62.9%)
Educational level no. (%)	<i>p</i> = 0.419				
Low		24 (19.1%)	51 (18.9%)	28 (21.5%)	103 (19.6%)
Middle		50 (39.7%)	135 (50.0%)	68 (52.3%)	253 (48.1%)
High		50 (39.7%)	80 (29.6%)	31 (23.9%)	161 (30.6%)
Other school-leaving qualification		2 (1.5%)	4 (1.5%)	2 (1.5%)	8 (1.5%)
Work-related data					
Employed no. (%)	<i>p</i> = 0.006	113 (89.7%)	237 (87.8%)	108 (83.1%)	458 (87.1%)
Days of sick leave due to pain in the last 3 months, more than 2 weeks no. (%)	<i>p</i> = 0.011	26 (20.6%)	74 (27.4%)	47 (36.2%)	147 (28.0%)
Pain history					
Pain duration [in years] (mean ± <i>SD</i> )	<i>p</i> = 0.037	13.57 ± 10.60	14.80 ± 10.49	17.14 ± 11.08	15.11 ± 10.72
Pain locations no. (mean ± <i>SD</i> )	<i>p</i> < 0.001	4.30 ± 2.22	5.21 ± 2.32	6.48 ± 2.55	5.31 ± 2.47
Average pain intensity (mean ± <i>SD</i> )	<i>p</i> < 0.001	4.23 ± 1.93	4.93 ± 1.73	5.57 ± 1.77	4.92 ± 1.85
Psychological status					
Depressive symptoms (CES-D; mean ± <i>SD</i> )	<i>p</i> < 0.001	20.18 ± 10.86	23.35 ± 11.18	26.30 ± 10.48	23.32 ± 11.12
Health status (SF-12; mean ± <i>SD</i> )					
Physical	<i>p</i> < 0.001	41.35 ± 8.51	37.36 ± 8.70	32.98 ± 8.94	37.25 ± 9.18
Mental	<i>p</i> = 0.181	39.27 ± 10.74	38.75 ± 10.95	36.91 ± 10.90	38.43 ± 10.90

materials (worksheets, printed cards, videos, package string, ball) for the exercises in each session. In addition, different participant booklets with information and worksheets were made and handed out for CG and IG patients. In general, each session of the training addressed a key topic and was equally structured by the following building blocks: Homework feedback (except 1st session), psychoeducation, practical relevance (self-reflection, exercise, video examples, role play or discussion), homework and feedback on each session.

The pain competence training included four sessions and discussed the interactions between behaviour and pain (1), emotions and pain (2), cognitions and pain (3) and stress and pain (4) [18,19]. While the first session discusses the basics of the biopsychosocial model and distinguishes positive from negative behaviour, the second session focuses on pain-reducing and pain-enhancing emotions. In the third session, cognitive restructuring is practiced, and the role of attention on pain perception is explained. The combined influences of behaviour and emotions on pain are highlighted and put together to form the vicious circle. In the fourth session, it is explained how stress arises, and personal stressful situations, stress responses and coping strategies are explored. Patients in the CG and IG participated in the pain competence training.

In addition, only patients in the IG received four sessions of cognitive-behavioural depression prevention training. In the first session (1a), the effects of dys-

functional behaviour such as avoidance or social isolation and functional behaviour such as relaxation or social interaction are discussed. The Activities-Emotions-Pain Protocol as an instrument for the promotion of the activity level is presented for patients to complete regularly during training. In the second session, especially nonverbal communication of pain is discussed (2a). The patients' own pain communication is reflected upon. In the third session (3a), automatic thoughts are discussed, and the phenomena of thought suppression and catastrophizing are worked out. The formulation of alternative positive self-instructions is practiced using the ABC-scheme. Finally, the distinction between adaptive and maladaptive coping strategies is practiced (4a). A psychotherapist guided all four to eight closed group sessions. Each group session lasted 75 minutes. After each session, the patients participated in a 25-minute group workshop without a psychotherapist to complete cognitive-behavioural exercises and promote participants' empowerment and a social exchange of experiences within the group [18].

#### 2.4. Outcome measures

For the present analysis, the primary outcome (depressive symptoms) and four secondary outcomes (anxiety, somatization, health status, average pain intensity) were selected and measured at each time of assessment. Depressive symptoms were measured with the German

version of the CES-D (ADS, [28]). The 20 items of the ADS assess the severity of depressive symptoms over the past two weeks on a four-point scale (0 = seldom, 3 = mostly, response range 0–60). The recommended cut-off score of  $< 22$  was applied.

Anxiety was measured using the 7-item anxiety subscale of the German version of the Hospital Anxiety and Depression Scale (HADS-D, [29]), which is rated on a four-point scale (0 = not at all, 3 = mostly, response range 0–21). Scores of 11 or higher were interpreted as clinically significant.

To measure somatization, the somatization subscale of the German short version of the Brief-Symptom-Checklist (Mini-SCL, [30]) was used. The 6-item questionnaire rates items on a five-point scale (0 = not at all, 4 = very strong, response range 0–24). According to the manual, scores were transformed into T-standards.

Health status was measured with the 6-item physical health and mental health subscales of the German version of the Short-Form-12 (SF-12, [31]). The standard score is from 0 to 100, and higher scores represent better physical and mental quality of life.

To measure the average pain intensity, the single-item average pain intensity of the German Questionnaire of Pain (DSF, [32]) was applied. The single item was rated on an 11-point scale with reference to the past two weeks.

### 2.5. Statistical analysis

For depressive symptoms, anxiety, somatization and average pain intensity, univariate two-way measures analyses of variance (ANOVA) were performed with *treatment condition* (CG, IG) and *stage of pain* (I–III) as between-subjects factors and *time of assessment* ( $t_0, t_1, t_2, t_3$ ) as a within-subjects factor. For health status, multivariate two-way repeated-measures ANOVA were conducted in the first step. Second, univariate two-way repeated-measures ANOVA were performed for physical and mental health. Furthermore, pairwise comparisons corrected by Bonferroni were used to detect mean differences. The significance level was set at  $p < 0.05$ . The clinical effect sizes of the ANOVA were interpreted as small ( $\eta = 0.01$ ), medium ( $\eta = 0.06$ ) and large ( $\eta = 0.14$ ; [33]). Additionally, clinical significance for between- and within-group effects was calculated using Cohen's  $d$ : effect sizes  $d = 0.20$ ,  $d = 0.50$  and  $d = 0.80$  were considered to be small, medium and high, respectively. The results of the PP analyses were validated by analyses after multiple imputations (MI,  $n = 1225$ ). Single missing values and missing

data due to dropouts from the study were substituted by 10 imputations. Analyses after MI were used only to validate the PP results because of the significant result on Little's Missing Completely at Random (MCAR) test [34] and the power of testing increased with MI. Overall, only results at least with a small effect size were interpreted (i.e.,  $d \geq 0.20$ ).

## 3. Results

### 3.1. Dropout analyses

A total of 2075 patients with CLBP were approached for the study, and 769 patients did not agree to participate. Thus, 1306 patients with CLBP were randomized and participated in the study at pre-assessment. During the 12-month follow-up, 675 patients dropped out due to different reasons (dropout rate: 51.68%; Fig. 1). Figure 1 shows that not returning the questionnaire on time or at all is the most common reason for dropping out. Other reasons are no consent for saving contact details, wrong mailing address, rehabilitation not completed, withdrawal of informed consent or other medical disease. Filter variables were also used during data analyses to examine the same patients. These filter variables were the ADS scores and the evidence of response bias at all assessment points [23], stage of pain (MPSS, [23]) and gender at pre-assessment. As a result, the sample size decreased to 526 patients, who were included in the PP. Furthermore, analyses after MI were conducted. The MI sample comprised all patients who agreed to participate in the study. The same filter variables as in PP analyses were used. Thus, the sample size was finally  $N = 1225$ . In Fig. 1, only the results of the PP are presented.

$\chi^2$  and  $t$  tests for pre-assessment indicated that the dropout rates of the treatment conditions did not differ ( $\chi^2_{(1)} = 0.03$ ,  $p = 0.866$ ). Patients who dropped out were more often male, younger, not married and reported a net household income under 1500 Euros and a shorter pain duration.

### 3.2. Rehabilitation outcome

None of the multi- and univariate repeated measures ANOVAs showed significant two-way interactions. However, a one-way interaction of *treatment condition* and *time of assessment* was significant for somatization. Furthermore, a significant one-way interaction of *stage of pain* and *time of assessment* was found for

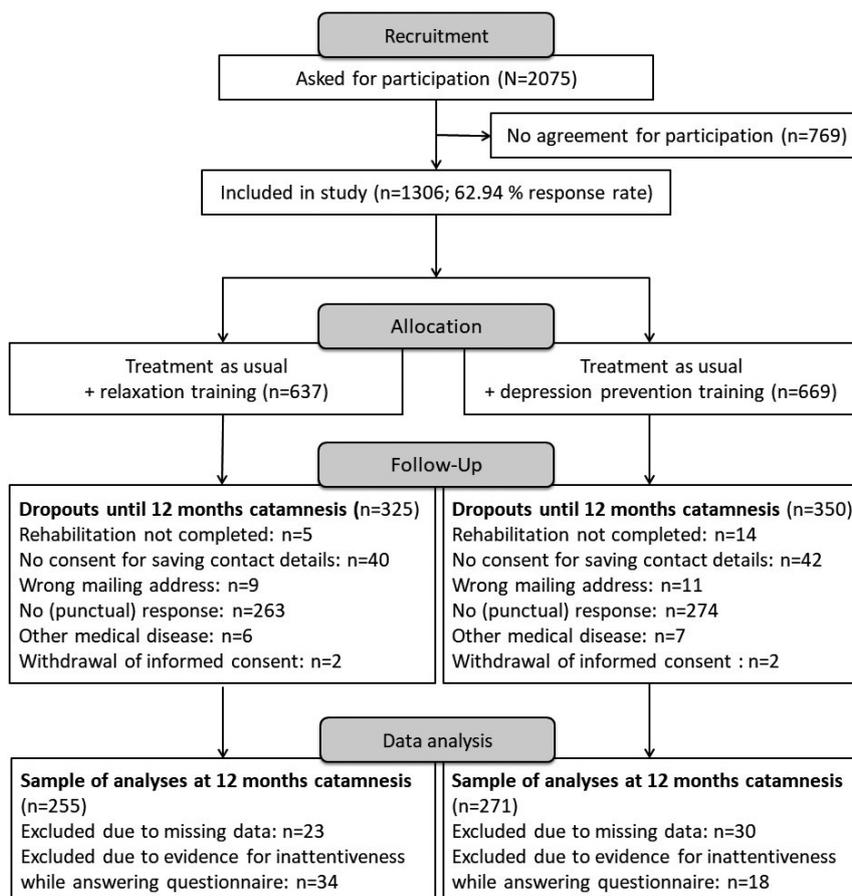


Fig. 1. Flowchart of sample sizes for control and intervention group (CONSORT).

depressive symptoms, anxiety, mental health and average pain intensity (Table 2). The following description of rehabilitation outcomes is focused on the interaction effects of time. Moreover, all presented main and interaction effects were confirmed by ITT analyses, except for the one-way interaction *treatment condition by time* in somatization.

### 3.2.1. Effects of treatment condition by time

As depicted in Table 3, only the IG improved significantly in somatization with a small effect size 6 months after rehabilitation ( $d = -0.21$ ). However, this beneficial mid-term effect could not be maintained in the long-term, showing a statistically significant effect without clinical relevance. Furthermore, significant declining effects were found for the IG ( $t_{1-t3}$ :  $d = 0.33$ ) and CG ( $t_{1-t3}$ :  $d = 0.47$ ) immediately after rehabilitation compared to those at the 12-month follow-up assessment, with small effect sizes. Moreover, no significant effects in somatization were observed between the two treatment conditions at any time of assessment.

### 3.2.2. Effects of stage of pain by time

Univariate repeated measures ANOVA yielded a simple interaction for *depressive symptoms* and *anxiety* (Table 2). First, patients in stage of pain I ( $t_{0-t2}$ :  $d = -0.54$ ), II ( $t_{0-t2}$ :  $d = -0.47$ ) and III ( $t_{0-t2}$ :  $d = -0.28$ ) reduced their *depressive symptoms* at the 6-month follow-up, with small to medium effect sizes. Only patients in stage of pain I ( $t_{0-t3}$ :  $d = -0.45$ ) and II ( $t_{0-t3}$ :  $d = -0.47$ ) could maintain these improvements in the long-term, with small effect sizes (Table 4a–4b). In contrast, *anxiety* significantly decreased at the 6-month (stage of pain I  $t_{0-t2}$ :  $d = -0.68$ ; II  $t_{0-t2}$ :  $d = -0.58$ ; III  $t_{0-t2}$ :  $d = -0.43$ ) and 12-month follow-ups (stage of pain I  $t_{0-t3}$ :  $d = -0.58$ ; II  $t_{0-t3}$ :  $d = -0.61$ ; III  $t_{0-t3}$ :  $d = -0.33$ ) for all stages of pain. At any time of the assessment, significant effects for depressive symptoms and anxiety between all stages of pain in expected directions were observed (Table 4a–4b). Multivariate ANOVA revealed a one-way interaction for *mental health*, which was confirmed

Table 2  
Results (ANOVA) for treatment condition (TC), stage of pain (MPSS), and time of assessment (T)

Variable		Factors						
		TC	MPSS	TC x MPSS	T	TC x T	MPSS x T	TC x MPSS x T
Depressive symptoms	$df_{1,2}$	1, 520	2, 520	2, 520	2.7, 1398.8	2.7, 1398.8	5.4, 1398.8	5.4, 1398.8
	$F$	0.20	23.88	0.99	171.76	0.56	2.96	1.44
	$p$	0.659	< <b>0.001</b>	0.371	< <b>0.001</b>	0.623	<b>0.010</b>	0.202
	$\eta^2$	0.000	0.084	0.004	0.248	0.001	0.011	0.006
Anxiety	$df_{1,2}$	1, 518	2, 518	2, 518	2.8, 1472.1	2.8, 1472.1	5.7, 1472.1	5.7, 1472.1
	$F$	0.41	19.44	0.42	176.76	1.39	2.63	1.40
	$p$	0.522	< <b>0.001</b>	0.659	< <b>0.001</b>	0.247	<b>0.017</b>	0.215
	$\eta^2$	0.001	0.070	0.002	0.254	0.003	0.010	0.005
Somatization	$df_{1,2}$	1, 518	2, 518	2, 518	2.9, 1481.7	2.9, 1481.7	5.7, 1481.7	5.7, 1481.7
	$F$	0.04	30.05	1.01	65.41	2.68	0.95	0.47
	$p$	0.843	< <b>0.001</b>	0.367	< <b>0.001</b>	<b>0.048</b>	0.453	0.822
	$\eta^2$	0.000	0.104	0.004	0.112	0.005	0.004	0.002
Health status (multivariate)	$df_{1,2}$	2, 455	4, 910	4, 910	6, 2734	6, 2734	12, 2734	12, 2734
	$F$	0.35	22.43	0.99	78.09	0.50	2.59	0.96
	$p$	0.702	< <b>0.001</b>	0.413	< <b>0.001</b>	0.813	<b>0.002</b>	0.483
	$\eta^2$	0.002	0.090	0.004	0.146	0.001	0.011	0.004
Physical health	$df_{1,2}$	1, 456	2, 456	2, 456	2.7, 1250.1	2.7, 1250.1	5.5, 1250.1	5.5, 1250.1
	$F$	0.49	42.30	0.83	40.54	0.71	0.51	0.92
	$p$	0.484	< <b>0.001</b>	0.438	< <b>0.001</b>	0.533	0.784	0.477
	$\eta^2$	0.001	0.156	0.004	0.082	0.002	0.002	0.004
Mental health	$df_{1,2}$	1, 456	2, 456	2, 456	2.8, 1309.9	2.8, 1309.9	5.8, 1309.9	5.8, 1309.9
	$F$	0.07	13.50	0.87	118.19	0.27	4.61	1.13
	$p$	0.789	< <b>0.001</b>	0.422	< <b>0.001</b>	0.839	< <b>0.001</b>	0.345
	$\eta^2$	0.000	0.056	0.004	0.206	0.001	0.020	0.005
Average pain intensity	$df_{1,2}$	1, 473	2, 473	2, 473	2.9, 1357.1	2.9, 1357.1	5.7, 1357.1	5.7, 1357.1
	$F$	0.05	39.50	1.16	61.42	0.58	3.24	0.81
	$p$	0.819	< <b>0.001</b>	0.314	< <b>0.001</b>	0.618	<b>0.004</b>	0.556
	$\eta^2$	0.000	0.143	0.005	0.115	0.001	0.014	0.003

Legend.  $df_{1,2}$  degrees of freedom,  $\eta^2$  eta-square (effect size). Bold effects  $p < 0.05$ .

Table 3  
Means ( $M$ ), standard error ( $SE$ ), within-group effect sizes (ES), and pairwise comparisons ( $p$ -values) for somatization\*

Variable	Control group (1)				Intervention group (2)				Dependent comparisons							
	$t_0$	$t_1$	$t_2$	$t_3$	$t_0$	$t_1$	$t_2$	$t_3$	$t_0-t_1$	$t_0-t_2$	$t_0-t_3$	$t_1-t_2$	$t_1-t_3$	$t_2-t_3$		
Somatization	$M$	6.73	4.63	5.69	6.01	6.77	4.20	6.23	6.14	<b>1</b> $ES$	-0.52	-0.11	-0.13	0.49	0.47	-0.02
										$p$	< <b>0.001</b>	<b>0.040</b>	<b>0.019</b>	< <b>0.001</b>	< <b>0.001</b>	0.691
	$SE$	0.31	0.26	0.30	0.31	0.31	0.26	0.31	0.31	<b>2</b> $ES$	-0.42	-0.21	-0.14	0.25	0.33	0.07
										$p$	< <b>0.001</b>	< <b>0.001</b>	<b>0.007</b>	< <b>0.001</b>	< <b>0.001</b>	0.143

Legend.  $t_0$  = pre.  $t_1$  = post.  $t_2$  = 6 months after rehabilitation.  $t_3$  = 12 months after rehabilitation. 1 = control group. 2 = intervention group. Bold effects  $p < 0.05$ . \*All independent comparisons were not significant.

in univariate ANOVA (Table 2). Once again, patients with all stages of pain benefited from rehabilitation at the 6-month follow-up, with small to medium effect sizes (stage of pain I $_{t_0-t_2}$ :  $d = 0.63$ ; II $_{t_0-t_2}$ :  $d = 0.56$ ; III $_{t_0-t_2}$ :  $d = 0.29$ ). However, only patients in stage of pain I ( $t_0-t_3$ :  $d = 0.60$ ) and II ( $t_0-t_3$ :  $d = 0.54$ ) significantly improved their mental health in the long-term, with medium effect sizes. In addition, no significant effects among all stages of pain were found at pre-assessment, but patients in stage of pain III scored lower in mental health than patients in stage of pain I and II at both follow-up-assessments (Table 4a-4b).

The average pain intensity significantly decreased among patients in stage of pain I ( $t_0-t_3$ :  $d = -0.63$ ) and II ( $t_0-t_3$ :  $d = -0.57$ ) at the 12-month follow-up (Table 4a-4b). All between-group comparisons were significant, showing enhanced average pain intensity with an increasing stage of pain.

#### 4. Discussion

In this multicentre study, the long-term rehabilitation outcomes of a German pain management and depression prevention training among patients with CLBP

Table 4a  
Means (*M*) and standard error (*SE*) for the interaction 'stage of pain' and 'time'

Variable		Stage of pain 1				Stage of pain 2				Stage of pain 3			
		<i>t</i> <sub>0</sub>	<i>t</i> <sub>1</sub>	<i>t</i> <sub>2</sub>	<i>t</i> <sub>3</sub>	<i>t</i> <sub>0</sub>	<i>t</i> <sub>1</sub>	<i>t</i> <sub>2</sub>	<i>t</i> <sub>3</sub>	<i>t</i> <sub>0</sub>	<i>t</i> <sub>1</sub>	<i>t</i> <sub>2</sub>	<i>t</i> <sub>3</sub>
Depressive symptoms	<i>M</i>	20.32	9.57	14.42	15.44	23.40	12.51	18.30	18.21	26.41	16.30	23.30	25.19
	<i>SE</i>	0.98	0.85	1.06	1.07	0.67	0.58	0.72	0.73	0.96	0.84	1.04	1.05
Anxiety	<i>M</i>	9.23	4.59	6.36	6.81	10.30	6.17	7.87	7.74	11.19	8.05	9.40	9.78
	<i>SE</i>	0.38	0.38	0.39	0.40	0.26	0.26	0.27	0.27	0.37	0.37	0.38	0.39
Mental health	<i>M</i>	38.80	51.36	45.66	45.37	38.35	48.45	44.46	44.22	36.73	45.08	39.91	37.05
	<i>SE</i>	1.05	1.00	1.12	1.09	0.71	0.67	0.75	0.74	1.00	0.96	1.06	1.04
Average pain intensity	<i>M</i>	4.27	3.06	2.95	3.15	4.98	3.66	3.99	3.96	5.54	4.78	4.82	5.22
	<i>SE</i>	0.17	0.18	0.19	0.18	0.11	0.12	0.13	0.12	0.16	0.17	0.18	0.17

Legend. *t*<sub>0</sub> = pre. *t*<sub>1</sub> = post. *t*<sub>2</sub> = 6 months-follow-up. *t*<sub>3</sub> = 12 months-follow-up.

Table 4b  
Effect sizes (*ES*), and pairwise comparisons (*p*-values) for the interaction 'stage of pain' and 'time'

Variable	MPSS	Independent comparisons				Dependent comparisons								
		<i>t</i> <sub>0</sub>	<i>t</i> <sub>1</sub>	<i>t</i> <sub>2</sub>	<i>t</i> <sub>3</sub>	MPSS	<i>t</i> <sub>0</sub> - <i>t</i> <sub>1</sub>	<i>t</i> <sub>0</sub> - <i>t</i> <sub>2</sub>	<i>t</i> <sub>0</sub> - <i>t</i> <sub>3</sub>	<i>t</i> <sub>1</sub> - <i>t</i> <sub>2</sub>	<i>t</i> <sub>1</sub> - <i>t</i> <sub>3</sub>	<i>t</i> <sub>2</sub> - <i>t</i> <sub>3</sub>		
Depressive symptoms	1-2	<i>ES</i>	0.28	0.31	0.33	0.23	1	<i>ES</i>	-0.98	-0.54	-0.45	0.51	0.62	0.09
		<i>p</i>	<b>0.009</b>	<b>0.004</b>	<b>0.003</b>	<b>0.032</b>		<i>p</i>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>	0.197
	1-3	<i>ES</i>	0.56	0.71	0.75	0.81	2	<i>ES</i>	-1.00	-0.47	-0.47	0.61	0.60	-0.01
		<i>p</i>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>		<i>p</i>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>	0.860
	2-3	<i>ES</i>	0.28	0.40	0.42	0.58	3	<i>ES</i>	-0.92	-0.28	-0.11	0.74	0.93	0.16
		<i>p</i>	<b>0.010</b>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>		<i>p</i>	< <b>0.001</b>	<b>0.001</b>	0.222	< <b>0.001</b>	< <b>0.001</b>	<b>0.015</b>
Anxiety	1-2	<i>ES</i>	0.25	0.37	0.35	0.21	1	<i>ES</i>	-1.10	-0.68	-0.58	0.42	0.52	0.10
		<i>p</i>	<b>0.020</b>	<b>0.001</b>	<b>0.002</b>	0.053		<i>p</i>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>	0.121
	1-3	<i>ES</i>	0.46	0.81	0.70	0.67	2	<i>ES</i>	-0.98	-0.58	-0.61	0.40	0.37	-0.03
		<i>p</i>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>		<i>p</i>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>	0.522
	2-3	<i>ES</i>	0.21	0.44	0.35	0.46	3	<i>ES</i>	0.75	0.43	0.33	-0.32	-0.41	-0.09
		<i>p</i>	<b>0.048</b>	< <b>0.001</b>	<b>0.001</b>	< <b>0.001</b>		<i>p</i>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>	0.171
Mental health	1-2	<i>ES</i>	0.04	0.28	0.10	0.10	1	<i>ES</i>	1.16	0.63	0.60	-0.55	-0.58	-0.03
		<i>p</i>	0.721	<b>0.016</b>	0.373	0.387		<i>p</i>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>	0.758
	1-3	<i>ES</i>	0.19	0.60	0.50	0.73	2	<i>ES</i>	0.93	0.56	0.54	-0.38	-0.41	-0.02
		<i>p</i>	0.154	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>		<i>p</i>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>	0.713
	2-3	<i>ES</i>	0.15	0.32	0.39	0.63	3	<i>ES</i>	0.76	0.29	0.03	-0.50	-0.77	-0.25
		<i>p</i>	0.187	<b>0.004</b>	<b>0.001</b>	< <b>0.001</b>		<i>p</i>	< <b>0.001</b>	<b>0.003</b>	0.775	< <b>0.001</b>	< <b>0.001</b>	<b>0.002</b>
Average pain intensity	1-2	<i>ES</i>	0.40	0.32	0.52	0.43	1	<i>ES</i>	-0.68	-0.74	-0.63	-0.06	0.05	0.10
		<i>p</i>	<b>0.001</b>	<b>0.005</b>	< <b>0.001</b>	< <b>0.001</b>		<i>p</i>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>	0.548	0.622	0.227
	1-3	<i>ES</i>	0.71	0.92	0.95	10.10	2	<i>ES</i>	-0.74	-0.56	-0.57	0.18	0.16	-0.01
		<i>p</i>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>		<i>p</i>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>	<b>0.007</b>	<b>0.014</b>	0.803
	2-3	<i>ES</i>	0.32	0.60	0.42	0.67	3	<i>ES</i>	-0.43	-0.40	-0.18	0.02	0.24	0.20
		<i>p</i>	<b>0.005</b>	< <b>0.001</b>	< <b>0.001</b>	< <b>0.001</b>		<i>p</i>	< <b>0.001</b>	< <b>0.001</b>	0.082	0.791	<b>0.011</b>	<b>0.012</b>

Legend. *t*<sub>0</sub> = pre. *t*<sub>1</sub> = post. *t*<sub>2</sub> = 6 months-follow-up. *t*<sub>3</sub> = 12 months-follow-up. MPSS = Mainz Pain Staging System. 1 = stage of pain 1. 2 = stage of pain 2. 3 = stage of pain 3. Bold effects *p* < 0.05.

were examined. Additionally, the stages of pain were considered.

#### 4.1. Rehabilitation outcome

The PP analyses revealed a significant interaction between *treatment condition* and *time of assessment* in somatization only; patients in the IG benefited in somatization at the 6-month follow-up assessments, showing a small effect size. However, the treatment conditions did not significantly differ at any assessment point. Moreover, the analyses after MI could not validate this interaction effect. Thus, no additional influence of de-

pression prevention training on somatization could be assumed. Overall, the missing interaction effects between *treatment condition* and *time of assessment* on the other outcomes must be discussed. In contrast to the current findings, results of our previous pain management training showed significant improvements in psychological parameters (e.g., depressive symptoms), especially for the IG at a 12-month follow-up [16]. The different clinical settings have to be considered. While the present study involved multidisciplinary rehabilitation, patients with CLBP in the previous study were treated in two orthopaedic clinics with less psychological elements [17]. The missing superiority of the current

depression prevention training could have been due to the biopsychosocial approach of the whole multidisciplinary rehabilitation and to the modified concept of the current pain management training [18]. In contrast to the earlier pain management training, more interactive methods, mindfulness-based interventions, and additional group workshops were included. Thus, patients in the CG could have already strengthened biopsychological aspects in the multidisciplinary rehabilitation.

Furthermore, patients in stages of pain I and II improved in depressive symptoms, anxiety, mental health, and average pain intensity in the medium- and long-term, with small to medium effect sizes. It can be assumed that patients in stage of pain I benefit from participation in pain management training alone and are oversupplied by the additional depression prevention training, even though no negative effects were observed in the present results. According to higher psychological impairments among patients in stage of pain II, treatment with the combined pain management and depression prevention training seemed appropriate for this subgroup. However, the present effects contradict earlier results, which did not demonstrate a significant long-term influence of the stages of pain on depressive symptoms, mental health, or average pain intensity [20]. Thus, it can be assumed that our modified depression prevention training is better adapted to the psychological and pain-related needs among patients with CLBP in stage of pain II. In contrast to the previous training, for example, the ABC scheme to reconstruct dysfunctional cognitions as well as more psychological elements to develop problem and emotion-focused coping strategies and to improve social support were included [18]. Moreover, recent studies demonstrated only a reduction in anxiety for patients in stage of pain I 24 months after treatment [20]. This finding supports our assumption that the modified group training with modern didactics and methods (e.g., mindfulness-based interventions) should be addressed in patients in stage of pain II. However, patients in stage of pain I would not be over-treated by participation in Debora.

Mixed results have been provided regarding the link between the stage of pain and the average pain intensity. In contrast to our non-significant results, Pflingsten et al. [24] found an improved pain intensity 6 months after rehabilitation. However, in agreement with the present findings, patients in a lower stage of pain had a greater long-term therapeutic success in average pain intensity [25]. Finally, similar results for depressive symptoms were found; patients in stage of pain I benefited most from reduced depressive symptoms [26]. Thus,

the findings of Gerrits et al. [35] can support that pain is a risk indicator for the development of depressive symptoms and anxiety. The present results add more evidence to the research on the relationship between chronic pain and mental disorders [35].

The rehabilitation success of patients in stage of pain III was lower than in the upper stages of pain and was not sustainable; this subgroup showed significant improvements in depressive symptoms, anxiety, mental health and average pain intensity at the 6-month follow-up, favourable effects could only be maintained in anxiety at the 12-month follow-up. These findings are in line with the unfavourable prognosis of Gerbershagen [23] regarding stage-specific treatment outcomes. Additionally, these recurrent effects lend support to the assumption that the multidisciplinary rehabilitation was likely to be insufficient to meet the need for psychological treatment in this subgroup. Therefore, treatment in psychosomatic rehabilitation is necessary.

#### 4.2. Limitations

The strengths of the present multicentre study, apart from the study design with cluster block randomisation and the sample size of 526 patients with CLBP, are above all the additional consideration of the stage of pain in the longitudinal section. Nevertheless, the study also has limitations, which are listed below.

First, the present study showed a high dropout rate until the 12-month follow-up assessment. However, dropout analyses revealed an equal distribution of patients who dropped out across the treatment condition. Thus, systematic effects can be excluded. Additionally, no significant differences between patients who dropped out and participants who stayed in the study depending on the treatment condition were detected. This means that participants in the intervention group did not drop out significantly more often than participants in the control group. Nevertheless, patients who dropped out and participants who stayed in the study significantly differed in terms of age, pain duration, gender, family status and net household income. However, analyses after MI confirmed almost all significant results of the PP analyses. Therefore, neither systematic effects nor an overestimation of the long-term effects from the PP analyses were supported. Due to the high dropout rate, it can be suspected that Little's MCAR-test for MI [34] became significant ( $2(5302) = 5626.40, p < 0.001$ ). For this reason, MI analyses should only validate the results from the PP analyses.

Second, the majority of patients in the present sample indicated a higher level of education. The results are

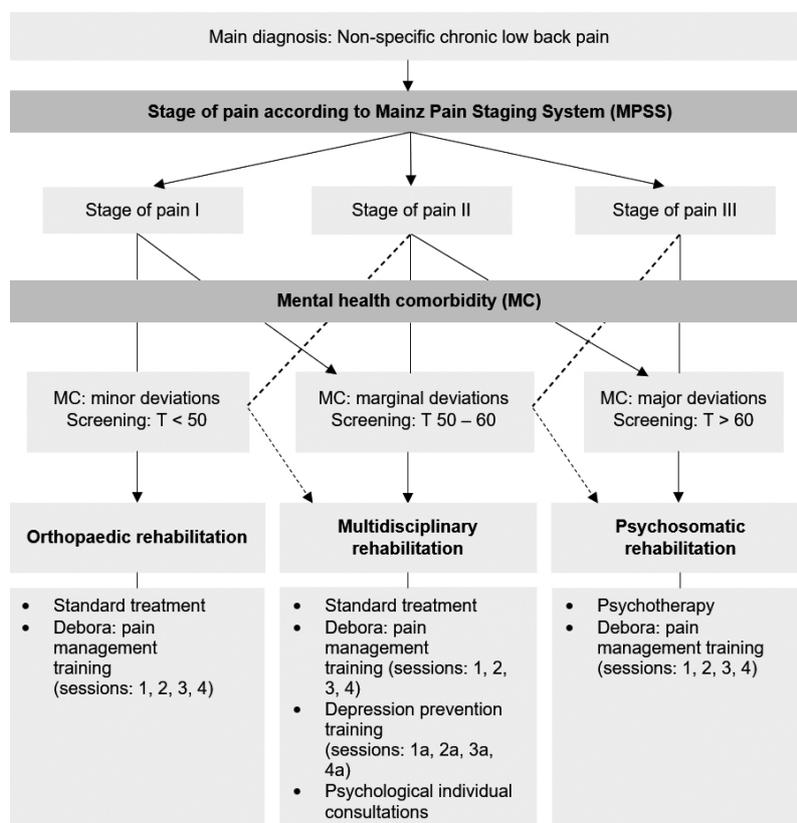


Fig. 2. Stepped care model.

limited to patients with similar sample characteristics. However, former studies ascertained unfavourable effects of cognitive-behavioural pain management trainings for patients with CLBP and a lower educational level (cf. [17,36]).

#### 4.3. Clinical implications

Overall, the current results confirm that pain management trainings with cognitive-behavioural elements such as Debora and previous programmes [11,12] are effective in the long-term. Moreover, a high stage of pain had a negative influence on the long-term success of rehabilitation. Therefore, early identification of psychosocial risk factors (yellow flags) and of the stage of pain among patients with CLBP are important (cf. [37]).

Based on the current results, a stepped care model for patients with CLBP was developed to adequately supply each subgroup [21,26,38] (Fig. 2). According to this allocation model, i) orthopaedic rehabilitation is recommended if patients with CLBP are in stage of pain I and a screening of mental comorbidities shows sub-clinical scores ( $T < 50$ ). Within the framework of stan-

dard orthopaedic treatment for CLBP, predominantly back pain-related functional impairments can be treated. Simultaneously, psychoeducational pain management training are recommended.

In contrast, ii) multidisciplinary rehabilitation should be chosen if patients are in stage of pain I or II and borderline mental health is diagnosed ( $T 50-60$ ). In this subgroup, additional psychological treatment elements in multidisciplinary rehabilitation could address the moderate psychosocial impairments of patients with CLBP and may prevent further persistence. A multidisciplinary rehabilitation is also recommended for patients who do not yet have a mental comorbidity ( $T < 50$ ) but are already in stage of pain II. Due to a higher psychological and pain-related burden, a higher risk of chronicity in this subgroup is assumed.

Finally, iii) psychosomatic rehabilitation is recommended for patients with CLBP in stage of pain II and III and mental comorbidities (screening result:  $T > 60$ ). In both cases, mental comorbidities (e.g., depressive symptoms, anxiety) can be adequately supplied within the framework of psychosomatic treatments. However, to ensure that CLBP is also treated, pain management

treatments must also be integrated in psychosomatic rehabilitation. In line with secondary or selective prevention, patients who have only a borderline score of mental comorbidities ( $T = 50\text{--}60$ ) but are already in stage of pain III should also participate in psychosomatic rehabilitation. By psychotherapeutic treatment, moderate psychosocial impairments can be appropriately addressed, and further exacerbation of a mental disorder prevented. In addition, pain management training is necessary to treat CLBP.

## 5. Conclusions

In summary, the present results show that patients in stage of pain I and II benefited from rehabilitation at the 6- and 12-month follow-up assessments in depressive symptoms, anxiety, mental health, and the average pain intensity, both statistically and clinically. Patients in stage of pain III showed lower beneficial effects in the mid-term and were able to maintain significant improvements only in anxiety 12 months after rehabilitation. Accordingly, the presented stepped care model for CLBP is necessary to prevent the development of mental disorders and the persistence of CLBP in stage of pain I and II. Simultaneously, there is a high need for more psychological treatments among patients in stage of pain III. Thus, the present study further elucidated the important role of the stages of pain and co-existing psychological symptoms for the treatment of patients with CLBP and contributes to the improvement of subgroup-specific treatment success and the prevention of further chronification of pain.

## Conflict of interest

None declared.

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