Aus der
Klinik und Poliklinik für Physikalische Medizin und Rehabilitation
der Ludwig-Maximilians-Universität München
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Wirkmechanismen in der Behandlung und Prävention chronischer Rückenschmerzen

Dissertation
zum Erwerb des Doktorgrades der Humanbiologie
an der Medizinischen Fakultät
der Ludwig-Maximilians-Universität zu München

vorgelegt von
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aus Aachen
2006

Mit Genehmigung
der medizinischen Fakultät der Universität München

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Tag der mündlichen Prüfung:	13. November 2006

Meinen Eltern

Dank

Mein besonderer Dank gilt vor allem meinem Doktorvater Prof. Dr. Gerold Stucki für die Beratung, kritische Begleitung und immer wieder anregenden Diskussionen bei der Entstehung dieser Arbeit.

Ebenso möchte ich meinen Projektleitern Thomas Ewert und Dr. Heribert Limm für ihre Unterstützung, wertvollen Kommentare und stets konstruktive Kritik meiner Dissertation sehr danken.

Ein herzlicher Dank gilt auch meinen Kolleginnen und Kollegen aus dem Projektteam, die durch ihren Einsatz im Rahmen des Projektes die Erstellung dieser Doktorarbeit mit ermöglicht haben.

Danken möchte ich natürlich auch allen Studienteilnehmern, die durch ihre Teilnahme an einem Präventionsprogramm Daten für diese Doktorarbeit geliefert haben.

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Lebenslauf

Vorwort

Beide Teile dieser Arbeit sind Artikel, die in der hier vorliegenden Form zur Publikation eingereicht worden sind.

Teil 1 der Arbeit ist ein systematischer Literatur- Review, der im European Spine Journal, Online First: 31.03.2006, DOI 10.1007/s00586-006-0073-4 veröffentlicht wurde.

Teil 2 der Arbeit ist zur Veröffentlichung in einem internationalen Journal eingereicht. Jeder Teil ist in sich abgeschlossen, sodass er auch unabhängig vom anderen gelesen werden kann. Da sich beide Artikel mit Wirkmechanismen in der Behandlung und Prävention chronischer Rückenschmerzen beschäftigen, waren jedoch gewisse thematische Überschneidungen in den Einleitungen unumgänglich.

Die Genehmigung einer vorzeitigen Veröffentlichung der Artikel wurde im Dekanat beantragt und mit dem Schreiben vom 23.05.2005 durch den Vorsitzenden des Promotionsausschusses im Dekanat der Medizinischen Fakultät erteilt.

Kurzfassung

Ziel Rückenschmerzen verursachen hohe sozioökonomische Kosten. Dabei kommt der Gruppe mit chronischen Rückenschmerzen eine besondere Bedeutung zu, da 80% der Behandlungskosten durch diese Patienten verursacht werden. Dies macht Rückenschmerzen neben Erkältungskrankheiten zum teuersten medizinischen Problem, zur teuersten muskuloskeletalen Erkrankung und zur häufigsten Ursache von Arbeitsunfähigkeit unter 45 Jahren. Die Verhinderung der Chronifizierung ist deshalb aus sozioökonomischen, aber auch ethischen Gründen („burden of disease“), ein überaus wichtiges Ziel.

Die vorliegende Arbeit beschäftigt sich deshalb mit Wirkmechanismen in der Behandlung von Rückenschmerzen, d.h. mit der Vorhersage des Behandlungserfolgs durch innerhalb eines Behandlungsprogramms erreichte Veränderungen.

Zur Behandlung und Sekundärprävention von Rückenschmerzen existieren eine Reihe von Interventionen, deren Effektivität belegt ist. Weitgehend unklar sind jedoch die zugrunde liegenden Wirkmechanismen. Ein besseres Verständnis der Wirkmechanismen würde es ermöglichen, Interventionen effizienter und damit auch kostengünstiger zu gestalten. Teil 1 der Arbeit ist ein systematischer Review, welcher Wirkmechanismen nicht-operativer Behandlungen chronischer Rückenschmerzen analysiert. Teil 2 der Arbeit untersucht relevante Wirkmechanismen in einem trainingstherapeutischen und einem multimodalen Programm zur Sekundärprävention von Rückenschmerzen.

Methoden Teil 1: Basierend auf einer systematischen Literatursuche in den Datenbanken Medline, Embase und PsycInfo wurde ein Review erstellt. Es wurden Studien ausgewählt, die u.a. die folgenden Einschlusskriterien erfüllen: (1) Behandlung chronischer Rückschmerzen mit Trainingstherapie, Verhaltenstherapie oder multimodalen Behandlungsansätzen, (2) Analyse von Veränderungen in Prädiktorvariablen und Anteil der aufgeklärten Varianz am Ergebnis mit multivariaten Verfahren, z.B. Regressionsanalysen. Aufgrund der Heterogenität der Daten hinsichtlich erhobener Variablen und eingesetzter statistischer Methoden wurden die Daten deskriptiv ausgewertet und zusammengefasst.

Teil 2: Zur Identifizierung relevanter Wirkmechanismen in der Sekundärprävention von Rückenschmerzen wurden Daten einer randomisierten klinischen Studie zur Überprüfung der Effektivität eines Trainings- und eines multimodalen Programms mit multiplen Regressionsanalysen ausgewertet. Es sollten Prädiktorvariablen identifiziert werden, die das Erfolgskriterium „Reduzierung von Beeinträchtigung“ nach Beendigung des Präventionsprogramms am besten vorhersagen. Als potentielle Prädiktorvariablen wurden Veränderungen in psychologischen Variablen und körperlichen Leistungstests berücksichtigt, sowie Interaktionen zwischen dem jeweiligen Programm und den Prädiktorvariablen, um zu überprüfen, ob sich die Wirkmechanismen in beiden Programmen unterscheiden.

Ergebnisse Teil 1: Es konnten 13 Studien in den Review eingeschlossen werden. Der Anteil der erklärten Varianz lag zwischen 5% und 71%. In den ausgewerteten Studien zeichnete sich - unabhängig von der Intervention - folgende Tendenz ab: Schmerzreduktion konnte am besten mit einer Abnahme von Beeinträchtigung und zu einem geringeren Teil mit der Verbesserung physischer Leistungsparameter erklärt werden. Abnahme von Beeinträchtigung wiederum wurde am besten sowohl mit Schmerzreduktion, als auch mit einer Zunahme aktiver Copingmechanismen und einer Reduzierung von Fear-avoidance Überzeugungen erklärt. Eine Rückkehr an den Arbeitplatz konnte vor allem durch eine Reduzierung der Beeinträchtigung und zu einem etwas geringeren Teil durch eine Zunahme aktiver Copingmechanismen sowie einer Reduzierung von Fear-avoidance Überzeugungen vorhergesagt werden.

Teil 2: In beiden Programmen zur Sekundärprävention von Rückenschmerzen konnte Reduzierung von Beeinträchtigung am besten mit Reduzierung von Schmerzintensität und Katastrophisieren erklärt werden. Die Zunahme von Kraft und Ausdauer hatte keinen statistisch signifikanten Einfluss auf den Behandlungserfolg. Insgesamt konnte durch das finale Modell 68.7% der Varianz erklärt werden. Es wurden keine signifikanten Interaktionen zwischen Programm und Prozessvariablen gefunden.

Diskussion und Schlussfolgerungen Die Ergebnisse der vorliegenden Arbeit zeigen, dass zur Vorhersage des Behandlungserfolgs bei chronischen Rückenschmerzen, sowie in der Sekundärprävention Veränderungen psychologischer, sowie schmerz- und funktionsbezogener Variablen eine größere Relevanz besitzen, als Verbesserungen körperlicher Leistungsparameter. Diese Ergebnisse stimmen mit den Aussagen bisher publizierter Reviews und anderer Studien überein: Dass nämlich psychologische Faktoren - insbesondere Tendenzen zum Katastrophisieren und fear-avoidance Überzeugungen - sowie Schmerzparameter Chronifizierung und Beeinträchtigung wesentlich besser vorhersagen, als körperliche Parameter. Von besonderer Bedeutung bei den vorliegenden Ergebnissen ist zudem, dass der Behandlungserfolg trainingstherapeutischer und multimodaler Verfahren vorrangig durch psychologische Wirkmechanismen, nämlich Veränderungen psychologischer Faktoren wie dysfunktionalen Überzeugungen, vermittelt wird. Dies ist umso interessanter, als trainingstherapeutische Programme keine direkten psychologischen oder kognitiv-behavioralen Interventionen beinhalten. Der Wert trainingstherapeutischer Interventionen scheint deshalb darin zu liegen, die Erfahrung zu vermitteln, dass Bewegung nicht schädlich ist, und hierdurch dysfunktionale Einstellungen und Bewältigungsstrategien zu verändern. Ob zur Erreichung dieses Ziels die Durchführung aufwändiger Trainingskonzepte an speziellen Geräten notwendig ist, gilt es zu überdenken. In Bezug auf multimodale Programme könnten die Ergebnisse bedeuten, den Schwerpunkt auf verhaltens- und erfahrungsorientierte - im Gegensatz zu edukativen und kognitiven Inhalten - zu legen.

Summary

Objectives To identify relevant change mechanisms, meaning changes in process variables through treatment predicting outcome in the treatment and prevention of chronic low back pain. There are effective interventions for the treatment and secondary prevention of chronic low back pain. However there is a lack of knowledge concerning the interrelationship between changes in treatment process variables and changes in outcome. It would be essential to know which components are clearly associated with a positive outcome. Knowing which variables influence treatment outcome would help refining treatments, so that they become more effective and economic. Part 1 is a systematic review that evaluates, which changes in treatment process variables predict outcome of exercise, behavioural and multimodal treatment of chronic low back pain. Part 2 analyses relevant treatment processes in an exercise versus a multidisciplinary secondary prevention program for low back pain, in order to identify prognostic factors for a successful intervention.

Methods Part 1: The databases Medline, Embase and PsychInfo were searched. Prospective studies analysing changes in treatment process variables through exercise, behavioural or multimodal treatment and their relation to treatment outcome using multivariate analysis were included. Because of heterogeneity of the included studies, a descriptive analysis was used to summarize the results.

Part 2: To identify relevant treatment processes in the secondary prevention of chronic low back pain, a randomised controlled trial for the effectiveness of an exercise versus a multidisciplinary prevention program was analysed using multiple regression analyses. The aim was to examine, how much variance in reductions of interference post intervention could be explained by pre- to post changes in physical and psychological parameters and to determine if there are different interactions between physical/psychological parameters and the program.

Results Part 1: 13 studies were identified. The proportion of explained variance in the included studies varied between 5% and 71%. The results consistently showed a tendency, that reduction in pain and disability and a transition towards more active coping mechanisms are more important when explaining successful treatment than changes in physical performance. Also changes in physical performance were only slightly associated with pain reduction, but not with changes in disability or return to work.

Part 2: Reductions of interference could be explained best by reductions of pain intensity and catastrophizing in the multidisciplinary and the exercise prevention program. The final model could explain 68.7% of variance. Program got a significant beta weight and could explain a small portion of variance in reductions of interference, meaning that the programs had slightly different influences on reductions of interference, in favour for the multidisciplinary program. Significant interactions between changes in process variables and program were not found, indicating that the same change mechanism in the multidisciplinary and the exercise program was relevant for changes in outcome.

Conclusions The results of this work raise the question, if changes in behavioural variables and reductions of disability facilitating an improvement in function are more important than physical performance factors for successful treatment and secondary prevention of chronic low back pain. The results are in accordance with results of other reviews and conducted studies. These concluded that disability in chronic low back pain is maintained primarily by factors other than objective medical data. Changes in physical performance factors do not seem to be good predictors for treatment efficacy. One main finding of this work is that treatment success in exercise and multimodal interventions is based on the same change mechanism. Namely changes in psychological factors, in terms of decreases in dysfunctional beliefs as catastrophizing. This is very interesting, because exercise programs do not involve any psychological intervention. Yet psychological variables show significant changes. The results suggest that the change mechanism, through which exercises are useful in the treatment of low back pain, might not be an betterment in physical variables, but a change in psychological attributes, insofar as people correct their irrational cognitions and appraisals by making experiences that differ from their expectations. These findings may have some implications for treatment refinement. In case of exercise, treatment refinement could mean putting more emphasis on positive experiences with physical activity than on an increase of muscle strength through repetitive exercise or flexibility through stretching. For multidisciplinary programs the findings question the supplemental value of cognitive components and suggest putting more emphasis on behavioural components.

Teil 1

What predicts outcome in non-operative treatments of chronic low back pain? A systematic review

ABSTRACT

Systematic reviews have shown that as non-operative treatments exercise, behavioural and multimodal treatment programs are effective for chronic low back pain. There is, however, a lack of knowledge concerning the association between changes in treatment process variables and changes in outcome for the three treatment forms. The objective of this systematic review was to evaluate which changes in treatment process variables predict outcome of exercise, behavioural and multimodal treatment of chronic low back pain. Medline, Embase and PsychInfo were systematically searched. A descriptive analysis was used to summarize the results regarding the outcomes pain, disability and return to work (RTW).

13 studies were identified. The results showed that functional coping mechanisms and pain reduction were associated with a decrease in disability and increase in RTW, and physical performance factors were not. Related to pain reduction decreases in disability, functional coping mechanisms as well as physical performance factors were associated. Strong conclusions cannot be drawn from this review, because of the heterogeneity and the limited number of studies. The results of this review raise the question if changes in behavioural variables and reductions of disability which facilitate an improvement in function, may be more important than physical performance factors for successful treatment of chronic low back pain. This is relevant for the refinement of future treatment programs.

1 INTRODUCTION

Many non-operative treatments are available for low back pain. Systematic reviews have shown that exercises [46], and behavioural and multimodal treatment programs [10, 45, 47] are effective for chronic low back pain. Core outcome measures include pain, disability, and return to work (51).

Exercises focus on an improvement of physical capacity. Studies have shown an association between sub-optimal back muscle function and chronic low back pain [5, 22, 32]. Therefore exercises mainly try to reverse muscle deficits and imbalances [30], supposing that physical factors such as increased muscle strength are important for reducing disability and pain [28, 29]. Behavioural treatment emphasizes the modification of behavioural processes assuming that pain and disability are not only influenced by somatic factors, but also by psychological and social factors [34, 47].

Multimodal treatment programs are based on the bio-psycho-social model of pain, which suggest that physical, psychological and social factors may play a role in decreasing pain and disability and increasing return to work [10].

Nevertheless, there is still a lack of knowledge concerning the association between changes in treatment process variables, defined as variables that are targeted by the intervention and are expected to predict or cause changes in the outcome variable, and actual changes in outcome. For example, it is unclear whether or not improvement in muscle function is associated with a decrease in disability due to exercises. The positive outcome of exercises could also be affected by other factors, such as psychological processes that accompany physical activation [30]. In behavioural treatment it might be more important to reduce pain-related distress, and enhance active coping, than to reduce distress due to other problems [34]. Also for multimodal treatment, which requires substantial staff and financial resources

[18], it would be helpful to know which components are clearly associated with a positive outcome. Knowing which variables influence treatment outcome would help refining treatments so that they become even more effective.

At present, no systematic review has been conducted that summarizes current findings of relevant treatment process variables in non-operative treatment of chronic low back pain. Therefore, the objective of this article is to review the evidence concerning relevant changes in treatment process variables in exercise, behavioural and multimodal therapy for chronic low back pain.

2 MATERIALS AND METHODS

2.1 Search strategy and study selection

Medline (1966- October 2004), PsycInfo (1872- October 2004) and Embase (1989 – October 2004) were searched for relevant articles using the following key words (Mesh and text words): back pain, backache, lumbago, multimodal, multidisciplinary, interdisciplinary, cognitive, behaviour, cognitive-behaviour, rehabilitation, functional restoration, exercise, active therapy, prognosis, predict, influence, process, treatment process, discriminate, relate, determine, risk factor, cause, change, reduction, decrease, increase, improve. Abstracts of all identified citations were retrieved and examined. The first author was responsible for the entire selection. A second reviewer checked the selection procedure by screening a random sample (n=250) of all articles.

Studies were included if they met the following criteria:

1) Subjects were older than 18 years.
2) Subjects had chronic low back pain, defined as low back pain lasting for at least 3 months.
3) The study design was prospective.

4) Subjects were given either exercise, behavioural or multimodal treatment.
5) The study analysed changes in treatment process variables and their relationship to treatment outcome variables. A treatment process variable is defined as a variable that is targeted by the intervention and is expected to predict or cause changes in the outcome variable.
6) The study had to be published in English or German.

References of all articles and one recently published review [34] were perused to identify additional relevant citations, but no additional study was found.

2.2 Methodological quality assessment

Two reviewers (TW and TS) independently assessed the methodological quality of the included studies using a modified version of a criteria set (Table 1) that was adapted from criteria lists used in other systematic reviews of observational studies [2, 3, 13].

Table 1: List of methodological criteria

		Criteria Definition	Score
Study population	A	Positive if inclusion and exclusion criteria are described	+ / – / ?
	B	Positive if the main features (description of sampling frame, distribution by age and sex) of the study population are stated	+ / – / ?
Intervention	C	Positive if intervention is described in detail according to duration, frequency and content	+ / – / ?
Follow up	D	Positive if the follow up is >= 12 months	+ / – / ?
	E	Positive if the drop out/ loss to follow up is <20% (or positive if the drop out until the end of treatment is < 20%)	+ / – / ?
Measurement of independent variables and outcome measurement	F	Positive if independent variables are measured using standardized measurements of acceptable quality	+ / – / ?
	G	Positive if data on outcome are collected using standardized measurements of acceptable quality	+ / – / ?
Analysis and data presentation	H	Positive if mean changes in independent variables and outcome through treatment are indicated	+ / – / ?
	I	Positive if the statistical model used was appropriate for the outcome studied and the measures of association estimated with this model are presented (including confidence intervals)	+ / – / ?
	J	Positive if the data analysis included a stratified or multivariate analysis	+ / – / ?
	K	Positive if the number of cases in the final multivariate model was at least 10 times the number of independent variables in the analysis	+ / – / ?
	L	Positive if the study controls for confounding	+ / – / ?
	M	Positive if it is described for all measured independent variables why they were entered in the model or why not	+ / – / ?
	N	Positive if it is clearly indicated how the change variable was built	+ / – / ?
	O	Positive if for every single variable remaining in the model statistical measures are indicated (either OR, Wilks Lambda, R^2 or ß) or if it is indicated that the variable was not significant or explained no significant amount of variance	+ / – / ?

The criteria referred to aspects of the study population, the intervention, study design, measurements, data analysis and presentation. The reviewers rated each criterion as positive (+), negative (-) or unknown (?) based on the information provided in the article. Disagreements between the reviewers were discussed in a consensus meeting. If disagreement persisted, a third reviewer (TE) was asked to make a final judgement.

2.3 Data extraction and analysis

Two independent reviewers (TW and TS) extracted data from the studies using a pre-defined data extraction sheet. A descriptive analysis was used to summarize the results of the studies regarding the most relevant outcomes (pain reduction, reduction of disability and return to work) [51]. If studies reported more than one statistical model for the same outcome, we referred to the model that explained the largest variance.

3 RESULTS

3.1 Selected studies

The literature search resulted in 1048 references. Only sixteen studies met the inclusion criteria. Some papers [12, 37, 38 and 30, 31] were based on findings from the same sample. These publications were considered as one study and consequently, a total of 13 studies were included in this review (see table 2).

Only two studies analysed changes in treatment process variables in exercises [23, 30]. One of these included three types of active therapy: active physiotherapy, muscle reconditioning and aerobic exercise [30]. In the other study, exercises consisted of a combination of aqua-fit classes and muscle-strengthening workouts [23].

Only two studies were identified on behavioural treatment [41, 44]. Duration of treatment was similar in both studies (10 weeks), but content and form (group versus individual) differed.

Nine studies were identified on multimodal treatment programs [1, 7, 8, 12, 21, 33, 35, 42, 57]. Most of the programs consisted of exercise and psychological-behavioural interventions, and some also included vocational counselling [7, 35]. Duration and intensity of treatments varied from daily to three times a week for a time period of 3 to 8 weeks.

Table 2: Description of included studies

	Study population	Intervention	Outcome	Change factor/explained variance
Exercise				
Le Fort 1994 [23] Case-series	Patients referring to a local rehabilitation program in a fitness location; mean duration of LBP: 87% > 3 months; all off work; N = 40	Aquafit classes and muscle strengthening workouts on training equipment for primary muscle groups; 2 aquafit and 3 muscle strengthening classes a week over at least 8 weeks	Return to work (yes/no)	First or repeated back injury OR = 2.5 Change in self-esteem OR = 0.80
Mannion 2001 [31] RCT	Patients were recruited by advertisement in the local media; outpatient; mean duration of LBP: 10.2 yrs.; N = 137	(I) active physiotherapy focusing on improving functional capacity and instructing them ergonomic principles; ½ hours individual (II): muscle reconditioning; 1 hour group sessions a 2-3 patients (III): aerobic and stretching classes, 1 hour sessions in small groups; 2 times a week for 3 months significant reductions in outcome for all groups with no group differences	Disability (post)	Change in pain 16% change in psychological distress 4.1% change in fear-avoidance beliefs 3.7% change in performance factors 0 sum: 23.8%
Behavioural				
Spinhoven 1991 [41] Controlled clinical trial	Patients were referred by local medical specialists or answered to an advertisement about the treatment; outpatient; mean duration of LBP: 12.7 yrs.; N = 42	Education, relaxation training, pain coping and enhancement of therapy maintenance; 10 weekly sessions a 2 hours	Pain (post) Uptime (post) Depression (post) Psychopathology (post) Medication (post) Pain (6 mo.)	Change in coping strategies 0 Change in active coping 13%, change in helplessness 0 change in perceived control 0 Change in helplessness 24%, change in active coping 0, perceived control 0 Change in helplessness 22%, change in active coping 0, change in perceived control 0 Not related to change in coping strategies Change in perceived control 14%, change in active coping 0, change in helplessness 0

	Study population	Intervention	Outcome	Change factor/explained variance
Behavioural				
Sullivan 2003 [44] Case-series	Claimants of a workers compensation board who were off work for at least 6 weeks due to LBP and showed at least one yellow flag were offered participation in the outpatient PDP program; mean time off work: 18.3 weeks; N = 80	goals: maintaining an activity log, activity scheduling, walking, increasing activity involvement, overcoming fear of injury; individual sessions conducted by a psychologist; 10 weekly sessions	Return to work (yes/no)	Change in Fear of movement Wilks Lambda=0.92 change in catastrophizing Wilks Lambda = 0.79 Change in depression 0 82% correct classification
Multimodal				
Altmaier 1993 [1] RCT	Patients of an inpatient rehabilitation program in a university hospital; off work due to LBP at least 3 months; mean duration of LBP not mentioned; 50% blue collar workers; N = 45 (post) and N = 42 (follow up)	(I) Physical therapy twice a day, aerobic and education (II) as (I) plus daily charting of exercises, relaxation training, biofeedback, instructions in cognitive-behavioural coping skills ; daily treatment for 3 weeks no differences in pain effectiveness between treatment conditions	Pain rating index (post) Pain intensity (post) Physical fitness (post)	Change in self-efficacy explained no variance in physical fitness and pain intensity at post measurement
			Pain rating index(6 mo.)	Change in specific self efficacy 5%
			Pain intensity (6 mo.)	Change in specific self efficacy 16.5%
			Physical fitness (6 mo.)	Change in specific self efficacy 10.9%
Dozois 1995 [7] Case-series	Patients in a Rehabilitation center; mean duration of LBP: 7.9 yrs.; N = 117	Psychological intervention, education, work and exercise conditioning, physical therapy, daily treatment a ? hours, in average over 11 weeks	Return to work	Change in Disability Wilks Lambda 0.86 ** Change in Depression 0 Change in distress 0 Change in functional capacity (lifting test) 0.86 ** Change in perceived employability and disability 0.89* Change in cognitive coping and suppression 0 Change in helplessness 0
Fisher 1998 [8] Case-series	Patients who were referred to a rehabilitation program by the psychology department of a orthopaedic hospital; mean duration of LBP: 7.3 yrs.; 87% LBP as main site of pain, 13% LBP as secondary complaint; N = 54	Graded activity program, learning self-management of pain and mood through relaxation and cognitive control techniques; daily over 3 weeks	Change in Disability	Change in emotional distress 20% Change in control cognitions 0 Change in pain 0 Sum: 20%; authors indicated: 28%

	Study population	Intervention	Outcome	Change factor/explained variance
Koopman 2004 [21] Case-series	Patients having undergone previous treatments with unsatisfactory results were referred to an outpatient training program by an insurance company; mean duration of LBP: 76.5 months; mean absence from work: 12.2 months; N = 42	Physical reconditioning based on graded activity, cognitive-behavioural group counselling and relaxation training; 3 sessions/ week a 6 hours over 12 weeks	Return to work (yes/no)	Increase in trunk flexibility OR = 1.17 (no other variable was included in analyses) Model correctly classified 69%
McCracken 2002 [33] Case-series	Patients with chronic LBP, lasting for more than 3 months; mean: 21.5 months; 51.7% had pain-related surgery; 96.6.% off work ; N = 59	Functional restoration program: exercises and behaviour therapy ; daily over 3 weeks	Pain (post)	Pain (pre) 14%; Change in physical capacity 28%, change in pain related anxiety 11%; sum: 48%
			Interference (post)	Interference (pre) 34%, change in physical capacity 0, change in pain related anxiety 8%; sum: 37%
			Affective distress (post)	Affective distress (pre) 6%, change in physical capacity 14%, change in pain-related anxiety 14%; sum: 27%
			Depression (post)	Depression (pre) 39%, change in physical capacity 0, change in pain related anxiety 15%, sum: 57%
Mellin 1993 [35] Case-series	Patients who were recommended to an inpatient treatment program by physicians; mean duration of LBP: not mentioned; mean time off work due to LBP during the preceding year: 151.3 days; off work at admission: 52%; N = 194	pre-program: explanation of program; hometraining: stretching, light physical exercises; program: physical exercises, cognitive-behavioural group therapy, back school education, relaxation training; socio-economic and vocational counselling; at least 5 hours a day for 4 weeks plus 3 days pre-program and 5 weeks home training = 9 weeks in total	Return to work	Change in spinal mobility, OR = 1.06 Change in trunk flexion n.s. Change in trunk extension n.s. Change in lifting strength n.s.
			Functional capacity in women	Change in spinal mobility ß = 0.29, level at discharge ß = 0.34 Change in trunk flexion n.s. Change in trunk extension n.s. Change in lifting strength n.s.

	Study population	Intervention	Outcome	Change factor/explained variance
Pfingsten 1997 [37, 38] **Hildebrandt 1997** [12] Case-series	Patients taking part in an outpatient rehabilitation program; man duration of LBP: 150.3 months; 81.1% off work, 19% had put off work due to low back pain at least 3 months prior to treatment; 50% blue-collar worker; N = 90	pre-program: education and stretching; program: aerobic, strength and endurance training, back school education, cognitive-behavioural group therapy and relaxation training; daily 7 hours a day (incl. 2 hours psychological intervention) over 8 weeks	Return to work (yes/no) Reduction of pain (yes/no) Satisfaction with treatment	Change in Disability r = 0.64, Change in Depression r = 0.42, Change in Physical variables 0, correct classification: 85.4% Change in disability (VAS score) r = 0.72, change in disability (FFbH) r = 0.68, change in trunk flexion r = 0.30, change in leg press performance (repetitions) r = 0.35 correct classification: 89.9% Change in disability (PDI) r = 0.64, Change in disability (VAS) r = 0.98, correct classification: 89.1% r = correlation with discriminative function
Strategier 1997 [42] RCT	Patients of an inpatient rehabilitation program in a university hospital; off work due to LBP at least 3 months; mean duration of LBP not mentioned; 50% blue collar workers; N = 40	(I) Physical therapy twice a day, aerobic and education (II) as (I) plus daily charting of exercises, relaxation training, biofeedback, instructions in cognitive-behavioural coping skills ; daily treatment for 3 weeks no differences in pain effectiveness between treatment conditions	Improvement in Physical fitness and pain (LBPRS, range of motion, patients and physicians perception)	Patient group by MPI 17.7% Change in Pain severity and interference 33.8% Change in psychosocial variables (life control, affective distress, support) 16.7% Sum: n.i.
Woby 2004 [57] Case-series	Patients being referred to a rehabilitation program, with at least 3 months LBP; mean duration of LBP: 6.3 yrs., N = 54	Stretching and strengthening exercises + behavioural education, outpatient; 5 sessions a 3.5 hours over 8 weeks	Change in Pain Change in disability	Demographics (age + sex) n.s. Change in Cognitive factors 14% n.s. = change in catastrophizing, fear avoidance beliefs, control over pain, ability to decrease pain Demographics (age and sex) n.s. Change in Pain intensity 43%*** Change in cognitive factors 22%*** Sum: 71%

N = N included in analysis; n.i. = not indicated; n.s. = not statistically significant; 0 = measured, but did not remain in final model

3.2 Description of methodological quality

Table 3 shows the results of the methodological quality assessment. Potential methodological flaws were identified that may have biased results in some studies. For example, inadequate description of intervention, follow up less than 12 months, drop out rate more than 20%, inappropriate model used, and not presenting statistical values for all potential variables.

Table 3: Results of methodological quality assessment

Methodological criteria	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**	**K**	**L**	**M**	**N**	**O**
Altmaier 1993 [1]	+	+	-	-	+	-	+	+	+	-	+	+	+	+	+
Dozois 1995 [7]	-	+	-	-	-	+	+	+	-	+	-	-	+	+	+
Fisher 1998 [8]	-	+	-	-	-	+	+	+	+	+	+	-	+	+	-
Koopman 2004 [21]	+	+	+	+	-	-	+	+	+	+	+	-	+	+	-
Le Fort 1994 [23]	+	+	+	-	-	-	+	+	+	+	+	-	+	+	-
Mannion 2001 [31]	+	+	+	-	+	-	+	-	-	+	+	+	+	-	-
McCracken 2002 [33]	+	+	+	-	?	-	+	+	+	+	?	+	+	+	+
Mellin 1993 [35]	-	+	+	+	-	+	+	+	+	+	?	+	-	+	-
Pfingsten 1997 [12,37,38]	+	+	+	+	+	+	+	+	+	+	+	-	-	+	+
Spinhoven 1991 [41]	+	+	+	-	-	+	-	+	-	+	?	+	+	+	-
Strategier 1997 [42]	+	+	-	-	+	+	+	+	+	+	-	+	+	-	+
Sullivan 2003 [44]	-	+	-	-	-	+	+	+	+	+	+	-	-	+	+
Woby 2004 [57]	+	+	+	-	-	+	+	+	+	+	-	+	+	+	+

3.3 Outcome

The included studies used different outcome measures. Main outcome variables were pain [1, 12, 33, 37, 38, 41, 57], return to work [7, 12, 21, 23, 35, 37, 38, 44] and disability / functioning [8, 30, 31, 33, 57]. Because there was only one study that reported a model predicting physical improvement / physical fitness, the results of this study are not presented.

3.4 Treatment process variables

The main treatment process variables included in the reported models were classified in five categories (see Table 4): 1) pain, 2) disability/functioning, 3) cognitive coping and appraisal, 4) mood / affect, and 5) physical performance factors [36].

Table 4: Definition of categories of independent variables and examples of measurement [34]

Category	**Measurement examples**
Pain: Measures of subjective pain experience including ratings of intensity, sensation and unpleasantness	e.g. Multidisciplinary pain inventory (MPI), McGill Pain questionnaire; VAS; Numerical rating scale (NRS-101);
Disability / functioning: all assessments measuring limitations in daily living and work due to low back pain	e.g. Oswestry Index, Pain disability index (PDI), Roland Morris Questionnaire, lifting tests, push/pull capacity
Cognitive coping and appraisal: cognitive strategies and appraisals used in attempts to manage pain, beliefs about health and illness, beliefs about how physical effort and work influence low back pain	e.g. Coping strategies questionnaire (CSQ) ; Back beliefs questionnaire; FEKB, back pain self-efficacy; fear-avoidance beliefs questionnaire (FABQ); Pain anxiety symptom scale (PASS);
Mood / affect: mood or affective state	e.g. Depression: Becks Depression Inventory; SCL-90 subscale, depression scale v. Zerssen; anxiety (State trait anxiety inventory-STAI), emotional distress
Physical performance factors: Measures of physical factors related to low back pain including strength, flexibility, mobility etc.	e.g. , leg press, back press, lumbar flexion; range of motion; isometric strength and fatigue; spine flexibility

3.4.1 Treatment process variables associated with pain reduction

Five studies were identified [1, 33, 12+37+38, 41, 57]. Changes in physical performance parameters explained variance in pain reduction in two studies [12, 33]. One study reported that changes in physical performance factors explained 28% of the variance in post treatment pain [33]. This study showed no statistically significant association between changes in disability and pain reduction [33]. The other study found medium correlations between improvement in physical performance factors and decreases in pain (r = 0.30 - 0.35) and high correlations (r = 0.72; r = 0.49) between reduction of disability and decreases in pain [12,37,38]. In three studies, changes in cognitive coping and appraisal could explain moderate amounts of variance (11%-16.5%) in pain reduction [1, 33, 41]. Two studies did not show statistically significant associations between changes in cognitive coping and appraisal and pain reduction [12, 57] or reduction of depression and pain reduction [12].

In summary (see also Table I in the appendix), physical performance factors showed a strong, disability and cognitive coping and appraisal both showed moderate associations with pain reduction.

3.4.2 Treatment process variables associated with improved disability

Four studies were identified [8, 30, 33, 57]. In two studies reductions of pain were highly associated with improvements in disability [30, 57]. The proportion of the variance that could be explained varied from 16% [30] to 43% [57]. However, one study did not find reductions in pain to have an influence on changes in disability [8]. There was no association between changes in physical performance factors and improvements in disability [30, 33]. Three studies found that changes in cognitive coping and appraisal explained 8% - 22% of the variance in improvements in disability [30, 33, 57]. One study found that changes in coping did not have any association with reduction in disability, but improvements in mood / affect explained 20% of the variance [8].

In summary (see also Table II in the appendix), changes in pain showed a relatively strong association, changes in cognitive coping and appraisal moderate associations, and changes in physical performance factors no association with reduction in disability.

3.4.3 Treatment process variables associated with return to work (RTW)

Six studies were identified [7, 12, 21, 23, 35, 44]. Three studies found no association between pain reduction and return to work [7, 12, 23], and two studies no association between physical performance factors and return to work [12, 23]. Two studies showed an association between increases in joint mobility (physical performance factor) and return to work, but these associations were weak (OR = 1.17 and 1.06, respectively) [21, 35]. Findings on the association between disability and return to work were conflicting. Two studies reported moderate (Wilks Lambda = 0.86 resp. 0.89) and high (r = 0.68-0.71) associations [7, 12], but two other studies did not [21, 23]. Although one study [44] reported that changes in fear of movement (Wilks Lambda = 0.92) and changes in catastrophizing (Wilks Lambda = 0.79) predicted return to work, two studies did not [7, 21]. Four studies found no statistically significant associations between reductions of depression and return to work [7, 21, 23, 44], one study reported a correlation of 0.42 between reductions in depression and return to work [12]. One study found that RTW could best be predicted by changes in self-esteem (OR=0.80, confidence interval 0.64 - 1.01) [23].

In summary (see also table III in the appendix), changes in disability and cognitive coping both showed some association with RTW. Whereas reductions of pain and increases in physical performance factors showed no or very slightly relations to RTW.

4 DISCUSSION

4.1 Treatment process variables explaining outcome

The results show that functional coping mechanisms and pain reduction seem associated with a decrease in disability and RTW, but not physical performance factors. However, changes in physical performance could explain significant amounts of variance in pain reduction together with decreases in disability and functional coping mechanisms. This is in accordance with results of other reviews that concluded that disability in chronic low back pain is maintained primarily by factors other than objective medical data [26, 27]. Changes in physical performance factors do not seem good predictors for treatment efficacy [11].

The interaction between reduction of pain and decrease in disability is supported by findings from cross-sectional and longitudinal studies that showed that pain intensity is related to the extent to which a person is disabled [4, 9, 14]. However, there are other studies that have shown that the relation between pain intensity and disability is relatively weak [52, 53]. These inconsistent findings suggest that factors may exist that mediate the relationship between these distinct constructs [54].

According to the bio-psycho-social model, attitudes, beliefs and distress play an increasing role in the development of chronic pain and disability [54]. Changes in these factors are expected to be related to positive treatment outcome. Decreases in fear-avoidance, especially catastrophizing, were dominant factors in the reported models, which is in line with the fear-avoidance model of pain [25, 48, 49, 56]. The role of mood for the prediction of treatment outcome remains unclear, because most studies did not include mood as an independent variable. The experience of pain seems accompanied by unpleasant feelings and distress, but it is unclear if targeting changes in mood would lead to reduction of pain or if negative mood disappears at the same time pain is reduced.

The results of this review may have some consequences for treatment refinement. Positive treatment outcome seems to be associated with decreased perceptions of a link between disability and pain through the reduction of fear-avoidance beliefs and catastrophizing. Therefore, treatment of back pain should focus more on altering coping schemes, e.g. fear-avoidance beliefs and enhancing experiences that decrease perceptions of a link between disability and pain. This has been also proven for rehabilitation of patients with chronic low back pain that have recently undergone surgery [6] . The fact that physical performance factors were not strongly associated with disability reduction and return to work does not mean that exercises are unimportant. Other studies have also shown that improvements in an exercise regime occur independently of changes in fitness [40] or more rapidly than real changes in muscle size could occur [17]. Therefore, the effects of exercise might be related to other factors such as improving self-belief and challenging misconceptions. Some studies support the hypothesis that personal experiences with activity that challenges existing misconceptions about disability and pain force patients to rethink their dealing with the problem and are powerful agents to change [15, 20, 39]. Treatment refinement in the case of exercise could indicate putting more emphasis on positive experiences with physical activity than on an increase of muscle strength through repetitive exercise or flexibility through stretching.

Most of the studies included in this review were not specifically designed to answer the question which change factors contribute most to treatment outcome. Further studies should choose independent variables, and outcome, based on a conceptual model. Such a model requires uniform, accepted frameworks of communication [43]. A conceptual model that takes all the interrelated and interacting dimensions into account is the International Classification of Functioning, Disability and Health (ICF) [55] which is based on the bio-psycho-social model. Also, with a theoretical model, stronger designs could be used that would give answers to the specific question as to which change factors are most important for successful outcome in the treatment of chronic low back pain. Vlaeyen and Morley [50] argue that it is necessary to define specific theory-driven hypotheses about which patient-treatment interactions to expect, and that replicated single-participant studies, with appropriate statistics, might be likely to enhance new developments in treatment process research.

4.2 Limitations of the review

One of the limitations of this review was the heterogeneity regarding study population, interventions, outcomes, and analyses. Firstly, the study populations were heterogeneous. Patients could be recruited in a rehabilitation center (7, 12), by advertisement [30], or through referral to a training program by their insurance company or a workers compensation board [21, 44]. Also, duration of low back pain varied from a mean of 18.3 weeks [44] to 12.7 years [41]. Secondly, the three intervention forms could vary in content and duration. Multimodal treatment, for example, could include exercises and behavioural education for 8 weeks [57] or physical therapy, exercises, relaxation training and cognitive-behavioural interventions for 3 weeks [42]. Thirdly, studies used different outcome measures and had different periods of follow up. Most of the included studies predicted outcome post-treatment [12, 33], but some also predicted outcome at 6-months [1] or 9-months follow up [7]. Fourthly, studies were heterogeneous with respect to number and kind of independent variables used for analyses, and method of inclusion and exclusion in the final model. Additionally, the studies used different statistical methods. These different statistical analyses result in different measures that are not directly comparable.

The models explained only small amounts of variance, so the treatment process still seems to be a “black box”. Other factors that haven´t been included in studies so far may still be associated with positive treatment outcome. For example, some authors have suggested that an increase in motivation to adopt a self-management approach to chronic pain can serve as a mediator or moderator for successful treatment [19].

4.3 Conclusions

Strong conclusions cannot be drawn from this review, because of the heterogeneity and the limited number of studies. The results of this review raise the question if changes in behavioural variables and reductions of disability which facilitate an improvement in function, may be more important than physical performance factors for successful treatment of chronic low back pain. Further research is needed to answer these questions. Knowing more about these associations would help to refine treatments and thus make them more effective and reduce health care costs.

APPENDIX

Table I: Treatment process variables predicting reduction in pain

Studies	Woby * 2004 [57]	Mc Cracken * 2002 [33]	Altmaier * 1993 [1]	Pfingsten * 1997 [12, 37, 38]	Spinhoven + 1991 [41]
Change factors					
Physical performance					
Mobility of joint functions		**x** } (28%)		**x** (r = 0.30)	
Muscle strength		**x**		**x** (r = -0.35)	
Disability/Functioning					
Lifting and carrying objects		0			
Limitations ins daily living due to pain				**x** (r= 0.49, 0.72)	
Cognitive coping and appraisal					
Fear-avoidance beliefs	0	**x** (11%)			
Catastrophizing	0			0	
Active coping			0 (post) **x** (6-mo.) (16.5%)		**x** (post) (13%)
Search for information				0	
Cognitive control over pain	0			0	**x** (6-mo) (14%)
Mood / affect					
depression				0	

* = multimodal; ~ = exercises; + = behavioural

x = assessed and in final model; 0 = assessed and not in final model

% = amount of explained variance in outcome; r = correlation coefficient with discriminative function analyses

Table II: Treatment process variables predicting reduction in disability

Studies	Woby * 2004 [57]	McCracken * 2002 [33]	Fisher * 1998 [8]	Mannion ~ 2001 [31]
Change factors				
Pain	**x** (43%)		0	**x** (16%)
Physical Performance				
Mobility of joint functions		0		0
Muscle functions		0		0
Disability/Functioning				
Lifting and carrying objects		0		
Cognitive coping and appraisal				
Fear-avoidance beliefs	**x** (22%)	**x** (8%)		**x** (3.7%)
Catastrophizing	**x** (22%)			**x** (4.1%)
Cognitive control over pain	**x** (22%)		0	**x**
Mood / affect				
Emotional distress			**x** (20%)	

* = multimodal; ~ = exercises; + = behavioural

x = assessed and in final model; 0 = assessed and not in final model

% = amount of explained variance in criteria; r = correlation coefficient with discriminative function analyses

Table III: Treatment process variables predicting return to work

Studies	Dozois * 1995 [7]	Koopman * 2004 [21]	Mellin * 1993 [35]	Pfingsten* 1997 [12,37,38]	Sullivan & Stanish + 1991 [44]	Le Fort & Hannah ~ 1994 [23]
Change factors						
Pain	0			0		0
Physical Performance						
Mobility of joint functions		**x** (OR=1.17)	**x** (OR= 1.06)	0		
Muscle functions		0	0	0		0
Cardiovascular fitness		0				0
Confidence						
Disability/Functioning						
Lifting and carrying objects	**x** (14%)	0				
Limitations in daily life due to pain	**x** (11%, 14%)			**x** (r=0.64)		0
Cognitive coping and appraisal						
Fear-avoidance beliefs					**x** (8%)	
Catastrophizing	0	0			**x** (24%)	
Active coping	0	0				
Search for information	0	0				
Cognitive control over pain	0	0				
Mood / affect						
Depression	0	0		**x** (r=0.42)	0	0
Confidence						**x** (OR = .80)

* = multimodal; ~ = exercises; + = behavioural

x = assessed and in final model; 0 = assessed and not in final model

% = amount of explained variance in criteria; r = correlation coefficient with discriminative function analyses

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Teil 2

Change mechanisms explaining reductions of interference in a multidisciplinary and an exercise program for the secondary prevention of chronicity in low back pain

ABSTRACT

Objectives: To identify relevant change mechanisms, meaning changes in process variables through treatment that predict outcome, in an exercise and a multidisciplinary secondary prevention program for low back pain.

Methods: Data of a controlled randomised trial to examine the effectiveness of an exercise and a multidisciplinary prevention program was analysed with multiple regression analyses. The specific aim was, to examine how much variance in reductions of interference post intervention could be explained by pre to post changes in physical and psychological parameters, and to determine if there are different interactions between physical/psychological parameters and program.

Results: 162 (89%) of participants could be included in the regression analyses. Reductions of interference at post measurement could be explained best by reductions of pain intensity and catastrophizing in the multidisciplinary and the exercise prevention program. There was no significant interaction between changes in process variables and program found The final model could explain 68.7% of variance.

Conclusions: The findings suggest, that treatment success in exercise and multidisciplinary interventions is mediated by the same change mechanism, meaning changes in pain and psychological factors in terms of decreases in dysfunctional beliefs as catastrophizing. Therefore the change mechanism through which exercises work, might not be a betterment in physical variables, but a change in psychological attributes, insofar as people correct their irrational cognitions by making experiences that differ from their expectations. This may have some implications for treatment refinement.

INTRODUCTION

There is a need for effective preventive interventions to avoid chronicity and disability due to low back pain. [1,2]

One intervention that has already proven to be effective in the secondary prevention of low back pain is exercise. [3] The mechanisms by which exercise may prevent low back pain are supposed to be: 1) they strengthen the back muscles and increase trunk flexibility, 2) they increase blood supply to the spine muscles, joints and intervertebral disks, minimizing injury and enhancing repair and 3) they improve mood and thereby alter the perception of pain. [3] Because the transition from acute to chronic back pain is influenced by many factors, mainly psychological ones [4,5, 6], also multidisciplinary programs, including physical, psychological and educational interventions, are recommended. But it is not clear yet which dimensions and in what balance are most important. [7]

Only a small number of studies have tried to identify the variables most responsible for positive outcomes but for the treatment of chronic low back pain. A recently published review found that changes in psychological factors and improvements in functioning were most relevant to treatment success. [8] For multidisciplinary and behavioural treatment it appears that positive treatment outcomes are associated with decreased perceptions of pain as disabling [9,10], negative emotional response to pain [11] and fear-avoidance beliefs. [12, 13] Also increased perceptions of control over pain [12,13,14] and increased self-efficacy [15] could predict better treatment outcomes. Furthermore Mc Cracken et al. [11] and Pfingsten et al. [10] could show that reduced pain-related anxiety and perceptions of pain as disabling were more important than increases in physical capacity. Findings from two studies that analysed treatment processes in exercise treatment for chronic low back pain suggest that the change mechanism in multidisciplinary and exercise treatment might be the same, because changes in psychological variables showed stronger associations to positive treatment outcome than changes in physical capacity. [16,17] Even in the study of Mannion et al. [16] increases in physical performance factors were not at all related to reductions in disability scores. Whereas reductions of psychological distress, including catastrophizing and fear-avoidance beliefs as well as increases in efficacy in controlling pain explained significant amounts of variance in reductions of disability. The authors assume that various psychological variables (e.g. fear-avoidance, catastrophizing) are addressed inadvertently by exercise, insofar as people experience something quite different from their expectations and thereby correct their irrational cognitions and appraisals. There are also other studies that support this hypothesis. [18,19,20]

Compared to exercise multidisciplinary programs require substantial staff and financial resources. [21]

However there is a lack of knowledge with regards to the treatment process in the secondary prevention of low back pain in order to refine intensive complex programs.

The effectiveness of a multidisciplinary and an exercise program has been discussed in another paper. [22]

The specific aim of the present study was, to examine how much variance in reductions of interference post intervention can be explained by pre to post changes in physical and psychological parameters, and to determine if there are different interactions between physical/psychological parameters and program.

We assume that despite the different contents in both programs the change mechanisms might be the same in the multidisciplinary and the exercise program. Therefore we assume that we find no significant interaction between process variables and program.

METHODS

2.1 Participants and Interventions

Data were collected from 183 nurses, which took part in a randomized controlled study to analyse the effectiveness of two different programs to prevent chronicity in low back pain. The inclusion criteria of the study were: 1) employed as nurse or comparable professional status; 2) age between 18 and 65 years or 3 years before retirement; 3) at least one low back pain episode in the previous two years. Excluded were nurses 1) with acute or chronic pain leading to a sick certificate; 2) having had surgery to treat back pain 6 months previously; 3) with insufficient fitness to participate in the exercise program. The randomization procedures were based on a pre-prepared randomisation list, which was generated from a random numbers table. Participants were randomly assigned to an exercise or a multidisciplinary prevention program.

2.2 Interventions

The exercise program consisted of 11 units during 13 weeks. The Exercise classes included strengthening for all main muscle groups, stretching and relaxation. The multidisciplinary prevention program consisted of 18 units during 13 weeks. In addition to the same exercise classes, educational and back school classes, segmental stabilization techniques, transfer to workplace (including lifting techniques), work hardening and cognitive-behavioural interventions have been administered.

2.3 Measures

2.3.1 Primary outcome variable

As primary outcome interference with daily life due to pain was measured by the german version (MPI-D) [23] of the West Haven Multidisciplinary Pain Inventory. [24]

2.3.2 Process variables

Pain

Pain intensity was measured with the scale 'pain intensity' of the german version [23] of the West Haven Multidisciplinary Pain Inventory.[24] This scale measures current pain intensity and average intensity in the last week with three items. Flor et al. [23] report high intercorrelations between the scales 'interference' and 'pain intensity' that loaded together on one factor 'pain and disability' in their factor analyses.

Physical measures

Muscle strength

Isometric muscle strength was measured with a hand-held pull gauge by a study member. The reliability and validity of the Muscle strength index (MSI) has been shown for healthy and ill populations. [25,26]

Static back endurance

The Biering-Sørensen Test (BS) [27,28] was used to measure the trunk extensor endurance by assessing the holding time. It is an international used disease specific measurement. A number of studies have found, that the Biering-Sørensen test discriminates between subjects with and without LBP, and showed sufficient reliability coefficients.

Lifting capacity (Pile)

The progressive isoinertial lifting evaluation (PILE) [29,30], a reliable, valid and sensitive measure, was employed to assess the lumbar lifting capacity (LFF).

Psychological measures

Depression

Depression was measured by the 20 item german version (ADS) of the Center for Epidemiologic Studies Depression Scale [31], and is described in detail by Hautzinger and Beiler [32].

Generalized and specific self-efficacy

Generalized self-efficacy was measured by a 10-item scale of Schwarzer [33], and has proven to be unidimensional, reliable and valid in many studies.

Specific self-efficacy was measured with a scale of Basler [34] that measures specific self-efficacy to have good postural habits in order to prevent back pain.

Fear avoidance

Fear-avoidance beliefs were measured using the german version of the fear avoidance-beliefs-questionnaire (FABQ-D), which is described in detail by Pfingsten [35,36]. It measures fear-avoidance beliefs on three subscales: cause through work, prognosis return to work, interrelation with activity. In this study only the two subscales “cause through work” and “interrelation with activity”, containing 11 items were used, because we assessed a working population.

Cognitive coping strategies

To measure cognitive evaluation of pain the CSQ-R was administered. The CSQ-R is a short version of the Coping Strategies Questionnaire developed by Rosenstiel and Keefe [37]. It contains 27 items, measuring cognitive coping strategies on six scales: praying, catastrophizing, ignoring pain, distraction, distancing and coping self statements. The CSQ-R has shown satisfactory internal consistency and validity. [38]

Stress

Stress was measured using a daily hazzles scale (KFB), which is a short 16 item-instrument to measure daily hazzles, and is described in detail by Flor. [39]

Job satisfaction

To measure job satisfaction parts of the Arbeitsbeschreibungsbogen (ABB), which is described in detail by Neuberger et al. [40] were administered.

2.4 Statistical Analyses

2.4.1 General analyses

Statistical analyses were conducted for those participants who completed the baseline and the post assessment. A series of analyses were performed to determine whether the baseline characteristics of participants in the exercise program differed of those in the multidisciplinary program. Change scores (Δ) for key outcome and process variables were calculated, by distracting baseline scores from post-scores.

2.4.2 Selection of variables for the regression analyses

Variables for the regression analyses were selected in two steps. First, partial correlation coefficients were calculated to examine the relation between changes scores in process variables and the change score in interference, while controlling for baseline value of the particular process variable. Only process variables with p values <.2 of the partial correlation coefficient were selected. Second, multiple regression analyses with reductions of interference as dependent variable were calculated separately for pain, physical and psychological measures to find out, how much variance can be explained, when considering these groups separately of each other. Only those variables remaining in the final model of each group were selected for the subsequent final regression analyses.

To prevent multicollinearity the relation between change scores in the process variables was delineated by computing a series of Pearson Product Moment Correlations. When a correlation of >.8 between two variables was calculated, the variable that had a smaller correlation coefficient with the outcome was excluded from regression analyses. In addition, residual analyses were carried out to investigate the appropriateness of the final regression model. Therefore normal distribution and autocorrelation of residuals were tested by the Durbin Watson test and homoskedesticity was checked with scatterplots.

2.4.3 Final Regression analyses

A multiple regression analyses was performed to determine which changes in process variables predict reductions in interference (MPI-D) for all groups of variables together. Firstly age, sex, baseline score in interference and baseline scores of selected change scores were entered, to control for the amount of variance that is already explained by these variables. Secondly change scores in process variables, as well as interaction terms between selected change scores and program, were included stepwise. Program was included as a covariate to determine the influence of program on reductions in interference.

3 RESULTS

3.1 General analyses

3.1.1 Subject characteristics

Of the 183 included participants 162 completed the baseline and the post assessment, and were therefore included in further analyses (see table 1).

There were no significant differences in baseline values between them.

Table 1: Subject characteristics of the study group[+] (n=162)

Variable	multidisciplinary program (n =80)	exercise program (n =82)	P value
Demographic features			
Age (yrs.)	38.6 (11,6)	41.5 (10,6)	0.10 [a]
Females (%)	74 (92.5%)	76 (92.7%)	0.60 [c]
Partnership (%)	46 (57.5%)	42 (52.2%)	0.26 [c]
High School diploma (%)	14 (17.5%)	10 (12.2%)	0.28 [c]
Nurses diploma (%)	64 (80%)	71 (86.6%)	0.97 [c]
Co-morbidity score)%)	1.4 (1.6)	1.6 (1.7)	0.41 [a]
Body mass index (kg/m^2)	25.4 (5.1)	26.3 (5.1)	0.48 [a]
Sports frequency per week	2.1 (2.0)	2.3 (2.0)	0.52 [a]
Pain type ††			0.78 [c]
Type I (%)	53 (66.3%)	55 (67.1%)	
Type II (%)	18 (22.5%)	19 (23.2%)	
Type III (%)	8 (10.0%)	5 (6.1%)	
Type IV (%)	1 (1.3%)	2 (2.4%)	
Missing	0 (0%)	1 (1.2%)	
Number of days in pain in the last 12 months	78.9 (100.3)	63.9 (91.2)	0.32 [b]
Persons with sick leave in the last 12 months (%)	7 (9.0%)	13 (15.6%)	0.17 [c]

[+] = mean (SD), unless otherwise stated.

†† = Type I : low disability, low pain intensity ; Type II : low disability, high pain intensity ; Type III : high disability, moderately limiting ; Type IV : high disability, severely limiting (Korff et al., 1992, 1993)

a = T-Test

b = Mann Withney U-Test

c = Qui Square Test

A withdrawl analysis for the 21 (11%), who failed to respond the post assessment detected a higher percentage of persons with sick leave days in the last 12 months in this group.

3.1.2 Pre- to post intervention changes in primary outcome and process variables

Table 2: pre to post changes in primary outcome and process variables
(means, 95% confidence intervals, unless otherwise stated)

Variable		multidisciplinary program n=80	Exercise program n=82	p~
Primary outcome		P		
Interference (MPI-D)	Baseline	1.4 (1.2-1.7)	1.5 (1.2 - 1.7)	.854
	Post	0.9 (0.7-1.1) **	1.1 (0.9-1.4) **	.074
Pain				
Pain severity (MPI-D)	Baseline	1.5 (1.3-1.8)	1.5 (1.3-1.7)	.876
	Post	1.1 (0.9-1.3) **	1.3 (1.1-1.5) *	.145
Physical variables				
Muscle strength (MSI)	Baseline	58.3 (55.8-60.7)	59.4 (56.9-61.9)	.526
	Post	61.1 (58.5-63.6) **	59.9 (57.4-62.4)	.516
Static back endurance (BS)	Baseline	90.7 (77.4-103.9)	94.5 (83.4-105.5)	.660
	Post	115.6 (103.1-128.2) **	109.8 (98.5-121.1) **	.489
Lifting capacity (PILE)	Baseline	22.9 (20.8-24.9)	19.2 (17.6-20.7)	.004
	Post	26.3 (24.1-28.5) **	25.8 (23.2-28.5) **	.787
Psychological variables				
Depression (ADS)	Baseline	11.0 (9.0-13.0)	12.0 (10.0-14.0)	.476
	Post	9.9 (8.0-11.8)	11.3 (9.4-13.2)	.306
Self efficacy (generic)	Baseline	2.9 (2.8-3.0)	2.9 (2.8-3.0)	.691
	Post	3.0 (2.9-3.0)	2.9 (2.9-3.0)	.701
Self-efficacy (specific)	Baseline	3.0 (2.9-3.2)	3.1 (3.0-3.2)	.621
	Post	3.4 (3.2-3.5) **	3.2 (3.1-3.4) **	.176
Fear-avoidance beliefs total (FABQ-D)	Baseline	2.5 (2.2-2.7)	2.7 (2.5-2.9)	.179
	Post	2.4 (2.2-2.6)	2.5 (2.2-2.7)	.621
FAB work (FABQ-D)	Baseline	2.2 (1.9-2.5)	2.4 (2.1-2.7)	.363
	Post	2.2 (1.9-2.5)	2.3 (2.0-2.6)	.650
FAB activity (FABQ-D)	Baseline	2.7 (2.5-3.0)	3.0 (2.8-3.2)	.162
	Post	2.6 (2.3-2.8)	2.7 (2.4-2.9) *	.720
Praying (CSQ)	Baseline	1.2 (0.8-1.5)	1.2 (0.9-1.5)	.883
	Post	1.3 (0.9-1.6)	0.9 (0.7-1.1) **	.065
Distraction (CSQ)	Baseline	2.6 (2.4-2.8)	2.6 (2.5-2.8)	.810
	Post	2.7 (2.5-2.9)	2.5 (2.3-2.7) *	.127
Distancing (CSQ)	Baseline	1.0 (0.8-1.2)	0.8 (0.7-1.0)	.308
	Post	1.1 (0.9-1.3)	0.9 (0.7-1.1)	.149
Catastrophizing (CSQ)	Baseline	0.8 (0.7-1.0)	1.0 (0.8-1.2)	.244
	Post	0.7 (0.6-0.9)	0.8 (0.6-0.9) **	.908
Coping self statements (CSQ)	Baseline	2.9 (2.7-3.1)	2.7 (2.5-3.0)	.430
	Post	2.5 (2.3-2.7) **	2.5 (2.3-2.8) **	.798
Ignoring pain (CSQ)	Baseline	2.6 (2.4-2.7)	2.5 (2.3-2.7)	.295
	Post	2.5 (2.3-2.6)	2.4 (2.2-2.7)	.860
Stress (KFB)	Baseline	1.4 (1.3-1.6)	1.6 (1.4-1.8)	.100
	Post	1.4 (1.2-1.5)	1.5 (1.3-1.7) *	.357
Work satisfaction (ABB)	Baseline	2.8 (2.6-3.0)	2.9 (2.7-3.0)	.712
	Post	2.9 (2.7-3.1) *	3.0 (2.8-3.2)	.805

~ p value for significance between groups
* intragroup mean differences over time p < .05
** intragroup mean differences over time p< .01
§ number of persons being able to segmental stabilize

In both programs significant changes occurred in some psychological and almost all physical process variables (table 2). There were no significant intergroup differences in outcome and process variables at baseline or post found.

3.2 Selection of variables for the final regression analyses

Table 3: Partial correlation coefficients and selected variables for final regression analyses

Process variables	**Partial correlations** r Between process variables and reductions in interference *	**Regression analyses for each group of variables** X = remaining in final model and therefore selected for subsequent final regression analyses
Pain		
Pain intensity (MPI-D)	**.559**	x
Physical variables		
Muscle strength (MSI)	-.092	
Static back endurance (BS)	-.051	
Lifting capacity (PILE)	**-.132**	x
Psychological variables		
depression (ADS)		
self-efficacy generic	-.071	
self-efficacy (specific)	-.098	
fear-avoidance (total)	.009	
fear-avoidance work	.042	
fear-avoidance activity	-.015	
CSQ – distraction	.006	
CSQ – distancing	.018	
CSQ – coping self statements	.074	
CSQ – ignoring	-.031	
CSQ – praying	**.131**	
CSQ - catastrophizing	**.361**	x
Stress (KFB)	.012	
job satisfaction (ABB)	**.108**	x

* bold = p<.2

None of the correlation coefficients between two variables exceeded .8, and therefore no variable had to be excluded.

Reductions in pain intensity were highly correlated with decreases in interference and selected for the subsequent regression analyses. The only physical variable, whose p-value of the correlation coefficient was smaller than 0.2 was increase in lifting capacity. Of the psychological variables the partial correlations of changes in praying and catastrophizing achieved p values <.2, and were therefore selected (table 3).

Reductions in pain intensity counted for 31.5% of variance in reductions of interference. Regarding physical variables change in lifting capacity explained 2.1% in variance in reductions of interference after controlling for sex, age and interference baseline. Stepwise regression analyses for the psychological variables revealed, that only decreases in catastrophizing were significantly able to contribute to explaining the variance in reductions of interference, counting for 13.6% of variance. Therefore changes in pain intensity, lifting capacity and catastrophizing were selected as potential predictors for the final regression analyses (table 4).

Table 4: Results of regression analyses for each group of variables with reduction of interference as dependent variable (N=162)

Group of variables and steps	**R^2**	**$R^{2\ change}$**	**ß**	**p**
Pain				
1. Control variables				
Sex	0.323	0.323	-0.021	.668
Age			-0.049	.311
Interference baseline (MPI-D)			-0.702	.000
Pain intensity baseline			0.460	.000
2. *Δ pain intensity (MPI-D)*	0.638	0.315	0.669	.000
Physical variables				
1. Control variables				
Sex	0.285	0.285	-0.083	.258
Age			-0.026	.708
Interference baseline (MPI-D)			-0.541	.000
Lifting capacity baseline			-0.071	.417
2. *Δ lifting capacity*	0.306	0.021	-0.184	.034
Psychological variables				
1. Control variables				
Sex	0.378	0.378	0.011	.851
Age			-0.041	.486
Interference baseline (MPI-D)			-0.737	.000
Catastrophizing baseline			0.395	.000
Praying baseline			0.087	.149
Work satisfaction baseline			0.092	.138
2. *Δ catastrophizing*	0.514	0.136	0.401	.000

3.3 Final Regression analyses

When increases in lifting capacity, decreases in catastrophizing, program, and terms for an interaction between changes in lifting capacity, respective catastrophizing, and program were entered simultaneously into a stepwise regression analyses, 68.7% of variance of reductions in interference could be explained together with the control variables.

Sex, Age, baseline scores in interference, pain intensity, catastrophizing and lifting capacity counted for 35.6% of variance. But beta weights of sex, age and baseline score lifting capacity didn´t reach statistical significance. Decreases in pain intensity counted for additional 29.7% of variance in decreases in interference. Reductions in catastrophizing explained a further 2.5 % of variance in outcome. As we controlled for baseline values program got in the final model as last variable and explained 0.9% of variance in outcome. The beta weight indicates that the multidisciplinary program had a minor bigger effect on reductions in interference. None of the interaction terms (changes in lifting capacity or catastrophizing x program) made a significant contribution to reductions of interference. The final regression model is presented in table 5.

Table 5: Stepwise regression analyses with changes in process variables and interaction with program as predictors and reductions of interference as outcome (N=162), final model

Step and variable	**R^2**	**$R^{2\ change}$**	**ß**	**p**
1. Control variables				
Sex	0.356	0.356	.004	.939
Age			.014	.776
Interference baseline (MPI-D)			-.746	.000
Pain intensity baseline (MPI-D)			.397	.000
Lifting capacity baseline (PILE)			-.041	.420
Catastrophizing baseline (CSQ)			.236	.000
2. Pain				
Δ pain intensity (MPI-D)	0.653	0.297	.569	.000
3. Psychological variables				
Δ catastrophizing (CSQ)	0.678	0.025	.205	.000
4. Program	0.687	0.009	-.099	.044

The predictor variables remaining in the regression analyses had tolerance levels that were all higher than 0.1 [41], indicating that the data were not affected by multicollinearity. The Durbin Watson statistic for each regression model didn’t achieve values smaller than 1 and bigger than 3, indicating that the standardized residuals were not autocorrelated. [42]

4 DISCUSSION

Reductions of interference could be explained best by reductions of pain intensity and catastrophizing in both programs. Also program got a significant beta weight, and could explain a small portion of variance in reductions of interference, meaning that the programs had slightly different influences on reductions of interference. There was no significant interaction between changes in process variables and program found. The hypothesis that the change mechanism that predicts reductions of interference is the same for both programs could therefore be confirmed.

Although some studies have shown that the relation between pain intensity and interference is relatively weak [35,43], in this study changes in pain intensity explained the biggest amount of variance in reductions of interference. This is concordant with studies of chronic low back pain patients. [13,16] Because treatments aimed at pain relief are often unsuccessful, especially if the cause for patients´ back pain cannot be identified, altering beliefs about back pain seems a more promising approach.

Decreases in catastrophizing, meaning catastrophic thoughts about pain, could explain 2.5% of total variance in outcome. The amount of variance, explained by decreases in catastrophizing might be underestimated because of the inclusion of pain intensity as a factor. Pain intensity and catastrophizing are correlated to each other (r=0.33), and in the preliminary analysis changes in catastrophizing were able to explain 13.6% of variance in reductions of interference. However, the result is in concordance with studies of Sullivan et al. [12] and Woby et al. [13] Also in the study of Mannion et al. [16] decreases in catastrophizing was included in the factor psychological distress that explained 4.1% of variance in disability reduction post treatment. Unlike to other studies [12,13,16], where reductions of fear-avoidance were more related to decreases in interference when compared to 'catastrophizing', changes in fear-avoidance beliefs were not related to reductions of interference in our study. The interpretation of this is unclear. According to the fear of movement model of chronicity in low back pain, a chain of reactions leads to disability, with catatrophizing leading to fear of movement. [44] The participants in our study were relatively healthy with only mild pain symptoms and degrees of disability. It might be that at this stadium catastrophizing has a stronger impact on disability. This explanation might be partly supported by the findings of Buer and Linton [45], who found that ‘catastrophizing’ and fear-avoidance were related to future disability, but ‘catastrophizing’ was present at quite low pain levels, whereas fear-avoidance beliefs were present not until more moderate levels of pain.

Program got a significant predictor for reductions of interference in the present study, although it explained only a very small amount of variance. Beta weights and mean values in reductions of interference indicate that the multidisciplinary program had a slightly stronger impact, even if mean comparisons between the two programs post intervention didn´t become statistically significant. One reason might be that because of controlling for differences in baseline values between the multidisciplinary and the exercise program, program could get a significant influence. This means, if bench marks would have been the same, interference would have been reduced somewhat more in the multidisciplinary program. Also in a study about treatment of chronic low back pain, there was no difference in decreasing catastrophizing about pain between an operant behavioural treatment program, including physical group training, and operant behavioural treatment + cognitive coping skills training. [46,47] In this study changes in catastrophizing mediated reductions of distorted mobility in both treatment groups. Despite the fact that program got a significant predictor in our study the supplemental value of a cognitive program to an exercise program therefore remains arguable.

The main finding from this study is that the same change mechanism, meaning changes pain and in psychological factors in terms of decreases in catastrophizing, is responsible for reductions in interference in an exercise and a multidisciplinary prevention program. This is interestingly because the exercise program doesn´t involve any psychological intervention, yet psychological variables showed significant changes, and were dominant in explaining variance in reductions of interference. To our knowledge there are no other studies that analysed changes processes in a relatively healthy population with recurrent low back pain. But regarding the exercise program our results are concordant with the study of Mannion et al.. [16] She could show in a population of chronic low back pain patients, who took part in an exercise program that amongst other psychological variables changes in catastrophizing and fear-avoidance beliefs accounted for 8% of variance in reductions of disability post-therapy. Whereas improvements in physical variables e.g. muscle strength, didn´t show an association to changes in disability. Also in a study of Le Fort [17] only increases in self-esteem following a muscle-strengthening program for chronic low back pain showed significant associations with return to work. Muscle strength and endurance measures showed no association. The results suggest that the change mechanism through which exercises are useful in the treatment of low back pain, might not be an betterment in physical variables, but a change in psychological attributes, insofar as people correct their irrational cognitions and appraisals by making experiences that differ from their expectations. That exercises might have an influence on psychological parameters has been shown already in some studies [18,19,48,49], especially for a decrease in fear-avoidance beliefs [18,48,49], and an increase self-efficacy for pain and function. [49] Our findings suggest that an exercise program may constitute a potent strategy for cognitive restructuring and promote less catastrophizing. As has already been stressed by Bandura [50] behaviour modification possibly constitutes the most potent strategy for cognitive restructuring.

Our findings may have some implications for treatment refinement. In the case of exercise treatment refinement could mean, putting more emphasis on positive experiences with physical activity than on an increase of muscle strength through repetitive exercise or flexibility through stretching. For multidisciplinary programs it questions the supplemental value of cognitive components, and suggests putting more emphases on behavioural components.

Some limitations of the study have to be acknowledged. The withdrawal analysis indicated more people with sick leave days in the non-participants group, which biases our results and might constitute a problem of external validity. Moreover the participants included in our study were relatively healthy with low baseline scores comparable to normal population in all parameters. For example mean values for interference or catastrophizing in chronic low back pain populations are about 5 [11] respective over 2.5. [13] The low baseline scores are also an explanation why we could measure only small changes over time. The adopted measurements were mostly validated in a clinical population and therefore may not be appropriate in the detection of specific preventive effects. Therefore it is questionable if it is possible to measure success and change mechanisms with the same parameters than in a population of chronic pain patients or if there are important other variables missing. Furthermore it has to be emphasized that correlational data cannot give information regarding causal relationships. Interference may be reduced as a result of changes in catastrophizing, reductions in catastrophizing may change as a result of reduced disability, or both may interact dynamically over time. Therefore longitudinal research is needed to examine more closely the sequential relationship among psychological and physical process variables and measures of adjustment. For example diary methods could be used to examine, whether interventions targeted at decreasing catastrophizing actually decreases catastrophizing, and whether changes in catastrophizing are followed by changes in interference. Vlaeyen and Morley [51] also argue that it is necessary to define specific theory-driven hypotheses about which patient-treatment interactions to expect, and that replicated single-participant studies, with appropriate statistics, might be likely to enhance new developments in treatment process research.

Despite the study limitations to our knowledge this is the first study that analysed treatment processes in a secondary prevention program for chronicity in low back pain, and that analysed a potential interaction between process variables and an exercises respective an multidisciplinary approach. Our results suggest that the same change mechanism, namely decreases in pain and in catatstrophizing, is responsible for reductions of interference in an exercise and a multidisciplinary prevention program. This result is supported by results of studies in chronic low back pain populations. It emphasizes on the fact that behaviour modification and new experiences possibly constitute the most potent strategy for cognitive restructuring. Further research is needed that analyses these connections more closely.

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Veröffentlichungen

Wessels T, van Tulder MW, Sigl T, Ewert T, Limm H and Stucki G
What predicts outcome in non-operative treatments of chronic low back pain? A systematic review. Eur Spine J Online First: 31.03.06, DOI 10.1007/s00586-006-0073-4.

Limm H, Wessels T, Rackwitz B, John J, Freumuth R, von Garnier K, Ewert T, Stucki G
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München, den 04.04.2006