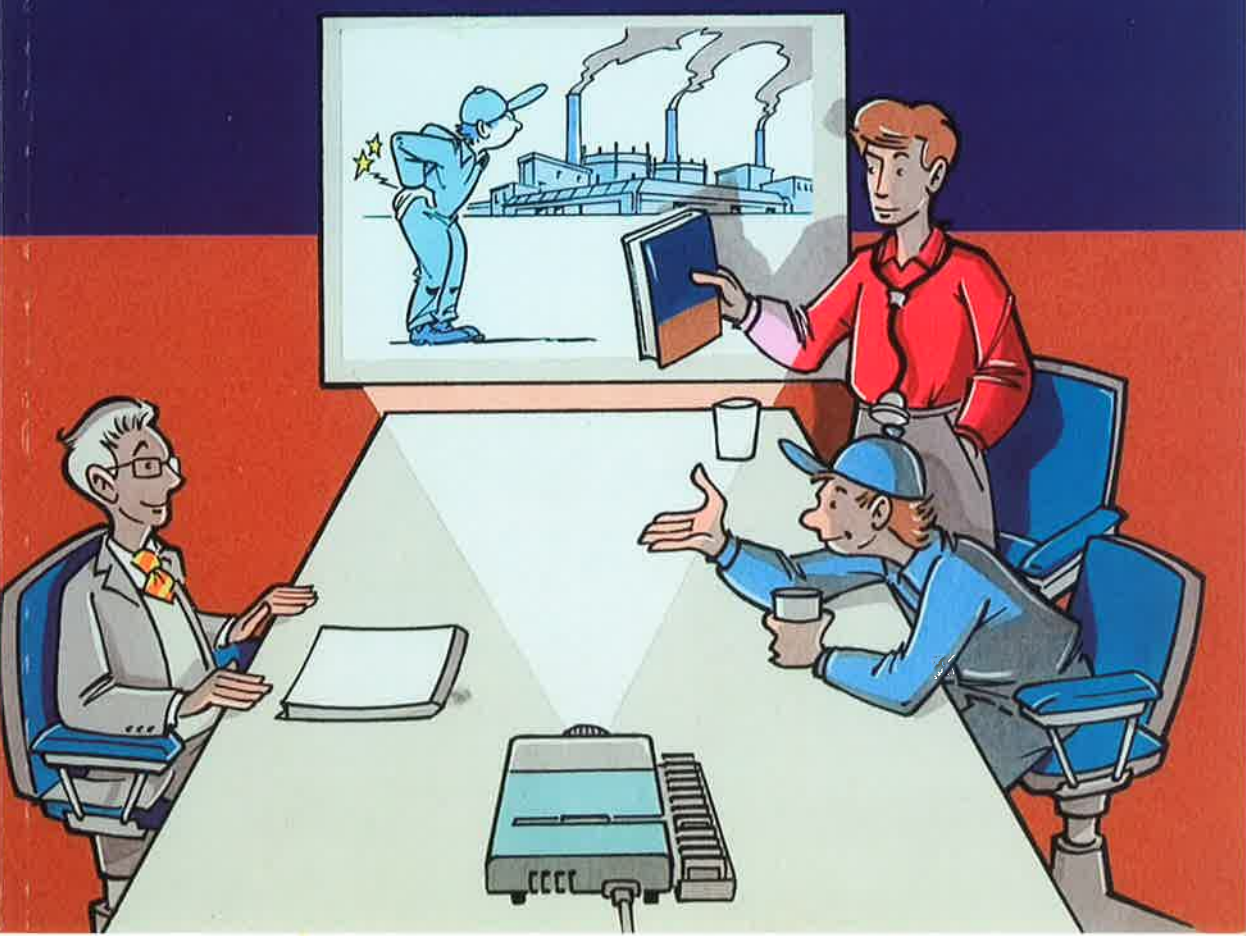
Han Anema

Low back pain, workplace intervention & return-to-work



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The study presented in this thesis was performed at the Institute for Research in Extramural Medicine (EMGO Institute) of the VU University Medical Center and TNO Work and Employment. The EMGO Institute participates in The Netherlands School of Primary Care Research (CaRe), which was acknowledged in 1995 by the Royal Netherlands Academy of Arts and Sciences (KNAW).
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Low back pain, workplace intervention & return-to-work

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door

Johannes Regnerus Anema

geboren te Steenwijk

promotoren: prof.dr. W. van Mechelen
prof.dr.ir. P.M. Bongers
prof.dr.ir. H.C.W. de Vet

Contents

Chapter 1 Introduction

A 33-year old nurse working in a hospital is presenting with low back pain (LBP) to her general practitioner (GP). The pain has started 4 weeks ago when she was lifting a heavy patient. The pain is located above the buttocks and is radiating into the left leg until the foot. There are no other symptoms. The findings during physical examination are: Limited flexion of the lower spine, Straight Leg Raising (SLR) is negative, no paresis of the muscles of the leg, tendon reflexes are normal and symmetrical. The medical diagnosis of the GP is 'non-specific LBP'. He advises the patient to avoid excessive bed rest and stay active. The GP gives the patient pain medication (paracetamol) according to the GP-guideline. Because the pain is not relieved after 2 weeks, the patient returns to her GP. The GP refers the worker to a physiotherapist for exercise therapy. Because the pain in the leg is not responding to the therapy, the physical therapist asks the GP to send the patient to a neurologist to exclude compression of the nerve root L5. The GP repeats physical examination and finds a light paresis of the dorsal flexor muscles of the left foot. After history taking, examination and a MRI, the neurologist can not find any indication for nerve root compression. The patient asks the GP whether she can go to work because she is now already two weeks off work. The GP advises the worker to return on light duties. The worker asked her employer for light duties. However, the employer questions the need of modified work. On request of the employer, the patient is also invited by the occupational physician (OP) of the hospital. The OP diagnoses non-specific LBP and advises to return-to-work irrespective of the pain because working would not damage her back. The OP asks if there are any obstacles in the workplace to return-to work. The worker answers that she can't lift patients or stand bending forward when she is washing a patient. The OP wonders whether and when he should advise modified work, or a physical exercise program? Or maybe he should advise both?

Occupational Low back pain (LBP)[1] is the most common disorder in industrialised countries and is frequently related to disability and absence from work [1]. The 12 month period prevalence rate of LBP for the working population in the Netherlands is estimated to be around 44.4% for men and 48.2% for women [2]. In addition, 7% of the Dutch working population is yearly reporting sick due to LBP [3]. Usually, the sickleave duration due to LBP is very short [4]. Frank et al[4]. divided sickleave duration due to LBP into three phases: acute phase (until 4 weeks of sickleave duration), subacute phase (4-12 weeks) and chronic phase (12 weeks and longer). A few workers with LBP are sicklisted for 3 months or more. However these workers are at serious risk for permanent occupational disability [4,5]. Therefore, effective interventions for LBP aimed at return-to-work are needed to prevent permanent occupational disability.

Questions about treatment effects of clinical and workplace interventions for occupational LBP are frequently asked by treating and occupational health care

[1] This thesis is directed to the consequences of LBP for work When the term 'Occupational LBP' is used, LBP in workers is meant irrespective there is a causal relationship between LBP and work.

professionals (OP, GP, medical specialists, ergonomists, physical therapists) and researchers as well as by workers and employers. In the following chapters of this thesis the following questions will be addressed.

Questions asked:

By the treating physician/therapist (GP, physical therapist or neurologist): What is the role of treating physicians with respect to return-to-work when they are treating workers with chronic LBP?

It is stated in literature that usual medical care of treating physicians for LBP may lead to unnecessary long absenteeism or disability [6]. Treating physicians e.g. are thought to have too little information about the physical demands of the job to make an appropriate decision when and how the worker can return-to-work [7]. In addition, it is stated that communication between treating physicians and OPs is poor, leading to delayed return-to-work [8,9,10]. However, there are to date no systematic studies about the role of the treating physician with respect to return-to-work in a well described population [11]. Therefore, a national cohort study was conducted (Chapter 2) to investigate the role of usual medical care of treating physicians and communication between OPs and treating physicians with respect to return-to-work of workers sicklisted for 3-4 months due to LBP.

By the employer: Do workers with ergonomic interventions return to work more quickly for a long-lasting period compared to workers without these interventions?"

Ergonomic interventions are frequently advised by OPs for return-to-work after LBP. Ergonomic interventions can be directed to the workplace or equipment design as well as directed to the work organisation, e.g. modified work/job tasks or restricted duties/hours [12]. There is limited evidence that (temporary) modified duties can facilitate return-to-work and reduce sick leave [13]. Conversely, in recent reviews a lack of modified work is mentioned as a risk factor for long-term disability [14,15]. A large multinational cohort study (Chapter 3) was conducted to study the occurrence and effectiveness of different kinds of ergonomic interventions on return-to-work. The study population comprised a multinational cohort with workers from six countries, who were sicklisted for 3-4 months due to LBP. Follow-up lasted up to two years after the first day of sickleave. The central research question was: "Do workers with ergonomic interventions return to work more quickly for a long-lasting period compared to workers without these interventions?"

By researchers: We are going to conduct a RCT on the effectiveness of four treatment options for occupational LBP: Workplace intervention (1) Clinical intervention (2) a combination of both interventions (3) and usual care (4). What are important aspects in the design of this study to answer the research questions?

A promising intervention strategy for return-to-work of workers sicklisted due to LBP is the multidisciplinary rehabilitation model developed and evaluated in a randomized

controlled trial (RCT) by Loisel et al. in Canada [16,17]. This model includes both workplace and clinical interventions for return-to-work after LBP.
Important issue is whether and how the Canadian study design and interventions have to be adjusted to be successfully applied another country, with a different health care and social security system. For example, Occupational Health Care in the Netherlands is delivered by the patient's own OP always in the setting of a private Occupational Health Service (OHS). In Canada, occupational care is delivered by the worker's GP. Also return-to-work interventions and wages in the Netherlands must be paid by the employer for the first 2 years of sickleave, regardless the cause of LBP. Chapter 4 describes how the Canadian interventions and study design were adjusted to the Dutch socio-economic context.

By workers and their occupational health professionals: How is the workplace intervention and its implementation evaluated by LBP-patients and their occupational health professionals?
Little is known about the content and implementation of ergonomic interventions applied in return-to-work-programs [13]. Westgaard and Winkel [18] concluded that future ergonomic intervention research should put more focus on the (description of the) intervention process to improve our understanding of barriers and facilitators to the implementation of ergonomic interventions. Employers and workers sometimes have conflicting interests in the application of ergonomic interventions. A promising method to negotiate necessary ergonomic interventions is Participatory Ergonomics (PE). In addition to the traditional ergonomic interventions, PE is based on active participation and strong commitment of both the workers and the management in the process to identify risk factors in the workplace, and to choose the most appropriate solutions for these risks [19]. PE-programs have been reported in the literature as an effective method for the prevention of musculoskeletal disorders, resulting in a decrease in musculoskeletal symptoms and work absenteeism rates in companies [20,21,22].
Chapter 5 comprises a pilot study describing the implementation of an intervention based on methods used in PE, however aimed at return-to-work after LBP. The implementation of ergonomic interventions (content, applicability, compliance, satisfaction, barriers, and proportion of interventions implemented) was evaluated for both the LBP-patients and their occupational health professionals.

By the OP: Should I advise a workplace intervention or should I simply follow the current occupational guideline?
Workplace interventions are widely advised by OPs as a return-to-work intervention after LBP. Although there is general consensus that workplace interventions may reduce time to return-to-work, evidence is based on limited studies mostly without a methodologically rigorous design [23,24]. In addition, there is consensus, but no evidence, that co-operation between all stakeholders involved in the return-to-work process is needed [5,25].

An intervention strategy shown to be effective for workers sicklisted due to LBP is the workplace intervention developed and evaluated in a randomized controlled trial (RCT) by Loisel et al. in Canada [16]. This workplace intervention consists of a workplace assessment and work modifications. It involved all major stakeholders in the process that lead to the actual interventions. The results of the study of Loisel et al. showed statistically significant positive effects of this intervention on sickleave, in comparison with usual care [17].
In Chapter 6 the results of a RCT are presented evaluating a Dutch workplace intervention, derived from the Canadian intervention. The question was whether the promising results of the study of Loisel et al. could be repeated in a RCT in another country, with a different health care and social security system.

By the OP and the physical therapist: Should I advise a worker sicklisted 8-10 weeks due to LBP a clinical intervention or should I simply follow the current occupational guideline?
Clinical interventions are often advocated for workers with sub acute non-specific LBP. A promising clinical intervention is a graded activity intervention (GA). GA intervention is a physical exercise program, based on operant-conditioning behavioral principals and aimed at improved functioning and return-to-work, regardless whether the pain persists. GA resulted in positive effects on return-to-work after sub acute LBP in blue collar workers in two large companies [26,27]. The question is whether GA is also effective in a working population covering industry, health care and services, which is more representative for the Dutch working population. In Chapter 7 we present the results of a pragmatic randomized controlled trial, in which workers are assigned to GA applied after 8 weeks of sick leave as part of a multistage return-to-work program, or to usual care according to the OP-guidelines [28].

By the occupational physician: Is a clinical, or a workplace intervention, or both, as part of multidisciplinary rehabilitation (more) effective for occupational LBP?
Although clinical interventions as well as workplace interventions are frequently advocated for sub acute occupational LBP, the effectiveness of these interventions in multidisciplinary rehabilitation have not yet been established. A recent Cochrane review [29], based on only two studies, concluded that multidisciplinary rehabilitation including clinical and workplace interventions is promising, but that there is a need for high-quality randomized controlled trials assessing the effectiveness of both interventions together and separately.
In Chapter 8, the effectiveness of a clinical and a workplace intervention separately and in combination, was evaluated for occupational LBP in a RCT. The interventions were derived from the Canadian study [17,18] and adjusted to the Dutch socio-economic context. Chapter 8 focusses also on the question whether the clinical intervention, the workplace intervention, or both were (more) effective for occupational LBP.

Occupational Medicine in the Netherlands plays an important role in reducing occupational disability. Most interventions in occupational medicine however are still not evidence based, therefore the scientific development of occupational medicine is needed [30]. This thesis is aimed to evaluate decisions to be taken in daily Occupational Health Care. At the end, this thesis tries to answer the following key questions: What is the optimum content of multidisciplinary rehabilitation for subacute LBP to prevent occupational disability? Which key stakeholders have to be involved in multidisciplinary rehabilitation?

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Chapter 2 Ineffective disability management by doctors is an obstacle for return-to-work: a cohort study on low back pain patients sicklisted for 3-4 months.

Anema JR, Van Der Giezen AM, Buijs PC, Van Mechelen W. *Published in Occup Environ Med. 2002 Nov;59(11):729-33.*

Abstract

Objectives To determine obstacles for return-to-work in disability management of low back pain patients sicklisted for 3-4 months

Methods A cohort of 467 low back pain patients sicklisted for 3-4 months, was recruited. A questionnaire was sent to their occupational physicians (OPs) concerning the medical management, obstacles to return-to-work and the communication with treating physicians.

Results The OPs of 300 of 467 patients participated in this study. In many cases OPs regarded the clinical waiting period (43%), duration of treatment (41%) and view (25%) of the treating physicians as obstacles for return-to-work. Psychosocial obstacles for return-to-work such as mental blocks, a lack of job motivation, personal problems and conflicts at work were all mentioned much less frequently by OPs. In only 19% of the patients was there communication between OP and treating physician. Communication almost always entailed an exchange of information and less frequently an attempt to harmonize the management policy. Surprisingly communication was also limited, when OPs felt that the waiting period (32%), duration of treatment (30%), and view (28%) of treating physicians inhibited return-to-work. Communication was significantly associated with the following obstacles for return-to-work: passivity with regard to return-to-work and clinical waiting period; Adjusted Odds Ratios (OR) were 3.35 (95% CI=1.64-6.82) and 2.23 (95% CI=1.04-4.79), respectively.

Conclusions Medical management of treating physicians is often an obstacle for return to work regarding low back pain patients sicklisted for 3-4 months, in the opinion of OPs. Nevertheless communication between OPs and the treating physicians in disability management of these patients is limited. More attention to prevention of absenteeism and bilateral communication is needed in medical courses.

Keywords: back pain, disability management, return-to-work.

Introduction

Managed care and disability management of sicklisted patients is a topic of discussion.[1] It is stated frequently that ineffective medical care of patients may result in a serious risk of unnecessarily (long) absenteeism, iatrogenesis and even permanent disability. According to Bruckman barriers for return-to-work or even iatrogenesis can originate from the treating physician; he described several ineffective medical practices that possibly are delaying functional recovery.[2]

Unnecessary long absenteeism or iatrogenesis can be caused also by fragmented and poorly co-ordinated medical care of sicklisted workers.[3] [4] A common reason for unnecessary lost days is that treating physicians have too little information about the physical demands of the job to make an appropriate decision when and how the worker can return-to-work.[5] In addition, many treating physicians do not recognise the work-relatedness of diseases, because they have no training in occupational medicine.[5][6][7] For these reasons co-operation between general practitioners (GPs) and occupational physicians (OPs) is recommended in recently published occupational health guidelines for the management of low back pain.[8] Opinion surveys in both the UK and the Netherlands indicate however that the co-operation between GPs and OPs in disability management is poor.[9] [10]

Although it is stated often that medical practices of treating physicians can be obstacles for return-to-work and that co-operation in disability management between OPs and treating physicians is poor, there appears to be no systematic study regarding these issues. Consequently, the objective of this study is to investigate: 1. Obstacles for return-to–work in general and in medical management; 2. Occurrence and content of communication in disability management between OPs and treating physicians regarding low back pain patients. In order to obtain an accurate picture of the obstacles for return-to-work and communication in disability management, we investigated data on the medical management of 300 low back pain patients who were sicklisted for 3-4 months.

Study design and Methods

This Dutch research project formed part of the international comparative study "Work Incapacity and Reintegration".[11] This was a prospective cohort study in which patients who were sicklisted for 3-4 months due to low back pain were followed up for two years in six countries. For this international comparative study, a cohort of patients was selected on the basis of the following inclusion criteria,[12] i.e.:

1. Being sicklisted and receiving full or partial compensation for at least 3 months due to low back pain (ICD-9 codes 721, 722, 724). Patients with low back pain due to fracture, inflammation or malignancy of the spine and patients with spinal surgery in the last year were excluded;
2. Having a paid job and an employer who has contracted an Occupational Health and Safety Services (OHS);
3. Age between 18 and 60 years.

The recruitment of the Dutch cohort was performed in co-operation with the Social Security administrations. A consecutive series of 1890 patients with back pain was selected in the period October 1994 to May 1995. These patients were asked by mail to participate in the study. 1087 (58%) patients agreed to participate and signed a letter of authorisation, drawn up according to the guidelines of the Royal Dutch Medical Association, permitting their OP to make available the data to be used for this study. Non-response analysis showed that there was hardly any difference between the response group and the non-response group with regard to demographic characteristics.[12] The inclusion criteria were checked by an answer form, filled in by the patients themselves. 620 patients did not meet the inclusion criteria, finally resulting in a cohort of 467 patients.
Between January and June, 1995 (after three months of absenteeism due to back pain), a questionnaire was sent to the OP of every patient that was included in the cohort. In this questionnaire questions were asked regarding the medical management of the patient concerning the diagnosis (ICD-9 codes), treatment, functional disabilities, factors influencing return-to-work (on a three-point scale: a factor has an inhibiting, promoting, or no role in return-to work), communication with the treating physicians and the content of this communication (on a two point scale: a subject was discussed between the OP and treating physician, or not discussed). When included in the cohort at 3 months of sickleave, every patient was asked about low back pain related and work related characteristics like pain intensity (Von Korff), back pain history, working hours and working status.

Statistical methods

All presented proportions have been calculated after excluding missing data. Factors influencing return-to-work, according to the OP, were dichotomised: 1. Factors inhibiting return-to-work 2. Factors promoting return-to-work, or factors which played no role in return-to-work. Results of univariate analysis are presented as odds ratios (odds of a communication regarding participants identified by a factor inhibiting return-to-work, compared with the odds of a communication regarding participants without that inhibiting factor). The corresponding 95 percent confidence intervals (95% CI) for the odds ratios (OR) are calculated.
Multiple logistic regression analysis was used to identify independent predictor variables (significant at $p< 0.05$ level). Potential predictor variables were those listed in table 3. Additional variables examined were age, gender and working status when the patient was included in the cohort. Results of multiple logistic regression analysis are presented as odds ratios, adjusted for the other variables i.e. all other inhibitory factors, age, gender and working status. Analysis was carried out using SPSS for Windows, release 7.5, 1997.

Results

The OPs of 300 (64%) of the 467 patients in the cohort, participated in the study. They completed the questionnaires at an average of 4.5 months after the first day of

absence from work. Non-response analysis showed that there was no difference between the subgroup of patients for whom the OP had returned the questionnaire and the total cohort with regard to either the demographic characteristics or the patient-reported aspects of the medical treatment. The characteristics of the 300 patients sicklisted for 3-4 months with low back pain, are presented in table 1. OPs who had not returned the questionnaire were questioned by telephone in order to get insight into reasons of their non-response. They gave as the main reason for not responding lack of time or the absence of the patient's medical file (due, for example, to reorganisation of the OHS or a switch of the patient's company to another OHS).

TABLE 1. Baseline characteristics of the cohort of patients sicklisted for 3-4 months

	Cohort (n=300)
Baseline characteristics	
Patient characteristics	
Mean (sd) age in years	39.4 (9.6)
Sex (% male)	58.3
Low back pain related characteristics	
Diagnosis	
% aspecific low-back pain	47.3
% (suspicion of) root compression	51.7
History of low back pain (% yes)	72.0
Mean (sd) pain intensity (Von Korff)	5.7 (2.2)
Work related characteristics	
Mean (sd) working hours	36.1 (14.8)
Working status (% (parttime) at work)	30
Work related back pain (% yes)	73

The OPs reported a number of obstacles for return-to-work in the 300 patients sicklisted due to low back pain (see figure 1). The OPs felt that the duration of treatment and the waiting time before treatment had had an inhibitory effect on the return-to-work, in 43% and 41% of the cases, respectively. According to the OPs, the view of the treating physicians regarding the return-to-work of the patient was an inhibitory factor in 25% of the cases. In the opinion of the OPs 33 % of the cases demonstrated a passive attitude with regard to the return-to-work. Psychosocial factors such as mental blocks (16%), a lack of job motivation (14%), personal circumstances (9%) and conflict at work (7%) formed an obstacle for the return-to-work much less frequently, in the opinion of the OP.

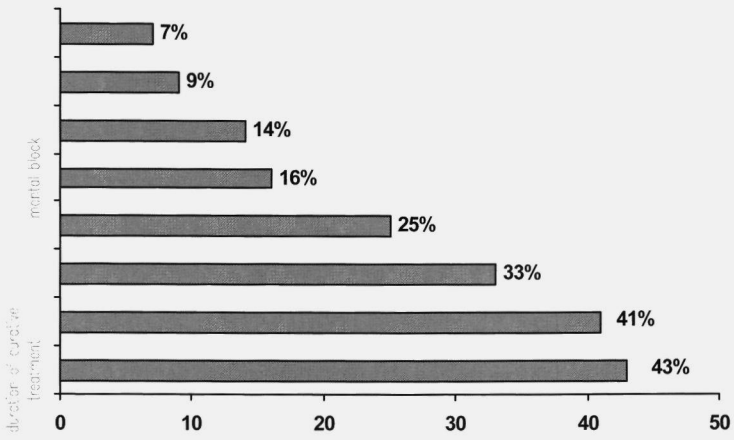

FIGURE 1. Factors inhibiting the return-to-work in low back pain patients (n=300) sicklisted for 3-4 months, in the opinion of their occupational physicians.

In 56 (19%) of the cases there was communication between OP and treating physician; for another 14 cases the OP reported to be planning to contact the treating physician in the immediate future. There was thus either actual or intended communication between OP and treating physician in a total of 70 cases (24%). In 43 of these cases the communication consisted of consultation with the general practitioner, in 23 cases with a specialist, and in 20 cases with a physiotherapist. The OPs indicated that communication with a treating physician was almost always for the purpose of requesting and exchanging information on the diagnosis, the treatment and the prognosis. Other subjects, such as an attempt to reach a common policy on case-management, were less often subject of the communication between the OP and the treating physician (see table 2).

Finally, we investigated whether there was more communication between the OP and the treating physicians in the presence of obstacles for return-to-work (see table 3). Such communication was limited in general, but occurred most frequently in the presence of psychosocial obstacles: mental blocks (36%), a lack of job motivation (40%) and passivity with regard to return-to-work (39%); Communication was even more limited, when OPs felt that the waiting period (32%), duration of treatment (30%), and view (28%) of treating physicians inhibited return-to-work. We used multiple logistic regression analysis to identify independent predictor variables for the occurrence of communication. Communication between OPs and treating physicians was significantly associated with the following obstacles for return-to-work: passivity with regard to return-to-work and clinical waiting period; Adjusted Odds Ratios (OR) were 3.35 (95 % CI=1.64- 6.82) and 2.23 (95% CI=1.04-4.79) respectively. All

other inhibiting factors, gender, age and working status were not significantly associated with communication.

TABLE 2. Reasons for consultation by the OP of the treating physician in 70 low back pain patients sicklisted for 3-4 months (n=300).

Reason for consultation	Number of patients (%) (n=70)*
To obtain information on the diagnosis	61 (97)
To obtain information on the treatment given by the treating physicians	59 (92)
To obtain information on the prognosis for medical recovery	51 (82)
To obtain information on the point of view regarding the patient	38 (60)
To harmonise the policy regarding the patient	37 (59)
To obtain information on the functional capacity of the patient	35 (57)
To obtain information on the prognosis with regard to work disability	33 (52)
To accelerate the diagnosis and/or treatment	22 (34)
To obtain information on the psychosocial functioning of the patient	12 (19)

*On each reason for consultation, 6-8 occupational physicians failed to answer this question; the numbers and percentages in this column have been calculated after excluding the missing data.

Discussion

To our knowledge, this is the first study to investigate obstacles for return-to-work by ineffective disability management of treating physicians, based on data concerning the medical management of a cohort of 300 low back pain patients. Till now the literature regarding this subject has been based principally on opinions of authors.[1][2][3][4][5][6][7] Surveys have shown that there are differences in the perception of frequency with which communication between OPs and GPs occurred.[9] [10] There is however no systematic study on the communication between treating physicians and occupational physicians in a well-described patient population.

Factors inhibiting return-to-work

In our study it was found that OPs considered the inhibitory effect of treating physicians to be of great influence on return-to-work of low back pain patients sicklisted for 3-4 months. In the opinion of the OPs, psychosocial factors only play a secondary role in a delay in return-to-work in these patients.[13] [14] Treating physicians should pay more attention in the medical management of their patients to the prevention of absenteeism and disability, according to OPs. This finding is supported by many publications about medical practices delaying return-to-work in patients with back pain. For example, treatment with exercise therapy in cases of acute low back pain has shown to prolong absenteeism.[15][16][17] Diagnostic labelling of patients presenting with back pain can also have detrimental effects on outcome.[8] [18] Van Wolde showed that in the Netherlands in general, absenteeism from work is prolonged by the long waiting periods for consultation of orthopaedic

surgeons and neurologists.[19] Finally, it has been shown that in cases of back pain therapeutic recommendations for (bed) rest or (undesirable) pain-related advice may confirm the patient in his pain-avoiding behaviour and thus inhibit return-to-work and prolong absenteeism.[17] [20]

TABLE 3. Proportions of cases leading to communication when the factor was inhibitory in low back pain patients sicklisted for 3-4 months, in the opinion of the occupational physician (N=300).

Factor*	*No of cases in which the factor was assumed inhibitory*	*Proportion of the cases leading to communication (%)*	*Univariate Odds Ratio° (CI)*	*Adjusted Odds Ratio° (CI)*
Clinical waiting period	112	36 (32)	2.16 (1,23-3.79)	2.23 (1.04-4.79)
Duration of curative treatment	117	35 (30)	1.81 (1.03-3.17)	1.06 (0.47- 2.40)
View of treating physician	67	19 (28)	1.41 (0.75-2.65)	0.96 (0.43- 2.11)
Employee is passive /non-co-operative	92	36 (39)	3.10 (1.77-5.42)	3.35 (1.64-6.82)
Job motivation	40	16 (40)	2.31 (1.15-4.67)	1.20 (0.43-3.33)
Mental block	44	16 (36)	2.10 (1.05-4.19)	1.67 (0.59-4.71)
Personal circumstances	25	5(20)	0.80 (0.28-2.20)	0.38 (0.10-1.45)
Conflict at work	19	6(32)	1.50 (0.55-4.12)	0.69 (0.19-2.59)

* On each factor, 22-34 occupational physicians failed to answer this question; the proportions in this column have been calculated after excluding the missing data.

° Association between communication and inhibitory factors is presented as Odds Ratio (OR) with its 95% confidence interval (CI). Results of multiple logistic regression analysis are presented as odds ratios, adjusted for the other factors i.e. all other inhibitory factors, age, gender and working status

Frequency and content of communication

In our study, communication between the OPs and the treating physicians regarding low back pain patients sicklisted for 3-4 months, was limited. Our findings are in agreement with those of two surveys regarding the perception of the frequency of communication between GPs and OPs.[9] [10] According to both surveys the lack of

regular communication can be explained by misunderstandings of treating physicians about the role and responsibilities of OPs.[9] [10]
In our study the content of the communication almost always concerned the informative exchange of factual data; communication in a broader sense, such as harmonization of the case-management policy, occurred much less frequently. Our results regarding the content of communication support the findings of the above mentioned Dutch survey [9] as well as the outcome of an audit on the communication between one OP and GPs carried out in the UK.[21] However, a limitation of our and the other studies is that the communication between OPs and treating physicians may be varied also in terms of type and nature. The possible explanation for the mainly informative exchange of factual data may be the legal rules of behaviour concerning the exchange of medical data in work-related matters. These rules were constructed for privacy and confidentiality reasons [5] and do not allow a "free" exchange of information. The point of departure for these rules is that treating physicians may provide only factual data to OPs in response to concrete questions and only with written consent of the patient.[22]

Lack of communication regarding obstacles for return-to-work
According to their respective clinical guidelines on back pain management OPs and treating physicians have a common goal: the prevention of dysfunction and prolonged disability.[8][23][24] Furthermore, there is moderate evidence that communication and co-operation between OPs and GPs regarding workers with low back pain is fundamental for improvement of clinical and occupational health management and its outcomes.[8] According to the Dutch guidelines on the management of low back pain, the OP should contact the treating physicians if in his opinion the medical management is inadequate, or is inhibiting return-to-work.[24] [25] In contrast to what one might expect, our study has shown that only a small proportion of the OPs who reported that treating physicians had an inhibitory effect on return-to-work, actually sought contact. There are two possible explanations for this lack of communication in the presence of obstacles in the medical management for return-to-work: 1. It is not yet common practice of OPs to debate the treatment persued by their colleagues, although in our opinion by doing so the OP fails to co-ordinate adequately the disability management of the patient; 2. In practice, the treating physician and the OP still have different goals instead of common goals, when treating the same patient. The latter explanation seems in our opinion the most likely explanation for this phenomenon; while the treating physician concentrates on the diagnosis and treatment of back pain, the OP attempts to limit the level of dysfunctioning resulting from the back pain. In order to prevent obstacles for return-to-work by ineffective disability management of doctors more education regarding this issue in medical course is needed to agree on common goals in medical management for treating physicians and OPs and to increase bilateral co-operation.

Conclusions

1. According to OPs the clinical waiting period, the duration of treatment and the view of the treating physicians are obstacles for return-to-work of many low back pain patients sicklisted for 3-4 months. 2. Nevertheless the co-operation between OPs and the treating physicians in disability management of these patients is limited and is directed primarily at exchange of information, rather than at harmonisation of management policy.

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Chapter 3 The effectiveness of ergonomic interventions on return-to-work after low back pain; a prospective two year cohort study in six countries on low back pain patients sicklisted for 3-4 months.

Anema JR, Cuelenaere B, van der Beek AJ, Knol DL, de Vet HC, van Mechelen W.
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Abstract

Objectives To study occurrence and effectiveness of ergonomic interventions on return-to-work applied for workers with low back pain (LBP).

Methods A multinational cohort of 1631 workers fully sicklisted 3-4 months due to LBP (ICD-9 codes 721, 722, 724) was recruited from sickness benefit claimants databases in Denmark, Germany, Israel, Sweden, the Netherlands and the United States. Medical, ergonomic and other interventions, working status and return-to-work were measured using questionnaires and interviews at three months, one and two years after the start of sickleave. Main outcome measure was time to return-to-work. Cox's proportional hazards model was used to calculate hazard ratios regarding the time to return-to-work, adjusted for prognostic factors.

Results Ergonomic interventions varied considerably in occurrence between the national cohorts: 23.4% (mean) of the participants reported adaptation of the workplace, ranging from 15.0% to 30.5%. Adaptation of job tasks and adaptation of working hours was applied for 44.8% (range 41.0%-59.2%) and 46.0% (range 19.9%-62.9%) of the participants, respectively. Adaptation of the workplace was effective on return-to-work rate with an adjusted hazard ratio (HR) of 1.47 (95% CI 1.25-1.72; $p<0.0001$). Adaptation of job tasks and adaptation of working hours were effective on return-to-work after a period of more than 200 days of sickleave with an adjusted HR of 1.78 (95% CI 1.42-2.23; $p<0.0001$) and 1.41 (95% CI 1.13-1.76; $p=0.002$), respectively.

Conclusions These results suggest that ergonomic interventions are effective on return-to-work of workers long-term sicklisted due to LBP.

Introduction

Occupational disability due to LBP is a multifactorial problem.[1] [2] Many studies suggest that individual factors as well as work-related factors are predictive for return-to-work after sickleave due to LBP.[3][4][5][6][7][8][9] In two recent reviews a lack of modified work is mentioned as a risk factor for long-term disability.[2] [10] Although work-related factors are predictive for return-to-work, to date most studies evaluated the effectiveness of medical interventions directed to the individual and not directed to the work environment.[11] [12] The review by Krause et al.[13] suggested that ergonomic interventions might be effective in the occupational rehabilitation of sicklisted workers. However, there is little evidence about the effectiveness of these interventions on return-to-work. Staal et al[11] recently concluded in their review that ergonomic interventions for the return-to-work of patients sicklisted due to LBP were only included in three RCTs.[14][15][16] One of these studies[14] even suggested that ergonomic interventions are more effective on return-to-work than clinical interventions.

Sickleave and disability due to LBP is a common, cross-national problem. Because the disability rates and costs due to long-term sickleave are increasing in many industrialised countries, the International Social Security Association (ISSA) initiated a multinational study to identify successful medical, ergonomic and social security interventions for the return-to-work of workers long-term sicklisted due to LBP.[17] Hanson et al reported that medical interventions in this multinational cohort study were not effective on return-to-work.[18]

The objective of our study was to study the occurrence and effectiveness of different kinds of ergonomic interventions on return-to-work within two years after the first day of sickleave. The study population comprised a multinational cohort with workers from six countries who are sicklisted for 3-4 months due to LBP. The central question was: "Do workers with ergonomic interventions show earlier return-to-work for a long-lasting period than workers without these interventions?"

Methods

Study design

This prospective 2-year cohort study comprised six cohorts of workers sicklisted due to LBP in the countries Denmark, Germany, Israel, the Netherlands, Sweden and USA. Because the study had a core design comprising several basic features[8][17][18][19], it was possible to integrate the national datasets to a homogenous internationally standardised dataset for cross-national analysis.[20]

Cohort recruitment and data collection

A consecutive series of 2825 workers fully sicklisted 3-4 months due to LBP (ICD-9 codes 721, 722, 724) were recruited in the period May, 1995 to September, 1996, through databases of sickness benefit claimants in the participating countries.[17] These workers were asked to participate and to sign a letter of authorisation,

permitting their data to be used for the cohort study. At 3-4 months (baseline), one (T2) and two years (T3) after the first day of sickleave data were collected using questionnaires and interviews.[18] The response rates at T2 and T3 were 85% and 77%, respectively. Non-response analysis showed that there were no major differences between the response group and the non-response group with regard to demographic characteristics.[18]
Because most ergonomic interventions could not be provided unless the worker returned to work, we studied the sample (n=1631) comprising participants, who have ever resumed work -for a long or short period- in the two years after the first day of sickleave. Of these participants 30-33% had missing data (on sickleave duration, work status, ergonomic interventions and confounding factors) in multivariate analyses. The multivariate samples concerning the studied ergonomic interventions had similar demographic, work and back pain characteristics (age, gender, pain intensity, sciatica, Hannover ADL and working hours) to the samples of the participants with missing data, except for gender (57.2-57.8% vs. 46.6-47.4% male) and sciatica (73.2-73.4% vs. 66.6-67.2%). However, both gender and sciatica were not identified as confounders in the multivariate analyses.

Interventions

Ergonomic interventions
Ergonomic interventions were selected based on two principles: the ergonomic intervention should be applied in every participating country and the ergonomic intervention should be applied as a stand-alone. The following three ergonomic interventions were identified: Workplace adaptation, adaptation of job tasks, and adaptation of working hours. Each ergonomic intervention was measured as a dichotomous variable: it was applied or not.[20] Pearson correlation coefficients between all ergonomic interventions were calculated and used to identify to what extent different ergonomic interventions coincided. All Pearson correlation coefficients of combinations of the selected ergonomic interventions were less than 0.4. Therefore, we examined them separately. The three ergonomic interventions are clarified in table 1.

TABLE 1. Definitions of workplace interventions

Workplace adaptation The realisation of adaptations in workplace including any technical aids, such as a different chair or desk/table, special tools, a lifting aid, an adapted transport during work, etc.
Adaptation in working hours Changes in number and /or pattern of working hours: different shifts, less or more hours ("partial work resumption"), more variation in hours, etc.
Adaptation of job tasks Change of job tasks, including minor changes such as not having to carry things.

Outcomes

Return-to-work

Two outcome measures were collected in the international database: 1. Date of first return-to-work; 2. Working status at T2 and T3. Unfortunately, no information was available about the duration of the initial work resumption. For this reason, return-to-work was defined as 'long-lasting' if a worker was still working at T3. Based on this definition the following dependent variable was calculated: the number of days from first day of sickleave until first date of work resumption resulting in long-lasting return-to-work. This implicates that for workers who did not work anymore at T3, time to return-to-work was censored at T3 in Cox regression analyses.

Potential confounders

Several demographic, health-related and work-related baseline characteristics were derived from the international database[20] and tested as potential confounding factors. It was decided to select only potential confounders, which were measured in all participating countries. Before we adjusted for confounding, the effect of each ergonomic intervention was corrected for the effect of other ergonomic interventions. An overview of all potential confounders, adjusted for in multivariate analysis is shown in table 2. We refer for detailed information about the content and categorisation of these variables to the technical guide of the International Database.[20]

TABLE 2. Listing of potential confounders and effect modifiers, adjusted for in multiple regression analysis

Demographic and patient-related characteristics

- gender, country, age, education and Quetelet Index

Work-related interventions and characteristics

- other ergonomic interventions (adaptation workplace, job tasks adaptation, working hours adaptation, therapeutic work resumption, job training, sheltered workshop)
- patient working hours, patient job duration, firm company size, patient work ability, attitude towards work, physical job demands, social support, job strain (Karasek Theorell's demand-support-control scale).

Health-related characteristics

- general health (subscale of SF-36), active coping, passive coping, co-morbidity (interference with work resumption), pain intensity (von Korff pain intensity scale), pain sciatica, sickleave history due to back pain (in the last year), patient functional limitations (Hannover ADL).

Medical interventions

- surgery, pain medication, passive treatment, manipulation, active treatment (individual or groupwise training, gymnastics, backschool).

Statistical Analysis

Univariate analyses
A Kaplan-Meier survival curve was estimated to describe the univariate relationships between ergonomic interventions and time until first return-to-work. Differences were tested using the log-rank test.

Multivariate analyses
When the Kaplan-Meier analysis showed that Cox's proportional hazards assumption was met, Cox's proportional hazards analysis was used to describe the multivariate associations between each ergonomic intervention and the time to first return-to-work. All potential prognostic factors were checked for confounding. All potential confounders were manually and separately entered into the multiple regression model. A prognostic factor was defined as a confounder if the regression coefficient of the outcome measure changed more than 10% when the factor was entered to the model. When a confounder was identified, this confounder was added to the model and this procedure was repeated until there was not more than 10% change of the regression coefficient. Analyses were performed using the SPSS 10.0 software package (SPSS Inc., Illinois, USA). A prognostic factor was defined as an effect modifier when it had a significant interaction with the intervention at a significance level of $p<0.05$.

Results

Baseline characteristics and return-to-work
The baseline characteristics of 1631 participants in the selected cohort are presented in table 3. These workers all returned to work for at least a short period during follow-up. A total of 1179 out of 1631 workers (72.3 %) were still working at T3 (i.e. 2 years after the first day of sickleave).

Occurrence and timing of ergonomic interventions
As shown in figure 1, the occurrence of different types of ergonomic interventions varied substantially between the national cohorts. All frequencies presented have been calculated for workers who have resumed their work at least for a short period. Ergonomic interventions were more often applied in the cohorts in Israel, the Netherlands, Denmark and USA than in the Swedish and German cohorts.

Adaptation of the workplace was applied for 23.4 % (mean) of the workers in all cohorts during two years after the first day of sickleave, ranging from 15.0 % in the German cohort to 30.5% in the Dutch cohort. Adaptation of job tasks was reported by 44.8% (mean) of the workers (range 41.0% in the American – 59.2% in the Danish cohort). Adaptation of working hours was applied for 46.0% (mean) of the workers, with a range of 19.9%-62.9% in German and Dutch cohort, respectively.

Combinations of ergonomic interventions occurred to a variable degree in the six cohorts. The most common combination was adaptation of job tasks and adaptation of working hours: ranging from 2% and 14% of the cases in the German and Swedish cohorts, respectively, 30-35% in the Danish, Dutch and American cohorts, and up to 52% of the cases in the Israeli cohort. Other combinations of 2 or 3 ergonomic interventions were relatively infrequent: In less than 17% of the working respondents in all cohorts. Exception was the Dutch cohort, in which 2 or 3 different types of ergonomic interventions coincided in up to 33% of the working respondents [17].

TABLE 3. Baseline characteristics of the cohort of participants sicklisted for 3-4 months (n=1631)

	Cohort (n=1631)
Baseline characteristics	
Patient characteristics	
Mean (sd) age (years)	41.1 (9.9)
Gender (% male)	54.3
Low back pain related characteristics	
Sciatica (%)	71.5
History of sickleave due to LBP in the last year (%)	56.8
Mean (sd) pain intensity (Von Korff)	5.5 (2.4)
Mean functional limitations (Hannover ADL; 0-100)	51.6 (23.6)
Work-related characteristics	
Mean (sd) working hours (h)	40.0 (10.9)
Mean (sd) social support [Karasek; 1-4]	3.20 (0.57)
Mean (sd) physical job demands [Karasek;1-4]	1.87 (0.69)
Mean (sd) job strain [Karasek; 0.25-4]	1.06 (0.41)

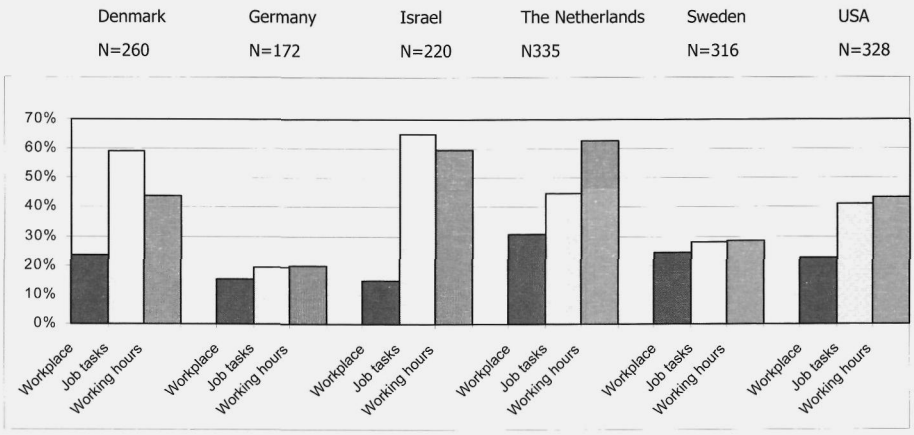

FIGURE 1. Ergonomic interventions in six participating countries applied for % of respondents (n=1631) who were sicklisted 3-4 months due to low back pain and returned to work during the first two years after the start of sickleave.

According to the respondents almost all ergonomic interventions were applied during the first year after the start of sickleave. The application of ergonomic interventions was not measured in relation to the timing of work resumption. Ergonomic interventions could be applied before, during and/or after work resumption. Workplace adaptation, when applied in the first year, found place around the 6th month of sickleave in all participating countries. Adaptation of job tasks was reported in the first year, ranging from 6 months in the Netherlands to 9 months in the US cohort. Adaptation of working hours was applied between 6 months in the Dutch cohort and 10 months in the USA.

Effectiveness of ergonomic interventions

Adaptation of the workplace

In the Kaplan-Meier analysis, the survival curves for workers who received the workplace adaptation and those who did not, differed significantly (log rank test; $p< 0.0001$). The curves are shown in figure 2. In the Kaplan-Meier analysis, the median duration of absence from work in the group with workplace adaptation was 206 days compared to 311 days for the group without this intervention. In the Cox regression analysis (n=1133) the adjusted HR of the return-to-work rates was 1.47 (95% confidence interval 1.25-1.72; $p<0.0001$) in favour of workers with a workplace adaptation. The results of these analyses, as well as the prognostic factors adjusted for in the final multivariate model, are presented in table 4. No significant interaction with the intervention was found.

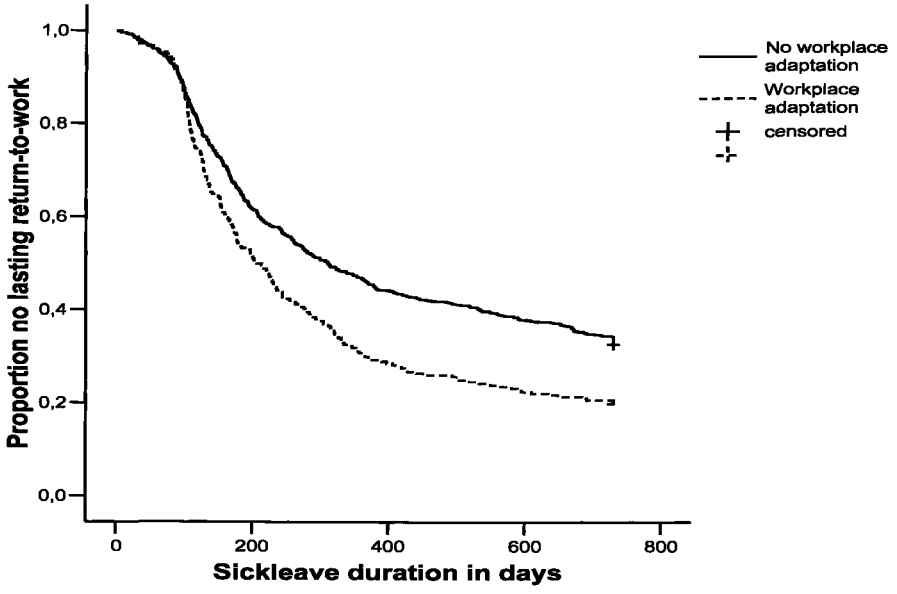

FIGURE 2. Survival curves of absence from work for workers with and without adaptation of the workplace.

Adaptation of job tasks

Based on the Kaplan-Meier analysis, the survival curves for workers who received the adaptation of job tasks and those who did not, did not differ significantly (log rank test; p=0.26). The median duration of absence from work for workers with adaptation of job tasks was 299 days compared to 244 days for workers without this intervention. The curves are shown in figure 3.

Cox's proportional hazards model (n= 1147) was used to calculate adjusted HRs to compare the return-to-work rates of both groups. However, an assumption of Cox's proportional hazards model is that the HR should remain constant over time. This was not the case for this intervention. When looking at the survival curves two different periods could be distinguished regarding the number of days after the first day of sickleave: Until 200 days of sickleave the rate of return-to-work seems to be in favourite of the non intervention group, whereas after this period the rate of return-to-work of the intervention group is higher.

TABLE 4. Results of the survival analyses (Kaplan-Meier and multiple Cox regression analyses)

	Median number of days off work		Log rank test	Unadjusted HR	Adjusted HRs for return-to-work (95% confidence interval), Cox regression	
	Intervention	No intervention	P-value			
Adaptation of workplace	206	311	<0.0001	1.44 (1.24-1.69)	1.47 (1.25-1.72) *	
Adaptation of job tasks	299	244	0.26	1.09 (0.95-1.24)	Workers ≤ 200 days of sickleave	Workers > 200 days of sickleave
					0.78# (0.65-0.95)	1.78# (1.42-2.23)
Adaptation of working hours	270	291	0.02	1.17 (1.03-1.35)	Workers ≤ 200 days of sickleave	Workers > 200 days of sickleave
					1.14° (0.99-1.32)	1.41° (1.13-1.76)

Cox regression analysis for adaptation of workplace, job tasks and working hours was based on n=1133, n=1147, n=1149 workers respectively.

* Adjusted for country, patient functional limitations (Hannover ADL)

Adjusted for other ergonomic interventions, patient work ability, patient job duration, country, physical job demands

° Adjusted for country, patient functional limitations (Hannover ADL), patient work ability, physical job demands

By means of Cox regression analyses with time-dependent covariates, we calculated HRs for workers with 200 and less days of sickleave to the date of first return-to-work and for workers with more than 200 days of sickleave. The results of the analyses, as well as the prognostic factors adjusted for in the final multivariate model, are presented in table 4. Return-to-work rate was in favour of the group without adaptation of work tasks for workers who returned to work within 200 days of sickleave (HR = 0.78; 95% CI 0.65-0.95, p=0.01). However, for workers who returned to work after 200 days the adjusted hazard was 1.78 in favour of the group with adaptation of job tasks (95% CI 1.42-2.23, p<0.0001). No significant interaction with the intervention was found.

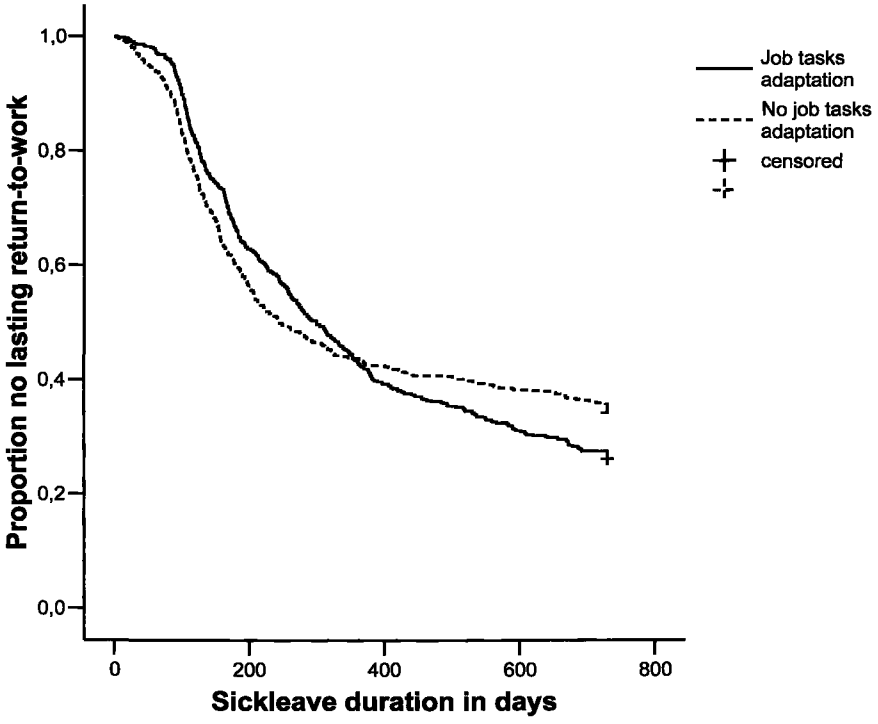

FIGURE 3. Survival curves of absence from work for workers with and without adaptation of job tasks.

Adaptation of working hours

The survival curves for workers who received adaptation of working hours and those who did not, differed significantly (Kaplan-Meier analysis; log rank test; p=0.02). The median duration of sickleave in the group with adaptation of working hours was 270 days compared to 291 days for the group without this intervention. The curves for both groups are shown in figure 4.

Based on the Kaplan-Meier analysis we calculated in the next step the HRs by means of Cox regression analyses with time-dependent covariates, for both the workers with 200 and less days of sickleave and for the workers with more than 200 days of sickleave (table 4). There was no difference in return-to-work rate between the group with and without adaptation of working hours for the workers who returned to work within 200 days of sickleave (HR = 1.14 (95% CI 0.99-1.32, p=0.08). However, for the workers who returned to work after 200 days the adjusted HR was 1.41 in favour of the group with adaptation of working hours (95% CI 1.13-1.76, p=0.002). No significant interaction with the intervention was found.

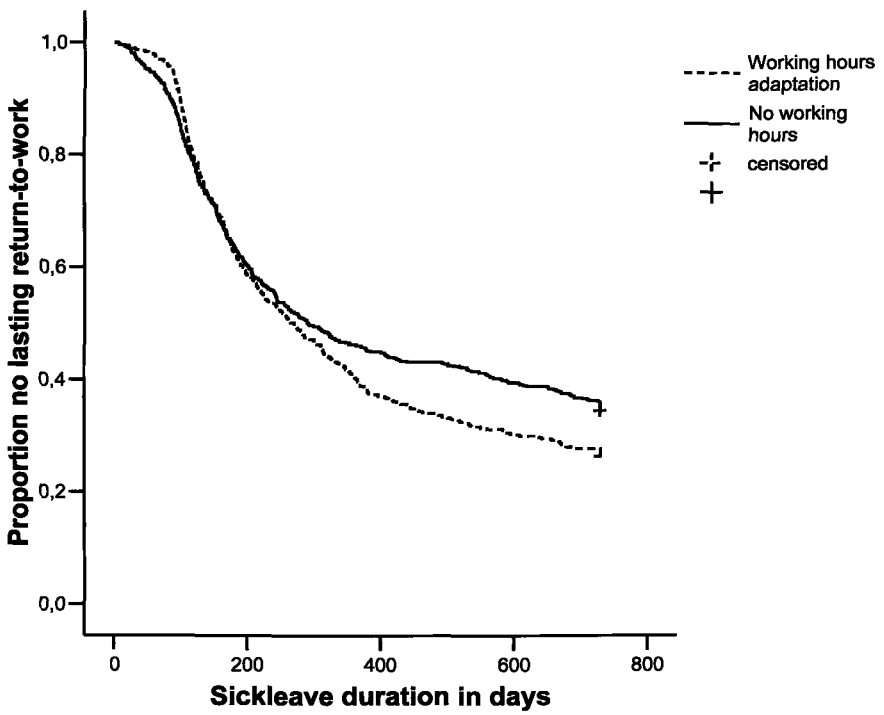

FIGURE 4. Survival curves of absence from work for workers with and without adaptation of working hours.

Discussion

In this paper the two-year follow-up results are presented of a unique multinational prospective cohort study regarding the effectiveness of ergonomic interventions on return-to-work after sickleave due to LBP. The results indicate that ergonomic interventions have a beneficial effect on return-to-work. Workplace adaptations and, on the long-term, adaptation of job tasks and working hours improved return-to-work rate.

Strengths and weaknesses of the study

A principal strength of this study is that, to our knowledge, this is the first prospective cohort study that describes the occurrence and effectiveness of different types of ergonomic interventions for the occupational rehabilitation of workers sicklisted due to LBP. In contrast to medical interventions, there is little evidence about the effectiveness of ergonomic interventions on return-to-work. Another strength of this study is that an international core design was used in six participating countries and an international standardised dataset was composed. This allowed us to pool the data to a large multinational cohort of workers sicklisted due to LBP and to perform a cross-national analysis.[17][20] Our analyses did not suggest that the effectiveness of these interventions is different in the participating countries. Therefore it has the benefit that the results of this study theoretically are generisable to all participating countries.

A limitation of this study is the observational design, which is susceptible to bias and confounding. Firstly, the association between ergonomic interventions and return-to-work can be confounded by other variables. For instance, ergonomic interventions could be offered to workers who have more chance to resume work by e.g. a better health status or lesser workload. In this case confounding causes an overestimation of the effectiveness. Therefore, we adjusted for the influence of many potential confounders, such as demographic, medical, work-related characteristics and interventions. However, the possibility that unknown factors confounded the association cannot be ruled out. Therefore, we have to be cautious with the interpretation of the results. They need to be confirmed in an intervention study with a randomised-controlled design. A second source of bias is that ergonomic interventions frequently coincide with work resumption. This can cause an overestimation of the effect of ergonomic interventions. Therefore, we included only participants who ever resumed work in the two years after the start of sickleave. A third possible source of bias is recall bias: Workers who returned to work long-lasting might assume that an ergonomic intervention contributed to their return-to-work, whereas workers who did not return to work long-lasting might more easily forget that they had received an ergonomic intervention.[21] This bias could cause an overestimation of the effect. However, recall bias is not likely, because information on ergonomic interventions was asked to the worker with a clear question including several examples. Fourthly, selective missing of data can occur if loss to follow-up is related to the outcome measure. For instance, a selective loss to follow-up of workers who received an ergonomic intervention and did not return to work longlasting. In this case the (selection) bias can cause an overestimation of the effect. However, comparison between groups with missing data and the study cohort revealed no major differences except for sciatica and gender. These variables were both not identified as confounders in the multivariate analysis.

Comparison with other studies

Although this study shows that ergonomic interventions are frequently applied as return-to-work interventions in several countries, there are to date few studies with methodologically rigorous designs that investigated the effectiveness of ergonomic interventions on return-to-work of workers with LBP.[11][12] To date Loisel et al.[14] performed the only one randomised controlled trial (RCT) evaluating the effectiveness of ergonomic interventions on return-to-work. In two other RCTs[15][16] ergonomic interventions were only applied when indicated and were minor part of a combination of interventions. Both RCTs reported negative results about the effectiveness of their intervention strategy on return-to-work. Loisel et al.[14] found that workers with ergonomic interventions returned 1.9 times faster than those with usual care. This ratio is comparable to the HRs we found in this cohort study. However, the ergonomic interventions in the Loisel et al. study were applied to workers sicklisted 4-6 weeks due to LBP compared to 3-4 months in our study. Our finding that some ergonomic interventions were successful for workers with more than 200 days sickleave could be explained by the late timing of these interventions. Another explanation for this phenomen is that in the first period of sickleave the vast majority of the patients will return to work as a result of the natural course of recovery after an episode of low back pain.[22] Return-to-work might occur in these patients, irrespective of an application of an ergonomic intervention. However, for patients with sickleave of more than 200 days, the chance to return-to-work becomes very low and an ergonomic intervention, like adaptation of job tasks or hours adaptation, might support or initiate return-to-work.

Meaning of this study

Our results suggest that ergonomic interventions are effective on long-lasting return-to-work for workers sicklisted 3-4 months due to LBP. Although most of the ergonomic interventions reveal effect on the long-term, the impact in the prevention of occupational disability due to LBP and in the reduction of costs to the society may be important. Principal meaning of this study is that interventions for the occupational rehabilitation of workers sicklisted due to LBP should include ergonomic interventions.

It will be difficult to study the effectiveness of ergonomic interventions on return-to-work in RCTs, because, as this study shows, the occurrence of these interventions is high in usual care. However, the effectiveness of ergonomic interventions on return-to-work should be demonstrated in future RCTs to rule out possible bias and confounding.

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Chapter 4 Cost effectiveness of a multi-stage return to work program for workers on sick leave due to low back pain, design of a population based controlled trial.

Ivan A Steenstra, Johannes R. Anema, Paulien M Bongers, Henrica CW de Vet, Willem van Mechelen. *Published in BMC Musculoskelet Disord. 2003 Nov 21;4(1):26.*

Abstract

Objective To describe the design of a population based randomized controlled trial (RCT), including a cost-effectiveness analysis, comparing participative ergonomics interventions between 2-8 weeks of sick leave and Graded Activity after 8 weeks of sick leave with usual care, in occupational back pain management.
Design RCT and cost-effectiveness evaluation.
Study population Employees sick-listed for a period of 2 to 6 weeks due to low back pain.
Interventions 1. Communication between general practitioner and occupational physician plus Participative Ergonomics protocol performed by an ergonomist. 2. Graded Activity based on cognitive behavioural principles by a physiotherapist. 3. Usual care, provided by an occupational physician according to the Dutch guidelines for the occupational health management of workers with low back pain.
Outcome measures Primary outcome measure is return to work. Secondary outcome measures are pain intensity, functional status and general improvement. Intermediate variables are kinesiophobia and pain coping. The cost-effectiveness analysis includes the direct and indirect costs due to low back pain. The outcome measures are assessed before randomization (after 2-6 weeks on sick leave) and 12 weeks, 26 weeks and 52 weeks after first day of sick leave.
Discussion The combination of these interventions has been subject of earlier research in Canada. The results of the current RCT will: 1. crossvalidate the Canadian findings in an different sociocultural environment; 2. add to the cost-effectiveness on treatment options for workers in the sub acute phase of low back pain. Results might lead to alterations of existing (inter)national guidelines.
Keywords Low back pain, Graded Activity, Participative Ergonomics, Return to work, Randomized Controlled Trial, Cost-effectiveness, Occupational health

Background

Arguments for publishing a design

In this article, we describe the design of an RCT and cost-effectiveness analysis of a multi-stage protocol roughly consisting of two interventions: an occupational intervention and a Graded Activity intervention. Publishing the design and rationale of this randomized controlled trial (RCT), including a cost-effectiveness analysis, before the results are available, has some important benefits. It gives the author a chance to elaborate on the content of the interventions [1]. This extensive information gives caregivers more insight in the practical application of the interventions in the study, which contributes to an easier implementation of the interventions in practice. It can be a helpful document for both researchers contemplating intervention or evaluation studies of LBP themselves as well as for research-users who try to make an informed choice between different return to work strategies. Furthermore, it offers the opportunity to consider the methodological quality of the study more critically, irrespective of the results. Usually methodological deficiencies are examined critically in case results are not in line with the expectations of the researcher or reader, but when results meet the expectations, methodological strengths and weaknesses will receive less attention. Finally, it may prevent publication bias. Trials that lead to adverse or negative results are less likely to be submitted for publication [2,3]. This can be avoided by publishing a priori the design of a study. Not only will the researcher be more inclined to publish the results, but in any case, data can still be requested from the researcher for inclusion in a systematic review.

Low back pain

Back pain is a common problem in Western societies. It causes major disability and considerable financial costs. Most costs (approx. 93%) are caused however by absenteeism from work in a limited number of cases [4]. Total costs estimates vary from 0.28 to 1.7 % of the Gross National Product, depending on the method used [5]. Most costs are caused by patients who are of work for more than 6 months [6,7]. Based on the report of the Quebec Task Force on Spinal Disorders [8] that recommended early intervention to reduce chronicity, a model has been developed by researchers at Sherbrooke University, Canada. Aim of this model was to treat sub-acute occupational back pain and to prevent transition to the chronic phase. The model has been evaluated in Canada in a population-based, randomized clinical trial [9] where it has proven to be an effective tool in return to work. Because of differences in legislation these results can not automatically be transferred to the Dutch situation.

Sick leave in the Netherlands

Sick leave is covered by a Law that regulates salary payment during sick leave and by the Working conditions law, which were implemented from 1994 to 2002. These laws were supplemented by several other acts resulting in the following consequences: 1.the employer has to pay at least 70 % of wages for the first full year of sick leave; 2. an inventory of work-related health risks and a contract with an occupational health service is obligatory for all companies. The most important supplement to these laws has been the implementation of the "Improved Gatekeeper Law" which became effective on April 1, 2002. According to this law payment by the employer for an additional year of wages during sick leave can be mandatory, in case the employer has not put enough effort into vocational rehabilitation of the worker during the first year of sick leave. On the other hand a worker can loose some of his employment protection in case the worker has not put enough effort into work resumption. Central working agreements between workers and employers ensure payment of 100% of wages in most cases during the first year of sick leave, regardless the above mentioned laws.

After the employers first year of sick leave "risk" period, a claim for disability benefits can be made. A national organisation assesses the working capacity of the injured worker. Based on this assessment a (partial) allowance can be rewarded. The magnitude of their allowance is based on the loss of earning capacity. Workers can be partial on disability benefit and get additional earnings from regular work or from unemployment benefits. In these cases earnings influence the magnitude of disability allowance.

Health care costs are covered by the National Health Insurance or by a private insurance for workers above a certain income threshold (€ 31.750 in 2003). Vocational rehabilitation costs paid for by the employer are covered by a tax reduction scheme for the employer and can be eligible also for a subsidy, in case costly work adjustments have to be made to keep the worker on the job.

Methods

Organisation of the study

The study is designed as a RCT and has been executed in 13 occupational health services. The conduct of the study is guided by a committee of representatives of all professional groups implementing the interventions in the study and by a representative of the grant provider. The most important task of this committee was the critical appraisal of the protocol in the study and the applicability of the interventions during the study. This committee will again be directive in the implementation of results in occupational health practice.

The study design, protocols, procedures and informed consent form were approved by the Medical Ethics Committee of VU University Medical Centre, and all participants provided written, informed consent. All participants were insured according to Dutch Law in case of any damage caused by participation in the study.

Study population

The source population (n = 100.000) consisted of the population of workers receiving care of the 99 participating OPs. The subjects in this study are on sick leave from regular work for 2 to 6 weeks due to low back pain. Workers have to be in the working age range, that is 18 to 65 years old and are able to understand Dutch in a way that they can give real informed consent and to complete written questionnaires (in Dutch).

The workers have low back pain defined as: pain localised in the lower back without a specific underlying cause, between the lower angle of the scapulae and above the buttocks (ICD-10 codes: M54.5, M54.4, M54.3, M54.1, M54.8 and M54.9).

The workers' OP informs the researchers whether inclusion in the study is justified on medical grounds. Following the Dutch guideline for low backpain in occupational care [10] patients are excluded in case of specific causes of low back pain: herniated discs with pareses; paralysis; spinal tumour; spinal fracture; ankylosing spondilitis; spinal stenosis; spondylolisthesis; specific rheumatological diseases; pregnancy, in case of serious psychiatric disorders; (ICD-10 code: M51, M51.2, M51.4, M51.3, M51.8, M40-M54, M45, M46.0, M46.1, M46.8, M49, and M46.9) or in case of a legal conflict at work, since other interventions are considered more appropriate in these cases. A worker is also excluded if he had been sick-listed due to low back pain less than one month prior to the current episode of sick leave, leaving only new incident cases for our study.

At the start of the study all OPs received additional training from a neurologist in distinguishing between different types of low back pain. In case of doubt the OPs working on the research team (JRA/ WvM) could be consulted.

Sample size

Workers still on sick leave at 8 weeks are randomized for the Graded Activity intervention. To detect a 30% difference in recovery rate (return to work) between the Graded Activity group and the usual care group, we need a sample size of 90 workers, resulting in 45 workers in both treatment arms where the second intervention is executed. This difference can be detected with a power (1-β) of 80% at α=.05 [11]. We estimate that 50% of the population will resume work between 2-8 weeks. Therefore we attempt to enrol 200 workers, resulting in 100 workers per treatment arm for the first intervention, i.e. participatory ergonomics. The sample size of 200 workers is sufficient to detect a 20% difference in recovery rate (return to work) between the occupational intervention group and usual care. We used our main outcome measure (lasting return to own or equal work) for this sample size calculation. We believe that a 20% difference in the primary outcome measure is relevant from both the societal as the employers perspective; this difference is statistically significant at α=.05 with a power (1-β) of 80%, assuming an intraclass-correlation coefficient of .15 to account for randomisation at OP level.

Treatment allocation

First randomization took place at the level of the OP, because part of the intervention had to be performed by the occupational physician. Performing one of the interventions during the whole trial reduced the risk of contamination and made performing the interventions easier for the participating OP's. The OP's were stratified before randomisation by economic sectors industry, health care and office work to avoid an unequal distribution in job characteristics after randomization in the treatment groups. A member of our research team (HCWdeV) randomized the OP's, using a series of random numbers.

We randomized the OP's at two different moments. We initially started out with 49 OP's, using a 1:1 ratio for randomization. One year later we were able to recruit 50 more OP's thanks to extra funding from the Dutch government. In the first year we experienced an imbalance in the number of included workers between the two groups, in favour of the intervention OP's. We therefore decided to randomise the second group of OP's using a different ratio. In total 39 OP's were randomized to the intervention group and 60 OP's were randomized to the care as usual group.

If included workers were off work for longer than 8 weeks, they were randomized at the workers level for the second intervention consisting of Graded Activity. An independent examiner (HCWdV) prepared the envelopes for this randomization by coding them according to a list of random numbers.

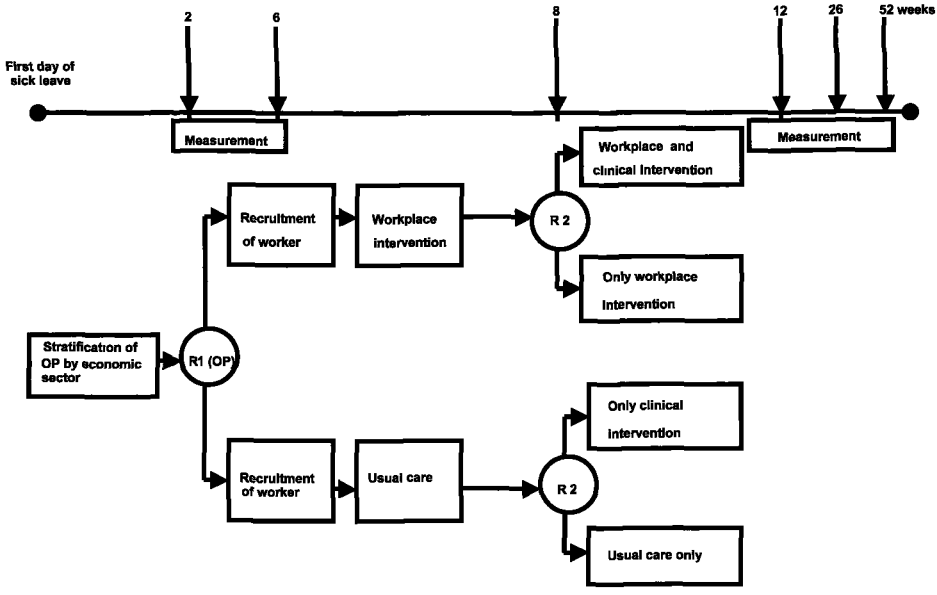

FIGURE 1. The design of the study

Blinding

Obviously, workers, physicians and other therapists can not be blinded for the allocated treatment. Treatment allocation is made known to the worker by the OP after informed consent and completion of the baseline questionnaire. As self-reported outcome measures are used, blinding of most of the outcome measurements during follow up is not possible. We evaluated patients' and physicians' expectations of the effect of the interventions on return-to-work in intervention and control groups to control for the lack of blinding. Since all questionnaires are sent to the worker by mail, no direct influence by the researchers or treating professionals is likely to happen. Similarly, the occupational physician cannot be blinded for treatment. The OP is responsible for providing data on the main outcome: sick leave. The registration of sick leave in the Netherlands is done by companies and managed by the occupational health service. Since these measurements are extracted mainly from automated databases, bias as caused by a lack of blinding is prevented for this outcome measure. The physiotherapists and ergonomists performing the interventions are not involved in performing any of the outcome measures.

Co-interventions and compliance

Co-interventions could not always be avoided. By informing the patients' GP we tried to minimise co-interventions. In both the intervention and control groups we registered co-interventions by asking the worker and the OP. These data can be used to adjust for co-interventions in the final multivariate analyses. In both the intervention and control groups we measured the compliance to the treatment allocation by asking patients, therapists and physicians independently about all interventions applied.

Usual care in the Netherlands

OP guideline

The Dutch occupational guideline on low back pain is an evidence-based guideline. The guideline advocates a visit of the worker to the OP's office at 2 weeks of sick leave due to low back pain. During this visit the OP diagnoses the low back pain. A patient history is made on localisation and radiation of pain, length of the current episode, previous episodes, muscle weakness, loss of sensitivity, miction disorders, general well being, weight loss and fever.

This anamnesis is, if considered appropriate, followed by a physical examination: function of the back and pain induced restrictions, test of Lasègue, the reversed test of Lasègue and tests of the reflexes of the knee and Achilles tendon are being performed.

Based on these findings the OP judges the presence of obstacles for return to work like inadequate sickness behaviour; psychosocial problems; subjective impairments; the effectiveness of curative treatment; working conditions and functional status.

The following interventions are promoted in cases of low back pain without sciatica and of low back pain with mild sciatica without paresis or paralysis:

- Education by the OP referring to: good prognosis and the importance of keeping up or returning to normal activities. The OP emphasises the fact that physical activity does not cause any damage.
- Advise by the OP to return to work within two weeks in the absence of further problems and, if necessary, temporary work adjustments regarding working hours or job content. The workplace is consulted on progress in actions regarding return to work.
- The general practitioner, or any other medical specialist, is consulted if curative treatment is considered inappropriate. Coping with low back pain, fear of movement and a planning for the resumption of normal activities is discussed with the worker, if considered appropriate.

In the occupational guideline a work place visit by an occupational therapist or ergonomist is optional. The OP guideline is in accordance with the GP guideline and PT guideline on low back pain.[12-14] . All guidelines advocate stimulating physical activity and counselling on good prognosis in low back pain in the first 6 weeks of back pain. After 6 weeks exercises or manipulation is considered useful within an active approach.

Description and aim of the Amsterdam Sherbrooke model

We replicated the study by Loisel et al [9], after adjustment of the Sherbrooke model for the Dutch situation of occupational health care and disability legislation. In most cases a worker consults his GP first before visiting his occupational physician in case of prolonged sick leave. The general practitioner initiates treatment, if necessary. Curative treatment and waiting lists are considered to be a barrier for return to work in the Netherlands [15]. Because of this, communication between the OP and GP was part of the intervention protocol to try to prevent contradictory advises for the workers and to facilitate return to work. Aim of the entire multi-stage back pain management protocol, and of every component separately, is earlier return to the same work as prior to the present episode of sick leave.

A precise description of the Canadian Sherbrooke model has been published elsewhere [16]. The Amsterdam Sherbrooke model can be divided roughly into two separate interventions. These are described in the following paragraphs.

The occupational intervention

The first intervention takes place between 2 to 8 weeks of sick leave. The OP, in collaboration with a occupational health nurse or ergonomist, delivered this occupational intervention. The intervention consists of the following steps:

1. Occupational back pain management and work resumption advice by the OP, according to the Dutch OP Guidelines for LBP[10].
2. As an elaboration of the guideline we developed a protocol for communication between the workers OP and the workers GP, to reach consensus on

counselling the worker in return to work. Aim was to resolve conflicting approaches by GP and OP, leading to conflicting information to the patient.
A short communication form was developed to inform the GP on the OP's management policy and to gather information on the treatment by the GP [17]. Informed consent has to be given by the employee to obtain this kind of information. The communication form had to be handed over to the GP by the employee.

3. In the occupational guideline a work place visit by an occupational therapist or ergonomist is optional. Because of practical and financial hindrances, the OP seldom makes a referral for such a workplace visit. A participative work adjustment protocol was implemented as a standard intervention in this study. This protocol is carried out by the OHS's ergonomist or Occupational Health nurse. The intervention has been based on methods used in participative ergonomics [18]. We altered existing group based methods to be applied at the level of the individual worker [19]. This method is similar to the method used in Sherbrooke [20].

Every OHS professional in the intervention group was trained in the occupational protocol initially for half a day, with 3-hour feedback sessions over the following 2 years. The ergonomist initiated implementation of the protocol in case of randomization of an eligible worker in the participative work adjustment protocol within one week after the workers' first visit to the OP. Even in case of very early return to work, the protocol was executed to prevent recurrences of sick leave due to low back pain. An extensive description of this protocol was published before [19].The protocol included the following seven steps:
Step 1. The ergonomist makes an appointment for a meeting with the worker with low back pain, the workers' direct supervisor and possible other stakeholders on the work site. If deemed appropriate the ergonomist collects additional information from the OP.
Step 2. The ergonomist makes an inventory of problems related to back pain based on descriptions from the worker and supervisor. He reaches consensus regarding these problems and prioritises in obstacles for return to work put forward by worker and supervisor.
Step 3. In a brainstorm session, all try to come up with as many solutions as possible to clear the obstacles for return to work. The ergonomist sorts out all the solutions. The ones put forward by the worker and supervisor are seen as most important. All solutions are judged on availability, feasibility and solving capability. Based on these considerations solutions are picked.
Step 4. Preparation for implementation of solutions: the ergonomist, worker and supervisor agree on a plan for action. Stakeholders are informed on the actions that they have to take. Responsibility for implementing the solutions is put on the workers' and supervisors' account as much a possible.

Step 5. For implementation of the solutions it may be necessary to give additional instructions or training to the worker at the worksite.
Step 6. One month after step 4 evaluation by the OP takes place with regard to implementation of the solutions agreed upon. Based on this evaluation, fine tuning of the work adjustment may prove to be necessary.
Step 7. The proposed improvements may need further anchoring in the organisation. A stakeholder has to be found for further support of the improvements.

The Graded Activity program
The second intervention was based on the principles of Graded Activity as developed by Lindström et al [21,22] and adjusted to the Dutch situation. This intervention was implemented by 47 physiotherapists from several in- and out-company training-centres, trained in the Graded Activity protocol. The intervention, adjusted to the Dutch situation, has been evaluated separately at our institute in another randomized clinical trial: the Amsterdam Graded Activity Study[23]. This trial differs from our trial with regard to the level of implementation.
The purpose of the program is to restore occupational function and to facilitate return to work. Primary aim of the program is return to previous work and not pain reduction. All subjects eligible for Graded Activity are sick listed for 8 weeks. During the program the worker is responsible for the results of the therapy. The worker has an active role and the physiotherapist acts as a coach and supervisor, using a hands-off approach. [24]
The Graded Activity program consists of the following components:

1. patient history and physical examination;
2. measurement of functional capacity;
3. an individual, submaximal, gradually increasing exercise program, with an operant-conditioning behavioural approach, based on the results of functional capacity tests, the demands from the patients work and the patients expectations on time to return to work.

Exercise sessions have a frequency of twice a week and last for an hour per session. The first session takes approximately 1.5 hours since a physical examination is part of the first session
The entire program consists maximally of 26 sessions (maximum duration is thus three months). The program should be stopped earlier if a lasting return to own or equal work has been established according to an earlier agreed upon schedule.
In the first session the physiotherapist takes the workers case history. Asking questions on the nature of low back pain (duration, intensity) and on the knowledge of the subject provided by other health care professionals and significant others. Furthermore it is important to know which actions and situations, both private and at work, are troublesome because of low back pain. The physiotherapist asks the worker on his expected date of return to work and the conditions that have to be provided to return to work. This case history should not take more than 5 minutes.

In the first session, the physiotherapist also performs a physical examination to assess range of motion of the spine. In case of radiating pain a short neurological examination should be performed (test of Lasègue or Bragard, knee tendon reflex and/ or Achilles' tendon reflex, sensibility test of the foot). Based on this physical examination, the physiotherapist confirms the diagnosis made by the occupational physician that no abnormalities could be found. Following the examination, the physiotherapist gives counselling on the origin of low back pain, the benign nature and good prognosis of back pain and the patients' own responsibility. This message might take extra effort and repetition in the following sessions.
The remainder of the first session and the following two sessions are used to get a good estimate of the workers functional capacity. The main objective of functional capacity evaluation is reaching a good starting point for therapy. Results on the test are not considered outcome measures in our study protocol. All exercises during the functional capacity evaluation are based on the working to tolerance principle [25]. This testing-phase is pain contingent, which means that the worker may stop if he feels pain or other discomfort.
From the start, the goal of the Graded Activity program is made clear by the physiotherapist: return to work by gradually increasing physical activities. The end of the program is reached as soon as return to regular work is established. The 3 months time limit is not communicated to the worker, because it will probably lead to a time lag. In dialogue, the worker and the therapist reach agreement on the date of return to work. The therapist gently adjusts unreal goals. The OP's expert opinion on return to work is being considered in this process. Every other six sessions the progress made and the date for return to work are evaluated.

The Graded Activity program consists of:

1. aerobic exercises on the stationary bike, or rowing machine
2. a step exercise
3. a lattisimus exercise, the initial weight can either be chosen by the physiotherapist or the worker; 20 to 30 repetitions in a test situation are considered to be an ideal test-result.
4. a dynamic extension exercise: preferably performed on a lower back bench, despite the fact that it might be somewhat frightening to the worker.
5. Abdominal exercise, for instance crunches, or a crossed version of the crunch where the heterolateral knee has to be touched.
6. Getting up from a simple chair, without hand support, possibly making the exercise heavier by holding a (heavy) object.

7/8. Exercises seven and eight are to be designed by the physiotherapist and the worker and should be based on the actions and situations mentioned in the anamnesis. They should simulate the problematic motions of the worker, preferably by simulating working situations.

Some of the exercises can be used as a home assignment. Besides the above mentioned equipment, dumbbells/ free weights and boxes have to be available for simulating working situations.

During the exercise part of the program (i.e. from session 4 onwards) time contingent principles are used, meaning that pain is not a reason for stopping or altering the program, unless a clear relapse (new injury) or deterioration to back pain as mentioned as exclusion criterion in the study population section has taken place. The exercise goals are defined based on the functional capacity evaluation. The starting point of the program is based on 70 % of the mean of all functional capacity test results. The load of each exercise at the end of the program (moment of return to work) is agreed upon at this starting point. The quotas should always be followed exactly, neither under-performed, nor over-performed. The latter might prove difficult for some, especially in the beginning stages of the program. The first quotas are slightly lower than baseline level, to ensure the experience of success ("sure to win"). Successful completion of the quotas should enhance the patients' motivation. Positive reinforcement is a key principle in operant conditioning theory and will be provided by reaching the quotas and by appropriate feedback from the physiotherapist.
In case the physiotherapist finds out that significant others, like partners or co-workers, influence the change in pain behaviour in a negative way, they are invited to attend one or more sessions to gain insight in the rationale of the therapy.
After return to work the worker meets with the physiotherapist for a last time to evaluate the experiences on the work floor.

Outcome assessment
The first assessment of workers (baseline) is scheduled during the first visit of the OP's office, that is at 2-6 weeks absence from work. There is a 1-year follow-up with assessments at 12 weeks, 26 weeks and 52 weeks after first day of sick leave. In this study records on sick leave were obtained from the occupational health services from the various co-operating companies. Registration of sick leave is a continuous process in occupational health services. It provides reliable data because of commercial interests and double registration at both the companies and the occupational health service. We will choose the occupational health services database since there is a known discrepancy with self reported sick leave [26,27].

Primary outcome measures
The primary outcome measure in this study is return to work in the year after the first day of sick leave. Since these measurements are gathered from the occupational physicians' records and checked with automated databases blinding is secured.

1. A. Lasting return to own or equal work: duration of work absenteeism due to low back pain in calendar days from the first day of sick leave to full return

work in own or other work with equal earnings, for at least 4 weeks without (partial or full) drop-out.

B. Net lasting return to work to own or equal work: net duration of work absenteeism due to low back pain with days of partial return to work converted into number of calendar days of full work absenteeism (net sick leave) from the first day of sick leave to full return work in own or other work with equal earnings, for at least 4 weeks without (partial or full) drop-out. This outcome will be used in all cost-effectiveness analyses.

C. Lasting return to any work: duration of work absenteeism due to low back pain in calendar days from the first day of sick leave to (partial or full) return to work for at least 4 weeks, without full drop-out.

2. Total number of days on sick leave due to any condition in the follow up period, since a shift in diagnosis and possible recurrences can be considered as a negative outcome of the interventions.

Return to work is defined in several ways. All definitions are listed in order of importance. Some definitions differ only in detail. The main differences are between lasting return to work and return to work and between time to return to work and the total number of days of sick leave in the year after first day of sick leave (including recurrences). We decided to use a four week period for lasting return to work since a four week period is regarded as a lasting return to work in Dutch occupational care.

De Vet et al [28] pointed out the importance of defining episodes of low back pain in occupational care and suggested the following definition:

- *An episode of work absence due to low back pain was defined as a period of work absence due to low back pain, preceded and followed by a period of at least 1 day at work.*

This study provides the opportunity to investigate differences in results due to different definitions.

Secondary outcome measures

In addition, data were collected on:

1. Functional status, using the Roland-Morris Disability-24 questionnaire [29]. This questionnaire is widely used in low back pain research and tested as summarised by Riddle [30], as a reaction to Davidson and Keating [31]. There is a valid version of the RDQ-24 available in Dutch [32]. The questionnaire has been adapted for the population in our study (acute and sub-acute low back pain with or without radiating pain). Test retest reliability is considered good over several periods of time [33]: on the same day: $r = 0.91$; after 3 weeks $r = 0.83$; after 6 months $r = 0.72$. Inter-/intrarater reliability is good; $r = 0.92$ in 2 raters. Construct-validity is considered good in comparison to several other questionnaires [32].

2. Pain intensity, measured on a 10 point visual analogue scale [34]. This scale consists of three short questions on pain at the moment of filling in the question, the most severe pain in the last week and the mean pain in the last week. All questions are answered on a 10-point scale. The total score is being calculated by taking the summed score of the three items. Test retest reliability of this scale is good with a Cohens' kappa from .66 to .93 [35].
3. Kinesiophobia, fear of incurring (new) physical damage through physical activity, is measured with Tampa Scale for Kinesiophobia [36]. The TSK consists of 17 items. The Dutch version has good reliability and validity. Filling in this questionnaire takes a few minutes. Items are scored on a four point scale from 1 (highly disagree) to 4 (highly agree). The total score is calculated through summed item scores, after reversal of the items four, eight, twelve and sixteen. The total score varies between 17 and 68 [37]. If a worker scores higher, than the fear for physical activity or injury is greater. The assumption is that with a high score, physical activity is being avoided. Test-retest reliability in acute low back patients is good with a Pearson's r=.78 (P≤ .01). Internal consistency ranges from alpha=.70 to 76 in acute low back patients [38].
4. Fear of movement, avoidance of activities and back pain beliefs are measured with the Fear Avoidance Beliefs Questionnaire [39]. The FABQ questionnaire consists of two subscales: one regarding physical activity (FABQ/pa) and one regarding work (FABQ/w). In acute low back pain patients internal consistency for the FABQ/pa ranged from alpha=.70 to .72 and for the FABQ/w subscale from alpha=.82 to .83. Test-retest reliability in acute low back pain is also good with Pearson's r=.64 in the FABQ/pa subscale and .80 in the FABQ/w subscale (P≤.01).Concurrent validity between TSK and FABQ is weak to moderately strong, ranging from r_s =0.33 to 0.59 (P<0.01).
5. Patient satisfaction, was measured with the short version of the Patient Satisfaction with Occupational Health Services Questionnaire PSOHQ [40].
6. Coping with pain was measured with the Pain Coping Inventory Scale. The PCI questionnaire measures cognitive and behavioural coping strategies of pain patients. The questionnaire consists of 34 items, scored on a four point scale (1= seldom to never, 2= sometimes, 3=often and 4=very often). The questionnaire consists of six subscales:
   1. transformation of pain
   2. distraction
   3. lowering demands
   4. withdrawal
   5. worrying
   6. resting.

ad 1/2. Transformation and distraction are considered as cognitive attempts to lead oneself away from pain.
ad 3. Lowering demands: actions aimed at continuing activities despite the pain.

ad 4. Withdrawal: avoiding annoying influences.
ad 5. Worrying; the cognitive component of pain-related fear that shows through unreal expectations and catastrophising thoughts on pain. Worrying can be considered as staying alert for potentially painful stimuli. The flip side of worrying is that it encourages avoiding behaviour like withdrawal and resting, and vice versa [41].
All coping scales have been proven to be sufficiently reliable and valid. They are sensitive enough to differentiate between coping strategies in pain patients[42].

Prognostic measures
Information was gathered at baseline on a number of factors that are considered as prognostic factors for sick leave. This enables us to adjust for these factors, in case the randomization fails to divide these variables equally over all groups.

1. Data on neurological signs, co-morbidity and economical and insurance status of the company are gathered by the treating OP.
2. Job content data [43,44] are collected at baseline from the worker since the job demands control model could be a predictor for return to work [45].
3. Data on workload are obtained at baseline using the Dutch Muskuloskeletal Questionnaire [46] as potential confounding variables.
4. Data on physical activity are gathered at baseline using a sub-scale of the Baecke physical activity questionnaire [47,48].

Cost effectiveness measures
Cost effectiveness will be evaluated from both the societal perspective and the employers perspective. The workers use of pain medication and use of medical and alternative medical resources is measured at baseline, at 12 weeks, 26 weeks and 52 weeks follow-up, using postal questionnaires, to calculate the direct costs of back pain in both groups. To compare the results of the cost effectiveness analysis with other conditions, general health status is measured according to the standard Dutch version of the EuroQol [49]. Indirect costs are not related to health care but are costs as a consequence of sickness, sick leave, disability and or death of productive persons, in paid and unpaid labour [50]. Since our study takes place in occupational care and since most costs are caused by absenteeism from work [4] we made an extra effort to gather good data on sick leave. Costs of sick leave due to low back pain will be calculated from the net number of days on sick leave and earnings as provided by the employee. In case a participant was reluctant to provide these data a proxy for earnings can be derived from function, age and working hours. The Occupational Health Service provides data on duration of sick leave and of vocational rehabilitation of the worker and the estimated productivity during vocational rehabilitation.

Analysis

Although we randomized at the OP-level for the first intervention, all analyses will be performed at the patient level. To check the assumption that observations on the OP-level are independent intraclass correlation will be calculated. To examine the success of randomization, descriptive statistics will be used to compare the baseline measurements of the four groups. If necessary, analyses will be adjusted for prognostic dissimilarities. The Cox Proportional hazard model will be used to analyse differences in time until RTW. Student's T-test will be used to analyse differences in total days on sick leave during the year of follow up. Longitudinal multivariate analyses will be used to examine differences in improvement in all secondary outcome measures between the treatment groups.

Indirect costs can be calculated using the friction cost approach (friction period 122 days) and the human capital approach [51] based on income as provided by the worker or as derived from function, age and gender. Boot strapping will be used for pair wise comparison of the mean groups to calculate mean differences and confidence intervals in costs and cost-effectiveness ratios for all interventions. All statistical analyses will be performed according to the intention-to-treat principle. In order to assess whether protocol deviations have caused bias, the results of the intention-to-treat analyses will be compared to per-protocol analyses, including only those employees who complied fully with an intervention protocol.

In case intraclass correlation on the OP-level is > .15, multilevel analysis will be performed to examine the influence of the individual OP.

Discussion

Our study differs from the study in Canada with respect to the randomization. Because of differences in organisation of occupational care in both countries the first randomization in our study was performed at the level of the participating OP, whereas in the Canadian study randomization took place at the worksite level. The researchers in both studies decided to do so to avoid contamination. The second randomization in our study took place in case of sick leave after 8 weeks. In doing so we differ from the design of the Canadian study where randomization took place over four treatment groups at baseline [52]. In our opinion return to work can be slowed down either by the worker or by the OP in case a worker knows that he is allocated to the Graded Activity intervention. This would result in a difference between Graded Activity and control group caused by the design of the study and not by the content of the Graded Activity intervention. Moreover, randomization for Graded Activity at the start of the trial results in a large number of workers (those who have already returned to work) who are not receiving the intervention.

In our cost effectiveness evaluation we did not consider productivity loss due to sickness prior and after the episode of sick leave due to low back pain as proposed by Brouwer et al [53]. Considering productivity loss prior and after the episode of absence could lead to an increase in estimated production losses of about 16%. We have considered productivity loss during vocational rehabilitation. Productivity loss in

our opinion is not only influenced by the cause of sick leave but also by the type of work. Some jobs can only be performed in case of full usability. Nurses for instance are called off sick leave only in case they can perform al necessary tasks, in all other cases they are on vocational rehabilitation with a restriction in for instance lifting tasks. Since the start of our study in 1999 a better insight in calculating costs has become available. The availability of instruments for the measurement of productivity losses in recent years can give a better estimate of costs in new research.
Although the interventions have been subject of earlier research, this study provides an international comparison on effectiveness of similar interventions. The results of this RCT will give greater insight to caregivers on treatment options for workers in the sub-acute phase of occupational low back pain. Results might lead to alterations of existing (inter)national guidelines. Furthermore, the results of this RCT will add to the cost-effectiveness of treatment options for workers in the sub-acute phase of occupational low back pain. This study can also provide valuable information to the small body of knowledge from the few studies that focus on effective interventions for return to work in workers on sick leave in the sub-acute phase. Inclusion of workers has stopped in October 2002. First 6 months results of this trial will be available at the end of 2003.

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Chapter 5 Participatory ergonomics as a return-to-work intervention: a future challenge?

Anema JR, Steenstra IA, Urlings IJ, Bongers PM, de Vroome EM, van Mechelen W.
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Abstract

Background Participatory ergonomics (PE) are to date often applied for prevention of low back pain (LBP). In this pilot-study a PE- program is applied for the disability management of workers sicklisted due to LBP.

Methods The process, implementation, satisfaction and barriers for implementation concerning the PE-program were analyzed quantitatively and qualitatively for 35 workers sicklisted 2-6 weeks due to LBP and their ergonomists.

Results Two-hundred-and-seventy ergonomic solutions were proposed to the employer. They were targeted more at work design and organisation of work (58.9%) than at workplace and equipment design (38.9%). They were planned mostly on a short-term basis (74.8%). Almost half (48.9%) of the solutions for work adjustment were completely or partially implemented within three months after the first day of absenteeism. Most workers were satisfied about the PE-program (median score 7.8 on a 10-point scale) and reported a stimulating effect on return-to-work (66.7%). Main obstacles to implementation were technical or organizational difficulties (50.0%) and physical disabilities of the worker (44.8%).

Conclusions This study suggests that compliance, acceptance and satisfaction related to the PE-program were good for all participants. Almost half of the proposed solutions were implemented.

Keywords: Low back pain; participatory ergonomics; return-to-work; sickleave; disability management; work adjustment; implementation; process; satisfaction.

Introduction

Low back pain is a major cause of occupational disability and high costs, due to medical care and workers' compensation claims. The 12 month period prevalence rate of low back pain for the working population in the Netherlands is estimated to be around 44.4% for men and 48.2% for women (Picavet et al., 1999). The total annual cost of low back pain to Dutch society, i.e. costs for medical care and workers' compensation claims, is estimated to be US$ 4.6 billion (van Tulder et al., 1995). Almost all of these costs, US$ 4.4 billion (93%), are due to workers' compensation claims. US$1.5 billion (33%) are due to compensation claims of a relatively small group of workers with long-term sickness absence due to chronic low back pain. To decrease occupational disability and costs due to low back pain, several different disability management programs have been developed aimed at return-to-work of workers sicklisted due to low back pain (Cooper et al., 1996; Isernhagen, 2000; Johanning, 2000; Shrey and Breslin, 1992; Yassi et al., 1995).

In addition to the traditional ergonomic interventions, the participatory ergonomics approach is based on active participation and strong commitment of both the workers and management in the process to identify risk factors in the workplace, and to choose the most appropriate solutions for these risks. Participatory ergonomics are increasingly used in the prevention of musculoskeletal disorders (MSD) of groups of workers (de Jong and Vink, 2000; Halpern and Dawson, 1997; Kuorinka et al., 1994; Marcal and Mazzoni, 1998; Pohjonen et al., 1996; Vink et al., 1995 and 1997; Wickstrom et al., 1993; Wilson, 1995). Participatory ergonomics programs have been reported in the literature as an effective method for the prevention of musculoskeletal disorders, resulting in a decrease in musculoskeletal symptoms and in work absenteeism rates in companies (Halpern and Dawson, 1997; Kuorinka et al. 1994; Marcal and Mazzoni, 1998; Wickstrom et al., 1993). However, participatory ergonomic interventions are applied seldom for the prevention of long-term disability, i.e. in return-to-work programs of individual workers, sicklisted due to low back pain (Elders and van der Beek, 2000). Although long-term absenteeism due to low back pain is associated both with individual and occupational risk factors (Hogendoorn et al., 2002), the disability management of individual workers sicklisted due to low back pain is usually limited to interventions directed to the individual and not to the work environment (Buckle and Stubbs, 1989; Cole and Frank, 1996; Stubbs, 2000).

Loisel et al. (2001) developed a participatory ergonomics intervention program as part of a multidisciplinary disability management program and reported a 1.9 faster return to regular work for the participatory ergonomics group when compared to usual care (Loisel et al., 1997). The present paper focuses on the implementation of a participatory ergonomics program in the Netherlands. This program is based on the Loisel et al. program and adjusted to the Dutch socio-economic context, i.e. the Dutch health care and social security system. In the Netherlands, for example ergonomic interventions cannot be applied by one research ergonomist, but have to be carried out by several ergonomists from different private Occupational Health Services (OHS).

Subjects and design

In this paper we describe the content, process, satisfaction and implementation concerning the Dutch participatory ergonomics program directed at the return-to-work of workers sicklisted due to low back pain. This evaluation functions as a pilot-study as part of a randomized controlled trial (RCT) on the effectiveness of a multidisciplinary disability management program for low back pain on return-to-work. This disability management program is derived from the Sherbrooke model (Loisel et al., 1994) and consists of multidisciplinary interventions for workers sicklisted due to low back pain: (1) the above mentioned participatory ergonomics intervention adjusted to the Dutch situation, applied between 2-6 weeks of sickleave, and (2) a clinical intervention directed only at the worker, applied after 8 weeks of sickleave. The occupational physician (OP) is the case manager who co-ordinates the application of these interventions. Workers were included in the RCT when they were absent from regular work between 2- 6 weeks due to low back pain. Workers with low back pain due to specific causes, with cardiological or psychiatric pathology, and/or a juridical conflict at work were excluded.

The aim of the disability management program is to intervene early in the process of disability, with complete return to the worker's regular work as final outcome or, if this is not possible, vocational rehabilitation to another job. Regular work is defined as the work performed just prior to the episode of work absenteeism due to back pain. Return-to-work on a part-time or light duty basis, is not considered as a complete return-to-work.

Seven OHS, 27 companies, 46 occupational physicians and 25 ergonomists agreed to participate in the RCT. Participants in the RCT were recruited through their occupational physicians.

Twenty-eight occupational physicians (OP) and the worksites which belong to them, were randomized to the participatory ergonomics intervention. The population of these 28 OPs consisted of a total of 24,832 workers working in 3 different sectors, i.e.: 15 worksites in health care institutions, 4 worksites in manufacturing plants and 10 worksites in service companies. The randomisation for the clinical intervention was performed on the level of the patient when the worker still was sicklisted after 8 weeks.

The evaluation described here concerns 45 consecutive patients who met the inclusion criteria and, after randomization, were referred to the participatory ergonomics program since the start of the RCT. The research question in this evaluation is what is the content, process, satisfaction and implementation concerning the participatory ergonomics program and ergonomic interventions. Primary outcome measures in this evaluation are: identified problems related to back pain, proposed ergonomic solutions, the implementation rate of ergonomic solutions and the level of satisfaction about the program and about the ergonomic solutions. Secondary outcome measures are the following process parameters: planned term for implementation of the ergonomic solution, compliance to the program and obstacles for implementation of the ergonomic intervention.

Description of the participatory ergonomics program

The aim of the early intervention participatory ergonomics program is to prevent sicklisted workers (with low back pain) from long-term disability and to rehabilitate them quickly by giving individualized advice on adjustments in the workplace. A manual was developed with the help of three experienced ergonomists to be used in OHS by participating ergonomists and occupational health nurses trained in ergonomics (throughout the text the word 'ergonomist' is used for all of these professionals). The preconditions of the program are:

- The participatory ergonomics program starts within one week after the sicklisted worker has visited the occupational physician for the first time; the visit has to take place within 6 weeks of sickleave for study inclusion
- The completion of the participatory ergonomics program takes no more than two weeks; a maximum of 6 hours is available for advice, including two *moments of contact*
- The goal is complete rehabilitation, i.e. return to regular work as soon as possible and no delay should be caused by work(place) adjustments
- The entire participatory ergonomics program has to be carried out even if return-to-work cannot be achieved; in this case the aim is to make a proposal for final return-to-work
- The occupational physician is the case manager who co-ordinates the application of the program and who is responsible for the evaluation of the implementation of the adjustments at the workplace.

The participating ergonomists were trained to use the manual and to guide the participatory ergonomics process. The first training consisted of four hours with theory about the method, including an explanation about the project and its procedures. However, most of the time was devoted to perform a role-play exercise to gain experience in asking the sicklisted worker and the supervisor about the risks and ergonomic solutions regarding the back problem to guide the process according to the nominal group technique (Delbecq et al., 1975; Urlings et al., 1994).

The manual describes a stepwise and systematic approach, with the following steps (see table 1.):

Step 1: The ergonomist checks whether the supervisor has been informed about this program, agrees with it and with its possible financial consequences. The ergonomist also asks who is responsible for adjustments in the workplace and what procedures should be followed.

Step 2 and 3: During one visit the ergonomist holds several interviews with the worker and his or her supervisor. First the ergonomist observes the worker in his/her workplace, using existing checklists (Voskamp, 1999). Observed elements are pushing, lifting, pulling, reaching, bending, postures and movements etc. Attention is paid to work organization, anthropometrical dimensions, collaboration with others, instructions, skills, materials and equipment. Then, two separate interviews are held with the worker and with his/her supervisor, to obtain a description of the main tasks

and specific features of these tasks in relation to the back problems. In these interviews the frequency and severity of each problem/risk is judged and then prioritized to select the most important problems. This is done by the worker and supervisor separately. After these interviews, on the same day, the ergonomist organizes a meeting with the worker, supervisor and possible other persons involved to brainstorm about possible solutions for the problems prioritized. Subsequently, all solutions are prioritized, on the basis of criteria involving existence, feasibility and solving capability of the solution.

TABLE 1. Summery of actions of the intermediary in each of the steps of the participatory ergonomics program

Steps	Actions of the ergonomist
1. Organizational preparation	Telephone call with human resource manager and/or occupational physician Telephone call with supervisor of the worker involved Planning appointment for first visit
2. Collecting problems/risks	Give introduction to the participatory ergonomics program Observation of the workplace Interview with worker about tasks and personal risks/problems Interview with supervisor about tasks and risks/problems of the worker Fill in scheme in manual, based on worker's, supervisor's and ergonomist's own opinion Meeting of worker, supervisor, ergonomist to prioritize risks/problems
3. Thinking of, collecting solutions	Meeting of worker, supervisor, ergonomist and others to think of or collect ideas for solutions, prioritize solutions Fill in scheme in manual
4. Preparation of the implementation	Make plan for implementation of solutions Contact the physician to discuss advice Fill in scheme in manual, send report to worker, supervisor and physician
5. Implementing solutions	If the employer agrees to implement solutions: Make appointment to visit worker to give instructions at work Inform and instruct (train) worker in adjusted work situation
6. Evaluation/control	Occupational physician checks whether advice is implemented

The method applied for this solution seeking approach is the so-called nominal group technique, see table 2. All the solutions, as well as the risks/problems associated with them are written down in the schemes of the manual, including the prioritization. Table 3 shows an example.

TABLE 2. The nominal group technique

Actions
In general: take one problem at a time and follow these steps
1. Explain the problem clearly
2. Supply 'post-its' to all participants
3. Let all participants write a solution on one or more 'post-its' (and courage them to be creative and to write in silence, making no contact with other participants). Suggest thinking in terms of technical, organizational and individual solutions.
4. Order the solutions
5. Ask for further information or more ideas
6. Judge the ideas on criteria of existence, feasibility and solving capability of the solution
Repeat this process until all problems are handled
Then prioritize all solutions

TABLE 3. Example of a scheme for solutions for a daycare aide

Risks/problems	Solutions	Evaluation criteria			Priority
		Exists already and is applicable on a short-term basis	Feasibility	Solving Capability	
Feeding children on small and low chairs in a day care center (bending of the back)	Let the children eat in chairs adjustable to the height of the day care aide's chair (with wheels)	++++	+	++++	1*
	Low adult chair with wheels for the day care aide	++++	++++	+/-	2**

To fill in this scheme, plus and minus can be used for the criteria:

- - = negative score on criterion
- + = positive score on criterion
- +/- = has both positive and negative aspects
- ? = not known

* This solution is aimed at the primary cause of the problem and is also an important solution for the collegues

** This solution is not aimed at the primary cause of the problem

Step 4: In this step a joint plan for implementation of the solutions is made by the worker, supervisor and ergonomist. This plan shows who is responsible for the implementation of a solution (who is to do what kind of activity, how and when). This plan for implementation is sent to the worker, the supervisor and the occupational physician. Also the ergonomist contacts the employer to arrange the implementation.

Step 5: Implementing solutions often means that workers have to acquire information or receive instruction on how to handle their new situation, for instance how to deal with a new job performance or with new equipment. To give this sort of information or to give instruction at the (renewed) workplace, the ergonomist makes an appointment with the worker. At the same time the supervisor is informed about how to encourage and guide the worker in his or her new work situation.
Step 6: The occupational physician evaluates the situation with the employer and the worker: have the solutions been implemented or have improvements been made?

Materials and Methods
Outcome and process measures were assessed in the following way. Questionnaires were sent to the worker, ergonomist and OP, 3 months after the first day of sickleave due to low back pain. The worker was asked whether ergonomic solutions had been advised and implemented. Solutions could have been implemented completely, partially or not at all, 3 months after the first day of sickleave. All participants (i.e. the worker, the ergonomist and the OP) were asked for their satisfaction about process and outcome of the participatory ergonomics program. Satisfaction was measured on a ten-point scale (1-10). The ergonomist was asked to indicate on a three-point scale, which factors influenced the application of the participatory ergonomics program and the implementation process (i.e. a factor can play an inhibiting role, promoting role or no role).
All ergonomists were asked to fill in the schemes for each single case. All identified problems/risks and ergonomic solutions mentioned in the schemes were analyzed qualitatively and classified (by JA & IU) according to the 'Ergonomics Abstracts' classification scheme (Stapleton, 2000). The term for implementation of solutions is classified into two categories: implementation within 3 months (short-term solutions), or after 3 months or more (medium/long-term solutions). The compliance to the participatory ergonomics protocol was assessed for each case by answering the following questions (1)'Are the risks/problems described adequately/properly?' (2)'Are the risks prioritized properly?' (3) 'Are the solutions mentioned related to the risks prioritized?' (4) 'Are solutions prioritized properly?' (5) 'Are solutions prioritized mentioned in the plan for implementation?' (6) Is a person made responsible for each solution and is a timetable for implementation mentioned in the plan?' The answers to these questions were used to calculate an overall indicator of performance i.e.: deviant (0), not deviant (1) to the protocol or not applicable. A total sum score per case < 6 was defined as deviant and 6 as not deviant.
The Ethics Committee of the VU University Medical Centre approved the study and all participating patients signed the consent form.

Statistical analysis
Only workers who actually had received the participatory ergonomic intervention were included in the statistical analyses in this study. Frequencies, measures of central tendency and dispersion were calculated of the following outcome measures:

1. identified problems/risk factors, 2. proposed and implemented ergonomic solutions and 3. obstacles for implementation. Frequencies, measures of central tendency and dispersion were calculated of the following process measures: 1. Proposed time until implementation of the ergonomic solutions, 2. compliance to the program 3. satisfaction about the program and about the ergonomic solutions. The relationship between process and outcome parameters was assessed by means of Chi-square tests. Pearson correlation coefficient was used to calculate the correlation of workers' satisfaction about the ergonomist and about the ergonomic solution. Statistical analyses were carried out using SPSS for Windows, (release 9.0, 1999).

Results

Thirty-five of the 45 patients (78%) with low back pain who were referred to the participatory ergonomics program, actually received the intervention. Four patients returned to their regular work before the participatory program had started. Six patients did not participate in the participatory ergonomics program for the following reasons: one worker did not agree with the participatory process, in three cases the trained ergonomist could not apply the protocol within the required timetable, in one case the protocol was not applicable according to the ergonomist due to co-existing psychological problems and one patient dropped out because of a conflict at work. The low back pain and work-related characteristics of the 35 patients taking part in the program are shown in table 4. The ergonomic interventions were carried out by 13 ergonomists in all three sectors: 19 interventions took place in health care institutions, 8 in manufacturing plants and 8 in service companies.

The workers received the ergonomic intervention at a median of 12 days after the first visit to the occupational physician. According to the ergonomists all workers and 97.7% of the employers were (actively) co-operating with the ergonomic intervention. According to our strict criteria in 61.8 % of the cases the participatory ergonomic intervention was applied completely according to the protocol.
The worker, supervisor and ergonomist identified 166 prioritized problems and/or risks. These problems/risks were classified into the following categories: physical workload (73 risk factors), workstation design/equipment design (49 risk factors), work design and organisation (21 risk factors), work stress (17 risk factors), and other risk factors (6). For all these risk factors a total of 270 different ergonomic solutions were proposed to the employer with a mean of 7.9 solutions per case (SD 3.9). The ergonomic solutions were classified into the following (sub)categories: (1.) Work design and organisation (159 solutions; 58.9%) consisting of hours adaptation (11 solutions), job design (64 solutions), training (42 solutions), supervision (9 solutions) and use of human support (33 solutions); (2.) Workplace and equipment design (97 solutions; 35.9%) consisting of workplace design (20 solutions), equipment design including furniture (77 solutions) and; (3.) Other ergonomic solutions (16 solutions; 5.2%).

TABLE 4. Baseline characteristics of the workers sicklisted due to low back pain (n=35)

Baseline characteristics	n=35
Patient characteristics	
Mean age (sd) in years	40.9 (7.8)
Gender (% male)	57.6
Low back pain related characteristics	
Initial diagnosis	
% aspecific low back pain	90.3
% (suspicion of) root compression	9.7
History of sickleave due to low back pain in previous year (% yes)	23.3
Mean (sd) pain intensity (VAS)	5.56 (1.83)
Mean (sd) functional disability (RDQ)	15.45 (3.63)
Work-related characteristics	
Occupation (%)	
Physically/mentally demanding	34.4
Mentally demanding	22.9
Physically demanding	17.1
Physically nor mentally demanding	20.0

The planned term until implementation of the solutions was dichotomized into two categories: 172 (74.8%) short-term solutions (less than 3 months), 58 (25.2%) medium term or long-term solutions. Solutions concerning work design and organization were significantly ($p<0.02$) associated with a planned short-term implementation. In figure 1 the distribution of solutions and the planned term for implementation is shown.

According to the workers 48.9% of the ergonomic solutions were partially or completely implemented 3 months after the first day of sickleave (figure 2). Analyzing the implementation per economic sector, the implementation rate in the health care and services sector was highest: 58.2% and 61.2 % respectively. In the industrial sector the implementation rate, 10.4%, was significantly ($p<0.001$) lower. In the industrial sector also significantly fewer solutions (60.5%) were planned on the short-term compared to the health care (78.8%) and the services sector (76.2%). There was a strong significant association between planning a proposed solution in the short-term and the actual implementation of this solution ($p<0.001$). In figure 2, the proportion of (partially) implemented and not implemented solutions is shown, for solutions planned in the short term and medium/long-term separately.

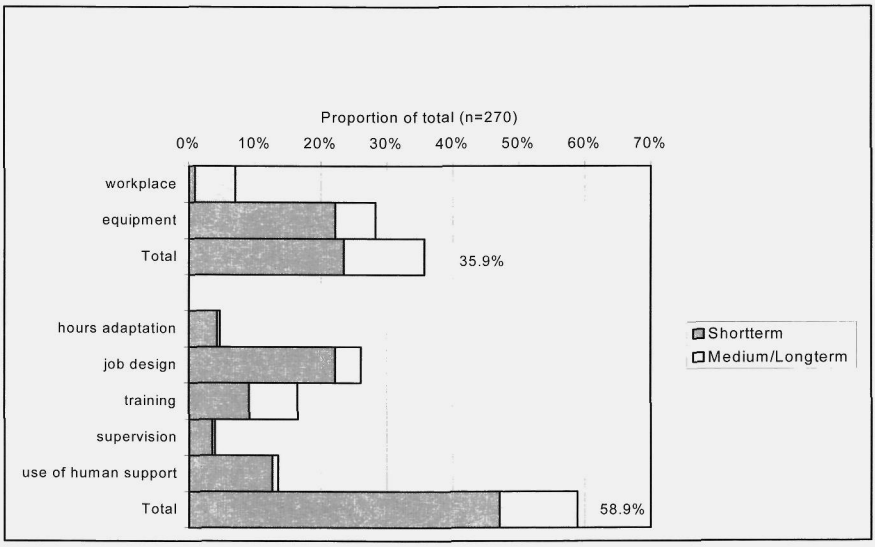

FIGURE 1. Proportion of all types of prioritized ergonomic solutions and the distribution of the planned term of implementation for each type of solution (n=270) among 35 workers

The ergonomists identified the following main obstacles for implementation of the ergonomic intervention: technical or organizational difficulties for work adjustments (50.0%), physical disabilities of the worker (44.8%), high physical workload (34.5%) and financial situation of the employer (26.7%).

The median score of the ergonomists' satisfaction about the work process and the effectiveness of the program was 7.0 on a 1-10 point scale. According to the ergonomists, motivating elements of the process of participatory intervention were: making an inventory of the problems with the worker (80.0% of the cases) and with the supervisor (60.0%), making an inventory of the solutions with the worker (73.3%) and with the supervisor (65.5%), commitment of the worker (66.7%) and of the supervisor (56.7%) to the prioritized ergonomic solutions, observation of the workplace (76.6%), and amount of time involved (60.0 %). No substantial inhibiting elements regarding the process of the participatory intervention were mentioned by the ergonomists. Finally there was a significant relationship between the ergonomists' satisfaction about the effectiveness of the intervention and the compliance to the protocol ($p<0.05$).

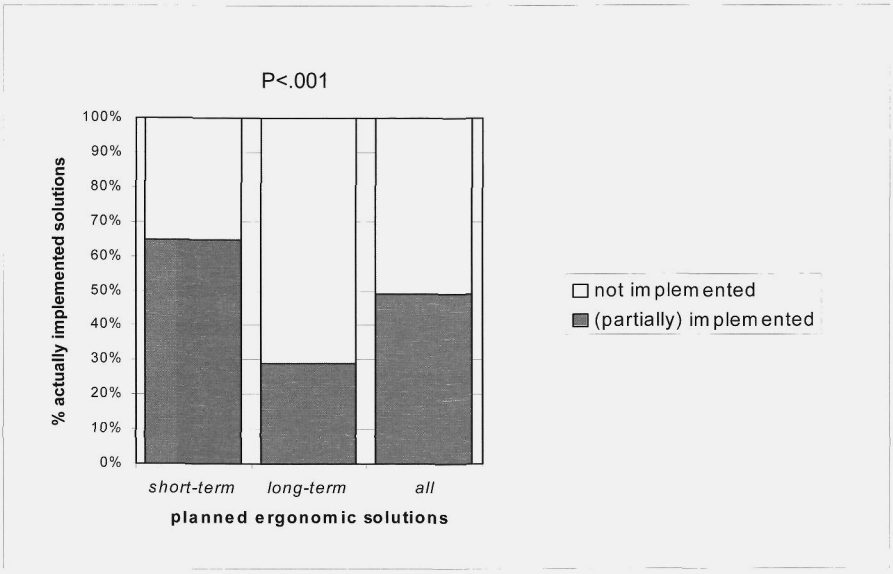

FIGURE 2. Implementation of ergonomic solutions by planned term for implementation (n=270). All proportions cumulate to 100%.

The workers were satisfied with the guidance by the ergonomist and the implemented solutions (median 7.8 on a 1-10 scale). There was a high correlation between the workers' satisfaction about the ergonomist and satisfaction about the solution implemented (Pearson correlation=0.82; significant at the 0.01 level). According to 78.9 % of the workers, they had a sufficient say in the ergonomic solutions. Two thirds of the workers and 55.6% of the ergonomists reported that into their opinion the implemented solutions had a stimulating effect on the work resumption. None of the workers or ergonomists concluded that the implemented solutions delayed work resumption.

Discussion

The aim of this paper was to describe the content, process and implementation of a participatory ergonomics program as part of a multidisciplinary disability management intervention. Application of participatory ergonomics as a return-to-work intervention for workers sicklisted due to low back pain is uncommon, because to date participatory ergonomics has almost exclusively been used for prevention of musculoskeletal disorders. Consequently, to date participatory ergonomics is applied to groups of healthy workers or individual workers with workrelated MSD (Bernacki et al, 1999), but not to individual sicklisted workers.

Moreover, from a descriptive perspective little is known about the structure and content of work adjustments applied in disability management programs (Krause et al., 1998). In line with this observation, Westgaard and Winkel (1997) concluded that

future ergonomic intervention research should put more focus on the (description of the) intervention process to improve our understanding of barriers and facilitators to the implementation of ergonomic interventions. This article intends to draw the attention to both of these aspects.

Compliance and applicability of the participatory ergonomics program

The program was implemented in 35 of the 45 cases (78%) eligible for the participatory intervention. The compliance of workers to the program was good; only one worker refused to participate in the program. None of the employers declined participation in the intervention after referral by the OP. According to the ergonomists, co-operation in the program of both employers and workers was good, although some were involved in a passive way. Finally, none of the employers, like in the Loisel et al. (2001) study, dropped out of the study after they signed the agreement to participate.

The participatory program was applied within the proposed time schedule in the majority of cases. Evaluation of the schemes filled in by the ergonomists showed that almost two thirds of the participatory ergonomics interventions were applied according to our strict quality criteria. Most of the proposed ergonomic solutions were planned, according to our protocol, in the short term in order to achieve a return-to-work as soon as possible. Therefore we conclude that the overall compliance and applicability of the program was good.

Frequency of problems at the workplace related to low back pain

Aspects of physical workload and problems related to workplace design were often mentioned by the workers and their supervisors as obstacles for return-to-work. Although back pain is also associated with psychosocial variables, the frequency of problems mentioned related to work organisation and work stress was relatively small. As in the study of Loisel et al. (2001) work organisation and work stress were not discussed as a problem in a structured way by the worker, supervisor and ergonomist. This can be explained by the fact that the worker and the supervisor are not used to relating back pain to work organisation and work stress. Moreover, work organisation and work stress are more difficult to discuss in the work setting than physical workload. Problems related to the physical workload and workplace design are more manifest and less abstract for workers.

Frequency of proposed ergonomic solutions

In the participatory ergonomics program used in this study, more solutions were proposed concerning work design and organization than solutions concerning workplace and equipment design. It seems that solutions concerning work design and organization were given more priority by the worker and supervisor than solutions concerning workplace and equipment. Many studies using a participatory ergonomics intervention for the prevention of MSD, however, report more solutions concerning workplace and equipment design than work design and organisation (de

Jong and Vink, 2000; Kuorinka et al., 1994; Vink et al. 1995 and 1997; Wilson, 1995).

This discrepancy can be explained by the different goals of participatory ergonomics when applied to prevention of MSD, or as a return-to-work intervention (Westgaard and Winkel, 1997). The aim of the former is to reduce the incidence of MSD and absenteeism by reducing the workload in general for a group of healthy workers. The goal of the latter is the return-to-work and prevention of (long-term) disability of an individual sicklisted worker by reducing the workload targeted to the individual's reduced work capacity. Consequently, due to these different goals ergonomic solutions are prioritized in a different way. For prevention, *workplace* adjustments are prioritized because they have to have a *more permanent and long-term* character in order to reduce the workload for a group of workers and because they are frequently aimed at the primary cause of the problem (Westgaard and Winkel, 1997). However, adjustments concerning *work design and organization* are prioritized as return-to-work intervention because they have to be implemented on a *short-term or temporary* basis in order to achieve a return-to-work as soon as possible and/or until the worker's disabilities are gone. This explanation is supported by our finding that ergonomic solutions in work design and organization were planned significantly more in the short term than adjustments of the workplace.

Implementation of ergonomic solutions

The employee-reported implementation rate of ergonomic solutions (48.9%) in our study is similar to the rate reported in the study of Loisel et al. (2001). In contrast to Loisel et al., we only asked the worker and not the employer, whether the solution was implemented, because we consider the workers' opinion as the most important factor in the process of return-to-work. Workers report lower implementation rates than employer representatives (Loisel et al., 2001), probably, because they are more critical about the final results of the implementation process. Also in contrast to Loisel et al. we evaluated the implementation of ergonomic solutions not at 6 but at 3 months after the first day of sickleave. We assumed that early intervention is essential to prevent long-term disability due to low back pain (Waddell and Burton, 2001). The implementation rate in our study will probably increase in time because most of the solutions planned for the medium or long-term had not been implemented at the moment of evaluation. This assumption is supported by the association observed between solutions planned in the short term and the actual implementation of these solutions.

According to the ergonomists obstacles for implementation were mostly related to technical or organizational difficulties for work adjustments and functional disabilities of the worker. It seems that in general employers are reluctant to adapt work to one individual worker when: (1.) The adjustment has a major impact on the workplace or work design; (2.) A worker has more functional disabilities. These obstacles for work adjustments can be an explanation why a lower implementation rate was achieved in the industrial sector than in the services and health care sector.

Satisfaction and perception of effectiveness of the participatory program

Most of the workers and ergonomists were satisfied about the participatory ergonomics program and the implemented work solutions. Satisfaction of the ergonomist was higher when the participatory ergonomics program was applied correctly according to our criteria. In general, most of the ergonomists reported that all steps in the program were facilitators in the intervention process and none was a significant barrier. Therefore the results of this study suggest that the acceptance and perception of effectiveness of the program was positive for the workers, as well as for the ergonomists. Finally, according to most of the workers and ergonomists the ergonomic intervention had accelerated return-to-work. Although the results are promising, future research has to confirm our findings about the acceptance, compliance and satisfaction of the program in a larger sample size. We are now conducting a RCT to evaluate the effectiveness of the program on return-to-work.

Conclusion

The objective of this study is to describe the content, process and implementation of a participatory ergonomics program as part of the disability management of workers sicklisted due to low back pain. The results suggest that the compliance, acceptance and satisfaction related to the program were good for the workers as well as the ergonomists. The proposed solutions were targeted more at work design than at the workplace and were planned mostly on short-time basis. Almost half of the solutions proposed were implemented three months after the first day of absenteeism. However, in the industrial sector only a small proportion of the solutions was implemented. The main obstacles to implementation were technical or organizational difficulties concerning work adjustment and functional disabilities of the worker.

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Chapter 6 Workplace interventions for workers on sickleave due to low back pain: a randomised controlled trial.

Johannes R Anema, Ivan A Steenstra, Paulien M Bongers, Henrica CW de Vet, Dirk L Knol, Willem van Mechelen *(submitted)*

Abstract

Background Workplace interventions are widely advocated for return-to-work after low back pain, but the effectiveness of these interventions has not been established.
Objective To evaluate the effectiveness of a workplace intervention for low back pain in occupational health care.
Design, setting and patients A population based randomized controlled trial (RCT) with a consecutive sample of workers (n=141) sicklisted for a period of 2 to 6 weeks due to non specific LBP, conducted at 13 Dutch Occupational Health Services between October 2000 and October 2003. A total of 114 participants (81%) completed the trial.
Intervention Participants were randomized to the workplace intervention (n=69) or usual care (n=72). Randomisation took place at the level of the occupational physician (OP). The workplace intervention consists of a workplace assessment, work modifications and case management involving all stakeholders.
Measurements Duration of sickleave due to low back pain until full return-to-work. Secondary outcome measures included functional status (Roland Disability Questionnaire) and pain intensity (10-point visual analogue scale), assessed before randomisation, and at 12 and 26 weeks after first day of sickleave.
Results The median duration of sickleave until full return-to-work in the intervention group was 64 days vs. 79 days for the usual care group (logrank test p=0.011). Workplace intervention was effective after 60 days of sickleave and onwards (hazard ratio = 2.5 [95% CI 1.5 to 4.1]; p=0.0003). The intervention group was more effective in improving functional status and pain than the usual care group. However, the effects were small, and not statistically significant.
Conclusions Workplace intervention was more effective than usual care on return-to-work of workers 2-6 weeks sicklisted due to non-specific low back pain.

Introduction

Low back pain (LBP) is the most common and expensive musculoskeletal disorder in Western countries [1]. Most of the costs are due to compensation claims of workers with sickleave absence due to LBP [2]. To date most studies evaluated the effectiveness of return-to-work interventions directed to the individual worker. Although workplace interventions are widely advocated as a return-to-work intervention for low back pain [3], the effectiveness of these interventions has not been established. [4,5,6,7]

In order to prevent occupational disability due to LBP, there is a need for effective co-operation between all stakeholders involved in the return-to-work process [8]. The relationships between these stakeholders are complex, because they have different, sometimes adverse interests. Scheel et al. [9] recently showed e.g. that the implementation of a return-to-work intervention can fail because of the lack of co-operation between all parties. It has been shown also that medical management of doctors can lead frequently to a negative effect on return-to-work after LBP [10]. A promising intervention strategy for workers sicklisted due to LBP is the workplace intervention developed and evaluated in a randomized controlled trial (RCT) by Loisel et al. in Canada [11,12]. This workplace intervention consisted of a workplace assessment, work modifications and involved all major stakeholders to achieve such interventions. The results of the study of the Loisel et al. showed significant positive effects of this intervention on sickleave, in comparison with usual care.[12]

In the present RCT, a Dutch workplace intervention, derived from the Canadian model, was evaluated. This Dutch intervention consisted of a workplace assessment, work modifications and case management in which all major stakeholders in the return-to-work process participated: i.e. the worker, the employer, the occupational physician (OP) and the worker's general practitioner (GP). This workplace intervention should lead to feasible work modifications leading to return-to-work [13].

The question is whether the promising results of the study of Loisel et al. [12] can be repeated in a study in another country with a different health care and social security system.

Methods

Study design and setting

This study was part of a single blind pragmatic population based RCT, evaluating a multistage return-to-work program for LBP. The intervention consists of a workplace intervention and a graded activity intervention. The effectiveness is evaluated in a multifactorial RCT. The design of that study was described in detail by Steenstra et al. [14]. The study we present here focuses on the effectiveness of the workplace intervention on return-to-work, functional status and pain. Thirteen Dutch occupational health services (OHS) were involved in this study.

Study population

The source population (n = 100.000) consisted of the worker's population of 99 participating OPs. Workers who were sicklisted due to non-specific LBP were invited for an occupational health consult with the OP. The researcher (IS) or the research assistant judged whether the workers met the inclusion criteria of the RCT. The worker's OP informed the researchers whether a subject should be excluded on medical grounds. The inclusion criteria of the RCT were:

- Low Back pain (ICD-10 codes: M54.5, M54.4, M54.3, M54.1, M54.8 and M54.9).
- Full or partial sickleave because of non-specific LBP, lasting 2-6 weeks;
- Age between 18 to 65 years
- Able to give written informed consent and to complete written questionnaires in Dutch.

The exclusion criteria were:

- LBP due to specific causes;
- Co-existing cardiovascular, psychiatric or juridical contra-indications;
- Pregnancy;
- Sickleave due to low back pain less than one month prior to the current episode of sickleave.

To detect a 20% difference in recovery rate (return-to-work), a sample size of 200 workers is needed [14]. To analyze the effectiveness of the workplace intervention independently, we studied the sample, excluding the participants who were randomized to the graded activity intervention after 8 weeks of sickleave.

Treatment allocation and blinding

To reduce the risk of contamination, randomization took place at the level of the OP, after prestratification by economic sector of their worker's population. Randomization procedure is described in detail elsewhere [14]. The research assistants who collected the baseline data were blinded for the treatment allocation. Treatment allocation was made known to the worker after informed consent and completion of the first questionnaire. Data on return-to-work were extracted from automated databases so bias as caused by a lack of blinding was prevented. Blinding of self-reported outcome measurements during follow-up was not possible. However, since all follow-up questionnaires were mailed to the worker, no direct influence by the researchers or treating professionals was likely to happen.

Interventions

The interventions in this study comprised:

1 Usual care group received occupational back pain management and work resumption advice given by the OP, according to the Dutch OP Guidelines for LBP.[15]

2 Workplace intervention group received in addition to the usual care group a worksite assessment, work modifications, based on methods used in participatory

ergonomics. The workplace intervention took place directly after inclusion. The OP, in collaboration with an ergonomist or an occupational health nurse, delivered this intervention. For each worker, a group was formed that included the ergonomist (process leader), the injured worker, the worker's supervisor, and possible other stakeholders. After observation of the worker's tasks by the ergonomist, obstacles for return-to-work were ranked independently by the worker and the supervisor. Following this, the ergonomist organized a meeting of the group of stakeholders to brainstorm and discuss about all possible solutions for the obstacles ranked highest with the aim to achieve consensus regarding feasible solutions. Based on the outcome of this meeting, solutions were recommended to the employer. A detailed description of this workplace intervention method is published elsewhere [13]. Finally, a short communication form was exchanged between the OP and the general practitioner (GP) to get commitment of the worker's GP on advising the worker in the return-to-work process [16].

Outcome measures and prognostic factors

Sickleave duration due to LBP was the primary outcome measure and functional status and pain were secondary outcome measures. Sickleave was defined in this study, following the Dutch social security laws, i.e.: duration of sickleave in calendar days from the first day of sickleave to full return-to-work in own work, for at least 4 weeks without (partial or full) drop-out. This implicates that for workers who returned to other work, time to return-to-work was censored in Cox regression analyses. In addition, the total duration of sickleave due to LBP (including all recurrences of sickleave episodes) was calculated for the entire six months follow-up period. Functional status of the worker was measured by the Roland Disability Questionnaire [17,18]. An individual score could vary from 0 (no disability) to 24 (severe disability). Pain intensity was measured on a 10-point visual analogue scale ranging from 0 (no pain) to 10 (very severe pain) [19].

Finally, data were collected on prognostic factors for duration of sickleave to adjust in case of dissimilarities between the treatment groups [14].

Statistical analyses

Descriptive statistics (mean with standard deviation; median with interquartile range) were calculated for potential prognostic variables and baseline values of outcome measures, in order to determine the prognostic similarity of the groups at baseline. Because the intraclass correlation coefficient for the OP's level was estimated at approximately 0, all analyses were performed at the worker's level. All analyses were conducted according to the intention-to-treat principle. In addition, per protocol analysis was conducted, excluding all workers who were not treated according to protocol.

Survival analyses (Kaplan Meier analyses with log rank test and Cox's regression analyses) were used to describe the univariate and multivariate associations between treatment allocation and the time to lasting return-to-work. Because the Cox

proportional hazard assumption of a constant hazard ratio was not met by the sickleave data, hazard ratios were calculated for specific follow-up periods by adding an interaction term between a specific follow-up period and treatment allocation to the model. Longitudinal random coefficient analyses were used to assess differences between treatment groups in improvement in all secondary outcome measures. The baseline value of the particular outcome variable was added to the model in order to correct for possible regression to the mean. In all multivariate analyses (Cox regression, longitudinal random coefficient) adjustments were made for gender. The total number of days of sickleave during 6 months follow-up due to LBP (including recurrences) were compared for both groups by Mann Whitney U tests. Values of $p<.05$ were considered statistically significant and survival analyses were performed using the SPSS 10.0 software package (SPSS Inc., Illinois, USA). The intraclass correlation coefficient for the OP-level was calculated using STATA (version 7) and random coefficient analyses using MlwiN (version 1.10).

Results

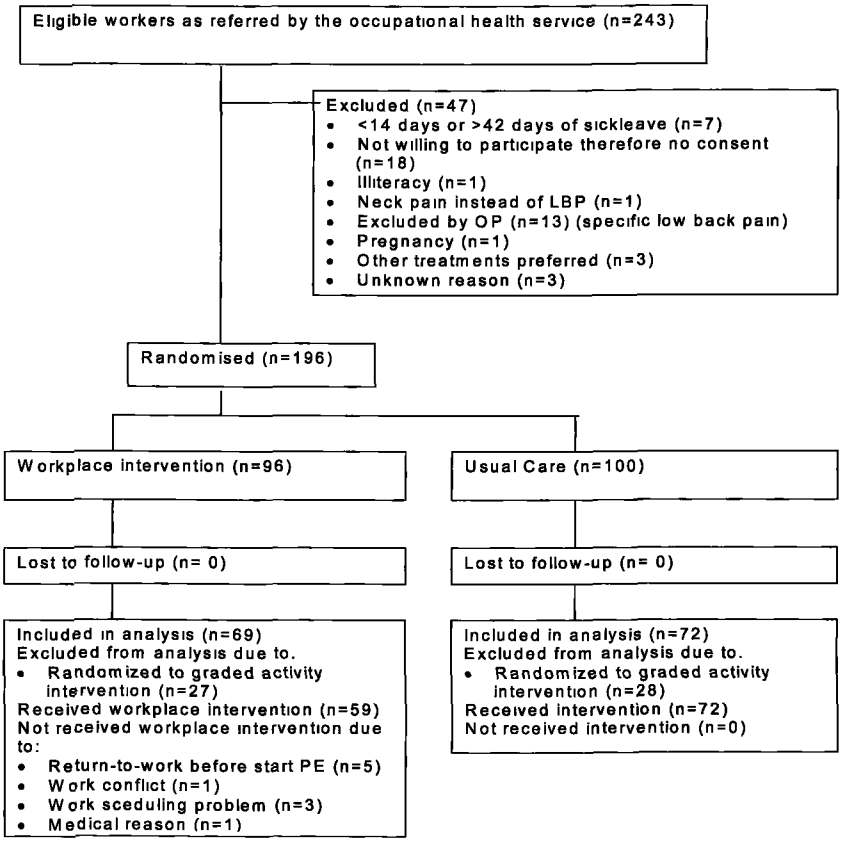

FIGURE 1. Flow diagram describing the progress of the workers through the phases of the trial.

Patient flow

The flow of the workers in this study during the recruitment, inclusion and the follow-up is presented in figure 1. The OPs referred 243 eligible workers to the research assistant from October 2000 till October 2002. Fourty-seven workers did not meet the inclusion criteria. Fifty-five workers randomized to the graded activity intervention were excluded for analysis in this study. Consequently, a total number of 141 workers were analyzed: 69 workers were assigned to the workplace intervention group and 72 workers to the usual care group.

Drop-out and non-compliance

Sickleave data (primary outcome measure) were collected continuously during follow-up from automated databases for all 141 included workers. For twenty-seven workers (19%) no follow-up data regarding the secondary outcome measures could be collected.

Ten workers were not compliant to the intervention protocol: 5 workers returned to work before an appointment for the workplace intervention was made. Five workers did not participate in the workplace intervention due to a work scheduling problem (3), a medical reason (1) or a work conflict (1). None of the workers quitted during the workplace intervention. All workers in the usual care group were compliant to the treatment of the OP, because it was not possible to withdraw from this treatment due to legal regulations.

Patient characteristics

Table 1 shows the baseline values of the outcome measures and the prognostic factors for the workplace intervention group and the usual care group. If the distribution of a variable was not normal, median value and the interquartile range (IQR, 25th and 75th percentiles) are presented. Except for gender, only minor non-significant differences were found between the baseline characteristics of both groups.

Workplace intervention

The workplace intervention had an average duration of 24 days (SD = 22) starting at the first consult with the OP. Fifteen ergonomists were involved in delivering the workplace interventions, with an average of 4.0 interventions per ergonomist. The frequency of consults (mean) with the OP in the Intervention group was 2.7 in the first 3 months and 2.0 between 3 and 6 months after the start of sickleave. The mean duration of these consults was 21 and 15 minutes, respectively. No adverse events or side effects were reported. Additional treatments in this group of 69 workers applied by other care givers than the OP were: regular physiotherapy 33 workers (48%), manual therapy 9 workers (13%), Cesar therapy 1 worker (1%), chiropractor care 2 workers (3%) and a visit to a medical specialist 3 workers (4%).

TABLE 1. Prognostic variables and baseline values of outcome measures

	Workplace intervention (n=69)	**Usual Care (n = 72)**
Baseline characteristics		
Age in years (mean, sd)	44.1 (8.8)	41.9 (9.6) *
Gender (male/female)	38/31	27/45
Economic sector:		
- Industrial	5	5
- Transportation	1	3
- Office work	17	12
- Health Care/Services	42	48
- Other	4	4
Heavy physical work index [1-4]† (mean; sd)	2.29 (0.68)	2.12 (0.65)
Job control [1-4]† (mean; sd)	2.61 (0.46)	2.56 (0.36)
Job demands [1-4]† (mean; sd)	2.53 (0.27)	2.54 (0.29)
Supervisor support [1-4]† (mean; sd)	2.96 (0.35)	3.05 (0.46)
Radiating pain (y/n)	11/58	15/57
Job satisfaction [1-4] ‡ (mean; sd)	1.62 (0.71)	1.70 (0.78)
Expectation of patients on return-to-work [1-5]† (mean; sd)	3.67 (1.16)	3.63 (1.09)
Sickleave prior to inclusion (partial/full)	14/55	24/48
Baseline values of outcome measures		
Sickleave (days) of current episode of LBP prior to inclusion (median, IQR)	20.5 (16-30)	22 (16-28)
Functional status (RDQ) (mean, sd)	14.4 (4.3)	14.3 (4.6)
Pain severity previous week (mean, sd)	6.4 (1.9)	6.3 (1.8)

IQR= interquartile range, 25th percentile to 75th percentile

* p<0.05

† higher score means a higher level of physically demanding work, job control, job demands, supervisor support, exspectation of return-to-work

‡ A higher score means a lower level of job satisfaction

Usual care

The frequency of consults (mean) with the OP in the usual care group was 3.0 in the first 3 months and 3.3 consults between 3 and 6 months after the start of sickleave. The mean duration of a consult was 19 and 15 minutes, respectively. From this group of 72 workers, 42 workers had regular physiotherapy (58%), 13 workers had manual therapy (18%), 4 workers had Mensendieck therapy (6%), and 12 workers visited a medical specialist (17%). None of the workers received a return-to-work intervention comparable to the workplace intervention.

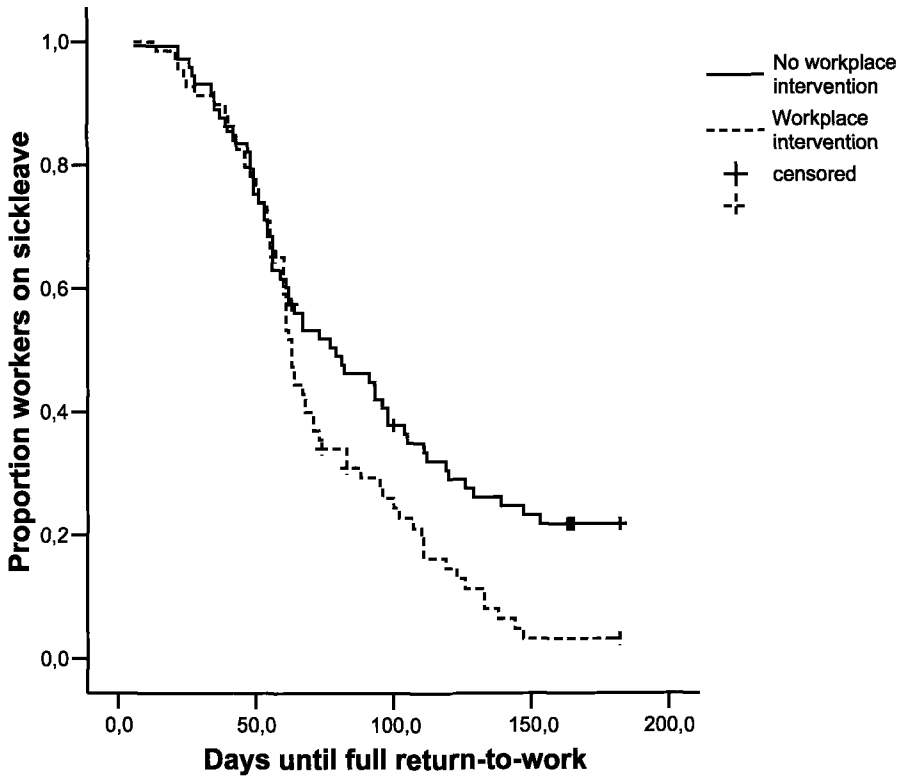

FIGURE 2. Survival curves of absence from regular or equal work for both the workplace intervention group and usual care group.

Sickleave

In the univariate analysis (Kaplan Meier), the median duration of the first continuous period of sickleave in the workplace intervention group was found to be 64 days (54-100) compared to 79 days (51-147) for the usual care group. This difference was significant (log rank test; p= 0.011). The curves of both groups over 6 months of follow-up are shown in figure 2. In the first 60 days after the start of sickleave the rate of return-to-work was more or less similar in both groups, while from

approximately 60 days after the start of sickleave and onwards the curves of the workplace intervention group and the usual care group diverged. We assumed that hazard ratios were constant within each of the two time periods. By means of Cox regression analyses (n=141) hazard ratios were calculated both for the workers with less than 60 days of absence from work after the start of sickleave and for the workers with 60 and more days of absence from work. The hazard ratio for the period up to 60 days of absence from work was 0.9 (95% CI 0.5 to 1.5, p=0.65). The hazard ratio for work absenteeism of 60 days and more was 2.5 (95% CI 1.5 to 4.1, p=0.003), in favor of the Intervention group. The results of these analyses are presented in table 2. The number of workers still on sickleave at 6 months follow-up in the workplace intervention group and the usual care group were 5 and 17 respectively.

TABLE 2. Results of the survival analyses (Cox regression) analyses regarding the first period of sickleave.

		Adjusted hazard ratios for return to regular work (95% confidence interval), Cox regression		
	Median number of days off regular work	Workers < 60 days of sickleave	Workers ≥ 60 days of sickleave	P value
Intention-to-treat analysis (n=141)				
Workplace intervention	64	0.9 (0.5 - 1.5)	2.5 (1.5 - 4.1)	P=0.0003
Usual care	79			
"Per protocol" analysis (n=131)				
Workplace intervention	64	0.8 (0.5- 1.5)	2.5 (1.5 - 4.1)	P=0.0005
Usual Care	79			

* Adjusted for gender

In the "per-protocol" analysis (n=131), the hazard ratio for the period up to 60 days after the start of sickleave was 0.8 (95% CI 0.5 to 1.5, p=0.55) and the hazard ratio for the period from 60 days of work absenteeism and onwards was 2.5 (95% CI 1.5 to 4.1, p= 0.005), in favor of the workplace intervention group.
The median of the total number of days of sickleave (including recurrences) during the 6 months of follow-up in the workplace intervention group was 64 (IQR=54-96) days compared to 79 (IQR=53-129) days, for the usual care group. This difference was not statistically significant (Mann Whitney U test, p = 0.13).

Functional status and pain intensity
Figure 3 and 4 present the mean values of the outcome measures functional status and pain intensity at baseline and follow-up.

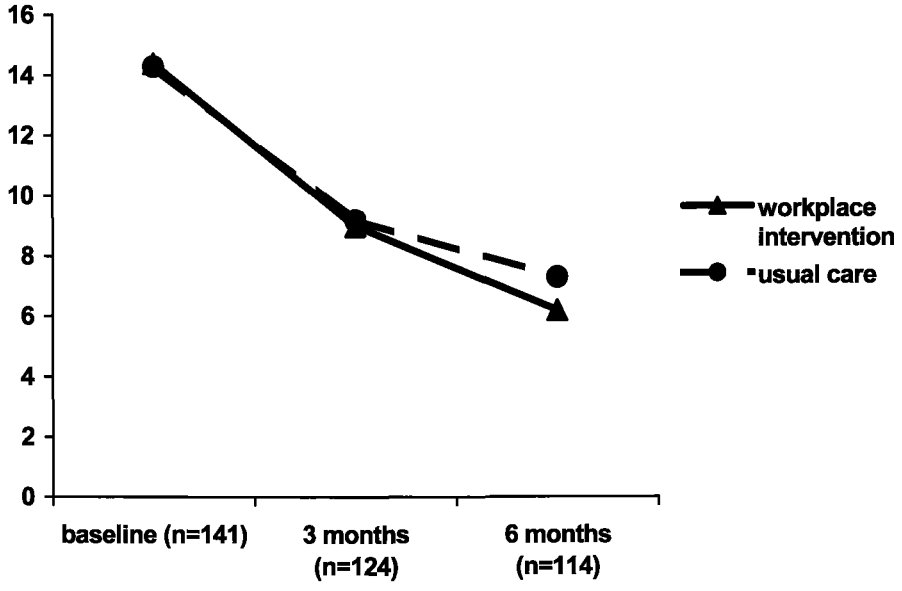

FIGURE 3. Mean values of the outcome measures functional status at baseline, and 3 and 6 months follow-up.

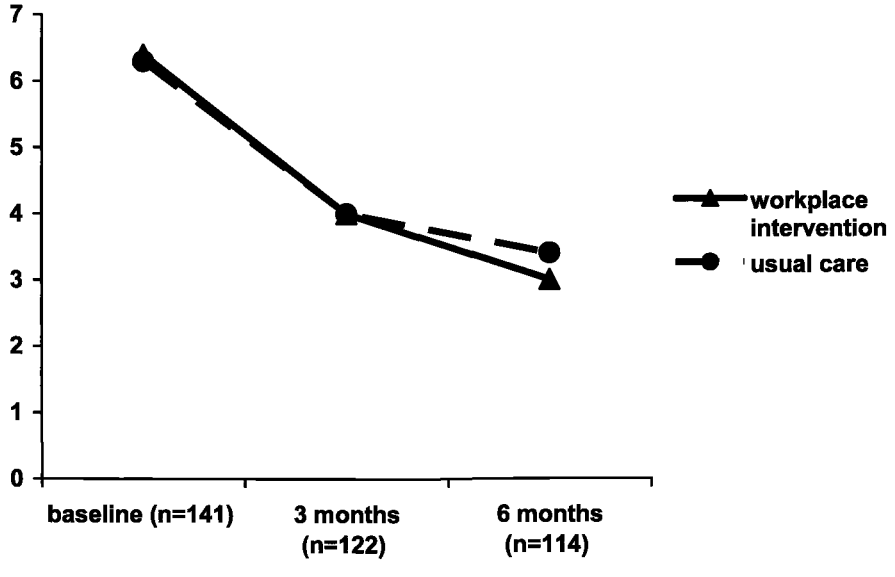

FIGURE 4. Mean values of the outcome measure pain intensity at baseline, and 3 and 6 months follow-up.

Both treatment groups improved in functional status and pain over time. Table 3 presents the mean improvement of these outcome measures at baseline and follow-up. In addition, the results of the regression analyses regarding the effects of the workplace intervention versus usual care, as well as the prognostic factors adjusted for in the final multivariate model, are presented in table 3. The differences between the groups in improvement of functional status and pain at 3 and 6 months were in favor of the workplace intervention group, but were not statistically significant.

TABLE 3. Results of multivariate analyses regarding the effects of workplace intervention on functional status and pain after 3 and 6 months of follow-up (intention-to-treat analysis).

	Mean (sd) Improvement		Effect of workplace intervention° *	95% CI
	PE	Usual Care		
Functional status (RDQ)				
3 months (n=124)	5.4	5.1		
			-0.595	-2.66 to 1.47
6 months (n=114)	8.2	7.0		
Pain intensity (VAS)				
3 months (n=122)	2.4	2.3		
			-0.119	-0.88 to 0.64
6 months (n=114)	3.4	2.9		

* Adjusted for the baseline value of the outcome measure, gender, levels of OP, time

° The effect is the regression coefficient derived from longitudinal random coefficient analysis (corrected for the baseline value of the outcome measure) which can be interpreted as the difference in adjusted improvement over time between the groups. No time interaction was found. Both differences are in favour of the Iintervention group.

Discussion

In this study a population based randomized controlled trial with a sample of workers (n=141) sicklisted 2 to 6 weeks due to non specific LBP, was conducted in Dutch Occupational Health Care to evaluate the effectiveness of a workplace intervention. The results of this study showed that workplace intervention had a beneficial effect on return-to-work from 60 days after the start of sickleave, in comparison to usual care. This delayed effect may be related to the start of the intervention (mean 22 days after the start of sickleave) and the duration of the intervention (mean 24 days). There was no significant effect on functional status and severity of low back pain.

A principal strength of this study is that, to our knowledge, this is to date one of the few RCTs that describe the effectiveness of workplace interventions involving all stakeholders in the return-to-work process of workers with LBP. Another strength of this study is that we achieved to conduct this RCT in many different companies, in

various economic sectors and involving many OHSs, OPs, occupational health nurses and ergonomists. Therefore it has the benefit that the results of this study may well be generalisable to occupational care in the Netherlands.

Comparison with other studies

The effects of a similar intervention in an occupational health care setting were previously studied in a RCT by Loisel et al [12] in Canada. This study showed comparable positive effects regarding return-to-work in favor of the workplace intervention group and no effects on pain scores at one-year follow-up. In the Canadian study the functional status was significantly better in the intervention group compared to the usual care group at one-year follow-up. In our study functional status improved more in the intervention group but this was not statistically significant.

Although both studies are similar in many aspects, it must be noticed that there are some differences. Firstly, the subjects in the Canadian study were sicklisted for 4-12 weeks before entering the study. In our study inclusion was limited to the workers sicklisted for 2-6 weeks and therefore the workplace intervention was applied earlier in the course of LBP. Further, all interventions in the Canadian study were applied by one multidisciplinary team in contrast to the Dutch intervention, which was applied by several professionals from different private OHS. In addition, the Social Security and Health Care System in the Netherlands [14] is very different compared to Canada. Therefore, the additional value of our study is that the workplace intervention has proven to be also effective in different national context and setting [14]. This study confirms our findings in a cross-national observational study indicating that the effectiveness of workplace interventions is relatively independent from contextual circumstances such as the organization of the health care and social security system [13].

Limitations of this study

A limitation of this study is the lack of blinding of the patients and OPs. It is however practically impossible to conduct a double blinded RCT on workplace interventions. However, our primary outcome measure –sickleave- was derived from automated databases, thereby avoiding bias caused by data derived from self-reported questionnaires. A second possible source of bias is the so-called 'Hawthorne effect': it cannot be excluded that the results are (partially) explained by the effect of the attention received by the intervention group. This bias could have caused an overestimation of the effect.

Finally, in this study it is not possible to identify the elements of the workplace intervention that contributed most to the favorable return-to-work-outcomes. In our opinion there are two key-elements in the succes of the workplace intervention: 1. The participation of all stakeholders involved in the return-to-work process 2. Stimulating patient involvement can lead to greater patient control and greater

adherence to the work modifications. The latter explanation fits in theories used in patient empowerment to improve the quality of medical care [20].

Clinical impact of this study

This study adds important evidence to the current limited evidence on the effectiveness of workplace interventions on return-to-work. Principal meaning of this study is that the occupational rehabilitation of workers sicklisted due to LBP should include workplace intervention. This study showed that workplace intervention was also promising to prevent long-term occupational disability due to LBP: the number of workers still on sickleave at 6 months of follow-up in the workplace intervention group was low compared to usual care. Once a worker is off work for 6 months there are very small chances of returning to work when left untampered [5]. Therefore, the impact of workplace intervention in the prevention of long-term occupational disability due to LBP and thus in the reduction of costs to the society seems important. However, although the results of our study are promising, the (cost)-effectiveness of workplace intervention has yet to be studied in the long-term.

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Chapter 7 The effectiveness of graded activity for low back pain in occupational healthcare, results of a randomized controlled trial.

Ivan A Steenstra, Johannes R Anema, Paulien M Bongers, Henrica CW de Vet, Dirk L Knol, Willem van Mechelen. *(submitted)*

Abstract

Context Low back pain is a common medical and social problem associated with disability and absence from work. Knowledge on effective return to work (RTW) interventions is scarce.
Objective To determine the effectiveness of graded activity as part of a multi stage RTW program.
Design Randomized controlled trial.
Setting Occupational health care.
Subjects 112 workers absent from work for more than 8 weeks due to low back pain, were randomized to either graded activity (n=55) or usual care (n=57).
Intervention. Graded activity, a physical exercise program aiming at RTW based on operant-conditioning behavioral principles.
Main outcome measures The number of days off work until lasting RTW, total number of days on sick leave, functional status and severity of pain.
Results Graded activity prolonged RTW. Median time until RTW was equal to the total number of days on sick leave and was 139 (IQR=69) days in the graded activity group and 111 (IQR=76) days in the usual care group (hazard ratio= 0.52 (95% CI=[0.32-0.86]). An interaction between a prior ergonomics intervention and graded activity, together with a delay in the start of the graded activity intervention, explained most of the delay in RTW (hazard ratio= 0.86, 95% CI= [0.40-1.84] without prior intervention and 0.39, 95% CI=[0.19- 0.81] with prior intervention). Graded activity did neither improve pain nor functional status clinically significantly.
Conclusions Graded activity was not effective on any of the outcome measures. Different interventions combined can lead to a delay in RTW. Delay in referral to graded activity delays RTW. In implementing graded activity special attention should be paid to structure and process of care.
Keywords low back pain, graded activity, randomized controlled trial, effectiveness, occupational health, cognitive behavioral, return-to-work.

Introduction

In this article, we describe the results of a randomized controlled trial (RCT) on the effectiveness of graded activity for workers on sick leave due to low back pain as part of an occupational back pain management program [1].

Back pain is a common problem in Western societies. It causes major occupational disability and considerable financial costs. Total costs estimates vary from 0.28 to 1.7 % of the Gross National Product, depending on the method used [2]. Approximately 93% of total costs are caused by absenteeism from work [3]. In general most costs are caused by workers who are off work for more than 6 months [4;5]. Based on the report of the Quebec Task Force on Spinal Disorders [6] researchers at Sherbrooke University, Canada developed an occupational back pain management program which aims at treating sub-acute back pain and preventing chronicity. The Sherbrooke program consists of an occupational intervention and a clinical intervention comparable to graded activity. It has been evaluated in a RCT(7-9). The back pain management program appeared to be an effective tool in fastening return to work (RTW)[7].

We have adapted the Sherbrooke intervention to Dutch occupational healthcare practice[1]. This means that we designed an occupational back pain management program consisting of two interventions. At inclusion workers could be randomized to an occupational intervention based on the participative ergonomics (PE) approach [10;11] or usual care by the occupational physician (OP). Workers still off work after 8 weeks could be randomized to the graded activity intervention. Graded activity has been developed and evaluated by Lindström et al.[12;13] and was adjusted to the Dutch situation and evaluated by Staal et al.[14]. It has proven to be an effective tool in fastening RTW for workers on sick leave due to low back pain in the sub-acute phase[12;14]. The question emerges whether graded activity can be equally effective as part of a multi-stage RTW back pain management program. In this paper the results of the graded activity intervention versus usual care are presented.

Study design and population

The interventions were evaluated in a four arm RCT (see figure 1) (usual care, graded activity only, participatory ergonomics only, and participatory ergonomics followed by graded activity). It was executed in 13 occupational health services and 16 physiotherapy centers [1].

The Medical Ethics Committee of VU University Medical Center approved the study design, protocols, procedures and informed consent procedure, and all participants provided written informed consent.

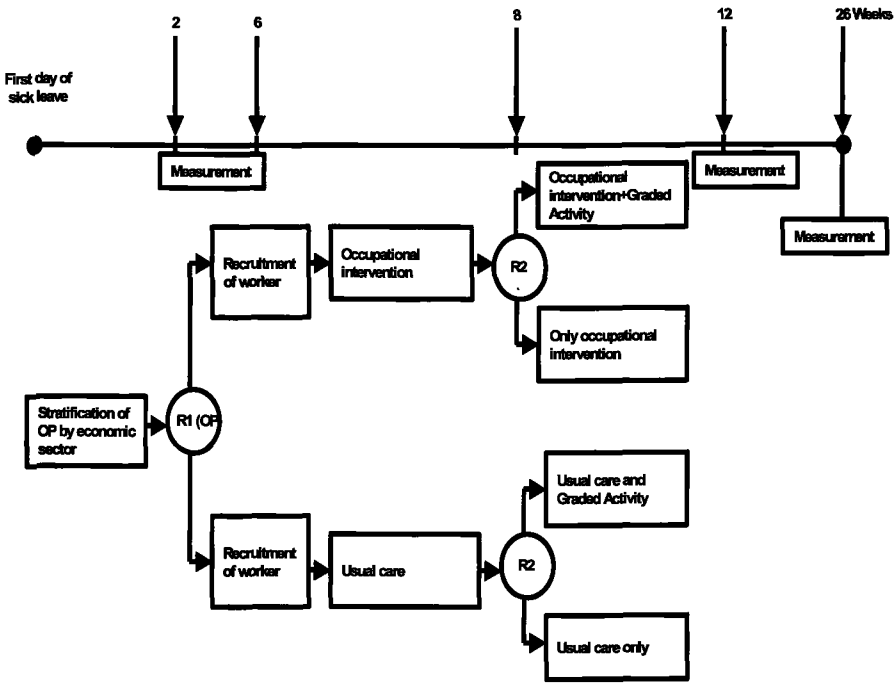

FIGURE 1. The two stage design of the study

R1 = Randomization on OP level after 2-6 weeks of sick leave

R2 = Randomization on worker level after 8 weeks of sick leave

Baseline characteristics at 2-6 week, follow up measurements of secondary outcomes at 12 and 26 weeks after first day of sick leave

Subjects

The source population for this study consisted of about 100.000 workers from 99 occupational physicians (OP). Subjects were randomized for the graded activity intervention at the workers level.

The inclusion criteria were:

- Low Back pain (ICD-10 codes: M54.5, M54.4, M54.3, M54.1, M54.8 and M54.9);
- Included in the multi-stage RTW back pain management program at 2 to 6 weeks of sick leave;
- Sick leave for longer than 8 weeks and no plans to return to work within a week;
- Age between 18 to 65 years;
- Able to give informed consent and to complete questionnaires in Dutch.

The exclusion criteria were:

- Low back pain due to specific causes;
- Co-existing cardiovascular, psychiatric contra-indications or juridical procedures;
- Pregnancy;
- Sick leave due to low back pain less than one month prior to the current episode.

Treatment allocation

An independent researcher (HCWdV) prepared the envelopes for randomization by coding them according to a list of random numbers. If a patient was eligible, an opaque envelope had to be opened by the OP. In case of randomization to graded activity the OP referred the worker to the physiotherapist (PT).

Sample size

To detect a 30% difference in recovery rate (RTW) we needed a minimum of 45 workers in both treatment arms[1]. This difference can be detected with a power (1-β) of 80% at α=.05 [15].

Blinding

Workers, OPs and PTs could not be blinded for the allocated treatment. Treatment allocation was made known to the worker after informed consent and completion of the first questionnaire. Therefore blinding of self-reported outcome measurements during follow up was not possible. However, since all follow-up questionnaires were mailed to the worker, no direct influence by the researchers or treating professionals was likely to happen. Data on RTW were extracted from automated databases so bias as caused by a lack of blinding was prevented.

Interventions

Usual care

In the Netherlands workers who are absent from work due to low back pain are guided throughout their sick leave according to the Dutch OP guidelines for low back pain [1;16;17]. By informing the patients' general practitioner (GP) we tried to minimize co-interventions.

Graded activity

The graded activity intervention was performed by 47 PTs from 16 in-company and out-company physiotherapy centers. A team of specialized PTs from the Staal et al.[14] trial trained all PTs in the graded activity protocol.

Graded activity aims to restore occupational function, i.e. return to previous work. During the program the worker has an active role in RTW and the PT acts as a coach and supervisor, using a hands-off approach [1;14]. The intervention consisted of an

individual, sub maximal, gradually increasing exercise program, with an operant-conditioning behavioural approach based on the findings from patient history, physical examination, functional capacity evaluation, the demands from the patients' work and the patients' expectations on time to RTW. The entire program consisted of 26 one-hour sessions maximally, with a frequency of two sessions a week. The first session took half an hour more since a physical examination was part of this session. The program stopped as soon as a lasting return to own or equal work had been established, according to an earlier agreed upon individual schedule[1].

Outcomes

De Vet et al.[18] pointed out the importance of defining episodes of low back pain. We restricted our analyses to time to RTW defined as:

1. Lasting return to own or equal work: i.e. duration of work absenteeism in calendar days from the first day of sick leave to full RTW in own or other work with equal earnings, lasting for at least 4 weeks without (partial or full) drop-out.
2. Total number of days on sick leave due to low back pain in the follow up period, since possible recurrences can be considered as a negative outcome of the interventions.

Secondary outcomes in this study were functional status, measured with the Roland-Morris Disability-24 Questionnaire [19-23] and pain intensity, measured on a 10 point visual analogue scale [24;25].

Data are available on the first 26 weeks of sick leave. The first assessment of workers took place at the first visit of the OP's office at 2-6 weeks after the first day of sick leave, with follow up assessments at 12 weeks and 26 weeks after the first day of sick leave.

Confounders

Data on prognostic factors for duration of sick leave were gathered at baseline: i.e. neurological signs, economical and insurance status of the company [26-32], job content data [33;34], workload [35] and co-interventions, fear avoidance beliefs [36] and kinesiophobia [37;38].

Statistical methods

All analyses were performed at the patient level. To check whether multilevel analysis on the OP level was required independency of observations within and among OPs was determined by calculation of intraclass correlation coefficients.

To examine the success of randomization, descriptive statistics were used to compare baseline characteristics. All covariates were forced into the multivariable models to adjust for prognostic dissimilarities. Cox regression analysis was used to analyze differences in time to RTW between the graded activity and usual care group. A time dependent covariate was used to adjust for the fact that

randomization took place 8 weeks after first day of sick leave. A Kaplan Maier curve was plotted to describe survival in both groups. Analysis of covariance was used to examine differences in improvement in secondary outcomes. The baseline values of the particular outcome variable were added to the model to adjust for possible regression to the mean. The coefficients of the analysis of covariance were estimated with random coefficient analysis[39] separately at 12 and 26 weeks since there was an interaction effect between intervention and time.
The analyses of primary and secondary outcomes were adjusted for gender and the effect of an earlier component of the back pain management program, i.e. the ergonomics intervention. All statistical analyses were performed according to the intention-to-treat principle. Stratified analyses were performed for groups that did and did not receive the earlier ergonomics intervention. In addition, per-protocol analyses were performed, excluding all workers who were not treated according to protocol. Values of $p<.05$ were considered statistically significant. Mann-Whitney U-tests were used to analyze differences in total days on sick leave due to low back pain during follow up because of the skewed distribution of this outcome. All analyses were performed with SPSS (version 11), except intraclass correlation coefficients for the OP level, which were calculated using STATA (version 7), and the covariance analyses which were performed with MLwiN (version 1.10).

Results

The occupational physicians referred 243 workers to the study from October 2000 till October 2002. Forty-seven workers did not meet the inclusion criteria. 84 had recovered before 8 weeks, leaving 112 workers to be randomized: 55 to graded activity and 57 to usual care (see figure 2). The characteristics of workers in both groups are presented in table 1.

Intraclass correlation coefficients among and within OPs were estimated as <0.01 so all regression analyses were performed on the workers level.
The interaction between the ergonomics intervention and the graded activity intervention was not statistically significant ($p=0.40$). Therefore adjusting for the effect of the ergonomics intervention seems appropriate before stratifying in our analyses.

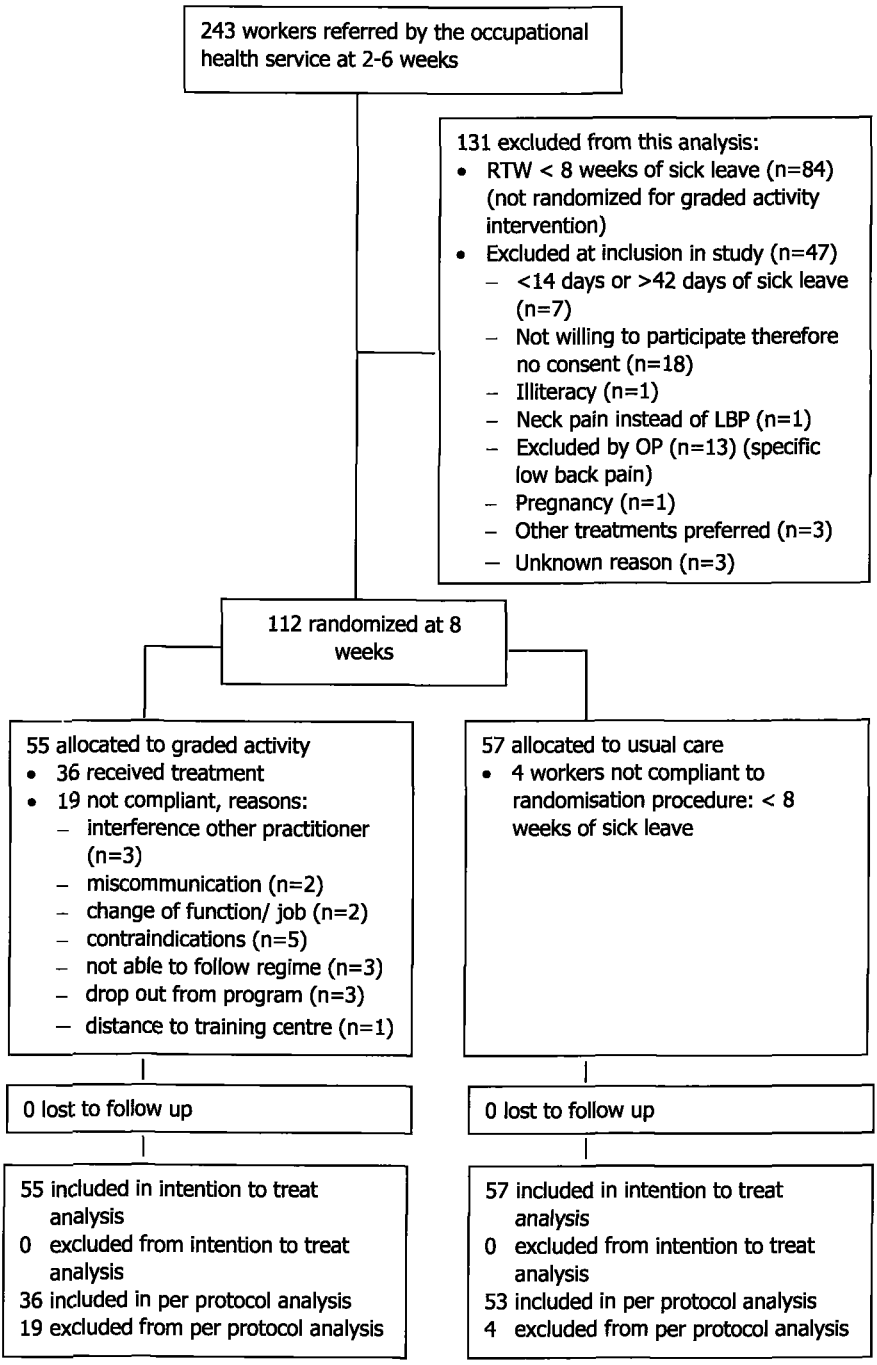

FIGURE 2. Flow diagram describing the progress of the workers through the phases of the trial

TABLE 1. Baseline values of outcome measures and potential prognostic variables

Baseline characteristics	Graded Activity	Usual care
N=112	55	57
Age, mean (SD)	41.34 (9.20)	43.16 (8.18)
No radiating pain vs. Radiating pain	44/ 11	44/ 13
Ergonomics intervention (yes/ no)	27/28	26/31
Men/ Women	19/36	26/31
Pain (mean score (SD)	6.60 (1.40)	6.80 (1.47)
Functional status (mean score (SD))	14.41 (4.47)	15.93 (3.29)
Kinesiophobia (mean score (SD))	39.95 (6.45)	39.58 (7.37)
Fear avoidance beliefs, physical activity subscale (mean score (SD))	18.10 (5.50)	17.60 (5.90)
Fear Avoidance Beliefs, work subscale (mean score (SD))	16.27 (7.08)	17.36 (6.85)
Static physical work index (mean score (SD)) ₸	2.20 (0.98)	2.10 (0.91)
Heavy physical work index (mean score (SD)) ₸	2.20 (0.70)	2.10 (0.71)
Job content questionnaire ₸		
• Job control (mean score (SD))	2.60 (0.33)	2.60 (0.41)
• Supervisor support (mean score (SD))	3.10 (0.41)	3.00 (0.40)
• Job demands (mean score (SD))	2.60 (0.34)	2.56 (0.31)
Days of sick leave on inclusion (mean score (SD))	26.20 (9.18)	26.07 (9.65)
Full sick leave on inclusion yes/ no	36/17	44/12

₸ A higher score means a higher level of physically demanding work, job control, job demands, supervisor support

Time until RTW

The median time until lasting return to own or equal work in calendar days differed significantly ($p<0.01$) between the graded activity group (139 days (IQR=69)) and the usual care group (111 days (IQR=76)) in favor of the usual care group. As there were no recurrences, for the median number of total days on sick leave due to low back pain in the 26 weeks follow up as calculated in the Kaplan Meier survival calculation (see figure 3) we found similar numbers (139 and 111, $p=0.03$).

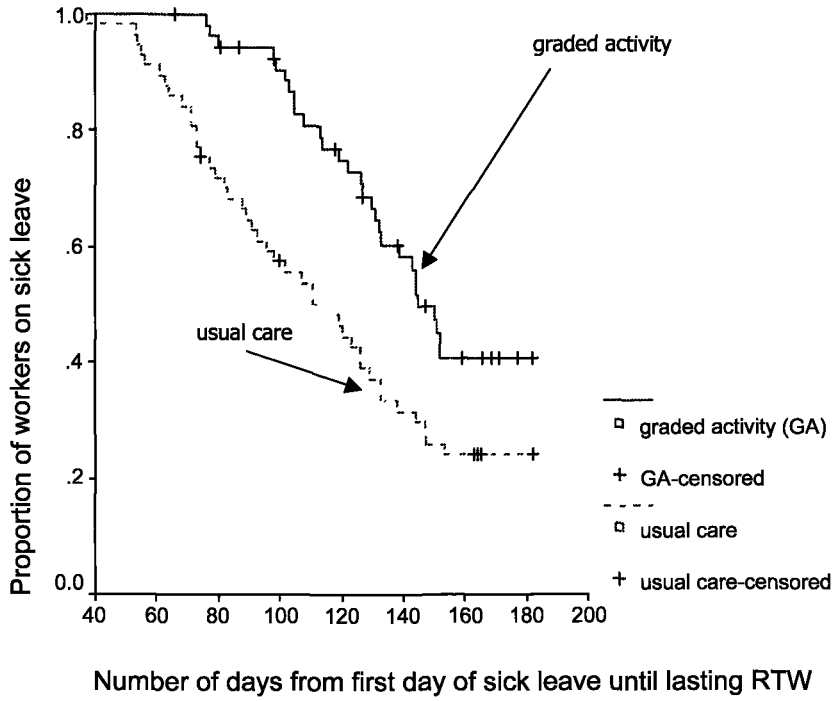

FIGURE 3. Unadjusted survival (Kaplan-Meier) curves until lasting RTW for the graded activity- and usual care group

Cox regression analysis adjusting for time of randomization, the effect of the ergonomics intervention and gender resulted in a hazard ratio of 0.52 (95% CI=[0.32-0.86], p=0.01), which is in favor of the usual care group (see table 2). Other confounding factors did not alter results.

In studying the process of referring workers to graded activity a substantial time lag was found between randomization and start of the graded activity intervention. Median delay was 13 days [IQR=0-28], mean delay was 19.27 (SD=21.16). Repeating the earlier Cox regression analysis while taking this delay into account the hazard ratio was 0.66 (95% CI=0.40-1.10, p=0.11). Again other confounding factors did not alter results.

Stratified intention to treat analysis

We stratified our population into subgroups that did and did not receive the ergonomics intervention in the first 8 weeks. The workers in both strata did not differ in baseline characteristics except for gender.

53 workers received the ergonomics intervention (see figure 2). Cox regression analysis adjusting for time of randomization, the effect of the ergonomics intervention, gender and the delay in referral resulted in a hazard ratio for this

stratum of 0.39 (95% CI=[0.19-0.81], p=0.01), in favor of the usual care group (see table 2). 59 workers did not receive the ergonomics intervention (see figure 2). Repeating the earlier Cox regression analysis for this stratum resulted in a hazard ratio of 0.86 (95% CI= [0.40-1.84], p=0.69). The p-value for the interaction between both interventions was 0.27.

Per protocol analysis

19 workers were not compliant to the protocol (for reasons see figure 2) leaving 36 workers in the graded activity group for this analysis. 4 workers had returned to work within 8 weeks after first day of sick leave and were falsely randomized by the occupational physician leaving 53 workers in the usual care group for this analysis.

Workers in both groups differed neither in baseline characteristics nor from the workers in the intention to treat analysis. The unadjusted median time until lasting return to own or equal work was 114 [IQR=77] calendar days for the graded activity group and 143.5 [IQR=61] calendar days for the usual care group. The hazard ratio for lasting RTW, adjusting for time of randomization, the effect of the ergonomics intervention and gender, was 0.57 (95% CI= [0.33-0.98], p=0.04), again in favor of the usual care group.

The hazard ratio, adjusting for time of randomization, delay in start of therapy, the effect of the ergonomics intervention and gender, was 0.68 (95% CI= [0.38-1.20], p=0.18).

Results of the stratified per protocol analysis

We again stratified our sample into subgroups that had and had not received the ergonomics intervention in the first 8 weeks. Workers in both strata did not differ in baseline characteristics, except for gender. The p-value for the interaction between both interventions was 0.12.

44 workers had received the first intervention. The hazard ratio for this stratum, adjusting for time of randomization, delay in start of therapy and gender, was 0.32 (95% CI=[0.14-0.71], p=0.005) in favor of usual care. 45 workers had not received the first intervention. The hazard ratio for this stratum, adjusting for gender and start of therapy, was 1.02 (95% CI= [0.44-2.38], p=0.97)(see table 2).

Secondary outcome measures

Table 3 shows: mean improvements in functional status, pain from baseline to 12 weeks and 26 weeks respectively

The effects reported in table 3 are the regression coefficients derived from random coefficient analysis adjusted for the OP level, baseline value of the outcome measure, gender and the ergonomics intervention. They can be interpreted as the differences in improvement between graded activity and usual care at both moments in time. Both treatment groups improved on all variables over. The differences in pain between the groups at 26 weeks were statistically significant and in favor of usual care.

TABLE 2. Results from the Cox regression analyses regarding first return to regular work

		Hazard ratios for return to regular work [95% Confidence Interval]*			
Intention-to-treat analysis (n=112)	median number of days (IQR)		+ adjusted for delay in referral	Prior ergonomics intervention	
				Yes	no
graded activity (n=55)	139.0 (69.0)	0.52 [0.32-0.86]	0.66 [0.40-1.10]	0.39 [0.19-0.81]	0.86 [0.40-1.84]
usual care (n=57)	111.0 (76.0)				
Per protocol analysis (n=88)					
graded activity (n=36)	143.5 (61.3)	0.57 [0.33-0.98]	0.68 [0.38-1.20]	0.32 [0.14-0.71]	1.02 [0.44-2.38]
usual care (n=53)	114.0 (77.5)				

*Adjusted for effect of ergonomics intervention, time of randomization and gender

TABLE 3. Mean improvements in functional status, pain from baseline to 12 weeks and 26 weeks respectively

Outcome	Mean (SD) Improvement		Effect of the graded activity intervention, [95% CI]
	graded activity	usual care	
Functional status (n=110)			
12 weeks (n =101)	11.5 (5.6)	11.0 (5.3)	1.78 [-0.06 - 3.57]
26 weeks (n =91)	7.9 (5.9)	7.5 (6.5)	1.99 [-0.33 - 4.32]
Pain (n=110)			
12 weeks (n =99)	5.3 (2.2)	4.9 (2.2)	0.43 [-0.31 - 1.16]
26 weeks (n =92)	3.7 (2.5)	3.2 (2.5)	1.03 [0.05 - 2.01]

* Adjusted for the baseline value of the outcome measure and gender.

The effect is the regression coefficient derived from random coefficient analysis which can be interpreted as the difference in adjusted improvement between the groups from baseline to 12 and 26 weeks, respectively.

Discussion

The objective of this paper was to answer the question whether graded activity can be effective as part of a multi-stage RTW back pain management program. None of our results show that graded activity improved RTW (see table 2), neither for functional status nor for pain in the first 26 weeks after the first day of sick leave. In our study graded activity actually caused a delay in RTW. A delay in the referral process may provide an explanation for these negative results. However, even after

adjustment for the delay in referral there is no positive effect from graded activity on RTW. Stratifying results for the ergonomics intervention gives another explanation: i.e. combining interventions led to a delay in RTW whereas the graded activity intervention without the ergonomics intervention had no effect on RTW. These findings are underpinned by the results from the per protocol analyses (see table 2).
Only 65% of workers randomized to the graded activity intervention complied to the protocol. This was probably caused by the fact that most workers at the inception point did not consider the consequences of randomization to the graded activity program at 8 weeks of sick leave. Nonetheless a per protocol analysis did not show a beneficial effect of the graded activity intervention on RTW after 26 weeks (see table 2).
Total days of sick leave due to low back pain in the first 26 weeks equaled the number of days on sick leave until lasting RTW, as no recurrences of sick leave due to low back pain occurred in both groups.
We did not find a statistically significant interaction between both interventions in our intention to treat analysis ($p=0.40$), but the interaction increased ($p=0.12$) in the per protocol analysis suggesting an interaction effect. If this interaction would have been the main point of interest of this study, the sample size should have been roughly four times the sample size we calculated for detecting the main effect [40]. Our results indicate that the OP should not refer a worker to both interventions. This is not in line with the additive effect of the clinical intervention found in the study by Loisel et al.[7].
In implementing graded activity special attention should be paid to structure and process of care, since graded activity seemed effective in RTW for workers on sick leave for 8 weeks [12] or less [14]. However the studies by Lindström et al.[12] and Staal et a.[14] were performed in specialized in-company physiotherapy clinics by a limited number of PTs. In our study workers were referred to 16 in- and out-company physiotherapy clinics, with 47 physiotherapists who had received additional training. In addition, referral in our study was done according to daily practice by the OP after notification by the researchers, instead of by the researchers in the previous studies [12;14]. Consequently, in order to have graded activity reach its potential in daily practice referral to a physiotherapy clinic must be improved, because a delay in referral delays RTW. If workers are referred to graded activity with a substantial delay, for instance after 12 weeks of sick leave, other therapies might be more appropriate although what works for whom and why is still unclear [41]. Considering these points our study should be characterized as an effectiveness trial, whereas the two previous studies were efficacy trials.
A longer follow up might give a more definite answer on the effectiveness of graded activity in our study since Staal et al.[14] found an effect starting at approximately 15.6 weeks after first day of sick leave.

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Chapter 8 Workplace or clinical intervention for occupational low back pain. A randomized controlled trial.

Johannes R Anema, Ivan A Steenstra, Paulien M Bongers, Henrica CW de Vet, Dirk L Knol, Willem van Mechelen.(*submitted*)

Abstract

Background Clinical interventions as well as workplace interventions are advocated for multidisciplinary rehabilitation of occupational low back pain (LBP). High-quality randomized controlled trials assessing the effectiveness of these interventions, separately and together, are needed.

Objective To evaluate the effectiveness of a workplace intervention, a clinical intervention and a combination of both for occupational LBP.

Design, setting and patients A population based randomized controlled trial with a sample of workers (n=196) sicklisted for a period of 2 to 6 weeks due to non specific LBP, conducted at 13 Dutch Occupational Health Services between October 2000 and October 2002.

Interventions Participants were randomized to the workplace intervention (n=96) or usual care (n=100). The workplace intervention consisted of a workplace assessment, work modifications and case management involving all stakeholders. Participants who were still on sickleave at 8 weeks, were randomised for a clinical intervention (n=55) or usual care (n=57). The clinical intervention comprised a graded activity program based on a cognitive behavioral principles.

Measurements Time until full return-to-work. Secondary outcome measures included functional status (Roland Disability Questionnaire) and pain intensity (10-point scale), assessed at baseline, and at 12, 26 and 52 weeks after the first day of sickleave.

Results The first period until full return-to-work for workers with the workplace intervention was 77 versus 104 days (median) for workers without this intervention (p=0.018). Workplace intervention was effective on return-to-work rate (HR = 1.7 [95% CI 1.2 to 2.3]; p=0.003). The clinical intervention applied 8 weeks after the start of sickleave delayed return-to-work, with an adjusted HR 0.4 ([95% CI 0.3 to 0.6]; p<0.001). A combination of both interventions had no effect on return-to-work. Workers with a workplace intervention improved more on functional status and pain intensity than workers without this intervention. However these effects were statistically not significant. The clinical intervention had a negative effect on functional status and pain.

Conclusion Workplace interventions should be recommended for multidisciplinary rehabilitation of subacute occupational LBP.

Introduction

Low back pain (LBP) is the most common and most expensive musculoskeletal disorder in the working population [1]. High costs are mainly due to frequent and long-term sickleave and disability [2]. The 12-month prevalence of sickleave due to LBP is 7% in the working population in the Netherlands [3]. Therefore, from an individual and societal perspective, effective interventions for occupational LBP aimed at return-to-work are needed.

Multidisciplinary rehabilitation including workplace as well as clinical interventions is frequently advocated for sub acute occupational LBP. A recent Cochrane review [4], based on only two studies, concluded that a multidisciplinary rehabilitation including workplace and clinical interventions is promising, but there is a need for high-quality randomized controlled trials assessing the effectiveness of these interventions together and separately. To date, only one comparative study evaluated the effectiveness of both workplace and clinical interventions for occupational LBP[5]. This Canadian study showed that a workplace intervention was effective, that the clinical intervention had no effect on return-to-work, and that the combination of both interventions had a small additional effect.

In the present RCT, the effectiveness on return-to-work of a workplace intervention, a clinical intervention separately and the combination of both, was evaluated. The interventions were derived from the Canadian study [5,6] and adjusted to the Dutch socio-economic context [7]. The workplace intervention consisted of workplace assessment, work modifications and case management in which all major stakeholders in the return-to-work process participated: i.e. the worker, the employer, the occupational physician (OP) and the worker's general practitioner (GP). The clinical intervention comprised a Graded Activity program, i.e. a gradually increasing exercise program based on a cognitive behavioral approach. This study should answer the question whether the workplace intervention at 2-6 weeks and the clinical intervention at 8 weeks after the start of sickleave, or both are (more) effective for the rehabilitation of occupational LBP.

Methods

Study design and setting

This study comprised a single blind pragmatic population based RCT, evaluating a workplace and a clinical intervention aimed at return-to-work after LBP. A factorial design was used [7], which resulted in four intervention groups: usual care, workplace intervention only, clinical intervention only and a combination of workplace and clinical intervention. Thirteen Dutch Occupational Health Services (OHS), 16 physiotherapy centers, 99 OPs, 25 ergonomists and 47 physiotherapists (PT) participated in this study. The Medical Ethics Committee of VU University Medical Center approved the study design, protocols, procedures and informed consent procedure, and all participants provided written informed consent.

Study population and sample size

The source population (n = ca.100.000) consisted of the worker's population of the participating OPs. Patients were randomized at the OP-level to the workplace intervention and at the patient level to the clinical intervention [7]. It was judged by the researchers whether the workers met the inclusion criteria of the RCT before the first visit to their OP. The worker's OP informed the researchers whether a subject should be excluded on medical grounds. The inclusion criteria were:

- LBP (ICD-10 codes: M54.5, M54.4, M54.3, M54.1, M54.8 and M54.9);
- Full or partial sickleave because of non-specific LBP, lasting 2-6 weeks;
- Age between 18 to 65 years;
- Able to give written informed consent and to complete written questionnaires in Dutch.

The exclusion criteria were:

- LBP due to specific causes;
- Co-existing cardiovascular, psychiatric or juridical contra-indications;
- Pregnancy;
- Sickleave due to LBP less than one month prior to the current episode of sickleave.

To detect a 20% and 30% difference in recovery rate (full return-to-work) for the workplace and clinical intervention respectively, a sample size of 200 workers is needed [7]. These differences can be detected with a power (1-β) of 80% at α=.05.

Treatment allocation

After stratification of the participating OPs by economic sectors (industry, health care and office work), OPs were randomized for the workplace intervention to avoid contamination (see figure 1). Workers who were off work for longer than 8 weeks, were randomized at the workers' level for the clinical intervention. An independent researcher (HCWdV) randomized the OPs and the workers using a list of random numbers and prepared the sealed envelopes to be opened by the OP in case of an eligible worker for the clinical intervention. The randomization procedure is described in detail elsewhere [7].

Blinding

The researcher and research assistant who collected the baseline data were blinded for the treatment allocation. Treatment allocation was made known by the OP to the worker after informed consent and completion of the first questionnaire. Data on return-to-work were derived from automated databases to prevent bias caused by a lack of blinding. Although blinding of self-reported outcome measurements during follow-up was not possible, there was no direct influence by the researchers or treating professionals because all questionnaires were mailed to the worker.

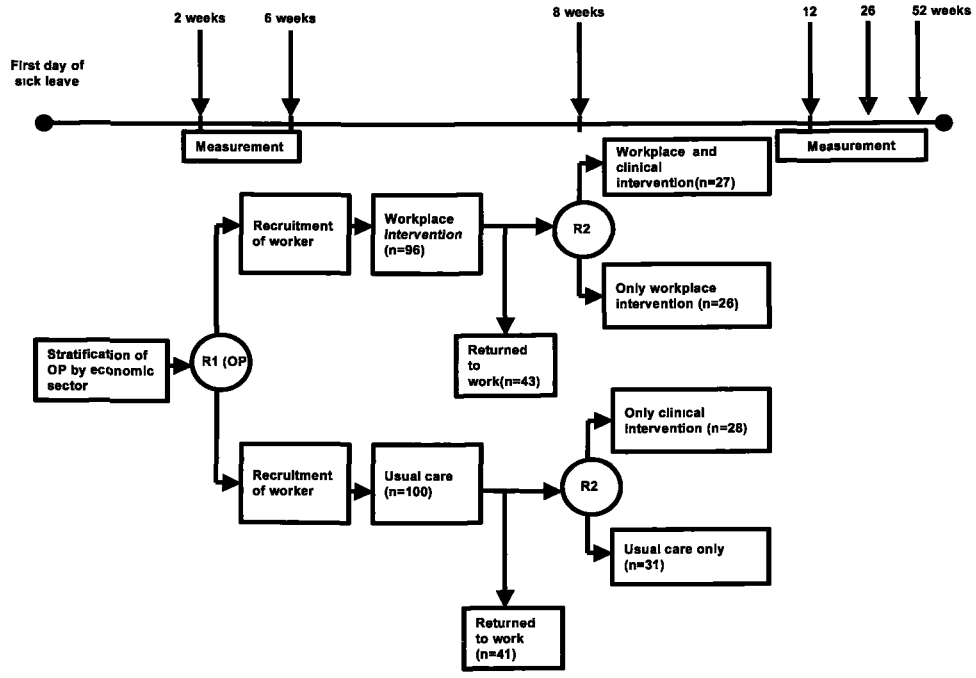

FIGURE 1. The design of the study

Interventions

Usual Care

All workers received occupational back pain management and work resumption advice given by the OP, according to the Dutch OP Guidelines for LBP. [8]

Workplace intervention

In addition to usual care, the workplace intervention group received a worksite assessment and work modifications, based on methods used in participatory ergonomics. The workplace intervention took place directly after inclusion. The OP, in collaboration with an ergonomist or an occupational health nurse, delivered this intervention. For each worker, a group was formed that included the ergonomist (process leader), the injured worker, the worker's supervisor, and possible other stakeholders. After observation of the worker's tasks by the ergonomist, obstacles for return-to-work were ranked independently by the worker and the supervisor. Following this, the ergonomist organized a meeting of the group of stakeholders to brainstorm and discuss about all possible solutions for the obstacles ranked highest with the aim to achieve consensus regarding feasible solutions. Based on the outcome of this meeting, solutions were recommended to the employer. A detailed description of this workplace intervention method is published elsewhere [9]. Finally,

a short communication form was exchanged between the OP and the worker's GP to prevent conflicting advises to the worker in the return-to-work process [10].

Clinical intervention
In addition to usual care, the clinical intervention group received a graded activity intervention. The graded activity intervention took place at eight weeks after the start of sickleave only if workers still were on sickleave. The intervention consisted of an individual, sub maximal, gradually increasing exercise program with an operant-conditioning behavioral approach and was delivered by a PT. The content of the program was tailor made and based on the findings from patient history, physical examination, functional capacity evaluation, the demands from the patients' work and the patients' expectations on time to return-to-work. The aim of this intervention is return to full own or equal work. During the program an active role of the worker in return-to-work is promoted and the PT acts as a coach and supervisor, using a hands-off approach [7,11]. The entire program consisted of two one-hour sessions a week with 26 sessions maximally. The first 3 sessions consisted of functional capacity evaluations. The program stopped as soon as a lasting return to own or equal work had been established, according to an agreed individual schedule [7].

Outcome measures and prognostic factors
Sickleave duration due to LBP was the primary outcome measure and functional status and pain were secondary outcome measures. Sickleave was defined in this study, following the Dutch social security laws, i.e.: duration of sickleave in calendar days from the first day of sickleave to full return-to-work in own or equal work, for at least 4 weeks without (partial or full) drop-out. This implicates that for workers who returned to other or not lasting work during the entire follow-up, time to return-to-work was censored in survival analyses. In addition, the total duration of sickleave due to LBP (including all recurrences of sickleave episodes) was calculated for the entire twelve months follow-up period. Functional status of the worker was measured by the Roland Disability Questionnaire [12,13]. An individual score could vary from 0 (no disability) to 24 (severe disability). Pain intensity was measured on a 10-point visual analogue scale ranging from 0 (no pain) to 10 (very severe pain) [14].
Finally, data were collected on prognostic factors for duration of sickleave to adjust in case of dissimilarities between the treatment groups [7].

Statistical analyses
To determine the prognostic similarity of the groups at baseline, descriptive statistics (mean with standard deviation; median with interquartile range) were calculated for potential prognostic variables and baseline values of outcome measures. All analyses were conducted at the worker's level. Multilevel analysis at the OP level was conducted and intraclass correlation coefficients were calculated to check whether there was independency of observations between OPs. All analyses were conducted according to the intention-to-treat principle.

Survival analyses (Kaplan Meier analyses with log rank test and Cox's regression analyses) were used to describe the univariate and multivariate associations between treatment allocation and the time to lasting return-to-work. Time dependent covariates in the multivariate models were used to adjust for the fact that treatment allocation for the workplace intervention and graded activity intervention took place at different moments after the start of sickleave. All potential confounders were manually and separately entered into the multiple regression models to adjust for prognostic dissimilarities. A prognostic factor was defined as a potential confounder when there was a $p<.10$ difference between groups in the baseline value of a prognostic variable or when it is a known prognostic factor in the literature [15]. Consequently, a potential confounder was added to the multiple regression model to check whether the –2*log likelihood of the model changed significantly when the factor was added. When the –2*log likelihood changed significantly ($p<.05$), the factor was entered into the final model [16]. Finally interaction was tested between workplace and clinical interventions and between these interventions separately and all confounders at baseline or prognostic factors found in the literature [15]. The total number of days of sickleave during entire follow-up due to LBP (including recurrences) was compared for groups by Mann Whitney U tests. Longitudinal random coefficient analyses were used to assess differences between treatment groups in improvement in the secondary outcome measures. The baseline value of the particular outcome variable was added to the model in order to correct for possible regression to the mean. Survival analyses were performed using the SPSS 10.0 software package (SPSS Inc., Illinois, USA). The intraclass correlation coefficient for the OP-level was calculated using STATA (version 7) and random coefficient analyses using MlwiN (version 1.10).

Results

Patient flow and drop out

The flow of the workers in this study during the recruitment, inclusion and the follow-up is presented in figure 1. Fifty-five OPs referred 243 eligible workers to the research assistant from October 2000 till October 2002. Forty-seven workers did not meet the inclusion criteria. Consequently, a total number of 196 workers were randomized for the workplace intervention: 96 workers were assigned to the workplace intervention and 100 workers to usual care. Eighty-four workers recovered before 8 weeks after the start of sickleave, leaving 112 workers to be randomized for the clinical intervention: 55 workers were assigned to the clinical intervention and 57 workers were assigned to usual care. The baseline characteristics of workers in all groups are presented in table 1.

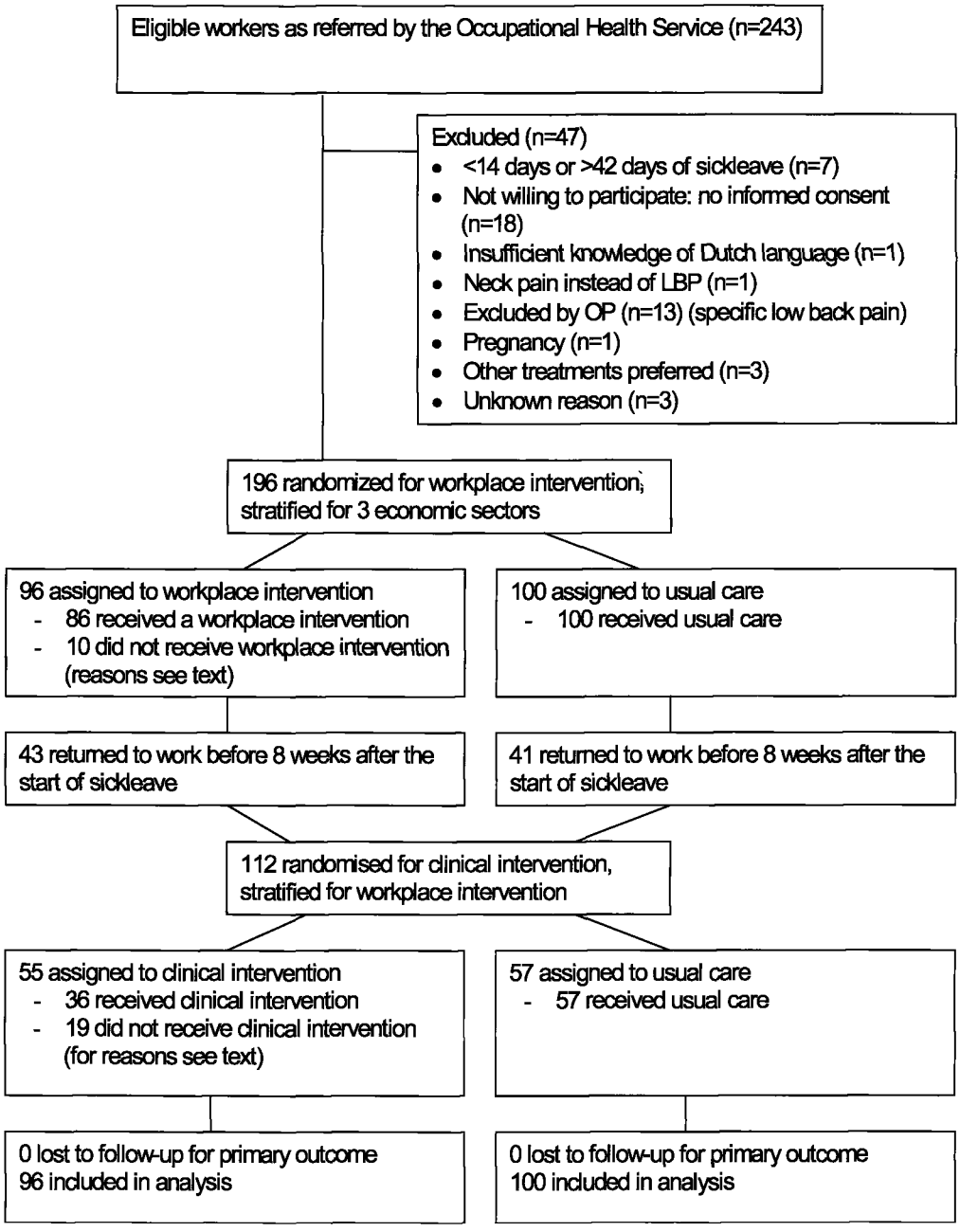

FIGURE 2. Flow diagram describing the progress of the workers through the phases of the trial.

Sickleave data (primary outcome measure) were collected continuously during follow-up from automated databases for all 196 (100%) included workers. For 24 workers (12%) no follow-up data regarding the secondary outcome measures could be collected.

Patient characteristics

Table 1 shows the baseline values of the outcome measures and the prognostic factors for the workplace intervention group and the usual care group. If the distribution of a variable was skewed, median value and the interquartile range (IQR, 25th and 75th percentiles) are presented. Except for gender, only small differences were found between the baseline characteristics of both groups.

TABLE 1. Prognostic variables and baseline values of outcome measures.

	Workers on sickleave > 2 weeks(n=196)		**Workers on sickleave > 8 weeks (n=112)**	
	Workplace intervention		**Clinical intervention**	
	Yes (n=96)	**No (n=100)**	**Yes (n=55)**	**No (n = 57)**
Baseline characteristics				
Age in years (mean, sd)	44.0 (8.6)*	41.2 (10.7)*	41.3 (9.2)	43.4 (8.3)
Gender (male/female)	51/45*	33/67*	19/36	27/30
Function:				
Industrial	11	6	7	3
Office work	20	17	9	15
Health Care	56	65	33	35
Other	8	8	3	4
Heavy physical work index [1-4] ⌶ (mean; sd)	2.0 (0.5)	2.1 (0.5)	2.0 (0.5)	2.0 (0.5)
Job control [1-4] ⌶ (mean; sd)	2.6 (0.4)	2.5 (0.4)	2.6 (0.3)	2.6 (0.4)
Job demands [1-4] ⌶ (mean; sd)	2.5 (0.3)	2.6 (0.3)	2.6 (0.3)	2.5 (0.3)
Supervisor support [1-4] ⌶ (mean; sd)	3.0 (0.3)	3.1 (0.5)	3.1 (0.4)	3.0 (0.4)
Radiating pain (y/n)	15/81	22/77	11/44	14/43
Job satisfaction [1-4] ǂ (mean; sd)	1.7 (0.8)	1.7 (0.8)	1.7 (0.8)	1.7 (0.8)
Expectation of patients on return-to-work [1-5] ⌶ (mean; sd)	3.6 (1.2)	3.6 (1.1)	3.4 (1.2)	3.5 (1.1)
Sickleave prior to inclusion (partial/full)	20/76	35/65	17/36	12/44
Baseline values outcome measures				
Sickleave (days) of current episode of LBP prior to inclusion (median, IQR)	26 (19-36)	24 (18-30)	26 (19-33)	24 (19-32)
Functional status (RDQ) (mean, sd)	14.9 (4.2)	13.8 (4.6)	14.4 (4.5)	15.8 (3.2)
Pain severity (mean, sd)	6.5 (1.7)	6.3 (1.7)	6.6 (1.4)	6.7 (1.5)

IQR= interquartile range, 25th percentile to 75th percentile. * p<0.15, ⌶ A higher score means a higher level of physically demanding work, job control, job demands, supervisor support, exspectation of return-to-work, ǂ A higher score means a lower level of job satisfaction

Interventions

Workplace intervention

The workplace intervention started at an average duration of 24 days (SD = 22) starting at the first consult with the OP, median 26 days (IRQ=19-36) after the start of sickleave. Fifteen ergonomists were involved in delivering the workplace interventions, with an average of 4.0 interventions per ergonomist. Ten out of 96 (10%) workers were not compliant to the intervention protocol: 5 workers returned to work before an appointment for the workplace intervention was made. Five workers did not participate in the workplace intervention due to a work scheduling problem (3), a medical reason (1) or a work conflict (1). None of the workers, who started, stopped during this intervention. No adverse events or side effects were reported. Additional treatments in this group of 96 workers applied by other care givers than the OP were: regular physiotherapy for 62/96 workers, manual therapy for 21/96 workers, Cesar therapy for 5/96 workers, chiropractor care for 7/96 workers, and a visit to a neurologist for 8/96 and to a orthopedic surgeon for 2/96 workers. There were no statistical differences between the (co-)interventions received by the workers who received the workplace intervention or not.

Clinical intervention

The clinical intervention had an average frequency of 14.1 sessions (SD = 6.8) starting at 64 days (mean; SD=17.6) after the start of sickleave. Forty-seven PTs were involved in delivering the clinical interventions. Nineteen workers out of 55 (35%) were not compliant to the clinical intervention for the following reasons: interference with other practitioners (3), miscommunication (2), change of function/ job (2), contraindications (5), not able to follow regime (3), drop out from the program (3) and distance to training centre (1).

Additional treatments in this group of 55 workers applied by other care givers than the OP were: regular physiotherapy 40/55 workers, manual therapy 22/55 workers, Cesar therapy 5/55 worker, chiropractor care 5/55 workers and a visit to a neurologist 6/55 and an orthopedic surgeon 4/55 workers. No adverse events or side effects were reported. There were no statistical differences between the (co-) interventions received by the workers who received the clinical intervention or not.

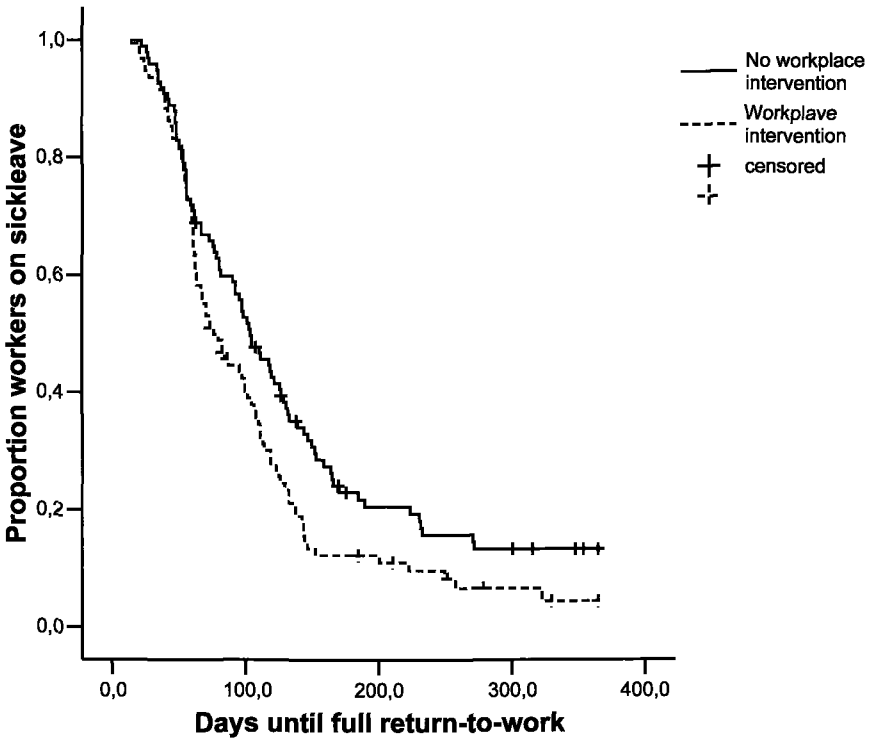

FIGURE 3. Survival curves of absence from regular or equal work for both the workplace intervention group and usual care group.

Sickleave due to LBP

Intraclass correlation coefficients among OPs were estimated as <0.01 so all analyses were performed at the worker's level. The interaction between the workplace intervention and the graded activity intervention was statistically not significant (p=0.61). Therefore one multivariate Cox regression model was used to describe the effectiveness of the workplace intervention and the clinical intervention, separately, adjusting for the effect the other intervention and confounding factors. The effects of the full intervention were calculated based on this model.

Workplace intervention

In the univariate analysis (Kaplan Meier), the time until first, lasting and full return-to-work in the workplace intervention group was found to be 77 days (median; IRQ 56-126) compared to 104 days (median; IRQ 56-166) for the non-intervention group. This difference was significant (log rank test; p= 0.02). The curves of both groups over 12 months of follow-up are shown in figure 2. By means of Cox regression analyses (*n*=196) *hazard ratios adjusted for the clinical intervention*, job demands and job control were calculated.

The hazard ratio was 1.7 (95% CI 1.2 to 2.3, p=0.003), in favor of the workplace intervention group. There was no dependency of observations found between OPs. The results of these analyses are presented in table 2. The number of workers who did not return to their own, full work for a long-lasting period during 12 months follow-up was 9 (9,4%) in the workplace intervention group versus 17 (17.2%) for workers who did not receive a workplace intervention.
The total number of days of sickleave (including recurrences) during the 12 months of follow-up in the workplace intervention group was 84 (median; IQR=58-132) days compared to 105 (median; IQR=60-166) days, for workers who did not receive a workplace intervention.

Clinical intervention

The time until first, full and lasting return-to-work in the clinical intervention group was found to be 144 days (median; IQR=113-233) vs. 111 days (IQR=74-153) for the non-intervention group (log rank test; p=0.030). The adjusted hazard ratio was 0.4 (95% CI 0.3 to 0.6, p<0.001), in favor of the non-intervention group (table 2). There was no dependency of observations found between OPs. The total number of days of sickleave (including recurrences) during the 12 months of follow-up in the clinical intervention group was 145 (median; IQR=119-233) days compared to 111 (IQR=74-164) days, for the not clinical intervention group.

TABLE 2. Results of the univariate and multivariate survival analyses analyses regarding time to full and lasting return-to-work.

	Univariate analyses		Adjusted hazard ratios for return to work (95% confidence interval), Cox regression analyses (n=196) **	
	Median number of days off regular work	Log rank	HR	P value
Comparison 1	N=196			
Workplace intervention	77		1.7 (1.2 to 2.3)*	P=0.002
No workplace intervention	104	P=0.02	1.0	
Comparison 2	N=112			
Clinical intervention	144		0.4 (0.3 to 0.6)#	P<0.001
No clinical intervention	111	P=0.03	1.0	
Comparison 3	N=112			
Full intervention	143		0.7 (0.3 to 1.2)~	P>0.05
No full intervention	126	P=0.49	1.0	

** There was no dependency of observations found between OPs. No interaction was found between workplace and clinical intervention.

* Adjusted for effect of clinical intervention, worker's functional status and job control.

\# Adjusted for effect of workplace intervention, worker's functional status and job control.

~ Adjusted for independent effects of workplace and clinical intervention, worker's functional status and job control.

Full intervention

The time until first, full and lasting return-to-work in the full intervention group was found to be 143 days (median; IQR=108-250) compared to 126 days (IQR=83-171) for the workers who did not receive both the workplace and clinical intervention (log rank test; p=0.49). The adjusted hazard ratio was 0.7 (95% CI 0.3 to 1.2, p> 0.05;table 2).

The total number of days of sickleave (including recurrences) during the 12 months of follow-up in the full intervention group was 144 (median; IQR=108-250) days compared to 129 (IQR=86-178) days, for the group that not received the full intervention.

TABLE 3. Mean improvements in functional status and pain from baseline at 12 months and differences in effects between the groups ° (intention-to-treat analysis).

		Functional status		Pain intensity	
Effects *N=196*		Mean improvement at 12 months (SD)	Effect [CI] °	Mean improvement at 12 months (SD)	Effect [CI] °
Comparison 1					
Workplace intervention	Yes	9.0 (6.2)	-0.25[-1.57 to 1.06]*	3.3 (2.6)	-0.20[-0.75 to .35]*
	No	8.1 (5.7)		2.9 (2.7)	
Comparison 2					
Clinical intervention	Yes	7.3 (6.2)	1.74[0.07 to 3.42] #	2.7 (2.6)	0.67 [-0.05 to .38]#
	No	9.9 (6.1)		3.7 (2.6)	
Comparison 3					
Full intervention	Yes	8.3 (7.9)	1.49 [-0.33 to 3.31]~	2.9 (2.6)	0.47[-0.42 to 1.35]~
	No	8.7 (6.0)		3.3 (2.6)	

° The effect is the regression coefficient derived from longitudinal random coefficient analysis which can be interpreted as the difference in adjusted improvement over time between the groups. No time interaction was found.

* Adjusted for the baseline value of the outcome measure, the effect of clinical intervention, gender, levels of OP, time

\# Adjusted for the baseline value of the outcome measure, the effect of workplace intervention, gender, levels of OP, time

~ Adjusted for the baseline value of the outcome measure, gender, levels of OP, time

Functional status and pain intensity

Table 3 presents the mean improvements in functional status and pain intensity from baseline to 12 months. In addition, the differences in effects between the groups are

presented as the regression coëfficients derived from random coefficient analyses multilevel multivariate analyses (intention-to-treat), are shown. Workers who received a workplace intervention, functional status and pain intensity improved more during follow-up than workers who did not receive a workplace intervention. However this effect was not statistically significant. Conversely, functional status and pain intensity improved more during follow-up in the non-clinical intervention group than in the clinical intervention group. The difference in improvement was statistically significant for functional status. Finally, there were no significant differences in improvement of functional status and pain between workers receiving both workplace and clinical interventions compared to workers who did not receive any of both interventions.

Discussion

An RCT was conducted for workers (n=196) sicklisted 2 to 6 weeks due to non-specific occupational LBP, to evaluate the effectiveness of a workplace intervention as well as a clinical intervention for multidisciplinary rehabilitation. The main finding of this study is that the workplace intervention after 2-6 weeks of sickleave had a positive effect on return-to-work, whereas the clinical intervention after 8 weeks of sickleave had a negative effect. With respect to the improvement in functional status and pain, the findings showed a comparable pattern, but showed in general no statistically significant differences.

A principal strength of this study is that, to our knowledge, this is to date one of the two RCTs [5] that evaluated in a comparative study the effectiveness of both a workplace intervention and a clinical intervention for occupational LBP. Another strength of this study is that a cross-national comparison can be made between the results of a Canadian study [5] and our study, due to comparable design and interventions. This gives a unique opportunity to compare the effect of interventions in different socio-economic settings [7].

Comparison with other studies

Despite the different socio economic context, the results in both the Canadian and the Dutch study were similar. Workplace intervention was effective on return-to-work for sub acute LBP in both studies, whereas the clinical intervention was not effective in the Canadian study [5] or even contra productive in our study. There may be two explanations for this finding: Firstly, it is well known that clinical interventions for occupational LBP, especially when these interventions last too long have the potential to delay return-to-work [17,18]. Secondly, failure for return-to-work in the (sub)acute phase of LBP seems to be rather a result of a failed social transaction to achieve modified work at the workplace than the result of the severity of the medical condition [19,20,21]. This explanation implicates that interventions should involve both worker and management in achieving modified work with return to full duties as the final goal. In addition, the timing of the workplace interventions was earlier than

the clinical intervention. It can not be ruled out that the workplace intervention was more effective due to the early timing.
In contrast to our findings, clinical interventions have proven to be effective on return-to-work in two other studies [11,22]. However, these studies were conducted in the well-controlled setting of one company and the interventions included a workplace visit [22] or were administered at the workplace of the worker by in-company therapists [11]. So, the positive effect of these clinical interventions might be explained by the fact that these interventions had also a workplace component and a natural involvement of the key stakeholders.

Limitations of this study

Blinding of the patients and therapists was impossible due to the character of the workplace and clinical interventions. However, information bias for our primary outcome measures was avoided, by deriving sickleave data from automated databases instead of self-reported questionnaires. An other possible source of bias is the difference in attention workers received, the so-called 'Hawthorne effect'. This can overestimate the effects of an intervention. However, comparable usual care interventions were given to all patients.
Although randomization was conducted at the OP-level, analyses were conducted at the worker's level. However, in multilevel analyses no dependency of observations was found between OPs. A large number of OPs participated and some treated only few patients. These may have been a selection of their population. However, this is not likely because patients were recruited by the research assistant before the first visit to the OP.
Workplace intervention and clinical intervention were not applied at the same time. Therefore it is not allowed to compare both interventions to eachother. Maybe patients randomized to the clinical intervention were more 'therapy resistant'. However, this cannot explain the negative effect of this intervention. In additin, the timing of this intervention was comparable to other studies [5,11,22].
Finally, the study design is not suitable to identify the working mechanisms behind the workplace and clinical intervention. In our opinion, qualitative research is needed to clarify the elements that contribute to the (opposite) effects of the workplace and clinical intervention.

Impact of this study

This comparative study adds important evidence to the current limited evidence on the effectiveness of workplace and clinical interventions for occupational low back pain [4]. Principal meaning of this study is that physicians should recommend workplace intervention after 2-6 weeks of sickleave instead of clinical intervention after 8 weeks of sickleave for the rehabilitation of occupational LBP. This study showed also that workplace intervention reduced occupational disability due to LBP by half at 12 months after the start of sickleave. Therefore, from a societal perspective, the impact of workplace intervention on the reduction of indirect costs

due to sickleave and disability pensions appears to be important. However, although the results of our study are convincing, the gains of cost-savings of the workplace intervention has yet to be studied in a cost-effectiveness study.

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Chapter 9 General Discussion

Putting together the current evidence and future steps

This thesis focuses on the effectiveness of multidisciplinary rehabilitation for workers on sickleave due to non-specific LBP. The program applied is derived from a Canadian model [1]. The first part of this chapter summarizes our main findings, and puts together the current evidence. In chapter 1, many questions were asked by LBP-patients, their health care professionals and employers. The following key questions could be extracted from these questions: What is the optimum content of multidisciplinary rehabilitation for non-specific LBP to prevent occupational disability? Which key stakeholders have to be involved in multidisciplinary rehabilitation? The answers on these questions are based on two empirical studies: a multinational cohort study and a randomized controlled trial (RCT). The aim of this thesis is to answer these key questions and contribute evidence-based occupational medicine. Although we have found answers, there are also new questions raised to be answered in future. The second part of this chapter deals with the next steps that should be taken to optimise rehabilitation and prevent occupational disability due to LBP in practice: i.e. learning from our experiences, reviewing clinical and occupational guidelines and, finally conducting new research.

Summarizing the main findings

Our RCT showed that a workplace intervention with active key stakeholder involvement, had a positive effect on return-to-work of workers sicklisted 2-6 weeks due to LBP. It also showed that a clinical intervention comprising Graded Activity had a neutral or even negative effect on return-to-work of workers sicklisted 8 weeks due to LBP. A year after the start of sickleave 90 of the 96 workers (91%) with LBP in the workplace intervention group fully returned to their own and full return to work in a median period of 77 days. In the group without workplace intervention 83 of the 100 (83%) workers returned to their own and full return to work in a median period of 104 days. Forty-three of the 55 workers (78%) with non-specific LBP in the clinical intervention group returned to their own and full return to work in a median period of 144 days in the year after the start of sickleave. In the group without clinical intervention 47 of the 57 (82%) workers fully returned to their own work in a median period of 111 days. These results confirm the findings in Canada [1] and support the conclusion that workplace intervention with active key stakeholder involvement after 2-6 weeks of sickleave is the preferred method for multidisciplinary rehabilitation for non-specific occupational LBP.

The main findings of this thesis are:

1. Treating physicians or therapists do not aim their usual medical care of workers sicklisted due to chronic LBP, at return-to-work. This might be an obstacle for return-to-work (RTW), based on results of a national cohort study;
2. Workplace interventions accelerate RTW, for workers sicklisted due to chronic LBP, based on results of a large multinational cohort study;

3. Workers and ergonomists/occupational nurses were satisfied about the workplace intervention based on a participatory approach. The participatory approach is based on a negotiation /shared decision making method of both the worker and supervisor in the process to identify and solve obstacles for return-to-work. Almost half of the ergonomic solutions were (partially) implemented within 3 months of sickleave; These results are based on a process analysis;
4. A workplace intervention based on a participatory approach with active involvement of all key stakeholders had a positive effect for workers sicklisted 2-6 weeks, whereas a clinical intervention, based on a cognitive behavioural approach had a negative effect on time to full and lasting return-to-work of workers sicklisted 8 weeks with non-specific LBP. These results are based on a RCT.

Definitions

Definition multidisciplinary rehabilitation

Karjalainen et al. [2] and Guzman et al. [3] used the following definition for 'Multidisciplinary rehabilitation': 'a biomedical or physical intervention and at least one of the following interventions psychological, social, or vocational interventions'. In addition, Karjalainen et al. [2] formulated the following essential features for multidisciplinary rehabilitation:

- A physician makes the diagnosis;
- Each intervention should be executed by a professional of that discipline. A psychologist needs to be involved with psychological or behavioral treatment, but a social worker, an occupational nurse, or an occupational physiotherapist may perform a social intervention. An occupational nurse or physiotherapist specialized in the field of occupational health care can provide the vocational intervention.
- The behavioral approach is a fundamental feature of multidisciplinary rehabilitation for musculoskeletal disorders.

According to this definition both the workplace and clinical intervention that we evaluated, can be classified as multidisciplinary rehabilitation. Our workplace intervention was a biosocial intervention including a occupational medicine intervention and a vocational intervention, whereas our clinical intervention is a biopsychological intervention including a occupational medicine intervention and a cognitive behavioral intervention, applied by a trained physiotherapist. In their review [2], Karjalainen et al. categorized a workplace visit(ation) as a workplace/vocational intervention. However, there are different definitions and descriptions used in the literature for workplace, occupational or vocational interventions. To our opinion, there is a need for a clear and uniform definition.

Definition of workplace intervention

Waddell & Burton [4] used the term 'occupational interventions' and described them as workplace organisational and/or occupational (health) management strategies which are aimed at organisational culture and high stakeholder commitment to improve safety, provide optimum case management and encourage and support early return to work. Frank et al. [5] defined 'workplace-based interventions', as the early provision of modified work, or inducements to report all occupational LBP (OLBP) early, or obtain care at work. Loisel et al. [6] designed an 'occupational intervention' including an occupational medicine and ergonomic interventions. According to the International Ergonomic Association (IEA) Classification ergonomic interventions are defined as interventions directed to the workplace, work organisation, conditions or work environment [7]. In the review of Durand et al. [8] workplace interventions were defined as interventions that included at least one work visit. In addition, workplace interventions were classified in the review of Durand et al. according to their goal 1. To modify the clinical intervention 2. To grade the return-to-work process 3. To modify the work environment.

To bring more uniformity in the language we use in our papers, we propose to use the term 'workplace intervention' only for interventions directed to the workplace, work organisation, conditions or work environment and/or occupational (case) management strategies with active stakeholder involvement of (at least) worker and employer. This definition is a synthesis of the IEA-definition [7] and the definition of Waddell et al. [4]

Putting together the current evidence: a shift of evidence?

What is the optimum content of multidisciplinary rehabilitation for workers sicklisted 2-6 weeks due to non-specific LBP? Biopsychological or biosocial?

According to many reviews, evidence for the effectiveness of return-to-work - interventions for non-specific LBP is based mostly on studies without a randomized controlled design [4,9,10,11]. Recently, a Cochrane review [2] concluded that a multidisciplinary biopsychosocial rehabilitation including a workplace visitation for working-age patients with non-specific LBP is promising. However, it was concluded that there is a need for high-quality randomized controlled trials assessing the effectiveness (of the different components) of such a multidisciplinary rehabilitation. This review was based on only two RCTs[1,13]. Both studies reported a positive effect of multidisciplinary biopsychological rehabilitation with a workplace intervention or visit in terms of return to work, sickleave, and subjective disability.

To our knowledge, to date three RCTs evaluating multidisciplinary biopsychosocial rehabilitation for workers with LBP, including our study, have been conducted recently and have applied the criteria for multidisciplinary rehabilitation used by Karjalainen et al.[2]. In addition to our study, we have summarized four currently available trials in table 1 [1, 12, 13, 14,]. As this table shows, these studies are difficult to compare: different type of interventions, applied at different sites, in

different working populations. Only two studies included a workplace intervention (according to our definition).

TABLE 1. Summarizing RCTs and the effects of multidisciplinary return-to-work interventions for workers sicklisted due to subacte LBP. [? Inconclusive effect (borderline statistically significant); 0 No effect (not statistically significant); + Effective (statistically significant); - Negative effect (statistically significant)]

1e author	Type of intervention	Population	Control group	Site of intervention	Involvement of stake-holders at the workplace	Effect on time to return-to-work
Anema et al., 2004	Workplace intervention consisting of ergonomic interventions	General working population; several companies	Usual care	Workplace	high level of involvement (incl. supervisor)	+
Loisel et al., 1997	Workplace intervention consisting of ergonomic interventions	General working population; several companies	Usual care	Workplace	high level of involvement (incl. supervisor)	+
Lindström et al., 1992	Clinical intervention consisting of Graded activity including work visit	Blue collar; one company	Usual care	Back pain clinic at worksite	low level of involvement (incl supervisor, incompany therapist)	+
Staal et al., 2004	Clinical intervention consisting of Graded activity	Blue collar; one company	Usual care	Back pain clinic at worksite	low level of involvement (incl incompany therapist)	+
Steenstra et al., 2004	Clinical intervention consisting of Graded activity	General working population; several companies	Usual care	Back pain clinic	No involvement	- or 0
Heymans et al., 2004	Clinical intervention consisting of High intensity back school (based on principles of graded activity)	General working population; several companies	Usual care	Back pain Clinic	No involvement	?

1e author	Type of intervention	Population	Control group	Site of intervention	Involvement of stake-holders at the workplace	Effect on time to return-to-work
Loisel et al., 1997	Clinical intervention consisting of Functional restoration	General working population; several companies	Usual care	Back pain *Clinic*	no involvement	0
Heymans et al., 2004	Clinical intervention consisting of Low intensity back school (*based on* Swedish back school)	General working population; several companies	Usual care	Back pain Clinic	no involvement	?

All other interventions can be classified as biopsychological interventions (with or without a workplace visit). Also the working population (general or blue collar) and site of the interventions (clinic or workplace) varied. Therefore, it is difficult to produce a concluding statement about the optimum content of multidisciplinary rehabilitation for occupational LBP. Moreover, in most studies the effectiveness of the different components of the multidisciplinary rehabilitation was not assessed.
In two studies, the Loisel et al. study [1] and our study, an analysis was made for the effectiveness of a workplace (i.e. biosocial) intervention (= workplace) and a clinical (i.e. biopsychological) intervention. A red line in the results of both studies is that the workplace intervention was effective on return-to-work for non-specific LBP, whereas the clinical intervention was not effective or even contra productive. However, an comparison can not be made because workplace and clinical interventions were administered at different moments during sickleave. In contrast to these findings, clinical interventions have proven to be effective on return-to-work in two other studies [12,13]. These studies were conducted in the well controlled setting of single company and the interventions included stakeholder involvement at the workplace: i.e. a workplace visit and a meeting with the supervisor [12], or interventions that were administered at the workplace by in-company therapists, familiar with the workplace and management [13]. In another recently conducted study [14] with a clinical intervention without workplace intervention or stakeholder involvement, inconclusive effects (low intensity) or no effect (high intensity) were reported. This might suggest that a positive effect of the multidisciplinary rehabilitation is not related to the clinical intervention but is primarily related to the workplace intervention i.e. a clinical intervention at the workplace or interventions with (active) involvement of stakeholders at the workplace. However we have to be cautious to draw preliminary conclusion without updating the Cochrane review [2].

Which key stakeholders have to be involved in multidisciplinary rehabilitation for non specific LBP?

According to the review of Waddell & Burton [4] there is moderate evidence that communication, co-operation, and common agreed goals between all stakeholders is fundamental in clinical and occupational health management for improvement of outcomes. They defined the key stakeholders in the return-to-work process involved as: the worker with LBP, the occupational health team, supervisors, management, and primary health care professionals. Frank et al. [15] identified the following key stakeholders in the return-to-work process for non-specific LBP: patients, employers, labour unions, care providers and payers. It is obvious that key stakeholders depend on the Health Care and Social Security system. In the Netherlands e.g. every worker has an OP who certifies sickness absence and a GP who is primarily responsible for medical treament. The role of the employer in the return-to-work process is very prominent due to the obligation to pay the wages and return-to-work interventions during the first 2 years of sick-leave. The role of Dutch labour unions & insurance companies in the return-to-work process has been limited until now. However currently this role is becoming more prominent due to a trend of privatisation of parts of our social security system. The relationships between the key stakeholders in the return-to-work process are complex, because they have different, sometimes adversarial interests. Scheel et al.[16,17,18] showed recently that the implementation of a rehabilitation/modified work program can fail because the lack of co-operation between all stakeholders. In figure 1 a simplified scheme is shown of the key stakeholders and their interactions. In the return-to-work process two relationships between key stakeholders can be distinguished with potentially adversarial interests.

- **Worker & supervisor**. These parties can miscommunicate, partly because they have such diverse interests and concerns [5]. The worker's primary concerns during sickleave are finance and job security, fear of reinjury, lack of workplace support and self image issues (embarrassment, overdependence on others) [19]. According to workers, the role of the supervisor in the return-to-work proces is important with respect to the following aspects: providing work accommodation, communication with the injured worker and responsiveness [20]. It is stated often that interpersonal interaction between employee and supervisor is an important factor in the return-to-work proces [20,21,22]. One of the obstacles for return-to-work and strong predictors for occupational disability is the lack or failure to provide modified work [23,24]. Chapter 3 showed that the provision of ergonomic interventions accelerates return-to-work. However, is it the provision of work accomodation itself or the communication process leading to modified work which facilitates return-to-work? Pransky et al. [25] hypothesize that communication based interventions may further improve health outcomes and reduce adversarial relationships.

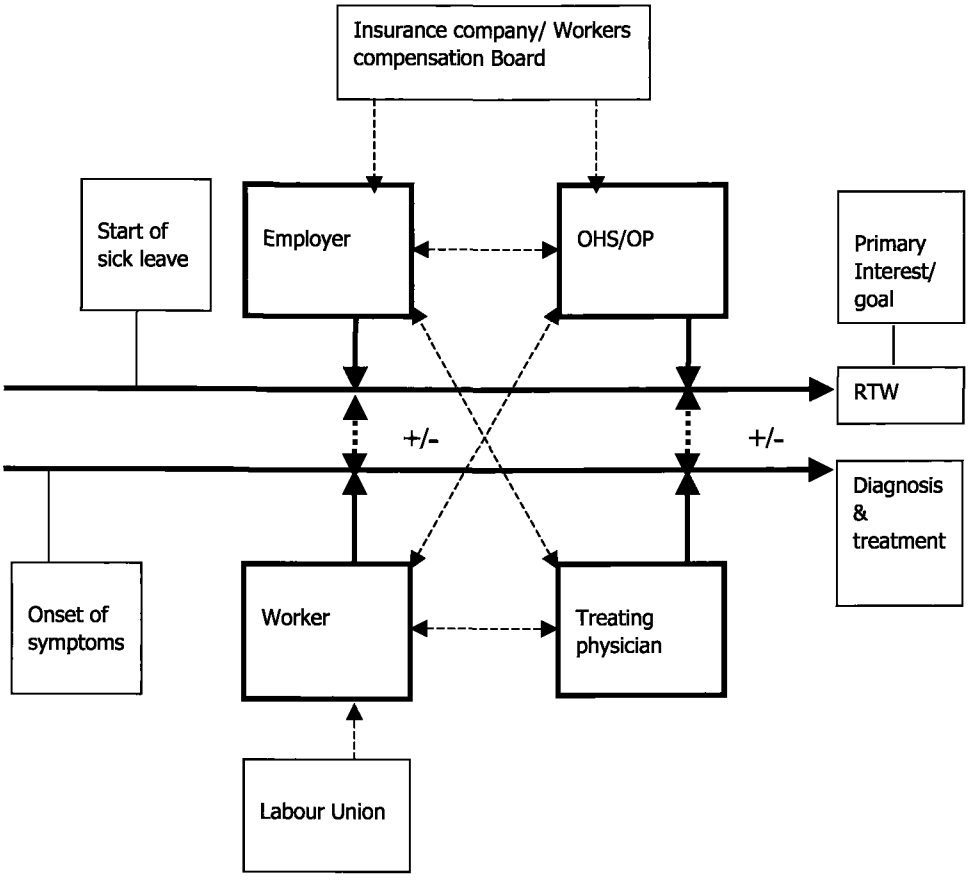

FIGURE 1. Key Stakeholders and their primary interests and interactions in return-to-work process

According to Frank et al. [15] failure for return-to-work is primarily due to to failed social transaction at the workplace. Frank et al. [5] suggested that a "neutral" person must have the power to negotiate any necessary job modifications with the workplace, the worker and the care providers. Occupational health nurses can have a vital role to mediate in this interpersonal process to overcome obstacles for return-to-work [26,27]. In chapter 5 we have described a workplace intervention using the participatory approach, applied by an ergonomist or occupational health nurse. The participatory approach is based on a negotiation /shared decision making method of both the worker and supervisor in the process to identify and solve obstacles for return-to-work. In chapter 5 it was also shown that the workers were satisfied about this method and the shared decision making proces with the supervisor. This negociation/shared decision making method could be an

essential part of the effectiveness of this intervention on return-to-work. However, more qualitative research is needed on worker's and supervisor's perceptions, their roles and the interaction process with regard to return-to-work, in addition to RCTs on the effectiveness of communication/negotiation based interventions on return-to-work, separately .

- **Curative health care & occupational health care**: Chapter two showed that in the opinion of OPs, usual medical care by treating physicians or therapists in the Netherlands is often an obstacle for return-to-work of workers sicklisted due to chronic LBP. It is discussed that treating physicians and therapists seem to be primarily directed at diagnosis and treatment of health related problems and diseases, and not at return-to-work. Obviously, OPs and treating physicians/ therapists have different goals. According to Bruckman & Harris [28] barriers for return-to-work can originate from the treating physician; they have described several ineffective medical practices for LBP that possibly are delaying functional recovery. Also Frank et al. [5] stated that treating physicians are likely to overtreat most patients with LBP: unnecessary medical care, excessive specialist referral, investigation, and treatment can cause prolonged sickleave. In addition, clinical advises not to return to normal duties or to return on restricted duties can delay return to work [29,30]. For this reason, we tried in our RCT to avoid in the workplace intervention group unnecessary treatments and contra productive clinical advices: i.e. the OP asked the worker's GP to leave the (case) management of the LBP to the OP. It remains however the question to what extent this element contributed to the effectiveness of the workplace intervention.

Main conclusions:

- Workplace intervention with active involvement of all key stakeholders in the RTW process (worker/employer and curative/occupational health care) is the preferred method for the multidisciplinary rehabilitation of non-specific LBP.
- However, qualitative research and RCTs are needed to clarify the contribution of key stakeholder communication/negotiation and avoiding RTW-delaying back pain management in the effectiveness of the workplace intervention.

Learning from our experiences

Recruitment: the influence of politicians and money?

In our RCT we encountered a lot of practical problems during the recruitment. Unfortunately, we have experienced in this project the infamous 'Law of Lasagne': despite our conservative estimations the actual inclusion of patients fell short to our expectations, when starting our intervention-project. After one year of inclusion only 64 of the intended 200 patients were included. Shortly before the start of our study the government abolished a Law called 'REA'; financing return-to-work interventions for LBP. One of the main obstacles for recruitment was that many employers did not

want to pay for an experimental intervention, of which the cost-effectiveness was not proven yet. This caused us and the participating OPs a lot of trouble to convince employers to participate. Frequent talks with the funding agency of the project were necessary to convince them not to stop the project but to give more money in stead to finance the interventions. We feared a vicious circle: If employers did not want to pay the interventions, we had no opportunity to show them whether the interventions were (cost)effective. One year after the start of the inclusion, the Ministries of Social Affairs & Employment and Health, Welfare & Sports recognised this dilemma and financed the interventions. Due to this recruitment problem we had to double our planned recruitment period and double the initial number of participating OPs and employers. In addition, a lot of efforts were made to achieve our preset goal: These efforts included newsletters, articles in newspapers, credit certification points, regular visits and phone calls, bottles of wine, cakes, a two-monthly award for the OP who recruited most patients, and a lottery to win a trip to Napels. In the second year we managed to double our inclusion (see figure 2). Unfortunately the introduction of a new Gatekeeper Law in 2002 appeared to be a new obstacle for inclusion rate in the second year [31]. Nevertheless, we managed to handle all these challenges, thanks to great efforts of our research team and especially to the efforts of Ivan Steenstra: We achieved almost our preset goal and finally succeeded to include 196 patients. Finally, we succeeded where many others did not due to implementation and recruitment problems, and/or a lack of power. However, it has to be mentioned that there was one real life obstacle we could not solve without help of others: money for interventions. We hope that the results of the cost utility study will help to solve this problem in the future, too.

Implementation: how to change behaviour of professionals?

It took us a lot of effort to convince 99 OPs, 47 PTs and 25 ergonomists/occupational health nurses to participate in our study and to implement the study protocol. We trained them all three times for 2-4 hours with an interval of 4 months. Role playings were an essential part of these training sessions. Fifty-five of the 99 OPs, that we trained, actually participated in our study. The majority of them treated one or two patients. A few treated more than 5. There were two OPs who treated more than 15 patients [see figure 2].

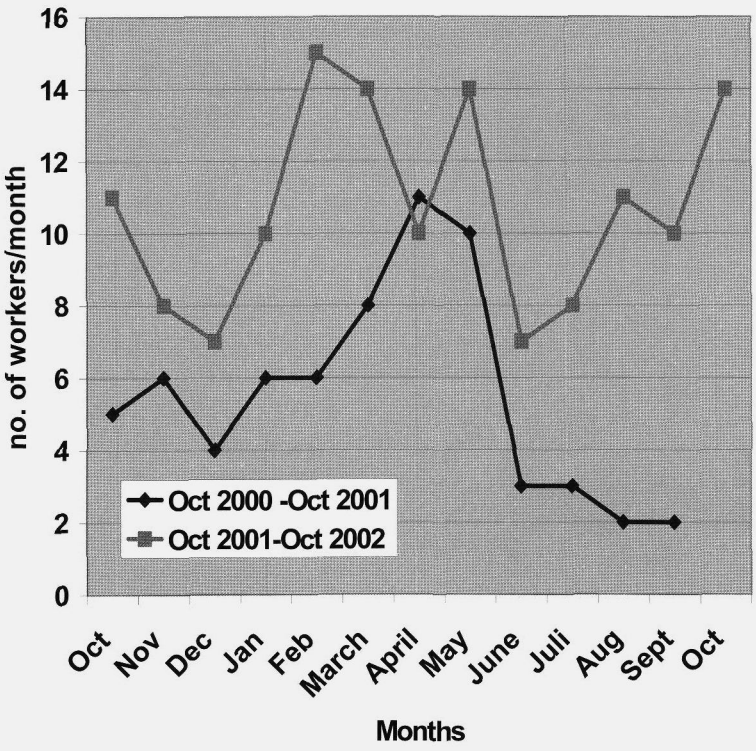

FIGURE 2. Recruitment rate of patients in our study

An important lesson we learnt is that it is better to recruit a few motivated professionals than a lot of less motivated professionals when you have to conduct an RCT within a certain time frame. This is not only more efficient in terms of costs and time, but it is also easier to implement the study protocol in the daily practice of a few motivated professionals. Therefore, we changed after one year our initial recruitment method aimed at recruiting OPs by recruiting their OHS into a method in which through local OP-circles we asked directly OPs themselves to participate. Rogers [32] identified 5 categories of professionals when you want to change behaviour: innovators, early adopters, early majority, late majority, and laggards. According to Rogers the distribution of these categories among professionals is representing a Gausse curve: innovators, early adopters, early majority, late majority, and laggards are 2.5%, 13.5%, 34%, 34% and 16% of these professionals respectively. In our study 11 of the 99 (11%) recruited OPs accounted for half of the cases. We learnt that it is important to find these innovators and/or early adopters among the participants of meetings of local OP-networks. This lesson is also important for the implementation of this new method/intervention.

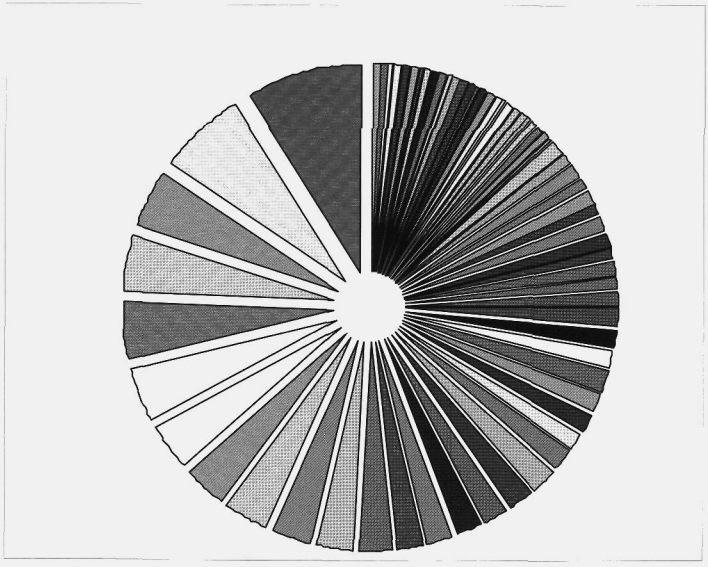

FIGURE 3. The circle of 'Rogers'. Distribution of OPs (n=55) who treated patients (n=196) in our study.

Methodological issues

Strengths

Methodological strengths and limitations of the research we conducted were frequently discussed in earlier chapters. Therefore, I will focus in this chapter focuses on the major strengths and limitations of our RCT. First the major methodological challenges and strengths are discussed. We wanted to evaluate an experimental method in a 'real life' setting. First, it was a challenge for us to conduct a RCT in a general working population with a diversity of economic sectors and employers. It would have been far easier to conduct a trial within one company, as one occupational health service or a limited number health care professionals. However, we choose to recruit more than a dozen OHS, and train over 175 health care professionals, and deal with more than 58 employers. Some of them were highly motivated, but most were not. A selected population of highly motivated professionals, workers and employers was avoided, because we wanted to know the effect of our interventions in the average practice of Dutch OHS. We did not ask patients during the intervention period to refrain from other therapies, like many others do, because we wanted to avoid a selected population of motivated patients. Consequently, everything that happens in real life could also happen in our RCT. The methodological advantage is now that the external validity of our RCT is good and that our interventions have more potential to be implemented on a large scale.

Limitations

Of course our RCT has some methodological limitations too. In Chapter 4, the randomization model was discussed. We decided to randomize for the workplace intervention at the OP-level to avoid possible contamination of workers receiving this intervention or not. The rationale was that this contamination would reduce the contrast between the intervention groups. However, this also caused us some troubles: in the first year we included relatively more workplace intervention cases than usual care cases. A possible explanation was that OPs who were randomized for the workplace intervention group were more focussed at the study because they were asked to alter their behaviour. Conversely, OPs who were randomized to the usual care group were less focussed, because they were asked to treat according to the current OP-guideline [33]. F.i., some OPs in the UC-group forgot to the refer patients to the research assistant, or even thought that they did not have to do anything! Finally, it cannot be ruled out that selection bias may have taken place although the OPs themselves were not directly involved in the recruitment and inclusion process. To balance the numbers of subjects in both groups, we changed the initial 1:1 ratio to a 1:3 ratio in favour of the usual care OPs when we randomized the 50 additional OPs whom we recruited in the second year. To check whether there was independency of observations between OPs, multilevel analysis at the OP level was conducted and intraclass correlation coefficients were calculated. Fortunately, we could not find any dependency. This might due to the large number of participating OPs.

It was decided also by the research team not to randomize into four groups in one step, like the original design in Canada, but to randomize in two steps. In the first step, all included workers were assigned randomly to the workplace intervention or not. However in the second step only workers who were still sicklisted after 8 weeks were randomized to the clinical intervention. The rationale behind this decision was that theoretically the effectiveness of two interventions could be applied more independently. We feared that a randomization for both interventions in one step could influence the case management of the OP knowing future interventions. As a result of our two step design no intended interaction could happen between both interventions. In addition, the efficiency of the trial has increased as only workers who were still on sickleave were randomized with a blocked randomisation scheme, guaranteeing equal group sizes for the clinical intervention and usual care. However, the randomization in two steps was difficult to explain to the participating workers and OPs. This may have been the reason that compliance to the clinical intervention (65%) was not so high as the compliance to the workplace intervention: Some OPs and workers reacted very surprised when they were informed with a letter about the result of the second randomization after 8 weeks absence of work.

Recommendations for future research and implementation

The new evidence gives a better opportunity to manage non-specific LBP and to accelerate return-to-work. Our results provide the first steps, but we do not reache

to the end. Main recommendations for future research are given below, but also recommendations to implement findings from our study in clinical guidelines/practice.

Updating Cochrane review

As discussed earlier in this chapter, it is important to update the Cochrane review on the effectiveness of multidisciplinary rehabilitation[2], as the number of RCTs evaluating the effectiveness of multidisciplinary rehabilitation for occupational LBP has recently grown –to our knowledge- by 150%. In addition, more information is available about effective components of multidisciplinary rehabilitation for occupational LBP.

Conducting new research

More knowledge is needed about the facilitators and obstacles in the return-to-work process and prevention of occupational disability due to non-specific LBP. Qualitative research methods, like personal and focus group interviews, are needed to get a better insight in role, expectations, interests of the worker, employer, and (occupational) health care professionals in the return-to-work process. Combination of insights derived from qualitative and quantitative research are needed to find an explanation for the opposite effects of return-to-work interventions presented in this thesis. In addition, research is needed to evaluate the satisfaction of patients, workers, care givers and employers with respect to the applied workplace intervention. These are important factors in enhancing compliance to and future implementation of the workplace intervention.

In addition, high quality randomized controlled trials are needed to evaluate the effectiveness of communication/negotiation based interventions on return-to-work and to evaluate the effectiveness of avoiding (para)medical treatment that delays return-to-work after non-specific LBP.

Reviewing clinical guidelines

To become integrated in clinical practice, the evidence of our RCT and other studies [12,14] should be translated into recommendations in the guidelines for the treatment of LBP of NVAB (Dutch Medical Board for Occupational Medicine), CBO (Dutch Institute for Healthcare Improvement) and NHG (Dutch Institute for improvement of general practice care). The NVAB, NHG and CBO published guidelines for the management of non specific LBP [33,34,35]. They recommend as a preferred method for LBP a multidisciplinary rehabilitation including a biopsychological approach, directed at patients with non-specific LBP. In our opinion, for the patients with non-specific OLBP, these recommendations seem to be based on inconclusive or conflicting evidence or opinions. Workplace intervention, for LBP with active stakeholder involvement is not recommended (as the first choice). According to the results of our RCT and other recently conducted studies [12,14], we recommend workplace intervention with active involvement of stakeholders as the

preferred method of treatment for occupational LBP. Now that new evidence has become available, update of the guidelines is urgently needed.

Next steps... towards evidence based Occupational Medicine

In summary, main recommendations originating from this thesis are:

- Occupational Medicine in the Netherlands plays an important role in reducing occupational disability. Most interventions in occupational medicine however are still not evidence based, therefore the scientific development of occupational medicine is needed. In 2003 the advisory committee for the government "Raad voor Gezondheidsonderzoek" released a report [36] and advised the development of scientific research in Occupational Medicine in the Netherlands. This thesis showed that workplace interventions can reduce occupational disability due to LBP and can potentially save a lot of costs for society. This thesis showed also that more qualitative research and high quality randomized controlled trials are needed. We hope our study will contribute to the insight that funding for the scientific research of occupational medicine is not only a necessary, but also very promising tool to reduce and prevent occupational disability in the Netherlands.
- The NVAB has released 6 guidelines since 1999 which are partly evidence based and partly consensus based. In 2004 the NVAB has started a guideline office to make more guidelines in occupational medicine. We hope that our study will contribute to the efforts of the NVAB to further improve the guidelines with emerging scientific evidence and to convince their members that evidence based occupational medicine has a high priority [37].

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Summary

Low back pain is the most common and expensive disorder in industrialized countries and is frequently related to disability and absence from work. Questions about treatment effects of workplace and clinical interventions for occupational LBP are frequently asked by treating and occupational health care professionals as well as by workers and employers (see chapter 1). In this chapter, answers to the questions below are summarized.

By the treating physician and therapist (GP, physical therapist or neurologist): What is the role of treating physicians and therapists with respect to return-to-work when they are treating workers with chronic LBP?
A cohort study including 467 low back pain patients sicklisted for 3-4 months was described (Chapter 2). The occupational physicians (OPs) of 300 of 467 patients answered a questionnaire concerning facilitators and obstacles for return-to-work, as well as communication between OPs and treating physicians. According to their OP for many patients the clinical waiting period (43%), duration of treatment (41%) and view (25%) of the treating physicians were an obstacle for return-to-work. Psychosocial obstacles for return-to-work played a minor role according to the OPs. There was about only 19% of the patients communication between OP and treating physician. Communication comprised more frequently an exchange of information than harmonization of the management policy with respect to return-to-work. Surprisingly, frequency of communication was limited also, when OPs felt that the waiting period (32%), duration of treatment (30%), and view (28%) of treating physicians inhibited return-to-work. In conclusion, usual medical care of treating physicians is not aimed at return to work and can often be an obstacle for return to work of low back pain patients sicklisted for 3-4 months, according to their OPs. Communication between OPs and treating physicians with respect to return-to-work policy of these patients is limited.

By the employer: Do workers with ergonomic interventions return to work more quickly for a long-lasting period compared to workers without these interventions?"
The occurrence and effectiveness of ergonomic interventions on return-to-work of workers with LBP was studied in Chapter 3. For this reason, a multinational cohort of 1631 workers fully sicklisted 3-4 months due to LBP was recruited from sickness benefit claimants databases in six countries (Denmark, Germany, Israel, Sweden, the Netherlands and the United States). Data on time to return-to-work, interventions (ergonomic, medical) and prognostic factors were collected by questionnaires and interviews at three months, one and two years after the start of sickleave. Ergonomic interventions varied considerably in occurrence between the national cohorts: 23.4% (mean) of the participants reported adaptation of the workplace, ranging from 15.0% to 30.5%. Adaptation of job tasks and adaptation of working hours was applied for 44.8% (range 41.0%-59.2%) and 46.0% (range 19.9%-62.9%) of the participants, respectively. Workers with adaptation of the workplace returned to work more quickly than workers without this intervention. Adaptation of job tasks and

adaptation of working hours were effective on return-to-work rate after a period of 200 days of sickleave. In conclusion, the results of this observational study suggest that:1. Ergonomic interventions are frequently applied as a return-to-work intervention; 2. Ergonomic interventions are accelerating return-to-work of workers long-term sicklisted due to LBP. However a randomized controlled intervention study is needed to confirm these findings.

By researchers: We are going to conduct a RCT on the effectiveness of four treatment options for occupational LBP: workplace intervention (1) clinical intervention (2) a combination of both interventions (3) and usual care (4). What are important aspects in the design of this study to answer the research questions?
In Chapter 4, we described how a Canadian multistage return-to-work program and study design was adjusted to the Dutch socio-economic context. The Dutch study will be able to cross-validate the Canadian findings in a different sociocultural context. Workers sicklisted for a period of 2 to 6 weeks due to low back pain were recruited in Occupational Health Services with help of their OPs. Workers were randomly assigned to four treatment arms: a workplace intervention, a clinical intervention, both interventions or usual care. The workplace intervention consisted of a workplace assessment and work modifications based on methods used in Participative Ergonomics (PE). The participatory approach is based on a standardized negociation and shared decision making process of worker, supervisor and expert to solve the obstacles for return-to-work (including workplace, work organisation and individual aspects). All major stakeholders in the return-to-work proces were involved in this intervention: worker, supervisor, the patient's OP and GP. The clinical intervention comprised a graded activity program based on cognitive behavioural principles, applied by a physiotherapist. Usual care was provided by the OP according to the Dutch guidelines for the occupational health management of workers with low back pain. Primary outcome measure was duration until full and lasting return to work (own or equal work). Main secondary outcome measures were pain intensity and functional status. The outcome measures were assessed at baseline and 12, 26 and 52 weeks after first day of sick leave.

By workers and their occupational health professionals: How is the workplace intervention and its implementation evaluated by LBP-patients and their occupational health professionals?
In a pilot-study a workplace intervention based on methods used in PE, was applied as a return-to-work intervention for workers with LBP. This intervention is involving all stakeholders.The process, implementation, satisfaction and barriers for implementation concerning the workplace intervention were described in Chapter 5. Quantitative and qualitative analyses were conducted for 35 workers sicklisted 2-6 weeks due to LBP and their ergonomists. Two-hundred-and-seventy solutions were proposed to the employer. Solutions were targeted more at work design and organisation of work (58.9%) than at workplace and equipment design (38.9%).

Almost half of the solutions were completely or partially implemented within three months after the first day of sickleave. Workers and ergonomists were satisfied about the workplace intervention. Main obstacles for implementation of the solutions were technical or organizational difficulties, and physical disabilities of the worker. This study suggested that compliance, acceptance and satisfaction related to the workplace intervention was good for all LBP-patients as well as their ergonomists.

By the OP: Should I advise a workplace intervention or should I simply follow the current occupational guideline?

In Chapter 6 the 26-weeks results of a randomized controlled trial (RCT) on the effectiveness of a workplace intervention for low back pain in Dutch Occupational Health Care were presented. We conducted a population based randomized controlled trial (RCT) at 13 Dutch Occupational Health Services, between October 2000 and October 2003. Workers who were randomized to the GA intervention after 8 weeks of sickleave were excluded from the analysis (n=84) in order to assess the effect of the workplace intervention independently. Consequently, a sample of workers (n=141) sicklisted for a period of 2 to 6 weeks due to non-specific LBP was included. Participants were randomized to the workplace intervention (n=69) or usual care (n=72). Randomization took place at the level of the OP. The workplace intervention consisted of a workplace assessment, work modifications and case management involving all stakeholders. Main outcome measures were time until lasting and full return-to-work, functional status and severity of pain. Outcomes were assessed at baseline, and at 3 and 6 months after the start of sickleave. The median duration of sickleave until full return-to-work at 6 months follow-up in the intervention group was 64 days, versus 79 days for the usual care group. The workplace intervention was effective after 60 days of sickleave and onwards (hazard ratio = 2.5 [95% CI 1.5 to 4.1]; p=0.0003). The workplace intervention group was more effective in improving functional status and pain than the usual care group. However, the effects were small, and statistically not significant. It was concluded that workplace intervention should be recommended by OPs for the return-to-work of workers 2-6 weeks sicklisted due to non-specific low back pain.

By the OP and the physical therapist: Should I advise a worker sicklisted 8-10 weeks due to LBP a clinical intervention or should I simply follow the current occupational guideline?

In Chapter 7, a pragmatic randomized controlled trial was described to evaluate the effectiveness of a clinical intervention in a general working population. The clinical intervention comprised a Graded activity program (GA) as part of a multi stage return-to-work program. GA is an individual physical exercise program based on a cognitive behavioral principles. Workers (n=112) sicklisted 8 weeks due to low back pain, were assigned randomly to either graded activity (n=55) or usual care (n=57). Primary outcome measure was duration until full and lasting return to work (own or equal work). Main secondary outcome measures were pain intensity and functional

status. Outcomes were assessed at baseline, and at 3 and 6 months after the start of sickleave. GA prolonged return-to-work in this setting. Median time until return-to-work was 139 days in the GA group and 111 days in the usual care group (hazard ratio= 0.52 (95% CI=[0.32-0.86]). GA did not improve pain or functional status significantly compared to usual care. More than one third of the workers were not compliant to the GA-protocol. It is concluded that GA was not effective on any of the outcome measures in a general worker population.

By the occupational physician: Is a clinical, or a workplace intervention, or both, as part of multidisciplinary rehabilitation (more) effective for occupational LBP?
Clinical interventions, as well as workplace interventions are advocated for multidisciplinary rehabilitation of occupational low back pain. Chapter 8 describes a comparative analysis in which the effectiveness of both interventions, separately and in combination, was assessed at 52 weeks after thwe first day of sickleave. A population based randomized controlled trial with 196 workers sicklisted for a period of 2 to 6 weeks due to non-specific LBP, was conducted at 13 Dutch Occupational Health Services between October 2000 and October 2003. Participants were randomized to the workplace intervention (n=96) or usual care (n=100). The workplace intervention consisted of work modifications and case management involving all stakeholders. Workers who were still on sickleave at 8 weeks, were randomized for a clinical intervention (n=55) or usual care (n=57). The clinical intervention comprised a graded activity program. Primary outcome measures comprised time until full and lasting return-to-work, secondary outcome measures were functional status and pain intensity. Outcomes were assessed before randomization, and at 12, 26 and 52 weeks after the first day of sickleave. After one year follow-up, the 26-weeks results were confirmed: The median time to full return-to-work for workers with the workplace intervention was 77 days, versus 104 days for workers without this intervention (p=0.018).The workplace intervention was effective on return-to-work rate (HR = 1.7 [95% CI 1.2 to 2.3]; p=0.003). The clinical intervention delayed return-to-work, with an adjusted HR 0.4 ([95% CI 0.3 to 0.6]; p<0.001). A combination of both interventions had no effect on return-to-work. Workers with a workplace intervention improved more on functional status and pain intensity than workers without this intervention, but this was statistically not significant. The clinical intervention had a negative effect on functional status and pain. It was concluded that a workplace intervention should be recommended for multidisciplinary rehabilitation of sub acute occupational LBP. GA intervention is not recommended.

The final chapter summarizes our main findings, puts together the current evidence, draws lessons to be learnt from our experiences, and finally gives recommendations for reviewing clinical and occupational guidelines and for new research to be conducted. Key questions addressed and answered are: What is the optimum content of multidisciplinary rehabilitation for sub acute LBP to prevent occupational

disability? Which key stakeholders have to be involved in multidisciplinary rehabilitation?

Main conclusions of this thesis are: 1 Workplace intervention with active involvement of all key stakeholders in the RTW process (worker/employer and curative/ occupational health care) is the preferred method for the multidisciplinary rehabilitation of non-specific LBP. 2. However, qualitative research and RCTs are needed to clarify the contribution of key stakeholder communication/negotiation and avoiding RTW-delaying back pain management in the effectiveness of the workplace intervention. Next steps have to be taken to optimise multidisciplinary rehabilitation of occupational LBP and to prevent occupational disability in practice.

Samenvatting

Lage rugpijn is de meest voorkomende en duurste aandoening in geïndustrialiseerde landen. Lage rugpijn leidt vaak tot verzuim en arbeidsongeschiktheid. Er bestaan veel vragen bij artsen en paramedici in de (bedrijfs)gezondheidszorg, werknemers en werkgevers over het effect van behandelingen en interventies op het werk bij verzuim door aspecifieke lage rugpijn. Voorbeelden van deze vragen staan in de casus in hoofdstuk 1. Dit proefschrift wordt samengevat in een 5-tal van deze vragen & antwoorden op basis van onderzoek.

Behandelaar (huisarts, fysiotherapeut, neuroloog): wat is de rol van de behandelaar bij de terugkeer naar werk van hun patiënten met chronische rugklachten?
In hoofdstuk 2 wordt een cohort-onderzoek beschreven waaraan 467 werknemers deelnamen met 3-4 maanden verzuim door lage rugpijn. De bedrijfsartsen van 300 van deze 467 werknemers vulden een vragenlijst in over de bevorderende en belemmerende factoren voor werkhervatting en de communicatie tussen bedrijfsarts en de curatieve sector. Volgens de bedrijfsartsen was bij veel van deze werknemers de wachttijd voor diagnostiek of behandeling (43%), de duur van de behandeling (41%) en de visie (25%) van de behandelaar een belemmering voor de werkhervatting. Psychosociale belemmeringen voor werkhervattingen, zoals bijv. een lage arbeidsmotivatie, speelden een ondergeschikte rol volgens de bedrijfsartsen. Bij slechts 19% van de werknemers was er (mondeling of schriftelijk) contact tussen de bedrijfsarts en de behandelaar. Als er contact was, dan bestond dat meestal uit informatie-uitwisseling en in veel mindere mate uit afstemming over de werkhervatting. Opvallend genoeg was er ook slechts in beperkte mate contact, als de bedrijfsartsen vonden dat de wachttijd (bij 32% van de werknemers), de behandelingsduur (30%), en de visie (28%) van de behandelaar een belemmering vormde voor de werkhervatting. De conclusie van dit onderzoek is dat de zorg van de curatieve sector, naar de mening van bedrijfsartsen, vaak een belemmering vormt voor werkhervatting na langdurig verzuim bij rugklachten. Ook de afstemming tussen bedrijfsartsen en behandelaars over het beleid bij werkhervatting was beperkt.

Werkgever: Hervatten werknemers die werkaanpassingen krijgen, sneller langdurig het werk dan werknemers die geen aanpassingen krijgen?"
In hoofdstuk 3 wordt het voorkomen en de effectiviteit van werkaanpassingen op de werkhervatting van werknemers met lage rugpijn beschreven. Een cohort van 1631 werknemers met volledig verzuim gedurende 3-4 maanden door lage rugpijn is geworven met behulp van de databases van sociale zekerheidsinstellingen in 6 landen (Denemarken, Duitsland, Israël, Zweden, Nederland en de V.S.). Gegevens over verzuimduur, interventies (ergonomische, medische) en voorspellende factoren werden verkregen door middel van vragenlijsten en interviews. Dit vond plaats 3 maanden, 1 en 2 jaar na de ziekmelding. Het voorkomen van werkaanpassingen verschilde aanzienlijk tussen de nationale cohorten in de 6 landen: gemiddeld 23.4% van de werknemers die het werk hervatten, kreeg een werkplekaanpassing met een spreiding van 15.0% tot 30.5%. Aanpassing van de taken en werktijden vond

respectievelijk bij 44.8% (spreiding 41.0%-59.2%) en bij 46.0% (19.9%-62.9%) van de werknemers plaats. Werknemers die een werkplekaanpassing kregen gingen sneller aan het werk dan werknemers die geen werkplekaanpassing kregen. Taak- en werktijden aanpassingen versnelden de werkhervatting na 200 ziektedagen. Hiermee kunnen we concluderen dat de resultaten van dit grote onderzoek uitwijzen dat werkaanpassingen vaak worden toegepast bij de werkhervatting en dat zij de werkhervatting versnellen van werknemers die langdurig ziekgemeld zijn met lage rugklachten. Wel is het nodig dat deze resultaten nog eens worden bevestigd in een onderzoek waar bij wijze van experiment door loting werknemers een werkaanpassing krijgen of niet.

Onderzoekers: Wij willen een experiment uitvoeren om te onderzoeken wat het meest effectief is om werkhervatting bij apecifieke lage rugpijn te bereiken: een werk(plek) aanpassing (1), een oefenprogramma (2), een combinatie van beide (3) of de zorg die op dit moment gebruikelijk is (4). Waar moeten we op letten bij de opzet van het onderzoek om deze vragen te kunnen beantwoorden?
In hoofdstuk vier wordt beschreven hoe een Canadees reïntegratieprogramma en de Canadese onderzoeksopzet is aangepast aan het unieke Nederlandse gezondheidszorg- en sociale zekerheidssysteem. Het doel was te onderzoeken of ook in Nederland dezelfde succesvolle resultaten als in Canada konden worden bereikt. Daarom werd in Nederland aan werknemers met 2-6 weken verzuim door lage rugpijn gevraagd mee te doen aan het onderzoek.
De werknemers werden door loting verdeeld over 4 groepen: werk(plek) aanpassing (1), een oefenprogramma (2), een combinatie van beide (3) of de zorg die op dit moment gebruikelijk is (4). De werk(plek)aanpassingen vonden na 2 weken verzuim plaats en bestonden uit een werkplekonderzoek door een ergonoom en werkaanpassingen volgens de participatieve methode. Deze methode houdt in dat de werknemer en diens leidinggevende onder leiding van een ergonoom tot een gezamenlijke keuze voor werkaanpassingen en plan van aanpak komen. Het doel daarvan was om belemmeringen voor werkhervatting weg te nemen. Alle belangrijke sleutelpersonen waren actief betrokken bij de werkhervatting: de werknemer, diens leidinggevende, de ergonoom bedrijfsarts en huisarts.
Als werknemers langer dan 8 weken verzuimden konden ze ook in aanmerking komen voor het graded activity oefenprogramma. Dit programma bestond uit een fysiotherapeutisch oefenprogramma, waarin onder leiding van een fysiotherapeut de belasting stapsgewijs voor de werknemer verhoogd werd. Deze methode is gebaseerd op cognitief gedragsmatige principes. Dit betekent dat de patiënt zoveel mogelijk wordt gestimuleerd, ondanks de pijn, de oefendoelen te bereiken. Het schema met deze oefendoelen werd door de fysiotherapeut met de werknemer van tevoren vastgesteld. Tenslotte betekende de gebruikelijke zorg dat de bedrijfsarts handelde volgens de bedrijfsgeneeskundige richtlijn voor begeleiding van werknemers met lage rugklachten.

Het belangrijkste te meten resultaat in dit onderzoek was het aantal dagen totdat volledige en duurzame werkhervatting was bereikt. Dit werk moest hetzelfde of gelijkwaardig zijn aan het werk dat de werknemer deed voor de ziekmelding. Daarnaast werd ook de afname van de pijn en de verbetering van het functioneren gemeten. Metingen vonden plaats aan het begin van het onderzoek, 3, 6 en 12 maanden na de ziekmelding.

Ergonomen, werknemers: wat vinden werknemers met aspecifieke lage rugpijn en ergonomen van het werkaanpassingsprogramma en hoe wordt het in de praktijk toegepast?

In een pilot-onderzoek werd het programma voor participatieve werkaanpassing toegepast bij werknemers die verzuimen met lage rugpijn. Het hele proces, de uitvoering van, de tevredenheid over en de belemmeringen voor werkaanpassingen worden beschreven in hoofdstuk 5. Gegevens werden verzameld en geanalyseerd op kwantitatieve en kwalitatieve wijze bij 35 verzuimende werknemers met rugklachten en hun ergonomen. Bij deze werknemers werden tweehonderd en zeventig (270) werkaanpassingen geadviseerd in het plan van aanpak. De meeste werk-aanpassingen waren gericht op aanpassingen van taken en de organisatie van het werk (58.9%). Werkplekaanpassingen en hulpmiddelen (38.9%) werden minder vaak geadviseerd. Bijna de helft van alle geadviseerde werkaanpassingen werd binnen 3 maanden na de ziekmelding ook geheel of gedeeltelijk uitgevoerd. Werknemers en ergonomen waren tevreden over deze methode voor werkaanpassingen. Belangrijkste belemmeringen bij de uitvoering van werkaanpassingen waren technische of organisatorische problemen en de lichamelijke beperkingen van de werknemer. Dit pilot-onderzoek geeft aan dat de acceptatie, tevredenheid en de wijze waarop het programma werd toegepast, goed was voor zowel de werknemers met rugklachten als hun ergonomen.

Bedrijfsarts: Moet ik een werknemer die 2-6 weken verzuimt met aspecifieke lage rugpijn aangepast werk adviseren of gewoon de bedrijfsartsenrichtlijn voor rugklachten volgen?

In hoofdstuk 6 worden de korte termijn effecten van werkaanpassingen op de werkhervatting beschreven bij werknemers met rugpijn. Wij voerden dit experimentele onderzoek uit bij 13 Arbodiensten tussen oktober 2000 and oktober 2003. Honderd één en veertig werknemers met 2-6 weken verzuim door rugpijn werden in deze analyse naar de korte termijn effecten opgenomen. Door loting waren ze ingedeeld in een groep die de werkaanpassingen kreeg (n=69) en een groep die de gebruikelijke zorg ontving (n=72). Zij werden gedurende 6 maanden na hun ziekmelding gevolgd. In de groep met werkaanpassingen duurde het gemiddeld 64 dagen tot volledige werkhervatting en in de groep die gebruikelijke zorg kreeg, was dat 79 dagen. Dit betekent dat werknemers met werkaanpassingen vanaf 60 dagen na de ziekmelding 2.5 keer zo snel het werk hervatten. Ook het functioneren en de pijn verbeterde meer in de groep met werkaanpassingen dan in de groep die

gebruikelijke zorg ontving. Deze laatste effecten waren echter klein en niet statistisch significant. Onze conclusie is dus dat bedrijfsartsen de werkaanpassingen volgens de participatieve methode zouden moeten adviseren om werkhervatting te bevorderen van werknemers met 2-6 weken verzuim door aspecifieke rugpijn.

Bedrijfsarts/fysiotherapeut: moet ik een werknemer die 8-10 weken verzuimt met aspecifieke rugpijn een 'graded activity' oefenprogramma adviseren of moet ik gewoon de bedrijfsartsenrichtlijn opvolgen?
Naast de hiervoor beschreven effecten van werkaanpassingen werden in hetzelfde experiment ook de korte termijn effecten van een graded activity oefenprogramma onderzocht. De resultaten daarvan staan in hoofdstuk 7. Werknemers die meededen met het onderzoek kwamen bij verzuim langer dan 8 weken in aanmerking voor het graded activity oefenprogramma. Deze analyse betrof honderd en twaalf werknemers met 8 weken verzuim door rugklachten die door loting waren ingedeeld in een groep met 55 werknemers die het graded activity programma ontving en in een groep met 57 werknemers die de gebruikelijke zorg kreeg. Beide groepen werden gedurende een half jaar na de ziekmelding gevolgd. Werknemers hervatten na graded activity het werk 0.5 keer zo snel als werknemers die de gebruikelijke zorg ontvingen. Gemiddeld aantal dagen tot volledige werkhervatting was 139 dagen in de graded activity groep vergeleken met 111 dagen in de gebruikelijke zorg groep. Wel werd duidelijk dat bij meer dan een derde van de werknemers, die waren toegewezen aan de graded activity groep, het oefenprogramma onvolledig of niet toegepast werd om uiteenlopende redenen. Voor beide groepen was er geen verschil in de verbetering van pijn en functioneren. Op basis van deze korte termijn effecten kan graded activity bij werknemers die 8 weken verzuimen met aspecifieke rugklachten niet geadviseerd worden. De lange termijn effecten moeten echter nog afgewacht worden om deze conclusie te kunnen trekken.

Bedrijfsarts: Wat is de meest effectieve multidisciplinaire aanpak voor werkhervatting bij aspecifieke lage rugklachten: een oefenprogramma, werkaanpassingen of beide?
In huidige multidisciplinaire behandelprogramma's worden oefenprogramma's en werkaanpassingen vaak geadviseerd bij aspecifieke rugklachten. In hoofdstuk 8 worden de lange termijn effecten van deze beide interventies afzonderlijk en gecombineerd beschreven. In deze analyse zijn alle 196 aan het hiervoor beschreven experiment deelnemende werknemers opgenomen. Zij zijn tot een jaar na de ziekmelding gevolgd. Door loting werden alle deelnemers na 2 weken verzuim door aspecifieke lage rugpijn eerst ingedeeld in een groep met werkaanpassingen (n=96) of een groep met gebruikelijke zorg (n=100). Werknemers die langer dan 8 weken verzuimden werden daarna opnieuw ingedeeld in een groep die het graded activity oefenprogramma (n=55) kreeg en een groep die de gebruikelijke zorg kreeg (n=57). Het gemiddelde aantal verzuimdagen tot volledige werkhervatting was voor werknemers die de werkaanpassing kregen 77 dagen en voor de werknemers die de gebruikelijke zorg kregen 104 dagen. Werknemers met werkaanpassingen keerden

1.7 keer sneller terug naar het werk. Werknemers die het oefenprogramma kregen, keerden 0.4 keer langzamer terug naar het werk. De combinatie van beide interventies versnelde noch vertraagde de werkhervatting. Bij werknemers met werkaanpassingen verbeterde het functioneren en de pijn meer dan bij werknemers zonder werkaanpassingen. Het verschil was echter niet statistisch significant. Het oefenprogramma had een negatief effect op de verbetering in functioneren en pijn vergeleken met werknemers die geen oefenprogramma hadden gekregen. De conclusie is dat werkaanpassingen aanbevolen zouden moeten worden bij de multidisciplinaire behandeling van werknemers met 2-6 weken verzuim door lage rugpijn.

In hoofdstuk 9 worden de belangrijkste resultaten samengevat, in perspectief van de huidige stand van wetenschap geplaatst, en lessen getrokken uit onze ervaringen. Tenslotte worden aanbevelingen gedaan voor het herzien van de huidige klinische en bedrijfsgeneeskundige richtlijnen en voor toekomstig onderzoek. Op de volgende kernvragen wordt een antwoord geformuleerd: wat is de optimale inhoud van multidisciplinaire behandeling voor werknemers die verzuimen met lage rugpijn om arbeidsongeschiktheid te voorkomen? Welke sleutelpersonen moeten betrokken worden bij de multidisciplinaire behandeling? De hoofdconclusies in dit proefschrift zijn: 1. Werkaanpassingen met actieve betrokkenheid van alle sleutelpersonen bij de werkhervatting (de werknemer/werkgever, en de curatieve en de bedrijfsgeneeskundige sector) is de aanbevolen methode voor de multidisciplinaire begeleiding bij verzuim door aspecifieke rugpijn.; 2. Echter, kwalitatief onderzoek en nieuwe experimenten zijn nodig om de afzonderlijke bijdrage vast te stellen van de afstemming tussen sleutelpersonen en het vermijden van vormen van begeleiding die de werkhervatting kunnen vertragen. Volgende stappen moeten worden gezet om de multidisciplinaire begeleiding van lage rugpijn in de praktijk te verbeteren en arbeidsongeschiktheid te voorkomen.

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Wetenschappelijke begeleiding en projectteam

Willem, jij was promotor en wetenschappelijk eindverantwoordelijke in dit project. Ik herinner me nog goed toen ik eind 1997 voor de eerste keer jouw kleine kamer binnen stapte. Overal lagen stapels boeken en manuscripten, die verraadden dat je het toen al druk had. Je bood me een stoel en een kop koffie aan te midden van deze stapels en nam de tijd mee te denken over mijn ambities om te promoveren. Jij was vanaf het begin enthousiast en gaf mij veel vertrouwen dat een aanvraag voor een AGIKO-beurs een goede kans maakte. Jij zei toen 'als dit niet lukt dan vreet ik mijn pet op...'. Dat was voor mij een enorme stimulans. Jij ging, met mij achter op je fiets, bij NWO langs toen in eerste instantie deze beurs werd afgewezen. En met succes! Ook waardeerde ik het zeer dat je mee ging op tournee om de medewerking van veel bedrijfsartsen, arbodiensten en bedrijven te vragen. Ik bewonder je inspanningen voor de academisering van ons vak en de manier waarop je in korte tijd als hoogleraar hieraan een mijns inziens belangrijke bijdrage hebt geleverd. Ook maakte je altijd even tijd als ik een luisterend oor of advies nodig had. Op zulke momenten waardeerde ik het zeer dat je alles af en toe even relativeerde en oog had voor meer dan het werk.

Paulien, jij was co-promotor en werd promotor. Je was de initiator en ook de projectleider van dit project. Onze eerste ontmoeting was in 1998 op de kamer van Willem en toen bracht jij mij in contact met het 'Sherbrooke' project. Pas een jaar later ging ik bij TNO werken en nu ben je zelfs mijn kamergenoot bij TNO. Ik heb veel waardering voor de manier waarop jij binnen TNO hebt zorggedragen dat ik kon promoveren. Daarbij viel mij vooral je pragmatische aanpak op. Je commentaar was voor mij vaak ook verfrissend. Ik hoop dat we in de toekomst veel blijven samenwerken.

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Management en collega's van TNO

Dick, jij was als teammanager in 1999 op zoek naar een schaap met 'vijf poten' ofwel een bedrijfsarts/onderzoeker. Dank voor je vertrouwen om mij in dienst te nemen op het thema "arbocuratieve samenwerking en Sociaal Medische Begeleiding". Ik kreeg veel ruimte van je om te zoeken naar een nieuwe methode om arbocuratieve samenwerking beter meetbaar te maken. Je was bereid om je sterk te maken voor mij in de organisatie en voor mijn promotieambities. Je respecteerde mijn keuze toen ik eind vorig jaar aangaf mijn loopbaan bij de universiteit te willen voortzetten. Ik waardeer het dat dit het afgelopen jaar weinig veranderd heeft aan ons uitstekende contact. Ik ben blij dat we de goede samenwerking in de toekomst zullen voortzetten: Ons eerste gezamenlijke project "transmural occupational care for LBP" vanuit TNO en VUmc is een feit en ik hoop dat er nog vele volgen.

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Kamergenoten en afdeling Soc. Geneeskunde/EMGO Instituut
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Veel werknemers melden zich ziek met lage rugklachten. Een klein deel daarvan blijft langdurig ziek en raakt zelfs arbeidsongeschikt. Bedrijfsartsen adviseren vaak werkaanpassingen en oefenprogramma's om de werkhervatting van werknemers met lage rugklachten te bevorderen, maar er is weinig wetenschappelijk bewijs dat dit effectief is. Dit proefschrift besteedt, naar analogie van Canadees onderzoek, o.a. aandacht aan de effectiviteit van een methode voor werkaanpassing met actieve betrokkenheid van werknemer èn werkgever. Deze methode blijkt werkhervatting te bespoedigen, hetgeen zowel gezondheidkundige als economische winst oplevert.

Han Anema (1964) is vanaf 1992 werkzaam in de bedrijfs- en verzekeringsgeneeskunde. In 1999 maakte hij de overstap naar TNO Arbeid en ontving hij van NWO een persoonlijke beurs voor het doen van promotie-onderzoek. In 2001 rondde hij de beroepsopleiding tot bedrijfsarts af met een internationale publicatie over de rol van artsen bij werkhervatting (hoofdstuk 2). Hiervoor ontving hij in 2002 de Reinier Zielhuispenning van de Nederlandse Vereniging voor Arbeids- en Bedrijfsgeneeskunde. Bij TNO Arbeid was hij als senior onderzoeker betrokken bij projecten op het terrein van 'Arbocuratieve samenwerking' en 'Effectiviteit van bedrijfsgeneeskundig handelen'. In dezelfde periode werkte hij 2 dagen per week op de afdeling Sociale Geneeskunde van het VU medisch centrum aan zijn promotie-onderzoek en volgde hij de Postdoctorale Opleiding Epidemiologie van het EMGO Instituut. In april 2004 trad hij als universitair docent in dienst bij de afdeling Sociale Geneeskunde, met als speciale opdracht te werken aan de 'Academisering van de Bedrijfsgezondheidszorg'.

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