The management of occupational low back pain

and its cost-effectiveness

Hynek Hlobil
The study presented in this thesis was conducted at the EMGO Institute for Health and Care Research, Department of Public and Occupational Health of the VU University Medical Centre, KLM Royal Dutch Airlines and KLM Health Services. The EMGO Institute participates in the Netherlands School of Primary Care Research (CaRe), which was re-acknowledged in 2005 by the Royal Netherlands Academy of Arts and Sciences (KNAW).

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De Boelelaan 1105

door

Hynek Hlobil

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prof.dr.ir. T. Smid
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Introduction
Pain is a common symptom in almost every one’s live. So is low back pain. Almost each of us at some time will experience low back pain that interferes with work, sport or routine daily activities. However, only few people develop chronic low back pain and permanent work disability. Nevertheless, the economic burden of LBP on the society is enormous due to medical costs and high costs of work absenteeism and occupational disability.\(^1\)\(^3\)

A Google search (February 2009) with the keyword combination ‘low back pain’ showed more than 33 million hits. A Pubmed search using term ‘low back pain’ revealed more than 16.000 publications, of which more than 2.200 are reviews. From these data it could be concluded that low back pain is a problem which occupies the mind of many scientists.

**Low back pain, what is it?**

The term low back pain is a description of symptoms. It means a pain, or ache, anywhere in the lower back, between the lower angel of the scapulae and the top of the legs.\(^4\) It is not a diagnosis, but merely a complaint. Low back pain can be categorized in numerous ways, for example according to the pathologic substrate of pain, i.e. specific and non-specific, or according the duration of complaints, i.e. acute, sub-acute or chronic low back pain.

Specific low back pain is attributable to objectively identifiable conditions such as arthritis, ankylosing spondylitis, spondylolysis or spondylolisthesis, infection of the disc space, spinal tuberculosis, malignant diseases such as multiple myeloma and metastatic disease, vertebral fracture or any other particular medical diagnosis. So called ‘red flag’ signs indicate possible serious spinal pathology and they should be recognised during diagnostic triage.\(^5\) The most alarming red flag signs are: presentation of low back pain under the age of 20, or first onset over 55, history of non-mechanical pain, thoracic localisation of pain, past history of malignant disease, steroid use or HIV infection, bad health and weight loss, widespread neurological symptoms or signs and structural deformity.\(^5\) In presence of red flag signs the patient should be referred to a specialist for thorough evaluation. Nerve root compression due to inter-vertebral disc hernia with pain irradiating to the lower extremity is usually accompanied by low back pain as well.

The diagnostic triage of LBP has to consist of clinical history-taking and physical examination to exclude specific types of low back pain. Consequently, non-specific low back pain is a diagnosis by exclusion of a specific cause. The majority of low back pain, about 85%, has a non-specific origin, or is, as Waddell states ‘an ordinary backache’.\(^5;\)\(^6\) A diagnostic triage
is necessary for the further management of low back pain.\textsuperscript{5} Non-specific low back pain and its management in occupational health care is the main issue of this thesis.

**Risk factors for non-specific low back pain**

There are many different demographic, physical, socioeconomic, psychological, and occupational factors contributing to the development of low back pain. Such factors are age, gender, socioeconomic status and education level, body mass index (BMI), tobacco use, perceived general health status, psychological factors such as depression.\textsuperscript{7} There is strong evidence that manual material handling, such as pushing and pulling and heavy lifting, high spinal loading, bending and twisting, whole body vibration, low social support at the workplace, and low work satisfaction are important factors for the development of low back pain in the working population.\textsuperscript{8-10} Psycho-social factors, referred to as ‘yellow flag’ signs are assumed to be the best predictors for chronicity and long-term disability. Therefore, a key goal of low back pain management is to identify so called ‘yellow flags’ that indicate increased risk for developing these problems. According to the 2004 edition of the New Zealand Acute Low Back Pain Guide the following factors can be considered as yellow flags: the belief that pain and activity are harmful, ‘sickness behaviours’ (like extended rest), low or negative moods, social withdrawal, treatment that does not fit best practice, problems with claim and compensation, history of back pain, time-off, problems at work, poor job satisfaction, heavy work, unsociable hours, overprotective family or lack of support.\textsuperscript{11} In this thesis we focus especially on factors which are important for return to work.

**Incapacity for work due to low back pain**

The burden to society of a certain disease can be estimated in epidemiological studies assessing the prevalence and incidence of a condition in the general population. There is an abundance of data describing the prevalence and incidence of low back pain. However, the results of studies differ substantially due to differences in definition for outcome measures, which have been used. The definition of the population at risk and the definition of an incident case influence the outcome. For example the incidence rate of LBP which lasted for at least 24 hours was reported in the general population to be around 18\% to 19\%.\textsuperscript{12} However, if we consider the incidence rate based on the number of patients who seeks medical or paramedical treatment than the rate varies between 2\% and 5\%.\textsuperscript{7}
Low back pain appears to be a frequent cause of work absenteeism. The yearly incidence rate of work absence due to LBP usually does not exceed 10%.\textsuperscript{13-16} It is obvious that not all workers having low back pain report themselves sick, especially when the pain does not interfere with physical demands of work duties. Recurrent episodes of low back pain are common and a history of low back pain is a strong predictor of future episodes.\textsuperscript{17-19} Reliable information about the natural course of low back pain is missing. Findings in the literature are based on various outcome measures, such as pain, disability, medical consultation, sick leave, or incapacity for work. Return to work or cessation of medical consultations do not necessarily correlate with the cessation of pain symptoms. These outcome measures are related, but they should not be considered interchangeable.\textsuperscript{19} For example, Waddell postulated that 90% of claimants return to work within 4 weeks. However, experience in general practice has learned us that 75% of LBP patients still suffer some pain one year after the onset of the episode.\textsuperscript{20,21}

**Duration of incapacity for work**

The duration of incapacity for work due to non-specific low back pain shows a characteristic curve of a steadily declining slope (figure 1).\textsuperscript{4} The majority of workers, about 90%, will return to work within a few days to 6

![Figure 1. Example of duration of benefit claims due to non-specific LBP, as distributed across all cases (Ontario Workers' Compensation Board, 1991), Frank 1996.\textsuperscript{4}](image)
However, the workers remaining off work after 3 months are at high risk for prolonged work-disability and a small percentage (about 10%) will still be off work at 6 months. Some of them (3% to 7%), develop long lasting disability for work and stay on sick leave benefits longer than one year. Those workers who are on sick leave for more than 3 months are responsible for large scale losses of productivity. In this thesis we will explore return to work as the most important outcome measure of a return to work intervention, and we will describe the natural course of work absence due to low back pain.

The cost of incapacity for work
Total costs of low back pain produce a substantial burden to society. Costs of illness must be considered for all stakeholders, including patients, medical doctors, and third-party payers, when deciding on the allocation of scarce healthcare resources. The total cost of illness has two main components: 1) direct (medical and nonmedical) costs; 2) indirect costs. Direct costs commonly include costs incurred for physician consultations, medications, hospital services, diagnostic testing, paramedical services such as physiotherapy, complementary and alternative medicine, but also other non-medical costs are included. Direct ‘health care’ costs can be estimated from records of insurance companies, or from files of patients. Direct ‘non-medical’ costs are related to goods and services consumed directly because of the illness, but which are not considered to be health care related. They include, for example, travel costs to attend medical or paramedical appointments, dietary costs, household help, and house adaptation for physically disabled.

Indirect costs commonly include costs related to work productivity. These employment costs include work absence resulting in productivity loss and decreased productivity of workers who come to work despite of illness. The latter, so-called presenteeism, is defined as decreased on-the-job performance due to the presence of health problems. It probably accounts for larger productivity loss than absenteeism.

Costs of low back pain may be estimated from different stakeholder perspectives. For example from a patient perspective, an employer perspective, an insurance company perspective, a governmental perspective, or a societal perspective. The latter includes all related costs. In this thesis we will focus on the employer’s perspective.

Long-term work absence or even permanent disability due to low back pain results in high compensation costs. For example in The Netherlands the total costs to society associated with low back pain were estimated in 1991 at 4.4 billion €, which was 1.7% of the 1991 GNP."
(More recent data are not available).
There are two main methods for estimating indirect costs associated with lost productivity. The most common approach is the human capital method, which assumes that the economic value of an employee’s productivity is equal to the cost of salary and benefits. Lost productivity is estimated by calculating costs related to the employee during work absence, including disability-related or early retirement related expenses.\textsuperscript{25} The friction costs approach assumes that employers replace employees who are absent for extended periods of time by workers from the labour market. The employers regain original productivity after a new worker is hired and properly trained. This friction period varies for different industries, job skills, education requirements, state of the labour market and socio-economic conditions of the country.\textsuperscript{29} There is a discussion about the use of either a human capital approach or friction costs method for the estimation of indirect costs. The friction cost methods can result in a three times lower estimate of indirect costs due to low back pain then estimation by means of the human capital approach.\textsuperscript{30}

The direct costs seem to contribute only for a small part to the total costs associated with low back pain. Regarding the indirect costs it must be mentioned, that a small percentage of workers who do not return to work because of low back pain for more than 3 months account for a large percentage of costs. An analysis of low back pain compensation claims in the period 1988-1996 from the privately insured US workers showed that 4.6-8.8\% of those who were for more than one year off work accounted for 77.6\%-90.1\% of all disability days and for 64.9\%-84.7\% of the indirect costs.\textsuperscript{31}

**Return to work interventions**

There are many categories of therapy or interventions for acute and chronic non-specific low back pain. These therapies are usually directed against pain and they are supposed to improve the functional status of the patient. Some of those therapies are evidence-based and some are evidence-informed, using clinical experience where research evidence is not fully available yet.\textsuperscript{32}

This thesis focuses on the management of sick-leave due to low back pain by occupational health services in the Netherlands. One of the main tasks of the occupational physician is to arrange social-medical assistance for sick-listed employees in order to ensure a safe and fast return to the original work, to prevent chronic disability and early retirement. Dutch occupational health services use, for the purpose of social-medical guidance of workers suffering from low back pain, professional guidelines,
which are evidence-based and authorised by the Dutch Society of Occupational Physicians.\textsuperscript{33} This occupational guideline is in line with national guidelines of other medical and paramedical disciplines on low back pain.\textsuperscript{34} Recommendations on return to work intervention are a part of these guidelines. However, there is little information available on the effectiveness and working mechanism of these return to work interventions, particularly in an occupational health care setting. One promising return to work intervention is a behaviour-oriented physical exercise program named Graded Activity, which was developed in Sweden.\textsuperscript{35} A modification of this intervention was used in the randomised clinical trial which is reported in this thesis. The purpose of the repetition of the trial was to find out if this successful method would also be effective in the Dutch situation.

**Characteristics of the Graded Activity intervention**

The graded activity intervention is based on operant conditioning principles using physical exercises as a structure for coping with physical pain. Fordyce has used operant conditioning in the treatment of chronic pain.\textsuperscript{36} Application of operant principles suggests that certain consequences of low back pain (e.g. medical consumption, care from house mates, sick-leave, etc) and pain behaviour have positive reinforcing properties for the patient’s behaviour. The positive consequences of the patients’ pain behaviour, i.e. rewording such behaviour, encourages that behaviour and increases its frequency. Thus, the reinforcement of the patients’ pain response may be largely responsible for the experience and presence of pain, rather than underlying pathology. The occurrence of behaviours that are followed by positive consequences or reinforcement will be increased in the future, while behaviours that are followed by negative consequences or punishment will decrease in the future. Positive consequences that follow every incidence of behaviour will increase the frequency of that behaviour. If the consequences stop abruptly, so called extinction, the behaviour will temporarily increase, but then subside quickly.\textsuperscript{36} The Graded Activity intervention in this study consisted of physical exercises applied according to a time-contingent scheme. The intervention is based on operant conditioning behaviour principles introduced in the treatment of chronic pain by Fordyce.\textsuperscript{36} The worker was diagnosed by an occupational health physician, who explained that non-specific low back pain does hurt, but does not mean any harm. The worker was referred to a specially trained physiotherapist, who repeated the physical examination, explained the mechanism of developing low back pain and reassured the worker about the favourable prognosis. This low back pain education
session was followed by three sessions of functional capacity evaluation. During these sessions the physical limit for each exercise was established. The worker, assisted by the physiotherapist, set goals for the physical exercises and made a time-contingent scheme for subsequent training and return to work. The return to work scheme consisted of achievable targets for partial and full return to work. The worker made a similar time-contingent plan for every exercise separately. The initial load of exercise started at a level below the average of the functional capacity, to ensure success during initial sessions. Once the exercise scheme was set, it could not be subject to change if the pain got worse or vice versa. The physiotherapist rewarded the worker verbally when the exercise goals were met and did not pay any attention to pain behaviour. The physiotherapist and occupational physician communicated on a regular basis in order to ensure reinforcement of the health behaviour of the worker.

Outline of this thesis
Chapter 2 is a literature review studying the effectiveness of return to work interventions for work absenteeism due to sub-acute low back pain. Randomized controlled trials were systematically collected and summarized with respect to severity of low back pain and functional status. In Chapter 3 evidence-based international guidelines on interventions for low back pain are compared according to the AGREE instrument and discussed. Chapter 4 and 5 present the results of our RCT on the effects of graded activity over two follow-up periods. The outcomes are presented in terms of return to work, reduction of pain and improvement of functional status. Chapter 6 describes the economic consequences of low back pain for the employer and compares the costs and benefits between the Graded Activity and Usual Care during this study. The indirect costs of low back pain are presented also for the second and third year after the initial intervention. In Chapter 7 the extend and natural course of work absenteeism due to low back pain is described. This chapter provides a brief comparison of the incidence rate of work absenteeism due to low back in the target population where the RCT was performed. The incidence is compared to the reference data from the literature. Furthermore, a description is provided of the natural course of non-specific LBP and nerve root compression in the study population. The main theme of this chapter is the construction of a prediction model for the duration of work absence, by using routine
administrative variables. The thought is that such a model can offer a handy tool for recognizing those workers who are at risk for developing work disability due to low back pain. Those workers could then profit from an early intervention. Finally, in chapter 8, a general discussion is presented on return to work interventions for non-specific low back pain placed in a broader perspective. Working mechanisms of interventions are discussed and recommendations for practical implementation of RTW interventions are made.
Reference List


The effectiveness of a return to work intervention for sub-acute low back pain: A systematic review

Abstract

The effectiveness of return to work (RTW) interventions for sub-acute low back pain (LBP) on work absenteeism, severity of pain and functional status were examined by means of systematic review of randomized controlled trials (RCT). Publications in the English language, meeting our selection criteria were identified by a computer-aided search and assessed for methodological quality. A best evidence synthesis was performed instead of statistical data pooling, because of heterogeneity of the interventions and study populations. Five out of nine studies comparing RTW intervention to usual care were identified as methodologically high quality studies. Strong evidence was found for the effectiveness of RTW interventions on RTW rate at 6-months of follow-up and for the effectiveness of RTW interventions on the reduction of days of absence from work at 12-months follow-up and longer. It can be concluded that RTW interventions are equal or more effective on absence from work due to sub-acute LBP in comparison to usual care.
Introduction

Low back pain is a major medical and social problem in industrialized Western countries that causes apart from individual physical and psychological distress, also great expenses to society.\(^1\)-\(^4\) It is one of the frequent occurring reasons for temporal or permanent disablement for work, and it is also associated with a loss of productivity.\(^4;\(^5\) The costs of LBP in the Netherlands are estimated to be for 93% attributable to non-medical, indirect costs, particularly due to work absenteeism and disability benefits.\(^4\) In approximately 95% of all occupational LBP cases there is no specific anatomical or patho-physiological explanation for the complaints.\(^6;\(^7\) This non-specific LBP is viewed as a benign self-limiting disorder, which usually resolves spontaneously within a few weeks. A small part of the LBP cases, however, may experience relapses and develop a chronic LBP syndrome.\(^8;\(^9\)

Intervening after the onset of LBP and work absenteeism is a practical alternative for primary prevention. Such therapeutic interventions are intended to prevent sub-acute LBP from becoming chronic with a long lasting disability for work.\(^5;\(^10;\(^11\) Return to the regular work without relapses, is the ultimate goal of these so called return-to-work interventions.\(^11\) Such interventions for LBP are often designed as therapeutic programs intended to improve physical functioning, and subsequently to enhance RTW. The RTW is seen by some researchers as a misleading indicator of the effectiveness of health care interventions, because RTW does not necessary correlate with the health status of the worker.\(^10\) However, it can be argued that from the occupational health care perspective RTW should be considered as an important primary outcome measure.

The present systematic review explores the scientific evidence of available randomized controlled trials on the effectiveness of RTW interventions for sub-acute LBP, in comparison to usual care, with regard to absenteeism from work, functional status and pain.

Methods

Search strategy for identification of RCTs

Randomized controlled trials published in the English language were identified by computer-aided searches in Medline, PsycINFO, Embase and the Cochrane Controlled Trials Register. All searches were performed from the date of availability of the databases until February 2004. A reference check for relevant publications was carried out to complete the search.
Chapter 2

The following keywords were used for the search: randomized (randomised) controlled trial, controlled clinical trial, random allocation, double blind method, single blind method, occupational therapy, rehabilitation, rehabilitation centers, experimental treatment outcome, experimental behavior therapy, recovery, back pain, LBP, backache, sciatica, back injury, sick leave, sick days, disability leave, employment status, disability evaluation, workers' compensation.

Criteria for selection of studies for the review

Two reviewers (HH and MS) independently selected publications to be included in this systematic review, using the following inclusion and exclusion criteria:

Type of study. Only randomized controlled trials were included.

Type of intervention. All studies, evaluating any type of outpatient intervention for sick-listed workers with LBP aimed at return to work, were included. One of the reference groups should receive traditional or usual care treatment, for example by a general practitioner or by other care providers. If applicable the reference group should receive no treatment at all.

Type of population. The subjects included should be adult age workers who were absent from paid work due to sub-acute, non-specific LBP, with or without referral to the leg. Studies evaluating surgical or pregnant subjects were excluded. The sub-acute period was defined as a period of LBP complaints for at least 4 weeks, but no more than 3 months.\(^5\)

Type of outcome measures. Work status should be one of the main outcome measures. Functional status and pain may be used as additional outcome measures.

Methodological quality assessment

The methodological quality was scored according to a list of 11 criteria based on the guidelines for methodological quality assessment as proposed by the Cochrane Collaboration Back Review Group.\(^12\) The methodological criteria list and their specifications are presented in Appendix.

An item was rated positive (+) when the information in the publication provided sufficient prove for fulfilling the criterion. An item was rated negative (-) in case of sufficient information about not fulfilling the criterion, or in case of lacking of any information about the item. An item was rated unclear (?) in case of an unclear interpretation.

Two reviewers (HH and MS) independently rated the methodological qual-
ity of the RCTs according to the list in Table 1. One study was rated by a third independent reviewer (GA) in order to prevent conflict of interest, because one of the reviewers (HH) was one of the investigators in this study. The differences in judgment were discussed and disagreements were solved between the reviewers. In case of persistent disagreement a fourth independent assessor (JBS) was consulted and asked to make a final judgment. The initial inter-observer reliability of the methodological quality assessment was evaluated by means of Cohen’s Kappa test.

Data extraction and analysis.

If available, following outcome measures were extracted for the follow-up periods of 6 months, 12 months, or for a longer follow-up period: work absenteeism expressed as the number of days of sick leave or as the RTW rate (percentage of workers who returned to work by the end of a follow-up period), pain intensity and functional status. When no exact data were reported, the values were approximated from the graphs or other statistics in the publication. Missing standard deviations of the outcomes were requested from the author of the publication, or were replaced by the standard deviation of the baseline value. Effect sizes were calculated for available outcome measures and follow-up periods using the MetaView option of Review Manager software (RevMan version 4.2.3). The calculated effect sizes were expressed for dichotomous data as a risk difference (RD) with corresponding 95% confidence intervals (CI) and for continuous data as standardized mean difference (SMD) also with corresponding 95% CI’s.

The best evidence synthesis.

In this review, we considered a RCT with a score of 5 or higher out of 9 possible points as a study of high methodological quality. Two of the eleven original items, i.e. blinding the patients and blinding of the intervention providers were post-hoc excluded. Those two items were scored negative in all studies and they are, to our opinion not suitable for the rating of the methodological quality of this type of studies, because it is not possible in this type of LBP studies to blind the therapy provider and/or the patient for type of treatment. The effect sizes were not pooled into a meta-analysis, because of the heterogeneity of the content of the interventions, study populations and study settings. Instead of it, a qualitative rating system was applied in order to summarize scientific evidence of the RCTs. The rating system was based on the methodological quality of the study and on the outcome
of the study. The outcomes of the studies were considered consistent if 75% or more trials reported statistically significant results in the same direction. Four levels of evidence were distinguished:

- **Strong evidence:** consistent findings among multiple high-quality RCTs
- **Moderate evidence:** consistent findings among multiple low-quality RCTs and/or one high-quality RCT
- **Limited evidence:** one low quality RCT
- **Conflicting evidence:** inconsistent findings among multiple RCTs
- **No evidence:** no RCTs available

**Clinical Relevance**

The clinical relevance of the studies was assessed by reviewers answering the following five questions: 1. Are the patients described and comparable to those in own practice? 2. Are the interventions and treatment settings described well enough so that the clinician can provide the same treatment for own patients? 3. Were all clinically relevant outcomes measured and reported? 4. Is the size of the effect clinically important? 5. Are the likely treatment benefits worth the potential harms?

**Results**

**Database search**

The database searches identified a total of 1,087 references. Reading the title and abstract, excluding references which were found in more than one database, and detailed reading of selected papers and screening their references resulted in the inclusion of 9 studies that met the inclusion criteria of this review. Four studies were described in more than one publication covering different follow up periods. The basic characteristics of the selected studies are described in Table 1.

**Study characteristics**

Among the nine studies included, two basic therapeutic modalities were used in all interventions, i.e. physical exercises or advice about it and education. These two modalities were supplemented with behavioral treatment in six studies, with ergonomic measures in another two studies, and with case management in six studies. All studies compared RTW interventions to either usual care provided by a
general physician, or by other care provider, or to no therapy at all. In two studies the duration of the entire intervention was restricted to less than 5 hours altogether\textsuperscript{15;17}; One study evaluated the effect of a coordinated primary health care program consisting of a single clinical consult and education session followed by weekly phone contacts with the subjects.\textsuperscript{20} In the remaining six studies, the interventions varied from two or three sessions per week\textsuperscript{13;18;21} to almost a full-time intervention for several weeks.\textsuperscript{14;16;19} In most of the studies no information was given about the duration of the LBP episodes prior the period of work absenteeism. Pre-intervention work absenteeism varied from 4 to 8 weeks. The follow-up period of the included RCTs varied from 18 weeks to more than 6 years. Two studies investigated a follow-up period shorter than 6 months\textsuperscript{20;21}, all other studies described a follow-up of at least 6 months or longer. Table 2 summarizes the results of the methodological quality score of the included studies.
<table>
<thead>
<tr>
<th>Reference</th>
<th>Number of cases</th>
<th>Case definition</th>
<th>Work absence</th>
<th>Follow-up</th>
<th>Description of the Intervention</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gatchel et al 14</td>
<td>High risk early intervention gr. (22) High risk non-intervention gr. (48) Low risk non-intervention group (54)</td>
<td>LBP</td>
<td>Less than 2 months</td>
<td>3, 12 months</td>
<td>Early intervention group received a functional restoration program with an interdisciplinary team approach consisting of 4 major components: psychology, physical therapy, occupational therapy, and case management. Five different sessions each administrated 9 times, examination and interdisciplinary conferences were spaced over a 3-week period. High risk and low risk non-intervention group did not receive any early intervention.</td>
<td>Days of absence from work Pain</td>
</tr>
<tr>
<td>Hagen et al 15;22</td>
<td>Intervention group (237) Control group (220)</td>
<td>LBP and sciatica</td>
<td>8-12 weeks</td>
<td>3, 6, 12, 36 months</td>
<td>Intervention group was examined at a spine clinic. Patients were informed about the good prognosis of LBP, they were advised to remain physically active and they received instructions on how to train and stretch at home. The visit at the spine clinic lasted 3 hours. Control group received no examinations at a spine clinic, the patients were treated within conventional primary health care.</td>
<td>RTW rate Days of absence from work</td>
</tr>
<tr>
<td>Haldorsen et al 16</td>
<td>Intervention group (142) Control group (81)</td>
<td>LBP and sciatica</td>
<td>8 weeks</td>
<td>12 months</td>
<td>Intervention group received a Multimodal Cognitive Behavioral Treatment, lasting 4 weeks, with 6 hours sessions, 5 days per week, given by physician, physiotherapists, psychologist, and nurse. Job modifications were discussed with the health services and the employer, and if necessary a re-education in an alternative job was arranged. Control group patients were followed up and treated by general practitioner particularly by physiotherapist.</td>
<td>RTW rate Pain</td>
</tr>
<tr>
<td>Indahl et al 17;23</td>
<td>A) Intervention group (512) Control group (463) B) Intervention group (245) Control group (244)</td>
<td>LBP and sciatica</td>
<td>8 - 12 weeks</td>
<td>A) 3,12 months B) 5 years</td>
<td>Intervention group received a light mobilization program. Patients were examined by a physician and were tested for functional capacity, health and psychological factors. They were educated about the causes of LBP, the relation between emotions and increase of pain and good prognosis of LBP. They were explained guidelines on lifting and how to deal with muscle spasm. The information was given at starting point and reinforced after 3, 12 months. Control group was not called in for examination. Patients were treated within the conventional medical system</td>
<td>RTW rate</td>
</tr>
<tr>
<td>Lindström et al 18</td>
<td>Intervention group (51) Control group (52)</td>
<td>LBP</td>
<td>6 weeks</td>
<td>12, 24 months</td>
<td>Intervention group received traditional care plus a graded activity program consisting of: 1) measurements of functional capacity 2) workplace visit 3) Swedish Back School 4) individual, sub maximal, gradually increased exercise program aimed to return to regular non-modified work. Control group was treated within traditional care recommended by home physicians.</td>
<td>RTW rate Days of work absence Pain Functional status</td>
</tr>
<tr>
<td>Reference</td>
<td>Number of cases</td>
<td>Case definition</td>
<td>Work absence</td>
<td>Follow-up</td>
<td>Description of the Intervention</td>
<td>Outcome measures</td>
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<tr>
<td>Loisel et al 19, 24</td>
<td>Clinical intervention (31) Occupational intervention (22) Full intervention (25) Usual care (26)</td>
<td>Thoracic or lumbar back pain</td>
<td>4 weeks to 3 months</td>
<td>12 months and 6.4 years</td>
<td>Occupational intervention included workers visits to occupational physician and a participatory ergonomics evaluation by an ergonomist started after 6 weeks of absence from work. Clinical intervention was implemented after 8 weeks absence from work and consisted of a visit to a back pain specialist and a &quot;back care school&quot; for one hour per day during four weeks. If RTW did not occur after the back school a multidisciplinary work rehabilitation therapy was proposed. Full intervention was a combination of both interventions. Usual care group received any treatment prescribed by attending physician.</td>
<td>RTW rate Days of work absence Pain Functional status</td>
</tr>
<tr>
<td>Rossignol et al 20</td>
<td>Intervention group (54) Control group (56)</td>
<td>Work related injury to thoracic, lumbar or sacral vertebral column</td>
<td>4 - 8 weeks</td>
<td>3, 6 months</td>
<td>Intervention group received a program for &quot;coordination of primary health care&quot; for LBP, which included a complete examination, recommendations for clinical management, and support to carry out the recommendations. The coordinating nurse called weekly the worker until RTW Control group received usual care</td>
<td>RTW rate Functional status Pain</td>
</tr>
<tr>
<td>Staal et al 13, 25</td>
<td>Graded activity group (67) Usual care group (67)</td>
<td>Non-specific LBP</td>
<td>LBP for at least 4 weeks Sick listed at inclusion</td>
<td>6, 12 months</td>
<td>The intervention group received besides the usual guidance from the occupational physician a graded activity intervention, supervised by the physiotherapist, with frequency of two 1-hour sessions per week, until full return to regular work. The intervention had a maximal duration of 3 months. The usual care group received usual guidance and advice from the occupational physician. General practitioners were requested to treat the participants according to the their LBP guidelines.</td>
<td>Days of absence from work; Pain; Functional status</td>
</tr>
<tr>
<td>Storheim et al 21</td>
<td>Exercise group (30) Cognitive intervention (34) Control group (29)</td>
<td>LBP</td>
<td>8–12 weeks</td>
<td>18 weeks</td>
<td>Both intervention groups underwent a routine back examination, explanation of X-rays and CT-scans, and general encouragement to resume daily activities and work. Cognitive group received 2 consultations, each lasting between 30 and 60 minutes with an explanation of pain mechanisms, education on muscle function, on lifting technique and how to cope with new attacks. Exercise group received a modification of The Norwegian Aerobic Fitness Model, focused on the LBP patient. The exercise period was 15 weeks with a minimum of bi-weekly exercise sessions each for 1 hour, preferably 3 sessions per week. The patients in the control group were treated by their general practitioner and had no restrictions of treatments or referrals.</td>
<td>Days of absence from work; Pain; Functional status</td>
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</table>

# Study B is a 5-years follow-up of a part of the subjects from the study A
In general, the methodological quality of the RCTs in this review was moderate, with a mean score of 4.7 points out of a range from 0 through 9 points. Five out of nine studies obtained more than 50% from the possible score and these studies were considered as high quality studies. Information about co-interventions and compliance with the treatment was not reported in the majority of the RCTs. Almost all RCTs assessed the outcome measures for all study groups at the same time and applied analyses according to the intention-to-treat principle. The initial inter-observer reliability of the methodological quality scores showed an substantial agreement (Kappa = 0.78).

**The effectiveness of RTW interventions for sub-acute LBP**

We identified 9 RCTs, which compared RTW interventions to usual care. Figure 1 gives an overview of the effect sizes on RTW rate, days of work absenteeism, functional status and severity of pain complaints for different follow-up times.
Effectiveness of a return-to-work intervention

Figure 1. Effect sizes of 9 randomized controlled trials on RTW interventions compared to usual care, arranged according to the follow-up periods and the outcome measures. Bars represent risk difference (RD) or standardized mean differences (SMD) with 95% confidence intervals (CI) for RTW rate, days of absence from work, functional status and pain score. The effect sizes laying to the left from the vertical zero line are in favor of the intervention treatments, the sizes to the right are in favor of the usual care.

<table>
<thead>
<tr>
<th>Follow-up period</th>
<th>RTW rate</th>
<th>Days of sick leave</th>
<th>Functional status</th>
<th>Pain score</th>
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<tbody>
<tr>
<td></td>
<td>RD 95% CI</td>
<td>SMD 95% CI</td>
<td>SMD 95% CI</td>
<td>SMD 95% CI</td>
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<tr>
<td>Follow-up 6 months</td>
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<tr>
<td># Hagen</td>
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<td># Indahl</td>
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<td># Lindström</td>
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<td># Rossignol</td>
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<tr>
<td># Staal</td>
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<tr>
<td># Storheim - cognitive</td>
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<td># Storheim - exercise</td>
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<tr>
<td>Follow-up 12 months</td>
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<tr>
<td># Gatchel</td>
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<td># Hagen</td>
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<td># Haldorsen</td>
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<td># Indahl</td>
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<td># Loisel</td>
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<tr>
<td># Staal</td>
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<tr>
<td>Follow-up 2 years</td>
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<tr>
<td># Hagen</td>
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<tr>
<td># Lindström</td>
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<tr>
<td>Follow-up 3 years</td>
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<tr>
<td># Hagen</td>
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<tr>
<td>Follow-up 5 years</td>
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<tr>
<td># Hagen</td>
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<tr>
<td>Follow-up 6.4 years</td>
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<tr>
<td># Loisel</td>
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</table>

* Standard deviation was lacking and was substituted with baseline value or from other study
# Study with high methodological quality
RD Risk difference
SMD Standard mean difference
CI Confidence interval
FT Results in favor of RTW intervention group
FC Results in favor of control group

Effect on work absenteeism expressed in RTW rate

Three high quality studies$^{13;15;20}$ and 3 low quality studies$^{17-19}$ provided data on RTW rate on a short-term follow-up up to 6 months. Five studies showed a positive effect$^{13;15;17;19}$ and only 1 high quality study$^{20}$ showed no effect of the RTW intervention on RTW rate. Therefore, we conclude that there is strong evidence for a beneficial effect of RTW interventions at 6-months of follow-up on the RTW rate, compared to usual care.
Three high quality studies\textsuperscript{14;15;25} and 4 low quality studies\textsuperscript{16-19} reported data on RTW rate at 12-months of follow-up. Two high quality studies\textsuperscript{14;15} showed beneficial effects on the RTW rate, and these findings were supported by two low quality studies.\textsuperscript{17;19} One high quality\textsuperscript{25} and two low quality studies \textsuperscript{16;18} showed no effect of the RTW intervention. Consequently, we concluded that there is conflicting evidence for the effectiveness of RTW interventions on the RTW rate at 12-months of follow-up.

There were two low quality studies\textsuperscript{23;24} and one high quality study,\textsuperscript{22} which investigated the long-term effect of RTW interventions on RTW rate. The follow-up periods varied between 24 months and 5 years. Based on these studies evidence was considered conflicting for the effects of RTW interventions on RTW rate for long-term follow-up between 2 and 5 years.

**Effects on work absenteeism expressed in days of sick leave**

Two high quality studies reported results on work absenteeism expressed as a number of days of sick leave due to LBP at 18-weeks and 6-months of follow-up.\textsuperscript{13;21} Storheim et al did not find any effects of the RTW intervention on the number of days of sick leave at 18-weeks follow-up, while Staal et al found beneficial effects at 6-months of follow-up. These two high quality studies showed conflicting evidence for the short-term effect of RTW interventions on the reduction of sick leave days. Results on the number of days of sick leave at 12-months of follow-up were reported in three high quality studies\textsuperscript{14;15;25}. All three studies reported a statistically significant reduction of days of sick leave due to RTW interventions. Results of the study by Gatchel et al are not presented in Figure 1 because the authors did not report standard deviations for days of sick leave.\textsuperscript{14} In the published data, a statistically significant effect of the intervention (p=0.001) was reported in favor of the RTW intervention. Based on the positive results of these three high quality studies we concluded that there is strong evidence for the effectiveness of RTW interventions on the reduction of the number of sick leave days at 12-months of follow-up.

One high quality study\textsuperscript{22} and two low quality studies\textsuperscript{18;24} investigated the long term effects of a RTW intervention on the number of days of sick leave at a follow-up varying between 2 years and 6.4 years. All these studies demonstrated a statistically significant beneficial effect of the RTW intervention on work absenteeism. Therefore, it is concluded that there is strong evidence for the effectiveness of these RTW interventions on work absenteeism at a follow-up between 2 and 6.4 years.
RTW interventions and functional status

Three high quality studies reported results on the effects of a RTW intervention on functional status at 6-months of follow-up.\textsuperscript{13;20;21} However, these high quality studies showed inconsistent results. Therefore we concluded that there is conflicting evidence for the effectiveness of a RTW intervention on the improvement of functional status, at 6-months of follow-up. Results on the effect of a RTW intervention on functional status at 12-months of follow-up were reported in one high quality study\textsuperscript{25} and in two low quality studies.\textsuperscript{18;19} Both low quality studies demonstrated a statistically significant effect on functional status in favor of the RTW intervention, but the high quality study did not confirm this positive effect. Therefore, we concluded that there is conflicting evidence of the effectiveness of RTW interventions on the improvement of functional status at 12-months of follow-up. There were no data with regard to the effectiveness of RTW interventions on functional status at follow-up longer than 12 months.

RTW interventions and pain

Three high quality studies reported data regarding the effect of RTW interventions on the reduction of pain at 6-months of follow-up.\textsuperscript{20;21;25} These high quality studies showed inconsistent effects of the RTW intervention on the severity of pain. We therefore conclude that there is conflicting evidence of the effectiveness of RTW intervention on pain at 6-months of follow-up. The results of 12-months of follow-up gave a similar picture. Five studies, two high quality studies\textsuperscript{14;25} and three low quality studies\textsuperscript{16;18;19} showed inconsistent results. Results of the study of Gatchel et al are not presented in Figure 1 due to lack of standard deviations.\textsuperscript{14} However the original publication reported a statistically significant effect of the intervention on the reduction of pain severity at 12-months of follow-up. Consequently we conclude that there is conflicting evidence on the effectiveness of RTW interventions on pain at 12-months of follow-up. There were no data available on the long-term effect of RTW interventions on the severity of pain.

Clinical relevance of the reviewed studies

All reviewed studies compared a RTW intervention to usual care and all studies were intended to be used in clinical practice. Population character-
istics, the content of the intervention and the outcome measures were described well enough to be judged by a clinician whether or not the intervention is applicable in a specific situation. Some studies did not demonstrate a statistically significant beneficial effect on one of the outcome measures with regard to RTW. However, in all these studies this effect was at least equal or better compared to usual care. None of the studies reported a potential harm of the RTW intervention to the workers. Altogether, we conclude that the clinical relevance of all studies was sufficient.

Discussion

The purpose of this review was to search for evidence for the effectiveness of RTW interventions on absence from work due to sub-acute LBP with a minimal duration of 4 weeks. Nine RCTs compared RTW interventions for sub-acute LBP with usual care. The results of this review, summarized in Table 4, showed that RTW interventions in comparison to usual care are effective in the reduction of days of absence from work due to sub-acute LBP.

Table 3. Summary of the results of the best evidence synthesis.

<table>
<thead>
<tr>
<th>Outcome measures</th>
<th>Follow-up 6 months</th>
<th>Follow-up 12 months</th>
<th>Follow-up long term</th>
</tr>
</thead>
<tbody>
<tr>
<td>RTW rate</td>
<td>++</td>
<td>+/-</td>
<td>+/-</td>
</tr>
<tr>
<td>Days of work absenteeism</td>
<td>+/-</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Pain</td>
<td>+/-</td>
<td>+/-</td>
<td>No data</td>
</tr>
<tr>
<td>Functional status</td>
<td>+/-</td>
<td>+/-</td>
<td>No data</td>
</tr>
</tbody>
</table>

The evidence was strong for the reduction of the number of days of absence from work at 12-months of follow-up or longer and for the RTW rate at a shorter follow-up. Scores for pain and functional status in these studies remained unchanged or got better under influence of the RTW intervention. Apparently, improvements in functional status and pain do not necessarily go together with earlier return to work.

Methodological consideration

Five out of nine studies met our criteria for high methodological quality. The decision about high and low methodological quality remains arbitrary and it depends largely on the cut-off point for the sum of positive scores. In this review a high quality study had to score positively on at least 50% of the 9 methodological quality items. If we would not reduce the number
Effectiveness of a return-to-work intervention

of methodological items from 11 to 9, we would have identified only 3 high quality studies.\textsuperscript{13,15,21}

The average methodological quality scores of the RTCs included in this review was moderate, which limits their validity and also the generalizability of the results to other populations. However, the methodological quality of the RCTs included is increasing during the recent years. Three out of the 5 high quality studies were published in 2003 or later.\textsuperscript{13,14,21} The fourth study appeared as a 3 years follow-up study also in 2003.\textsuperscript{22}

The heterogeneity of the interventions with regard to their content and intensity, and the heterogeneity of the population with regard to different social security systems also limits generalizability of the results of this review. A clinician or an occupational physician should take in account these facts when choosing a particular RTW intervention for his specific situation.

The use of different outcome measures for the effectiveness of the RTW interventions, i.e. days of absence from work and RTW rate, was another problem in this review. The RTW rate is based on a dichotomous outcome of work status (being absent from work or not) and provides information about the percentage of subjects that had returned to work at a certain moment, without giving quantitative information on the number of days of absence from work and corresponding productivity loss. These data on days of absence from work would be necessary for an estimation of the economic burden of LBP.

**Content of RTW interventions for LBP?**

The optimal RTW intervention for sub-acute LBP is probably a mixture of exercise, education, behavioral treatment and ergonomic measures, but it is not clear which component, or which combination of components, is the most effective. Furthermore, there could be other critical factors responsible for success of such RTW intervention, which were not recognized in the RCT’s in this review. These factor are challenge for future research on the field of RTW interventions.

**When do we have to start with a RTW intervention for LBP?**

Elders et al concluded in their review that starting the intervention in the sub acute phase of LBP seems preferable.\textsuperscript{27} Gatchel et al demonstrated that an early intervention in the form of functional restoration in subjects with a high risk for developing chronic LPB was effective in reducing absence from work and costs.\textsuperscript{14} The RTW interventions in the earlier, acute phase of LBP did not appear to be effective on absence from work, proba-
bly because of the favorable self-limiting course of LBP and absence from work during this acute phase.\textsuperscript{28-30} Treating patients who would recover without treatment anyway, is not cost-effective, and may even lead to an unnecessary prolonging of the period of being absent from work.\textsuperscript{31} The sub-acute phase of LBP, between 4 and 12 weeks of absence from work or duration of complaints, seems to be the most suitable phase for the start of the therapy in order to prevent the LBP from becoming chronic.

**Conclusions**

This review found strong evidence for the effectiveness of RTW interventions on the reduction of work absenteeism due to sub-acute LBP at three out of six follow-up evaluations. Three other follow-up evaluations showed an equal effect of RTW intervention and usual care. Furthermore, no evidence was found that usual care was more effective than a RTW intervention on the reduction of work absenteeism. Future research on the effectiveness of RTW interventions should concentrate on the evaluation of a limited number of promising RTW interventions. It is also needed to understand more thoroughly which component of RTW interventions or a combination of these components may help to shorten work absenteeism due to sub-acute LBP.
Reference List


Appendix

Criteria list for the methodological quality assessment of intervention studies on the effectiveness of RTW interventions.

A Was the method of randomization adequate?
A random assignment sequence. Examples of adequate methods are a computer generated random number table and the use of sealed opaque envelopes. Methods of allocation using date of birth, date of admission, hospital numbers, or alternation should not be regarded as appropriate.

B Was the treatment allocation concealed?
Assignment generated by an independent person not responsible for determining the eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about the eligibility of the patient.

C Were the groups similar at baseline regarding the most important prognostic indicators?
In order to receive a (+) groups have to be similar at baseline regarding demographic factors, duration and severity of complaints and symptoms, and value of main outcome measure(s).

D Was the outcome assessor blinded to the intervention?
The reviewer determines if enough information about blinding is given in order to score a (+).

E Were co-interventions avoided or similar?
Co-interventions should either be avoided in the trial design or similar between the index and control groups.

F Was the compliance acceptable in all groups?
The reviewer determines if the compliance to the interventions is acceptable, based on the reported intensity, duration, number and frequency of sessions for both the index and control groups.

G Was the drop-out rate described and acceptable?
The number of participants who were included in the study but did not complete the observation period or were not included in the analysis must be described and reasons given. If the percentage of withdrawals and drop-outs does not exceed 20% for short-term follow-up and 30% for long-term follow-up and does not lead to substantial bias a (+) is scored.

H Was the timing of the outcome assessment in all groups similar?
Timing of outcome assessment should be identical for all trial groups and for all important outcome assessments.

I Did the analysis include an intention-to-treat analysis?
All randomized patients are reported/analyzed in the group they were allocated to by randomization for the most important moments of effect measurement (minus missing values) irrespective of noncompliance and co-interventions.
Occupational health guidelines for the management of low back pain: an international comparison

J B Staal, H Hlobil, M W van Tulder, G Waddell, A K Burton, B W Koes, W van Mechelen
Occupational health guidelines for the management of low back pain: an international comparison
Occup Environ Med 2003;60:618–626
Abstract

Background: The enormous socioeconomic burden of low back pain emphasises the need for effective management of this problem, especially in an occupational context. To address this, occupational guidelines have been issued in various countries.

Aims: To compare available international guidelines dealing with the management of low back pain in an occupational health care setting.

Methods: The guidelines were compared regarding generally accepted quality criteria using the AGREE instrument, and also summarised regarding the guideline committee, the presentation, the target group, and assessment and management recommendations (that is, advice, return to work strategy, and treatment).

Results and Conclusions: The results show that the quality criteria were variously met by the guidelines. Common flaws concerned the absence of proper external reviewing in the development process, lack of attention to organisational barriers and cost implications, and lack of information on the extent to which editors and developers were independent. There was general agreement on numerous issues fundamental to occupational health management of back pain. The assessment recommendations consisted of diagnostic triage, screening for “red flags” and neurological problems, and the identification of potential psychosocial and workplace barriers for recovery. The guidelines also agreed on advice that low back pain is a self-limiting condition and, importantly, that remaining at work or an early (gradual) return to work, if necessary with modified duties, should be encouraged and supported.
Introduction

Low back pain is one of the most common health problems in industrial countries. Despite its benign nature and favourable course, low back pain is commonly associated with incapacity, productivity loss due to sick leave, and corresponding high costs to the society.\(^1\)

In view of that impact, there is an obvious need for effective management strategies, based on scientific evidence derived from studies of sound methodological quality. Usually, these are randomised controlled trials (RCTs) on the effectiveness of therapeutic interventions, diagnostic studies, or prospective observational studies on risk factors or side effects. The scientific evidence, which is summarised in systematic reviews and meta-analyses, provides a solid basis for guidelines on the management of low back pain. In a previous paper, Koes et al compared various existing clinical guidelines for the management of low back pain targeted at primary health care professionals, which showed a large measure of commonality.\(^2\)

However, low back pain is also an important issue in occupational health care because of the associated incapacity for work, productivity loss and sick leave. The problems in the field of occupational health care are different and management focuses mainly on counselling the worker with low back pain, and addressing the issues of assisting him or her to continue working, or to return to work after sick listing. Several guidelines, or sections of guidelines, have now been published dealing with the specific issues of management in an occupational health care setting. Since the evidence is international, it would be expected that the recommendations of different occupational guidelines for low back pain would be more or less similar. However, it is not clear whether the guidelines meet currently accepted quality criteria.

This paper critically appraises available occupational guidelines on the management of low back pain, and compares their assessment and management recommendations.

Methods

Guidelines on the occupational health management of low back pain were retrieved from personal files of the authors. Retrieval was checked by a Medline search using the keywords “low back pain”, “guidelines” and “occupational” up to October 2001, and personal communication with experts in the field. Guidelines had to meet the following inclusion criteria:

- Guidelines aimed at the management of workers with low back pain (in occupational health care settings or addressing occupational is-
sues), or separate sections of guidelines that dealt with these topics.

- Guidelines available in English or Dutch (or translated into these languages).
- The exclusion criteria were:
  - Guidelines on primary prevention (i.e. prevention before the onset of the symptoms) of work-related low back pain (e.g. lifting instructions for workers).
  - Clinical guidelines for the management of low back pain in primary care.

The quality of the included guidelines was appraised using the AGREE-instrument, which is a generic tool designed primarily to help guideline developers and users assess the methodological quality of clinical practice guidelines. The AGREE-instrument provides a framework for the assessment of quality on 24 items (Table 1), each rated on a 4-point scale. The full operationalisation is available on www.agreecollaboration.org. Two reviewers (BS and HH) independently rated the quality of the guidelines, and then met to discuss disagreements and to reach consensus on the ratings. When they could not reach consensus, a third reviewer (MvT) reconciled remaining differences and made a final decision on the ratings. To facilitate analysis in this review, ratings were transformed into dichotomous variables of whether each quality item was or was not met.

The selected guidelines were further characterised and compared regarding the guideline committee, the presentation of the guideline, the target group, and the extent to which the recommendations were based on available scientific evidence. The assessment recommendations were also summarised and compared, as were recommendations on advice, treatment and return to work strategies. All of this information was extracted directly from the published guidelines.

Results

Selection of studies

Our search found ten guidelines, but four were excluded because they dealt with the management of low back pain in primary care, were aimed at the guidance of sick listed employees in general (not specifically low back pain), were intended for the primary prevention of low back pain at work, or were not available in English or Dutch. The final selection therefore consisted of the following six guidelines, listed by date of issue:
1. Canada (Quebec)

2. Australia (Victoria)
   Guidelines for the management of employees with compensable low back pain. Victorian WorkCover Authority, Australia (1996) (This Guideline is a revised version of guidelines developed by the South Australian WorkCover Corporation in October 1993).

3. USA

4. New Zealand

5. The Netherlands

6. UK

Two guidelines (4 and 6) could not be evaluated independently from additional documents to which they refer (4b-c, 6b-d) so these documents were also included in the review.

Appraisal of the quality of the guidelines

Initially, there was agreement between the two reviewers regarding 106 (77%) of the 138 item ratings. After two meetings, consensus was
Chapter 3

reached for all but four items, which required adjudication by the third reviewer. The final ratings are presented in Table 1.

All included guidelines clearly presented the different options for the management of low back pain in occupational health. In five of the six guidelines the overall objectives of the guideline were described specifically, the target users of the guideline were clearly defined, easily identifiable key recommendations were included, or key review criteria were presented for monitoring and / or audit purposes. The results of the AGREE-appraisal demonstrated that none of the guidelines paid sufficient attention to potential organisational barriers and cost implications in implementing the recommendations. It was also unclear for all included guidelines whether or not they were editorially independent from the funding body, and whether or not there were conflicts of interest for the members of the guideline development committees. Furthermore, it was unclear for all guidelines whether experts had externally reviewed the guidelines prior to publication. Only the UK guideline clearly described the method used for the formulation of the recommendations, and provided for updating the guideline.

The development of the guidelines

Table 2 presents background information on the development process of the guidelines. The target users for the guidelines were physicians and other health care providers in the field of occupational health care. Several guidelines were also directed at informing employers, workers or members of organisations interested in occupational health. The Dutch guideline was only targeted at the occupational health physician. The guideline committees responsible for the development of the guidelines were generally multidisciplinary, including disciplines like epidemiology, ergonomics, physiotherapy, general practice, occupational medicine, occupational therapy, orthopaedics, and representatives of employers’ associations and trade unions. Chiropractic and osteopathic representatives were in the guideline committee of the New Zealand guidelines. The Quebec task force (Canada) also included representatives of rehabilitation medicine, rheumatology, health economics, law, neurosurgery, biomechanical engineering, and library sciences. In contrast, the guideline committee of the Dutch guideline consisted only of occupational physicians.

The guidelines were issued as a separate document, as a chapter in a textbook, or as several inter-related documents.
Table 1. Ratings * of the six selected occupational health guidelines for low back pain on AGREE items.

<table>
<thead>
<tr>
<th>Item</th>
<th>Canada (Quebec)</th>
<th>Australia (Victoria)</th>
<th>USA</th>
<th>New Zealand</th>
<th>The Netherlands</th>
<th>UK 11,12,13,14</th>
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<tbody>
<tr>
<td>1. The overall objective(s) of the guideline is (are) specifically described.</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
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<tr>
<td>2. The clinical question(s) covered by the guideline is (are) specifically described.</td>
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<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>3. The patients to whom the guideline is meant to apply are specifically described.</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
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<td>4. The guideline development group includes individuals from all the relevant professional groups.</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
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<tr>
<td>5. The patients’ views and preferences have been sought.</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
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<td>0</td>
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<tr>
<td>6. The target users of the guideline are clearly defined.</td>
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<td>1</td>
<td>1</td>
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<td>1</td>
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<tr>
<td>7. The guideline has been piloted among target users.</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
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<tr>
<td>8. Systematic methods were used to search for evidence.</td>
<td>1</td>
<td>0</td>
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<tr>
<td>9. The criteria for selecting the evidence are clearly described.</td>
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<td>0</td>
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<tr>
<td>10. The methods used for formulating the recommendations are clearly described.</td>
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<td>0</td>
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<tr>
<td>11. The health benefits, side effects and risks have been considered in formulating the recommendations.</td>
<td>0</td>
<td>0</td>
<td>1</td>
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<tr>
<td>12. There is an explicit link between the recommendations and the supporting evidence.</td>
<td>1</td>
<td>0</td>
<td>1</td>
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<td>13. The guideline has been externally reviewed by experts prior to its publication.</td>
<td>0</td>
<td>0</td>
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<tr>
<td>14. A procedure for updating the guideline is provided.</td>
<td>0</td>
<td>0</td>
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<tr>
<td>15. The recommendations are specific and unambiguous.</td>
<td>0</td>
<td>0</td>
<td>1</td>
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<tr>
<td>16. The different options for management of the condition are clearly presented.</td>
<td>1</td>
<td>1</td>
<td>1</td>
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<tr>
<td>17. Key recommendations are easily identifiable.</td>
<td>1</td>
<td>0</td>
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<tr>
<td>18. The guideline is supported with tools for application.</td>
<td>0</td>
<td>0</td>
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<tr>
<td>19. The potential organisational barriers in applying the recommendations have been discussed.</td>
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<td>0</td>
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<tr>
<td>20. The potential cost implications of applying the recommendations have been considered.</td>
<td>0</td>
<td>0</td>
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<tr>
<td>21. The guideline presents key review criteria for monitoring and/or audit purposes.</td>
<td>1</td>
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<tr>
<td>22. The guideline is editorially independent from the funding body.</td>
<td>0</td>
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<tr>
<td>23. Conflicts of interest of guideline development members have been recorded.</td>
<td>0</td>
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</tbody>
</table>

* Rating ‘1’ means quality item was met; rating ‘0’ means quality item was not met or unclear.
<table>
<thead>
<tr>
<th>Country</th>
<th>Guideline Committee</th>
<th>Target group</th>
<th>Presentation</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada (Quebec)</td>
<td>Multidisciplinary: Epidemiology, Community Medicine, Rehabilitation, Physical Therapy, Rheumatology, Health economics, Orthopaedics, Law, Occupational Medicine, Neurosurgery, Occupational Therapy, Biomechanical engineering, Ergonomics, Biostatistics, Library Sciences.</td>
<td>Health care professionals, professionals in allied fields who assess and treat disabled workers, members of organisations interested in occupational health and safety.</td>
<td>Report: publication in journal. 4</td>
<td>Comprehensive literature search, weighing of the evidence based on type and quality of studies.</td>
</tr>
<tr>
<td>Australia (Victoria)</td>
<td>Multidisciplinary: Orthopaedics, Rehabilitation Medicine, Workers compensation management, Representative of union of workers, General practice.</td>
<td>Practitioners managing work related low back pain.</td>
<td>Guideline document: guideline is a revised version of guidelines developed by the South Australian WorkCover Corporation in October 1993.</td>
<td>Recommendations supported by references or based on consensus and common practice, no explicit weighing of evidence.</td>
</tr>
<tr>
<td>New Zealand</td>
<td>Multidisciplinary: Physiotherapy, General practice, Osteopathy, Chiropractic, Occupational therapy, Ergonomics, orthopaedics, Representatives of employers’ associations and trade unions.</td>
<td>Employer, worker, treatment providers.</td>
<td>Separate guidelines for the management of low back pain in the workplace, and for the assessment of psychosocial ‘yellow flags’. Patient booklet.9</td>
<td>There is no information in either guideline on search strategies and there are hardly any links between recommendations and references. Management suggestions outlined in the ‘yellow flags’ guideline are reported to be based on the best available evidence to date.9</td>
</tr>
<tr>
<td>UK</td>
<td>Multidisciplinary: Occupational medicine, Orthopaedics, Ergonomics, Physiotherapy, General Practice, Nursing, Government policy, Scientific adviser.</td>
<td>Occupational health practitioners.</td>
<td>Guideline documents, evidence review, leaflet for practitioners, separate guide for people at work and employers, and patient booklet (The Back Book).14</td>
<td>Comprehensive literature search, weighing of the evidence based on number and quality of studies (3-star system), recommendations directly linked to relevant studies, some recommendations based on good practice (legally or by consensus).</td>
</tr>
</tbody>
</table>
The UK 13, USA 6 and Canadian 4 guidelines provided information on the search strategy applied to the identification of relevant literature and the weighing of the evidence. On the other hand, the Dutch 10 and the Australian 5 guidelines supported their recommendations only by references. In the New Zealand guidelines there were no direct links between recommendations and references\textsuperscript{7,8,9} and the reader was referred to other literature for background information.

**Patient population and diagnostic recommendations**

Despite the fact that all guidelines focused on workers with low back pain, it was often not clear whether they dealt with acute or chronic low back pain or both. Acute and chronic low back pain were often not defined, and when cut-off points were given (e.g. < 3 months) it was usually not clear whether these referred to the onset of symptoms or to absence from work. However, the Canadian guideline introduced a classification system (acute/subacute/chronic) based on the distribution of claims of spinal disorders by time since absence from work.\textsuperscript{4}

All guidelines distinguished specific and non-specific low back pain. Specific low back pain concerns the potentially serious ‘red flag’ conditions like fractures, tumours or infections, and the Dutch and UK guidelines also distinguished the radicular syndrome or nerve root pain.\textsuperscript{10-13} All guidelines were consistent in their recommendations to take a clinical history and to carry out a physical examination including neurological screening. In cases of suspected specific pathology (‘red flags’), X-rays were recommended by most guidelines. In addition, the New Zealand and the US guideline also recommended X-rays when symptoms did not improve after four weeks.\textsuperscript{6,9}

The UK guideline stated that X-rays are not indicated and do not assist occupational health management of the patient with low back pain (as distinct from any clinical indications).\textsuperscript{11-13}

Most of the guidelines considered psychosocial factors - ‘yellow flags’ - as obstacles to recovery that should be addressed by health care providers. The New Zealand\textsuperscript{9} and UK guideline\textsuperscript{11,12} explicitly listed factors and suggested questions in order to identify those psychosocial ‘yellow flags’.

All guidelines addressed the importance of the clinical history identifying physical and psychosocial workplace factors relevant to low back pain, including physical demands of work (manual handling, lifting, bending, twisting, and exposure to whole body vibration), accidents or injuries, and perceived difficulties in returning to work or relationships at work. The Dutch and the Canadian guidelines contained recommendations to carry out a workplace investigation 10 or an assessment of occupational skills when necessary.\textsuperscript{4}
<table>
<thead>
<tr>
<th>Country</th>
<th>Patient population</th>
<th>Diagnostic classification</th>
<th>Examination</th>
<th>X-rays</th>
<th>Psychosocial factors</th>
<th>Workplace factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada (Quebec)</td>
<td>Subjects (workers) with activity related spinal disorders</td>
<td>11 categories ranging from LBP without radiation to chronic pain syndrome and “other diagnoses”. Further classification of duration (&lt;7 days, 7 days –7 weeks, &gt;7 weeks) and working status (working or idle); idle means absent from work, unemployed or inactive.</td>
<td>0-4 weeks absence from work: history and complete physical examination (including neurological examination); in case of serious disease further investigation. 4-7 weeks absence from work: re-evaluation, radiograph and sedimentation rate. Not working after 6 weeks: referral to musculoskeletal specialist. After 3 months of absence from work: consultation of multidisciplinary team.</td>
<td>If signs suggest a specific or serious disease.</td>
<td>Identification of chronic pain syndrome, psychosocial factors tend to complicate the clinical problem after 3 months from the onset of a spinal disorder.</td>
<td>0-4 weeks absence from work: identify work factors that may have caused the problem. 4-7 weeks absence from work: assessment of occupational skills (to assist in returning to work).</td>
</tr>
<tr>
<td>Australia (Victoria)</td>
<td>Workers with compensable low back pain.</td>
<td>Back pain (non specific). Back strain (till 8 weeks after injury). Back pain with specific diagnosis.</td>
<td>History. Physical examination: inspection, palpation and movements; signs of nerve root tension and irritation (SLR etc.); sign of impairment of nerve conduction (neurological examination); functional signs to assess possible psychological involvement (over-reaction, pain on simulated force, superficial or non-anatomical tenderness, regional weakness or sensory loss, SLR discrepancy); examination of sacroiliac joints.</td>
<td>Non-radicular LBP: at 4 to 6 weeks after onset: to show individuals with spondylolisthesis or degenerative diseases. Findings must be related to clinical presentation. LBP with radicular symptoms (back and leg pain with abnormal unilateral signs): at onset of complaints.</td>
<td>Psychosocial history: circumstances or difficulties at home and in the workplace, employment history, previous workers compensation episodes. After 2 and 6 weeks of absence from work: psychological or psychiatric referral.</td>
<td>Work history: duties, perceived difficulties in returning to work, relationships at work. After 2 and 6 weeks of absence from work: determine need for vocational assessment.</td>
</tr>
<tr>
<td>Country</td>
<td>Patient population</td>
<td>Diagnostic classification</td>
<td>Examination</td>
<td>X-rays</td>
<td>Psychosocial factors</td>
<td>Workplace factors</td>
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<tr>
<td>USA</td>
<td>Workers with &lt; 3 months activity intolerance due to LBP and/or back related leg symptoms related to occupational injury or exposure.</td>
<td>Potentially serious low back disorders (red flags). Degenerative disorders. Non-specific disorders.</td>
<td>Medical history. Physical examination: general observation, regional examination of the low back, neurological screening, testing for lumbosacral nerve root tension.</td>
<td>When symptoms do not improve over 4 weeks, or in cases of red flags.</td>
<td>Not mentioned.</td>
<td>Perceived work relatedness of limitations, information on specific job duties.</td>
</tr>
<tr>
<td>New Zealand</td>
<td>Workers with acute low back pain.</td>
<td>Acute (LBP &lt;3 months); Recurrent. Chronic (LBP&gt;3 months). Red flags: potentially serious conditions. Yellow flags: potential psychosocial obstacles to recovery.</td>
<td>History Screening for red and yellow flags.</td>
<td>Only in cases of ‘red flags’ or when the symptoms do not reduce in intensity after 4 weeks.</td>
<td>Screening for yellow flags.</td>
<td>Identify difficult tasks (heavy work, lots of lifting and forceful movements, bending and twisting, a lot of driving). Investigate accidents or injuries.</td>
</tr>
</tbody>
</table>
Summary of recommendations for the assessment of low back pain

- Diagnostic triage (non-specific low back pain, radicular syndrome, specific low back pain).
- Exclude ‘red flags’ and neurological screening.
- Identify psychosocial factors and potential obstacles to recovery.
- Identify workplace factors (physical and psychosocial) that may be related to the low back pain problem and return to work.
- X-rays restricted to suspected cases of specific pathology.

Recommendations regarding information and advice, treatment, and return-to-work strategies

Most of the guidelines recommended reassuring the employee and providing information about the self-limiting nature and good prognosis of low back pain. Encouragement of return to ordinary activity as normally as possible was frequently advised.

In line with the recommendation to return to normal activity, all guidelines also stressed the importance of returning to work as rapidly as possible, even if there is still some low back pain and if necessary starting with modified duties in more severe cases. Work duties could then be increased gradually (hours and/or tasks), until full return to work was reached. The US and Dutch guidelines provided explicit time schedules for return to work. The Dutch guideline proposed return to work within two weeks with adaptation of duties when necessary. The Dutch guideline also stressed the importance of time-contingent management with regard to return to work. The US guideline proposed every attempt to maintain the patient at maximal levels of activity, including work activities; targets for disability duration in terms of return to work were given as 0-2 days with modified duties, and 7-14 days if modified duties are not used/available.

In contrast to the others, the Canadian guideline advised return to work only when symptoms and functional restrictions had improved.

In general, the most frequently recommended treatment options in all the included guidelines were: medication for pain relief, gradually progressive exercise programmes, and multidisciplinary rehabilitation. The US guideline recommended referral within two weeks to an exercise programme consisting of aerobic exercises, conditioning exercises for trunk muscles and exercise quota. The Dutch guideline recommended that if there is no progress within two weeks of work absence, workers should be referred to a graded activity programme (gradually increasing exercises).
and if no progress by four weeks, then to a multidisciplinary rehabilitation programme.\textsuperscript{10} The UK guideline recommended that workers, who have difficulty returning to normal occupational duties by 4-12 weeks, should be referred to an active rehabilitation programme. This rehabilitation programme should include education, reassurance and advice, a progressive active exercise and fitness programme, and pain management according to behavioural principles; it should be embedded in an occupational setting and directed strongly towards return to work.\textsuperscript{11,12,13} Extensive lists of possible treatment options were presented in the guidelines of Canada and Australia\textsuperscript{4,5} although most of these were not based on scientific evidence.

**Summary of recommendations regarding information, advice, return to work measures and treatment in workers with low back pain.**

- Reassure the worker and provide adequate information about the self-limiting nature and good prognosis of low back pain.
- Advise the worker to continue ordinary activities and working or to return to normal activity and work as soon as possible, even if there is still some pain.
- Most workers with low back pain manage to return to more or less normal duties quite rapidly. Consider temporary adaptations of work duties (hours/tasks) only when necessary.
- When a worker fails to return to work within 2-12 weeks (there is considerable variation in the time scale in different guidelines), refer them to a gradually increasing exercise programme, or multidisciplinary rehabilitation (exercises, education, reassurance and pain management following behavioural principles). These rehabilitation programmes should be embedded in an occupational setting.

**Discussion**

The management of low back pain in an occupational health setting must address the relationship between low back complaints and work, and develop strategies aimed at a ‘safe’ return to work. This review compared available occupational health guidelines from various countries. Guidelines are rarely indexed in Medline, so when searching for guidelines we had to rely primarily on personal files and personal communication.
Table 4. Occupational guidelines: Recommendations regarding information and advice, return to work measures and treatment

<table>
<thead>
<tr>
<th>Country</th>
<th>Information/advice</th>
<th>Return to work measures</th>
<th>Treatments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada (Quebec)</td>
<td>Reassure patient on benign nature of condition and on its compatibility with work. Counselling on posture and lifestyle.</td>
<td>If symptoms have improved or do not cause functional restriction, return to work should be considered. If after 3 months the worker has not resumed work a multidisciplinary team should be consulted (with assistance from the Worker’s compensation board), whose composition will depend on the underlying problem.</td>
<td>Analgesics, NSAIDs. Intense pain/spasm: bed rest for 2 days, prescription renewed if pain/spasm still intense. When no improvement: physiotherapeutic modalities including instruction and practice in proper posture and body mechanics at rest and during movement.</td>
</tr>
<tr>
<td>Australia (Victoria)</td>
<td>Set up a treatment plan, which includes elements of medical treatment and procedures to facilitate the injured worker’s return to work. Decisions and actions regarding the treatment plan should be fully discussed with the worker.</td>
<td>A work place visit by the treating practitioner increases the understanding of the working environment and the available range of duties. Where possible, return workers to their normal duties. Where this is not possible, modify their normal tasks. Bring in occupational rehabilitation services when necessary.</td>
<td>The purpose of treatment is to improve function, with a view to return to work. Different treatment options are listed for short term (24 hours – 6 weeks after injury), medium term (6 to 12 weeks after injury) and long term complaints.</td>
</tr>
<tr>
<td>USA</td>
<td>Provide assurance and education about back problems. Recommend activity alterations to decrease symptoms. Encourage return to full activity.</td>
<td>Review of work duties to decide whether modifications can be accomplished without employer notification and to determine whether modified duty is available. Without co-morbidity or complicating factors (employment, legal issues): maintain patient at maximal levels of activity, including work activities; target for return to work with modified duty is 0-2 days; target for return to work without modified duty is 7-14 days.</td>
<td>Temporary avoidance of activities that increase mechanical stress on spine. Gradual return to normal activities. Low stress aerobic exercise and conditioning exercises for trunk muscles after 2 weeks. Discussion of surgical option in case of persistent and severe sciatica and clinical evidence of nerve root compression if symptoms persist after 1 month of conservative therapy.</td>
</tr>
<tr>
<td>Country</td>
<td>Information/advice</td>
<td>Return to work measures</td>
<td>Treatments</td>
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</tr>
<tr>
<td>New Zealand</td>
<td>LBP usually self-limiting, serious back injuries are not common.</td>
<td>Advice to modify or continue work. Provide options for modified work tasks and a gradual return to work. Get occupational advice if needed. Set return to work plan. Contact between employer, case manager and treatment provider important.</td>
<td>Advise to continue usual activities and work if appropriate. Simple pain relief (paracetamol and anti-inflammatory medication). Manipulation (only in first 4 to 6 weeks). Eventual referral to specialist in case of 'red flags'.</td>
</tr>
<tr>
<td>The Netherlands</td>
<td>Non specific low back pain and lumbosacral radicular syndrome (light complaints): explanation about good prognosis; activity is not harmful. Lumbosacral radicular syndrome (severe complaints): after treatment, the above mentioned advice.</td>
<td>Non specific LBP and lumbosacral radicular syndrome (light complaints): return to work within 2 weeks in absence of complications, adaptation of duties (hours or tasks) when necessary. Lumbosacral radicular syndrome (severe complaints): advice on temporary work adaptation. Specific low back pain: look for acceptable work adaptation in consultation with employer.</td>
<td>When no improvement within 2 weeks of work absence: eventual referral to graded activity programme (gradually increasing exercise programme). When no improvement within 4 weeks of work absence: referral for multidisciplinary rehabilitation.</td>
</tr>
<tr>
<td>UK</td>
<td>Employers and workers must be aware that: LBP is common and frequently recurrent but acute attacks are usually brief and self-limiting. Physical demands at work are one factor influencing LBP but are often not the most important. Case management needs to be directed at both physical and psychosocial factors. Expected recovery times have to be discussed, as is the importance of continuing ordinary activities as normally as possible despite pain. Workers with low back pain should receive the key information (The Back Book).</td>
<td>Remain at work or return in early stage even if there is still some low back pain. Advice employers on the actions required, which may include maintaining sympathetic contact with the absent worker. Consider temporary adaptation of the job or pattern of work. Address the common misconception of the need to be pain free before return to work. Encourage the employer to establish a surveillance system to identify those off work with low back pain for over 4 weeks so that appropriate action can be taken. Advise employers on ways in which the physical demands of the job can be temporarily modified to facilitate return to work.</td>
<td>Refer the worker who is having difficulty returning to normal occupational duties at 4 – 12 weeks to an active rehabilitation programme. The rehabilitation programme should consist of education, reassurance and advice, exercise, and pain management according to behavioural principles; the programme should be embedded in an occupational setting and strongly directed towards return to work.</td>
</tr>
</tbody>
</table>
Quality aspects and development process of the guidelines

The assessment by the AGREE instrument\textsuperscript{3} showed some differences in the quality of the guidelines reviewed, which may partly reflect the variation in the dates of development and publication of the guidelines. The Canadian guideline, for example, was published in 1987 and the Australian guideline in 1996.\textsuperscript{4,5} The other guidelines were more recent and incorporated a more extensive evidence base and more up-to-date guideline methodology.

Several common flaws related to the development process of the guidelines were demonstrated by the assessment by the AGREE instrument. Firstly, it is important to make clear whether a guideline is editorially independent from the funding body, and whether there are conflicts of interest for the members of the guideline committee. None of the included guidelines clearly reported these issues. Further, reported external review of the guideline by clinical and methodological experts prior to publication was also lacking in all guidelines included in this review.

Several guidelines provided comprehensive information on the way relevant literature was searched and translated into recommendations.\textsuperscript{4,6,11,13} Other guidelines supported their recommendations by references,\textsuperscript{5,7,9,10} but this does not permit assessment of the robustness of the guidelines or their recommendations.

Guidelines depend on the scientific evidence, which changes over time, and it is striking that only one guideline provided for future update.\textsuperscript{11,12} Possibly, there are updates planned for the other guidelines but they are not explicitly stated (and conversely stating there will be future update does not mean it will actually occur). This lack of reporting may also hold true for other AGREE criteria that we rated negatively. The use of the AGREE framework as a guide for both the development and the reporting of guidelines should help to improve the quality of future guidelines.

Assessment and management of low back pain

The diagnostic procedures recommended in the occupational health guidelines were largely similar to the recommendations of clinical guidelines\textsuperscript{2} and, logically, the main difference was the emphasis on addressing occupational issues. The reported methods for addressing workplace factors in the assessment of low back pain of the individual worker concerned the identification of difficult tasks, risk factors and obstacles for return to work by occupational histories. Obviously, these obstacles for return to work not only concern physical load factors, but also work-related psychosocial
problems regarding responsibilities, co-operation with co-workers and the social atmosphere at the workplace. Screening for work-related psychosocial ‘yellow flags’ may help to identify those workers who are at risk for chronic pain and disability. A potentially important feature of the guidelines is that they were consistent regarding their recommendations to reassure the employee with low back pain, and to encourage and support return to work even with some persisting symptoms. There is general consensus that most workers do not have to wait until they are completely free of pain before returning to work. The lists of treatment options provided by the Canadian and Australian guidelines may reflect the lack of evidence at that time, leaving users of the guidelines to choose for themselves. It is however questionable whether such lists really contribute to improved care and in our view guideline recommendations should be based on sound scientific evidence. The US, Dutch and UK occupational guidelines recommend that active multidisciplinary treatment is the most promising intervention for return to work, and this is supported by strong evidence from RCTs. However, more research is still needed to identify the optimum content and intensity of those treatment packages. Despite some evidence for a contribution of workplace factors in the aetiology of low back pain, systematic approaches for workplace adaptations are lacking, and are not offered as recommendations in the guidelines. Perhaps this represents a lack of confidence in the evidence on the overall impact of workplace factors, a difficulty of translation into practical guidance, or because these issues are confounded with local legislation (which was hinted at in the UK guideline). It may be that the ‘participatory ergonomics’ intervention, which proposes consultations with the worker, the employer and an ergonomist, will turn out to be a useful return to work intervention. The potential value of “getting all the players onside” was stressed in the Dutch and the UK guidelines, but further evaluation of this approach and its implementation is required.

**Development of future guidelines in occupational health care**

The purpose of this review was to give both an overview and a critical appraisal of occupational guidelines for the management of low back pain. The critical appraisal of the guidelines is meant to help direct future development and planned updates of guidelines. In the still emerging field of guideline methodology we consider all past initiatives as laudable; we recognise the need for clinical guidance, and appreciate that guidelines developers cannot wait for research to provide all the methodology and evidence required. However, there is room for improvement and future
guidelines and updates should consider the criteria for proper development, implementation and evaluation of guidelines as suggested by the AGREE collaboration.

The implementation of the guidelines is beyond the scope of this review, but it was noted that none of the guideline documents specifically described implementation strategies, so it is uncertain to what extent the target groups may have been reached, and what effects that may have had. This may be a fruitful area for further research.

The very existence of these occupational health guidelines shows that existing primary care clinical guidelines for low back pain are considered inappropriate or insufficient for occupational health care. There is a clear perception internationally that the needs of the worker experiencing back pain are intrinsically linked to a variety of occupational issues not covered by usual primary care guidance and, consequently, practice. What emerges is that, despite the methodological flaws, considerable agreement is evident on a range of fundamental occupational health strategies for managing the worker with back pain, some of which are innovative and challenge previously held views. There is agreement on the fundamental message that prolonged work loss is detrimental, and that early work return should be encouraged and facilitated; there is no need to wait for complete symptom resolution. Although the recommended strategies vary somewhat, there is considerable agreement on the value of positive reassurance and advice, availability of (temporary) modified work, addressing workplace factors (‘getting all the players onside’), and rehabilitation for workers having difficulty returning to work.
References list


Graded Activity for Low Back Pain in Occupational Health Care Randomised, Controlled Trial


Abstract

**Background:** Low back pain is a common medical and social problem frequently associated with disability and absence from work. However, data on effective return to work after interventions for low back pain are scarce.

Objective: To determine the effectiveness of a behavior-oriented graded activity program compared with usual care.

**Design:** Randomized, controlled trial.

**Setting:** Occupational health services department of an airline company in the Netherlands.

**Patients:** 134 workers who were absent from work because of low back pain were randomly assigned to either graded activity (n = 67) or usual care (n = 67).

**Intervention:** Graded activity, a physical exercise program based on operant-conditioning behavioral principles, to stimulate a rapid return to work.

**Measurements:** Outcomes were the number of days of absence from work because of low back pain, functional status (Roland Disability Questionnaire), and severity of pain (11-point numerical scale).

**Results:** The median number of days of absence from work over 6 months of follow-up was 58 days in the graded activity group and 87 days in the usual care group. From randomization onward, graded activity was effective after 50 days of absence from work (hazard ratio, 1.9 [95% CI, 1.2 to 3.2]; P = 0.009). The graded activity group was more effective in improving functional status and pain than the usual care group. The effects, however, were small and not statistically significant.

**Conclusions:** Graded activity was more effective than usual care in reducing the number of days of absence from work because of low back pain.
Introduction

Nonspecific low back pain is an uncomfortable medical condition that causes frequent disability and absence from work. Most episodes of low back pain resolve fairly quickly and cause only short periods of absence from work. However, some workers with low back pain miss work for several days to weeks and are at risk for more permanent disability. To reduce the individual and socioeconomic burden related to this absenteeism, we need effective intervention strategies in occupational health care settings that promote safe and rapid return to work. One promising and often-advocated intervention strategy for workers with prolonged nonspecific low back pain is active rehabilitation that is directed toward return to normal activity and work. Examples are graded activity interventions that include physical exercise, application of operant-conditioning behavioural principals, and promotion of improved functioning and safe return to work even if pain persists. In a randomized, controlled trial, Lindström and colleagues found that a graded activity intervention reduced absence from work more than did traditional care in Swedish workers employed in the automobile industry. We investigate, in a second randomized, controlled trial, whether absence from work because of low back pain is reduced more with graded activity intervention than with traditional care in an occupational health care setting in the Netherlands.

Methods

Study Design and Population

The study was a single-blind, randomized, controlled trial in an occupational health services center (KLM Health, Safety and Environment) at Schiphol Airport, Amsterdam, the Netherlands. The center provides occupational health services for all employees of a major Dutch airline (KLM Royal Dutch Airlines). The source sample (n = 20,000) consisted of workers who were employed in the following organizational units of the airline: baggage and aircraft turnaround services, passenger services, engineering and maintenance, cargo, and cabin and cockpit. Workers who were listed as absent from work because of low back pain were invited for a consultation with the occupational physician. Those who were thought to be eligible for inclusion were referred to the research assistant, who judged whether they met the inclusion criteria: full or partial absence from work because of nonspecific low back pain and low back
pain symptoms with a minimum duration of 4 weeks in succession. The exclusion criteria were low back pain with radiation below the knee with signs of nerve-root compression; cardiovascular contraindications for physical activity, as checked according to the Physical Activities Readiness Questionnaire; any conflict between worker and employer with legal involvement; or pregnancy. Workers who met the inclusion criteria were informed of the purpose and procedures of the study and were enrolled after giving informed consent. The Medical Ethical Committee of the VU University Medical Center, Amsterdam, the Netherlands, approved the study.

Treatment Allocation

The participants were assigned to graded activity or usual care on the basis of block randomization, after prestratification for the organizational unit in the workplace from which they were recruited (the 5 organizational units listed earlier) and for the severity of pain symptoms (scored on a scale of 0 to 10; severity scores were <6 or ≥6 points). This resulted in a total of 10 strata. Randomized, permuted blocks of 4 allocations were generated for each stratum through a computer-generated random-sequence table. Opaque, sequentially numbered, sealed envelopes were prepared for each stratum by a researcher who was not involved in enrolling the participants or assigning them to their groups. The envelopes contained a sheet of paper that indicated 1 of the 2 interventions. Participants learned their group assignments after a research assistant completed the baseline measurements and delivered the sealed envelopes.

Blinding

The research assistants who collected the data were blinded to the treatment allocation. All participants were repeatedly asked not to reveal any information about their treatment allocation. The participants and treatment providers were not blinded to treatment allocation.

Interventions

In the Dutch occupational health care system, occupational physicians guide disabled workers who are absent from work through their disability period. These occupational physicians are employed by occupational health services that are paid for by the companies. The occupational physicians adhere to back pain management strategies that consist of
advising workers on ergonomics, prevention, and return-to-work schedules and advising and communicating with other stakeholders (such as health care providers and representatives of the workplace). Disabled workers who participated in the present study were assigned to either graded activity or usual care within the context of the Dutch occupational health care setting.

**Graded Activity**

The intervention group received the usual guidance from the occupational physician about work-related problems and barriers to return to work as well as the graded activity intervention supervised by a physiotherapist. Three physiotherapists who worked in a private practice at Schiphol Airport provided the treatment according to the graded activity protocol. Two of those physiotherapists were also trained as manual therapists, and 1 was also a human movement scientist. Before the study, the physiotherapists had been specifically trained to treat patients with low back pain according to behavioral principles. A research physiotherapist who was experienced in treating patients with chronic pain in rehabilitation centers instructed the physiotherapists in three 2-hour sessions and practiced patient–therapist interactions with them through role-play. Before the study, the physiotherapists treated several patients according to the graded activity protocol to gain more experience. The physiotherapists made audiotapes of the intervention sessions before and during the study period. The contents of these audiotapes were assessed and discussed with the research physiotherapist in 3 additional meetings. Furthermore, the physiotherapists summarized the treatment after each session, and researchers used these summaries to review the sessions. The same physiotherapist treated participants each time, except for temporary stand-in sessions that were supervised by colleagues because of holidays or other reasons. Specific therapists were not systematically selected to treat specific participants; selection was based on pragmatic reasons, such as the time available in the work schedules of the physiotherapists or the days of treatment preferred by the participants. Table 1 presents the concept and content of the graded activity intervention.

The intervention consisted of 1-hour exercise sessions that participants attended twice per week until they returned completely to regular work or until the maximum therapy duration of 3 months was reached. At the start of the intervention, the physiotherapist inquired about the participant’s medical history and completed a brief physical examination consisting of flexion, extension, and lateroflexion of the lumbar spine and a brief screening for nerve-root pain. The purpose of the physical exami-
nation was to confirm the diagnosis of benign, nonspecific low back pain and to reduce participants’ fears about any presumed underlying disease. The participants were reassured that despite the annoying pain, nothing was seriously wrong with their backs. Subsequently, the physiotherapist and participant decided on a set of general exercises and individually tailored exercises. Both types of exercises had to be performed during each session. The general exercises were aerobic exercises, such as cycling or

### Table 1. Description of the graded activity intervention

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disciplines</td>
<td>Physiotherapist, occupational physician (case manager).</td>
</tr>
<tr>
<td>Concept</td>
<td>Pain and its related behaviours (pain behaviour), like for example physical inactivity, complaining, or sick leave, are under the control of learning (operant conditioning). Favorable consequences that follow pain behaviour will reinforce the future occurrence of pain behaviours. Exercise and physical activity are considered to be incompatible with pain behaviour. The stimulation of exercise behaviour may therefore lead to a decrease of competing pain behaviours.</td>
</tr>
<tr>
<td>Sessions</td>
<td>Two sessions of one hour a week, supervised by the physiotherapist, until full return to regular work. The intervention has a maximal duration of 3 months.</td>
</tr>
<tr>
<td>Education messages</td>
<td>Pain does hurt, but this does not mean harm. Exercise and physical activity is recommendable and safe, despite of pain complaints. Improvement of functioning is the primary goal and not pain relief.</td>
</tr>
<tr>
<td>Exercises</td>
<td>General exercises (aerobic exercises, abdominal, back and leg exercises) and individually tailored exercises to simulate and exercise problematic work tasks, or problematic activities of daily living.</td>
</tr>
<tr>
<td>Baseline values of maximal performance</td>
<td>During the first three sessions workers are asked to perform each exercise separately until pain tolerance (pain-contingent). The average results of these three functional capacity evaluations serve as baseline values for the quota-based exercise program.</td>
</tr>
<tr>
<td>Date of return to work</td>
<td>After the third session the worker proposes a date of work resumption (after consultation with the physiotherapist) which corresponds with the end of the intervention period.</td>
</tr>
<tr>
<td>Exercise program</td>
<td>The worker determines, in cooperation with the physiotherapist, for each exercise an exercise scheme with gradually increasing exercise quotas. The exercise quotas start at a level below the average baseline value (in order to be sure of success experiences) and are gradually increased during the course of the intervention.</td>
</tr>
<tr>
<td>Time-contingent management</td>
<td>The exercise quotas are not subject to change during the course of the intervention regardless the experience of more or less pain</td>
</tr>
<tr>
<td>Return to work</td>
<td>The worker may return to work partially or with modified duties before returning to full regular work. Partial return to work is considered to be of therapeutic value. Appointments with regard to this return-to-work plan are also applied on a time-contingent basis.</td>
</tr>
</tbody>
</table>
rowing, and strengthening exercises for large muscle groups, and most were carried out in a gym while using exercise equipment. The strengthening exercises were a floor abdominal sit-up exercise, a dynamic back extension exercise, a leg-press exercise, a latissimus pull-down exercise, and standing up from a low chair. Participants in the graded activity group had to perform not only these general exercises but also individually tailored exercises, which imitated physical tasks at work or difficult and painful activities of daily living. For example, a participant who reported back problems while lifting and moving suitcases from a luggage wagon into an airplane might be given an exercise to practice lifting and moving a suitcase with a certain number of repetitions. During the first 3 sessions, the maximal performance (for example, the maximum number of repetitions) was assessed for each exercise separately, and the average score for each exercise over the 3 sessions was used as a baseline value for specifying a gradually progressive exercise scheme. Subsequently, the participant was asked to propose a date for full return to regular work, which would consequently be the end point of the physical exercise program. Before returning to full regular work, participants could return to work with modified hours and duties. Advised by the physiotherapist, the participant then decided on a gradually increasing quota for each exercise to achieve a preset exercise goal immediately before the proposed date of full return to work. The increase in the quota was visualized for each exercise in a graph drawn by the participant (Figure 1), which was intended to give visual feedback on the participant’s improvement during the course of the intervention. The exercises were started during the fourth session at a level below the average maximal functional capacity assessed during the first 3 sessions to guarantee that the participant could complete the exercise quota and succeed. The exercise quota was gradually increased during the course of the intervention, according to the time-contingency principle. The preset increasing exercise quota was fixed, and the participant had to perform the exercises each session according to this quota, regardless of the amount of pain. The physiotherapist verbally praised the participant each time 1 of the preset exercise goals was achieved. In general, the physiotherapists were instructed to pay particular attention to the participants’ improvements rather than their pain. It should further be stressed that the primary goal of the physical exercises was not to improve aerobic endurance, muscle strength, or any other aspect of physical fitness but to make the disabled worker aware that it was safe to move and to be physically active despite his or her pain. The participants could have also consulted their general practitioners, as well as the occupational physician, for their low back pain during the study period. Therefore, their general practitioners were in-
formed about the study and the principles of the graded activity program. They were requested to treat the participants according to the low back pain guidelines issued by the Dutch College of General Practitioners. These guidelines advocate an active approach and possible referral for exercise therapy in patients with chronic low back pain. However, the general practitioners were asked not to refer the participants for any additional treatments for low back pain during the course of the graded activity intervention.

**Usual Care**

The usual care group received the usual guidance and advice from the occupational physician. Other types of treatment were not required, except that the participants were not allowed to attend treatment sessions at the same physiotherapy practice where the participants in the graded activity group were treated. The general practitioners of all participants in the usual care group were also requested to treat the participants according to the low back pain guidelines of the Dutch College of General Practitioners.

**Outcome Measures and Data Collection**

Outcome measures were the total number of days absent from work be-
cause of low back pain, functional status, and pain. Functional status and pain were measured at baseline and 3 and 6 months after randomization. Data on days absent from work because of low back pain were continuously collected in the electronic medical records of the company. The primary outcome was the total number of days of absence from work (both initial days and days of recurrent episodes of absence from work) because of low back pain over the entire follow-up period. During followup, some participants might have returned to partial work with modified hours or duties (for therapeutic reasons) but remained on the work absenteeism list. Full return to regular work was defined as any full return to regular work with a minimum duration of 4 weeks. This means that recurrent episodes of absence from work because of low back pain within 4 weeks of full return to regular work were considered as belonging to the same first continuous period of absence from work, which is in accordance with the Dutch social security laws. The functional status of participants was assessed by using the Roland Disability Questionnaire. This questionnaire consists of 24 items relevant for the functional status of a patient with low back pain. The scoring was based on the number of positive responses. An individual score could range from 0 (no disability) to 24 (severe disability). The Dutch translation of the Roland Disability Questionnaire was a reliable, valid, and responsive outcome measure. The average pain intensity in the previous week was evaluated by the participant on an 11-point numerical scale ranging from 0 (no pain) to 10 (very severe pain). Physical activity at baseline was measured with the Baecke Questionnaire. This is a self-administered questionnaire (16 items) consisting of 3 constructs: physical activity at work; sport during leisure time; and physical activity during leisure time, excluding sport. Although most participants were fully absent from work at baseline, we compared only the baseline scores for sport during leisure time with physical activity during leisure time, excluding sport. Data about any treatment received during the study period other than graded activity were collected in both groups through diaries and questionnaires.

Statistical Analyses

To calculate sample size, we assumed that a statistically significant difference of 5 days of absence from work because of low back pain between the groups was the smallest clinically important difference. This difference would correspond with the point at which the costs of the graded activity intervention equalled the profits of the reduction in days of absence from work. The calculations showed that with a power of 0.90 and a significance level of 0.05, a target sample of 70 participants in each group was
Chapter 4

Figure 2. Flow diagram showing the progress of the participants through the phases of the trial.

Eligible workers as referred by the occupational physician (n = 150)

Excluded (n = 16)
- Already returned to full regular work: 9
- Not willing to participate and therefore no informed consent: 4
- Illiterate: 1
- Neck pain instead of low back pain: 1
- Contraindication for physical activity (high blood pressure): 1

Randomly assigned (n = 134)

Allocated to graded activity (n = 67)
- Received treatment: 64
- Did not adhere: 3

Allocated to usual care (n = 67)
- Physiotherapy: 38
- Manual therapy: 6
- Mensendieck exercise therapy: 6
- Chiropractor: 3
- Commercial back school: 1
- Content of usual care unknown: 7

Data available for analyses:
- Absence from work: 67
  - 3 months: 62
  - 6 months: 61
- Pain:
  - 3 months: 61
  - 6 months: 60

Data available for analyses:
- Absence from work: 67
  - 3 months: 64
  - 6 months: 60
- Pain:
  - 3 months: 63
  - 6 months: 59

P value less than 0.05 was considered statistically significant.

Cox regression for repeated events was analyzed with Stata, version 7 (Stata Corp., College Station, Texas), and the random coefficient analyses were performed with MLwiN, version 1.1 (Centre for Multilevel Modelling, Institute of Education, London, United Kingdom).
Results

From April 1999 to January 2001, the occupational physicians referred 150 workers. Sixteen workers did not meet the inclusion criteria (Figure 2). A total of 134 participants were randomly assigned to either the graded activity group (n = 67) or the usual care group (n = 67). Data on the number of days of absence from work were available for all randomly assigned participants since work loss data were available regardless of the worker’s participation in treatment or follow-up. Thirteen participants withdrew from the study during follow-up and did not complete the functional status and pain measurements. Except for the cases already mentioned and several incidental missing values for some variables, the data set for the entire follow-up period was complete. Of the 13 participants who withdrew from the study, only 3 did not adhere to the graded activity intervention protocol. One non-adherent participant withdrew from the study immediately after randomization, declining to participate in the graded activity intervention. The 2 other participants were dissatisfied with the content of the graded activity sessions and withdrew after a few sessions. Table 2 shows the baseline characteristics and baseline values of the outcome measures for both groups. There were only small differences between the treatment groups.

Content of Treatments

The participants who were assigned to the graded activity group attended a mean (±SD) of 13 ± 5.4 treatment sessions. The graded activity intervention had an average duration of almost 7 weeks. One physiotherapist changed jobs a few months after the start of the study. She had provided the graded activity treatment for 7 participants. The median number of days that these participants were absent from work because of low back pain after randomization was 53 days. To replace this physiotherapist, we trained another physiotherapist during the study period. He treated 15 participants, and the median number of days that they were absent from work because of low back pain after randomization was 54 days. The third physiotherapist delivered treatment during the entire study period for 44 participants, who were absent from work because of low back pain after randomization for a median of 65 days. Eight participants who received the graded activity intervention reported that they used nonsteroidal anti-inflammatory drugs, and 3 participants reported that they used painkillers during the intervention period. Sixty of the 67 participants (90%) in the usual care group completed and returned their diaries about the usual care they received.
Figure 2 shows the different types of care received by participants in the usual care group. They had received a mean (±SD) of 13 ± 8.4 sessions of treatment from various caregivers. Sixteen participants reported that they had used non-steroidal anti-inflammatory drugs, and 6 participants reported that they had used painkillers either with their treatment or separately. The remaining 7 participants in the usual care group who did not return their diaries did not receive any treatment similar to the graded activity intervention. In the Dutch system, such interventions in an occupational health care setting cannot be delivered without knowledge or involvement of the occupational physician.

**Absence from Work Because of Low Back Pain**

The median total number of days of absence from work because of low back pain after randomization was 58 days in the graded activity group and 87 days in the usual care group. In the first 50 days after randomization, the rate of return to work was more or less similar in both groups, although from approximately 50 days after randomization and onward, the
curves of the graded activity group and the usual care group diverged. We assumed that hazard ratios were constant within each time period. Through Cox regression analyses for repeated events, hazard ratios were calculated for the participants with fewer than 50 days of absence from work after randomization and for the participants with 50 or more days of absence from work after randomization. The hazard ratio for the period up to 50 days after randomization was 1.0 (95% CI, 0.6 to 1.8; \( P > 0.2 \)), and the hazard ratio for the period from 50 days after randomization was 1.9 (CI, 1.2 to 3.2; \( P > 0.009 \)), which was in favor of the graded activity intervention. Per-protocol analysis was also performed, excluding the 3 non-adherent participants in the graded activity group. In this case, the hazard ratio for the period up to 50 days after randomization was 1.1 (CI, 0.6 to 1.9; \( P > 0.2 \)), and the hazard ratio for the period from 50 days after randomization was 2.0 (CI, 1.2 to 3.2; \( P = 0.004 \)), in favor of the graded activity group.

**Table 3. Improvements in functional status and pain from baseline at 3 and 6 months and differences in effects between the groups**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Participants</th>
<th>Mean Improvement ± SD</th>
<th>Effect of graded activity intervention † (95% CI)*</th>
<th>( P ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Graded Activity</td>
<td>Usual Care</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Functional status †</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>124</td>
<td>6.3 ± 6.7</td>
<td>4.9 ± 6.2</td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td>120</td>
<td>7.8 ± 6.6</td>
<td>6.4 ± 6.6</td>
<td>-1.5 (-3.3 to 0.4)</td>
</tr>
<tr>
<td>Pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>122</td>
<td>2.8 ± 2.4</td>
<td>2.5 ± 2.8</td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td>118</td>
<td>2.9 ± 3.1</td>
<td>2.7 ± 2.8</td>
<td>-0.4 (-1.1 to 0.4) §</td>
</tr>
</tbody>
</table>

* Adjusted for the baseline value of the outcome measure, age, sex, duration of absence from work before randomization, and either partial or full absence from work at baseline. 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. Both differences favor the graded activity group.

† As measured by using the Roland Disability Questionnaire.
Functional Status and Pain

Both treatment groups improved in functional status and pain over time (Table 3). The differences between the groups in improvement of functional status and pain at 3 and 6 months favored graded activity but were not statistically significant.

Discussion

We found that graded activity for low back pain in an occupational health setting had a beneficial effect on absence from work but had no statistically significant effect on functional status and pain when compared with usual care. The reduction in days of absence from work because of this intervention is promising and confirms results of an earlier Swedish trial by Lindström and colleagues\textsuperscript{3,4}. We found that graded activity did not affect return to work until more than 50 days after randomization. The apparent delayed effect may relate to the time involved in the intervention (on average, 13 treatment sessions twice per week) because participants might be less inclined to return to work during active treatment periods. Functional status results showed a tendency toward improvement with graded activity (point estimate of effect, 1.5 points on the Roland Disability Questionnaire scale), but it was not statistically significant. Whether a difference of this magnitude could be clinically important is debatable.\textsuperscript{20} Stratford and colleagues\textsuperscript{21} compared scores on the Roland Disability Questionnaire with a global rating of change to classify patients as having changed a clinically important amount or not. They suggested that a change of 1 to 2 points is clinically important for patients with little disability, which was defined as an initial score of 0 to 8 points. In the present study, mean (±SD) baseline scores were 13.1 ± 4.8 points. Detecting clinically important changes for patients scoring within this baseline range may require changes of 5 points or more.\textsuperscript{21} Furthermore, changes detected by the Roland Disability Questionnaire do not necessarily apply to work-related functioning because no item on the questionnaire is related to work. We found that the intervention did not affect pain severity. This finding corresponds with the general principle of the graded activity intervention, which primarily focuses on improvement in functioning and return to work and not on pain relief. We do not consider pain relief a prerequisite for returning to work, and participants were told that they could safely return to work despite pain. To shift participants’ attention away from negative symptoms, such as increasing pain, numbness, tiredness, or paresthesia, we did not routinely question or monitor them for these adverse events. The caregivers did not ignore these symptoms but focused on the abilities, not the disabilities, of the participants.
general, disabled workers’ return to work does not depend only on their medical condition or their perception of their medical condition. It also depends on other contextual factors, such as compensation, legal issues, and the culture of the workplace. In the Netherlands, workers usually receive their full salary during the first year of absence from work, regardless of the cause of their disability. The graded activity intervention in this study was aimed at changing the way disabled workers perceive and cope with their back pain. Its goal was to convince workers that their pain was benign by telling them that it was safe to return to work and by giving them experiences (that is, physical exercise and resumption of work activities) that supported that message. In our view, this change in workers’ perception of their medical condition and subsequent return to work is relatively independent from contextual circumstances, such as compensation issues and the organization of the health care system. If so, our findings, which are similar to those of a previous trial involving Swedish workers, may be generalizable across several settings. Nevertheless, future randomized, controlled trials in this field across different occupational and organizational settings are needed to clarify both the mechanisms and the generalizability of our results.
Reference List


The Effects of a Graded Activity Intervention for Low Back Pain in Occupational Health on Sick Leave, Functional Status and Pain: 12-Month Results of a Randomized Controlled Trial

The Effects of a Graded Activity Intervention for Low Back Pain in Occupational Health on Sick Leave, Functional Status and Pain: 12-Month Results of a Randomized Controlled Trial
Journal of Occupational Rehabilitation, Vol. 15, No. 4, December 2005
Abstract

Introduction: Low back pain is an important medical and social problem that can lead to disability from work and sick leave. Methods: The present study evaluated the effects of a behaviourally oriented graded activity intervention for sick-listed workers with low back pain, consisting of a physical exercise programme based on operant conditioning behavioural principles that is aimed at a safe and rapid return to work. The study, a single-blinded randomised, controlled trial, compared this intervention with usual care, in the occupational health service department of KLM Royal Dutch Airlines. One hundred and thirty-four workers, sick-listed due to low back pain, were randomly assigned to either a graded activity intervention (n=67) or usual care (n=67). Outcome measures during 12 months of follow-up included days of sick leave due to low back pain (initial period of sick leave, recurrent episodes of sick leave, total number of days of sick leave), total number of days of sick leave due to all causes functional status and severity of pain complaints. Results: The graded activity group returned back to work faster with a median of 54 days compared to 67 sick leave days in the usual care group. The graded activity intervention was more effective after approximately 50 days of sick leave post randomisation (HRR = 1.9, CI 1.2 to 3.1, p=0.01), but not before then. Differences between the groups in number of recurrent episodes of sick leave due to low back pain, total number of days of sick leave due to low back pain, and total number of days of sick leave due to all diagnoses, were in favour of the graded activity group, although not statistically significant. No effects of the graded activity intervention were found for functional status or pain. Conclusion: Graded activity intervention is a valuable strategy for stimulating return to work of workers who are sick-listed due to low back pain.
Introduction

Non-specific low back pain (LBP) is one of the most common complaints in the Western world, with a lifetime prevalence that can reach 85%.\(^1\) Although non-specific LBP does not have a clear patho-anatomical substrate, and is considered a self-limiting benign condition in most patients, the disabling pain behaviour can result in a disuse syndrome and chronic disability. From the occupational health care perspective, preventing long-term disability and sick leave is important. It seems appropriate to begin with an intervention in the sub-acute stage of LBP, i.e. between 4 weeks and 3 months of sick leave, taking into account the expected spontaneous recovery in the acute phase of LBP, and the necessity for early prevention of the development of chronic LBP.\(^2-5\) A promising intervention for sub-acute LBP is a graded activity intervention (GA), as first developed by Lindström et al. in Sweden.\(^6\) In the present randomized controlled trial (RCT), effects of a GA intervention on return to work (RTW), functional status and pain severity were compared with usual care. We investigate, whether GA intervention has similar beneficial effects under special social-economic circumstances in a single company the Netherlands. The short-term effects of this intervention after 3 and 6 months of follow-up have already been reported elsewhere,\(^7\) and this paper describes the effects over a 12-month follow-up period.

Methods

Study design and population

The study was a single blind RCT, carried out in the occupational health service department of the Royal Dutch Airlines (KLM) at Schiphol Airport. The source population consisted of approximately 25,000 workers, employed by KLM. Workers who were sick-listed between the 1st of April 1999 and the 1st of January 2001 because of LBP were referred to the occupational physician (OP) for medical evaluation. The OP referred workers who were eligible for inclusion and willing to take part in the study, to the research assistant, who checked them against the inclusion and exclusion criteria. The inclusion criterion was non-specific LBP for at least 4 weeks prior the inclusion to the study, with either full or partial sick leave due to LBP. Non-specific LBP criterion excluded fractures, tumors, or infections (5); other exclusions were pain radiating below the knee, cardiovascular or medical contra-indications for physical activity according to the Physical Activities Readiness Questionnaire (PAR-Q)\(^8\) pregnancy, or legal conflict.
between worker and employer. Full or partial sick leave meant that the worker was listed as less than 100% fit for his work duties and received full or partial sickness pay according to the Dutch Sickness Benefit Act. Measurements were taken before randomization at baseline, and at 3, 6 and 12 months after randomization. Treatment allocation was by means of block randomization in 10 strata, with blinding of the outcome assessors, as described in detail elsewhere. The Medical Ethical Committee of the VU University Medical Centre, Amsterdam, the Netherlands, approved the study.

**Interventions**

Workers who were randomized to either the GA group or the UC group received identical usual advice from the OP. This included discussions about managing sick leave, improving work conditions, and preventing recurrence of LBP. The OP in the Netherlands did not provide medical treatment, as this was provided by general practitioners (GP) or medical specialists.

**Graded activity intervention**

Before the start of the study, three physiotherapists were trained to deliver the GA intervention, consisting of one-hour exercise sessions given twice a week until the workers achieved full return to regular work, or when the maximum therapy duration of 3 months had been completed. At the start of the intervention, the physiotherapist inquired about the worker’s medical history and carried out a brief physical examination. The intake was completed with an explanation about the benign nature and good prognosis of non-specific LBP. The physiotherapist together with the worker determined a set of suitable physical exercises. During the first three sessions, the maximal performance was assessed for each exercise separately, and at the end of the third session, the worker was asked to propose a date for full return to regular work. This date would also serve as the end-point of the physical exercise programme. The worker and the physiotherapist agreed on a gradually increasing quota for each exercise and the date for RTW. This gradually increasing programme according to a time-contingent principle started in the fourth session, at approximately 70% of the average performance level, as assessed during the first three sessions. The GPs of the workers were informed about the study and the principles of the GA programme. They were requested to adhere to the guidelines for LBP issued by the Dutch College of general practitioners, and not to re-
fer these workers to other care-providers for any additional treatment for LBP during the course of the intervention.

**Usual care**

There were no specific requirements or restrictions with regard to the type of treatment, except that the workers in the UC group were not allowed to receive any treatment in the physiotherapy practice at Schiphol Airport where the sessions for the GA group were held. The GPs were informed about the study and the allocation of their patient to the UC group, and they were asked to adhere to their professional guidelines for LBP. 10

**Outcome measures and data-collection**

Outcome measures included total number of days of sick leave due to LBP, functional status and severity of pain. Follow-up measurements were performed at 3, 6 and 12 months after randomization. The sick leave data were collected from the electronic medical records of the occupational health services for the entire study period. Data about any treatment received during the study period other than GA were collected in both groups through diaries and questionnaires. The physiotherapists who applied the intervention reported data on the number of sessions completed in the GA programme.

**Sick leave**

For the purpose of this study, the first continuous period of sick leave due to LBP was defined as the number of days of sick leave from randomization until the date of full return to regular work. Workers, who returned to work partially, or with modified duties, remained on the sick list until they made a full return to regular work. Full return was operationalized as any full return to regular work with a minimum duration of 28 days. This means that absence from work because of low back pain within 28 days of full return were considered as belonging to the same first continuous period of sick leave. This definition is based on then-valid Dutch Sickness Benefits Act which considers recurrences of sick leave within 28 days as a continuous sick leave period. Cumulative completing of 365 sick leave days entitle the worker to receive disability benefits. This operationalization of full return is arbitrary as work absence due to LBP is determined by a large number of factors, which are not only health related. The GA group and the UC group were compared with regard to the duration of the initial post-randomization period of sick leave due to LBP, the
number of recurrent episodes of sick leave due to LBP, and the total number of days of sick leave due to these recurrent episodes. In addition, the total number of days of sick leave due to LBP and due to other diagnoses, and the total number of workers on sick leave at 12 months were calculated, and compared between the two groups.

**Functional status and pain**

Functional status was assessed by means of the Roland Disability Questionnaire (RDQ), which was scored by counting the number of positive responses. The individual scores can vary from 0 (no disability) to 24 (severe disability).\(^{11;12}\) Average pain intensity, experienced during the week preceding the measurement, was reported on an 11-point visual analogue scale (VAS) scale, ranging from 0 (no pain) to 10 (very severe pain).\(^{13}\)

**Statistical analyses for comparing the GA group and the UC group**

The effect of the GA intervention on sick leave was analyzed by means of survival analysis. Kaplan-Meier curves were used to describe the distribution of the duration of the initial post-randomization period of sick leave. A Cox multivariable regression model was used to estimate hazard ratios for RTW and 95% confidence intervals. The incidence-rate of LBP recurrences, incidence-rate ratio and its 95% confidence interval were calculated in order to compare the differences between the groups. The total number of days of sick leave was analyzed by means of a Mann–Whitney U-test. The total number of workers in each group who were still on sick leave at 12 months was compared by means of a chi-square test.

The effects of the GA intervention on functional status and pain severity at the 12-month follow-up were analyzed by means of linear regression analysis. The group allocation was the dichotomous independent variable, where the baseline values of functional status and severity of pain were entered in the models as covariates.

In both the Cox regression analyses and the linear regression analyses, adjustments were made for age, gender, duration of sick leave due to LBP before randomization, and partial or full sick leave at baseline. The statistical analyses were performed according to the intention-to-treat principle. An alternative per-protocol analysis, excluding all workers who were not treated according to the protocol, was only performed for the sick leave data.

The data were analyzed in SPSS statistical software (Version 10.1; SPSS Inc., Chicago Ill.) The level of statistical significance was set at \(p< 0.05\).
Results

Baseline similarity and drop-outs

From the population of approximately 25,000 workers, a total of 2,550 cases of sick leave due to LBP for at least one day were registered during a 21-month period. Of these cases, 529 met the study criteria and at last 150 workers were identified as eligible and referred by the occupational physicians to the research assistant for the intake procedure. A flow-chart of the participants in the trial and drop-outs is presented in Figure 1. A total of 134 workers were included in the trial and randomly allocated to either the GA group (n = 67) or the UC group (n = 67). The data on baseline characteristics of the GA group and the UC group did not show significant differences and as it have been reported in more detail elsewhere.  

Loss to follow-up

A total of 14 workers withdrew from the trial, or did not show up for the follow-up measurements, despite several reminders. This group of 14 drop-outs did not differ significantly with regard to baseline characteristics from the 120 workers who completed all follow-up measurements and questionnaires. Sick leave data were available for all 134 workers for the entire follow-up period.

Non-compliance

Of the 14 workers who withdrew from the study during the 12 months of follow-up, only 3 were not compliant with the graded activity intervention protocol. One of them withdrew from the study immediately after randomization and refused to take part in the GA programme and two others refused to carry on with the GA programme after a few sessions, because they were disappointed with the content of the intervention.
Fig. 1. Flow-chart of the participants and dropouts in the trial. *Between brackets: number of workers. †Sick leave data were available for all included workers for the entire 12-month follow-up period.
Initial post-randomization sick leave period

The median duration of the first continuous period of sick leave after the randomization was 54 days in the GA group and 67 days in the UC group. The Kaplan Meier curves in Figure 2 show the cumulative RTW to full duties during the 12-month follow-up period. The difference between the RTW of the groups over the whole follow-up year was just above the level of significance (log-rank test, p=0.06). In the first 50 days after randomization, the RTW rate was almost the same in both groups. From approximately 50 days after randomisation and onwards the RTW curves of the GA group and the UC group diverge with a more or less constant hazard ratio up to 299 days after randomisation. At that point there was an acceleration in RTW rate in the UC group caused by RTW of 7 workers in the UC group. In the GA group there were no more workers who returned to work after 277 days after randomisation. At 12 months of follow-up five workers in the GA group and eight workers in the UC group were still sick-listed and received a partial or full disability benefits payment.

Hazard ratios for RTW were calculated for the period up to 50 days after randomization and between 50 and 365 days after randomization by means of Cox regression analysis for repeated events, similar to the method reported in a previous paper.\textsuperscript{15} For the period up to 50 days after randomization the calculated hazard ratio was 1.0 (95% CI: 0.6 to 1.8, p = 0.99). For the period from 50 days after randomization and onwards the hazard ratio was 1.9 (95% CI: 1.2 to 3.1, p=0.01), in favour of the GA group. A per-protocol analysis, excluding the 3 non-compliant workers in the GA group who withdrew during the intervention period, showed even higher hazard ratio for this period from 50 days and onwards: 2.5 (95% CI: 1.5 to 4.1, p < 0.01), again in favour of the GA group.
Recurrences of sick leave due to LBP

A total of 30 workers, 14 in the GA group and 16 in the UC group, had one or more recurrent episodes of sick leave due to LBP. This difference between the two groups was not statistically significant (p=0.68). These recurrent episodes consisted of a total of 800 days in the GA group and 831 days in the UC group. The difference between the groups in the total number of days of sick leave due to these recurrent episodes of LBP over the entire 12-month follow-up period was not statistically significant (p = 0.75).
Table 1. Total and median number of days of recurrent episodes of sick leave due to LBP, due to other diagnoses, and due to LBP and other diagnoses together over 12-months follow-up.

<table>
<thead>
<tr>
<th></th>
<th>Graded Activity (n=67)</th>
<th>Usual Care (n=67)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Days of sick leave</td>
<td>Median (IQR)</td>
<td>Days of sick leave</td>
</tr>
<tr>
<td>LBP, including recurrences</td>
<td>6,589</td>
<td>67 (49–67)</td>
<td>9,446</td>
</tr>
<tr>
<td>Other diagnoses</td>
<td>2,376</td>
<td>15 (2–41)</td>
<td>2,016</td>
</tr>
<tr>
<td>LBP and other diagnoses together</td>
<td>8,965</td>
<td>93 (70-169)</td>
<td>11,462</td>
</tr>
</tbody>
</table>

Note: IQR = interquartile range

Total number of days of sick leave due to LBP and other diagnoses

Table 1 presents the total number and the median of days of sick leave over the 12-month follow-up period due to LBP, due to other diagnoses then LBP, and due all diagnoses together. The differences for all three comparisons between the GA group and the UC group were not statistically significant.

At 12 months follow-up after randomization, 5 workers in the GA group and 8 workers in the UC group had not fully returned to regular work, a difference that was not statistically significant (p=0.38).

Functional status and severity of pain

Table 2 presents the results for functional status and pain severity. The mean score on the RDQ and the mean score for pain severity decreased almost equally for both groups from the baseline to the 12 months of follow-up. There were no statistically significant differences in the improvement of these outcome measures between the groups.
Discussion

This paper describes the effects of a GA intervention for non-specific LBP, compared to UC during a 12-month follow-up period. The results confirmed a trend that was similar to that of the results at 3 and 6 months of follow-up: i.e. statistically significant effects with regard to RTW rate in favour of the GA group from approximately 50 days after randomization and onwards, and no differences between the groups in the improvement in functional status and pain severity. The fact that the improvement in functional status and pain severity did not differ between the groups, in contrast to the improvement of RTW rate in the GA group should be considered. Apparently, other factors than pain or functional status influence workers’ decisions to return back to work. In this RCT, both groups received equal attention from the OP as the number of consultation was not significantly different (p=0.16). There were also no other known factors that could account for a Hawthorne or placebo effect. We believe that shorter sick leave in the GA group is due to worker participation in scheduling of own RTW using practical knowledge of rehabilitation possibilities at the workplace. The cognitive behavioural structuring of the physiotherapy and time-contingency of the GA intervention may also be important factors in faster RTW.

The reduction in the total number of days of sick leave due to LBP over a 12-month follow-up period was quite substantial in the GA group compared to the UC group, however this difference was not statistically significant. The non-significant findings may be explained by the fact that this trial was underpowered for inherently skewed nature of sick-leave data. Nevertheless these results give an indication of the magnitude of a possible reduction of work absenteeism that can be achieved.

In the UC group there were less days of sick leave due to other reasons than LBP: i.e. 2,016 versus 2,376 days. This statistically non-significant difference in favour of the UC group could be explained by the greater

---

Table 2. Mean improvements in functional status and pain from baseline to 12-month follow-up.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Mean improvement ± SD (Number of participants)</th>
<th>Effect of Graded Activity (95%CI)*</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Graded Activity</td>
<td>Usual Care</td>
<td></td>
</tr>
<tr>
<td>Functional status †</td>
<td>7.3±6.0 (n = 60)</td>
<td>6.7±6.7 (n = 60)</td>
<td>-0.6 (-2.8 to 1.5)</td>
</tr>
<tr>
<td>Pain</td>
<td>2.9±3.1 (n = 60)</td>
<td>2.7±3.0 (n = 59)</td>
<td>-0.2 (-1.2 to 0.8)</td>
</tr>
</tbody>
</table>

* Adjusted for age, gender, duration of sick leave due to LBP before randomization, and partial or full sick leave at baseline.
† As measured by using Roland Disability Questionnaire
number of workers in the GA group who were at risk of becoming sick-listed due to other diagnoses than LBP. The RTW curve for the UC group showed a considerable increase in RTW approximately 300 days after randomization. This increase in RTW rate occurred near the end of the 52-week period, and the end of employer obligation to continue full wage payments. According to the Dutch Sickness Benefits Act and Disablement Benefits Act, wage replacement can be reduced to 70% of the original wage after 52 weeks of continued sick leave. The RTW acceleration in the UC group is probably because these workers wanted to avoid the negative social and financial consequences of decreased benefits.

Comparison of the results of the present trial with those of other studies is hampered by the fact that RCTs on the effects of this specific intervention for LBP in an work setting are scarce. The Swedish study carried out by Lindström et al. is the only RCT, as far as we know, that is comparable to this study with regard to treatment setting and content of the intervention. Lindström et al. found positive effects of the GA intervention on RTW after 2 years of follow-up in workers who were sick-listed due to LBP. Both the Swedish study and the present trial reported favourable results of a GA intervention on RTW, which may provide support that this type of RTW intervention is a valuable strategy to speed up the RTW of sick-listed workers with LBP. In other less comparable RTW interventions for sub-acute LBP, based on a mixture of exercise, education, behavioral treatment and ergonomic measures, interventions were also more effective than UC with respect to RTW.

Move data from this paragraph to results, but probably good to keep discussion here. In order to determine generalizability of findings within the KLM population regarding the first period of continuous sick-leave, trial data were compared with data of workers from the source population who had been on sick-leave for non-specific low back during the period of inclusion for the intervention, but who had not been referred to the trial because of various reasons (i.e. so-called ‘non-participants’). In total, it concerned 379 non-participants. These non-participants were comparable to the workers included in the trial regarding mean age (38 ± 8 versus 37 ± 8) and the number of days on sick leave prior to randomization (42 days). However, non-participants significantly differed (p<0.001) from those included in the trial regarding sex distribution (i.e. 6% females in the trial population versus 26% in the non-participants). Sick-leave data of the first period of continuous sick leave of these non-participants were retrieved from the automated sick-leave registry in an identical way as the sick-leave data from the workers participating in the trial. Subsequently sick-leave data of the first period of continuous sick leave of three groups
(i.e. both trial groups and the non-participants) were compared by means of survival analysis. The Kaplan Meier return-to-work curve for the non-participants (see figure 3) was almost identical to the return-to-work curve for the UC group (log-rank test: p=0.29). This suggests that the selection of workers who were eligible and willing to participate in the trial was not different with regard to RTW behaviour compared to the group of non-participants. Therefore, we believe that the results of the trial with regard to RTW may be generalizable to other KLM workers with non-specific LBP. The fact that the trial groups counted a smaller proportion of females (6% versus 26%) could be used as an argument against generalizability of the results to both sexes. However, sex-specific additional analysis of return-to-work data in the non-participants group showed statistically insignificant difference in this measure between the sexes (log-rank test; p=0.68), which supports the generalizability of the results of the trial to both male and female workers. As this trial and the study of Lindström et al. were both carried out within one single company, it remains uncertain whether the results can be generalized to occupational health care practice in various types and sizes of companies. In our opinion, however, there are some factors that are critical in the success of a GA intervention, such as the skills of the OP’s and the physiotherapists in treating patients, and effective communication between the OP’s and the different caregivers, and between the OP’s and the managers on the shop floor. Future researchers and policy-makers should consider these factors when studying, or when implementing this type of intervention in an occupational health care setting.

**Conclusion**

The GA intervention in comparison to UC resulted in a statistically significant speed up of initial RTW after 50 days of intervention for sick leave due to sub-acute LBP. The reduction in the number of days of sick leave due to LBP and due to other diagnoses was in favour of the GA intervention, but this reduction was statistically not significant. Factors that are critical for the success of the GA intervention should be taken into account when the intervention is implemented and these factors should be subject of future research.
Figure 3 Kaplan Meier curves for the usual care group (n = 67) and non-participants (n = 379)

Note: * Post randomization days of sick leave for usual care group, and days of sick leave excluding the first 42 days of sick leave for non-participants
Chapter 5

References
Substantial sick leave costs savings due to a graded activity intervention for workers with non-specific sub-acute low back pain.

Hlobil H, Uegaki K, Staal JB, de Bruyne MC, Smid T, van Mechelen W. Substantial sick leave costs savings due to a graded activity intervention for workers with non-specific sub-acute low back pain
Eur Spine J (2007) 16:919–924
Abstract

The objective of this study is to compare the costs and benefits of a graded activity intervention to usual care for sick-listed workers with non-specific low back pain. The study is a single blind, randomized controlled trial with 3-year follow-up. A total of 134 (126 men and 8 women) predominantly blue collar workers, sick-listed due to low back pain were recruited and randomly assigned to either graded activity (n=67; mean age 39 ± 9 years) or to usual care (n=67; mean age 37 ± 8 years). The main outcome measures were the costs of health care utilization during the first follow-up year and the costs of productivity loss during the second and the third follow-up year. At the end of the first follow-up year an average investment for the graded activity intervention of €475 per worker, only €83 more than health care utilization costs in usual care group, yielded an average savings of at least €999 (95% CI: -1073; 3115) due to a reduction in productivity loss. The potential cumulative savings were an average of €1661 (95% CI: -4154; 6913) per worker over a 3-year follow-up period. It may be concluded that the graded activity intervention for non-specific LBP is a cost-beneficial return-to-work intervention.
Introduction

Work-related low back pain (LBP) is usually a benign, self-limiting condition which resolves spontaneously within a few weeks. The incidence and prevalence of work-related LBP are particularly high in industries characterized by manual labor.2;4 In a small subset of workers, work-related LBP may result in extended periods of work-absenteeism and greater utilization of health care services, two consequences which have a significant socio-economic impact.2;7;18;19;24 The prevention of the occurrence of chronic LBP and the minimization of work-absenteeism is a common goal for workers, employers, policy makers and health care providers. Most economic evaluations have been performed from the societal perspective where all relevant costs are summed together without consideration for who actually pays. However, this approach has limited relevance for the company, where knowing who pays what is of critical interest and importance for decision-making.9;17;19;23 From the literature, it appears that the initiation of return-to-work interventions (RTW), such as graded activity (GA) during the sub-acute phase of LBP (4 – 6 weeks after the onset of work absenteeism) may be promising.5 For instance, the recent studies have shown that RTW interventions for sub-acute LBP are more effective in reducing short- and long-term absence from work than usual care (UC).6;8-11;15-17;22 However, the available information about the costs and benefits of such interventions is still limited. The aim of this study is to compare the long term costs and benefits of a GA intervention for sub-acute work-related LBP to UC from the perspective of the employer.

Methods

Study design

The study design, the content of the GA intervention and clinical outcomes have been reported in detail elsewhere.22 In short, the study was a single-blind, randomized controlled trial conducted at the Royal Dutch Airlines between April 1, 1999 and December 31, 2000. Sick-listed employees who had suffered LBP complaints for a minimum of 4 weeks were recruited by in-house occupational physicians and randomized by means of block randomization and stratification on the level of department to either UC or GA. All subjects received routine guidance from their occupational physician. In addition, the GA subjects followed twice a week a 60-minute physical exercise session with a cognitive behavioral approach under the
supervision of specifically trained physiotherapists. They stay on program until they fully returned to their previous duties, or until the maximum therapy duration of 3-months was reached. The UC subjects were permitted to seek and receive any type of treatment with the exception of a GA program.

Definitions and Data Collection

Sick-leave days, named as "lost productivity days (LPD)”, were used as a proxy measure of productivity loss. Recurrences were defined as partial or full sick-leave due to LBP following a full return to work for at least 28 calendar days. Disabled workers were those who were completely or partially sick-listed for more than 52 weeks. Baseline data included age, gender, job assignment, wage group, and the number of sick-leave days due to the present episode of LBP accumulated before randomization. During all follow-up years, the recurrences of LBP, the total number of sick-leave days as well as the number of disabled workers were obtained from the electronic database of the occupational services. The health care utilization data were collected by means of cost diaries during the first follow-up year.

Economic evaluation

HCU costs were estimated using the Dutch guidelines for cost analysis in health care research. The unit prices of treatments and medications, were derived from the available tariffs publications.\textsuperscript{1,3,20} The total LPD’s were quantified as gross and net ones. The number of gross LPD’s (GLPD) reflects the total number of calendar days that workers were completely or partially sick-listed. The partial LPD was counted for its percentage of work absence and expressed as net LPD’s (NLPD). The cost of LPD’s of each worker was calculated by multiplying the mean daily wage increased by an additional 80% for secondary benefits. The costs of NLPD’s were recalculated after correction for a possible 25% or 50% decrease in productivity, because of the possibility that the workers may perform at a lower level than usual when they were partially recovered or were working in reassigned duty or in therapeutic position.

Data Analysis

Non-cost data were analyzed using SPSS (version 11.0; SPSS Inc., Chicago, Ill).
The economic evaluation was performed according to the intention-to-treat principle. The HCU costs, and lost productivity costs were analyzed using a bias-corrected and accelerated bootstrapping method with 2000 replications. The mean costs of HCU were analyzed for the entire study population after imputation of missing data via the hot deck method and after interpolation for non-observed months.\textsuperscript{21}

**Results**

**Subjects**

During the 21-month enrollment period, 150 workers were eligible to participate in the study. Ultimately, 134 employees were randomized to either usual care (N = 67) or graded activity (N = 67). During the second follow-up year three subjects and in the third year another two subjects left the company and were lost to follow-up (Figure 1).

**Baseline measurements**

As reported in detail elsewhere, there were no relevant between-group differences with respect to age, gender or job, nor in the mean number of GLPD’s and NLPD’s prior to randomization.\textsuperscript{22}

**Health care utilization**

The return rate of the cost diaries was 84\% and there were 93 workers who returned all diaries (UC = 46; GA = 47). Non-responders did not significantly differ from responders in terms of baseline characteristics. The HCU data during the first year of follow-up are presented in Table 1. During the first three months, the GA subjects received significantly (p=0.001) more physiotherapy than the UC. GA subjects attended an average of 13 GA sessions of one hour duration, which is an equivalent to 26 (S.D. = 11) standard physiotherapy sessions of 30 minutes. UC subjects attended on average 9 (S.D. = 9) standard physiotherapy sessions. However, in the subsequent months, the UC subjects attended a larger number of physiotherapy sessions, and by the end of the 12-month follow-up period, the difference between the groups was no longer significant.

The mean difference in the number of GLPD’s at each follow-up period was in absolute number of days in favour of the GA group. A similar pattern was observed for the NLPD’s (Table 2). During the three-year follow-up
69% of UC subjects and 67% of GA subjects suffered a recurrence of work absenteeism due to LBP. None of these differences was statistically significant.

**Work-disabled employees**

In the first follow-up year, thirteen subjects (GA = 5; UC = 8) were deemed work-disabled due to LBP. By the end of the second follow-up year one additional worker from the GA group became work disabled. By the end of the third follow-up year the total number of work disabled subjects had decreased to 11 (GA = 5; UC = 6) as one subject had found a higher paying position within the company, and two subjects had left the company and were lost to follow-up.

**Cost-benefit analysis**

The mean differences in HCU costs between groups were similar for complete case analysis and imputed case analysis. Therefore, only the results of the latter will be reported.

The mean total cost of the GA intervention was € 475. During the first three months of follow-up, the HCU costs were higher in the GA than in the UC. In the same period, the UC group has spent less on physiotherapy and more on other medical services. At the end of the first year the average between-group difference in HCU costs was € 83 (95% CI: −467 to 251) lower in the UC, but not statistically significant (Table 3).
Figure 1. Flow chart of the participants and dropouts during the three-year follow-up period

Source population (25,000)*

Sick-listed (2,550) for at least 1 day due to LBP in the period from April 1, 1999 to December 31, 2000

Specific LBP or radicular syndrome (129)

Non-specific LBP (2,421)

Fulfilled inclusion criterions and were randomized (134)

Allocated to Graded Activity (64 ♂; 3 ♀)
Received Graded Activity (64)
• Not compliant with treatment (3)

Allocated to Usual Care (62 ♂; 5 ♀)
• Received Usual Care (67)

Data available at 1st follow-up year:
• Sick leave data (67)
• 1-3 month cost diary (56)
• 6th month cost diary (55)
• 12th month cost diary (58)
• All 3 cost diaries (46)

Follow-up 12 – 24 months
• Sick leave data (65)
• Left company (2)

Follow-up 24 – 36 months
• Sick leave data (65)

Data available at 1st follow-up year:
• Sick leave data (67)
• 1-3 month cost diary (59)
• 6th month cost diary (54)
• 12th month cost diary (57)
• All 3 cost diaries (47)

Follow-up 12 – 24 months
• Sick leave data (66)
• Left company (1)

Follow-up 24 – 36 months
• Sick leave data (64)
• Left company (2)

*Between parentheses: number of workers. Lost productivity days and recurrences

Substantial sick leave costs savings
Table 1. Health care utilization (number of consultation, examinations or medications) during the first follow-up year.

<table>
<thead>
<tr>
<th></th>
<th>General Practitioner</th>
<th>Occupational physician</th>
<th>CT scans or MRI scans</th>
<th>X-ray of lumbar back</th>
<th>Physiotherapy or paramedical sessions</th>
<th>Specialist</th>
<th>Alternative therapist</th>
<th>Pain medication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Graded activity (n = 67)</td>
<td>2.2 (4.1)</td>
<td>3.9 (3.5)</td>
<td>0.2 (0.9)</td>
<td>0.5 (1.8)</td>
<td>35.1 (21.9) a</td>
<td>0.3 (1.2)</td>
<td>0.7 (4.2)</td>
<td>1.2 (2.1)</td>
</tr>
<tr>
<td>Usual care (n = 67)</td>
<td>4.5 (6.9)</td>
<td>4.8 (4.1)</td>
<td>0.03 (0.2)</td>
<td>0.4 (1.3)</td>
<td>27.6 (48.7)</td>
<td>0.3 (0.9)</td>
<td>1.4 (5.6)</td>
<td>1.6 (2.6)</td>
</tr>
<tr>
<td>P-value b</td>
<td>0.008</td>
<td>0.16</td>
<td>0.22</td>
<td>0.86</td>
<td>0.25</td>
<td>0.94</td>
<td>0.38</td>
<td>0.32</td>
</tr>
</tbody>
</table>

a One 60-minute Graded Activity session is an equivalent to two standard 30-minute physiotherapy sessions
b ANOVA, level of significance P < 0.05

Table 2. Mean difference between GA group and UC group of gross and net lost productivity days and costs during 3 years of follow-up.

<table>
<thead>
<tr>
<th>Follow-up period</th>
<th>Quantification</th>
<th>Mean difference of lost productivity days GA-UC, (95% CI)</th>
<th>Mean difference of costs of lost productivity in 1999 EURO GA – UC, (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>First year (N = 134)</td>
<td>Net</td>
<td>9.1 (-14.8 – 31.5)</td>
<td>999 (-1,073 – 3,115)</td>
</tr>
<tr>
<td></td>
<td>Gross</td>
<td>40.4 (4.7 – 78.8)</td>
<td>3655 (157 – 6,933)</td>
</tr>
<tr>
<td>Second year (N = 131)</td>
<td>Net</td>
<td>-1.1(-24.6 – 24.5)</td>
<td>118 (-2,079 – 2,541)</td>
</tr>
<tr>
<td></td>
<td>Gross</td>
<td>12.1(-27.6 – 49.7)</td>
<td>1522 (-2,315 – 5,126)</td>
</tr>
<tr>
<td>Third year (N =129)</td>
<td>Net</td>
<td>2.8 (-15.6–20.7)</td>
<td>467 (-1,173 – 2,207)</td>
</tr>
<tr>
<td></td>
<td>Gross</td>
<td>13.3 -24.7 – 50.1</td>
<td>1685 (-1,673 – 5,623)</td>
</tr>
<tr>
<td>Cumulative (N = 134)</td>
<td>Net</td>
<td>12.0 (-50.2-64.9)</td>
<td>1661 (-4,154 – 6,913)</td>
</tr>
<tr>
<td></td>
<td>Gross</td>
<td>79.2 (-23.8-192.3)</td>
<td>7581 (-3,262 – 17,348)</td>
</tr>
</tbody>
</table>
Table 3. Mean HCU costs, in 1999 Euros, and between group differences during the first 3-months of follow-up and entire first year

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>Group</th>
<th>Mean GA intervention cost ± SD</th>
<th>Mean physiotherapy cost ± SD</th>
<th>Difference in intervention costs (UC-GA)</th>
<th>Mean other medical cost ± SD</th>
<th>Difference in other medical costs</th>
<th>Mean total health care costs ± (SD)</th>
<th>Mean difference of total health care costs (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-months</td>
<td>GA</td>
<td>475 ± 203</td>
<td>0</td>
<td>- 307</td>
<td>26 ± 62</td>
<td>44</td>
<td>501 ± 215</td>
<td>- 263 (-346 - -172)</td>
</tr>
<tr>
<td></td>
<td>UC</td>
<td>0</td>
<td>168 ± 169</td>
<td></td>
<td>69 ± 89</td>
<td></td>
<td>238 ± 218</td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>GA</td>
<td>#</td>
<td>631 ± 396</td>
<td>- 151</td>
<td>168 ± 391</td>
<td>67</td>
<td>800 ± 680</td>
<td>- 83 (-467 - -251)</td>
</tr>
<tr>
<td></td>
<td>UC</td>
<td>0</td>
<td>481 ± 877</td>
<td></td>
<td>236 ± 324</td>
<td></td>
<td>716 ± 1,096</td>
<td></td>
</tr>
</tbody>
</table>

SD = Standard deviation; CI = Bootstrapped 95% Confidence Interval
GA = Graded Activity; UC = Usual Care
#Included in total cost of physiotherapy interventions

Substantial sick leave costs savings 105
At the end of the first follow-up year the gross mean cost difference based on GLPD’s and the net mean cost difference in terms of NLPD’s was in favour of the GA group, i.e. € 3655 (95% CI: 157-6933) and € 999 (95% CI: -1073 to 3115), respectively. This direction of the between-group difference was maintained in the second and third follow-up years as well, but it was not statistically significant. The costs of productivity loss were the main cost driver in this study with 87% and 90% of the total net costs in GA and UC group, respectively.

Sensitivity analysis

The recalculation with a 25% and 50% decrease in work performance in the first follow-up year, resulted in an increase in the mean difference in costs between the GA and UC from € 999 to € 1663 and € 2327 in favour of the GA group for a 25% and 50% decrease in work performance, respectively. Comparable findings were observed for the second and third follow-up years.

In the first follow-up year an average investment in the GA intervention of € 475 (SD 203) per worker yielded a savings of € 999 (95% CI: -1073;3115) due to a reduction in productivity loss. Over a three-year period, the potential saving was calculated at an average of €1661 (95% CI: -4154;6913) per worker. When the first year difference in HCU costs between the groups is considered, an additional expenses to GA intervention of € 83 (95% CI: -467;251) resulted in the aforementioned savings on sick leave benefits.

Discussion

Although the general direction of the cost-benefit findings in this study was robust and constantly in favour of the intervention group over all follow-up years and the GA group returned significantly faster back to work, the mean cost differences were not statistically significant. This is a common problem in trials which are underpowered for skewed data distribution such as costs of health utilization or productivity loss. The study was performed within a single company and the majority of the subjects were male, blue-collar workers. These factors should be taken in account when one will generalize the findings to other work situation. We used sick-leave days as a proxy measure for productivity loss. However, it is not clear how accurately this proxy measure reflects true production losses. First of all, the actual level of production loss may be influenced by the type of compensation mechanisms that exist within a job title. For example, work normally performed by the absent employee
may be completed by colleagues, or made up upon RTW during usual working hours. In such a situation, the absenteeism of the employee would not lead to productivity loss and therefore, should not be considered a cost. In this study, the majority of employees had service-related jobs, e.g. airplane maintenance technicians, pilots, baggage handlers, where the possibility of postponing production until later or “doing more with less” were not viable options. Furthermore, the way in which productivity loss costs are estimated can lead to quite different results. In our study, we estimated productivity loss costs in four different ways: gross, net, and with an assumption of either 25% or 50% decreased work performance. The gross estimation is likely to be an overestimation as workers who return to their original duties on a part-time basis, or who perform alternative job tasks, conduct work in some format. On the other hand, the net cost estimation may be an underestimation as workers who are still not fully recovered may not be 100% productive. The sensitivity analysis in which a 25% or 50% decrease in work performance was assumed, albeit arbitrarily, takes this into consideration. This inaccuracy of lost productivity estimation could be partially solved by the use of recently developed questionnaires for measuring health-related work performance.13;14

There are only few published cost-benefit and/or cost-effectiveness evaluations of RTW interventions for sub-acute LBP. Loisel et al. demonstrated that an occupational intervention in combination with participatory ergonomics and multidisciplinary work rehabilitation were cost-beneficial and cost-effective at mean follow-up of 6.4 years.17 Gatchel et al. showed that an early intervention program for workers who were at high risk for developing chronic LBP significantly reduce the number of work disability days and the total costs at 12 months follow-up.6 Recent Finnish research by Karjalainen et al. disclosed a reduction in the total number of sick leave days and total costs for workers who experienced hinder at their work due to sub-acute LBP and who participated in a mini-intervention when compared to UC.12 The findings of our study that a RTW intervention for sub-acute LBP is cost-beneficial, although not statistically significant, in comparison to UC are in accordance with these studies. The results suggest that GA is associated with a positive return on investment and this study provides a framework for further research. Such future research should not only concentrate on the evaluation of more trials, but also on further developing of methodology of economic evaluation for practical use by employers, occupational services and also by workers.
Conclusions

The GA intervention for non-specific LBP may be a cost-beneficial RTW intervention from the employer’s point of view. This intervention was marginally more expensive than UC, while benefits were substantial and remained noticeable 3 years after the initial intervention. The costs of health utilization were only a fraction of the total cost of the LBP in the working population and the economic burden of productivity loss was the main cost driver.
Substantial sick leave costs savings

Reference list


Can we predict the duration of work absence due to low back pain

Hlobil H, Schellart TJM, Staal JB, Smid T, van Mechelen W
Submitted
Abstract

Objective: To identify ‘easy to obtain’ prognostic variables for return to work (RTW) at different stages of work absenteeism.

Methods: The population at risk consisted of 28,124 airline employees. The LBP cohort included 2,445 airline workers who reported unfit for their work due to an episode of LBP during a period of 21 months. This LBP cohort was followed up for one year after inclusion. Work absence data due to LBP and data on prognostic factors were collected from routine databases. Prognostic models were built for different time strata of work absence.

Results: The incidence of work absenteeism due to LBP in the population at risk varied between 4.2% for women to 7.3% for men. Within 28 days, 66% of the workers had returned to work and within 91, 182 and 273 days these RTW percentages had increased to 84%, 91% and 94%, respectively. Cox regression analysis showed that seven variables predicted an earlier RTW within twelve months: 1) male sex, 2) non-specific nature of LBP, 3) age 4) no work relatedness of LBP, 5) no history of LBP absenteeism, 6) a higher wage and 7) white collar occupation. However, the basic model explained only 10% of the variance (pseudo-$R^2$) of RTW.

Conclusions: Work absence due to non-specific LBP has a good prognosis. The prognostic model constructed from routinely collected data has a too low explained variance for easy day to day use. It should be expanded with more variables or clinical factors.
Introduction

Low back pain (LBP) is one of the leading causes of work absence and work disability, especially in workers performing unskilled manual tasks. The prevalence of LBP and associated sick-leave is highest in non-sedentary occupations and in the older age categories. The annual prevalence of LBP in the general population is estimated between 22% and 65%, and the life-time prevalence ranges from 11% to 84%. The annual incidence of LBP in the general population is estimated between 4% and 20%, and it is dependent on age and physical demands of the job and history of previous LBP. The incidence of work absence due to LBP usually does not exceed 10%. The majority of workers, about 90%, will return to work within a few days to 6 weeks. However, the workers remaining off work after 3 months are at high risk for prolonged work-disability and they are responsible for large scale losses of productivity. A small proportion of workers with long-term absenteeism accounts for the majority of workers compensation costs and some of them become even permanently disabled for work. The total costs of LBP are for about 90% determined by non-medical expenses, related to costs of work absence and disability. Identifying workers who are at risk for a prolonged work absence is therefore essential for effective disability management and for reduction of the total expenses connected to LBP.

The purpose of this study is to investigate the natural course of work absence due to LBP and to identify prognostic factors for return to work at different stages of work-absence. These stages represent natural milestones in the return to work process supervised by the occupational health physician (OP), who has to assess the prognosis for return to the original job or to advice replacement into a fitting job. Second purpose is to construct a prognostic model, based on variables which are easy to obtain from standard data, collected for human resources management purposes or for sick-leave database purposes.

Methods

The study population and the LBP cohort.

The study population consisted of 28,124 workers (16,528 men, 11,596 women) of Dutch airlines ground and flying staff based in the Netherlands and receiving occupational health care form the occupational health services (OHS). The mean age (S.D.) was 39 (9), 34 (8), 37 (8) years for
men, women and the total group, respectively. The LBP cohort included 2,445 workers who reported unfit for own work because of LBP with or without sciatica for at least one day during the observation period between the 1st of April 1999 and 31st of December 2000. There were 67 workers excluded from this group, because of their simultaneous participation in a graded activity intervention as part of an ongoing randomized controlled trial. The diagnosis was recorded into a database of the OHS as ICPC codes: L02 Back symptom, L03 Low back symptom, L84 Back syndrome without radiating pain, L86 Back syndrome with radiating pain. The work relatedness of the LBP was recorded also in this database. The workers’ absenteeism was followed up during a twelve months period, starting with the first day of work-absence. Work-absence due to LBP in the period of the twelve months preceding entry into the study was retrospectively retrieved from the sick-leave database. The data on other potential prognostic factors, including age and gender, were supplemented from the human resources database. White-color workers were defined as workers performing no physical tasks. All other workers were classified as blue collar workers. Relatively low wage was considered a wage lower than a mean gross salary of 1890 €, which was earned by 65% of workers. In order to detect the potential contributing significance of the duration of employment as a prognostic factor for RTW employment cycles of 9 years were defined. The distance between work and home was divided in 5 categories: less than 14 km, between 14 and 20, between 21 and 25 kilometer, between 36 and 54 and more than 54 kilometers in order to study a relationship of the distance to work and RTW. Front office employees were those in direct contact with the public. Part-time employees were those working less than 80% of regular working hours. The primary outcome variable in this study was the number of calendar days of work-absence due to LBP, until full return to the original work during the follow-up period.

**Statistics**

To estimate the rate of occurrence of LBP in the population at risk we used incidence density which, was calculated as the number of new cases of LBP during a 21 months follow-up period divided by the number of person-years at risk.

A Kaplan-Meier survival analysis was used to describe the probability of a full RTW. Statistically significant prognostic factors (P<0.05) for RTW were identified by an univariate log-rank test and included in a model. Backward stepwise regression analysis based on Cox proportional hazard model was applied to these variables, in order to identify statistically sig-
significant prognostic factors. Interaction terms were added to determine whether the model could be improved. This procedure was performed separately for subjects remaining on work-absence for longer than 1 day, 4, 13, 26 and 39 weeks, respectively. The choice of these time points is given by the fact that they can be seen as milestones, because at these time points, by legislation, the prognosis for RTW has to be assessed and reported to the employer, or to the Dutch social security institution. The stability of the final Cox regression model was examined by means of a bootstrap test with 1000 replications. In order to describe the sensitivity and specificity of the model, the ROC curve was constructed. At last, multiple logistic regression was applied to the model in order to identify prognostic factors for RTW after 4, 13, 26 and 39 weeks of follow-up.

Results

The basic characteristics of the LBP cohort, the prognostic variables and the incidence density are given in Table 1 and Table 2. The LBP complaints reported in this study consisted for 95% of non-specific LBP and for only 5% of nerve-root-pain. There were no cases of specific LBP complaints, such as metastasis to the lumbar vertebra, fractures or inflammation of the spine.

The one year incidence of work-absence due to LBP in the entire population at risk varied between 4.2% for women to 7.3% for men, with a mean of 6.2% for both sexes. The incidence was highest with 9.7% for blue-collar workers (9,521 men and women). The incidence in the white-collar workers group (18,603 men and women) was 4.2%.

During the follow-up period of one year 80.1% workers of LBP cohort did not show any recurrence of work absence due to LBP, while 22.2% of men and 13.0 % of women encountered one or more recurrent episodes of work-absence due to LBP.
### Table 1. Characteristics of 2445 workers sick-listed with LBP

<table>
<thead>
<tr>
<th>Return-to-work and prognostic variables</th>
<th>Mean (SD)</th>
<th>Median</th>
<th>% of 1st state*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Work absence duration in calendar days (1-364)</td>
<td>53.50 (88.61)</td>
<td>15.00</td>
<td></td>
</tr>
<tr>
<td>Work status after one year (1=not at work, 2= at work)</td>
<td></td>
<td></td>
<td>3.4</td>
</tr>
<tr>
<td>Gender (1=male, 2=female)</td>
<td></td>
<td></td>
<td>75.3</td>
</tr>
<tr>
<td>Age male, years</td>
<td>39.7 (8.2)</td>
<td>38.80</td>
<td></td>
</tr>
<tr>
<td>Age Female, years</td>
<td>35.99 (8.24)</td>
<td>34.68</td>
<td></td>
</tr>
<tr>
<td>Years in services</td>
<td>12.19 (8.34)</td>
<td>8.08</td>
<td></td>
</tr>
<tr>
<td>Years in service (1=0-8, 2=9-17, 3=18-26, 4=&gt;26)</td>
<td>1.97 (0.91)</td>
<td>2.00</td>
<td></td>
</tr>
<tr>
<td>Mean gross wage, €</td>
<td>2229 (1939)</td>
<td>1715</td>
<td></td>
</tr>
<tr>
<td>Mean gross wage (1&lt; € 1890, 2≥ € 1890)</td>
<td></td>
<td></td>
<td>65.1</td>
</tr>
<tr>
<td>Part-time/fulltime work (1=part-time, 2 = fulltime)</td>
<td></td>
<td></td>
<td>15.9</td>
</tr>
<tr>
<td>White/blue collar work (1=white, 2=blue)</td>
<td></td>
<td></td>
<td>26.4</td>
</tr>
<tr>
<td>Distance home to work</td>
<td>33.99 (28.89)</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>Distance home to work in km (1=&lt;14, 2=14-20, 3=21-35, 4=36-54, 5=&gt;54)</td>
<td>2.98 (1.29)</td>
<td>3.00</td>
<td></td>
</tr>
<tr>
<td>Back/front office (1=back, 2=front)</td>
<td></td>
<td></td>
<td>68.4</td>
</tr>
<tr>
<td>Non-specific LBP (1=non-specific, 2=root pain)</td>
<td></td>
<td></td>
<td>94.8</td>
</tr>
<tr>
<td>Work relatedness of LBP (1=no, 2=yes)</td>
<td></td>
<td></td>
<td>91.8</td>
</tr>
<tr>
<td>History of LBP complaints (1=no, 2 =yes)</td>
<td></td>
<td></td>
<td>93.1</td>
</tr>
</tbody>
</table>

* Only for dichotic variables

### Table 2. Characteristics of population at risk (n = 28,105 workers) and incidence of work

<table>
<thead>
<tr>
<th>Population at risk</th>
<th>Mean age ± SD</th>
<th>Time at risk</th>
<th>Non-specific LBP</th>
<th>Nerve root pain</th>
<th>Year Incidence LBP (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men (16,516)</td>
<td>39.0 ±9.16</td>
<td>26,673</td>
<td>1,806</td>
<td>90</td>
<td>7.11</td>
</tr>
<tr>
<td>Female (11,589)</td>
<td>34.1 ±8.22</td>
<td>18,356</td>
<td>569</td>
<td>37</td>
<td>3.30</td>
</tr>
<tr>
<td>Total (28,105)</td>
<td>37.0 ±9.11</td>
<td>45,030</td>
<td>2,375</td>
<td>127</td>
<td>5.56</td>
</tr>
</tbody>
</table>
The natural course of work-absence due to LBP

The Kaplan Meier curve in Figure 1 illustrates the natural course of LBP absenteeism due to LBP in men and women. Within 28 days, 66% of the workers had returned to work and within 91, 182 and 273 days these percentages had increased to 84%, 91% and 94%, respectively (see Table 2). At the end of the follow-up period 3.4% of workers had not fully returned to work and consequently they were entitled by law to a partial or full disability benefit. The duration of work-absence for all workers was skew-distributed, with a mean of 51 days (95% CI: 52; 59) and a median of 16 days (95% CI: 15; 17). The natural courses of work-absence due to non-specific LBP and due to nerve-root-pain were significantly different for the entire one year follow-up period. Comparison of these two diagnoses revealed that the workers sick-listed due to non specific LBP demonstrated a significant earlier RTW in the first three months than the workers sick-listed due to nerve-root-pain. However, after 182 days the RTW rate in the remaining nerve-root-pain group was significantly higher than that in the non specific LBP group (Figure 2 and Table 3).

Figure 1. Natural course of sick-leave due to LBP for 1,896 men (M) and 606 women (W)
Figure 2. Kaplan Meier plots for non-specific LBP and nerve root pain. The first chart shows a RTW of all workers during 12 months follow up period. The second chart shows RTW of 219 workers who are still off work for more than 182 days.
Table 3. Results of Log Rank test of Kaplan-Meier analysis for different time periods.

<table>
<thead>
<tr>
<th>Prognostic factor</th>
<th>df</th>
<th>0 tot 365 days (n = 2445)</th>
<th>28-365 days (n = 861)</th>
<th>91-365 days (n = 388)</th>
<th>182-365 days (n=219)</th>
<th>273-365 days (n=151)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>LR</td>
<td>P</td>
<td>LR</td>
<td>P</td>
<td>LR</td>
</tr>
<tr>
<td>Gender (male)</td>
<td>1</td>
<td>0.03</td>
<td>.86</td>
<td>0.6</td>
<td>.46</td>
<td>5.4</td>
</tr>
<tr>
<td>Non specific LBP</td>
<td>1</td>
<td>77.8</td>
<td>.00</td>
<td>7.4</td>
<td>.01</td>
<td>5.0</td>
</tr>
<tr>
<td>Age</td>
<td>3</td>
<td>9.31</td>
<td>.03</td>
<td>4.3</td>
<td>.23</td>
<td>0.7</td>
</tr>
<tr>
<td>No work relatedness</td>
<td>1</td>
<td>106.6</td>
<td>.00</td>
<td>9.3</td>
<td>.00</td>
<td>2.8</td>
</tr>
<tr>
<td>No LBP history</td>
<td>1</td>
<td>17.9</td>
<td>.00</td>
<td>4.7</td>
<td>.03</td>
<td>6.2</td>
</tr>
<tr>
<td>White-collar worker</td>
<td>1</td>
<td>15.7</td>
<td>.00</td>
<td>0.3</td>
<td>.59</td>
<td>4.2</td>
</tr>
<tr>
<td>Low salary</td>
<td>1</td>
<td>12.8</td>
<td>.00</td>
<td>3.1</td>
<td>.08</td>
<td>3.6</td>
</tr>
<tr>
<td>Employment cycles</td>
<td>6</td>
<td>17.2</td>
<td>.01</td>
<td>7.4</td>
<td>.29</td>
<td>9.1</td>
</tr>
<tr>
<td>Home – work distance</td>
<td>6</td>
<td>13.2</td>
<td>.04</td>
<td>3.1</td>
<td>.80</td>
<td>5.8</td>
</tr>
<tr>
<td>Front office tasks</td>
<td>1</td>
<td>6.1</td>
<td>.01</td>
<td>1.3</td>
<td>.26</td>
<td>2.7</td>
</tr>
<tr>
<td>Part-time employment</td>
<td>1</td>
<td>0</td>
<td>.98</td>
<td>0.4</td>
<td>.51</td>
<td>0.2</td>
</tr>
</tbody>
</table>

Prognostic factor speeds up RTW if statistically significant (full return to work is the event)
n = number of participants on sick-leave at the beginning of the period
df = degree of freedom; LR = Log rank test, P = P value
Table 4. Results of Cox proportional hazard regression analysis for duration of work absence at different work absence periods.

<table>
<thead>
<tr>
<th>Prognostic factors</th>
<th>Work absence period</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0 to 365 days (n = 2445)</td>
</tr>
<tr>
<td></td>
<td>HR</td>
</tr>
<tr>
<td>Gender - male</td>
<td>1.23</td>
</tr>
<tr>
<td>Non specific LBP</td>
<td>2.46</td>
</tr>
<tr>
<td>Older age</td>
<td></td>
</tr>
<tr>
<td>19-30 years</td>
<td>1.30</td>
</tr>
<tr>
<td>30-40 years</td>
<td>1.19</td>
</tr>
<tr>
<td>40-50 years</td>
<td>1.19</td>
</tr>
<tr>
<td>No LBP work relatedness</td>
<td>2.22</td>
</tr>
<tr>
<td>No LBP history</td>
<td>1.43</td>
</tr>
<tr>
<td>White-collar occupation</td>
<td>1.17</td>
</tr>
<tr>
<td>Low salary</td>
<td>0.88</td>
</tr>
<tr>
<td>Employment duration</td>
<td></td>
</tr>
<tr>
<td>0-9 years</td>
<td></td>
</tr>
<tr>
<td>9-18 years</td>
<td></td>
</tr>
<tr>
<td>18-26 years</td>
<td></td>
</tr>
</tbody>
</table>

Return to work = event; CI = Confidence Interval, HR = Hazard Ratio; n = number of workers on work absence at the beginning of the period; Only statistically significant results are displayed.
Table 5. Results of multivariate logistic regression analysis for different time periods.

<table>
<thead>
<tr>
<th>Prognostic factors</th>
<th>Work absence more than 28 days</th>
<th>Work absence more than 91 days</th>
<th>Work absence more than 182 days</th>
<th>Work absence more than 273 days</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR</td>
<td>CI</td>
<td>P-value</td>
<td>OR</td>
</tr>
<tr>
<td>Gender – male (1)</td>
<td>0.64</td>
<td>0.51;0.81</td>
<td>.00</td>
<td>0.55</td>
</tr>
<tr>
<td>Non specific LBP (1)</td>
<td>0.08</td>
<td>0.05;0.13</td>
<td>.00</td>
<td>0.09</td>
</tr>
<tr>
<td>No LBP work related- ness (1)</td>
<td>0.15</td>
<td>0.10;0.21</td>
<td>.00</td>
<td>0.19</td>
</tr>
<tr>
<td>No LBP history (1)</td>
<td>0.49</td>
<td>0.35;0.68</td>
<td>.00</td>
<td>0.49</td>
</tr>
<tr>
<td>White-collar worker (1)</td>
<td>0.80</td>
<td>0.64;0.99</td>
<td>.04</td>
<td></td>
</tr>
<tr>
<td>Low salary (1)</td>
<td>1.35</td>
<td>1.09;1.69</td>
<td>.01</td>
<td>1.63</td>
</tr>
<tr>
<td>Distance home to work &gt;55 km</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-13 km (1)</td>
<td>1.64</td>
<td>1.17;2.29</td>
<td>.00</td>
<td></td>
</tr>
<tr>
<td>14-20 km (1)</td>
<td>1.28</td>
<td>0.94;1.76</td>
<td>.12</td>
<td></td>
</tr>
<tr>
<td>21-35 km (1)</td>
<td>1.34</td>
<td>0.99;1.82</td>
<td>.06</td>
<td></td>
</tr>
<tr>
<td>36-54km (1)</td>
<td>1.17</td>
<td>0.85;1.61</td>
<td>.33</td>
<td></td>
</tr>
<tr>
<td>Age &gt; 50 years</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19-30 years (1)</td>
<td>0.62</td>
<td>0.40;0.97</td>
<td>.038</td>
<td>0.55</td>
</tr>
<tr>
<td>30-40 years (1)</td>
<td>0.64</td>
<td>0.45;0.91</td>
<td>.014</td>
<td>0.63</td>
</tr>
<tr>
<td>40-50 years (1)</td>
<td>0.63</td>
<td>0.43;0.93</td>
<td>.019</td>
<td>0.57</td>
</tr>
</tbody>
</table>

Return to work = event; OR = Odds ratio; CI = 95% confidence interval
Prognostic factors

The Kaplan Meier analysis revealed that nine of the eleven variables were statistically significant and added to the model: i.e. type of LBP, age, work relatedness of LBP, history of LBP, white- or blue-collar occupation, wage, duration of employment, distance home to work, working in back or front office (Table 3). The variable gender was added to the model although it was not statistically significant: according to the literature gender is an important predictive variable for LBP. Cox proportional hazard analysis of these variables was performed using the duration of work-absence as the dependent variable and RTW (to all duties in own work) as the event. This multivariate analysis showed that seven variables independently predicted an earlier RTW within twelve months: 1) male, 2) non-specific LBP, 3) lower age than 50 years, 4) no work relatedness of LBP 5) no history of LBP absenteeism, 6) a higher wage and 7) white-collar occupation (see Table 4).

Analysis of interaction terms revealed that the factor nerve-root-pain was time-dependent and that stratification for non-specific LBP and nerve-root-pain gave some improvement of the model. This basic model explained only 10% of the variance (pseudo-R2) of the outcome variable. The internal validity of the basic model was evaluated by means of a bootstrap procedure. We used 1000 bootstrap runs with all eleven prognostic variables. This analysis revealed that in 44% of all runs all 10 variables from the basic model were jointly significant. On average, seven variables of the basic model appeared in 90% bootstrapped models. The stability and the significance of the estimated coefficients of the basic model were tested by using 1000 bootstrap runs as well. The bootstrapped coefficients were equal or even stronger than the values of the coefficients in the basic model. The value of the coefficients for the area under the curve in the bootstrap procedure and its confidence interval were almost identical to that in the basic model (AUC 0.68; 95% CI: 0.61; 0.74). These results imply that the internal validity of the basic model is good.

The logistic regression analysis showed that eight variables were significantly associated with continuation of work-absence in one or more of the respective time period (see Table 5). Gender (male), non specific LBP, no work relatedness of LBP, no history of LBP in the previous year and white-collar occupation gave a significantly higher chance of RTW after four weeks of work-absence, and lower salary and home-work distance shorter than 13 kilometers had an opposite effect. After three months of work-absence the odds ratio’s (OR) for two variables, i.e. white-collar worker and home-work distance, were not significant any more and after six
Can we predict the duration of work absence

months the variables gender and lower salary had turned into non significant variables. The variable non-specific LBP and no work relatedness of LBP remained significant for all time periods, but the OR’s were getting gradually weaker. The variable history of LBP in previous year remained significant also, with a stable OR during the respective time periods. Workers older than 50 years had a significantly higher chance to stay on work-absence for longer than 3 and 6 months.

Discussion

The natural course of work absence due to LBP

The incidence of work absence due to LBP has been reported in several studies. 1;13;23-26 Our results are similar to results found by Watson et al. who has reported a year incidence of work-absence due to LBP of 5.6%.9 Watson included, comparable to our study, the cases from the very beginning of work-absence unlike many studies on insurance data, which usually include cases after two or more weeks of work absence. The incidence rate of work absence due to LBP in our study may have been influenced by two situations. We may have missed some cases of a short-term work-absence on the one hand. But on the other hand we included cases where LBP has become a complaint of convenience for people who are disabled for other than a medical reason. 27 A higher incidence of LBP of blue collar workers was also observed in several other studies. 1;13 A higher physical work load of blue collar workers is probably accountable for developing LBP. 28;29 The incidence of LBP work-absence is usually higher for men, but there are some exceptions. For example, Hagen found a higher incidence for women in her study, and explained this by recent growing participation of women on labor market, accompanied by an initial healthy worker effect. 25 With respect to the duration of work absence we refer to the studies of Hashemi and Watson, who followed the LBP work-absence from the first day of work-absence.9;26 Within one month between 83% and 89% of the workers had returned to work. After three months of follow-up these percentages were between 88% and 90% and after 6 months was the rate between 90% and 92%. The study of McIntosh showed similar results: about 12% of the claimants received benefits longer than 6 months.30 In the studies of Hashemi, Watson and McIntosh the RTW rate after 12 months was 93%, 95% and 97% respectively.9;26;30 Based on these studies and on our results, it seems that the natural course of work absence
has not been changed significantly during the last two decades.\textsuperscript{9;13;24-26}

**Prognostic model for RTW**

A prognostic model for RTW for daily practice of occupational health services should focus on the identification of variables that are easily available and can be reliably collected. The predictive variables in this study were selected from databases used for work absence administration and from personnel records. However, disadvantage of this approach was that only one clinical variable was available for the model, i.e. the medical diagnosis.

In the Netherlands, the duration of work absence determines whether a worker will be invited by the occupational physician (OP) for a prognostic assessment. The OP is obliged by law to advise about the prognosis for RTW to the employer before the sixth week of work absence and further prognostic assessments by the OP are repeated approximately every 6 weeks. It is obvious that a predictive model together with results of clinical findings may be helpful in determining the prognosis of RTW.

The variables used in our prognostic model and identified with the Cox proportional hazard regression for the entire follow-up period of 365 days have been reported as important predictors for RTW also by other researchers. Age, gender and white collar occupation have been recognized in a recent systematical review as significant and independent predictive factors for the duration of work absence.\textsuperscript{21} Nerve root pain has been documented in several studies as a factor postponing RTW.\textsuperscript{21;30-33} The work-relatedness of LBP established by the OP is however seldom mentioned as a prognostic factor for RTW. Steenstra et al. found, comparable to our study, an association of the work relatedness of LBP with postponed RTW (beta 1.43, CI: 1.1; 1.86).\textsuperscript{34} The history of work absence due to LBP was reported by several studies as a predictive factor, but according to a systematic review this factor has more influence on the frequency of recurrences than on the duration of work absence.\textsuperscript{21} Our results suggest that work absence due to LBP in the year prior to the inclusion into the study postpones the RTW. Kuijer et al. reported in their systematic review that there was no evidence found for income as a prognostic factor for the continuation of work absence.\textsuperscript{35} In our study we found that low salary had a negative influence on RTW.

Explained variances of models predicting duration of work absence have been reported between 18\% and 54\%.\textsuperscript{34;36;37} The explained variance of 10\% of our model was too low compared to these studies. This implicates that the RTW was only marginally influenced by the prognostic factors identified in our study. The main explanation for this result is the limited
number of available prognostic variables in our model, and also the fact that these variables did not reflect any clinical, psychological or job-related factors, or workers expectations about RTW, as was the case in the reference studies mentioned above.

To improve a prognostic model, one has to consider which prognostic factor has a potential to do so. For use in occupational health care the OP needs a simple prediction instrument, which is easy to administer to workers who are not able due to medical problem or who are not willing to complete extensive questionnaires. It would be a challenge for future studies to construct and evaluate such a practical prediction instrument.

**Comparison of two methods.**

In this study the prognostic factors were evaluated for different work absence periods. We used two methods for this evaluation, in order to demonstrate possible differences in results between them. With Cox proportional hazard regression we estimated the hazard for delayed RTW only for those workers who had remained sick-listed at the beginning of each shifting time period. We observed that the direction and relative significance of prognostic factors had changed in workers who had remained off work. Interesting examples are the variables gender (male) and non-specific LBP. Both these variables, if considered over the entire follow-up period, showed a hazard ratio which indicated a faster RTW. However, this has changed during follow-up: in the period between 91 to 365 days and 273 to 365 days women returned to work faster than men, and the initial good prognosis of non-specific LBP became worse. Workers suffering from nerve root pain for longer than 182 days returned to work faster than workers with non specific LBP. We have no clear explanation for this phenomenon. One can hypothesize that the initial diagnosis of non-specific LBP was not accurately recognized by the OP, or that the workers with non specific LBP were developing chronic LBP due to other than biomedical reasons.

This change in prognosis for RTW was not detectable with the second method, where we used logistic regression. This analysis allows to identify the variables which influence RTW of all workers during each shifting time period. In our study the variables nerve root pain, work-related complaints and a history of a LBP in the previous year significantly prolonged RTW. Two of these three variables, gender and non-specific LBP were also statistically significant with the Cox regression for the 151 workers who remained sick-listed for longer than nine months; however, the important difference was that the association with RTW had an opposite direction, compared to the results of logistic regression. We made similar observa-
tions for these two variables for work-absence longer than 3 and 6 months. The method where we used the Cox regression analyzes the hazard for delayed RTW of workers who were sick-listed at the beginning of certain time period. This method resembles the every day working-practice of the OP, who evaluates only workers on sick-leave. When used as in this study, such method provides additional information about the changing of prognostic factors during long-term work absence. To our opinion this method should be preferred for the evaluation of prognostic factor for RTW in occupational health care.

**Conclusions**

Yearly, approximately one out of every twenty workers reported unfit for work due to LBP. Work absence due to non-specific LBP had good prognosis. More than two-third of sick-listed workers had returned to work within 4 weeks. The prognostic model constructed from routinely collected data had too low explained variance for practical day to day use and should be expanded with more suitable variables and clinical factors. The prognostic factors may change during follow-up in the group of workers remaining on sick-leave from an unfavorable to a favorable factor and vice versa. This change is detectable by applying Cox regression over different time period.
Can we predict the duration of work absence

Reference List


General Discussion
The main scope of this thesis are the economic consequences of not returning to work and the effect of return-to-work (RTW) interventions on the shortening of work absence due to LBP.

During the past two decades LBP has attracted major attention of numerous scientists and medical professionals, because of its enormous impact on worker’s individual life and on consequences to society.

The graded activity intervention for LBP is one of the recent attempts, which could help to manage absenteeism due the LBP. This intervention was originally developed and introduced by Lindström for the management of work absence due to sub-acute LBP in the Volvo factories in Sweden. The graded activity intervention is based on operant conditioning principles applied by means of a physical exercise programme. For the purpose of the study described in this thesis the Swedish programme was adjusted for the Dutch situation. This adapted graded activity intervention was evaluated in the population of a large Dutch employer with almost 30,000 employees. Besides the effects on outcome measures pain, functional status and RTW we also focused on cost-effectiveness.

In the first part of this chapter we will discuss the study results and compare them with the results of two other RTW interventions, which have been performed in the Netherlands in the same period. In the second part we will deal with factors, which can make RTW interventions more successful. Finally, we provide recommendations for everyday occupational health care practice, policy makers and future research.

**The main findings of the randomised controlled trial**

The graded activity intervention group of 67 workers was compared to 67 workers who were randomised in the usual care group. During the initial period of 50 days following the randomisation the groups did not differ in RTW rate. However, after that period the graded activity group demonstrated a significantly faster RTW rate during the follow-up of 12 months compared to usual care group (HRR = 1.9, CI 1.2 to 3.1, p=0.01). Consequently, this higher RTW rate resulted in a 12 months accumulated difference of 2,857 sick-leave days due to LBP in favour of the graded activity group. The mean number of sick leave days including recurrences during the 12 months follow-up period, was for the usual care group 141 (SD 102) and for the graded activity group 98 (SD 67). Despite of this marked and substantial difference in sick-leave days this result was statistically not significant. A comparable result with a slightly smaller difference of 2,497 sick-leave days was observed for sick leave due to all medical diagnosis together. Besides the above mentioned results there
were statistically not significant differences for the entrance to a disability pension after 12 months of sick leave (5 workers versus 8 workers), the number of recurrences of LBP absenteeism (14 versus 16) and the total number of recurrent sick-leave days (800 versus 831), all in favour of the graded activity group.

It should be mentioned that faster RTW of the graded activity group did not correlate with the improvement of severity of low back pain and functional status. The pain score did differ only marginally between the groups and there was only a small improvement of functional status in favour of graded activity group. These results suggest that earlier RTW can neither be explained by improvement of pain severity nor by improvement of functional status, but that it is probably driven by other mechanisms.

The cost-benefit analysis showed that the mean costs of medical expenses for graded activity were € 475. This was only € 83 more than the mean medical costs spent by the usual care group. On the benefit side, the most conservative estimation of savings on sick leave compensation costs was € 999 in favour of the graded activity intervention. This direction of the between-group differences was maintained in the second and the third follow-up year as well. However the between-group differences were in those years smaller than in the first follow-up year. Although the general direction of the cost-benefit findings in this study was robust and consistently in favour of the graded intervention group over all three follow-up years the mean differences were statistically not significant. This is a common problem in comparable trials, which are underpowered for a skewed data distribution of outcome data such as the costs of health care utilization, productivity loss or sick-leave days. The costs of productivity loss were the main cost driver in this study, with 87% and 90% of the total net costs in the graded activity and the usual care group, respectively.

The natural course of work-absence due to LBP and its prediction model

The one year incidence of work-absence due to LBP in our study population of 28,124 workers varied between 4.2% for women to 7.3% for men, with a mean incidence of 6.2% for both sexes.2 The incidence was highest with 9.7% for blue-collar workers. These data are in line with results of studies using the same methodology of the incidence rate estimation, starting at the first sick-leave day.3;4

Work absenteeism due to LBP has a good prognosis. Sixty-six percent of absentees had returned to work within 28 days. Within 91, 182 and 273 days these percentages had increased to 84%, 91% and 94%, respectively. Only 3.4% of workers had not fully returned to work within 12
months and they were consequently entitled by law to a partial or full disabil-
ity benefit (WAO). It seems, by comparison of our results with previous studies, that the natural course of work absence due to LBP has not been changed significantly during the last two decades.\textsuperscript{3-7}

The multivariat analysis showed that seven routinely collected variables independently predicted an earlier RTW within twelve months. These variables were: being male, having non-specific LBP, being younger than 50 years, having non-work related LBP absenteeism, having no history of LBP absenteeism 12 months before entry in the study, earning a higher wage and a having white-collar occupation. The prediction model consisting of these variables explained, however, only 10\% of the variability of the duration of work absence. We conclude therefore that such a model should be combined with more clinical variables to be able reach a higher explained variability, which is necessary for practical daily use.

Another interesting finding was that the prognostic factors during follow-up in the group of workers remaining on sick-leave may change from an unfavourable to a favourable factor and vice versa. This change was detectable only by applying Cox regression over different time periods. This method assessed the workers remaining on sick leave in different periods of time, which mimics the work routine of the occupational physician (OP).

**Generalizability of our results**

This RCT and the study on natural course of LBP were performed on the workforce of KLM Royal Dutch Airlines, a company employing at that time approximately 28,000 workers in different job positions. The choice for a single large company makes the study population homogeneous with respect to one corporate identity and one social contract between the employer and the trade unions. On the other hand the participants in the study were heterogeneous with respect to their jobs characteristics, gender, education level and socio-economic status. There were participants with blue collar position, white collar workers and also flying staff with quite specific job characteristics. Another feature is the specific characteristic of the Dutch occupational health care system and the role of the occupational physician (OP) with regard to the certification of work absence, the reintegration guidance of a sick-listed worker and the limited curative competence of the OP. Taking those aspects into account we believe that the outcomes of this study may be generalized in the Netherlands outside the KLM framework to large industrial settings and companies.
**Limitations of the study**

With respect to the methodology there are limitations of this RCT, especially with regards to double blinding. It is impossible to carry out a practical experiment with double blinding methodology for an intervention and a usual care group. Such a RCT can be only single blinded, i.e. for the researcher and not for the participants. The combination of usual care with an experimental intervention awakes expectations of the participant to get a new sort of therapy. There is also systematic attention by the trial physiotherapist, which could generate in the intervention group some placebo or Hawthorne effect.

The participants in the study were recruited by their occupational physicians. From at least 579 eligible cases only 150 workers (26%) were referred for intake in the study. The exact reasons why 74% of eligible workers were not referred for the intake was not investigated. From personal communications with occupational physicians and from our own observations we can suggest some reasons. One of the reasons not to participate could be that a worker was not prepared to take part in the study, for example because the worker was not willing to refrain from already ongoing physiotherapy. In addition, some of the workers did not meet the inclusion criteria. It is also plausible that some occupational physicians were not compliant to the study protocol and ‘forgot’ to refer the worker to the study, because such action was too much time consuming or did not belong to their daily OP routine. This recruitment problem was also observed in other studies and it could be, beside a potential problem for generalizability of the result, also a practical obstacle for research execution in daily occupational health care practice. For example, in another Dutch study on LBP, from 99 occupational physicians involved in recruiting workers for a study, 11% of them recruited more than 50% of participants.8

**Comparison to other studies**

The results of our study can be compared with the original study of Lindstrom.1 Both the Swedish study and the present trial reported favourable results of a graded activity intervention on RTW. This evidence provides support that this type of RTW intervention is a valuable strategy to speed up the RTW of sick-listed workers with LBP. There are studies which used graded activity principles as a part of a multistage RTW intervention for LBP, e.g. the Canadian Sherbrook study of Loisel and its Dutch replication performed by Anema and Steenstra.9-11 In the Sherbrook study a graded activity like programme was called ‘clinical
intervention’. This clinical intervention was in the Sherbrook trial effective on RTW, but in the Amsterdam variant this clinical intervention performed worse than all other interventions.\textsuperscript{10} The explanation for this failure of the clinical intervention in the Dutch trial had probably several reasons: the clinical intervention was used as a secondary intervention, following a workplace intervention or usual care. This caused a referral delay to the physiotherapist and probably a high drop out rate due to a concurrence of the clinical intervention with already ongoing physiotherapy. We suggest that the term graded activity intervention should be used only for the interventions as originally introduced by Lindström and not for the Sherbrook clinical intervention, in order to avoid mis-interpretation of the effectiveness of graded activity as done by Anema and Steenstra.\textsuperscript{1,9}

The results of another Dutch study performed by Heymans can be compared with our study. In this study, a high intensity back school was based on principles of operant conditioning similar tot graded activity.\textsuperscript{12} The high intensity back school was not more effective than usual care. This in contrast to a low intensity back school which resulted in a faster, but statistically not significant RTW rate and in beneficial effects on functional status and kinesiophobia in the first 3 months of follow-up.

In both Dutch studies, i.e. the replicated Sherbrook trial and the back school interventions trial, the method of operant conditioning and graded activity principals were used. Both studies were performed in multiple companies, involving a large number of occupational physicians recruiting the workers, and many physiotherapy settings delivering the interventions. For example, the clinical intervention was offered to workers from a large number of companies by 16 in- and out-company physiotherapy clinics, with a total of 47 physiotherapists involved. This diversity of professionals makes it difficult to develop a graded activity therapy routine and it can hinder effective communications between the physiotherapist, occupational physician and employer. Basically, these are 3 different interventions with the common principle of operant conditioning and graded activity. It is probable that the effect of the graded activity intervention is not only determined by the operant conditioning elements and the gradually increasing training quota, but also by circumstantial factors, additional intervention content and timing of the intervention, short communication lines, the number of medical professionals involved in the study and their experience, their motivation, coaching style and their knowledge of work conditions in the company, etc. It would be interesting to identify the independent contribution of these factors to the effectiveness of these interventions.
Cost-effectiveness of graded activity intervention

The present RCT also studied the cost-effectiveness of graded activity intervention in an occupational health care setting. Cost-effectiveness studies in occupational health care are rarely performed, despite that they are needed, especially because of the high sick-leave costs. Such findings are useful to all stakeholders and especially to payers of sick-leave benefits. When making a cost-effectiveness evaluation in occupational health care, the researcher has to make a choice regarding the evaluation perspective. As the majority of the costs of LBP can be attributed to compensation costs of sick-leave and are paid by the employer, the insurance company or the government, this perspective should be present in all occupational health care studies. The second main perspective concerns the costs of medical care. This perspective is important for the insurance company or governmental policy makers, but also for the worker who pay the insurance premium or a part of not tax-deductable or reimbursable costs of some therapies. The third perspective is the patient’s perspective. The patient pays for non-medical costs connected to being unable to do usual daily activities, such as care for the children, housekeeping or pay for travelling to the clinic etc. Occupational health care has no or limited effect on those latter costs. Beside that, it is difficult to specify if some costs are made in causal connection to the medical problem or if they are connected to the lifestyle of the patient, for example the cost for a housekeeper.

In our study we have restricted the cost-effectiveness evaluation to direct ‘medical’ costs and to indirect costs of ‘work absence’. The direct medical costs were collected by means of medical cost diaries. The practical problem with costs diaries compared to the data recorded by the insurance company is recall bias and loss of data due to non-response. On the other hand, the cost diary method enables the collection of other costs data, which are not known to the insurance company, such as costs of not insured alternative therapies or medication purchased over the counter. The diary method can be used also for collection of non-medical data, for example data about the societal impact of the health problem. In case of LBP the direct medical costs vary in the range of 10% to 15% of the total costs. These direct costs are usually partially or fully compensated by the insurance company. In some cases, especially in case of a multidisciplinary intervention or an extended rehabilitation programme, the employer or workers pay for these not deductible costs. For the estimation of indirect costs we used the human capital method, because this method in our opinion represents the cost which the Dutch employer has to pay for sick leave for at least 2 years in the current social
security system. At the time we performed the study the waiting time for receiving a disability pension was only 12 months. An alternative method used for the estimation of the direct costs is the friction costs method, which assumes that absent workers will be replaced after an adaptation period (i.e. the friction period), which is needed to find or to train a suitable replacement. The value of the production losses is not estimated by using actual wage, but by estimating the added value of a worker. Additionally, the friction costs method is not suitable for calculation of the net costs of sick-leave, which are based on partial RTW to the original or temporary job.

We can compare the results of our study with the two already mentioned Dutch studies with respect to RTW and cost-effectiveness. All three studies were performed in the same research institute, in the same country and within one socio-economic system. In Table 1 we have summarised the most important results from these three studies over a follow-up period of 12 months. The estimation of the direct cost of health care utilisation for the graded activity intervention, the clinical intervention and high intensity back school varied from € 800 to € 3.145, and for usual care between € 716 and € 2.436. The highest estimation of the direct costs was 3 to 4-times higher than the lowest one.

In all three studies the diary method was used to collect data on direct costs. In 2 studies the diaries were collected 3 times during the 12 months follow-up period, and in the third study every 6 weeks, in total 9 times, during follow-up. The higher direct costs, especially in the study by Steenstra et al, cannot be explained from the method of collection of the data, but was probably caused by higher costs of their workplace intervention and their clinical intervention. The estimation of the mean direct medical cost of the usual care was for both Dutch studies quite similar, € 1889 and € 1841, respectively, but substantially higher in comparison to the direct costs in our study i.e. € 716. We are not able to explain those differences. If we speculate, a possible source of this difference might be a later inception of workers in our study than in the other two studies, which might have caused that a substantial part of the direct costs of usual care were made prior to the randomisation.

It is also interesting to give some attention to the duration of sick leave until full RTW, as this outcome measure has a direct effect on the costs of sick-leave. The mean number of sick-leave days until full return to own work varied in the three studies between 86 and 109 days for the most successful interventions and between 126 and 140 sick leave days for usual care. Those data are not adjusted for sick-leave duration prior to inception in the studies.

Pooled effect of all three studies together favours statistically significant
General discussion

Figure 1. Pooled data analysis for number of sick-leave days until full RTW from three Dutch RTW (Return-to-Work) interventions compared to UC (Usual Care).

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Mean</th>
<th>SD</th>
<th>Total</th>
<th>Mean</th>
<th>SD</th>
<th>Total</th>
<th>Mean Difference</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Random, 95% CI</td>
<td>Random, 95% CI</td>
</tr>
<tr>
<td>Anema &amp; Steenstra</td>
<td>109</td>
<td>77</td>
<td>135</td>
<td>96</td>
<td>100</td>
<td>100</td>
<td>-20.01 [-50.32, 1.61]</td>
<td></td>
</tr>
<tr>
<td>Heymans</td>
<td>106</td>
<td>96</td>
<td>126</td>
<td>106</td>
<td>103</td>
<td>103</td>
<td>-33.63 [-49.34, 8.34]</td>
<td></td>
</tr>
<tr>
<td>Hilbii &amp; Staal</td>
<td>66</td>
<td>67</td>
<td>123</td>
<td>67</td>
<td>123</td>
<td>123</td>
<td>-20.26 [-42.81, -5.76]</td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>261</td>
<td>270</td>
<td>100%</td>
<td>-27.21 [-43.69, -10.73]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

RTW interventions above usual care, see Figure 1. The comparison of indirect costs of sick-leave meets some methodological problems, as in our study we used a human capital method and in the other two studies a friction costs method was used. We believe that costs of sick-leave should be absolutely transparent, in order to make clear which part of total costs can be reduced by an intervention and to motivate the employer to use cost-effective interventions. That implicates that a consensus on this issue should be reached for further research on cost-effectiveness in occupational health care.

Return on investment

Return on investment (ROI) is a popular metric, because of its versatility and simplicity. It is a performance measure, which can be used to evaluate the efficiency of an investment or to compare the efficiency of a number of different investments. To calculate the ROI, the benefit of an investment (gain minus cost) is divided by the cost of the investment; the result is expressed as a percentage or a ratio.

$$ROI = \frac{(Gain \ from \ Investment \ - \ Cost \ of \ Investment)}{Cost \ of \ Investment}$$

If an investment does not have a positive ROI, or if there are other opportunities with a higher ROI, then the investment should be reconsidered. The ROI calculation can be modified to suit the situation - it all depends on what one includes as returns and costs.
In our study the ROI was 25%, based on costs of the graded activity intervention, without considering the costs of usual care, which are paid by the health care insurance company. If we take into account only the difference between the cost of the usual care and the costs of the graded activity intervention, than the ROI was in our study 989%. We made identical ROI calculations using the results of both other Dutch studies. In the study of Heymans the ROI was for the low intensity back school 53%. There were no additional costs of intervention and the benefits were in the intervention group higher than in the usual care group. We did not calculate the ROI as there was no investment necessary to gain the benefit. In the study of Steenstra the ROI was -70% for the costs paid for the workplace intervention and the clinical intervention, and 6% if we take into account only the additional costs above the usual care.

The costs of sick leave are directly connected to the number of sick-leave days after randomisation. The mean number of sick-leave days was in our study the lowest i.e. 86 days, compared to 106 and 109 sick-leave days in the Heymans and Steenstra studies, respectively. However, these data are not fully comparable, as the median number of sick-leave days before the inception in the trial was in our study higher than in the other two studies, see Table 1.

What influences RTW?

RTW following work absence due to LBP has been recognized as a process influenced by a variety of medical, social, psychological, and economic factors.\textsuperscript{20-23} The work environment, health care, the insurance system all have a significant influence on RTW outcomes, apart from the underlying medical condition. The employee’s psychological processes initiating and sustaining RTW is influenced by these factors and the employee himself takes the final decision of going back to work. The RTW can be seen as a complex human behaviour change, involving physical recovery, motivation, and interaction with a number of parties.

In our study we applied an operant conditioning approach in order to speed-up RTW. We hypothesised about the working mechanism of the graded activity intervention. It was assumed that it can help the worker to change his cognition and believes about pain related fears. There was no reduction in pain between the groups, but there were statistically significant reductions of fear-avoidance beliefs about physical activity and work during the entire follow-up and reduction of fear of movement or (re)injury 3 months post-randomisation. However, these effects on pain-related fears have appeared without any causal relation with faster RTW.\textsuperscript{24} Apparently there were other behaviour factors which have influenced the
RTW of our workers. As the guidance condition provided by the OP were

Table 1. Comparison of three Dutch studies on RTW intervention for low back pain.

<table>
<thead>
<tr>
<th>Study</th>
<th>RTW Intervention</th>
<th>Usual Care</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anema</strong>&lt;sup&gt;9&lt;/sup&gt; Steenstra&lt;sup&gt;17&lt;/sup&gt;</td>
<td><strong>Work Intervention n = 96</strong></td>
<td><strong>n = 100</strong></td>
</tr>
<tr>
<td>Mean direct costs excl. hospitalisation, € ± SD</td>
<td>2,215 ± 1,585</td>
<td>1,889 ± 1,706</td>
</tr>
<tr>
<td>Mean sick leave cost (friction costs method), € ± SD</td>
<td>4,904 ± 4,536</td>
<td>5,575 ± 5,558</td>
</tr>
<tr>
<td><strong>Return On Investment</strong></td>
<td>-70% † &amp; 6%‡</td>
<td></td>
</tr>
<tr>
<td>Mean sick leave days until full RTW ± SD</td>
<td>108.5 ± 76.8</td>
<td>135.2 ± 96.1</td>
</tr>
<tr>
<td>Median sick leave before randomisation, days (IQR)</td>
<td>77 (56-126)</td>
<td>104 (56-166)</td>
</tr>
<tr>
<td><strong>Heymans</strong>&lt;sup&gt;12;18&lt;/sup&gt;</td>
<td><strong>Low Intensity Back School n=98</strong></td>
<td><strong>n=103</strong></td>
</tr>
<tr>
<td>Mean direct costs incl. hospitalisation, € ± SD</td>
<td>996 ± 869</td>
<td>1,841 ± 3,713</td>
</tr>
<tr>
<td>Mean sick leave cost (friction costs method), € ± SD</td>
<td>10,182 ± 6,050</td>
<td>11,709 ± 6,923</td>
</tr>
<tr>
<td><strong>Return On Investment</strong></td>
<td>53%† &amp; *</td>
<td></td>
</tr>
<tr>
<td>Mean sick leave until full RTW, days ± SD</td>
<td>106.3 ± 99.1</td>
<td>125.5 ± 106.2</td>
</tr>
<tr>
<td>Median sick leave until full RTW, days</td>
<td>75</td>
<td>95</td>
</tr>
<tr>
<td>Median sick leave before randomisation, days (IQR)</td>
<td>29 (13)</td>
<td>28 (13)</td>
</tr>
<tr>
<td><strong>Hlobii</strong>&lt;sup&gt;16&lt;/sup&gt; Staal&lt;sup&gt;19&lt;/sup&gt;</td>
<td><strong>Graded Activity n = 67</strong></td>
<td><strong>n = 67</strong></td>
</tr>
<tr>
<td>Mean direct costs, € ± SD</td>
<td>800 ± 680</td>
<td>716 ± 1,096</td>
</tr>
<tr>
<td>Man cost of sick leave € ± SD</td>
<td>Net days 5,216 ± 5,842</td>
<td>Net days 6,215 ± 6,949</td>
</tr>
<tr>
<td>Human capital method</td>
<td>Gross days 9,407 ± 8,649</td>
<td>Gross days 13,062 ± 11,349</td>
</tr>
<tr>
<td><strong>Return On Investment</strong></td>
<td>25%† &amp; 1089%‡</td>
<td></td>
</tr>
<tr>
<td>Mean sick leave days until full RTW ± SD</td>
<td>86.40 ± 90.61</td>
<td>128.46 ± 122.71</td>
</tr>
<tr>
<td>Median sick leave until full RTW, days (IQR)</td>
<td>54 (41-87)</td>
<td>67 (36-174)</td>
</tr>
<tr>
<td>Median sick leave before randomisation, days (IQR)</td>
<td>43 (31-68)</td>
<td>41 (25-65)</td>
</tr>
</tbody>
</table>

SD=Standard Deviation; IQR=Inter Quartile Range;
† ROI value is based on mean of total cost of RTW intervention
‡ ROI value is based on additional mean cost of RTW intervention above Usual care cost
* ROI was not calculated as there was no extra investment necessary to gain the benefit

for both groups identical, another plausible explanation for behaviour change should be sought in the stringent time-contingent approach of the graded activity intervention and in the clear coordination of and communication about therapeutic en RTW processes. Self-efficacy of workers might also have played an important role in faster RTW. Graded activity as implemented in our study had probably enhanced this
self-efficacy by guiding the rehabilitation process, by helping to set achievable goals for therapy and by gradual RTW as an adaptation to work. All important players in the rehabilitation process had supported the worker by short communication lines in achieving the ultimate goal, i.e. RTW. Unfortunately, this is only a hypothesis, which is not supported by scientific data and it needs further exploration.

The fact that the behavioural approach of the graded activity intervention did not influence the severity of pain, but resulted in faster RTW may indicate that RTW is for a great deal influenced by behaviour. It is probably not only the behaviour of the worker, but also the behaviour of other stakeholders in the RTW process. In that context, Franche has propose a heuristic model for RTW-behaviour which would bring together both the employee as well as the impact of interactions with the health care system, the employer, the workplace, the insurance system, and the importance of collaboration of all stakeholders. This new model would also be compatible with socio-medical models of occupational disability. The Readiness for RTW model of Franche is based on the Phase Model of Occupational Disability and the Readiness for Change Model, which is an evidence-based model used in health promotion and addressing an individual’s ability to initiate and maintain behaviour change. Recently, this model was validated in a prospective cohort study of 632 claimants with work-related back or upper extremity complaints. The result of the study supported sufficient validity of a newly developed 22-item instrument for evaluation of Readiness for RTW. The work by Franche supports our hypothesis that RTW is for a great deal driven by behaviour changes.

An example of behaviour change induced by change in the social system was the introduction of Dutch Gatekeeper Law. By 1st of April 2002 the Improved Gatekeeper’s Act was enacted. From January 2004 the 52 weeks continued wage payment period was prolonged to 104 weeks. During this period, both the employer and the sick-listed worker must do all they reasonably can do to improve the chances of returning to work. If the employer does not do his utmost best to reintegrate a sick-listed employee, he will be required to extend salary payment for up to another year. This new law has resulted in a lower influx into long term disability, which has decreased from 1.55% to 0.46% in 2001 and 2006, respectively. The same pattern was seen for work absenteeism, which has decreased from a year average of 5.3% to 4.0% between 2002 and 2005.
Intervention strategies and RTW

In this study we have evaluated one of possible RTW interventions for absenteeism due to LBP. In our study this intervention was successful, in the other two Dutch studies similar interventions did not work better, or even prolonged the duration of work absenteeism compared to usual care. What is best intervention for LBP? It is difficult to say if we take those 3 studies into account. There are probably more approaches which can lead to success. The causes of illness and sick leave have a multi-causal character and there are many stakeholders involved in the RTW process. Besides that, work absenteeism is a process of (gradual) transition from one stage into another; from a healthy status to work absenteeism, and vice versa, with or without complaints. The prognosis can change during this transition process and success of a particular intervention is determined by the stage of the process and by the timing of an intervention. It seems that early mini-interventions are effective in the reduction of the (future) sick-leave, as demonstrated by Karjalainen. The evidence of the effectiveness of LBP interventions is gathered in mono- or multidisciplinary guidelines. These guidelines provide the best available evidence for daily occupational health practice. Comparisons, using the AGREE instrument, of the international guidelines dealing with the management of LBP have shown that the guidelines generally met quality criteria and that they agreed on fundamental issues regarding the management of LBP in occupational health care. Besides mono-disciplinary guidelines for occupational health care, general practitioner and physiotherapist, multi-disciplinary guidelines have been developed for all medical and paramedical stakeholders dealing with LBP patients. Finally, there are also guidelines for insurance physicians for the assessment, therapy and guidance of the optimal reintegration process. However, physicians’ adherence to clinical guidelines varies significantly. Results of studies in the USA and the Netherlands suggest that about 30–40% of patients do not receive care according to present scientific evidence and about 20–25% of care provided is not needed or is potentially harmful. This is also valid for clinical practice guidelines for LBP. Feuerstein reported that only 10 to 40% of LBP cases received during 4 year follow-up clinical guidelines practice adherent care. The adherence to the clinical guidelines was related to better functional outcomes, lower health care costs, higher levels of patient satisfaction and better general health. At this point, adherence to the clinical guidelines and to evidence-based interventions seems the best strategy in primary care and occupational health care. The advantage of such strategy is that all providers of medical care will advice in the same way and will guide the patient towards the
same therapeutic direction. All medical professionals around the LBP patient can be sure about consistent advice of colleagues and they should empower such an advice.

Conclusions

Based on the results of our study, it can be concluded that graded activity as a RTW intervention for low back pain is more effective than usual care. This intervention is from the point of view of the employer cost-effective and it shows a positive return on investment. Based on the comparison of the results of 3 Dutch studies it seems that all three RTW interventions are able to speed up RTW compared to usual care. The ROI of a specific intervention can vary from a single digit percentage to values exceeding 100%. It is not clear which component of the interventions is most effective on RTW and which critical success factors are responsible for that effect. The assessment of direct and indirect costs varies too much per study and it is not possible to compare the absolute amount of costs among the different studies. Two different methods for the estimation of indirect costs make comparison even more difficult. For economic evaluation from the perspective of the employer and from the point of view of occupational health care, the human capital method is a more appropriate choice than the friction costs method. The human capital method offers to the employer more accurate information about costs of sick-leave. There is probably a gap between the professional guidelines or protocols and their practical implementation and adherence to them in daily occupational health care practice.

Recommendations for future research on RTW intervention for LBP

The results of our study gave some answers, but it has generated also a number of new questions. Some of those question should be addressed in future research on this theme. First of all, future research should focus on the determinants of RTW behaviour in order to identify the factors which are essential in modifying this behaviour. The results of such research could be used for developing future interventions. Second, an important theme of future research is the identification of those workers who are in danger of prolonged sick-leave. A good prediction tool could help the OP to offer the workers with bad prognosis an adequate intervention at an early stage of sick-leave. The third field of future research should focus on the tuning of optimal in-
Interventions for various group of sick-listed workers. In this field we see an important role for light (early) interventions for those who have some complaints, but are not off work yet. Timing of an adequate intervention is here crucial. This tuning of various interventions could be placed in a stepped care process for LBP, which needs to be constructed and evaluated.
Reference List


Summary
Almost each of us at some time will experience low back pain (LBP) that interferes with work, sport or routine daily activities. Non-specific low back pain is basically a self-limiting disease. However, in some cases it can turn into a chronic state. The socio-economic consequences of low back pain for the worker, the employer and society are substantial. A delay in return to work (RTW) results in high compensation costs or even in a disability pension. These work-related costs are higher than the costs of treatment. In order to prevent the development of more permanent disablement and sick-leave, there is a need for effective intervention strategies embedded in occupational health care which aims at a safe and rapid return to work of workers with low back pain. A promising intervention strategy consists of active rehabilitation directed at return to normal activity and work. An example of such active rehabilitation is the graded activity intervention, which was successful in the Volvo factories in Sweden. This thesis focuses on evaluation of a graded activity intervention in Dutch occupational health care setting.

Chapter 2 presents the results of a systematic review of the literature on the effectiveness of return to work interventions for sub-acute low back pain on work absenteeism, severity of pain and functional status. Nine randomized clinical trials met the methodological quality selection criteria were included in the review. A best evidence synthesis was performed. Five out of nine randomized controlled trials (RCT) comparing RTW intervention to usual care were identified as methodologically high quality studies. Strong evidence was found for the effectiveness of RTW interventions on RTW rate at 6-months of follow-up and for the effectiveness of RTW interventions on the reduction of days of absence from work at 12-months follow-up and longer. Scores for pain and functional status in these studies remained unchanged or improved as a result of the RTW intervention. Apparently, improvements in functional status and pain do not necessarily go together with earlier return to work. Based on these findings we can conclude that RTW interventions are equally or more effective on reduction of work absence due to sub-acute low back pain, in comparison to usual care. The optimal RTW intervention for sub-acute low back pain is probably a mixture of exercise, education, behavioral treatment and ergonomic measures. But it is not clear which component, or which combination of components, is the most effective.

Chapter 3 reports on a comparison of available national guidelines on the management of low back pain in occupational health. The guidelines were
compared regarding generally accepted quality criteria using the AGREE instrument, and summarised with regard to the guideline committee, the presentation of the guideline, the target group, and assessment and management of the nature of the recommendations (i.e. advice, return-to-work strategy and treatment).

The results showed that the quality criteria were met in varying degrees by the guidelines. Common flaws concerned the absence of proper external reviewing in the development process, lack of attention to organisational barriers and cost implications, and lack of information on the extent to which editors and developers were independent.

There was general agreement on numerous issues fundamental to occupational health care management of low back pain. The assessment recommendations consisted of diagnostic triage, screening for ‘red flag’ signs and neurological problems, and the identification of potential psychosocial and workplace barriers for recovery. The guidelines also agreed on the advice that low back pain is a self-limiting condition, and that remaining at work or an early (gradual) return to work, if necessary in modified duties, should be encouraged.

Chapter 4 and 5 report on the results of randomized controlled trial on the return to work effects of the graded activity intervention compared to usual care. The RCT was carried out in KLM Royal Dutch Airlines by occupational health services at Schiphol Airport in the Netherlands. The trial population consisted of KLM employees who were partially or full sick-listed because of non-specific low back pain. The low back pain had to be present for at least 4 weeks.

The graded activity intervention can be described as a physical exercise program, applying operant conditioning behavioural principles. The goals of the intervention were an improvement of functioning and a rapid and safe return to work, despite possibly persisting pain complaints. The graded activity intervention was applied by a specially trained in-house physiotherapist.

From a population at risk of about 28,000 KLM employees, a total of 134 were randomly assigned to graded activity (67 workers) and to usual care (67 workers). Measurements of baseline characteristics and the outcomes measures functional status and pain took place at baseline before randomisation, and 3 and 6 months after randomisation. Sick leave data were continuously recorded in the company sick-leave registration system. The median duration of the first post-randomization continuous period of sick leave was 54 days in the graded activity group and 67 days in the usual care group. The graded activity intervention was effective from 50 days after randomization and onwards. For this period the hazard ratio
was in favor of the graded activity group during both 6 and 12 months follow-up periods. The differences between the groups in number of recurrent episodes of sick leave, total number of days of sick leave due to low back pain, and total number of days of sick leave due to all diagnoses, were in favor of the graded activity group, although not statistically significant.

Both groups improved in functional status and pain over time. The mean differences between the two groups in improvement for functional status and pain at 3, 6 and 12 months were in favor of the graded activity group. The differences were however small and statistically not significant. The graded activity intervention did not effect pain severity more than usual care. This finding corresponds with the general principle of the graded activity intervention, which aims at improvement of functioning and in particular at return to work and not at pain reduction.

Chapter 6 reports on results of a comparison of the costs and benefits of a graded activity intervention to usual care for sick-listed workers with non-specific low back pain during a 3-year follow-up. The main outcome measures were the costs of health care utilization during the first follow-up year and the costs of productivity loss during the second and the third follow-up year. The mean total cost of the graded activity intervention was € 475. During the first three months of follow-up, the health care utilization costs were higher in the graded activity than in the usual care group. In the same period, the usual care group had spent less on physiotherapy and more on other medical services. At the end of the first year the average between-group difference in health care utilization costs was € 83 lower in the usual care group, but not statistically significant. The average saving per worker in graded activity group yielded at least € 999 due to a reduction in productivity loss. The potential cumulative savings were an average of € 1661 per worker over a 3-year follow-up period.

The graded activity intervention for non-specific low back pain may be a cost-beneficial RTW intervention from the employer’s point of view. This intervention was marginally more expensive than usual care, while benefits were substantial and remained noticeable 3 years after the initial intervention. The costs of health utilization were only a fraction of the total cost of the low back pain in the working population and the economic burden of productivity loss was the main cost driver.

Chapter 7 reports on the analysis of ‘easy to obtain’ prognostic variables for return to work (RTW) at different stages of work absenteeism. The low back pain cohort included 2,445 airline employees from a population of 28,124 employees who reported unfit for their work due to an episode of low back pain during a period of 21 months. This low back pain cohort was followed for 12 months after inclusion. Work absence data due to low back
pain and data on prognostic factors were collected from electronic sick-leave databases. Prognostic models were built for different time strata of work-absence. The incidence of work absence due to low back pain in the population at risk varied between 4.2% for women to 7.3% for men. Within 28 days, 66% of the workers had returned to work and within 91, 182 and 273 days these RTW percentages had increased to 84%, 91% and 94%, respectively. Cox regression analysis showed that seven variables predicted an earlier RTW within twelve months: 1) male sex, 2) non-specific nature of low back pain, 3) younger age 4) no work relatedness of low back pain, 5) no history of low back pain absenteeism in previous 12 months, 6) a higher wage and 7) white collar occupation. However, the basic model explained only 10% of the variance (pseudo-\(R^2\)) of RTW. Work absence due to non-specific low back pain has a good prognosis. The prognostic model constructed from routinely collected data has a too low explained variance for routine day to day use. The model should be expanded with more variables or clinical factors. Chapter 8 discusses the main results of graded activity intervention and its generalizability for other occupational health care settings in the Netherlands and in other countries. The data on the natural course of low back pain absenteeism learned us that this absenteeism has a good prognosis. However, it still bears a significant economic problem for the employer. Performing a RCT in an occupational health practice has some limitations. For instance with concern to blinding of the participants for the intervention, or compliance of the occupational physicians with the recruitment protocol. The graded activity trial was compared to other two Dutch studies on RTW intervention for low back pain absenteeism, which were performed in the Netherlands almost at the same time. Both of the studies used interventions based on cognitive behavior principles. However, these interventions were different with respect to timing of the therapy, the experience of the therapist and combination with other interventions. The cost-effectiveness of the graded activity intervention is discussed from the point of view of the employer and insurance company. Return of investment is introduced as a practical indicator, which can help the employer to make decision about implementation of a RTW intervention in daily practice. This pooling of sick leave data of our study and the two other Dutch studies together supported the conclusion that the RTW interventions perform statistically significant better than usual care. RTW can be seen as a complex human behaviour change, involving physical recovery, motivation, and interaction with a number of parties.
Optimal intervention should be based on behavioural principals and workplace intervention. At this point, adherence to the clinical guidelines and to evidence-based interventions seems to be the best strategy in primary care and occupational health care. The advantage of such strategy is that all providers of medical care will advice in the same way and will guide the patient towards the same therapeutic direction. The chapter ends with conclusions and general recommendations for future research.
Samenvatting

Handelen bij werkgebonden lage rugpijn en de kosten-effectiviteit daarvan.
Lage rugklachten is een vaak gehoorde klacht. Velen van ons ervaren ooit in het leven een episode van lage rugklachten met arbeidsverzuim en/of een beperking in de dagelijkse activiteiten tot gevolg. Lage rugpijn wordt gekenmerkt door een goedaardig verloop en spontaan herstel. Bij een enkeling echter, kunnen lage rugklachten overgaan in een chronische aandoening.

De sociaal-economische gevolgen van lage rugpijn zijn voor de medewerker, werkgever en de maatschappij aanzienlijk. Langdurig arbeidsverzuim brengt hoge verzuimkosten en soms ook blijvende arbeidsongeschiktheid met een gedeeltelijke of volledige afkeuring met zich mee. Ter voorkoming van langdurig arbeidsverzuim en blijvende arbeidsongeschiktheid zijn effectieve bedrijfsgeneeskundige "return-to-work" (RTW) interventies noodzakelijk. Een voorbeeld van een veelbelovende RTW interventie is een Zweeds rehabilitatieprogramma genaamd graded activity. Dit programma, gericht op een snelle terugkeer in de gebruikelijke dagelijkse activiteiten en in het arbeidsproces, werd in de Volvo fabrieken met succes uitgeprobeerd.

Dit proefschrift handelt over de evaluatie van het graded activity programma in de Nederlandse situatie met behulp van een gerandomiseerd experimentele onderzoek, zogenaamde randomised controlled trial (RCT).

In hoofdstuk 2 van dit proefschrift wordt een systematisch literatuuronderzoek naar de effectiviteit van de RTW interventies voor sub-acute lage rugklachten beschreven. Daarnaast worden de resultaten van deze interventies op de ernst van de rugpijn en op de functionele toestand behandeld.

Aan de hand van een systematisch literatuuronderzoek zijn negen RCTs geïdentificeerd die voldeden aan de methodologische criteria. Slechts vijf studies met een hoge methodologische kwaliteit werden voor verdere analyse geselecteerd. Uit de analyse blijkt dat er een sterk bewijs bestaat voor de effectiviteit van RTW interventies op de werkhervattingsnelheid gedurende de 6 maanden follow-up en voor de reductie van het aantal verzuimdagen gedurende de follow-up van 12 maanden en langer. De uitkomsten van de RTW interventies voor pijn en functionele status zijn in deze studies doorgaans gelijk aan de controlegroep. Hieruit kan geconcludeerd worden dat de werkhervattingsnelheid niet hand in hand gaat met een afname van pijn en/of een verbetering van de functionele status score. Op grond van de gevonden gegevens wordt geconcludeerd dat de effectiviteit van RTW interventies gelijk is aan of beter dan de effectiviteit van de gebruikelijke zorg.

De ideale RTW interventie voor subacute lage rugpijn is waarschijnlijk een combinatie van oefentherapie, voorlichting, gedragstherapie en ergonomi-
sche maatregelen. Het is echter niet duidelijke welke component of welke combinatie van deze componenten het meest effectief is.

In hoofdstuk 3 wordt de vergelijking van beschikbare nationale bedrijfsgeneeskundige richtlijnen voor behandeling en begeleiding van lage rugklachten behandeld. Deze richtlijnen zijn beoordeeld aan de hand van de algemeen geaccepteerde kwaliteitscriteria die door het AGREE instrument worden gehanteerd (samenstelling van de richtlijnwerkgroep, de presentatie van de richtlijn, de doelgroep en aanbevelingen voor diagnostiek, behandeling en werkhervatting strategie).

De uitkomst van de vergelijking laat zien dat er variaties zijn in de mate waarin de richtlijnen aan de kwaliteitscriteria voldoen. De meest voorkomende onvolkomenheden zijn de afwezigheid van afdoende externe toetsing van het ontwikkelproces van de richtlijn, een te kort aan aandacht voor de organisatorische belemmeringen en kostenconsequenties bij het uitvoeren van de richtlijn in de praktijk, en tenslotte gebrekkige informatie over de mate van mogelijke belangenverstrengeling van de richtlijnontwikkelaars. Over het algemeen bestaat er overeenstemming over vele zaken aangaande bedrijfsgeneeskundige behandeling en begeleiding van lage rugklachten. De adviezen voor beoordeling van lage rugpijnklachten bestaan uit het uitvoeren van een diagnostische triage, beoordeling van rode-vlaggen en neurologische problematiek, en het identificeren van potentiële psycho-sociale werkplekgebonden belemmeringen voor het herstel. De richtlijnen onderschrijven het advies dat de lage rugpijn een goedaardige aandoening is en dat het doorwerken met klachten of een spoedige stapsgewijze werkhervatting al dan niet met aangepaste belasting niet schadelijk is en gestimuleerd en ondersteund dient te worden.

In hoofdstuk 4 en 5 worden de resultaten van een RCT naar de effecten van het graded activity programma in vergelijking met de gebruikelijke zorg gepresenteerd. In hoofdstuk 4 worden de resultaten van de eerste 3 en 6 maanden na de loting gepresenteerd en hoofdstuk 5 behandeld resultaten over de follow-up van 12 maanden. Het graded activity programma is een stapsgewijs opgebouwd lichamelijk oefenprogramma dat gebruik maakt van gedragsbeïnvloeding op basis van operante leerprincipes. De behandeling wordt uitgevoerd door speciaal getrainde fysiotherapeuten. De focus bij de behandeling is gelegd op de verbetering van het functioneren door het stimuleren van activiteiten en handelingen die de werknemer ondanks eventuele pijnklachten nog kan doen. De RCT is uitgevoerd bij de arbodienst van KLM. De onderzoeksgroep bestond uit de werknemers van KLM die ten tijde van het onderzoek partieel
Samenvatting

of volledig arbeidsongeschikt waren wegens lage rugklachten. De voor-
waarde voor deelname aan het onderzoek was dat de lage rugpijn
minstens 4 weken bestond.

Uit de populatie van 28,000 KLM medewerkers zijn in totaal 134 deelne-
mers door middel van een loting toegekend aan het graded activity
programma (67 medewerkers) of aan de gebruikelijke zorg groep (67 me-
dewerkers). De functionele status, pijn en andere basisvariabelen zijn
vastgelegd voor de indeling in de 2 groepen, en in de 3 en 6 maanden
daarna. Gegevens over het arbeidsverzuim zijn doorlopend geregistreerd
met behulp van het verzuimregistratiesysteem van de arbodienst.

De mediane duur van de onafgebroken verzuimperiode tot volledige werk-
hervatting in eigen functie bedroeg 54 dagen in graded activity groep en
67 dagen in de gebruikelijke zorg groep. De positieve effecten van de gra-
ded activity interventie op de werkhervating werden zichtbaar 50 dagen
na de loting. De verschillen tussen de groepen ten aanzien van het aantal
arbeidsverzuimrecidieven, het totaal aantal verzuimdagen wegens lage
rugklachten en ook wegens alle andere diagnosen waren in het voordeel
van de graded activity groep, maar statistisch niet significant.

Beide groepen toonden verbetering in de functionele status en in de re-
ductie van pijn. De gemiddelde verschillen in de verbetering van de
functionele status en pijnreductie waren in voordeel van de graded activity
groep. Deze verschillen waren echter marginaal en statistisch niet signifi-
cant. Deze bevinding komt overeen met de algemene doel van het graded
activity programma, namelijk verbeteren van het functioneren, met name
terugkeer naar het werk en niet de reductie van pijn.

In hoofdstuk 6 worden de resultaten van de kosten-en-baten analyse ge-
durende de follow-up van 3 jaar beschreven. De gemiddelde kosten van
het graded activity programma bedroegen € 475. In de eerste 3 maanden
waren de gemiddelde kosten van het graded activity programma hoger
dan de behandelkosten van gebruikelijke zorg. In deze periode werd door
de gebruikelijke zorg groep minder geld besteed aan fysiotherapie, maar
meer geld aan andere medische behandelingen. Aan het eind van het eer-
ste jaar was het gemiddelde verschil in de totale medische behandel-
kosten van het graded activity programma slechts 83 € hoger dan de
kosten van gebruikelijke zorg. Dit verschil is statistisch niet significant.

De kosten van arbeidsverzuim vielen in de graded activity groep aanzien-
lijk lager uit, waardoor de gemiddelde besparing van de totale kosten van
de behandeling en het arbeidsverzuim, in de meest conservatieve variant,
€ 999 bedroeg. De totale cumulatieve besparing over 3 jaar was gemid-
deld € 1661 per medewerker in de graded activity groep.

Vanuit de invalshoek van de werkgever lijkt het graded activity program-

ma kost-effectief te zijn. Dit programma leek marginaal meer te kosten dan gebruikelijke zorg, maar de opbrengsten waren aanzienlijk. Dit effect was zelfs na 3 jaar nog waarneembaar. De behandelkosten maakten slechts een klein deel uit van de totale kosten.

In hoofdstuk 7 wordt verslag gedaan van de analyse naar de betekenis van routinematig verkrijgbare prognostische variabelen voor de voorspelling van de werkhervattingsnelheid. Het lage rugklachtencohort van 2,445 werknemers werd samengesteld gedurende een periode van 21 maanden uit de populatie van 28,124 KLM medewerkers. Elke individueel lid van de cohort werd gedurende 12 maanden na de aanvang van het arbeidsverzuim gevolgd. De gegevens over het arbeidsverzuim en over de prognostische factoren waren afkomstig van het geautomatiseerde verzuimregistratiesysteem van de arbodienst. Het prognostische model werd opgebouwd voor verschillende verzuimduurperioden.

De incidentie van werkverzuim door lage rugpijn bedroeg in de onderzochte populatie 4,2% voor vrouwen en 7,3% voor mannen. Binnen 28 kalenderdagen heeft 66% medewerkers hun eigen werk volledig hervat. De hervattingspercentages bedroegen binnen 91, 182 en 273 dagen respectievelijk 84%, 91% en 94%. Door middel van een Cox regressie analyse zijn zeven variabelen die werkhervatting binnen 12 maanden na de ziekmeldung konden voorspelen geïdentificeerd. Deze variabelen zijn: 1) mannelijk geslacht, 2) niet specifieke lage rugpijn, 3) jongere leeftijd, 4) geen relatie van de klachten met het werk, 5) geen verzuim wegens lage rugklachten in voorgaande 12 maanden, 6) hogere salaris en 7) ‘witte boorden’ beroep. Het basismodel was in staat slechts 10% van de variantie van de werkhervatting te verklaren (peudo-R2).

Het prognostisch model, dat gebruik maakt van routinematig beschikbare variabelen heeft een te lage voorspellende waarde om dit model in dagelijkse praktijk te kunnen toepassen. Een dergelijk model zou waarschijnlijk uitgebreid moeten worden met additionele klinische variabelen.

In hoofdstuk 8 worden belangrijkste resultaten van de gepresenteerde RCT becommentarieerd in het licht van de toepasbaarheid van het graded activity programma in andere bedrijfsgeneeskundige praktijken in Nederland en andere landen.

Daarnaast is aandacht besteed aan de vergelijking van deze studie met andere Nederlandse onderzoeken naar RTW interventies en aan de ‘return of investment’ van deze interventies. Tenslotte worden aanbevelingen voor toekomstige onderzoeken op het gebied van lage rugklachten gegeven.

De uitvoering van een RCT in de bedrijfsgeneeskundige praktijk kent een
Samenvatting

aantal beperkingen. Een voorbeeld hiervan zijn de problemen met de blinding van de deelnemers voor het type interventie, of de opvolging van het onderzoeksprotocol door de deelnemende bedrijfsartsen.
Het graded activity onderzoek is vergeleken met twee andere Nederlandse onderzoeken die vergelijkbare RTW interventies voor lage rugklachten bij-na gelijktijdig hebben uitgevoerd. De beide studie gebruikten interventies die gebaseerd zijn op operante leerprincipes van gedragsbeïnvloeding. Deze interventies verschillen echter van ons onderzoek wat betreft de tijdsplanning van de aanvang van de behandeling, de ervaring van de behandelende fysiotherapeuten en de interactie met andere interventies, waardoor de uitkomsten niet zonder meer vergelijkbaar zijn.
De kosten en baten van het graded activity programma worden in deze studie voornamelijk beschouwd vanuit de invalshoek van de werkgever en de verzekeringsmaatschappij. Return of investment wordt aangedragen als een praktische maat die de werkgever kan helpen bij het maken van een beslissing over de implementatie van een bepaalde interventie in de dagelijkse praktijk.
Samenvoeging van de werkverzuimdata van de twee Nederlandse onderzoeken en onze studie ondersteunt de conclusie dat RTW interventies gericht op een snelle werkhervatting effectiever zijn dan gebruikelijke zorg.
Werkhervatting na ziekte kan beschouwd worden als een complex gedragsproces, bestaande uit fysiek herstel, motivatie, en een wisselwerking met vele actoren in de omgeving. De optimale interventie zou gebaseerd moeten zijn op gedragbeïnvloeding en werkplekinterventie. De beste strategie in de eerste lijnzorg en in de bedrijfsgezondheidszorg is dan ook opvolging van professionele richtlijnen. Het voordeel van een dergelijke strategie is dat alle zorgproviders een raamwerk aangeboden krijgen waardoor interdisciplinaire samenwerking beter tot stand kan komen. De medewerker kan dan uiteindelijk profiteren van een eenduidige boodschap en begeleiding.
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Dankwoord

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Hynek
Over de auteur