Chapter 8

General discussion
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The main aim of this thesis was to study the effectiveness and cost-effectiveness of integrated care for sick-listed patients due to chronic low back pain. A randomized controlled trial was carried out derived from a comparable study for patients sick-listed for 2-6 weeks due to sub-acute back pain. This chapter will summarize the main finding of this thesis and the main findings will be compared to existing literature. Furthermore, methodological limitations and considerations of this study will be discussed. This will be followed by a context analysis for implementation of the integrated care. In the final part of this chapter, implications of the study results for future research and practice will be discussed.

**Summarizing the main findings from this thesis**

The total costs of back pain have decreased in The Netherlands from € 4.2 billion in 1991 to € 3.5 billion in 2007. However, these costs remain tremendous and the economic impact is mostly due to the indirect costs of work absenteeism and disability. An intervention focussed on return to work for sick-listed patients with chronic low back pain showed very positive results on absenteeism and disability. The intervention, the integrated care program combining a patient-directed and a workplace-directed intervention, substantially reduced disability due to chronic low back pain in private and working life. The median duration until sustained return to work was 88 days in the integrated care group and 208 days in the usual care group. Besides, patients in the integrated care group improved significantly more on functional status compared to patients in the usual care group. No effects between the two groups were found for pain improvement. In addition, the integrated care program was also cost-effective in comparison with usual care from a societal perspective. The feasibility of the integrated care program was evaluated by questionnaires (quantitative) and telephone interviews (qualitative). Both approaches showed that stakeholders involved in the implementation of the integrated care program were satisfied about the program. Adherence to the integrated care program was in accordance with the protocol and compliance of the patients who were eligible to participate in the integrated care program was high. Overall conclusion, integrated care has great potential to increase the effectiveness of care for patients long term sick-listed due to chronic low back pain and to reduce high costs due to chronic low back pain for society.

**Key messages**

*The results of this thesis lead to the following key messages.*

1. The total societal costs of back pain have decreased over the years. Still, the economic impact is tremendous and mostly due to work absenteeism and disability. In spite of the observed decrease in the number of people receiving a disability pension, there is room for more cost savings. Development and evaluation of an intervention concerning the social security system and implementation of evidence-based return to work interventions are therefore needed. (Based on results of Chapter 2)
2. The integrated care program, combining a patient-directed and a workplace-directed intervention, for sick-listed patients with chronic low back pain has large potential to significantly reduce the societal costs, to increase the effectiveness of care, to gain quality of life and to improve function on a broad scale. So it has the potential for large gains for patients, society as well as employers. (Based on Chapter 6 and Chapter 7)

3. The feasibility of the integrated care program is very good. The program is applicable to shift patients’ goal setting from pain oriented towards function restoration and return to work. Satisfaction and compliance of the involved stakeholders was good. (Based on results Chapter 4 and Chapter 5)

**Comparison with other studies**

There are studies that have investigated comparable aspects of our intervention or studies which have investigated a similar intervention in a different target group. We can conclude that no research has been done with an identical intervention for sick-listed patients with chronic low back pain.

There are reviews reporting on related topics like a review of Ostelo et al. (2005) in which the objective was to determine if behavioural therapy is more effective than reference treatments for chronic low back pain. They focussed on clinical outcomes and concluded that by comparing operant treatment to waiting list control no significant differences could be detected on general functional status or on behavioural outcomes.¹ A review of Schonstein et al. (2003) focussed on the effect of physical conditioning programs that included a cognitive-behavioural approach for patient with chronic low back pain. Their conclusion was that there is evidence that such programs can reduce the number of sick days lost at 12 months follow-up by an average of 45 days, when compared to general practitioner usual care or advice for employees with chronic back pain.²

The review of van Oostrom et al. (2009) determined the effectiveness of workplace interventions compared to usual care or clinical interventions on work-related outcomes and health outcomes.³ They identified six randomized controlled trials that evaluated the effects of workplace interventions on work disability. Five studies included employees with musculoskeletal disorders of which three studies on low back pain.⁴⁻⁶ These three studies reported on patients sick-listed due to (sub)acute pain. The results of this review show that there is moderate-quality evidence to support the use of workplace interventions to reduce sickness absence among employees with musculoskeletal disorders when compared to usual care. Their conclusion was that workplace interventions were effective to reduce sickness absence among employees with musculoskeletal disorders, however, were not effective to improve health outcomes among employees with musculoskeletal disorders.

The results of our study can be added to reviews like described above. Our study showed that the combination of graded activity and a workplace intervention reduced disability in both working and private life due to chronic low back pain by a median of 120 days during a follow-up period of 12 months.
**Terminology**
During the execution of the BRIDGE study we changed the name multidisciplinary outpatient care into integrated care. Our main reason was that we think the latter term is better explaining the content of the intervention. Integrated care refers to the integration of curative medicine and occupational medicine and implies the involvement of several disciplines in primary and outpatient care.

**Methodological considerations**
The CONSORT Statement is an evidence-based, minimum set of recommendations for reporting randomized controlled trials. It is fair to conclude that the quality of our study was good since our randomized controlled trial met most of the CONSORT Statement requirements.
However, there are a few aspects to consider. First of all, the selection of patients was time consuming. The inclusion period lasted two years and three months in which patients were recruited from five participating hospitals. In total, over 3,000 patients were sent a letter. Of them 219 patients were eligible to participate and 134 patients were randomized. These numbers of patients are relatively low if they are compared to numbers of the social security systems which show that almost 95,000 persons per year receive a disability pension because of back pain problem. It is fair to conclude that only a small part of our target group can be reached by recruitment via medical specialists. The main reason for that could be in the fact that guidelines for primary physicians do not indicate to refer patients sick-listed due to chronic low back pain to secondary care. Therefore, we think that it would have been better to recruit via general practitioners or occupational physicians.
Second aspect is related to identification of the target population. The interviews executed in the qualitative study and the baseline questionnaires have given us a good idea of the target population (age, duration of sick leave, health care consumption, etc). To help general practitioners and occupational physicians to select the appropriate patients for integrated care it would be useful if they could use a clinical prediction rule which can help them to identify those patients who are at high risk for long-term disability. Another aspect to consider is the used cost categories. An underestimation of the productivity costs in both groups is likely since costs of presenteeism were not considered. Net cumulative days of sick leave were used as proxy for productivity loss. We did not measure presenteeism, i.e. productivity loss caused by reduced productivity when an employee is at work. Presenteeism may have occurred when employee returned to work. The last aspect to consider is related to the external validity of the results of this thesis. We evaluated the integrated care program in Dutch society. The clinical diagnosis, occupational function and the company size participants were working for varied a lot. These features will contribute to successful implementation. However, the integrated care program was executed by a selective group of health care professionals who were trained by the research team. Only the training for the physical therapists to work with graded activity program is nationally available. Training for the occupational therapists to execute
the work(place) intervention and the training for the clinical occupational physicians to execute the integrated care-management are not available on a national basis yet. The latter has to be realized before implementation on a national basis can be done. Since health care systems and social security systems over countries differ to a great extent, the study findings may be valid in the Netherlands only.

**Implications for implementation**
Implementing new evidence is challenging. Successful implementation acquires a good understanding of the characteristics of the new intervention, the target group and its setting. The process evaluation of our study (Chapter 5) revealed barriers related to the intervention and target group. In next part we will discuss barriers for implementation in the four systems (workplace, healthcare, compensation and personal system) and the different stakeholders who are acting in the systems and who need to collaborate.9

**Employers**
Dutch policies are aware of the high societal costs due to back pain and therefore already focus on promoting job retention, reducing disability benefit inflow and decreasing the demand on health care. New laws have been introduced in the social security system, aimed at stimulation of return to work by strengthening the responsibility for return to work of both the worker and the employer. Employers have the obligation to do their utmost to facilitate re-integration during the two years of sickness absence in which the employee can not be dismissed. Dutch policy stimulates employers to look for re-integration measures which can prevent prolonged absence from work. A country cohort study showed that individual packages of work interventions and flexible (partial) disability adapted to the individual needs and capacities are important for preventing work disability due to low back pain.10 The results of the feasibility study of integrated care showed that employers are interested to comply with integrated care. Only a few did not because their employee did not want them to participate in the study. In conclusion, these results show that when an employee is on sick leave because of chronic low back pain it seems very reasonable for employers to use integrated care.

**Health care providers**
The health care system also focuses on work resumption by emerging evidence-based medicine guidelines for low back pain for clinical and primary care practice aimed to achieve effective and efficient patient care.11-13 A system barrier for implementation of the integrated care program is related to incoherence of the curative health care system and the occupational health care system. There still seems to be a lack of coherence and action which focuses on the patient as well as on the worker. General practitioners have a gatekeeper role in the sick note system. Workers/patients with back complaints mostly visit their general practitioner. In spite of a worker being on sick leave, the treatment of general practitioners still seems to be primarily directed at diagnosis and treatment of health-related problems. Work-related factors are rarely identified or managed by general
practitioners. If general practitioners do focus on work-related factors, their coordination with occupational physicians in disability management is poor. This poorly coordinated care can cause unnecessary long work absenteeism. Stronger co-operation with occupational health professionals is desirable and likely to have a tremendous impact on workers and on the economic burden of back pain. Work is an essential feature of adult’s working and social life. Prolonged work disability may lead to poorer quality of life and loss of social identity, and it can also result in permanent exclusion from work. In conclusion, much needs to be done to make health care professionals aware of the link between back pain and the high probability of work disability.

**Patients/ workers**

If Dutch employers do not satisfy all reintegration steps, they might have to pay an additional year of wages. But Dutch law also states that workers might lose employment protection if they put too little effort into vocational rehabilitation. The results on compliance of the participants in our RCT showed that patients sick-listed due to chronic low back pain comply with integrated care in spite of the intensive treatment. Also the results of the qualitative interviews showed that most participants were positive about integrated care.

**Policymakers**

A system barrier for implementation of the integrated care program can be found in the insurance system of the Netherlands. This system is divided: employers or income insurance companies pay for sick leave benefits and the health insurance system pays for the care patients receive. This separation results in that health insurance companies have no interest to fund treatment focussed on return to work because only the employer will gain of such investment. The employer will benefit of the result of the integrated care by a significant reduction of sick leave benefit. The question is: who will pay for the execution of the integrated care program? The cost price of execution of the integrated care program was estimated at € 1472. The Gatekeeper Improvement Act obliges employers to play an active role in the re-integration process of a sick-listed worker. Therefore, it seems plausible that the employer will need to pay the costs. On the other hand, occupational therapy and physical therapy to restore working capacity can be not declared to the health care system. Also declaration of the treatment given by a clinical occupational physician is not possible yet. Policy interventions are needed. Therefore we believe that the clinical occupational physician and occupational health interventions to restore working capacity should be paid by the health insurance companies.

**Recommendations for future research**

This is the first trial to investigate the (cost-) effectiveness of an integrated care program for sick-listed patients with chronic low back pain. The findings of our study indicate that it is important to take all elements of the bio-psychosocial model into account when treating a patient who resumes work because of chronic low back pain. This means that
for a patient sick-listed long term due to chronic low back pain, a cognitive behavioural treatment and also a workplace visit and work adaptation is essential to return to work. The current study design is not suitable for assessment of the effectiveness of the different elements of the integrated care (integrated care-management, workplace intervention, graded activity), because these elements were provided as an integrated intervention. To explore which element(s) of the intervention had the most effect, a factorial design can be used in future research. Another recommendation is related to the rapid growing population of the self-employed in The Netherlands (nowadays 14% of the Dutch working population). They do not have access to an occupational physician since they do not have an employer who is responsible for re-integration of their sick-listed employee. Self-employed persons are characterized by a high level of intrinsic motivation to work. They often only stop working when their complaints are already advanced. Since their working weeks are often extremely long, time to recover is limited. These factors will negatively influence the return to work process which can prolong their disability duration. Our study showed that self-employed are interested to participate in research (16%). Since there is still a lack of information on the effectiveness of interventions for this specific group, it would be interesting to apply the integrated care program on this specific population only. Finally, it would be very interesting to explore the health care consumption and sick leave pattern of chronic low back pain patients after 1 year follow-up. Our study showed that during follow-up the mean extra health care expenses in the integrated care group were € 289 compared to usual care, besides the € 1472 for the integrated care treatment. On the other hand, patients in the usual care group had sought care for a mean of € 1697. It is very plausible this trend will continue after one year.

**Recommendations for practice and policy**

**Employers**

The results of our RCT showed that it is cost-effective and acceptable for employers to execute the work(place) intervention and to look for obstacles and solutions for return to work. The short-term implementation of these solutions (within 3 months) was 74% in our RCT, in contrast to only 50% in comparable studies for sick-listed patients due to (sub-)acute low back pain. The cost-benefit analyses of integrated care compared to usual care from a societal perspective showed a return-on-investment of € 26, i.e. every € invested in integrated care will return an estimated € 26. These results show that when an employee is on sick leave because of chronic low back pain it seems very reasonable for employers to use integrated care.

**Health care providers**

When patients long-term on sick leave due to chronic low back pain consult health care providers it will be important for health care providers to change their goal setting from curative treatment to guidance of their patients in their return to work process by using the integrated care protocol.
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Patients/ workers
It will not only be the health care providers who should change their goal setting, also patients should change their goal setting. Nowadays, patients visit health care providers mainly for diminishing their pain complaints. It will be important for patients who have prolonged work disability due to chronic low back pain that they will have more focus on function restoration. The results of the qualitative interviews with participants of the BRIDGE-study show that it is possible for this population to change their goal setting.

Policymakers
We also want to make a recommendation related to the reimbursement of health care. The current way of reimbursement will be a problem for the implementation of integrated care. Chronic diseases are treated by multiple health care providers in primary but also in the outpatient care setting. Nowadays, diagnostic treatment codes (DBC) are used by health care providers in the outpatient setting to reimburse their care. It is desirable to create a DBC for chronic diseases in which one person is responsible for the care given and will contract the health care providers he wants to cooperate with. Besides this recommendation, we also want to advise to up-date existing guidelines for health care professionals and to incorporate our findings. By existing guidelines we think about the guidelines for occupational health care\textsuperscript{13}, for clinical care like general practitioners\textsuperscript{17}, as well as the multidisciplinary guideline for low back pain\textsuperscript{18}. Besides these up-dates of guidelines, more focus is needed on the effective implementation of the guidelines since developing evidence-based guidelines does not guarantee improved quality of care.

Implementers
A recommendation for the implementers is to generate an education course in which health care providers are trained in the work(place) intervention and clinical management intervention. Besides, the process evaluation of the integrated care program revealed that according to the health care professionals, the main barrier for implementation was related to time consumption for the execution of the program. We think this barrier can be solved by introducing a web-based system in which all data related to return to work process is documented and is accessible for all stakeholders involved in the return to work process of their patient. However, there are several Dutch laws concerning this topic (Personal data protection act and Medical treatment agreement act) which makes the realisation of a web-based database a real challenge.

References

General discussion


(15) Buijs PC. A lack of coordination between OPs and treating physicians was known for years, but not recognized. Tijdschrift voor Bedrijfs- en Verzekeringsgeneeskunde 2001;(9):133-138.
