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ORIGINAL PAPER

Economic Evaluation of a Multi-Stage Return to Work Program for Workers on Sick-Leave Due to Low Back Pain

Ivan A. Steenstra · Johannes R. Anema · Maurits W. van Tulder · Paulien M. Bongers · Henrica C. W. de Vet · Willem van Mechelen

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Abstract *Objective*: To evaluate the cost-effectiveness and cost-utility of a return to work (RTW) program for workers on sick-leave due to low back pain (LBP), comparing a workplace intervention implemented between 2 to 8 weeks of sick-leave with usual care, and a clinical intervention after 8 weeks of sick-leave with usual care. *Design*: Economic evaluation alongside a randomised controlled trial (RCT). *Study population*: Workers sick-listed for a period of 2 to 6 weeks due to LBP. *Interventions*: 1. workplace assessment, work modifications and case management). 2. physiotherapy based on operant behavioural principles. 3. usual care: provided by an occupational physician. *Outcomes*: The primary outcome was return to work (RTW). Other outcomes were pain intensity, functional status, quality of life and general health. The economic evaluation was conducted from a societal perspective. Outcomes were assessed at baseline (after 2–6 weeks on sick-leave), and 12 weeks, 26 weeks, and 52 weeks after the first

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I. A. Steenstra · J. R. Anema · M. W. van Tulder · P. M. Bongers · H. C. W. de Vet · W. van Mechelen (✉)
Institute for Research in Extramural Medicine, VU University Medical Center, Amsterdam, The Netherlands
e-mail: w.vanmechelen@vumc.nl

I. A. Steenstra · J. R. Anema · W. van Mechelen
Department of Public and Occupational Health, VU University Medical Center, Amsterdam, The Netherlands

I. A. Steenstra · J. R. Anema · P. M. Bongers
TNO Work and Employment, P.O. Box 718, 2130 AS Hoofddorp, The Netherlands

I. A. Steenstra · J. R. Anema · P. M. Bongers · W. van Mechelen
Body@Work, Research Center Physical Activity, Work and Health, TNO-VU, Amsterdam, The Netherlands

M. W. van Tulder
Institute for Health Sciences, VU University, Amsterdam, The Netherlands

I. A. Steenstra
Institute for Work and Health, Toronto, ON, Canada

day of sick-leave. *Results*: The workplace intervention group returned to work 30.0 days (95% CI = [3.1, 51.3]) earlier on average than the usual care group at slightly higher direct costs (ratio of 1 day: €19). Workers in the clinical intervention group that had received usual care in the first 8 weeks returned to work 21.3 days (95% CI = [− 74.1, 29.2]) later on average. The group that had received the workplace intervention in the first 8 weeks and the clinical intervention after 8 weeks returned to work 50.9 days (95% CI = [− 89.4, − 2.7]) later on average. A workplace intervention was more effective than usual care in RTW at slightly higher costs and was equally effective as usual care at equal costs on other outcomes. A clinical intervention was less effective than usual care and associated with higher costs. *Conclusion*: The workplace intervention results in a safe and faster RTW than usual care at reasonable costs for workers on sick-leave for two to six weeks due to LBP.

Keywords Low back pain · Operant behavioural · Participative Ergonomics · Return to work · Randomized Controlled Trial · Cost-effectiveness · Occupational health

Introduction

Background

Low back pain (LBP) is a common problem in Western societies. It causes major disability and considerable costs to society. A delay in return to work (RTW) results in high compensation and treatment costs. In the United States costs due to disability caused by LBP were estimated to be more than $37.5 billion per year [1], costs due to production losses in the United Kingdom were estimated at $6.6 billion [2] and costs in the Netherlands were estimated at $4.6 billion, of which $3.1 billion were caused by work absenteeism [3]. Total costs estimates vary from 0.28 to 1.7 % of the Gross National Product, depending on the method used [4]. Most costs (approx. 93%) are however the result of absenteeism from work caused by a limited number of cases [3, 5, 6].

Hlobil et al. [7] conclude in their review that there is strong evidence for the effectiveness of return to work interventions on the return to work rate after 6 months and on the reduction of days of absence from work after ≥ 12 months. They also mention that "a more thorough understanding is also needed about which ... combinations of ... components can help to shorten work absenteeism." In the editorial by Loisel [8] our study is mentioned as adding substantially to the knowledge on the topic of return to work interventions.

Based on the report of the Quebec Task Force on Spinal Disorders [9] that recommended early intervention to reduce chronicity, a model has been developed by researchers at Sherbrooke University, Canada. The aim of this model was to treat sub-acute occupational LBP and to prevent transition to the chronic phase. The model has been evaluated in Canada in a population-based, randomized clinical trial (RCT) [10], which showed that compared to usual care a workplace intervention was more effective, that the clinical intervention had no effect on return-to-work (RTW), and that the combination of both interventions had a slightly larger effect than the workplace intervention alone. In a cost-benefit and cost-effectiveness analysis performed from the insurers' perspective with a mean follow up of 6.4 years, a trend towards cost-effectiveness and cost benefit was found [11].

We replicated this study in the Netherlands [12] to cross validate the Canadian findings in a different sociocultural environment and to add knowledge on the cost-effectiveness of treatment options for workers in the sub acute phase of LBP.

Objectives

To assess whether the workplace intervention, the clinical intervention, or both are effective and at what costs compared to usual care in another socio-cultural environment. The workplace intervention between 2–8 weeks of sick-leave and consisted of a workplace assessment, work modifications and case management in which all major stakeholders in the return-to-work process participated: i.e. the worker, the employer, the occupational physician (OP) and the worker's general practitioner (GP). The clinical intervention, which occurred after 8 weeks, comprised a graded activity program, i.e. a gradually increasing exercise program based on an operant behavioral approach.

Methods

Design of the study

The study is designed as a RCT with a factorial design (see Figs. 1) and has been executed in 13 occupational health services (OHS). The Medical Ethics Committee of VU University Medical Center in Amsterdam approved the study design, protocols and procedures, and all participants provided written, informed consent.

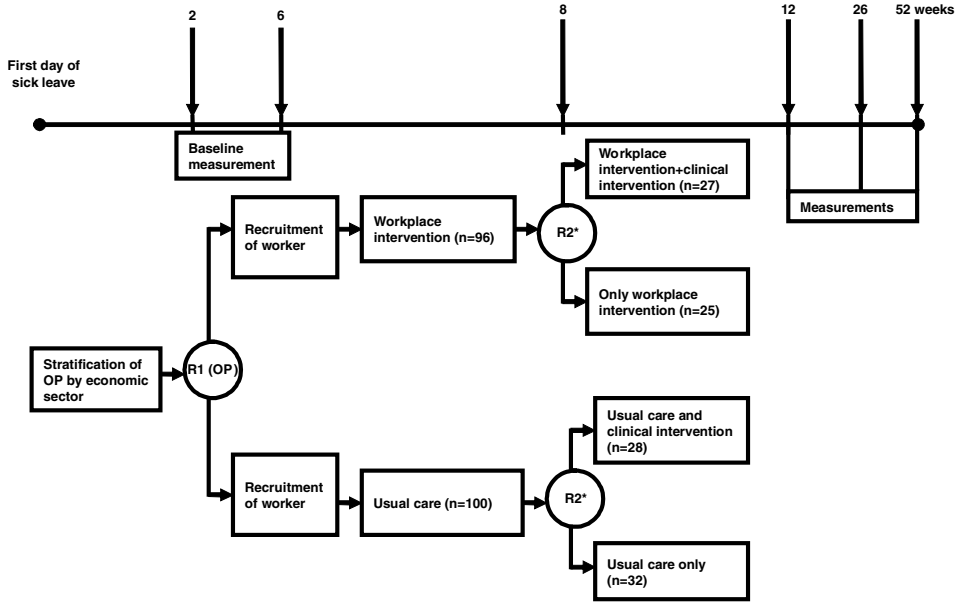

Fig. 1 The two stage design of the study

Treatment allocation

There were two randomisation procedures in this trial. Because part of the intervention had to be performed by the occupational physician (OP), the randomisation for the workplace intervention and usual care took place at the level of the OP to reduce the risk of contamination. The OPs were stratified by economic sector (i.e. industry, health care and office work) to avoid an unequal distribution in job characteristics after randomization. The second randomisation procedure allocated workers who were still off work after 8 weeks to the clinical intervention or usual care. An independent researcher (HCWdV) randomized the OPs and the workers using a list of random numbers and prepared the sealed envelopes to be opened by the OP in case of an eligible worker for the clinical intervention [9].

Study population

From October 2000 till October 2002, workers with LBP were recruited by 55 OPs. Participants in this study had to be on sick-leave from regular work for 2 to 6 weeks due to LBP, aged 18 to 65 years old, and able to understand Dutch to give informed consent and to complete written questionnaires. LBP was defined as pain localised in the lower back between the lower angle of the scapulae and above the buttocks, without a specific underlying cause. Patients were excluded by their OP in case of specific causes of LBP [13]; pregnancy; serious psychiatric disorders; in case of a legal conflict at work [12]; or in case a worker had been sick-listed due to LBP less than one month prior to the current episode of sick-leave, leaving only incident cases of sick-leave due to LBP for our study.

Sample size

Because of the course of sick-leave due to LBP a smaller number of patients would be available for the second randomisation [14]. Therefore we first calculated sample size for the comparison of the clinical intervention with usual care at 8 weeks of sick-leave. To detect a 30% difference in lasting RTW between the clinical intervention group and the usual care group, a sample size of 90 workers was required, resulting in 45 workers in both treatment arms after 8 weeks. This 30% difference can be detected with a power $(1-\beta)$ of 80% at $\alpha = .05$ [15]. We estimated that 50% of the population would resume work between 2 and 8 weeks. Therefore we attempted to enrol 200 workers, resulting in 100 workers per treatment arm. A 20% difference in lasting RTW is relevant from both the societal and the employers perspective; this difference is statistically significant at $\alpha = .05$ with a power $(1-\beta)$ of 80%, assuming an intraclass-correlation coefficient of .15 to account for randomisation at OP level. We calculated that a sample size of 200 workers has enough power to detect a 20% difference in lasting RTW between the workplace intervention group and usual care.

Interventions

The Amsterdam Sherbrooke model

The original Canadian Sherbrooke intervention model [16, 17] was modified to Dutch occupational health care and Dutch disability legislation. This modified version of the Sherbrooke

model has been described extensively elsewhere [12]. The most important difference in the workplace intervention consisted of participative ergonomics and that the Dutch situation required a small special committee formed with every case. The special committee consisted of the worker, his/her supervisor and a specially trained work and health professional (ergonomist, occupational health nurse, occupational therapist or occupational physiotherapist) from the OHS. The recommendations for RTW made by the committee in a one day session were communicated to the OP. In the Canadian trial the fist step consist of an examination of the worker by an OP and a workplace visit by an ergonomist. Followed by participative ergonomics involving the worker, management, the unions and a back pain advisory group [16].

The clinical intervention was based on the graded activity protocol as developed by Staal et al. [18] and was based on behavioural methods [19, 20]. In the original Sherbrooke trial the clinical intervention consisted of a more intensive program, consisting of two consecutive steps [16].

Usual care

In the Netherlands, workers who are absent from work due to LBP are guided throughout their sick-leave according to the Dutch OP guidelines for LBP [21, 22]. In this guideline good prognosis of LBP is emphasized, resuming daily activities and work within two weeks. Workplace interventions are mentioned as an option and a clinical intervention is recommended after 12 weeks of sick-leave. By informing the patients' general practitioner (GP) we tried to minimize co-interventions. Workers in all groups were not restricted in obtaining additional care for their LBP.

The workplace intervention

The workplace intervention (WI) took place right after inclusion and at least before 8 weeks of sick-leave. The intervention consisted of:

1. Usual care and in addition.
2. A workplace assessment and work modifications based on participative ergonomics [23–25], which involved all important stakeholders: the OHS's ergonomist or occupational health nurse, the worker on sick-leave, the workers supervisor and possible others.
3. Communication between the OP and the GP, to reach consensus on counselling the worker in RTW [26].

The clinical intervention

The clinical intervention (CI) consisted of a graded activity program based on operant behavioural therapy principles based on the findings from patient history, physical examination, functional capacity evaluation, the demands from the patients' work and the patients' expectations on time to RTW. The entire program consisted of 26 one-hour sessions maximally, with a frequency of two sessions a week. The first session took half an hour more since taking the patients history and a physical examination were part of this session. The program ended as soon as a full RTW had been established, according to an earlier agreed upon individual schedule . During the program the worker had an active role in RTW and the physiotherapist (PT) acted as a coach and supervisor, using a hands-off approach [19, 27].

Primary outcomes measure

Primary outcome measure for this cost-effectiveness evaluation was lasting RTW, defined as the duration of work absenteeism due to LBP in calendar days from the first day of sick-leave to full return to own or other work with equal earnings, for at least 4 weeks without (partial or full) drop-out. RTW was registered continuously in the OHS' sick-leave database.

Secondary outcome measures

Clinical outcomes included functional status, measured with the well validated Roland Disability Questionnaire [28, 29]; pain intensity, measured on a 10-point numerical rating scale [30, 31]. General health status was measured with a VAS (0–100 mm). Quality of life were measured using the Dutch version of the EuroQol [32, 33], and expressed in utilities. Effects of all outcome measures were expressed as differences within each intervention group between baseline and last follow-up. Outcome measures were assessed at baseline (2–6 weeks after the first day of sick leave), and at 12, 26 and 52 weeks after first day of sick-leave.

Blinding

Obviously, workers, physicians and other therapists could not be blinded for the allocated treatment. As self-report questionnaires were used for all secondary outcome measures, blinding of these during follow-up was not possible. But, since all questionnaires were sent to the worker by mail, no direct influence by the researchers or treating professionals was likely to happen. Sick-leave data were extracted from automated databases, therefore bias due to a lack of blinding for our primary outcome was limited.

Economic evaluation

The economic evaluation was evaluated from the societal perspective. Direct health care and direct non-health care costs, as well as indirect costs were measured. Direct health care costs included the costs of the workplace and the clinical intervention to which patients were randomly allocated, and additional visits to a health care provider (general practitioner, manual therapist, physiotherapist, medical specialist, other health care professionals), prescription medication, professional home care and hospitalisation. Direct non-health care costs included out-of-pocket expenses, and costs of paid and unpaid help. Indirect costs consisted of loss of production due to LBP related absence from paid and unpaid work (i.e. volunteer work, schooling) [34]. Direct and non-direct health care costs were measured retrospectively at 12 weeks, 26 weeks and 52 weeks after the first day of sick-leave, using postal questionnaires. RTW was assessed as full RTW, partial RTW or return to modified work. Partial RTW meant that a worker could be at work for 50% of productivity as estimated by the workers OP. Based on partial RTW, the net number of calendar days on sick-leave due to LBP during follow-up was calculated, taking reduced productivity into account. For example, working for 50% for one calendar day of work was counted as half a day of sick-leave. The OHS provided data on the duration of sick-leave, the estimated productivity during vocational rehabilitation and the number and duration of consultations with the OP.

Direct costs were estimated according to Dutch guidelines for cost analysis in health care research [35]. In case prices were not provided by these guidelines, tariffs of the Dutch Central Organisation for Health Care Charges (CTG) were used to estimate costs. The costs of prescribed medications and over the counter medication were estimated using prices provided by the Royal

Table 1 Prices used in economic evaluations

Direct healthcare costs	€
Occupational physician (per hour)	147.7
General practitioner (session of max. 20 min)[a]	24.8
Physiotherapist (session of 25 min)[a]	21.23
Manual therapist (session of max. 45 min)[b]	32.03
Mensendieck exercise therapy (session of max. 30 min.)[a]	22.90
Hospitalisation (per day)[a]	276.05
Professional home care (per hour)[a]	26.71
Medical specialist[a]	121.49
Workplace intervention	681
Clinical intervention	942
Direct non-health care costs	
Alternative therapist (per session)[c]	25
Acupuncture[c]	41.60
Help from partner/friends (per hour)[a]	8.93
Indirect costs	
Absenteeism unpaid labour (per hour)[a]	8.93

[a]Fee according to Dutch guideline.

[b]Tariff according to Dutch Central Organization for Health Care Charges.

[c]Fee according to professional organization and mean price of different practices.

Dutch Society for Pharmacy. Costs of the workplace intervention were based on 8 hours of work multiplied by the fee of an OHS' ergonomist. The price of the clinical intervention was the market price of a similar intervention from the graded activity provider. Prices of visits to alternative health care providers, e.g. acupuncturists and homeopaths, were estimated by the fee suggested by the professional organisations. An overview of all costs is presented in Table 1.

Costs of production losses due to sick-leave from LBP were calculated by multiplying the net number of days on sick-leave due to LBP during follow-up by the estimated price of production loss of a worker per day of sick-leave based on age and sex [35]. The costs from production loss due to paid labour were calculated using the friction cost approach. In the friction cost approach the assumption is made that every worker in the production process can be replaced and production losses cease to exist after a certain friction period. The friction period was estimated to be 122 days [35]. The costs in the cost-effectiveness plane of RTW do not include costs due to LBP related sick-leave during follow-up, since this would lead to a sick-leave outcome in both numerator and denominator.

Baseline characteristics

Data on neurological signs, function, job content data [36–38], expectations of RTW, prior sick-leave and data on workload [39] were obtained at baseline to identify potential confounding variables.

Analysis

All analyses were carried out according to the intention-to-treat principle. All patients, including withdrawals and patients with poor compliance, were included in the analyses. Data on the primary outcome measure RTW and on indirect costs due to sick-leave were available for all

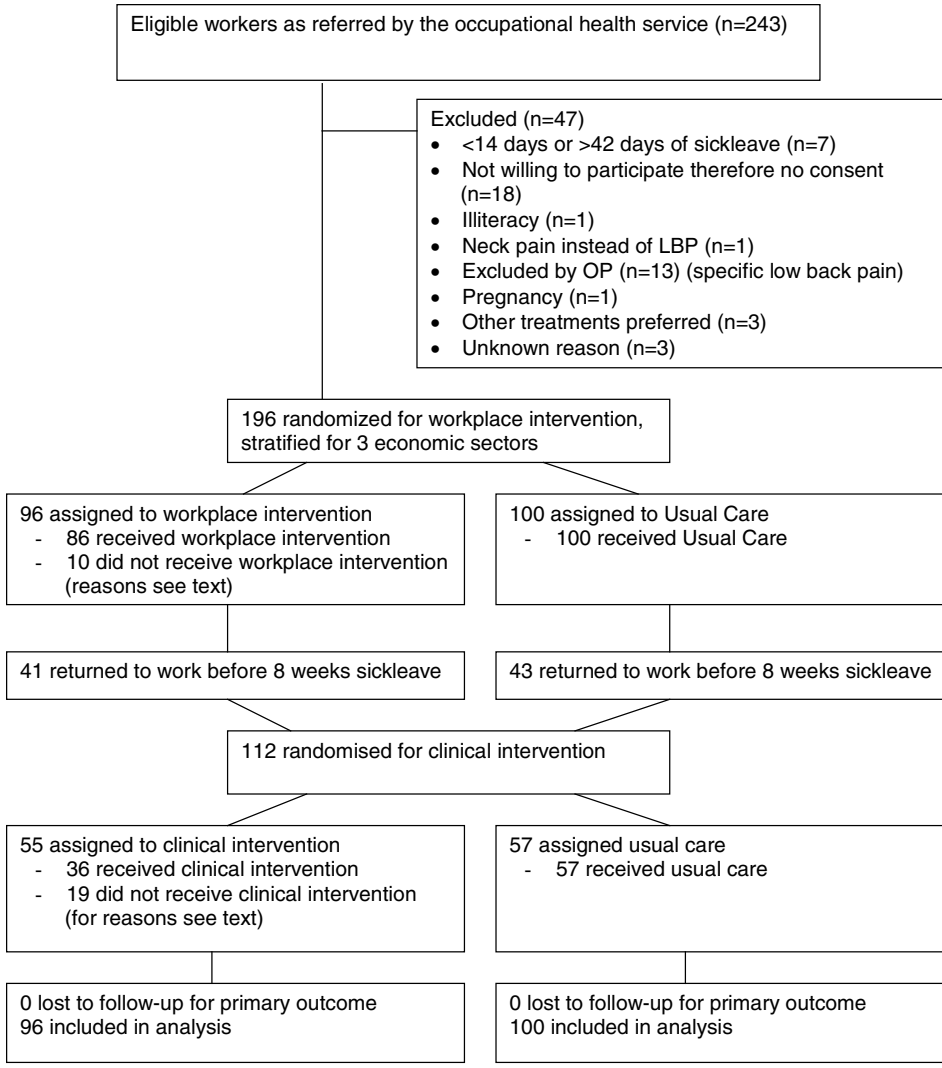

Fig. 2 Flow diagram describing the progress of the workers through the phases of the trial*

workers, since these data were provided by the OHS. We imputed missing data on direct costs and cost from unpaid labour based on group means at each measurement. Missing data on secondary outcome measures at 52 weeks were substituted applying the last value carried forward method. We excluded workers who missed all data on direct costs and secondary outcomes for the cost effectiveness analyses of all secondary outcomes.

Bootstrapping was used for pair wise comparison of the mean differences in direct health care costs, direct non-health care costs, total direct costs, total indirect costs and total costs between the intervention groups. Bootstrapping was also conducted for the pair wise comparison of effect in terms of RTW. Confidence intervals (95% CI) were obtained by bias corrected and accelerated (Bca) bootstrapping (2000 replications) [40]. Workers randomised for the clinical intervention from both the workplace intervention group and the usual care group were analysed

separately, resulting in pair wise comparisons within three groups. Comparisons were made between the workplace intervention (WI) group vs. the usual care (UC) group, between the clinical intervention following workplace intervention (WI*CI) group vs. usual care following workplace intervention (WI*UC) group and between the clinical intervention following usual care (UC*CI) group vs. usual care only (UC*UC) group (this latter group was randomised to usual care at both randomisation points and received usual care during both intervention periods). Which means that workers that were not randomised for the clinical intervention because of RTW before 8 weeks were not included in the cost-effectiveness analysis of the clinical intervention.

Cost-effectiveness ratios were calculated by dividing the difference between the mean costs of two interventions by the difference in the mean effects of the two interventions. RTW, functional status, pain intensity and general health were included as outcomes in the cost-effectiveness analysis. A cost-utility analysis was also performed, in which the effects on the Euroqol were expressed as utilities. A cost-utility ratio and corresponding 95% CI was estimated for the same pair wise comparisons. Cost-effectiveness ratios were plotted on an cost-effectiveness plane. In the diagram the horizontal axis represents the difference in effect between the experimental intervention group and usual care, and the vertical axis represents the difference in costs between the two interventions. If all points are in the south-west or the north-east quadrant the choice between the programmes is clear. In the south-west quadrant the experimental intervention is both more effective and less costly than usual care. The experimental intervention dominates usual care. In the north-east quadrant the opposite is true. In the north-west and south-east quadrants the choice depends on the additional costs that are considered acceptable to gain effectiveness [41–43]

Sensitivity analysis

As indirect costs due to production losses related to LBP form a major part of the total costs, the method of measurement is important. Therefore our sensitivity analyses include three variations on the measurement of indirect costs. To calculate costs of production losses in paid labour, the costs of one day of productions loss was estimated based on age and gender [35]. Because there were differences in age and sex between groups, although small, the cost per day of sick leave differed (€108 in the WI vs. €93 in the UC). In a first sensitivity analysis we calculated indirect costs due to production losses in paid labour by using the mean costs due to production losses for the entire population at €100 per day, adjusted for age and sex to enable extrapolation to the general population.

Secondly, we calculated the indirect costs of production loss in paid labour using number of calendar days instead of net number of days on sick-leave. Thirdly, in addition to the friction cost approach we also calculated costs using the human capital approach. This method values all days lost due to sick-leave due to LBP by multiplying all days by the costs of one day of production loss.

Results

After the inclusion period a total of 196 workers were included in the trial and were randomised to the workplace intervention ($n = 96$) or usual care ($n = 100$) (see Fig. 2). Ten workers (10%) were did not fully comply to the workplace intervention protocol: 5 workers returned to work before an appointment for the intervention was made and 5 workers did not participate in the intervention due to a work scheduling problem ($n = 3$), a medical reason ($n = 1$) or a work conflict ($n = 1$). After 8 weeks 112 workers who had not yet returned to work, were randomised for the

clinical intervention ($n = 55$) and usual care ($n = 57$). Nineteen workers out of 55 (35%) were not compliant to the clinical intervention for the following reasons: interference with another practitioner ($n = 3$), miscommunication ($n = 2$), change of function/job ($n = 2$), contraindications ($n = 5$), not able to follow regime ($n = 3$), drop-out from program ($n = 3$) and distance to training centre ($n = 1$).

Data on sick-leave were available for all workers. 172 (88%) workers returned to work during the 52 weeks follow-up questionnaire. Every patient had to fill in 3 questionnaires during follow-up, resulting in a total of 588 questionnaires. Sixty-eight of these questionnaires were not returned (12%). We excluded 8 workers (4%) with missing data on both all direct costs and all secondary outcomes from the cost effectiveness analyses of all secondary outcomes. Eleven workers (6%) were excluded because of missing data on the general health question, and 10 workers (5%) were excluded in the analysis of quality of life because of missing data. Eight from the remaining 188 workers (3.6%) missed data on secondary outcome measures at 52 weeks; using the last value carries forward method we could impute these data. Complete cost data were available for 81 workers (80.8%) in the UC group and 75 (77.3%) in the WI group. In the group of workers that were randomised for the clinical intervention after 8 weeks of sick-leave, complete cost data were available for 43 (78.2%) in the clinical intervention groups and 45 (78.9%) in the usual care groups. Missing data were equally distributed among the workplace intervention group, clinical intervention group and usual care groups. Since workers with missing direct cost data had a smaller net number of days on sick-leave during follow-up (i.e. WI = 31.2 vs. 51.1 and UC = 42.1 vs. 68.3) and did not differ on baseline, imputing the group mean for missing data probably led to an overestimation of direct costs for the whole group.

Patient characteristics

Table 2 shows the baseline values of the outcome measures and the prognostic factors for the WI group and the UC group. If the distribution of a variable was not normal, the median value and the interquartile range (IQR) are presented. Except for gender, only small differences were found in the baseline characteristics between these groups. The baseline values for both groups randomized to the clinical intervention and usual care are also presented in Table 2. Estimated costs of production loss per day were significantly higher for the WI group compared to the UC group. The group that received UC*CI scored significantly better on functional status and quality of life at baseline compared to the UC*UC group.

Clinical effects

The WI group returned to work 30.0 days (95% CI = [3.1–51.3]) earlier than the UC group. There were no significant differences between the WI group and the UC group on any of the secondary outcomes (see Table 3).

Workers in the WI*CI group returned to work 50.9 days (95% CI = [− 89.4, − 2.7]) later than the workers in the WI*UC group. Workers in the UC*CI group returned to work 21.3 days later (95% CI = [− 74.1, 29.2]) compared with workers in the UC*UC group. Again, there were no significant differences between the groups on any of the secondary outcome measures.

Health care utilisation

Health care utilisation of all workers randomised to the workplace intervention and usual care is presented in Table 4. Health care resources were used equally between both groups. The number of hours missed from unpaid work was higher in the WI group and in the WI*UC group. The

Table 2 Potential prognostic variables and baseline values of outcome measures for all groups

	Workers on sickleave > 2 weeks ($n=196$)		Workplace intervention < 8 weeks ($n=52$)		Usual care < 8 weeks ($n=60$)	
	Workplace intervention		Clinical intervention		Clinical intervention	
	Yes ($n=96$)	No ($n=100$)	Yes ($n=27$)	No ($n=25$)	Yes ($n=28$)	No ($n=32$)
Baseline characteristics						
Age in years (mean; SD)	44.0 (8.6)	41.2 (10.7)	43.6 (7.9)	43.5 (6.7)	39.2 (9.9)	43.3 (9.5)
Gender (male/female)	51/45*	33/67*	13/14	14/11	6/22	13/19
Estimated cost of production loss per calendar day (in €) (mean; SD)	108.4 (33.9)*	93.0 (35.4)*	104.1 (32.1)	114.3 (35.4)	83.8 (25.9)	98.5 (38.5)
Job type:						
Industrial	11	6	6	0	2	3
Transportation	2	3	1	0	0	1
Office work	20	17	3	7	5	8
Health Care/Services	56	65	15	17	18	18
Other	6	5	2	1	2	2
Heavy physical work index [1–4] (mean; SD)	2.0 (0.5)	2.1 0.5)	2.0 (0.6)	2.0 (0.4)	2.1 (0.4)	2.1 (0.5)
Job control [1–4][a] (mean; SD)	2.6 (0.4)	2.5 (0.4)	2.6 (0.3)	2.6 (0.3)	2.5 (0.3)	2.6 (0.5)
Job demands [1–4][a] (mean; SD)	2.5 (0.3)	2.6 (0.3)	2.5 (0.4)	2.5 (0.3)	2.7 (0.3)	2.5 (0.3)
Supervisor support [1–4][a] (mean; SD)	3.0 (0.3)	3.1 (0.5)	3.0 (0.4)	3.0 (0.3)	3.2 (0.4)	3.1 (0.4)
Radiating pain (y/n)	15/81	22/77	4/23	5/20	7/21	9/23
Job satisfaction [1–4][b] (mean; SD)	1.7 (0.8)	1.7 (0.8)	1.7 (0.8)	1.7 (0.8)	1.7 (0.8)	1.7 (0.8)
Expectation of patients on return-to-work [1–7][a] (mean; SD)	3.6 (1.2)	3.6 (1.1)	3.4 (1.2)	3.6 (1.1)	3.5 (1.1)	3.4 (1.1)
Sick-leave prior to inclusion (partial/full)	20/76	35/65	21/6	21/4	22/6	24/8
Baseline values outcome measures						
Sick-leave (days) of current episode of LBP prior to inclusion (median, IQR)	26 (19–36)	24 (18–30)	24 (10–38)	27(11–42)	24 (11–40)	25.5 (14–37)
Functional status (RDQ) (mean, sd)	14.9 (4.2)	15.3 (3.3)	16.2 (4.0)	15.3 (3.3)	12.7 (4.4)*	16.2 (3.1)*
Pain severity (mean, sd)	6.5 (1.7)	6.6 (1.7)	6.8 (1.3)	6.6 (1.7)	6.3 (1.5)	6.9 (1.4)
Quality of life (mean, sd)	0.53 (0.25)	0.552 (0.217)	0.47 (0.24)	0.55 (0.22)	0.58 (0.30)*	0.43 (0.28)*
General health (mean, sd)	62.1 (16.5)	61.4 (11.1)	60.5 (17.4)	61.4 (11.1)	65.0 (14.2)	57.8 (15.7)

Note. IQR, Interquartile range, 25th percentile to 75th percentile.

[a]A higher score means a higher level of physically demanding work, job control, job demands, supervisor support, expectation of return-to-work.

[b]A higher score means a lower level of job satisfaction.

*$p < 0.05$.

Table 3 Mean improvements within the groups and mean differences in all groups

					Workplace intervention in first 8 weeks				Usual care in first 8 weeks			
		n	Mean improvement (SD)	Mean Difference [95% CI]		*n*	Mean improvement (SD)	Mean Difference [95% CI]		*n*	Mean improvement improvement	Mean Difference [95% CI]
Lasting RTW	WI	96	100.14(96.38)	29.97 (3.11, 51.26)[a]	CI	27	160.78 (78.66)	−50.90 [− 89.36, −2.68][a]	CI	28	172.75 (85.87)	−21.34 [− 74.06, 29.21][a]
	UC	100	130.12 (69.58)		UC	25	109.88 (62.55)		UC	32	151.41 (105.11)	
Functional status	WI	94	−7.84 (5.69)	0.92 [− 0.81, 2.64]	CI	27	−8.29 (6.98)	1.79 [− 1.85, 5.42]	CI	27	−6.12 (4.62)	3.06 [− 0.07–6.19]
	UC	94	−8.75 (6.29)		UC	24	−10.08 (5.77)		UC	31	−9.18 (6.87)	
Pain severity	WI	94	−2.45 (2.65)	0.20 [− 0.57, 0.97]	CI	27	−2.41 (2.39)	0.38 [− 1.13, 1.90]	CI	27	−2.07 (2.32)	0.99 [− 0.48, 2.46]
	UC	94	−2.65 (2.69)		UC	24	−2.79 (2.98)		UC	31	−3.06 (3.15)	
Quality of life	WI	94	0.21 (0.27)	−0.04 [− 0.12, 0.04]	CI	27	0.22 (0.25)	−0.05 [− 0.20, 0.11]	CI	27	0.19 (0.21)	−0.11 [− 0.25, 0.03]
	UC	92	0.26 (0.29)		UC	24	0.27 (0.30)		UC	31	0.30 (0.31)	
General health	WI	94	12.6 (20.75)	−1.77 [− 7.77, 4.24]	CI	26	11.77 (21.42)	−2.52 [− 14.80, 9.76]	CI	27	6.04 (21.44)	8.45 [− 3.22, 20.12]
	UC	91	14.38 (20.63)		UC	27	160.78 (78.66)		UC	31	14.48 (22.71)	

Note. WI, Workplace intervention; UC, Usual care; CI, Clinical intervention; SD, Standard deviation; [95% CI], 95 % Confidence interval.

[a] Bootstrapped because of right skewed distribution.

Table 4 Health care utilisation, paid work and unpaid work

Type of utilisation	WI		WI in first 8 weeks ($n=52$) CI		UC in first 8 weeks ($n=60$) CI	
	Yes ($n=96$)	No ($n=100$)	Yes ($n=27$)	No ($n=25$)	Yes ($n=28$)	No ($n=32$)
Occupational physician (in minutes of consultation)	86.3 (45.0)	94.8 (50.0)	92.0 (37.7)	110.9 (38.2)	115.8 (40.1)	110.4 (49.3)
General practitioner (no. of visits)	1.2 (1.9)	1.5 (1.9)	1.4 (1.7)	0.9 (1.4)	1.5 (2.5)	1.8 (1.9)
Physiotherapist (no. of visits)	12.8 (12.7)	13.3 (12.1)	13.0 (9.4)	10.0 (9.7)	16.7 (14.4)	13.2 (11.0)
Manual therapist (no. of visits)	2.1 (4.2)	3.4 (6.5)	4.1 (6.1)	1.9 (3.8)	3.2 (5.5)	4.1 (7.8)
Mensendieck therapy (no. of visits)	1.8 (7.8)	2.2 (6.5)	2.4 (7.6)	1.4 (5.9)	1.2 (4.1)	2.6 (5.7)
Medical specialist (no. of visits)	0.5 (1.4)	0.9 (2.6)	1.5 (3.9)	0.3 (1.1)	0.6 (1.4)	0.8 (2.2)
Alternative health care (no. of visits)	1.1 (3.2)	0.5 (1.5)	1.1 (2.6)	1.5 (4.7)	1.2 (2.9)	0.2 (0.5)
No. of diagnostic tests	0.6 (1.1)	1.0 (1.8)	1.2 (1.9)	0.9 (1.5)	0.6 (0.9)	0.8 (1.1)
Professional home care (hours)	0.2 (1.4)	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)
Unpaid help (hours)	59.6 (118.7)	59.3 (102.9)	53.8 (101.1)	42.7 (80.2)	86.0 (189.9)	75.5 (87.7)
Paid help (hours)	2.5 (9.4)	4.1 (21.4)	1.5 (6.3)	4.2 (13.9)	1.6 (7.2)	10.9 (36.6)
Absenteeism from unpaid work (hours)	241.8 (297.9)	225.8 (170.9)	262.5 (199.6)	340.3 (504.7)	260.0 (237.4)	260.8 (188.2)
Hospitalization (in days)	0.0 (0.3)	0.4 (2.4)	0.3 (1.1)	0.1 (0.4)	0.0 (0.0)	0.1 (0.7)
Sick-leave (net days)	77.3 (53.9)	93.1 (68.8)	122.0(74.5)	85.9 (51.5)	110.4 (55.3)	102.4 (71.5)
Sick-leave in calendar days	108.5 (76.8)	135.2 (96.1)	181.7 (83.3)	115.3 (65.7)	172.9 (180.8)	155.9 (104.4)

Note. WI, Workplace intervention; UC, Usual care; CI, Clinical intervention.

mean number of total days on sick-leave is lower in the WI group. For the groups that had been randomised to the clinical intervention or usual care after 8 weeks, the mean total number of days on sick-leave was lower in the UC groups compared to the CI groups.

Prescribed medication use during follow-up was ranged from 52.1% in the WI group to 50.5% in the UC group. 55.6% in the WI*CI group and 30.4% (7/23) in the WI*UC group used prescribed medication. Prescribed medication use was 53.6% (15/28) in the UC*CI group and 59.4% (19/32) in the UC*UC group. Over-the-counter medication ranged from 39.4% in the WI group to 48.5% in the UC group,. And 37.0% in the WI*CI group and 35.7% in the WI*UC group used over-the-counter medication. Over the counter medication had been used by 35.7% in the UC*CI group and by 40.6% in the UC*UC group.

During the study 7 workers were hospitalised. Two of them were from the UC group and had returned to work, although in one of these cases a herniated disc was diagnosed. One of them from the WI group had returned to work within 8 weeks and was later operated on a herniated disc. One worker in the UC*CI group was operated on a herniated disc. One worker in the UC*UC group was treated by a neurosurgeon. One worker from the WI was hospitalised for pain treatment. One worker in the UC*CI group was hospitalised for pain treatment later that year.

Costs

The mean costs for the WI vs. UC group, the WI*UC vs. WI*CI group and the UC*UC vs. UC*CI group are presented in Table 5. The differences in costs are presented in Table 6. Indirect costs were slightly lower for the WI group compared to the UC group. Direct costs were slightly higher in the WI group compared to the UC group, mainly because of the higher cost of the intervention. Costs as caused by hospitalisation were higher in the usual care group, but were only small when compared to the total costs. Total direct costs in both CI groups were slightly higher as compared to the UC groups. Total costs were slightly higher in the WI*CI group compared to the WI*UC group, mainly caused by higher costs from production losses in paid labour and costs of the intervention. However, confidence intervals of all cost differences were large and all included 0 (no difference in costs).

Cost-effectiveness and cost-utility analyses

Cost-effectiveness and cost-utility ratios are presented in Table 7. The ratio for the primary outcome RTW shows that an additional €19 are needed in the WI group for one days less sick-leave compared with UC. Since most cost-effect pairs for the secondary outcome measures in the WI group are located in the northeast and southeast quadrants of the cost-effectiveness plane (Fig. 3), it can be concluded that there is no major difference in costs between WI and UC but that WI was associated with larger effects.

Since most cost-effect pairs in the WI*CI group are located in the northwest quadrant (see Fig. 4a), it can be concluded that CI in this group was less effective and associated with higher costs in all outcomes. The CI is less effective than UC in the group that had received UC in the first 8 weeks. Since most cost-effect pairs of the UC*CI group are located in the northwest and southwest quadrant (see Fig. 4b), it can be concluded that CI in this group was less effective and associated with higher costs in the outcome RTW and with equal costs in all secondary outcomes.

Table 5 Mean total costs during follow-up

	WI		WI in first 8 weeks CI		UC in first 8 weeks CI	
Costs[a]	Yes ($n=96$)	No ($n=100$)	Yes ($n=27$)	No ($n=25$)	Yes ($n=28$)	No ($n=32$)
Direct health care costs	2215 (1585)	1889 (1706)	3145 (1387)	2436 (2280)	2749 (1485)	1849 (1428)
hospitalization costs	11 (79)	120 (671)	0 (0)	22.1 (110.4)	69.01(315.4)	34.5 (195.2)
Direct non-health care costs	618 (1099)	607 (958)	862 (1721)	498 (848)	550 (896)	798 (916)
Total direct costs	2833 (2219)	2495 (2158)	4007 (2726)	2935 (2519)	3299 (1769)	2647 (1983)
Production losses in unpaid labour	1256 (621)	1038 (1512)	1236 (1232)	1726 (2577)	1095 (662)	1123 (697)
Production losses in paid labour (sick leave)	4904 (4536)	5575 (5558)	7149 (5241)	6436 (5165)	6143 (2860)	7115 (7057)
Total costs without sick-leave	4089 (3211)	3534 (2547)	5243 (3480)	4660 (4464)	4395 (2119)	3770 (2487)
Total costs	8993 (6216)	9109 (6375)	12391 (7383)	11096 (6720)	10537 (3601)	10885 (7363)

Note. WI, Workplace intervention; UC, Usual care; CI, Clinical intervention.

[a]Mean costs (SD) in €.

Table 6 Difference in mean total costs (in Euro) during the complete follow-up period

Costs	WI vs. UC*	WI*CI vs. WI*UC*	**UC*CI vs. UC*UC***
Direct health care costs	− 327 [− 801, 166]	− 695 [− 2231, 534]	− 899 [− 1610, 80]
Direct non-health care costs	− 11 [− 276, 305]	− 363 [− 955, 438]	247 [− 287, 720]
Total direct costs	− 338 [− 938, 264]	− 1058 [− 2632, 475]	− 652 [− 1594, 511]
Production losses in unpaid labour	− 218 [− 544, − 107]	489 [− 622, 1601]	27 [− 325, 380]
Production losses in paid labour (sick leave)	671 [− 711, 1985]	− 713 [− 3453, 2331]	973 [− 1676, 3503]
Total costs without sick-leave	− 556 [− 1284, 282]	− 583 [− 3050, 1917]	− 624 [− 1847, 733]
Total costs	116 [− 1790, 1919]	− 1282 [− 5011, 2589]	348 [− 2722, 3004]

*Mean difference [95% CI] in €.

Sensitivity analyses

Using a fixed sum of €100,- per day of production loss instead of estimations based on age and gender , resulted in mean costs due to production losses of €4697,- in the WI group and €5854,- in the UC group. Overall this resulted in more cost-effect pairs in the south-east quadrant of the cost-effectiveness planes of all secondary outcomes. Since sick-leave days were not accounted for in the denominator of the RTW ratio, the cost-effectiveness plane for this outcome remains unchanged.

In the second sensitivity analysis we compared net working days of sick-leave used in this study with calendar days on sick-leave as commonly used [43] which leads to the conclusion that using net days on sick-leave resulted in a lower estimate of costs and smaller differences between the groups.

Thirdly, in addition to the friction cost approach we also calculated costs using the human capital approach. Using this method resulted in a higher estimate of costs and larger differences between the groups.

Discussion

This study is one of the first cost-effectiveness studies on LBP in occupational health care. The effectiveness of a workplace intervention, followed by a clinical intervention was studied. The workplace intervention was effective on the main outcome of this study: lasting RTW at slightly higher costs: an additional €19 are needed in the WI group for one days less sick-leave compared with UC. It should be noted that costs due to sick-leave are not included in the estimation of this ratio. Adding sick-leave costs to the total costs in this analysis would have resulted into sick-leave in both numerator and denominator leading to a cost-benefit analysis and not a cost-effectiveness analysis.

This study is a replication of a trial performed earlier in Canada. Although the sociocultural contexts differ between Canada and The Netherlands, in both studies the workplace intervention was effective for lasting RTW. In our study there was no positive effect for the clinical intervention, where the Canadian study showed a small beneficial effect for the combination of the clinical intervention and the workplace intervention. The clinical intervention led to a delay in RTW at higher costs than usual care.

All subjects in our study improved over time on all secondary outcomes, however none of the intervention groups improved significantly compared to usual care. The workplace intervention was more effective than usual care in improving most secondary outcomes at equal costs. The

Table 7 Cost-effectiveness and cost-utility ratios in the cost-effectiveness planes for RTW, functional status, pain, quality of life and general health

	UC vs. WI					WI < 8 weeks UC vs. CI					UC < 8 weeks UC vs. CI				
Outcome measure	Ratio	NE[a]	SE[b]	SW[c]	NW[d]	Ratio	NE[a]	SE[b]	SW[c]	NW[d]	Ratio	NE[a]	SE[b]	SW[c]	NW[d]
Lasting RTW	WI 19*	91	8	0	1	CI 11	0	0	27	73	CI 29	12	4	13	71
Functional status (RDQ)	WI –129	35	46	9	10	CI 617	9	6	18	67	CI 191	0	2	64	34
Pain severity	WI –816	24	35	19	22	CI 2867	17	12	12	59	CI 591	2	11	56	32
Quality of life	WI –1483	39	44	10	7	CI 24416	20	7	17	56	CI 5447	3	8	59	31
General health	WI –8	31	36	15	18	CI 854	27	9	10	54	CI 69	2	3	63	32

Note. WI, Workplace intervention; UC, Usual care; CI, Clinical intervention.

[a]NE: second treatment mentioned more effective but more costly.

[b]SE: second treatment mentioned dominates: more effective and less costly.

[c]SW: second treatment mentioned less costly but less effective.

[d]NW: second treatment less effective and more costly.

*ratio indicates difference in costs vs. difference in effects.

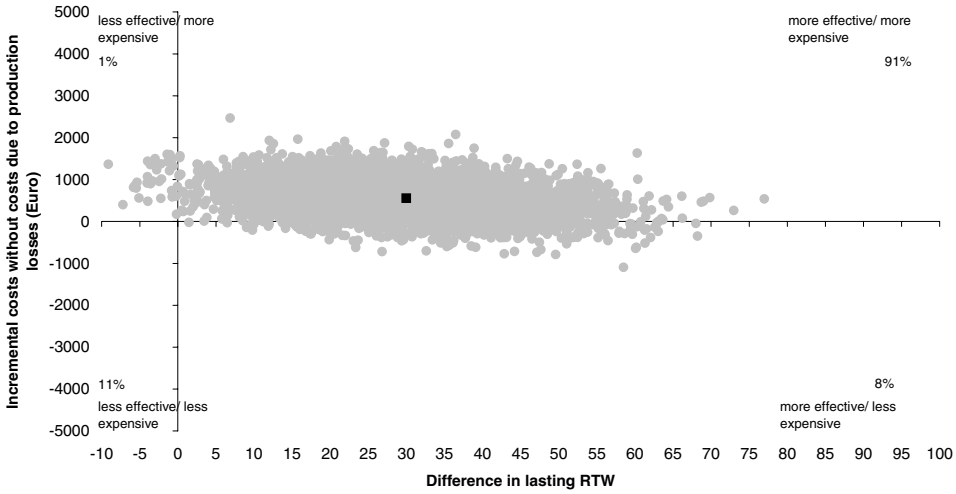

Fig. 3 Cost-effectiveness planes for work absence comparing workplace intervention and usual care

clinical intervention was less effective on all secondary outcomes at higher costs. A paper discussing possible reasons on why the clinical intervention was not successful has been published recently [44]. The main reasons were that the numbers of workers in these groups were small and that compliance to the protocol was poor, a delay in referral to the intervention explained some of the lack in success for this intervention. The effectiveness study on both interventions will be published in the near future [45]. The fact that the intervention is workplace based, time contingent and involved both the worker and his supervisor are considered to be the key elements for success.

This is the first RCT in occupational care that took partial RTW into account using net number of days on sick-leave. The number of calendar days on sick-leave until full return to work is normally used in cost-effectiveness analyses [43]. The latter will lead to an overestimation of indirect costs, and consequently also total costs. In the Netherlands, workers on sick leave may return to work partially at first as part of their treatment, and the time at work may be gradually increased until they have fully returned to work. For example, a worker who usually works 1.0 full time equivalent (fte) may start working for 50% (0.5 fte) for two weeks, 80% for another two weeks, and fully return to work (1.0 fte) after 4 weeks. Also, workers may return to modified work or to another job. Although they may be full-time present at work, this will lead to productivity loss compared with their original work/job before their low back pain.

We have tried to include these aspects in our calculation of productivity loss by using net days of sick-leave. We think that the approach used in this study leads to a more valid estimate of production losses in case of sick-leave.

We did not take into account productivity loss due to LBP prior and following the episode of sick-leave due to LBP. Full productivity may not have been reached after full RTW. Taking this fact into account could lead to an increase in estimated production losses [46]. Productivity depends on the cause of sick-leave, but also on the type of work. Some jobs can only be performed in case of full and unrestricted RTW. Nurses, a large proportion of our study population, for instance are called off sick-leave only in case they can perform all necessary tasks. Until then they may be on vocational rehabilitation with a restriction in, for instance, lifting tasks. During

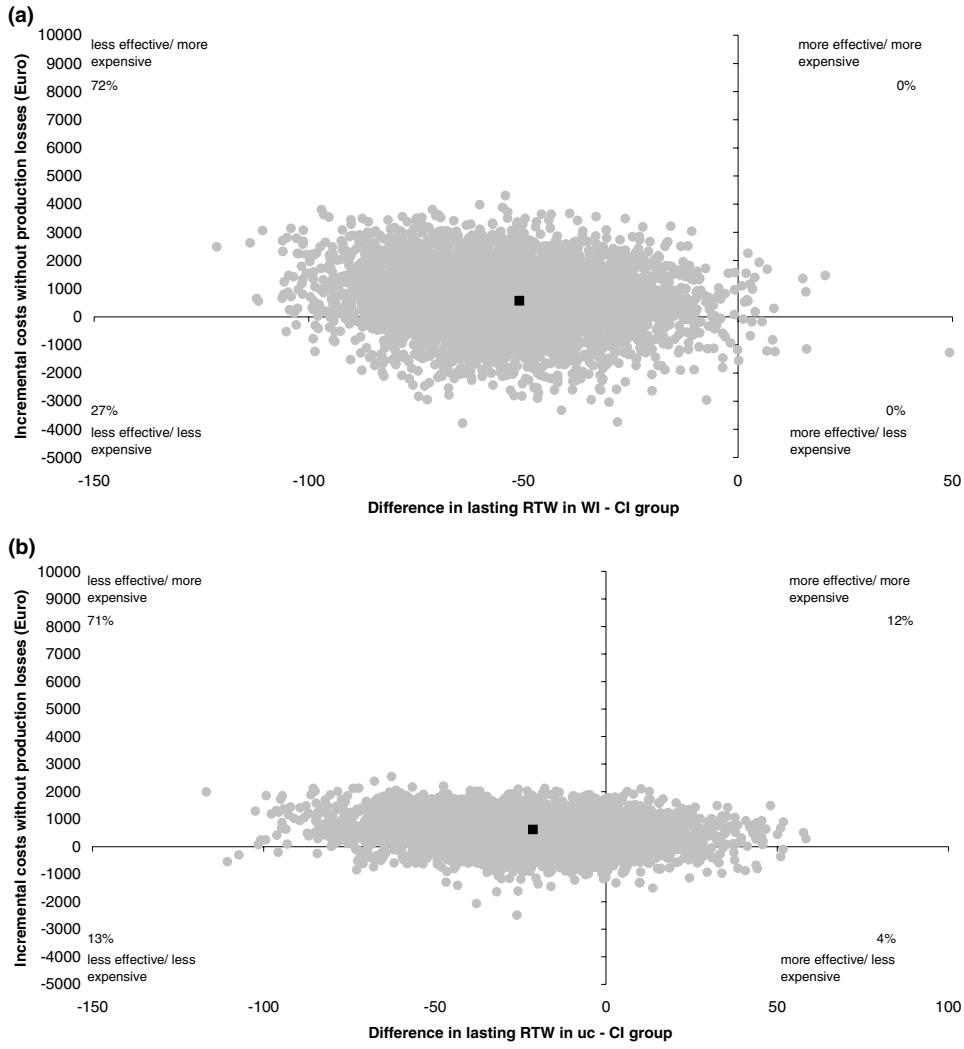

Fig. 4 (**a**) Cost-effectiveness planes for work absence comparing clinical intervention and usual care after 8 weeks in the workplace intervention group. (**b**) Cost-effectiveness planes for work absence comparing clinical intervention and usual care after 8 weeks of usual care

vocational rehabilitation they are considered to be on sick-leave. It is difficult to calculate productivity losses in these cases. Since the start of our study in 1999, some advances have been made in this area, such as development of new instruments for measuring productivity losses in recent years [46]. However, further research is needed to improve measuring productivity loss in economic evaluations.

We questioned workers during follow-up on cost data by sending retrospective questionnaires at 12, 26 and 52 weeks after the first day of sick-leave. In other studies other methods are used [43]. When using cost diaries [47, 48] a sample of costs during a limited number of weeks is taken and extrapolated to the total follow-up. An economic evaluation using an insurance

database [49] does not value costs of unpaid labour and out-of-pocket expenses. It is not clear which method leads to a more valid estimate of direct costs.

The results can be easily generalised to occupational practise in the Netherlands since subjects were recruited from a wide variety of professions and 81% (196/243) of all workers with LBP referred to the study by the OHS could be included. Furthermore, in a pragmatic trial [50], like ours, subjects are not restricted in their choice of getting treatment from other professionals during the entire follow-up which makes health care utilisation in all groups in this trial comparable to health care utilisation in daily practice. From the sensitivity analysis in which we used a fixed price (€100) for one day of production it shows that the difference in costs between the workplace intervention and usual care is potentially larger when this intervention is implemented in the general population compared to the difference in costs between both groups in our study. Since the results from Canada with regard to the effectiveness of the workplace intervention are replicated in this study, the results might be generalised to other societies with comparable socio-economic circumstances. The clinical intervention showed only small effects in the Canadian study and in case of a prior workplace intervention a negative effect in our study, therefore the combination of interventions is not recommended.

Implementation of the workplace intervention can lead to more effective guidance of workers on sick-leave due to LBP, resulting in cost reduction. A workplace intervention is only optional following the occupational guideline [51] nowadays, since (cost) effectiveness has not been proven sufficiently until now. Workplace interventions therefore are hardly used in usual care at this early stage of sick leave. We performed our economic evaluation from the societal perspective. However, since interventions in occupational care in the Netherlands have to be paid by employers; an additional analysis from the employer's perspective seems appropriate to provide adequate information for convincing the employer to implement the workplace intervention in case a worker is on sick leave due to LBP for 2 to 6 weeks.

Competing interests

None

Authors' contributions

IAS carried out data collection and drafted the manuscript. JRA participated in data collection. PMB and WvM conceived of the study, and participated in its design and co-ordination. HCWdV resolved statistical and methodological issues, MvT advised on design, conduct and analysis of the economic evaluation. IAS, JRA, PMB, HCWdV and WvM participated in development of research protocols. All authors read and corrected draft versions of the manuscript and approved the final manuscript.

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