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ORIGINAL ARTICLE

Cost-effectiveness evaluation of an RCT in rehabilitation after lumbar spinal fusion: a low-cost, behavioural approach is cost-effective over individual exercise therapy

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Abstract Recently, Christensen et al. reported the clinical effects of a low-cost rehabilitation program equally efficient to a relatively intensive program of individual, physiotherapist-guided exercise therapy. Yet, the low-cost approach is not fully supported as an optimal strategy until a full-scale economic evaluation, including extra-hospital effects such as service utilization in the primary health care sector and return-to-work, is conducted. The objective of this study was to conduct such evalution i.e. investigate the cost-effectiveness of (1) a low-cost rehabilitation regimen with a behavioural element and (2) a regimen of individual exercise therapy, both in comparison with usual practice, from a health economic, societal perspective. Study design was a cost-effectiveness evaluation of an RCT with a 2-year follow-up. Ninety patients having had posterolateral or circumferential fusion (indicated by chronic low back pain and localized pathology) were randomized 3 months after their spinal fusion. Validated pain- and disability index scales were applied at baseline and at 2 years postoperative. Costs were measured in a full-scale societal perspective. The probability of the behavioural approach being cost-effective was close to 1 given pain as the prioritized effect measure, and 0.8 to 0.6 (dependent on willingness to pay per effect unit) given disability as the prioritized effect measure. The probability of the exercise therapy approach being cost-effective was modest due to inferior effectiveness. Results proved robust to relevant sensitivity analysis although a differentiated cost-effectiveness ratio between males and females was suspected. In conclusion, a simple behavioural extension, of setting up group meetings for patients, to a regimen with a strict physiotherapeutic focus was found cost-effective, whereas the cost-effectiveness of increasing frequency and guidance of a traditional physiotherapeutic regimen was unlikely in present trial setting.

Keywords Rehabilitation · Lumbar spinal fusion · Chronic low back pain · Health economic evaluation · Cost-effectiveness evaluation

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Introduction

The efficacy of lumbar spinal fusion has been intensively investigated over the past 10 years, however, with divergent conclusions [2, 3, 7–9, 11, 12, 19, 20, 29]. In such light, the influence of the postoperative rehabilitation regimen is under-informed as very few controlled, clinical trials have been reported. A recent Cochrane review of evidence in rehabilitation after first-time lumbar disc surgery concludes that it is unclear what the exact content of postsurgery rehabilitation should be [23]. A recent original study by Christensen et al. investigated two experimental approaches against the usual regimen for rehabilitation after lumber spinal fusion [4]. Patients allocated to a low-cost regimen including a behavioural element performed significantly better than patients allocated to usual practice and equal to patients allocated to physiotherapist-guided, individual exercise therapy. The same study was extended to investigate whether the superior performance of the behavioural group was due to substitution of in-hospital care with service utilization in the primary health care sector, which was rejected [28]. However, the low-cost intervention is not fully supported as an optimal strategy

until a full-scale economic evaluation, including extra-hospital effects such as service utilization in the primary health care sector and return-to-work, is conducted.

The objective of this study was to conduct such evalution i.e. investigate the cost-effectiveness of (1) a low-cost rehabilitation regimen with a behavioural element and (2) a regimen of individual, physiotherapist-guided exercise therapy, in comparison with usual practice, from a societal perspective.

Materials and methods

From 1996 to 1999, a cohort of 115 patients was invited to participate in the present trial at a single-centre university hospital. Inclusion criteria were severe chronic low back pain caused by localized lumbar or lumbosacral segmental instability, age between 20 and 60 years, no comorbidity including metabolic bone disease and osteoporosis (if suspected the patient was referred to bone-mineral density test), clinical indication of newly developed lumbar nerve root compression, or psychosocial instability (qualitatively assessed and/or by psychosocial scales of Dallas Pain Questionnaire).

For varying reasons, 25 of the patients refused inclusion: 12 patients considered the distance between hospital and residence to be too long; five patients regarded obligations at work to be pre-emptive; four patients, because of postoperative pain, thought a rehabilitation program would be too demanding; three patients objected to random allocation; and one patient had already begun an intensive training program. Thus, a total of 90 patients were included in the trial by time of randomization at 3 months postoperative. Using sealed envelopes, block randomization was conducted to ensure even distribution of surgical techniques among the three randomization groups as 63% had each received a posterolateral spinal fusion with pedicle screw instrumentation and 37% had received a circumferential fusion. Table 1 summarizes baseline characteristics in the randomization groups.

The experimental regimens were (1) extension of the usual practice by invitation to three group meetings over an 8-week period (hereafter behavioural) to facilitate inter-patient exchange of experiences for the promotion of cooping and (2) individual physiotherapist-guided exercise therapy (hereafter training) conducted in the physiotherapy department of the hospital twice weekly for 8 weeks. The hospital's usual practice (hereafter usual practice) for postoperative rehabilitation is an oral instruction by a physiotherapist after which the patients receive a videotape with exercises for home-training. Interventions are described in more detail in the clinical report [4].

The conduction of present study was approved by the local ethical committee and the national data protection agency, whereas the purpose of health economic evaluation was blinded to both patients and doctors.

Table 1 Baseline characteristics at trial entry

Baseline characteristics	Usual practice (n = 30)	Behavioural (n = 30)	Training (n = 30)
Age[a]	45 [24, 59]	47 [24, 60]	48 [26, 59]
Females	25 (83)	15 (50)	20 (67)
Diagnostic entity for fusion surgery[b]			
Spondylolisthesis	9 (30)	14 (47)	9 (30)
Primary degeneration	11 (37)	8 (27)	12 (40)
Secondary degeneration	10 (33)	8 (27)	9 (30)
Type of fusion surgery			
Posterolateral (instrumented)	19 (63)	20 (67)	18 (60)
Circumferential	11 (37)	10 (33)	12 (40)
Occupational status before fusion surgery			
Working	14 (48)	14 (47)	13 (43)
Sick-listed	9 (31)	11 (37)	13 (43)
Retired or pensioned due to sickness	6 (21)	3 (10)	4 (13)
Retired or pensioned due to age	0 (0)	2 (7)	0 (0)

Values are number of patients (%) unless stated otherwise

[a] Median values [min, max]

[b] Primary degeneration = no previous surgery and secondary degeneration = secondary degeneration after decompressive surgery or accelerating degeneration after decompressive surgery

Economic methodology

Perspective, time frame, and theoretical cost-term

A societal viewpoint was adapted, hence all possible activity and resource consumption, occuring as consequences to interventions, contribute to overall costs. In economic terms, costs are defined as marginal, opportunity costs from a societal perspective. Unless otherwise described in the following, the time frame was fixed by the date of index surgery + 90 days (time of randomization) to the date of index surgery + 720 days (2 years postoperative). All costs are expressed in 2002-EUR, and both costs and effects were discounted at an annual rate of 3%.

Service utilization in the primary health care sector

Contacts to general practitioners, medical specialists, physiotherapists, psychologists, or chiropractors in the primary health care sector were recorded uniquely per patient in The National Health Insurance Service Registry (run by the National Health Service). Contacts were valued using tariffs of the collective agreements between the National Health Service and the societies of medical specialists or therapists. Specific to contacts to general practitioners, costs were marked-up to 130% as a 'charge to cost mark-up' [1].

Medication

Prescribed medication was recorded uniquely per patient in the Register of Prescribed Medication (run by Danish Medicines Agency). Medication was valued using market prices.

Re-operations and re-hospitalizations

Costs of interventions were included in the costs of hospital treatment (surgery) related to back pain. Irrespective of being caused by back pain or comorbidity, any other service utilization in the secondary health care sector was recorded uniquely per patient in The National Patient Registry (run by the National Health Service). Service utilization was valued using Diagnosis-Related-Grouping (DRG) tariffs.

Patient's costs

Over-the-counter medication [25], visits to complementary practitioners [25], and family time and paid help [10] were estimated from the literature and applied as a base-cost. Transport for hospital treatment was included and valued by a fixed price adapted from a previous study conducted in this patient population [27].

Productivity costs

Productivity costs were recorded from the Social Science Research Register (run by Statistics Denmark), which records number of days at work, part-time work, sick leave, retirement, pension etc. uniquely per patient. The Friction Cost method was used for valuation of productivity costs [15]. This method takes into account that an employer can replace an employee who has been disabled to work within a certain friction time; hence society suffers productivity costs only in the period of friction (in contrast to the Human Capital method [24] that fully accumulates absent time as production loss). In addition, costs of hiring and training a substitute worker in the event of long-term sick leave >14 days, or early retirement due to illness, were included in productivity costs. These costs were set at EUR 1,346. Calculations were based on a 3-month friction period and 2002 national average gross incomes in age- and gender-matched groups.

Clinical outcome and measure of effectiveness

The pain- and disability index scales of the Low Back Pain Rating scale (LBPR) questionnaire was applied at baseline and end-point in connection with patients' visits to the outpatient clinic [18]. The pain index scale ranges from 0 to 60 and summarizes responses of six questions concerning leg- and back pain. The applied disability scale was slightly different from the original instrument in comprising only 13 questions (original comprise 15). This index concerns physical and psychosocial capacity for daily living, for example, 'Can you sleep at night without interfering low back pain?' and each question can be answered by 'yes', 'partly', 'no', and 'don't know'. Responses are weighted by attaching values of 0 to 'yes', 1 to 'partly' and 'don't know', and 2 to 'no' for the calculation of the index score. For the particular purpose of economic evaluation, delta-values were calculated (difference between baseline and endpoint observations with positive values indicating improvement).

Statistical analysis

Intention-to-treat analysis was conducted, and all estimates were reported using arithmetic means and 95% bias-

Table 2 Patient's service utilization 3 to 24 months after lumbar spinal fusion and in-hospital rehabilitation among 90 patients randomly allocated to three rehabilitation protocols

	Usual practice (n = 28)	Behavioural (n = 30)	Training (n = 30)
Primary health care sector			
Contacts to			
GPs	40 (56, 144)	25 (16, 35)	23 (15, 33)
Specialist doctors	4 (2, 7)	2 (1, 3)	3 (1, 6)
Physiotherapists	28 (10, 59)	25 (5, 59)	21 (9, 44)
Psychologists	0 (0, 2)	0 (0, 0)	0 (0, 0)
Chiropractors	0 (0, 0)	1 (0, 2)	0 (0, 1)
Medication	29 (19, 43)	17 (11, 24)	14 (9, 21)
Secondary health care sector (hospitals and outpatient clinics)			
Related to back pain			
Surgery (and in-hospital rehabilitation)	1 (1, 1)	1 (1, 1)	1 (1, 1)
Other admissions	0 (0, 0)	0 (0, 0)	0 (0, 0)
Outpatient clinic	3 (2, 4)	3 (2, 4)	2 (2, 3)
Related to comorbidity			
Surgery	1 (0, 1)	1 (0, 1)	1 (0, 1)
Other admissions	0 (0, 0)	0 (0, 0)	0 (0, 0)
Outpatient clinic	1 (0, 2)	1 (0, 2)	1 (0, 2)
Patient's costs			
Over-the-counter medication[a]	N/A	N/A	N/A
Complementary medicine[a]	6	6	6
Transportation	16 (13, 19)	14 (11, 18)	14 (11, 17)
Family time/paid help[b]	484	484	484
Societal costs (productivity costs)			
Friction Cost method	29 (13, 48)	24 (9, 38)	28 (14, 45)
Human Capital method	637 (477, 790)	384 (250, 540)	541 (384, 672)

Note: none of the categories of service utilization were significantly different among randomization groups (Kruskal–Wallis' test)

Values are mean number of services (95% bootstrapped, bias-corrected confidence intervals)

[a] Estimated from the literature, Rivero-Arias et al. [25]

[b] Estimated from the literature, Fritzell et al. [10]

corrected confidence intervals using bootstrapping. Bootstrapping refers to a non-parametric technique for estimating precision in data: by 10,000 repetitive drawings from the sample, assuming that the sample is representative of the population, the random variation is estimated [6]. Non-parametric statistics of Kruskal–Wallis and Mann–Whitney U tests were used to compare randomization groups. Incremental cost-effectiveness was reported using the cost-effectiveness plane and acceptability curves. Analysis was conducted using statistical software STATA Intercooled (ver 8.0, StataCorp, USA).

Results

In the process of extracting register data, recordings on two patients (usual practice group) were lost due to a coding error. We had no possibility of a second attempt as the extraction was undertaken by an external programmer. Compliance with the regimens was monitored by one designated physiotherapist: 2/30 in usual practice group, 3/30 in behavioural group, and 4/30 in the training group did not comply with the rehabilitation regimen for various reasons: dissatisfied with allocation, moved to other region, had cancer, had manipulation treatment, or inconsistent compliance. Intention-to-treat analysis was conducted with a follow-up rate of 88% when combining the loss of register data (n = 2) with non-compliance (n = 9) and having imputed two non-responders of the 2-year follow-up with their 1-year follow-up responses.

Service utilization and its costs

Service utilization is shown in Table 2. No statistically significant differences were found although there are

Table 3 Total costs of patient's service utilization 3 to 24 months after lumbar spinal fusion and in-hospital rehabilitation among 90 patients randomly allocated to three rehabilitation protocols

	Usual practice (n = 28)	Behavioural (n = 30)	Training (n = 30)
Primary health care sector			
Contacts to			
GPs	445 (285, 675)	264 (168, 395)	242 (159, 333)
Specialist doctors	79 (37, 130)	69 (29, 139)	108 (33, 256)
Physiotherapists	198 (35, 481)	134 (27, 340)	75 (28, 142)
Psychologists	15 (0, 77)	0 (0;0)	0 (0;0)
Chiropractors	0 (0, 0)	7 (2, 16)	2 (0;7)
Medication	580 (306, 990)	279 (149, 527)	269 (159, 438)
Total primary health care	1,317 (852, 1,926)	755 (477, 1,108)	696 (483, 925)
Secondary health care sector (hospitals and outpatient clinics)			
Related to back pain			
Surgery (and in-hospital rehabilitation)	763 (98, 2,069)	785 (178, 2,011)	657 (367, 1,815)
Other admissions	0 (0, 0)	0 (0, 0)	66 (0, 329)
Outpatient clinic	508 (405, 630)	453 (343, 603)	409 (327, 493)
Related to comorbidity			
Surgery	1,561 (508, 3,509)	1,454 (732, 2,524)	1,711 (633, 3,241)
Other admissions	367 (63, 932)	288 (34, 898)	258 (78, 624)
Outpatient clinic	319 (157, 562)	237 (87, 453)	526 (234, 962)
Total secondary health care	3,521 (2,024, 5,540)	3,217 (2,012, 4,756)	3,626 (2,146, 5,621)
Patients' costs			
Over the counter medication[a]	36	35	35
Complementary medicine[a]	200	198	199
Transportation	1,441 (1,177, 1,742)	1,274 (976, 1,672)	1,246 (998, 1,537)
Family time/paid help[b]	16,047	15,894	15,925
Total patients' costs	17,724	17,402	17,405
Societal costs (productivity costs)			
Friction Cost method	3,044 (1,354, 5,398)	2,618 (1,113, 4,352)	2,987 (1,476, 4,810)
Human Capital method	54,540 (40,436, 67,858)	36,051 (23,519, 50,874)	51,046 (37,178, 65,351)
Grand total[c]	25,607 (22,780, 29,136)	23,992 (21,543, 26,864)	24,715 (22,518, 27,171)

Note: except for costs of the experimental protocols (included in costs of surgery and in-hospital rehabilitation due to back pain) none of the categories of costs were significantly different across randomization groups (Kruskal–Wallis' test)

Values are mean discounted 2002-EUR (95% bootstrapped, bias-corrected confidence intervals)

[a] Estimated from the literature, Rivero-Arias et al. [25]

[b] Estimated from the literature, Fritzell et al. [10]

[c] With inclusion of productivity costs estimated using the Friction Cost method

tendencies of the experimental groups expressing less service utilization in the primary health care sector than the group having usual practice. Also, the number of days unable to participate in labour market seems lower in the experimental groups as compared with usual practice. Table 3 shows total costs of patients' service utilization and again, there are tendencies but no statistically significant differences.

Table 4 summarizes cost differences between usual practice and each of the two experimental groups. The behavioural group demonstrates a tendency of lower costs by all sub-perspectives; however, none of the differences are statistically significant. The training group demonstrates a tendency of lower costs, primarily, in the primary health care sector.

Rate of return to work

The rates of return-to-work by time of the 2-year follow-up were 50% (10 of 20 patients who were on sick leave or working preoperatively) in the group allocated to usual

Table 4 Cost differences by various viewpoints; usual practice versus behavioural or training approaches

	Usual practice versus behavioural	*P*-value[§]	Usual practice versus training	*P*-value[§]
Primary health care costs	–563 (–1,225, 17)	0.116	–622 (–1,259, –111)	0.131
Secondary health care costs	–304 (–2,562, 1,811)	0.852	105 (–2,364, 2,568)	0.565
Patient costs	–323 (–785, 172)	0.084	–319 (–737, 107)	0.090
Societal costs	–415 (–3,115, 2,117)	0.902	–56 (–2,828, 2,381)	0.904
Total	–1,615 (–5,783, 2,517)	0.474	–892 (–5,051, 2,877)	0.744

Values are mean discounted 2002-EUR (95% bootstrapped, bias-corrected confidence intervals)

[§] Mann–Whitney *U* test

practice, 60% (15 of 25 patients) in the behavioural group and, 62% (16 of 26 patients) in the training group. Differences between groups were not statistically significant.

Effectiveness of interventions

Figure 1 shows improvement over time across randomization groups. Obviously, there is no statistically significant difference among groups although, especially concerning pain, there is a tendency of the behavioural group performing superior to other groups and the training group performing worse than other groups.

Incremental cost-effectiveness ratio (ICER)

The cost-effectiveness planes comparing the experimental regimens with usual practice are illustrated in Fig. 2a and b. Each estimate in the plane represents a bootstrapped replication of the ICER to illustrate the empirical uncertainty surrounding it. Figure 2a illustrates cost-effectiveness of the behavioural regimen in comparison with usual practice. Replicates are primarily located in the south-east quadrant of the plane, which indicates a more effective and a cost-saving intervention. The response of the pain index is characterized by greater variation than that of the disability scale, which is partly due to the wider scaling (range of pain scale 0 to 60 whereas range of disability scale is 0 to 26). Figure 2b illustrates cost-effectiveness of the training approach in comparison with usual practice. Replicates are dragging towards the western part of the plane indicating clinical inferiority of the training approach as compared with usual practice.

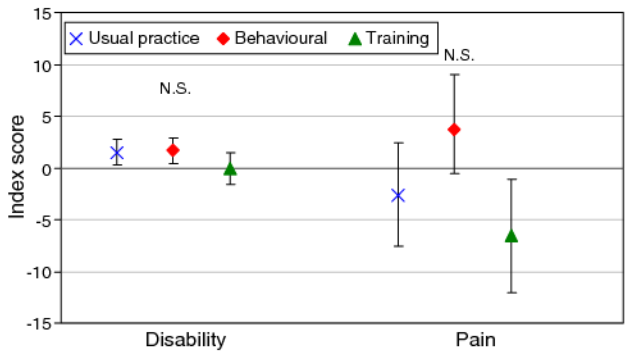

Fig. 1 Clinical outcome across groups. Values are mean change in disability or pain index from time of randomization into rehabilitation group to 2 years postoperative. Error bars are 95% bootstrapped, bias-corrected confidence intervals

Figure 3 presents a cost-effectiveness acceptability curve, which is a transformation of the cost-effectiveness planes of Fig. 2a and b. Since decision-makers' threshold value of willingness to pay is not explicit, these diagrams each present the probability of the intervention being cost-effective as a function of hypothetical threshold values. The reason why the curves do not cut the *y*-axis at zero (intuitively, zero willingness to pay results in zero probability of cost-effectiveness) is that the interventions involve cost-savings for some patients, whereas the reason why not all curves show increasing probabilities for increasing willingness to pay (intuitively, infinite willingness to pay would result in a probability of cost-effectiveness approaching one) is that interventions involve effects inferior to usual practice for some patients. The probability of the behavioural approach being cost-effective is close to 1 given pain as the prioritized effect measure, and 0.8 to 0.6 (dependent on willingness to pay) given disability as the prioritized effect measure. The probability of the training approach being cost-effective is modest due to inferior effectiveness.

Sensitivity analysis

One-way sensitivity analysis was conducted for the following scenarios: (1) assuming non-respondents did worse than respondents; by imputing performance of non-

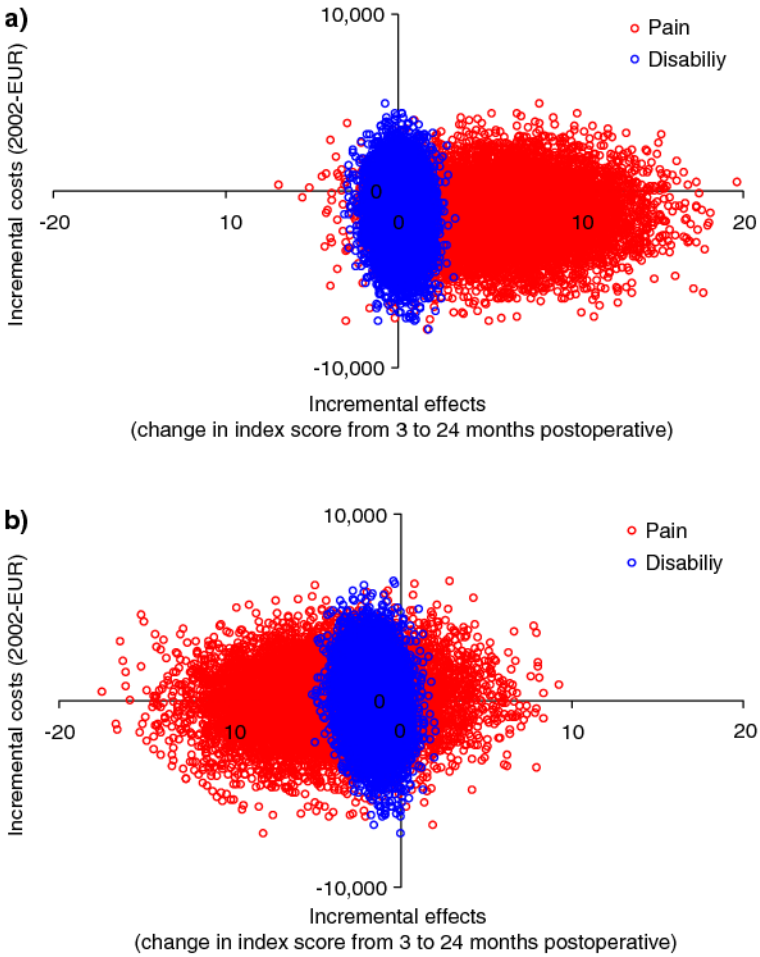

Fig. 2 Cost-effectiveness of rehabilitation regimens. Each *dot* is a bootstrapped estimate of the ICER generated from original samples of $n = 58$ and $n = 60$. **a** Behavioural approach in comparison with usual practice; replicates are moderately dragging towards the south-east quadrant which indicates a more effective and cost-saving rank of the behavioural approach. **b** Training approach in comparison with usual practice; replicates are dragging towards the Western part of the plane which indicates underperformance of the training approach

respondents with the lower quartile of improvement in their randomization group and (2) stratifying analysis on gender to investigate impact from gender-skewed randomization (although of completely random nature). Figure 4 presents these sensitivity analyses which represent a series of 'what if' scenarios with one key parameter modified at a time. Because of the low probabilities of the training approach being cost-effective, sensitivity analyses are presented only for the relationship between the behavioural approach and the usual practice. Figure 4 has one probability function sticking out; the disability-related curve when females are excluded from analysis presents a declining probability for increasing willingness to pay until stagnating just below 25%. The explanation is that females perform relatively better allocated to the behavioural approach over usual practice or, in other words, females are worse off with usual practice than males are.

Discussion

To the best of our knowledge this is the first study to report on an economic evaluation of rehabilitation regimens after lumbar spinal fusion. Having performed a full-scale economic evaluation, we are able to support previously reported clinical findings in favour of the behavioural approach: the patients better off do also express less service utilization and absenteeism from work, which leads to superior cost-effectiveness.

In the field of behavioural rehabilitation without preceding surgery Goossens et al. investigated the surplus value of (a) individual cognitive treatment and relaxation and (b) a cognitive therapy of group discussion when added to an operant treatment of exercise therapy [14]. The authors concluded no significant clinical difference between groups but, whereas the individual cognitive therapy generated higher costs, the group discussion tended to decrease total costs.This is in line with the present findings in that a cognitive element of group discussion is cost-effective in the rehabilitation of patients with severe, chronic low back pain. In the light of present trial, it is futhermore interesting that the effect of the cognitive group discussion is detectable—even on top of rehabilitation after surgery, where a lot of biological factors, for example, wound and bone healing, and reconstitution of muscles, take place.

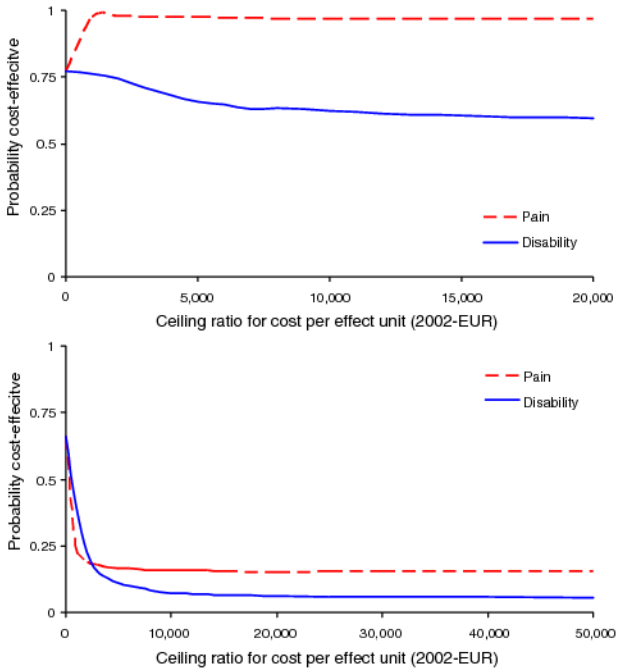

Fig. 3 Probability of the rehabilitation approaches being cost-effective as a function of hypothetical ceiling ratios of willingness-to-pay; the behavioural approach demonstrates probabilities not below 0.6 to 0.8, whereas the training approach demonstrates probabilities declining with increasing willingness to pay

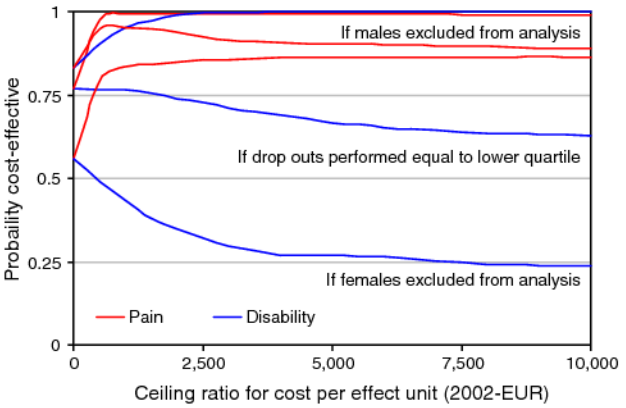

Fig. 4 Sensitivity analysis in relation to cost-effectiveness of the behavioural approach compared with the usual practice

Internal validity

For measurement and valuation of costs, we used a series of national registers whose validity has been investigated and found reasonable for use in clinical research. In particular, the agreement between other gold standard sources and registers has been found to move toward 75–90% with respect to diagnoses and, most likely, considerably higher with respect to events and costs of events because payment to health care providers cannot be proceeded until reporting to registries is accomplished [13, 21, 22].

As the primary effect measure, we used a selected part of the validated LBPR questionnaire: the physical test was not administered and 2 of 15 questions concerning disability were excluded [18]. Clearly, any deviation from the validated form potentially affects the performance of this instrument. As two-thirds of patients were also monitored using the Dallas Pain Questionnaire, we were able to scatter the correlation of the two instruments (Kendal's Rank correlation 0.36, $P = 0.0004$) which indicated some agreement [17]. However, the fact that we did not fully comply with the validated form of the LBPR may be a limiting factor of this study.

Females and males, respectively, had different gains from the interventions. It is interesting whether the behavioural element—or indeed the lack of such—has impact to females in particular? The gender-issue was primarily apparent in relation to the disability scale, whereas gender performance was equal on the pain scale. Females are known to have higher health care service utilization than males [16] but in this study the gender-issue was primarily linked to clinical differences, which is supported by a recent rehabilitation study in conservative treatment of chronic low back pain [26]. However, differences could also be due to measurement bias; a recent systematic review in rehabilitation after discectomy concludes conflicting evidence depending on the choice of effect measure [23].

The sample size for present trial was adapted from the clinical trial as is common in economic evaluations that run alongside clinical trials. Clearly, a size of 30 patients in each group may not be sufficient to detect differences in costs, particularly, because costs have been found to vary excessively in comparison with clinical outcomes [14]. This makes it even more surprising that we were able to identify such high probability of the low-cost intervention being cost-effective. Indeed that a policy decision has to be made whether we have significance or not hence delaying a decision on the grounds of 'not enough information' or 'insignificance' is the same as accepting routine practice, which in this case was the absolutely least cost-effective option. This is an evolving position in the cost-effectiveness literature [5].

The most important limiting factor of this study is the choice of comparator. Any intervention can prove attractive if the comparator is poor enough and surely, the historic regimen of usual practice was not impressive in terms of comprehensiveness. On the other hand, the trial was truly innovative by time of initiation where there was very limited focus on comprehensive postoperative rehabilitation. Today, some 10 years later, there is not yet clinical certainty about the optimal strategy [23].

External validity

In addition to local practice, unit costs, and type of patients considered for spinal fusion, external validity is related to the content of usual practice. Obviously, if usual practice is not lacking a behavioural element generalisation is not relevant at all. Another issue could be that the effect of a behavioural element may be closely related to a cultural dimension possibly varying across countries.

Conclusion

In conclusion, a simple behavioural extension, of setting up group meetings for patients, to a regimen with a strict physiotherapeutic focus was found cost-effective, whereas the cost-effectiveness of increasing frequency and guidance of a traditional physiotherapeutic regimen was unlikely in present trial setting.

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