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Sick leave reductions from a comprehensive manual therapy programme for low back pain: the Gotland Low Back Pain Study

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Objective: To evaluate if a comprehensive manual therapy programme reduces sick leave due low back pain and facilitates return to work more than the conventional optimized activating care.
Design: A randomized controlled trial over a 10-week period with a two-year follow-up.
Setting: Primary health care and Visby Hospital, Municipality of Gotland, Sweden.
Subjects: One hundred and sixty patients (70 women, 90 men, ages 20–55 years) with acute or subacute low back pain with or without pain radiation into the legs.
Interventions: Standardized optimized activating care ($n=71$) versus a comprehensive pragmatic manual therapy programme including specific corticosteroid injections ($n=89$).
Main measures: Sick leave measured as net sick leave volume, point prevalence and return to work.
Results: After 10 weeks, significantly more manual therapy patients than reference patients had returned to work (hazards ratio 1.62, 95% confidence interval (CI) 1.006–2.60, $P<0.05$), and among those on sick leave at baseline, significantly fewer were still on sick leave (8/58 versus 13/40, ratio 0.35, 95% CI 0.13–0.97, $P<0.05$). For all other measures there were inconclusive differences in favour of the manual therapy group. No significant differences remained after two years.
Conclusions: The manual therapy programme used in this study decreased sick leave and increased return to work more than the standardized optimized activating care only up to 10 weeks but not up to two years.

Introduction

In the year 2000 the Swedish Council on Technology Assessment in Health Care assessed available treatments for low back pain. A positive view was taken towards manual treatment for acute low back pain, but the report also stated that there are no treatment programmes for acute low back pain with sufficiently demonstrated clinical efficacy as well as cost-effectiveness.[1] More and better studies were requested.

Since then a number of reviews have been published, several covering the same set of randomized controlled trials. However, the results from these

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trials have been interpreted differently in different reviews. As a result, the evidence of effect has led to different recommendations in various countries regarding how manual therapy should be given for low back pain.[2]

Sick leave measures are key outcomes since, in their various forms, they are important both as measures of medical treatment success and measures of cost in economic evaluations.[3,4] More than 90% of the cost of low back pain emanates from outside the health care systems.[5] However, these measures are not among the outcome measures most commonly used since the regulations and availability of sickness absence data varies between countries. A Swedish review found that scientific evidence regarding sick leave in relation to low back pain was limited.[6] Since treatment of low back pain cannot be regarded as successful unless the patients' ability to work has been fully restored and the patient has returned to work, this needs to be taken into account in studies of low back pain treatment and must be part of comprehensive low back pain management.

This randomized controlled trial had the aim of evaluating the effects of adding manual therapy, including muscle stretching and steroid injections, to the stay-active approach. Design and data on pain and disability reduction have been reported previously.[7,8]

Study population and methods

A randomized, controlled, clinical trial was undertaken in the Swedish province of Gotland from January 1994 to December 1998. The design and underlying population have been described in detail previously.[7,8] Briefly, a design with four treatment groups was used: two experimental and two reference groups with treatment items added successively (Figure 1). The two-group comparison (manual treatment versus no manual treatment) was the primary planned analysis, and pain, disability rating and sick leave were the main outcome measures. The previous articles present the same two-group comparison.[7,8]

A power calculation indicates that approximately 180 patients would be needed to achieve statistical power of more than 80%, in order to find significant differences for the two-group comparison. However, inclusion was stopped at 160 patients owing to the fact that were too few new patients in the area. The power reduction was marginal, 78% instead of 83% for point prevalence at 10 weeks among those on sick leave at baseline, and 82% rather than 86% for the return to work.

Low back pain patients who preliminarily fulfilled the inclusion criteria shown in Table 1 were referred to the study by their GPs or physicians at Visby Hospital. Patients on sick leave for longer than two weeks were referred by the local office of the Social Insurance Agency (a government agency running the mandatory national social insurance scheme applicable to all Swedish residents). However, the majority of these patients had already been referred to the study by their physicians. The recruiting physician, a GP not involved in the treatment, examined all patients and made the final decision of whether or not they fulfilled the inclusion criteria.

A total of 316 patients were assessed, of whom 156 were not included for reasons given in Figure 1. The excluded patients have been described previously.[8] When the remaining 160 patients had given their informed consent for participation they were randomized to one of the four treatment groups, using sealed pre-prepared envelopes with group assignments derived from a random table. The envelopes were inaccessible to everyone but the study monitor. A weighted randomization procedure was used, aiming at allocation of 45% of the patients to the two reference groups and 55% to the manual therapy groups. The study was approved by the Research Ethics Committee at Uppsala University.

Treatments

A detailed description of therapists, treatment content and amount of each treatment modality has been presented elsewhere.[7] Briefly, the treatment was provided individually, in groups, or both. Treatment modalities were chosen by physicians and physiotherapists according to the patients' needs from a 'toolbox' specific to each group (i.e. a pragmatic design).

The stay active concept (i.e. encouraging the patients to take part in physical activities and

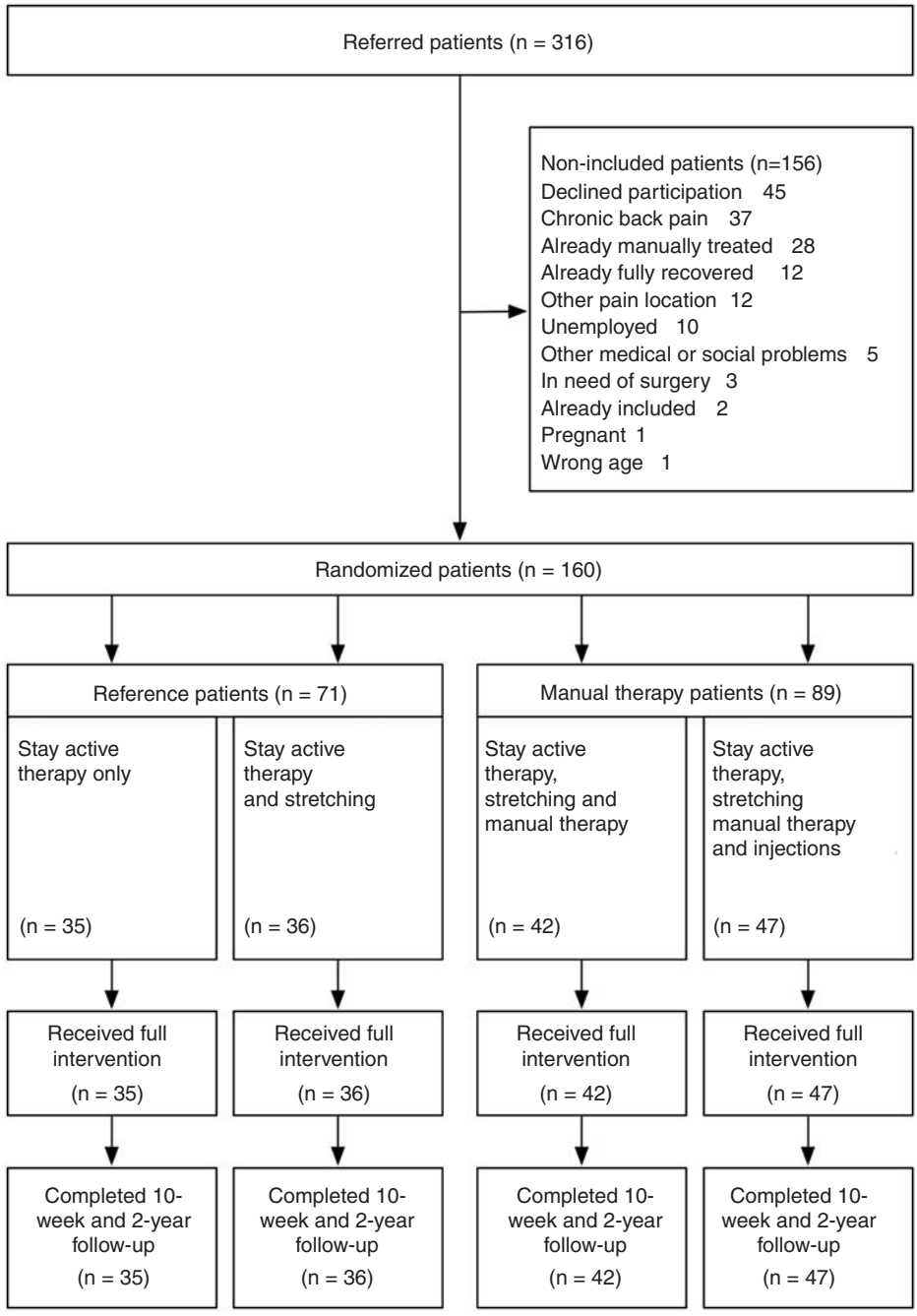

Figure 1 Flowchart of the study population, with reasons for non-inclusion.

Table 1 Inclusion criteria

- Age 20–55 years
- Acute or subacute perceived low back pain (i.e. pain below the level of the seventh thoracic vertebrae) with or without pain radiating to one or both legs, not requiring surgical or rheumatological interventions. Patients with demonstrated or suspected herniated disks were included if surgery was not considered. Low back pain was to dominate the clinical condition but other musculoskeletal symptoms, not requiring sick leave, were allowed
- Symptom duration of three months or less, preceded by at least two months of relative freedom from symptoms
- Consent to treatment and follow-up for 10 weeks
- Agreement not to consult therapists other than those participating in the study during the 10-week treatment period
- Employed, with no threat of job loss
- Native Swedes articulate enough not to jeopardize the verbal contact with the physicians or the physiotherapists
- Absence of other conditions or circumstances which might jeopardize completion of treatment and follow-up (e.g. pregnancy, malignant tumours, alcoholism or severe psychiatric disorders)
- No previous treatment of current complaints with specific mobilization or manipulation
- No previous participation in the Gotland study

other activities) was the basic management strategy for all the groups. Medical exercise therapy, sequential exercise and non-specific traction were included in the stay active concept. Passive treatment modalities, such as heat, were included in order to achieve equal expectations of the treatment for all groups. Two orthopaedic surgeons at Visby Hospital and eight physiotherapists treated the patients in the reference groups. The first reference group was treated only with the basic management strategy. The second reference group received the same strategy plus muscle stretching.

Two general practitioners at primary health care centres in Visby and nine physiotherapists, all moderately trained in manual therapy,[7] treated the manual therapy groups. The first manual therapy group received the full reference treatment, plus specific mobilization, spinal manipulation, and auto-traction when indicated.[7] The second manual therapy group received the same therapy plus steroid injections when indicated.[9] Nineteen of the 47 patients eligible for injections had indications for, accepted and received a total of 28 injections (median one injection per patient, range 1–4).[7] The physicians were instructed to certify as short periods of sick leave as possible at each consultation and to prescribe drugs when indicated.

Outcomes

The outcome variables were sick leave and return to work. At the time of the study sick leave was reported to the Social Insurance Agency that paid the compensation, except for the first two weeks which were reported to and paid by the employers, without always being reported to the Social Insurance Agency. Sick leave periods of up to seven days could be self-certified by the patient. Beginning with the second week, a sicklisting certificate issued by a physician was required. Sick leave information from two months before inclusion until two years after start of treatment was obtained from the Social Insurance Agency, from medical records, from the questionnaires filled out by the physicians and from patient diaries. Baseline for the sick leave analyses was set to the day of the first appointment with the treating physician in the study. The information included first and last day of each sick leave period, diagnosis, and extent (25, 50, 75 or 100% sick leave).

Number of net days (number of days times sick leave extent) was computed for sick leave owing to low back pain, other locomotor system complaints, other causes, and 'unspecified diagnoses' (sick leave compensated for by the employers) for the two months preceding inclusion, the 10-week treatment period and the subsequent 94-week follow-up period.

The rate of return to work was analysed for patients who were on sick leave at baseline. The day of return to work was defined as the first day after conclusion of the initial sick leave period. The initial sick leave period was regarded as concluded if followed by at least one week with no sick leave owing to low back pain. If a new episode

of sick leave occurred, the previous return to work date was accepted as long as the duration of the new episode was shorter than the intervening sick leave-free period, otherwise the day after the end of the new episode was used. The assessments were made independently by two of the authors, one blinded to group status, with excellent agreement (Spearman correlation coefficient 0.99).

Statistical considerations

The intention-to-treat concept was followed. No patients were lost during the follow-up of sickness absence data, but four patient records could not be retrieved and two patients did not participate for the full treatment period (Figure 1). Data were analysed with the JMP and SAS statistical programme packages.[10,11] Summary statistics, such as proportions, means and confidence intervals (95% CI) were computed using conventional parametric methods. Differences in continuous variables between the two groups were analysed with Student's *t*-test. The chi-square test was applied when discrete data were analysed.

In order to adjust for possible confounding factors, multivariate linear or logistic regression analyses were performed. Sick leave data were used as the dependent variable and age, sex, pain radiation distal to the knee, and treatment group as the independent variables. The distribution of net days of sick leave was skewed toward high values. Therefore, data were log transformed before the linear regression analysis. The mean of log-transformed data corresponds to the median of non-transformed data. Cox proportional hazards regression, providing hazards ratios (HR) and their 95% CI, was used in the analysis of return to work. All tests were two-tailed and the alpha level was 0.05.

Results

Baseline data

Baseline data and previous low back pain infirmity are shown in Table 2. No significant baseline differences between manual therapy and reference groups were found. However, on the one hand the manual therapy groups had a higher proportion of women and more sick leave at inclusion and during the two years preceding baseline, while on the other hand the reference groups tended to have somewhat longer duration of the current episode. Seventy-four per cent ($n = 119$) of all patients had a history of sick leave owing to low back pain during the last two years, of short duration in the majority of cases. The groups were thus reasonably similar regarding baseline data.

The vast majority of the sick leave days during the two months preceding baseline were attributable to low back pain (Figure 2). During this period the mean number of net days of sick leave, irrespective of cause, was 8.2 (median 6.0, interquartile range 0.0–11.0) in the manual therapy groups, and 9.3 (median 5.5, interquartile range 2.0–12.0) in the reference groups. Among those who were on sick leave at baseline, the corresponding numbers of net days were 11.5 (median 8.5, interquartile range 5.0–12.0) and 12.8 (median 9.0, interquartile range 4.0–14.0), respectively. All differences were non-significant.

Treatment period

During the 10-week treatment period, 93% of all sick leave was attributable to low back pain (Figure 2). Altogether, 104 patients were on sick leave at some time during the period, 17 patients were on sick leave during the entire 10-week period, and 25 patients were on sick leave at the end of the period. The manual therapy groups had inconclusively less sick leave than the reference therapy group, whether measured as mean or median values, or whether the complete study population or only those on sick leave at baseline were included. Sick leave data for the period are given in Table 3, only those on sick leave at baseline are shown since there were no significant differences for the whole study population.

The differences between the treatment groups in terms of sick leave prevalence rate at the end of the period were larger than during the period. Again, the manual therapy groups had inconclusively lower rates than the reference therapy groups. For those on sick leave at baseline this difference was statistically significant ($P < 0.05$) (Table 3).

The manual therapy group had a significantly faster rate of return to work than the reference

Table 2 Characteristics of the study population

Characteristics	Stay active only		Stay active and stretching		Stay active, stretching and manual therapy		Stay active, stretching, manual therapy and injections		Difference between experimental and reference patients	
	n	Mean or %	*n*	Mean or %	*n*	Mean or %	*n*	Mean or %	Difference	95% CI
Age, years		41.8 (±8.3)		40.3 (±8.2)		42.1 (±8.9)		41.1 (±8.7)	0.5	−2.2–3.2
Women, %	13	37.1	12	33.3	20	47.6	25	53.2	−15.4	−30.9–0
Cigarette smokers, %	16	45.7	15	41.7	18	42.9	22	46.8	1.3	−14.4–17.0
Current low back pain episode										
Duration, days		25.5 (±26.9)		35.1 (±26.8)		24.6 (±21.5)		25.1 (±27.9)	−5.5	−13.6–2.6
On sick leave at inclusion,%	27	77	20	56	29	69	34	72	4.6	−10.0–19.2
Previous history of low back pain										
Previous similar low back pain episode,%	27	77.1	32	88.9	37	88.1	38	80.9	1.1	−10.5–12.8
Time since first low back pain episode, years		10.3 (±7.3)		7.1 (±6.0)		9.8 (±6.9)		10.8 (±7.8)	1.7	−0.7–4.2
Number of previous episodes		5.0 (±6.2)		3.2 (±3.1)		3.7 (±3.2)		3.7 (±4.6)	−0.3	−1.8–1.2
Mild chronic complaints last two years,%	9	33.3	11	34.4	16	43.2	15	39.5	7.4	−9.3–24.2
Mean VAS of chronic complaints, mm		23.4 (±6.6)		21.3 (±10.0)		23.4 (±12.2)		19.6 (±15.0)	−0.8	−7.6–6.1
Sick leave due to low back pain last two years,%	29	82.9	21	58.3	32	76.2	37	78.7	7.1	−6.7–20.9
1–5 days,%	13	24.5	4	19.1	16	50.0	20	54.5		
6–30 days,%	11	25.6	11	52.4	11	34.4	10	27.0		
1–3 months,%	5	33.3	3	14.3	4	12.5	3	8.1		
more than 3 months,%	0	0	3	14.3	1	3.1	4	10.8		
X-ray because of previous low back pain,%	18	51.4	14	38.9	12	28.6	17	36.2	−12.5	−27.7–2.7

VAS score, visual analogue scale score of pain. Standard deviations are given in parentheses.

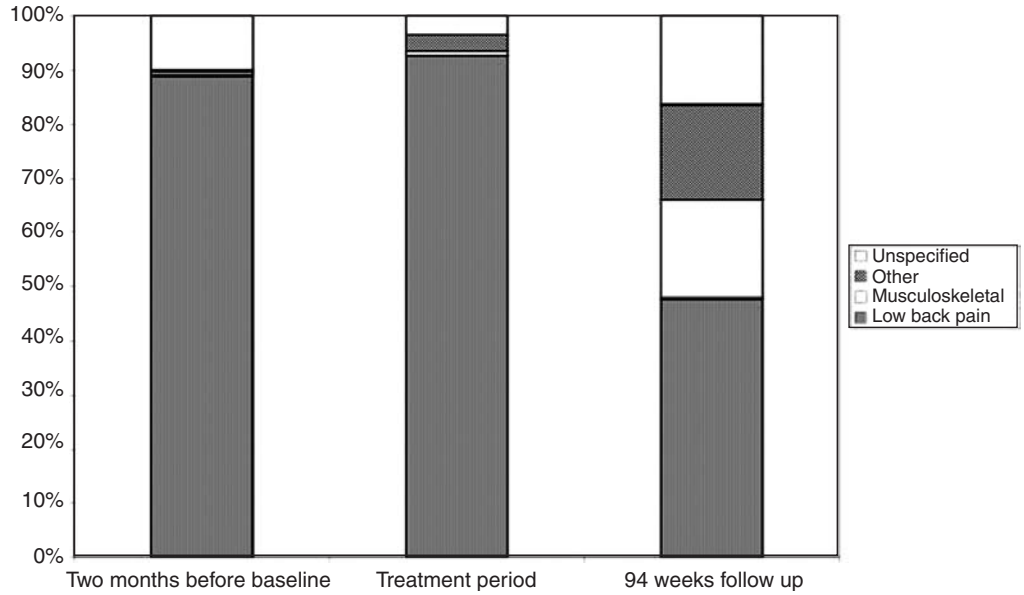

Figure 2 Proportion of sick leave net days by diagnostic group before study start, during and after the treatment period. Each period is based on the patients who were on sick leave during that period.

group (Table 4). At the end of the treatment period 71.1% ($n = 28$) of the reference group and 86.6% ($n = 51$) of the manual therapy group had returned to work (HR 1.62, 95% CI 1.006–2.60, $P < 0.05$). As shown in Table 4 the group differences became evident as early as after one week.

Two-year follow-up

When the 10-week treatment period was finished, the study population was followed for another 94 weeks, until two years from baseline. During those 94 weeks, the average number of net days of sick leave for all causes was 57.6 (median 12, interquartile range 0.5–45.8). Forty-eight per cent of these days were attributable to low back pain, and in 16% the cause was unknown since they were self-certified (Figure 2).

At the end of the two-year follow-up period, five patients were still on sick leave due to low back pain, yielding a prevalence of 3.1% (Table 3). There were no significant differences between the two treatment groups, whether based on the complete study population or only on those who were on sick leave at baseline. Long-term absenteeism from work was infrequent in both groups at the end of the two-year follow-up.

Discussion

The manual therapy treatment reduced sick leave due to low back pain during the treatment period better than the reference treatment. This was found both in prevalence of individuals on sick leave at the end of the treatment period and as rate of return to work. In addition, there was an inconclusive trend towards fewer net days of sick leave in the manual therapy group than in the reference group.

Strengths of the study

The study sample was drawn from a geographically defined area. The data collection was complete and uniform. Since all sick leave in Sweden is handled by the Social Insurance Agency, all sick leave was processed uniformly and data could be

Table 3 Sick leave due to low back pain during the treatment period and during two years of follow-up

	Stay active only		Stay active and stretching		Stay active, stretching and manual therapy		Stay active, stretching, manual therapy and injections		Comparison between the reference and the manual therapy groups	
	n	Mean or %	*n*	Mean or %	*n*	Mean or %	*n*	Mean or %	Ratio	95% CI
On sick leave at baseline	22		18		30		28			
Treatment period										
Mean net days through period		25.2 (±24.5)		29.3 (±19.6)		19.0 (±18.1)		21.7 (±20.0)	0.73	0.51–1.06
Prevalence rate at ten weeks,%	6	27.3	7	38.9	5	16.7	3	10.7	0.35	0.13–0.97
94 week follow-up period										
Mean net days through period		38.1 (±85.8)		37.3 (±69.6)		18.6 (±42.8)		71.4 (±174.4)	0.75	0.32–1.76
Proportion with any sick leave	7	31.8	8	44.4	9	30.0	6	21.4	0.60	0.23–1.53
Mean net days through period		119.8 (±119.8)		83.8 (±85.5)		61.8 (±60.2)		333.4 (±243.7)	1.56	0.50–4.90
Prevalence rate at two years,%	3	13.6	0	0	0	0	2	7.1	0.39	0.05–2.84

Standard deviations are given in parentheses.

Table 4 Cumulative rate of return to work after baseline examination analysed with Cox proportional hazards regression

Follow-up time, weeks	Still on sick leave, %			
	Reference		Manual therapy	
	n	%	*n*	%
At baseline	41	100	59	100
1	33	85.64	48	77.84
2	24	61.84	29	45.98
3	23	55.98	24	39.15
4	21	50.83	21	33.49
5	18	44.53	18	27.05
6	18	42.38	16	24.96
7	17	38.00	12	20.93
8	14	32.42	10	16.19
9	13	30.09	9	14.35
10	13	28.9	8	13.44

Numbers represent those still on sick leave.

obtained from one official source. The study population is therefore representative of this patient group. To assure completeness, the official data were supplemented with information from the patients and from the physicians. The sick leave data for the additional 94 weeks of follow-up were based on official data only and may therefore be incomplete, owing to incomplete reporting of sick leave compensated by the employer. However, both groups were probably equally affected. Since almost all sick-listing during the treatment period was attributable to low back pain, the possibility of an artifical decrease of sick leave for low back pain attributable to an undue 'shift' from low back pain to other diagnoses was small.

There were moderate baseline differences in age, sex and pain radiation distribution between the groups, adjusted for in the analyses. The results are consistent with previously reported reduction of pain and disability.[7] Contamination by parallel competing treatment was sparse and similar in both groups.[7] For these reasons we do not believe that the results are biased to such an extent as to affect the conclusions.

Weaknesses and limitations

One explanation for the unusual completeness of our data was that the study area was an

island and, in its entirety, covered by one local Social Insurance Office. The limited size of the catchment area, on the other hand, caused the flow of eligible patients to dwindle at the end of the inclusion period and resulted in a reduction of the study size. A larger geographical recruitment area would have increased the statistical power but at the same time, as in previous other studies, caused problems with data loss and treatment contamination.

The pragmatic design is sometimes regarded as a weakness. This can make it more difficult to draw conclusions on the effectiveness of individual treatment components. A wide enough array of available treatment components and sufficient expected differences between interventions are necessary when the condition studied is as heterogeneous as low back pain of short duration. To maximize the possible knowledge gained in this study a four-group randomization was used to allow the additional evaluation of contributions from muscle stretching and injections.

Measures of sickness absence

Sick leave data pose analytical problems owing to the severe skewness toward high values, largest when no minimum period of sickness absence is required for participation. Possible solutions are to restrict the analyses to the population on sick leave at baseline or to log transform the data before analysis. We applied both approaches.

Little attention has been paid to the implications of the various quantitative measures of sick leave. Both Muchinsky and Hensing *et al.* reviewed more than 70 definitions of sickness absence and found lacking validation and no consensus about how sick leave should be measured.[12,13] We have not found any validation studies on sick leave measures used in randomized controlled trials. Measurements of pain and disability have been scrutinized more thoroughly than measures of sick leave, as illustrated by the set of standard outcome measures proposed by Deyo *et al.*[3]

We used administrative register data as well as self-reported data and three methods for data analysis, since it has been shown that administrative workers' compensation data underestimate sickness absence in a US setting,[14,15] but overestimate it in a Swedish setting.[16] Linton *et al.* recommended caution when interpreting self-reports of sick leave.[17]

Results from other studies

The design and results from a number of randomized controlled clinical trials of manual therapy with sickness absence as outcome are shown in Table 5. It is not based on a systematic review and may be incomplete. However, it is provided as an illustration of the heterogeneity of designs and methods used.

In the Säter study, similar to the present one, the manual therapy group had significantly less sick leave than the reference group.[18] In another Swedish clinical trial one group received manual therapy from physiotherapists, another group received intensive physical training and a third group traditional therapy from GPs.[19,20] No significant sick leave differences between the groups were found, using similar official data sources to those used in the present study. Wreje *et al.* compared the effects of a single manual therapy session as treatment of pelvic joint dysfunction with the effects of massage.[21] The manual therapy group reported significantly less sick leave after a three-week follow-up. Skargren *et al.* compared manual therapy performed by chiropractors with physiotherapy in a clinical trial.[22–24] They found no significant differences between the groups on the effects on sick leave.

Meade *et al.* used the duration of absence from work as one of several outcome measures in a clinical trial, comparing the effects of two types of manual therapy given by chiropractors and physiotherapists to low back pain patients.[25,26] They reported less sick leave in a subgroup. Cherkin *et al.* compared chiropractic care, physiotherapy without manual therapy, and no treatment but an educational booklet to treat low back pain.[27] They found no statistically significant effects on sick leave.

Few manual treatment programmes thus reduced sick leave more than the reference treatment. There may be several reasons for this, such as lack of efficacy of the treatments evaluated, inadequate measures of sick leave, non-treatment

Table 5 Selected randomized controlled trials of manual therapy in non-chronic low back pain with sickness absence as an outcome measure

Study	Sample	Experimental intervention	Reference intervention	Follow-up	Sick leave measure	Notes	Results
Meade[25,26]	Chiropractic or hospital outpatients	Chiropractic ($n=384$)	Physiotherapy including manual therapy ($n=357$)	2 years	Time off work (yes or no)	Data presented only for subgroup with jobs (158 of 741 patients) (E 21%, R 35%, $P=0.05$). Pragmatic. Data collection and analysis not reported. Drop-outs	E = R
Wreje[21]	Selected patients with sacroiliac dysfunction ($n=46$).	Single pelvic manual treatment by physician ($n=18$)	Single massage treatment (transverse frictions) by physician ($n=21$)	3 weeks	Median duration ±10 days of sick leave	Self-reported data. Inconsistent with other outcome measures. 15% drop-outs. Author treated both groups	E > R
Blomberg[18]	Population based, acute/subacute, radiating pain allowed	Primary health care, manual therapy steroid injections ($n=53$)	Primary health care, conventional, activating, optimized ($n=48$)	8 months	Net sick leave volume. Point prevalence	Official data. Pragmatic. Consistent with other outcome measures	E > R
Skargren[22–24]	Patients attending GP for back or neck complaints	Chiropractic ($n=219$)	Physiotherapy ($n=192$)	1 year	Days off work. Point prevalence	Self-reported data. Patients with neck and low back pain not differentiated. 21% drop-outs after first treatment session. High amounts of contaminating treatment	E = R
Cherkin[27]	Patients who had LBP 7 days after primary care contact within HMO. Patients with sciatica excluded	Chiropractic ($n=119$)	1. Physical therapy (McKenzie) group ($n=129$) 2. Information booklet ($n=65$)	2 years	Missing work (yes/no)	Self-reported data. HMO data also used, stated to give similar results (for sickness absence?)	E = R
Seferlis[19,20]	Patients seeking primary, occupational, or emergency care for LBP. Radiating pain allowed	Manual treatment programme ($n=60$)	1. Intensive training programme ($n=60$) 2.Traditional general practice ($n=60$)	1 year	Days off work, adjusted for partial sick leave?	Official data. Actually treated analysis. Up to 32% drop-outs, with significantly different sick leave. Authors prescribed sick leave for more than one treatment group	E = R
This report	Population-based, acute or subacute LBP. Radiating pain allowed	Primary health care, manual therapy, steroid injections ($n=89$)	Stay active primary care by orthopaedic surgeons and physiotherapists ($n=71$)	2 years	Net sick leave volume. Point prevalence. Return to work	Official and patient record data. Pragmatic. Consistent with other outcome measures	E > R

E, experimental; R, reference; > means 'better than'; sign., significant; LBP, low back pain; HMO, health maintenance organization.

factors influencing sickness absence, or too low statistical power. Most studies appear to have sufficient statistical power to detect group differences of the size we found. This means that the reasons for non-significance in other studies could be linked to the treatment methods used or the precision in outcome measures. The positive studies in Table 5 have similarities in the manual methods used and in that medical doctors gave at least part of the manual treatment. At least in the Swedish social security system, these factors may contribute to the significant differences found. Also, we tested a fairly comprehensive treatment concept whereas others tended to test narrower manual treatment concepts, and we had high precision in our outcome measurement.

Implications

In a previous report we showed that the manual therapy treatment reduced pain and improved functional ability.[7] These measures may be regarded as 'softer' outcomes than sick leave measures, including return to work, since the latter are more objective measures and may also be regarded as more comprehensive measures of recovery. In this report a number of measures of sick leave, including return to work after being sick-listed, were used as outcomes. It thus appears that the manual therapy treatment not only affects pain and functional ability but also return to work (i.e. termination of sick leave), which increases the scientific support for the tested comprehensive manual therapy programme.

In this report a 'black box' approach to the treatment programmes was used, by which the therapists were allowed to use the most appropriate treatment modalities for a specific patient from a list specific for each allocation group. This is similar to the approach as used in clinical practice, to which the results should be applicable. But one question that still remains unanswered is what treatment modality contributed to the effect on low back pain. Evaluation of these single treatment modalities is now indicated, since we know that the content of the black box used in this study works. However, there is as yet no information available as to whether there is an independent effect of single modalities or whether there is a synergy (i.e. whether single modalities can be used or whether more than one modality or even the whole box is needed to achieve the effect).

In conclusion, there is evidence that the treatment methods used in this study decrease sick leave rates. This conclusion is supported by the findings from the Säter study, which had a slightly different design but used the same manual treatment concept and very similar outcome measures.[18,28] However, more research and standardization are needed to establish the relative value of different measures of sick leave as well as the absolute and relative effectiveness of various forms of 'manual' treatment in reducing sick leave. Therefore, the relative contributions of different treatment modalities and different therapists should be the focus of further investigations.

Clinical messages

- Manual therapy as performed in this study may reduce sickness absence attributable to acute or subacute low back pain.
- Differences were seen as early as 10 days after start of treatment.

Competing interests

None declared.

Contributors

SB conceived the study, designed the trial and monitored study progress. All the authors took part in the data collection, data editing, and performed statistical analyses. JB and KS drafted the manuscript. MG and SB participated in the editing of the manuscript. All the authors read and approved the final version of the manuscript.

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