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Does maintained Spinal manipulation therapy for chronic non-specific low back pain result in better long term outcome?

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Abstract:

Study Design. A prospective single blinded placebo controlled study was conducted.

Objective. to assess the effectiveness of spinal manipulation therapy (SMT) for the management of chronic non-specific low back pain (LBP) and to determine the effectiveness

of maintenance SMT in long-term reduction of pain and disability levels associated with chronic low-back conditions after an initial phase of treatments.

Summary of background. SMT is a common treatment option for low back pain. Numerous clinical trials have attempted to evaluate its effectiveness for different subgroups of acute and chronic LBP but the efficacy of maintenance SMT in chronic non-specific LBP has not been studied.

Subjects and Methods. 60 patients with chronic, nonspecific LBP lasting at least 6 months were randomized to receive either (1) 12 treatments of sham SMT over a one-month period, (2) 12 treatments, consisting of SMT over a one-month period, but no treatments for the subsequent nine months, or (3) 12 treatments over a one-month period, along with "maintenance spinal manipulation" every two weeks for the following nine months. To determine any difference among therapies, we measured pain and disability scores, generic health status, and back-specific patient satisfaction at baseline and at 1-month, 4-month, 7-month and 10-month intervals.

Results: Patients in second and third groups experienced significantly lower pain and disability scores than first group at the end of 1-month period (P=0.0027 and 0.0029 respectively). However, only the third group that was given spinal manipulations during the follow-up period showed more improvement in pain and disability scores at the 10-month evaluation. In the no maintained SMT group, however, the mean pain and disability scores returned back near to their pretreatment level.

Conclusion. SMT is effective for the treatment of chronic non specific LBP. To obtain long-term benefit, this study suggests maintenance spinal manipulations after the initial intensive manipulative therapy.

Mini abstract:

This study was conducted to assess the effectiveness of maintenance spinal manipulation therapy in long-term reduction of pain and disability associated with chronic low-back conditions after an initial phase of treatments. To obtain long-term benefit, this study suggests maintenance spinal manipulations after the initial intensive manipulative therapy.

Key points:

This study demonstrated that spinal manipulation therapy is an effective modality in chronic non-specific LBP for short-term effects.

Application of spinal manipulation therapy yielded better results when compared with the sham manipulation.

We suggest that maintained spinal manipulation is beneficial to patients of chronic non-specific LBP particularly those who gain improvement after initial intensive manipulation to maintain the improved post-treatment pain and disability levels.

INTRODUCTION

Low back pain (LBP) is one of the most common musculoskeletal ailment worldwide. It affects up to 80% of the adult population at some point during their lives.[1] A simple and practical classification, divided LBP into three main categories - the so-called "diagnostic triage" [2]: specific spinal pathology, nerve root pain/radicular pain and non-specific LBP. Chronic LBP is defined as LBP persisting for at least 12 weeks.[3] "Non-specific" chronic LBP is the LBP that is not attributable to a recognizable, known specific pathology (such as infection, tumour, osteoporosis, fracture, structural deformity, inflammatory disorder e.g.

ankylosing spondylitis, radicular syndrome or cauda equine syndrome). Non-specific LBP represents about 85% of LBP patients seen in primary care.[4] About 10% will go on to develop chronic, disabling LBP.[5] It is this group of LBP that utilizes the majority of healthcare and socioeconomic costs.[6,7]

Many reviews evaluated the role of spinal manipulation (SM) as a treatment of LBP. The majority of these reviews, concluded that SM is an efficacious treatment for non-specific LBP.[8-13] However, most reviews restricted their positive conclusions to patients with acute non-specific LBP. Some studies suggest that patients with chronic non-specific LBP are likely to respond to SM.[14] A recent high quality review of literature stated that Cochrane review found SM moderately superior to sham manipulation for chronic LBP. [15] However research evidence,[16] recognizes that not all patients with LBP should be expected to respond to a manipulation intervention. Thus the debate whether or not SM constitutes an efficacious treatment continues.[17]

Most of the studies concerned about the therapeutic effects of SM investigated theses effects only for short-term. One possible way to reduce the long-term (>6 months) effects of LBP is maintenance care (or preventive care).[18] In a previous study, manipulated patients with chronic non-specific LBP had improved within 2 weeks and after this time, new cases of improvement occurred for every visit, and at the 12th visit, approximately 75% of the patients had improved.[19] Another study found that the thrust manipulation treated group of patients showed the best outcome compared to the no manipulation and non-thrust manipulation patients with improved pain and 66% reduction in Oswestry scores over a period of 4 sessions and by the end of 12 sessions further improvement was obtained.[20] This raises the question if, the more the sessions offered the greater the improvement achieved, so it is hypothesized that if spinal manipulation therapy (SMT) can be maintained for longer periods it will be more beneficial in maintaining the desirable outcomes obtained after short-term treatment.

However, studies investigating the role of maintained manipulation in reducing pain and disability associated with chronic non-specific LBP are lacking. To the best of our knowledge, no one had searched this concept except one study of Descarreaux et al.[21] who reported the positive effects of continued manipulation treatment in maintaining functional capacities and reducing the number and intensity of pain episodes after an acute phase of treatment.

The goal of this study was to assess the effectiveness of SMT for the management of chronic non-specific LBP and to determine the effectiveness of maintenance SMT in long-term reduction of pain and disability levels associated with chronic low-back conditions after an initial phase of treatments.

METHODS

Patients

Eligible subjects were patients aging between 20 and 60 years with chronic non-specific LBP (that lasted for at least 6 months). A total of 154 patients were examined, 61 patients were excluded while 93 patient were eligible and enrolled in this study. Patients with: "red flags" for a serious spinal condition (e.g., tumor, compression fracture, infection), signs consistent with nerve root compression (i.e., positive straight leg raise <45°, or diminished reflexes, sensation, or lower extremity strength), structural deformity, spondylolithesis, spinal stenosis, ankylosing spondylitis, osteoporosis, prior surgery to the lumbar spine or buttock, obvious psychiatric disorders, referred pain to the back, widespread pain (e.g. fibromyalgia), obese patients, current pregnancy, patients older than 60 or younger than 20 years, and patients who had previous experience with SMT were excluded.

All patients were recruited from the Outpatient Clinics of Rheumatology and Rehabilitation Department in XXX University Hospital, which is one of the major university hospitals,

treating large number of patients with different causes of LBP in a specialized outpatient clinic dedicated for back pain. The physicians conducting the trial are MD certified, well trained, have been in practice for more than 10 years with good experience in managing LBP, and they are staff members of Rheumatology & Rehabilitation Department, XXX University.

All patients underwent a standardized baseline evaluation prior to treatment consisted of detailed history taking and physical examination. Subjects were asked to identify the mode and date of onset of their LBP. Also patients were asked for present symptoms suggestive of specific spinal disease, prior back therapy (including manipulation or surgery) or prolonged use of corticosteroids. All patients underwent local musculoskeletal examination as well as full neurological examination. Blood sample was withdrawn from every patient and sent to the laboratory for complete blood count, erythrocyte sedimentation rate and c-reactive protein analysis. Lateral and antero-posterior radiograph films followed by magnetic resonance imaging of the lumbar spine were also taken in an attempt to rule out the specific diseases of the lumbar spine.

Group Classification and Procedures

After the baseline evaluation, the eligible patients were assigned randomly to one of three groups matched for age and sex. The study was initially designed to include 3 groups; with the first (control) group comprises more patients than the other 2 groups as we presumed that patients who may not complete the trial will mostly belong to this group. It was planned to randomize 40%, 30%, and 30% of patients to the first, second and third groups respectively. Patients allocation is shown in figure.1.

Randomization was performed using sequential sealed envelopes prepared before enrollment of the patients. Patients were randomized twice, first for the treating clinician and second for the treatment group. Then, first envelope was opened, and only the treating fellow

subsequently opened the sealed second envelope and recorded the allocation of patients as they entered the trial. Patients whom manipulated by one physician were assessed throughout all the trial follow-up intervals by the other physician who was completely blind to group assignment of patients being assessed. Patients were not allowed to talk about the type of care they received.

After randomization patients started the first phase treatment (1-month period). During this phase, all participants are informed about back instructions and received 12 sessions of manipulation (or sham manipulation) followed by back exercise in form of pelvic tilt range of motion (ROM) exercise.

The first group (age range: 21-53 years) received 12 treatments consisting of sham spinal manipulations using minimal force over a 1-month period (control group), but no treatments for the subsequent 9 months. The second group (age range: 23-48 years), received 12 treatments consisting of standardized spinal manipulations 3 times weekly over a 1-month period, but no treatments for the subsequent 9 months (no maintained SMT group). The third group (age range: 20-50 years), also received same intensive treatment of spinal manipulations as second group over a 1-month period “initial intensive SMT”, along with "maintenance SMT" every 2 weeks for the following 9 months (maintained SMT group).

Clinical Interventions

Subjects in second and third groups received the same manipulation technique. Spinal manipulation is defined as a high velocity thrust to a joint beyond its restricted range of movement.[22]

The manipulation technique is performed with the patient supine. The side to be manipulated first will be the more symptomatic side based on the patient's complaint followed by manipulation of the opposite side. If the patient cannot specify a more symptomatic side, the

therapist may select either side for manipulation. The therapist stands on the side opposite of that to be manipulated. The patient is passively moved into side-bending towards the side to be manipulated (the patient will lie with the more painful side up). The patient interlocks the fingers behind his or her head. The therapist passively rotates the patient, and then delivers a quick thrust to the anterior superior iliac spine in a posterior and inferior direction. If a pop sound occurred, the therapist will proceed to instruct the patient in the ROM exercises. If no pop is produced, the patient will be repositioned and the manipulation will be attempted again. If no pop sound occurred, the manipulation was attempted again (a maximum of 2 attempts per side was permitted). If no pop sound is produced after the second attempt, proceed to instruct the patient in the pelvic tilt ROM exercises.[23]

Sham manipulation included SM techniques which consisted of manually applied forces of diminished magnitude aimed purposely to avoid treatable areas of the spine and to provide minimal likelihood of therapeutic effect.[24]

Patients in all treatment groups will be instructed in a pelvic tilt ROM exercise after manipulation (or sham manipulation). Subjects are asked to lie on their back and bend the hips and knees so that their feet are flat on the surface. Subjects then attempt to flatten their back on the table by slightly "drawing in" their stomach and rotating the hips backwards. The motion is to be performed in a pain-free range. Subjects will be instructed to perform 10 repetitions after each manipulation and 10 repetitions 3 times daily on the days they did not attend the session. Pelvic tilt aimed to increase the flexibility of the lower back and pelvis.

Outcome Measures

The primary endpoint was the patient's self-evaluation of their disability status by use of the Oswestry disability questionnaire after maintained SMT for 10 month period.

Outcome Measures included:

1. Subjective patient-based assessments: they are increasingly being used to evaluate the outcome of LBP [25]. Patients completed the following questionnaires at baseline, and at 1, 4, 7 and 10 -month period:
    a. Disease-specific: The Oswestry disability questionnaire was used as a LBP-specific functional assessment. [26] It has been shown to be a valid indicator of disability in patients with LBP. The questionnaire consists of 10 items addressing different aspects of functional capacities. Each item is scored from 0 to 5, with higher values representing greater disability. The total score is multiplied by 2 and expressed as a percentage.
    b. Pain levels were assessed on a visual analogue scale (VAS). The VAS consisted of a continuous 100-mm scale. Patients were told that one end of the VAS (0) referred to no pain and the other end (100) referred to the worst pain, and they were asked to mark the level of their pain. VAS is a valid tool to indicate the current intensity of pain.[27]
    c. Generic instruments: short form-36 (SF-36) was used. This is a 36-item general health questionnaire that measures 8 dimensions: general health perception, physical function, physical role, bodily pain, social functioning, mental health, emotional role and vitality. The SF-36 is a valid and reliable instrument widely used to measure generic health status, particularly for monitoring clinical outcomes after medical interventions [28].
    d. Patient's global assessment of outcomes: assessed by asking the patients to compare their current back related-health status with their baseline status, with the following choices: (a) much better; (b) somewhat better; (c) mostly the same; (d) somewhat worse; and (e) much worse. This five level instrument has a score range 1-5 (best to worse).

2. Objective measure: Mobility tests are widely used as an objective measure in patients with LBP. The participants underwent two mobility tests: the modified Schober test [29], and the lateral bending measurement.

Partial blindness of the participants was established, we planned at the study design not to tell the enrolled patients to which treatment group they were randomly assigned, but since the maintained SMT group could be easily discriminated especially in the second phase of the trial, we tried to minimize the risk of bias and overcome this difficulty, by blinding participants to the study hypothesis. Partial information given to our participants consisted of not informing them about the existence of a placebo, participants were aware that different procedures were being compared but not that one treatment was a control. Thus, participants could reasonably expect an improvement regardless of treatment received. To overcome the difficulties in maintaining blinding of participants in the phase of maintenance, participants in the maintained SMT and control arms did not attend treatment and assessment concurrently and both are not informed about the purpose of the study.

The local ethical committee had approved this work. An informed consent was taken from each patient before enrollment in the study.

Data analysis

All statistical analyses were performed using SPSS for windows version 17.0 (SPSS, Chicago, IL). Continuous data (age and duration of LBP) obtained at baseline were expressed as mean ±standard deviation (SD) and compared between each two groups using student's t test. Gender (categorical data) was expressed in number and percent and compared using the chi-square test. The outcome measures were obtained for 5 different time intervals (baseline, after the first month, and each 3 months in the follow-up periods). The outcome measures between each 2 groups at the end of the first phase were compared using student's t test.

During second phase we compared the outcome measures among the groups at the end of 4^{th}, 7^{th} and 10^{th} months. Statistical significance was set at $p < 0.05$.

Cases with missing values pose an important challenge in this study. Five patients (of the 93 patients who underwent the baseline evaluation) withdraw during the first phase before the start of the sessions. The remainder 88 patients were evaluated at baseline, entered the subsequent sessions and had completed the phase-1 treatment and then revaluated at the end of phase-1. Of these 88 patients, 80 patients were evaluated at the 4 month, 71 patients at 7 month and 60 patients at the 10 month evaluation. Simply discarding these cases, by the method of listwise deletion, rendering our analysis inaccurate. Multiple Imputation is a statistical technique for handling and analyzing incomplete data sets, that is, data sets for which some entries are missing. The purpose of Multiple Imputation is to generate possible values for missing values, thus creating several "complete" sets of data. Application of the technique requires three steps: imputation, analysis and pooling.

In our study, the variables containing the missing data are operated to generate 5 complete data sets other than the original dataset (imputation step). The 5 complete data sets are computed and analyzed (analysis step). The results of the analyses are provided plus a "pooled" output that estimates what the results would have been if the original dataset had no missing values (pooling step). These pooled results are generally more accurate than those provided by single imputation methods. The pooled data were analyzed using standard procedures (mean, standard error of mean and the student's t test).

RESULTS

Comparison among the 3 groups

Despite the 3 groups of patients were similar at baseline evaluation (table 1), patients in the second and third groups experienced significantly lower pain and disability scores compared to the control group after the first phase of treatments i.e. after 1-month period. By the end of

second phase of treatment (after 10-month period), patients with maintained SMT had significantly lower pain and disability scores compared to the patients of the no maintained SMT group.

Change of VAS pain score during the 10-month period

The initial phase of treatment yielded a reduction of 12.35 and 13.36 mm in the second and third groups respectively while it is reduced only by 8.03 mm in the control group on the pain scale (table 3). At the 4-month and 7-month evaluation the mean pain score gradually elevated back toward the pretreatment level in the no maintained SMT group. However pain score in the maintained SMT group continue improving (tables 4, 5). By the end of the study pain score yielded a reduction of 19.26 mm in the maintained SMT group while it is returned near to the pre-treatment level in the group of patients who discontinued their therapy interventions (table 6 and figure 2).

Change of Oswestry Disability Score

The greater difference, however, was seen in disability scores over the duration of the study. By the end of first phase, SMT significantly reduced the disability score in no maintained SMT group and maintained SMT when compared to the control group ($P=0.005$ and $P=0.007$ respectively). Analysis of the data after the 10-month period showed that while the disability score of the patients in the no maintained SMT group returned back nearly to their pretreatment level, the score was significantly lower in patients who received maintenance SMT compared to the no maintained SMT group ($P<0.001$). In the maintained SMT group the disability score is reduced by an average of 18.98 points lower than baseline level (table 6 and figure 3). At the 4-month and 7-month evaluation the mean disability score gradually elevated back toward the pretreatment level in the no maintained SMT group. However disability score in the maintained SMT group continue improving.

Change of SF-36 score

SF-36 questionnaire showed significantly better outcome after 1-month period for both the second and third groups compared to the control group (table 3), this continued to improve during the second phase only for the maintained SMT group while the no maintained SMT group showed progressively reducing SF-36 score (tables 4,5). By the end of the second phase, there was significant difference in the score between the maintained and no maintained groups (table 6).

Change of spinal mobility

Measurement of spine flexion and lateral bending yielded increase in their ROM in the maintained SMT group in the first phase and continued to increase in the second phase, while in the no maintained SMT group the spinal movement increased in the first phase only and decreased to near the pretreatment level by the end of the second phase.

Patient's global assessment of outcomes

The patient's global assessment of outcomes was obtained at the end of phase 2 (at the 10-month evaluation) from the 60 patients who had completed the treatment program. Patient's global assessment scale is significantly better in the maintained SMT compared to no maintained SMT and control groups (P=0.015). In the maintained SMT, 13 (65%) patients reported better outcome (scores 1 and 2) at the end of the treatment program compared to only 7 (35%) and 6 (30%) patients reported better outcome in the no maintained SMT and control groups respectively. On the other hand only 3 (15%) patients in the maintained SMT reported worse outcome (scores 4 and 5) compared to 6 (30%) and 9 (45%) patients in the no maintained SMT group and control groups respectively.

Interestingly, the most common adverse effects reported in this study were local discomfort and tiredness but no serious complications were noted. Most adverse effects were transient and began with 24 hours after treatment and were of mild to moderate severity.

DISCUSSION

This study confirms previous reports showing that spinal manipulation is an effective modality in chronic non-specific LBP especially for short-term effects.[30-37] as the disability and pain scores in our study are significantly reduced in the short-term evaluation - but not in long-term - when compared with the sham manipulation.

The current study also evaluated the effects of maintained SMT in maintaining levels of pain and functional capacity gained after an initial phase of treatment. VAS pain and Oswestry Disability Score remained at the better post-treatment levels only for the group with maintained SMT whereas VAS of pain and Oswestry Disability Score returned to their pre-treatment levels for the no maintained SMT group.

We designed this trial to deliver SMT in 3 sessions weekly then bimonthly in the second phase. One query had to be investigated is the frequency of the sessions and the intervals between sessions. The observations from previous literature can make us suppose that the unsatisfactory finding during follow up may be attributed to widely separated manipulation sessions as the trials in which increased numbers of SMT sessions were applied obtained better outcome in short-term, and continued for sometime after stoppage of treatment, than the trials used less numbers of sessions. e.g. studies that applied twelve[18] or ten sessions[38] during 6-week therapy period found that SMT resulted in greater short-term pain relief and disability reduction. On the other hand, studies in which lesser number of sessions over longer treatment period were offered, achieved either mild to slightly moderate benefit on short-term

only[39] (8 sessions over 12 weeks) or no benefits over sham treatment (7 sessions over 5 months).[24] However, further researches are needed to find out the optimum frequency and number of the sessions offered to obtain and maintain the best desirable effects.

Only sham-controlled studies in which the control intervention mimicked SM can tell us whether the clinical outcomes of SM are due to specific or non-specific (e.g. placebo) effects.[17] So, we enrolled in our study sham SMT in comparison to thrust manipulation and our finding of effectiveness of manipulation versus a sham procedure, agreed with other studies showing that SMT had more short-term pain and disability reduction than sham SMT. [34,40]

An important issue to be discussed is the state of blindness in the current trial. Partial blindness of the participants was established, by blinding participants to the study hypothesis. Blinding participants to the study hypothesis was proposed either with the use of a sham procedure or when participants and/or health care providers could not be blinded to the treatment they received.[41] Wood et al. [42] showed that lack of blinding yielded exaggerated treatment effect estimates for subjective outcomes but had no effect on objective outcomes. We included in our trial the main domains of patient-based outcomes recommended for evaluating the treatment of spinal disorders [43] and additionally we assessed spinal mobility as an objective outcome to support the patient-based assessments.

The disability score difference (> 14 points) observed after 10 months in current study between the maintained SMT group and no maintained SMT group is statistically significant and clinically important. Fritz and Irrgang [44] showed that a 6-point difference in the Oswerstry Questionnaire was the minimal clinically important difference. This 6-point difference is the

amount of change that distinguishes between patients who have improved and those who remained stable.

The postulated modes of action of SMT include disruption of articular or peri-articular adhesions, improve of trunk mobility [45], relaxation of hypertonic muscle by sudden stretching, release of entrapped synovial folds or plica, attenuation of alpha-motor neuron activity, enhancement of proprioceptive behavior and release of beta endorphins thus increase pain threshold.[46] This mechanisms are expected to sustain during maintenance of SMT.

The major limitation of the current study is missing data from patients who declined to follow up at different intervals of the study. The method for handling missing data by "listwise deletion" will generally be biased because this method deletes cases that are missing any of the variables involved in the analysis. Moreover, since deletion of incomplete cases discards some of the observed data, complete-case analysis is generally inefficient as well; that is, it produces inferences that are less precise than those produced by methods that use all of the observed data. We tried to deal with this situation by using special statistical technique; "Multiple Imputation" which is applied for handling and analyzing incomplete data sets, that is, data sets for which some entries are missing. Imputation is a more appropriate approach to handling nonresponse on items for several reasons. First, imputation adjusts for observed differences between item nonrespondents and item respondents; such an adjustment is generally not made by complete-case analysis. Second, imputation results in a completed data set, so that the data can be analyzed using standard software packages without discarding any observed values.[47] Experience has repeatedly shown that multiple imputation tends to be quite reasonable method for replacing missing values. It has been shown that by using proper method to create imputations, the resulting inferences will be statistically valid and properly reflect the uncertainty due to missing values. For proper imputation the application of the technique requires 3 steps: imputation, analysis and pooling.[48] The SPSS version 17 program used in the

current study fulfill these 3 requirements. The technique application is mentioned in details under the statistical analysis section.

We delivered maintained therapy to patients in this study for 10 months which proved efficacy in terms of reducing pain and disability, but whether this gained effect will last and for how long, this is an issue should be investigated and discussed in further longitudinal studies with attempts might be made to prolong the intervals gradually between sessions with more prolonged follow-up after treatment. However, since patients did benefit from the maintenance treatments, we believe that periodic patient visits permit proper evaluation, detection and early treatment of any emerging problem, thus preventing future episodes of LBP.

Future researches must focus on for how long SMT should be maintained and when to stop it without relapse of pain and how often frequency rate of sessions is helpful. Larger further studies may be carried out to put answers and deduct this debate.

CONCLUSION

SMT is effective for the treatment of chronic non specific LBP. To obtain long-term benefit, this study suggests maintenance spinal manipulations after the initial intensive manipulative.

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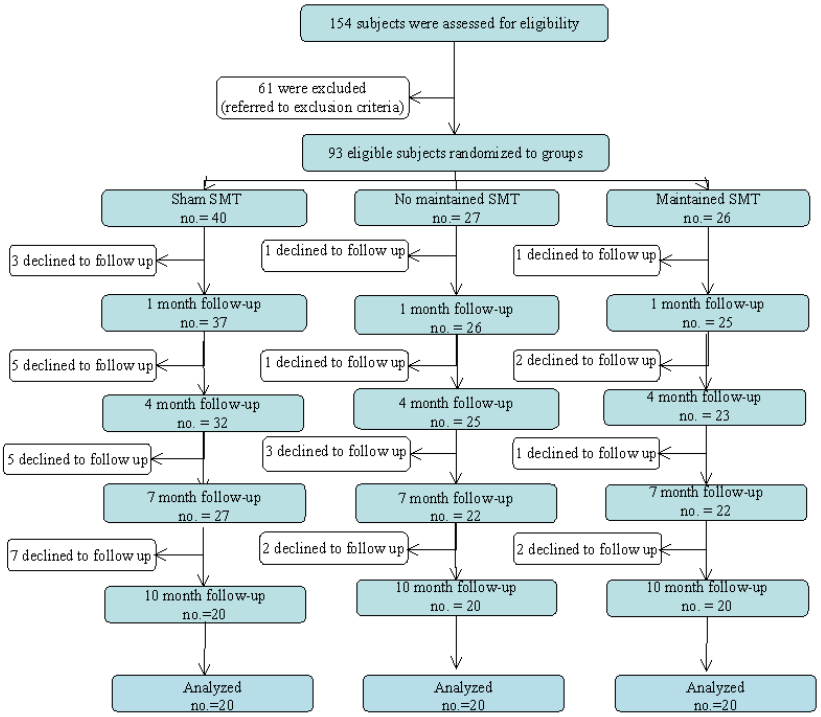

Figure 1. Flow diagram of participants through the trial.

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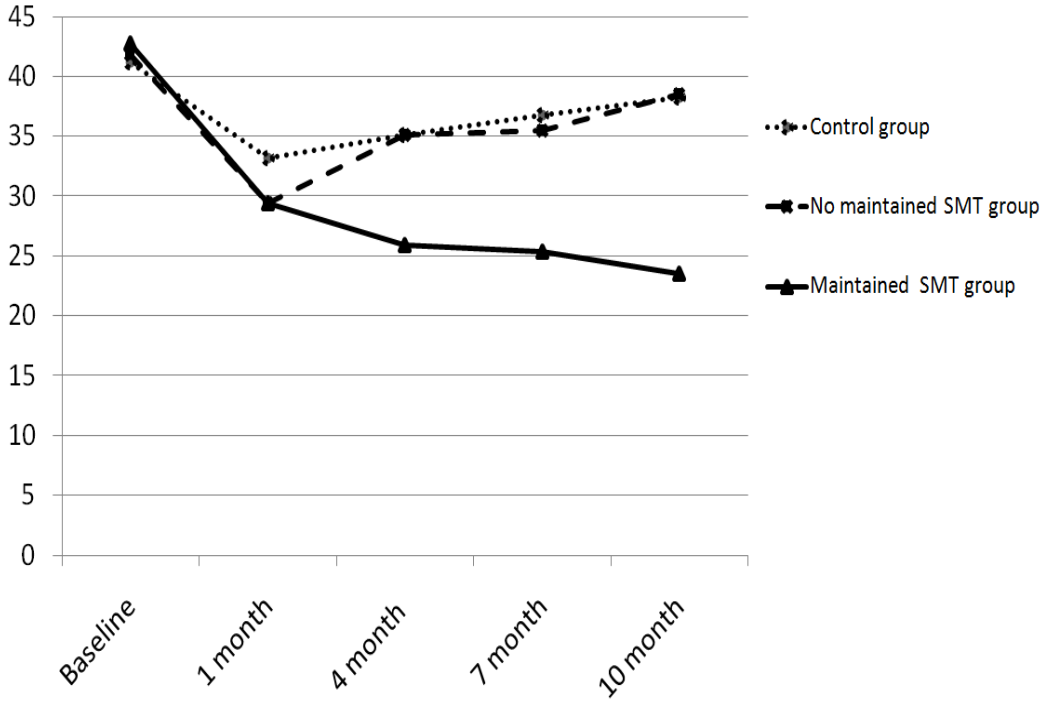

Figure 2. Pain score (VAS) over the 10-month period

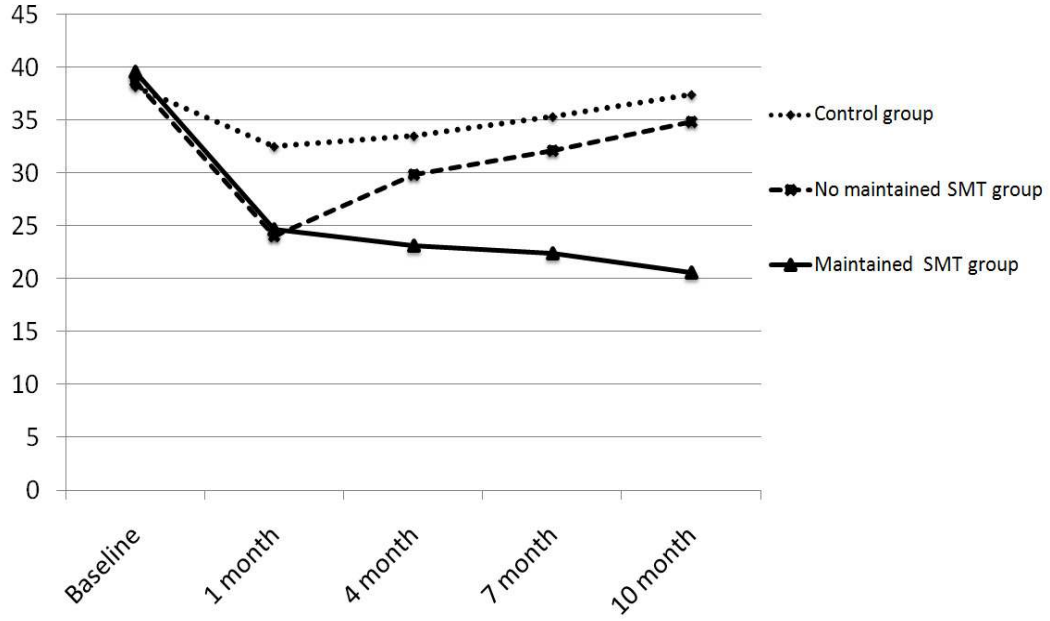

Figure 3. Oswestry Disability Score (%) over the 10-month period

Table 1. Demographic and baseline characteristics for all subjects.

	Control group		No maintained SMT group		Maintained SMT group		P
Number	37		26		25		
Female (n, %)	9	(24.324%)	7	(26.923%)	6	(24.000%)	
Male (n, %)	28	(75.676%)	19	(73.077%)	19	(76.000%)	
Age (years) (Mean ±SD)	42.3784	±9.66480	40.2692	±11.67067	41.6000	±11.03404	>0.05
LBP Duration (months) (Mean ±SD)	18.8123	±4.772	18.3842	±4.657	18.4426	±4.797	

Table 2. Subjective and objective outcome measures at baseline.

	Control Group (no=37)		No maintained SMT group (no=26)		Maintained SMT group (no=25)		Student's t test
	Mean	SE	Mean	SE	Mean	SE	P
Oswestry Disability Score (%)	38.10 81	2.442 06	38.69 23	3.050 23	39.60 00	2.628 05	>0.05[a] >0.05[b] >0.05[c]
VAS (mm)	41.21 62	2.642 67	41.80 77	3.307 34	42.80 00	2.832 55	>0.05[a] >0.05[b] >0.05[c]
SF-36	27.47 00	1.297 12	27.75 11	1.618 68	28.25 00	1.389 72	>0.05[a] >0.05[b] >0.05[c]
Modified Schober's test (cm)	19.09 46	0.330 98	18.51 92	0.420 15	18.66 00	0.362 54	>0.05[a] >0.05[b] >0.05[c]
Right Lateral Bending Test	14.91 89	0.559 36	14.96 15	0.999 20	14.96 00	0.841 59	>0.05[a] >0.05[b] >0.05[c]

Left Lateral Bending Test	14.86	0.545	14.88	0.980	14.88	0.817	>0.05[a]
	49	47	46	31	00	15	>0.05[b]
							>0.05[c]

[a] comparison of no maintained SMT vs. control [b] comparison of maintained SMT vs. control, [c] comparison of no maintained vs. maintained SMT.

Table 3. Subjective and objective outcome measures at the end of 1-month (phase 1).

	Control Group (no=37)		No maintained SMT group (no=26)		Maintained SMT group (no=25)		Student's t test
	Mean	SE	Mean	SE	Mean	SE	P
Oswestry Disability Score	32.54	2.060	24.07	1.817	24.64	1.573	0.005[a]
(%)	05	13	69	80	00	62	0.007[b]
							>0.05[c]
VAS (mm)	33.18	1.193	29.46	1.163	29.44	1.131	0.035[a]
	92	60	15	85	00	49	0.034[b]
							>0.05[c]
SF-36	27.05	1.297	31.64	1.618	32.13	1.389	0.030[a]
	33	12	00	68	89	72	0.011[b]
							>0.05[c]

Modified Schober's test (cm)	18.8946	0.33098	20.1192	0.42015	20.0600	0.33828	0.024[a] 0.020[b] >0.05[c]
Right Lateral Bending Test	15.3243	0.42457	17.1538	0.84797	17.1600	0.71805	0.040[a] 0.022[b] >0.05[c]
Left Lateral Bending Test	15.2973	0.42068	17.0769	0.83006	17.0800	0.69503	0.042[a] 0.023[b] >0.05[c]

[a] comparison of no maintained SMT vs. control [b] comparison of maintained SMT vs. control, [c] comparison of no maintained vs. maintained SMT.

Table 4. Subjective and objective outcome measures at the 4-month.

	Control Group (no=37)		No maintained SMT group (no=26)		Maintained SMT group (no=25)		Student's t test
	Mean	SE	Mean	SE	Mean	SE	P
Oswestry Disability Score (%)	33.4644	2.13469	29.8324	2.10918	23.1108	1.62002	>0.05[a] <0.001[b] 0.012[c]

VAS (mm)	35.16 89	1.253 72	35.16 43	1.283 73	25.88 85	1.225 50	>0.05[a] <0.001[b] <0.001[c]
SF-36	26.38 02	1.305 85	29.16 19	1.621 12	32.84 08	1.397 91	>0.05[a] <0.001[b] >0.05[c]
Modified Schober's test (cm)	18.61 48	0.337 17	19.52 84	0.422 94	20.93 10	0.333 33	>0.05[a] <0.001[b] <0.001[c]
Right Lateral Bending Test	14.85 79	0.391 46	15.52 88	0.816 53	17.84 23	0.632 90	>0.05[a] <0.001[b] 0.026 [c]
Left Lateral Bending Test	14.83 12	0.385 60	15.45 22	0.795 39	17.76 14	0.607 43	>0.05[a] <0.001[b] 0.022 [c]

[a] comparison of no maintained SMT vs. control [b] comparison of maintained SMT vs. control, [c] comparison of no maintained vs. maintained SMT.

Table 5. Subjective and objective outcome measures at the 7-month.

	Control Group (no=37)		No maintained SMT group (no=26)		Maintained SMT group (no=25)		Student's t test
	Mean	SE	Mean	SE	Mean	SE	P
Oswestry Disability Score (%)	35.31 68	2.107 99	32.17 89	2.127 04	22.38 03	1.635 21	>0.05[a] <0.001[b] <0.001[c]
VAS (mm)	36.80 55	1.395 85	35.53 50	2.130 20	25.38 41	1.655 49	>0.05[a] <0.001[b] <0.001[c]
SF-36	26.11 31	1.314 85	27.78 40	1.625 49	33.05 29	1.407 80	>0.05[a] <0.001[b] 0.015[c]
Modified Schober's test (cm)	18.18 29	0.349 80	19.08 44	0.423 93	22.24 74	0.347 05	>0.05[a] <0.001[b] <0.001[c]
Right Lateral Bending Test	14.95 29	0.381 08	14.81 01	0.641 94	18.24 34	0.622 09	>0.05[a] <0.001[b] <0.001[c]

Left Lateral Bending Test	14.92 67	0.373 75	14.73 33	0.610 26	18.16 02	0.598 28	>0.05[a] <0.001[b] 0.026[c]

[a] comparison of no maintained SMT vs. control [b] comparison of maintained SMT vs. control, [c] comparison of no maintained vs. maintained SMT.

Table 6. Subjective and objective outcome measures at the end of 10-month (phase 2).

	Control Group (no=37)		No maintained SMT group (no=26)		Maintained SMT group (no=25)		Student's t test
	Mean	SE	Mean	SE	Mean	SE	P
Oswestry Disability Score (%)	37.43 74	2.204 09	34.90 58	2.356 02	20.61 90	1.531 87	>0.05[a] <0.001[b] <0.001[c]
VAS (mm)	38.29 02	2.123 43	38.52 55	2.450 16	23.54 49	1.586 03	>0.05[a] <0.001[b] <0.001[c]
SF-36	25.90 79	1.268 52	27.64 89	1.616 89	33.70 29	1.410 08	>0.05[a] <0.001[b] 0.005[c]

Modified Schober's test (cm)	17.86 92	0.361 73	18.21 85	0.422 28	22.67 72	0.372 20	>0.05[a] <0.001[b] <0.001[c]
Right Lateral Bending Test	14.95 04	0.405 72	15.12 52	0.667 73	18.68 39	.5859 9	>0.05[a] <0.001[b] <0.001[c]
Left Lateral Bending Test	14.92 65	0.400 79	15.04 89	0.639 28	18.60 14	0.563 50	>0.05[a] <0.001[b] 0.026[c]

[a] comparison of no maintained SMT vs. control [b] comparison of maintained SMT vs. control, [c] comparison of no maintained vs. maintained SMT.