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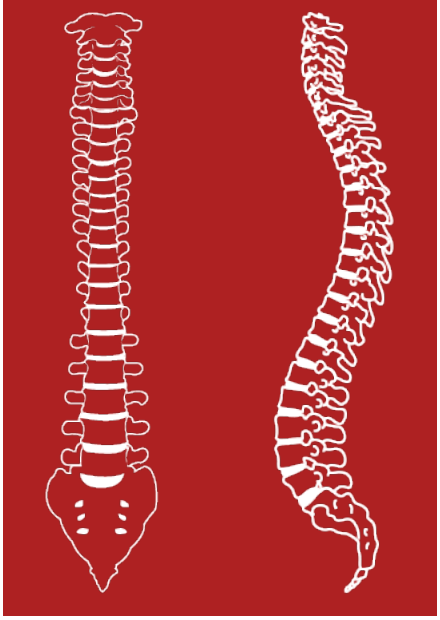

PHYSIUM en el tratamiento del dolor en pacientes con lumbalgia crónica

PHYSIUM in the treatment of pain in patients with chronic low back pain

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RESUMEN

Antecedentes
El masaje es un tratamiento muy utilizado en el dolor de la lumbalgia crónica. PHYSIUM es un dispositivo médico no invasivo que administra un masaje estandarizado por presión negativa.

Métodos
21 pacientes con lumbalgia crónica clínicamente confirmada, que no respondieron a tratamientos manuales previos fueron incluidos en este estudio, analítico, longitudinal y prospectivo, para evaluar la seguridad y la efectividad de 4 a 10 sesiones de PHYSIUM en la reducción de la intensidad del dolor, evaluada por la escala EVA. Se registraron los efectos adversos durante el estudio. Los pacientes que respondieron, se les administró un tratamiento de mantenimiento y se siguieron 33 semanas.

Resultados
18/21 (85,7%) pacientes respondieron al tratamiento. Presentaron una reducción significativa en la intensidad del dolor (5,6±2,0) respecto al nivel basal (t-test; $p<0,001$) entre la sesión 5ª y 9ª, con un cambio de 84,2%. No se observaron efectos adversos graves. Los pacientes que respondieron al tratamiento, que recibieron el tratamiento de mantenimiento, se les siguió durante las 33 semanas sin observarse recidivas.

Conclusiones
El tratamiento con PHYSIUM en pacientes con lumbalgia crónica se considera seguro y eficaz en la reducción en la intensidad de dolor. En estudios comparables la reducción del dolor es mayor que en otros tratamientos paralumbalgia crónica. El tratamiento de mantenimiento ayuda a evitar recidivas, aportando beneficios a largo plazo. El masaje administrado con PHYSIUM es un tratamiento novedoso que puede ser una alternativa efectiva a los tratamientos actuales.

Palabras clave
Masaje, lumbalgia crónica, recaída.

ABSTRACT

Background
Massage is a therapy used to reduce pain of chronic back pain patients. PHYSIUM is a non-invasive device that standardizes massage by negative pressure. To evaluate the safety and effectiveness of therapeutic massage administered through PHYSIUM in reduction of pain intensity in chronic LBP patient's non-responders to other manual therapies.

Methods
21 chronic LBP patients confirmed clinically were included in a pragmatic, analytical, longitudinal, prospective cohort study evaluating effectiveness and safety of treatment sessions in reduction of pain intensity assessed by VAS scale. Patients who responded to therapy were followed for additional 33 weeks on a maintenance treatment. Adverse events were registered.

Results
18/21 (85,7%) patients responded to the treatment, showing a statistical significant reduction of pain intensity of 5,6±2,0 in VAS (paired t-test; p<0,001), and a change of 84,2% in VAS. Most of patients responded to the treatment between sessions 5 and 9. Eighteen patients who responded to treatment received a protocolized maintenance treatment. No relapses were observed. No severe adverse events were reported.

Conclusions
Treatment with PHYSIUM was efficacious and safe, demonstrated by pain intensity reduction in non-responder patients with chronic LBP, with no severe adverse events for persistent low back pain. The maintenance treatment avoids relapses, providing long-lasting benefits. Massage administered by PHYSIUM presented greater pain reduction than long term follow up in comparable back pain trials, PHYSIUM can be an effective alternative to conventional medical care for persistent back pain. PHYSIUM massage has potential of being a novel highly efficacious treatment for persistent back pain.

Keywords
Massage, chronic back pain, relapse.

INTRODUCTION

Low back pain (LBP) is one of the most common and costly musculoskeletal disorders in modern society. It is often recurrent and sometimes persistent.
Seventy percent to 85% of the population will experience LBP at some time in their lives (1). Ten percent of patients with acute back pain are at risk of developing chronic pain, disability and decreasing quality of live (2). Back pain (BP) is one of the top causes for lost work days and visits to medical offices. In Spain, back pain is the most prevalent disease in adult population over 20 years old, with 14.8% of acute LBP, 7.7% of chronic LBP, and 0.8% of inflammatory back pain (3). BP accounts for more than 90% of social costs for back-related disability. In Europe, the costs associated with LBP alone, represent between 1.7% and 2.1% of gross domestic product annually (4).
The management of patients with chronic LBP is complicated by psychosocial factors, uncertain diagnoses, and treatments that are only moderately effective. At present, more than 50 pharmacological and/or physical therapies are being used to relieve pain, lessen suffering, and to manage LBP. Drugs (NSAIDs, muscle relaxants or corticosteroids) can relief pain but are associated with adverse events (5), (6), (7). Current management guidelines for LBP recommend conservative therapies such as manual therapy, physical activity and exercise to lower pain and improve back mobility; but outcomes are highly variable (1), (5), (8).
Physiotherapists select treatments based on their training and individual preferences, patient preferences, or physical form (tiredness, tone of muscle) of the patient. Current therapies for chronic LBP do not contribute to the prevalence decrease of LBP symptoms; there is a need of better treatments to address the unmet needs of this patient population (9), (10).
Therapeutic massage (TM) is a conservative treatment, considered an effective and well tolerated in patients with chronic LBP by the Cochrane Collaboration (11) and other authors (12), (10), (13), (14), (15), (16), (17), without major risks or adverse effects. The administration of TM is not standardized. TM treatments vary widely due to different levels of training and to individual differences associated with specific strokes, variations in pressure, special techniques, and anatomic sites to which treatment is applied. This leads to large inter- and intra-therapist variability of TM (18).
Differences in massage administration, due to methods, tiredness, tone of muscle of patient and other factors explain the challenges of achieving TM standardization. Optimal dosage of massage therapy is very difficult to define and replicate for a given physical therapist; thus, difficult to evaluate in controlled clinical studies (18). All these challenges lead physicians to avoid prescribing TM as first line therapy (15).
PHYSIUM is a non-invasive device that delivers therapeutic massage through a vacuum pump. This pump is under full computerized control by the practitioner, who can apply specific amounts of pressure and pulsations. The device is a mobile carrier with eight adjustable and two mobile arms. Each arm ends with a head applicator that provides massage through vacuum. The head applicators allow up to treat up to 8 different areas of the body on fixed parallel positions. The head applicators are interchangeable polypropylene cups of different sizes and shapes, designed for different body areas. The applicators are in contact with the patient's skin and deliver negative pressure that creates the massaging action. A computer controls the mechanical stimulus, with pressure ranging from a minimum of 40 mbar up to a maximum of 250 mbar. Therapists apply the head applicators over the target muscles. Which muscles are affected and the degree of injury is assessed by the Saló-Darder test (SD). This biomechanical diagnostic test identifies the primary injury in a chronic muscular disorder. The SD method is based on the premise that the state of stress, traumatic injury, or degenerative processes in tissues (muscles, fascias, joints, nerves, blood and lymph vessels, organs, viscera), bring retraction (muscular system), adherences (fascial system), and/or scarring fibrosis which cause limitation of

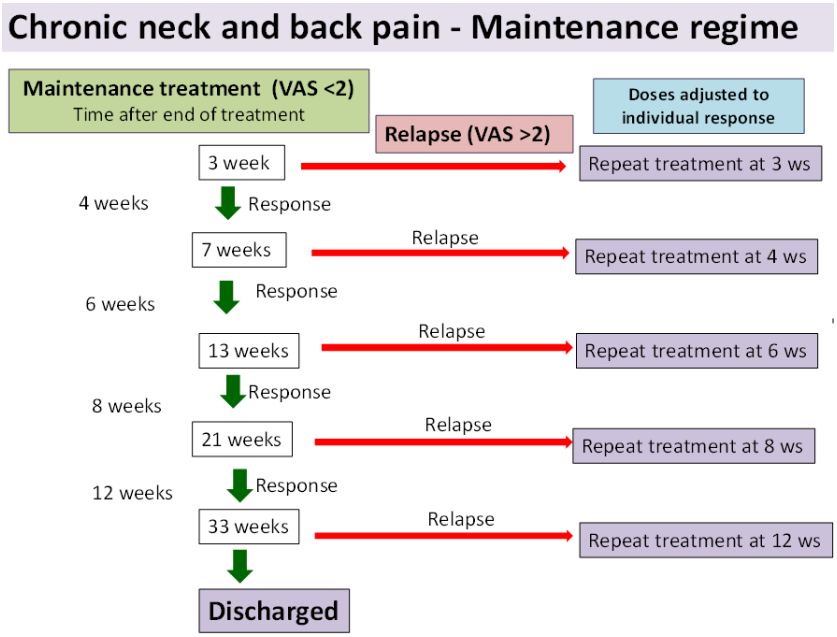

Figure 1: PHYSIUM maintenance therapeutic regimen in patients with unstable chronic back pain

Table 1: Demographic characteristics of study population at baseline

	PHYSIUM (n = 21)
Race Caucasian Other	 100% 0%
Pain intensity at baseline (±SD) from averaged VAS scores (0 = none and 10 = maximum severity)	6,33±1,68
Duration of back pain	18 years

Table 2.: Treatment with PHYSIUM on average VAS pain score in patients with (average ± SD)

Patients	(n = 21)
Baseline pain intensity (±SD)	6,3±1,7
End of treatment pain intensity (±SD)	1,0±2,1*
Pain remission (W 4 to W 10) (±SD)	5,6 ±2,0
% Change	85,7%

* p<0.001, Paired t-test

Table 3.: VAS pain score by treatment session in Back Pain patients

Treatment sessions	VAS Average ± SD	Number of patients treated	Responders before the session
Baseline (W 1)	6,3±1,68	21	0
Session 3 (W 3)	2,6 ±2,87	21	0
Session 5 (W 5)	1,6±3,07	12	9/21
Session 8 (W 8)	1,0±3,34	8	4/12
Session 10 (W10)	0,7 ±3,61	3	4/8
Week 11		0	1/3
Responders			18

movement (muscular, joint and fascial), as well as pain and inflammation (muscular, joints and fascial), and are linked to stenosis in the aponeurosis of the vascular and nervous systems (21). The therapeutic regimen has been previously optimized in order to minimize the number of massage sessions.

PHYSIUM uses defined treatment protocols (applicator location on the body surface, pressure, and pulsations) and thus standardizes TM administration. Massage delivered by PHYSIUM is independent of a given individual physical therapist. Treatment protocols can be transferred and reproduced in any given practice that has PHYSIUM

This study aims to evaluate the safety and the effectiveness of the therapeutic massage administered through PHYSIUM in the pain reduction in chronic LBP patients non-responders to other manual therapies.

MATERIAL & METHODS

The study was designed as pragmatic, analytical, longitudinal, prospective cohort, to evaluate the effectiveness and safety of therapeutic massage applied with PHYSIUM in patients with LBP lasting more than 12 weeks.

Participants: Twenty one patients of both genders, between 18 and 77 years old, all of them Caucasian, with unstable chronic LBP confirmed clinically and active disease with a Visual Analogical Scale (VAS) +-6 (19), were included in this open label study. These patients did not respond to at least 20 previous sessions of combined manual therapy treatments, as used in the usual practice. The study was conducted at the Saló Darder Therapeutic Institute, Barcelona-Spain. Subjects were recruited between October 2011 and December 2013. All study participants accepted to be included after being informed of the study protocol. Treatments and outcome measures were obtained at this centre. The study protocol was approved by Saló Darder Therapeutic Institute Ethics Committee. Patients of both genders, aged between 18 and 65, diagnosed with chronic nonspecific low back pain with pain and/or functional disability lasting over 12 weeks, and who measured ≥6 on VAS pain scale, were included in the study. Any patient with important pathologies, such as back pain as a result of trauma or fracture, nerve damage or severe psychiatric condition, including clinical depression; suffering from fibromyalgia, or autoimmune disease articulate, history of spinal surgery within the last 6 months, systemic problem affecting the sensitivity, back pain as a result of a fracture, disc herniation with neurological deficits, a process of infection or injury at the time of the first visit or screening and taking other medical treatment or pregnant women after the third month of pregnancy were excluded.

Intervention: Patients were diagnosed by a physician, and

evaluated by a manual therapist using SD test to find the primary lesion and to determine the optimal treatment program. This diagnostic test identifies which muscles are working properly and which are in a retractable process. Muscles in a retractable process lead to a pathological chain, which involves chronic tension on the muscle-connective system (20). SD method identifies the primary muscular injury using a test trawl tissue, examining the whole body to determine whether muscles are under normal conditions. The SD method, evaluates not only every muscle unit, but it also assesses restrictions of the joint capsule of main joints. The diagnosis of joint capsule is a key factor to determine a proper treatment protocol (21). To evaluate low back pain by the SD test the patient is placed in standing position. The evaluator stands behind the patient and performs the drive test of the thoracolumbar fascia L2- L3. The patient does a lumbar flexion and if the valuation point drag caudally, lateral, anterior (it can be also right, left or bilateral) indicates the affected muscular chain by biomechanical stress on the spine. The evaluator continues performing the assessment test with the same procedure following the muscle tensional chain, up to the reach the beginning of the chain (primary lesion). Once the muscular chain responsible of the tension is diagnosed, the physiotherapist proceeds to relax the muscle of the tensioned chain by the treatment with PHYSIUM. Physiotherapist place the PHYSIUM heads on the skin points located over the tensioned chain and applies a protocol specifically designed for the treatment of low back pain.
Patients were treated with PHYSIUM by trained and certified physical therapists of Salo Darder Institute of Barcelona, Spain. Patients received a standardized treatment for chronic LBP controlled by PHYSIUM device, which consisted in:

a) First stage: Reduction of muscular tension. It is selected one of the two following programs, based on possible existence of hyperalgesia.

- Presence of hyperalgesia: P.18. Maximum Pressure 80mb, Lower Pressure 5mb. Frequency Time Up 0.4seg- Longer Pressure Time 0.4sec - Down Time 0,4sec.
- Absence of hyperalgesia: P.17. Higher Pressure 60mb, Lower Pressure 5mb. Frequency Time Up 0.9sec- Longer Pressure Time 0.4sec- Down Time 0,6sec.

b) Second stage:
During the treatment it is use one of the three commented treatment programs, depending of patient's age.

- Patients under 55 years: P.0: Higher Pressure 100mb, Lower Pressure 0mb. Frequency Time Up 0.4sec- Longer Pressure Time 0.4sec- Down Time 0,4sec.
- Patients between 55 and 65 years: P1. Higher Pressure 90mb, Lower Pressure 0mb. Frequency Time Up 0.4sec-Longer Pressure Time 0.4sec- Down Time 0,4sec.
- Patients over 65 years: P2. Higher Pressure 80mb, Lower Pressure 0mb. Frequency Time Up 0.4sec-Longer Pressure Time 0.4sec- Down Time 0,4sec.

c) Third stage:
It is used a single program, applicable in all treated patients

- P.13: Higher Pressure 100mb, Lower Pressure 0mb. Frequency Time Up 1sec-Longer Pressure Time 8sec- Down Time 1sec.

Physical therapists used the same protocol for chronic LBP and administered each patient a minimum of 4 sessions and a maximum of 10 sessions of 60 minutes each, once a week. Head applicators were placed depending on the affected muscles or injured muscular chains diagnosed by the SD test. The total number of sessions for each patient depended on VAS score. Sessions where stopped when VAS score reached ≤2. Patients who didn't attend the following sessions were considered dropouts.
Follow up and maintenance treatment: All patients that responded were enrolled to receive a maintenance treatment up to 33 weeks after the last intervention treatment. Maintenance treatment started 3 weeks after the last intervention session. At this time patients were examined for pain and treated with PHYSIUM. Patients that did not relapse (VAS≤2) were examined and treated again on weeks 7, 13, 21, and 33 and were discharged at this point (Fig. 1). This therapeutic regimen was adapted to the different outcomes: (a) Patients who relapsed (VAS >2) at any maintenance visit were treated with a schedule of visits spaced by the same period of time since the last visit before relapse. b) Patients who responded to the maintenance treatment (VAS <1) had their next visit extended in time following the visit schedule described above.

Evaluation

Pain reduction: The primary efficacy endpoint was change in pain intensity measured by VAS (22), (23) between baseline and the last examination (between 4 and 10 weeks). Pain measurements were collected during the treatment at baseline and before treatments at visits 3, 5, 8 and 10.
Pain was classified as a) mild (≤3), b) moderate (>3 to <5.5) and c) severe (≥5,5) according to Collins et al (22). A reduction of pain was considered efficacious when VAS reached ≤ 2.
Relapses: Relapses were defined as VAS >2 and assessed by measuring pain intensity at week 33 (visit 15) from the start of treatment, and during maintenance treatment weeks 3, 127, 13, 21, and 33.

Safety: All side effects, both spontaneously reported by patients or observed by the therapist, were recorded.

Statistical Analysis: Statistical analysis was performed with the on-line Statistical package QuickCalcs (www.graphpad.com/quickcalcs). Descriptive statistics of demographics (race, pain intensity at baseline measured by VAS and duration of back pain were analyzed. The results are presented by mean, standard deviation and 95% confidence interval.
Outcome data was analyzed by Intention to Treat. The primary statistical hypothesis (pain intensity in the LBP) was tested using paired t-test to compare mean reduction in pain intensity rates at the end of PHYSIUM treatment therapy versus baseline. The level of statistical significance was established at 0.05. Safety measurements also were studied calculating rate of adverse events by patient and by session. Relapse was reported by patients reporting pain and used to estimate the rate of relapse.

RESULTS

Demographic characteristics

Twenty one patients of both genders, with duration of their back pain of 18 years, and a mean pain intensity of 6,3±1,7 VAS scale were included in the study and described in Table 1.
Primary Outcome: Pain at the end of 4-10 sessions of treatment
Baseline pain had a VAS of 6,3±1,7;at the end of the treatment reached a VAS of 1, with a global pain reduction of 5,6 ±2,0, and a change of

Figure 2: Pain reduction (VAS) after treatment with PHYSIUM in patients with unstable chronic back pain

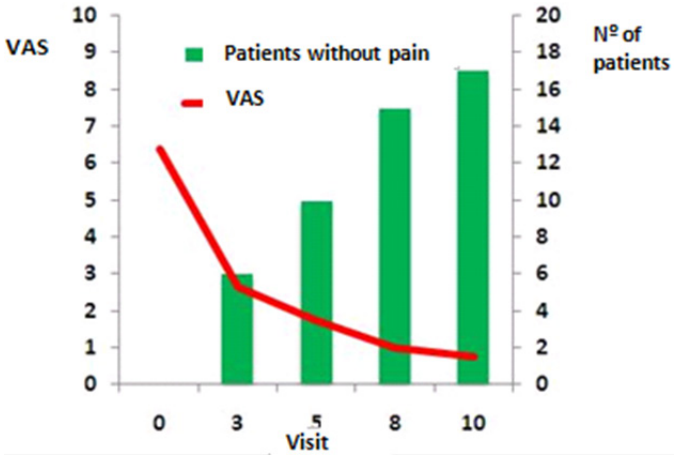

Table 4.: VAS pain score by treatment session in Back Pain patients during maintenance therapy

Maintenance treatment sessions	Number of patients treated	Responders before the next session
Session 1 (W 3)	18	18
Session 2 (W 7) (4 w later)	16	16
Session 3 (W 15) (8 w later)	7	7
Session 4 (W 33) (12 w later)	4	4

84,2% (Table 2). This reduction in pain intensity between the baseline and end of treatment (sessions 4 to 10) was statistical and clinical significant ($p<0,001$).
18/21 (85, 7%) patients responded to PHYSIUM treatment (VAS<1). Nine out of 21 patients responded between sessions 3 and 4 (at week 5), 4/21 patients in session 5 to 7 (at week 8), 4/21 at sessions 8 to 9 (at week 10), and 1/21 at sessions 10 (at week 11) (see Table 3). No patients dropped out after few sessions or they don't attend the following sessions.

Secondary Outcome: Pain relapses
Eighteen patients who responded to PHYSIUM treatment (VAS≤ 2) received a maintenance treatment to avoid relapses 3 weeks after the end of the intervention phase of the study. Four weeks later 16 patients received a second maintenance treatment. Eight weeks later 7 patients received a third treatment, and finally 12 weeks later (at 21 weeks 4 patients received the last session of maintenance treatment. Patients that completed this treatment were discharged (Fig. 1).
Fifteen (78,9%) patients who did not have pain left voluntarily the maintenance treatment during the follow up; the highest rate occurred after the second session (7/18 patients – 38,9%) (Table 4). Patients, who did not return to the next maintenance treatment session, were interviewed by phone in order to collect the reason for termination. No patients under maintenance treatment presented pain relapses. Patients that terminated voluntarily the maintenance treatment did not report any pain relapse. All patients were advised to return to the center if pain reappeared.

Safety
No severe adverse effects were reported.
2 (10%) patients presented pain of mild intensity during session 1 close to lumbar area (sciatica and pain in right trochanter) and 1 (5%) patient presented a mild hematoma.

Our results support the hypothesis that a standardized massage administered with PHYSIUM in non-responder patients with LBP to other manual therapy is a safe and effective treatment that can lead to long term improvements for chronic back pain sufferers. An important reduction in the level of pain (89% of change) in 18/21 (85,7%) subjects between 4 and 10 sessions was observed. This effect on the pain over time is greater than results observed for long term follow up in comparable back pain trials10; 11;12;13;14;15;16;17; 24; 25; 26, without serious risks or adverse effects.
PHYSIUM delivers a standardized massage therapy independent of the individual physical therapist, avoiding variability related problems such as differences intra e inter-therapists, massage therapy dosage (including pressure, time, pulsations, and administration on injured areas), and consequently MT treatment with PHYSIUM is reproducible.
Maintenance treatment with PHYSIUM avoided pain relapses in 18 patients with chronic back pain after 4 sessions and up to 33 weeks at discharge, after the last intervention treatment.

DISCUSSION

The results of this study suggest that massage with PHYSIUM is an effective treatment for chronic LBP, with benefits that persist for more than 33 weeks.
Study design: This was a pilot, pragmatic, prospective, analytical study. We believe that pragmatic studies are better suited for LBP studies (15), because treatments follow real life clinical practice and may produce more useful results.
Major strengths of this study were the involvement of massage therapists in developing treatment protocols, minimal "co-interventions", high compliance rates, high follow-up rates, and short-term follow-up. The absence of widely accepted physiotherapeutic standards make the research of the safety and effectiveness of massage therapies for LBP difficult to conduct, to interpret and to reach clear conclusions (15):
The standardization achieved with PHYSIUM facilitates study design and execution, and data interpretation, which increases the robustness and reliability of the study compared to other studies that evaluate other methods of massage that are less reproducible.
The primary limitations of this study are the use of a single study site and the absence of a control group. However, to overcome this weakness, we selected a population of non-responders patients to other therapies. Thus, the patient population included in the study was extremely challenging in order to show efficacy for a novel treatment, because the lack of response to other MT treatments. The small number of patients was not an issue because the difference in efficacy between baseline and end of treatment was statistically significant and was associated with long lasting clinical improvement in a patient population that did not respond to other MT therapies. Other limitations include a limited duration follow-up after maintenance period, which we plan to address in subsequent studies
In the future, other clinical trials comparing PHYSIUM with standard therapy and larger sample size will be performed. We plan to study other variables in addition to the intensity of pain, for example mobility, and HEOR like QoL, Well-Being or satisfaction with the treatment of patients. Massage therapy delivered by PHYSIUM will increase homogeneity and standardization of treatments and will allow the design of treatment protocols with broad applicability, as recommended elsewhere (15).

CONCLUSIONS

In conclusion, the therapeutic massage administered with PHYSIUM is an effective and safe massage therapy, demonstrated by the pain reduction in non responder patients to other manual therapy, with no severe adverse events for persistent low back pain. The maintenance treatment avoids relapses not only during treatment but also more than 33 weeks after the discharge of patients, providing long-lasting

benefits. Massage administered by PHYSIUM shows better and long lasting effects than other manual therapy studies and might be an effective alternative to conventional medical care for persistent back pain.

NOTES

Abbreviations
Salo Dader Test: SD test.

Competing interests
DB and GH declare that they work at SD Institute and DT and CCL at the Clinical Department of MC Health Tech.

Authors' contributions
DB, GH, DT and CCL conceived the trial and developed the trial design. CCL and DT lead the trial management team, and produced the first draft of the study protocol. DB and GH contributed to the development of the trial design, interventions and the physiotherapist training program. CCL and DT participated in analysis of the data.
All authors contributed to the refinement of the detailed trial protocol, drafting and approval of the final manuscript.

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