No increase in 6-week treatment effect of Mechanical Diagnosis and Therapy with the use of the LUMBOback in people with non-acute non-specific low back pain and a directional preference of extension: a pilot randomized controlled trial.

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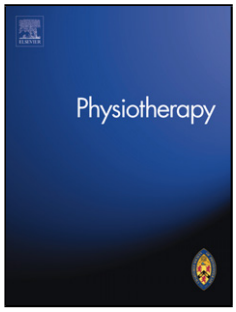

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No increase in 6-week treatment effect of Mechanical Diagnosis and Therapy with the use of the LUMOback in people with non-acute non-specific low back pain and a directional preference of extension: a pilot randomized controlled trial

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ABSTRACT

Objectives: To pilot the methods for a randomized controlled trial (RCT) to investigate whether the treatment effect of Mechanical Diagnosis and Therapy (MDT) is enhanced with the LUMOback.

Design: Assessor blinded RCT with 3 and 6-week follow-ups.

Setting: An outpatient clinic.

Participants: Primary eligibility criteria were: a directional preference of lumbar extension, ≥18 years of age, and non-specific low back pain lasting for ≥1 month.

Interventions: The MDT group undertook extension exercises (10 reps/3h) and postural correction using a lumbar roll at home. The MDT+LUMOback group also wore the LUMOback daily, providing a vibration alert in a slouched posture.

Main outcome measures: The Global Rating of Change Scale (GRCS) (0-6), recruitment rate per month, treatment sessions, compliance rate of wearing the LUMOback, participants' adherence with treatment, dropout rate and the stage of the MDT program at six weeks.

Results: Twenty-two participants were included for 20 months (a recruitment rate of 1.1 patients/month). Dropout rate was 9%. The mean (SD) of the GRCS of the MDT and MDT+LUMOback groups were 4.7 (0.8) and 4.7 (0.5) at the 3-week follow-up and were both 4.9 (0.5) at the 6-week follow-up. The patients undertook a mean of 6.7 sessions for six weeks and exercises with mean of 3.7 set/day in each group. The mean compliance rate of wearing the LUMOback was 88%. Nobody was discharged from the intervention with full recovery within six weeks.

Conclusions: Data indicated a promising method for the full RCT, but a rationale for the full RCT was not justified.

Clinical Trial Registration number: UMIN000018380

Contribution of paper

- It was the ultimate aim to investigate if the treatment effect of Mechanical Diagnosis and Therapy (MDT) could be enhanced with the use of real-time feedback with the LUMOback in patients with a directional preference of lumbar extension.
- Regarding the methodology to achieve that aim, recruitment of participants in multiple centers was considered necessary, because of the low recruitment rate in the current study.

- However, further investigation in a multi-center trial using the current methods is not justified due to the lack of difference in the treatment effect of MDT within six weeks, with or without the use of the LUMOback for assisting postural correction.

Keywords: back pain; exercise therapy; lumbosacral region; manipulative therapies; posture; proprioceptive feedback

BACKGROUND

Low back pain (LBP) results in economic and healthcare burden throughout the world [1]. In patients with acute LBP (i.e. symptom duration <1 month), moderate-quality evidence showed no clear differences between different exercise regimes [2]. However, the following are also recommended with strong-evidence [3]: mechanical loading strategies in a specific direction resulting in centralization to be undertaken in patients with LBP with related (referred) lower extremity pain including acute LBP; and mechanical loading strategies in a specific direction resulting in improvement of symptoms and mobility of the back to be undertaken in patients with acute, subacute or chronic LBP. The specific direction resulting in centralization and/or improvement of symptoms and mobility is termed directional preference (DP). Therefore, exercise therapy with mechanical loading strategies in the DP is an evidence-based approach for all patients with LBP with or without referred pain.

A previous study suggested that individuals with LBP had more slouched habitual lumbopelvic posture than individuals without any history of LBP [4]. Furthermore, an awkward posture, such as slouched posture, is a risk factor for LBP, and the risk increases when this posture is combined with prolonged sitting [5]. Therefore, postural correction/education to maintain the lumbar lordosis is likely to be

important to enhance the treatment effect of exercise therapy in the DP, particularly for patients who have LBP with or without referred pain and a DP of lumbar extension.

Mechanical Diagnosis and Therapy (MDT) is one of the most commonly used physical therapy approaches for the management of LBP [6, 7], which includes a biopsychosocial perspective [8] and puts an emphasis on patient education [9]. In patients with a DP for extension, MDT includes exercise therapy in the DP, such as extension in lying, and postural correction/education using a lumbar roll to avoid kyphotic lumbar posture with posterior pelvic tilt. Recent developments in wearable device technologies may also be useful for postural correction. The LUMOback (Lumo Bodytech Inc., Mountain View, CA, USA) device, which works on i-phone application, continuously monitors the pelvic position during everyday life and can provide real-time feedback to avoid a slouched posture using a vibration alert. Therefore, it was hypothesized that the treatment effect of MDT could be enhanced with the use of real-time feedback with the LUMOback in patients with a DP of lumbar extension. However, there has been no study using MDT with the LUMOback and it was considered prudent to undertake a pilot randomized control trial (RCT) before undertaking a full RCT.

The purpose of this study was to pilot the methods proposed to conduct a full RCT to investigate whether the treatment effect of MDT is enhanced with the LUMOback in patients with LBP and a DP of lumbar extension. In particular, the following aspects were investigated: 1) recruitment rate per month, 2) number of treatment sessions, 3) compliance rate of wearing the LUMOback, 4) adherence with treatment, 5) dropout rate and 6) stage of the MDT program at six weeks. The secondary purpose was to undertake a preliminary comparison in patient reported-outcomes and to estimate the variability of these outcomes in this patient population.

METHODS

Design

This study was a single-center assessor blinded parallel group RCT, where one group of interventions was MDT only (MDT group) and the other was MDT with real-time feedback using the LUMOback (MDT+LUMOback group). All patients provided written consent before data collection. The study design was approved by the institutional research ethics committee (XXXX) and pre-registered in the trial registration (UMIN000018380).

Patients

Patients were recruited via advertising in a local orthopedic clinic in XXX from August 2015 to March 2017. Inclusion criteria of participants were: 1) ≥18 years of age, 2) non-specific LBP diagnosed by an orthopedic surgeon (XX), 3) symptoms lasting for more than one month, 4) using a smartphone, 5) undertaking LBP management based on MDT only, and 6) with a DP for extension. The following patients were not considered eligible: 1) patients with a history of back or lower limb surgery or trauma within the past six months, 2) patients with a history of nerve root block within the past four weeks, 3) patients with a history of neuropathic pathology such as diabetes or polyneuropathy, vascular disease in the lower extremity, systemic disease or inflammatory arthropathy, 4) patients with any contraindication to manual therapy techniques such as fracture, infection or severe osteoporosis, and 5) individuals who could not communicate effectively.

Interventions

The MDT interventions (20-40 minutes) were undertaken in an orthopedic outpatient clinic by one author (XX), who was a credentialed MDT physical therapist, with MDT diploma clinical training, which is the highest level of training in the MDT

program. In total, the therapist undertook 772 hours of official MDT training [10].

At the initial MDT session, a DP of extension was established, for which acceptable inter-examiner reliability has been established [11]. The MDT interventions were undertaken for six weeks as a systematic review with high-quality studies supported the use of exercise interventions including MDT for at least six weeks [12].

The MDT intervention included postural correction in sitting, which was aided using a McKenzie lumbar roll (The Original McKenzie® Lumbar Roll™, OPTP, Minneapolis, USA). A lumbar roll was provided to each patient and the patients were asked to use the lumbar roll during sitting. For home exercises, patients were instructed to undertake 10 repetitions of mechanical loading in the direction of lumbar extension every three hours, using various forms of the exercise (Appendix 1), five sets per day.

At follow-ups, trouble shooting in postural correction and exercises including progression and adjustment of exercises were undertaken. Manual therapy techniques including exercises with therapist's overpressure and passive posterior-anterior joint mobilization were used when it was considered that recovery with home exercises had reached a plateau. When absence of symptoms lasted for more than one week, reproduction of symptom or movement restriction was tested using three sets of 10 repetitions of flexion in lying. When neither symptom reproduction nor movement restriction occurred from the test, exercises with mechanical loading of lumbar flexion was incorporated into the home exercises if patients had limitation of lumbar flexion. The limitation may have been due to physical aspects such as adapted shortening of the extensor muscles, and/or mental aspects such as fear/anxiety of forward bending. In the current study, phases of the MDT interventions were defined as: 1) a phase of reducing derangement when there were symptoms; 2) a phase of maintaining reduced derangement when absence of symptoms lasted for more than

one week; 3) a phase of recovery of function when neither symptom reproduction nor movement restriction occurred with flexion in lying and 4) discharge due to full recovery.

In the MDT+LUMOback group, patients were asked to wear the LUMOback daily for the full 6-week of the intervention, except when playing water sports, taking a shower or sleeping. Detailed information about the LUMOback is found in a previous study [4]. Briefly, a threshold of 'very slouched' was considered clinically relevant in the MDT intervention [4] and thus a 'very slouched' posture which lasted for more than five seconds triggered feedback with LUMOback vibration.

Outcome measures proposed for the full trial

The treatment effect was assessed with a 7-point Global Rating of Change Scale (GRCS) (0=worse than ever, 1=much worsened, 2=slightly worsened, 3=no change, 4=slightly improved, 5=much improved, 6=completely recovered). The GRCS were assessed at three and six weeks after the initial MDT session.

Secondary outcome measures

The current study included demographic and patient-reported measures, and objective measures. In the demographic and patient-reported measures, the following were assessed: 1) age and gender, 2) symptom information including pain location, pain intensity, pain duration, magnitude of disability, self-reporting functional limitations, and quality of life. In the objective measures, sagittal mobility of the trunk was assessed by a blinded examiner. The pain intensity, magnitude of disability, self-reporting functional limitations, quality of life and sagittal mobility of the trunk were assessed at the initial MDT session and at three and six weeks.

The demographic and patient-reported measures

Pain location was assessed with a body chart, in which a higher score indicated more distal pain (Appendix 2). The pain intensity was assessed with the P4, where a sum score of 0 indicates no pain and that of 40 indicates the highest possible pain level. Pain duration was defined as the number of days and/or months since the last pain-free month according to a previous recommendation [13]. The magnitude of disability was assessed with the Oswestry Disability Index Japanese version, where 0% indicates no disability and 100% indicates the greatest disability. The self-reported functional limitation was assessed with the Patient Specific Functional scale, where an average score of 0 indicates the maximum limitation and that of 10 indicates no limitation. The quality of life was assessed with the physical component summary score, indicating quality of life in physical aspects, and the mental component summary score, indicating quality of life in mental aspects, of the 36-Item Short-Form Health Survey version 2-week. The value of 50 indicates Japanese normal, and the greater the value is, the better the condition is.

The objective measures

The sagittal mobility of the trunk in standing was assessed with the Finger Floor Distance (FFD) [14] and a Modified Schober's Test [15]. In the FFD, positive value indicates that the finger reaches above the floor and negative value indicates that the finger reaches below the floor. In the Modified Schober's Test, the value of 15.0cm indicates no movement of lumbar extension, and smaller values indicate greater lumbar extension range of motion in standing.

Outcome measures in the pilot trial

The recruitment rate per month, treatment sessions, and dropout rate were recorded. The compliance rate of wearing the LUMOback was defined as the

proportion of days with a change of posture score through a day, which was a proportion of time in a day with neutral pelvic posture relative to the time with a 'very slouched' posture. The participants' adherence with treatment was assessed with an exercise diary, where one check was marked when 10 repetitions of the exercise were undertaken. The number of sets with 10 repetitions of exercises per day was calculated. The MDT program at six weeks was recorded in terms of the four phases of the intervention as listed before.

Sample size estimation

Sandvik et al. [16] recommended using 10 individuals for a pilot study; allowing for 10% of dropout, 11 patients were recruited for each group.

Randomization

Randomization was undertaken using sealed opaque envelopes, with concealed allocation maintained as patients selected an envelope with the intervention group. Patients were asked not to reveal their intervention group to the examiner for the sagittal mobility of the trunk.

Data analysis

The descriptive analysis was undertaken and mean (SD) or number (%) was calculated. For the outcome measures proposed for the full trial, the mean value of the GRCS was presented for each group at each follow-up along with the mean difference between the groups and its associated 95% confidence intervals (CIs). The mean value of the change from baseline to each follow-up and its mean difference between the groups with its associated 95% CIs was also calculated using descriptive analyses in other outcome measures proposed for the full trial.

RESULTS

Appendix 3 presented a flow-chart of the patients. Twenty-two participants were included in randomization over 20 months, and thus the recruitment rate per month was 1.1 patients per month. It was also estimated that 2.9 patients need to be assessed for eligibility to find one patient to be included in the study. Dropout rate was 9% at six weeks.

Table 1 summarized the characteristics of the patients at baseline; and Table 2 presented the mean values and differences, with 95% CI, between groups at follow-ups.

There was nobody who rated the GRCS≤2 in each follow-up. The mean (SD) of the GRCS of the MDT group and MDT+LUMOback group were 4.7 (0.8) and 4.7 (0.5), respectively and its difference (95% CIs) between the groups was 0 (-0.6 to 0.6) at the 3-week follow-up. The mean (SD) of the GRCS of the MDT group and MDT+LUMOback group were equally 4.9 (0.5) and its difference (95% CIs) between the groups was 0 (-0.5 to 0.5) at the 6-week follow-up. Mean changes and differences (95% CI) between groups in other outcome measures are presented in Table 2. Appendix 4 presented the mean (SD) of the outcome measures proposed for the full trial except the GRCS at each follow-up.

The mean (SD) treatment sessions from the baseline to the 3-week follow-up were 4.0 (1.2) sessions in the MDT group and 4.1 (0.8) sessions in the MDT+LUMOback group and those from the 3-week follow-up to the 6-week follow-up were 2.8 (1.2) sessions and in the MDT group and 2.4 (0.7) sessions in the MDT+LUMOback group. The mean (SD) of the number of sets with 10 repetitions of exercises per day was 3.7 (1.5) sets per day in the MDT group and 3.7 (1.6) sets per day in the MDT+LUMOback group, respectively. There was nobody who did not

undertake the exercises at all over three successive days. In the MDT+LUMOback group, the mean (SD) compliance rate of wearing the LUMOback was 88% (15%), where the mean (SD) posture score was 64% (14%). Table 3 demonstrated the phase of the MDT program at six weeks in both groups.

DISCUSSION

In the current study, the methods proposed to conduct the full RCT were piloted in: 1) recruitment rate per month, 2) treatment sessions, 3) compliance rate of wearing the LUMOback, 4) participants' adherence with treatment, 5) dropout rate and 6) MDT program at six weeks. It was also undertaken to make a preliminarily comparison of patient reported-outcomes between the MDT and MDT+LUMOback group and to estimate the variability of these outcomes.

The compliance rate of wearing the LUMOback was 88%, which indicates high compliance rate of the LUMOback. Patients in both groups undertook home exercises a mean of 3.7 sets per day. If 100% compliance was defined as 5 sets per day, the 3.7 sets per day was 74% compliance. Previously compliance rate of home exercise has been reported as about 60% [17], with 80-90% rated as good adherence [18]. Therefore, home exercise adherence can be considered acceptable. The dropout rate was 9%, which is also considered to be acceptable [19]. The MDT program at six weeks was mostly at the early phase of reducing derangement and there was nobody who was discharged from the intervention. In addition, the mean of the GRCS was 4.7 in each group. These findings suggest that six weeks would be reasonable as duration of the MDT intervention to compare the size of the treatment effect. There was nobody who rated the GRCS$\leq$2 in each follow-up, which indicates that the method tested in the current study was safe and acceptable to the participants. The mean posture score of the MDT+LUMOback group over the 6-week intervention was 64%, which is similar

to those without a history of LBP in a previous study [4]. Therefore, it is assumed that postural correction had been successfully undertaken in the patients of the MDT+LUMOback group. These would all be positive findings of the current methods to progress to a full trial.

In contrast, negative findings of the current method to progress to a full trial were also detected. The recruitment rate was 1.1 patients per month, and it was estimated that 2.9 patients need to be assessed for eligibility to find one study patient. Thus it would be expected that assessment of 180 patients would be required, and the recruitment process take five years to include 30 participants in each group. As the current pilot study was undertaken in a single orthopedic outpatient clinic with one therapist, a multi-center trial would be needed to generate a better recruitment rate. It should also be noted that there was not a placebo or no treatment control group, which might be unacceptable to those actively seeking treatment. However, a potential reason for the limited recruitment rate may be that patients in the current cohort had a lack of confidence to manipulate the wearable device.

A promising method for the full trial has been considered, but preliminarily data of the patient reported-outcomes between the MDT and MDT+LUMOback groups indicate a need to reconsider undertaking a full trial. All baseline measures did not seem comparable. For example, the FFD was not comparable, considering its minimum detectable change of 4.5cm [20], which would not be surprising because of the small sample size. However, all measures demonstrated negligible mean difference between the groups at each follow-up, with 95% CIs that included zero. This indicates that any clinically important differences in the treatment effect are not likely to be detected between the MDT and MDT+LUMOback groups at least for six weeks. Thus, rather than undertaking the full trial, a promising future research agenda may be: investigating patients' preference to keep using the LUMOback for their

management of posture; and comparing recurrence rate of LBP between those with and without the use of a wearable device to manage habitual posture such as the LUMOback using a long-term follow-up. However, there is a lack of consensus about whether posture is actually a risk factor for LBP [5, 21, 22].

Limitations

A limitation of the current study is that current data was contaminated by a self-selection bias. In particular, using the LUMOback might have been limited to patients who had an interest in, and expectations for, physical therapy interventions and technologies. It is known that patient expectations influence treatment effect [23], and that they are different between placebo-controlled clinical trials and clinical practice [24]. The MDT+LUMOback group undertook interventions that were more than normal clinical practice, whereas the MDT group undertook interventions that were very close to clinical practice. It may be possible that the treatment effect in the current study was greater than other studies using MDT without cutting-edge interventions or placebo-controlled trials.

Another limitation is that reasons for the lack of group differences in the treatment effect are unclear due to the lack of LUMOback data in the MDT group. It might be possible that postural correction undertaken in MDT is sufficient to minimize habitual posture with lumbar lordosis and posterior pelvic tilt. It might also be possible that correction of habitual posture is not as important as undertaking exercises in a DP unless habitual posture is extremely impaired. Further studies with monitoring habitual lumbopelvic posture before and during the course of the MDT management would be required.

CONCLUSION

Data of the pilot study provide suggestions for a promising method. However, preliminarily data of group comparisons indicate no clinically important difference in the treatment effect of MDT within six weeks with or without the use of the LUMOback for assisting postural correction. Thus, further investigations in a multi-center trial with the current method are not justified.

Conflict of Interest: There is no conflict of interest.

Ethical Approval: This study was approved by the institutional research ethics committee in the Saitama Prefectural University (No. 28011).

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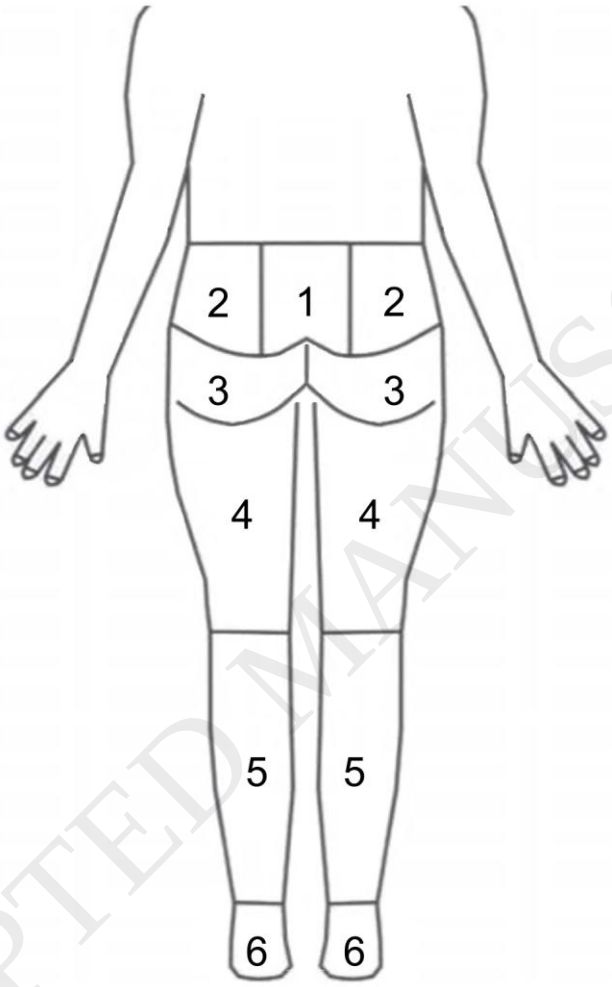
FIGURE LEGENDS

FIGURE 1. Body chart to assess pain location.

FIGURE 2. Flow of the participants.



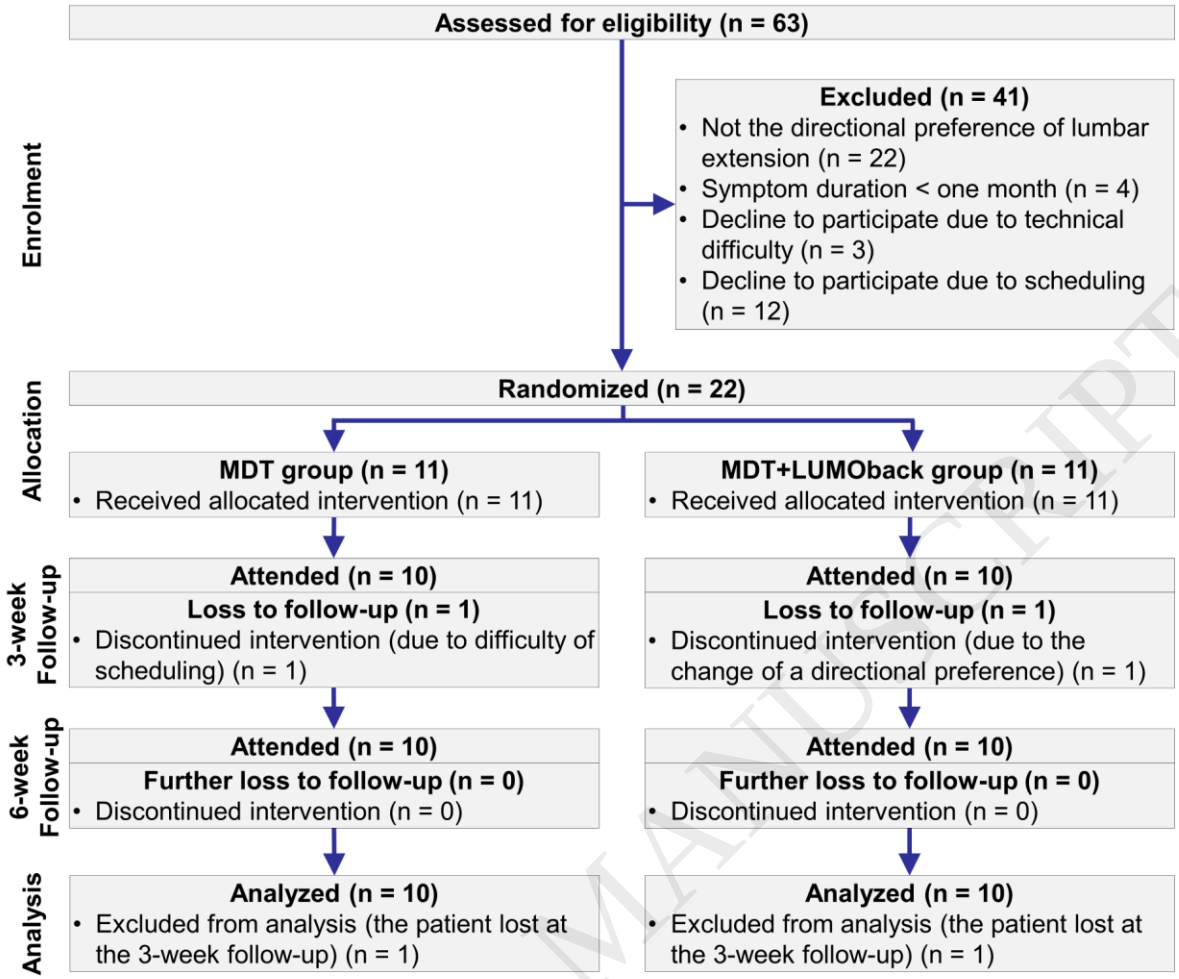


TABLE 1. Summary of the patients analyzed in the current study at the initial Mechanical Diagnosis and Therapy (MDT) session.

Variables	**MDT group (n = 10)**	**MDT+LUMOback group (n = 10)**
Women, number (%)	3 [30%]	5 [50%]
Age (years)	40.4 (13.8)	41.1 (10.7)
Pain location (1-41)[a]	16.8 (10.3)	9.8 (8.3)
P4 (0-40)[b]	19.7 (7.8)	18.6 (5.5)
Pain duration (months)	26.5 (35.9)	24.4 (37.2)
Oswestry Disability Index (%)[c]	28.4 (15.8)	29.1 (8.3)
Patient Specific Functional scale (0-10)[d]	4.3 (1.5)	4.5 (1.7)
SF-36v2 physical component summary score (national standard value, 50)[e]	36.1 (6.5)	40.8 (7.8)
SF-36v2 mental component summary score (national standard value, 50)[f]	48.8 (3.8)	47.2 (8.2)
Figure Floor Distance (cm)[g]	1.1 (9.5)	12.0 (18.2)
Lumber extension range of motion (cm)[h]	12.6 (1.4)	12.8 (0.8)

Abbreviations: MDT group, patients undertook MDT; MDT+LUMOback group, patients undertook MDT using real-time postural feedback with the LUMOback; SF-36v2, 36-Item Short-Form Health Survey version 2.

[a]A higher sum score indicated more spreading pain.

[b]0 = no pain, 40 = the highest pain intensity.

[c]Greater values indicate more severe disability.

[d]0 = unable to perform activity, 10 = able to perform activity at the same level as before

injury or problem.

[e]50 = national average, greater values indicate a better condition.

[f]Positive value indicates that the finger reaches above the floor and negative value indicates that the finger reaches below the floor.

[g]measured by a Modified Schober's Test [15]: Max = 15.0 cm, smaller values indicate grater lumbar extension range of motion in standing.

Values are presented as mean (SD) or numbers [%].

TABLE 2. The mean (SD) value of the change from baseline to each follow-up[a] and its mean difference between the groups with its associated 95% confidence intervals (CIs).

	3-week follow-up			**6-week follow-up**		
Variables	**(A) MDT group (n = 10)**	**(B) MDT+LUMOback group (n = 10)**	**(A-B) Difference [95% CIs]**	**(A) MDT group (n = 10)**	**(B) MDT+LUMOback group (n = 10)**	**(A-B) Difference [95% CIs]**
P4 (0-40)[b]	-5.1 (10.6)	-6.7 (7.7)	1.6 [-7.6 to 10.8]	-10.0 (10.7)	-12.1 (6.5)	2.1 [-6.7 to 10.9]
ODI (%)[c]	-12.4 (17.3)	-10.0 (9.4)	-2.2 [-16.1 to 11.7]	-17.0 (19.0)	-19.6 (9.5)	2.6 [-12.3 to 17.5]
PSFS (0-10)[d]	2.4 (2.1)	1.9 (3.0)	0.6 [-2.0 to 3.2]	3.6 (2.2)	3.8 (3.0)	-0.3 [-2.9 to 2.3]
PCS[e]	4.3 (10.5)	1.8 (12.1)	2.5 [-8.7 to 13.8]	13.7 (13.0)	13.6 (8.3)	0 [-10.7 to 10.8]
MCS[e]	6.0 (5.8)	3.7 (6.9)	2.3 [-4.0 to 8.6]	2.6 (8.5)	2.1 (4.0)	0.4 [-6.1 to 7.0]
FFD (cm)[f]	-2.7 (4.9)	-0.6 (6.6)	-2.2 [-7.9 to 3.6]	-2.7 (9.6)	-3.3 (11.2)	0.6 [-9.8 to 10.9]
Ex ROM	-0.5 (0.8)	-0.6 (1.3)	0.1 [-0.9 to 1.1]	-0.7 (0.9)	-1.2 (1.0)	0.5 [-0.4 to 1.5]

(cm)[g]

Abbreviations: MDT, Mechanical Diagnosis and Therapy; MDT group, patients undertook MDT; MDT+LUMOback group, patients undertook MDT using real-time postural feedback with the LUMOback; ODI, Oswestry Disability Index; PSFS, Patient Specific Functional scale; PCS, SF-36v2 physical component summary score; MCS, SF-36v2 mental component summary score; FFD, Figure Floor Distance; Ex ROM, Lumber extension range of motion.

[a][Value at each follow-up] – [Value at the baseline]

[b]A higher sum score indicated more spreading pain. 0 = no pain, 40 = the highest pain intensity.

[c]Greater values indicate more severe disability.

[d]0 = unable to perform activity, 10 = able to perform activity at the same level as before injury or problem.

[e]50 = national average, greater values indicate a better condition.

[f]Positive value indicates that the finger reaches above the floor and negative value indicates that the finger reaches below the floor.

[g]measured by a Modified Schober's Test [15]: Max = 15.0 cm, smaller values indicate grater lumbar extension range of motion in standing.

TABLE 3. MDT program at six weeks in each group.

MDT program	**MDT group (n = 10)**	**MDT+LUMOback group (n = 10)**
Phase of reducing derangement	6 (60%)	7 (70%)
Phase of maintaining reduced derangement	2 (20%)	1 (10%)
Phase of recovery of function	2 (20%)	2 (20%)
Discharge	0 (0%)	0 (0%)

Values are presented as numbers (%).