

Rehabilitation therapy using the HUBER platform in chronic non-specific low back pain: a randomized controlled trial

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ABSTRACT

BACKGROUND: Non-specific chronic low back pain (NSCLBP) refers to a complex condition that involves structural, biomechanical, cognitive, psychological, social, and lifestyle issues. First-line therapies include physical therapy and exercise, as well as psychological follow-up and pain medication.

AIM: The aim of this study was to assess the impact of a 6-week center-based program using a multi-axis motorized platform (HUBER) connected with force sensors, that allows the patients to execute isometric exercises on the spine flexion-to-extension ratio at 60 and 120°/s, pain, trunk flexibility, and disability.

DESIGN: The design of the study was prospective, active control, parallel-group, assessor-blinded, randomized controlled trial.

SETTING: The setting was outpatients physical therapy clinic.

POPULATION: The population analyzed presented NSCLBP. METHODS: Seventy individuals with NSCLBP were randomized into 2 intervention arms (1:1 ratio): 1/standard rehabilitation group (STAND)

METHODS: Seventy individuals with NSCLBP were randomized into 2 intervention arms (1:1 ratio): 1/standard rehabilitation group (STAND) with physiotherapy, balneotherapy and cycloergometer exercises and 2/HUBER rehabilitation group (HUB) with physiotherapy, balneotherapy and HUBER exercises. Both programs lasted 6 weeks, with 4 sessions of 2 hours each per week. RESULTS: Each group reported statistically significant improvements on the isokinetic spine strength, flexibility of the trunk, lumbar joint mobility, muscular endurance of the trunk and of the lower limbs, pain score and disability (P<0.05). The spine flexion/extension ratio at 60° /s improved similarly between groups (-22.23 for HUB, and -13.04 for STAND; P=0.178) with a greater effect size in HUB. Only HUB reported a significant improvement in the spine flexion-to-extension ratio at 120° /s (from 87.3 to 78.6, P=0.012). HUB reported a greater decrease in the Disclification of the trunk of Oswestry Disability Index (-16.83) compared to STAND (-12.11), with a statistically significant effect between groups (P=0.036). CONCLUSIONS: Exercises performed on the HUBER platform added to physiotherapy and balneotherapy are as effective as a standard reha-

bilitation program with physiotherapy, balneotherapy and cycloergometer exercises to improve isokinetic spin strength, lumbar joint mobility, flexibility and muscular endurance of the trunk and the lower limbs. In addition, exercising with the HUBER platform result in a greater reduc-tion in disability compared to a standard rehabilitation program (clinicalTrials.gov: NCT05437016).

CLINICAL REHABILITATION IMPACT: A variety of intervention techniques, including supervised exercise and manual therapy are now used to manage persistent NSCLBP. The added value of the HUBER device on disability suggests that the platform could be beneficial.

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KEY WORDS: Low back pain; Rehabilitation; Muscle strength; Exercise; Surveys and questionnaires.

ow back pain (LBP) is more common as people get sufferers develop non-specific chronic low back pain ✓older and have more sedentary lifestyles.¹ Some LBP (NSCLBP), which is chronic, debilitating and can have a detrimental impact on patients' Quality of Life, leading to impairments and work absences.^{1,2} In France in 2017, low back pain (LBP) was the second most common reason for seeing a family doctor and caused work absences in one out of five cases.3 The French national health insurance agency estimates that LBP results in the loss of 12.2 million working days, which directly costs companies over 1 billion euros.³ In NSCLBP, the term "nonspecific" implies no known pathoanatomical cause.² Instead, it refers to pain that arises from musculoskeletal structures, such as the muscles, ligaments, or facet joints in the lower back, without a clear structural or anatomical cause.² The primary cause of NSCLBP is mechanical dysfunction, which includes osteoarthritis, lumbar spinal stenosis, facet joint or sacroiliac joint injury, and injured intervertebral discs.4 Reduced muscular mass and strength in the trunk and lumbar musculature have also been linked to NSCLBP.5 NSCLBP has been shown to have a detrimental impact on trunk neuromuscular response, global muscle strength, endurance, and mobility, as well as on daily living skills.² NSCLBP is no longer considered an isolated musculoskeletal problem, and it has been defined as a complex disorder involving structural, biomechanical, cognitive, psychological, social, and lifestyle factors.^{2, 6} A diagnosis of NSCLBP is made in the absence of any known pathoanatomical cause,² and diagnostic investigations have no role in the management of NSCLBP. Diagnostic testing is only useful when the clinician suspects a specific disease process that would be treated differently than NSLBP.2 In accordance with recommendations, non-pharmacological strategies such as physical therapy and exercise have been suggested as first-line therapies, combined with psychological support and pain medication if necessary.^{2, 6-8} A complete NSCLBP rehabilitation program employs physiotherapy with the goal of reducing chronic pain while encouraging proprioceptive and postural work, spinal mobility, flexibility, and muscle-strengthening of the spinal region.^{2, 7-11} Multidisciplinary and comprehensive rehabilitation programs also serve to reduce the patient's anxiety, using reassurance strategies, recommendations to stay active and education. The objective of these programs is to also improve the Quality of Life and alleviate fear-avoidance beliefs about physical activity and work that may affect and contribute to their LBP and resulting disability.^{1, 2} There is ongoing discussion over the best exercises to use in the management of NSCLBP as well as the impact of various exercise modalities on pain intensity and functional limitation outcomes.9 The HU- BER 360® Evolution device (LPG® Systems, Valence, France) has been designed to meet the needs of a functional rehabilitation program designed to improve mobility, strength, and pain management in NSCLBP patients receiving physiotherapy. The HUBER 360[®] Evolution is a motorized platform with force sensors that enables multi-axis movements. It creates a constant imbalance as the patient applies pressure to the handles during the exercise. Studies on the impact of a training program using the HUBER platform have shown improvements in body composition, balance, strength, cardiorespiratory capacity and cognitive performance in healthy older adults, 12-14 older women with mild cognitive impairment¹⁵ and people with cardiovascular disease.^{16, 17} Exercise programs using the HUBER Platform that have been published range in length from 4 to 8 weeks, with 2 to 4 sessions lasting 30 minutes each. To our knowledge, two studies have been conducted on individuals with NSCLBP using the HUBER Platform,18, 19 but alternative platforms are being investigated.²⁰ Our pilot study¹⁹ involved 12 NSCLBP individuals who participated in a 6-week rehabilitation program including 24 sessions with the HU-BER platform. The findings suggest positive effects of the rehabilitation program on multiple outcomes.^{18, 19} In both studies, the lack of an active control group to compare the HUBER Platform rehabilitation programs to other therapeutic exercise techniques limits the generalizability of the results. Comparative studies are needed to optimize the management of NSCLBP patients in order to provide effective rehabilitation programs. The aim of this study was to evaluate the effectiveness of a 6-week in-center program with the HUBER platform compared with a standard program on spinal flexion-extension ratio at 60 and 120°/s, trunk flexibility, pain, and disability in individuals with NSCLBP.

Materials and methods

Patients

A total of 70 individuals with NSCLBP were included. Eligibility criteria for the rehabilitation program were: 1) age between 20 and 55 years old; and 2) NSCLBP (longer than 3 months) with clinical and radiological examination. Exclusion criteria were: 1) LBP from a specific etiology (trauma, tumor, inflammatory or infectious disease); 2) major anatomical deformities of the spine; 3) any conditions that would make rehabilitation impossible; 4) recent surgery (within three months); and 5) corticosteroid use.

Study design

Following the medical evaluation during the first day, the research's procedures were explained to patients. All assessments were completed within two days of the consent form being signed. Individuals with NSCLBP were randomized into 2 intervention arms (1:1 ratio) that was blindly evaluated: 1/ standard rehabilitation group (STAND) and 2/ HUBER rehabilitation group (HUB). The rehabilitation program was then started, and it ran for six weeks, four times per week. Postrehabilitation evaluations were conducted over the course of the final two days of the stay under the same conditions as at baseline and in the same chronological order. The North West II research ethics board at the University Hospital Center of Amiens (Picardie, France), gave its approval to the study protocol (N.: 2022-A00885-38; ClinicalTrials.gov: NCT05437016). Prior to participation, all individuals gave their written informed consent. The study was carried out in conformity with the guidelines set forth in the Helsinki Declaration. The study was conducted between June and December 2022.

Measurements

Baseline clinical evaluation

The clinical evaluation included an investigation of warning signs (such as neurological symptoms, paresthesia, significant trauma, and significant structural deformity of the spine). This "red flag" indicates an underlying pathology that necessitates specific and/or urgent treatment. The search for chronicization factors "vellow, blue and black flags" (such as inappropriate pain behaviors, especially avoidance or reduction of activity, related to fear, workrelated issues) was also undertaken. The clinical examination included an assessment of spinal mobility, flexibility of the lumbo-pelvic-femoral complex muscles, and muscular endurance of the trunk and lower limb muscles. In the event of lower limb irradiation, a peripheral neurological assessment was also performed. A thorough examination of the patient's pain, his experience with his pathology, the history of his LBP, and his beliefs about physical activity and work was also performed. The examinations described below were then performed at baseline and at 6 weeks.

Isokinetic spine strength

Isokinetic dynamometry (CON-TREX, TP-500; Physiomed, Leeds, UK) examines the joint range of motion, trunk flexion, and extension strength at various angular velocities.^{21, 22} Isokinetic strength testing is a useful approach to assess trunk extension and flexion in healthy individuals as well as in patients with LBP.21, 22 The effectiveness of rehabilitation programs evaluation by standardized methods such as isokinetic assessment is important.21,23 The reliability of this method in NSCLBP patients is very good.²² Some studies have demonstrated that flexor/extensor ratio imbalances have been related to back pain.5, 24, 25 In our study, the spinal flexors and extensors were explored at speeds of 60 and 120°/s.26 Patients first performed a 10-minute warm-up on a cycle ergometer before the isokinetic procedure. They were then set up in a standing position, with legs, pelvis, and chest kept in place with fastening material. A preliminary phase was carried out with less than maximal exertion. The patient was informed of the apparatus's operational principle and was given advice on how to produce maximum repetitive effort throughout their movements, whether they consist in bending or in extending. The protocol started with 10 continuous passive mobilization at 15°/s. After 1 min of recovery, 6 consecutive submaximal bending-extension movements with trunk ante-flexion at 60°/s were performed. After another 1 min recovery, a maximal evaluation was performed at 60° /s with 3 repetitions at an amplitude of - 10-60°. The same protocol was applied at 120°/s. The maximum moment of force (MMF) in Newton-meters (Nm) for the 2 speeds during the 3 repetitions recorded (the moment of highest force during a series). The mean power (MP) in watts (W), the total workload (TW) in Joules (J) were recorded at both 60 and 120°/s. The flexor/extensor ratios at 60 and 120°/s are the flexor/extensor ratios for the aforementioned parameters. The same operator performed all tests for a given patient to avoid interoperator variability.

Fear and Avoidance Belief Questionnaire

Fear and Avoidance Belief Questionnaire (FABQ)²⁷ is a self-reported questionnaire which specifically focuses on how a patient's fear avoidance beliefs about physical activity and work may affect and contribute to their LBP and resulting disability. Sixteen questions scaled from 0 to 6 (a higher score indicates fear avoidance behaviors). The Physical Activity subscale (FABQ-PA) ranges from 0 to 24 and the Work subscale (FABQ-W) ranges from 0 to 42.

Oswestry Disability Index

Oswestry Disability Index (ODI)²⁸ is a self-completed questionnaire containing ten topics concerning the intensity of pain, lifting, ability to care for oneself, ability to walk, ability to sit, sexual function, ability to stand, social

life, sleep quality, and ability to travel. Each topic category was followed by 6 statements describing different potential scenarios in the patient's life relating to the topic. The patient checked the statement which most closely resembled their situation. Each question was scored on a scale of 0-5 with the first statement being zero and indicating the least amount of disability and the last statement is scored 5 indicating the most severe disability. The scores for all questions answered are summed, then multiplied by two to obtain the index (range 0 to 100). Zero is equated with no disability and 100 is the maximum disability possible. Moreover, the following examinations were also performed at baseline and at 6 weeks: 1/ flexibility of the trunk (the hamstring, psoas, and quadriceps), 2/ the spine lumbar range of motion in flexion, extension, and right and left lateral flexion was measured using the dual inclinometer procedure, 3/muscular endurance of the trunk (Shirado-Ito and Sorensen tests) and the lower limbs (Killy Test), 4/ pain (Visual Analogue Pain Scale graduated from 0 to 10) and 5/ cardiorespiratory fitness (submaximal test to predict $VO2_{max}$). Details of these examinations are described in our previous study¹⁹ and in Supplementary Digital Material 1 (Supplementary Text File 1).

Rehabilitation exercises

HUBER platform

The HUBER 360[®] Evolution is a multi-axis motorized platform with force sensors (Figure 1). The platform can rock back and forth and from side to side, resulting in a permanent imbalance while the patient must continue to apply pressure to the handles if the prescribed exercise requires it. A blue gauge on the screen illustrates the target that must be achieved. Gauges are used to report the pulling and pushing force on the handles of the HUBER. The balance and distribution of the patient's center of mass are represented on the screen by targets to be reached by the patient (through mass transfers). Both programs (HUB and STAND) are center-based and lasted 6 weeks, with 4 sessions of 2 hours each per week (a total of 24 sessions). All the sessions were supervised by a physiotherapist and included for both groups: 1h of physiotherapy, 30min of balneotherapy. And 30min of exercise on cycloergometer for STAND or 30min of exercise on the HUBER platform for HUB (all in the same order). All the training sessions for both groups involved mobility, flexibility, and muscular strengthening. These exercises focused on lumbo-pelvicfemoral complex self-awareness and multidirectional lumbar spine mobility. We gradually combined bodyweight exercises with aerobic exercises and muscle strengthening of the lower limbs, trunk, and spine extensors. Specific exercises on the HUBER platform lasted 30min: to generate low-high force levels against the handles, HUBER workouts need the synergistic activation of multiple muscle groups in the lower limbs, trunk, and upper limbs. Pulling and pushing movements on the handles were incorporated in the workout. The positions of the feet on the platform and the hands on the grips changed depending on the exercises. The handles are built with strain gauges, which give users with feedback on the force developed. An interactive interface showing the desired target, informed the subject of their ability to maintain the required force level. Each



Evolution Platform. muscle-Coordination and strengthening exercise on the HUBER Platform. The platform moves back and forth and left and right. The patient must push on the handles with the arms, but the movement starts from the legs with the core engaged. The target is represented by a dark gray

HUBER session featured three sorts of exercises: mobility, stretching, and muscle strengthening. The lower limbs, pelvis, and lumbar and thoracic spine were the primary targets for mobility exercises. Mobilization times ranged from 10 to 15 seconds with varying amplitudes tailored to the patients, followed by 10 seconds of active recovery (where the amplitude was less essential) for 8 to 12 sets per mobilized region. Stretching exercises (20 seconds followed by 10 seconds rest) focused mostly on the posterior chain (lower limbs and thoracic and lumbar spine). Patients did 10 to 12 repetitions of each muscle group. The first two weeks mainly consisted of learning all the functional movements, practice lumbar and pelvic joint mobility exercises, and engage in stretching with a physiotherapist. Balneotherapy followed the same principles but with higher joint and muscle amplitudes. On the HUBER platform, patients had to perform balance exercises, spinal and hip mobility, and coordination exercises. Sessions lasted 30 minutes, with 10-15 isometric contractions per exercise. Gentle muscle stretching was initiated, primarily in the lower limbs. Over the next two weeks, exercises became more challenging, integrating higher muscle loads and complex movements. Aerobic exercises were introduced, focusing on strengthening spinal extensor muscles and improving cardiorespiratory capacities. The HUBER mobility programs intensified, targeting the lower limbs, core and upper body. STAND incorporated higher intensity intervals exercises. During the final two weeks, exercise intensity increased in both balneotherapy and physiotherapy. The HUBER platform introduced more complex exercises, emphasizing coordination, balance, and muscle strengthening. Isometric exercises in the platform created imbalance, and patients-maintained pressure on the handles to achieve targets. STAND included continuous and high intensity interval cycloergometer sessions (more details on rehabilitation programs are given in Supplementary Text File 1).

Data analysis

Sample size calculation

Sample size calculation was based on the primary outcome (change at 6 weeks from baseline in the flexor to extensor ratio measured by Cybex at 60°/s), targeting a group differential effect between the HUBER exercises program *vs.* standardized exercises program. The calculation was supported by existing values available in the literature for exercises with the HUBER platform in NSCLBP patients.^{18, 19} Assuming the pooled standard deviation is 14.7 and using a significance level of P=0.05, a sample size of 33 subjects in each group will have an 80% power to detect a group difference mean of 10 (difference between HUB mean of -38.65 and STAND mean of -28.30, for an effect size of 0.67). Given an attrition rate of 6%, 35 participants will be recruited per intervention group for a total of 70 participants. The randomization list was generated in Stata SE 15.1 (StataCorp LP, College Station, TX, USA) by an independent biostatistician and submitted to the study coordinator. After inclusion and completion of all initial assessment procedures, the study coordinator informed the patient and his physiotherapist of the randomization group. The investigators and assessors remained blind to the group. Patients were informed that during each assessment they should not reveal their group to the person carrying out the examination.

Statistical analysis

All data are presented as means, standard deviations (SD), or frequency and percentages. To control for the normality of the distribution of each variable, the histograms and skewness-kurtosis indexes were analyzed. Paired Student's t-test or Wilcoxon Signed-Rank Test were used to compare the intervention's effectiveness in each group (based on the change between postintervention and preintervention data) as well as the effect size (Hedges's g). After examination of assumptions (normality, skewness and kurtosis, homogeneity of variances and regression slopes), mean changes in the spine flexion-to-extension ratio at 60°/s from baseline was analyzed using a one-way analysis of covariance (ANCOVA) model (group as independent variables) controlling for baseline value and sex. Secondary outcomes were analyzed similarly to the primary outcome. Analyses were performed on subjects who completed all assessment procedures at baseline and at the end of the study according to the randomization group. There were no missing data. Dropouts were excluded from the analysis. Statistical analyses were performed with Stata SE 15.1 (StataCorp LP), and the significance level was set to P=0.05.

Results

From the 70 NSCLBP patients that were randomized, 65 patients completed the study for the final analysis (HUB N.=33, and STAND N.=32) (Supplementary Digital Material 2: Supplementary Figure 1). No selection bias was observed for baseline characteristics between randomized participants that completed all the study (N.=65) and those that drop out (N.=5) (Supplementary Digital

Material 3: Supplementary Table I, II). Patients were receiving optimal pharmacology therapy and there was no difference in the baseline clinical profile between groups (Table I). Baseline and postintervention characteristics are reported in Table II and Table III. Briefly, both groups showed significant improvement almost in all parameters studied (all P<0.05). The spine flexion/extension ratio at 60°/s improved similarly between groups ($F_{(1,61)}=2.41$, P=0.178) with a greater effect size in HUB compared to STAND (Hedge's g=0.71 *vs.* 0.33 respectively). The adjusted means of changes in the spine flexion-to-extension ratio at 60°/s according to the groups adjusted for sex and the baseline value are -22.23 and -13.04 respectively for HUB and STAND group (P=0.178). There is a trend in mean changes between groups in the extensor and the peak torque at 120°/s (P=0.066 and P=0.076 respectively). Only HUB reported a significant improvement in the spine flexion-to-extension ratio at 120°/s (from 87.3 to 78.6, P=0.012) but the difference between the two groups was not significant (P=0.09). Interestingly, there is a statistically significant effect on the ODI changes between groups ($F_{(1,61)}$ =4.61, P=0.036), as well as in the flexibility of the hip flexors (Modified Thomas Test) ($F_{(1,61)}$ =16.64, P<0.001; $F_{(1,61)}$ =9.80, P=0.027, respectively for the right and left side). The adjusted means of changes in the Oswestry Score according to the groups are -16.83 (95% CI -19.89 to -13.78) after the 6-week program and -12.11 (95% CI -15.21 to -9.01) respectively for the HUBER and the control group (P=0.036) with a greater effect size in HUB.

TABLE I.—Baseline clinical characteristics.

Variables	HUBER (N.=33)	STAND (N.=32)	Р
Age	41.48±9.40	42.56±8.37	0.684
Sex (female), N. (%)	12 (36%)	18 (52%)	0.108
Weight (Kg)	78.38±20.15	74.72±10.88	0.864
Heigh (cm)	174.09±8.32	172.06±7.66	0.311
Body Mass Index, kg·m ²	25.82±6.40	25.44±4.07	0.641
Pharmacological treatments (number of patients concerned by each class of therapy)			
Analgesic step 1/2/3	10/8/5	8/1/0	
Antidepressant	3	2	
Antiepileptic	2	2	
ACE inhibitors	1	0	

ACE: angiotensin-converting enzyme inhibitors

*Analgesic step from 1 to 3 refers to the WHO Pain Ladder with Pain Management Guidelines: step 1 - mild pain (1-3/10); step 2 - moderate pain (4-6/10); step 3 - severe pain (7-10/10).

	HUBER (N.=33)				STAND (N.=32)				
	Pre	Post	Р	Hedges's g	Pre	Post	Р	Hedges's g	ANCOVA
Iso Fr 60 (Nm)	179.96±79.86	198.55±66.91	0.009	0.25	143.50±59.90	174.75±55.59	< 0.001	0.53	0.792
Iso Exr 60 (Nm)	194.16±87.48	271.58 ± 95.06	< 0.001	0.84	168.98 ± 94.24	226.27±96.35	< 0.001	0.59	0.126
Ratio 60	99.28±33.23	77.33±27.58	< 0.001	0.71	98.50±47.31	85.17±31.55	0.037	0.33	0.125
Peak torque moy./kg 60 (Nm/kg)	2.36±0.92	3.41±1.16	< 0.001	1.00	2.11±1.12	2.87±1.17	< 0.001	0.65	0.090
Iso Fr 120	170.24±73.37	193.18±75.81	0.023	0.30	140.97±58.46	165.01±50.38	< 0.001	0.44	0.611
Iso Exr 120	200.17±80.79	246.80 ± 76.40	< 0.001	0.59	169.70±76.35	200.86 ± 72.80	< 0.001	0.41	0.066
Ratio 120	87.26±25.67	78.63±20.46	0.012	0.37	90.82±33.05	86.33±24.17	0.297	0.15	0.097
Peak torque moy./kg 120 (Nm/kg)	2.48 ± 0.78	3.13±0.88	< 0.001	0.76	2.12±0.91	2.57±0.87	< 0.001	0.49	0.076

TABLE III.—Flexibility of the trunk.

	HUBER (N.=33)			STAND (N.=32)					
	Pre	Post	Р	Hedges's g	Pre	Post	Р	Hedges's g	ANCOVA
Dual inclinometry Flex° (°)	18.18±9.42	19.09±5.65	0.539	0.12	14.38±10.61	17.50±8.23	0.072	0.33	0.958
Dual inclinometry Ext° (°)	16.97±10.15	21.52±12.09	0.006	0.40	16.53±11.68	20.93±11.25	0.084	0.38	0.916
DI inclination right (°)	13.18±7.69	15.00±6.61	0.206	0.25	10.94±7.34	14.38 ± 5.64	0.004	0.52	0.999
DI inclination left (°)	11.52±6.43	14.55±6.30	0.008	0.47	9.84±5.61	14.53±6.64	< 0.001	0.75	0.479
Modified Thomas Test right (°)	22.17±9.10	19.55±9.30	0.034	0.28	22.34±8.80	26.03±8.12	0.002	0.43	0.001
Modified Thomas Test left (°)	19.90±8.85	19.39±9.74	0.652	0.05	21.19±8.54	26.09 ± 7.80	0.001	0.59	0.003

Discussion

The originality of our study was to compare the effectiveness of two rehabilitation exercise methods in individuals with NSCLBP: an all-in-one platform exercises that has not been thoroughly explored in this population versus a standard program. The main results can be summarized as follows: 1) both groups report clinically and statistically significant improvements on the isokinetic spine strength, flexibility of the trunk, lumbar joint mobility, muscular endurance of the trunk and of the lower limbs, pain, disability, and Quality of Life; 2) the exercises performed on the HUBER platform are as effective as a standard program in improving isokinetic spine strength; and 3) HUB reported a greater decrease in the Oswestry Disability Score compared to STAND indicating a decrease in the impact of LBP on their Quality of Life. To our knowledge, this is the largest randomized study that compare the effectiveness of exercise-based rehabilitation on a HUBER platform versus a standard program. The previous studies using the HUBER platform in NSCLBP18, 19 did not have an active control group, making it challenging to associate the improvement to the HUBER platform.

Isokinetic spine strength

In our study the strength of the trunk muscles at 60° /s was significantly improved in both groups without a significant difference between them but with greater effect size in HUB. At 120°/s we can observe a slight trend in favor of HUB for the peak torque and the extensor strength. Even though the effect size is twice as large for HUB compared to STAND, the exercises performed on the HUBER platform are not statistically more effective than the standard program on the ratio at 60 and 120°/s. Literature has shown that exercise therapy for lumbar stability appear to enhance isokinetic strength measurements such as the F/E ratio at 60°/s (from 169.1% to 107.4% following rehabilitation),²⁹ Quality of Life assessments, and pain score.²⁹ A normal flexor/extensor ratio should be between 60 and 70%.³⁰ In another study,³¹ the F/E ratio at 120°/s was significantly improved from 112% to 107% after a daily exercise training with an isokinetic protocol.³¹ A recent meta-analysis showed no superiority of resistance exercises or stabilization exercises compared to control groups on core muscle strength in NSCLBP (the standardized mean difference between the stabilization exercises and the control groups was 0.21 (95% CI -0.28 to 0.69) P=0.399).32 In chronic LBP patients, there is a strength imbalance in favor of a lack of spinal extensor strength, the ratio is therefore generally greater than 1 in these patients.^{26, 30} This imbalance has been identified as a potential risk factor for LBP and has been associated with back pain in previous studies.^{24, 25} The severity of LBP is associated with decreased isometric and isokinetic strength of trunk muscles.⁵ In our study, the ratio at 120°/s only improved in HUB. These results are intriguing since the flexors/extensors ratio at 120°/s most closely approximates muscle balance in the activities of daily living of patients whereas low-speed movements at 60°/s are more reliable for assessing muscle strength.^{30, 33} Our results on the F/E ratio at 120°/s may partly explain the improvements in the Oswestry Score in HUB. However, the amplitude and modalities of isokinetic assessment do not directly transfer to daily life activities. Further studies are needed to investigate the external validity of those improvements.

Flexibility of the iliopsoas and rectus femoris

The Modified Thomas Test assesses the flexibility of the iliopsoas and rectus femoris muscles. A lack of amplitude may be due to muscle contracture, capsulo-ligamentary retraction, or hypoextensibility of these muscles. A lack of flexibility in the ilio-psoas and/or rectus femoris muscle could be a risk factor for developing or maintaining chronic low back pain. In our protocol, the standard group performed cycloergometer. Patients were free to perform this exercise with varying degrees of trunk flexion. Most of the exercises in the HUBER protocol are performed in a flexed position at the lower limbs, hip and trunk, with a tendency to retrovert the pelvis. Our results can be explained by both the differences in positions on the machines between STAND and HUB, and the daily use of the quadriceps STAND patients, resulting in a greater strengthening of these muscle groups.

Oswestry Disability Index

The ODI and the Fear and Avoidance Belief Questionnaire scores were significantly improved in our study in both groups but to a greater extend in HUB (for ODI only), suggesting a reduced disability and improved Quality of Life. The deep abdominal and lumbar muscles are stimulated by the varying ranges of motion of the rotating platform. This enables the development of muscle strength at the superficial and deep levels, which is necessary to preserve good postural balance, coordination, and proprioception. Several reasons could explain the significant improvement in the scores on these questionnaires (Table IV): 1) the HUBER could increase the recruitment of deep muscles in different destabilizing positions compared to the cycloergometer; 2)

TABLE IV.—Questionnaires.									
	HUBER (N.=33)				STAND (N.=32)				
	Pre	Post	Р	Hedges's g	Pre	Post	Р	Hedges's g	ANCOVA
Pain Visual Analog Scale (/10)	3.51±1.99	1.42±1.16	< 0.001	1.26	3.27±1.81	1.78±1.54	< 0.001	0.88	0.195
Oswestry Disability Index	29.70±10.97	13.21±6.78	< 0.001	1.78	30.08±10.53	17.59±11.22	< 0.001	1.13	0.036
FABQ work	62.69±26.89	48.05±28.05	0.002	0.53	60.82±27.66	53.28±30.45	0.048	0.26	0.213
FABQ physical activity	44.53±24.36	26.27±16.53	0.002	0.87	52.70±19.55	34.08 ± 22.05	< 0.001	0.88	0.140
*FABQ: Fear and Avoidance Belief Questionnaire.									

the isometric contractions, which is the main mode of contraction on the HUBER, could be a factor that modulates the isometric muscle strength, which was not measured in this study. In this case, isometric muscle strength would facilitate certain activities such as load-lifting tasks;³⁴ and 3) the HUBER allows the patient's attention to be focused on the fun aspect of the exercises by giving them goals to achieve continuously. Patients could then perform movements with reduced kinesiophobia, which is prevalent in some occupational therapies for chronic pain.35 Further studies are needed to address the specific relationships between an exercise type and disability improvements. Exercises on the HUBER platform are also efficient in increasing the core muscles' capacity for endurance, which may lessen the symptoms and recurrence of LBP.36 Other techniques have also been shown to improve the Oswestry Scores such as kinesio taping.³⁷ In a comprehensive review and meta-analysis, the weighted mean difference between kinesio taping vs. conventional therapy for ODI was -7.11 (95% CI -8.70 to -5.51) in favor of kinesio taping.³⁷ In our study, the Oswestry Score improvement after the 6-week program suggesting that exercising on the HU-BER platform is effective to reduce functional limitation. However, further comparative studies are needed between different management techniques. Pilates exercise program is also effective in improving disability (ODI score) in NSCLBP.38 Individualization of rehabilitation methods is important, and patients with high Oswestry Scores may need to be referred to the most effective techniques such as kinesio taping, Pilates exercises or targeted exercises on the HUBER platform.

Rehabilitation in NSCLBP

Exercises for rehabilitation on moving or even unstable surfaces successfully engage the proprioceptive system and offer constant feedback to preserve balance and spatial awareness.^{18, 20} The HUBER platform is an alternative form of exercise known to have a positive effect on body composition, balance, strength, cardiorespiratory fitness, and cognitive function in different populations.^{13-16, 18, 36} In healthy older women, an 8-week balance and core resistance training program with HUBER platform (3 times per week) were more effective in improving balance ability, trunk muscle strength, leg power, and body composition when compared to traditional Pilates training.¹⁴ The HUBER platform is an "all-in-one" device, associating balance, coordination, cognitive and strength training and may have a place in therapy for NSCLBP. Furthermore, the exercise program was guided through an application (available on the screen) which required less supervision by the physiotherapists once the patient was independent and understood the exercises.^{16, 17} The best type of exercise is still up for debate, and there is no evidence to support the superiority of one form of exercise over another in the treatment of NSCLBP.10 A variety of intervention techniques, including supervised exercise and manual therapy are now used to manage persistent LBP. For lowering pain intensity and functional limitations, Pilates and McKenzie therapy appear to be more efficient than other modalities of exercise therapy.9, 39 According to one systematic review and meta-analysis comparing stabilization exercises vs. manual therapy (11 trials; N.=895),40 and two Cochrane reviews studying the effects of Pilates (10 trials; N.=510)⁴¹ and Motor Control Exercise (32 trials; N.=2628),42 there is no evidence that one exercise therapy technique is better than another. Among other techniques used, ultrasound, thermotherapy, kinesio taping and transcutaneous electrical nerve stimulation therapy have also been proposed in the treatment of pain and muscle relaxation in NSCLBP, but the results are debated, and these techniques cannot be used in isolation but as an adjunct to a comprehensive multimodal treatment. Nonetheless, exercise intensity may also play a crucial effect in improving disability and exercise capacity in NSCLBP.11 Overall, long-term, persistent, tailored exercise-based treatment techniques are more likely to result in pain and functional improvements.⁴³

Limitations of the study

It is important to note some of our study's limitations, including the fact that we did not examine the medium-

long term impacts (i.e., beyond 6 months). Future studies should evaluate whether patients maintain healthy lifestyle behaviors, such as frequent physical activity and good spinal mobility without pain, with a follow-up visit at six months. Furthermore, men and women can exhibit different pain sensitivities.44 Our study does not allow a sex-difference evaluation because our randomization was not stratified by sex, but future research should take this factor into account. Confounding factors such as age, sex, Body Mass Index, physical activity levels and chronic low back pain severity could have an impact to the variability of the results. This can affect the overall generalizability of the findings to a broader population. Subgroup analyses are also required. Moreover, in some studies, the use of the flexor/extensor ratio is poorly correlated with disability indices. In the study by Shin et al., the correlation between the strength ratio of the lumbar flexor and extensor muscles was significant but weak with the disability index.45 Finally, we cannot exclude a dilution of the results because the rehabilitation programs are not done only on the HU-BER palateform vs. on the cycloergometer. Balneotherapy, physiotherapy and stretching are also part of the programs. It is therefore difficult to isolate the benefits observed only with the use of the HUBER platform.

Conclusions

Altogether, the exercises performed on the HUBER platform added to physiotherapy and balneotherapy are as effective as a standard rehabilitation program with physiotherapy, balneotherapy and cycloergometer exercises to improve isokinetic spine strength, lumbar joint mobility, flexibility and muscular endurance of the trunk and the lower limbs. Furthermore, exercising with the HUBER platform result in a greater reduction in disability compared to a standard rehabilitation program. The added value of the HUBER device suggests that the platform could be beneficial.

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Conflicts of interest

LPG Systems lent a HUBER 360[®] Evolution device to the Treboul Functional Rehabilitation Center, ORPEA/CLINEA, 29100, Douarnenez, France. *Authors' contributions*

Vincent Le Moal and Mélanie Tantot have equally contributed to the study; Vincent Le Moal, Mélanie Tantot, Éric Mévellec, Florent Besnier and Thibaut Guiraud have given substantial contributions to the study conception; Florent Besnier and Thibaut Guiraud contributed to the study design; Florent Besnier contributed to the data analysis; Vincent Le Moal, Mélanie Tantot, Éric Mévellec, Isabelle Nouy-Trollé and Emmanuelle Lemoine-Josse contributed to the data collection; Vincent Le Moal, Mélanie Tantot and Florent Besnier contributed to the manuscript original draft preparation; Éric Mévellec, Isabelle Nouy-Trollé, Emmanuelle Lemoine-Josse, Florent Besnier and Thibaut Guiraud contributed to the manuscript final draft, revision and editing; Thibaut Guiraud contributed to the study supervision. All authors read and approved the final version of the manuscript. *History*

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SUPPLEMENTARY DIGITAL MATERIAL 1

Flexibility of the trunk

Flexibility testing of the hamstring, psoas and quadriceps muscles were performed. Hamstring: the patient's contralateral lower limb was extended on the table while they were both lying supine. Then the therapist extended the knee to its maximum range of motion while flexing the hip at 90 degrees (according to the sensations of the patient). On both legs, the angle (in degrees) of the popliteal joint between the tibia and the femur was measured using an inclinometer attached to the anterior tibial tuberosity. Psoas: the iliopsoas muscle group and the hip flexors were evaluated for flexibility using the modified Thomas' Test. Both of the patient's legs were left hanging at the edge of the table as they lay on their back. To guarantee that the lumbar spine is stretched and flat on the table to prevent an anterior tilt of the pelvis, they first used both arms to flex both knees to their greatest range of motion. In order to stabilize the pelvis and flatten the lumbar lordosis, the patient next dropped the tested limb toward the table while maintaining maximum flexion in the contralateral hip and knee. The inclinometer was positioned in its final position along the femur's midline, between the greater trochanter and the lateral femoral condyles (in degrees). The angle of hip flexion was used to calculate the iliopsoas length. Quadriceps: Ely's Test heel-buttock distance was used to measure the flexibility of the quadriceps. The patient was lying prone. The therapist was positioned at the side of the leg being evaluated, next to the patient. The patient's knee was bent to twist their heel toward their buttock as closely as feasible. While holding the leg at the heel with the other hand, one hand was on the lower back. It was measured in centimeters how far apart the heel and buttock were. For comparison, the test is conducted on both sides.

Lumbar joint mobility

The spine lumbar range of motion in flexion, extension, and right and left lateral flexion was measured using the dual inclinometer procedure. Flexion/Extension: The participant was placed in a neutral position. The inclinometers were set to 0 and placed on the thoracolumbar junction (T12-L1) and sacrum (S1). The patient leaned forward as far as possible, with the arms left in front and without bending the knees. Then the value of the 2 inclinometers was registered. The degree of lumbar flexion is the subtraction of the inclinometer figure of S1 from that of T12-L1 (in degrees). The same process is used for lumbar extension when the patient leans back as far as possible with his arms at his sides. S1 was subtracted from T12-L1. Lateral Flexion: On the S1 and T12 vertebrae's frontal planes, inclinometers were positioned. By guiding their right hands down the lateral thigh and towards the right knee, the participants were instructed to laterally bend to the right. The two inclinometers' measurements were then taken. The discrepancy in right lateral flexion values between the T12 and S1 inclinometers provided this information. For left lateral flexion, the right lateral flexion process was repeated.

Muscular endurance of the trunk

The Shirado-Ito Test is a static abdominal muscle endurance test that is currently used to evaluate low back pain. The participant was positioned on their back with their legs and hips bent at a 90-degree angle and their heels resting on a box. The hands were on the shoulders and the arms were crossed across the chest. The neck flexed, and the shoulder blades were raised off the floor. If the patient became fatigued or the shoulder blades lowered, the test was terminated. The length of time the patient had to hold the posture was timed.

The Sorensen Test involved isometrically contracting the muscles that extend the trunk. On a Roman chair, the participant was lying face down with the iliac spines attached to the edge of the support. A module positioned on the rear of the leg, above the heel, barred the lower limb. The chest wasn't excessively arched or too bowed; it was just the right straightness. The goal was to hold the position as long as possible; the timer is stopped as soon as the torso sags.

Muscular endurance of the lower limbs

The Killy Test was used to measure the endurance of the knee extensors in isometric position. The participant had to lean his back against a wall. The ankles, knees, and hips were bent at 90 degrees with the arms at the side of the body. The test was timed.

Pain intensity evaluation

A visual analogue pain scale graded from 0 to 10 was used to quantify the amount of pain that a patient feels from none (0) to an extreme amount of pain (10).

Cardiorespiratory fitness

To predict VO2max, the Canadian Aerobic Fitness Test was performed (Jette et al. Can Med Assoc J, 1976). Based on their age and sex, subjects stepped up and down a double step (40.6 cm height), following the directions and stepping in time with the designated metronome. One foot was placed on the middle step, two on the top step, one on the middle step, and both feet were placed on the ground during the six-pace cycle of stepping. The person began stepping for three minutes. For ten seconds, the pulse rate was recorded (between 5 & 15 seconds after stepping). Stepping was resumed at 3 minutes 25 seconds if the pulse rate was within a designated safety zone [24]. If the pulse ceiling still had not been reached, the subject continued for a third stage, at a stepping rate appropriate to a person who was 10 years younger than themselves. Using the equation by Jette et al., the results were then converted to a predicted VO2max: VO2max (mL/kg/min) = 42.5 + 16.6 (E) - 0.12 (M) - 0.12 (HR) - 0.24 (A). Where E is the energy cost of the final test stage in L/min [24], M is the body mass in kg, HR is the heart rate in beats/min and A is the subject's age in years.

Rehabilitation program for HUBER and Standard groups

The first two weeks mainly consist of learning all the functional movements (*e.g.*, squats, lunges, empty deadlifts, and work of the transverse muscle) and practicing lumbar and pelvic joint mobility exercises with a physiotherapist. These exercises help reintegrate these underused areas into the patient's motor pattern. Stretching exercises are also performed. The balneotherapy program uses the same main principles but with higher joint and muscle amplitudes (depending on the patient's tolerance) given the reduction of gravity in the water.

On the HUBER platform, patients performed low levels of balance exercises, spinal and hip mobility, and coordination. The exercises included pulling and pushing exercises on the handles. The placement of the feet on the platform and the hands on the handles varied according to the exercises proposed. Each session lasted 30 minutes. The force level ranged from 40 to 50% of the maximum voluntary contraction during the first 2 weeks. Participants performed between 10 and 15 isometric contractions per exercise ranged from 30 to 45 seconds with 10-15 seconds of passive recovery. An interactive interface with bar graph materialized as a target, informed the subject about their ability to maintain the required force level. Gentle muscle stretching was initiated, especially in the lower limbs (triceps surae, hip abductors, quadriceps, hamstrings).

STAND performed up to 30 minutes of cycloergometer at a light to moderate intensity, *i.e.*, with a level of difficulty of the perceived exertion of 10 to 12 on the Borg Scale gradually from 6 to 20. A physiotherapist or a kinesiologist supervised all the exercises sessions.

Over the next two weeks, higher muscle load was integrated, and exercises became more complex, recovery times decreased, and work times increased. Aerobic exercises such as interval-training, climbing stairs, circuit training, etc.) were also introduced for everybody. The strengthening of the spinal extensor muscles started with body weight only and then followed by weight training (deadlifts, squats, and kettlebell swings). In balneotherapy, the exercises were more focused on muscle strengthening of the lower limbs and the trunk, and on improving the cardiorespiratory

capacities of the patients. Jumps in the pool during the balneoptherapy were also introduced during this phase.

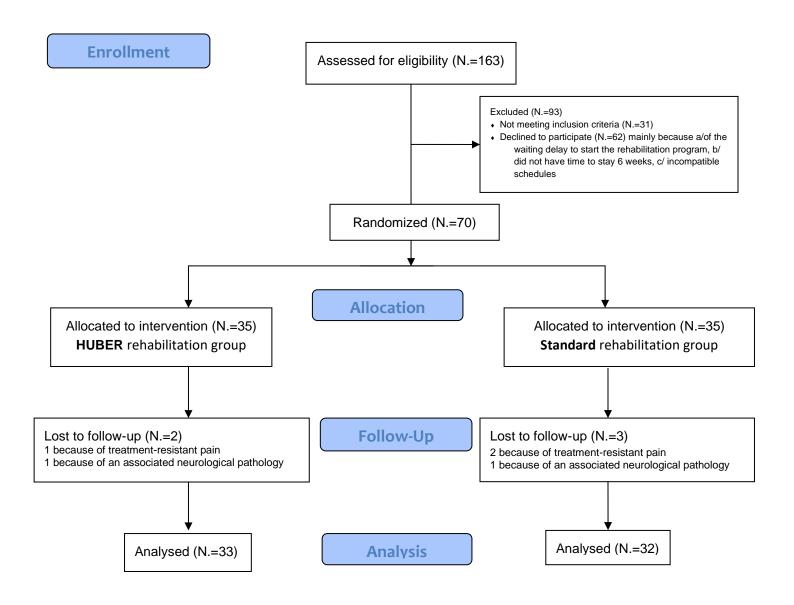
The mobility programs were maintained on the HUBER, but their intensities were increased to reach a moderate to slightly difficult intensity. Muscle strengthening and high-intensity interval training sessions focused on the lower limbs, core, and upper body. Each isometric contraction ranged from 30 to 45 seconds followed by 10 seconds of passive recovery with 20 and 30 contractions per exercise.

STAND performed a 30-minutes continuous cycloergometer session at a moderate to slightly difficult intensity (*i.e.*, with a perceived exertional difficulty level of 12 to 14 on the Borg Scale graduated from 6 to 20). Higher intensity interval sessions were also incorporated.

During the last two weeks patients continued to practice the learned exercises in the same structure. In balneotherapy as in physiotherapy, the intensity of the exercises is increased to reach a difficult intensity for interval exercise training and circuit training. On the HUBER platform, more complex exercises in terms of coordination and balance (with different placement of feet on the platform and hands on the handles), and muscle-strengthening were added. The platform moved back and forth and side to side, during isometric exercises to permanently create an imbalance. The patient had to maintain pressure on the handles, in order to achieve the target from the screen. The higher the target, the harder they had to push or pull. Each isometric contraction ranged from 30 to 45 seconds followed by 10 seconds of passive recovery. STAND performed 30 minutes of cycloergometer alternating between a continuous and moderate-slightly difficult intensity session (*i.e.*, 12 to 14 on the Borg Scale) and a high intensity interval session.

SUPPLEMENTARY DIGITAL MATERIAL 2

Supplementary Figure 1.—CONSORT 2010 flow diagram.



SUPPLEMENTARY DIGITAL MATERIAL 3

	HUBER, N.=33				STAND, N.=32				
	Pre	Post	Р	Hedges's g	Pre	Post	Р	Hedges's g	ANCOVA
Popliteal angle test right (°)	139.75±17.28	147.58±13.87	0.001	0.49	145.62±15.12	153.75±13.50	< 0.001	0.56	0.481
Popliteal angle test left (°)	138.74±16.44	147.88±12.99	< 0.001	0.61	146.09±16.20	153.75±13.26	< 0.001	0.51	0.710
Distance heel-buttocks right (cm)	8.58±8.39	4.03±4.63	< 0.001	0.66	6.03±6.73	2.91±3.51	< 0.001	0.58	0.811
Distance heel-buttocks left (cm)	7.55 ± 7.54	4.70±5.25	0.004	0.43	6.47±6.95	3.59±4.61	< 0.001	0.48	0.619
Biering-Sorensen Test (sec)	82.55 ± 40.07	114.97±46.66	< 0.001	0.74	77.62±51.23	121.43±57.11	< 0.001	0.80	0.469
Shirado-Ito Test (sec)	79.70±64.81	115.85±109.60	0.002	0.40	66.93±50.76	89.40±62.28	0.001	0.39	0.458
Killy test (sec)	55.33±30.81	186.45±148.53	< 0.001	1.20	55.09±33.90	191.56±173.00	< 0.001	1.08	0.932
VO2 _{max} (mL.kg.min)	33.67±7.13	36.42±7.86	< 0.001	0.37	32.70±8.66	35.28 ± 8.25	< 0.001	0.30	0.706

Supplementary Table I.—Flexibility and muscular endurance of the trunk.

Variables	Completed the study (N.=65)	Drop out (N.=5)	Р
Randomization group	HUB N.=33; STAND N.=32	HUB N.=2; STAND N.=3	
Sex; N. female (%)	30 (46%)	3 (60%)	
Age	42.02±8.86	44.20±6.14	0.591
Weight(Kg)	76.58±16.25	73.80±15.11	0.712
Heigh (cm)	173.09±8.01	170.60±9.96	0.511
Body Mass Index, kg·m ²	25.64±5.34	25.30±4.43	0.891
Iso Fr 60 (Nm)	162.01±72.56	151.30 ± 56.08	0.748
Iso Exr 60 (Nm)	181.76±91.05	131.50±39.51	0.227
Ratio 60	98.90±40.45	119.58±48.61	0.281
Peak Torque moy./kg 60 (Nm/kg)	2.24±1.03	1.84 ± 0.76	0.400
Iso Fr 120	155.60±67.44	128.78±26.14	0.382
Iso Exr 120	184.94±79.47	127.40±32.54	0.114
Ratio 120	89.04±29.41	105.58±27.65	0.228
Peak Torque moy./kg 120 (Nm/kg)	2.30±0.86	1.78 ± 0.72	0.194
Pain Visual Analog Scale (/10)	3.40±1.90	5.11±2.05	0.057
Oswestry Disability Index	29.88±10.68	37.80±6.87	0.108
FABQ work	61.77±27.08	75.72±23.47	0.267
FABQ physical activity	48.55±22.34	42.57±28.33	0.573
VO2max	33.19±7.88	31.44±7.16	0.665

Supplementary Table II.—Analysis of bias of selection for baseline inclusion characteristics.

Analysis of bias of selection for baseline inclusion characteristics among randomized participants that completed all the study procedures and those that drop out. Values

are indicated as mean±SD.