Pilot Study

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Digital therapeutics-based lumbar core exercise for patients with low back pain: A prospective exploratory pilot study

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Abstract

Objective: This study aimed to implement a digital therapeutics-based approach based on motion detection technology and analyze the clinical results for patients with chronic low back pain (LBP).

Methods: A prospective, single-arm clinical trial was conducted with 22 patients who performed mobile app-based sitting core twist exercise for 12 weeks. Clinical outcomes were assessed using the visual analog scale (VAS) for LBP, Oswestry Disability Index-Korean version (K-ODI), and EuroQol-5 dimension 5-level version (EQ-5D-5L) every 4 weeks after the initiation of treatment. Laboratory tests for factors associated with muscle metabolism, plain X-ray for evaluating sagittal balance, and magnetic resonance imaging for calculating cross-sectional area (CSA) of back muscles were performed at pretreatment and 12 weeks post-treatment.

Results: The study population included 20 female patients with an average age of 45.77 ± 15.45 years. The clinical outcomes gradually improved throughout the study period in the VAS for LBP (from 6.05 ± 2.27 to 2.86 ± 1.86), K-ODI (from 16.18 ± 6.19 to 8.64 ± 5.58), and EQ-5D-5L (from 11.09 ± 3.24 to 7.23 ± 3.89) ($p < 0.001$, respectively). The laboratory test results did not show significant changes. Pelvic incidence (from $53.99 \pm 9.70°$ to $50.80 \pm 9.20°$, $p = 0.002$) and the mismatch between pelvic incidence and lumbar lordosis (from $8.97 \pm .67°$ to $5.28 \pm 8.57°$, $p = 0.027$) decreased significantly. Additionally, CSA of erector spinae and total back muscles increased by 5.20% ($p < 0.001$) and 3.08% ($p = 0.013$), respectively.

Conclusions: The results of this study suggest that the efficacy of digital therapy-based lumbar core exercise for LBP is favorable. However, further large-scale randomized controlled studies are necessary.

Keywords

Back muscles, exercise, low back pain, mobile app, motion

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Introduction

Background

Low back pain (LBP) is a highly prevalent condition that imposes individual and social burdens on the global population.[1] Prolonged sitting and a sedentary lifestyle, which have become ubiquitous following technological developments, have been associated with the increasing prevalence of LBP among older and young individuals.[2–4] The point prevalence of LBP is 9.4%, and lifetime prevalence exceeds 60%–80%.[5] Additionally, LBP can become chronic, with 44%–78% of patients suffering from relapses, if persistent for more than 3 months.[6–8] Chronic LBP can cause a vicious cycle of functional disability, which interferes with daily life or occupational activities and results in social and economic burdens.[9]

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The treatment strategies of LBP are complex because of the diverse causes. Various physical factors, including nerve, bone, muscle, joint, and ligaments, and non-physical factors, such as occupation, lifestyle or posture related to biomechanics, and psychological status, are linked to the source of LBP.[10,11] While 15%–30% of LBP has a specific medical etiology, the remaining portion is considered non-specific LBP of undetermined origin.[8,12,13] Even in specific case of spinal disease, such as herniated disc and spondylolisthesis, effective treatment of LBP is complicated by multifactorial conditions, such as sagittal balance or back muscle problems.[14–17] Accordingly, in addition to conventional treatment, including pharmacologic therapy, intervention, or surgery, a multidisciplinary conservative approach should be considered for effective treatment of LBP, which can include back muscle exercises, posture correction, and lifestyle modifications.[10]

Among various conservative treatments, lumbar core exercises have been extensively used clinically to strengthen the lumbar back muscles and improve pain. Previous research has proven the efficacy of exercise treatment for both specific LBP due to spinal diseases and nonspecific LBP.[18–20] A recent finite element analysis of the correlation between the spine structure and paraspinal muscles reveled a close relationship between the strength and volume of the paraspinal muscles and the load of the lumbar intervertebral discs.[21] Moreover, several recent meta-analyses have described the clinical significance of exercise treatment for LBP over other conservative treatments.[22–24]

Previous work

Digital therapeutics or digital therapy refers to evidence-based therapeutic interventions delivered via software and/or devices for treating, monitoring, or preventing medical disorders.[25] The concept of digital therapeutics emerged with the development of mobile and wearable devices, mobile apps, and data management technologies enabling internet-based delivery of care. Unlike the traditional facility-based treatment system, which involves face-to-face meetings between patient and physician for diagnosis, prescription, and treatment, digital therapeutics allows for contactless examination and monitoring.[26]

Digital therapeutics has been developed in various medical conditions and can be used independently or in conjunction with other treatment strategies. Over the last decade, digital therapeutics has been applied in various fields, including cognitive behavioral therapy for mental health, rehabilitation, cardiovascular disease, pulmonary disease, diabetes, and pain management.[27–34]

Recently, digital therapy has been introduced for managing LBP.[35] Several clinical trials have reported that digital therapeutics based on remote education, life modification, or muscle stimulation using a wireless device can significantly improve pain and quality of life in patients with LBP.[36–40] This finding is consistent with research showing that education and communication are related to better long-term outcomes during physical therapy.[41,42] Additionally, digital therapeutics can improve patient compliance and retention by promoting impressive user experience.[43,44]

However, the scientific evidence supporting the use of digital therapeutics for self-exercise in patients with LBP has not been firmly established. This could be due to the fact that traditional strategies for LBP primarily involve face-to-face sessions with physical therapists. Additionally, it is challenging to identify a standardized exercise protocol based on evidence and to accurately measure and track quantitative outcomes.

Goal of this study

We have developed a digital therapy-based lumbar exercise protocol for patients with LBP using a mobile app with motion detection technology. The main exercise protocol for this prototype mobile app is the sitting core twist exercise. The built-in camera of the mobile device can recognize the main joints of the subject with this mobile software. This system monitors the performance of simple movements of the sitting core twist exercise, checks whether they are properly performed, and collects data on exercise frequency and duration.

We have applied this app on patients with chronic LBP to induce their interest in exercise treatment, monitor their performance, and investigate their clinical progress.

Methods

Trial design and ethics

This was an exploratory pilot study conducted at a single center, using a single-arm, open-label design.

The entire research process was carried out in compliance with global/local ethics and was approved by the Institutional Review Board of our institute (GCIRB2022-032). This study was registered as a clinical trial in the Clinical Research Information Service of South Korea (CRIS, KCT0008262).

Aims

The primary endpoint of the study was to assess the improvement of clinical symptoms based on pain severity, quality of life, and patient satisfaction during a 12-week treatment period. The secondary endpoint was to measure quantitative changes on plain X-ray and magnetic resonance imaging (MRI) at the end of treatment.

Sample size

The sample size was calculated from following formula:

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 \, \sigma^2}{d^2}$$

The average difference of the effect value after treatment (d) was set to 2.0, and the standard deviation (σ) of the main effect value was set to 2.5 based on previous research results after conservative treatment.[7,23,24,45] A sample size of 19 subjects was derived with a significance level of 5% and power of 95%. Finally, a total of 25 subjects were targeted for recruitment, regarding a dropout rate of 25%.

Recruitment

Participants were recruited from the outpatient clinics of two neurosurgeons specializing in LBP and spine disease. All potential subjects were screened to determine eligibility based on the subsequent inclusion/exclusion criteria.

The inclusion criteria were as follows: (1) adults aged 20–70 years with moderate-to-severe LBP (visual analogue scale (VAS) pain score ≥4) for more than 3 months; (2) patients with nonspecific LBP, mild-to-moderate lumbar disc herniation, spinal stenosis, or spondylolisthesis, who do not require surgery; and (3) patients who voluntarily decided to participate in this trial and follow the trial protocol.

The exclusion criteria were as follows: (1) those requiring surgery, such as those with paralysis, bladder or bowel dysfunction, or extreme pain that makes daily activities impossible; (2) patients with a previous surgery for implanting instruments into the lumbar spine; (3) patients who are unable to understand consent or have difficulty performing the exercise protocol independently (for example, patients with a mental disorder or reduced cognitive function); (4) pregnant women or women planning to become pregnant during the study period; (5) patients with a contraindications for MRI, such as claustrophobia or in situ implants; and (6) those ineligible to participate in this trial based on the researcher's judgment.

Over a 6-month period, we approached eligible patients to gauge their interest in voluntarily participating in this study. Written informed consent was obtained from all participants before the commencement of the study.

Time frame

The study was conducted over 6 months, with a follow-up period of 12 weeks.

All patients were instructed to perform the digital therapy-based exercises daily for 12 weeks, following detailed protocols. Prior to treatment, all patients were briefed and provided informed consent. Baseline assessments, including clinical survey, laboratory tests, plain X-ray, and MRI for lumbar spine, were conducted before treatment. Regular visits for clinical surveys, treatment monitoring, and physician advisement were scheduled at 4, 8, and 12 weeks post-treatment. At the end of the 12-week period, laboratory tests, plain X-ray, and MRI for lumbar spine were repeated to compare findings with those conducted before treatment (Figure 1).

Exercise protocol and mobile app

We devised a sitting core twist exercise so that patients with LBP could easily follow it anytime and anywhere, such as in the workplace, in public places, or at home. The directions for the sitting core twist exercise are as follows: (1) sit upright on a chair with your back straight and hips away from the backrest in a neutral position; (2) flex both elbows 90° angle, and bring them simultaneously forward side by side; (3) while facing front and keeping the whole spine straight, rotate your trunk, including arms and shoulders, from your waist to one side as far as you can; (4) still gazing directly to the front, return to the neutral posture; (5) rotate to the other side in the same way while maintaining your gaze toward the front; and (6) return to the neutral posture. Completing this cycle was counted as one repetition (Figure 2).

We advised our patients to initiate this exercise with approximately 50 repetitions per day and gradually increase the frequency based on their individual capacity and preference throughout the study period. They could choose to perform multiple sets of 10 or 20 repetitions or complete all repetitions at once. We estimated that even individuals unfamiliar with exercise would be capable of performing it at least 50 times a day and that its effectiveness would increase as they progressively expanded the exercise regimen according to their ability.

All participants were provided with a cell phone equipped with a pre-installed mobile app and a simple cell phone holder. This mobile app is based on motion detection technology to identify the patient's movements, guide them in performing the correct motions, and collect data related to the exercise (Figure 3). Furthermore, when a full cycle of exercise is successfully completed, engaging audio and visual cues are designed to appear. Prior to clinical implementation, the mobile app creators rigorously tested the app to ensure its functionality and accurate data collection, and they validated it through demos. The number and duration of exercise were recorded on each individual's cell phone, and we were able to retrieve the data from the devices. The data collected by this app facilitates the assessment of exercise performance and the delivery of feedback to patients during each regular visit.

Outcome assessment

A certified investigator performed the screening, clinical surveys, and data collection during the study period. The baseline data recorded included age, sex, body mass index, clinical diagnosis, symptom duration, previous treatment history, and medical history. Additionally, we collected data on the amount of exercise performed,

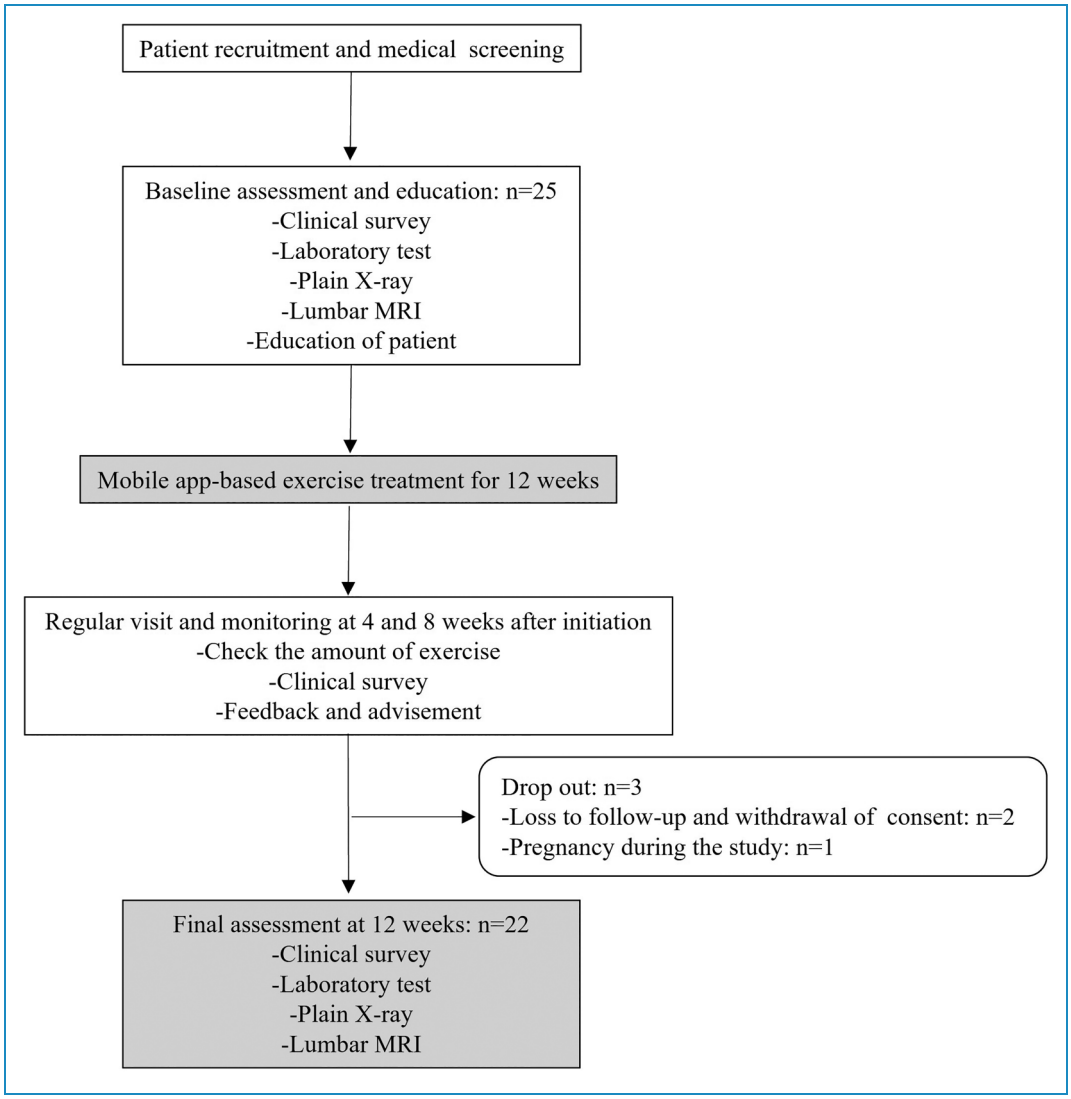

Figure 1. Flow diagram of the patient recruitment and study processes.

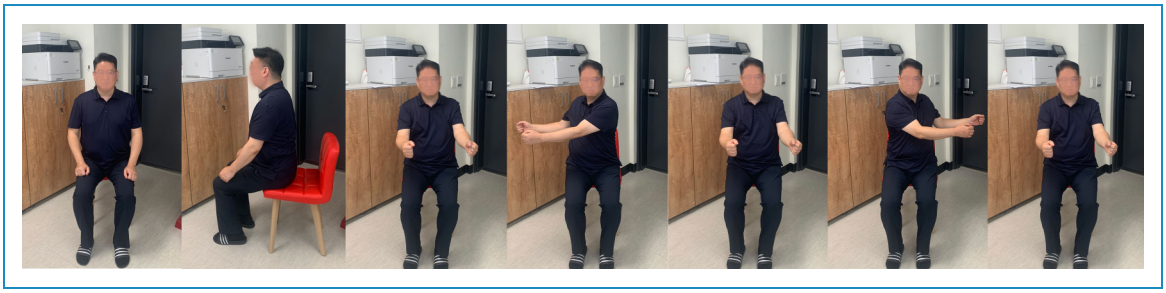

Figure 2. Photos illustrating all the steps from preparation to completion of one cycle of the sitting core twist exercise.

including duration (minutes/day) and frequency (times/day), from the device to assess the interest and compliance of patients at every visit.

The parameters of clinical outcome consisted of VAS of LBP with a range of 0–10 points, daily life quality based on the Korean version of the Oswestry Disability Index (K-ODI) and EuroQol-5 dimension 5-level version (EQ-5D-5L),[46,47] and patient satisfaction according to Odom's criteria.[48] All clinical outcomes were assessed at pretreatment and at 4, 8, and 12 weeks post-treatment.

Figure 3. Photographs of the mobile app interface developed using motion detection technology. The top row displays the contour image extracted from the raw image and subsequent creation of a virtual three-dimensional image, enabling the labeling of major joint biomarkers. The bottom row illustrates the biomarkers established in major joints to detect movements during exercise, which can be configured in the shoulder, elbow, and wrist of the upper extremities and the hip joint. The data accumulated in this app enables the evaluation of exercise performance and feedback delivery to the patients at each regular visit.

Laboratory testing was conducted to measure creatine phosphokinase (CPK), lactate dehydrogenase (LDH), erythrocyte sedimentation rate (ESR), and high-sensitive C-reactive protein (CRP) before and at 12 weeks post-treatment to evaluate the risk of muscle damage associated with excessive exercise.

Radiological data, including plain X-ray of the lumbar and whole spine and lumbar MRI using Skyra 3T® (Siemens, Erlangen, Germany) at 1-mm isovoxel and 3-mm slice thickness, were collected before treatment and at 12 weeks after treatment. Almost all patients already had previous plain X-rays and MRI for clinical diagnosis. However, these scans were repeated to evaluate the sagittal balance and the surrounding back muscles, respectively, prior to and 12 weeks after treatment.

We used the picture archiving communication system of PiView (Infinitt Healthcare, Seoul, Korea) for digital imaging and communications in medicine for imaging analysis. Plain X-ray was used to measure the profile of sagittal balance, including pelvic tilt (PT), sacral slope (SS), pelvic incidence (PI), lumbar lordosis (LL), sagittal vertical axis (SVA), mismatch between pelvic incidence and lumbar lordosis (PI–LL mismatch), and lumbar range of motion (ROM) calculated from lumbar lordosis in extension−lumbar lordosis in flexion.[49–51] MRI was used to measure the cross-sectional area (CSA) of the paraspinal muscles, including the multifidus, erector spinae (including the longissimus and iliocostalis lumborum), quadratus lumborum, and the psoas major. CSA was measured by drawing outlines on PiView and was calculated as mm^2 at the level of the upper margin of L4 vertebra.[52,53]

Two independent investigators (one neurosurgeon and one radiologist) measured radiological parameters from the same image twice, and inter-rater reliability was analyzed. The final value was the average of the results by the two investigators.

During the follow-up period, participants were asked to report any side effects or discomfort that occurred during exercise, such as exacerbation of pain, arthralgia, fatigue, and dehydration.

Adjuvant treatment

Prior to the start of exercise treatment, the medications taken for pain control were assessed, and patients were allowed to continue taking these medications at their discretion. Maintenance, tapering, or cessation was determined based on the patient's decision during the treatment period. Patients were also allowed to continue or discontinue their usual self-exercise or physical therapy interventions

performed prior to study registration based on their preference. However, invasive treatments that could significantly affect the clinical outcome, such as lumbar intervention or acupuncture, were not permitted.

Statistical analysis

Data management and statistical analyses were performed using SPSS (version 27.0; IBM Corporation, Armonk, NY, USA). Pearson's chi-square test, one-way analysis of variance (ANOVA), and paired *t*-test were used regarding the types of data collected. Intraclass coefficient correlation (ICC) was analyzed to assess inter-observer reliability.

The values were expressed as mean ± standard deviation (SD), mean and 95% confidence interval (CI), or median and interquartile range (IQR), depending on whether the data were normally distributed or not. Statistical significance was accepted at a *p*-value of <0.05.

Results

Baseline characteristics

Out of the 25 subjects initially registered, 22 were included in the final cohort after the exclusion due to loss to follow-up, simple consent withdrawal, and pregnancy. The 22 study subjects consisted of two men and 20 women with an average age of 45.77 ± 15.45 years and a mean body mass index of 23.10 ± 3.56. Clinical diagnoses included 15 cases of nonspecific LBP, six cases of herniated lumbar disc, and one case of spondylolisthesis. The median duration of symptoms from onset to study registration was 12.17 months (IQR, 5.50–30.42). Twelve patients had previously undergone a nerve block, 20 were currently taking pain medication, and eight had various comorbidities (Table 1).

Table 1. Demographic data and baseline characteristics.

Characteristics	Subjects (n = 22)
Age (years)	45.77 ± 15.45
Men/Women	2/20
Body mass index (kg/m^2)	23.10 ± 3.56
Diagnosis	
Herniated lumbar disc	6 (27.3%)
Spondylolisthesis	1 (4.5%)
Non-specific	15 (68.2%)
Median duration of symptom (month)	12.17 (IQR, 5.50–30.42)
Previous nerve block: Yes/No	12/10
Medication prior to study registration: Yes/No	20/2
NSAID	9
Acetaminophen + tramadol	3
Gabapentin	2
Pregabalin	1
Combination	5
Comorbidities: Yes/No	8/14
Hypertension	2
Cerebrovascular disease	1
Diabetes	1
Major depressive disorder	1
Thyroid disease	3
Liver disease	1
Kidney disease	1
Osteoporosis	1
Previous lumbar discectomy	2

Amount of exercise

The overall mean exercise duration was 23.31 ± 13.30 min/day, while the overall mean frequency of cycles completed was 424.19 ± 272.73 times/day. Exercise duration decreased slightly at 8 weeks post-treatment compared to that at 4 weeks post-treatment but remained steady at 12 weeks ($p = 0.028$, one-way ANOVA). The frequency of exercise performed did not vary significantly across the visits ($p = .827$, one-way ANOVA) (Table 2).

Clinical outcomes

The mean pretreatment VAS score for LBP was 6.05 ± 2.27, which gradually decreased to 4.52 ± 2.34 at 4 weeks, 3.53 ± 2.09 at 8 weeks, and 2.86 ± 1.86 at 12 weeks after treatment ($p < 0.001$, one-way ANOVA). The VAS difference between the pretreatment and 12 weeks post-treatment was 3.19 (95% CI, 2.19–4.19; $p < 0.001$, paired *t*-test), and the degree of improvement reached 52.73% over the baseline (Table 3).

Table 2. Data related to the amount of exercise from mobile app.

Characteristics	4 weeks	8 weeks	12 weeks	Average	*P* value
Exercise duration (minutes/day)	25.91 ± 13.76	22.64 ± 12.15	21.38 ± 15.17	23.31 ± 13.30	.028[a]
Frequency of exercise (times/day)	426.05 ± 253.90	427.25 ± 258.32	419.27 ± 330.68	424.19 ± 272.73	.827[a]

[a]One-way analysis of variance

Table 3. Clinical outcome according to VAS of LBP, K-ODI, EQ-5D-5L, and Odom's criteria.

Characteristics	Baseline	4 weeks	8 weeks	12 weeks	*P* value
VAS back	6.05 ± 2.27	4.52 ± 2.34	3.53 ± 2.09	2.86 ± 1.82	< .001[a]
K-ODI	16.18 ± 6.19	11.73 ± 6.34	10.00 ± 5.70	8.64 ± 5.58	< .001[a]
EQ-5D-5L	11.09 ± 3.24	9.09 ± 2.93	8.09 ± 2.83	7.23 ± 3.89	< .001[a]
Odom's criteria					
Excellent/Good/Fair/Poor		4/6/13/2	4/9/9/0	6/10/6/0	
Success rate		45.45%	59.09%	72.72%	.003[c]

[a]One-way analysis of variance, [b]paired t-test, [c]Pearson's chi square test
CI, confidence interval; EQ-5D-5L, EuroQol-5dimension 5 level version; K-ODI, Korean version of Oswestry Disability Index; VAS, visual analog scale

The mean K-ODI improved significantly from 16.18 ± 6.19 to 11.73 ± 6.34 at 4 weeks, 10.00 ± 5.70 at 8 weeks, and 8.64 ± 5.58 at 12 weeks after treatment ($p < 0.001$, one-way ANOVA). The K-ODI also gradually improved at every visit, and eventually the degree of improvement reached 46.66% over the baseline after 12 weeks. The difference in K-ODI between pretreatment and 12 weeks post-treatment was 7.55 (95% CI, 5.35–9.74; $p < 0.001$, paired *t*-test) (Table 3).

Similarly, the mean EQ-5D-5L improved significantly from 11.09 ± 3.24 to 9.09 ± 2.93 at 4 weeks, 8.09 ± 2.83 at 8 weeks, and 7.23 ± 3.89 at 12 weeks post-treatment ($p < 0.001$, one-way ANOVA). EQ-5D-5L also gradually improved at each visit except for the visit at 12 weeks, finally improving by 34.81% over the baseline after 12 weeks. The difference in EQ-5D-5L between pretreatment and 12 weeks post-treatment was 3.86 (95% CI, 2.39–5.34, $p < 0.001$, paired *t*-test) (Table 3).

According to Odom's criteria, the success rate, which indicates good or excellent outcomes, gradually increased from 45.45% at 4 weeks to 59.09% at 8 weeks and 72.72% at 12 weeks post-treatment. Odom's criteria distribution at 8 weeks was significantly different from that at 4 weeks after treatment ($p = 0.003$, Pearson's chi-square test) (Table 3).

In addition, among the 20 patients who were taking medications before treatment, seven continued taking their medication, five tapered off, and eight patients discontinued their medication (Table 3).

Laboratory test

No significant differences were observed in any of the laboratory test results between before treatment and 12 weeks after treatment (Table 4).

Radiological outcomes

The ICC analysis revealed high inter-observer reliabilities for the measurement of quantitative findings, ranging between 0.858 and 0.978.

Although not statistically significant, the PT, SS, and SVA tended to decrease after treatment. Accordingly, PI decreased significantly from 53.99° ± 9.70° to 50.80° ± 9.20° (a decrease of 5.91% from baseline; mean difference, 3.19° (95% CI, 21.93°–10.44°); $p = 0.002$, paired *t*-test). PI–LL mismatch decreased from 8.97°±9.67° to 5.28° ± 8.57° (a decrease of 41.14% from baseline; mean difference, 3.69° [95% CI, 0.47°–6.91°]; $p = 0.027$, paired *t*-test). LL and lumbar ROM did not differ significantly (Table 5).

The CSA of both erector spinae muscles increased from 1325.55 ± 307.97 mm^2 to 1394.46 ± 293.65 mm^2 (an improvement of 5.20% from baseline; mean difference,

Table 4. Laboratory findings before and after treatment.

Characteristics	Baseline	12 weeks	Difference (Baseline − 12 weeks)	*P* value
CPK (U/L)	107.70 ± 51.20	106.75 ± 50.52	0.95 (95% CI, -17.86–19.76)	.917[a]
LDH (U/L)	190.05 ± 28.46	188.53 ± 25.83	1.53 (95% CI, -6.83–9.88)	.706[a]
ESR (mm/hr)	4.65 ± 3.05	5.40 ± 3.52	-0.75 (95% CI, -2.03–0.53)	.234[a]
hsCRP (mg/dL)	0.16 ± 0.10	0.26 ± 0.18	-0.10 (95% CI, 0.29–0.09)	.219[a]

[a]Paired t-test
CI, confidence interval; CPK, creatinine phosphokinase; ESR, erythrocyte sedimentation rate; hsCRP, high-sensitive C-reactive protein; LDH, lactate dehydrogenase

Table 5. Radiological findings of sagittal balance based on plain X-ray.

Characteristics	Baseline	12 weeks	Difference (Baseline − 12 weeks)	*P* value
Pelvic tilt (°)	19.88 ± 7.74	18.10 ± 6.39	1.78 (95% CI, -0.07–3.62)	.058[a]
Sacral slope (°)	34.11 ± 6.22	32.70 ± 5.01	1.41 (95% CI, -0.57–3.39)	.152[a]
Pelvic incidence (°)	53.99 ± 9.70	50.80 ± 9.20	3.19 (95% CI, 1.30–5.07)	.002[a]
Lumbar lordosis (°)	45.02 ± 7.19	45.52 ± 7.95	-0.50 (95% CI, -2.99–1.99)	.678[a]
PI–LL mismatch (°)	8.97 ± 9.67	5.28 ± 8.57	3.69 (95% CI, 0.47–6.91)	.027[a]
Sagittal vertical axis (mm)	10.47 ± 34.05	0.52 ± 30.86	9.95 (95% CI, -3.44–23.34)	.136[a]
Range of motion (°)	23.82 ± 12.94	22.81 ± 9.88	1.01 (95% CI, -2.70–4.71)	.575[a]

[a]Paired t-test
CI, confidence interval; PI–LL mismatch, Mismatch between pelvic incidence and lumbar lordosis

68.91 (95% CI, 39.61–98.21)); $p < 0.001$, paired *t*-test). The changes in the other muscle segments were insignificant. The total CSA of back muscles also increased from 5823.07 ± 1317.09 mm^2 to 6002.42 ± 1363.37 mm^2 (an improvement of 3.08% from baseline; mean difference, 179.34 (95% CI, 41.67–317.02); $P = .013$, paired *t*-test) (Table 6) (Figure 4).

Side effects

No side effects were noted, except for one case of transient aggravation of LBP in the first 4 weeks, with the VAS increasing from 5 to 6. However, even in that case, the pain improved after continued treatment, with the VAS decreasing from 6 to 3 at 8 weeks.

All patients were more interested in the mobile app-based exercise protocol than in previous self-exercise or conventional exercise treatment. While two patients initially reported poor motion detection, but they improved their compliance after retraining during their first regular follow-up.

Discussion

Design of exercise protocol and mobile app

Although various types of lumbar core exercises for chronic LBP have been introduced, the lack of a standard exercise protocol and scientific monitoring based on data are the major limitations for applying exercise treatment.[54] Many combined exercise therapies are derived from assumption and empirical practice, and the objective effects of each single exercise motion have not been sufficiently identified.[22] Even patient-customized motor skill training programs in functional activities, which are advanced exercise treatments, have not yet been standardized and are too complicated for patients to perform independently.[55,56]

To overcome these limitations, we devised a sitting core twist exercise as an example of a simple and standardized training for back muscle strengthening. Among the diverse exercise motions for back muscles, core twist exercises, including standing lower body twist, standing weighted twist, and twisting curl-up exercise, can effectively strengthen

Table 6. Cross-sectional area of muscles based on magnetic resonance imaging.

Characteristics	Baseline	12 weeks	Difference (Baseline − 12 weeks)	*P* value
Multifidus muscle (mm^2)				
Right	405.40 ± 142.57	416.23 ± 153.07	10.83 (95% CI, -3.65–25.32)	.135[a]
Left	409.49 ± 139.95	413.53 ± 150.73	4.04 (95% CI, -10.30–25.45)	.699[a]
Erector spinae muscle (mm^2)				
Right	1317.45 ± 279.11	1372.35 ± 287.68	54.90 (95% CI, 16.47–93.34)	.007[a]
Left	1333.66 ± 349.43	1416.57 ± 320.50	82.91 (95% CI, 34.99–130.84)	.002[a]
Sum of both erector spinae	1325.55 ± 307.97	1394.46 ± 293.65	68.91 (95% CI, 39.61–98.21)	< .001[a]
Quadratus lumborum muscle (mm^2)				
Right	369.29 ± 109.03	406.52 ± 130.43	37.23 (95% CI, -7.09–81.55)	.095[a]
Left	427.10 ± 142.16	413.98 ± 150.10	-13.12 (95% CI, -49.18–22.94)	.458[a]
Psoas muscle volume (mm^2)				
Right	788.55 ± 239.57	775.38 ± 264.11	-13.17 (95% CI, -68.92–45.28)	.628[a]
Left	772.15 ± 235.15	787.86 ± 239.95	15.72 (95% CI, -27.28–58.71)	.456[a]
Total back muscles (mm^2)	5823.07 ± 1317.09	6002.42 ± 1363.37	179.34 (95% CI, 41.67–317.02)	.013[a]

[a]Paired t-test
CI, confidence interval

several back muscles.[57–59] Based on this concept, we have developed a modified sitting core twist exercise that patients with chronic LBP can easily perform anywhere and anytime. Additionally, the movement is simple enough that software based on motion detection technology can easily recognize the joint motion.

Based on this sitting core twist exercise, we have developed a prototype of a mobile app utilizing motion detection technology. Once properly educated on the protocol, patients can perform exercise independently following a mobile app. This software allows for the quantitative collection of exercise treatment data and facilitates efficient monitoring/prescription by medical professionals. Furthermore, our future plans include the development of a remote data clouding and automatic analysis system. Remote monitoring, supervision, and adjustment by a physician are possible via data sharing.[60] Additionally, the motivation and compliance of the subjects are engaged through encouraging sound and video effects every time one cycle is completed.

Back muscle strengthening and clinical results

The MRI findings indicate a slight but statistically significant increase in the CSA of the erector spinae and total paraspinal muscles (5.20% and 3.08%, respectively, from baseline). An increasing trend in the CSA of other paraspinal muscles, except the psoas muscle, was also noted, although this was not statistically significant. These findings are consistent with previous studies that found a relationship between exercise therapy and core muscle enhancement.[61–63] We believe that the increase in CSA will become more significant with prolonged exercise treatment. We also hypothesize that the reinforced part of the muscle or the change in volume can vary depending on the type of exercise motion.

All clinical parameters also improved (34.81%–52.73% from baseline), and patient satisfaction was 72.72% at 12 weeks post-treatment. These findings support the suggestion of previous researchers that core exercises significantly increase the muscle activity and mass of the paraspinal muscles, thereby clinically improving pain and quality of life.[64–68] Furthermore, this efficacy of mobile app is comparable or even superior to other conservative treatments, such as conventional pharmacologic treatment, chiropractic, physical therapy, or massage.[24,45,69–71] Although these comparisons are indirect with the results of previous reports, the degree of improvement in pain and quality of

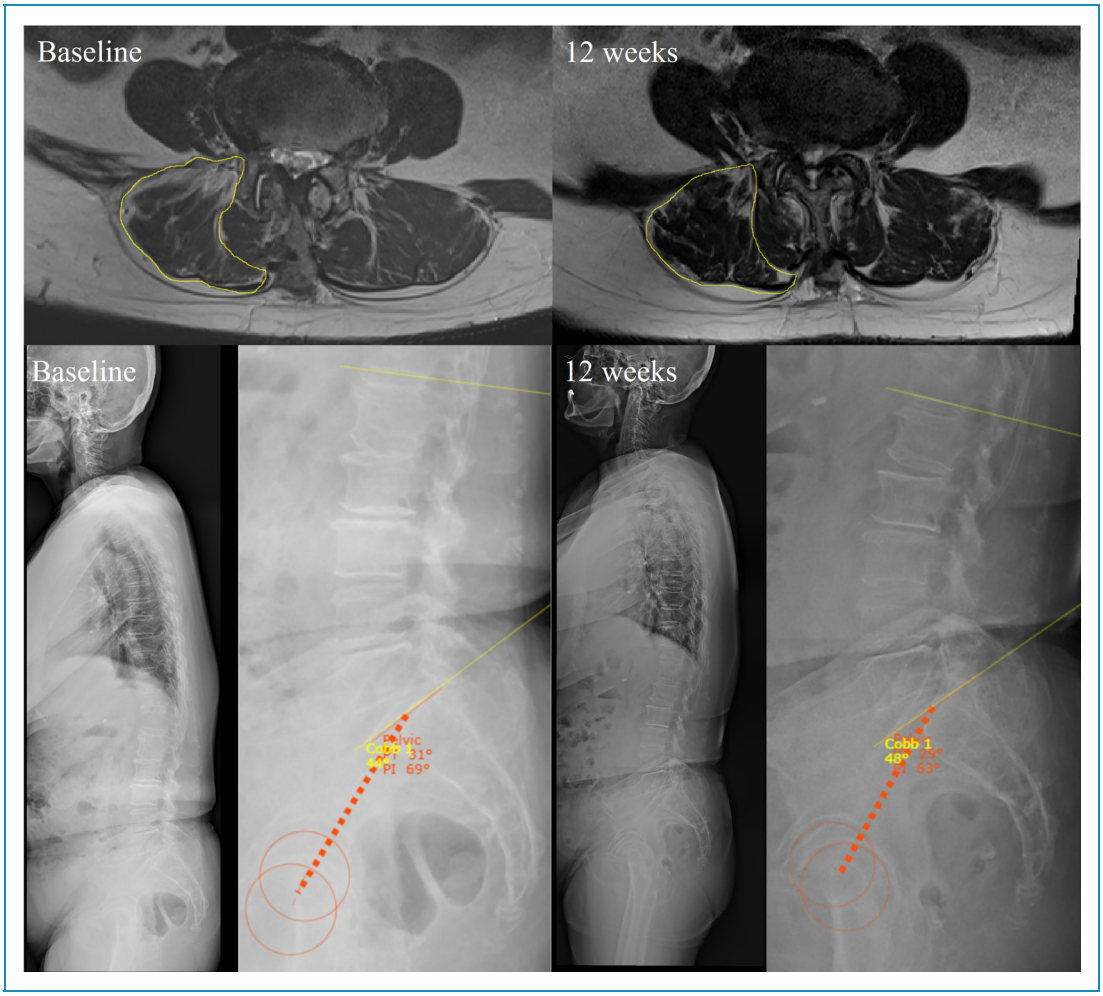

Figure 4. Representative case illustration of a 72-year-old female patient who had been experiencing nonspecific LBP for 6 months. The patient reported a significant improvement in clinical parameters after 12 weeks of treatment, with the VAS score for LBP decreasing from 8 to 4, the K-ODI score decreasing from 27 to 8, and the EQ-5D-5L score decreasing from 18 to 9. MRI results showed that the CSA of the erector spinae increased from 1306.24 mm^2 to 1621.53 mm^2 (a 24.14% improvement) after treatment. In addition, plain X-ray results showed an improvement in sagittal balance, with the PI decreasing from 69° to 63° (an 8.70% improvement) and the PI–LL mismatch decreasing from 25° to 15° (a 40.00% improvement). CSA, cross-sectional area; EQ-5D-5L, EuroQol-5 dimension 5-level version; K-ODI, Korean version of the Oswestry Disability Index; LBP, low back pain; LL, lumbar lordosis; MRI, magnetic resonance imaging; PI, pelvic incidence; PI-LL mismatch, mismatch between pelvic incidence and lumbar lordosis; VAS, visual analog scale.

life, as well as patient satisfaction, is a remarkable achievement.

Moreover, in terms of complication, this mobile app-based exercise is safe and effective. Compared to the risk of various complications after drug administration or intervention,[45,70] this treatment was sufficiently safe without any serious adverse events, except for a minor and transient worsening of LBP. The laboratory results related to muscle metabolism were also stable at the final follow-up.

Additionally, regarding patient compliance, the retention of patients was consistently maintained above a certain level during follow-up, although the duration of exercise declined slightly with time. Although patients were initially advised to gradually increase their exercise amount from the initial 50 times/day, the average of 424.19 ± 272.73 times/day with 23.31 ± 13.30 min/day was considered an appropriate and manageable amount. The significant increase in exercise frequency beyond the initially recommended amount can be attributed to the mobile app's effectiveness in generating interest. Furthermore, as patients experienced the positive effects of the exercise, they might naturally maintain or expand their exercise routine.

Impact on sagittal balance

The natural course of PI, which is the sum of PT and SS, is controversial. Classically, PI has been accepted as a constant value with a normal range of 35°–85° that is specific

to each individual after reaching bone maturity.[50] However, the pelvis may function as an anchor for the spinal axis and a modulator of sagittal balance.[72] Based on this concept, some authors have suggested that PI varies according to pathological status, posture, aging process, or sex and vice versa.[73] For example, PI has been found to increase in patients with various spinal degenerative diseases involving the sacroiliac joint realignment, including sagittal imbalance, spondylolisthesis, stenosis, disc herniation, or postsurgical correction.[74–76] Some studies also suggest that the aging process increases PT, PI, and PI–LL mismatch due to increasing sacral–femoral distance or pelvic retroversion.[77] Consequently, some authors infer that PT and PI tend to increase in patients with chronic LBP.[78]

In the present study, PI decreased significantly from baseline by 5.91% after 12 weeks of exercise therapy. Moreover, interestingly, PI–LL mismatch improved significantly by 41.14% from baseline. These findings suggest that strengthening the lumbar core muscle induces correct spinal balance as indicated by slight pelvis anteversion, decreased PT, decreased PI, and decreased PI–LL mismatch, sequentially. The correlation between decreased PI and PI–LL mismatch, muscle strengthening, and improved clinical results after exercise therapy objectively confirms the suggestions of previous studies.[74–76,78]

Conversely, several previous studies have suggested that the LL or ROM is smaller in patients with LBP than in healthy subjects.[79–81] However, the present study found no significant difference in LL and ROM before and after treatment. This means that the major sagittal parameter affected by the proposed core exercise is spinopelvic relation or balance, not simply LL or ROM.

Limitation and significance of this study

This study has several limitations. Firstly, the most significant limitation is the absence of a control group. Due to its single-arm design, objective comparisons with a control group were not possible, and the placebo effect cannot be ignored. Secondly, we were unable to control the confounding factors that affect outcomes, such as medication and other self-exercises. Nevertheless, we tried to reduce bias by allowing patients to continue the treatment they were receiving prior to registration and by prohibiting the introduction of new interventions during the study period. Thirdly, the sample size was small, mostly female, and the follow-up was short. The preponderance of female patients arose from a coincidental high number of voluntary female participants with chronic LBP during the study period and not from any bias in patient recruitment. However, since this study is an exploratory pilot study, it sufficiently demonstrated the efficacy and safety of the intervention.

This study provides objective evidence of the efficacy of a sitting core twist exercise based on mobile app for patients with LBP. We believe that the findings of this research are valuable because this is the first methodological study investigating radiological outcomes, as well as clinical outcomes, on digital therapy-based exercise treatment for patients with LBP. However, large-scale randomized controlled trials with long-term follow-up are necessary to confirm results of this study.

Conclusions

This pilot study demonstrates the efficacy and safety of digital therapeutics-based exercise treatment for patients with chronic LBP. Digital therapeutics could enhance favorable compliance by stimulating patient's interest while enabling scientific monitoring and patient-specific prescription based on collected data. Although further clinical investigation is necessary to confirm clinical efficacy, this study can serve as a basis for the development of digital therapy for spinal diseases.

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