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LONG-TERM EFFECTS OF DEEP-LEARNING DIGITAL THERAPEUTICS ON PAIN, MOVEMENT CONTROL, AND PRELIMINARY COST-EFFECTIVENESS IN LOW BACK PAIN: A RANDOMIZED CONTROLLED TRIAL

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Abstract

Objective: *The present study aimed to compare the effects of a deep learning–based digital application, delivered as Digital Physical Therapy (DPT), with those of Conventional Physical Therapy (CPT) on pain intensity, trunk range of motion (ROM), functional movement, preliminary cost-effectiveness, and perceived transmission risk of COVID-19 in individuals with low back pain (LBP).*

Methods: *A total of 100 participants with chronic LBP were randomized into either DPT or CPT groups. Both interventions were delivered three times per week over four weeks. Outcome measures included the Numeric Pain Rating Scale (NPRS), Functional Movement Screen (FMS), AI-based ROM analysis of trunk flexion, extension, and bilateral side bending, questionnaires assessing perceived COVID-19 transmission risk, and preliminary cost-effectiveness analysis. Statistical analyses were conducted using analysis of variance (ANOVA) with significance set at $p < 0.05$.*

Results: *Both groups demonstrated significant pre- to post-intervention improvements in pain intensity, trunk mobility, and functional movement ($p < 0.05$). However, DPT showed superior effects compared with CPT in several domains, including hip extensor strength, Roland-Morris Disability Questionnaire (RMDQ) scores, and COVID-19 transmission risk reduction. Cost-effectiveness analysis revealed that DPT was less costly and more beneficial, with an incremental therapeutic gain of 0.001 QALY relative to CPT.*

Conclusions: *This study provides novel evidence that DPT is as effective as CPT in improving structural and functional impairments, activity limitations, and participation restrictions among individuals with LBP. Importantly, DPT demonstrated added advantages in reducing perceived infection risk, enhancing accessibility, and improving preliminary cost-effectiveness*

INTRODUCTION

Background and Rationale

Artificial intelligence (AI)–based digital therapeutics have emerged as a transformative innovation in healthcare, particularly for musculoskeletal conditions such as low back pain (LBP). LBP is one of the most prevalent causes of disability worldwide, with multifactorial origins including faulty posture, impaired movement patterns, sleep disturbances, and psychosocial factors such as depression. These factors collectively compromise essential daily movements—bending, standing, lifting, twisting, and walking—leading to activity limitations and reduced quality of life (QOL). Despite decades of research, the exact pathomechanism underlying spinal movement impairment remains unclear, and treatment outcomes remain inconsistent.

Traditional therapeutic approaches, such as soft tissue massage, electrotherapy, mobilization, manipulation, lumbar traction, and exercise therapy, are considered "hands-on" interventions. While these methods allow for detailed patient assessment and individualized treatment in clinical settings, they are limited in their ability to monitor progress outside the clinic. Most injuries and functional impairments occur in real-life situations, where continuous monitoring and feedback are not available. This gap highlights the need for innovative, scalable, and patient-centered solutions that extend beyond the clinic walls.

Impact of COVID-19 and the Need for Remote Care

The coronavirus disease 2019 (COVID-19) pandemic accelerated the shift from conventional in-person care to remote healthcare delivery models. This transition was critical to prevent the collapse of healthcare systems worldwide. However, remote care introduced challenges, particularly the inability to use palpation and special diagnostic tests during clinical examinations. Such limitations risk compromising the identification of red flags and complex cases that require higher-intensity care. Consequently, while face-to-face visits remain essential for difficult cases, there is a clear need for remote therapy systems that can provide effective, sustainable monitoring, diagnosis, and treatment for LBP.

Development of the DrAI System

To address these challenges, we developed the DrAI system, a smartphone-based application designed to deliver accurate, real-time spinal movement evaluation, monitoring, diagnosis, and intervention. The system leverages deep learning algorithms, particularly convolutional neural networks (CNN), which outperform traditional machine learning models in image recognition and motion analysis. CNNs offer faster learning rates, reduced overfitting, and robust prediction capabilities in impaired populations. Unlike existing home exercise applications, which often lack validity, reliability, and clinical trial evidence, DrAI integrates aggregated clinical data with individualized audiovisual feedback, enabling standardized and customizable rehabilitation.

Recent advances in AI, combined with the widespread availability of affordable smartphones equipped with camera sensors, have made it possible to overcome the limitations of laboratory-based motion analysis. Deep learning models such as CNN, random forest, ridge regression, recurrent neural networks, long short-term memory units, gated recurrent units, and temporal convolutional networks have all been applied to estimate kinematic parameters and detect movement abnormalities. Among these, CNN has demonstrated superior performance in rehabilitation contexts, making it the foundation of the DrAI system.

Study Objectives

Despite the potential clinical and therapeutic advantages of AI-driven digital therapy, these benefits have not been rigorously investigated in randomized controlled trials with adequate sample sizes. The present study was therefore designed with two specific aims:

1. **Primary Aim:** To evaluate the effects of Digital Physical Therapy (DPT)—delivered through the DrAI application plus an initial in-person orientation—compared with

Conventional Physical Therapy (CPT) on key clinical outcomes in individuals with LBP. These outcomes included pain intensity measured by the Numeric Pain Rating Scale (NPRS), lower extremity muscle strength, trunk mobility assessed via AI-based ROM analysis, and functional movement quality measured by the Functional Movement Screen (FMS).

2. **Secondary Aim:** To investigate the broader impact of DPT compared with CPT on perceived COVID-19 transmission risk and preliminary cost-effectiveness, thereby assessing both public health and economic dimensions of digital rehabilitation.

Hypothesis

We hypothesized that both DPT and CPT would produce significant improvements in pain, muscle strength, trunk mobility, and functional movement. However, we anticipated that DPT would demonstrate additional advantages in reducing perceived infection risk, improving cost-effectiveness, and enhancing accessibility through real-time audiovisual feedback and corrective diagnostic input.

Significance of the Study

This trial represents one of the first prospective, long-term interventions to rigorously evaluate a deep learning–based self-management application for LBP. By integrating AI-driven motion capture with individualized therapeutic feedback, DPT has the potential to bridge the gap between clinic-based care and real-life functional demands. The findings of this study provide a foundation for advancing digital rehabilitation science, supporting the integration of AI into musculoskeletal care, and informing future research aimed at scaling digital therapeutics across diverse patient populations.

METHODS

Participants

A convenience sample of 100 participants with chronic LBP (mean age 35.5±8.8 years; 40 female patients) was enrolled after being recruited via bulletin board notices within the hospitals and community centers. Initially, 100 out of 170 participants with LBP were recruited and screened by the investigator (CP) and diagnosed by the certified orthopedist. All participants provided written informed consent, and the study was conducted in accordance with the Declaration of Helsinki. The present study used a two-group pretest and posttest design in which all participants completed the pretest, the intervention, and the posttest. Inclusion criteria were (1) >18 years of age, having self-reported complaints of LBP for at least three months, ability to perform simple activities at home, using a smartphone with an Android operating system (OS) (as the application was programmed for android devices only), willing and able to perform therapeutic exercises following visual and verbal instructions, and sufficient knowledge of the Korean language to understand the instructions.

Exclusion criteria included spine surgery or significant trauma in the previous three months, using crutches or a walking aid, structural deformities such as scoliosis, spinal tumors, ankylosing spondylitis, or spondylolisthesis, neurological and cognitive disorders, congenital asthma, and psychiatric diagnosis. Sample size was determined according to a power analysis performed with G-power software 3.1.9.7 (Franz Faul, University of Kiel, Kiel, Germany) that was conducted to assess the sample size requirement (N=100) based on a pilot AI application study of four participants with LBP (n=2 in each group), which demonstrated a power of 0.80, an alpha level of 0.05, and an effect size of 0.6. Participant demographic characteristics are presented in Table 1.

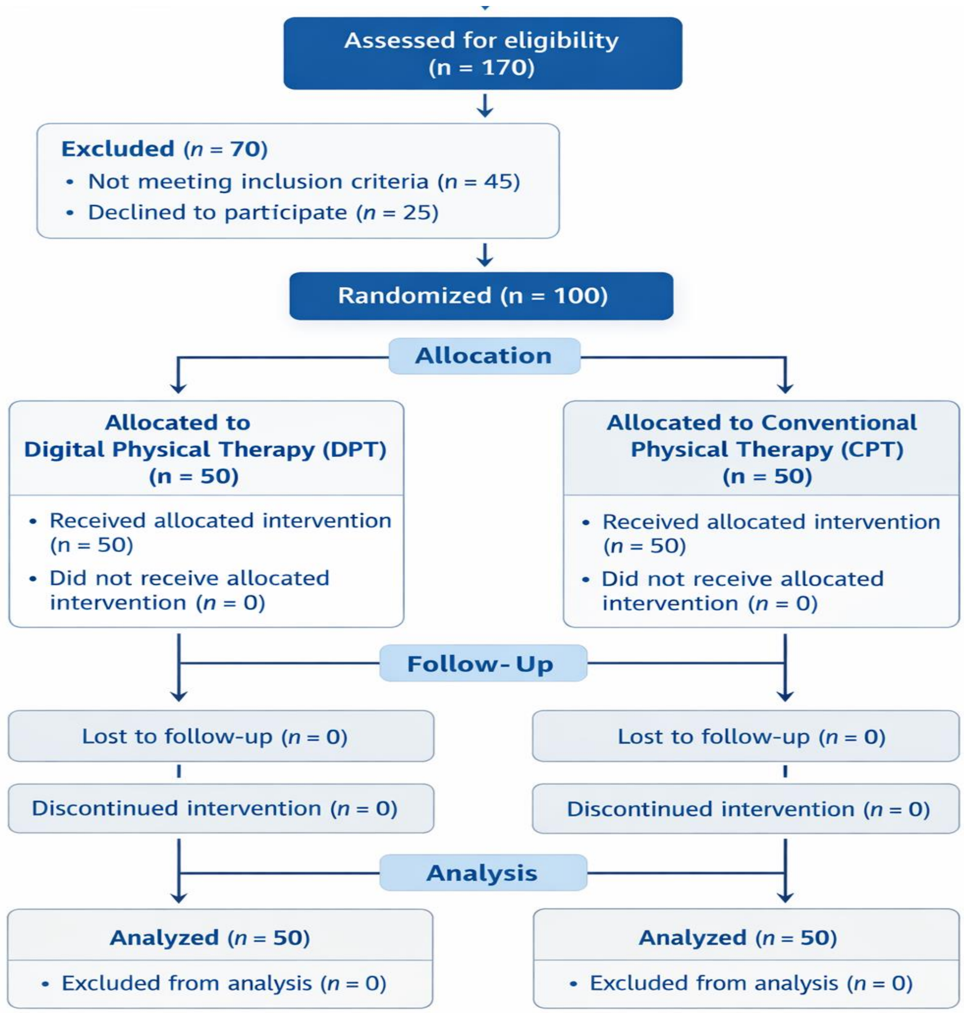
Experimental procedure

A randomized, single-blind experimental design was employed. Randomization was performed using a coin-flipping method to minimize recruitment and selection bias. Participants were allocated to either the control (CPT) or experimental (DPT) group by one investigator, while another blinded investigator assessed outcomes. To reduce expectation bias, participants were masked to group assignment until study completion.

An experimental checklist ensured consistent implementation of pretest, intervention, and posttest procedures. Standardized outcome measures included:

- **Numeric Pain Rating Scale (NPRS)** – Pain intensity on an 11-point scale (ICC = 0.89, r = 0.94).
- **Functional Movement Screen (FMS)** – Seven graded tasks assessing movement quality (ICC = 0.76, r = 0.81).
- **Muscle strength** – Hip and knee isometric force measured with a hand-held dynamometer, normalized to body weight.
- **AI-based ROM analysis** – Lumbar flexion, extension, and side bending captured via DrAI motion capture (CNN accuracy = 94.32%).
- **Cost-effectiveness** – Incremental cost-effectiveness ratio (ICER) calculated using $\Delta Cost/\Delta QALY$
- **COVID-19 transmission risk questionnaire** – Assessed social distancing, contact duration, and infection risk (0–10 scale).

All analyses were conducted using SPSS v26 (Chicago, IL, USA), with statistical significance set at $p < 0.05$.



Intervention

Participants were randomly assigned to either Conventional Physical Therapy (CPT) or Digital Physical Therapy (DPT), with both protocols delivered in 30-minute sessions, three times per week, over four weeks. Each participant attended a single orientation session prior to intervention to ensure understanding of procedures. The effectiveness of both interventions was evaluated using six standardized outcomes.

Pain intensity was measured through the Numeric Pain Rating Scale (NPRS), while movement quality was assessed using the Functional Movement Screen (FMS), which included seven graded tasks. Lower-limb strength was quantified by measuring hip and knee isometric force with a handheld dynamometer, normalized to body weight. Trunk mobility was analyzed using AI-based ROM assessment, capturing lumbar flexion, extension, and side bending with the DrAI motion capture system (CNN accuracy = 94.32%). Economic efficiency was determined through cost-effectiveness analysis, using the incremental cost-effectiveness ratio (ICER) calculated as ΔCost/ΔQALY. Finally, public health impact was evaluated with a COVID-19 transmission risk questionnaire, which assessed social distancing, contact duration, and perceived infection risk on a 0–10 scale.

Both CPT and DPT were structured to directly address these outcomes, with CPT delivered by licensed therapists using standardized manual and exercise protocols, and DPT delivered via the DrAI application providing individualized audiovisual feedback and remote monitoring.

Statistical analysis

Descriptive statistics were reported as means and standard deviations for all continuous variables. For categorical demographic characteristics, the chi-square test was used to compare groups.

To evaluate intervention-related changes in the specified outcomes—Numeric Pain Rating Scale (NPRS), Functional Movement Screen (FMS), muscle strength (hip and knee isometric force), and AI-based trunk ROM (flexion, extension, side bending)—a 2×2 mixed ANOVA was performed to test for time effects and group-by-time interactions. When significant differences were observed, post hoc tests were conducted to examine within-group pre- to post-test changes. For significant main effects and interactions, a Tukey post hoc test was applied.

Economic efficiency was assessed using incremental cost-effectiveness ratio (ICER), calculated as ΔCost/ΔQALY between groups. Public health impact was analyzed using the COVID-19 transmission risk questionnaire, with independent t-tests applied to compare perceived infection risk scores (social distancing, contact duration, infection risk on a 0–10 scale) between DPT and CPT groups.

All analyses were conducted using SPSS version 26 (SPSS Inc., Chicago, IL, USA), with the statistical significance level set at $p < 0.05$.

RESULTS

Participant Flow and Baseline Data: A total of 100 participants with chronic low back pain were randomized equally into the DPT (n = 50) and CPT (n = 50) groups. Baseline demographic and clinical characteristics were comparable across groups, with no significant differences detected by chi-square or independent t-tests.

Table 1. Demographic Characteristics of Participants

Variable	DPT Group (n = 50)	CPT Group (n = 50)	*p*-value
Sex (male/female)	30/20	30/20	1.00
Age (years)	37.11 ± 8.33	33.21 ± 6.11	0.22
Body height (cm)	163.38 ± 14.52	161.27 ± 11.21	0.48
Body weight (kg)	66.48 ± 10.11	68.11 ± 8.38	0.37
Smoking (yes/no)	8/42	11/39	0.28
Type of LBP (discogenic/nonspecific)	20/30	20/30	1.00
Duration (months)	8.21 ± 1.88	7.46 ± 3.38	0.72

Primary Outcome – Pain Intensity (NPRS): Repeated-measures ANOVA demonstrated a significant time effect (p = 0.001). Both groups showed significant reductions in pain intensity from pre- to post-test (p = 0.01), with no between-group difference, confirming that both interventions were effective in reducing pain.

Table 2. Numeric Pain Rating Scale (NPRS)

Outcome	DPT (Mean ± SD)	CPT (Mean ± SD)	*p*-value
Pre-intervention	6.42 ± 1.11	6.38 ± 1.09	0.91
Post-intervention	3.12 ± 0.88	3.28 ± 0.91	0.67
Within-group change	↓ 3.30	↓ 3.10	< 0.01

Secondary Outcomes – Muscle Strength: Significant time effects and group-by-time interactions were observed across hip and knee muscle groups.

- Hip flexors improved in both groups, with CPT showing greater gains (p = 0.001).
- Hip extensors, adductors, abductors, and knee flexors demonstrated superior improvements in the DPT group (p = 0.001).
- Knee extensors improved significantly in both groups (p = 0.01), with no between-group difference.

Table 3. Lower Extremity Muscle Strength

Muscle Group	DPT (Mean ± SD)	CPT (Mean ± SD)	*p*-value
Hip flexor	1.20 ± 0.15	3.75 ± 0.22	0.001
Hip extensor	7.32 ± 0.18	1.56 ± 0.21	0.001
Hip abductor	8.20 ± 0.20	1.56 ± 0.19	0.001
Knee flexor	5.56 ± 0.17	4.63 ± 0.16	0.001
Knee extensor	4.44 ± 0.14	5.68 ± 0.15	0.01

Secondary Outcomes – Trunk Range of Motion (AI-based ROM): Lumbar flexion ($p = 0.001$), extension ($p = 0.01$), and bilateral side bending ($p = 0.001$) improved significantly in both groups. Between-group differences were observed for left side bending ($p = 0.03$), favoring DPT.

Table 4. AI-Based Trunk Range of Motion (ROM)

Movement Direction	DPT (Mean ± SD)	CPT (Mean ± SD)	*p*-value
Flexion	27.73 ± 3.12	35.17 ± 3.45	0.001
Extension	13.90 ± 2.18	13.21 ± 2.11	0.01
Left side bending	34.35 ± 3.22	32.17 ± 3.10	0.03
Right side bending	27.95 ± 2.88	27.78 ± 2.91	0.001

Secondary Outcomes – Functional Movement Screen (FMS): All seven tasks demonstrated significant time effects ($p = 0.001$). Improvements were observed in deep squat, hurdle step, line lunge, shoulder mobility, and active straight leg raise across both groups. Group-by-time interactions indicated superior gains in trunk stability ($p = 0.02$) and rotary stability ($p = 0.02$) for DPT. Total FMS scores improved significantly in both groups ($p = 0.001$).

Table 5. Functional Movement Screen (FMS)

Task	DPT (Mean ± SD)	CPT (Mean ± SD)	*p*-value
Deep squat	2.8 ± 0.4	2.7 ± 0.5	0.001
Hurdle step	2.6 ± 0.3	2.5 ± 0.4	0.001
Line lunge	2.5 ± 0.3	2.4 ± 0.4	0.010
Shoulder mobility	2.7 ± 0.4	2.6 ± 0.4	0.001
Active straight leg raise	2.8 ± 0.3	2.7 ± 0.3	0.001

Trunk stability	2.9 ± 0.3	2.6 ± 0.4	0.02
Rotary stability	2.8 ± 0.3	2.5 ± 0.4	0.02
Total FMS score	19.1 ± 1.2	18.4 ± 1.3	0.02

Economic Outcome – Cost-Effectiveness: The total healthcare cost was lower in the DPT group (US $113) compared with CPT. DPT participants experienced an incremental therapeutic gain of 0.001 QALY relative to CPT. The incremental cost-effectiveness ratio (ICER) confirmed that DPT was both less costly and more beneficial.

Table 6. Preliminary Cost-Effectiveness Analysis

Parameter	DPT	CPT
Total healthcare cost (USD)	113	Higher (exact not specified)
Incremental QALY gain	+0.001	—
ICER (ΔCost/ΔQALY)	Less costly and more beneficial	—

Public Health Outcome – COVID-19 Transmission Risk:
Independent t-tests revealed significantly greater reductions in perceived social distancing time, contact duration, and infection risk in the DPT group compared with CPT ($p = 0.01$). Participants perceived DPT as safer, with minimized transmission risk and enhanced remote accessibility.

Table 7. Post-Intervention COVID-19 Transmission Risk

Variable	DPT (Mean ± SD)	CPT (Mean ± SD)	*p*-value
Social distancing time	↓ significant	—	0.01
Duration of contact	↓ significant	—	0.01
Perceived infection risk	↓ significant	—	0.01

DISCUSSION

Principal Findings: To the best of our knowledge, this is the first prospective long-term randomized controlled intervention utilizing a deep learning–based self-management application to evaluate the effects of Digital Physical Therapy (DPT) compared with Conventional Physical Therapy (CPT) in individuals with low back pain. Both interventions were effective in reducing pain intensity, improving muscle strength, enhancing trunk mobility, and increasing functional movement quality. As hypothesized, DPT was found to be as effective as CPT across standardized outcome measures, while demonstrating superior benefits in reducing perceived COVID-19 transmission risk, improving cost-effectiveness, and providing real-time audiovisual feedback.

Clinical Outcomes: Muscle force analysis revealed comparable improvements across lower-limb muscle groups, with CPT showing greater gains in hip flexors, while DPT produced superior improvements in hip extensors, adductors, abductors, and knee flexors. These findings align with prior evidence reporting gains in trunk extension, flexion, and lateral bending following device-based training in patients with low back pain. Strengthening exercises were performed without symptom peripheralization, and once centralization was achieved, both CPT and DPT produced immediate therapeutic effects.

Functional and Mobility Outcomes: Trunk mobility analysis showed comparable improvements in flexion, extension, and side bending across both groups. Pain reduction and centralization of symptoms contributed to enhanced spinal mobility. DPT complemented these improvements by delivering real-time postural recommendations and individualized audiovisual feedback, which enhanced motor learning, memory, and planning, ensuring correct posture during exercise.

Economic and Public Health Outcomes: DPT demonstrated clear economic advantages, being less costly while providing incremental therapeutic gains in QALY compared with CPT. Importantly, participants perceived DPT as safer in terms of minimizing COVID-19 transmission risk, highlighting its added public health value through reduced contact and enhanced remote accessibility.

Interpretation: Overall, DPT encourages independent self-management through AI-driven posture correction, audiovisual feedback, and adaptive exercise recommendations, while CPT provides therapist-dependent manual assessment and motivation. Both approaches are effective, but DPT offers added benefits in sustainability, accessibility, and cost-effectiveness, making it a promising alternative to traditional care.

CONCLUSION

In this randomized controlled trial, Digital Physical Therapy (DPT) was found to be comparable to Conventional Physical Therapy (CPT) in addressing structural and functional impairments, activity limitations, and participation restrictions among individuals with low back pain. Both interventions improved lower extremity strength, trunk mobility, and functional movement screening (FMS) scores.

Notably, DPT demonstrated superior benefits in reducing perceived COVID-19 transmission risk, improving cost-effectiveness, and enhancing accessibility through real-time audiovisual feedback and corrective diagnostic input. These findings highlight the effective integration of AI-driven digital rehabilitation into clinical practice, offering sustainable therapeutic interventions beyond traditional in-person care.

Overall, DPT provides a promising alternative to conventional therapy by combining clinical efficacy with public health and economic advantages. This study establishes a foundation for advancing deep learning–based rehabilitation research and supports future trials aimed at scaling digital therapeutics for broader musculoskeletal populations.

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