A Randomized Controlled Trial for a Novel Digital Therapeutic for Treatment of Patellofemoral Pain, a Dilemma in Orthopedics.

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INTRODUCTION: Patellofemoral pain (PFP) is a common disease that causes functional impairments and psychological distress, mainly in younger patients. Most patients visit an orthopedic surgeon for treatment, but surgical treatment for this disease is known to be ineffective or may even worsen symptoms, so nonsurgical treatment is recommended. However, comprehensive nonsurgical care is limited by accessibility, cost, and time barriers. This study aimed to evaluate the efficacy of a mobile app–based digital therapeutic (DT) that integrates exercise therapy and cognitive-behavioral therapy (CBT) for PFP.

METHODS: A total of 216 participants who had chronic PFP (≥3 months) with no or minimal radiographic knee osteoarthritis were enrolled in a randomized controlled trial and assigned 1:1 to either the DT group or control group. The DT group received an 8-week program via mobile app combining personalized exercise therapy and CBT modules, followed by a 4-week observation period. The control group received one face-to-face exercise education session, standardized educational materials, and daily logs for self-directed exercises. Assessments were conducted at baseline and at 4, 8, and 12 weeks after intervention. At each period, we assessed usual and worst pain (visual analogue scale, 0–100), functional disability (Anterior Knee Pain Scale; AKPS), quality of life (EQ-5D-5L), pain catastrophizing (Pain Catastrophizing Scale; PCS), and depressive symptoms (Patient Health Questionnaire-9). All randomized participants were included in the intention-to-treat (ITT) population. One participant with no outcome data was excluded from efficacy analyses. Missing values were imputed using the last observation carried forward method, and primary analyses were conducted using a modified ITT dataset including participants with at least one outcome assessment.

RESULTS: There were no statistically significant differences in baseline characteristics, including age, sex, body mass index (BMI), and pain score, between the two groups. At both week 8 and week 12, the DT group showed significantly greater reductions in usual pain ($p < 0.001$ for both) and worst pain ($p = 0.008$ and $p < 0.001$, respectively) (Table 1). Functional outcomes (AKPS) and quality of life (EQ-5D-5L) also improved significantly more in the DT group at both time points (all $p < 0.01$). PCS was significantly lower in the DT group at week 12 ($p = 0.016$). Exercise adherence during the 8-week intervention was higher in the DT group (80.9%) than in the control group (71.3%). CBT adherence in the DT group was 74.6%, reflecting strong engagement with both physical and psychological components of the DT. Figure 1 presents longitudinal changes in clinical outcomes.

DISCUSSION AND CONCLUSION:

This novel mobile app–based DT combining exercise and CBT resulted in significantly greater improvements in pain, function, and psychological outcomes compared to usual care. High adherence supports the feasibility and acceptability of this DT for PFP with potential for broad clinical application for a variety of patients with PFP-type symptoms.

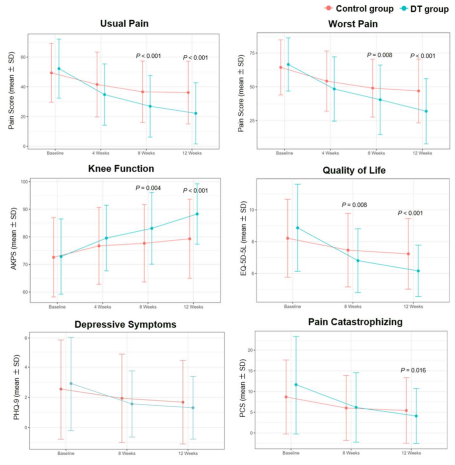

Figure 1. Longitudinal Changes in Clinical Outcomes Between Groups
Values are presented as mean ± standard deviation, with error bars representing standard deviation. AKPS = Anterior Knee Pain Scale; PHQ-9 = Patient Health Questionnaire-9; PCS = Pain Catastrophizing Scale. Only statistically significant p-values are shown.

Table 1. Changes in Clinical Outcomes Over Time

Variable	Timepoint	DT Group (n = 107)	Control Group (n = 108)	p-value
Usual Pain (VAS 0–100)	Baseline	52.3 ± 19.9	49.4 ± 19.8	0.290
	4 weeks	34.8 ± 20.6	41.6 ± 21.9	0.026
	8 weeks	26.9 ± 20.8	36.7 ± 20.7	<0.001[1]
	12 weeks	22.2 ± 20.6	31.2 ± 21.1	<0.001[1]
Worst Pain (VAS 0–100)	Baseline	66.6 ± 19.7	64.4 ± 20.4	0.384
	4 weeks	48.4 ± 23.8	54.3 ± 22.0	0.068
	8 weeks	40.5 ± 25.7	49.1 ± 21.5	0.008[1]
	12 weeks	31.9 ± 24.2	47.0 ± 21.5	<0.001[1]
Knee Function (AKPS)	Baseline	72.9 ± 13.6	72.6 ± 14.4	0.810
	4 weeks	79.6 ± 11.9	76.7 ± 13.9	0.271
	8 weeks	83.1 ± 13.0	77.7 ± 14.0	0.004[1]
	12 weeks	88.3 ± 10.9	79.3 ± 14.4	<0.001[1]
Quality of Life (EQ-5D-5L)	Baseline	8.9 ± 2.7	8.2 ± 2.5	0.055
	8 weeks	6.8 ± 2.0	7.5 ± 2.3	0.008[1]
	12 weeks	6.2 ± 1.6	7.2 ± 2.2	<0.001[1]
Depressive Symptoms (PHQ-9)	Baseline	2.9 ± 3.1	2.6 ± 3.3	0.182
	8 weeks	1.6 ± 2.2	1.9 ± 2.9	0.830
	12 weeks	1.3 ± 2.1	1.7 ± 2.8	0.581
Pain Catastrophizing (PCS)	Baseline	11.7 ± 11.9	8.7 ± 8.9	0.164
	8 weeks	6.2 ± 8.4	6.0 ± 7.9	0.374
	12 weeks	4.1 ± 6.6	5.4 ± 7.9	0.016[1]

DT, digital therapeutic; AKPS, Anterior Knee Pain Scale; EQ-5D-5L, EuroQol 5-Dimension 5-Level scale; PHQ-9, Patient Health Questionnaire-9; PCS, Pain Catastrophizing Scale. Values are presented as mean ± standard deviation. Between-group differences at each timepoint were analyzed using independent t-tests when data satisfied normality assumptions, and Mann–Whitney U tests otherwise. Statistical significance was determined using the Bonferroni correction.
[1]Statistically significant p-value after Bonferroni correction.