From Clinic to Smartphone: A Randomized Controlled Trial of a Novel Digital Therapeutics for Patellofemoral Pain Integrating Exercise and Cognitive-Behavioral Therapy

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Faculty Disclosure Information

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- Authors Chan Yoon and Sanghee Lee are affiliated with EverEx.

Introduction

- **Challenges in Management of Patellofemoral Pain (PFP)**
  - Poor adherence to standard exercise therapy due to lack of continuous monitoring and personalized guidance.
  - Psychological factors often neglected despite their impact on recovery.
  - Limited access due to barriers such as time, cost, and geographic distance.

- **Need for a Comprehensive Approach**
  - Integrating Cognitive-Behavioral Therapy (CBT) with exercise therapy can address both physical and psychological factors.
  - Although CBT is effective for chronic pain, its application in PFP remains underexplored.

- **Opportunity for Digital Therapeutics (DTx)**
  - Mobile platforms can enhance accessibility, adherence, and engagement by providing tailored, scalable interventions.

Purpose

- To evaluate the effectiveness and safety of a novel digital therapeutic (MORA Cure PFP) integrating exercise therapy and Cognitive-Behavioral Therapy (CBT) for managing PFP.

- Comparative assessment with a control group receiving usual care to determine pain reduction, knee function improvement, and psychological outcomes.

Methods

- **Study Design**
  - Randomized Controlled Trial (RCT) comparing a with two parallel groups: Digital Therapeutic Group (DTx Group) vs. Control Group
  - Duration: 12 weeks (8 weeks intervention → 4 weeks observation)
  - Assessments at 4, 8, and 12 weeks to evaluate intervention efficacy and sustainability

- **Participants**
  - **Inclusion criteria**
    - Chronic PFP: pain lasting ≥3 months around or behind the patella.
    - Pain triggered by squatting and at least two of the following: prolonged sitting, cycling, running, stairs, kneeling, compression test, palpation tenderness
  - **Exclusion criteria**
    - Osteoarthritis exceeding K-L grade 2, recent knee injury or surgery (within 3 months), patellar tendinitis diagnosed by imaging, use of narcotic pain medications, pregnancy, etc.

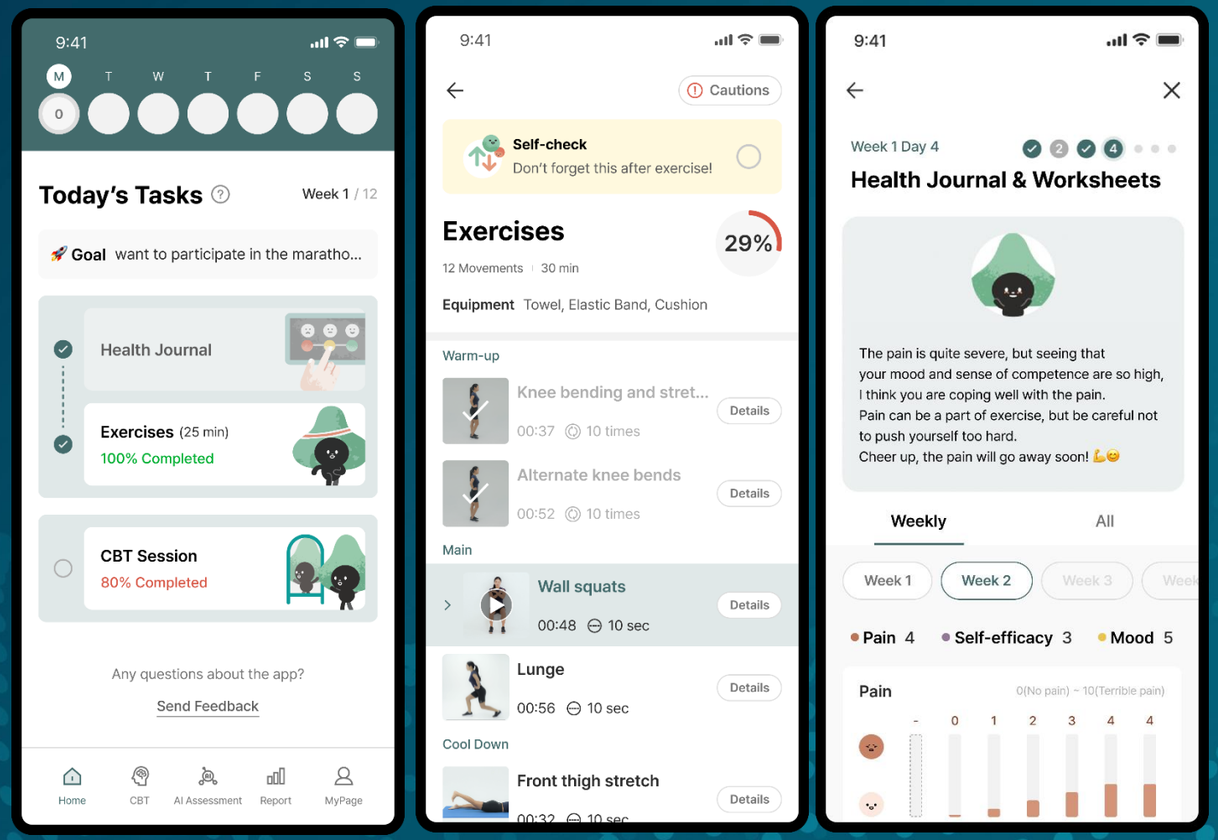
- **Statistics**
  - Between-group comparisons at baseline and follow-up time points were conducted using Student's t-test or Mann–Whitney U test, with Bonferroni correction applied for multiple comparisons.

Intervention

- **DT group**
  - **MORA Cure (PFP)**: 8-week digital therapy combining exercise therapy & CBT.
  - **Personalized & auto-adjusted plans**: customized exercise programs that adapt based on progress.
  - **Daily Progress Tracking**: monitored through app usage and feedback.

- **Control group**
  - **Single in-person education session**: at least 15 minutes of face-to-face exercise education provided by healthcare professionals.
  - **Standardized education materials**: instructional materials for self-directed exercise.
  - **Manual exercise logging**: daily exercise recorded manually in diaries.

MORA Cure (PFP)



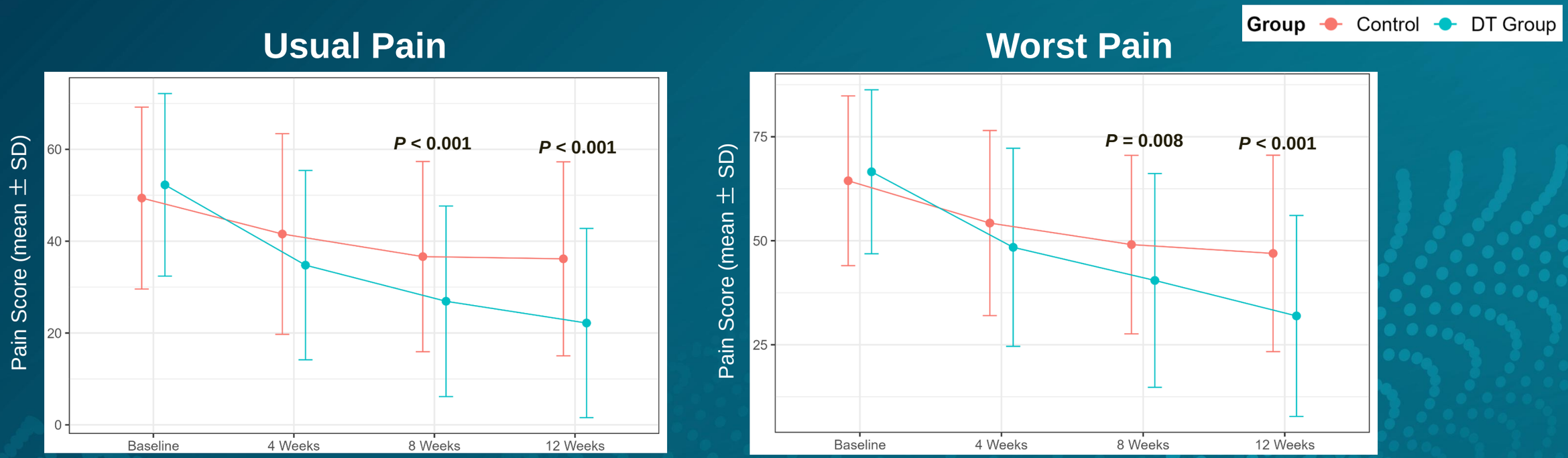
- **Exercise**
  - Hip, knee, and core strengthening & stretching exercises
  - Progressive overload: gradually increased intensity based on progress
  - Encouraged to maintain exercises for an additional 4 weeks post-intervention
- **CBT**
  - One session per week, with daily worksheets for self-monitoring
  - Contents included: understanding the nature of pain, developing pain coping strategies, identifying and correcting cognitive errors related to pain.

Baseline Characteristics of Study Participants

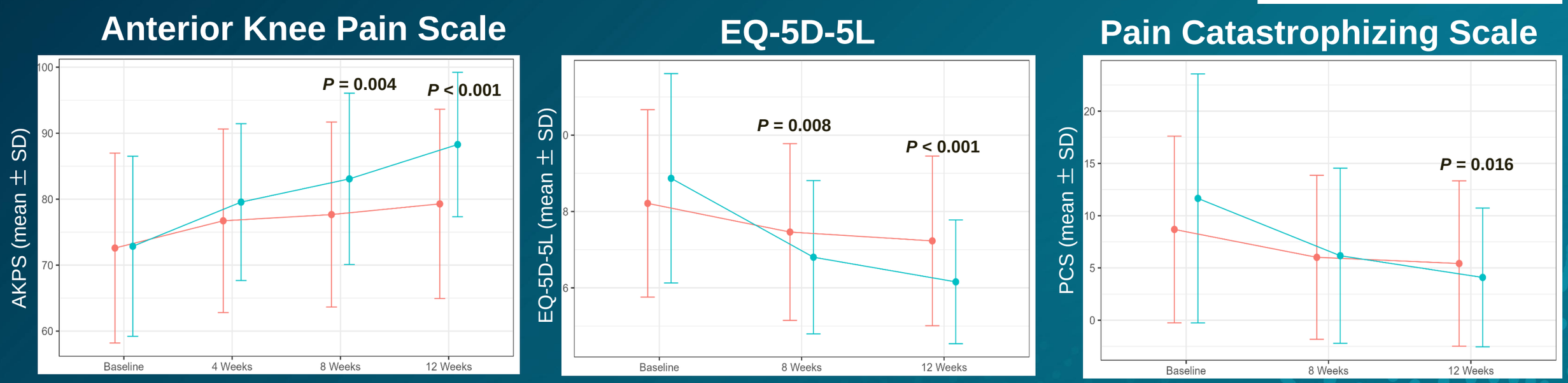
Variables	DT group (n = 107)	Control group (n = 108)	P-value
Age (years)	38.5 ± 10.5	39.8 ± 9.7	0.352
Female (n, %)	67 (62.6%)	78 (72.2%)	0.175
Body Mass Index (kg/m^2)	22.7 ± 3.0	23.3 ± 3.8	0.432
Usual pain	52.3 ± 19.9	49.4 ± 19.8	0.290
Worst pain	66.6 ± 19.7	64.4 ± 20.4	0.384
Anterior knee pain scale (AKPS)	72.9 ± 13.6	72.6 ± 14.4	0.810
EQ-5D-5L	8.9 ± 2.7	8.2 ± 2.5	0.055
Patient Health Questionnaire-9 (PHQ-9)	2.9 ± 3.1	2.6 ± 3.3	0.182
Pain catastrophizing scale (PCS)	11.7 ± 11.9	8.7 ± 8.9	0.164

Values are mean ± standard deviation.
P-values were calculated using t test or Mann-Whitney U test.
(For sex variable, Chi-square test was used)
Usual pain and worst pain were measured using a 100-point Visual Analog Scale (VAS).

Primary and Secondary Outcomes over Time



- The DT group showed significantly greater improvements in usual pain and worst pain at 8 and 12 weeks.



- Functional disability (AKPS) and quality of life (EQ-5D) showed significant improvement in the DT group compared to the control group at both 8 and 12 weeks.
- Pain catastrophizing (PCS) also demonstrated significant improvement in the DT group at 12 weeks.

- **Adherence Rates (Over 8 weeks)**
  - **Exercise: DT group (80.5%) > Control group (70.7%); p < 0.001**
  - **CBT (DT group only): 82.7%**

  → Indicates strong engagement with both the physical and psychological components of the digital intervention.

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Discussion

- **MORA Cure (PFP) significantly improved pain, knee function, quality of life, and cognitive distortion compared to usual care in patients with PFP.**

- Findings suggest that the inclusion of CBT in the treatment regimen may enhance outcomes by addressing pain-related psychological distress, which has often been overlooked in standard PFP management.

- The observed improvements in functional disability and quality of life emphasize the importance of a holistic, biopsychosocial approach in PFP management.

- High adherence rates further support the feasibility and acceptability of digital therapeutics for PFP.

Discussion

- **Strengths**
  - Large sample size with balanced randomization
  - Potentially scalable intervention model applicable to a wide range of clinical settings, including remote and underserved populations

- **Limitations**
  - **Preliminary Data Analysis**
    Although data collection for all participants has been completed, this analysis was performed prior to the final database lock to meet the ePoster submission deadline. Therefore, the findings presented here are based on an interim dataset and may be subject to minor changes upon final database lock.
  - Limited follow-up duration (12 weeks) may not fully capture long-term efficacy or adherence.

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