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Digital therapeutic combining exercise and cognitive–behavioural therapy reduces pain in patients with chronic patellofemoral pain: a multicentre randomised controlled trial

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ABSTRACT

Objectives To evaluate whether an 8-week smartphone-based multidisciplinary digital therapeutic (DTx) combining exercise and cognitive–behavioural therapy reduced usual knee pain at 8 weeks compared with education and exercise instruction in chronic patellofemoral pain (PFP).

Methods This multicentre, parallel-group randomised controlled trial included 216 participants with chronic PFP, defined as anterior or retropatellar pain lasting at least 3 months with activity-related provocation, recruited from orthopaedic outpatient clinics at 10 hospitals in the Republic of Korea. Participants were randomly assigned to the DTx group (MORA Cure PFP) or a control group receiving PFP-related education, one-time exercise instruction, printed materials and self-monitoring exercise diaries. The DTx intervention included personalised home-based exercises, weekly cognitive–behavioural sessions and self-reflective daily worksheets. Outcomes were assessed at baseline, 4, 8 and 12 weeks. The primary endpoint was usual pain at 8 weeks, measured using a 0–100 mm visual analogue scale (VAS). Secondary outcomes included worst pain, knee function (Anterior Knee Pain Scale; AKPS), health-related quality of life assessed using the 5-level EQ-5D version (EQ-5D-5L) and the EQ visual analogue scale (EQ VAS), and psychological distress (Patient Health Questionnaire-9 and Pain Catastrophizing Scale (PCS)). Longitudinal changes were analysed using linear mixed-effects models.

Results For the primary endpoint, usual pain at week 8 favoured the DTx group (between-group mean difference −12.5 mm, 95% CI −17.1 to −7.8). Secondary outcomes at week 8 also favoured the DTx group, including worst pain (−10.7 mm, 95% CI −15.9 to −5.4), knee function (AKPS, 5.2 points, 95% CI 2.7 to 7.7), health-related quality of life (EQ VAS 10.7 points, 95% CI 7.1 to 14.4) and pain catastrophising (PCS, −1.8 points, 95% CI −3.3 to −0.3). Exercise adherence exceeded 80%, with no device-related or intervention-related serious adverse events reported.

Conclusion An 8-week smartphone-based multidisciplinary DTx programme reduced usual pain at 8 weeks compared with education and exercise instruction in patients with chronic PFP, with improvements in pain, knee function, health-related quality of life and psychological outcomes. These findings support the potential role of an integrated DTx package for delivering exercise and cognitive–behavioural support in PFP care.

Trial registration number NCT06260865.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Exercise therapy is the first-line treatment for patellofemoral pain (PFP); however, outcomes are often limited by poor adherence and unaddressed psychosocial factors. Although cognitive–behavioural therapy (CBT) has shown benefits for other chronic pain conditions, its integration into PFP care has been minimal.

WHAT THIS STUDY ADDS

⇒ To our knowledge, this is the first adequately powered randomised controlled trial to show that a smartphone-based multidisciplinary intervention combining personalised exercise and CBT significantly improves pain, function, quality of life and psychological well-being in PFP.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Delivering high-quality exercise instructions and psychological support typically requires sustained clinician involvement and considerable healthcare resources, which can limit accessibility and scalability. This study demonstrates that digitising these components enables broader, cost-efficient delivery of multidisciplinary care aligned with clinical guidelines for PFP.

INTRODUCTION

Patellofemoral pain (PFP) is a prevalent musculoskeletal condition affecting nearly one in four individuals annually.[1] Symptoms often persist despite the absence of structural pathology, limiting daily and athletic activities. Left-unaddressed, chronic PFP may increase the risk of osteoarthritis, underscoring the need for proactive management.[2–4] Clinical guidelines recommend exercise therapy, particularly targeting hip and knee strength and

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flexibility, as the primary conservative approach.[5 6] However, adherence is often inconsistent and long-term outcomes remain suboptimal, with only a few achieving long-term improvements from standard exercise therapy alone.[7 8] This raises important questions about how to better support adherence and engagement. Emerging evidence suggests that psychosocial factors, such as fear, catastrophising and depressive symptoms, influence pain perception and recovery in PFP.[9–12] This has led to growing interest in incorporating cognitive–behavioural therapy (CBT) into PFP treatment, given its well-established effectiveness in managing chronic pain conditions such as low back pain.[13 14] CBT addresses both cognitive distortions and behavioural factors such as catastrophic thinking about pain and fear-avoidant behaviour, which can interfere with rehabilitation adherence and recovery in PFP.[10 15–17] To our knowledge, its application in PFP care remains limited.

Digital therapeutics (DTx), delivered through mobile applications, offer a promising platform to combine physical and psychological rehabilitation. These tools can provide tailored exercise programmes, education and CBT-based strategies at home, extending support beyond clinical visits. Early findings from other conditions, such as chronic low back pain and shoulder disorders, suggest that multidisciplinary digital care may enhance adherence and outcomes compared with standard physiotherapy.[18–20] However, digital interventions for PFP have yet to combine exercise and cognitive–behavioural strategies in a single multidisciplinary approach. A recent randomised controlled trial (RCT) showed that a digital exercise programme improved pain and function in patients with anterior knee pain, but it did not include psychological support or report adherence.[21]

Building on our preceding exploratory study,[22] we conducted an adequately powered, multicentre RCT to evaluate whether an 8-week multidisciplinary DTx programme combining structured exercise with CBT-informed content would reduce usual pain at 8 weeks, as the primary endpoint, compared with education and exercise instruction in patients with chronic PFP.

METHODS

Study design and randomisation

This multicentre, parallel-group RCT was conducted to evaluate the efficacy of the multidisciplinary DTx programme MORA Cure PFP (EverEx, Seoul, Republic of Korea) in individuals with PFP. This trial was conducted across 10 secondary and tertiary hospitals in South Korea between April 2024 and March 2025. The protocol and statistical analysis plan were finalised before recruitment and registered at ClinicalTrials.gov (NCT06260865).[23]

Participants were recruited from orthopaedic clinics and randomly assigned in a 1:1 ratio to either the DTx or control group. Computer-generated block randomisation was performed by an independent third party. The randomisation list was embedded in the interactive web response system, and the block size was not disclosed to investigators or study personnel to preserve allocation concealment. Outcome assessors were blinded to group allocation.

Study participants

Eligible participants had PFP in at least one knee, with anterior or retropatellar pain lasting 3 months or more. Participants were required to report pain during squatting and in at least two of the following activities: prolonged sitting, cycling, running, stair climbing, kneeling, patellar compression or facet palpation. All participants provided written informed consent before enrolment.

Knee radiographs were obtained at screening unless radiographs obtained within the preceding 3 months were available for review. Kellgren-Lawrence grade was assessed by the designated orthopaedic investigator at each site. Participants with radiographic osteoarthritis exceeding Kellgren-Lawrence grade 2 were excluded. Other exclusion criteria included recent fracture or dislocation, knee surgery, imaging-confirmed patellar tendinopathy within 3 months, current use of narcotic analgesics, anticipated use of restricted treatments during the study period, pregnancy and recent participation in another clinical trial.

Concurrent treatments for knee pain, such as intra-articular injections, surgery or use of narcotic analgesics, were not permitted during the study. Acetaminophen (650 mg) was permitted as a rescue medication in cases of significant pain, based on investigator judgement. Participants currently using analgesics were encouraged to switch but could continue if deemed necessary. Participants were instructed to avoid analgesics within 24 hours of each visit, when feasible.

Intervention

A Template for Intervention Description and Replication (TIDieR)-informed description of the DTx and control interventions is available in online supplemental table 1. Participants in the DTx group received an 8-week multidisciplinary intervention via the MORA Cure PFP application (figure 1), combining personalised exercises and digital CBT. Exercises targeted both hip and knee muscles through strengthening and stretching, following clinical practice guidelines for PFP.[6 24] At baseline, each participant underwent a functional movement assessment using video-based pose estimation (eg, squat and single-leg squat) and completed the Anterior Knee Pain Scale (AKPS). These baseline data were used by an app-embedded algorithm to assign the initial exercise level. Thereafter, exercise difficulty was adjusted after each exercise session according to participant-reported pain and perceived exertion using the Borg Rating of Perceived Exertion. Exercises were progressed or regressed to maintain an appropriate therapeutic challenge while avoiding symptom aggravation. Participants were instructed to complete daily therapeutic exercise sessions of approximately 30 min.

The CBT component consisted of eight standardised weekly digital sessions that addressed core psychological aspects associated with musculoskeletal pain (figure 2). Topics included motivational enhancement, psychoeducation, emotional awareness, behavioural activation, activity pacing, cognitive restructuring and goal setting with problem-solving. Although the weekly CBT-informed sessions were not individually modified, the daily worksheets supported individualised reflection on pain perception, emotional states and perceived self-efficacy, reinforcing CBT-informed strategies in everyday life.

After the 8-week treatment period, participants in the DTx group retained access to the exercise modules through the MORA Cure PFP application and were encouraged to maintain their exercise routines during the 4-week follow-up period (weeks 9–12). While the weekly CBT sessions were completed by week 8, the daily worksheet feature remained accessible throughout the follow-up period to

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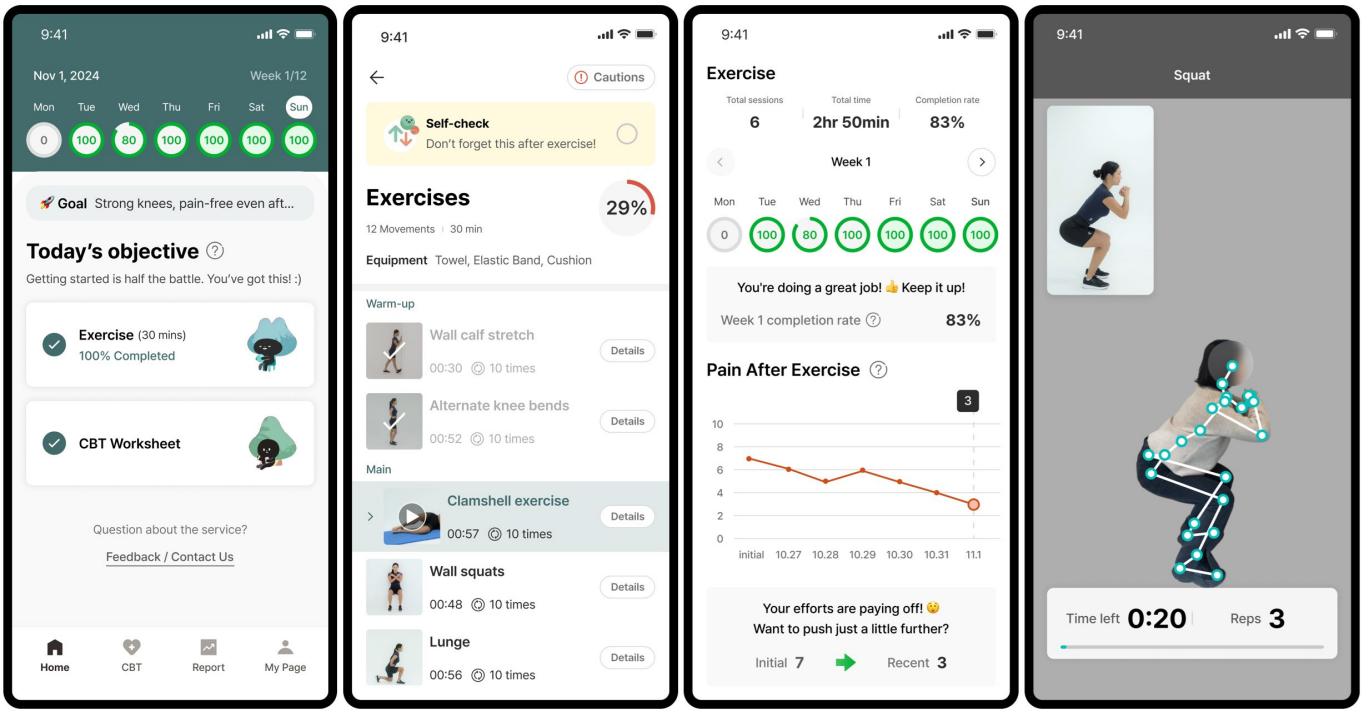


Figure 1 Overview of the MORA Cure programme for patellofemoral pain. CBT, cognitive–behavioural therapy.

enable continued self-monitoring and reinforcement of CBT strategies.

The control group received standardised non-digital education and exercise instruction. This included PFP-related education, self-care guidance and a one-time in-person exercise instruction session of at least 15 min provided by a healthcare professional experienced in musculoskeletal disease treatment. Participants also received printed educational and exercise materials, including a predefined staged progression of recommended home exercises and were encouraged to perform the exercises independently at home and record their exercise duration in a daily exercise log.

Outcome measures

Outcome measures were assessed at predefined time points. The primary endpoint was usual pain at week 8, defined as the participant's usual pain intensity during the past week, measured using

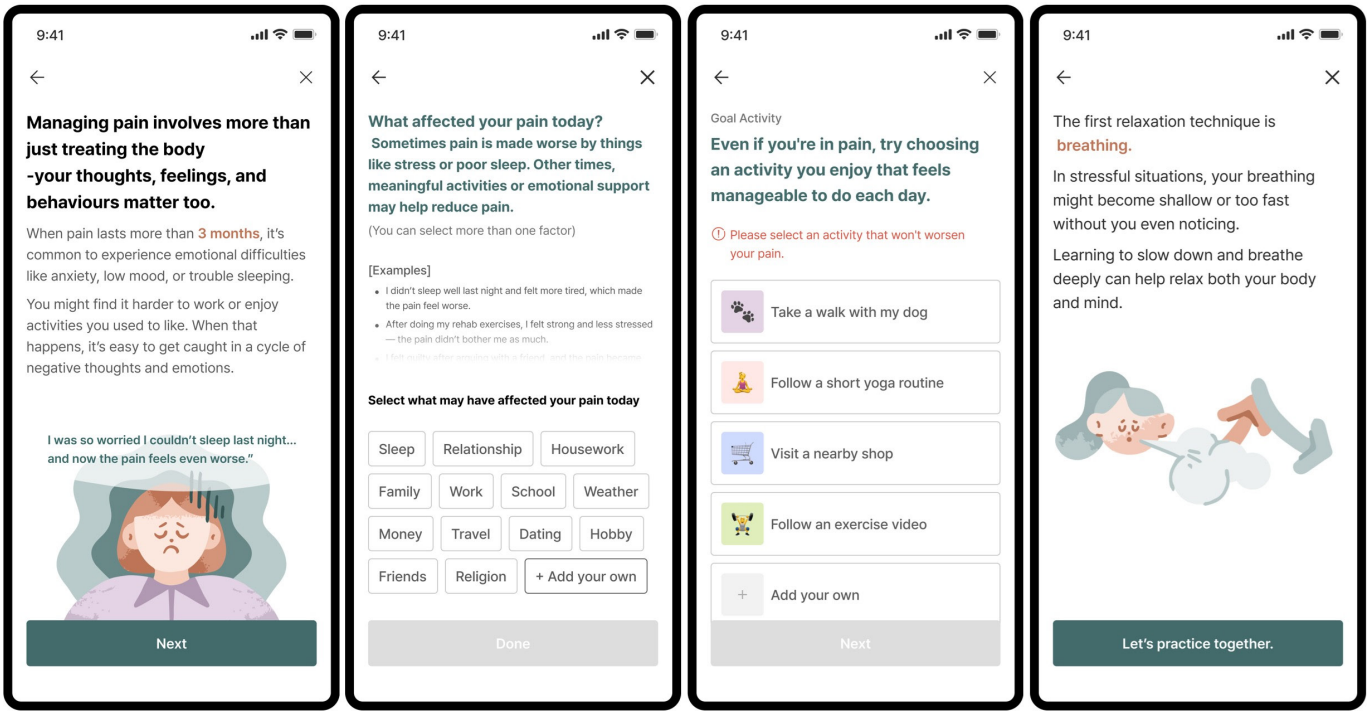


Figure 2 Overview of the digital cognitive–behavioural therapy sessions in the MORA Cure programme for patellofemoral pain.

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a 0–100 mm visual analogue scale (VAS), with higher scores indicating greater pain. Usual pain was also assessed at baseline, week 4 and week 12 as secondary time-point assessments. For interpretation, the previously reported SE of measurement (SEM) for VAS pain in individuals with PFP is 6 mm, and the minimal clinically important difference (MCID) is 20 mm.[25]

Secondary outcomes included worst pain, knee function, health-related quality of life and psychological outcomes. Worst pain was defined as the participant's worst knee pain intensity during the past week and was measured using a 0–100 mm VAS. Knee function was assessed using the AKPS, also known as the Kujala Score, a 13-item questionnaire assessing symptoms and functional limitations in patellofemoral disorders.[26] The AKPS ranges from 0 to 100, with higher scores indicating better knee function. For the AKPS, the previously reported SEM is 3.1 points and the MCID is 10 points.[25] Usual pain, worst pain and AKPS were collected at baseline, 4 weeks, 8 weeks and 12 weeks.

Health-related quality of life was evaluated using the5-level EQ-5D version (EQ-5D-5L) and the EQ visual analogue scale (EQ VAS). EQ-5D-5L index values were calculated using the Korean value set and range from −0.066 to 1, with higher values indicating better health-related quality of life.[27] EQ VAS ranges from 0 to 100, with higher scores indicating better perceived health. Psychological outcomes included the Pain Catastrophizing Scale (PCS), which ranges from 0 to 52, with higher scores indicating greater pain catastrophising, and the Patient Health Questionnaire-9 (PHQ-9), which ranges from 0 to 27, with higher scores indicating more severe depressive symptoms. Health-related quality of life and psychological outcomes were measured at baseline, 8 weeks and 12 weeks.

Baseline demographic data, including age, sex, height and weight, were also obtained. Outcome assessments were conducted in person at baseline, 8 and 12 weeks; week 4 assessments were conducted by phone.

Compliance and safety monitoring

Treatment compliance was assessed over the 8-week intervention period. In the DTx group, exercise performance was automatically recorded by the application. Two adherence metrics were calculated: the first was proportional adherence, defined as the percentage of days the prescribed exercise was completed out of 7 days each week, and the second was threshold-based weekly adherence, defined as 100% adherence for any week in which exercises were performed on at least 3 days. The 3-day-per-week criterion is consistent with a frequency commonly used in exercise interventions for PFP and with the WHO-recommended frequency of muscle-strengthening activities in adults (2 or more days per week).[28 29]

In the control group, exercise adherence was assessed using participant-completed paper exercise diaries, which were reviewed at follow-up visits. Weekly exercise time was calculated from the recorded exercise duration and compared with the target exercise time specified in the educational and exercise materials provided.

CBT adherence in the DTx group was assessed by completion rates of weekly sessions and daily worksheets, allowing evaluation of engagement with both structured therapy and daily self-directed practice.

Safety monitoring was conducted throughout the 12-week study period. At each study visit, participants were systematically asked about any new or worsening symptoms that could be related to the intervention and were encouraged to report any adverse events through the application or by contacting the study coordinator directly.

Sample size

The sample size was determined based on a previous exploratory RCT on the effects of DTx.[22] In that study, mean pain intensity during the past week at week 8, measured using the Numeric Pain Rating Scale (NPRS; 0–10), was 2.31 (SD 1.49) in the intervention group and 3.18 (SD 2.43) in the control group, corresponding to an estimated effect size (Cohen's d) of 0.428. Because the exploratory trial used an NPRS and the present trial used a 0–100 mm VAS for the primary pain endpoint, the sample size calculation was based on the standardised effect size rather than the raw mean difference, as both instruments assessed the same construct of pain intensity over the previous week. Using a two-sided significance level of 0.05 and a statistical power of 80%, the required sample size was calculated to be 86 participants per group. Allowing for an anticipated dropout rate of 20%, the final target sample size was set at 108 participants per group, resulting in a total of 216 participants.

Statistical analysis

Baseline characteristics were summarised using means and SD for continuous variables and proportions for categorical variables. Longitudinal outcomes were analysed using linear mixed-effects models for repeated measures (MMRM). Fixed effects included group, time (treated as a categorical variable) and their interaction, with each baseline outcome value included as a covariate. An autoregressive covariance structure was applied to account for within-subject correlations over time, and model parameters were estimated using restricted maximum likelihood. MMRM analyses were performed using the *nlme* and *emmeans* packages in R (V.4.4.2).

All analyses were performed in a modified intention-to-treat (mITT) population, which included all randomised participants with available baseline data for each outcome. One participant was excluded from all the analyses owing to missing baseline data. Missing follow-up data were assumed to be missing at random and handled within the MMRM framework without imputation. Statistical significance was set at $p<0.05$.

Equality, diversity and inclusion

This multicentre RCT was conducted across 10 secondary and tertiary hospitals in the Republic of Korea, with broad eligibility criteria to support inclusion of individuals with diverse ages, genders and clinical presentations. The intervention was delivered via a mobile application, improving accessibility regardless of geographical or socio-economic context. The author team includes senior and early career researchers from diverse medical specialties, including orthopaedics, psychiatry and rehabilitation medicine. This multidisciplinary approach ensures a comprehensive and well-rounded perspective on the research.

RESULTS

Study participants

In total, 216 participants were randomised equally to the control and DTx groups (figure 3). One participant in the DTx group did not initiate the intervention, resulting in 107 who received the MORA Cure PFP intervention.

Study discontinuation occurred in 11 participants in the DTx group and 18 participants in the control group, and the study was completed by 97 and 90 participants, respectively. Reasons for study discontinuation and loss to follow-up are shown in

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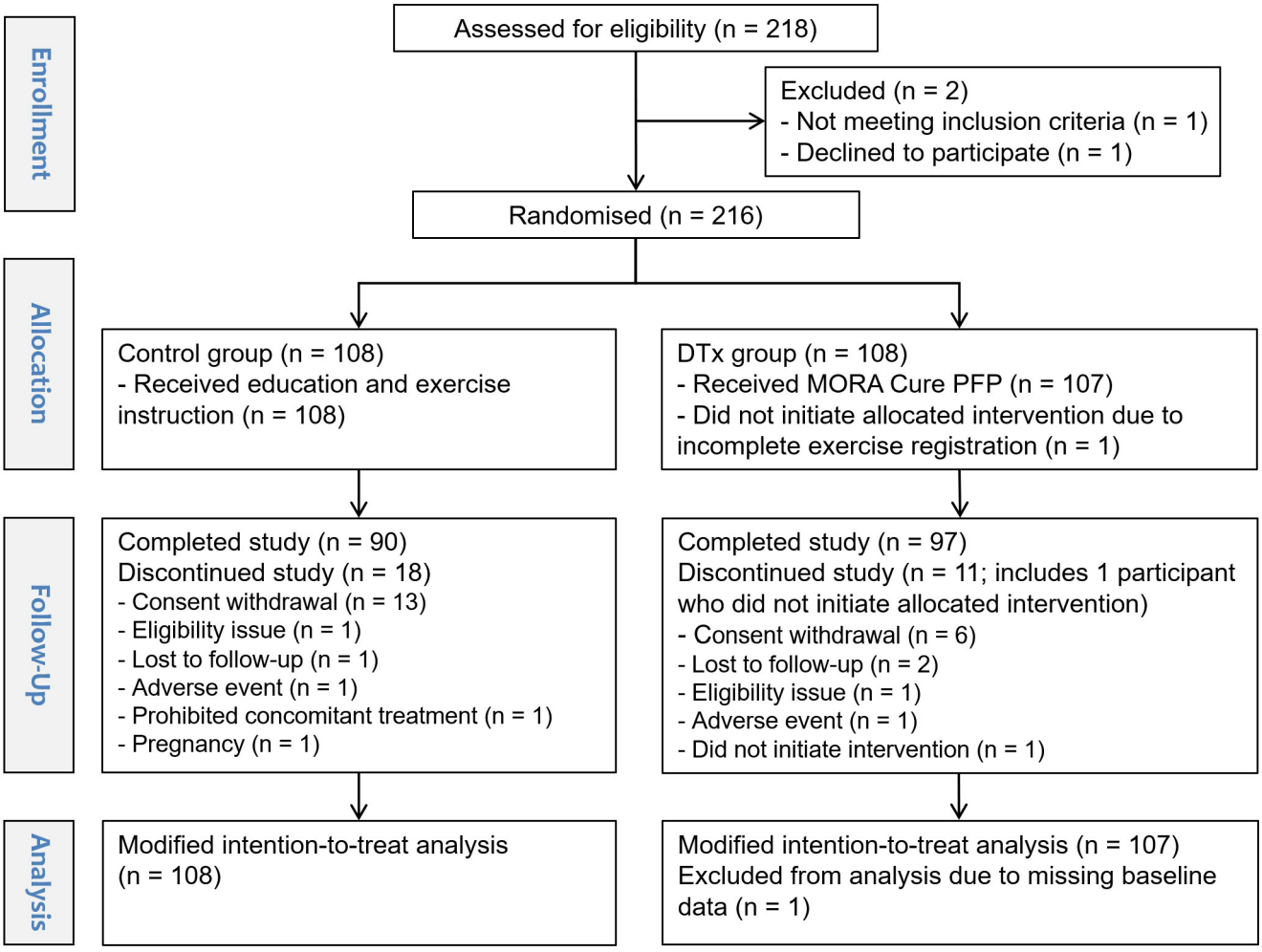


Figure 3 CONSORT diagram of participant flow. CONSORT, Consolidated Standards of Reporting Trials; DTx, digital therapeutics; PFP, patellofemoral pain.

figure 3. After excluding one participant in the DTx group owing to missing baseline data, the mITT analysis included 107 participants in the DTx group and 108 participants in the control group.

Baseline demographic and clinical characteristics are summarised in table 1. The mean age was 38.5±10.5 years in the DTx group and 39.8±9.7 years in the control group. The proportions of female participants in the DTx and control groups were 62.6% and 72.2%, respectively. Body mass index, pain intensity, functional status and psychological measures were generally similar between groups.

Table 1 Baseline characteristics of study participants

Variable	DTx group (n=107)	Control group (n=108)
Age (years)	38.5±10.5	39.8±9.7
Female (n, %)	67 (62.6)	78 (72.2)
BMI (kg/m^2)	22.7±3.0	23.3±3.8
Usual pain	52.3±19.9	49.4±19.8
Worst pain	66.6±19.7	64.4±20.4
AKPS	72.9±13.6	72.6±14.4
EQ-5D-5L index	0.8±0.1	0.8±0.1
EQ VAS	71.3±16.5	72.1±16.0
PHQ-9	2.9±3.1	2.5±3.3
PCS	11.5±11.9	8.7±8.9

AKPS, Anterior Knee Pain Scale; BMI, body mass index; DTx, digital therapeutics; EQ-5D-5L, 5-level EQ-5D version; EQ VAS, EQ visual analogue scale; PCS, Pain Catastrophizing Scale; PHQ-9, Patient Health Questionnaire-9.

Outcome measures

Table 2 summarises the least-squares mean estimates and between-group differences for the primary and secondary outcomes over 12 weeks, and figure 4 shows the corresponding outcome trajectories.

For the primary endpoint, usual pain at week 8 was lower in the DTx group than in the control group, with a between-group mean difference of −12.5 mm (95% CI −17.1 to −7.8). The between-group difference in usual pain was already evident at week 4 (−9.0 mm, 95% CI −13.6 to −4.5) and increased by week 12 (−16.0 mm, 95% CI −20.7 to −11.4).

Secondary pain and functional outcomes also favoured the DTx group. At week 8, the between-group difference was −10.7 mm for worst pain (95% CI −15.9 to −5.4) and 5.2 points for AKPS (95% CI 2.7 to 7.7). These differences increased by week 12, reaching −16.7 mm for worst pain (95% CI −21.9 to −11.5) and 8.7 points for AKPS (95% CI 6.2 to 11.2).

Health-related quality of life and psychological outcomes were also better in the DTx group at week 8. The between-group difference was 0.06 for the EQ-5D-5L index (95% CI 0.04 to 0.08), 10.7 points for EQ VAS (95% CI 7.1 to 14.4), −1.8 points for PCS (95% CI −3.3 to −0.3), and −0.6 points for PHQ-9 (95% CI −1.1 to 0.0).

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Table 2 LS means and between-group differences for the primary endpoint and secondary outcomes

Outcome	Time point	DTx LS mean (SE)	Control LS mean (SE)	Δ (95% CI)	P value
Usual pain	Baseline	51.5 (1.6)	50.3 (1.6)	1.2 (−3.3 to 5.6)	0.601
	Week 4	33.1 (1.6)	42.1 (1.6)	−9.0 (−13.6 to −4.5)	<0.001
	Week 8*	23.9 (1.7)	36.4 (1.7)	−12.5 (−17.1 to −7.8)	<0.001
	Week 12	19.3 (1.6)	35.3 (1.7)	−16.0 (−20.7 to −11.4)	<0.001
Worst pain	Baseline	65.9 (1.8)	65.1 (1.8)	0.8 (−4.1 to 5.8)	0.742
	Week 4	46.8 (1.8)	54.4 (1.8)	−7.6 (−12.7 to −2.5)	0.004
	Week 8	37.6 (1.8)	48.2 (1.9)	−10.7 (−15.9 to −5.4)	<0.001
	Week 12	28.8 (1.8)	45.5 (1.9)	−16.7 (−21.9 to −11.5)	<0.001
AKPS	Baseline	72.9 (0.9)	72.8 (0.9)	0.1 (−2.3 to 2.5)	0.941
	Week 4	79.9 (0.9)	77.2 (0.9)	2.7 (0.2 to 5.1)	0.032
	Week 8	83.8 (0.9)	78.5 (0.9)	5.2 (2.7 to 7.7)	<0.001
	Week 12	89.2 (0.9)	80.5 (0.9)	8.7 (6.2 to 11.2)	<0.001
EQ-5D-5L index	Baseline	0.78 (0.01)	0.79 (0.01)	−0.01 (-−0.03, to 0.01)	0.471
	Week 8	0.89 (0.01)	0.83 (0.01)	0.06 (0.04, to 0.08)	<0.001
	Week 12	0.92 (0.01)	0.85 (0.01)	0.08 (0.06, to 0.10)	<0.001
EQ VAS	Baseline	71.6 (1.2)	71.9 (1.2)	−0.3 (−3.7 to 3.2)	0.876
	Week 8	82.5 (1.3)	71.8 (1.3)	10.7 (7.1 to 14.4)	<0.001
	Week 12	85.3 (1.3)	73.7 (1.3)	11.7 (8.0 to 15.3)	<0.001
PHQ-9	Baseline	2.7 (0.2)	2.6 (0.2)	0.2 (−0.4 to 0.7)	0.562
	Week 8	1.2 (0.2)	1.8 (0.2)	−0.6 (−1.1 to 0.0)	0.049
	Week 12	1.0 (0.2)	1.6 (0.2)	−0.6 (−1.1 to 0.0)	0.045
PCS	Baseline	10.5 (0.5)	9.5 (0.5)	1.1 (−0.4 to 2.5)	0.145
	Week 8	4.5 (0.5)	6.3 (0.5)	−1.8 (−3.3 to −0.3)	0.019
	Week 12	2.4 (0.5)	5.7 (0.5)	−3.3 (−4.8 to −1.7)	<0.001

EQ-5D-5L index values were derived using the Korean value set and range from −0.066 to 1.[27]
Estimates derived from linear mixed-effects models adjusted for baseline.
*The prespecified primary endpoint was usual pain at week 8, defined as knee pain intensity over the previous week on a 0–100 mm visual analogue scale; all other outcomes and time points were secondary.
AKPS, Anterior Knee Pain Scale; DTx, digital therapeutics; EQ-5D-5L, 5-level EQ-5D version; EQ VAS, EQ visual analogue scale; LS, least-squares; PCS, Pain Catastrophizing Scale; PHQ-9, Patient Health Questionnaire-9; Δ, between-group difference (DTx–control).

Compliance and adverse events

During the 8-week intervention period, threshold-based weekly adherence, defined as completing exercises on at least 3 days per week, was 80.9% in the DTx group and 71.3% in the control group. Using a stricter definition based on the daily completion of seven sessions per week, the proportional adherence rates were 56.1% and 49.8% in the two groups, respectively.

In the DTx group, adherence to the CBT component was also assessed over an 8-week period. The average completion rate of the weekly sessions was 74.6% and the average adherence to daily worksheets was 41.2%.

Adverse events were reported in 14 participants in each group, corresponding to 25 events in the DTx group and 20 events in the control group (online supplemental table 2). The reported events were heterogeneous and included musculoskeletal symptoms, respiratory or infection-related events, gastrointestinal symptoms, dermatological conditions and other incidental medical events, without a clinically apparent imbalance between groups. One serious adverse event occurred in the DTx group: lumbar foraminal stenosis, which led to study discontinuation and was assessed by the investigators as unrelated to the study intervention. In the control group, one participant discontinued due to plantar warts; this event was also assessed as unrelated to the assigned intervention. No device-related or intervention-related serious adverse events occurred in either group.

Protocol deviations were documented during trial conduct. Most were visit-window deviations, while the remaining deviations primarily involved operational or assessment-related procedures. No cases of missing informed consent and no randomisation violations were reported.

DISCUSSION

Overview of findings

The primary objective of this trial was to evaluate whether an 8-week multidisciplinary DTx programme reduced usual pain compared with education and exercise instruction in patients with chronic PFP. The prespecified primary endpoint was usual pain at week 8. The DTx group had lower usual and worst pain than the control group from week 4, and these between-group differences increased through week 12. For the primary endpoint, the between-group difference in usual pain was −12.5 mm at week 8 and increased to −16.0 mm by week 12. These findings indicate a consistent treatment effect on pain that emerged early and continued to increase after the active 8-week intervention period.

Functional outcomes showed a similar pattern. The between-group difference in AKPS was 5.2 points at week 8 and increased to 8.7 points at week 12, indicating greater functional recovery in the DTx group. Beyond pain and function, the DTx group showed superior outcomes in terms of the quality of life, depressive symptoms and pain catastrophising, highlighting the broad therapeutic impact of the intervention.

Regarding clinical magnitude, the week-8 between-group difference in usual pain exceeded the previously reported SEM of 6 mm, supporting an effect beyond measurement error, but

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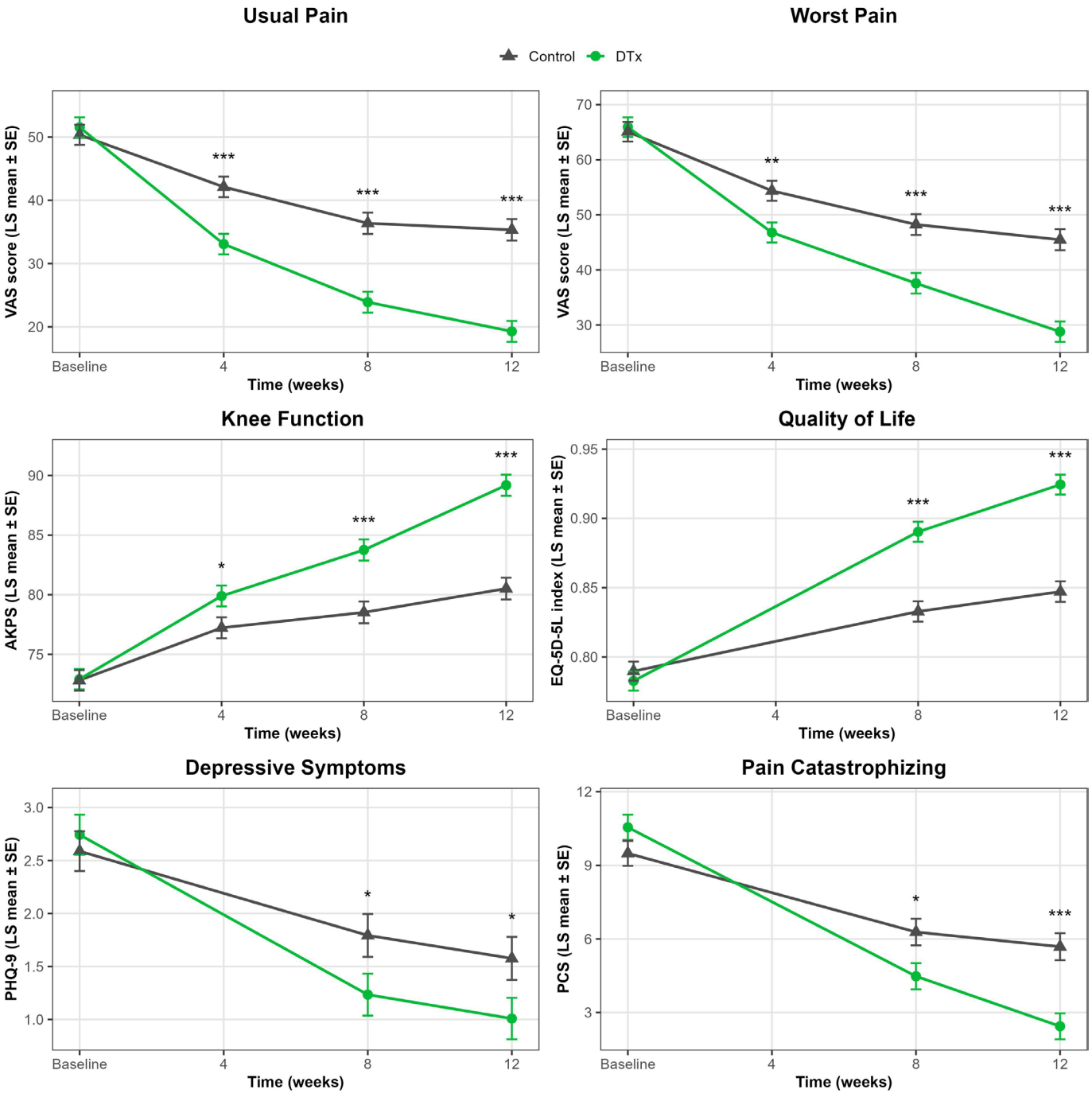


Figure 4 Trajectories of pain, function, quality of life and psychological outcomes over 12 weeks in the digital therapeutics and control groups. Values represent LS means and SEs from linear mixed-effects models adjusted for baseline. Asterisks indicate statistically significant between-group differences at each time point (p<0.05: *, p<0.01: **, p<0.001: ***). AKPS, Anterior Knee Pain Scale; DTx, digital therapeutics; EQ-5D-5L, 5-level EQ-5D version; LS, least-squares; PCS, Pain Catastrophizing Scale; PHQ-9, Patient Health Questionnaire-9; VAS, visual analogue scale.

remained below the reported MCID of 20 mm for VAS pain.[25] The primary comparative pain effect should therefore be interpreted as measurable but modest at week 8, while the larger between-group difference at week 12 and the consistent improvements across secondary outcomes support the overall direction of benefit. Descriptively, mean within-group improvements from baseline in usual pain and AKPS exceeded their corresponding MCID thresholds at weeks 8 and 12 in the DTx group, but not in the control group.

Previous PFP trials have reported short-term improvements in pain and function after 6–8 week interventions, including home-based exercise with health education and rehabilitation programmes for runners with PFP.[30 31] These findings support 8 weeks as a clinically plausible timeframe for detecting early changes in pain and patient-reported function, while longer follow-up remains necessary to determine durability.

These findings should be interpreted in the context of established evidence supporting exercise-based rehabilitation for PFP.[32] Recent digital knee pain research reported that a 90-day personalised digital exercise therapy programme with educational content improved pain and AKPS compared with prescribed physiotherapy in patients with anterior knee pain.[21]

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A randomised trial of a sequential cognitive and physical approach in adolescents with PFP supports the clinical rationale for addressing both physical and psychosocial contributors to PFP, showing greater short-term improvements in function and pain than with a non-sequential physical impairment-based approach.[33]

Exercise therapy is already an established first-line treatment for PFP[5 6 24]; the added value of this trial lies in evaluating an integrated app-delivered DTx package that combines personalised exercise, CBT-informed support and self-monitoring in patients with chronic PFP. The findings should therefore be interpreted as the effect of the combined package, rather than as evidence for digital delivery or any single component alone. Because the control group did not receive the same intervention in an in-person format, this trial cannot determine whether digital delivery itself was the active component. Similarly, the independent contribution of CBT-informed content cannot be separated from the combined intervention. These findings support the potential role of an integrated DTx approach for delivering structured exercise and behavioural support in chronic PFP care.

Clinical implications

These findings have significant clinical implications. A multidisciplinary digital approach appears to improve access to and engagement in PFP care. For instance, average weekly adherence rate was 81% in the DTx group when full weekly adherence was defined as exercising three or more days per week, likely supported by the app's built-in reminders and feedback. The favourable psychological outcomes, including reduced pain catastrophising, suggest that integrating physical and behavioural strategies may be relevant in chronic PFP care. By combining biomechanical exercises with psychological support, the MORA Cure PFP is designed to address both the physical and psychosocial contributors to PFP. Delivering integrated care via smartphones helps overcome access barriers and extends the reach of therapy beyond clinical visits.

This study has several strengths. This is the first adequately powered RCT of a multidisciplinary app-based intervention for PFP. The high-quality design, including randomisation and blinded outcome assessment, and the use of validated measures add credibility to the findings. We also assessed a broad range of outcomes (pain, function, quality of life and psychological health), providing a comprehensive evaluation of their impact. Safety monitoring revealed no device-related or intervention-related serious adverse events, and adverse events were broadly comparable between groups. Unlike self-reported logs, digital adherence metrics enable the objective tracking of engagement.

Limitations

However, these results should be interpreted in light of several limitations. First, although short-term improvements were observed during and shortly after the 8-week active treatment period, the follow-up period was limited to 12 weeks; therefore, the durability of benefits beyond this period remains unknown. Second, because the DTx programme was delivered as an integrated package, we could not isolate the independent contribution of CBT-informed content from the effects of personalised exercise, education and self-monitoring. In addition, fewer participants completed all daily CBT worksheets, suggesting room to enhance engagement with psychological components. Third, exercise adherence was automatically recorded by the application in the DTx group, whereas adherence assessment in the control group relied on participant-completed paper exercise diaries reviewed at follow-up visits; therefore, between-group comparisons of adherence should be interpreted cautiously. Fourth, the control group received standardised education and exercise instruction; future studies comparing the DTx programme with more intensive supervised rehabilitation would help further clarify its relative effectiveness. Finally, most participants had low baseline depressive symptoms; therefore, the effects of CBT in more distressed patients remain unclear.

CONCLUSIONS

In this adequately powered, multicentre RCT, an 8-week multidisciplinary DTx programme produced a statistically significant reduction in usual pain at 8 weeks compared with education and exercise instruction in patients with chronic PFP, although the between-group difference was below the reported MCID for VAS pain. Secondary outcomes, including worst pain, knee function, health-related quality of life and pain-related psychological outcomes, also favoured the DTx group. These findings support the integrated app-delivered DTx package as a clinically relevant option for delivering personalised exercise and CBT-informed support in chronic PFP care.

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