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Original Research

Prospective, Single-blind, Randomized Controlled Trial to Evaluate the Effectiveness of a Digital Exercise Therapy Application Compared With Conventional Physical Therapy for the Treatment of Nonoperative Knee Conditions

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List of abbreviations: DETA, digital exercise therapy application; MCID, minimal clinically important difference; PF, Physical Function; PI, Pain Interference; PROMIS, Patient-Reported Outcomes Measure Information System; PT, physical therapy.

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KEYWORDS
Clinical trial;
Digital technology;
Knee injuries;
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Therapeutics

Abstract *Objective:* To evaluate the effectiveness and adherence of a home exercise therapy program using a digital exercise therapy application (DETA) compared with conventional physical therapy (PT).
Design: Parallel group, randomized controlled trial.
Setting: Two clinics in a tertiary care academic center.
Participants: Participants (N=60) were enrolled within 1 week after a provider visit for knee pain. Inclusion criteria: age 18-75 years, knee pain diagnosis, and clinician-prescribed PT.
Interventions: Participants were randomized to complete either an 8-week intervention of conventional PT (enrolled n=29; complete n=26) or the DETA (enrolled n=31; completed n=24).
Main Outcome Measures: Patient-Reported Outcomes Measurement Information System (PROMIS) Pain Interference (PI) and Physical Function (PF) scores implemented via computer adaptive tests; number of exercise sessions completed per week (adherence).
Results: Compared with the PT group, the DETA group reported significant decreases in PROMIS-PI scores (-6.1 ± 6.7 vs -1.5 ± 6.6, $P<.05$, $d=0.78$) and increases in PROMIS-PF scores (6.0 ± 6.6 vs -0.8 ± 5.8, $P<.01$, $d=0.89$) after 8 weeks. No group differences in adherence were observed ($P>.05$).
Conclusions: Use of this DETA resulted in greater pain and functional improvements compared with PT, with no differences in adherence. It is possible this application may be a viable alternative to conventional PT in certain cases. A larger sample from various geographic locations is needed to improve generalizability and for subgroup analysis. Further investigation is warranted to determine the factors responsible for the differences observed between the groups.

Musculoskeletal conditions are responsible for more costs to the United States health care system and cause more disability than any other group of conditions.[1] Approximately 25% of adults experience knee pain, making it one of the most common physical ailments seen in medicine.[2] The first line of treatment for most knee conditions is generally nonoperative, typically consisting of physical therapy (PT), education, and/or pharmacologic interventions.[3] Early access and high adherence to PT can improve outcomes, alleviate pain, and reduce total musculoskeletal-related health care costs from medications, injections, operations, and other treatment modalities.[4,5] Unfortunately, conservative treatments for knee pain are often underused.[6]

Recent evidence has shown that relatively few individuals who would qualify for PT for their knee condition actually receive it.[7-9] This can especially become problematic for individuals with limited health care access because of living in medically underserved areas, a lack of insurance, or high out-of-pocket costs for conservative treatments.[10] These issues are particularly important for people with lower socioeconomic status, which has been associated with higher prevalence of knee pain and worse health-related quality of life.[11-14] Digital health applications have seen a substantial rise over the past decade[15] and can help address challenges to PT access and adherence. Programs that promote self-management and self-efficacy can provide longer-term improvement in outcomes of musculoskeletal patients treated with PT.[16] It is possible that an interactive, mobile-based application could help individuals manage their condition from home and improve pain and functional outcomes.

A digital exercise therapy application (DETA) was recently developed to address these needs. The application was designed with input from physiatrists and physical therapists and built on evidence that suggests a stepped and progressive exercise therapy program personalized to the user and coupled with education and self-management can better identify individuals who would benefit from a particular intervention to improve outcomes.[17-19] The DETA provides evidence-based home exercise therapy video programs for nonoperative knee conditions and validated outcome measures for tracking progress. On starting the application, the individual is asked questions concerning their baseline pain and function, health history, exercise levels, and various demographic and psychosocial factors. The assessment is designed to indicate the severity of the individual's injury as well as their potential to improve from therapy, and their baseline exercise difficulty is adjusted accordingly (fig 1). Participants are asked during through their program about their pain and function; changes in these outcomes are used to adjust the exercises during the program. The DETA provides individuals with access to detailed, step-by-step instructions of each exercise; educational materials; session reminders; and gamification techniques to improve engagement.

The primary goal of this randomized controlled trial was to evaluate the effectiveness of the DETA compared with conventional PT, which is considered the standard of nonoperative care for improving function and reducing pain in individuals with knee conditions.[20] An 8-week intervention with the DETA was hypothesized to improve pain and function greater than an 8-week conventional PT intervention. Pain and function were measured using the Patient-Reported Outcomes Measurement Information System (PROMIS) Pain Interference (PI) and Physical Function (PF) scales, respectively. The secondary aim of the study was to assess differences in adherence to therapy between the 2 interventions, measured using the number of therapy sessions completed per week.

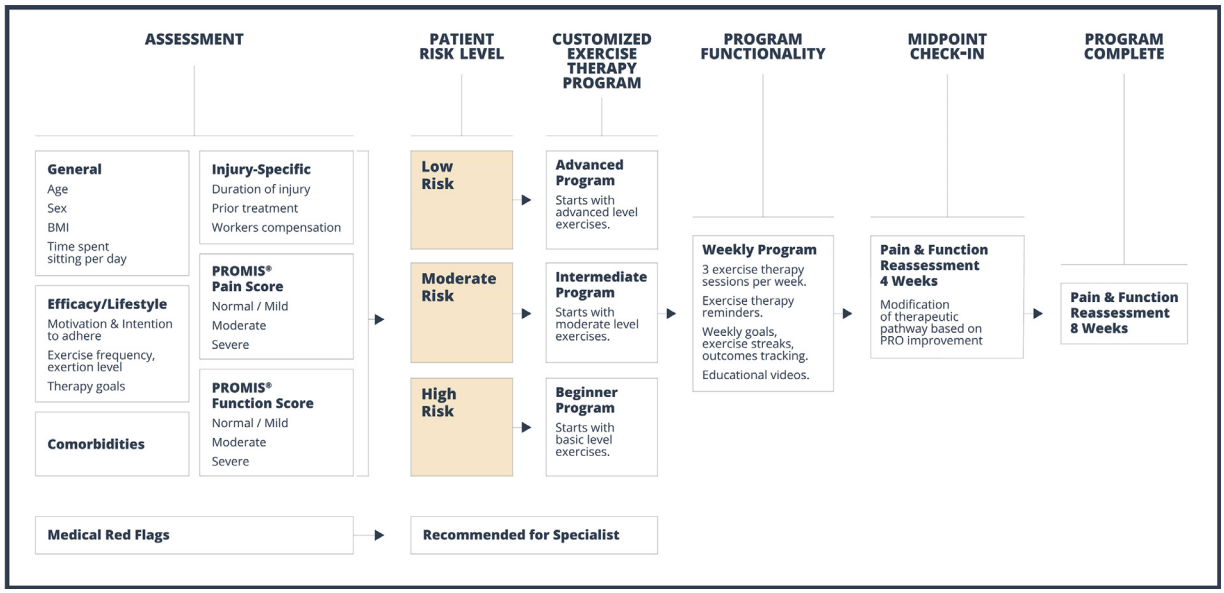

Fig 1 DETA flow diagram depicting the risk stratification. Patients entered information about their injury, lifestyle, history, exercise level, comorbidities, red flags, pain, and function. The model placed users into a risk category based on these parameters, which was used to determine the starting point for their program. Abbreviation: BMI, body mass index.

Methods

Study procedures

This was a single-institution, multicenter, single-blind, randomized controlled trial performed at a large tertiary care academic center from January 2020 to May 2020. Study sites included 2 sports medicine centers and a physical medicine and rehabilitation musculoskeletal clinic. Individuals who were prescribed PT for nonoperative knee conditions were randomly assigned to the at-home DETA program or conventional PT (control). The treatment group received the DETA via a mobile application, whereas the control group received a prescription for standard outpatient PT for knee pain. Outcome measures were collected at baseline and 8 weeks. The study was approved by the local Institutional Review Board and registered with ClinicalTrials.gov (NCT04323267). All participants gave informed consent prior to any study procedures. Consolidated Standards of Reporting Trials guidelines were followed.

Participants

Participants were identified from an electronic health record report, which included all patients who received a PT prescription and a common *International Classification of Disease, Tenth Revision* diagnosis of knee pain or another nonoperative knee condition. Eligible individuals were sent an email to inquire about participation, and participants consented and enrolled via telephone within 1 week after seeing their provider. Inclusion criteria were age range 18-75 years, a diagnosis of knee pain, average knee pain over the past week rated at least 4 of 10 on an 11-point numeric rating scale (0=no pain, 10=maximum pain), and clinician-prescribed physical therapy. Eligible diagnoses included patellofemoral pain syndrome, primary knee osteoarthritis, knee joint disorder, patellofemoral disorder, meniscal tear, iliotibial band syndrome, pes anserine bursitis, knee tendonitis, knee bursitis. Exclusion criteria included body mass index $\geq$35 kg/m^2, no access to a smartphone, inability to speak English, history of total joint or knee surgery in the past 12 months, completion of PT in the past 12 months, or advice for a total knee replacement by a physician. The Consolidated Standards of Reporting Trials enrollment diagram is depicted in Figure 2. Both DETA and control group participants were informed they would receive a $20 gift card after completing their 8-week follow-up questionnaire.

Randomization and blinding

Once consented and enrolled, participants were randomly assigned in a 1:1 ratio parallel design to either (1) at-home DETA or (2) standard PT using block randomization procedures in Research Electronic Data Capture.[21,a] Because age may be a confounder for knee pain,[14] participants were stratified into aged $\geq$40 years and <40 years to ensure equal distribution across both treatment groups. Because of the nature of the intervention, participants could not be blinded. However, the treating physicians were not involved in the study and were unaware of group allocation. The statistician responsible for data analysis was also blinded to group allocation.

Power Analysis

A power analysis was conducted using changes in Knee Injury and Osteoarthritis Outcome Scale Pain subscale scores reported by a previous randomized controlled trial, comparing conventional PT to a digital care program for chronic knee pain.[22] A Wilcoxon-Mann-Whitney test design was used for the power analysis with a 1:1 allocation ratio and normal distribution. With a conservative effect size of 0.85, 2 tails, and α of 0.05, there is 80% power to detect significant

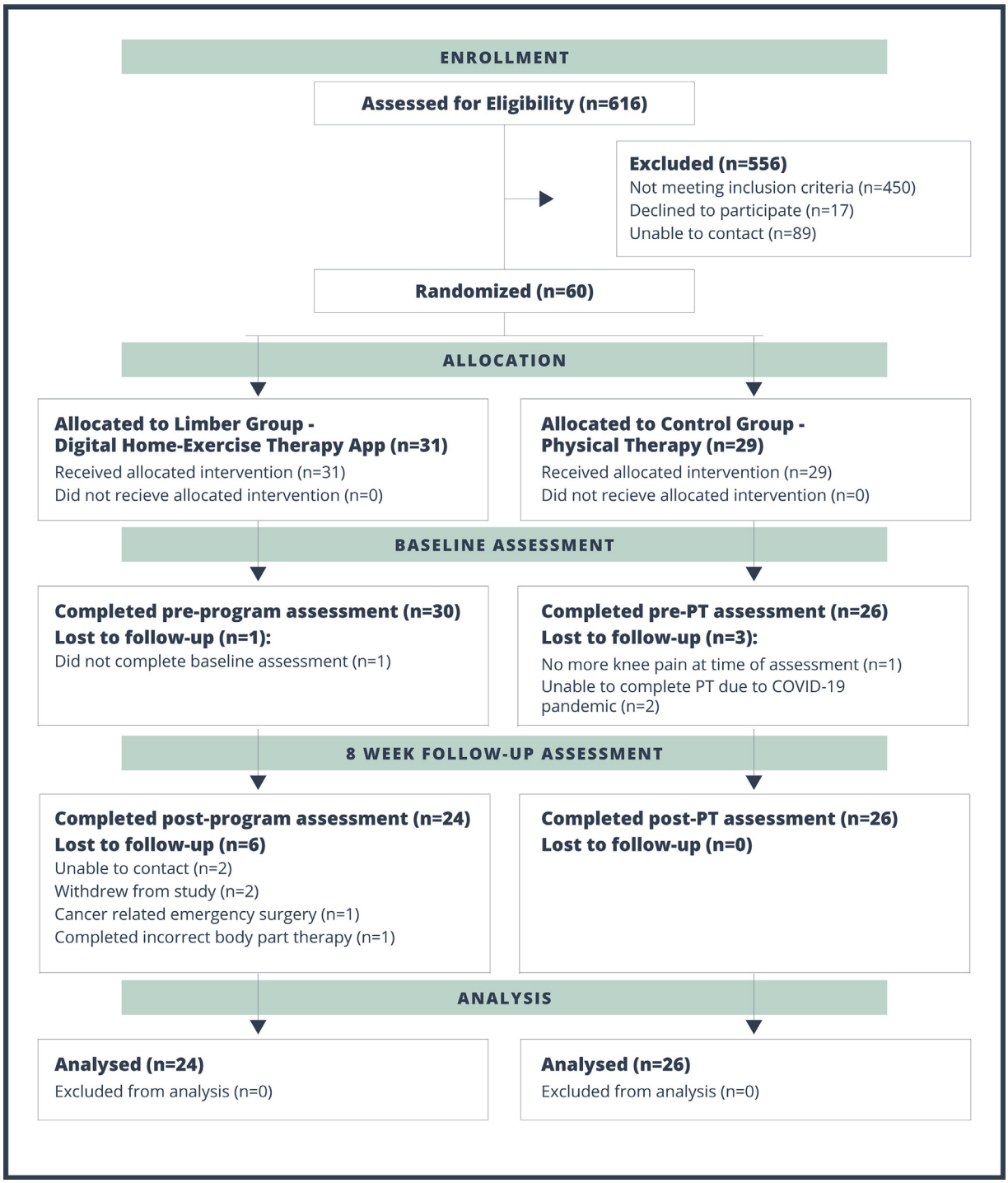

Fig 2 Consolidated Standards of Reporting Trials enrollment flow diagram.

differences in changes in pain scores between the 2 groups with 48 participants (24 per group). Assuming an attrition rate of 20%, 60 participants was the target sample size. This sample size has been considered adequate in other studies using PROMIS domains for orthopedic injuries.[23,24] Although the aforementioned study used the Knee Injury and Osteoarthritis Outcome Scale pain subscale, this subscale has been shown to strongly correlate with the PROMIS Computer Adaptive Tests used in the present trial.[25]

Interventions

DETA (intervention group)

Participants who were randomized to the intervention were instructed to download the Limber Health DETA[b] on their mobile devices and were provided with a black exercise band.[c] They completed a screening questionnaire composed of questions related to their health status, pain and function levels, physical abilities, and goals. Responses to the

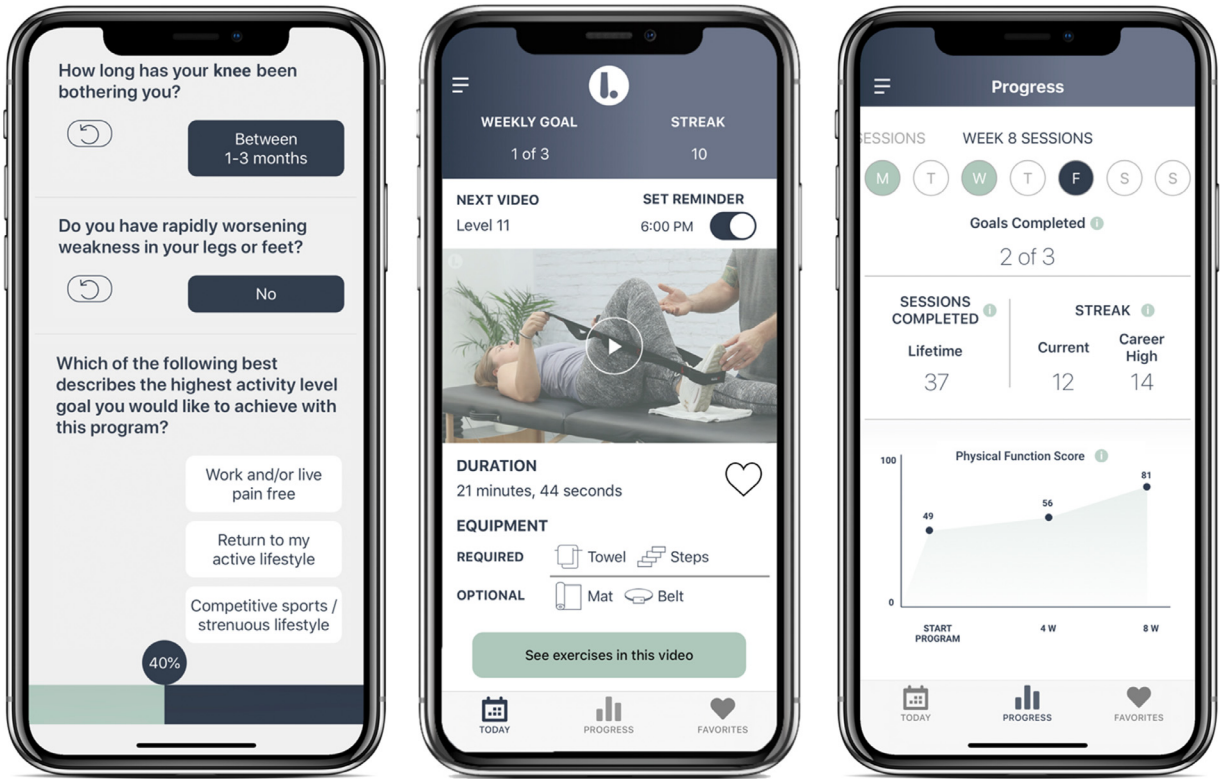

Fig 3 Screenshots of DETA. From left to right: Left image provides an example of the DETA assessment. After patient is assessed with the screening questionnaire, the middle image demonstrates the home tab, which features the next video in the patient's program. The image to the right is the progress tab, which shows metrics on improvement in patient reported outcome measures.

questionnaire were used to determine the difficulty level of their program (see fig 1).

The program included 3 video sessions per week for 8 weeks. Each video was approximately 15-25 minutes in length and provided a follow-along sequence of various exercises for knee pain, narrated and described by the physical therapist in each video (fig 3). Participants' pain and function were reassessed at the 4-week mark, and the exercise difficulty was adjusted to match the change in PROMIS PI and PF scores. Participants continued the adjusted treatment program to completion at the 8-week mark.

PT (control group)

Participants in the control group were given an 8-week prescription for standard PT by their treating provider (board-certified physiatrists and orthopedic specialists). An example of a PT prescription provided by the physician is presented in figure 4. They were instructed to complete outcome assessments prior to starting their therapy and at the end of 8 weeks. Treatment programs, home programs, exercise progressions/regressions, and treatment methods were determined by each individual physical therapist as is the standard of care. This type of control group has also been used as an active comparator in other randomized controlled trials investigating an internet-based therapy program.[20,26]

Outcome measures

The primary outcomes for this trial were 8-week changes in PROMIS-PI and PROMIS-PF scores, which were collected at baseline and at the end of the 8-week intervention. The secondary outcome was adherence to therapy, which was measured by the number of videos completed in the DETA group and the number of self-reported PT sessions completed in the control group. Details of the outcome measures are as follows. Outcome measures for both groups were collected and managed using Research Electronic Data Capture[21] PROMIS Computer Adaptive Tests electronic data capture tools hosted at Mayo Clinic.

PROMIS Pain Interference and Physical Function

Participants' pain and function were measured using PROMIS-PI and PROMIS-PF scores. PROMIS measures were designed to quantify an individual's health status and are easily administered and able to be applied to a broad population.[27,28] Psychometric properties have been established when measuring PT outcomes, including high correlations with legacy measures and very good reliability (>0.90).[29] The surveys implement computer adaptive testing using item-response theory to reduce the amount of questions asked.[28] PROMIS measures have been validated in a variety of knee conditions against legacy measures.[24,30-33] Scoring methodology includes a T score metric (mean, 50±

Fig 4 Example of a PT prescription provided by the physician. This is an example of a prescription provided by the physician. However, the actual therapy program for each participant was decided on by their individual therapist, as is the standard of care.

10). Higher PI and PF scores represent worse pain and greater functional status, respectively.

The PROMIS-PF scale measures self-reported capability rather than actual performance of physical activities. It uses a 5-point adjectival scale (ranging from "Without any difficulty" to "Unable to do") to assess difficulty with a number of activities, such as walking upstairs. The PROMIS-PI scale measures self-reported pain interference with everyday activities. It also uses a 5-point adjectival scale to measure how much pain interferes with daily activities (ranging from "Not at all" to "Very much"). Minimal clinically important differences (MCIDs) for PROMIS-PI and PROMIS-PF of 2.0 and 2.4, respectively, have been established in a trial comparing physical therapy with tai chi for knee osteoarthritis.[34]

Adherence measures

In the DETA group, adherence to therapy was assessed using a report generated by the application, which included the number of sessions completed. The DETA technology captures the length of time each participants watches an exercise video. A session was considered complete if a participant watched >75% of the video. In the PT group, participants were contacted by phone and self-reported the number of sessions they completed each week, which included in-person PT visits and any PT-prescribed home exercise sessions.

Monitoring of adverse events

Participants were monitored for adverse events throughout the study by a research coordinator, who periodically contacted them via telephone. Additionally, participants were instructed to contact the investigators if an adverse event occurred during the study.

Statistical methods

All tests were conducted with R v3.6.2.[d] Continuous variables were summarized as mean ± SD, median (range), and interquartile ranges. Categorical variables were reported as frequencies (percentage) and tested for differences between the 2 groups using chi-square tests. Mixed-effects

Table 1 Participant demographics and clinical information

Demographics	DETA (n=24)	Standard PT (n=26)	Total (N=50)
Age (y), mean ± SD	58.5±13.7	55.9±13.3	57.1±13.4
Sex, n (%)			
Male	12 (50.0)	17 (65.4)	29 (58.0)
Female	12 (50.0)	9 (34.6)	21 (42.0)
BMI (kg/m^2), mean ± SD	26.7±3.7	27.5±4.4	27.1±4.0
Primary diagnosis, n (%)			
Osteoarthritis	17 (70.8)	15 (57.7)	32 (64.0)
Patellofemoral syndrome	4 (16.7)	7 (26.9)	11 (22.0)
Other	3 (12.5)	4 (15.4)	7 (14.0)

NOTE. "Other" diagnoses included meniscus tears, medial collateral ligament injuries, and miscellaneous. No statistical differences in demographic or clinical information were observed between the 2 groups (P>.05).
Abbreviation: BMI, body mass index.

models were used to examine the interaction between time and group on PROMIS-PI and PROMIS-PF between baseline and post intervention. Time and group were considered fixed effects, and random intercepts were included to account for variance in participant baseline scores. After a significant interaction effect, post hoc analyses were conducted with Bonferroni adjustments to account for multiple comparisons. Treatment effect sizes were calculated as the mean difference between the 2 groups divided by their common SD and interpreted as small (d=0.2), medium (d=0.5), and large (d=0.8).[35] Between-group differences in adherence were tested using 2-sample t tests. All tests were 2-sided with α level set at 0.05 for statistical significance.

Results

Participants

Sixty participants were enrolled and randomized into DETA (n=31) and PT (control, n=29) groups. Ten participants were lost to follow up (7 in DETA group, 3 in PT group). Details are provided in the enrollment diagram (see fig 2). Participant demographic data are presented in table 1.

Table 3 Baseline and 8-wk PROMIS-PF scores by group

Time	DETA		Standard PT	
	Mean ± SD	95% CI	Mean ± SD	95% CI
Baseline	44.7±6.6	42.1-47.3	46.1±5.5	43.3-48.8
8 wk	50.7±7.5	48.0-54.4	46.5±8.5	44.1-53.4
8-wk change	6.0±6.6*	3.5-8.4	0.8±5.8	−1.6 to 3.3

NOTE. Mixed-effects models were built to test the interaction between group and time. Post hoc analyses were conducted after a significant interaction. A significant interaction between group and time was noted (P<.05).
Abbreviation: CI, confidence interval.
* Significant within groups, P<.001.

Primary outcomes

Group differences in primary outcomes are presented in tables 2 and 3. Decreases in PROMIS-PI at 8 weeks were significantly greater in the DETA group than the PT group $F_{1.52.5}$=6.41, P<.05, d=0.78). The DETA group also experienced a significantly greater increase in PROMIS-PF scores at 8 weeks than the PT group ($F_{1.50.2}$=9.07, P<.01, d=0.89). Post hoc analyses indicated significant changes in the DETA group for both outcomes (P<.001) and no changes in the PT group (P>.05). A total of 66.7% of the patients in the DETA group achieved MCID in PROMIS-PI (decrease of ≥2.0) and PROMIS-PF (increase of ≥2.4) compared with 46.2% and 34.6% in the PT group, respectively.

Adherence

In the PT group, participants self-reported an average of 3.2±1.7 in-person and prescribed home exercise sessions per week over the course of the trial. Participants in the DETA group completed an average of 2.6±1.1 sessions per week. There was no difference in number of sessions per week between the 2 groups (P>.05).

Safety monitoring

No adverse interventions were reported in either group when contacted at 8-week follow-up.

Table 2 Baseline and 8-wk PROMIS-PI scores by group

Time	DETA		Standard PT	
	Mean ± SD	95% CI	Mean ± SD	95% CI
Baseline	58.8±6.7	56.5-61.4	57.0±5.3	54.6-60.0
8 wk	52.7±6.8	50.2-55.2	55.5±7.5	53.0-58.0
8-wk change	−6.1±6.7*	−8.7 to −3.5	−1.5±6.6	−4.1 to 1.1

NOTE. Mixed-effects models were built to test the interaction between group and time. Post hoc analyses were conducted after a significant interaction. A significant interaction between group and time was noted (P<.05).
Abbreviation: CI, confidence interval.
* Significant within groups, P<.001.

Discussion

PT is the standard of care as the first line of treatment for knee pain.[3,4] Digital home exercise therapy programs provide an opportunity to overcome many of the obstacles that exist to provide an optimal therapy episode of care. However, before implementing such a tool in the clinic, its effectiveness needs to be evaluated. The primary purpose of this study was to compare outcomes of a novel DETA with those of conventional PT, the current standard of care. Ultimately, the goal was to determine whether a DETA could be a therapeutic option for individuals with nonoperative knee pain. The secondary aim was to investigate whether the participants using the DETA would be more adherent to their program than those prescribed conventional PT.

The 8-week DETA intervention was superior to standard PT in this sample. Changes in the DETA group surpassed the MCID in both PROMIS-PI and PROMIS-PF[31,34] and exhibited large effect sizes; no such response occurred in the standard PT group. Functional improvements were greater than pain improvements in this study, which mirrors prior randomized trials.[36] Prior trials have also found either no difference or improvements of small to moderate effect in the intervention group compared with control.[36] The DETA adjusts the difficulty of the baseline exercises to the user, focuses on active and functional exercises, and uses a progressive approach to exercise therapy. The application takes into account the users' change in pain and function to further alter the progression of exercises. The combination of these approaches may yield improved outcomes over a more static PT regimen. It is possible these factors contributed to the greater improvements in pain and function compared with the PT group.[19,37] Unfortunately, the PT regimens of the control group members were not collected nor were they standardized between participants, so it is not known whether their therapists used a similar approach. Future studies could implement a standardized PT program to account for this potential confounder.

The secondary aim of this study was to evaluate differences in therapy adherence between the 2 interventions. Given the engaging properties of the application, it was expected that participants would complete more exercise sessions per week than the PT group. Contrary to the hypothesis, however, no differences were observed between the 2 groups. These findings were encouraging because improvements in outcomes were greater in the DETA group despite similarities in adherence, a finding that is contrary to what has been shown in the literature.[38] A larger number of dropouts was observed in the DETA group, which is a consistent theme among digital health interventions and may be a function of poorer adherence.[39] No patterns were observed among this sample with respect to demographics or baseline pain and function that would indicate why these participants dropped out.[39,40] A larger sample would allow for subgroup analysis to determine predictors of adherence.

Study limitations

This study had a number of limitations. First, the coronavirus disease 2019 pandemic may have affected some participants' ability to complete their in-person PT episode. To address the concern, recruitment and enrollment were halted and participants who could no longer complete in-person PT sessions were excluded (see fig 2). Halting the study may have affected its power. Post hoc power analyses were conducted and indicated sufficient power to reject the null hypotheses that changes in PROMIS-PI (β=0.23) and PROMIS-PF (β=0.13) were no different between groups. Despite sufficient power, a sample size of 70 would likely yield more precise estimates of outcomes.[41] The interventions and exercises performed in clinic and at home by members of the control group were not controlled in this study. The standard PT care was established by participants' physical therapists and may have varied based on location and clinic specialties. However, physical therapy interventions determined by the physical therapist are currently the standard of care and may not have affected generalizability. Participants were not blinded and outcomes were self-report, which may have introduced bias despite blinding of the treating physician. Adherence was self-reported in the PT group, whereas being automatically collected by the application in the DETA group. Recall bias may have influenced these results. The sample was heterogeneous with respect to the primary knee pain diagnoses and was recruited within a single hospital system. It is possible this program is more effective for certain conditions, yet this was unable to be tested. Recruitment of a larger sample size would allow for subgroup analyses, and the inclusion of different geographic locations would improve generalizability.

Conclusions

The purpose of this study was to demonstrate the effectiveness of an 8-week DETA for nonoperative knee pain by comparing it with conventional PT. In this sample, the DETA program resulted in greater increases in physical function and decreases in pain interference compared with standard PT. These results were observed without any significant difference in adherence to the therapy protocols. Although further research is needed with a larger and more geographically diverse sample, this investigation suggests a DETA can be a viable alternative to standard PT for treatment of nonoperative knee conditions.

Suppliers

a. REDCap; Vanderbilt University.
b. Limber Health application; Limber Health Inc.
c. Exercise band; Fabrication Enterprises.
d. R, v3.6.2; The R Foundation.

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