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Translating Comprehensive Conservative Care for Chronic Knee Pain Into a Digital Care Pathway: 12-Week and 6-Month Outcomes for the Hinge Health Program

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Original Paper

Translating Comprehensive Conservative Care for Chronic Knee Pain Into a Digital Care Pathway: 12-Week and 6-Month Outcomes for the Hinge Health Program

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Abstract

Background: Chronic knee pain (CKP) affects a large number of adults, many of whom do not receive best-practice care and are at high risk for unnecessary surgery.

Objective: The aim of this study was to investigate the effect of the Hinge Health 12-week digital care program (DCP) for CKP on knee pain and function, with secondary outcomes of surgery interest and satisfaction, at 12 weeks and 6 months after starting the program.

Methods: Individuals with CKP were recruited onto the 12-week program, comprising sensor-guided physical exercises, weekly education, activity tracking, and psychosocial support such as personal coaching and cognitive behavioral therapy (CBT). We used a single-arm design with assessment of outcomes at baseline, 12 weeks, and 6 months after starting the program. We used a linear mixed effects model with Tukey contrasts to compare timepoints and report intention-to-treat statistics with last observation carried forward.

Results: The cohort consisted of 41 individuals (32 female, mean age 52 years, SD 9 years). Between baseline and week 12, participants reported clinically significant improvements in the Knee Injury and Osteoarthritis Outcome Score (KOOS) pain and Knee Injury and Osteoarthritis Outcome Score-Physical Function Short Form (KOOS-PS) function scales of 16 points (95% CI 12-21, P<.001) and 10 points (95% CI 6-14, P<.001), respectively. Significant reductions of 57% (mean difference 30, 95% CI 21-38, P<.001) and 51% (mean difference 25, 95% CI 16-33, P<.001) in visual analog scale (VAS) knee pain and stiffness, respectively, were observed at 12 weeks, as well as a 67% reduction in surgery interest (mean reduction 2.3 out of 10, 95% CI 1.5-3.1, P<.001). Average satisfaction at week 12 was 9.2 out of 10. Critically, all improvements were maintained at 6 months at similar or greater magnitude.

Conclusions: Participants on the Hinge Health DCP for CKP showed substantial clinical improvements that were maintained 6 months after enrolling in the program. This shows that DCPs carry strong potential to deliver evidence-based, cost-effective care to those suffering from CKP.

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KEYWORDS

chronic pain; osteoarthritis, knee; digital health; conservative management

Introduction

Background

Chronic knee pain (CKP) is one of the most common health conditions [1] and is a characteristic presenting symptom of knee osteoarthritis (OA) [2]. People living with CKP experience a reduced quality of life [3] and are at risk of developing concomitant musculoskeletal and mental health conditions [4,5]. CKP is most effectively treated by comprehensive chronic pain programs, comprising not only physical exercise but also education, psychosocial support, and weight loss [6-9]. Such programs have shown clinically relevant reductions in pain that last up to 5 years [10,11] and medical cost savings due to a reduced need for injections, drugs, and surgery [8], with one intervention for CKP due to knee OA showing a 75% (8/41 had knee replacement in control vs 2/42 in treatment) reduction in rate of total knee replacements [12]. Comprehensive care for CKP due to knee OA is also more effective at reducing pain in the long-term compared with physical therapy only [13-16]. However, chronic pain programs are rare for CKP, and over 80% of individuals with CKP due to knee OA receive suboptimal conservative care [17]. Furthermore, CKP patients show poor adherence to existing treatments [18].

The lack of widespread best-practice conservative care for those suffering from CKP drives patients toward total knee arthroplasty (TKA), an expensive intervention which almost doubled in rate between 2000 and 2010 in the United States [19]. Further exacerbated by an aging population, TKAs now represent one of the main cost drivers for self-insured employers and the largest in-patient cost for Medicare, alongside hip replacements. Despite the popularity of the procedure, many patients undergoing TKA may have avoided or at least delayed surgery through comprehensive conservative care [12], with 34% of TKAs performed in the United States regarded as inappropriate [20]. For those that do undergo TKA, the benefits are partly offset by serious adverse events [21,22]. Even more wasteful are arthroscopic debridement surgeries, which have no discernible effect on the patient beyond placebo yet remain one of the most common interventions with 500,000 procedures every year in the United States alone [23]. As such, there is huge scope for effective nonsurgical treatment solutions to improve patient outcomes and drive down the surging costs associated with CKP.

A digital care program (DCP), whereby each facet of evidence-based care is digitized, aims to deliver care more efficiently, effectively, and in a way that would improve outcomes while decreasing costs. In particular, a DCP for CKP administered remotely would allow patients access to the program at any time and place, provide a single touchpoint for every aspect of care, enable rich data collection on patient behavior and progress, and drastically reduce the marginal cost of additional patients receiving treatment. Furthermore, as poor adherence can limit long-term effectiveness of a program for CKP [18], a DCP incorporating remote sensing would enable very precise monitoring of adherence levels to exercise therapy, affording personalized and timely interventions during the course of treatment. Digital health is moving into many different domains of health care, ranging from cognitive behavioral therapy (CBT) for pain and depression to remote monitoring of heart patients [24-26]. In diabetes prevention, a digital health program has shown positive outcomes that persisted up to 2 years after completion of the program [27], and a digital sleep therapy program was found to be effective in a randomized controlled trial [28]. However, the musculoskeletal field has seen relatively little digital innovation and was judged to be "in its infancy" in this regard [29].

The American College of Rheumatology recommends those suffering from CKP to participate in cardiovascular and strengthening exercise, self-management training, psychosocial intervention, and weight loss for overweight patients [7]. In line with these recommendations, we have developed a 12-week DCP for CKP. The program builds on previous work in digital musculoskeletal care, which studied individual components of digital care in isolation, such as diagnosis [30], CBT [25], exercise with telephone-based coaching [31], exercise with pain coping training [32], and behavioral change approaches [33].

Aims of This Study

The aims of this study were to (1) determine the change in pain and function between baseline and follow-up (week 12 and 6 months) in participants in the 12-week Hinge Health DCP and (2) assess changes in surgery interest and patient satisfaction between baseline and follow-up.

Methods

Research Design

We used a single-arm design with patient-reported outcome measures (PROMs) collected before starting the program ("baseline"), at the end of the 12-week program, and at 6 months after starting the program.

Participants

The 12-week Hinge Health DCP was deployed at two sites in the United States, both of which compensated Hinge Health for the deployment. All potential participants were employees of a self-insured employer, covered by their medical plan. Potential participants were recruited by email, letters mailed to their home address, and fliers posted in the workplace, and were screened for inclusion by Web-based questionnaire. For inclusion, subjects had to provide written informed consent, have lived with knee pain for at least 3 months in the past 12 months, and had to meet at least 2 of the following additional inclusion criteria derived from the American College of Rheumatology criteria for OA of the knee [2]: morning stiffness lasting less than 30 min, crepitus on movement, bony tenderness, bony enlargements, lack of warmth of the knee to the touch, and age of 50 years or older. Exclusion criteria were knee surgery or trauma in the past 3 months. We obtained ethical approval to conduct a research study as part of these deployments from the Western Institutional Review Board (WIRB 20160949).

An a priori sample size calculation was performed for comparing the primary outcomes of pain and function. Using an alpha level of .05, a power of 0.8, and a medium effect size of 0.5, 33 subjects were needed. Recruitment of 41 participants accounted

for a potential dropout rate of 20% over the course of the study. As there were a limited number of places available on the program, we invited eligible applicants on a first come, first serve basis. Users were not compensated for their time, but could participate in the program free of charge.

Intervention

The Hinge Health DCP is a 12-week program (Figure 1) which aims to equip participants with the knowledge and tools to self-manage their condition without prescription drugs and surgery as long as possible. The program comprises sensor-guided physical exercise, education, CBT, psychosocial support through teams and personal health coaches, weight loss, and activity tracking. In the week before the official start of the program, each invited participant was assigned to a team of 15-20 participants and taken through a 30-min in-person onboarding session led by a trained Hinge Health representative. During this session, the participant was provided with a tablet computer preloaded with the Hinge Health app as well as wearable bands with motion sensors to be used during guided exercises (Figure 2), and shown how to use the main features of the app and perform sensor-guided exercise therapy. This was followed within a few days by a 30-min call with a personal coach, who was an employee of Hinge Health trained for interaction with participants. The purpose of the call was for the coach to establish themselves as the primary touchpoint for the participant throughout the program, orient the participant to the program, help set goals, and identify and alleviate practical barriers to adherence. Every week on the program participants had to complete a number of goals. These components of the program are discussed below. Participants were allowed to keep their tablet computer and movement sensors after completion of the 12-week program, and they could continue to interact with the program as desired to access education, communicate with teammates, log symptoms, and track activities; however, no activities were required of participants during this maintenance phase.

Figure 1. User flow in the Hinge Health digital care program. (a) Every odd-numbered week. (b) Only for those with a starting body mass index (BMI) of 25 kg/m2 or greater. (c) Only on a subset of weeks and only for those users who qualified for the respective cognitive behavioral therapy module (see "Methods" section).

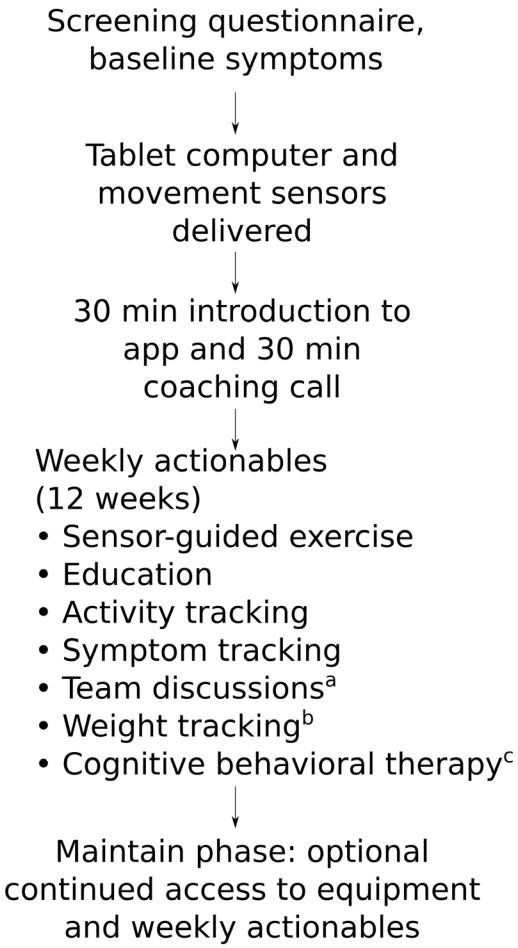


Figure 2. Tablet computer and sensors as part of the Hinge Health kit. (a) A screenshot of the home screen. Weekly actionables are indicated by stars, followed by an overview of fellow team members and the team discussion feed. Further functionality—including a progress screen, education articles, and private communication channel with the coach—are available through the menu. (b) Placement of sensors for exercise therapy.

Exercise Therapy

Participants had a weekly exercise repetitions goal for sensor-guided exercises, which increased over the course of the program. Approximately 15 min of stretching and strengthening exercise for 3-4 days per week was sufficient to reach their weekly goal. Specifically, we provided the following sensor-guided exercises: standing quad stretch (pulling heel toward buttocks), seated quad stretch (pull leg toward chest), half squats, forward lunges, leg raise (raising lower leg behind the body until parallel with floor while holding chair), seated leg raise (raising lower leg to horizontal while seated), and hamstring stretch (foot on raised object, reach to touch toes with straight leg). The app tracked the execution of the exercises and provided real-time feedback to the user to ensure that the exercises were performed correctly. Before starting a new exercise, a narrated video showed correct execution, and this video remained available to the participant throughout the program. Crucially, the sensors afforded an objective avenue to monitor adherence.

Education

Education articles were presented once per week, for a total of 12 education articles, each requiring approximately 10-20 min of reading. Each article consisted of approximately 6 pages, and we tracked consumption of each page. A piece of education was marked complete if the participant reached the final page of the article.

Symptom Logging

Participants were asked to log their pain and stiffness symptoms on a visual analog scale (VAS) at least twice a week, alongside any treatments they had been using for their knee. Participants were prompted to fill out questionnaires at predetermined timepoints in order to track PROMs. The specific timepoints for each PROM are outlined below.

Activity Tracking

A self-report activity tracker helped log any physical activity they performed during the week, encouraging at least three 30-min sessions per week of low-impact exercise.

Cognitive Behavioral Therapy

CBT modules were provided. One was provided to all users (*pacing activity levels*), whereas others were provided based on data provided by users: the *weight loss* CBT for participants with a body mass index >25 kg/m^2; the *coping with pain* CBT for users with a score greater than 30 on the pain catastrophizing scale; the *low mood* and *anxiety* CBT for participants with a score of 10 or higher on the Hospital Anxiety and Depression Scale (HADS), respectively.

Team and Coach Interaction

The coach facilitated in-app team discussions, while encouraging team members to discuss anything of interest with their teammates on the team feed (accessible via the app). Participants communicated with the coach through the tablet app, phone, SMS, or email. The participants could initiate a conversation

at any time and the coach would respond within the same day. Moreover, the coach sent weekly messages to introduce the week's education, provide feedback on completed CBT modules, send an overview of the participant's performance in the previous week, and encourage the user to attend to their weekly goals on Wednesdays and Fridays, if the participant was behind on their goals.

Primary Outcomes: Pain and Function

We used the Knee Injury and Osteoarthritis Outcome Score (KOOS) 9-question pain subscale [34,35], as well as the 7-question Knee Injury and Osteoarthritis Outcome Score-Physical Function Short Form (KOOS-PS) to assess function [36]. KOOS questionnaires were asked at baseline (screening) as well as at week 4, 8, and 12 of the program, and scored from 0 (no symptoms) to 100 (extreme symptoms). Both questionnaires were also administered at the 6-month timepoint.

Secondary Outcomes

Participants reported on their knee pain and function by completing VAS questions at baseline (screening) and twice per week during the program, asking "Over the past 24 h how bad was your knee pain?" and "Over the past 24 h how bad was your knee stiffness?" respectively. The left pole was set to 0 and contained the text "none," and the right pole was set to 100 and contained the text "worst imaginable." Unlike other PROMs, VAS reports were optional in the app. To assess overall satisfaction with the program, we asked "On a scale of 0-10, how likely is it that you would recommend the Hinge Health program to a friend or colleague?" at week 6 and week 12. We tracked participants' self-reported likelihood of undergoing knee surgery at baseline (screening), week 6, and week 12 of the program by asking "On a scale from 0 to 10, how interested are you in knee surgery?" All secondary outcomes were also assessed at 6-month timepoint.

Statistical Analysis

We report *intention-to-treat* statistics with last observation carried forward. We used a linear mixed effects model implemented through LME4 [37] and implemented Tukey contrasts to compare timepoints through the "multcomp" package [38] in the statistical computing software R (version 3.3.2, The R Project for Statistical Computing). We modeled a single within-subject factor "time" (levels: baseline, 12 weeks, 6 months), and a separate baseline for each participant. We modeled time as a categorical factor and therefore do not assume a linear relationship between time and outcome measures. We report the contrast estimate, 95% CI on the estimate, and *P* value. *P* values <.05 were considered significant. We also examined the *per protocol* results. Due to the low dropout rate, these results were not meaningfully different from the *intention-to-treat* results and are therefore not reported here.

Results

Participants

Demographics of participants are presented in Table 1. On average, participants were aged above 50 years, had a BMI over 25 kg/m^2, and predominantly female. At baseline, 66% (27/41) of users were not doing any physical therapy-style exercise and 54% (22/41) were active 90 min or less per week including walking, suggesting a predominantly sedentary lifestyle. There were no significant differences in any of the demographics or baseline data between those who completed the PROMs at 6 months and those who did not (*P*>.05 for all).

Table 1. Demographics and relevant baseline data.

Metric	All Participants	Completed 12 week PROMs[a]	Completed 6 month PROMs	Did not complete 12 week	Did not complete 6 month
n (% of all participants)	41 (100)	37 (90)	33 (80)	4 (10)	8 (20)
Age in years, mean (SD[b])	52 (9)	52 (9)	54 (8)	54 (4)	47 (9)
BMI[c] (kg/m^2), mean (SD)	29 (7)	28 (7)	29 (7)	32 (6)	27 (7)
Height (cm), mean (SD)	169 (10)	169 (10)	168 (8)	171 (4)	176 (13)
Weight (kg), mean (SD)	82 (17)	80 (17)	81 (17)	92 (15)	83 (19)
Female, n (%)	32 (78)	29 (78)	28 (85)	3 (75)	4 (50)
PT-like exercise[d] at baseline, n (%)	14 (34)	13 (35)	11 (33)	1 (25)	3 (38)
Active 90+ min per week at baseline, n (%)	19 (46)	19 (51)	18 (55)	0 (0)	1 (12)
Pain catastrophizing scale[e], mean (SD)	14 (9)	13 (10)	13 (10)	19 (5)	16 (8)
Had knee surgery in past, n (%)	17 (41)	15 (41)	15 (45)	2 (50)	2 (25)
Arthritis diagnosed by doctor, n (%)	18 (44)	17 (46)	17 (52)	1 (25)	1 (12)

[a]PROMs: patient-reported outcome measures.

[b]SD: standard deviation.

[c]BMI: body mass index.

[d]PT-like exercise: answer to screening question "Do you currently do any physical therapy-style exercises?"

[e]Pain catastrophizing scale: from 0 (no catastrophizing) to 52 (extreme).

Intervention Engagement

Engagement across each of the relevant goals provided to participants in the program are shown in Table 2. Participants performed sensor-guided physical exercises on 42.9 days on average, or 3.6 days per week—in line with the goal of 3-4 days exercise per week. On such an average active day, participants performed 39 repetitions across various exercises. Participants also completed the majority of their education articles, consuming education on 89% (10.7/12) of weeks. The average participant completed 1.9 (SD 0.8) of the 3.3 (SD 0.8) CBT sessions offered.

Primary Outcomes: Pain and Function

Participants reported highly significant improvements on the KOOS pain subscale (Figure 3; improvement at week 12 from baseline: 16 points, 95% CI 12-21, $P<.001$) that were maintained at 6 months (improvement from baseline: 18 points, 95% CI 14-23, $P<.001$). Knee function also significantly improved at 12 weeks (KOOS-PS, Figure 3; improvement at week 12 from baseline: 10 points, 95% CI 6-14, $P<.001$) and was maintained at 6 months (improvement from baseline: 14 points, 95% CI 9-18, $P<.001$).

Table 2. Engagement with the Hinge Health digital care program (DCP) for chronic knee pain (CKP).

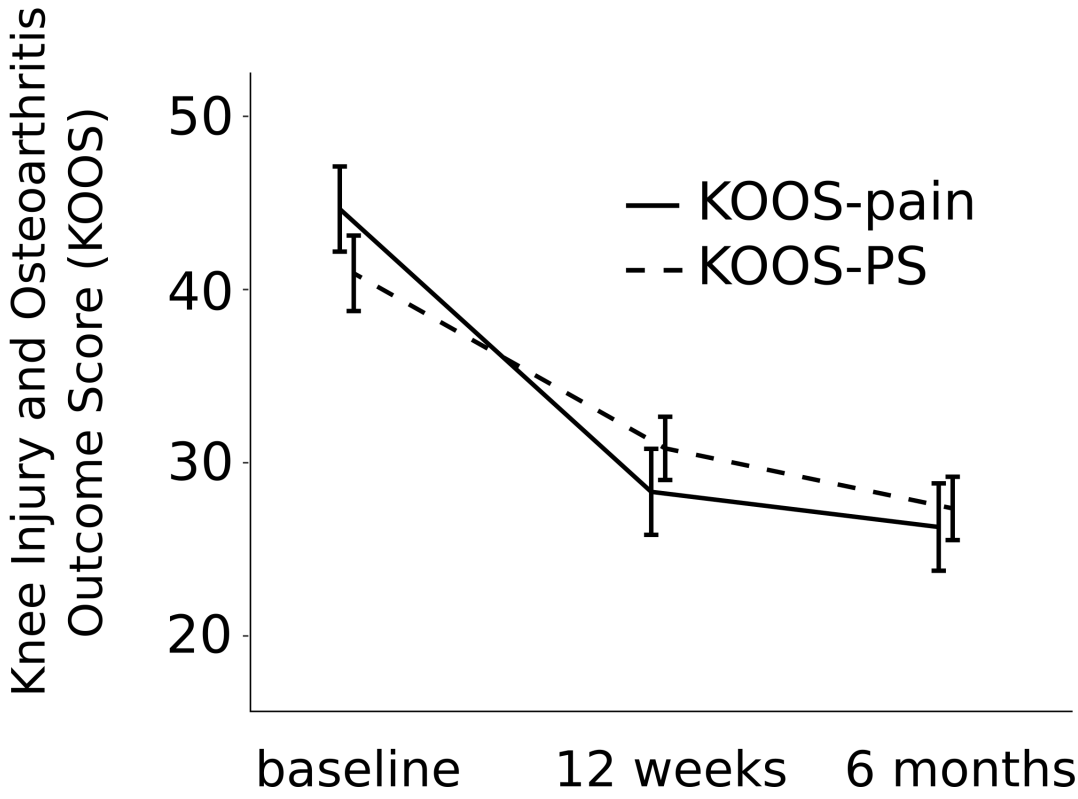
Metric	All Participants	Completed 12 week PROMs[a]	Completed 6 month PROMs	Did not complete 12 week	Did not complete 6 month
Days with sensor-guided exercise, mean (SD[b])	42.9 (16.1)	44.8 (15.2)	46.7 (14.5)	26 (16.1)	27.4 (13.3)
In-app physical exercise repetitions, mean (SD)	1685.5 (1150)	1772.6 (1163.1)	1881.2 (1175)	880.2 (665.1)	878.1 (565.8)
Offline activities logged in hours, mean (SD)	24.9 (11.5)	26 (11.4)	27.2 (11.3)	14.8 (5.8)	15.4 (5.8)
Education articles read, mean (SD)	10.7 (2.1)	10.9 (1.6)	11.1 (1.5)	8.5 (4.4)	8.9 (3.1)
CBT[c] session completed, mean (SD)	1.9 (0.8)	1.9 (0.8)	2 (0.7)	1.5 (1)	1.4 (1.1)
Team posts and comments, mean (SD)	12.3 (7.7)	12.9 (7.7)	13.9 (7.4)	6.2 (3.2)	5.4 (3.9)

[a]PROM: patient-reported outcome measure.

[b]SD: standard deviation.

[c]CBT: cognitive behavioral therapy.

Figure 3. Knee Injury and Osteoarthritis Outcome Score (KOOS) pain subscale and Knee Injury and Osteoarthritis Outcome Score-Physical Function Short Form (KOOS-PS)—which measures knee function—over the course of the 6-month assessment period. Error bars indicate standard error of the mean (SEM).

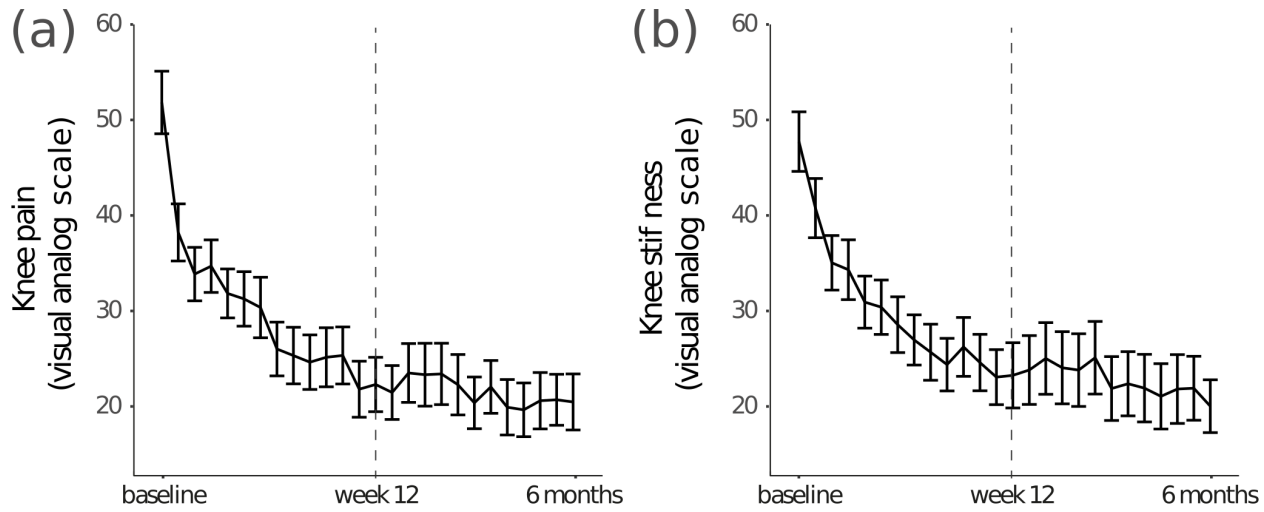


Secondary Outcomes

Visual Analog Scales

Between baseline and week 12, participants reported a 57% reduction in knee pain (Figure 4; from 52 to 22 points; mean difference 30, 95% CI 21-38, *P*<.001) and 51% reduction in knee stiffness (Figure 4; from 48 to 23; mean difference 25, 95% CI 16-33, *P*<.001). These improvements were maintained at 6 months for both knee pain (mean improvement 31, 95% CI 23-40, *P*<.001) and stiffness (mean improvement 28, 95% CI 20-36, *P*<.001).

Figure 4. Visual analog scale assessment of (a) knee pain and (b) knee stiffness over the course of the 6-month assessment period. The dotted line indicates the last week of the 12-week program. Error bars indicate standard error of the mean (SEM).



Surgery Intent

Surgery interest significantly decreased over the course of the program from 3.5 out of 10 at baseline to 1.2 out of 10 at 12 weeks (67% reduction; mean reduction 2.3, 95% CI 1.5-3.1, *P*<.001). At 6 months participants still expressed low interest in surgery (69% reduction; mean reduction: 2.4, 95% CI 1.6-3.2, *P*<.001). Of the 17 participants at high risk of surgery at baseline—defined as a surgery interest of 5 or higher—by week 12 only 3 remained at high risk. At 6 months, still only 3 remained at high risk for surgery, 2 of whom also were at high surgery risk at week 12, and 1 of whom had moved into the high-risk category between week 12 and 6 months.

Satisfaction

Participants expressed high satisfaction with the program. At week 12, on average participants rated the program 9.2 out of 10 (SD 1.3). By 6 months, the average rating was 9.3 (SD 1.1).

Discussion

Principal Findings

Although CKP is a common cause of severe chronic pain and disability affecting millions of individuals, accessible comprehensive treatment programs that address multiple components of care are lacking. The challenges to effectively delivering a program involving physical therapy, education, and psychosocial support are diverse and substantial—including time constraints on primary care appointments, paucity of reimbursement for education, and lack of awareness of the psychosocial risk factors that impact outcomes for CKP. Moreover, there are significant practical and cost barriers faced by the patient—such as traveling to physical therapy appointments, large patient costs, sourcing and paying for childcare, or having to seek out education and psychosocial support on their own. Finally, tracking outcomes and program adherence is difficult if not impossible in the traditional outpatient setting, and there is a distinct lack of technology-enabled solutions for patients. The results of this study demonstrated that the Hinge Health 12-week DCP for individuals with CKP produced clinically and statistically significant improvements in knee pain, stiffness, and function that lasted over a period of 6 months following initiation of the 12-week program, and were accompanied by a significant reduction in surgery interest as well as high satisfaction. Furthermore, the digitization of exercise therapy allowed for precise tracking of participation and adherence, showing that on average participants completed exercise therapy between 3 and 4 days each week.

Participants' KOOS pain and function scores improved by clinically significant 16 and 10 points, respectively, at the end of the 12-week program. Similarly, VAS pain and stiffness scores improved by clinically significant 58% and 50% at the end of the 12-week program. These improvements are greater than or of similar magnitude to other treatment programs that have shown efficacy for CKP, including a 12-week graded physical activity exercise program which found improvements in WOMAC pain and function of 25% and 22%, respectively, immediately after program completion [39]; an 8-week exercise and education program which found improvements in WOMAC pain, stiffness, and function scores of 23%, 17%, and 23%, respectively, immediately after the completion of the program [40]; and a 6-week exercise, education, and self-management program which found improvements in WOMAC pain and function of 31% and 26%, respectively, immediately at the end of the program [10]. Deyle et al [41] found greater improvement

in WOMAC score at the end of a 4-week program of manual therapy and supervised exercise (52%) versus a home-based exercise program (26%). However, the clinical intervention was more expensive than the home-based intervention and did not lead to better long-term outcomes [41], and the home-based intervention did not include any program components such as education or behavioral therapy which may improve long-term outcomes. The format of the program also did not allow the researchers to track adherence to the home exercise.

The clinically significant improvements in KOOS pain and function in this study were maintained at 6 months after starting the program, with improvements of 18 and 14 points, respectively. Similarly, the improvements in VAS pain and stiffness scores were maintained, with improvements of 60% and 58% at the 6-month timepoint, respectively. These results suggest strong maintenance of effect of the program. Similar long-term effects have been reported in other intervention programs of similar length [10,12,39-41], with clinical improvements reported to be maintained as long as 30 months after completing the programs. Although the long-term effect of the Hinge Health DCP, in particular the effect related to exercise, may in part be dependent on continued adherence to the program [42], the behavioral, educational, and psychosocial components of the program may improve the potential for long-term effects [10]. Furthermore, the comprehensive conservative care program incorporating exercise may also influence the need for future surgical treatments, as a previous treatment program incorporating exercise and manual physical therapy found a 75% reduction in TKA after participation in the program [12]. Similarly, comprehensive pain management programs for chronic back pain demonstrate a reduced need for surgery of 67% as compared with alternative medical care [6]. Surgical interventions such as TKA are effective at improving pain and symptoms following surgery, with studies finding between approximately 50% and 75% of patients experience improvement after surgery [43,44]. However, even in individuals with CKP that have all indications to warrant surgery, afflicted individuals are often reluctant to consider invasive surgical procedures, with data showing only 15-32% are willing to consider surgery for their knee pain [45,46]. In this study, surgery interest significantly decreased over the course of the 12-week program, with no participant increasing in intent for surgery. These improvements in pain and function could be maintained over the long-term, thereby circumventing surgery and its cost. However, the follow-up period of this study was too short to draw a definitive conclusion on the matter, and future research will be needed to more fully understand the economic effects of the program.

Strengths and Limitations

The results of this study demonstrate that the Hinge Health DCP shows promise for providing participants with a program to effectively manage their CKP condition. However, this study has several limitations. This was a single-arm study without blinding of the participants, and thus any placebo effect, for example, due to simply being accepted into the program, or regression to the mean was not able to be evaluated. Future work with a more rigorous study design such as a randomized, controlled trial as compared with standard care or multiple baseline trial will be needed to better understand the effect of the program as compared with standard care. Although the sample size was relatively small, the results demonstrated large effect sizes for primary outcomes which showed highly significant results and should be confirmed in larger future studies.

The study enrolled participants with self-reported CKP, but did not require a physician-diagnosis of knee OA. However, our recruitment questionnaire utilized questions specific to clinical diagnosis for knee OA derived from the American College of Rheumatology criteria for OA of the knee [2], and our inclusion criteria are similar to those of other knee OA studies [12,39-41]. Furthermore, participants included in this study showed typical demographics and characteristics of people living with CKP (Table 1). Our participants were predominantly female, and although a higher prevalence of knee OA and knee pain are reported in female versus male [47,48], future work should include a larger male participant population to better understand potential differences in program response due to sex.

Study results showed good subject engagement with exercise and education. However, due to the comprehensive nature of the program, it is not possible to determine if all components of the program are integral to the study results. As shown in Figure 4, we noted a substantial drop in knee pain and stiffness between baseline (screening) and the first VAS score reported, potentially as a positive consequence of the exercises performed as part of onboarding, regression to the mean, and perceived improvements due to the positive news of being accepted onto the program. To confirm that the program achieved improved outcomes not just between baseline and the first VAS, we also compared the average VAS ratings in weeks 1-4 of the program against those in weeks 9-12, and observed highly significant reductions in pain (9.3 points, 95% CI 5.7-12.8, $P<.001$) and stiffness (8.4 points, 95% CI 4.8-12.0, $P<.001$). Deyle et al [12] also noted a rapid reduction in symptoms of 20-40% after only a few treatment sessions, which was attributed to improvement from the initial therapy. Although other treatments of similar duration have found lasting effects [10,12,39,40,49], the relatively short time frame of this study, to 3 months follow-up after completion of the program, or 6 months after enrollment, requires future work to evaluate the potential of the program for long-term improvement in symptoms.

Conclusions

The results of this study demonstrated clinically and statistically significant improvements in pain, function, and stiffness following a 12-week digitally based program designed to address multiple components of care for CKP. Although the initial results with this program are promising, future research will be needed to understand the long-term effects of the program. Due to the adaptability of the system, future work may also investigate the effect of a similar program on other chronic pain conditions such as lower back pain.

In conclusion, the results of this pilot study of the 12-week digital Hinge Health DCP demonstrate improvements in knee pain, stiffness, and function which were maintained to 6 months after enrollment into the program. The program greatly reduced surgery interest in participants, providing strong evidence that

the program may be an effective intervention to delay or significantly reduce the incidence of more invasive and costly treatments for CKP such as surgery.

Acknowledgments

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Conflicts of Interest

All authors except JCE-H work at Hinge Health. JCE-H is a paid domain expert consultant.

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Abbreviations

CBT: cognitive behavioral therapy
CKP: chronic knee pain
DCP: digital care program
HADS: Hospital Anxiety and Depression Scale
KOOS: Knee Injury and Osteoarthritis Outcome Score
KOOS-PS: Knee Injury and Osteoarthritis Outcome Score-Physical Function Short Form
OA: osteoarthritis
PROM: patient-reported outcome measure
TKA: total knee arthroplasty
VAS: visual analog scale

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2.

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Original Paper

Effects of a 12-Week Digital Care Program for Chronic Knee Pain on Pain, Mobility, and Surgery Risk: Randomized Controlled Trial

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Abstract

Background: Chronic knee pain, most commonly caused by knee osteoarthritis, is a prevalent condition which in most cases can be effectively treated through conservative, non-surgical care involving exercise therapy, education, psychosocial support, and weight loss. However, most people living with chronic knee pain do not receive adequate care, leading to unnecessary use of opiates and surgical procedures.

Objective: Assess the efficacy of a remotely delivered digital care program for chronic knee pain.

Methods: We enrolled 162 participants into a randomized controlled trial between January and March 2017. Participants were recruited from participating employers using questionnaires for self-assessment of their knee pain, and randomized into treatment (n=101) and control (n=61) groups. Participants in the treatment group were enrolled in the Hinge Health digital care program for chronic knee pain. This is a remotely delivered, home-based 12-week intervention that includes sensor-guided exercise therapy, education, cognitive behavioral therapy, weight loss, and psychosocial support through a personal coach and team-based interactions. The control group received three education pieces regarding self-care for chronic knee pain. Both groups had access to treatment-as-usual. The primary outcome was the Knee Injury and Osteoarthritis Outcome Score (KOOS) Pain subscale and KOOS Physical Function Shortform (KOOS-PS). Secondary outcomes were visual analog scales (VAS) for pain and stiffness respectively, surgery intent, and self-reported understanding of the condition and treatment options. Outcome measures were analyzed by intention to treat (excluding 7 control participants who received the digital care program due to administrative error) and per protocol.

Results: In an intent-to-treat analysis the digital care program group had a significantly greater reduction in KOOS Pain compared to the control group at the end of the program (greater reduction of 7.7, 95% CI 3.0 to 12.3, *P*=.002), as well as a significantly greater improvement in physical function (7.2, 95% CI 3.0 to 11.5, *P*=.001). This was also reflected in the secondary outcomes VAS pain (12.3, 95% CI 5.4 to 19.1, *P*<.001) and VAS stiffness (13.4, 95% CI 5.6 to 21.1, *P*=.001). Participants' self-reported likelihood (from 0% to 100%) of having surgery also reduced more strongly in the digital care program group compared to the control group over the next 1 year (–9.4 percentage points, pp, 95% CI –16.6 to –2.2, *P*=.01), 2 years (–11.3 pp, 95% CI –20.1 to –2.5, *P*=.01), and 5 years (–14.6 pp, 95% CI –23.6 to –5.5, *P*=.002). Interest in surgery (from 0 to 10) also reduced more so in the digital care program compared to control group (–1.0, 95% CI –1.7 to –0.2, *P*=.01). Participants' understanding of the condition and treatment options (on a scale from 0 to 4) increased more substantially for participants in the digital care program than those in the control group (0.9, 95% CI 0.6 to 1.3, *P*<.001). In an analysis on participants that completed the intervention (per protocol analysis) all primary and secondary outcomes remained significant at greater effect magnitudes compared to intention to treat, with those completing the program showing a 61% (95% CI 48 to 74) reduction in VAS pain compared to 21% (95% CI 5 to 38) in the control group (*P*<.001). Accounting for the cost of administering the program, we estimate net cost savings on surgery alone of US $4340 over 1 year and $7900 over 5 years for those participants completing the digital care program compared

to those in the control group receiving treatment-as-usual. In an exploratory subgroup analysis including only participants exhibiting clinical symptoms of osteoarthritis the program proved equally effective.

Conclusions: This trial provides strong evidence that a comprehensive 12-week digital care program for chronic knee pain, including osteoarthritis, yields significantly improved outcomes for pain, physical function, stiffness, surgery risk, and understanding of the condition, compared to a control group.

Trial Registration: International Standard Randomized Controlled Trial Number (ISRCTN) 13307390; http://www.isrctn.com/ISRCTN13307390 (Archived by WebCite at http://www.webcitation.org/6ycwjGL73)

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KEYWORDS

osteoarthritis, knee; chronic pain; exercise; education; cognitive behavioral therapy; computers, handheld; coaching; non-invasive; digital health; digital therapy; digital care program

Introduction

Background

Chronic knee pain (CKP), often caused by knee osteoarthritis, affects 1 in 4 individuals over the age of 55 [1], and is a major health condition [2] that is becoming increasingly prevalent [3]. The effects of CKP are far-reaching and not limited only to the knee joint. Rather, chronic pain can result in negative effects on general health status including social functioning, energy and vitality, general health perception, limitations due to emotional and physical problems [4], negative effects on quality of life [5], productivity [6], emotional well-being [7], and health care costs [8].

Current recommendations for management of chronic pain suggest that treatments addressing multiple aspects of pain, including physical, psychological, and social, are most effective as compared to a single therapy [9,10]. Recommended components of effective non-pharmacological care for chronic musculoskeletal pain include physical activity, patient education, weight reduction, and self-management and coping strategies [9,11–13]. Thus, an effective treatment algorithm for CKP is a comprehensive program consisting of the main components of recommended conservative care.

Such comprehensive programs for chronic pain - including knee osteoarthritis (OA), one of the most common diagnosis for CKP [11] - have been shown to improve pain and function [15–23] and reduce utilization of total knee arthroplasty (TKA) [12]. However, despite research into comprehensive programs for CKP, utilization of such programs outside of the research arena is rare. For example, it is estimated that 80% of individuals with CKP due to knee OA are not adequately treated with conservative care [13]. This, in turn, leads many patients to undergo costly knee surgeries that could have been otherwise avoided [14]. Thus, there is a significant need to improve access and increase use of a comprehensive treatment program for the large population of individuals affected by CKP.

Digital technology has the potential to effectively provide comprehensive CKP programs. A digital care program (DCP) incorporating multiple components of recommended care could allow for more efficient, effective, and economical treatment by overcoming barriers to behavior change often observed in traditional in-person care, such as travel time, missed work, cost of care, and limited access to healthcare. Furthermore, a DCP incorporating remote sensing would allow for monitoring of patient adherence, a critical barrier limiting long-term effectiveness of treatment programs [15,16]. Only a few studies, however, have examined the use of digital technologies for CKP, investigating web-based platforms for physical activity and exercise [17,18], pain coping training [19], and more comprehensive programs incorporating education and exercise [20-22]. In particular, there are limited studies using a more rigorous randomized controlled design [18,19,22], and the use of digital health in musculoskeletal conditions is regarded as early stage [23].

We have developed a 12-week program for CKP called the Hinge Health DCP [24]. It consists of recommended components of non-pharmacological care for chronic musculoskeletal pain and includes sensor-guided exercise therapy promoting local muscle strengthening and stretching, education, cognitive behavioral therapy, psychosocial support through teams and personal health coaches, weight loss, and activity tracking. We have previously shown that the Hinge Health 12-week DCP improves clinical outcomes of pain, function, and stiffness over a period of 6 months after initiation of the program in a single-arm study of individuals with CKP [24]. The purpose of this study was to assess the short-term effectiveness (12 weeks after initiation) of the Hinge Health DCP in improving knee pain and disability in subjects with CKP, as compared to a control group receiving treatment as usual and knee care education only. We employed a randomized controlled trial with the hypothesis that the DCP would cause a greater improvement in outcome than the control treatment.

Methods

Study Design

This study was a two-armed, randomized, controlled, unblinded trial of participants with chronic knee pain. Online applications were invited from employees and their dependents at participating employers spread out over 12 office locations. Participants were recruited through emails and posters distributed through the participants' employers between January and March 2017. The trial was approved by the Western Institutional Review Board, and participants completed the intervention at home. The trial was performed in compliance with the Helsinki Declaration for research involving human subjects and in line with ICH-GCP guidelines. The trial was

preregistered at International Standard Randomized Controlled Trial Number (ISRCTN) 13307390. We followed CONSORT guidelines for reporting this trial.

Study Population

We assessed the eligibility of all applicants that completed the baseline questionnaire for CKP through their web browser. Participants provided informed consent as part of this questionnaire using a checkbox and digital information sheet. The inclusion criteria were: (1) age over 18, (2) knee pain for at least 1 month in the last 12 months, (3) participating in the collaborating employers' health plans, and (4) provision of informed consent. The exclusion criteria were (1) a prior diagnosis of rheumatoid arthritis, (2) surgery on the knee less than 3 months ago, and (3) an injury to the knee less than 3 months ago. We did not include knee OA as an inclusion criterion, though we did assess the presence of OA through 6 self-reported clinical criteria, whereby 3 or more positive criteria suggested OA: age over 50 years, stiffness for <30 minutes in the morning, crepitus, bony tenderness, bony enlargement, and no palpable warmth [11]. As there were a limited number of places available on the program, eligible applicants were prioritized for enrollment, with those exhibiting greater pain, disability, and surgery intent prioritized over those showing less. Applicants that were not prioritized were placed on the waitlist (n=73). Participants were not paid for their time, other than an incentive offered to complete the outcome questionnaire for those that did not complete it within 4 days of first invitation.

Randomization

Eligible applicants were randomized into the trial twice weekly during the signup period. Batches of selected participants were then randomized into treatment and control using a 60:40 (treatment: control) ratio (n=115) or using an 80:20 ratio (n=47). The 80:20 ratio represents a deviation from the study protocol due to an administrative error and was only used for a restricted time. The effective allocation ratio was therefore 62:38 (treatment: control). When a batch of applicants was randomized, an algorithm shuffled the batch and selected the first 60% (or 80%) to enter the treatment, and the remaining 40% (or 20%) to enter control. As such, the person(s) reviewing the applicants had no way of knowing whether any given applicant would end up in the treatment or control group (concealed allocation). After randomization, participants in the treatment group received an email inviting them to complete their profile and receive their kit to participate in the DCP, whereas those in the control group received an email with three education articles to help them care for their knee. Due to the nature of the study, neither the study staff nor the participants were blinded to group allocation.

Study Intervention

The treatment group received the Hinge Health 12-week DCP for CKP. The contents of this program have been described previously [24]. In short, participants received a tablet computer with the Hinge Health application installed, and two custom Bluetooth sensors with straps to be used on the upper and lower leg during the in-app exercise therapy. Participants were assigned a personal coach that provided support and accountability throughout the program and were placed in a team to provide peer support through a discussion feed within the app. Participation was completed entirely remotely through the app, at times and places chosen by the participant. Reminders were provided by text message and email if the participant was not engaging at the recommended intensity with the program. On a weekly basis, participants in the DCP were set the goal of completing 3 sessions of sensor-guided exercise therapy, reading one to two education articles, logging their symptoms at least twice, performing cognitive behavioral therapy (CBT; subset of weeks only), working at weight loss (if overweight), and tracking at least three 30-minute sessions of aerobic activities. Details of each of these components of the DCP are described elsewhere [24]. Each participant also maintained access to treatment as usual (TAU).

The control group received three pieces of education, presented digitally, that is also part of the Hinge Health DCP. These articles discussed the importance of self-care, how to deal with setbacks in knee pain, and how to manage communication and relationships when living with CKP. The control group maintained access to TAU and were informed that they would be reconsidered for the program when new places became available following the 12-week study.

The application was developed, owned, and sponsored by Hinge Health, Inc. The 12-week program received extensive testing over a 2-year period prior to starting the trial. All participants received the same version of the program, and there were no major application updates during the course of the trial.

Study Outcomes

Primary Outcomes

The preregistered primary outcomes were the Knee Injury and Osteoarthritis Outcome Score (KOOS) Pain subscale [25], and the KOOS Physical Function Shortform (KOOS-PS, referred to as "KOOS short version" in preregistration) scale [26]. Both scales span from 0 (no pain or impaired function, respectively) to 100 (extreme pain or impaired function, respectively), and were assessed at baseline and at the end of the 12-week DCP in the intervention and control groups. Both surveys are composite measures which may confound multiple conditions, however the digital nature of the program precluded individual clinical evaluation. Additionally, those in the treatment group were asked to complete both questionnaires at weeks 4 and 8 as part of the DCP. To conclude a positive effect of treatment we required a significant effect on *both* primary outcomes, though we note this was not specified in the preregistration.

Secondary Outcomes

We describe multiple preregistered secondary outcomes. Firstly, a visual analogue scale (VAS) for the question "Over the past 24 hours, how bad was your knee pain?" from 0 ("none") to 100 ("worst imaginable"). Secondly, a VAS for the question "Over the past 24 hours, how bad was your knee stiffness?" from 0 ("none") to 100 ("worst imaginable"). Thirdly, we assessed surgery intent using multiple questions: "What do you think are the chances you'll have knee surgery in the next year, in %?" as well as the same question for 2 and 5 years into the future. We also asked "On a scale of 0 to 10 how interested are

you in knee surgery?" with labels "not at all" at 0, and "definitely going to get surgery" at 10. Lastly, we asked "Thinking about your symptoms, how well do you feel you understand your condition and your treatment options?" with answers "Not at all", "Slightly", "Moderately", "Very well", "Completely", coded from 0 to 4. All data were assessed at baseline and at the end of the 12-week DCP in both the intervention and control groups. Additionally, those in the treatment group were asked to complete these questions at various points during the DCP: the VAS twice each week, and the questions related to surgery and understanding of their condition at week 6.

Sample Size

The minimal clinically important difference for KOOS is considered to be approximately 10 points on the 100-point scale, and a standard deviation of 15 is recommended for power calculations [27]. Although we did not use the full KOOS scale, we assumed its derivate questionnaires would have similar properties and used a standard deviation of 15 to perform power calculations. The number of participants needed in each group to detect a 10-point difference given a Type I error rate of 0.05 and power of 0.8 is 36. Given our unequal allocation ratio, this would need to be at least 54 in the treatment group and 36 in the control group for a total of at least 90 participants in the trial. As we had two primary endpoints albeit not independent of one another, we significantly over-recruited participants into the trial. We opted for an unequal allocation ratio to ensure we would be able to enter a certain minimum number of people into the treatment arm, a criterion mandated by the commercial nature of the deployments.

Statistical Analysis

Our primary analysis was conducted using a modified intent-to-treat approach. This analysis included all participants that were randomized, including those in the treatment group that never started the DCP. However, we excluded 7 participants in the control group that were enrolled in the DCP due to an administrative error (including these participants does not materially affect the statistical significance of the results). We describe baseline characteristics for the treatment and control groups using frequencies, means, and standard deviation. For those participants in the treatment group that performed at least one session of exercise therapy and those that completed the week 12 outcome questionnaire respectively, we also provide descriptive statistics of their engagement with the DCP. The analysis of primary and secondary outcomes was performed using a linear mixed model using the Linear Mixed-Effects Model ("lme4") package in R [28] with within-subject factor "time point" (baseline or outcome) and between-subject factor "group" (treatment or control) and their interaction. We modeled a separate baseline for each participant, effectively examining the change scores only (in lme4 this was performed as "score ~ timepoint*group + (1|participant)", where (1|participant) models an intercept for each participant separately). We assessed normality of the residuals based on quantile-quantile (QQ)-plots. If we did not have outcome data for a participant, we used last observation carried forward (LOCF). For those in the control group, this meant their baseline was carried forward; for those in the treatment group this meant either their baseline was carried forward, or data collected during the course of the DCP. We also analyzed all primary and secondary outcomes with baseline carried forward (BOCF) also for the treatment group (rather than LOCF). We also omitted LOCF and instead allowed the mixed-effects model to account for the missing data, which yielded an identical pattern of results as using LOCF and BOCF. We also report the primary and secondary outcomes following a per-protocol analysis to assess the effect of the program on those that complete it. Lastly, we performed an exploratory subgroup analysis using the same primary and secondary outcomes on participants that met the criteria for knee OA as defined by having at least 3 out of 6 clinical criteria: age >50 years, stiffness in the morning <30 min, crepitus, bony tenderness, bony enlargement, and no palpable warmth [11].

Surgery Cost Savings

We report the expected savings on surgery costs based on participants' self-assessment of their likelihood to have surgery. The calculation estimates the cost of knee surgery at US $40,000 [29]. For example, a 10-percentage point reduction in self-reported 1-year surgery likelihood would translate into a cost saving of US $4000 in the first year, minus the costs of the program per participant. The net cost saving is not considered a primary or secondary outcome of the clinical trial and is only calculated for those participants completing the trial (per protocol).

Results

Study Population

A total of 309 people completed the screening for CKP in January or February 2017, of which 162 entered the trial and were randomized (Figure 1). Of those 162 individuals, 62% entered the treatment arm (101/162) and 38% entered the control arm (61/162). Seven participants in the control arm were given the DCP due to administrative error and have all been excluded from all following results. The errors afflicted this set of participants completely at random (ie, not as a function of symptoms, demographics, or otherwise) and their exclusion, therefore, does not bias the findings; in contrast, including these participants would have led to an underestimation of the true effect of treatment. The baseline demographics were comparable between groups (Table 1), with the average participant 46 years of age and overweight. At baseline, all but 1 participant believed the DCP would help them delay surgery, and 87% (135/155) believed the DCP could help them avoid surgery altogether. A substantial minority (41%) had already undergone knee surgery in the past, though none were actively rehabilitating. The only difference in demographics between both groups was the gender balance; there were more women in the treatment compared to control group (43% versus 26% respectively).

Table 1. Demographics of the control and treatment groups. The term SD refers to standard deviation.

Characteristic	Treatment	Control	All
Number of participants	101	54	155
Age in years, mean (SD)	46 (12)	47 (12)	46 (12)
Body Mass Index (kg/m2), mean (SD)	27 (5)	28 (4)	27 (5)
Female, n (%)	43 (43)	14 (26)	57 (37)
Physical Training-like exercise at screening[a], n (%)	33 (33)	17 (31)	50 (32)
Fear avoidance[b], n (%)	6 (6)	6 (11)	12 (8)
Godin activity score[c], mean (SD)	34 (23)	39 (25)	36 (24)
Hours sedentary per day, mean (SD)	6 (3)	6 (3)	6 (3)
Think Digital Care Program can delay surgery, n (%)	100 (99)	54 (100)	154 (99)
Think Digital Care Program can avoid surgery, n (%)	87 (86)	48 (89)	135 (87)
Taking antidepressants, n (%)	2 (2)	0 (0)	2 (1)
Taking opioids, n (%)	5 (5)	3 (6)	8 (5)
Self-efficacy[d], mean (SD)	11 (3)	10 (3)	11 (3)
Surgery on the knee in the past, n (%)	45 (45)	19 (35)	64 (41)
Knee osteoarthritis[e], n (%)	75 (74)	44 (81)	119 (77)

[a]Positive answer to the question “Do you currently do any physical therapy-style exercises?”

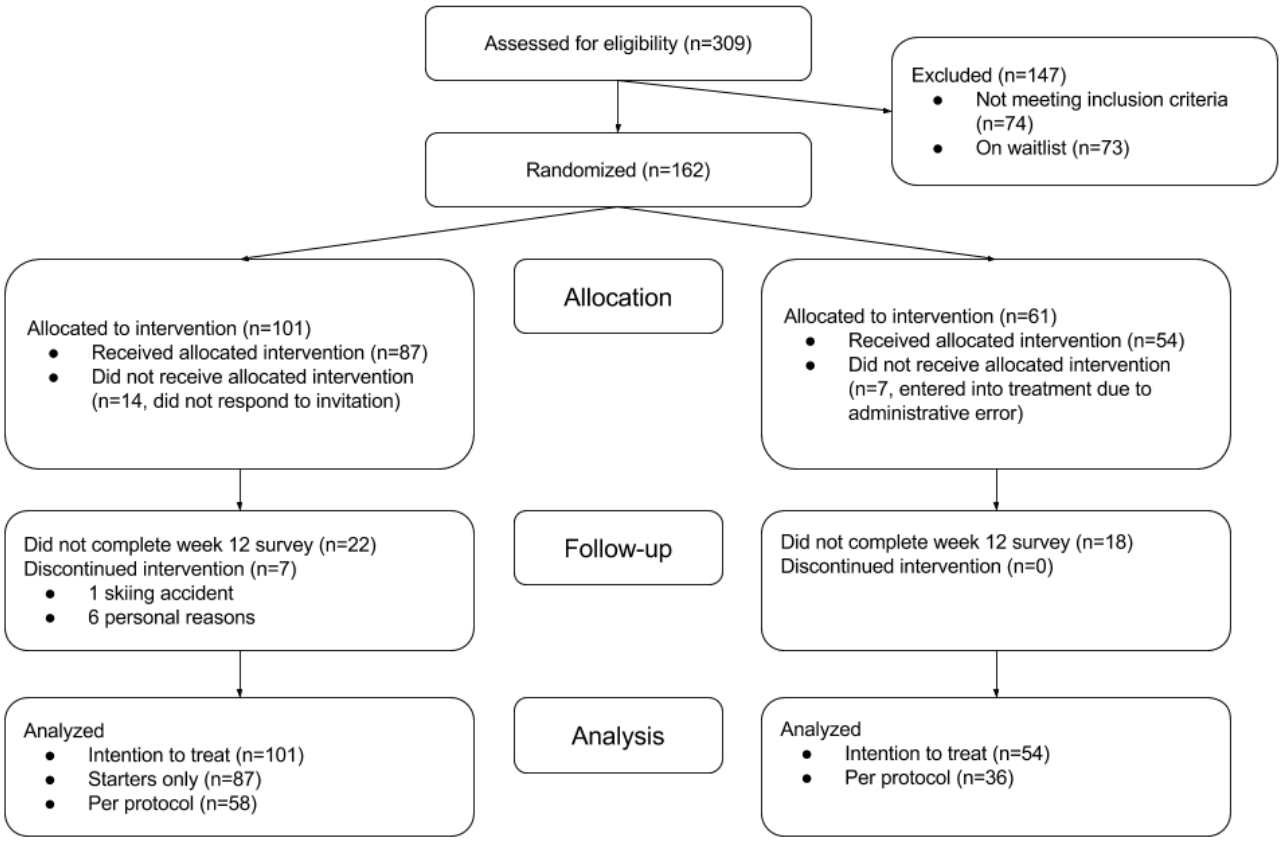
[b]Positive answer to the question “It's really not safe for a person with a condition like mine to be physically active.”

[c]Composite score; 24 indicates “active”, 14-23 indicates “Moderately active”, and <14 indicates “Insufficiently active/sedentary” [30].

[d]Health self-efficacy assessment, scores from 0 (no self-efficacy) to 15 (high self-efficacy) [31].

[e]Defined as satisfying at least 3 out of 6 clinical criteria for osteoarthritis [11].

Figure 1. Participant flow diagram.



Participant Flow

Participants in the treatment group were lost at three stages. First, of the 101 participants randomized to treatment, 14 did not respond to our invitation to take part in the DCP or subsequent follow-up communications. Second, 7 participants actively withdrew during the course of the DCP, due to injury or for personal reasons (eg, time constraints or stress at work, Figure 1). Third, 22 participants did not complete the week 12 online outcomes survey.

In the control group, 7 participants were placed in the DCP due to an administrative error. A further 18 participants did not complete the week 12 outcomes survey.

Engagement

For participants in the treatment group, we tracked completion of each component of the DCP. Participants that started the DCP (n=87), defined as performing at least one sensor-guided workout, performed an average of 33 in-app workouts, or an average of 2.5 workouts per week from week 0 (introduction to the program) to 12. Users that completed the outcome questionnaires at 12 weeks (n=59) performed 43 sensor-guided workouts (3.3 workouts per week), compared to the 3 times per week that is recommended in the DCP. Average weekly engagement with the DCP was 76% for those that started the program, and 95% for those that completed it. Participants that completed the 12-week follow-up read approximately 10 education articles, completed 2 Cognitive Behavioral Therapy (CBT) sessions, posted on the feed 8 times, and contacted their coach over text message or in-app message about 7 times.

Outcomes

Primary Outcomes

Both primary outcomes improved significantly more in the treatment group compared to the control group (Table 3). We observed a statistically significant mean group difference for KOOS Pain whereby the treatment group improved by 7.7 (95% CI 3.0 to 12.3) points more than the control group. Similarly, the treatment group improved by 7.2 (95% CI 3.0 to 11.5) points more than the control group on the KOOS-PS scale.

Secondary Outcomes

Each of the secondary outcomes also showed the DCP to be superior to control (Table 3). The VAS pain and stiffness scores, although improved in the control as well as the treatment group, improved by 12 (95% CI 5.4 to 19.1) points more for those in the DCP than in control. The self-reported likelihood of surgery in the next 1, 2, and 5 years, as well as interest in having surgery, all decreased more for those in the DCP than those in control over the 12-week period. Lastly, participants on the DCP improved their understanding of their condition and treatment options more than those in the control group. All primary and secondary outcomes remained statistically significant in an analysis using baseline carried forward for the treatment group rather than last observation carried forward.

Per Protocol Analysis

We also provide results for only those participants that received their allocated intervention and completed the outcome questionnaires (n=58 for treatment, n=36 for control) in Table 4. The per protocol results are fully consistent with the intent-to-treat analysis.

Based on the reductions in surgery likelihood we also calculated the net savings per participant of the program after accounting for the costs of delivering the program. The 1-year net saving of the digital care program is US $4340 (13.1% * US $40,000, corrected for the cost of the digital care program), the 2-year savings are US $4660, and the 5-year savings are US $7900.

Subgroup Analysis: Knee Osteoarthritis

An intent-to-treat analysis on participants with knee osteoarthritis (75/101 in the treatment group; 44/54 in the control group) showed results consistent with the original intent-to-treat analysis presented in Table 3 in terms of the magnitude of the group difference and statistical significance.

Table 2. Engagement indicators for each of the aspects of the Digital Care Program. "Starters" indicates participants performed at least one sensor-guided workout. "Finishers" indicates participants that completed the outcomes questionnaires at week 12 follow-up.

Indicator	All Starters (n=87)	All Finishers (n=59)
Number of workouts, mean (SD)	33.1 (24)	42.9 (17.3)
Users engaging with the program per week, n (%)	66.3 (76.2)	55.9 (94.8)
Users active with sensor-guided exercise in weeks 1-4, n (%)	78 (89.7)	58 (98.3)
Users active with sensor-guided exercise in weeks 5-8, n (%)	69 (79.3)	56 (94.9)
Users active with sensor-guided exercise in weeks 9-12, n (%)	60 (69)	55 (93.2)
Offline activities logged in hours, mean (SD)	9.6 (9.1)	13.2 (8.8)
Education articles read, mean (SD)	7.3 (4.5)	9.6 (3.1)
Cognitive Behavioral Therapy session completed, mean (SD)	1.4 (1.2)	1.8 (1.1)
Team posts and comments, mean (SD)	6.1 (7.2)	8.4 (7.6)
In-app messages sent to coach, mean (SD)	5.9 (5.6)	6.6 (5.7)

Table 3. Primary and secondary outcomes for the intent-to-treat analysis of treatment and control groups. The mean group difference as well as the *P* value for the interaction are derived from the linear mixed effects model. Each of the primary and secondary outcomes favors the treatment over the control group. *P* values uncorrected for multiple tests. KOOS: Knee injury and Osteoarthritis Outcome Score; PS: Physical Function Shortform; VAS: visual analogue scale.

Outcome	Treatment at baseline, mean (SD)	Treatment at outcome, mean (SD)	Control at baseline, mean (SD)	Control at outcome, mean (SD)	Group difference, mean (95% CI)	Interaction, *P* value
Primary Outcomes						
KOOS Pain (0-100)	41.0 (14.1)	30.3 (17.1)	41.4 (16.5)	38.4 (17.2)	–7.7 (–12.3 to –3)	.002
KOOS-PS (0-100)	53.8 (12.3)	44.6 (16.7)	54.5 (15.7)	52.5 (16.2)	–7.2 (–11.5 to –3)	.001
Secondary Outcomes						
VAS Pain score (0-100)	45.2 (21.4)	26.6 (22)	44.7 (20.3)	38.3 (22.2)	–12.3 (–19.1 to –5.4)	.001
VAS Stiffness score (0-100)	42.6 (23.4)	25.1 (22.3)	47.4 (21.9)	43.2 (21.6)	–13.4 (–21.1to –5.6)	.001
Surgery chance next year, %	24.5 (26.9)	14.7 (25)	24.3 (26.2)	23.9 (29.1)	–9.4 (–16.6 to –2.2)	.01
Surgery chance next two years, %	32.1 (31)	19.1 (26.9)	31.7 (27.9)	30 (28.9)	–11.3 (–20.1 to –2.5)	.01
Surgery chance next five years, %	47.8 (35)	27.5 (32.9)	49.8 (32.7)	44.1 (33.6)	–14.6 (–23.6 to –5.5)	.002
Surgery interest (0-10)	3.03 (3.41)	1.92 (2.93)	3.02 (3.32)	2.89 (3.21)	–1.0 (–1.7 to –0.2)	.01
Understanding of condition and treatment options (0-4)	1.92 (1.01)	2.68 (0.937)	1.94 (1.04)	1.76 (1.03)	0.9 (0.6 to 1.3)	<.001

Table 4. Per protocol results. All participants that completed their assigned treatment and completed the week 12 outcome questionnaire are included. KOOS: Knee Injury and Osteoarthritis Outcome Score; PS: Physical Function Shortform; VAS: visual analogue scale.

Outcome	Treatment at baseline, mean (SD)	Treatment at outcome, mean (SD)	Control at baseline, mean (SD)	Control at outcome, mean (SD)	Group difference, mean (95% CI)	Interaction, *P* value
Primary outcomes						
KOOS Pain (0-100)	39.6 (14.5)	21.8 (13.4)	39.2 (14.7)	34 (12.9)	–12.6 (–18.7 to –6.5)	<.001
KOOS-PS (0-100)	52.9 (12.6)	37.4 (16.1)	51.8 (16.4)	48.4 (15.9)	–12.1 (–17.7 to –6.6)	<.001
Secondary outcomes						
VAS Pain score (0-100)	44.1 (21.5)	17.2 (16.2)	45.5 (19.6)	35.8 (21.8)	–17.3 (–26.3 to –8.3)	<.001
VAS Stiffness score (0-100)	42.4 (24.3)	15.9 (17.3)	47.4 (22.1)	40.8 (20.9)	–19.9 (-30.4 to –9.4)	<.001
Surgery chance next year, %	21.6 (24.9)	7.59 (18.5)	20.8 (21.9)	20 (26.3)	–13.1 (–24.1 to –2.2)	.02
Surgery chance next two years, %	28.1 (29.1)	12.1 (21.5)	27.4 (25)	25.3 (26.9)	–13.9 (–26.6 to –1.3)	.03
Surgery chance next five years, %	48.7 (33.9)	18.2 (26.5)	48.6 (29.9)	40.1 (30.9)	–22 (–35 to –9.1)	.001
Surgery interest (0-10)	2.93 (3.28)	1.31 (2.39)	3 (3.3)	2.78 (3.14)	–1.4 (–2.5 to –0.3)	.01
Understanding of condition and treatment options (0-4)	1.88 (1.03)	3.09 (0.657)	1.83 (1.06)	1.56 (0.998)	1.5 (1.1 to 1.9)	<.001

Discussion

Principal Findings

While CKP is a prevalent cause of disability worldwide [1,2], comprehensive conservative programs for the condition are lacking. The Hinge Health DCP has been designed to address this lack of chronic pain programs and incorporates components of best-practice conservative care for CKP in a digital format that provides flexibility to the user. The results of this randomized controlled trial demonstrated large improvements in knee pain, physical function, and stiffness in individuals with CKP on the Hinge Health DCP that were significantly greater than a control group receiving knee care education and treatment as usual over a period of 12 weeks after program initiation. Participant surgery interest also significantly decreased and understanding of their condition increased in the treatment group as compared to the control group. The positive results of this study demonstrate the potential of the Hinge Health DCP as a treatment for a large number of individuals affected by CKP that otherwise would be at risk for surgery.

Analysis of primary study outcomes demonstrated large improvements in both KOOS pain and function scales in the treatment group. Similarly, significantly greater improvements in physical function (KOOS-PS) scores were observed in the treatment group as compared to the control group. When considering individuals who started on and completed the study

as per protocol, the improvements observed in KOOS Pain and function scores were 45% in the treatment group as compared to 13% in control, and 29% in treatment as compared to 7% in control, respectively. The improvements observed in the treatment group exceeded recommended minimal clinically important changes for KOOS [27], while the small improvements in the control group did not. The group difference in KOOS did not quite reach the minimal clinically important difference due to the relatively large drop-off which 'diluted' the improvements of those that completed the program. Nonetheless, the clinically significant improvements demonstrated at the end of the 12-week program for not only the primary outcome measures but also secondary metrics provide strong evidence for the benefits of the Hinge Health DCP for individuals affected by CKP.

Similar large improvements that were significantly greater in the treatment group than in control were noted in secondary outcomes of VAS pain and stiffness scales. At the end of the 12-week program, per protocol participants in the treatment group had 61% and 63% improvements in VAS pain and stiffness, as compared to 21% and 14%, respectively, in the control group. Subjects' perception of surgery interest and surgery requirements also changed favorably at the end of the 12-week Hinge Health DCP, with a 63% reduction in the belief that they would require surgery within the next 5 years in the per protocol treatment group as compared to a reduction of 17% in the control group. It is also important to note that the Hinge Health DCP was safe for participants, as there were no reported adverse events during the 12-week program.

The results of this study demonstrated comparable or greater improvements in pain, physical function, and stiffness as compared to other treatment programs for CKP. Bossen et al [18] demonstrated improvements of 15% in physical function and 35% in pain at 3 months after initiation of a 9-week web-based behavior graded physical activity intervention in patients with knee and/or hip OA. Hughes et al [32] found improvements in Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain, stiffness, and function scores of 23%, 17%, and 23%, respectively, at the end of an 8-week exercise and behavior-change program for OA. Similarly, Hurley et al [33] demonstrated per protocol improvements in WOMAC pain and function of 31% and 26%, respectively, at the end of a 6-week rehabilitation program combining self-management and exercise for CKP. While the current study did not investigative the longer-term effect of the Hinge Health DCP past the end of the 12-week program, data from prior studies of treatment programs of similar duration (6-12 weeks) [18,22,32-34] showed improvement in outcomes can be maintained as long as 30 months after program completion [33]. Thus, it is likely that the results of the Hinge Health DCP would be maintained after the 12-week program.

The improvements observed as a result of the Hinge Health DCP have the potential to translate into substantial economic savings, however, in lieu of long-term data are based on participant self-report. Based on results for participants' self-reported likelihood of having surgery, the potential savings per completing participant due to surgery avoidance alone equate to US $4340 net cost savings on surgery over the first year in individuals using the Hinge Health DCP as compared to treatment as usual. Other integrated rehabilitation programs for CKP have also demonstrated lower healthcare costs as compared to usual care [33]. Thus, while the long-term effect of the Hinge Health DCP may in part be dependent on continued adherence to the program [35], it is anticipated that the behavioral, educational, and psychosocial components of the program have the potential for long-term clinical and economic effects [33].

When interpreting the results of this study, its strengths and limitations should be considered. Strengths of this study include the randomized controlled study design, and that the study was designed, conducted, and analyzed according to a pre-specified protocol. Further, the digital format of the program provides flexibility to individuals to participate at times and places convenient to them. While the results of this study demonstrate significantly greater improvements in primary and secondary outcomes with the Hinge Health DCP as compared to control, this study did not investigate the long-term effect of the Hinge Health DCP past the end of the 12-week program. Thus, further work is needed to evaluate the long-term impact of the Hinge Health DCP as compared to control. Our prior work suggests the potential for long-term effects as it demonstrated improved patient-reported outcomes in a single-arm study 6 months after program initiation [24]. We are in the process of collecting multi-year data and these results will be published in due course. A second point to note is that preliminary analyses not shown here suggest that BMI, gender, and surgery risk all affect the risk of dropping out. We plan to investigate risk factors for failure to adhere to the DCP in an upcoming study. Finally, around 20% of participants had less than 3 months of pain over the past 12 months, which does not strictly meet a definition of chronic pain. In a larger cohort, the efficacy of the program on long-term versus intermittent knee pain should be examined.

The study enrolled a representative population with CKP problems. While CKP is a hallmark symptom of knee OA [11], a diagnosis of knee OA was not required for inclusion in this study. Analysis of participant baseline data demonstrated that 74% of individuals in the treatment arm and 80% of individuals in the control arm had knee OA as defined by clinical diagnosis for knee OA derived from the American College of Rheumatology criteria for OA of the knee [11]. A sub-group analysis of these participants confirmed the successful outcome of the Hinge Health DCP in the primary and secondary outcomes over the 12-week period as compared to control, demonstrating the applicability of the program to highly prevalent knee OA.

The comprehensive nature of the Hinge Health DCP addresses multiple components of recommended management for CKP [9,10]. However, it is therefore unknown if all components of the program (sensor-guided exercise therapy, education, cognitive behavioral therapy, weight loss, and psychosocial support) are necessary to attain the reported results. Similar to other studies investigating interventions for CKP and knee OA, [18,22,32,34,36] due to the nature of this study, participants could not be blinded as to the intervention, and thus we cannot rule out the possibility of an attention effect. The attrition rate for week 12 patient-reported outcomes was in line with other studies for CKP [18]. Further, as the rate was similar in both

control and treatment it is not anticipated to have impacted the findings of the study.

Conclusion

Individuals with CKP who used the Hinge Health DCP for 12 weeks experienced significantly greater improvement in self-reported clinical outcome measures of pain, physical function, stiffness, as well as surgery intent and understanding of their condition, as compared to a control group receiving knee education articles and treatment as usual. Given the observed benefits, the Hinge Health DCP may be an effective comprehensive treatment program for individuals with CKP.

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Authors' Contributions

GM, PS, and DP conceived of the study. All authors helped design the study. PS was responsible for data collection and analysis. All authors contributed to the manuscript.

Conflicts of Interest

All authors except JH work at Hinge Health, Inc. Author JH is a paid domain expert consultant.

Multimedia Appendix 1

CONSORT - EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 648KB-Multimedia Appendix 1]

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Abbreviations

BMI: body-mass index
CBT: cognitive behavioral therapy
CKP: chronic knee pain
CONSORT: Consolidated Standards of Reporting Trials
DCP: digital care program
KOOS: Knee injury and Osteoarthritis Outcome Score
OA: osteoarthritis
PS: Physical Function Shortform
VAS: visual analogue scale

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Randomized controlled trial of a 12-week digital care program in improving low back pain

Raad Shebib[1,2], Jeannie F Bailey[3], Peter Smittenaar[1], Daniel A Perez[1], Gabriel Mecklenburg[1] and Simon Hunter[1]

Low back pain (LBP) is the leading cause of disability throughout the world and is economically burdensome. The recommended first line treatment for non-specific LBP is non-invasive care. A digital care program (DCP) delivering evidence-based non-invasive treatment for LBP can aid self-management by engaging patients and scales personalized therapy for patient-specific needs. We assessed the efficacy of a 12-week DCP for LBP in a two-armed, pre-registered, randomized, controlled trial (RCT). Participants were included based on self-reported duration of LBP, but those with surgery or injury to the lower back in the previous three months were excluded. The treatment group (DCP) received the 12-week DCP, consisting of sensor-guided exercise therapy, education, cognitive behavioral therapy, team and individual behavioral coaching, activity tracking, and symptom tracking – all administered remotely via an app. The control group received three digital education articles only. All participants maintained access to treatment-as-usual. At 12 weeks, an intention-to-treat analysis showed each primary outcome—Oswestry Disability Index ($p < 0.001$), Korff Pain ($p < 0.001$) and Korff Disability ($p < 0.001$)—as well as each secondary outcome improved more for participants in the DCP group compared to control group. For participants who completed the DCP (per protocol), average improvement in pain outcomes ranged 52-64% (Korff: 48.8–23.4, VAS: 43.6–16.5, VAS impact on daily life: 37.3–13.4; $p < 0.01$ for all) and average improvement in disability outcomes ranged 31–55% (Korff: 33.1–15, ODI: 19.7–13.5; $p < 0.01$ for both). Surgical interest significantly reduced in the DCP group. Participants that completed the DCP had an average engagement, each week, of 90%. Future studies will further explore the effectiveness of the DCP for long-term outcomes beyond 12 weeks and for a LBP patient population with possibly greater baseline pain and disability. In conclusion, the DCP resulted in improved LBP outcomes compared to treatment-as-usual and has potential to scale personalized evidence-based non-invasive treatment for LBP patients.

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INTRODUCTION

According to the World Health Organization, low back pain (LBP) is the leading cause of disability worldwide with a global prevalence of 7.2%,[1] affecting 4 in 5 individuals in their lifetime.[2,3] Clinical diagnosis of LBP is difficult due to its multifactorial etiology and in turn, 90% of cases are designated as non-specific with no clear underlying cause.[4,5] Given the uncertainties in diagnoses, localized LBP is treated with a broad variety of interventions including activity modification, physical therapy, pain medication, and spine injections. If symptoms do not improve, surgical intervention may be recommended. In the US, the economic costs of LBP are the highest in the world exceeding $100B per year[6] and this is in part due to the high rates of surgical intervention.[7] Health systems are not equipped to manage this growing population affected by LBP.

Patients pursuing non-invasive treatments have better outcomes for reducing disability and returning to work compared to those pursuing surgical intervention.[8] In an evidence-based guideline, the American College of Physicians recommends to first pursue non-pharmacological conservative treatments for LBP because they are deemed less harmful.[9] While exercise, rehabilitation, and cognitive behavioral therapy are among the most effective non-pharmacological conservative care treatments for ameliorating LBP symptoms, implementations of such care from a traditional clinical model has, so far, revealed inconsistent results.[9,10] This is likely due to the high degree of patient engagement, commitment, and self-management needed to adhere and complete these time-intensive at-home treatment plans. The amount of patient engagement in a treatment plan is shown to directly relate to health outcomes,[11] and is often an overlooked component in otherwise promising interventions.

Digital health technology can provide care for a large population and improve outcomes for non-invasive treatments by allowing providers to monitor adherence and activate patients to engage in their recovery. A digital therapy approach can integrate multiple conservative care channels while also tracking outcomes and providing biofeedback. The utilization of self-regulatory tools such as biofeedback as an engagement tool in non-specific LBP rehabilitation has been shown to promote greater than 80% adherence.[12] Biofeedback enables patients to better learn how to voluntarily control and track therapeutic exercise by converting physical movement into meaningful visual and auditory cues.[13] Biofeedback is believed to help patients gain awareness of their movement physiology and learn to self-regulate and even challenge themselves to make progress in response to the real-time feedback.[13]

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Table 1. Demographics of the control and treatment groups

	Treatment group (DCP)	Control group	All participants
Number of participants	113	64	177
Age in years, mean (SD)	43 (11)	43 (12)	43 (11)
Body-mass index (kg/m^2), mean (SD)	26 (5)	26 (4)	26 (4)
Female, %	37%	48%	41%
physical therapy-like exercise at screening[a], %	39%	50%	43%
Godin activity score[b], mean (SD)	38 (32)	40 (27)	39 (30)
Hours sedentary per day, mean (SD)	5.9 (3.3)	5.4 (2.9)	5.8 (3.2)
Think DCP can help delay surgery, %	99%	100%	99%
Think DCP can help avoid surgery, %	95%	100%	97%
Taking opioids, %	10%	8%	9%
Self-efficacy[c], mean (SD)	10.0 (3.7)	10.2 (3.3)	10.1 (3.6)
Healthcare visits for LBP in 12 weeks prior to screening, *n* (SD)	1.8 (3.5)	1.5 (3.0)	1.7 (3.3)
Back surgery > 3 months ago, %	12%	12%	12%
Experience neck pain, %	32%	33%	32%
Experience upper back pain, %	33%	17%	27%
STarT[d] low risk, %	46%	45%	46%
STarT medium risk, %	35%	39%	37%
STarT high risk, %	19%	16%	18%

SD standard deviation
[a]Positive answer to the question "Do you currently do any physical therapy-style exercises?"
[b]Composite score, 24 indicates "active", 14-23 indicates "Moderately active", and <14 indicates "Insufficiently active/sedentary"[35]
[c]Health self-efficacy assessment, scores from 0 (no self-efficacy) to 15 (high self-efficacy)[36]
[d]STarT Back Screening Tool, risk of persistent pain[37]

Surprisingly, results from prior randomized controlled trials of digital intervention on managing LBP with conservative care are largely unconvincing[14] with only one prior study demonstrating a positive effect from a 3-week cognitive behavioral therapy digital intervention.[15] Beyond the variability in theoretical underpinnings behind prior digital intervention studies, other issues may include the passive dissemination of content to patients and not assessing patient engagement. A digital care program (DCP) similar to the program tested here has recently been shown to be effective in alleviating knee pain outcomes and intent for surgery.[16,17] The conservative care components of this unique DCP, including aerobic exercise, sensor-guided physical therapy-like exercises, patient education, and cognitive behavioral therapy, are known to be effective in treating LBP.[18–22]

In addition, the inclusion of personal health coaching, education, and group support are aimed at enhancing patient engagement in self-management of their symptoms.

In this study we assessed the efficacy of a 12-week DCP for LBP in a two-armed, pre-registered, randomized, controlled trial (RCT). Participants randomized into the treatment group received the 12-week DCP, consisting of sensor-guided exercise therapy, education articles, cognitive behavioral therapy, team discussions, activity tracking, symptom tracking, and 1-on-1 coaching, all from their home through a dedicated app on a complementary tablet computer. Participants randomized into the control group received three digital education articles only, and all participants maintained access to treatment-as-usual. that can include physician visits, pain medication, diagnostic imaging, and potential recommendations for later injections and/or surgery. Based on evidence of the potential for non-invasive therapies for treating LBP, we hypothesized that strong engagement with these multi-model conservative care approaches would improve pain and disability scores (primary outcomes), and subject understanding of their condition and their interest in surgery (secondary outcomes), compared to the control group. These outcomes as well as the eligibility criteria were registered prior to the initiation of the study (ISRCTN #42338218).

RESULTS

Study population

Table 1 describes the demographics and screening data for the 177 participants randomized in the RCT. The average participant was 43 years old (SD: 11), slightly overweight (mean (SD) body mass index: 26 (4) kg/m^2), and reasonably active (Godin activity score of 39). We observed no statistically significant difference in the gender ratio between groups (two-sided test of proportions, chi-squared = 1.70, $p = 0.19$). Nearly all participants were convinced that the DCP could help them either avoid surgery altogether (97%) or at least delay surgery (99%). The rate of opioid use in this population was 9%. A minority (12%) received some type of surgery on the back prior (>3 months) to starting the DCP, though participants still actively rehabilitating from surgery were excluded from the study. About 1 in 3 experienced pain not only in the lower back but also upper back (27%) and/or neck (32%). We observed a difference in prevalence of upper back pain (two-sided test, chi-squared = 4.2, $p = 0.04$). However, including upper back pain as covariate in the regression analyses did not change the results, hence this difference is not discussed further.

Lastly, we observed no statistically significant differences in baseline scores for any of the primary and secondary outcomes (two-sided tests; all $p \geq 0.10$).

Participant flow

Figure 1 represents a CONSORT flow diagram. As noted in the Methods, we used an uneven allocation ratio such that 113 (64%) participants entered DCP treatment, and 64 (36%) entered control. A number of participants were lost prior to the start of the DCP, when participants might have changed their mind about participating without communicating intent to withdraw during

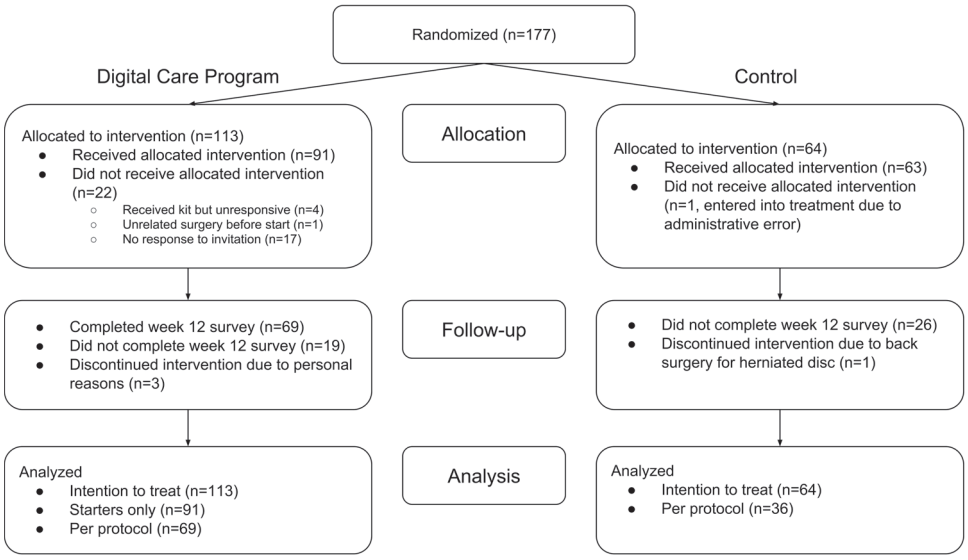

Fig. 1 CONSORT flow diagram

Table 2. Engagement indicators for each of the aspects of the DCP. "Starters" indicates participants performed at least one sensor-guided workout. "Finishers" indicates participants that completed the outcomes questionnaires at 12-week follow-up. SD: standard deviation

	All starters ($n = 91$)	Finishers ($n = 69$)
Number of workouts, mean (SD)	35.7 (28.9)	44.8 (26.7)
Users engaging with the program per week, % (*n*)	75%	90%
Users active with sensor-guided exercise in weeks 1–4, %	90%	99%
Users active with sensor-guided exercise in weeks 5–8, %	77%	94%
Users active with sensor-guided exercise in weeks 9–12, %	68%	87%
Offline activities logged in hours, mean (SD)	12.1 (12.5)	15.3 (12.5)
Education articles read, mean (SD)	7.4 (4.4)	9.2 (3.3)
Cognitive Behavioral Therapy session completed, mean (SD)	1.4 (1.2)	1.7 (1.1)
Team posts and comments, mean (SD)	4.9 (4.7)	6.3 (4.6)

the remote screening and onboarding process. Nonetheless, these participants are included in the intention-to-treat analysis.

Engagement

A major benefit of digital programs is the ability to track each participant's daily engagements with the DCP over the 12 week program. Engagement with the program in the DCP group is summarized in Table 2. Participants that started the DCP ($n = 91$), defined as performing at least one sensor-guided workout, performed an average of 36 in-app workouts, or 3.0 workouts per week from week 1 to week 12. Users that completed the outcome questionnaires at week 12 ($n = 69$) performed 45 sensor-guided workouts (3.8 workouts per week), compared to the 3 times per week recommended in the DCP. Average weekly engagement, defined as any progress towards the weekly goals, was 75% for those that started the program, and 90% for those that completed the program. Participants that completed the week 12 follow-up read 9.2 education articles, completed 1.7 cognitive behavioral therapy sessions, and posted on the feed 6.3 times. Participant engagement levels met or exceed all goals set by the program.

Primary and secondary outcomes

The intention-to-treat results in Table 3 and Fig. 2 show participants on the DCP experienced statistically significant greater improvements at week 12 on all primary and secondary outcomes compared to the control group. The conservative intention-to-treat analysis - in which every randomized participant is included irrespective of completion - shows the DCP's causal effect on participants' wellbeing as measured in LBP (primary outcome: Korff Pain; secondary outcome: VAS pain), disability (primary outcomes: Korff Disability, Oswestry Disability Index; secondary outcome: VAS Impact on Daily Life), as well as secondary outcomes of understanding of LBP and reduction in back surgery interest.

The intention-to-treat analysis in Table 3 shows the *average* benefit of the program on all those that were randomized, irrespective of whether they withdrew before even starting or finishing the DCP. As such, the intention-to-treat analysis underestimates the benefit of the program for those that complete the program. The per protocol analysis in Table 3 demonstrates that participants who completed the DCP experienced greater benefits across all outcomes compared to those that completed the control arm. For example, VAS pain dropped 62%, from 43.6 to 16.5 on a scale from 0 to 100, in those that completed the DCP, compared to an 8% reduction in the control group.

Finally, we also examined what proportion of per protocol participants reached a minimally important change (MIC) in their ODI and VAS pain scores. The MIC is 10 points for ODI, 15 points for VAS, or 30% of baseline.[23] Table 4 shows that participants in the treatment group are significantly more likely to achieve MIC

Table 3. Primary and secondary outcomes. Results are listed for both the intention-to-treat group, which includes subjects who did not start or complete the 12-week program (ITT), as well as per protocol results for subjects that completed 12-week program (PP)

		DCP at baseline, mean (SD)	DCP at outcome, mean (SD)	Control at baseline, mean (SD)	Control at outcome, mean (SD)	Group difference, mean (95% CI)	Group difference, *p*-value
Primary outcomes							
Korff pain	ITT	51.1 (17.8)	33.8 (21.6)	51.4 (17.4)	50.5 (21.4)	−16.4 [−22, −10.9]	<0.001
	PP	48.8 (17.8)	23.4 (16.1)	47.5 (16.1)	49.1 (21.4)	−26.9 [−33.8, −20]	<0.001
Korff disability	ITT	34.3 (23.1)	21.5 (19.6)	40.3 (24)	40.5 (25.7)	−13 [−19.3, −6.7]	<0.001
	PP	33.1 (24.3)	15 (15.5)	34.2 (20.2)	37.3 (24.3)	−21.3 [−30.8, −11.7]	<0.001
ODI	ITT	21.7 (12.1)	17.6 (12)	21 (9.66)	21.1 (11.2)	−4.1 [-6.5, −1.8]	<0.001
	PP	19.7 (11.4)	13.5 (9.46)	18.9 (7.4)	19.7 (10.6)	−6.9 [−10.5, −3.3]	<0.001
Secondary outcomes							
VAS Pain score	ITT	46.3 (20.9)	25.8 (21.4)	45.4 (20.8)	40.8 (23.2)	−16 [−22.5, −9.4]	<0.001
	PP	43.6 (20.5)	16.5 (15.5)	42.6 (19.4)	39.2 (23.6)	−23.7 [−31.9, −15.5]	<0.001
VAS impact on daily life score	ITT	38.6 (26.6)	21.1 (20.7)	43.9 (25.2)	38.2 (26.1)	−11.8 [−19.3, −4.3]	0.002
	PP	37.3 (28.2)	13.4 (14.8)	40.9 (24.7)	35.3 (27.3)	−18.3 [−29, −7.7]	0.001
Surgery interest	ITT	0.894 (1.71)	0.619 (1.35)	1.39 (2.55)	1.53 (2.67)	−0.4 [−0.7, −0.1]	0.01
	PP	0.681 (1.59)	0.333 (0.918)	0.639 (1.31)	0.972 (1.89)	−0.7 [−1.2, −0.2]	0.006
Understanding of condition and treatment options (0-4)	ITT	1.81 (0.95)	2.47 (1.07)	1.77 (1.03)	1.94 (0.871)	0.5 [0.2, 0.7]	0.0005
	PP	1.94 (0.838)	3 (0.594)	1.5 (1.06)	1.78 (0.797)	0.8 [0.4, 1.2]	0.0001

All *p*-values are from two-sided statistical tests
SD standard deviation, *ODI* Oswestry Disability Index, *VAS* visual analogue scale

compared to the control group for both ODI and VAS, irrespective of how the MIC is defined precisely. The only exception is the ODI MIC of 10 points, which was achieved by 28% of treatment and 11% of control participants ($p = 0.09$). This can be attributed to the low number of participants in the control group, whereas a test of proportions requires greater sample size than the regression models used in Table 3. Overall, 81% of treatment participants achieved MIC on VAS either as expressed by absolute or percentage improvement, compared to 31% in the control group ($p < 0.001$). Similarly, 58% of the participants receiving the digital care program reached either MIC for ODI compared to 25% in the control group ($p = 0.003$).

DISCUSSION

Results from this RCT assessing the efficacy of a 12-week DCP for LBP found subject-reported pain and disability significantly improved compared to a control group undergoing treatment-as-usual. Results also demonstrated a reduced interest in pursuing LBP surgery following the DCP, which is likely attributable to the reduced reported pain and disability. Improved outcomes were observed in the context of a comprehensive approach involving conservative therapies for LBP as well as strong engagement of participants. The positive results from this work support the potential for using a DCP as a treatment for the large number of individuals with LBP that medical experts recommend receive non-invasive therapies before drugs or surgery.

Analysis of subject-reported pain and disability demonstrated significant improvement in all related outcomes for DCP group compared to control group. When considering participants who completed the study per protocol, the improvement in Korff pain, VAS pain, and its impact on daily life were 52%, 62%, and 64% for the DCP treatment group compared to 3%, 3 and 9% for the control group. Similarly, the per protocol improvement in Korff disability and Oswestry Disability Index were 55 and 31% for the DCP treatment group compared to 9 and 4% for the control group. Oswestry Disability Index is a widely used metric of LBP disability. Despite the study's baseline Oswestry Disability Index scores being low, we observed improvements that fell within the range of Minimally Important Change.[23] Based on other clinical studies, the DCP could have a greater impact on subjects with more severe and longer-lasting LBP.[9,24–26]

Participants' understanding of condition and treatment options demonstrated a 55% improvement for the DCP compared to 19% for control group in a per protocol analysis. Critically, the DCP treatment group showed a 52% decrease in average interest in surgery while the control group showed a 53% increase in average interest in surgery. Although baseline values for surgical interest were low for our study population, we anticipate—and have confirmed this in an unpublished follow-up study—that surgical interest would be similarly reduced for a sample with more severe LBP symptoms and chronicity. Confirming long-term reductions in surgery utilization following the DCP will be important, as LBP presents a large economic burden throughout the world. Compared to non-invasive treatment options, the costs associated with spinal surgery are significantly greater and have been shown to deliver no better outcomes.[27,28] The positive impact from the DCP on LBP demonstrates potential for both direct and indirect cost savings by avoiding surgery and regaining function in daily life. Beyond potentially avoiding invasive surgical interventions for LBP, the effectiveness of a DCP may mitigate the rising use of harmful opioids for coping with LBP. The assumed impact of the DCP on reducing missed work days and reliance on opioids as a treatment for LBP were not included in the present study and will be assessed in future studies using clinical populations with a higher prevalence of these characteristics.

The success of any non-invasive therapy to impact clinical outcomes requires patients to actually use and engage with the treatment. Typical clinically administered non-invasive care approaches have shown promising but inconsistent results on LBP patient outcomes.[9] Interestingly, results from the few prior RCTs on digital programs for self-management for LBP are mostly inconclusive regarding effectiveness.[14] Beyond the variability in the types of intervention and outcomes assessed among prior studies, another source of inconsistent and unconvincing results may be due to inadequate patient adherence to the conservative therapies.

A strength of using a digital program for disease management is the potential to enhance patient involvement in their recovery process and outcomes. A recent study of a mobile app delivering

multidisciplinary treatment for pain related to LBP found the app had a positive effect on VAS pain, but compared to our study, they reported both a lower improvement in VAS pain and lower percentage of subject participation over the 4- to 12-week treatment period.[29] Although some percentage of subject dropout is expected, at the 12-week point Huber et al. retained only 17% of participants compared to our DCP retaining 76% of participants that started the program. We attribute our higher retainment of participants to

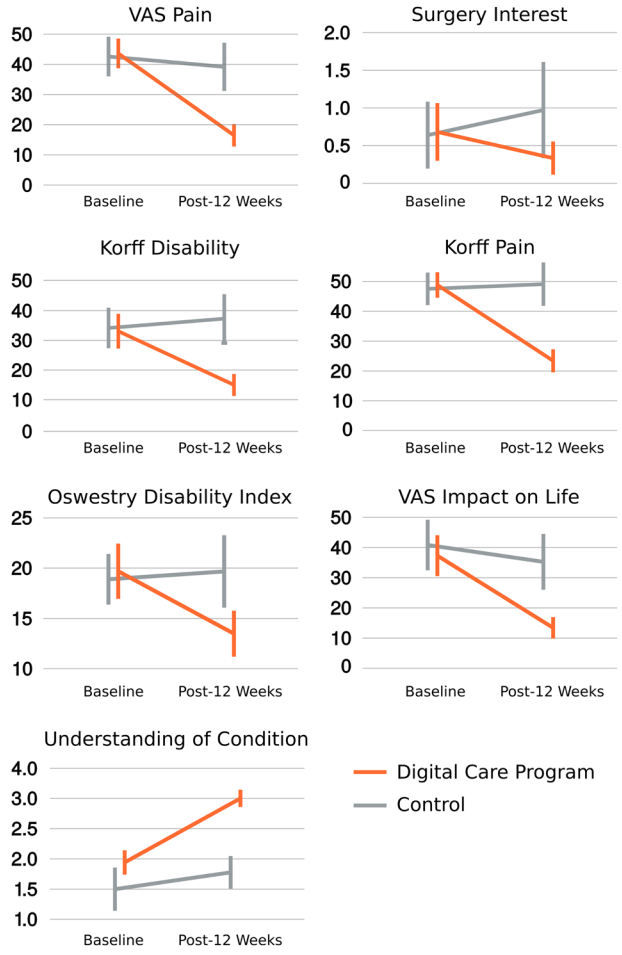

Fig. 2 All per protocol primary and secondary outcomes visualized. Korff, Oswestry disability index, and visual analog scale (VAS) outcomes are on scales from 0 to 100; surgery interest is on a scale from 0 to 10; and understanding of condition is on a scale from 0 to 4. Error bars represent 95% confidence intervals

elements of the DCP aimed at enhancing user engagement, including health coaching, peer group interaction, weekly checklists, and points goals, each of which could be adjusted to the individual needs of the user Beyond the benefits of enhanced participation with the program, patient engagement is critical for the success of these digital applications for self-managing LBP because it aids the development of healthy habits and routines that successfully manage LBP. Studies show that greater self-management competency[30] and greater adherence to rehabilitation exercise programs[31] are associated with a stronger sense of internal control during a patient's musculoskeletal care process.

The DCP evaluated here is built to maximize patient engagement by providing unhindered access to tailored content and real-time feedback through sensors and coaching. Participants were able to complete the entire program through a tablet app at home or anywhere else, whether or not they had wireless internet available. The weekly checklist of actions could be completed at any time of day, in whichever order was most convenient. A dedicated health coach provided unlimited behavioral coaching via telephone, email, in-app message, and text message to provide support or encouragement during periods of decreased engagement, symptom flares, general questions or technical issues. In contrast, in traditional LBP care participants have to spend significant time traveling to their care provider at specific times in the week; they have to manage multiple providers for different services (e.g. physical therapy exercises, cognitive behavioral therapy); the care provider is not usually on standby for questions or issues that come up during the day; and critically, the care provider has no way of monitoring daily patient engagement and wellbeing.

Participants engaged well with the program. Though we observed drop-off after randomization (19%) for participants who filled out the online screener but did not continue to the DCP, 76% of participants that started the DCP completed their assessment after 12 weeks and in an average week of the DCP, 90% of them engaged with the program. Though no conclusive evidence is reported here, we attribute this strong engagement to a personalized experience for participants. They could complete the tasks set out at their convenience, with weekly checklists and points goals, as well as a professional health coach and peer group to keep participants accountable. Novel content was introduced throughout the 12 weeks, with users unlocking new education, and new sensor-guided exercises. We recommend others developing DCPs to consider the user's desire for diverse novel content and convenience. There is an opportunity to continue to further personalize the participant DCP experience by leveraging artificial intelligence to optimize recommendations. Furthermore, a DCP has the potential to scale delivery of evidence-based recommended care to the ever-growing worldwide number of LBP patients.

When interpreting the results of this study, its strengths and limitations should be considered. Strengths of this study include

Table 4. Proportion of participants reaching a minimal important change (MIC) in the per protocol group. The MIC are taken from Ostelo et al. (2008) and represent a change in the VAS or ODI score, respectively, that is considered meaningful to the participant. It is defined as either a 15/10 absolute point change for VAS/ODI, or as a 30% reduction from the baseline score. We also show how many participants reached either of the MIC definitions (last two rows). The *p*-values show the outcome of a two-sided test of proportions between treatment and control, revealing a larger proportion of participants in treatment achieved MIC than in control

MIC achieved for outcome	Treatment	Control	*p*-value for test of proportions
VAS, 15-point reduction	48/69 (70%)	8/36 (22%)	<0.001
ODI, 10-point reduction	19/69 (28%)	4/36 (11%)	0.09
VAS, 30% reduction	56/69 (81%)	10/36 (28%)	<0.001
ODI, 30% reduction	38/69 (55%)	9/36 (25%)	0.006
VAS, absolute OR percentage reduction	56/69 (81%)	11/36 (31%)	<0.001
ODI, absolute OR percentage reduction	40/69 (58%)	9/36 (25%)	0.003

the randomized controlled study design, and that the study was designed, conducted, and analyzed according to a pre-specified protocol. Also, the digital format of the program provides flexibility and convenience for users, supporting adherence to the program. One possible limitation includes that the treatment in this RCT was non-blinded and while this is common within the field, it prevents us from knowing whether the effect of the trial may be in part due to the participant's expectation that their symptoms would diminish as they were assigned to the treatment. A second concern is due the remote nature of the program, participants were not assessed by a clinician, their medical records were not evaluated, and generally there was little coordination with the conventional healthcare system. However, LBP is commonly diagnosed through self-report as done in this study. We also used standard questionnaires to screen for any complaints that may indicate specific conditions (red flags) and referred those to healthcare professionals. This DCP was designed so participants could independently seek traditional care if desired. Future studies will investigate the effect of the DCP on a clinical cohort and clinical status of participants will be followed.

Another concern is that participants in the control group would exaggerate their week-12 symptoms in an attempt to gain preferential access in the next round of the program. Though this is a possibility, we hoped to deter participants from overstating their symptoms by guaranteeing participation in the following round for those initially placed in the control group. Additionally, if overstating symptoms was widespread, we would have expected scores across the board to substantially increase at week 12, however the per protocol scores either decreased or increased by a few points at most. Finally, while this study found significant improvements in primary and secondary outcomes associated with the DCP, a last limitation is that our trial did not investigate outcomes beyond the first 12 weeks. Next steps include studies on outcomes from multi-year follow-up.

In conclusion, this RCT shows that care provided using a DCP substantially reduces pain, disability, and surgery interest in those living with LBP. In the per protocol DCP treatment segment, we found strong patient engagement. Care from the DCP was achieved through a program that was delivered remotely, using technology that has the potential to scale evidence-based conservative care to an ever-growing worldwide number of LBP patients.

METHODS

Study design

This study was a two-armed, randomized, controlled, unblinded trial of participants with chronic non-specific LBP. Employees and their dependents at participating employers, across 12 locations in the US, were invited to complete an online application. Employees were highly diverse, and included both office and service based roles such as data analysts, drivers, catering staff, and outdoor instructors. Participants were recruited through emails, direct mail, and posters between January and March, 2017. The trial was approved by the Western Institutional Review Board and we have complied with all ethical regulations. Participants provided informed consent and completed the intervention at home. The trial was preregistered at International Standard Randomized Controlled Trial Number (ISRCTN) 42338218. We followed CONSORT guidelines for reporting this trial.

Study population

We assessed the eligibility of all applicants that completed the baseline questionnaire for LBP through a web-based questionnaire. Participants provided informed consent as part of this questionnaire by ticking a checkbox after reading the digital information sheet. The inclusion criteria were: (1) age over 18 years, (2) non-specific LBP for at least 6 weeks in the past 12 months, (3) participating in the collaborating employers' health plans, and (4) provision of informed consent. The exclusion criteria were (1) surgery on the back less than 3 months ago, (2) injury to the back less than 3 months ago, (3) did not indicate 'lower back' when asked about pain location. As there were a limited number of places available on the program, eligible applicants were prioritized for enrollment, with those exhibiting greater pain, disability, and surgery intent prioritized over those showing less. Applicants not selected for the study were placed on a waitlist for future deployments at the same site outside of the scope of the trial. Participants were not paid for their time, other than an incentive offered to complete the outcome questionnaire for those participants that did not complete it within 4 days of first invitation. No harm was observed or reported in either arm of the experiment.

Randomization

Applicants were randomized into the trial twice weekly during the signup period by randomizing batches of participants into treatment and control using a 60:40 treatment-to-control ratio ($n = 128$) or using an 80:20 ratio ($n = 49$). The 80:20 ratio was used for a restrictive period of time due to administrative error. The effective allocation ratio was therefore 64:36 treatment-to-control. When a batch of applicants was randomized, an algorithm with random seed shuffled the batch and selected the first 60% to enter the treatment, and the remaining 40% to enter control. The person reviewing the applicants had no way of knowing whether any given applicant would enter treatment or control (concealed allocation). After randomization, participants in the treatment group received an email inviting them to complete their profile and received the kit to participate in the DCP, whereas those in the control group received an email with three education articles to help them care for their back. Due to the nature of the study, neither the study staff nor the participants were blinded to group allocation.

Study intervention

The treatment group received a 12-week DCP for LBP developed by physical therapists, medical doctors, engineers, and subject-matter experts at a digital health company. Participants received a tablet computer with the DCP app installed, and two bluetooth wearable motion-sensors with straps to be placed along the lower back and torso during the in-app exercise therapy. Participants were assigned a personal coach that provided unlimited support and accountability throughout the program and were placed in a team to provide peer support through a discussion feed within the app. All app participation was completed remotely, at times and places chosen by the participant. Each week, participants in the DCP were instructed to complete 3 sessions of sensor-guided physical exercise, read 1 to 2 education articles, log their symptoms at least twice, perform cognitive behavioral therapy on a subset of weeks, and track a recommended 3 aerobic activities per week. Each participant also maintained access to treatment as usual.

The control group received three digital education articles from the DCP. These articles discussed the importance of self-care, how to deal with setbacks in LBP, and how to manage communication and relationships when living with chronic LBP. The control group maintained access to treatment-as-usual and were informed that they would be reconsidered for the program when enrollment reopened after the 12-week study.

The 12-week program received extensive testing over a 2-year period prior to starting the trial. All participants received the same version of the program, and there were no major app updates during the course of the trial.

Study outcomes

Primary outcomes. Participants completed the Modified Von Korff (MvK) scales[32] at screening and at week 11 (control group), or screening, week 4, week 8, and week 11 (treatment group). The MvK yields a pain and a disability metric, both from 0 (minimum) to 100 (maximum). The third primary outcome was the Oswestry Disability Index[33] (ODI) which falls between 0 (no disability) to 100 (complete disability). The ODI was collected at baseline and week 11 for both treatment and control groups. To conclude a positive effect of treatment we required a significant effect on all three primary outcomes, though we note this was not specified in the preregistration.

Secondary outcomes. First, a visual analogue scale (VAS) for the question "Over the past 24 h, how bad was your back pain?" from 0 (none) to 100 (worst imaginable). Second, a VAS for the question "Over the past 24 h, how much has back pain interfered with your daily activities?" from 0 (none) to 100 (worst imaginable). Thirdly, we assessed surgery intent using the question "On a scale of 0 to 10 how interested are you in back

surgery?" with labels "not at all" at 0, and "definitely going to get surgery" at 10. Lastly, we asked "Thinking about your symptoms, how well do you feel you understand your condition and your treatment options?" with answers "Not at all", "Slightly", "Moderately", "Very well", "Completely", coded from 0 to 4. All data were assessed at baseline and at the end of the 12-week DCP in both the treatment and control groups. Additionally, those in the treatment group were asked to complete these questions at various points during the DCP: the VAS twice each week, and the questions related to surgery and understanding of their condition at week 6.

Sample size. We assessed the required sample size to detect a difference in change of 10 points on the 100-point MvK pain scale, with a standard deviation of 20 based on past experience with the questionnaire. The number of participants needed in each group to detect a 10-point difference given a Type I error rate of 0.05 and power of 0.8 was calculated. Given our unequal allocation ratio, we would need at least 79 in the treatment group and 53 in the control group for a total of at least 132 participants in the trial. We opted for an unequal allocation ratio to ensure we would be able to enter a certain minimum number of people into the treatment arm, a criterion mandated by the commercial nature of the deployments.

Statistical analyses. Our primary analysis was conducted using an intent-to-treat approach. This analysis included all participants that were randomized, including those in the treatment group that never started the DCP, as well as those in control that were enrolled in the DCP by accident. We describe baseline characteristics for the treatment and control groups based on the screening questionnaire. We also describe metrics of engagement (not a registered outcome) with the DCP for two groups of participants: those in the treatment group that performed at least one session of exercise therapy, and those that completed the week 12 outcome questionnaire. The analysis of preregistered primary and secondary outcomes was performed using a linear mixed model using the "lme4" package[34] in R with factors "time point" (baseline or outcome) and "group" (treatment or control) and their interaction. We modeled a separate baseline for each participant, effectively examining the change scores only (in lme4 this was performed as "score~timepoint*group + (1|participant)", where (1|participant) models an intercept for each participant separately). We assessed normality of the residuals based on quantile-quantile (QQ)-plots. If we did not have outcome data for a participant, we used last observation carried forward (LOCF). We also analyzed all primary and secondary outcomes with baseline carried forward (BOCF) also for the treatment group (rather than LOCF). We also omitted LOCF and instead allowed the mixed-effects model to account for the missing data, which yielded an identical pattern of results as using LOCF and BOCF. We also report results for a per protocol analysis to assess the effect of the program on those that completed it. All *p*-values are from two-sided tests.

Code availability

Analysis code is available on request due to privacy or other restrictions. All code was written in R version 3.x.

DATA AVAILABILITY

Data are available on request due to privacy or other restrictions.

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AUTHOR CONTRIBUTIONS

R.S., P.S., D.A.P., G.M., and S.H. conceived of the study and designed it. P.S. oversaw data collection and performed statistical analysis. All authors contributed to the interpretation of the data. J.F.B. and P.S. drafted the manuscript. All authors revised the manuscript and approved the final content. R.S. and J.F.B. are co-first authors.

ADDITIONAL INFORMATION

Competing interests: All authors except J.F.B. are employed and/or hold equity at Hinge Health, Inc. J.F.B. is a paid domain expert consultant with no other competing interests. The remaining authors declare no competing interests.

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Digital Care for Chronic Musculoskeletal Pain: 10,000 Participant Longitudinal Cohort Study

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Original Paper

Digital Care for Chronic Musculoskeletal Pain: 10,000 Participant Longitudinal Cohort Study

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Abstract

Background: Chronic musculoskeletal pain has a vast global prevalence and economic burden. Conservative therapies are universally recommended but require patient engagement and self-management to be effective.

Objective: This study aimed to evaluate the efficacy of a 12-week digital care program (DCP) in a large population of patients with chronic knee and back pain.

Methods: A longitudinal observational study was conducted using a remote DCP available through a mobile app. Subjects participated in a 12-week multimodal DCP incorporating education, sensor-guided exercise therapy (ET), and behavioral health support with 1-on-1 remote health coaching. The primary outcome was pain measured by the visual analog scale (VAS). Secondary measures included engagement levels, program completion, program satisfaction, condition-specific pain measures, depression, anxiety, and work productivity.

Results: A total of 10,264 adults with either knee (n=3796) or low back (n=6468) pain for at least three months were included in the study. Participants experienced a 68.45% average improvement in VAS pain between baseline intake and 12 weeks. In all, 73.04% (7497/10,264) participants completed the DCP into the final month. In total, 78.60% (5893/7497) of program completers (7144/10,264, 69.60% of all participants) achieved minimally important change in pain. Furthermore, the number of ET sessions and coaching interactions were both positively associated with improvement in pain, suggesting that the amount of engagement influenced outcomes. Secondary outcomes included a 57.9% and 58.3% decrease in depression and anxiety scores, respectively, and 61.5% improvement in work productivity. Finally, 3 distinct clusters of pain response trajectories were identified, which could be predicted with a mean 76% accuracy using baseline measures.

Conclusions: These results support the efficacy and scalability of a DCP for chronic low back and knee pain in a large, diverse, real-world population. Participants demonstrated high completion and engagement rates and a significant positive relationship between engagement and pain reduction was identified, a finding that has not been previously demonstrated in a DCP. Furthermore, the large sample size allowed for the identification of distinct pain response subgroups, which may prove beneficial in predicting recovery and tailoring future interventions. This is the first longitudinal digital health study to analyze pain outcomes in a sample of this magnitude, and it supports the prospect for DCPs to serve the overwhelming number of musculoskeletal pain sufferers worldwide.

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KEYWORDS

musculoskeletal pain; low back pain; patient engagement; exercise therapy; telemedicine; telerehabilitation; mobile phone

Introduction

Background

Chronic musculoskeletal pain has vast global prevalence [1] and annual costs in the hundreds of billions of dollars in the United States [2,3]. Musculoskeletal disorders are debilitating and may contribute to the opioid epidemic, as they are the most common noncancer indication for an opioid prescription in the United States [4-6]. Nonsurgical care, including exercise, education, and behavioral health, is universally recommended as the first-line treatment for the majority of chronic musculoskeletal conditions [7] given that it can achieve similar outcomes to surgery with reduced cost and lower risk [8,9]. However, conservative care has significant barriers to effective implementation and requires higher patient engagement to be successful [10,11]. Notably, conservative care administered in a clinical setting is also costly, and ongoing monitoring is often infeasible. Given the growing burden of chronic musculoskeletal pain, a scalable and effective mode of conservative care delivery is needed.

Digital health interventions have the potential to improve conservative care outcomes for chronic musculoskeletal pain by increasing patient engagement through electronic delivery of interventions. This approach can better enable patients to take a proactive role in their treatment and learn to self-manage their chronic pain symptoms. With the ubiquity of smartphones, low-cost sensor technology, and advanced analytical approaches to assess complex health care data, the prospect of digital technology for improved patient care is apparent and is reflected in the growing number of clinical trial protocols and review papers on the topic [12]. Digital therapies are shown to be effective for improving outcomes associated with conditions requiring self-management and behavioral change, such as type 2 diabetes [13], hypertension [14], and insomnia [15]. In addition, patient willingness to seek surgical treatment is shown to decrease following participation in a digital care program (DCP) [16]. Chronic pain, although often difficult to diagnose and treat clinically, is also shown to improve with the aid of digital therapy [10]. For chronic musculoskeletal pain specifically, the DCP in this study was previously evaluated in two randomized control trials and demonstrated effectiveness for improving pain and disability associated with knee pain [17] and low back pain [18]. Although these previous musculoskeletal pain studies show potential for a digital therapeutic approach to improve outcomes, they are limited in sample size (<200 subjects) and real-world effectiveness has yet to be shown. In this study, we assessed engagement and subject-reported outcomes over a 12-week period following enrollment in the DCP in a sample of over 10,000 users with chronic knee or back pain.

Objectives

This study had two objectives. First, we sought to determine whether the DCP is scalable and effective in a large sample of real-world patients. Given the magnitude of the chronic musculoskeletal pain population, scalability is one of the greatest potential benefits of a DCP, so the efficacy of a DCP in a large sample of real-world patients is important to assess. Key questions include if high levels of engagement can be sustained and if efficacy demonstrated in smaller randomized control trials is maintained in the larger real-world population. On the basis of results from the smaller randomized control trials, we hypothesized that the DCP would improve subject-reported pain over a 12-week period and that engagement with the DCP would be a necessary factor for improvement. A scalable digital intervention for engaging patients with safe conservative therapies for lasting self-management would have the potential to reduce the economic burden and improve the quality of life for a large population of patients.

Second, we sought to analyze the large dataset generated from the DCP to generate novel insights into patient recovery trajectories, which would create an opportunity to develop personalized interventions for individual patients. Little is known about the patient-specific response and rate of improvement for chronic musculoskeletal pain between clinical visits. Patients are typically assessed by clinicians during initial evaluations and, then, at follow-up appointments that may be weeks or months apart. A DCP enables regular (eg, weekly) collection of subject-reported outcomes throughout the recovery process. Statistical modeling methods can then be applied to these large longitudinal datasets to assess the rate of change in outcomes and if baseline data can predict recovery response. In this study, we used statistical modeling on a large longitudinal sample to evaluate nonlinear changes in pain over time and predict subject-specific pain response groups (rapid vs gradual) from baseline demographic data. Understanding how pain improves over time would inform our knowledge of pain recovery, identify variables associated with recovery, and allow for better care of patients unlikely to have rapid pain responses.

Methods

Study Design

This was a retrospective cohort study of consecutively recruited participants. Employees and their dependents at 30 participating employers across the United States were invited to complete a web-based application to participate in the Hinge Health DCP. Employees were diverse and included both office and service-based roles such as data analysts, manual laborers, truck drivers, catering staff, and outdoor instructors. Participants with low back or knee pain were recruited through email, direct mail, and posters. The trial was approved by the Western Institutional Review Board and complied with all ethical regulations. Participants provided informed consent and completed the intervention remotely. Each participant participated in 1 of 2 digital care pathways: 1 for chronic knee pain and the other for chronic low back pain. The only differences between the 2 pathways were the specific exercise regimens and some condition-specific education materials (eg, anatomy and surgical options). To mitigate the risks of selection bias, we included all

participants who had registered in the Hinge Health program by the cutoff date (May 6, 2019). We were able to verify that the study sample provided adequate power (after correcting for intrauser clustering effects, a sample size of 10,000 gave us a power of 0.97 to detect a 5-point change in our primary outcome with a type 1 error rate of 0.01). A summary of the key attributes of the cohort is provided in Table 1.

Inclusion criteria to qualify for participation in the DCP included being ≥18 years and not >80 years at the time of enrollment, having at least 12 weeks of back or knee pain, and having a baseline visual analog scale (VAS) score for pain greater than 0. Additional inclusion criteria for this study included starting the DCP, defined as completing at least one exercise session or reading 1 educational paper in the first 2 weeks following registration. Participants were excluded during registration by completing a screening questionnaire, which rejected patients with *red flag* symptoms, including signs of fracture, joint instability, infection, cancer, and cauda equina syndrome. Thus, this study included all consecutively qualified participants who enrolled in the DCP between February 6, 2017, and May 6, 2019, meeting the above inclusion and exclusion criteria

Table 1. Demographics and outcome measures (N=10,264).

Variables	Baseline			Final		
	Overall	Back pain (n=6468)	Knee pain (n=3796)	Overall	Back pain (n=6468)	Knee pain (n=3796)
Age (years), mean (SD)	43.57 (11.14)	42.58 (10.91)	45.26 (11.33)	N/A[a]	N/A	N/A
BMI, mean (SD)	30.25 (7.42)	29.76 (7.11)	31.09 (7.84)	N/A	N/A	N/A
Gender						
Female, n (%)	5132 (50.00)	4981 (48.53)	5388 (52.49)	N/A	N/A	N/A
Measures, mean (SD)						
Pain (VAS[b])	45.13 (22.42)	45.81 (22.16)	43.98 (22.81)	14.24 (15.31)	14.23 (15.12)	14.33 (15.59)
PHQ-9[c]	3.05 (5.34)	3.35 (5.49)	2.54 (5.04)	1.85 (3.97)	2.12 (4.12)	1.43 (3.38)
PHQ-9[d]	12.01 (4.61)	11.99 (4.56)	12.06 (4.73)	5.05 (5.72)	5.10 (5.73)	4.95 (5.70)
GAD-7[e]	3.93 (5.50)	4.39 (5.69)	3.15 (5.08)	2.21 (3.83)	2.48 (3.99)	1.77 (3.51)
GAD-7[f]	11.49 (4.10)	11.56 (4.13)	11.32 (4.04)	4.78 (5.05)	4.84 (5.01)	4.65 (5.12)
One-year surgery likelihood (0-100)	12.67 (21.55)	9.07 (17.89)	18.80 (25.51)	4.14 (12.44)	2.88 (9.26)	6.26 (16.1)
WPAI[g] (0-100)	31.74 (26.79)	34.12 (26.37)	27.54 (27.02)	11.45 (15.60)	12.24 (15.58)	10.17 (15.57)
KOOS—pain[h]	N/A	N/A	15.23 (6.66)	N/A	N/A	10.04 (5.81)
Modified von Korff	N/A	15.95 (5.03)	N/A	N/A	7.75 (5.44)	N/A

[a]N/A: not applicable.

[b]VAS: visual analog scale.

[c]PHQ-9: patient health questionnaire 9-item scale.

[d]The mean and SD of the scores in depressed (PHQ-9>5) subjects.

[e]GAD-7: generalized anxiety disorder 7-item scale.

[f]The mean and SD of the scores in anxious (GAD-7>5) subjects.

[g]WPAI: work productivity and activity impairment.

[h]KOOS—pain: knee injury and osteoarthritis outcome score—pain subscale.

Digital Care Program

Following registration, participants received a tablet computer via mail with the Hinge Health app installed, along with 2 Bluetooth wearable motion sensors with straps and instructions to be placed above and below the painful region during the in-app exercise therapy (ET). In the lower back program, a sensor was placed on the posterior lower back and anterior chest, and for the knee program, a sensor was placed over the anterior tibia and thigh. Sensors utilized standard accelerometer and gyrometer technology (InvenSense MPU-6050, TDK Electronics, Tokyo, Japan) and were used to objectively monitor compliance and performance of exercises. ET sessions comprised light-intensity stretching and strengthening exercises commonly used in clinical practice. The ET sessions were administered using animations and instructional videos to demonstrate how to perform each exercise. While performing the exercise, the app then displayed real-time graphics showing the position of the user's relevant body parts based on the wearable sensors and indicated if the exercise was within the

desired range of movement (see Multimedia Appendices 1 and 2.

Participants were assigned a personal coach and communication was performed via text message, email, or in-app messaging throughout the DCP. Health coaches completed certification through a coaching school approved by the National Board for Health & Wellness Coaching. Coaches attempted to interact with participants via their preferred communication method at least weekly. Phone calls with the coach were also offered to participants up to 3 times during the DCP. Each participant was also placed on a peer support team of 20-30 participants that utilized a discussion forum within the app, as previous qualitative research showed this to be an important feature [19]. All app participation was completed remotely, at times and places chosen by the participant. Each week, participants were instructed to complete at least three sessions of sensor-guided ET, read 2 education papers, and log their symptoms at least twice. Participants were able to complete more ET sessions or read more education papers if desired. Behavior change topics were addressed through education papers and brief interactive modules, and focused on common cognitive behavioral therapy topics, including catastrophizing, active coping methods, and fear avoidance. Additional behavior change mechanisms used in the program included goal setting and tracking. Finally, participants were encouraged to engage in 3 aerobic exercise activities per week and perform up to 4 brief modules based on cognitive behavioral therapy between weeks 3 and 9. Each participant also maintained access to treatment as usual. The app was developed, owned, and sponsored by Hinge Health, Inc.

Outcomes

The primary outcome was VAS pain for the question "Over the past 24 hours, how bad was your [back/knee] pain?" from 0 (*none*) to 100 (*worst imaginable*). This was asked weekly during the 12-week period immediately after an ET session, and participants also had the option to report VAS unprompted, for a total of up to 2 pain scores per week. Our definition of a minimally important change in VAS pain was a 30% or 20-point decrease from baseline. Secondary outcomes included the patient health questionnaire 9-item scale (PHQ-9, 0-27) for depression, the generalized anxiety disorder 7-item scale (GAD-7, 0-21) for anxiety, the work productivity and activity impairment (WPAI) scale, the knee injury and osteoarthritis outcome score—pain subscale (KOOS—pain, 100-0) for knee pathway participants, the Modified von Korff scale (MvK, 0-100) for back pathway participants [20,21], and surgery likelihood ("What do you think are the chances you'll have [back/knee] surgery in the next year, in %?", 0-100%). These secondary outcomes were collected at baseline, 6-weeks, and 12-weeks. Other baseline measurements obtained at week 0 consisted of participants' age, gender, and BMI. Participants' engagement with the DCP was measured by recording the number of ET sessions completed, the number of coaching interactions, and the number of education papers read. Each coaching interaction was further categorized as participant-to-coach or coach-to-participant; phone calls with a coach were not recorded as an interaction. Program satisfaction was asked at week 12 ("On a scale of 0-10, how likely is it that you would recommend the Hinge Health program to a friend or colleague?", 0-10).

Statistical Analysis

The distribution of gender and BMI in the knee and back pathways were compared using 2-sided Fisher's exact test and Mann-Whitney test, respectively. The association of baseline variables with program completion status was modeled using a logistic regression model and Wald's confidence intervals for the odds ratios (ORs) estimated. Exploratory analyses visualized the relationship between overall pain reduction over the course of the DCP and the total number of ET sessions (grouped in equisized bins assuming an average of 35 ET sessions for program completers). VAS pain trends were modeled using piecewise linear regression splines. Intersubject variability in the rate of change was modeled through random effects and used a first-order autoregression correlation structure to model within-subject correlation in residuals. Optimal knot locations for the spline were determined by a cross-validation procedure that evaluated model fit on a grid of knot locations. The fixed effects were estimated using a linear mixed-effects model (Multimedia Appendix 3). Significance (*P* value) evaluation was based on Wald *t* values with a Satterthwaite correction. For pain-response subgroup analysis, a Gaussian mixture model was fitted to the estimated spline coefficients to discover clusters corresponding to subgroups within the cohort, each with a distinct pain reduction trend. Adjusted ORs were computed to understand the association between participants' characteristics and the representative pain reduction trends for each subgroup. Finally, classification algorithms were trained to distinguish the 3 response groups based on the participants' demographic and baseline measurements alone, and performance was evaluated using 5-fold cross-validation. All analyses were performed using R statistical computing software.

Results

Participant Demographics and Digital Care Program Completion

Of the 10,264 DCP participants, 6468 self-reported back pain and were enrolled in the back-pain pathway and 3796 self-reported knee pain and were enrolled in the knee-pain pathway. The average age was 43.6 years, and the average BMI was 30.25. The proportion of female participants in the DCP was 50.00% (5132/10,264). Compared with the back-pain pathway, BMI was 1.3 kg/m^2 higher (P<.001) and the proportion of female participants was 3.9% higher (P<.001) in the knee-pain pathway. The difference in mean age between pathways was not significant (Table 1).

In all, 73.04% (7497/10,264) of the participants completed the DCP (referred to as *completers*), defined as completing at least one exercise session or reading 1 educational paper in weeks 9-12. Older users were more likely to complete the DCP (OR 1.037, 95% CI 1.03-1.04), whereas those with a higher BMI were less likely to complete the DCP (OR 0.973, 95% CI 0.97-0.98). No other baseline measures were significantly associated with completion (Multimedia Appendix 3). On average, completers engaged in 10.45 weeks with 35.02 ET

sessions and 19.39 education sessions. Table 2 summarizes the engagement by pathway for all participants and completers. No injuries or other adverse effects of DCP engagement other than temporary discomfort were reported.

Table 2. Mean engagement and SD for the full cohort and for completers by pathway (N=10,264).

Variables	All			Completers		
	Overall	Back pain	Knee pain	Overall	Back pain	Knee pain
Number of participants, n (%)	10,264 (100.00)	6468 (63.02)	3796 (36.98)	7497 (73.04)	4676 (72.29)	2821 (74.32)
Weeks engaged (ET[a] session or education session), mean (SD)	8.46 (3.9)	8.36 (3.92)	8.63 (3.86)	10.45 (2.15)	10.39 (2.17)	10.54 (2.1)
ET sessions per week, mean (SD)	2.93 (1.47)	2.85 (1.46)	3.05(1.47)	3.26 (1.39)	3.18 (1.41)	3.4 (1.34)
Total ET sessions, mean (SD)	27.43 (20.56)	26.48 (20.45)	29.04 (20.65)	35.02 (18.68)	34.04 (18.86)	36.65 (18.25)
Education sessions per week, mean (SD)	2.24 (1.55)	2.2 (1.55)	2.31 (1.56)	2.44 (1.28)	2.4 (1.27)	2.5 (1.3)
Total Education session, mean (SD)	15.33 (13.27)	14.81 (13.00)	16.24 (13.67)	19.39 (12.92)	18.84 (12.71)	20.29 (13.20)
Coach interactions per week, mean (SD)	7.03 (3.21)	6.99 (3.09)	7.09 (3.39)	7.23 (3.25)	7.21 (3.15)	7.27 (3.4)
Total coach interactions, mean (SD)	84.08 (43.3)	83.55 (42.02)	84.97 (45.36)	91.47 (43.42)	91.03 (42.33)	92.19 (45.16)

[a]ET: exercise therapy.

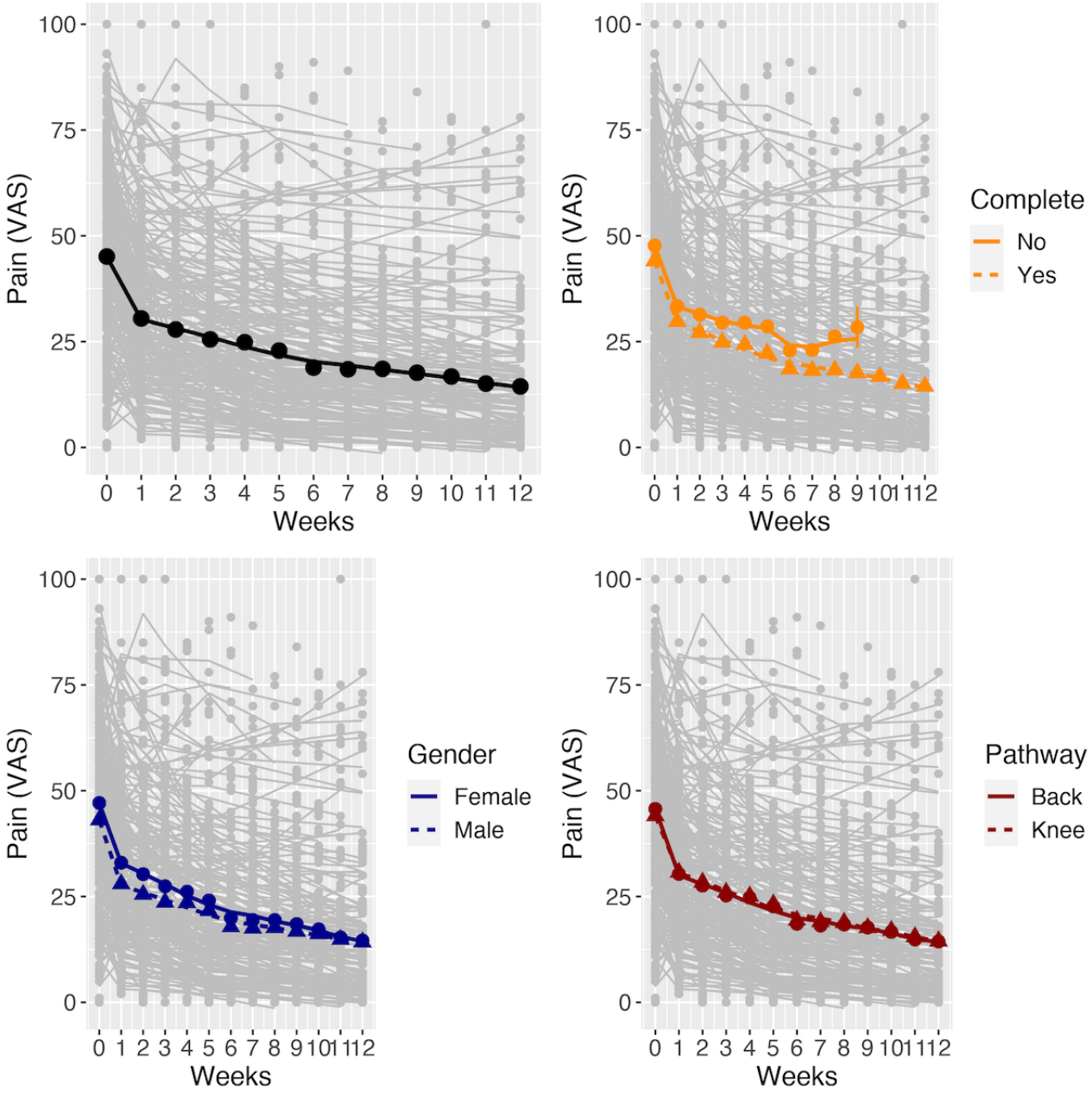
Longitudinal Changes in Pain

On the basis of a linear mixed effects model, the estimated mean reduction in pain by week 12 was 68.45% (30.89 points). Participants' pain scores changed nonlinearly over time (Figure 1). The mean change in pain scores per week (adjusted for sex, pathway, baseline age, BMI, anxiety, and depression scores) was 15.96 points for week 1 (P<.001) and 1.11 points per week for weeks 6-12 (P<.001) but was not significant for weeks 2-5. The conditional and marginal R-squared statistics [22] for our model were 0.94 and 0.54, respectively.

Minimally important change from baseline pain (defined as either a VAS pain reduction of 20 points or 30% with respect to baseline) was achieved by 78.60% (5893/7497) of completers and 69.60% (7144/10,264) of all participants.

Completers demonstrated greater pain reduction than noncompleters (Figure 1, top right) with an increased mean reduction rate of 0.48 points per week (SE 0.14) in weeks 2-5. Final pain reduction was nearly identical for both male and female genders (Figure 1, bottom left). However, there was a significantly higher mean reduction rate for male participants in the first week (mean difference=0.89 points per week, SE 0.46), and lower mean reduction rates in weeks 2-5 (difference=0.47 points per week, SE 0.09) and weeks 6-12 (difference=0.22 points per week, SE 0.05). Compared with the knee pathway, the back pathway was associated with a higher mean pain reduction rate (difference=3.1 points per week, SE 0.48) in the first week, but the pathway was not a significant variable in later weeks (Figure 1, bottom right).

Figure 1. Longitudinal changes in pain. The panels show the average pain scores computed for the entire study cohort (circles) and the fitted means (lines) computed for weeks 0-12 of the study. Top left shows the overall fitted mean. The plots on the top right, bottom left and bottom right show the means for subjects grouped by completion status, gender, and pathway, respectively. Weekly recorded pain and fitted curves for a random sample of subjects are plotted in gray on each panel. Error bars indicate 1 SE of the mean. F: female; M: male; VAS: visual analog scale for pain.

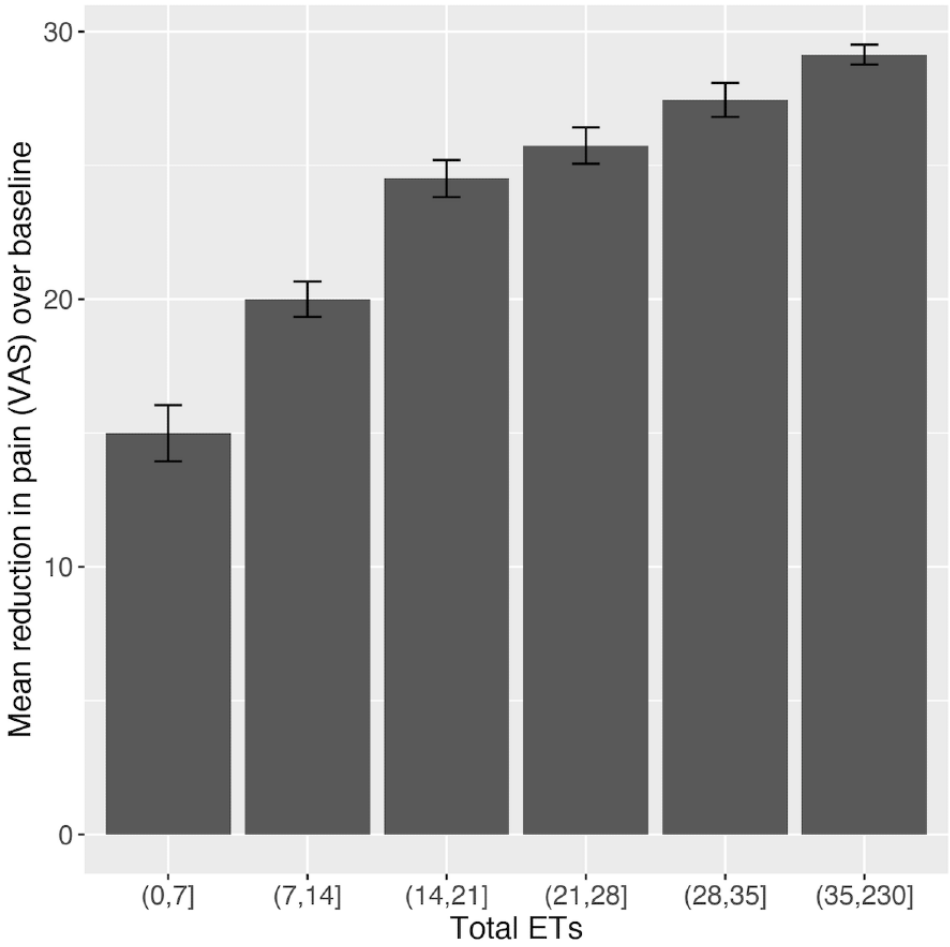


Effect From Engagement

Increasing levels of ET engagement in the DCP were associated with greater reductions in VAS pain score (P<.001; Figure 2). Notably, the relationship between the change in pain score and the number of ET sessions was nonlinear, with initial ET sessions contributing a higher proportion of the mean reduction achieved. The rate of reduction (adjusted for gender, pathway, baseline age, BMI, anxiety, and depression scores) for the initial 10 ET sessions was 1.9 VAS points per session (SE 0.2; P<.001).

The number of weekly coach interactions was also associated with a reduction in pain with a mean reduction of 0.18 VAS points per interaction (SE 0.06; P=.003) for the first 30 interactions. The number of participant-to-coach interactions, specifically, was associated with a mean rate of reduction in pain of 0.30 VAS points per interaction (SE 0.1; P=.003) for the first 20 interactions. The number of coach-to-participant interactions was not significantly associated with pain reduction.

Figure 2. Association between pain reduction and ET sessions. Bar plots show the mean reduction in pain achieved over the DCP grouped by the total number of ET sessions. Error bars indicate 1 SE of the mean. DCP: digital care pathway; ET: exercise therapy; VAS: visual analog scale for pain.



Mental Health and Other Secondary Outcome Measures

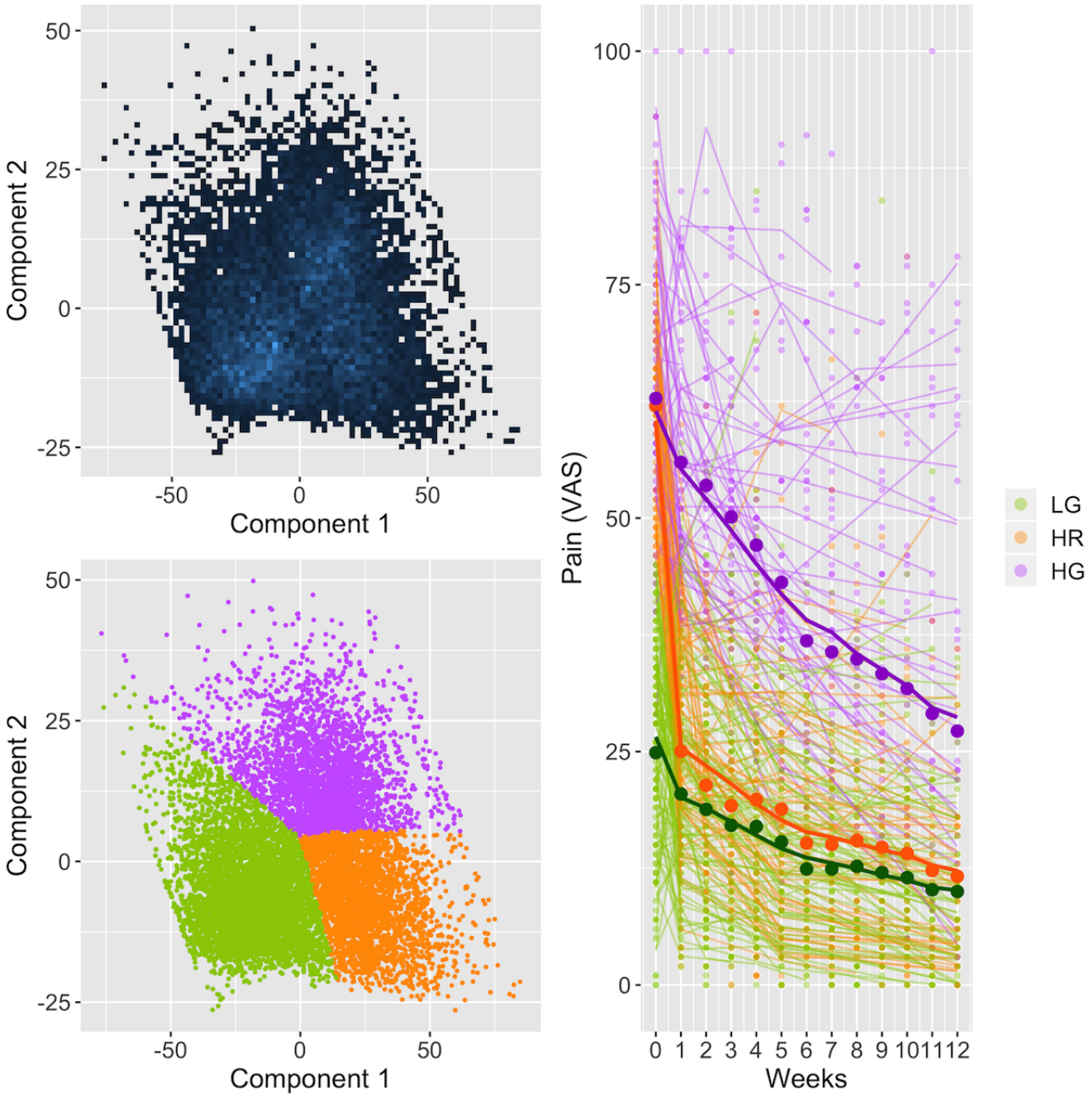
For participants categorized as having depressive symptoms (PHQ-9≥5) at baseline, the mean baseline PHQ-9 score was 12.01 and decreased by 57.9% to 5.05 at week 11 (P<.001). Differences between the pathways were not significant. The percentage of patients with depressive symptoms at baseline and at the end of the study was 21.1% and 11.4%, respectively. For participants categorized as having anxiety symptoms (GAD-7≥5) at baseline, the mean baseline GAD-7 score was 11.49 and decreased by 58.3% to 4.78 at week 11 (P<.001). The back pathway participants had a 0.46 point (P<.001) greater mean GAD-7 reduction than those in the knee pathway. The percentage of patients with anxiety symptoms at baseline and the end of the study was 28.3% and 14.2%, respectively (PHQ-9 and GAD-7 values at week 6 were carried forward to impute missing values at week 12).

With respect to baseline, the mean surgery likelihood score decreased by 67.4% (8.15 points, P<.001) overall, and by 66.8% and 68.2% for knee and back pathway participants, respectively. The mean KOOS—pain decreased by 33.9% (5.19 points, P<.001) in knee pathway participants and the mean MvK decreased by 51.4% (8.20 points, P<.001) in the back pathway participants. The within-participant correlation coefficients for KOOS—pain and MvK scores (with VAS pain) were 0.59 (95% CI 0.58-0.61) and 0.80 (95% CI 0.79, 0.81), respectively, indicating strong correlations between the primary and secondary pain variables. The mean WPAI score decreased by 63.94% from baseline (20.29 points, P<.001). The DCP final satisfaction score was 8.97/10 with a net promoter score of +64/100.

Distinct Pain Response Groups

Intersubject variation in pain reduction trends motivated a subgroup analysis of pain response, and 3 distinct response groups emerged (Figure 3). Participants with high pain at baseline and gradual improvement were designated as *high gradual* (HG). Participants with high baseline pain but a rapid decline were labeled *high rapid* (HR), and those with low baseline pain and gradual response were labeled *low gradual* (LG). All LG participants had baseline pain below 50. HR participants had the highest mean pain reduction over the duration of the DCP (48.8 points, 80.0%), followed by the HG (33.3 points, 54.1%) and LG group (15.3 points, 64.0%).

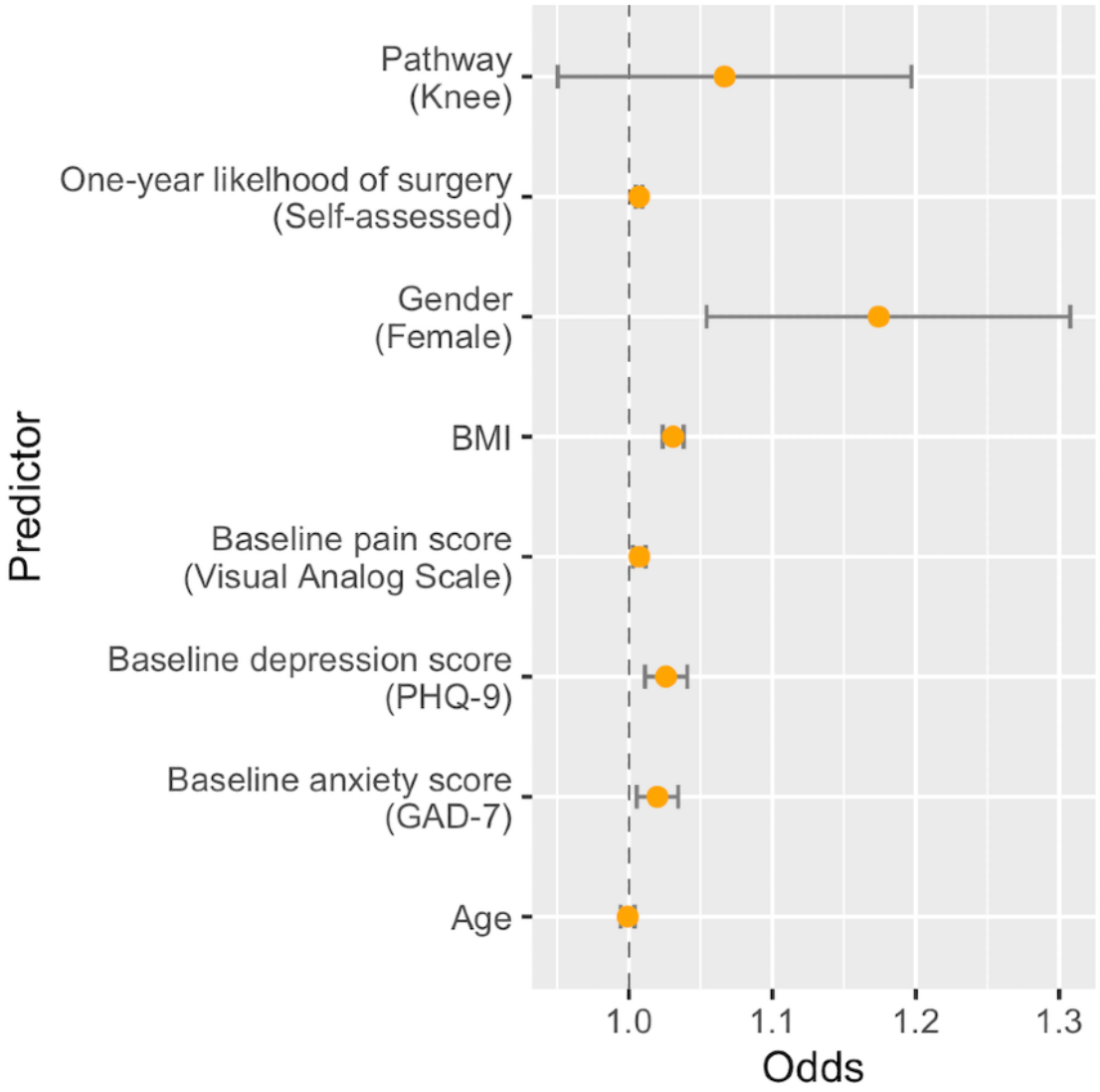
Figure 3. Pain response subgroups. Pain reduction trend clusters obtained by fitting a 3-component GMM identified 3 subgroups (HG, HR, and LG response). (Top left) 2D density plot of the first 2 principal components of the fitted splines shows each of the 3 subgroups. (Bottom left) Curves denoted by their respective principal components 1 and 2 are assigned to a cluster based on maximum posterior likelihood. (Right) Random sample of pain reduction trends colored by subgroup and the respective mean trends. 2D, 2 dimensional; GMM, Gaussian Mixture Model; HG, high-gradual; HR, high-rapid; LG: low-gradual.



Relative to the HR response, female participants had 17.3% (P=.002) higher odds of an HG response (Figure 4). The odds of an HG response also increased by 3.1% (P<.001) per unit increase in BMI and increased by 2.2% (P=.001) and 2.1% (P=.002) per unit increase in PHQ-9 and GAD-7, respectively.

Classification of response groups based on baseline attributes achieved a mean accuracy of 76% (SE 0.3%) using a random forest algorithm, evaluated using 5-fold cross-validation. The classifier had a mean area under the precision-recall curve of 68.92% (SE 2.04%). Nearly equal numbers of participants belonged to the HR and HG response groups. Subgroup analysis details are provided in Multimedia Appendix 3.

Figure 4. Association of baseline variables with a high-gradual or high-rapid pain reduction trend. For each baseline variable, the plotted values indicate the odds ratios for a gradual response (with reference to a high-rapid response) for a unit increase in the corresponding predictor. The error bars denote the 95% profile-likelihood CIs.



Discussion

Principal Findings

This study demonstrated the positive effect of a 12-week DCP on chronic musculoskeletal pain outcomes in a large sample of real-world patients. Specifically, participants experienced a 68.5% average improvement in VAS pain between baseline and 12 weeks, and 78.60% (5893/7497) of program completers (7144/10,264, 69.60% of all participants) achieved clinically meaningful improvement. Completion was high, with 73.04% (7497/10,264) of participants reaching the final month, and completers engaged in a mean of 35.0 ET sessions, 19.4 education sessions, and 91.5 coach interactions during the DCP. It is well known that unless a digital health intervention fits into users' daily lives, only a small proportion of all participants who sign up actually complete the program [23,24]. The exceptional completion rate of our study may be due to the multipronged strategy of our DCP that uses both a digital and a human interface to engage with participants. Furthermore, both the number of ET sessions and participant-to-coach interactions were positively associated with improvement in pain, supporting that the level of participant engagement influenced outcomes. These results support the effectiveness of a DCP for musculoskeletal pain in the real-world setting, and the large sample size supports the prospect for scalability to serve a large number of chronic low back and knee pain sufferers worldwide.

Comparison With Literature

The observed 68.5% average improvement in VAS pain in this DCP outperforms the pain reduction effect sizes observed in a variety of conservative care interventions with similar timeframes. For pain associated with knee osteoarthritis, comparable conservative care interventional studies demonstrate an average improvement in VAS pain of 19%-48% [25-28]. For low back pain, comparable studies demonstrate average improvements in VAS pain of 29%-53% [29-34]. Similarly, a systematic review of randomized clinical trials for low back pain showed a within-group standardized mean difference of 1.07 (95% CI 0.87-1.27) for pain reduction at 13 weeks [35], whereas a standardized mean difference of 1.37 (95% CI

1.33-1.40) for pain reduction at 12 weeks was observed in this study. Not only does this study demonstrate greater improvement in pain for both knee and low back pathways but it also has a much larger sample size than previous studies, which typically did not exceed 100 subjects. Furthermore, this study found a strong correlation between changes in VAS pain and secondary pain measures (KOOS—pain for knee and MvK for back), further supporting the validity of the VAS pain measurements. Finally, compared with other studies utilizing therapeutic exercise for chronic pain, this study demonstrated a similar lack of adverse events. This is likely attributable to the benefits and safety of light intensity stretching and strengthening exercises, and in this study may also be due to the exercise guidance provided by the wearable sensors.

Patient Engagement

Notably, most previous studies have occurred in traditional clinical settings, where multiple barriers prevent both patients and clinicians from engaging in conservative care [36]. For example, adherence of chronic low back pain patients to home exercises prescribed from traditional physical therapy ranges from 30% to 50% and remains a significant challenge for administering effective care [37,38]. A primary benefit of a digital care approach for chronic musculoskeletal pain is the ability to engage patients with their treatment and self-management. Smartphone apps can cost-effectively deliver education and encourage healthy behaviors, whereas sensors can provide exercise guidance and track engagement [39]. The DCP in this study engaged 73.04% (7497/10,264) of users to completion, with completers engaging in 10.5 of the 12 weeks, including 3.3 ET sessions, 2.4 education papers, and 7.2 coach interactions per week (mean ET sessions 2.9, mean education sessions 2.2, and 7.0 coach interactions per week among all participants). Notably, this study demonstrated an association between pain improvement and both the number of ET sessions and the number of coach interactions, suggesting that the level of participant engagement impacted the results. Specifically, the first 10 ET sessions and the first 30 coach interactions were the most influential in pain improvement. Of note, a recent study evaluating a DCP in a similar population showed lower engagement and no relationship between exercise and pain reduction, suggesting that specific program implementation details (ie, sensor-guided exercises and health coaching) may have a large effect on outcomes [40].

Mental Health Outcomes

Depression and anxiety are known to often occur in patients with chronic musculoskeletal pain [41], so the effects of this DCP on symptoms of depression and anxiety were also assessed. Behavioral health coaching and education on cognitive behavioral therapy concepts were key elements of the DCP's multimodal digital care approach. A large body of research confirms the effect of psychological factors, such as depression and anxiety, on chronic pain [42,43]. In particular, an association between chronic low back pain and psychological factors has been shown, and related therapeutic approaches, including cognitive behavioral therapy and mindfulness-based stress reduction, have demonstrated effectiveness for back pain reduction [44]. This study showed that outcomes for participants with symptoms of depression and anxiety decreased on average by 57.9% and 58.3%, respectively, over the course of the DCP. This suggests a strong relationship between mental health and pain improvement; however, a causal relationship between these entities cannot be determined. Notably, mental health improvements were very similar across knee and back pathways, whereas a small difference (0.46 points) in GAD-7 outcomes was noted. This is unlikely to be clinically meaningful. Future work will further explore the effect of coaching and other behavioral health support on pain and functional outcomes.

Predicting Pain Response

In addition to clinical effectiveness, another potential benefit of a DCP is the insight gained from longitudinal tracking of outcome data in large populations. The large sample size in this study, combined with data collection at regular and relatively frequent time intervals, enabled the discovery of distinct clusters of pain response trajectories over time. Participants were classified as gradual versus rapid pain responders, and patient-specific features that influenced the likelihood of pain response category were identified. By clustering distinct trends in pain response over time for each subject, we specifically uncovered 3 distinct pain response subgroups. Two groups had high baseline pain but differed in the rate of recovery (rapid vs gradual), whereas the third group had low baseline pain with gradual recovery. Notably, we were able to forecast with 76% accuracy which of these pain response groups a user would fall into based on their baseline information. Looking specifically at the 2 groups with high baseline pain, the rapid response was more likely to occur in male participants, those with lower BMI, or those with lower depression or anxiety scores. These pain response groups enable a better understanding of temporal changes in pain during the rehabilitation process and may ultimately help to identify pain recovery mechanisms. Furthermore, continued research into response patterns may ultimately allow for a more personalized approach to care, including more accurate prognosis and additional treatment options for patients likely to have a more gradual recovery.

Strengths and Limitations

This study has several limitations, including the lack of a control group and the lack of physical function outcomes. Notably, previous randomized trials of this DCP on smaller populations (N<200) demonstrated positive effects on pain and functional outcomes (Oswestry disability index, KOOS—physical function short form) compared with control groups [17,18]. This study assessed outcomes in a sample of more than 10,000 users and demonstrated similar effectiveness. Another limitation of this study is the lack of long-term outcomes, and future studies should assess if participants are able to sustain healthy behaviors and self-management promoted in the DCP. Some potentially important demographic variables (ie, education, ethnicity, income, and smoking status) and medical history variables (ie, diabetes, hypertension, and mental health) were not obtained. Finally, this study was conducted through employers, which limits the applicability to clinical settings with higher proportions of uninsured, elderly, or work-disabled patients. However, this study was conducted with employees from 30 different companies across the United States and included a

wide diversity of job types (eg, truck drivers, manual laborers, office workers), suggesting that the findings are applicable to a broad population. In addition, older patients were more likely to complete the program than younger ones, emphasizing that digital health tools are not only useful to the younger population.

The strengths of this study include the large sample size in the real-world setting, which demonstrated scalability and enabled the discovery of unique features, such as distinct pain response clusters in longitudinal real-world data. In addition, this study had similar age and sex distributions for knee and back pain participants, enabling direct comparison of the separate knee and back pathways. The average pain response for these separate pathways was quite similar (Figure 1), which is notable given the assumed underlying pathological differences between knee and back pain, but supports recent work urging practitioners to move beyond separating body regions when managing chronic musculoskeletal pain [45]. Finally, this study demonstrates significant improvements in self-reported workplace productivity (WPAI, 61.5% improvement) and surgery likelihood (67.4% reduction), suggesting that a DCP may have considerable economic benefits.

Future Directions

DCPs may ultimately be used to complement clinical musculoskeletal practice, and further research is warranted on their use by patients and providers. This study supports the efficacy and scalability of a DCP for facilitating safe conservative care and promoting healthy behavior change. However, critical reviews have identified a lack of external and long-term validation of digital health tools [46]. Many previous studies on digital interventions for chronic low back pain have presented unconvincing results [47]. Given that digital health tools are typically developed in the private sector, and good clinical research can be time-consuming and challenging, we see a need for collaborative efforts between industry and academic medicine to optimize digital health technologies for effective conservative care implementation, adoption, and access in the broad, real-world population with musculoskeletal pain.

Conclusions

This study supports the efficacy and scalability of a DCP for chronic low back and knee pain in a large, real-world population. Participants demonstrated very high completion and engagement rates, and a significant positive relationship between engagement and pain reduction was identified. This is the first longitudinal digital health study to analyze musculoskeletal health outcomes in a sample of this magnitude, and it supports the prospect for DCP scalability to serve the overwhelming number of chronic back and knee pain sufferers worldwide. Furthermore, the large sample size enabled the prediction of rapid versus gradual pain response from baseline information, which may prove beneficial for prognosis and tailoring future interventions.

Acknowledgments

The sponsors of the study, Hinge Health, Inc, facilitated data collection. The sponsor and all authors participated in the decision to submit the paper for publication.

Authors' Contributions

JB, VA, and JK contributed to the study design, analysis plan, interpretation, and manuscript drafting. JB and VA contributed equally with JB leading analysis strategy and interpretation for clinical impact, VA conducting statistical analysis, and each drafting half of the manuscript. MS, PZ, DK, and MF contributed to manuscript drafting and editing. All the authors had access to all the raw data. JB and VA led all data analysis, data interpretation, and writing of the report.

Conflicts of Interest

JB and VA were academic collaborators in this study and were paid as consultants for their expertise in conducting this study. JB and VA had unrestricted access to the data and led the analysis and interpretation of the results. Subsequent to paper completion, author VA became employed at Hinge Health, Inc, and received salary and equity compensation. Author JK is employed at Hinge Health, Inc, and receives salary and equity compensation. MF and DK are clinical advisors to Hinge Health, Inc, and receive equity compensation. Authors PZ and MS have no relevant declarations.

Multimedia Appendix 1

Hinge Health Digital Care Pathway.
[PDF File (Adobe PDF File), 41435 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Hinge Health Digital Back Pathway - woodpecker exercise.
[MP4 File (MP4 Video), 24823 KB-Multimedia Appendix 2]

Multimedia Appendix 3

Supplementary tables and figures.
[DOCX File , 260 KB-Multimedia Appendix 3]

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Abbreviations

DCP: digital care program
ET: exercise therapy
GAD-7: generalized anxiety disorder 7-item
HG: high gradual
HR: high rapid
KOOS—pain: knee injury and osteoarthritis outcome score—pain
LG: low gradual
MvK: Modified von Korff scale
OR: odds ratio
PHQ-9: patient health questionnaire 9-item scale
VAS: visual analog scale
WPAI: work productivity and activity impairment

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Older Adult Use and Outcomes in a Digital Musculoskeletal (MSK) Program, by Generation

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Objective: We investigated use and clinical outcomes in a digital musculoskeletal (MSK) program, by generation.

Method: This longitudinal study uses retrospective data collected online or by app. The study included adults with 12 or more weeks of pain who took part in a digital MSK program. We compared Gen Z and Millennials, Gen X, working age Baby Boomers, and retiree age Baby Boomer and Silent Generation. Program use outcomes were program start, program completion, and number of exercises, educational articles, and messages to coaches. Clinical outcomes were changes in pain, depression, and anxiety from baseline to 12 weeks. We calculated descriptive statistics and conducted adjusted regression models.

Results: Odds of starting the program were significantly higher for Gen Xers (OR: 1.12) and working age Baby Boomers (OR: 1.37) vs. Gen Zers and Millennials. Compared to Gen Zers and Millennials, we observed significantly higher odds of program completion among Gen Xers (OR: 1.62), working age Baby Boomers (OR: 2.24), and retirees (OR: 2.36). Compared to Gen Zers and Millennials, retirees had 19 more exercise sessions (IRR: 1.69), accessed 11 more articles (IRR: 1.84), and sent 4 more messages to coaches (IRR: 1.26). Compared to Gen Z and Millennials, we observed no significant differences in change in pain for Gen Xers, working age Baby Boomers, or retirees.

Conclusions: Adults from multiple generations took part in a digital MSK program. Findings suggest that older generations used a digital MSK program more than younger generations, but had similar pain outcomes.

Keywords: telemedicine, aged, engagement, musculoskeletal pain, depression, anxiety, digital technology, utilization

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INTRODUCTION

Chronic musculoskeletal (MSK) pain is a leading cause of disability and cost in the United States, especially among older adults. Prevalence and incidence rates in the United States of osteoarthritis, back and neck pain, and other MSK disorders are among the highest in the world (1). In 2018, 134.5 million adults in the United States reported MSK conditions with older adults experiencing higher prevalence rates of MSK conditions and limitations compared to younger adults (2, 3).

Furthermore, chronic MSK pain often occurs together with depression and anxiety (4). Pain makes it more challenging to identify depression and anxiety and can exacerbate depression and anxiety symptoms. Depression and anxiety can also increase pain severity, the experience of pain, and the pain duration (5–8).

To prevent and manage MSK pain and associated comorbidities, clinical guidelines recommend evidence-based exercises, education, and additional supports (9, 10). Reviews have concluded that exercise therapy vs. usual care offered pain reduction, reduced depression severity, and improved quality of life (11, 12). Pain neuroscience education can further enhance these benefits (13).

Digital health approaches can facilitate access to these types of conservative therapies by providing interactive tools, connecting users with health teams and offering choices for how, when, and where to access care (14). A meta-analysis of four studies of good methodological quality showed that digital MSK programs significantly improved knee osteoarthritis pain (15). Another review of 8 RCTs of moderate quality found that digital health improved low back pain intensity and disability (16).

We must ensure that digital MSK programs meet the needs of a growing older adult population with MSK conditions. But, to date, no studies have examined whether the use and effectiveness of digital MSK programs differs by generation. Studies have shown that older generations use general technology and digital health technology, but to a lesser extent compared to younger generations (17–20). Further, the effectiveness for older populations remains uncertain (21).

In summary, gaps remain in our understanding about digital MSK program use and outcomes between generations. Thus, we sought to address two objectives. Our primary objective was to examine differences in digital MSK program use between generations. Our secondary objective was to examine differences in digital MSK program outcomes between generations. Better understanding about program use and outcomes by generation will allow us to make program improvements that meet the various needs and desires of a range of users.

METHOD

Study Design

We conducted a longitudinal study using retrospective data collected from participants of a digital MSK program.

Intervention

The digital MSK program was offered as a benefit to employees and dependents of participating employers. We recruited through email, workplace posters or presentations, and mailings. Those interested in the program registered online by creating a member profile and completing a baseline questionnaire.

After registering, we reviewed the baseline questionnaires to ensure that participants met the following program criteria: age 18 or older; pain in the low back, knee, shoulder, hip, or neck; baseline visual analog scale (VAS) pain score >0; pain lasted for at least 12 weeks; and member covered by employer's health plan. Exclusion criteria were signs of fracture, joint instability, infection, cancer, and cauda equina syndrome.

All accepted participants received tablet computers with a program app and wearable motion sensors (InvenSense MPU-6050, TDK Electronics, Tokyo, Japan). These materials enabled members to receive technology-guided exercise therapy sessions, coaching, and education for chronic pain. To facilitate exercise sessions, animations and videos within the app demonstrated how to perform light-intensity stretching and strengthening exercises. The app and sensors displayed body position of the participant in real-time while completing exercises and indicated to participants whether they were within the appropriate range of movement.

In addition, a personal health coach communicated with participants via text message, email, or in-app messaging. The program offered participants unlimited text and email messages and up to three phone calls with coaches. Participants could also take part in discussion forums with 20–30 other participants. Finally, participants received educational resources covering their condition and treatment options, as well as behavior change topics, such as catastrophizing, coping methods, and fear avoidance.

Overall, participants were encouraged to complete at least three sensor-guided exercise sessions per week, read at least two education papers per week, and log symptoms twice per week. Participants were also encouraged to engage in at least three aerobic exercise activities per week.

Study Population

In addition to meeting program criteria, this study applied the following inclusion criteria: registered between February 2017 and April 2020 and 12 or more weeks had passed from the time of registration, had registered for only one pathway (i.e., back, knee, shoulder, hip, or neck), had complete baseline data, and provided informed consent through waiver of written documentation.

Data Collection

Data were collected online or through the program app at baseline during registration and 12 weeks later.

Variables

We organized variables around Andersen's model of health service use (22) (**Supplementary Figure 1**). The model shows that contextual factors (i.e., system, environment) and individual (i.e., predisposing, enabling, and need) factors explain service use factors. These factors, in turn, influence perceived and evaluated health outcomes.

The predisposing factor of participant generation was the independent variable of interest and defined as Gen Z or Millenial (born between 1981 and 1999), Gen X (born between 1965 and 1980), working age Baby Boomer (born before 1964 and under age 65), and retiree age Baby Boomer or Silent Generation (age 65 or older) (23). The rationale for distinguishing working age from retiree age Baby Boomers is retirees may have more time to engage in a digital MSK program or self-care generally.

For our primary study objective about digital MSK program use, we focused on five service use outcomes: program start (i.e., completing one exercise session or accessing one educational paper after registering); program completion (i.e., completing

exercise sessions or accessing education articles between program weeks 9 and 12); total exercise sessions by program week 12; total education articles read by program week 12; and total number of member-initiated messages to coaches by program week 12.

For our secondary study objective about digital MSK program outcomes, we focused on three measures captured for each individual participant. Change in pain was pain scores at baseline minus pain scores at 12 weeks. Baseline and 12 weeks pain scores were based on responses to the question "Over the past 24 h, how bad was your [back/knee/shoulder/hip/neck] pain?" from 0 (none) to 100 (worst imaginable) presented on a horizontal visual analog scale. We also examined change in depression or anxiety by 12 weeks among the subgroup with moderate or severe depression or anxiety at baseline. Change in anxiety (no/yes) was defined as reported moderate or severe anxiety at baseline and reported no moderate or severe anxiety at 12 weeks. Moderate or severe anxiety was a score of 10 or higher on the Generalized Anxiety Disorder 7-item scale (GAD-7). Change in depression (no/yes) was defined as reported moderate or severe depression at baseline and reported no moderate or severe depression at 12 weeks. Moderate or severe depression was a score of 10 or higher on the Patient Health Questionnaire 9-item scale (PHQ-9). The GAD-7 and the PHQ-9 with cutoffs at 10 points have been shown to have acceptable performance for identifying anxiety and depression (24–26).

Covariates included contextual (e.g., state of residence), predisposing (e.g., gender, exercise frequency per week [<1 h, 1–2.5 h, more than 2.5 h]), and need (e.g., program pathway and baseline measures of pain, anxiety, depression, and body mass index categories [underweight, normal, overweight, obese]) factors.

Statistical Analysis

To characterize the population, we conducted descriptive analyses (e.g., means, frequencies) for predisposing and need factors, by generation. We examined differences using chi-square tests for categorical variables and one-way ANOVA for continuous variables. We conducted unadjusted and adjusted regression analyses, per protocol. For the primary objective, logistic regression was conducted for binary outcomes, including program start and completion. Generalized linear models (Poisson regression) was used among program starters for outcome variables representing counts, including total number of exercise sessions, articles and messages. Models were adjusted for contextual (e.g., state of residence), predisposing (e.g., gender, exercise frequency), and need (e.g., program pathway and baseline pain, anxiety, depression, and BMI) factors.

For the secondary objective, linear regression was conducted for the continuous change in pain outcome. Models were adjusted for contextual (e.g., state of residence), predisposing (e.g., gender, exercise frequency), and need (e.g., program pathway and baseline anxiety, depression, and BMI) factors. Logistic regression was conducted for binary outcomes, including change in anxiety and depression by week 12. This model controlled for contextual (e.g., state of residence), predisposing (e.g., gender, exercise frequency), and need (e.g., program pathway and baseline pain and BMI) factors. All analyses were performed using STATA statistical computing software.

The study was approved by the Western Institutional Review Board and complied with all ethical regulations.

RESULTS

The digital MSK program registered 13,535 Gen Zers or Millennials (mean age 31.32, SD 4.33, median: 32), 16,982 Gen Xers (mean age 46.15, SD 4.68, median: 46), 9,262 working age Baby Boomers (mean age: 58.70, SD 2.90, median: 58), and 1,462 retiree age Baby Boomers or Silent Generation members (mean age: 68.55, SD 4.17, median: 67). **Table 1** compares the characteristics of the different generations who registered for the program. Differences between generations were statistically significant for all variables. Compared to younger generations, a smaller percentage of the retiree age generation was female, exercised <1 h, was in the back pathway, and reported moderate to severe anxiety or depression. The retiree generation also had lower baseline pain than younger generations.

Differences in Digital MSK Program Use Between Generations

We examined 5 digital MSK program use outcomes: program start, program completion, and total number of exercise sessions, educational articles, and coach messages. **Table 2** shows differences between generations on program start. Out of registrants, 86.17% of Gen Z and Millenials started the program vs. 87.56% of Gen Xers, 90.01% of working age Baby Boomers, and 87.00% of retiree age Baby Boomer and the Silent Generation. In adjusted models, we find that the odds of starting the program were significantly higher for Gen Xers (OR: 1.12, 95% CI: 1.04, 1.20) and working age Baby Boomers (OR: 1.37, 95% CI: 1.25, 1.49) compared to the Gen Z and Millennial group. We detected no statistically significant differences in odds of starting between the retiree age generation vs. the Gen Z and Millennial generation (OR: 1.02, 95% CI: 0.87, 1.20).

Table 2 also presents program completion, by generation. Among the members who started the program, 66.91% of Gen Zers and Millennials completed the program compared to 75.51% of Gen Xers, 81.53% of working age Baby Boomers, and 83.02% of retiree age Baby Boomers and the Silent Generation. Compared to Gen Z and Millenials, we observed significantly higher odds of program completion among Gen Xers (OR: 1.62, 95% CI 1.53, 1.71), working age Baby Boomers (OR: 2.24, 95% CI: 2.09, 2.40), and retiree age generations (OR: 2.36, 95% CI: 2.02, 2.75) in adjusted models.

Generation was significantly associated with number of exercise sessions, educational articles, and coaches messages among those who started the program. Compared to Gen Z and Millennials, the retiree age generation had an average of 19 more exercise sessions (adjusted IRR: 1.69; 95% CI: 1.61, 1.71), accessed 11 more articles (adjusted IRR: 1.84; 95% CI: 1.76, 1.93), and sent 4 more messages to coaches (IRR: 1.26; 95% CI: 1.19, 1.32) by week 12 (**Table 3**).

TABLE 1 | Description of members who registered for the program.

Factor	Variable	Gen Z or Millennial (n = 13,535)		Gen X (n = 16,982)		Working age Baby Boomer (n = 9,262)		Retiree age Baby Boomer and Silent Generation (n = 1,462)		
		Percent or mean	Sd	Percent or mean	Sd	Percent or mean	Sd	Percent or mean	Sd	*P*-value
Predisposing										
	Gender (%)									$p < 0.001$
	Female	50.35	50.00	54.07	49.84	53.98	49.84	44.73	49.74	
	Male	44.29	49.67	41.56	49.28	41.09	49.20	45.14	49.78	
	Other or unspecified	5.36	22.53	4.38	20.45	4.92	21.64	10.12	30.17	
	Weekly exercise (%)									$p < 0.001$
	<1 h	35.30	47.79	41.34	49.25	41.02	49.19	35.02	47.72	
	1–2.5 h	40.80	49.15	39.25	48.83	38.66	48.70	39.81	48.97	
	More than 2.5 hours	23.90	42.65	19.40	39.55	20.32	40.24	25.17	43.41	
Need										
	Pathway (%)									$p < 0.001$
	Back	66.46	47.22	60.53	48.88	50.05	50.00	49.45	50.01	
	Hip	4.53	20.79	6.81	25.19	8.11	27.30	11.29	31.65	
	Knee	27.16	44.48	31.51	46.46	40.62	49.11	37.76	48.49	
	Neck	0.64	7.99	0.38	6.18	0.30	5.49	0.41	6.40	
	Shoulder	1.21	10.94	0.77	8.72	0.92	9.54	1.09	10.41	
	BMI categories (%)									$p < 0.001$
	Underweight	1.15	10.64	0.63	7.91	0.73	8.54	0.82	9.03	
	Normal	31.56	46.48	18.55	38.87	18.55	38.87	22.91	42.04	
	Overweight	30.08	45.86	30.55	46.06	34.19	47.44	38.44	48.66	
	Obese	37.22	48.34	50.27	50.00	46.52	49.88	37.82	48.51	
	Baseline pain (mean)	46.54	21.85	48.15	22.44	47.83	22.72	46.28	22.91	$p < 0.001$
	Moderate or severe anxiety at baseline (%)	32.88	46.98	23.65	42.49	15.95	36.61	12.11	32.63	$p < 0.001$
	Moderate or severe depression at baseline (%)	26.52	44.14	20.24	40.18	14.93	35.64	11.63	32.07	$p < 0.001$

Differences in Digital MSK Program Outcomes Between Generations

Average pain scores decreased 27.13 points for Gen Z and Millennials, 28.21 points for Gen X, 27.28 points for working age Baby Boomers, and 25.60 points for retiree age Baby Boomer and Silent Generation. Compared to Gen Z and Millennials, we observed no statistically significant differences in change in pain for Gen Xers, working age Baby Boomers, or the retiree age generation in adjusted models (**Table 4**).

Compared to baseline, 79.28% of Gen Zers and Millennials were no longer reporting moderate to severe anxiety at 12 weeks vs. 81.16% of Gen Xers, 87.82% of working age Baby Boomers, and 91.36% of retiree age Baby Boomers and Silent Generation adults. Compared to Gen Zers and Millennials, working age Baby Boomers (OR: 2.05, 95% CI: 1.56, 2.69) and retiree age Baby Boomers and Silent Generation (OR: 2.71, 95% CI: 1.19, 6.20) had significantly higher odds of anxiety improvement in adjusted models. We detected no significant differences in odds between Gen Xers compared to younger generations (**Table 4**).

Compared to baseline, 78.39% of Gen Zers and Millennials were no longer reporting moderate to severe depression at 12 weeks vs. 77.76% of Gen Xers, 81.14% of working age Baby Boomers, and 85.51% of retiree age Baby Boomers and Silent Generation adults. Compared to Gen Zers and Millennials, working age Baby Boomers (OR: 1.31, 95% CI: 1.01, 1.71) had significantly higher odds of symptom improvement in adjusted models. We detected no significant differences in odds between Gen Xers or retiree age generations compared to younger generations (**Table 4**).

DISCUSSION

This study focused on two objectives. The first objective examined digital MSK program use between generations. Between 86 and 90% of the four generations started the program (i.e., completed one exercise or accessed one education material) after registering.We found that 83% of the retiree age generation completed the program, which exceeded the relatively high completion rates of younger generations (range: 67–82%). In our study, older generations also had more exercise, articles, and messages to coaches compared to younger adults.

TABLE 2 | Program start and completion outcomes, by generation.

Outcome	Generation	Percent (%)	Unadjusted model			Adjusted model		
			OR	95% CI		OR	95% CI	
Program start (n = number registered)	Gen Z and Millennial (n = 13,535)	86.17	Ref			Ref		
	Gen X (n = 16,982)	87.56	1.13	1.06	1.21	1.12	1.04	1.20
	Working age Baby Boomer (n = 9,262)	90.01	1.45	1.33	1.57	1.37	1.25	1.49
	Retiree age Baby Boomer and Silent Generation (n = 1,462)	87.00	1.07	0.92	1.26	1.02	0.87	1.20
Program completion (n = number starting the program)	Gen Z and Millennial (n = 11,663)	66.91	Ref			Ref		
	Gen X (n = 14,870)	75.51	1.52	1.44	1.61	1.62	1.53	1.71
	Working age Baby Boomer (n = 8,337)	81.53	2.18	2.04	2.33	2.24	2.09	2.40
	Retiree age Baby Boomer and Silent Generation (n = 1,272)	83.02	2.42	2.08	2.81	2.36	2.02	2.75

TABLE 3 | Program engagement outcomes, by generation.

Outcome	Generation	Descriptive result (mean)	Unadjusted model			Adjusted model		
			IRR	95% CI		IRR	95% CI	
Number of exercise sessions	Gen Z and Millennial	25.86	Ref			Ref		
	Gen X	33.35	1.29	1.26	1.32	1.34	1.31	1.36
	Working age Baby Boomer	41.20	1.59	1.56	1.63	1.62	1.58	1.66
	Retiree age Baby Boomer and Silent Generation	45.26	1.75	1.67	1.83	1.69	1.61	1.76
Number of educational articles	Gen Z and Millennial	12.57	Ref			Ref		
	Gen X	17.61	1.40	1.37	1.43	1.41	1.38	1.45
	Working age Baby Boomer	22.85	1.82	1.77	1.86	1.80	1.76	1.85
	Retiree age Baby Boomer and Silent Generation	23.73	1.89	1.80	1.98	1.84	1.76	1.93
Number of messages to coaches	Gen Z and Millennial	16.43	Ref			Ref		
	Gen X	19.35	1.18	1.15	1.21	1.17	1.14	1.19
	Working age Baby Boomer	21.17	1.29	1.26	1.32	1.28	1.24	1.31
	Retiree age Baby Boomer and Silent Generation	20.86	1.27	1.20	1.34	1.26	1.19	1.32

Past research suggests some reasons for the increased digital MSK program use among older generations that we observed. First, age interacts with attitude about digital health technology to influence adoption. In paying more attention to their MSK pain, older generations may be more likely than younger adults to use the digital MSK program (27). Second, members of older generations may have appreciated that the programs enabled them to manage their needs themselves and at home, especially among those with mobility or transportation access challenges (16). Third, older generations may have decided to use this technology because they viewed digital health for MSK as being useful and aligned with their needs and values (28). Fourth, support and interaction with live coaches may have further encouraged engagement and helped members to form an exercise habit (29, 30). Evidence suggests that older adults may respond better than younger adults to exercise counseling and education similar to that offered by the program (31).

The second study objective examined change in clinical outcomes among digital MSK program participants, by generation. We did not detect significant differences in changes in pain when comparing older generations to Gen Zers and Millennials. This is in contrast with previous research showing that the benefits of exercise on pain are often more pronounced among younger adults (32). When viewed in conjunction with program use, we interpret our result as showing that older generations need to do more exercise and read more articles

TABLE 4 | Change in clinical outcomes, by generation.

Outcome	Generation (*n* = people with pre and post scores)	Descriptive		Unadjusted model			Adjusted model		
		Mean	(SD)	Beta	95% CI		Beta	95% CI	
Change in pain score	Gen Z and Millennial (*n* = 4,000)	−27.13	(23.39)	Ref			Ref		
	Gen X (*n* = 6,861)	−28.21	(23.60)	−1.08	−2.00	−0.17	−0.85	−1.77	0.07
	Working age Baby Boomer (*n* = 4,607)	−27.28	(23.39)	−0.15	−1.14	0.84	−0.39	−1.40	0.62
	Retiree age Baby Boomer and Silent Generation (*n* = 739)	−25.60	(23.09)	1.53	−0.29	3.34	0.46	−1.37	2.29
Outcome	**Generation (*n* = number with moderate or severe symptoms at baseline)**	**Percent with change by week 12 (%)**		**Unadjusted model**			**Adjusted model**		
				OR	95% CI		OR	95% CI	
Improvement in moderate or severe anxiety at baseline to 12 weeks	Gen Z and Millennial (*n* = 1,308)	79.28		Ref			Ref		
	Gen X (*n* = 1,603)	81.16		1.13	0.94	1.35	1.17	0.97	1.42
	Working age Baby Boomer (*n* = 714)	87.82		1.88	1.45	2.45	2.05	1.56	2.69
	Retiree age Baby Boomer and Silent Generation (*n* = 81)	91.36		2.76	1.26	6.07	2.71	1.19	6.20
Improvement in moderate or severe depression at baseline to 12 weeks	Gen Z and Millennial (*n* = 967)	78.39		Ref			Ref		
	Gen X (*n* = 1,304)	77.76		0.96	0.79	1.18	1.05	0.85	1.30
	Working age Baby Boomer (*n* = 647)	81.14		1.19	0.92	1.52	1.31	1.01	1.71
	Retiree age Baby Boomer and Silent Generation (*n* = 69)	85.51		1.63	0.82	3.24	1.47	0.72	2.98

to achieve similar changes in pain as younger participants. To better support older adults, future research can examine in greater depth characteristics of older adults (e.g., self-efficacy, environmental factors) who may need to engage more in digital health programs to experience meaningful clinical outcomes.

We also found that older generation was associated with higher odds of anxiety improvement at 12 weeks compared to Gen Zers and Millennials. Previous reviews have shown the effect of 3–12 week exercise programs on improving anxiety, but have found no moderating effect of age (33). The reasons for our program's impact on anxiety among older adults are unclear and warrant additional research. One possibility may be that our program focuses on MSK-related concerns like fall prevention among older adults and addresses anxiety associated with fall-related concerns (34).

Our study participants may not be representative of older adults generally as the study only includes people who opted into a digital MSK program. First, a previous study of a nationally representative sample of older adults found that older adults are less likely to use health information technology vs. younger adults (35). In contrast, our study suggests that older adults who do choose to use a digital MSK program are even more engaged than younger adults. Second, we do not have information about the number eligible for the program or their characteristics. It is not clear how many people were offered the opportunity to participate and if program registration differed by generation. Our program may have included early digital MSK adopters who were more motivated to use or comfortable using technology in daily life. This is in contrast to reports that older adults have less awareness, less trust, lower self-efficacy, and more security and quality concerns about new health technologies (36, 37). Future research can examine self-selection into or out of digital health programs to better tailor programming to later adopters (38). To ensure that digital health programs meet the needs of later adopters, programs should adhere to design best practices that focus on usability and accessibility for older users and persons with disabilities (39).

We examine generational differences in digital MSK program use and outcomes, but generation is a proxy for knowledge, skills, attitudes, and motivations that influence engagement (40). Future research could measure these constructs directly and examine the mediating and moderating effects of age or generation (27).

We use a behavior-based definition of program use that consists of program completion and number of exercises, articles accessed, and coach messages. But these measures may not reflect the "depth" of interaction with the digital MSK program as the measures do not capture affective and cognitive engagement (41). Future research can incorporate broader engagement constructs relevant to older adults and examine the relationship between context, engagement, and behavior change (42).

This study likely omitted important system, predisposing, and enabling factors that influence both program use and health outcomes. For example, the program does not collect

predisposing factors such as education or income or enabling factors such as internet access. Further, this prevents us from comparing our study sample to the general adult population to assess generalizability of findings.

This is an observational study that included consecutive program participants meeting inclusion criteria. The large sample sizes in this study may have resulted in detection of spurious relationships between generation and outcomes. In addition, we cannot establish the program's causal effect on pain improvements. However, the results provide evidence about program applicability in the real world with a wide range of ages.

Findings from our study confirm that older generations actively use a digital MSK program that involves app and sensor-guided exercise, app-based education, and remote health coaches. On average, older generations interact with a digital MSK program more than younger counterparts and may experience similar improvements in health outcomes. A digital MSK program holds promise for the growing population of older adults with chronic MSK pain.

DATA AVAILABILITY STATEMENT

The datasets presented in this article are not readily available because requests for proprietary data will be considered on a case by case basis. Requests to access the datasets should be directed to Grace Wang, grace.wang@hingehealth.com.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by WCG, Western Institutional Review Board (20160949). Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

AUTHOR CONTRIBUTIONS

GW and JK contributed to conception and design of the study. GW organized the data. GW, MY, and JB contributed to the statistical analysis. GW wrote the first draft of the manuscript. All authors contributed to manuscript revisions, read, and approved the submitted version.

SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fdgth.2021.693170/full#supplementary-material

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Conflict of Interest: GW and JK are employed by and have equity interest in Hinge Health, Inc. JB and MY received consulting fees from Hinge Health, Inc.

6.

High-Frequency Impulse Therapy for Treatment of Chronic Back Pain: A Multicenter Randomized Controlled Pilot Study

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CLINICAL TRIAL REPORT

High-Frequency Impulse Therapy for Treatment of Chronic Back Pain: A Multicenter Randomized Controlled Pilot Study

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Purpose: This study aims to examine high-frequency impulse therapy (HFIT) impact on pain and function among patients undergoing care for chronic low back pain (CLBP).

Methods: A pilot randomized-controlled trial of HFIT system versus sham was conducted across 5 orthopedic and pain center sites in California, USA. Thirty-six patients seeking clinical care for CLBP were randomized. Primary outcome was function measured by the Six Minute Walk Test (6MWT). Secondary outcomes were function (Timed Up and Go [TUG] and Oswestry Disability Index [ODI]), pain (Numerical Rating Scale [NRS]), quality of life (Patient Global Impression of Change [PGIC]), and device use. Patients were assessed at baseline and every week for 4 weeks of follow-up. Mann–Whitney *U*-test was used to analyze changes in each outcome. Repeated measures ANOVA was used to assess the effect of treatment over time.

Results: The average age of subjects was 53.9 ± 15.7 (mean ± SD) years, with 12.1 ± 8.8 years of chronic low back pain. Patients who received an HFIT device had a significantly higher 6MWT score at weeks 2 [Cohen's *d* (95% CI): 0.33 (0.02, 0.61)], 3 [0.32 (0.01, 0.59)] and 4 [0.31 (0.01, 0.60)], respectively, as compared to their baseline scores ($p < 0.05$). Patients in the treatment group had significantly lower TUG scores at week 3 [0.30 (0.04, 0.57)] and significantly lower NRS scores at weeks 2 [0.34 (0.02, 0.58)] and 4 [0.41 (0.10, 0.67)] ($p < 0.05$).

Conclusion: A larger-scale RCT can build on the findings of this study to test whether HFIT is effective in reducing pain and improving function in CLBP patients. This study shows encouraging evidence of functional improvement and reduction in pain in subjects who used HFIT. The efficacy and minimally invasive nature of HFIT is anticipated to substantially improve the management of CLBP patients.

Keywords: HFIT, pain, chronic pain, neuromodulation, noninvasive treatment

Introduction

Chronic low back pain (CLBP) poses significant morbidity for patients, affecting over 76 million people in the United States with total costs related to low back pain (LBP) exceeding $100 billion per year.[1] Existing pharmaceutical treatments, such as opioids, can be effective solutions to CBLP, but tend to cause side effects, including sedation, nausea, constipation and respiratory depression.[2] Approximately 51% of patients who live with back pain are unable to tolerate pharmacological pain treatments due to such side effects.[3] Exercise therapy is a commonly used and moderately effective approach for managing CLBP;[4] however, it may take several weeks to experience pain relief. Newer treatments in neuromodulation for refractory CLBP include novel devices in spinal cord and

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peripheral nerve stimulation.[5] While these technologies have improved options for pain control, they require surgical implantation, which increases risks to patients and costs to payors. As a result, there continues to be a great need for an effective, drug-free, non-implanted treatment for CLBP.

Transcutaneous electrical nerve stimulation (TENS) is a form of electrical stimulation therapy used by pain physicians and physiotherapists to treat both chronic and acute forms of musculoskeletal pain. Studies have determined that while TENS can be effective for temporary treatment of musculoskeletal pain, it has not been demonstrated to be effective for long-term treatment of chronic musculoskeletal pain.[6] A significant limitation for TENS is the ability to deliver adequate and precise electrical fields through the skin, which acts as a resistor.[7] Methods to overcome the capacitance of the skin structures include higher energy delivery (increased current or intensity) or higher voltage in order to charge the skin structures, such that subsequent field charges may pass through the skin. Studies have demonstrated that high-frequency forms of electrical stimulation (10 kHz and greater frequencies) are effective for the treatment of chronic and acute pain and are thought to be due to the different mechanism of action of high-frequency neuromodulation.[8–10] The ultra-high frequency system, known as high-frequency impulse therapy (HFIT), involves using specific waveforms in the 30–150 kHz range to both overcome the resistance of the skin and to deliver a higher frequency than TENS. Studies have also demonstrated that high frequency electrical stimulation can affect the firing of action potentials.[11]

This study describes a pilot study using an HFIT device (Enso, San Francisco, CA) in order to evaluate the impact on pain reduction and increase in function among patients with CLBP. We hypothesize that the cohort randomized to use the HFIT device will have a clinically significant increase in function and a clinically significant decrease in back pain compared to the sham group. This study also aims to examine patient use of the HFIT device versus the sham device.

Methods

Study Design

This is a pilot, double-blind, placebo-controlled randomized trial, designed to assess functional and pain outcomes of utilizing an HFIT device in subjects with CLBP due to mechanical back pain, degenerative disc disease, degenerative arthritis or disc compression. Patient recruitment and in-person data collection were performed at 5 clinical sites (orthopedic and pain centers) in California, USA. Patients were evaluated at baseline and then with weekly follow-up visits for 4 weeks. The preliminary, interim 4-week results from the first 36 patients enrolled in this protocol are presented here. The study was registered on ClinicalTrials.gov, (Identifier NCT03320863), approved by the institutional review boards of University of California San Francisco (UCSF) and conducted in accordance with the Declaration of Helsinki.

Participants

Subjects were evaluated, consented and enrolled based on the protocol's inclusion and exclusion criterion. Key inclusion criteria were (1) Mechanical or non-specific axial back pain, as diagnosed by a board-certified physician; (2) Baseline pain of ≥ 6.0 out of 10.0 on the Numerical Rating Scale (NRS); (3) Functional debilitation by pain (e.g. difficulty walking); (4) Minimal radicular symptoms with no effect on functionality, medication or quality of life; (5) Expressing disability ≥ 80% due to LBP (based on Likert scale); and (6) Experiencing chronic pain for ≥ 6 months. Key exclusion criteria included (1) Not owning or having access to a smartphone; (2) Spinal instability, joint instability, or ≥ grade 2 spondylolisthesis with instability; (3) Primary symptoms due to spinal stenosis; (4) Diagnosis of cancer or malignant tumors in the last 5 years and (5) Undergoing surgery to solve pain related to study indication in the past 6 months.

The treatment group was given an HFIT device (Figure 1) and instructed to use the device for one hour or more daily. The control group was provided with a sham HFIT device that displayed LED light animations in order to simulate treatment (without delivering electrical pulses) and instructed to use the device for one hour or more daily. In both groups, patients applied the device themselves and controlled treatment durations and intensities through a smartphone app. The app included a HIPAA compliant chat feature that allowed subjects to ask questions and resolve technical issues (e.g. pad use or placement). A study coordinator also contacted participants in both groups three times per week to provide support and answer questions.

Randomization

Clinicians at participating clinical sites determined eligibility during the patients' appointments and described the study. Research coordinators at the clinical sites then

Figure 1 HFIT Device.
Notes: HFIT device (left), HFIT device worn on model (right).
Abbreviation: HFIT, high-frequency impulse therapy.

conducted the informed consent process. Subjects were randomized 1:1 to receive either an HFIT device or a sham HFIT device to supplement their existing pain regiment. Allocation concealment was ensured using the sequentially numbered opaque sealed envelopes (SNOSE) method. Participants, investigators and staff interacting with patients were all blinded to subject assignments and did not have access to information regarding which patients received a functional device and which patients received a sham device. Participants were told that depending on the treatment they received, the device may or may not provide a sensation. Study site coordinators explained it was possible to deliver high frequency electrical energy across the skin without sensation.

On weeks 1, 2, 3 and 4, patients were prompted by a smartphone app to fill out questionnaires concerning functionality and quality of life. Patients also visited the clinic again to perform follow-up testing for functionality through the Six Minute Walking Test (6MWT) and Timed Up and Go Test (TUG) at weeks 1, 2, 3 and 4. After the 4-week visit, participants were informed of group assignment.

Outcomes

The primary outcome of the study was 6MWT, utilized to assess functional mobility. 6MWT measures the distance walked (in meters) within 6 minutes, with higher values indicating better outcomes. Secondary outcomes measuring functional mobility included the TUG test, which measures the time it takes (in seconds) to stand, walk 3 meters and return to a seated position, as well as the Oswestry Disability Index (ODI), which ranges from 0 ("no disability") to 50 ("most disability").

The Numerical Rating Scale (NRS) was used to evaluate pain, where scores ranged from 0 ("no pain") to 10 ("worst pain imaginable"). The Patient Global Impression of Change (PGIC) was used to measure the patient's belief about the efficacy of treatment, which ranged from 1 ("no change") to 7 ("a great deal better"). In order to evaluate whether subjects in one group used their device more frequently than another group, device utilization was also measured through the app (in hours per week).

All outcome measures were assessed at predefined study visits (baseline, 1, 2, 3, and 4 weeks). Functionality tests were administered by a clinician at a clinical site. Patient-reported outcome measures were recorded through self-administered questionnaires completed by patients. Data was collected through daily surveys and weekly questionnaires via a smartphone app.

Statistical Analysis

Because this was a pilot study, formal sample size calculations were not conducted. However, to ensure a reliable estimate in powering a future full-scale study with 90% statistical power, a minimum of 15 participants per treatment arm is recommended if a moderate effect size between 0.3 and 0.7 is expected.[12] To ensure the validity of pilot studies, 15 to 20 participants per treatment arm are typically required.[13] The present study enrolled a total of 36 participants. The results of this pilot study will be used to provide the necessary parameters for a future larger trial.

Baseline demographic and clinical characteristics were presented as proportions or as means with standard

deviations. To assess improvement, the Mann–Whitney *U*-test was used to compare whether changes in scores from baseline to 4 weeks in the treatment group were greater than the control group, where a one-sided $p < 0.05$ was considered statistically significant. Effect sizes (Cohen's *d*) were estimated to show the magnitude of the experimental effect. 95% confidence intervals (CI) around effect size were estimated by bootstrap (using 1000 replications). Longitudinal results were assessed using two-way mixed analysis of variance (ANOVA). Bonferroni correction was used to correct for multiple comparisons. Complete case analysis was used. Analyses were performed using R version 4.0.5 (R Core Team, Vienna, Austria).

Results

Population Characteristics

From April 2017 to September 2018, patients were enrolled and assessed for eligibility with 36 subjects proceeding through baseline evaluations and randomized (17 HFIT therapy, 19 sham; Figure 2). The average age of all randomized subjects was 53.9 ± 15.7 (mean ± SD) years and the average length of chronic back pain was 12.1 ± 8.8 years. The average baseline 6MWT, TUG, NRS pain, and ODI scores were 348 ± 78.7 meters, 12.9 ± 2.4 seconds, 7.5 ± 0.9, and 42.1 ± 13.8, respectively. Baseline characteristics for the two groups are shown in Table 1.

Outcomes

Function

The study examined patient function over time. Patients who were randomized to HFIT had a significantly greater improvement in 6MWT (primary outcome) than subjects who received the sham device at Week 2 (61.46 ± 48.22 vs 21.60 ± 55.53 meters, p = 0.024) [Cohen's d (95% CI): 0.33 (0.02, 0.61)], Week 3 (71.07 ± 44.50 vs 42.13 ± 59.14 meters, p = 0.030) [0.32 (0.01, 0.59)] and Week 4 (89.57 ± 54.36 vs 55.53 ± 66.53 meters, p = 0.035) [0.31 (0.01, 0.60)], compared to their baseline scores (Table 2).

Additionally, subjects who received the HFIT device also had a significantly greater improvement in TUG than subjects who received the sham device at Week 3 (−4.07 ± 2.40 vs −2.45 ± 1.94 seconds, p = 0.039) [0.30 (0.04, 0.57)]. No significant differences were found between the ODI scores of the groups.

Pain

When examining pain, we found a significantly greater improvement in NRS pain scores in patients who received the HFIT device at Week 2 (−3.83 ± 1.99 vs −2.00 ± 2.30,

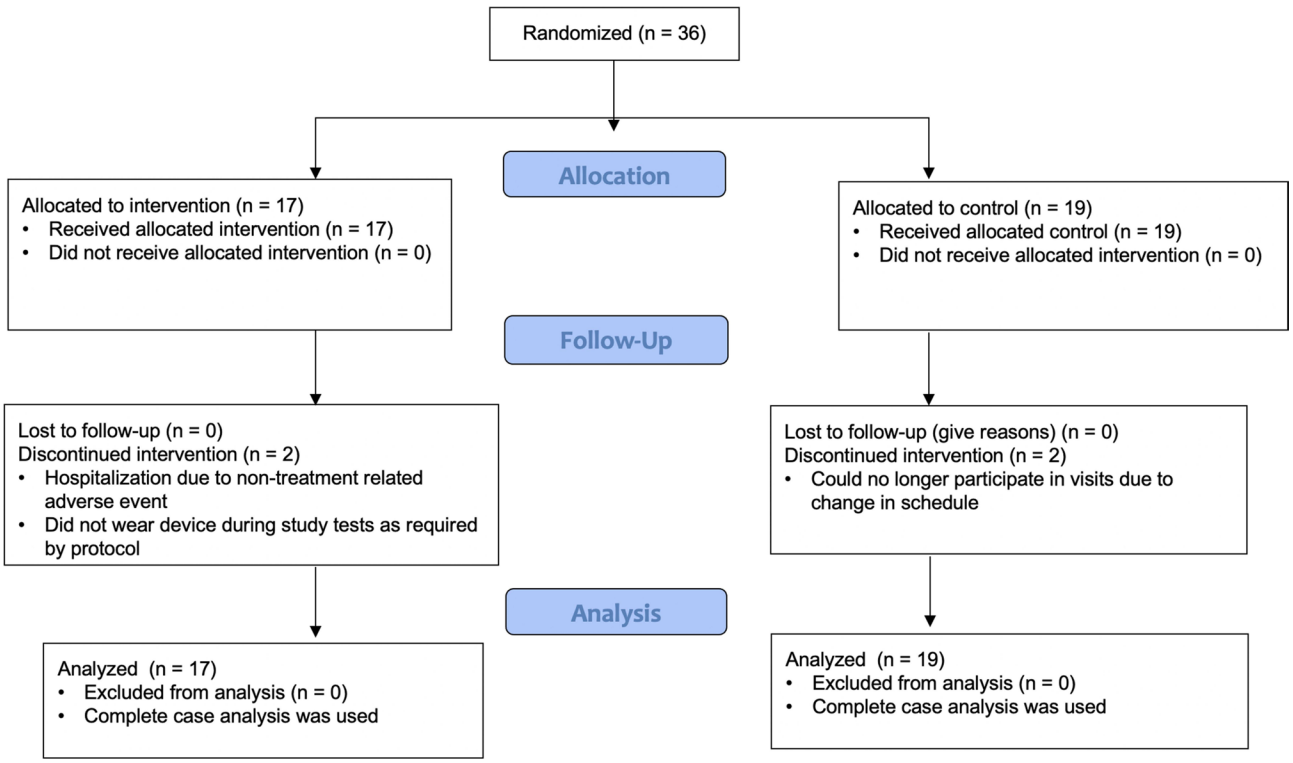

Figure 2 Flowchart.

Table 1 Baseline Characteristics

	Treatment (N=17)	Control (N=19)	Total (N=36)
Age (years)			
Mean ± SD	54.0 ± 15.7	53.9 ± 16.2	53.9 ± 15.7
Min – Max	30.0–75.0	26.0–80.0	26.0–80.0
Sex – freq (%)			
Male	3 (17.6%)	6 (31.6%)	9 (25.0%)
Female	13 (76.5%)	13 (68.4%)	26 (72.2%)
Race – freq (%)			
White	13 (76.5%)	18 (94.7%)	31 (86.1%)
Non-white	4 (23.5%)	1 (5.3%)	5 (13.9%)
Weight (lbs)			
Mean ± SD	186 ± 59.5	182 ± 39.0	184 ± 49.1
Length of pain (years)			
Mean ± SD	12.2 ± 6.72	12.1 ± 10.0	12.1 ± 8.80
6MWT (meters)			
Mean ± SD	337 ± 93.9	358 ± 63.1	348 ± 78.7
TUG (seconds)			
Mean ± SD	13.2 ± 2.9	12.5 ± 1.8	12.9 ± 2.4
NRS Pain			
Mean ± SD	7.5 ± 0.8	7.5 ± 1.0	7.5 ± 0.9
ODI			
Mean ± SD	40.9 ± 10.2	43.1 ± 16.5	42.1 ± 13.8
PGIC			
Mean ± SD	4.3 ± 0.8	4.2 ± 0.6	4.2 ± 0.7

Abbreviations: SD, standard deviation; 6MWT, Six Minute Walk Test; TUG, Timed Up and Go; NRS, Numerical Rating Scale; ODI, Oswestry Disability Index.

p = 0.023) [0.34 (0.02, 0.58)] and Week 4 (−4.21 ± 2.49 vs −1.88 ± 2.22, p = 0.007) [0.41 (0.10, 0.67)].

Beliefs and Device Usage

The study also examined beliefs about treatment efficacy and how often devices were used each week. We found that patients assigned to the HFIT device reported a significantly greater improvement in PGIC than subjects who received the sham device at Week 1 (0.93 ± 0.80 vs 0.29 ± 0.59, p = 0.006) [0.43 (0.12, 0.71)] and Week 4 (1.17 ± 0.94 vs 0.20 ± 1.47, p = 0.022) [0.34 (0.04, 0.62)], compared to their baseline scores.

Furthermore, we also found that subjects who were provided with a HFIT device used their device significantly more often than subjects who had received a sham device (26.00 ± 18.86 vs 19.98 ± 20.90 hours per week, p = 0.010).

In two-way mixed ANOVA for repeated measures, there was not enough evidence to show a statistically significant two-way interaction between treatment and time for the outcomes of interest. There was a significant main effect of time on 6MWT [F(2.59, 28.5) = 21.6, p < 0.001], TUG [F (1.74, 19.1) = 27.1, p < 0.001], NRS pain [F(2.72, 27.2) = 9.50, p < 0.001], ODI [F(2.09, 25.1) = 6.74, p < 0.05], and PGIC [F(2.11, 29.6) = 1.19, p < 0.001], demonstrating that the mean outcome scores after the HFIT treatment were significantly better than the mean outcome scores before the treatment.

Discussion

To date, this is the first pilot RCT study to utilize ultra-high frequency transcutaneous stimulation for the treatment of CLBP. Exploratory analyses showed improved function, pain and device usage outcomes in the HFIT active arm compared to the sham arm as a trend over time (Figure 3). Results indicate a statistical improvement in functional outcomes 6MWT and TUG over time, but not in ODI. Although all are functional outcomes, 6MWT and

Table 2 Assessment of Outcomes Over Time

Measure	Timepoint	Effect Size (95% CI)	p-value
6MWT	Day 1 After	0.03 (−0.30, 0.30)	p = 0.4370
	Week 1	0.21 (−0.11, 0.51)	p = 0.1036
	Week 2	0.33 (0.02, 0.61)	p = 0.0238*
	Week 3	0.32 (0.01, 0.59)	p = 0.0302*
	Week 4	0.31 (0.01, 0.60)	p = 0.0350*
TUG	Day 1 After	0.18 (0.15, 0.48)	p = 0.1479
	Week 1	0.28 (0.05, 0.56)	p = 0.0506
	Week 2	0.23 (0.11, 0.54)	p = 0.0908
	Week 3	0.30 (0.04, 0.57)	p = 0.0393*
	Week 4	0.22 (0.12, 0.49)	p = 0.1024
NRS Pain	Day 1 Before	0.003 (−0.32, 0.33)	p = 0.5129
	Day 1 After	0.22 (−0.53, 0.12)	p = 0.0971
	Week 1	0.26 (−0.52, 0.08)	p = 0.0635
	Week 2	0.34 (0.02, 0.58)	p = 0.0227*
	Week 3	0.11 (0.25, 0.47)	p = 0.2524
	Week 4	0.41 (0.10, 0.67)	p = 0.0071*
ODI	Week 1	0.12 (−0.22, 0.44)	p = 0.7607
	Week 2	0.02 (−0.36, 0.32)	p = 0.4623
	Week 3	0.09 (−0.26, 0.39)	p = 0.7016
	Week 4	0.22 (0.11, 0.49)	p = 0.1011
PGIC	Week 1	0.43 (0.12, 0.71)	p = 0.0057*
	Week 2	0.26 (−0.06, 0.55)	p = 0.0591
	Week 3	0.19 (−0.12, 0.49)	p = 0.1302
	Week 4	0.34 (0.04, 0.62)	p = 0.0223*

Notes: Mann–Whitney *U*-test of timepoint versus first timepoint. *p<0.05; Cohen's metric for effect sizes: 0.2 - small, 0.5 - medium, 0.8 – large.

Abbreviations: 6MWT, Six Minute Walk Test; TUG, Timed Up and Go; NRS, Numerical Rating Scale; ODI, Oswestry Disability Index; PGIC, Patient Global Impression of Change.

TUG are assessed by a clinician, whereas ODI is assessed by the patient. Additionally, the ODI questionnaire focuses on activities of daily living rather than a timed test, which may result in differences in improvement. Patients may experience relief in different outcomes at different times, which is in line with other neuromodulation studies in that it often takes six months or longer to feel relief.[14,15] Overall, results support the possibility of testing whether there is robust improvement in function and pain with HFIT treatment in a full-scale randomized controlled trial.

Although studies have shown that opioids can be effective in pain reduction, individual adverse events, such as nausea, vomiting, dizziness and constipation are more frequent in opioid users.[16] In a meta-analysis of 22 randomized and quasi-randomized controlled trials that compared oral or transdermal opioids with no treatment in patients with hip or knee osteoarthritis, there was a difference in improvement of 12% between opioids and placebo, but patients receiving opioids had 3.76 times the risk of dropping out due to adverse events compared with patients who were not.[17] Results from controlled clinical trials show approximately 50–70% of patients with chronic non-cancer pain fail opioid therapy and those who do respond report mild or moderate reduction in pain for a short term.[18] When intermittently prescribed, opioids provide a very low-grade certainty of evidence when it comes to evaluating meaningful responses to treatment. Furthermore, opioids also come with the risk of addiction, misuse and overdose.

In comparison with TENS devices, HFIT also shows promising results. Although TENS has been widely used for over 30 years as a therapeutic complement to pain management, there is conflicting evidence in showing its effectiveness for CLBP. In a qualitative synthesis study,[6] results from four placebo-controlled randomized controlled trials failed to consistently demonstrate whether TENS was beneficial in improving CLBP. Furthermore, a meta-analysis of twelve randomized TENS studies in treating CLBP suggested that TENS may offer short-term improvement of functional disability, but did not show improvement of LBP.[19] Exercise therapy has been shown to provide a clinically meaningful reduction in pain and has also been one of the only interventions that demonstrates sustained improvement and relief.[16] Because of the evidence behind the success of conservative therapies such as exercise, HFIT should not be a substitute for exercise therapy, but can instead be used to supplement and support such approaches. As a complement to exercise therapy, HFIT can work in conjunction by producing short-term pain relief which may allow patients to exercise more comfortably and minimize post-exercise pain. By using both therapies together, patients may be able to work towards achieving both short-term and long-term pain relief.

There are several inherent advantages to HFIT therapy. The therapy can be continued or discontinued quickly and does not require surgical intervention. Moreover, HFIT provides patients with a solution that does not limit function and physical therapy protocols, whereas treatments such as opioids can cause drowsiness and reduce overall function. Not only does HFIT avoid the potential adverse side effects, but it also provides local pain relief (without affecting any other parts of the body) that is both non-drug based and non-invasive.

Results from this study also demonstrated that device utilization was significantly higher in the active group throughout the course of the study, suggesting not only patients did experience a difference in pain relief when

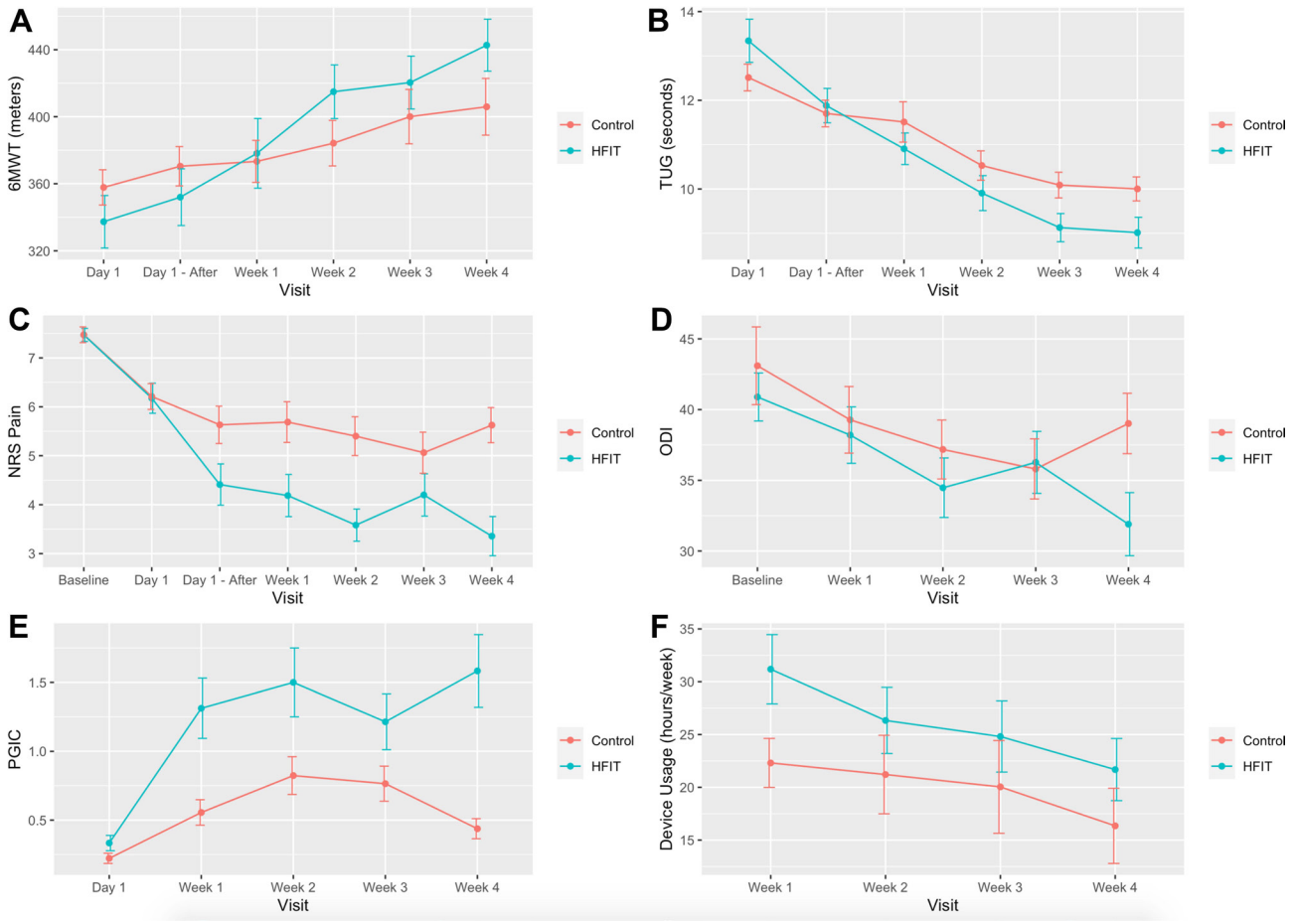

Figure 3 Longitudinal mean scores for outcomes.
Notes: (**A**) 6MWT, (**B**) TUG, (**C**) NRS Pain, (**D**) ODI, (**E**) PGIC, (**F**) Device Usage; Error bars show standard errors.
Abbreviations: 6MWT, Six Minute Walk Test; TUG, Timed Up and Go; NRS, Numerical Rating Scale; ODI, Oswestry Disability Index; PGIC, Patient Global Impression of Change.

using the HFIT therapy device but over time they preferred to continue using the device more regularly. While TENS units usually require direct adjustment of the hardware to modify the electrical stimulation parameters, the HFIT system is able to be modified using a communicating smartphone system. As a result, software adjustments may be performed remotely, which is distinct from current common TENS systems.

Strengths of this study include the study design, a multicenter double-blinded, sham-controlled randomized clinical trial. Strict methods were followed to assess the feasibility of conducting a full-scale trial. Multiple outcomes measuring function and pain were recorded. However, limitations of this study need to be acknowledged. Although the results presented support HFIT therapy as a viable treatment for chronic back pain, the data is from a pilot study with short-term follow-up results at 4 weeks and a full randomized controlled trial is required for more generalizable results. This pilot study adhered to strict inclusion and exclusion criteria, but enrollment and assessment numbers will be documented in future studies. This study also allowed for full patient control of their HFIT utilization. It is possible that users would expect a sensation from the HFIT device, even though they were informed they should not.

This pilot study shows encouraging early improvement in pain and functional assessments as well as increased utilization; however, future research using this pilot data is needed to advance HFIT as a mainstream treatment for CLBP. The results of this pilot study support conducting a larger, longer-term randomized controlled trial in order to evaluate sustained pain relief, improvement in function and reduction in analgesic use. Future studies will also develop protocols for use and location for treatment for various pain syndromes and other indications.

Conclusion

This pilot study is the first evaluation of HFIT therapy for CLBP in a sham controlled, randomized manner. Patients who were randomized to use the HFIT device showed significant improvements in both functional and pain outcomes throughout the weeks of follow-up. Based on the results of this pilot trial, a larger-scale RCT is feasible and can build on the findings of this study to test whether HFIT is effective in reducing pain and improving function in CLBP patients. The efficacy, minimally invasive nature and ease of use of HFIT offer patients an alternative solution to pharmaceutical treatments and is anticipated to substantially improve the management of CLBP patients.

Data Sharing Statement

De-identified data are available upon request from the corresponding author.

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Disclosure

Drs. Kasra Amirdelfan, Surekha Reddy, Vinay Reddy, Michael Yang and Amitabh Gulati received personal consulting fees from Thimble Bioelectronics Inc. Dr. Kasra Amirdelfan reports personal fees and/or advisory board from Nevro Inc, Medtronic, Boston Scientific, Saluda, Biotronik, Nalu, Presidio, Vivex, Mesoblast, and PainTEQ. Dr. Mindy Hong is employed at Hinge Health and received salary and nominal equity compensation. Dr. Bobby Tay reports personal fees for consulting from Biomet/Zimmer, Lumetra, Stryker, and DePuy Synthes Spine and institutional fellowship grants from OMEGA and NuVasive, outside the submitted work. Dr. Prasad Shirvalkar reports non-financial support from Abbott Neuromodulation, Nevro Inc, and Saluda Medical, outside the submitted work. In addition, Dr. Prasad Shirvalkar has a patent spinal cord stimulation methods pending. Dr. Amitabh Gulati is on the clinical advisory board of Hinge Health with nominal equity compensation. Dr. Amitabh Gulati also reports personal fees for consulting and/or advisory board from SPR Therapeutics, Nalu Medical, Medtronic Inc, AIS HealthCare, Tremeau Pharmaceuticals, and Flowonix, during the conduct of the study. The authors report no other potential conflicts of interest in this work.

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Clinical outcomes one year after a digital musculoskeletal (MSK) program: an observational, longitudinal study with nonparticipant comparison group

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RESEARCH ARTICLE

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Clinical outcomes one year after a digital musculoskeletal (MSK) program: an observational, longitudinal study with nonparticipant comparison group

Grace Wang[1*], Manshu Yang[2], Mindy Hong[1], Jeffrey Krauss[1] and Jeannie F. Bailey[3]

Abstract

Background: The evidence base for the impact of digital health on musculoskeletal (MSK) outcomes is growing, but it is unclear how much digital MSK programs address pain and function in the intermediate and long term.

Methods: This observational study of digital MSK program participants versus nonparticipants ($n = 2570$) examined pain, function, depression, and anxiety at 3, 6, and 12 months, and health care use at 12 months. The intervention group engaged in a digital MSK program that included exercise, education, and coaching for at least 3 months. The nonparticipant group registered, but never started the program. We collected data in app or by emailed survey at 3, 6, and 12 months after registering for the program. We conducted descriptive analyses and unadjusted and adjusted regression modeling.

Results: The odds ratio of achieving a minimally clinically important difference (MCID) in pain improvement for the intervention versus the nonparticipant group was 1.97 (95% CI: 1.28, 3.02; $p = .002$) at 3 months, 1.44 (95% CI: 0.91, 2.25; $p = .11$) at 6 months, and 2.06 (95% CI: 1.38, 3.08; $p = .004$) at 12 months in adjusted models. The odds ratio of achieving a MCID in functional improvement for the intervention versus the nonparticipant group was 1.56 (95% CI: 1.03, 2.38; $p = .01$) at 3 months, 1.55 (95% CI: 1.02, 2.37; $p = .04$) at 6 months, and 1.35 (95% CI: 0.89, 2.06, $p = 0.16$) at 12 months in adjusted models. For those with moderate to severe depression or anxiety at baseline, we observed statistically significant lower odds of moderate to severe depression or anxiety at 3 months, 6 months, and 12 months for the intervention versus the nonparticipant group in adjusted models ($p < .05$). At 12 months, the percentage with invasive, imaging, and conservative services was higher for the nonparticipant versus intervention group by 5.7, 8.1, and 16.7 percentage points, respectively ($p < 0.05$).

Conclusions: A digital MSK program may offer participants sustained improvement in pain, depression, and anxiety with concomitant decreases in health care use.

Keywords: Telemedicine, Musculoskeletal pain, Function, Depression, Anxiety

Background

Chronic musculoskeletal (MSK) pain is a leading cause of disability and health care cost in the United States. Rates of osteoarthritis, back and neck pain, and other MSK disorders in the United States are among the highest in

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the world, with 134.5 million adults in the United States reporting MSK conditions in 2018 [1, 2].

Chronic MSK pain lasts or recurs for more than 3 months and may fluctuate in intensity over time [3]. Pain may be an aching and throbbing sensation in the background; or, pain may be intermittent, sharp, and stabbing [4]. Chronic MSK pain may hinder activities of daily living, including walking, getting up from sitting, opening a jar, or reaching overhead. Furthermore, chronic MSK pain often occurs with and exacerbates depression and anxiety [5]. Depression and anxiety can also influence pain severity and duration [6–9].

To improve MSK function, and reduce pain and associated comorbidities, evidence-based clinical guidelines typically recommend conservative therapies before invasive treatments [10]. First line, conservative therapies include exercise and education because of their safety and impact on outcomes [4, 11–14]. For example, a meta-analysis of 3514 trial participants found that exercise reduced lower back pain an average of 10.7 points out of 100 and reduced functional limitations by 10.2 points out of 100 versus control groups [11]. Studies have also demonstrated the effectiveness of pain neuroscience education with exercise on significantly decreasing pain, disability, kinesiophobia, and pain catastrophizing among persons with chronic MSK pain [13].

Digital health approaches are now used to deliver conservative therapies via interactive tools. These approaches may help to facilitate care access because of the convenience of digital health (e.g., members can access services at all hours and locations and during periods with severe pain symptoms) [15]. In addition, participants of digital health programs have seen significant improvements in knee and back pain [16, 17]. For example, Du et al's systematic review found moderate-quality evidence that digital MSK programs resulted in statistically significant back pain improvements at immediate and short-term follow-ups and functional improvement at immediate follow-ups when compared to waiting-list, usual care, or active controls (e.g., health education) [17].

Although the evidence base for the impact of digital health on MSK outcomes is growing, previous research is limited in the following ways. It is still unclear how much digital MSK programs address pain and function in the intermediate and long term. The impact on depression and anxiety is not yet well established. Many previous digital MSK program evaluations are small randomized controlled trials with high internal validity, but questions remain about how engagement in real world settings affects program outcomes. Finally, researchers have not examined how participation in digital MSK programs influences use of traditional, in-person health care services.

To address these gaps, our study focused on three objectives. The primary objective was to examine pain improvement at 3, 6, and 12 months for digital MSK program participants versus nonparticipants. The secondary objective was to examine functional and mental health outcomes at 3, 6, and 12 months for digital MSK program participants versus nonparticipants. For both these objectives, we hypothesized that digital MSK program participants would have better outcomes versus nonparticipants at 3, 6, and 12 months. Finally, we explored self-reported health care use for digital MSK program participants versus nonparticipants at 12 months. Results from this study provide evidence about whether a digital MSK program offers participants sustained improvement in pain, function, and mental health with concomitant decreases in health care use.

Methods

Study design

We conducted an observational, longitudinal cohort study design comparing digital MSK program participants versus nonparticipants.

Digital MSK program description

Employers offered the digital MSK program to employees and dependents as a health or wellness benefit. Recruitment was conducted through email, workplace posters or presentations, and mailings. Registration involved creating a member profile and completing a baseline application online. After registering, participants had access to the program for 1 year. They could renew after 1 year if their employer continued to offer the program as a health benefit.

The digital MSK program's goal was to help participants manage chronic MSK pain by offering exercise therapy, education, and personal health coaching. Materials provided to registrants included tablet computers with a program app and wearable motion sensors (InvenSense MPU-6050, TDK Electronics, Tokyo, Japan).

The program delivered exercise therapy and education through "playlists" accessed in the app. Each playlist presented three to five exercises that were specific to back, knee, shoulder, hip, or neck pain. The curriculum included more than 60 distinct stretching, strengthening, balance and mobility exercises. Each playlist included stretching, strengthening, balance and mobility activities. The playlist presented 1 to 2 sets of 3 to 10 repetitions depending on the difficulty and type of exercise, and we recommended completing playlists at least 3 times per week. Animations and videos within the app demonstrated how to perform exercises, the number of repetitions, and how long to hold positions. By pairing with the sensors, the app displayed body position during exercises

in real-time and provided feedback about the appropriate range of movement. As participants progressed through the program, the playlists presented more challenging exercises and/or added more repetitions. Progression was individualized based on how often a member engaged and completed an exercise playlist. For example, the app introduced new playlists after the member completed an earlier playlist three times.

After the exercises, the playlist delivered educational resources about MSK pain-related topics, such as pain neuroscience, movement, treatment options, coping, lifestyle changes, relaxation, social support, and habit creation. Each playlist was designed to take less than 15 min, and health coaches (described next) actively encouraged participants to complete at least three playlists per week for the first 3 months. Our program retains between 67 to 83% of members through month 3 depending on age group, with members of different age groups averaging 26 to 45 exercise sessions through month 3 [18]. Participants then had access to the program for the remainder of the year with decreased coaching. As a wholly virtual program, participants could choose when and where to complete playlists.

In addition to exercise and education, the digital MSK program provided personal support to adhere to the program. Each participant was matched to a personal, certified health coach. Coaches initiated contact with participants via text message and communicated with members asynchronously over time via text message, email, or in-app messaging. In addition, participants could schedule up to three phone calls with health coaches. The coach acted as a supportive accountability partner to help participants build an exercise habit. Coaches worked with participants to set goals, identify challenges to performing exercises, and implement strategies to overcome challenges. Coaches also answered questions about the technology, playlists, and educational resources. Coaches provided support for the duration of a participant's engagement with the program. The intervention group members in the sample sent a total of 88,565 messages to coaches by month 3, averaging 22 messages per person. This is consistent with our previous reports [18]. Members could also take part in virtual discussion forums with 20 to 30 others.

Study participants

Study participants met the following criteria: created an account; provided informed research consent; age 18 or older; pain in the low back, knee, shoulder, hip, or neck; baseline visual analog scale (VAS) pain score greater than 0; pain lasted for at least 12 weeks; and member covered by employer's health plan. Exclusion criteria were signs of fracture, joint instability, infection, cancer, and cauda equina syndrome. We used the information provided in the baseline application to determine whether participants met these criteria. We did not require formal diagnoses from medical providers.

At the time of program registration, we provided an information sheet about the program and our research. Only participants who acknowledged reviewing the information sheet and agreed to the research provisions were included in this study. The study (reference number #20160949) was reviewed and approved by WIRB-Copernicus Group® Institutional Review Board (OHRP/FDA IRB registration number IRB00000533) at WIRB-Copernicus Group® (1019 39th Avenue SE Suite 120, Puyallup, Washington 98,374–2115). Study subjects acknowledged online that they provided informed consent before study inclusion. The ethics committee approved the waiver of written documentation of informed consent because the program is entirely digital.

This study was designed to include multiple follow-up time points with all final data collection occurring in quarter (Q) 2–2021. Thus, we retrospectively identified three separate cohorts. Cohort 1 registered in Q2–2020, Cohort 2 registered in Q4–2020, and Cohort 3 registered in Q1–2021. Within each of these cohorts, nonparticipants registered for the program but did not complete any exercise therapy sessions and did not access any educational articles. The intervention group completed exercise therapy sessions or accessed educational articles through month 3 (completer subgroup) or completed exercise therapy sessions or accessed educational articles in months 3 to 6 (long term subgroup).

To sample, we stratified on body region (back, knee, shoulder, hip, neck), cohort (cohort 1, cohort 2, cohort 3), and group (nonparticipants, completer, long term). Then we randomly sampled $n = 114$ per region-cohort-group. After excluding individuals who did not provide informed consent, Cohorts 1 included $n = n = 570$ nonparticipants and $n = 1140$ digital MSK program participants. Cohort 2 included $n = n = 535$ nonparticipants and $n = 1057$ digital MSK program participants. Cohort 3 included $n = 545$ nonparticipants and $n = 523$ digital MSK program participants.

Table 1 shows each cohort's progression from registration through final data collection. For example, Cohort 1 registered for the program in Q2–2020 and completed 3, 6, and 12 month data collection in app in Q3–2020, Q4–2020, and Q2–2021, respectively. In Q2–2021, we also emailed surveys to all nonparticipants and intervention group members who did not enter 12-month follow-up data in app.

Table 1 Cohort activities over time

	Q2_2020	Q3_2020	Q4_2020	Q1_2021	Q2_2021
Cohort 1	Registers; intervention group completes program	Completes 3 month follow-up in app	Completes 6 month follow-up in app		Completes 12 month follow-up in app or email survey
Cohort 2			Registers; intervention group completes program	Completes 3 month follow-up in app	Completes 6 month follow-up in app or email survey
Cohort 3				Registers; intervention group completes program	Completes 3 month follow-up in app or email survey

Variables

The following section describes outcomes, exposures, and covariates.

Outcomes

The primary outcome was achieving a minimally clinical important difference (MCID) in pain improvement (no/yes). To create this dichotomous variable, we gathered baseline and follow-up responses to the question "Over the past 24 hours, how bad was your [back/knee/shoulder/hip/neck] pain?" from 0 (none) to 100 (worst imaginable). Next, we calculated the change from baseline to follow-up. A person achieved MCID in pain improvement if they showed at least a 20 point decrease or 30% improvement [19].

We included three secondary outcomes. One secondary outcome was achieving a MCID in functional improvement (no/yes). To create this dichotomous variable, we gathered baseline and follow-up responses to the 11-item Roland Morris Disability Questionnaire (RMDQ-11, back only), Knee injury and Osteoarthritis Outcome Score Physical Function Short form (KOOS-PS, knee only), Hip Disability and Osteoarthritis Outcome Score Physical Function Short form (HOOS-PS, hip only), Shoulder Pain and Disability Index (SPADI, shoulder only), Neck Pain and Disability Scale short form (sf-NPAD, neck only). Next, we calculated the change from baseline to follow-up. A person achieved MCID in functional improvement if they showed at least: 30% improvement on the RMDQ-11 [20, 21]; or 8 point improvement on the KOOS-PS [22–24]; or 9.3 point improvement on the HOOS-PS [25, 26]; or 13 point improvement on the SPADI [27–29]; or 12 point improvement on the sf-NPAD [30, 31]; or no limitations at follow-up.

Another secondary outcome was moderate or severe depression at follow-up (no/yes). To create this dichotomous variable, we first gathered baseline and follow-up responses to the Patient Health Questionnaire 2-item scale (PHQ-2). Those who screened positive (i.e., score of 3 or higher) on the PHQ-2 received the PHQ 8-item scale (PHQ-8). Moderate or severe depression was a score of 10 or higher on the PHQ-8. The last secondary outcome was moderate or severe anxiety (no/yes). To create this dichotomous variable, we first gathered baseline and follow-up responses to the Generalized Anxiety Disorder 2-item scale (GAD-2). Those who screened positive (i.e., score of 3 or higher) on the GAD-2 received the GAD 7-item scale (GAD-7). Moderate or severe anxiety was a score of 10 or higher on the GAD-7. Cutoffs at 10 points have been shown to have acceptable performance for identifying anxiety and depression [32–34].

We explored health care utilization among emailed survey respondents at 12 months. We asked: Since signing up for [the digital MSK program] about 12 months ago, have you had any of the following for your <back/knee/shoulder/hip/neck> pain? Respondents indicated whether or not they had any of the following services: conservative care (e.g., office visit with a doctor or a physical therapist), invasive procedures (e.g., emergency department or urgent care center visit, overnight stay in a hospital, injections, or surgery), or imaging (e.g., MRI, scan, X-ray).

Exposures

The nonparticipant group registered, but did not complete exercise therapy sessions and did not access educational articles. The intervention group completed exercise therapy sessions or accessed educational articles through month 3 (completer subgroup) or completed exercise therapy sessions or accessed educational articles in months 3 to 6 (long term subgroup). Exercise completion and educational article access were recorded when participants used the app. Therefore, we did not record information about exercises completed outside the app.

Confounders

Model covariates included cohort, gender, age, exercise frequency per week at baseline (less than 1 h, 1 to 2.5 h, more than 2.5 h), BMI at baseline, pain region (back, knee, shoulder, hip, neck), baseline anxiety, baseline depression, and state of residence.

Data sources

Baseline data were collected via an online survey that the nonparticipant and intervention groups completed at program registration.

The intervention group took part in the digital MSK program and entered data in app at follow-up time points. If intervention group members did not enter data in app, trained data collectors from a data collection firm representing the digital MSK program emailed the intervention group members surveys about current pain, function, and mental health status at the final follow-up time point for their cohort (e.g., 12 months for cohort 1). For example, cohort 1 may have entered data in app at 3 months, in app at 6 months, and then by emailed survey at 12 months. The data collection firm emailed and called nonresponders with reminders to complete the emailed survey. Intervention group members also had the option to complete the survey by phone.

The data collection firm also emailed the nonparticipant group surveys about their current pain, function, and mental health status at the final follow-up time point for their cohort. That is, the cohort 1 nonparticipants completed emailed surveys at 12 months, cohort 2 nonparticipants completed emailed surveys at 6 months, and cohort 3 nonparticipants completed emailed surveys at 3 months. The data collection firm emailed and called nonresponders with reminders to complete the emailed survey, and the nonparticipant group could choose to complete the survey by phone. Upon completion of emailed surveys, nonparticipant and intervention group members received $25 gift cards.

Study size

We estimated a sample size that enabled pairwise comparisons among the groups at each follow-up time point. The minimally clinically important difference for VAS pain is 20 points on a scale of 0 to 100 [19]. Based on previous results from RCTs, we assumed a standard deviation of 22 for the VAS scores within each group for power calculation [35]. Bonferroni correction was used to account for multiple comparisons among groups. To achieve 80% statistical power, we needed at least 47 participants in each group to detect a 15-point difference in VAS (Cohen's $d = 0.68$), given an overall Type I error rate of 0.05.

Statistical methods

Summary statistics were estimated for gender, age, exercise frequency per week at baseline, BMI at baseline, baseline anxiety, and baseline depression. Descriptive statistics were reported at 3, 6 and 12 months for the percentage of patients who achieved a MCID in pain improvement, a MCID in functional improvement, moderate to severe depression, and moderate to severe anxiety. For these dichotomous outcomes, we used a two-proportions z-test to compare the intervention group versus the nonparticipant group at each timepoint.

We conducted unadjusted and adjusted regression analyses. For the primary outcome of achieving MCID in pain, we conducted multivariable-adjusted logistic regression at 3, 6 and 12 months controlling for gender, age, state of residence, exercise frequency per week at baseline (less than 1 h, 1 to 2.5 h, more than 2.5 h), pain region (back, knee, shoulder, hip, neck), cohort, baseline BMI, baseline anxiety, and baseline depression.

For the secondary outcome of achieving MCID in function, multivariable-adjusted logistic regression at 3, 6 and 12 months controlled for gender, age, state of residence, exercise frequency per week at baseline, cohort, baseline pain, baseline BMI, baseline anxiety, and baseline depression. We examined moderate to severe depression or anxiety at follow-up among the subset with moderate to severe depression/anxiety at baseline. The multivariable-adjusted logistic regression models at 3, 6 and 12 months controlled for gender, age, state of residence, exercise frequency per week at baseline, baseline pain, and baseline BMI.

We conducted a subgroup analysis examining descriptive statistics for program completers versus long term engagers. For dichotomous MCID in pain improvement, two-proportions z-tests were used to compare the program completers versus the long term users group at 3, 6 and 12 months.

The primary analysis employed complete case analysis, i.e., excluded missing values. To address missing data, sensitivity analysis for MCID in pain improvement was performed using multiple imputation by chained equations ($n = 10$ imputations) assuming data were missing at random. All variables from the regression model were included in the imputation model.

All analyses were performed in R version 4.0.5 (R Core Team, Vienna, Austria).

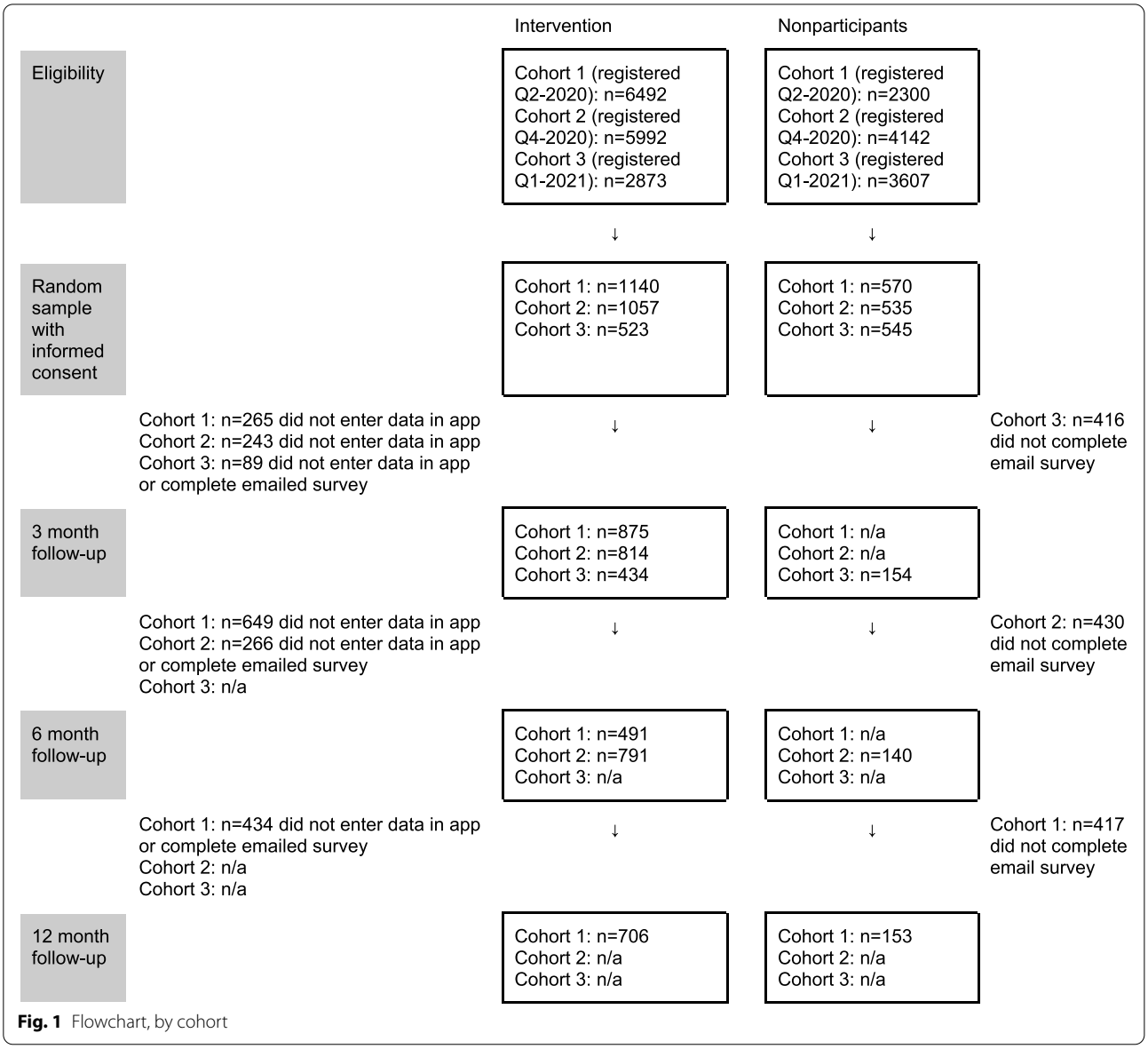

Fig. 1 Flowchart, by cohort

Results

Flowchart

Figure 1 reports on the number of intervention group members and nonparticipants at each study stage, by cohort. Overall, we achieved a 70% response rate at 3 months (2277/3265), a 52% response rate at 6 months (1422/2732), and a 50% response rate at 12 months (859/1710).

Sample characteristics

Table 2 shows the characteristics of sampled nonparticipant and intervention groups at baseline. About 63% of the intervention group is female versus 59% in the nonparticipant group. The intervention group has a mean age of 49.3 years old versus 45.8 years in the nonparticipant group. Over 70% of the intervention group was overweight or obese compared to 79% of the nonparticipant group. Compared to the intervention group, a larger percentage of the nonparticipant group exercised less than 1 h per week, experienced moderate to severe anxiety, and experienced moderate to severe depression. Characteristics of the analytic sample who responded to follow-up surveys are similar to the study sample (Additional File 1).

Descriptive results

The percentage achieving MCID in pain improvement was significantly higher for the intervention group

Table 2 Study sample characteristics at baseline

	Comparison ($N = 1650$)	Intervention ($N = 2720$)	Total ($N = 4370$)
Gender			
Female	975 (59.1%)	1704 (62.7%)	2679 (61.3%)
Male	662 (40.1%)	995 (36.6%)	1657 (37.9%)
Other	3 (0.2%)	6 (0.2%)	9 (0.2%)
Prefer Not to Answer	10 (0.6%)	15 (0.6%)	25 (0.6%)
Age*			
Mean (SD)	45.8 (12.4)	49.3 (12.1)	48.0 (12.3)
Median [Min, Max]	45.8 [18.3, 87.5]	50.4 [18.1, 86.2]	48.8 [18.1, 87.5]
BMI*			
Underweight (< 18.5)	16 (1.0%)	36 (1.3%)	52 (1.2%)
Normal (18.5–24.9)	326 (19.8%)	772 (28.4%)	1098 (25.1%)
Overweight (25.0–29.9)	502 (30.4%)	865 (31.8%)	1367 (31.3%)
Obese (> 30.0)	806 (48.8%)	1047 (38.5%)	1853 (42.4%)
Exercise Frequency*			
Less than 1 h	630 (38.2%)	729 (26.8%)	1359 (31.1%)
1 to 2.5 h	647 (39.2%)	1158 (42.6%)	1805 (41.3%)
More than 2.5 h	373 (22.6%)	833 (30.6%)	1206 (27.6%)
Percent with Moderate/Severe Anxiety*	421 (25.5%)	461 (17.0%)	882 (20.2%)
Percent with Moderate/Severe Depression*	291 (17.6%)	282 (10.4%)	573 (13.1%)

* $p < 0.05$ comparing groups for chi-square test of independence for categorical variables and two-sample t-test for continuous variables

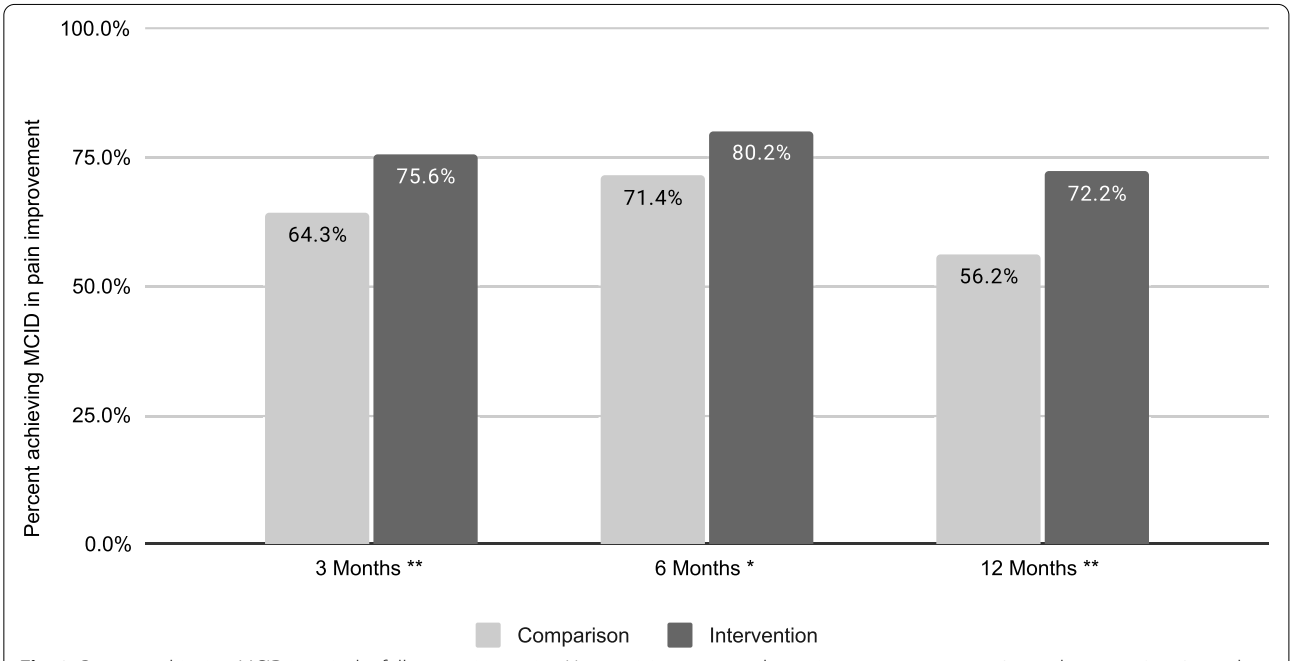

Fig. 2 Percent achieving MCID in pain, by follow-up time point. Nonparticipant group denominator was $n = 154$ at 3 months, $n = 140$ at 6 months, and $n = 153$ at 12 months. Intervention group denominator was $n = 2123$ at 3 months, $n = 1282$ at 6 months, and $n = 706$ at 12 months. Differences between comparison and intervention group were statistically significant at * $p <= .01$ and ** $p <= .001$

versus the nonparticipant group by 11.3 percentage points at 3 months, 8.8 percentage points at 6 months, and 16.0 percentage points at 12 months ($p < .05$, Fig. 2). In addition, pain scores decreased from 48.7 points (SD 22.7) at baseline to 24.4 (SD 25.5) at 3 months, 26.3 (SD 26.3) at 6 months, and 32.7 (SD 28.9) at 12 months

among the nonparticipant group (data not shown). The intervention group's pain decreased from 45.0 (SD 22.0) at baseline to 18.2 (SD 19.6) at 3 months, 14.3 (SD 17.8) at 6 months, and 22.1 (SD 23.3) at 12 months (data not shown).

On secondary outcomes, the percentage achieving a MCID in functional improvement was higher for the intervention group versus the nonparticipant group by 12.6 percentage points at 3 months, 15.2 percentage points at 6 months, and 2.2 percentage points at 12 months (Fig. 3).

Among those with moderate to severe depression at baseline, the percentage with moderate to severe depression at followup was significantly higher for the nonparticipant group versus the intervention group by 34.7 percentage points at 3 months, 43.5 percentage points

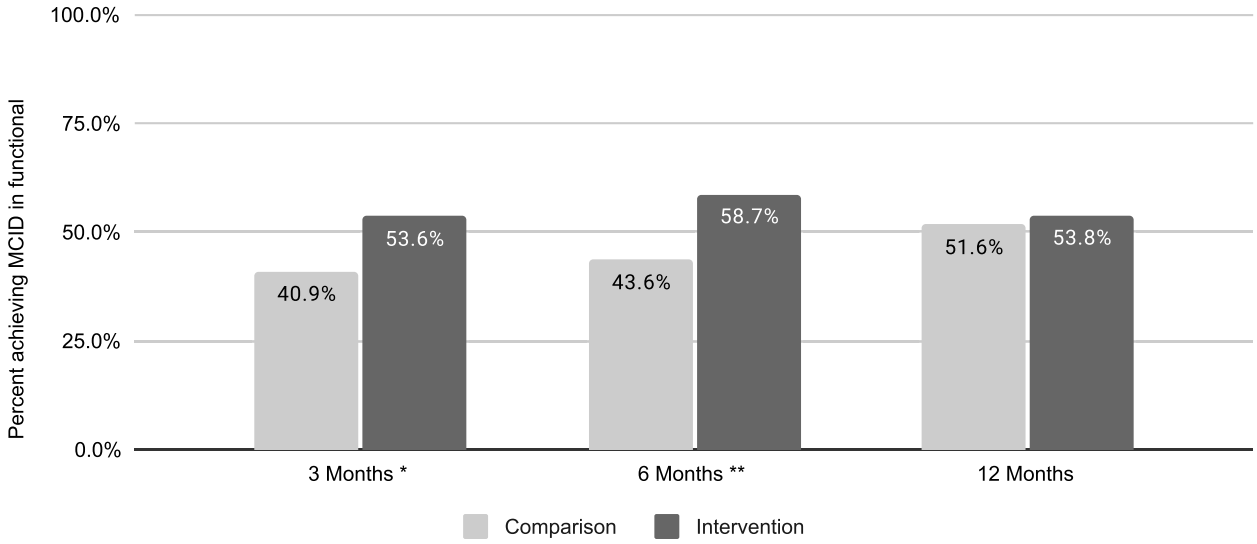

Fig. 3 Percent achieving MCID in function, by follow-up time point. Nonparticipant group denominator was $n = 154$ at 3 months, $n = 140$ at 6 months, and $n = 153$ at 12 months. Intervention group denominator was $n = 2123$ at 3 months, $n = 1282$ at 6 months, and $n = 706$ at 12 months. Differences between comparison and intervention group were statistically significant at * $p <= .01$ and ** $p <= .001$

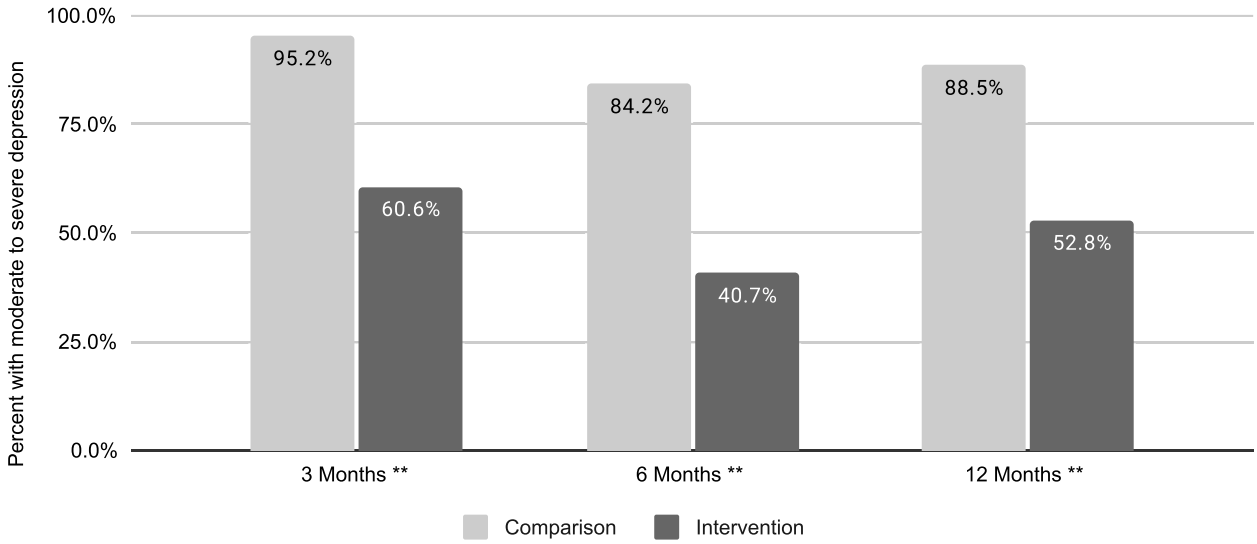

Fig. 4 Percent with moderate to severe depression, among those with moderate to severe depression at baseline, by follow-up time point. Nonparticipant group denominator was $n = 21$ at 3 months, $n = 19$ at 6 months, and $n = 26$ at 12 months. Intervention group denominator was $n = 175$ at 3 months, $n = 118$ at 6 months, and $n = 89$ at 12 months. Differences between comparison and intervention group were statistically significant at * $p <= .01$ and ** $p <= .001$

at 6 months, and 35.7 percentage points at 12 months ($p <= 0.001$, Fig. 4).

Among those with moderate to severe anxiety at baseline, the percentage with moderate to severe anxiety at followup was significantly higher for the nonparticipant group versus the intervention group by 26.8 percentage points at 3 months, 40.5 percentage points at 6 months, and 19.8 percentage points at 12 months ($p <= 0.01$, Fig. 5).

Figure 6 shows descriptive results for self-reported health care use. At 12 months, the percentage with conservative (e.g., office or therapy visit), invasive (e.g., surgery, injections, emergency room), and imaging services was higher for the nonparticipant group versus the intervention group by 16.7 percentage points, 5.7 percentage points, and 8.1 percentage points, respectively ($p < 0.05$).

Main results

Table 3 shows results from unadjusted and adjusted models for primary and secondary outcomes. In adjusted models, we observed higher odds of achieving a MCID in pain improvement at 3 months (OR: 1.97; 95% CI: 1.28, 3.02; $p = .002$), at 6 months (OR: 1.44; 95% CI: 0.91, 2.25; $p = .11$), and 12 months (OR: 2.06; 95% CI: 1.38, 3.08; $p = .004$) for the intervention versus the nonparticipant group.

In adjusted models, we observed higher odds of achieving MCID in functional improvement at 3 months (OR: 1.56; 95% CI: 1.03, 2.38; $p = .01$), 6 months (OR: 1.55; 95% CI: 1.02, 2.37; $p = .04$), and 12 months (OR: 1.35; 95% CI: 0.89, 2.06; $p = 0.16$) for the intervention versus the nonparticipant group.

For the subgroup with moderate or severe depression at baseline, we observed lower odds of moderate or severe depression at 3 months (OR: 0.27; 95% CI: 0.12, 0.60; $p = .002$), 6 months (OR: 0.41; 95% CI: 0.18, 0.91; $p = 0.026$), and 12 months (OR: 0.35; 95% CI: 0.19, 0.65; $p = 0.001$) for the intervention versus the nonparticipant group in adjusted models. For the subgroup with moderate or severe anxiety at baseline, we observed lower odds of moderate or severe anxiety at 3 months (OR: 0.21; 95% CI: 0.09, 0.43; $p < .001$), 6 months (OR: 0.15; 95% CI: 0.07, 0.31; $p < .001$), and 12 months (OR: 0.34; 95% CI: 0.19, 0.61; $p < .001$) for the intervention versus the nonparticipant group in adjusted models.

Subgroup analyses

We examined intervention subgroups defined by engagement duration. The completer subgroup was defined as those completing exercise sessions only through month 3, while the long term subgroup also completed exercise sessions in months 4 through 6. We did not detect significantly different percentages in the two subgroups achieving a MCID in pain improvement at 3 months. But, the percentage achieving a MCID in pain improvement was higher for the long term group versus the completer group by 10 percentage points at 6 months, and 9 percentage points at 12 months ($p <= .004$) (Additional File 2).

Sensitivity analyses

We conducted a sensitivity analysis applying a multiple imputation by chained equations approach for

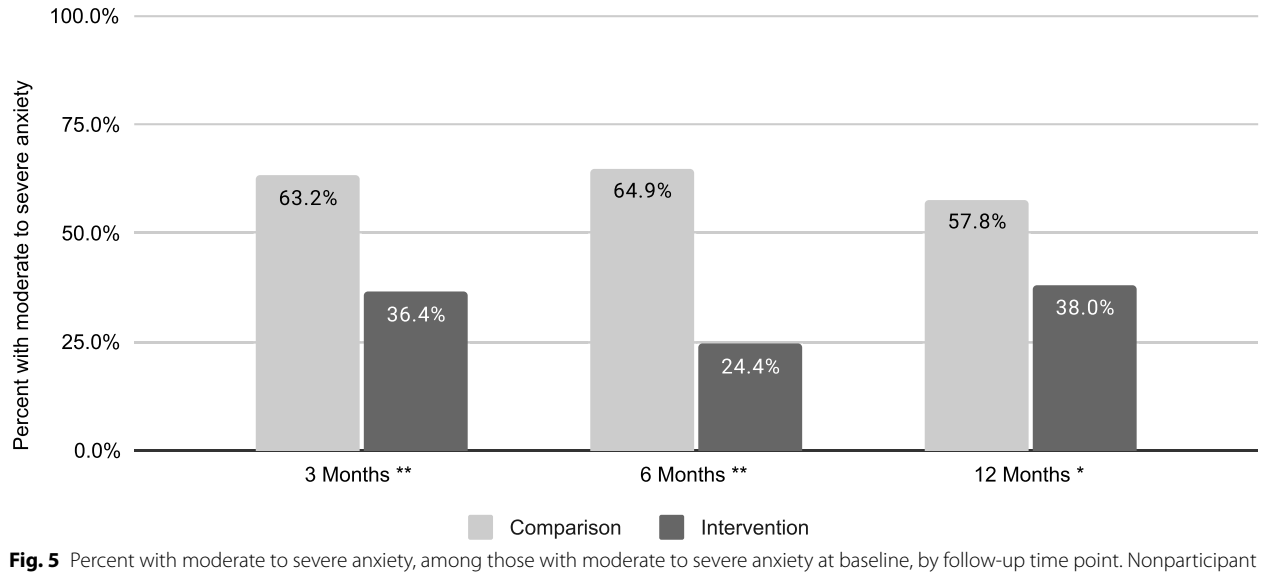

Fig. 5 Percent with moderate to severe anxiety, among those with moderate to severe anxiety at baseline, by follow-up time point. Nonparticipant group denominator was $n = 38$ at 3 months, $n = 37$ at 6 months, and $n = 45$ at 12 months. Intervention group denominator was $n = 297$ at 3 months, $n = 205$ at 6 months, and $n = 166$ at 12 months. Differences between comparison and intervention group were statistically significant at * $p <= .01$ and ** $p <= .001$

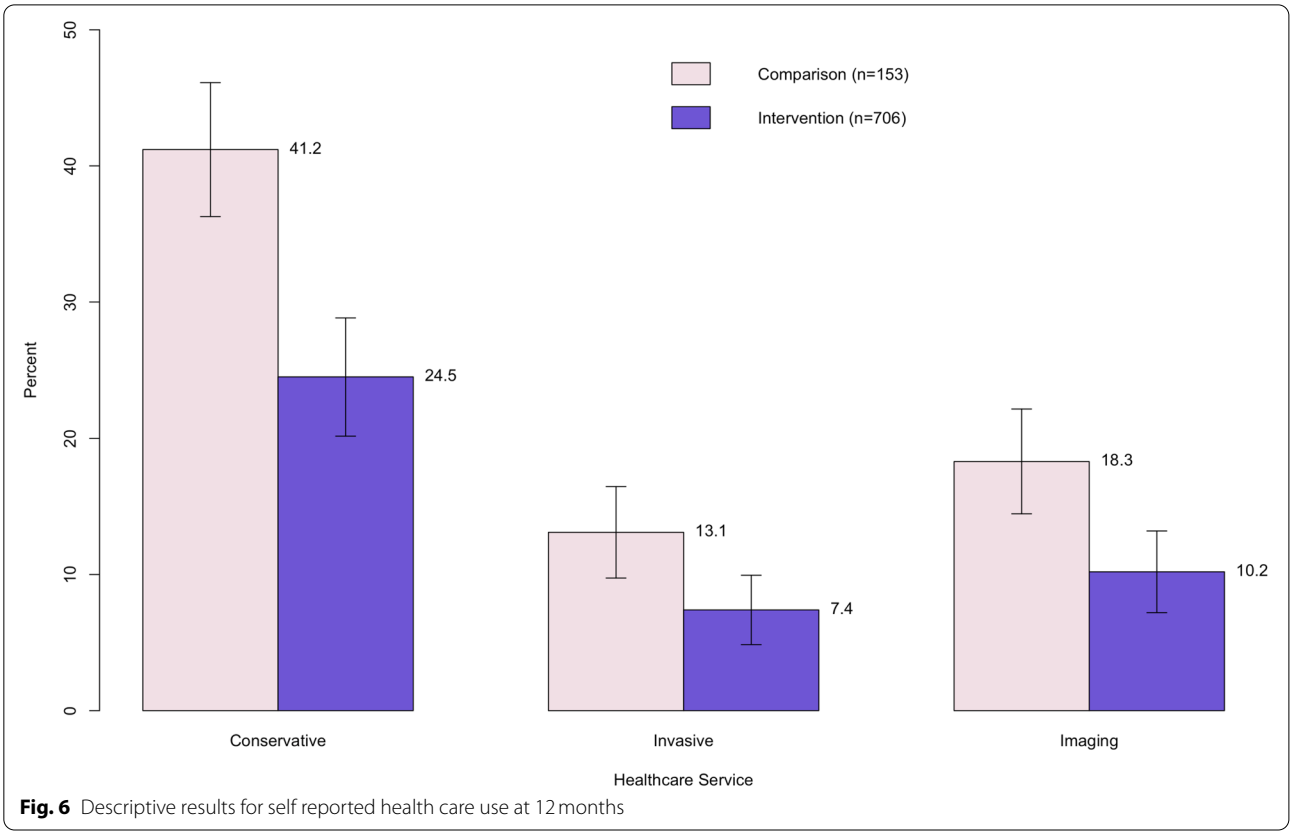

Fig. 6 Descriptive results for self reported health care use at 12 months

Table 3 3, 6, and 12 month results in unadjusted and adjusted models comparing the intervention group to the nonparticipant group (reference)

Primary Outcome	Timepoint	Unadjusted OR (95% CI)	Adjusted OR (95% CI)	*p*-value
Pain (MCID)	3 months	1.72 (1.21, 2.42)	1.97 (1.28, 3.02)	0.002
	6 months	1.62 (1.08, 2.38)	1.44 (0.91, 2.25)	0.113
	12 months	1.97 (1.37, 2.82)	2.06 (1.38, 3.08)	0.004
Secondary Outcome				
Function (MCID)	3 months	1.67 (1.20, 2.33)	1.56 (1.03, 2.38)	0.010
	6 months	1.84 (1.30, 2.63)	1.55 (1.02, 2.37)	0.041
	12 months	1.14 (0.80, 1.61)	1.35 (0.89, 2.06)	0.160
Moderate or severe depression	3 months	0.41 (0.25, 1.43)	0.27 (0.12, 0.60)	0.002
	6 months	0.33 (0.19, 0.62)	0.41 (0.18, 0.91)	0.026
	12 months	0.40 (0.24, 0.70)	0.35 (0.19, 0.65)	0.001
Moderate or severe anxiety	3 months	0.34 (0.21, 1.80)	0.21 (0.09, 0.43)	< 0.001
	6 months	0.22 (0.13, 0.37)	0.15 (0.07, 0.31)	< 0.001
	12 months	0.48 (0.29, 0.80)	0.34 (0.19, 0.61)	< 0.001

MCID in pain improvement. The odds ratios for the intervention versus the nonparticipant group was 1.37 at 3 months (95% CI: 1.08, 1.73; $p = 0.008$), 0.96 at 6 months (95% CI:0.78, 1.19; $p = 0.12$), and 1.38 at 12 months (95% CI: 1.12, 1.69; $p = .002$) in adjusted models.

Discussion

This observational study examined pain, function, depression, and anxiety at 3, 6, and 12 months and health care use during the 12 months after starting a digital MSK program versus a nonparticipant group. We found significant associations between the intervention and clinically

meaningful pain improvement at 3 and 12 months and functional improvement at 3 and 6 months. Among the subset of persons with moderate or severe depression or anxiety at baseline, the intervention group was significantly associated with symptom improvement at all timepoints. Finally, a smaller percent of intervention group members used invasive, imaging, or conservative services at 12 months versus the nonparticipant group.

Participation in a digital MSK program was significantly associated with a MCID in pain improvement in the short and long term. Based on adjusted models, the percentage that achieved a MCID in pain improvement was higher for the intervention versus the nonparticipant group by 14 percentage points at 3 months, 14 percentage points at 6 months, and 12 percentage points at 12 months. Over half of the intervention and nonparticipant groups experienced meaningful pain improvements over time. We propose that people with chronic pain likely registered for the digital MSK program while experiencing elevated pain. By 12 months, the nonparticipant group achieved pain improvement with the help of traditional health care services, but still did not experience the same results as the intervention group.

Our pain improvement findings were consistent with previous research about the effectiveness of exercise training on decreasing chronic MSK pain [36–40]. For low back pain, Quentin et al's meta analysis of 13 studies reported that home-based exercise training decreased low back pain versus control groups (effect size = −0.97, 95% CI −1.14 to −0.79) [36]. Skelly et al's meta analysis reported that exercise was associated with decreased back pain versus control groups at short-term (11 trials, pooled difference −1.21 on a 0 to 10 scale, 95% CI −1.77 to −0.65), intermediate-term (5 trials, −0.85, 95% CI −1.67 to −0.07), and long-term (1 trial, difference −1.55, 95% CI −2.76 to −0.34). For knee osteoarthritis, the same report showed pain improvement for intervention versus control groups in the short term (8 trials, −0.47, 95% CI −0.86 to −0.10); intermediate term (11 trials, −1.34, 95% CI −2.12 to −0.54), and long term (4 trials, −0.30, 95% CI −0.49 to 0.00). For hip osteoarthritis, exercise showed a small improvement in only short-term pain compared with usual care (3 trials, −0.30, 95% CI −0.70 to −0.02) [40]. Narrative systematic reviews have also found that exercise is associated with pain improvement for hip osteoarthritis, subacromial shoulder pain, and chronic pain from multiple diagnoses [37–39].

Participation in a digital MSK program was significantly associated with functional improvement in the short and medium term. A significantly larger percentage of digital MSK program participants showed meaningful functional improvement versus a nonparticipant group at 3 and 6 months. Other studies have examined the benefits of multidisciplinary and exercise programs on function for people with chronic pain conditions [39–41]. A review of Cochrane reviews found that function was significantly improved for persons with chronic pain after exercise interventions in 14 reviews (small to moderate effect sizes) [39]. For low back pain, Skelly et al's meta analysis found that exercise showed improvement in only short-term function compared with control groups (10 trials, pooled standardized mean difference (SMD) −0.31, 95% CI −0.50 to −0.13). For knee osteoarthritis, exercise was associated with improved function compared with control groups in the short term (8 trials, pooled SMD −0.29, 95% CI −0.46 to −0.11), intermediate term (11 trials, pooled SMD −0.63, 95% CI −1.17 to −0.10), and long term (4 trials, pooled SMD −0.22, 95% CI −0.34 to −0.08). In hip osteoarthritis, exercise was associated with functional improvement versus control groups in the short term (3 trials, pooled SMD −0.33, 95% CI −0.58 to −0.11), intermediate term (2 trials, pooled SMD −0.28, 95% CI −0.55 to 0.02), and long term (1 trial, SMD −0.37, 95% CI −0.74 to −0.01) [40]. However, in our study, the odds ratios for MCID in function for the intervention versus the nonparticipant group declined over time. One reason may be related to ongoing participation in the digital MSK program. To sustain functional improvement, we hypothesize that participants may need to regularly complete exercise sessions over time. To continue to show improvements over time, the digital MSK program may need to include more motor skill training in addition to strength and flexibility exercises. For example, van Dillen et al. successfully used motor skill training to target how people performed functional activities, and this approach resulted in functional improvements that endured [42].

Participation in a digital MSK program was significantly associated with improvements in depression and anxiety at all timepoints among persons with moderate to severe depression and anxiety at baseline. In contrast to our findings, previous research estimates about exercise and depression have been unclear [43]. One reason may be that exercise may be less effective for people with depression in the absence of chronic MSK pain. A digital MSK program may address MSK pain through exercise and engagement and thus reduce depressive symptoms exacerbated by MSK pain. Our study's results on anxiety were consistent with research showing the positive and lasting effect of exercise on anxiety [44]. The program's low intensity exercises and educational articles may have helped participants to experience less fear of movement, more self-efficacy about managing pain, and "time out" away from anxious thoughts.

Significantly fewer participants of a digital MSK program reported health care use at 12 months versus a

nonparticipant group. One possible reason for this result was that a digital MSK program prevented the need for health care services, especially invasive services, because of improved pain and function outcomes over time. A digital MSK program may have also acted as a substitute for usual care, especially conservative care. That is, participants may have practiced the exercises and stretches through the program instead of going to in-person therapy. Because these cohorts registered for the program during the COVID-19 pandemic, the percent using in-person health care was likely lower than usual in both groups, but it is unclear whether the pandemic influenced health care use differently in the nonparticipant versus the intervention group.

As an observational study, we propose that findings were generalizable to a population of people with MSK pain with expressed interest in a digital MSK program. Similar to U.S. national estimates, our study included more females than males with chronic pain and more people who were overweight or obese than normal weight [45]. The study included people willing to participate in a digital health program and may not be generalizable to later adopters of health technology. We analyzed data collected from people who responded to surveys administered in app, by email, and by phone, and the results may not apply to non-respondents. However, we found that the baseline characteristics of the respondents was similar to that of the study sample (Table 1 and Additional File 1).

The study had the following limitations. First, this was an observational study and not a RCT. Thus, we cannot establish causality of the intervention's effect on outcome improvement. In addition, the intervention group and nonparticipant group differed on baseline characteristics. But, we controlled for these measured variables in the adjusted models. Furthermore, results about improvement in depression and anxiety were among only those with moderate to severe symptoms at baseline.

Second, we may have omitted important confounding variables that attenuate outcomes estimates. For example, we did not collect data about medications that patients used before, during, or after the digital MSK program. Medication use may have influenced both program engagement as well as pain, function, and mental health outcomes. We cannot account for unmeasured factors like motivation. The intervention group may include people more motivated to manage pain and report pain improvement, thereby biasing our results upwards. We also did not collect medical diagnoses from study participants, and patients with different diagnoses may have pain with different attributes. As a result, we are unable to adjust for diagnosis as a confounding variable or use diagnosis in stratified analyses (e.g., analyze results for members with only inflammatory arthritis).

Third, our response rate for the nonparticipant group was lower than for the intervention group. The lower response rate in the nonparticipant group may have biased our estimates upwards if there were more non-respondents in the nonparticipant group who also had improved outcomes. Finally, as a wholly digital health program, we include patient reported outcomes in this study and have not included any physician reported or objective assessments.

We propose the following research to build on the findings from this study. First, future studies can examine intermediate and long term follow-up for each care pathway (i.e., back, knee, shoulder, hip, neck) separately. Second, we recommend additional study of the interplay between pain and function and a digital MSK program. In the current study, improvements in pain at 12 month were not accompanied by the same magnitude of functional improvements. Third, we recommend studying the influence of engagement with a digital MSK program on clinical outcomes. Compared to those who engaged for only 3 months, people who engaged in the digital MSK program for 6 months were more likely to experience better pain outcomes in the long term. But engagement duration did not capture different aspects of engagement, including affective and cognitive investment, and how engagement may change over time [46].

Conclusions

This study examined multiple clinical outcomes at three time points over a 12 month period. More participants of a digital MSK program experienced meaningful pain and functional improvement versus a nonparticipant group that never took part in the program. These results were demonstrated in the short, medium, and long term. We evaluated the program in real world settings so that results were more generalizable than results from tightly controlled clinical trials. We provided preliminary evidence about how a digital MSK program influenced use of traditional, in-person health care services. In conclusion, this study provided evidence that a digital MSK program may have had a lasting impact on improved pain, depression, and anxiety alongside decreased health care use.

Abbreviations

GAD-2: Generalized Anxiety Disorder 2-item scale; GAD-7: Generalized Anxiety Disorder 7-item scale; HOOS-PS: Hip Disability and Osteoarthritis Outcome Score Physical Function Short form; KOOS-PS: Knee Injury and Osteoarthritis Outcome Score Physical Function Short form; MCID: Minimally clinical important difference; MSK: Musculoskeletal; sf-NPAD: Neck Pain and Disability Scale short form; PHQ-2: Patient Health Questionnaire 2-item scale; PHQ-8: Patient

Health Questionnaire 8-item scale; Q: Quarter; SPADI: Shoulder Pain and Disability Index; VAS: Visual analog scale.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12891-022-05188-x.

Additional file 1. Analytic sample characteristics.

Additional file 2. Descriptive results for pain and function, by subgroups defined by engagement duration.

Acknowledgements
Not applicable.

Authors' contributions
GW and JK designed the study. GW, MY, and MH analyzed data. GW, MY, MH, JK, and JB interpreted data and were major contributors in writing the manuscript. GW, MY, MH, JK, and JB read and approved the final manuscript.

Funding
Hinge Health, Inc., provided the digital MSK program to participants. Hinge Health, Inc. employees and manuscript authors GW, MH, and JK designed the study, interpreted results, and wrote the manuscript. Hinge Health, Inc. employees GW and MH analyzed data.

Availability of data and materials
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
The study (reference number #20160949) was reviewed and approved by WIRB-Copernicus Group® Institutional Review Board (OHRP/FDA IRB registration number IRB00000533) at WIRB-Copernicus Group® (1019 39th Avenue SE Suite 120, Puyallup, Washington 98374–2115). Study subjects acknowledged online that they provided informed consent before study inclusion. The ethics committee approved the waiver of written documentation of informed consent because the program is entirely digital.

Consent for publication
N/A.

Competing interests
Hinge Health, Inc. employees and manuscript authors GW, MH, and JK designed the study, interpreted results, and wrote the manuscript. Hinge Health, Inc. employees GW and MH analyzed data. GW, MH, and JK have equity interest in Hinge Health, Inc.

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Publisher's Note

8.

Clinical Outcomes After a Digital Musculoskeletal Program for Acute and Subacute Pain: Observational, Longitudinal Study With Comparison Group

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Original Paper

Clinical Outcomes After a Digital Musculoskeletal Program for Acute and Subacute Pain: Observational, Longitudinal Study With Comparison Group

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Abstract

Background: Telerehabilitation for musculoskeletal (MSK) conditions may produce similar or better outcomes than usual care, but most telerehabilitation studies address only chronic or postsurgical pain.

Objective: We aimed to examine pain and function at 3, 6, and 12 weeks for individuals with acute and subacute MSK pain who took part in a digital MSK program versus a nonparticipant comparison group.

Methods: We conducted an observational, longitudinal study with a nonparticipant comparison group. The intervention group had video visits with physical therapists who recommended exercise therapies and educational articles delivered via an app. Nonparticipants were those who were registered but unable to participate because their benefit coverage had not yet begun. We collected pain and function outcomes through surveys delivered at 3-, 6-, and 12-week follow-ups. We conducted descriptive analyses, unadjusted regression, and mixed effects regression adjusting for baseline characteristics, time as fixed effects, and a time*group interaction term.

Results: The analysis included data from 675 nonparticipants and 262 intervention group participants. Compared to baseline, the intervention group showed significantly more pain improvement at 3, 6, and 12 weeks versus nonparticipants after adjusting for baseline factors. Specifically, the intervention group's pain scores decreased by 55.8% at 3 weeks versus baseline, 69.1% at 6 weeks, and 73% at 12 weeks. The intervention group's adjusted pain scores decreased from 43.7 (95% CI 41.1-46.2) at baseline to 19.3 (95% CI 16.8-21.8) at 3 weeks to 13.5 (95% CI 10.8-16.2) at 6 weeks to 11.8 (95% CI 9-14.6) at 12 weeks. In contrast, nonparticipants' pain scores decreased by 30.8% at 3 weeks versus baseline, 45.8% at 6 weeks, and 46.7% at 12 weeks. Nonparticipants' adjusted pain scores decreased from 43.8 (95% CI 42-45.5) at baseline to 30.3 (95% CI 27.1-33.5) at 3 weeks to 23.7 (95% CI 20-27.5) at 6 weeks to 23.3 (95% CI 19.6-27) at 12 weeks. After adjustments, the percentage of participants reporting that pain was better or much better at follow-up was significantly higher by 40.6% at 3 weeks, 31.4% at 6 weeks, and 31.2% at 12 weeks for intervention group participants versus nonparticipants. After adjustments, the percentage of participants with meaningful functional improvement at follow-up was significantly higher by 15.2% at 3 weeks and 24.6% at 12 weeks for intervention group participants versus nonparticipants.

Conclusions: A digital MSK program may help to improve pain and function in the short term among those with acute and subacute MSK pain.

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KEYWORDS

telemedicine; acute; subacute; musculoskeletal; pain; function; clinical; quality of life; intervention; longitudinal study; physical therapy; physiotherapy; physical therapist; physiotherapist; exercise; physical activity; telehealth; eHealth; digital health; patient

education; education material; education resource; health resource; mHealth; mobile health; health app; observational study; video consult; eConsult; virtual care

Introduction

Acute, subacute, and chronic musculoskeletal (MSK) conditions are a leading cause of disability and cost in the United States [1]. The rates of back pain, neck pain, and other MSK disorders in the United States are among the highest in the world [1]. In 2019, 39% of American adults reported back pain, 37% reported lower limb pain (eg, hips, knees, and feet), and 31% reported upper limb pain (eg, hands, arms, and shoulders) in the 3 months prior [2].

MSK conditions include injuries or pain in joints, ligaments, muscles, nerves, tendons, and structures that support limbs, neck, and back. They may be a result of exertion, repetitive motions, strain, or exposure to force, vibration, or awkward posture [3]. Acute pain is often defined as lasting 4 weeks or less. Subacute pain duration is from 4 to 12 weeks, and chronic pain duration is more than 12 weeks [4,5].

MSK conditions are a common cause of health care use in the United States. For example, 72.4 million office visits and 9.9 million emergency department visits were for MSK conditions in 2018 [6,7]. Of these, more than 4 million emergency department visits were for sprains and strains alone. Although providers and patients may pursue different pain management approaches for acute and subacute needs, numerous studies and clinical guidelines recommend education and exercise [8,9].

Telerehabilitation, a branch of telehealth that uses telecommunications technologies to control or monitor remote rehabilitation, is increasingly used to deliver MSK care [10]. Telerehabilitation for MSK conditions may produce similar or even better pain-, functional-, and health-related quality of life outcomes than usual care, but most telerehabilitation studies address only chronic or postsurgical pain [10-12]. Therefore, we aimed to determine whether telerehabilitation was associated with improved clinical outcomes in acute and subacute MSK conditions. Our primary objective was to examine pain and function at 3, 6, and 12 weeks for participants of a digital acute MSK program versus a nonparticipant comparison group. A secondary objective was to examine engagement among the intervention group. The findings contribute to a growing evidence base about the role of digital health for managing a range of MSK needs.

Methods

Study Design

We conducted an observational, prospective cohort study comparing digital MSK acute program participants (herein, intervention group) to nonparticipants at 3, 6, and 12 weeks.

Acute Program

Employers offered the acute program to employees and adult dependents as a health benefit. Recruitment was conducted through post and email. Registration involved creating a member profile and completing an application over the internet.

Developed by physical therapists (PTs), the acute program's goal was to help participants address acute or subacute MSK pain through digital physical therapy consultation, exercise therapy, and education. Participants had access to an acute program app for use on personal tablets or smartphones.

The acute program began with a video visit with a licensed PT. The PT conducted a subjective interview to learn more about the participant's history and goals and guided them through a series of movement tests to assess their current level of function. After the video visit, the PT provided a plan with recommended exercises and education that were available to participants through the app. The app provided this information through "sessions."

Each session presented a set of exercises that were specific to acute back, knee, shoulder, hip, neck/upper back, elbow/wrist/hand, or ankle/foot pain. Each session included stretching, strengthening, balancing, and mobility activities, based on the participant's functional limitations and goals determined during the consultation. The session presented 1 to 2 sets of 3 to 10 repetitions of each exercise (depending on the difficulty and type of exercise), with each session's duration ranging from 5 to 20 minutes. Graphics along with written and audio cues demonstrated how to perform the exercises, the number of repetitions for each exercise, and how long to hold the positions. As participants progressed through the program, their exercises were adjusted by the PT to gradually advance them toward their goals. This included adjusting the exercise variation, number of repetitions, hold time, and use of resistance with resistance bands (if applicable).

After participants completed the exercises for that session, the app presented educational resources about acute and subacute MSK pain–related topics, such as pain neuroscience, movement, treatment options, coping techniques, healthy lifestyle practices, relaxation tools, social support, and habit formation. Lastly, the participant was able to leave a note for their PT, rate their pain, or record any additional activity they had completed recently. As a wholly digital program, participants could choose when and where to meet with PTs via video and complete sessions.

Study Participants

First, for each week between July and October 2021, we identified individuals meeting the inclusion and exclusion criteria based on information provided in the application. Inclusion criteria were aged ≥18 years; back, knee, shoulder, hip, or neck pain; visual analog scale (VAS) pain score >0; pain for less than 12 weeks; and covered by employer's health plan. Exclusion criteria were signs of fracture, joint instability, infection, cancer, and cauda equina syndrome.

Second, we categorized the individuals as part of the intervention or nonparticipant group. The intervention group had a first video visit with a PT in the past week and a published care plan. Nonparticipants were those who applied to the acute program but were declined because their employers did not yet offer the acute program as a benefit. Everyone in the intervention

group and a sample of the nonparticipants were invited to the study. To sample nonparticipants, we stratified them by pain region (ie, back, knee, shoulder, hip, and neck) and conducted a propensity score match based on baseline pain and function.

Between August and November 2021, we invited participants to complete an email survey 3 weeks after registration (nonparticipants) or video visit (intervention). We excluded individuals who did not provide informed consent or those who had pain for more than 12 weeks. Between August 2021 and January 2022, we sent surveys at 6 and 12 weeks after registration (nonparticipants) or video visit (intervention) to those who completed the 3-week follow-up survey and agreed to be recontacted (Table 1).

Table 1. Timeline for an example cohort who registered or had video visits between July 7, 2021, and July 13, 2021.

Date	Event
July 7-13	• Nonparticipant group registers • Intervention group has a physical therapist video visit
July 14	Apply inclusion and exclusion criteria and sample
August 4-11	Complete 3-week follow-up by email survey
August 25 to September 1	Complete 6-week follow-up by email survey
October 6-13	Complete 12-week follow-up by email survey

Ethics Approval

Study subjects acknowledged via the internet that they provided informed consent. The WIRB-Copernicus Group Institutional Review Board (Office of Human Research Protections/Food and Drug Administration Institutional Review Board registration number IRB00000533) at the WIRB-Copernicus Group reviewed and approved this study.

Outcomes

The primary outcome was pain improvement based on the response to the following question: "Over the past 24 hours, how bad was your [back/knee/shoulder/hip/neck] pain?" with a score from 0 (none) to 100 (worst imaginable).

A secondary outcome was the patient's global impression of change (PGIC) based on the response to the following question: "Compared to when you first registered for Hinge Health, how would you rate your [back/knee/shoulder/hip/neck] pain now?" Pain rated as better or much better was coded as 1; pain rated as much worse, worse, a little worse, unchanged, or a little better was coded as 0.

Another secondary outcome was minimal clinically important difference (MCID) in functional improvement (herein, functional improvement). To create this dichotomous variable (no/yes), we gathered responses to the 11-item Roland Morris Disability Questionnaire (RMDQ-11, back only), Knee injury and Osteoarthritis Outcome Score Physical Function Short form (KOOS-PS, knee only), Hip disability and Osteoarthritis Outcome Score Physical Function Short form (HOOS-PS, hip only), Shoulder Pain and Disability Index (SPADI, shoulder only), and Neck Pain and Disability Scale short form (sf-NPAD, neck only). Next, we calculated the change from baseline to follow-up. MCID in functional improvement is defined as either at least 30% improvement on the RMDQ-11 [13,14]; 8-point improvement on the KOOS-PS [15-17]; 9.3-point improvement on the HOOS-PS [18,19]; 13-point improvement on the SPADI [20-22]; 12-point improvement on the sf-NPAD [23,24]; or no limitations at follow-up.

For the intervention group's engagement, we collected the number of video visits and app-based exercise therapy sessions completed by 12 weeks. Exercise completion was recorded when participants used the app. We did not record exercises completed outside the app.

Exposures

Nonparticipants were those who were registered but did not take part in the acute program. The intervention group had one or more PT video visits, a published care plan, and access to exercise guidance and education via the acute program app.

Confounders

Model covariates included registration month (July, August, September, or October), age at baseline, pain region (back, knee, shoulder, hip, or neck), and the use of health care services at 12 weeks (no/yes). The health care services were conservative care (eg, office visit with a doctor or physical therapist), over-the-counter medications, prescription pain medications, and invasive procedures (eg, emergency department or urgent care center visit, overnight stay in a hospital, injections, or surgery).

Data Sources

The web-based application completed at program registration provided baseline data. We emailed follow-up surveys and up to 2 reminders at 3, 6, and 12 weeks after registration (nonparticipants) or the first PT video visit (intervention). Respondents received gift cards for US $20 at 3 weeks, US $25 at 6 weeks, and US $35 at 12 weeks.

Study Size

Sample size was based on detecting noninferiority of the intervention versus nonparticipants at 6 weeks after registering or video visit. For VAS pain scores, we chose a noninferiority margin of 10 points because this is less than the 20-point reduction for MCID in pain improvement [25]. Assuming SDs of 21.4 for pain [26], 80% power, and a 1-sided 2.5% significance level, we needed 57 participants per arm (N=114).

Statistical Methods

Summary statistics were estimated for baseline characteristics of age, pain region, registration month, and baseline pain. We conducted 2-tailed *t* tests (for continuous variables) and chi-square tests (for categorical variables) to show whether there were significant differences between the intervention group and nonparticipants at baseline. Descriptive statistics reported at 3, 6, and 12 weeks were mean (SD) VAS pain scores, the number and percentage of participants who perceived better or much better pain (PGIC) at follow-up compared to registration, and the number and percentage of participants who achieved an MCID in functional improvement.

Unadjusted and adjusted linear mixed effects regression models were used to model pain improvement, and generalized linear mixed effects models were used for PGIC and functional improvement. Covariates were baseline age, pain region, registration month, and health care service use at 12 weeks. PGIC and functional improvement models also included baseline pain. Time was treated as a categorical predictor to allow the modeling of nonlinear change trends over time. A 2-way time*group interaction term captured the treatment effect at each time point. Estimated predicted probabilities and marginal effects are presented below.

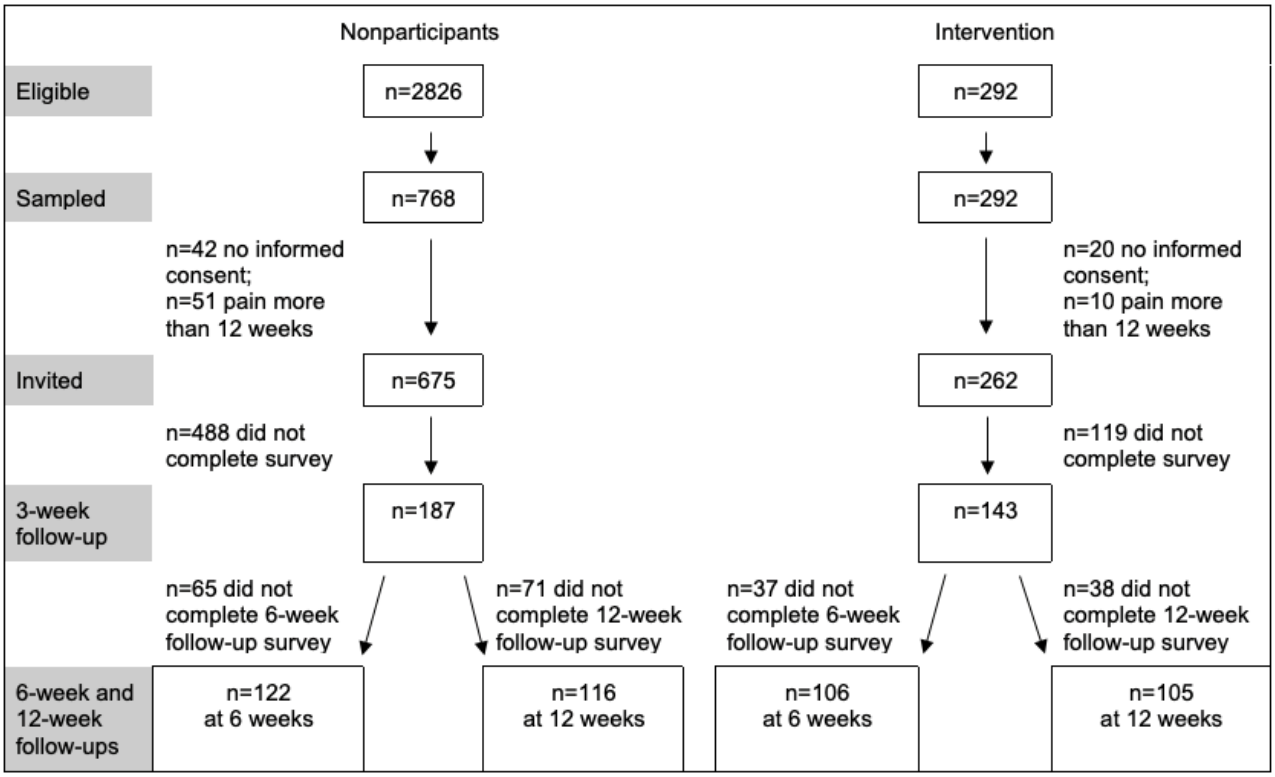
The primary analysis used all available data. The maximum likelihood estimation method was used, assuming data were missing at random. Analyses were performed in Stata (version 17.0; StataCorp) and R statistical software (version 4.0.5; R Foundation for Statistical Computing).

Results

Flowchart

Figure 1 reports the intervention and nonparticipant groups at each study stage.

Figure 1. Flowchart, by group.



Sample Characteristics

Table 2 shows the baseline characteristics for the nonparticipant and intervention groups. We detected no significant differences between the 2 groups at baseline. The mean age of the total sample was 44.1 (SD 11.9) years. At registration, mean pain was 43.0 (SD 22.3) out of 100. The largest (31.9%, 299/937) percentage of the sample registered for back pain and the smallest (13.8%, 129/937) registered for hip pain.

Table 2. Baseline characteristics.

Characteristic	Nonparticipant group (n=675)	Intervention group (n=262)	All participants (N=937)
Age (year), mean (SD)	44.0 (12.1)	44.4 (11.3)	44.1 (11.9)
Baseline pain, mean (SD)	42.9 (22.5)	43.2 (21.7)	43.0 (22.3)
Pain region, n (%)			
Back	225 (33.3)	74 (28.2)	299 (31.9)
Hip	87 (12.9)	42 (16)	129 (13.8)
Knee	119 (17.6)	53 (20.2)	172 (18.4)
Neck	140 (20.7)	49 (18.7)	189 (20.2)
Shoulder	104 (15.4)	44 (16.8)	148 (15.8)
Registration month, n (%)			
July	124 (18.4)	54 (20.6)	178 (19)
August	170 (25.2)	60 (22.9)	230 (24.5)
September	236 (35)	77 (29.4)	313 (33.4)
October	145 (21.5)	71 (27.1)	216 (23.1)

Descriptive Results

Nonparticipants' absolute decrease in pain from baseline was 11.5 points at 3 weeks, 17.9 points at 6 weeks, and 18.2 points at 12 weeks. The intervention group's absolute decrease in pain from baseline was 24.0 points at 3 weeks, 29.0 points at 6 weeks, and 30.5 points at 12 weeks (Table 3).

The percentage of participants reporting that pain as better or much better (PGIC) was 69.3% (104/150) at 3 weeks, 73.9% (85/115) at 6 weeks, and 78.5% (95/121) at 12 weeks in the intervention group. For nonparticipants, the percentages were 26% (51/196) at 3 weeks, 38.5% (50/130) at 6 weeks, and 43.1% (53/123) at 12 weeks. PGIC was higher for the intervention group than the nonparticipant group by 43.3 percentage points at 3 weeks, 35.4 percentage points at 6 weeks, and 35.5 percentage points at 12 weeks.

The percentage of participants reporting meaningful functional improvement was 56.5% (105/186) at 3 weeks, 67.9% (91/134) at 6 weeks, and 77.7% (94/121) at 12 weeks in the intervention group. For nonparticipants, the percentages were 39.3% (77/196) at 3 weeks, 51.6% (66/128) at 6 weeks, and 50.8% (62/122) at 12 weeks. The percentage reporting functional improvement was higher for the intervention group than the nonparticipant group by 17.2 percentage points at 3 weeks, 16.3 percentage points at 6 weeks, and 26.9 percentage points at 12 weeks (Table 3).

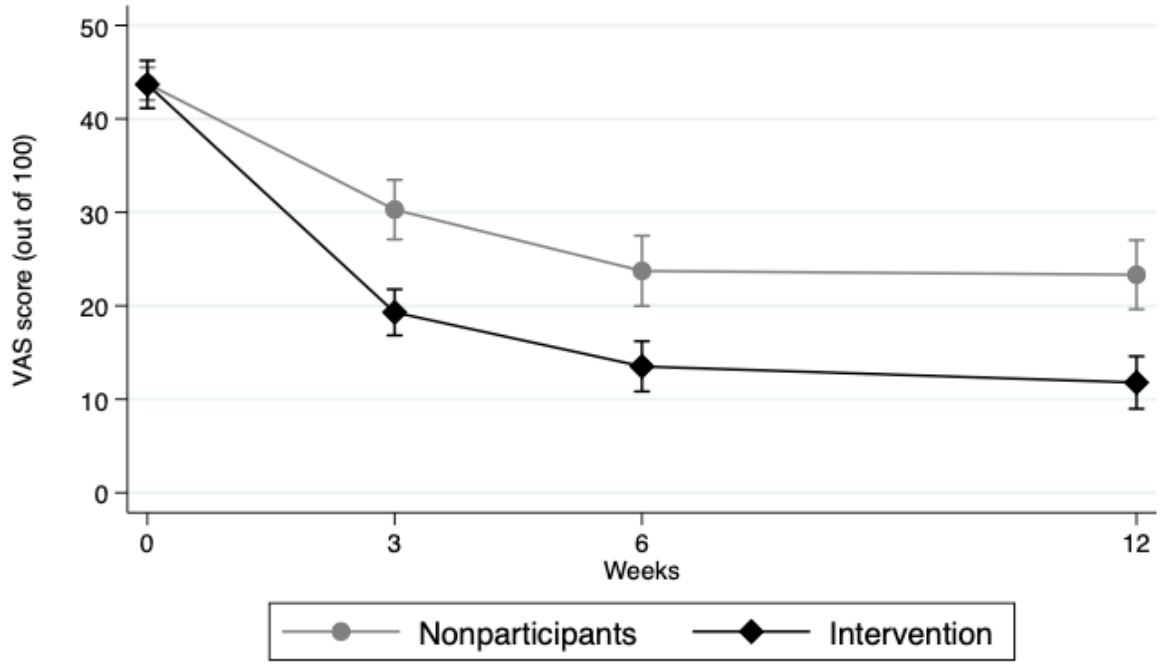
Table 3. Descriptive results: outcomes over time for nonparticipant and intervention groups.

Outcome, timepoint	Nonparticipant group	Intervention group
Pain score, mean (SD)		
Baseline	42.9 (22.5)	43.2 (21.7)
3 weeks	31.4 (22.8)	19.2 (17.9)
6 weeks	25.0 (21.6)	14.2 (16.0)
12 weeks	24.7 (20.5)	12.7 (14.2)
Patient's global impression of change, n (%)		
3 weeks (nonparticipant group: n=196; intervention group: n=150)	51 (26)	104 (69.3)
6 weeks (nonparticipant group: n=130; intervention group: n=115)	50 (38.5)	85 (73.9)
12 weeks (nonparticipant group: n=123; intervention group: n=121)	53 (43.1)	95 (78.5)
Functional improvement, n (%)		
3 weeks (nonparticipant group: n=196; intervention group: n=150)	77 (39.3)	105 (56.5)
6 weeks (nonparticipant group: n=130; intervention group: n=115)	66 (51.6)	91 (67.9)
12 weeks (nonparticipant group: n=123; intervention group: n=121)	62 (50.8)	94 (77.7)

Main Results

The intervention group showed significantly lower adjusted pain scores at follow-up compared to nonparticipants (Figure 2). For nonparticipants, adjusted pain scores decreased from 43.8 (95% CI 42-45.5) at baseline to 30.3 (95% CI 27.1-33.5) at 3 weeks to 23.7 (95% CI 20-27.5) at 6 weeks to 23.3 (95% CI 19.6-27) at 12 weeks. For the intervention group, adjusted pain scores decreased from 43.7 (95% CI 41.1-46.2) at baseline to 19.3 (95% CI 16.8-21.8) at 3 weeks to 13.5 (95% CI 10.8-16.2) at 6 weeks to 11.8 (95% CI 9-14.6) at 12 weeks.

Figure 2. Adjusted VAS score over time. Results adjusted for age, pain region, registration month, health care service use, and time as fixed effects. VAS: visual analog scale.



After adjustments, the intervention group showed a significantly higher percentage of people reporting pain was better or much better (PGIC) at follow-up versus nonparticipants. The adjusted percentage of nonparticipants who reported better or much better pain increased from 26.5% (95% CI 20.7%-32.4%) at 3 weeks to 40.9% (95% CI 32.7%-49.1%) at 6 weeks to 46.3% (95% CI 38%-54.6%) at 12 weeks. The adjusted percentage of intervention group who reported better or much better pain increased from 67.1% (95% CI 59.4%-74.9%) at 3 weeks to 72.3% (95% CI 64.1%-80.5%) at 6 weeks to 77.5% (95% CI 69.7%-85.3%) at 12 weeks (Figure 3).

The intervention group showed a significantly higher percentage of people reporting functional improvement at 3 weeks and 12 weeks compared to nonparticipants. The adjusted percentage of nonparticipants reporting functional improvement increased from 39.1% (95% CI 32.6%-45.5%) at 3 weeks to 53.2% (95% CI 44.9%-61.6%) at 6 weeks to 53.2% (95% CI 44.4%-61.9%) at 12 weeks. The adjusted percentage of intervention group reporting functional improvement increased from 54.3% (95% CI 48%-60.5%) at 3 weeks to 67.2% (95% CI 60%-74.3%) at 6 weeks to 77.8% (95% CI 70.7%-84.9%) at 12 weeks (Figure 4).

Multimedia Appendix 1 shows the unadjusted and adjusted regression model results.

Figure 3. Adjusted proportion of participants reporting pain is better or much better over time. Results adjusted for age, baseline pain, pain region, registration month, health care service use, and time as fixed effects.

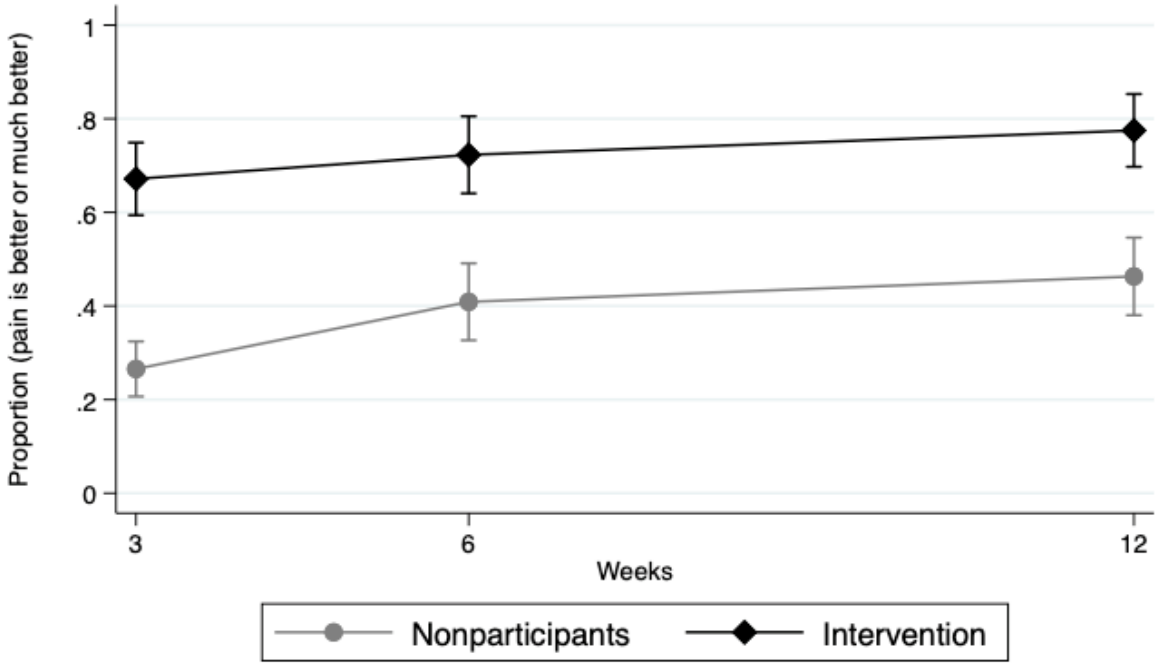
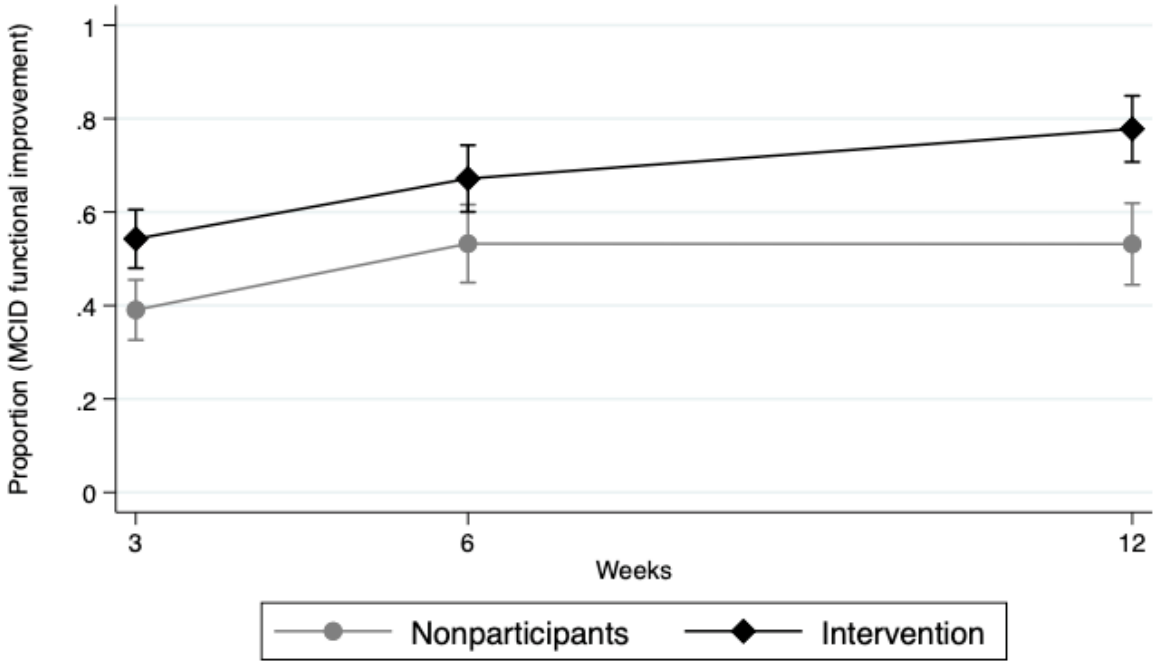


Figure 4. Adjusted proportion of participants with MCID in functional improvement over time. Results adjusted for age, baseline pain, pain region, registration month, health care service use, and time as fixed effects. MCID: minimal clinically important difference.



Engagement

By 12 weeks, the intervention group averaged 1.8 (SD 1.1; range 1-6) video visits and 17.7 (SD 21.2; median 10; range 0-103) exercise therapy sessions.

Discussion

Principal Results and Generalizability

This observational study examined pain and function at 3, 6, and 12 weeks after starting a digital MSK program for acute and subacute MSK conditions versus nonparticipants. We found significant associations between the intervention and both pain

improvement and PGIC at 3, 6, and 12 weeks. A significantly larger percentage of the intervention group also reported clinically meaningful functional improvement versus the nonparticipant group at 3 and 12 weeks.

As an observational study, we propose that findings are generalizable to the population of people with acute and subacute MSK pain with expressed interest in a digital acute MSK program. However, the study may not be generalizable to later adopters of health technology or all people with MSK pain.

Comparison to Prior Work

VAS pain scores improved from baseline to follow-up for nonparticipants and intervention group members. However, the magnitude of pain improvement was significantly greater for the intervention group. The intervention group's pain score improved from baseline by more than 10.9 points at 3 weeks, 10.1 points at 6 weeks, and 11.5 points at 12 weeks versus nonparticipants. This 10.1 to 11.5 point difference is similar to pain improvement shown in meta-analyses of spinal manipulative therapy (mean difference: 10; 95% CI 4-16) and exceeds that of nonsteroidal anti-inflammatory drugs for acute back pain (mean difference: 7; 95% CI 4-11) [27,28]. Our results are also consistent with recent meta-analyses reporting that exercise is an efficacious treatment for acute and subacute low back pain in the immediate term [9].

We detected statistically significant associations between the digital MSK program and meaningful functional improvement. In contrast, the effect of traditional services and medications on functional improvement have not been consistently demonstrated in acute MSK injuries [5]. Our study found that a significantly greater percentage of the intervention group reported meaningful functional improvement versus nonparticipants at 3 and 12 weeks, but not at 6 weeks. This may be due to the small sample size. We also suggest that nonparticipants' function improved over time but at a slower rate than the intervention group. Furthermore, the intervention group continued to make progress in function beyond the 6-week mark, whereas nonparticipants' functional improvement plateaued between 6 and 12 weeks. The ways that a digital acute MSK program changes the trajectory of functional improvement over time and in the long term are an area for additional research in the future.

We found that the intervention group averaged 1.8 video visits and 17.7 exercise therapy sessions by week 12. Although we did not collect self-reported information about exercises conducted without the app, this engagement data about completed exercise sessions demonstrated the feasibility of using app-based data to monitor member adherence to recommended exercises. This objective measure of adherence may supplement self-reports about efficacy and confidence in doing exercises. Adherence to exercises delivered through digital health programs has been shown to match or exceed that of in-person programs, and improved adherence is associated with better treatment outcomes for MSK needs [29-32].

Strengths and Limitations

Study strengths include the use of data from 2 prospective cohorts who were similar in age, pain, and pain region at baseline. As a result, the study resulted in the longitudinal monitoring of a digital acute MSK program versus a nonparticipant group. Further, to our knowledge, our study is the first to evaluate a digital MSK program for acute and subacute needs against a nonparticipant group. The comparison group is essential given the natural history of acute and subacute MSK conditions. Improvement was assessed using 3 different outcomes, and we evaluated the program in real-world settings.

First, a study limitation is that this observational study cannot establish the causality of the intervention's effect on outcomes. Second, we may have omitted important confounding variables (eg, motivation) that attenuate outcome estimates. Furthermore, we did not document the types of medications that study participants took to address pain and function. To build on current findings, we recommend a randomized controlled trial to establish causality and account for the effect of unmeasured factors. Third, more granular follow-up timepoints (eg, weekly) could provide more insight into the longitudinal course of pain and function in an acute digital MSK program. Future studies could use daily diaries to document exercise adherence and changes in daily pain to show time to pain resolution in days or weeks. Fourth, the study examines acute and subacute needs as a whole, and we do not report on outcomes for each region (ie, back, knee, shoulder, hip, or neck) separately. It is possible that the outcomes vary from region to region, and positive outcomes in one region might mask neutral or even negative outcomes in another region. To address this concern, we controlled for region in the regression models. Future studies could examine outcomes for specific regions or present stratified results.

Conclusions

This study provided evidence that a digital acute MSK program may help improve pain and function in the short term among those with acute and subacute MSK needs. Future studies can build upon these results to further evaluate the extent to which digital health effectively manages a range of MSK needs, including acute and subacute needs.

Acknowledgments

Hinge Health, Inc provided the digital musculoskeletal program to participants.

Data Availability

The data sets generated during and/or analyzed during the current study are not publicly available because data are proprietary but are available from the corresponding author on reasonable request.

Authors' Contributions

GW, MY, MH, JK, and JFB designed the study. GW, MY, and MH analyzed the data. GW, MY, MH, JK, and JFB interpreted data and were major contributors in writing the manuscript. GW, MY, MH, JK, and JFB read and approved the final manuscript.

Conflicts of Interest

GW, MH, and JK are employees of Hinge Health, Inc and have equity interest in Hinge Health, Inc.

Multimedia Appendix 1

Unadjusted and adjusted models comparing the intervention group to nonparticipants for each outcome.
[DOCX File , 14 KB-Multimedia Appendix 1]

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Abbreviations

HOOS-PS: Hip disability and Osteoarthritis Outcome Score Physical Function Short form
KOOS-PS: Knee injury and Osteoarthritis Outcome Score Physical Function Short form

MCID: minimal clinically important difference
MSK: musculoskeletal
PGIC: patient's global impression of change
PT: physical therapist
RMDQ-11: 11-item Roland Morris Disability Questionnaire
sf-NPAD: Neck Pain and Disability Scale short form
SPADI: Shoulder Pain and Disability Index
VAS: visual analog scale

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