Smartphone-Delivered Pain Self-Management Education For Chronic Low Back Pain: A Usability Study

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Abstract

The aim of this study was to examine usability of a chronic pain self-management education tool, delivered via a low risk general wellness device. Of 117 fully eligible candidates, 37 people with chronic low back pain were enrolled into an 8 week, smartphone-delivered, coach-supported program that integrates evidence-based principles from pain neuroscience education, cognitive behavioral therapy, and mindfulness meditation. We observed high rates of program completion (85%) and completion of twice-daily ratings of pain, mood, and sleep (87.6%). Participant engagements heavily focused on Aivo Health Coach messaging (671 total clinic messages sent) and social peer group comments, posts, and likes (560 total peer group actions). Coach and peer group engagement metrics were not significantly associated with degree of pain relief. Exploratory analyses revealed that 49% of participants experienced moderate to substantial pain relief (>20% decrease in back pain intensity from baseline) with the Aivo Program. This study suggests that the Aivo Program shows preliminary evidence as a pain self-management tool for people living with chronic low back pain.

Keywords: mobile health, digital therapeutics, chronic pain, mindfulness, usability.

The Problem of Chronic Pain

Chronic pain is an enormous societal burden, with healthcare costs exceeding $500 billion annually in the USA. Back pain is the leading cause of chronic pain in the USA, and worldwide it is the sixth greatest cause of work days lost due to disability. Chronic low back pain is the single largest cause of lost work and has major personal and societal consequences. There is no single treatment that is effective for relieving chronic pain, regardless of treatment modality. The ability to relieve the impact of chronic low back pain would reduce health care expenditures, increase overall productivity, and improve quality of life for millions of Americans.

Chronic pain impacts diverse aspects of a person's life. As a result, the perception of pain becomes entangled with its biopsychosocial impact. The consequences of living with chronic low back pain conflate nociception with negative mood and distorted motivation (Baliki and Apkarian 2015). For these reasons the gold standard psychological treatment for chronic pain, cognitive behavioral therapy (CBT), targets and ameliorates the sequelae of chronic pain, rather than pain proper (Cunningham, Kashikar-Zuck, and Coghill 2019; Ehde, Dillworth, and Turner 2014). Importantly, the concepts and coping strategies imparted by combined mindfulness-CBT programs can be extracted from the therapeutic context to inform self-guided education for people living with chronic pain.

Concepts derived from cognitive behavioral and mindfulness theories are used in a broad variety of wellness tools available to the general public. The development of an educational tool that adapts these concepts to chronic pain can help people understand the impact of pain and develop optimal coping strategies needed to reduce this impact. Establishing a broad base of coping skills is essential for maintaining health and a healthy lifestyle, even in the presence of ongoing pain.

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However, there are currently no broadly available digital health strategies that meet the enormous need for education and support for people living with chronic pain.

MATERIALS AND METHOD

The Aivo Health Program Intervention

Aivo Health aims to reverse the cycle of pain by delivering self-guided pain management education through a low-risk general wellness device. The Aivo Program incorporates ideas from evidence-based approaches, including mindfulness-based stress reduction, cognitive behavioral therapy, behavioral activation therapy, and pain neuroscience education validated by high quality studies (Anheyer *et al.* 2017; Richmond *et al.* 2015; Wood and Hendrick 2019). Aivo content is delivered via text, animations, videos, podcasts, and guided meditations and was created by a clinical psychologist trained in chronic pain management and approved by two independent licensed psychologists.

Aivo educational themes focus on enhancing daily function with cognitive and behavioral coping strategies, managing emotions related to chronic low back pain, promoting positive lifestyle choices (e.g., stress management, exercise, sleep hygiene), and instilling learners with knowledge needed to weigh risks and benefits of their health care options. Educational content is followed by guided exercises related to the impact and consequences of living with chronic pain. Based on each participant's stated health goals, the app provides personalized content and recommendations by filtering information to individual-specific characteristics. Participants choose which recommendations they wish to pursue. Motivation and support are provided by Health Coaches via in-app chat and social interactions with other users takes place in a moderated social forum.

Participants were directed to use the Aivo program each day for 20-30 minutes, Monday to Friday. App use included rating pain intensity twice a day and consuming daily "playlists" of educational content. Participants received morning and evening reminder notifications to rate their pain (at 9:00 AM and 9:00 PM, participant's local time) every day during the study.

Study Design

This study uses a single-armed quasi-experimental, pre-/post-intervention design to assess the utility of an app-based approach to pain management. Symptoms of pain, mood, and sleep were collected at baseline and twice daily throughout an 8 week study period to determine whether consistent interaction with the app facilitates engagement and adherence. Investigation of these parameters is expected to support the use of the app as an educational tool for individuals living with chronic low back pain.

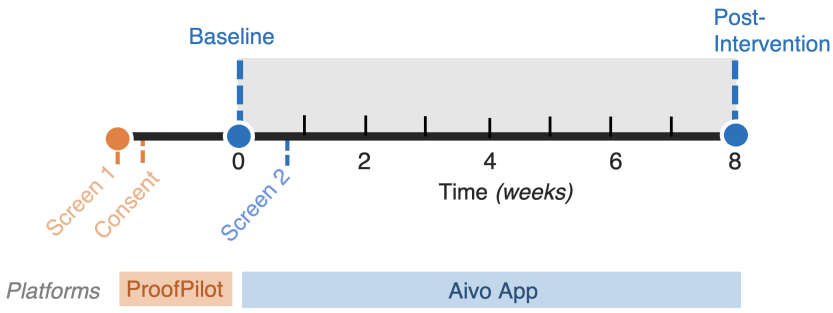

Figure 1. The study design for this 8 week study includes screening and consent through the ProofPilot platform prior to downloading the Aivo app. Participants are screened for one week of consistent app use prior to study enrollment.

Table 1. Demographic characteristics of participants with chronic low back pain

	All Participants Mean *(SD)*	Improvers* Mean *(SD)*	Non-Improvers* Mean *(SD)*
Sample size	37	18	19
Gender	33 F / 4 M	17 F / 1 M	16 F / 3 M
Age	53.34 *(9.04)*	48.00 *(17.43)*	54.29 *(8.30)*
Type of Pain(s)			
Low Back	100% (37/37)	100% (18/18)	100% (19/19)
Whole-body	11% (4/37)	5% (1/18)	16% (3/19)
Arthritis	5% (2/37)	0% (0/18)	10% (2/19)
Migraine	3% (1/37)	6% (1/18)	0% (0/19)
Knee	3% (1/37)	6% (1/18)	0% (0/19)
Hip	3% (1/37)	6% (1/18)	0% (0/19)
Pain Duration (yrs)	16.74 *(12.73)*	18.88 *(11.93)*	14.82 *(13.43)*
Pain at Entry	5.58 *(2.11)*	6.24 *(1.79)*	*5.00 (2.26)*
Month Prior to Entry			
Average Pain	6.86 *(1.69)*	6.94 *(1.39)*	6.79 *(1.96)*
Peak Pain	8.64 *(1.22)*	8.65 *(1.11)*	8.63 *(1.34)*
Pain change over time			
Comes and goes	32% (12/37)	22% (4/18)	42% (8/19)
Stays the same	5% (2/37)	11% (2/18)	0% (0/19)
Stays the same, with flares	62% (23/37)	67% (12/18)	58% (11/19)
Prior Treatments			
Over the counter medications	97% (36/37)	94% (17/18)	100% (19/19)
Prescription medications	86% (32/37)	89% (16/18)	84% (16/19)
Physical therapy	78% (29/37)	78% (14/18)	79% (15/19)
Injections / nerve blocks	68% (25/37)	67% (12/18)	68% (13/19)
Electrical stimulation / TENS	57% (21/37)	50% (9/18)	63% (12/19)
Surgery	27% (10/37)	28% (5/18)	26% (5/19)
Psychological Treatment	14% (5/37)	17% (3/18)	11% (2/19)

* Improvement classification is based on exploratory analyses.

The study was conducted in accordance with the International Conference on Harmonisation guidelines for Good Clinical Practice and the Code of Federal Regulations on the Protection of Human Participants. The protocol, screening, and informed consent documents were approved by IntegReview (Protocol #2551). Participants did not receive monetary compensation for the study.

RESULTS

Participants and Recruitment

Participants underwent initial screening and electronic informed consent via the ProofPilot platform. Of the 404 prospective participants screened through ProofPilot, 60 individuals did not meet inclusion criteria. Of the 344 individuals who met inclusion criteria, 264 completed e-consent and were given unique promo codes to download the Aivo app onto their personal devices. The app was downloaded by 117 of eligible and consented individuals. To be enrolled in the study, individuals who downloaded the Aivo app were asked to complete 1 week of consistent app content to demonstrate motivation to self-manage their condition. To remain enrolled in the study, participants had to show adequate motivation, defined as > 50% compliance to app use defined in the study protocol. A total of 37 individuals met enrollment criteria throughout the 8 week study.

The following inclusion criteria were applied:

1. Low back pain lasting more than 3 months in men or women between ages 18-75;
2. Resides in the United States;
3. In generally stable health;
4. Provided informed consent;

5. Strong motivation throughout trial (greater than 50% daily app use); and
6. Demonstrated five days of consistent daily use of app prior to formal enrollment.

Prospective participants meeting any of the following were excluded from the study:
1. Low back pain associated with systemic symptoms;
2. Significant neurological conditions and/or medical diseases; or
3. In the judgment of the investigator, unable or unwilling to follow instructions related to app use.

Statistical Analysis

Data analysis was performed on anonymized data by an external consultant. Normally distributed data were assessed with paired t-tests comparing baseline and post-intervention daily pain, mood, and sleep ratings. Distribution normality was determined with Shapiro-Wilk test and examined with a QQ plots. Non-normal data were evaluated with Wilcoxon Signed-Rank Test. Correlations were evaluated with Pearson's method. For this exploratory study, a sample size of 37 was deemed appropriate given the large number of within-subjects measures over the course of the 8 week study. For all analyses, we adopted an alpha level of $p<0.05$ (two-tailed).

Sample Description

Thirty-seven participants (33 females, 4 males) took part in the study (demographics and pain history presented in Table 1). Low back pain was the primary complaint in all participants, with secondary pain complaints including whole-body pain (11%), arthritis pain (5%), migraine (3%), knee pain (3%), and hip pain (3%). Participants had chronic low back pain for an average of 16.7 years. In the month prior to study entry, average pain intensity was 6.8/10 and peak pain intensity was 8.6/10. The majority of participants (62%) reported that back pain tended to stay the same over time, with occasional pain flares. Approximately one-third of participants (32%) reported that pain "comes and goes," and a minority (5%) reported that pain intensity stays the same over time.

All participants had tried prior treatments for pain that provided temporary or no relief. Most participants had managed their pain using over the counter medications (97%) or prescription medications (86%). A large percentage (78%) tried physical therapy, injections/nerve blocks (68%), and electrical stimulation/ transcutaneous electrical nerve stimulation (TENS) (57%), with partial or temporary relief. Less than a third (27%) of participants had prior surgery to treat pain, and 14% tried any form of psychological treatment to treat pain. In summary, participants had exhausted many first- and second-line treatments for pain management prior to trying the Aivo Program.

The current sample reported an average pain intensity of 5.6 (out of 10, average over the first week), which corresponds with moderately strong pain that interferes with daily activities and is consistent with clinically significant pain. On average, the group's mood was neutral (5.5/10) and sleep was okay (5.1/10). All group averages for pain, mood, and sleep are shown in Table 2.

Table 2. Baseline characteristics of participants with chronic low back pain

	PAIN Baseline / 8 wks	MOOD Baseline / 8 wks	SLEEP Baseline / 8 wks
All Participants	**5.63** *(0.31)* / **4.65** *(0.38)***	**5.52** *(0.25)* / **5.73** *(0.30)*	**5.13** *(0.33)* / **5.63** *(0.34)*
Improvers*	**5.70** *(0.40)* / **3.49** *(0.37)***	**5.75** *(0.31)* / **6.24** (0.24)	**4.49** (0.35) / **5.72** (0.39)**
Non-Improvers*	**5.57** *(0.49)* / **5.76** *(0.54)*	**5.30** *(0.40)* / **5.24** *(0.52)*	**5.73** *(0.53)* / **5.55** *(0.58)*

* Improvement classification is based on exploratory analyses.
** Paired t-tests between baseline and 8 weeks were significantly different, $p < 0.01$.

Table 3. Engagement metrics during the 8 week study

	TOTAL Engagement	Coach Messages	PEER GROUP Comments	Posts	Likes
All Participants	**1231**	**671**	**224**	**112**	**224**
Improvers*	632	304	130	51	147
Non-Improvers*	599	367	94	61	77

* Improvement classification is based on exploratory analyses.

Program Completion

On average, participants completed 87.6% of twice-daily pain ratings. Participants entered an average of 1.8 ratings each day out of the requested 2 daily ratings. On average, participants completed 85.0% of all program content, or the equivalent of 2.2 pieces of content each day during the 8 week program.

We conducted exploratory analyses to determine whether program completion metrics were related to degree of pain relief. Participants who achieved more than 20% pain relief ("improvers," n=18) were more consistent with twice-daily ratings (91%) compared to those who reported less than 20% pain relief (84%). Similarly, participants who achieved more than 20% pain relief consumed more program content than those who experienced less pain relief (89% versus 81%, respectively).

Program Engagement

Participants completed an average of 125.57 sessions (SD=90.8) over 55.19 days (SD=33.8), with an average of 2.14 sessions/day (SD=0.5). On average, participants engaged with the Aivo program on 6.8 days out of 7 during the 8 week program.

Participants sent a total of 671 messages in the clinic chat to their health coach. Interestingly, some participants communicated regularly with their health coach, and others preferred not to communicate with their health coach at all. No differences in health coach communication were observed between Aivo improvers and non-improvers (see Table 3 for all clinical and social engagement metrics).

Peer group activity consisted of 112 social forum posts, 224 comments in response to social forum posts, and 224 "likes" of posts and comments. Again, some participants were heavily active on the social forum, and other participants preferred to focus on the Aivo Program without emphasizing peer interactions.

Degree of engagement showed no correlation with amount of pain reduction.

Impact on Symptom Reduction

Exploratory analyses were conducted to understand the potential impact of the Aivo Program on symptom reduction in study participants. Across all participants, a significant reduction in pain was observed from baseline (average = 5.63, SE = 0.31) to 8 weeks (average = 4.65, SE = 0.38), $t(1,36) = 3.99$, $p < 0.01$. Therefore, a significant improvement in pain intensity was observed following 8 weeks of the Aivo program.

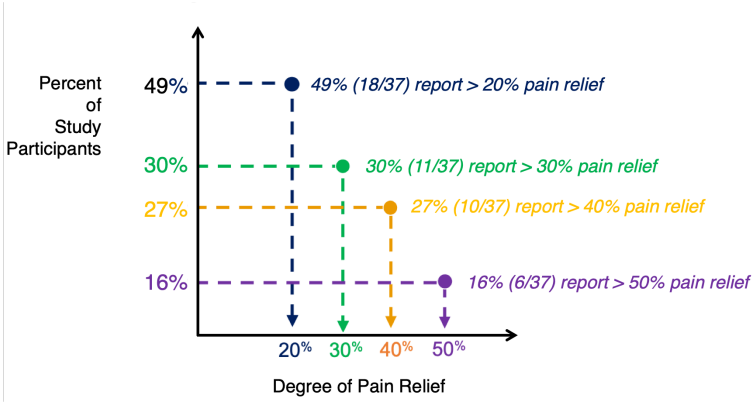

Figure 2. Participants who responded to the Aivo intervention (y axis) exhibited differing degrees of pain relief (x axis). Aivo "improvers" were defined as people who reported >20%pain reduction after the 8 week trial (**midnight blue**), although a subset of people reported 30% pain reduction (**green**), 40% pain reduction (**orange**) or 50% pain reduction (**purple**). Exact number of participants are shown for each category of pain relief.

Given that the pain medicine literature considers 20% pain reduction to be a clinically meaningful effect, we adopted this threshold to identify Aivo intervention "improvers." Aivo improvers showed a significant reduction in pain from baseline (average = 5.70, SE = 0.40) to 8 weeks (average = 3.49, SE = 0.37), $t(1,17) = 9.35$, $p < 0.01$. Aivo improvers also reported a significant improvement in sleep from baseline (average = 4.49, SE = 0.35) to 8 weeks (average = 5.72, SE = 0.39), $t(1,17) = -2.81$, $p < 0.01$. In Aivo improvers, a nonsignificant trend toward improved mood was also observed over the 8 week study. No significant changes in pain, mood, or sleep were observed in the “non-improver” group who exhibited < 20% pain reduction. To summarize, participants who experienced significant pain relief with the Aivo Program also reported significant improvements in sleep during the study.

Figure 2 illustrates degrees of pain relief in Aivo improvers, which ranged from 20% to 74% pain reduction following the 8 week program. Specifically, 49% of participants (18 of 37 people) reported greater than 20% reduction in pain, 30% of participants (11 people) reported over 30% pain reduction, 27% of participants (10 people) reported over 40% pain reduction, and 16% of participants (6 people) reported 50% pain reduction.

The trajectories of pain reduction varied dramatically across Aivo improvers. Figure 3 illustrates how twice-daily pain ratings revealed rapidly changing pain intensity levels in six improvers across the 8 week study. A subset of participants experienced a dramatic drop in pain within 2-3 weeks in the Aivo program, whereas pain relief was a more gradual process in other participants. Short-term exacerbations in pain were commonly observed in many participants who showed significant pain relief at the end of the intervention.

In a subset of Aivo improvers, we observed elevations in mood during brief and prolonged periods of pain relief. In most cases, elevations of positive mood remained stable even with mild-to-moderate fluctuations in pain. Three case studies of Aivo improvers who showed concurrent improvements in pain and mood are detailed in Figure 4.

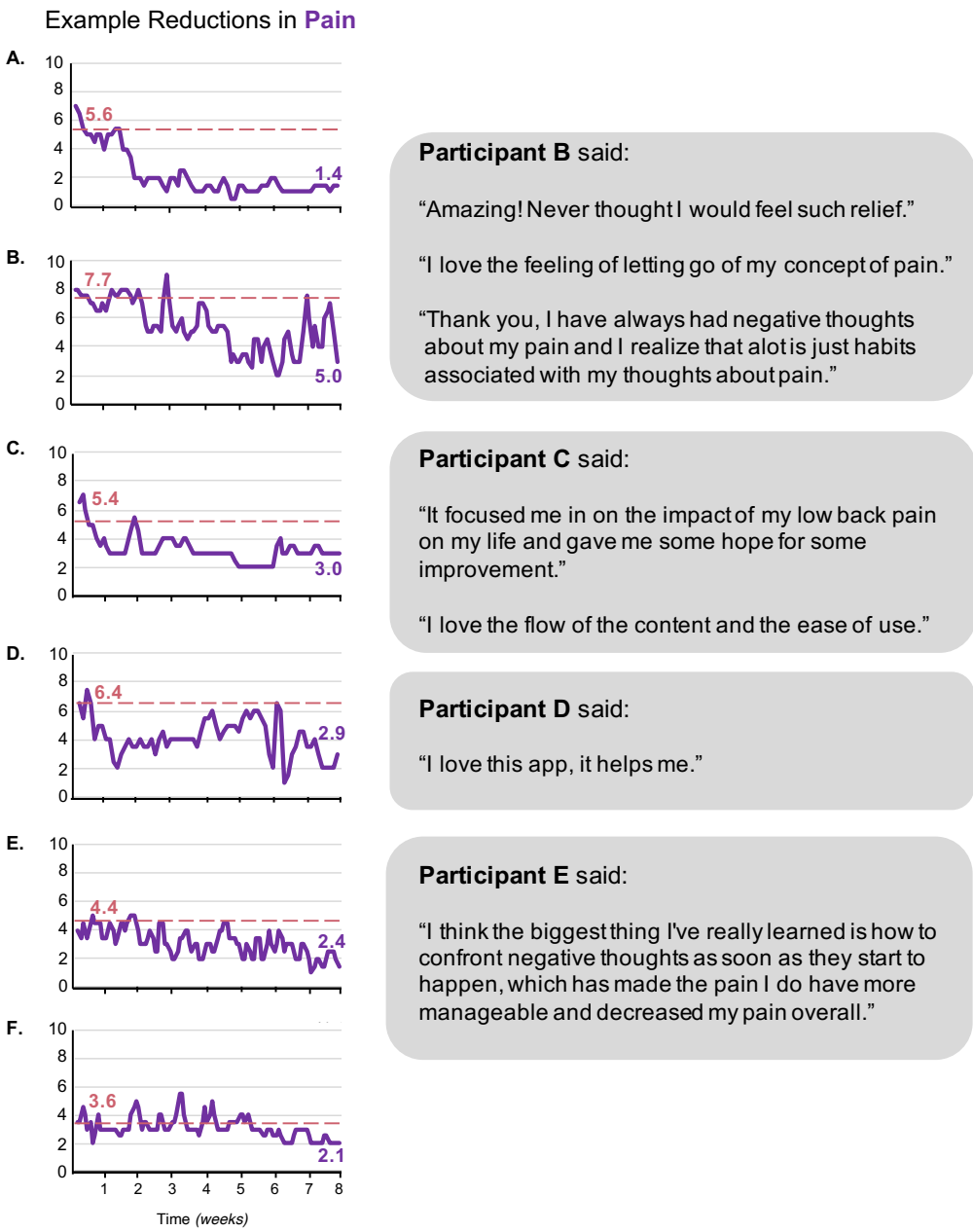

Figure 3. Each Aivo "improver" who exhibited >20% reduction in pain had a unique journey to pain relief. Here we show data from 6 participants who provided twice-daily pain ratings throughout the 8 week study. For each participant, baseline average pain is marked with a red dotted line. Baseline pain averages (red) and post-8 week pain averages (**purple**) are listed for each participant.

Discussion

The findings of this single-armed quasi-experimental, pre-/post-intervention study support the usability and feasibility of a chronic pain self-management education tool, delivered via a low-risk general wellness device. A high percentage of participants enrolled in the study (87.6%) completed of twice-daily ratings and completed 85.0% of all program content. Participants completed an average of 125.57 sessions over 55.19 days, with an average of 2.14 sessions each day on 6.8 out

of 7 days during the 8 week program. These real-world completion rates appear to be greater than industry standard alternatives like in-person cognitive behavioral therapy for chronic pain (Kerns *et al.* 2014; Malins *et al.* 2020).These feasibility results and evidence of preliminary efficacy are clinically meaningful, given the urgent need for education and support for people living with chronic low back pain.

Exploratory analyses revealed the degree of pain relief exhibited by Aivo "improvers" ranged from 20% to 74% following the 8 week Aivo program, with significant improvements in sleep quality observed at the end of the intervention. By collecting two pain measurements per day, we obtained high-resolution data that revealed the ebb and flow of pain intensity throughout the study period. Our previous work has established brain-based physiological mechanisms underlying these subjective fluctuations of chronic low back pain (Baliki *et al.* 2006; Reckziegel *et al.* 2019). Each person's unique trajectory of pain relief reinforces the importance of a personalized approach to pain management. By continuously tracking pain and related symptoms, the Aivo Program empowers participants to build a unique path to pain self-management from the comfort of their home.

Based on exploratory analyses, a potential time-based interaction between pain and mood was identified in a subset of improvers that merits further investigation in future work. Pain is, by definition, part sensory and part emotional. The link between pain and negative emotion has been well-studied in the pain field (Porreca and Navratilova 2017). Previous investigations focused on the relationship between pain and mood at single time points. In the current study, the high resolution data collected from twice-daily ratings allowed a glimpse into the dynamic relationship between pain and mood. Even within a single day, we observed that surges in pain can create short-term drops in mood that make it more difficult to cope with rising pain. Further studies are needed to determine whether the Aivo intervention provided protection against more enduring drops in mood during the study period.

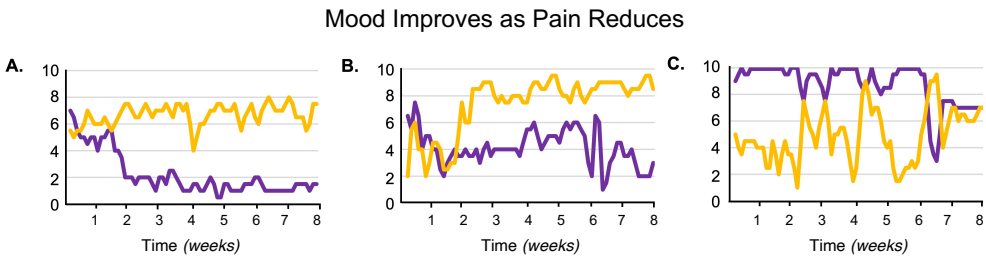

Figure 4. In a subset of participants, pain relief (**purple**) is accompanied by improvements in mood (**orange**). (A) A participant exhibiting rapid reduction in pain within 3 weeks shows improving mood that lasts throughout the 8 week study. (B) Another participant who reports rapid pain reduction within 2 weeks shows sustained elevations in mood, despite transient pain flare events that ultimately resolve during the study period. (C) A participant who showed high, sustained pain levels shows clear elevations in mood during transient reductions in pain, before exhibiting a significant reduction in pain at the end of the study.

Participants showed strong engagement with their health coach and with their peer group. The Aivo Program was designed to accommodate a range of personal preferences related to coach and peer support. Social support is an under-utilized approach to chronic pain management that helps people with pain manage feelings of isolation, obtain encouragement, and facilitates sharing of pain self-management strategies (Matthias *et al.* 2016). A close evaluation of program engagement metrics, including coach messages and social forum posts, comments, and "likes," highlighted that social engagement within the app did not correlate with degree of pain relief in the current study. Nevertheless, for a subset of participants these avenues of social support were daily sources of inspiration that supported their personal pain journey.

Strengths and Limitations

Major strengths of this study focus on the novelty of the intervention and the rich data set collected through the app. This is one of the first studies conducted of a mobile health intervention that specifically targets pain, mood, and sleep, with symptom changes rivaling success observed with in-person psychological support for chronic low back pain. Our rich data set suggests that a multidisciplinary approach combining daily symptom ratings, consistent content consumption, coach support, and peer group support interact synergistically to improve symptoms over time. The continuous monitoring of daily pain, mood, and sleep using daily ratings facilitates high-resolution symptom tracking that is not feasible in standard healthcare settings and thus improves on the existing model of pain management. We recognize our study has several limitations, including small sample size, lack of a control group, and a limited number of outcome measures. Exploratory analyses identifying pain reduction need to be confirmed in future clinical trials comparing the Aivo Program to standard treatments for chronic low back pain to verify effectiveness. Nevertheless, the promising findings in such a small sample reinforce the potential of the Aivo Program to support people who live with chronic low back pain.

Conclusions

The Aivo Program fosters respect, dignity, and compassion for people who live with ongoing low back pain by providing education and strategies needed to reclaim their minds and bodies. The 8 week Aivo Program is a coach-supported intervention that provides self-guided pain management education and is a promising tool for people who live with chronic low back pain. Given the enormous need for education and support for people living with chronic pain, an evidence-based digital health strategy like the Aivo Program can help reverse the cycle of chronic pain.

Conflicts of Interest

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: all authors had financial support from Aivo Health, Inc. for the submitted work. M. Farmer is employed as Chief Clinical Officer of Aivo Health, Inc., receives salary from the company, and owns stocks of the company. Dr. Apkarian serves as an unpaid Scientific Advisor for Aivo Health, Inc. and owns stocks of the company.

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