Journal of Pain Research

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ORIGINAL RESEARCH

Digital Rehabilitation for Acute Low Back Pain: A Prospective Longitudinal Cohort Study

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Background: Low back pain (LBP) has a lifetime prevalence of 70–80%. Access to timely and personalized, evidence-based care is key to prevent chronic progression. Digital solutions may ease accessibility to treatment while reducing healthcare-related costs.

Purpose: We aim to report the results of a fully remote digital care program (DCP) for acute LBP.

Patients and Methods: This was an interventional, single-arm, cohort study of patients with acute LBP who received a DCP. Primary outcome was the mean change in disability (Oswestry Disability Index – ODI) after 12 weeks. Secondary outcomes included change in pain (NPRS), analgesic consumption, surgery likelihood, depression (PHQ-9), anxiety (GAD-7), fear-avoidance beliefs (FABQ-PA), work productivity (WPAI) and engagement.

Results: A total of 406 patients were enrolled in the program and of those, 332 (81.8%) completed the intervention. A significant disability reduction of 55.1% (14.93, 95% CI 13.95; 15.91) was observed, corresponding to a 76.1% responder rate (30% cut-off). Disability reduction was accompanied by significant improvements in pain (61.0%), depression (55.4%), anxiety (59.5%), productivity (65.6%), fear-avoidance beliefs (46.3%), intent to pursue surgery (59.1%), and analgesic consumption (from 35.7% at baseline to 10.8% at program end). DCP-related patient satisfaction score was 8.7/10.0 (SD 1.4).

Conclusion: This study demonstrated the utility of a multimodal DCP for patients with acute LBP. Very high adherence rates and patient satisfaction were observed, alongside significant reductions in all assessed outcomes, consistent with the growing body of evidence supporting the management of acute LBP with DCPs.

Keywords: physical therapy, telerehabilitation, digital therapy, eHealth, musculoskeletal conditions

Plain Language Summary

Low back pain (LBP) has a very high lifetime prevalence (70–80%) and is a leading cause of absenteeism. In about 65% of patients, acute episodes of LBP are not resolved after 12 months, challenging the notion that spontaneous recovery protects most individuals from long-term LBP. Therefore, preventing progression to chronic pain is a priority.

Current guidelines emphasize exercise-based treatments, combined with pain self-management strategies as the indicated approach. Major care barriers relate to access, time and travel constraints. Digital telerehabilitation programs have shown similar results to in-person care, and may solve these challenges, while improving engagement and reducing costs. These programs are still not well explored for acute LBP management.

Received: 14 April 2022
Accepted: 11 June 2022
Published: 3 July 2022

In this study, we assessed the progress of a large group of patients going through a digital care program managed by a physical therapist. This program integrates exercise, education on back pain, and tools for mental strength and self-management. Exercises are guided through a tablet and motion trackers which provide real-time feedback during each exercise.

We report meaningful improvements in disability (55.1%), pain (61.0%), mental health (55.4–59.5%), surgery likelihood (59.1%) and productivity (65.6%), which were associated with high engagement and satisfaction levels. Importantly, individuals at higher risk (with higher initial pain) were not less likely to respond to the treatment.

This study supports the utility of digital care programs in the early stage of LBP management, to improve functionality, well-being and productivity.

Introduction

Low back pain (LBP) has long been the world's leading cause of years lived with disability[1] and a leading cause of worker absenteeism.[2–4] The lifetime prevalence of LBP is extremely high (70–80%),[5–7] which is expected to worsen, given the rise in life expectancy and increasing rate of obesity and persistently lower levels of physical activity than our ancestors engaged in.[7,8] In the United States (US), nearly 66 million adults suffer from LBP,[9] which was the major contributor for the more than $134.5 billion (95% CI, $122.4-$146.9 billion) in healthcare spending for spine pain in 2016.[10]

Evidence shows that about 65% of patients with acute LBP will still report pain after 12 months,[11] questioning the assumption that spontaneous recovery protects most individuals from long-term LBP. Preventing progression to a chronic disease state is a priority, which might be attained through individually tailored evidence-based interventions in the acute and subacute stages of LBP.[12–14] Current research and guidelines place emphasis on active exercise-based treatments embedded in a biopsychosocial framework using cognitive behavioral therapy (CBT) and self-management.[15–19] Such interventions can promote significant recovery at lower costs, which include reduced utilization of health-care services,[20] a reduction in unnecessary imaging procedures,[21,22] and fewer surgeries.[23] Exercise-based treatments, combined with education have been demonstrated to reduce the risk of future episodes of LBP and facilitate return to work.[24–28] However, several barriers continue to prevent widespread access to such interventions, namely a lack of available providers in some regions, which may particularly impact vulnerable populations, and constraints associated with travel and treatment time,[29] which have been amplified during the COVID pandemic.[30]

Entirely digital interventions, consisting of programs managed remotely/asynchronously by health-care professionals using communication-based technologies, show great potential in overcoming such challenges and improving care, as reflected in the growing number of clinical trials and systematic reviews.[31–35] These may be more affordable and accessible than in-person rehabilitation, while easing caregiver burden.[36,37] Patient adherence and empowerment may also be maximized through these approaches.[38] Most telerehabilitation studies have been focused on populations with chronic LBP,[32,33,35,39–42] while acute LBP is less well-explored.[34,43–45]

Previously, we have demonstrated the effectiveness of tailored digital care programs (DCP) in other musculoskeletal conditions.[46–52] The present study aims to assess the outcomes and engagement of a fully remote multimodal DCP integrating exercise and education, including major components of CBT, on a real-world cohort of patients with acute LBP stratified by pain level at baseline. We hypothesize that this multimodal DCP can provide significant improvement independent of the reported pain at baseline to an extent comparable to those reported in the literature for other conventional or telerehabilitation approaches.

Methods

Study Design

Single-arm, decentralized study assessed clinical and engagement-related outcomes after a multimodal digital care program (DCP), in patients with acute LBP. This study is part of a trial that was prospectively approved by the New England Institutional Review Board (number 120190313) and registered on ClinicalTrials.gov (NCT04092946) on September 17th 2019. The study was conducted in accordance with the Declaration of Helsinki. An exploratory analysis using baseline pain as a risk stratification variable was additionally pursued to ascertain the potential impact of this parameter on observed outcomes. The home-based DCP was delivered between June 29th 2020 and November 4th 2021.

Participants

Individuals participating in health plans of employers from 44 states in the US, older than 18 years of age and reporting acute LBP (defined as pain below the costal margin and above the inferior gluteal folds less than 12 weeks in duration) were invited to apply for SWORD Health's DCP (Draper, Utah, USA) through a dedicated website. Exclusion criteria included: (1) a health condition (eg, cardiac, respiratory) incompatible with at least 20 minutes of light to moderate exercise; (2) receiving treatment for active cancer; and (3) reporting rapidly progressive loss of strength and/or numbness in the arms/legs or unexplained change in bowel or urinary function in the previous 2 weeks.

Informed consent was obtained from all participants before study start. To prevent the risk of selection bias, consecutive participants were enrolled until the cut-off date of August 12th, 2021. This cut-off date resulted in the inclusion of 23% (92/406) participants with acute LBP already studied by Costa et al.[51]

Intervention

The current intervention was previously described.[51,52] Briefly, a 12-week telerehabilitation intervention consisting of exercise, education and CBT was delivered through a DCP, which interfaced between the patient and an assigned physical therapist (PT) who monitored the patient for the study duration. An FDA-listed class II medical device comprised two inertial motion trackers, a mobile app on a dedicated tablet, and a cloud-based portal, was made available. Personalized exercise sessions (Annex 1) were performed independently at the patients' convenience through the tablet display (3 sessions per week were recommended). By placing trackers on the thoracic and lumbar regions through straps, the system provided real-time video and audio biofeedback on performance. A cloud-based portal enabled asynchronous and remote monitoring by the assigned PT, who adjusted the exercise program as needed. The education and CBT component, developed according to current clinical guidelines and research, included topics centered around anatomy, physiology, symptoms, evidence-based treatments, fear-avoidance, and active coping skills (including dealing with feelings of anxiety and depression). The CBT program was based on third-generation CBT techniques – mindfulness, acceptance and commitment therapy and empathy-focused therapy. Education and CBT components were delivered on a weekly basis. These were delivered through written articles, audio content and interactive modules. Bi-directional communication was ensured through a built-in secure chat within a smartphone app (at least one touchpoint each week) and video calls (at least once every 4 weeks). Participants who did not engage in any exercise session for 28 consecutive days were considered dropouts.

Outcomes

Outcomes were collected at baseline, 4, 8 and 12 weeks, and mean changes were calculated between baseline and 12 weeks.

Primary outcome was self-reported disability, using the Oswestry Disability Index (ODI), which has been validated for patients with acute and subacute LBP.[53,54] ODI includes 10 items scored using a 5-point Likert scale (score range 0–100%), whereby higher scores correspond to greater disability.[55] Secondary outcomes included the following clinical and engagement outcomes:

Pain level, using the Numerical Pain Rating Scale (NPRS), through the question: "Please rate your average pain over the last 7 days from 0 (no pain at all) to 10 (worst pain imaginable)"

Analgesic consumption: "Are you currently taking any pain medication?"

Willingness to undergo surgery: "How likely are you to have surgery to address your condition in the next 12 months?" (range 0 - not at all likely; 100 - extremely likely)

Generalized Anxiety Disorder (GAD-7) 7-item scale (range 0-21)[56] to assess anxiety, and Patient Health (PHQ-9) 9-item questionnaire (range 0-27) to assess depression.[57,58] A threshold equal or greater than 5 was used to identify at least mild anxiety or depression

Fear-Avoidance Beliefs Questionnaire for physical activity (FABQ-PA), which includes 4 items scored on a 7-option Likert scale (0-24)[59]

Work Productivity and Activity Impairment (WPAI) for general health questionnaire, evaluated employed participants to assess overall work impairment (WPAI overall: total presenteeism and absenteeism from work), presenteeism (WPAI work), absenteeism (WPAI time) and activities impairment (WPAI activity)[60]

Engagement: through completion of the program (considered as the retention rate); number of completed exercise sessions; time spent performing exercise sessions; and overall satisfaction (Net promoter score) through the question: "On a scale from 0 to 10, how likely is it that you would recommend this intervention to a friend or neighbor?"

Safety and Adverse Events

Patients were instructed to report pain and fatigue scores (graduated from 0 to 10) at the end of each exercise session, as well as any adverse events when they occurred. These were continuously monitored remotely by the PT.

Data Availability

All relevant data underlying the study are included in the article or available as Supplementary Material. The protocol, de-identified data and analysis codes may be provided on request to the corresponding author.

Statistical Analysis

The study population demographics and clinical data, as well as usability metrics are characterized through descriptive statistics with differences between completers and non-completers assessed through independent samples *t*-test, one-way ANOVA with Bonferroni post-hoc or Chi-squared test.

Latent growth curve analysis (LGCA) was used to model the trajectories of all outcome variables over time, following an intent-to-treat principle. Because higher levels of baseline pain intensity are a risk factor for chronicity and poorer outcomes,[61,62] an exploratory analysis using baseline pain as a risk stratification variable was pursued. Three groups (risk groups: low, medium and high) were created based on pain levels at baseline: (i) mild (≤3), (ii) moderate (4–6), and (iii) severe (≥7).[63] Missing data was dealt with full information maximum likelihood estimation.[64–67] Intercept, slope and curve were determined to represent each variable trajectory. Intercept provides information on baseline values, slope represents the outcome estimated linear change over time, while curve indicates whether a leveling effect exists. Models were adjusted for covariates and fitted as random effects allowing each to vary between individuals (see structural equation and path diagram for the LGCA used in Supplementary Figure 1). A robust sandwich estimator for standard errors was used in all model estimation. Analyses were performed both for unfiltered cases and filtering for (i) >0 for surgery intent and WPAI, and (ii) ≥5 points for GAD-7 and PHQ-9. A conditional analysis was also performed to assess the influence of age, sex, and body mass index (BMI) as covariates. Model fit estimation was assessed through chi-squared test, root mean square error of approximation (RMSEA), confirmatory fit index (CFI), and standardized root mean square residual (SRMR).[68,69]

Logistic regression analysis was performed to identify the association of baseline variables with being a responder for pain reduction, considering a minimum clinically important difference (MCID) of 30% between baseline and treatment end.[70,71]

Bivariate correlations (Pearson r) were used to investigate associations between outcomes. Correlations were classified as weak until 0.24, moderate 0.25–0.49, strong 0.50–0.74 and very strong 0.75–1.0. Significance levels were set at $p < 0.05$ in all analyses. LGCA was coded using R (version 1.4.1717) and all other analyses were performed using SPSS (version 17.0, SPSS Inc, Chicago, Illinois, USA).

Results

Eligibility screening was conducted for 496 participants. From these, 25 (5.0%) declined participation and 65 (13.1%) were excluded, with 406 starting the program. The study flow diagram is presented in Figure 1. Program completion rate was 81.8% (332/406).

Baseline Characteristics

Participant's baseline demographics (N = 406) are presented in Table 1. The average participant was middle-aged (mean 46.6 years (SD 11.8)) with moderate pain (mean pain score 4.50, 95% CI 4.29; 4.70) and an average disability of 14.93

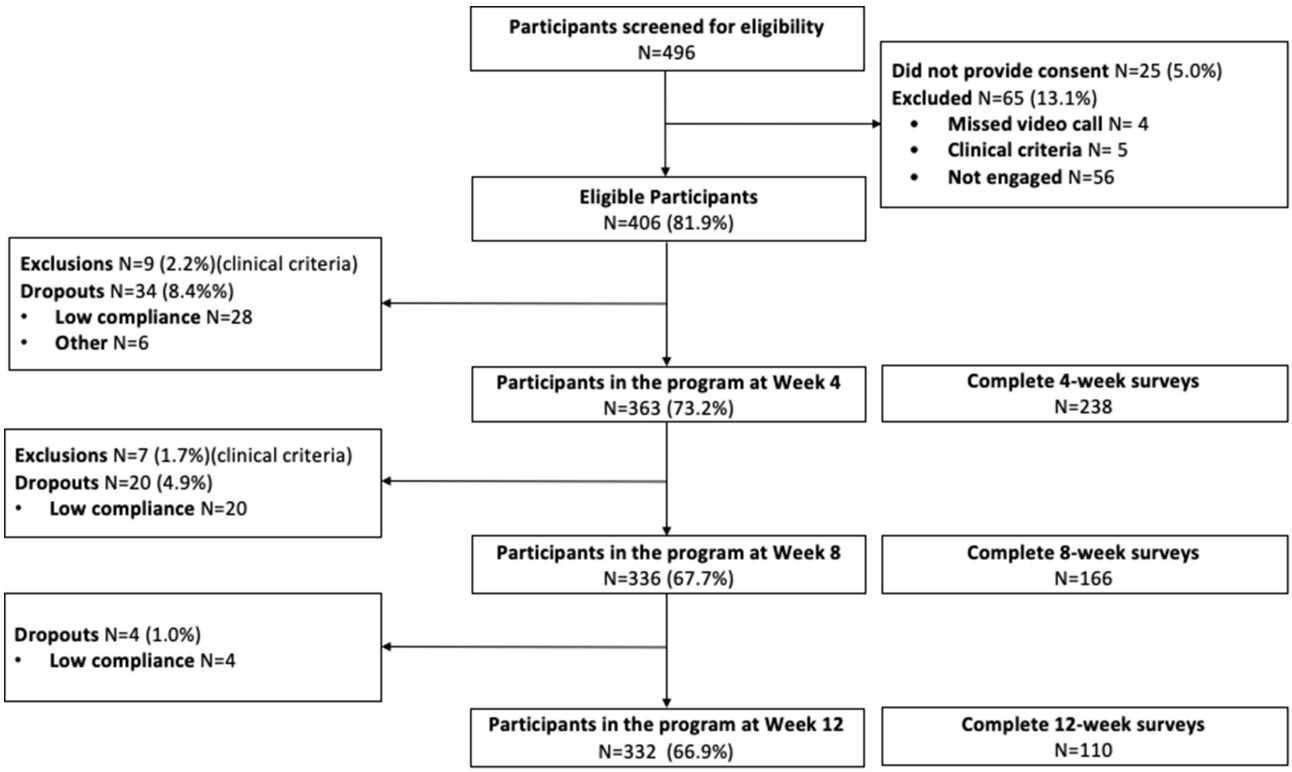

Figure 1 Study flow diagram.

(ODI) (95% CI 13.95, 15.91). Baseline clinical characteristics divided by risk subgroups are presented in Supplementary Table S1. Differences are discussed further within subgroup analyses.

Comparing completers (N = 332) with non-completers (N = 74), the latter were younger (p = 0.015) at baseline (Supplementary Table S2). No significant differences were observed in terms of baseline clinical measures, including the type of pain presentation (with or without radiating pain).

Clinical Outcomes

For each outcome variable, a multiple-group LGCA was conducted to model changes in clinical outcomes over time, considering the entire cohort and then each subgroup following an intent-to-treat principle (N = 406), alongside model fit (Supplementary Tables S3 and S4, respectively). Results from the unconditional model are presented in Table 2, while the impact of covariates is presented in the conditional model (Supplementary Table S5).

Primary Outcome

ODI

Participants reported a significant reduction in ODI (p < 0.001, Supplementary Table S3), of 8.22 points (95% CI 6.93; 9.51) representing an overall change of 55.1% (Table 2, Figure 2). Females, and those with higher BMI at baseline reported higher baseline ODI levels (p < 0.001 and p = 0.005, respectively), with females recovering at a faster pace (−0.96 per week, p = 0.006) (Supplementary Table S5). Considering the recommended minimal clinically important improvement cutoff of 30% for disability,[70,71] an odds ratio (OR) of 3.19 (95% CI 2.10; 5.00) was observed, corresponding to an 76.1% responder rate (p < 0.001). The OR for being a responder was not influenced by age, BMI nor mental health status at baseline (Supplementary Table S6).

Table 1 Baseline Characteristics of Study Participants (N = 406)

Characteristic	Estimate
Age (years), mean (SD)	46.6 (11.8)
Age categories (years), N (%):	
<25	4 (1.0)
25–40	137 (33.7)
40–60	209 (51.5)
> 60	56 (13.8)
Sex, N (%)	
Female	190 (46.8)
Male	216 (53.2)
BMI, mean (SD)	28.3 (6.2)
BMI categories, N (%):	
Underweight (<18.5)	4 (1.0)
Normal (18.5–25)	125 (30.8)
Overweight (25–30)	151 (37.2)
Obese (30–40)	103 (25.4)
Obese grade III (>40)	23 (5.7)
Pain radiating to lower limb[a], N (%):	
No pain	281 (69.6)
With pain	123 (30.4)
Employment status, N (%):	
Employed (part-time or full-time)	385 (94.8)
Unemployed (not working or retired)	21 (5.2)
Occupation type[b], N (%):	
White collar	164 (40.3)
Blue collar	122 (30.0)
Other (eg retired)	36 (8.8)

Notes: Missing values: [a]N = 2; [b]N = 85.
Abbreviation: BMI, body mass index.

Secondary Outcomes

Pain

Significant reduction was observed for pain, translating to an improvement of 61.0% at 12 weeks (mean change 2.74, 95% CI 2.38; 3.11). Females and those with higher BMI reported more pain at baseline ($p = 0.002$ and $p = 0.005$, respectively, Supplementary Table S5). Females showed a faster recovery pace compared to males (−0.15, $p = 0.042$). Pain reduction was strongly correlated with disability (ODI) recovery ($r(117)=0.580$, $p < 0.001$).

Analgesic Usage

One-third of the participants (35.7%, 144/403) reported analgesic usage at baseline. An overall reduction of analgesic consumption was observed, with only 10.8% of participants (12/111) still taking analgesics by study end.

Surgery Intent

Willingness to undergo surgery decreased along the study timeline at a pace of −2.42 points (SD 0.95) per week ($p < 0.001$), resulting in a reduction of 59.1% by end of program (Table 2). Participants who had higher BMI scores at baseline reported greater willingness to undergo surgery before the intervention ($p = 0.006$) but recovered at a faster pace (−0.24 per week, $p = 0.013$). Older participants recovered at a slower pace (0.06 per week, $p = 0.049$).

Mental Health and Fear-Avoidance Beliefs

Significant improvement was observed on both mental health indicators ($p < 0.001$), revealing a mean change of 59.5% for GAD-7 (4.93 points, 95% CI: 3.77; 6.09) and 55.4% for PHQ-9 (4.70 points, 95% CI: 3.36; 6.03) at end of program.

Table 2 Changes in Clinical Outcomes Between Baseline and 12-Weeks: Intent-to-Treat (Unconditional Model)

Outcome, Mean (95% CI)	N	Baseline	End of Program	Mean Change	% Change
ODI	406	14.93 (13.95; 15.91)	6.71 (5.45; 7.97)	8.22 (6.93; 9.51)	55.1%
Pain Level	406	4.50 (4.29; 4.70)	1.75 (1.42; 2.09)	2.74 (2.38; 3.11)	61.0%
Surgery Intent >0 Surgery Intent (all)	135 403	9.94 (6.45; 13.43) 4.73 (3.63; 5.82)	4.07 (−1.53; 9.67) 1.80 (0.49; 3.11)	5.87 (0.45; 11.29) 2.92 (1.41; 4.44)	59.1% 61.9%
FABQ-PA	406	11.21 (10.23; 12.18)	6.02 (5.15; 6.89)	5.19 (4.01; 6.36)	46.3%
GAD-7 ≥5 GAD-7 (all)	100 403	8.29 (7.57; 9.01) 2.92 (2.56; 3.29)	3.36 (2.25; 4.47) 1.33 (0.98; 1.68)	4.93 (3.77; 6.09) 1.59 (1.21; 1.98)	59.5% 54.5%
PHQ-9 ≥5 PHQ-9 (all)	67 403	8.47 (7.50; 9.44) 2.37 (2.05; 2.70)	3.77 (2.52; 5.02) 0.93 (0.64;1.22)	4.70 (3.36; 6.03) 1.45 (1.12; 1.78)	55.4% 60.9%
WPAI Overall >0 WPAI Overall (all)	192 345	29.44 (26.10; 32.78) 16.08 (13.70; 18.46)	10.13 (3.70; 16.56) 5.41 (2.26; 8.55)	19.31 (12.03; 26.58) 10.67 (6.98; 14.37)	65.6% 66.4%
WPAI Work >0 WPAI Work (all)	187 345	27.32 (24.46; 30.17) 14.41 (12.33; 16.50)	9.45 (3.67; 15.24) 5.37 (2.44; 8.31)	17.86 (11.48; 24.25) 9.04 (5.80; 12.28)	65.4% 62.7%
WPAI Time >0 WPAI Time (all)	51 345	23.25 (15.47; 31.02) 3.24 (1.81; 4.67)	3.24 (−0.10; 6.58) 0.19 (−0.09; 0.46)	20.01 (11.34; 28.67) 3.06 (1.66; 4.46)	86.1% 94.3%
WPAI Activity >0 WPAI Activity (all)	295 403	32.67 (30.13; 35.21) 23.66 (21.34; 25.97)	7.46 (4.66; 10.26) 5.98 (4.22; 7.74)	25.21 (21.77; 28.65) 17.68 (15.08; 20.28)	77.2% 74.7%

Notes: Analyses were performed both for unfiltered cases and filtering for above zero (>0) for surgery intent (individuals with intention to undergo surgery at baseline) and WPAI (individuals with productivity impairment at baseline); and above or equal to five (≥5) points for GAD-7 and PHQ-9 (individuals with at least mild anxiety and depression at baseline).

Abbreviations: ODI, Oswestry Disability Index; GAD-7, Generalized Anxiety Disorder 7-item scale; PHQ-9, Patient Health 9-item questionnaire; FABQ-PA, Fear-Avoidance Beliefs Questionnaire for physical activity; WPAI, Work Productivity and Activity Impairment questionnaire.

Reduction of PHQ-9 scores was slower in participants with higher BMI (0.05 per week, $p = 0.012$), and was correlated with ODI recovery ($r(117)=0.276$, $p = 0.003$). Regarding fear-avoidance beliefs (FAB), a significant improvement of 46.3% (mean change 5.19, 95% CI 4.01; 6.36) was observed.

Work Productivity

Productivity recovery improved significantly by 65.6% on WPAI overall score (mean change 19.31, 95% CI 12.03; 26.58, $p < 0.001$), 65.4% on the WPAI work score (mean change 17.86, 95% CI 11.48; 24.25, $p < 0.001$) and 77.2% on WPAI activity (25.21, 95% CI 21.77; 28.65). Regarding WPAI time, 14.8% (51/345) individuals had some degree of absenteeism at baseline which was reduced by 86.1% (20.01; 95% CI 11.34; 28.67) by program end. Older participants experienced a faster recovery pace on work (−0.12, $p = 0.028$) and therefore on WPAI overall (−0.15, $p = 0.011$). Females presented with higher baseline levels of activity impairment ($p = 0.031$), with no effect on recovery pace. Overall productivity recovery was correlated with disability (ODI) recovery ($r(94)=0.476$, $p < 0.001$), pain reduction ($r(94)=0.409$ $p < 0.001$), lower willingness to undergo surgery ($r(94)=0.363$, $p < 0.001$) and improvement in mental health indicators: anxiety (GAD-7, $r(94)=0.368$, $p < 0.001$) and depression (PHQ-9, $r(94)=0.362$, $p < 0.001$).

Engagement and Usability-Related Outcomes

Participants performed an average of 33.2 (SD 29.2) sessions, and engagement levels were high (average 2.7 sessions a week, SD 1.3; completers: 2.8 sessions a week, SD 1.3), independent of whether individuals experienced low, medium or high pain levels at baseline ($p = 0.450$). Total exercise duration was 1345.5 minutes (SD 289.7). Higher levels of engagement were observed in the first weeks (3.2, SD 1.7 at 4 weeks vs 2.2, SD 1.5 after 4 weeks, $p < 0.001$). Each participant read on average 4.3 pieces of educational and CBT content (SD 6.9). Average satisfaction was 8.7 (SD 1.4) with 65% (251/385) of participants reporting a 9 or 10, 29% (113/385) reporting 7 or 8 and 6% (21/385) reporting 6 or less.

Sub-Group Analysis: Risk Stratification

According to the pain thresholds proposed by Miró et al,[63] risk subgroups were created. Besides pain, these also differed on ODI ($p < 0.001$), analgesic consumption ($p < 0.001$), surgery intent ($p = 0.011$), FABQ ($p < 0.001$) and productivity impairment ($p < 0.001$), but not on mental health scores ($p = 0.493$ and $p = 0.094$, for anxiety and depression, respectively) (Supplementary Table S1). Higher risk subgroups (medium and high pain levels at baseline) had poorer clinical metrics. All subgroups had similar demographic characteristics, except for sex ($p = 0.016$), BMI ($p = 0.029$), and pain radiating to lower limb ($p = 0.020$), with males and those with lower BMI and without radiating pain to lower limb reporting lower pain levels at baseline. Despite the existence of referred leg pain being reported as a poorer prognostic factor,[12,13,72] herein no significant improvement differences were observed between participants with or without radiating pain, with the exception of WPAI activity, with higher improvement observed in those with radiating pain (Supplementary Table S7).

A higher recovery pace was observed in the medium and high-risk subgroups for pain (Figure 2), which translated into greater mean change in these subgroups (61.2% (3.06 95% CI 2.59; 3.54) and 66.8% (5.08 95% CI 4.16; 6.01)) vs 56.9% (1.32 95% CI 1.01; 1.64) (Table 3 and Supplementary Table S4). These subgroups reached mean changes above the minimal clinically important improvement of 30%,[70,71] with a higher OR observed in the high-risk subgroup (OR 7.50, 95% CI 2.12; 47.60), corresponding to an 88.2% responder rate ($p < 0.001$); participants within the medium-risk subgroup had an OR of 6.50 (95% CI 3.27; 14.81), corresponding to an 86.7% responder rate ($p < 0.001$). Higher mean changes were also observed in the medium and high-risk subgroup for ODI with a change of 8.25 (95% CI 6.26; 10.24) and 15.51 (95% CI 12.04; 18.97), respectively, vs in low-risk patients (5.08 95% CI 3.58; 6.58) (Figure 2). Greater productivity impairment recovery was observed in the high-risk subgroup compared with medium and low-risk subgroups (21.95 95% CI 12.65; 31.26 vs 10.05 95% CI 4.43; 15.67 and 5.65 95% CI 2.76; 8.54, respectively). Higher mean changes were also observed in the high-risk subgroup for surgery intention, anxiety, depression and FABQ without reaching statistical significance (Table 3). Analgesics intake decreased in all groups from 21.0% (30/143), 38.5% (72/187) and 56.8% (42/74), to 2.6% (1/39), 16.4% (9/55) and 11.8% (2/17), for low, medium and high-risk patients, respectively.

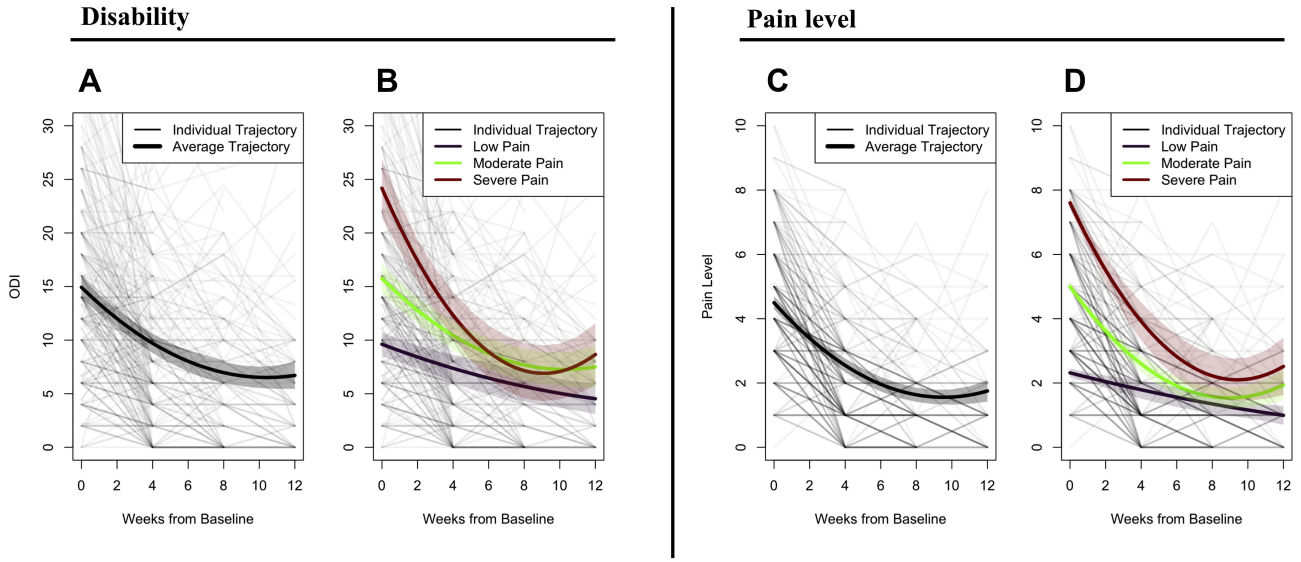

Figure 2 Longitudinal changes across time for ODI and pain level. Individual trajectories are depicted in lighter lines (with darker lines meaning overlap of trajectories), while average trajectories are depicted in bold lines, with shadowing depicting 95% confidence intervals. (**A**) Overall ODI change; (**B**) ODI change by risk groups; (**C**) overall pain change; (**D**) pain change by risk groups.

Table 3 Outcomes Changes Between Baseline and End of Program Based on Risk Subgroups: Intent-to-Treat Approach (Unconditional Model)

	Low			Medium					High				
Outcome Mean (95% CI)	**N**	**Mean Change**	**% Change**	**N**	**Mean Change**	**% Change**	**Difference Medium-Low**	**p**	**N**	**Mean Change**	**% Change**	**Difference High-Medium**	**p**
ODI	144	5.08 (3.58; 6.58)	52.8%	188	8.25 (6.26; 10.24)	52.3%	3.17 (0.62; 5.71)	**0.015**	74	15.51 (12.04; 18.97)	64.2%	7.25 (3.42; 11.09)	**<0.001**
Pain Level	144	1.32 (1.01; 1.64)	56.9%	188	3.06 (2.59; 3.54)	61.2%	1.74 (1.21; 2.27)	**<0.001**	74	5.08 (4.16; 6.01)	66.8%	2.02 (1.06; 2.98)	**<0.001**
Surgery Intent	143	2.13 (0.03; 4.29)	77.2%	186	2.65 (0.55; 4.74)	51.8%	0.52 (−2.45; 3.49)	0.732	74	5.59 (1.84; 9.35)	73.7%	2.95 (−1.05; 6.94)	0.149
GAD-7	143	1.65 (1.11; 2.19)	62.3%	186	1.52 (0.94; 2.11)	51.4%	−0.13 (−0.93; 0.68)	0.761	74	1.63 (0.41; 2.84)	48.7%	0.10 (−1.28; 1.49)	0.886
PHQ-9	143	1.13 (0.75; 1.51)	58.5%	186	1.47 (0.94; 1.99)	58.8%	0.34 (−0.31; 0.99)	0.312	74	2.04 (0.93; 3.15)	69.9%	0.58 (−0.69; 1.84)	0.373
FABQ-PA	144	4.75 (2.65; 6.84)	44.9%	188	5.32 (3.52; 7.11)	48.6%	0.57 (−2.36; 3.50)	0.703	74	4.97 (1.60; 8.35)	37.7%	−0.34 (−4.21; 3.53)	0.863
WPAI Overall	125	5.65 (2.76; 8.54)	66.9%	156	10.05 (4.43; 15.67)	62.5%	4.40 (−1.45; 10.25)	0.141	64	21.95 (12.65; 31.26)	68.9%	11.90 (2.02; 21.78)	**0.018**
WPAI Work	125	4.91 (2.22; 7.59)	64.3%	156	7.32 (2.55;12.09)	53.0%	2.41 (−2.64; 7.46)	0.349	64	21.92 (14.44; 29.40)	73.9%	14.60 (6.69; 22.50)	**<0.001**
WPAI Time	125	1.60 (0.10; 3.30)	93.6%	156	2.95 (1.00; 4.90)	100%	1.35 (−1.21; 3.92)	0.301	64	6.04 (1.36; 10.73)	85.4%	3.09 (−1.97; 8.16)	0.232
WPAI Activity	143	7.66 (4.33; 10.99)	59%	186	19.02 (15.46; 22.58)	79%	11.36 (6.50; 16.21)	**<0.001**	74	34.08 (26.49; 41.67)	77.4%	15.06 (6.74; 23.38)	**<0.001**

Note: Significant p-values are presented in bold.

Abbreviations: ODI, Oswestry Disability Index; GAD-7, Generalized Anxiety Disorder 7-item scale; PHQ-9, Patient Health 9-item questionnaire; FABQ-PA, Fear-Avoidance Beliefs Questionnaire for physical activity; WPAI, Work Productivity and Activity Impairment questionnaire.

https://doi.org/10.2147/JPR.S369926 DovePress

Discussion

Main Findings

This multimodal DCP was able to promote high engagement and completion rates, which translated into clinically meaningful improvements in all outcome measures. A significant reduction in disability was observed (55.1%), with a 76.1% responder rate based on a minimal clinically important improvement of 30%.[70,71] Importantly, this recovery was accompanied by improvements in pain (61.0%), depression (55.4%) and productivity (65.6% improvement). Meaningful reductions were also noted in surgery likelihood (59.1%), fear-avoidance beliefs (46.3%), anxiety (59.5%) and analgesic consumption (from 35.7% at baseline to 10.8% at program end).

Significant improvements in all LBP risk subgroups were seen after the DCP, with higher reductions in pain, ODI, analgesics intake, and productivity impairment in the high-risk subgroup, suggesting that higher risk individuals are not less likely to respond to this treatment, as has been reported previously.[61]

Comparison with Literature

Telerehabilitation has demonstrated similar outcomes in comparison to in-person rehabilitation for LBP.[32,41,73] However, telerehabilitation studies focusing specifically on acute or sub-acute cohorts are still scarce in the literature, varying not only in the type of intervention but also in treatment duration and reported outcomes, making a direct comparison with the DCP in the present study difficult.[43–45]

Del Pozo et al[44] conducted an RCT comparing a web-based exercise-related intervention to standard occupational care. After a nine-month regimen, an ODI reduction was observed in 37% of the intervention group vs 6.8% of the control group. Although the absolute reduction was not reported, these results seem to suggest that a web-based approach can support LBP rehabilitation. Reported disability recovery with conventional therapies ranges between 22.9% and 53.5%.[74,75] Herein, an ODI change of 55.1% was observed, aligned with the highest recoveries reported, and in line with evidence showing that multimodal approaches can be better than usual care for effective acute LBP recovery.[28] Disability improvements greater than reported in the present study were only observed in cohorts where pain onset started in less than 16 days or with high baseline disabilities (>20%).[76,77]

In a retrospective study by Huber et al involving patients with LBP, the authors did not find difference in pain reductions for acute, subacute and chronic cohorts (mean change 21.9%) following an app-based intervention including patient education, video-guided physical therapy, and mindfulness training.[78] Within conventional therapy studies, interventions comprising exercises and/or CBT have reported pain reductions ranging from 28% to 79.4%.[74,76,77,79,80] Herein, we observed a mean change in back pain scores of 2.74 (95% CI 2.38; 3.11), corresponding to an overall 61.0% reduction, which is higher than that reported in most studies,[74,79,80] but not in some which excluded participants with low disability at baseline.[76,77]

Willingness to undergo surgery has been found to be one of the strongest predictors of future surgery.[81,82] Herein, an overall 59.1% reduction in the willingness to undergo surgery was observed, which was higher (74%) in the high-risk subgroup. These results are consistent with the recommendation to trial conservative therapies first.[83,84]

The number of participants reporting analgesic intake decreased until program end. However, the lack of universally applied measures to quantify analgesic consumption precludes direct comparison to other studies.

Fear-avoidance beliefs have been associated with transition into chronic LBP.[85] In this study, we observed a 46.3% improvement in FABQ-PA, higher than that reported for other CBT or exercise interventions (22.0% to 28.6% improvements).[79] Moreover, significant reduction in both anxiety (59.5%) and depression (55.4%) was observed to a greater extent than that reported by Hill et al[75] (15.8–23% for anxiety and 18.3–29.3% for depression, using HADS). Similarly, Jensen et al[86] described an RCT that compared a multidisciplinary intervention with usual care and reported higher mental health recoveries with the former. The superior results herein reported might reflect the pertinence of having a multimodal DCP which combines PT-monitored exercise programs with education and CBT components.

High productivity improvement was observed, with a 65.6% reduction in overall WPAI, which combines improvements in both presenteeism (65.4%) and absenteeism (86.1%). Productivity recovery was positively correlated with reductions in disability, pain, surgery likelihood, anxiety and depression. These results are consistent with evidence that

a multimodal biopsychosocial treatment plan can effectively increase the likelihood of return-to-work and fewer sick leave days at 12-months follow-up.[17,28]

In this study, a completion rate of 81.8% was obtained, in line with that reported by telerehabilitation and conventional programs tackling acute LBP (17.8–97%) with higher completion rates being reported only in studies with much smaller cohorts.[44,61,75,77,78,84] Higher engagement rates were observed in the first weeks of intervention, which paralleled steeper improvements in all outcomes early on, in accordance with what has also been reported for other telerehabilitation interventions.[42,87]

Subgroup Analysis

The hurdles and socioeconomic burden imposed by chronic conditions have directed research towards identifying risk factors for chronicity and tailoring care accordingly (personalized medicine).[72,74,75,77,83] Current recommendations are evolving[88] and the argument that a large majority of patients will recover rapidly from acute LBP is debatable.[11,89,90] Three distinct subgroups were created based on baseline pain levels, to determine the results of the tailored DCP across these subgroups, particularly in high-risk individuals. In line with what was reported by other authors,[13,91] the high-risk subgroup in the present study presented with greater baseline disability, FABQ scores and a higher frequency of radiating pain, but also expressed higher willingness to pursue surgery, had a higher rate of analgesic intake and experienced greater productivity impairment. This suggests that subgrouping LBP patients according to pain level was suitable to identify those at higher risk.

The observed changes in outcomes were better across subgroups with higher levels of risk (medium and high) for pain, ODI, analgesic intake, PHQ-9 and productivity impairment. Pain reductions ranged from 56.9%, to 61.2% and 66.8% for low, medium and high-risk patients, respectively. Other studies that tailored care following risk stratification found improvements in the same range: from 52.8% to 75% in medium-risk and 50% to 79.4% in high-risk patients.[75,77] Similar results were observed for disability, with greater improvement found in higher risk groups.[75,77] Patients with worse baseline clinical outcomes might be at higher risk to transition into chronic states, and they simultaneously present a greater opportunity for improvement, if the condition is tackled appropriately. This supports the recommendation that multimodal treatment should be employed to optimize outcomes,[17,18,28] and suggests that higher risk individuals are not less likely to respond to a remote DCP.

Strengths and Limitations

The strengths of this study include the novelty of the approach – amulti-component DCP managed by PTs, which combines exercises with real-time biofeedback within a biopsychosocial framework.[92,93] The digital format favors accessibility, while the regular communication with the same PT may enhance adherence, thereby maximizing clinical outcomes.[38,94] Other strengths include the large sample size focused on a less studied acute cohort, stratified by risk, as well as the broad set of secondary outcome measures[56–60] comprising multiple domains.

The major limitation is the lack of a control group. However, considering the high accessibility of this DCP, using a "wait list" control group would not be ethical. Still, taken together, the aspects reported herein on engagement and observed outcomes, as well as the insights derived from the exploratory analysis, will help guide future RCT comparing the DCP against in-person intervention, supporting member stratification based on baseline pain levels. Other limitations include the lack of long-term follow-up to assess the persistence of results and relapse rates, and failure to assess the effect of each individual component.

Conclusions

This study demonstrated the utility of a multimodal DCP for patients with acute LBP across different risk groups. Very high adherence rates and patient satisfaction were observed, alongside clinically significant reductions in disability, pain, analgesic consumption, surgery intent and mental health, which in turn resulted in marked productivity recovery. These results strengthen the argument for managing acute LBP by tailoring care to specific needs and addressing its different domains to effectively reduce disability and pain and consequently mitigate the economic burden. Future RCTs

comparing the DCP with in-person PT or other digital programs should include risk stratification for chronicity and longer-term follow-up assessments in order to provide further insights into recovery pathways.

Abbreviations

ANOVA, Analysis of variance; BMI, Body mass index; CBT, Cognitive behavioral therapy; CFI, Confirmatory fit index; CI, Confidence interval; DCP, Digital care program; FABQ-PA, Fear-Avoidance Beliefs Questionnaire for physical activity; FDA, Food and Drug Administration (Federal agency); GAD-7, Generalized Anxiety Disorder 7-item questionnaire; ITT, Intent-to-treat; LBP, Low back pain; LGCA, Latent growth curve analysis; MCID, Minimal clinically important difference; NPRS, Numerical Pain Rating Scale; ODI, Oswestry Disability Index; OR, Odds ratio; PHQ-9, Patient Health 9-item questionnaire; PT, Physical therapist; RCT, Randomized controlled trial; RMSEA, Root mean square error of approximation; SRMR, Standardized root mean square residual; US or USA, United States of America; WPAI, Work Productivity and Activity Impairment questionnaire.

Data Sharing Statement

All data relevant to the study are included in the article or are available as Digital Content at Supplementary Material. Only de-identified individual participant data is provided. Further information, including the study protocol, can be found at ClinicalTrials.gov (NCT04092946).

Ethics Approval and Informed Consent

The study was approved by the New England IRB (protocol number 120190313) and prospectively registered in ClinicalTrials.gov, NCT04092946, 17/09/2019. This study was conducted in accordance with the approved guidelines. All patients were informed about the purpose and procedures of the study and provided informed consent.

Acknowledgments

The authors acknowledge the team of physical therapists responsible for the management of participants. The authors also acknowledge the contributions of João Tiago Silva and Quemuel Araújo in data validation (both employed at SWORD Health).

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Funding

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Disclosure

Fabíola Costa, Dora Janela, Maria Molinos, Virgílio Bento, Vijay Yanamadala and Fernando Correia are employees at SWORD Health, the study sponsor. Fernando Correia, Vijay Yanamadala and Virgilio Bento also hold equity from SWORD Health. Robert Moulder, Jorge Lains, Justin Scheer and Steven P. Cohen, receives scientific advisor honorarium from SWORD Health, and do not have equity or stock option grants from SWORD Health. The authors report no other conflicts of interest in this work.

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