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Fear Avoidance Beliefs in Upper-Extremity Musculoskeletal Pain Conditions: Secondary Analysis of a Prospective Clinical Study on Digital Care Programs

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Abstract

Background. Fear-avoidance beliefs (FAB) have been associated with poorer prognosis and decreased adherence to exercise-based treatments in musculoskeletal (MSK) pain. However, the impact of high FAB on adherence and outcomes in upper extremity MSK (UEMSK) pain is poorly explored, particularly through exercise-based digital care programs (DCP). **Objective.** Assess the adherence levels, clinical outcomes and satisfaction in patients with UEMSK pain and elevated FAB after a fully remote multimodal DCP. Associations between FABQ-PA and clinical outcomes were conducted. **Methods.** Secondary analysis of an ongoing clinical trial. Participants with UEMSK pain (shoulder, elbow, and wrist/hand) and elevated FAB-physical activity (FABQ-PA ≥ 15) were included. Adherence (completion rate, sessions/week, total exercise time) and mean change in clinical outcomes—disability (QuickDASH), numerical pain score, FABQ-PA, anxiety (GAD-7), and depression (PHQ-9)—between baseline and end-of-program were assessed. Associations between FABQ-PA and clinical outcomes were conducted. **Results.** 520 participants were included, with mean baseline FABQ-PA of 18.02 (SD 2.77). Patients performed on average 29.3 exercise sessions (2.8 sessions/week), totalizing 338.2 exercise minutes. Mean satisfaction was 8.5/10 (SD 1.7). Significant improvements were observed in all clinical outcomes. Higher baseline FAB were associated with higher baseline disability ($P < .001$), and smaller improvements in disability ($P < .001$) and pain ($P = .001$). Higher engagement was associated with greater improvements in FABQ-PA ($P = .043$) and pain ($P = 0.009$). **Conclusions.** This study provides evidence of the potential benefits of a structured and multimodal home-based DCP in the management of UEMSK pain conditions in patients with elevated FAB in a real-world context.

Introduction

Musculoskeletal (MSK) pain is the leading cause of disability worldwide [1]. Although low back pain is the top cause of pain-related disability and receives an even higher proportion of research funding and attention, upper extremity musculoskeletal (UEMSK) pain (i.e., shoulder, elbow, and wrist/hand pain) accounts for 31.8% of all occupational injuries (with an incidence of 29.2 per 10,000 US workers in 2016) and is responsible for the longest periods of absenteeism according to the US Bureau of Labor [2].

Exercise-based approaches are recommended as first-line treatment for UEMSK pain [3, 4]. However, even with evidence-based treatments, optimizing recovery trajectories relies on patient adherence [5]. Time or travel constraints, costs, and availability of nearby providers [6] are the main challenges in accessing care. At a patient level, both the psychological domain, as well as maladaptive beliefs in pain perception and disability can impact treatment adherence [7]. As a result, compliance with treatment programs is very low, especially for home-based exercise programs, where lack of compliance can reach 70% [8]. Therefore, contemporary approaches, following a biopsychosocial perspective, acknowledge the role of maladaptive beliefs and psychological health in MSK conditions as a modifiable target, addressing them to improve treatment effectiveness [9–12].

Acknowledging the role of the psychological domain and maladaptive beliefs in pain perception and disability may provide a modifiable target that can be used to impact adherence and outcomes.

The fear-avoidance beliefs (FAB) model hypothesizes that the sensory and emotional component of pain may contribute to the perception of pain as a threat. In this way, any form of physical activity is viewed as a potential cause for increased pain or structural damage, resulting in dysfunctional and deleterious cognitive-behavioral effects, consequential healing delays and even transition to chronic pain [13, 14]. Research has shown that FABs contribute to worse clinical presentations [12, 15] and poorer prognosis [11, 16] with preliminary evidence in shoulder pain.

Although well-investigated in other musculoskeletal conditions [17], the contribution of FAB on adherence to exercise-based treatments and general UEMSK pain management has been insufficiently explored [16]. Yet, one might expect FAB to be more detrimental in home-based interventions, where the lack of supervision and accountability does not prevent the negative spiral imposed by the fear of pain.

Previously we explored the utility of a completely-remote digital care program (DCP) in upper limb MSK conditions [17–19]. This multimodal DCP integrates exercise, education and cognitive behavioral therapy (CBT) and is managed by a physical therapist (PT) who continuously and asynchronously monitors patients. This DCP offers a more holistic approach, empowering patients in their own recovery, contributing to higher treatment adherence. In past studies, average baseline FAB values were not particularly high, and those cohorts reported significant improvements across all clinical outcomes [18–20]. This study represents an exploratory sub-analysis of the data collected within an ongoing clinical trial with the goal of determining whether patients with UEMSK pain and high FAB would adhere to this DCP, and whether they would report outcome improvements and satisfaction in ranges similar to the ones published previously. We hypothesized that, despite the initial high FAB, this cohort would adhere to the intervention and report clinically significant outcome improvements after this DCP.

Methods

Study Design

This is a secondary analysis of data collected within a prospective, decentralized study approved by the New England Institutional Review Board (number 120190313) and registered on ClinicalTrials.gov (NCT04092946) on September 17, 2019. This ongoing study is focused on assessing clinical and engagement-related outcomes in patients with MSK pain after a home-based multimodal DCP. The present study focused on individuals with UEMSK pain conditions and high levels of FAB ($\geq$15) who underwent the DCP between June 19, 2020, and November 23, 2021. Previous studies have demonstrated that a score $\geq$15 on the fear-avoidance beliefs questionnaire for physical activity (FABQ-PA) is associated with poorer prognosis [21].

Participants

Adults (>18 years of age) with self-reported MSK pain in the upper extremity (i.e., shoulder, elbow, and wrist/hand), who were beneficiaries of employer health plans and applied for the SWORD Health DCP were invited to participate in this study, and complete a screening questionnaire on a dedicated website. All subjects provided informed consent.

Exclusion criteria were: (1) self-reported FAB below the 15 cutoff [21]; (2) serious injury not cleared for active exercise by the attending physician; (3) presence of a health condition (e.g., cardiac, respiratory or other) incompatible with at least 20 minutes of light to moderate exercise; (4) undergoing treatment for cancer; (5)

rapidly progressive loss of strength and/or numbness in the affected arm. Eligibility was confirmed through a video call with a physical therapist (PT), who performed the screening for clinical red flags.

Participants did not receive any compensation for participating in the study.

Intervention

As previously noted [19, 20], this DCP is composed of exercise and psychoeducation components delivered in a completely remote format. Each participant is assigned to a PT upon enrollment who prescribes a tailored intervention and monitors the patient throughout the entire program. The exercise sessions consist of gradual progressive movement exposure and are performed through a Food and Drug Administration (FDA)-listed class II medical device, including a tablet with a pre-installed app, using camera-based and/or wearable motion-tracking sensors. The tablet displays the prescribed exercises through audio-videos, while sensors digitize motion, providing real-time biofeedback along with instructions to guide patients during their sessions. Wearable motion trackers positioning depends on the anatomical region addressed (Figure 1).

This technology enables patients to perform sessions independently at their convenience. Data obtained from the exercise sessions are stored on a cloud-based platform, being asynchronously monitored through a web-based portal by the assigned PT who adjusts the exercises according to the patients' progression. Participants were recommended to perform at least 3 exercise sessions per week. Absence of an exercise session for 28 consecutive days resulted in classification of the participant as a dropout. Participants were still considered if they were compliant with the intervention but failed to complete a given reassessment survey.

The psychoeducational component incorporates patient education and CBT, delivered through a dedicated smartphone app. The main topics in the educational component include fear-avoidance, pain reconceptualization, active coping skills, importance of exercise, activity pacing/modification and associated myths about MSK pain. The CBT program was based on third-generation techniques—mindfulness (namely, mindfulness meditation and body scanning), acceptance and commitment therapy (namely, non-judgmental observation, acceptance of the pain experience, cognitive defusion, and goal setting), and empathy-focused therapy (toward self and others), compounded into an 8-week progressive program consisting of self-guided interactive modules, including pre-recorded meditations and habit releaser tasks. This content was developed under current clinical guidelines and research by a multidisciplinary team including psychiatrists and psychologists. The educational articles and interactive modules were delivered through a dedicated smartphone app, which also included a built-in secure chat, as an extra communication channel between patients and PTs. Both chat and video calls were used to promote therapeutic alliance. Program duration lasted between 8 and 12 weeks, depending on the condition.

Outcome Measures

Clinical outcomes were assessed at baseline, 4, 8, and 12 weeks, and mean changes were calculated between baseline and end-of-program for each outcome.

The following adherence metrics were studied: percentage of participants that completed the program (completion rate), number of exercise sessions performed per week, number of completed exercise sessions, cumulative time dedicated to exercise sessions (minutes) and number of psychoeducational articles read.

The following self-reported outcomes were assessed:

1. *Fear-avoidance beliefs related to physical activity* through FABQ-PA subscale, a five-item questionnaire scored from 0 to 24 with higher scores indicating greater fear-avoidance [22]. The individual items of the FABQ were modified to replace the word "back" with "shoulder" or "elbow" or "wrist/hand," as previously reported [16, 22–25]. This scale has been reported as viable and reliable for upper-limb MSK conditions (ICC 0.88) [22]. Within FABQ, the FABQ-PA subscale is the most

Figure 1. Motion trackers positioning for hand/wrist (in this case camera-vision is also applied to track movements) (left image) and for shoulder and elbow (right image).

commonly used outcome measure, as it can be used in a wider population that includes unemployed participants [26];

2. *Disability* through Quick Disabilities of the Arm, Shoulder and Hand questionnaire (QuickDASH), which is a valid and reliable scale (ICC=0.90 shoulder pain; excellent) [27] that assesses the impact of upper limb pain on functionality in the past week. It consists in an 11-item questionnaire scored on a Likert scale, with scores from 0 to 100%, with higher scores related to worse functioning [27];

3. *Pain* assessed through an 11-point numerical pain rating scale (NPRS) through the question "Please rate your average pain over the last 7 days: 0 (no pain at all) to 10 (worst pain imaginable)" [28]. This scale has been reported as valid and reliable for pain in upper limb (ICC=0.74 shoulder pain; moderate) [27];

4. *Mental health* through Generalized Anxiety Disorder 7-item scale (GAD-7) (scores 0–21) was applied to assess anxiety severity in clinical practice and research (reliability: Cronbach's alpha=0.92 (excellent); ICC=0.83 (excellent)) [29]. Patient Health 9-item questionnaire (PHQ-9) (scores 0–27) was chosen for its strong scale validity (area under the curve in diagnosing major depression=0.95); reliability: Cronbach's alpha=0.89 (excellent)) as a brief measure of depression severity [30]. Both scales evaluated symptomatology in the past 2 weeks. A cutoff threshold of ≥ 5 indicates at least mild anxiety/depression, respectively [29, 30];

5. *Patient satisfaction* assessed by the question: "On a scale from 0 to 10, how likely is it that you would recommend this intervention to a friend or neighbor: 0 (not at all likely) to 10 (extremely likely)?".

Safety and Adverse Events

Participants rated their pain and fatigue levels at the end of each exercise session (0–10 NRS, with 10 being the most severe) to allow PT monitoring. They were also advised to report any adverse event when it occurred to the assigned PT through any communication channel.

Data Availability

All relevant data is included in the article or available as Supplementary Data Material. De-identified data and analysis codes may be provided upon reasonable request to the corresponding author.

Statistical Analyses

Study sample demographic characteristics and adherence metrics were analyzed through descriptive statistics, with continuous variables reported as mean (standard deviation—SD) and categorical variables as frequencies (percentage). Differences in baseline characteristics between completers and non-completers (participants that were excluded or dropped out after starting the program) were assessed through χ^2 tests for categorical variables and independent samples t-tests for continuous variables.

Clinical outcomes were modeled through latent growth curve analysis (LGCA), enabling estimation of trajectories over time, based on the individual trajectories and considering time as a continuous variable [19, 20]. This methodology belongs to the same family of linear mixed-effects modeling but is estimated as a structural equation model [31] (see Supplementary Data Figure 1), taking into consideration that repeated measures on the same individual are correlated. LGCA has the advantages of providing a measure of model fitness (e.g., how well the model explains the data set), and allowing the use of full information maximum likelihood (FIML) to address missing data [32, 33]. FIML estimation considers all available data at each time point from all participants to calculate maximum likelihood estimates, outperforming other modern imputation models such as multiple imputation by chained equations (MICE) or listwise deletion [32, 33].

Analyses followed an intent-to-treat approach, considering all participants and additionally filtering for GAD-7 and PHQ-9 above 5 points at baseline to assess clinically relevant scores. The models were controlled for the time-point of patients discharge (8 or 12 weeks) and adjusted for the following covariates: age, sex and body mass index (BMI), fitted as random effects allowing each to vary between individuals. The impact of adherence on outcomes was modeled using cumulative time dedicated to exercise sessions as a time-invariant covariate. All models were estimated with a robust sandwich estimator for standard errors.

Model fit estimation was assessed through χ^2 test, root mean square error of approximation (RMSEA), confirmatory fit index (CFI), and standardized root mean square residual (SRMR), using the following cutoff criteria: CFI = close to 0.95; RMSEA = close to 0.06 and SRMR = close to 0.08 [34].

Additionally, dual LGCA models were used to estimate Pearson correlations between FABQ-PA and other clinical outcomes, either at baseline or with respective changes.

Significance levels were considered as $P < .05$ in all analyses. LGCA was coded using R (version 1.4.1717) and all other analyses using SPSS (version 17.0, SPSS Inc, Chicago, Illinois, USA).

Results

Participants

From 617 screened participants who had FABQ-PA scores ≥ 15 at baseline, 26 did not provide consent, 14 missed the video call, 10 did not submit the baseline survey and 47 did not initiate the program (Figure 2). In total, 520 subjects from 47 states in the United States started the program. The study completion rate was 75.4% (392/520). The demographic characteristics of the entire cohort (N = 520) are provided in Table 1. On average, participants were of middle age (mean 50.4, SD 10.6), had a BMI score above 25 (mean 27.7, SD 5.6), and were employed (92.5%). An even distribution between females and males was observed. No significant baseline demographic and clinical differences were observed between completers (N = 392) and non-completers (N = 128) (Supplementary Data Table S1),
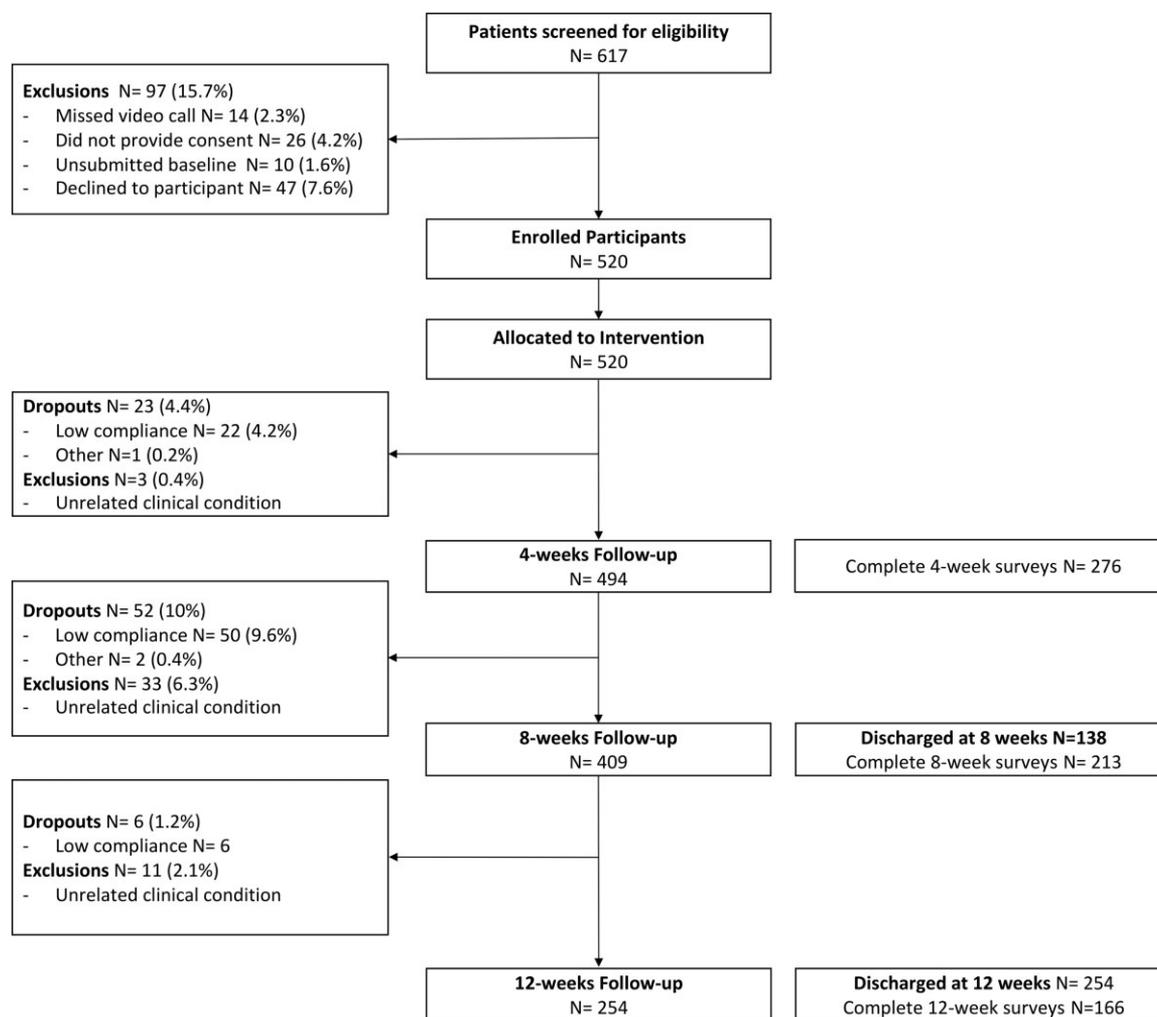
Figure 2. Study flow chart.

except for age (51.1, SD 10.6 vs 48.9, SD 10.5), which was higher in the completers group.

Adherence-Related Outcomes

Considering all enrolled participants (i.e., including dropouts and exclusions) an average of 2.8 (SD 1.7) sessions per week was observed, with completers performing 3.3 (SD 1.6) sessions per week. Participants performed on average 29.3 (SD 21.9) exercise sessions, with completers performing on average 36.0 sessions (SD 20.7), with total treatment times of 338.2 (SD 253.8) and 419.3 (SD 238.6) minutes, respectively.

The influence of time dedicated to exercise sessions on outcomes change was estimated by comparing individual to average change trajectories (Table 2). In both unfiltered (not shown) and filtered analysis (Table 2), increased amounts of time spent on exercise sessions were associated with greater improvements in FABQ-PA ($P = .043$) and pain ($P = 0.009$) by end of program, but not with disability or anxiety. Regarding depression, association was only found in the filtered analysis (i.e., when considering only participants with baseline PHQ-9

scores >5), with greater time spent exercising resulting in lower than average improvements in depression scores ($P = .039$). However, this may be a result of a small subgroup of participants with baseline PHQ-9 scores >5 at baseline who had lower changes than average in depression scores but very high engagement (2–3 times above the mean). In fact, when considering the whole sample, the impact of increased exercise time on depression change becomes positive, but not statistically significant (estimated hourly improvement compared to average of 0.3604; $P = .13$), which seems to corroborate this interpretation.

Regarding the psychoeducational component, participants read on average 4.4 (SD 7.1) articles. Patients communicated with their PT through the built-in app chat an average of 8.5 (SD 10.3) days throughout the DCP. Satisfaction with the program was high with an overall mean score of 8.5/10 (SD 1.7) reported by patients.

Clinical Outcome Metrics

Clinical outcome metrics LGCA and respective model fitness are presented in Supplementary Data Table S2.

Table 1. Baseline characteristics of study participants (N = 520)

Characteristic	Entire Cohort (N = 520)
Age (years), mean (SD)	50.4 (10.6)
Age categories (years), N (%):	
<25	4 (0.8)
25–40	107 (20.6)
40–60	301 (57.9)
>60	108 (20.8)
Sex, N (%)	
Female	272 (52.3)
Male	247 (47.5)
Nonbinary	1 (0.2)
BMI, mean (SD)*	27.7 (5.6)
BMI categories, N (%)*:	
Underweight (<18.5)	4 (0.8)
Normal (18.5–25)	178 (34.3)
Overweight (25–30)	192 (37.0)
Obese (30–40)	125 (24.1)
Morbidly obese (>40)	20 (3.9)
Laterality	
Left	207 (39.8)
Right	288 (55.4)
Both	25 (4.8)
Pain duration, N (%):	
Acute (<12 weeks)	201 (38.7)
Chronic (>12 weeks)	319 (61.3)
Employment status, N (%):	
Employed (part-time or full-time)	481 (92.5)
Unemployed (not working or retired)	39 (7.5)

*1 missing value.

BMI = body mass index.

Table 2. Effect of cumulative time (in hours) dedicated to exercise sessions on the average change trajectories for the different outcome variables

Outcome	Estimate Hourly Improvement Compared to Average Change	P
FABQ-PA	**−1.02**	**.043**
QuickDASH	−0.68	.425
Pain level	**−0.34**	**.009**
GAD-7 > 5	0.68	.334
PHQ-9 > 5	**2.03**	**.039**

A negative estimate refers to an end score lower than the average. For example, for FABQ-PA, each hour performed above the average cumulative time dedicated to exercise, would result in a final score 1.015 points lower than the average at the end the program. Significant P values are presented in bold.

FABQ-PA = Fear-Avoidance Beliefs Questionnaire for physical activity; QuickDASH = Quick Disabilities of the Arm, Shoulder and Hand questionnaire; GAD-7 = Generalized Anxiety Disorder 7-item scale; PHQ-9 = Patient Health 9-item questionnaire.

Participants reported FABQ-PA mean scores of 18.02 (SD 2.77) points at program start, which decreased to 10.32 (95% confidence interval [CI] 9.51, 11.12) at program end, below the defined threshold of 15 points (Table 3 and Figure 3). No significant differences were observed between the FABQ-PA scores of completers and dropouts (18.0, SD 2.7 vs 18.1, SD 2.9, respectively).

Regarding disability, patients reported 31.53 points (SD 13.27) in QuickDASH and moderate pain intensity (mean 5.13, SD 1.72) at program start, which significantly improved throughout the DCP, with an average change of 54.4% (17.15 points, 95% CI 15.44, 18.87) for QuickDASH, and 57.0% (2.92 points, 95% CI 2.65, 3.20) for pain (Table 3).

Despite high levels of FAB, low levels of mental distress indicators (anxiety and depression) were reported at baseline: 2.83 (95% CI 2.48, 3.18) and 2.28 (95% CI 1.98, 2.59), respectively. Only 14% (75/520) of participants reported at least mild depression symptoms (>5), scoring on average 9.68, (95% CI 8.94, 10.42). Nineteen percent (98/520) of participants reported anxiety symptoms (>5), resulting in an average baseline score of 9.85 points, (95% CI 9.05, 10.64), with both anxiety and depression scores nearing the 10-point threshold of moderate distress [30]. Significant improvements were found at program end in these subpopulations (Table 3).

Associations between FAB and Clinical Outcomes

A significant association between baseline levels of FABQ-PA and baseline disability (QuickDASH: r = 0.296, 95% CI 0.15, 0.44, P < .001) was found, wherein patients with higher severity of FAB had higher disability. A correlation was also found between baseline FABQ-PA and changes in disability (QuickDASH: r = 0.233, 95% CI 0.150, 0.312, P < 0.001) and pain (r = 0.140, 95% CI 0.055, 0.223, P = .001). This translates to an association between higher FAB at baseline and lower overall changes in QuickDASH and pain.

The FABQ-PA change across the study was correlated with disability change (QuickDASH: r = 0.471, 95% CI 0.19, 0.75, P = .001), wherein higher changes in FABQ-PA paralleled higher changes in disability.

Discussion

The results in the present study show that participants with UEMSK pain and concomitant elevated FAB at baseline were able to maintain very high levels of exercise-sessions adherence, alongside significant improvements in all the studied clinical domains.

Both high FAB levels [7] and home-based interventions have been associated with lower treatment compliance [35]. In the present study, however, despite the initial high FABQ scores, a high completion rate was observed, within the range of previously reported by us [20] and other authors [23]. Adherence levels, objectively measured by the number of exercise sessions performed per week, were also within the range of previously reported by us [19, 20] and above that reported in other studies [23]. The fact that the current study recruited participants who self-applied to the program (versus other studies like Granvinken et al., which recruited patients referred to rehabilitation services) may have resulted in a

Table 3. Outcome changes between baseline and end-of-program: Intent-to-treat approach (unconditional model)

Outcome, Mean (95% CI)	N	Baseline	End-of-program	Mean Change	% Change
FABQ-PA	520	18.02 (17.78; 18.26)	10.32 (9.51; 11.12)	7.71 (6.89; 8.52)	42.8%
QuickDASH	507	31.53 (30.18; 32.89)	14.38 (12.73; 16.02)	17.15 (15.44; 18.87)	54.4%
Pain level	520	5.13 (4.97; 5.29)	2.21 (1.97; 2.45)	2.92 (2.65; 3.20)	57.0%
GAD-7 > 5	98	9.85 (9.05; 10.64)	5.10 (3.95; 6.24)	4.75 (3.49; 6.01)	48.2%
GAD-7	520	2.83 (2.48; 3.18)	1.63 (1.28; 1.98)	1.19 (0.83; 1.56)	42.3%
PHQ-9 > 5	75	9.68 (8.94; 10.42)	4.55 (2.84; 6.25)	5.13 (3.67; 6.60)	53.0%
PHQ-9	520	2.28 (1.98; 2.59)	1.34 (1.00; 1.69)	0.94 (0.58; 1.13)	41.0%

FABQ-PA = Fear-Avoidance Beliefs Questionnaire for physical activity; QuickDASH = Quick Disabilities of the Arm, Shoulder and Hand questionnaire; GAD-7 = Generalized Anxiety Disorder 7-item scale; PHQ-9 = Patient Health 9-item questionnaire.
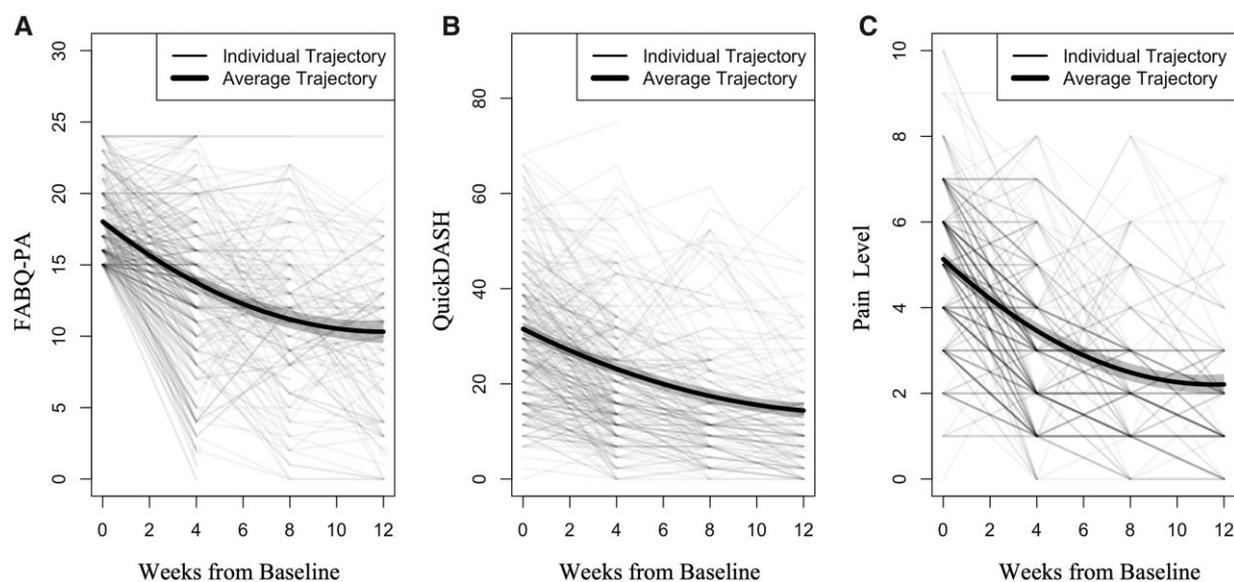
Figure 3. Longitudinal trajectories across time. (**A**) FABQ-PA; (**B**) QuickDASH; (**C**) Pain level. Lighter lines represent individual trajectories (with darker lines meaning overlap of trajectories), while average trajectories calculated through LGCA are depicted in bold lines, with shadowing representing 95% confidence intervals. LGCA = latent growth curve analysis.

higher participant motivation and contribute to justify the higher adherence found in the previous study. Still, the results herein suggest that high FAB was not detrimental for program adherence.

The recommendation to include a biopsychosocial approach on MSK pain is not new [9, 10], and evidence supports its implementation in UEMSK pain [11, 36]. As reported by Wertli et al. [37], higher odds of clinical improvement are observed when FAB was specifically targeted by multimodal interventions. Accordingly, clinical practice guidelines recommend addressing FAB in managing MSK conditions [37]. In the present study, this multimodal DCP was associated with a significant reduction in FAB of 42.8%, to a final score considerably below the threshold associated with poor prognosis [21].

Exercise-based treatments have been reported to be efficient at FAB reduction [38] although to a lesser extent than the reported herein [23, 39]. Importantly, increased amounts of time spent on exercise sessions were significantly associated with enhanced improvements in FABQ-PA and pain levels. This finding is in line with prior reports of higher decreases in FAB among patients who complied with higher exercise dosages [17]. We hypothesize that, in the DCP presented herein, gradual movement exposure may have allowed successful patient progression despite high initial FAB related to exercise.

The improvements observed in disability (54.4%) are significant when compared to those reported by other studies (17.0-61%) [23, 39–41], despite the high heterogeneity among studies, including the use of different

outcome measures. Pain reduction reported in the present study (57.0%) also favorably compares to that reported in the literature (15.9–66%) [23, 41]. Unfortunately, most studies did not report FAB burden at baseline, with the exception of two studies which started with lower FABQ levels [23, 39, 42]. The results of the present study challenge the assumption that individuals with high FAB do not benefit from home-based exercise interventions [35], and might explain the high satisfaction scores reported by patients.

Nevertheless, in the present study, higher baseline FAB scores were correlated with greater disability, in line with what is reported in the literature [22, 24, 25]. Compared to our findings, worse baseline status (poorer functionality and higher pain) was observed in studies where average baseline FAB levels were much lower [19, 20]. Correlation showed that higher baseline FAB levels were associated with lower changes in disability and pain. Importantly, the decrease in FAB was correlated with disability reduction, which further reinforces that FAB may influence UEMSK pain recovery, adding to the growing body of literature dedicated to clarifying this relationship [11].

Interestingly, despite high baseline FAB scores, only a small portion of participants reported comorbid anxiety and depression, similar to what was reported by Karlsson et al. [35] but in contrast to that reported by other authors [43]. This may be explained by the diverse cohort in the present study, which includes distal joints (elbow and wrist/hand) besides shoulder conditions. The association between psychological factors and different MSK conditions outcomes continues to be a vibrant area of research, with previous studies yielding conflicting results [11, 44]. The reported differences may be related to differences in study populations (participants with work compensation, private insurance or referred from hospitals), joint involvement/diagnoses, or outcome metrics between studies.

Although no causal inference can be implied from this study design, multiple aspects of the current intervention might have contributed to the observed outcomes: (i) the convenience offered by remote care, with real-time biofeedback supporting the correct execution of exercises and serving a motivational role; (ii) the continuous monitoring and accessible communication with the assigned PT, who gradually adjusted exercise demands according to patient progression, enabling gradual exposure to movement; and (iii) the educational and CBT components to demystify pain as a threat and provide pain self-management tools. Future studies will clarify to what extent each DCP component impacts the overall observed change.

These results reinforce a trend where the convenience of digital modalities, and their comparable effectiveness with in-person interventions in the treatment of MSK conditions [45, 46] fosters further development of new ways of providing healthcare services. Combining interventions from different specialties in the same intervention might be the path to acknowledge each individual as a whole and personalize programs to a patient's specific health status at any given time. Future research will disclose the role of digital interventions as potential solutions to overcome the lack of access and adherence to rehabilitation treatments [47, 48].

Strengths and Limitations of the Study

The strengths of this study include a high sample size derived from real-world patients with diverse UEMSK pain conditions from geographically diverse regions, and balanced female and male participation. FAB domain is still scarcely explored in UEMSK pain conditions [23, 39] and particularly in remote digital care interventions [19, 20], so focusing specifically on patients who report high FAB scores at baseline addresses this gap in research. The DCP described in the present study followed a multimodal evidence-based approach within the context of a biopsychosocial framework, using innovative technology to allow real-time biofeedback. The set of outcome measures comprised objectively measured adherence metrics (which precludes the social desirability response bias of self-reported engagement [6]), validated outcome measures for pain [28, 49], disability [27], and mental health [29, 30], while further explores the modified FABQ-PA for UEMSK pain conditions [16, 22–25]. Given the gap in research and the set of outcome measures assessed, the fact that this study describes a large sample size derived from real-world patients, with diverse UEMSK pain conditions from geographically diverse regions, and balanced female and male participation, provides support to generalization of the findings, and indicate that DCPs can be successfully used to engage populations with UEMSK pain and high FAB. These findings reinforce the potential utility of digital tools as a way to maximize engagement in these subsets of patients.

Limitations are mainly related to the study design—a single-arm open-label study with no control or comparator group. However, this study focused on an exploratory analysis of real-world data to support further research. Considering the high accessibility of this DCP, using a wait-list control group would not be practical and might not be ethical. Moreover, the study design precluded the individual assessment of each component of the multimodal intervention, and long-term follow-up was not carried out. These limitations should be considered in the planning of future studies.

Conclusions

This is the first study providing preliminary evidence of the potential benefits of a structured and multimodal home-based DCP in the management of UEMSK pain in patients with high FAB. Very high adherence, completion rates and patient satisfaction were observed, suggesting

the utility of this approach in a real-world scenario and challenging the association of high FAB and reduced adherence. This study also shows that multimodal approaches can be effective in addressing FAB even within a cohort with high FAB at baseline, and suggests that gradual exposure to exercise may be an effective strategy in these patients. Furthermore, while supporting associations between higher FAB levels and higher disability, as well as with lower rates of improvement, this study also shows that important reductions in disability can be achieved in these patients. These findings suggest the importance of multimodal care programs and, at the same time, the ability for these programs to be delivered digitally. Further research will clarify the association between FAB and UEMSK pain clinical outcomes, and how this can be modified by multimodal interventions.

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Supplementary Data

Supplementary data are available at *Pain Medicine* online.

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