#### ORIGINAL RESEARCH

# Evaluating Digital Rehabilitation Outcomes in Chronic Musculoskeletal Conditions Across Non-Obesity, Obesity, and Severe Obesity

Ana P Pereira<sup>1,\*</sup>, Dora Janela<sup>1,\*</sup>, Anabela C Areias<sup>1</sup>, Maria Molinos<sup>1</sup>, Xin Tong<sup>2</sup>, Virgílio Bento<sup>1</sup>, Vijay Yanamadala<sup>1,3,4</sup>, Steven P Cohen<sup>5,6</sup>, Fernando Dias Correia<sup>1,7</sup>, Fabíola Costa<sup>1</sup>

<sup>1</sup>Sword Health, Inc, Draper, Utah, USA; <sup>2</sup>Department of Psychology, University of Virginia, Charlottesville, VA, USA; <sup>3</sup>Department of Surgery, Quinnipiac University Frank H. Netter School of Medicine, Hamden, Connecticut, USA; <sup>4</sup>Department of Neurosurgery, Hartford Healthcare Medical Group, Westport, Connecticut, USA; <sup>5</sup>Northwestern Feinberg School of Medicine, Chicago, Illinois, USA; <sup>6</sup>Walter Reed National Military Medical Center, Uniformed Services University of the Health Sciences, Bethesda, Maryland, USA; <sup>7</sup>Neurology Department, Centro Hospitalar E Universitário Do Porto, Porto, Porto, Portugal

\*These authors contributed equally to this work

Correspondence: Fabíola Costa, Sword Health Inc, 13937 Sprague Lane Ste 100, Draper, UT, 84020, USA, Tel +1 385-308-8034, Fax +1 801-206-3433, Email f.costa@swordhealth.com

**Background:** Obesity is a known risk factor and aggravator of musculoskeletal (MSK) conditions. The rising prevalence of obesity calls for scalable solutions to address MSK conditions in this population, given their complex clinical profile and barriers to accessing care.

**Purpose:** To evaluate the engagement and clinical outcomes of a fully remote digital care program in patients with MSK conditions, focusing on those with and without comorbid obesity.

**Patients and Methods:** A post-hoc analysis of a prospective, longitudinal, single-arm observational home-based study conducted between August, 2023, and August, 2024. Adults suffering from chronic MSK pain were categorized according to their body mass index (BMI) into non-obesity, obesity and severe obesity. Outcomes included completion rates, engagement, satisfaction, pain (minimal clinically important change: 30%), impairment in daily activities, and patient global impression of change (PGIC). Depending on the clinical outcomes, latent basis growth analysis and logistic regression were used.

**Results:** Completion rates were high across all groups (77.5–85.6%), although slightly lower in the obesity groups. Fairly similar engagement was observed with both exercise sessions and the educational content (1.9–2.2 exercise sessions per week; 8.10–9.31 educational content videos watched). Obesity groups interacted more with the physical therapists than the non-obesity group (severe obesity: 24.6 (SD 10.1); obesity: 23.2 (SD 10.46) vs non-obesity: 22.4 (SD 9.8), P < 0.001). Despite higher baseline risk and clinical impairment in the obesity groups, all groups showed significant pain reductions, with pain responder rates ranging from 56.6 to 63.6%, slightly lower in the severe obesity group. Improvements in daily activities were significant across groups, alongside a positive PGIC (50.4–53.6%). Satisfaction was very high (>9/10) in all BMI groups.

**Conclusion:** Despite worse baseline clinical presentations, obesity groups achieved high completion rates, engagement, and significant clinical improvements comparable to the non-obesity group, highlighting the potential of a digital program for this population.

**Plain Language Summary:** Obesity is a common risk factor for musculoskeletal conditions. With obesity rates rising, it is important to find scalable ways to help people with musculoskeletal conditions who are also dealing with obesity, especially since these patients often face challenges in accessing care. Digital telerehabilitation has emerged as an alternative to improve care access, while promoting similar results to in-person care, but its suitability to manage patients with both musculoskeletal and obesity conditions remains underexplored. This study evaluated the suitability of a fully remote digital care program for patients with musculoskeletal conditions, both with and without obesity. We analyzed data from a study of patients with chronic pain, grouping them by body mass index (BMI) into non-obesity, obesity, and severe obesity. Completion rates were high for all BMI groups (77.5–85.6%), though

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slightly lower for people with obesity. Despite patients with obesity starting the program with more severe pain and limitations, all groups showed significant reductions in pain. Improvements in daily activities were seen across all groups, and over half of the participants reported positive changes in their condition. Satisfaction with the program was very high in all groups (over 9 out of 10). In conclusion, the remote digital care program was effective for patients with musculoskeletal conditions, including those with obesity, helping them achieve high participation and significant clinical improvements. This study highlights the potential of digital care to effectively manage musculoskeletal conditions among patients with obesity.

Keywords: body mass index, physical therapy, telerehabilitation, ehealth, pain

#### Introduction

Musculoskeletal (MSK) pain affects 1.71 billion people worldwide, being the leading cause of disability.<sup>1</sup> A significant proportion of patients with MSK conditions also present with comorbidities, with obesity (body mass index – BMI  $\geq$ 30 kg/m<sup>2</sup>) being one of the most common.<sup>2</sup> According to the World Health Organization (WHO), the global prevalence of obesity has doubled since 1990, with over 890 million people currently affected.<sup>3</sup> Obesity imposes a tremendous socioeconomic burden, contributing to a reduction of 3–8 years in disease-free life<sup>4</sup> and 160 million disability-adjusted life years (DALYs).<sup>5</sup> Approximately, \$180.7 billion are spent annually worldwide on MSK conditions attributable to high BMI.<sup>6</sup>

The relationship between obesity and MSK conditions is complex and bi-directional. Chronic pain can contribute to obesity through physical inactivity, medication side effects, or unhealthy eating habits as a coping strategy.<sup>7–9</sup> Conversely, obesity is a risk factor for the onset of MSK pain<sup>7</sup> and exacerbates symptoms severity.<sup>10,11</sup> This relationship is underpinned by shared pathophysiological mechanisms, including vascular dysfunction and adipose tissue inflammation,<sup>12</sup> which likely synergistically amplify the overall burden.<sup>2</sup> Populational data shows that obesity is associated with multiple health risk factors that range from socioeconomic determinants to additional health conditions.<sup>13</sup> Along with increased stress on nearly all somatic tissues, patients with obesity often face weight bias from clinicians, which can negatively impact their care.<sup>14</sup> They are also predisposed to sleep disorders that heighten pain sensitivity<sup>15</sup> and experience a higher affective component of pain,<sup>16</sup> which may be less responsive to pharmacological and physical interventions. Since exercise can improve mood, sleep and negative affect, an exercise program can be particularly beneficial in this population.

Non-pharmacological interventions, encompassing exercise, education and behavioral change strategies, are recommended as the first-line approach for MSK conditions, particularly in patients with comorbid obesity.<sup>17–19</sup> However, numerous hurdles challenge rehabilitation access and success,<sup>20</sup> namely time and geographic constraints.<sup>21</sup> These barriers are particularly evident in patients with obesity, where discomfort during physical activity, combined with fear-avoidance beliefs about exercise and fear of stigma related to weight, often leads to resistance toward initiating exercise-based interventions.<sup>22–24</sup>

Given the high prevalence of patients with obesity and the unique challenges these patients face while addressing MSK conditions, it is crucial to explore new delivery modes such as remote digital care in this population. Digital care has emerged as an effective<sup>25,26</sup> and promising solution to address access barriers, by enabling patients with MSK conditions to benefit from rehabilitation without facing long commute times, constraints in scheduling in office hours or being blocked into long-lasting waiting lists due to insufficient physical therapists in their area.

While previous studies have evaluated the impact of BMI on pain or function following traditional in-person physical therapy,<sup>27–34</sup> with a few reporting poorer outcomes with higher BMI,<sup>31–34</sup> the impact of obesity or BMI on remote rehabilitation outcomes remains largely unexplored.<sup>35</sup>

In this study, we aim to assess the engagement and clinical outcomes of patients with and without obesity following a fully remote digital care program (DCP). This DCP has been proven effective compared to in-person physical therapy,<sup>36,37</sup> showing benefits across diverse patient populations, regardless of race/ethnicity,<sup>38</sup> or socioeconomic background.<sup>39</sup> As digital interventions continue to expand and gain broader adoption, the findings from this work have the potential to guide clinicians and patients in understanding the value of remote rehabilitation programs as viable

alternatives for MSK care. This progress paves the way for new research opportunities aimed at optimizing care delivery and improving access.

## **Materials and Methods**

#### Study Design

This is a post-hoc analysis of a prospective, longitudinal, single-arm observational study. It was approved by the Advarra IRB (Pro00063337) and registered on ClinicalTrials.gov (NCT05417685) on June 14th, 2022. This study was conducted in accordance with the Declaration of Helsinki. Patients included in this study were enrolled and treated remotely at home via a digital care platform, between August 1st, 2023, and August 19th, 2024. This study is reported in accordance with STROBE guidelines (Supplementary Table 1).

#### Population

Eligible participants were adults ( $\geq$ 18 years-old), beneficiaries of employer health plans with chronic MSK pain (defined as persistent or recurrent pain lasting  $\geq$ 3 months, in line with the criteria of the ICD-11<sup>40</sup>) located in any of the following anatomical regions: ankle, elbow, hip, knee, low back, neck, shoulder, wrist or hand, who provided baseline weight and height.

Exclusion criteria included (1) health conditions incompatible with at least 20 minutes of light to moderate exercise; (2) ongoing cancer treatment; and (3) presence of signs or symptoms indicative of serious pathology (eg, rapid progressive motor weakness or sensory alterations or bowel or bladder dysfunction). All participants provided informed consent.

#### Interventions

The intervention consisted of a fully remote DCP including home-based exercise, education, and cognitive behavioral therapy (CBT) for up to 12 weeks tailored to patients' conditions, developed according to current guidelines,<sup>17–19</sup> as described elsewhere.<sup>36,37,39</sup>

Patients applied for the study through a dedicated website and then completed a baseline form with demographic and clinical information before being assigned a licensed doctor of physical therapy (PT), with at least 3 years of experience. During the onboarding video call or dynamic questionnaire, the assigned PT performs a complete anamnesis and physical examination of patients, which includes a thorough assessment to confirm chronic MSK pain and to exclude the presence of potential red flags. In the case of red flags or suspicion of non-MSK conditions, the patient is referred to a physician for medical screening. Intervention goals were established through shared decision-making.

An FDA-listed class II medical device was provided to patients to perform the exercise sessions, being composed of a dedicated tablet with a mobile app, motion tracking, and a cloud-based portal. Sessions were displayed through videos on the tablet with real-time audio and visual biofeedback on exercise performance. Patients were monitored by the PT throughout the program, who adjusted the intervention asynchronously through the cloud-based portal. Bi-directional communication was ensured via a secure chat within a smartphone app.

Education was provided through short videos via a smartphone app and included topics about pathophysiology, pain reconceptualization, active coping skills, the role of exercise, fear-avoidance behaviors, nutrition (balanced meals and portions, healthier options common misconceptions), and strategies on how to integrate daily physical activity.<sup>17–19</sup> The CBT component was delivered through interactive and audio modules via email and focused on mindfulness, acceptance and commitment therapy, and empathy-focused therapy.<sup>41</sup>

## Body Mass Index and Comorbidities Data

Weight and height were self-reported by patients during onboarding and used to calculate BMI, which was categorized according to thresholds defined by WHO:<sup>3</sup> non-obesity as BMI <30 kg/m<sup>2</sup>, obesity as BMI  $\ge$ 30–40 kg/m<sup>2</sup> and severe obesity as BMI  $\ge$ 40 kg/m<sup>2</sup>.

Comorbidity data, namely cardiovascular disease (including hypertension) and diabetes (type I or II), were collected from electronic health records of the initial clinical assessments conducted by PTs, where patients were asked if they had

any relevant medical history information and/or red flags. These comorbidities were chosen since they are highly prevalent in this population and rank among the leading contributors to DALYs.<sup>1</sup>

#### Outcomes

Data was collected at baseline, 9th, 19th, and 24th sessions, according to the patient's discharge time point. Longitudinal changes were estimated between baseline and program end. Outcome measures comprised:

(1) Pain intensity: measured by the Numerical Pain Rating Scale (NPRS) specific for the symptomatic body region: "Please rate your average pain over the last 7 days" from 0 (no pain at all) to 10 (worst pain imaginable)".<sup>42</sup> This scale is reported as valid and reliable for pain intensity (ICC =  $0.58-0.93^{43,44}$ ). Response rate was calculated considering a minimal clinically important change (MCIC) of 30%, which was defined according to IMMPACT guidelines for clinical trials;<sup>45</sup>

(2) Impairment in performing activities of daily living: evaluated by question 6 of the Work productivity and activity impairment (WPAI) questionnaire for general health,<sup>46</sup> a validated tool with demonstrated reliability.<sup>47–49</sup> Higher scores indicate greater impairment (0–100);

(3) Patient global impression of change (PGIC): evaluated by the question "Since the beginning of your program, how has your overall quality of life and/or physical ability improved?". This is the most used for patient-reported global assessment in clinical trials of chronic pain,<sup>50</sup> and is validated across several musculoskeletal conditions<sup>51–53</sup> with good to excellent reliability.<sup>52,53</sup> Scores ranged between 1 and 7 with 5 to 7 denoting clinically important improvements as reported previously;<sup>45,54</sup>

(5) Engagement: assessed by completion of the program (completion rate), average sessions per week, communication between PT and patient, and number of educational videos watched;

(6) Satisfaction: 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 any adverse events when they occurred to their PT. Additionally, pain and fatigue scores (graduated from 0 to 10) were collected at the end of each session and monitored remotely by the PT.

## Data Availability

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

#### Statistical Analysis

Descriptive statistics were used to report cohort's baseline characterization through means and proportions. Comparisons between BMI categories for continuous variables were performed using independent samples t-tests and ANOVA. Chi-squared tests were used for categorical variables.

A latent-basis growth analysis (LBGA) was used to model clinical outcome trajectories across time following an intention-to-treat approach. LBGA is a type of structural equation model that calculates overall change based on individual trajectories and allows the growth trajectory to be freely estimated at key timepoints. Advantages of this methodology include (1) the capture of nonlinear patterns of change, where the pace and timing of change may vary across individuals;<sup>55</sup> (2) provision of model fit measures; and (3) the handling of missing data through full information maximum likelihood (FIML), which outperforms listwise deletion and other imputation models.<sup>56,57</sup> A multiple-group LBGA was conducted to compare outcomes across BMI categories since it creates separate submodels for different groups (within a single overarching model) while accounting for unbalanced group sizes. Multiple-group LBGA estimates all parameters simultaneously in a single analysis, precluding the need for multiple comparison corrections.

WPAI activity analysis was performed for patients with baseline clinically relevant scores (ie, WPAI Activity > 0). A robust sandwich estimator was used for standard errors.

A conditional analysis was conducted to assess the influence of covariates – gender, age, treatment duration and presence of comorbidities – on both intercept and slope, fitted as random effects.

A binary logistic regression was performed to compute the odds ratio (OR) for: (1) completing the study; (2) reaching an MCIC of 30% for pain, adjusted for the aforementioned covariates; and (3) reporting improved perception of overall quality of life and/or physical ability (ie, selecting PGIC answer 5, 6, or 7) both at 5th session and program end.<sup>45,54</sup> Z-tests were applied to evaluate differences on PGIC between the 5th session and program end. All analyses were adjusted for gender, age and presence of comorbidities.

Descriptive statistics were performed using commercially available software (SPSS v22, IBM, Armonk, NY), and statistical analyses through R Studio (version 2023.09.1+494). Statistical significance was defined as P < 0.05 considering a two-sided hypothesis test.

#### Results

From a total of 39,400 screened patients, 26,491 started the study, of which 22,145 completed the intervention (Figure 1). From those at study start, 57.0% (N = 15,112) of patients did not have obesity, 33.3% (N = 8823) had obesity, and 9.6% (N = 2556) had severe obesity.

#### **Baseline Characteristics**

Overall, the cohort was mainly composed by middle-aged patients (41–60 years: N = 14,687, 55.4%), women (N = 15,905, 60.0%), non-Hispanic White (N = 19,030, 71.8%), full-time employees (N = 21,861, 82.5%), and those living in urban areas (22,592, 85.3%) (Table 1).

Patients with obesity or severe obesity were slightly older (mean age of 50.6 years-old, SD = 11.2, and 49.1 years-old, SD = 10.5, respectively), included a higher proportion of women (59.6%, N = 5258; 75.6%, N = 1932, respectively), were more likely to identify as Black (11.4%, N = 1002; 5.3%, N = 390, respectively), and more likely to reside in rural areas (16.2%, N = 1427; 17.4%, N = 445, respectively) compared to patients without obesity (all P < 0.001). Educational attainment was also lower among those with higher BMI, with fewer patients holding a graduate degree among the obesity and severe obesity groups (21.6%, N = 1903; 19.4%, N = 495, respectively; P < 0.001). Employment status



Figure I Study flow chart.

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Table I	Baseline	Characteristics	of the	Total	Cohort and	Stratified	by I	Patients	BMI	Category
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	Total Cohort (N=26,491)	Non-Obesity (N=15,112)	Obesity (N=8823)	Severe Obesity (N=2556)	P-value <sup>a</sup>
Age in years, mean (SD)	49.4 (11.9)	48.7 (12.4)	50.6 (11.2)	49.1 (10.5)	<0.001
Age category in years, N (%):					<0.001
<25	399 (1.5)	318 (2.1)	61 (0.7)	20 (0.8)	
2540	6197 (23.4)	3897 (25.8)	1745 (19.8)	555 (21.7)	
41–60	14,687 (55.4)	7918 (52.4)	5163 (58.5)	1606 (62.8)	
>60	5208 (19.7)	2979 (19.7)	1854 (21.0)	375 (14.7)	
Gender, N (%) <sup>b</sup> :					<0.001
Woman	15,905 (60.0)	8715 (57.7)	5258 (59.6)	1932 (75.6)	
Man	10,246 (38.7)	6218 (41.1)	3449 (39.1)	579 (22.7)	
Non-binary	177 (0.7)	77 (0.5)	69 (0.8)	31 (1.2)	
Other	18 (0.1)	9 (0.1)	7 (0.1)	2 (0.1)	
Prefer not to specify	97 (0.4)	66 (0.4)	22 (0.2)	9 (0.4)	
BMI (kg/m²), mean (SD)	30.1 (7.3)	25.3 (3.0)	33.9 (2.7)	45.8 (5.6)	<0.001
Weight (lbs), mean (SD)	191.4 (0.3)	162.3 (0.2)	215.0 (0.3)	281.9 (0.9)	<0.001
Race/ethnicity, N (%):					<0.001
Asian	1778 (6.7)	1465 (9.7)	286 (3.2)	27 (1.1)	
Black	2266 (8.6)	874 (5.8)	1002 (11.4)	390 (15.3)	
Hispanic	2082 (7.9)	1082 (7.2)	804 (9.1)	196 (7.7)	
Non-Hispanic White	19,030 (71.8)	10,902 (72.1)	6312 (71.5)	1816 (71.0)	
Other	666 (2.5)	380 (2.5)	204 (2.3)	71 (2.8)	
Prefer not to specify or NA	669 (2.5)	409 (2.7)	215 (2.4)	56 (2.2)	
Education level, N (%):					<0.001
Less than high school diploma	304 (1.1)	198 (1.3)	81 (0.9)	25 (1.0)	
High school diploma	2531 (9.6)	1168 (7.7)	1030 (11.7)	333 (13.0)	
Some college	6928 (26.2)	3152 (20.9)	2870 (32.5)	906 (35.4)	
Bachelor's degree	9831 (37.1)	6095 (40.3)	2939 (37.1)	797 (31.2)	
Graduate degree	6897 (26.0)	4499 (29.8)	1903 (21.6)	495 (19.4)	
Geographic location, N (%):					<0.001
Urban	22,592 (85.3)	13,119 (86.8)	7370 (83.5)	2103 (82.3)	
Rural	3819 (14.4)	1947 (12.9)	1427 (16.2)	445 (17.4)	
Not Available	80 (0.3)	46 (0.3)	26 (0.3)	8 (0.3)	

(Continued)

	Total Cohort (N=26,491)	Non-Obesity (N=15,112)	Obesity (N=8823)	Severe Obesity (N=2556)	P-value <sup>a</sup>
Employment status, N (%):					<0.001
Full-time job	21,861 (82.5)	12,213 (80.8)	7460 (84.6)	2188 (85.6)	
Part-time job	1383 (5.2)	920 (6.1)	367 (4.2)	96 (3.8)	
Retired	1648 (6.2)	991 (6.6)	552 (6.3)	105 (4.1)	
Not employed	1371 (5.2)	834 (5.5)	384 (4.4)	153 (6.0)	
Not Available/Prefers not to Answer	228 (0.9)	154 (1.0)	60 (0.7)	14 (0.5)	
Clinical data, mean (SD)					
Symptomatic anatomical area, N (%	<b>6):</b>				<0.001
Ankle	2245 (8.5)	1079 (7.1)	884 (10.0)	282 (11.0)	
Elbow	537 (2.0)	400 (2.6)	120 (1.4)	17 (0.7)	
Нір	3090 (11.7)	1800 (11.9)	1015 (11.5)	275 (10.8)	
Knee	4029 (15.2)	1917 (12.7)	1491 (16.9)	621 (24.3)	
Low back	8724 (32.9)	4837 (32.0)	3031 (34.4)	856 (33.5)	
Neck	2854 (10.8)	1886 (12.5)	796 (9.0)	172 (6.7)	
Shoulder	4131 (15.6)	2658 (17.6)	1210 (13.7)	263 (10.3)	
Wrist	881 (3.3)	535 (3.5)	276 (3.1)	70 (2.7)	
Number of comorbidities, N (%):				·	<0.001
0	23,671 (89.4)	14,030 (92.8)	7544 (85.5)	2097 (82.0)	
I	2393 (9.0)	971 (6.4)	1060 (12.0)	362 (14.2)	
2	427 (1.6)	(0.7)	219 (2.5)	97 (3.8)	
Comorbidity category, N (%):					
Cardiovascular diseases	2177 (8.2)	840 (5.6)	988 (11.2)	349 (13.7)	<0.001
Diabetes Type I or II	1070 (4.0)	353 (2.3)	510 (5.8)	207 (8.1)	<0.001
Pain Medication intake, N (%):	7332 (27.7)	3468 (22.9)	2839 (32.2)	1025 (40.1)	<0.001
Pain Intensity, mean (SD)	4.8 (2.1)	4.6 (2.0)	5.0 (2.1)	5.3 (2.0)	<0.001
WPAI activities >0, mean (SD) <sup>c</sup>	38.02 (23.7)	35.59 (22.9)	39.55 (23.9)	45.66 (24.9)	<0.001

**Notes:** <sup>a</sup>Significant P-values are italicized. Comparisons between BMI categories for continuous variables were performed using independent samples t-tests and ANOVA and for categorical variables through Chi-squared tests. <sup>b</sup>N=48 missing data; <sup>c</sup> N=20,378.

Abbreviations: BMI, body mass index; NA, not available; WPAI, Work Productivity and Activity Impairment Questionnaire.

varied across groups, with patients with obesity being more likely to be employed full time than the non-obesity group (N = 2188, 85.6%; P < 0.001).

Regarding clinical variables, the predominant symptomatic anatomical area was low back which remained consistent across BMI categories, with a higher proportion of patients with severe obesity suffering from knee pain (24.3%, N = 621; P < 0.001). Patients reporting either diabetes (Type I or II) or a cardiovascular disease accounted for 10.6% (N = 2820) of the total population, with the latter being more prevalent (8.2% vs 4.0%). The presence of comorbidities was higher among the

population with obesity or severe obesity (14.5% and 18%, respectively) than in the non-obesity group (7.1%, P < 0.001). Patients with severe obesity were more likely to take medications for pain (40.1%, N = 1025), had higher baseline pain intensity and mental health scores, and poorer function, indicating a greater disease burden (all P < 0.001).

## Engagement and Satisfaction

Overall completion rate was 83.6%. Completion rates were influenced by BMI, with the non-obesity group having higher odds of completing the program compared to the obesity (81.9%, N = 7223 vs 85.6%, N = 12,941; adOR 1.39, 95% CI 1.27; 1.52, P < 0.001) and the severe obesity groups (77.5%, N = 1981; adOR 1.73, 95% CI 1.52; 1.97, P < 0.001).

Weekly engagement was similar across groups, with the severe obesity group reporting slightly fewer sessions per week (average number of sessions per week: non-obesity 2.2 (SD 1.0); obesity 2.1 (SD 1.0); severe obesity 1.9 (SD 1.0), P < 0.001; Table 2).

Engagement with educational content was high across all groups, with over 8 watched episodes (average 8.9, SD 16.8; Table 2). The average number of videos watched was 9.3 (SD 17.1) in the non-obesity group, 8.7 (SD 16.8) in the obesity group, and 8.1 (SD 14.2) in the severe obesity group.

Patients in the obesity and severe obesity groups had more interactions with the PT than the non-obesity group (severe obesity: 24.6 (SD 10.1); obesity: 23.2 (SD 10.5) vs non-obesity: 22.4 (SD 9.8), P < 0.001).

Overall, satisfaction with the program was high (entire cohort: 9.1, SD 1.5) and similar across BMI categories (severe obesity: 9.2 (SD 1.4), obesity: 9.2 (SD 1.5), non-obesity: 9.1 (SD 1.6), P = 0.045; Table 2).

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Outcomes Mean (SD)	Entire Cohort	Non-Obesity	Obesity	Severe Obesity	P-value <sup>a</sup>
<b>Exercise</b>	2.2	2.2	2.1	1.9	<0.001
(number of sessions per week)	(1.0)	(1.0)	(1.0)	(0.9)	
Education	9.0	9.3	8.7	8.1	<0.001
(video watched)	(16.8)	(17.1)	(16.8)	(14.2)	
Communication	22.9	22.4	23.2	24.6	<0.001
(number of text interactions with the PT)	(10.1)	(9.8)	(10.5)	(10.1)	
Satisfaction	9.1 (1.5)	9.1 (1.6)	9.2 (1.5)	9.2 (1.4)	0.045

Table 2 Patient Engagement and Satisfaction Stratified by Body Mass Index

Note: <sup>a</sup>Significant P-values are italicized.

## **Clinical Outcomes**

Clinical outcomes are presented in Table 3 (model estimates and fitness are available in <u>Supplementary Table 2</u>), and differences in outcome changes between groups are presented in Table 4.

#### Pain

Despite higher baseline pain intensity among patients with obesity, significant and comparable pain reductions were observed across BMI groups by program end, which exceeded the two-point threshold<sup>45</sup> (non-obesity: -2.33, 95% CI -2.39; -2.39; -2.39; -2.39; obesity: -2.43, 95% CI -2.52; -2.35; severe obesity: -2.31, 95% CI -2.49; -2.13; all P < 0.001; obesity vs severe obesity: -0.12; 95% CI -0.32; 0.08, P = 0.227; Tables 3 and 4). Considering an MCIC of 30%,<sup>45</sup> the non-obesity (63.6% 95% CI: 62.3; 64.9, N = 7458) and obesity groups (62.1% 95% CI: 60.7; 63.5, N = 4069) were associated with a higher odds of a positive response compared to the severe obesity group (56.6% 95% CI 54.2; 59.0, N = 1013), corresponding to an adjusted OR of 1.34 (95% CI: 1.18; 1.51, P < 0.001) and 1.26 (95% CI: 1.18; 1.51, P < 0.001), respectively.

 Table 3 Program End and Estimated Outcome Mean Change for the Entire Cohort and Stratified by BMI Category: Intent-to-Treat Analysis

Outcome, Mean (95% CI)	Time	Total Cohort (N=26,491)	Non-Obesity (N=15,112)	Obesity (N=8823)	Severe Obesity (N=2556)	P-value <sup>a</sup>
Pain intensity	n intensity Program end		2.24 (2.18; 2.29)	2.52 (2.44; 2.60)	3.00 (2.82; 3.18)	<0.001
	Mean Change	-2.37 (-2.42; -2.33)	-2.33 (-2.39; -2.28)	-2.43 (-2.52; -2.35)	-2.31 (-2.49; -2.13)	<0.001
	Response rate	62.2 (61.1; 63.3)	63.6 (62.3; 64.9)	62.1 (60.7; 63.5)	56.6 (54.2; 59.0)	<0.001
WPAI - Activity>0	Program end	18.09 (17.52; 18.66)	16.02 (15.37; 16.66)	19.63 (18.64; 20.61)	24.34 (22.20; 26.49)	<0.001
	Mean Change	-19.99 (-20.57; -19.40)	-19.58 (-20.24; -18.91)	-20.06 (-21.06; -19.05)	-21.41 (-23.60; -19.22)	<0.001

Note: <sup>a</sup>Significant P-values are italicized.

Abbreviation: WPAI, Work Productivity and Activity Impairment questionnaire.

Table	4 Differences	in Changes	in	Clinical Outcomes	Across	BMI	Categories

Outcome, Mean (95% CI)	Non-Obesity vs Obesity	P-value	Non-Obesity vs Severe Obesity	P-value	Obesity vs Severe Obesity	P-value
Pain intensity	0.10 (0.00;0.20)	0.051	-0.02 (-0.21;0.16)	0.812	-0.12 (-0.32;0.08)	0.227
WPAI Activity >0	0.06 (-0.07; 0.17)	0.435	0.18 (-0.05; 0.41)	0.117	0.14 (-0.11; 0.38)	0.271

Abbreviation: WPAI, Work Productivity and Activity Impairment questionnaire.

## Activities of Daily Living

All groups reported significant improvements in performing activities of daily living by program end (non-obesity:  $-19.99\ 95\%\ CI:\ -20.57;\ -19.40;\ obesity:\ -20.06\ 95\%\ CI:\ -21.06;\ -19.05;\ severe\ obesity:\ -21.41;\ 95\%\ CI:\ -23.60;\ -19.22,\ P < 0.001\ for\ all,\ Table 3),\ with no\ significant\ differences\ between\ groups\ (P > 0.05\ for\ all,\ Table 4).$ 

## Patient Global Impression of Change

At the 5<sup>th</sup> session, 25.2% of patients reported improvements in their overall quality of life and/or physical ability. Despite statistical differences observed between groups, these are unlikely to be clinically significant given the similar proportions of patients reporting improvement across groups (non-obesity: 24.4%, 95% CI 23.3; 26.0, obesity: 25.8%, 95% CI 25.6; 27.0; severe obesity: 26.8%, 95% CI 24.8; 28.9). By the end of the program, the overall proportion of patients reporting improvements rose to 52% (95% CI 50.8; 53.1, P < 0.001). When stratified by BMI group, 53.6% (95% CI 52.2–55.1) of patients in the obesity group reported improvements, compared to 51.1% (95% CI 49.7–52.4) in the non-obesity group and 50.4% (95% CI 47.9–52.8) in the severe obesity group.

## Impact of Covariates

Women reported higher baseline pain and impairment in daily living activities across all BMI categories (P < 0.001, <u>Supplementary Table 3</u>). Older age was linked to increased pain but not impairment in daily activities, except in patients with severe obesity, whereby WPAI activities impairment increased with age (P = 0.009, <u>Supplementary Table 3</u>). Comorbidities influenced baseline pain in both non-obesity and obesity groups (P < 0.001 for non-obesity; P = 0.043 for obesity).

Pain reduction during the program was unaffected by covariates, except in the non-obesity group, whereby women and older patients showed a steeper decline (women: -0.152, P < 0.001; age: -0.072, P < 0.001). Women without obesity experienced faster improvements in activities of daily living (-0.144, P = 0.012), whereas older patients with obesity had slightly slower progress (0.099, P = 0.025). Covariates did not affect MSK condition recovery for any outcome in patients with severe obesity (P > 0.05), and perception of change was similarly unaffected across groups and time points (P > 0.05).

#### Discussion

#### Main Findings

Completion rates were very high across the entire cohort, ranging from 77.5% to 85.6%, being slightly lower in the obesity groups. Engagement with exercises and educational content was fairly similar across groups (from 1.9 to 2.1 in exercise sessions per week; 8.10 to 9.31 for educational content), with obesity groups interacting significantly more with the physical therapists than the non-obesity group.

Despite the high prevalence of risk factors and greater disease burden in obesity groups at baseline, significant and comparable pain reductions (exceeding the 2-point threshold)<sup>45</sup> were observed across all groups, reflecting the high success rates (62.2%), which were only slightly lower in the severe obesity group. Importantly, high and similar improvements were reported for activities of daily living across all groups. These positive outcomes were translated into high PGIC scores and very high satisfaction levels with the program, >9/10, regardless of group. These results underscore the high acceptability of the program and its feasibility to manage MSK conditions among the obesity population.

#### Comparison with Literature

To our knowledge, this is the first study to evaluate the impact of BMI on engagement and clinical outcomes of a fully remote DCP for MSK pain. Patients living with obesity often face additional risk factors that range from socioeconomic determinants of health to multiple co-occurring health conditions.<sup>13</sup> In this study, the obesity groups exhibited baseline demographic and clinical characteristics typically associated with a higher risk for poor prognosis. These included older age,<sup>33,58</sup> Black race/ethnicity,<sup>59</sup> lower educational attainment,<sup>33,58</sup> comorbidities,<sup>10,11,31</sup> and greater disease burden manifesting as higher pain levels and functional impairment.<sup>10,60</sup> Obesity is strongly associated with treatment failure in several interventions, namely surgery and invasive procedures (eg, spinal injections).<sup>61,62</sup>

Further compounding these obesity-related challenges, this population can experience higher resistance to exercise-based interventions, as well as access hurdles to physical therapy. Exercise is a critical component of MSK pain management, with benefits extending beyond the MSK system, such as improving cardiovascular health and metabolic function and anti-inflammatory effects, which is particularly important in a population often characterized as being in a perpetual low-grade systemic inflammatory state.<sup>60,63,64</sup> This study demonstrated high overall engagement with the intervention, with completion rates ranging from 77.5% to 85.6%, being only slightly lower in the severe obesity group. Engagement with exercise sessions and educational content was fairly similar across groups, again slightly lower in the severe obesity group. Prior research has found similar patterns between patients with and without obesity, where comparable levels of engagement were reported in one study regardless of BMI category.<sup>65</sup> This study, however, did not include data on patients with severe obesity,<sup>65</sup> and the overall lack of literature in this population limits further contextualization.

High engagement with educational content may be particularly important since increased health literacy is associated with improved outcomes,<sup>66</sup> including greater knowledge of one's condition and a lower susceptibility to misconceptions about exercise, thereby empowering patients with better self-management tools.<sup>21</sup>

Along with education, the on-demand availability of the PT may have contributed to the high responder rate, as patients who feel accountable and supported are more likely to participate in a patient-centric treatment approach.<sup>21</sup> A previous study assessing the perspectives of patients with obesity on telehealth found that participants considered telephone and text message support highly beneficial, providing encouragement, motivation and accountability via simple and convenient modes of communication.<sup>67</sup> Indeed, in this study high levels of interactions were reported across all groups but most prominently among

the severe obesity group. This highlights the need for paying particular attention to nurturing a therapeutic relationship in obesity groups.

The accessibility and convenience afforded by the DCP may have fostered the meaningful improvements observed. Obesity groups demonstrated significant and similar improvements in pain and function compared to the non-obesity group at program end. Overall pain reduction exceeded the 2-point threshold identified by IMMPACT guidelines as the MCIC,<sup>45</sup> reflecting the uniformly high response rates observed across BMI categories. Importantly, similarly robust outcomes were observed in terms of activities of daily living impairment, reinforcing the intervention's positive effects on quality of life regardless of BMI. Previous literature evaluating the impact of BMI on pain and function has predominantly focused on traditional in-person physical therapy, with heterogeneous findings.<sup>27–33,65</sup> Whereas some studies have found no significant differences in improvements across BMI groups,<sup>27–30,65</sup> others have reported poorer outcomes among patients with a higher BMI.<sup>31–33</sup>

As the program progressed, patients' perceptions of their overall quality of life and/or physical ability improved across all BMI groups. Of note, at program end, a higher perception of change was reported by the obesity group, translating into very high satisfaction levels (>9.0/10) regardless of BMI category. The multimodal nature of this DCP may have contributed to outcomes, as suggested by previous research assessing transdisciplinary treatment for chronic pain.<sup>68</sup>

#### Strengths and Limitations

The study has several important strengths. Considering the growing population suffering from MSK conditions and concomitant obesity, a group that faces sometimes daunting barriers to care access,<sup>21</sup> evaluating the potential of digital interventions as an alternative delivery mode is very timely. Additionally, the large real-world cohort, including a proportional number of patients with obesity and severe obesity as reported in the US population, greatly enhances generalizability.<sup>69,70</sup>

There are several limitations to this study that warrant discussion. First, despite BMI being widely used as a measure of poor fitness and being overweight, it may not be the best anthropometric measure. Further studies should incorporate body composition analysis, including muscle mass, fat distribution, and visceral fat presence. Visceral fat has a particularly important role in systemic low-grade inflammation, a known contributor to the onset and progression of several musculoskeletal conditions.<sup>60,64</sup> Also, the reliance on self-reported BMI may introduce inaccuracies. However, given the fully remote nature of this intervention, obtaining direct, objective BMI measurements was not feasible. Second, although we accounted for diabetes and cardiovascular diseases, other comorbidities such as psychiatric ones were not considered, leaving uncertainty regarding their potential impact on the outcomes. As was previously noted, patients with obesity have high co-prevalence rates of psychiatric disorders,<sup>71</sup> which are themselves independent predictors of pain treatment failure.<sup>62</sup> including for physical therapy.<sup>33</sup> Third, the analysis did not account for potential concomitant care received during the intervention period, including pharmacological treatments, which is a potential confounding factor to address in future research. In one randomized comparative-effectiveness study, a combination of physical therapy with pharmacological treatments was found to be an additive effect for back pain.<sup>72</sup> As this is a post-hoc analysis, we were limited to the data available from the original clinical study. As such, we foster to mitigate their influence by applying LGBA which accounts for latent patterns that may not be explicit on the studied variables. Fourth, the study design did not allow for evaluating the individual impact of DCP components on outcomes. Finally, the lack of long-term follow-up limits our ability to assess the program's sustained benefits.

## Conclusion

This real-world context study highlights the potential of an MSK digital care intervention to deliver equitable care across diverse patient populations, regardless of BMI. The high completion rates, engagement, and significant clinical improvements achieved in the obesity groups were comparable to the non-obesity group, despite a higher disease burden. Overall, patients were highly satisfied with the program, underscoring the DCP's convenience, feasibility, and ability to contribute to a positive quality of life in patients living with obesity. Such programs offer a scalable, patient-centered approach, improving accessibility specially important for underserved populations or individuals that face unique barriers to traditional care. Future research will strengthen the evidence in this field by further exploring unmeasured factors as well as to provide insights on the long-term stance of these findings.

## **Abbreviations**

adOR, Adjusted Odds Ratio; ANOVA, Analysis of variance; CI, Confidence Interval; DALY, Disability-adjusted life years; DCP, Digital care program; BMI, Body Mass Index; US, United States; CBT, Cognitive behavioral therapy; FDA, United States Food and Drug Administration; FIML, Full information maximum likelihood; GAD-7, Generalized Anxiety Disorder 7-item scale; IMMPACT, Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials; LBGA, Latent-basis growth analysis; MCIC, Minimal Clinically Important Change; MSK, Musculoskeletal; NA, Not Available; NPRS, Numerical Pain Rating Scale; PGIC, Patient Global Impression of Change; PHQ-9, Patient Health 9-item questionnaire; PT, Physical Therapist; SD, Standard Deviation; US, United States; WHO, World Health Organization; WPAI, Work Productivity and Activity Impairment.

## **Data Sharing Statement**

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

## **Ethics Approval and Informed Consent**

The study was approved by the Advarra IRB (protocol number Pro00063337) and prospectively registered in ClinicalTrials.gov (NCT05417685) on June 14th, 2022. 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 managing the participants. The authors also acknowledge the contributions of Daniel Rodrigues and Guilherme Freches in data processing (all employees of 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 work was supported by Sword Health Inc. and also developed within the scope of project n° 62—"Responsible AI", financed by European Funds, namely the Recovery and Resilience Plan—"Componente 5: Agendas Mobilizadoras para a Inovação Empresarial", included in the NextGenerationEU funding program.

## Disclosure

Authors Ana P. Pereira, Dora Janela, Anabela C. Areias, Maria Molinos, Virgílio Bento, Vijay Yanamadala, Fernando Dias Correia, and Fabíola Costa were employed by the company Sword Health Inc., the sponsor of this study. Virgílio Bento, Vijay Yanamadala, and Fernando Dias Correia also hold equity in Sword Health, and Virgílio Bento is the CEO of the same company. Xin Tong and Steven P. Cohen receive scientific advisor honorarium from SWORD Health. The study sponsor, Sword Health, was involved in the study design, data collection and interpretation, and writing of the manuscript. The authors report no other conflicts of interest in this work.

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