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Does a Digital Care Program for Adult Scoliosis Improve Outcomes? A Pilot Study

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Abstract

Background: Adult Scoliosis (AS) affects an estimated 51 million adults in the United States, approximately half of whom have related back pain. Nonoperative therapy is first-line treatment, but has been shown to provide minimal benefit. The National Scoliosis Clinic's (NSC) Scoliosis Realignment Therapy (SRT) is a personalized scoliosis-specific exercise program delivered remotely through a computer or mobile device. A pilot study was conducted to assess pain and functional outcomes associated with SRT.

Methods: NSC members were enrolled from April 1, 2024 to May 31, 2024. Participants reported their pain and health-related outcomes at baseline and 6 weeks using the Scoliosis Research Society Health-Related Quality of Life Questionnaire (SRS-22r) and Oswestry Disability Index (ODI). Data were analyzed using a linear mixed-model approach.

Results: Twenty-three users completed the six-week survey. The majority (22/23) were female and the mean age was 65 years. There was no statistical difference in baseline Total SRS-22r score or ODI between study participants who completed the 6-week surveys and those who were lost to follow up. Following six weeks of SRT, significant improvement in the Pain ($P<0.001$), Self-Image ($P=0.05$), and Mental Health ($P<0.001$) subdomains of the SRS-22r, and Total SRS-22r scoring ($P<0.001$) was observed. The improvement in the Pain subdomain exceeded the minimal clinically important difference threshold.

Conclusion: The SRT remote digital program offers a nonoperative approach to improving outcomes and holds promise for transforming the current adult scoliosis care paradigm.

Keywords: Adult scoliosis • Adult deformity • Nonoperative management • Scoliosis realignment therapy • Digital health

Introduction

Adult Scoliosis (AS) is a debilitating disease affecting approximately 38% of adults over the age of 40 and 68% of the population aged 60 years and older, with 51% experiencing back pain [1-3]. Individuals with AS also experience negative impacts on quality of life and functional capacity [4]. With a growing elderly population, effective management of AS is critical in reducing the high burden of this disease.

As a condition caused by chronic structural abnormalities and a degenerative spine, the pain often worsens if left untreated. While operative treatment has been shown to offer improved outcomes over nonoperative treatment in the management of AS [5-7] nonoperative treatment remains the first-line therapy due to the associated risks of spinal surgery [8]. Not all patients are surgical candidates and surgery is often reserved for those with debilitating disease or neurological deficits [9]. However, data show limited efficacy of current nonoperative management of AS and substantial healthcare costs, albeit with low associated risks to the patient [10,11]. Alternative nonoperative treatments focused on core strengthening and symptom management are currently being employed as possible tools for management of AS without the associated risks of surgery [9-12].

The National Scoliosis Clinic's Scoliosis Realignment Therapy (SRT) is a digital health program that provides accessible remote therapy modules for individuals with scoliosis. The modules were developed in conjunction with ScolioPilates®, and are designed specifically for adults with scoliosis, differentiating the modality from standard physical therapy. Scolio-Pilates® is a scoliosis-specific exercise that includes elongation, corrective breathing, strengthening and corrective activities of daily living. In addition to the therapy modules, the program also includes education, community, and live virtual group sessions, as well as AI-driven technology to assess curvature and provide personalized therapy solutions. An advantage of this digital program is users can access the content from their home without the need to maintain an in-person presence to participate in the program.

The effectiveness of SRT has not yet been explored. As such, the primary purpose of this pilot study was to assess pain, quality of life, and functional outcomes associated with participants enrolled in SRT.

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Methods

Adult individuals with symptomatic scoliosis based on prior outside diagnosis were recruited for the study from April 1, to May 31, 2024. Inclusion criteria were any current or recently enrolled user of SRT and 18 years and older. The program registration fee was waived for individuals who chose to participate in the study. Following agreement to participate, SRT users completed surveys at baseline and 6 weeks including the following validated health questionnaires: Scoliosis Research Society Health-Related Quality of Life Questionnaire (SRS-22r) and Oswestry Disability Index (ODI). Baseline was defined in the surveys as functional scores prior to beginning to use the SRT program, and in some cases, were retrospective depending on user join date. Demographics, medical history, healthcare resource utilization, and satisfaction were also reported. Participants were provided two weeks to respond to surveys before reminders were sent. Users that failed to complete surveys following the 2-week reminder were considered lost to follow up.

Statistical analysis

SRS-22r subdomain scoring consisting of perceptions of functionality, pain, self-image, and mental health were calculated at baseline and 6-week timepoints. In this 22 question survey, the maximum score of 5 reflects highest quality of life, while a minimum score of 1 reflects very poor quality of life. ODI, a subjective, 10 question self-reported level of function was also calculated at the baseline and 6-week timepoints. An ODI score of 0 represents no disability, while a score 50 represents complete disability. The Minimal Clinically Important Difference (MCID) for SRS-22r Total and subdomains is 0.4 [13] and for ODI is 6 points [14]. Utilization of healthcare resources, opioid usage, healthcare spending, and SRT program usage were also collected.

A Student *t-test* was used to compare baseline Total SRS-22r and ODI scores of individuals who completed the 6-week survey *vs.* those who were lost to followup to ensure no differences existed between groups. Changes in patient-reported outcomes from baseline to 6 weeks were analyzed using a linear mixed-model approach to account for repeated measures within individuals, while maintaining the ability to use remaining data at baseline to estimate group means. The longitudinal mixed-model was specified using restricted maximum likelihood and Welch's two-sided t-tests were calculated using Satterthwaite's approximation. Statistical analyses were performed using R with the lmerTest package.

Results

In total, 53 NSC members were enrolled in the pilot study and completed the baseline survey, of which 23 (43%) completed the 6-week survey. Reasons for discontinuation included lack of time and disengagement. The mean age of the 6-week completers was 65 years with a mean time since scoliosis diagnosis of 35 years; the majority were female (95.7%) (Table 1).

In the three months prior to filling out the baseline survey, the 6-month completers incurred an average of $536 in out-of-pocket medical expenses, including spine imaging (30.4%) and daily opioid pain medication (17.4%), for scoliosis or back pain. The majority of respondents (60.9%) to the 6-week survey reported performing the SRT exercises 3-5 times per week.

Analyses of missing responses

Thirty study participants failed to respond to the 6-week survey. Baseline mean Total SRS-22r and ODI for individuals that completed the 6-week survey compared to those who dropped out were not significantly different (Total SRS-22r: 3.0 *vs.* 3.1, P=0.56; ODI: 15.3 *vs.* 16.1, P=0.69), indicating that baseline outcomes exhibited good homogeneity prior to initiating SRT and 6-week outcomes were likely unaffected by dropout status alone.

SRS-22r (quality-of-life)

At baseline, the mean Total SRS-22r score was 3.06 out of a 5-point scale,

Table 1. Baseline characteristics of 6-week survey completers (N=23).

Characteristic		
Age in years, mean (SD)	65.8 (12.3)	
Gender, n (%)	Female	22 (95.7.3%)
	Male	1 (4.3%)
Race, n (%)	White	21 (91.3%)
	Hispanic or Latino	1 (4.3%)
	Mixed, more than 4	1 (4.3%)
Time since scoliosis diagnosis in years, mean (SD)	35.2 (23.1)	
Charlson Comorbidity Index, mean (SD)	2.41 (1.26)	
Healthcare spending in prior 3 months[1], mean (SD)	$536 (1090)	
Spine imaging in prior 3 months[2], n (%)	No	15 (65.2%)
	Yes	7 (30.4%)
	Did not respond	1 (4.3%)
Over-the-counter pain medication usage, n (%)	Less than once a week	6 (26.1.5%)
	Weekly	5 (21.7%)
	Daily	3 (13.0%)
	Never	8 (34.7%)
	Did not respond	1 (4.3%)
Opioid pain medication usage, n (%)	Less than once a week	1 (4.3%)
	Weekly	0 (0%)
	Daily	4 (17.4%)
	Never	17 (73.9%)
	Did not respond	1 (4.3%)

1. For scoliosis or back pain
2. Includes X-ray, CT, and MRI

Table 2. SRS-22r and ODI scores at baseline and after six weeks of SRT program participation (Baseline N=53, six week N=23)[1].

Outcome Measure	Baseline (SD)	Six Week (SD)	Effect Size	P-Value
SRS-22r Function	3.5 (0.75)	3.7 (0.69)	0.12	P=0.22
SRS-22r Pain	3.0 (0.70)	3.5 (0.76)	0.502	P<0.001
SRS-22r Self-Image	2.7 (0.68)	2.8 (0.62)	0.21	P=0.05
SRS-22r Mental Health	3.3 (0.88)	3.6 (0.79)	0.38	P<0.001
SRS-22r Total	3.1 (0.59)	3.4 (0.60)	0.34	P<0.001
ODI	16 (7.3)	14 (7.1)	-1.7	P=0.13

1. Data from all 53 participants was used in the mixed-model approach to more accurately estimate the mean and variance at the baseline time point
2. Difference between baseline and six-week pain subscores was greater than MCID of 0.4

with a significant improvement following six weeks of program utilization (Table 2), resulting in a mean score 3.35 (P<0.001). Specifically, significant improvement in the Pain (3.0 vs. 3.5; effect size [ES]=0.50, P<0.001), Self-Image (2.7 vs. 2.8; ES=0.21, P=0.05) and Mental Health subdomains (3.3 vs. 3.6; ES=0.38, P<0.001) was observed. Of these domains, improvement in the Pain subdomain exceeded the MCID of 0.4. An increase in the Functionality subdomain was also observed, but was not statistically significant.

ODI (functionality)

To further assess changes in disability, ODI scores were compared to evaluate levels of self-reported functionality. The mean ODI score at baseline was 15.7 (SD=7.3): "Moderate Disability" and improved to 13.6 (SD=7.1): "Mild Disability" following six weeks of therapy. However, this result was nonsignificant (P=0.13), consistent with the lack of significant improvement solely in the SRS-22r Functionality subdomain.

User satisfaction

Participants reported high satisfaction with the program, averaging a 9.5/10, where 1 reflects extremely dissatisfied and 10 reflect extremely satisfied. Qualitative data from participant responses indicated that the majority of individuals would be very disappointed (73%) or somewhat disappointed (27%) if they were unable to continue use of SRT. Formative comments revolved around the program helping to improve pain control, increased strength and posture, receiving more information about their condition, and ease of accessibility from home.

Discussion

This pilot study sought to determine the effectiveness of SRT, a personalized digital therapy program for adults with scoliosis. After six weeks of participation, statistically significant improvements in pain, self-image, and mental health were observed. As such, SRT may offer an opportunity for effective symptom control, as well as reduce patient out-of-pocket healthcare spending and payor expenditures.

There is a paucity of evidence supporting the effectiveness of nonoperative treatment in the management of AS, although it is universally employed as first-line treatment [15]. Glassman, et al. evaluated nonoperative treatment of AS and found no significant reduction in patient outcomes after two years of follow up [10]. Specifically, the authors observed no change in Total SRS-22 score in the nonoperative treatment group after 2 years of follow up (3.3 *vs.* 3.3, p=0.405) and no significant change in any of the SRS-22 subdomains. Compared to our results, we observed an improvement in Total SRS-22 score at 6 weeks follow up from 3.1 to 3.4 (p<0.001) with significant improvements in pain, self-image, and mental health subdomains. Glassman SD, et al. noted that nonoperative treatment programs employed in their study were variable and were not well-defined, including a variety of nonspecific indications and techniques. Digital care therapies such as SRT may allow for more effective treatment and monitoring. Liu S, et al. evaluated certain factors that may predict whether patients would benefit from nonoperative management [16]. They determined that higher baseline pain scores and lower coronal deformity in the thoracolumbar region were identified in patients that responded to nonoperative therapy, and noted that while overall results suggested minimal improvement in the cohort, 54% of patients did significantly improve in pain or activity at 2 years follow up [16].

SRT has several advantages including its accessible, online format, low risk to the participant, and personalized tailoring of therapeutic exercises. The results from this study suggest significant improvements in SRS-22r scores including Pain (P<0.001), Self-Image (P=0.032), and Mental Health (P=0.001) subdomains of the SRS-22r, and Total SRS-22r scoring (P<0.001). Pain scores reached the 0.4 threshold of MCID, with an improvement from 3.0 to 3.5, suggesting there is a perceivable benefit to the patients receiving SRT treatment. This was supported by the high user satisfaction rate, which may also be a result of its remote format and ease of access. These outcomes are an improvement from standard nonoperative modalities, such as physical therapy, chiropractic care, and medications, and suggest the possibility for improved effectiveness of nonoperative treatment.

There are several limitations in this study. While 53 users were enrolled in the study, only 23 users completed the 6-week survey. Nevertheless, despite the high dropout rate, baseline Total SRS-22r and ODI scores between groups demonstrated no statistical difference, suggesting low risk of attrition bias. Additionally, not all participants (18 out of 23) were able to be distributed baseline surveys prior to their initiation of the SRT program, which may increase the risk of recall bias. Future research will evaluate SRT in a larger cohort over a longer term.

Conclusion

The SRT program is convenient and accessible, obviating the need for in-person services. Users reported high satisfaction rates, which may reflect the convenience or the improved function and pain. The SRT remote digital program offers a nonoperative approach to improving outcomes and holds promise for transforming the current adult scoliosis care paradigm.

Acknowledgement

None.

Conflict of Interest

Karena Thek is the Co-founder of ScolioPilates(R).

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