# Physical Therapist–Led Exercise Assessment and Counseling in Integrative Cancer Care: Effects on Patient Self-reported Symptoms and Quality of Life

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#### Abstract

Background. Exercise - contributes to improved treatment-related outcomes. We reviewed characteristics of cancer patients referred for physical therapist-led exercise counseling at a comprehensive cancer center and its effects on selfreported symptoms and quality of life. Methods. Patients presenting for outpatient exercise counseling from February 2016 to May 2017 completed the Edmonton Symptom Assessment Scale (ESAS; 0-10 scale, 10 most severe) preencounter/post-encounter and Patient-Reported Outcomes Measurement Information System (PROMISIO) global health assessment pre-encounter. Counseling included assessment and education. ESAS individual items and subscales of physical distress (PHS), psychological distress, and global distress (GDS) were analyzed. We used paired t-tests to compare (1) ESAS symptoms pre-encounter/post-encounter and (2) ESAS and PROMISIO scores at baseline (pre-encounter) and first follow-up. Results. Of 350 participants, most were female (77.7%), Caucasian (66.3%), and had breast cancer (43%). Baseline (pre-encounter) symptom scores (frequency; mean) included poor sleep (68.2%; 3.5), poor well-being (67.4%; 3.2), and fatigue (64.7%; 3.1). Comparing pre-encounter/postencounter ESAS outcomes, we observed statistically and clinically significant reduction in GDS (-3.32; SD = 6.52; P < .001). On follow-up, statistically and clinically significant improvements were observed for fatigue (-1.22; P = .01), GDS (-4.81; P = .01), PHS (-3.1; P = .03) and PROMIS10 global health, mental health, and physical health scores (all P < .05). Conclusion. Patients presenting for exercise counseling had a low to moderate symptom burden and experienced significant improvement in GDS. Longitudinal evaluation revealed improvement in global health and fatigue. Additional research is needed to learn more about patient selection and timing of exercise counseling.

#### **Keywords**

integrative oncology, physical therapy, complementary health approaches, patient reported outcomes, cancer, exercise counseling

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## Introduction

Exercise during and after cancer treatment has been found to be safe and is recommended by organizations including the American Institute for Cancer Research, the American Cancer Society, and the American College of Sports Medicine (ACSM). Benefits of exercise in this setting can include help in decreasing fatigue<sup>1,2</sup>; restoration of muscle mass and strength<sup>1</sup>; improvement in sleep quality<sup>1</sup>; reduction in long-term and late effects of cancer treatment<sup>1</sup>; restoration of balance and mobility<sup>1</sup>; decrease in bone loss from hormonal therapies, radiation, or inactivity<sup>3</sup>; assistance in losing weight, which may improve overall survival<sup>4</sup>; decrease in risk of cancer recurrence<sup>5-7</sup>; and reduction in

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depression and anxiety.<sup>8</sup> A recent literature review of lifestyle factors and their effect on risk reduction for breast cancer recurrence found that exercise, more than weight management, diet, smoking, alcohol intake, or vitamin supplementation, had the most profound impact on decreasing the risk of recurrence or death from breast cancer.<sup>6</sup>

Although physical activity and exercise are often terms used interchangeably, in order to deliver clear instructions to patients about how to get the most benefit from their efforts to be active, it is important to differentiate between the two. Whereas physical activity is defined as any form of movement involving skeletal muscles that expends energy, exercise is a physical activity that is planned, structured, repetitive, and with purpose.<sup>9</sup> It is important that exercise during and after cancer treatment be approached with care, considering the patient's current physical abilities, exercise goals, prior fitness level, and practical experience with exercise. A physical therapist specializing in exercise for people with cancer can help develop a safe, individualized exercise plan to assist patients in meeting health needs and managing symptoms and treatment-related side effects.<sup>10-14</sup>

Integrative medicine seeks to bring evidence-informed, nonconventional approaches into conventional medical care in a way that is coordinated and safe.<sup>15</sup> At the Integrative Medicine Center, University of Texas MD Anderson Cancer Center, a physical therapist–led exercise counseling service provides evidence-informed physical ability assessment and exercise education to patients during or after cancer care. Referrals are made to exercise counseling after the patient is first evaluated by an integrative medicine physician and/or advanced practice provider as part of a comprehensive evaluation of the patient's physical and psychosocial needs.<sup>16</sup>

Although there has been increased interest in prescribing exercise to support health during and after cancer care, little has been published on real-world initiatives to implement exercise counseling as part of the standard of care. As part of our exercise counseling service, we have also integrated self-reported outcomes assessments into routine clinical care in an effort to learn more about the immediate and long-term effects of this intervention. This retrospective analysis reports on the characteristics of those referred for exercise counseling at a comprehensive cancer center, provides insight into the feasibility of integrating patient selfreported outcome assessments as part of this clinical service, and examines the effects of the exercise counseling session on self-reported symptoms and quality of life.

# Methods

Patients were referred to exercise counseling after a comprehensive physical and psychosocial health evaluation performed by an integrative medicine physician and/or advanced practice provider. Referrals to exercise counseling could only come from within the integrative medicine center, and referrals to the integrative medicine center could only come from centers within the cancer hospital. Patients referred for exercise counseling included but were not limited to (1) those interested in guidance regarding physical activity for health, weight loss, and/or symptom management given their cancer history; (2) patients not currently meeting recommended ACSM exercise guidelines<sup>10</sup>; and (3) patients already exercising but uncertain if their exercise program is appropriate given their overall health goals and cancer history. Care was taken to distinguish patients more appropriate for traditional outpatient physical therapy services than for exercise counseling. Patients with functional limitations that caused them to be unsafe or inappropriate to participate in generalized aerobic and strengthening exercise independently had their care transferred to traditional outpatient physical therapy.

Before and after the exercise counseling session, patients completed the Edmonton Symptom Assessment Scale-Financial Spiritual (ESAS-FS).<sup>17,18</sup> The Patient-Reported Outcomes Measurement Information System (PROMIS10) scale was only completed by patients at the time of their exercise counseling session if it had not already been completed within the prior 30 days as part of another clinical service in our center. Per the settings of our patient-reported outcomes system, if a PROMIS10 scale has not been completed by a patient in the prior 30 days, it will electronically push the form to the patient for completion at their next clinical service in our center. Patient self-reported outcome assessments were collected electronically using an iPad. These collected data were stored in a secured, HIPAA compliant, FileMaker Pro database as part of an institutional review board-approved protocol; a waiver of informed consent was granted for this retrospective analysis. Data were analyzed for exercise counseling sessions taking place between February 2016 and May 2017.

#### Intervention

The exercise counseling session, approximately 60 minutes in length, was led by a physical therapist with specialized oncology training. Results of patient self-reported assessments from current and, if applicable, prior, counseling sessions were made available as an electronic and/or printed summary report to the physical therapist during the clinical encounter. The clinical assessment included a review of the patient's symptom summary report, medical record, current functional status, and current and previous exercise habits and capabilities. Current functional status/physical ability was assessed during the exercise counseling session using measures such as 5 times sit-to-stand, 30-s single-limb stance, tandem walk, timed bicep curls, and grip strength dynamometry. Patients received individualized education regarding the benefits of exercise, taking into account their specific cancer, treatment, physiological responses to treatment, risk for (short- or long-term) side effects, and any relevant comorbidities or preexisting musculoskeletal concerns. Patient education also included training in energy conservation techniques (eg, adjusting posture, prioritizing activities, planning time for rest, asking for help, and/or delegating tasks where possible) to assist in the management of fatigue.<sup>19</sup> Individualized exercise recommendations were developed, including short- and long-term exercise goals and plans for follow-up sessions. Patients were often guided through whole body strengthening exercises to ensure proper form and understanding regarding recommended exercises.

#### Measures

The ESAS-FS includes 10 core symptoms (pain, fatigue, nausea, depression, anxiety, drowsiness, appetite, wellbeing, shortness of breath, and sleep) and additional items of spiritual pain and financial distress on a numerical scale of 0 to 10 (10 = worst possible expression of that symptom). ESAS subscales scores included global distress (GDS, 0-90), physical distress (PHS, 0-60), and psychological distress (PSS, 0-20). The GDS is the sum of pain, fatigue, nausea, drowsiness, appetite, shortness of breath, anxiety, depression, and well-being scores. The PHS is a sum of pain, fatigue, nausea, drowsiness, appetite, and shortness of breath. The PSS is a sum of anxiety and depression. Clinically significant change is described as a reduction  $\geq 1$  on any individual symptom score or a reduction  $\leq 3$  for the GDS and  $\geq 2$  for the PHS and PSS subscales.<sup>20,21</sup>

The PROMIS10,<sup>22</sup> an assessment of global health, includes 10 self-report items that can be divided into mental health and physical health subscales. Responses are converted into T-score values, with T-score distributions standardized to the mean for the US population. Higher scores represent better global, mental, or physical health.

### Data Analyses

Data were analyzed for self-reported symptoms collected pre– and post–exercise counseling. Summary statistics (sample size, mean, SD, and ranges) were obtained for baseline demographics, clinical characteristics, ESAS individual symptoms and subscales, and PROMIS10 scores. Paired *t*-tests were conducted for change in pre-encounter/ postencounter ESAS symptom scores and subscales and change from baseline visit to follow-up visit within 60 days for ESAS symptom scores, subscales, and PROMIS10 scores. For calculations regarding symptom score change from pre-encounter/postencounter and baseline to first follow-up, only those reporting an ESAS symptom score  $\geq 1$  at baseline were included in the analysis.

#### Results

#### Demographics

Data were evaluated for 350 individuals completing an exercise counseling session during the time period February 2016 through May 2017. Pre-exercise counseling ESAS data were available for 337/350 (96.3%) participants; pre-ESAS and post-ESAS data were available for 281/350 (80.3%) participants. Baseline PROMIS10 data were available for 313/350 (89.4%) participants. On review of demographics, the average age of patients was 55.8 years; the majority were female (77.7%) and white (66.3%), with place of residence in the state of Texas (92.9%) and with the most frequent primary cancer diagnoses being breast (43.4%), gastrointestinal (16.3%), and thoracic/head and neck (9.7%; see Table 1).

## Baseline Symptoms and Quality of Life

Of all 12 ESAS symptoms, highest (worst) symptom scores in patients presenting for exercise counseling were observed for poor sleep (3.5), well-being (3.2), and fatigue (3.1; see Supplemental Material 1, baseline symptoms). In the subset of ESAS physical symptoms, the highest (worst) physical symptom scores were for fatigue (3.1), poor appetite (2.4), and pain (2.3). The most frequently reported symptoms at the baseline counseling visit included poor sleep (68.2%), poor well-being (67.4%), and fatigue (64.7%). With regard to quality of life, the PROMIS10 global health (raw) score was 31.4 (SD = 7.1). Results for the PROMIS10 subscales (raw score, means) include a mental health subscale score of 12.4 (SD = 3.3) and physical health score of 13.0 (SD = 3), both within 1 SD below the US population mean.

# Pre-exercise and Postexercise Counseling ESAS Symptom Change

For each symptom, we calculated the change in symptom score before and after the exercise counseling visit. With the goal of assessing the effect of the intervention on presenting symptoms, our analysis only included symptoms for which the baseline ESAS symptom score was reported as  $\geq 1$  (Table 2). Individual symptom scores in the moderate (4-7) range included poor sleep (4.21) and financial distress (4.01). We observed statistically significant improvement for all presenting ESAS symptoms and subscales (P < .001), with clinically significant improvement only for GDS (-3.32, SD = 6.52; change of GDS  $\geq 3$  denotes clinically significant reduction).

### Longitudinal Change for ESAS and PROMISIO

Time to first follow-up visit was on average 57.7 days, with 31.4% (110/350) having at least 1 follow-up visit. In the

| Characteristics |                            | n (%) <sup>a</sup>        |
|-----------------|----------------------------|---------------------------|
| Age             |                            | Mean (SD) = 55.83 (12.76) |
| Gender          | Female                     | 272 (77.7%)               |
|                 | Male                       | 78 (22.3%)                |
| Race            | White or Caucasian         | 232 (66.3%)               |
|                 | Hispanic                   | 50 (14.3%)                |
|                 | Asian                      | 29 (8.3%)                 |
|                 | Black or African American  | 26 (7.4%)                 |
|                 | Other/Not specified        | 13 (3.7%)                 |
| Marital status  | Married/Significant other  | 247 (70.6%)               |
|                 | Single                     | 47 (13.4%)                |
|                 | Divorced/Legally separated | 33 (9.4%)                 |
|                 | Widowed                    | 22 (6.3%)                 |
|                 | Other                      | I (0.3%)                  |
| Residence       | Harris Country             | 110 (31.4%)               |
|                 | Seven surrounding counties | 53 (15.1%)                |
|                 | Rest of Texas              | 162 (46.3%)               |
|                 | Rest of the United States  | 13 (3.7%)                 |
|                 | International              | 12 (3.4%)                 |
| Cancer          | Breast                     | 152 (43.4%)               |
|                 | Gastrointestinal           | 57 (16.3%)                |
|                 | Thoracic/Head and neck     | 34 (9.7%)                 |
|                 | Gynecological              | 25 (7.1%)                 |
|                 | Genitourinary              | 21 (6.0%)                 |
|                 | Lymphoma/Myeloma           | 20 (5.7%)                 |
|                 | Sarcoma                    | 11 (3.1%)                 |
|                 | Leukemia                   | 9 (2.6%)                  |
|                 | Central nervous system     | 8 (2.2%)                  |
|                 | Melanoma                   | 7 (2.0%)                  |
|                 | Endocrine glands           | 5 (1.4%)                  |
|                 | Other                      | (0.3%)                    |
| Stage           | Advanced                   | 70 (20.0%)                |
| -               | Local                      | 108 (30.9%)               |
|                 | Unstaged                   | 172 (49.1%)               |

Table 1. Patient Demographics and Clinical Characteristics (n = 350).

<sup>a</sup>Unless otherwise mentioned.

subset of patients with at least 1 follow-up visit within 60 days of their initial visit (n = 37), we calculated symptom change for individual ESAS symptom scores and subscales (pre-encounter to post-encounter; Table 3). We observed statistically significant improvement (P < .05) in symptoms of fatigue, depression, appetite, and ESAS subscales of GDS and PHS. Clinically significant improvement (ESAS individual score change  $\geq 1$ ) was only observed for the individual symptom of fatigue and for ESAS subscales of GDS and PHS (change of GDS  $\geq$ 3 or PHS  $\geq$ 2). We also calculated change in PROMIS10 guality-of-life scores between the initial and follow-up visits within 60 days (n = 89; Table 4). We observed statistically significant improvement in the global health total score (P = .005) as well as significant improvement in the mental health (P = .004) and physical health (P = .034) subscale scores.

## Discussion

There has been increased recognition regarding the importance of physical activity for individuals during and after cancer care, with favorable effects on quality of life, mood symptoms, recurrence risk, and mortality as well as notable improvements in fitness, muscle strength, and body composition.<sup>23,24</sup> We explored the immediate and longitudinal effects of an exercise counseling service on selfreported symptoms and quality of life of patients at a comprehensive cancer center, which was provided as part of an integrative medicine program. In addition, as part of our effort to improve clinical care and track outcomes, we successfully integrated an electronic system for capturing self-reported outcomes as part of our standard clinical practice, with assessment completion rates exceeding 80%

| ESAS Symptoms and<br>Subscales | Baseline Difference Between Pre/Post Values |                    |                    |                               |         |  |
|--------------------------------|---|--------------------|--------------------|-------------------------------|---------|--|
|                                | n   | Mean, Pre-exercise | Mean, Postexercise | Mean Change (SD) <sup>a</sup> | P Value |  |
| Pain                           | 179   | 3.46               | 2.93               | -0.54 (1.55)                  | <.001   |  |
| Fatigue                        | 218   | 3.85               | 3.04               | -0.81 (1.99)                  | <.001   |  |
| Nausea                         | 62  | 2.77               | 1.79               | -0.98 (1.55)                  | <.001   |  |
| Depression                     | 124   | 3.1                | 2.48               | -0.62 (1.38)                  | <.001   |  |
| Anxiety                        | 164   | 3.34               | 2.41               | -0.93 (1.54)                  | <.001   |  |
| Drowsiness                     | 141   | 3.27               | 2.72               | -0.55 (1.54)                  | <.001   |  |
| Appetite                       | 170   | 3.99               | 3.26               | -0.73 (1.95)                  | <.001   |  |
| Wellbeing                      | 227   | 3.82               | 2.96               | -0.86 (1.55)                  | <.001   |  |
| Shortness of breath            | 83  | 2.75               | 2.13               | -0.61 (1.52)                  | <.001   |  |
| Sleep                          | 230   | 4.21               | 3.7                | -0.51 (1.57)                  | <.001   |  |
| Financial distress             | 156   | 4.01               | 3.5                | -0.51 (1.4)                   | <.001   |  |
| Spiritual pain                 | 92  | 2.89               | 2.17               | -0.72 (1.36)                  | <.001   |  |
| GDS <sup>b</sup>               | 252   | 18.52              | 15.2               | -3.32 (6.52)                  | <.001   |  |
| PHS <sup>♭</sup>               | 249   | 11.7               | 9.82               | -1.89 (4.81)                  | <.001   |  |
| PSS <sup>b</sup>               | 175   | 5.33               | 4.08               | -1.25 (2.3)                   | <.001   |  |

**Table 2.** Summary Statistics With Paired t-Test Results for the Change in Pre/Post ESAS Symptoms and Subscales for Those Who Have a Symptom Score at Baseline of I or Greater.

<sup>a</sup>For all symptoms, a change in score of  $\geq 1$  is considered clinically significant. For predetermined subscales, clinical significance is defined as follows:  $\geq 3$  for global distress score (GDS);  $\geq 2$  for physical distress score (PHS) and psychological distress score (PSS).

<sup>b</sup>GDS equals sum of pain, fatigue, nausea, depression, anxiety, drowsiness, appetite, well-being, and shortness of breath (total score 0-90); PHS equals sum of pain, fatigue, nausea, drowsiness, appetite, and shortness of breath (total 0-60); and PSS equals sum of depression and anxiety.

| ESAS Symptoms and   |    |                     | First Follow-up Within | Mean Change       |                      |
|---------------------|----|---------------------|------------------------|-------------------|----------------------|
| Subscales           | n  | Baseline, Mean (SD) | 60 Days, Mean (SD)     | (SD) <sup>a</sup> | P Value <sup>₅</sup> |
| Pain                | 37 | 3.03 (2.42)         | 2.57 (2.21)            | -0.46 (2.27)      | .23                  |
| Fatigue             | 37 | 3.97 (2.71)         | 2.76 (2.02)            | -1.22 (2.75)      | .01                  |
| Nausea              | 37 | 0.51 (1.15)         | 0.54 (1.41)            | 0.03 (1.82)       | .93                  |
| Depression          | 37 | 2.62 (3.04)         | 1.78 (2.44)            | -0.84 (2.48)      | .05                  |
| Anxiety             | 37 | 2.51 (2.73)         | 2.27 (2.55)            | -0.24 (1.59)      | .36                  |
| Drowsiness          | 37 | 1.43 (1.83)         | 1.08 (1.46)            | -0.35 (1.65)      | .20                  |
| Appetite            | 37 | 3.14 (2.53)         | 2.16 (2.06)            | -0.97 (2.47)      | .02                  |
| Well-being          | 37 | 3.68 (2.54)         | 3.03 (2.09)            | -0.65 (2.38)      | .11                  |
| Shortness of breath | 37 | 1.03 (1.96)         | 0.92 (1.66)            | -0.11 (1.15)      | .57                  |
| Sleep               | 37 | 3.65 (2.46)         | 3.08 (2.47)            | -0.57 (1.82)      | .07                  |
| Financial distress  | 37 | 2.59 (2.99)         | 2.11 (2.59)            | -0.49 (1.92)      | .13                  |
| Spiritual pain      | 37 | 1.38 (2.37)         | 1.19 (2.25)            | -0.19 (1.27)      | .37                  |
| GDS <sup>c</sup>    | 37 | 21.92 (12.57)       | 17.11 (12.4)           | -4.81 (10.16)     | .01                  |
| PHS <sup>c</sup>    | 37 | 13.11 (7.35)        | 10.03 (7.3)            | -3.08 (7.98)      | .03                  |
| PSS <sup>c</sup>    | 37 | 5.14 (5.66)         | 4.05 (4.65)            | -1.08 (3.68)      | .08                  |

Table 3. Paired t-Test Results for ESAS Scores at Baseline and First Follow-up Within 60 Days.

<sup>a</sup>For all symptoms, a change score of  $\geq 1$  is considered clinically significant. For predetermined subscales, clinical significance is defined as follows:  $\geq 3$  for the global distress score (GDS);  $\geq 2$  for physical distress score (PHS) and psychological distress score (PSS).

<sup>b</sup>The *P* values less than .05 (in bold) suggest a statistically significant change between baseline and first follow-up within 60 days.

<sup>c</sup>GDS equals the sum of pain, fatigue, nausea, depression, anxiety, drowsiness, appetite, well-being, and shortness of breath (total score 0-90); PHS equals sum of pain, fatigue, nausea, drowsiness, appetite, and shortness of breath (total 0-60); and PSS equals sum of depression and anxiety.

(completion rates of 80% or more are considered an exceptional response rate).  $^{25}$ 

Our results suggested that a single exercise counseling consultation had beneficial effects on self-reported physical and psychosocial symptoms and quality of life. For those patients who came for a follow-up counseling session, longitudinal benefits were noted for symptoms of fatigue, physical distress, and global distress. With fatigue as one of

| PROMIS10                 | n  | Baseline,<br>Mean (SD) | First Follow-up Within 60<br>Days, Mean (SD) | P Value <sup>a</sup> |  |
|--------------------------|----|------------------------|--|----------------------|--|
| Mental health subscale   | 89 | 12.9 (3.1)             | 13.6 (3.2)                                   | .004                 |  |
| Physical health subscale | 89 | 13.3 (2.9)             | 13.8 (2.8)                                   | .034                 |  |
| Global total score       | 89 | 32.4 (6.9)             | 33.9 (7.1)                                   | .005                 |  |

Table 4. Paired t-Test Results for PROMISIO Scores at Baseline and First Follow-up Within 60 Days.

Abbreviation: PROMISIO, Patient-Reported Outcomes Measurement Information System.

<sup>a</sup>The *P* values less than .05 (in bold) suggest a significant change between baseline and first follow-up within 60 days.

the most frequent problems at the initial exercise counseling visit, the noted improvement in fatigue on follow-up lends support to the beneficial effects of exercise counseling on cancer-related fatigue. According to clinical practice guidelines on the use of integrative therapies for breast cancer patients, energy conservation counseling receives a grade B recommendation for management of fatigue.<sup>26</sup> Our observed improvements in fatigue are aligned with the content of the exercise counseling program because all patients were educated on energy conservation as part of fatigue management.

There are several limitations to note, including that this study was conducted at a single institution. This institution is a comprehensive cancer center, which could influence the type of patients evaluated and referred for exercise counseling. Patients included in this analysis were not randomized, with referrals to exercise counseling based on clinical judgment after an initial consultation completed in an integrative medicine clinic. Longitudinal data available for analysis were limited to those patients who returned for a follow-up visit within the 60-day period; as a result, follow-up data were available for a little more than 30% of all patients seen for an initial consultation. A significant limitation includes the fact that we were unable to track adherence to energy conservation techniques or the prescribed exercise plan. Also, we do not have information as to where patients were in their cancer treatment trajectory; patients participating in exercise counseling may have done so at any point from diagnosis, through active treatment, and into survivorship or advanced disease (eg, changes in health status, medications, or cancer treatment type). As a result, the changes observed between the initial and follow-up encounters cannot be solely attributed to the intervention and may be a result of factors not assessed. However, the acute effects on symptoms from pre-encounter to postencounter can be attributed to the counseling session. Given the large number of paired t-tests performed, all statistical significance should be interpreted as hypothesis generating that warrant further confirmation in future studies, rather than as conclusive findings. Clinically significant improvements in fatigue and the ESAS subscales of GDS and PHS support the clinical utility of exercise counseling, but the small sample size and nonrandomization precludes a definitive finding.

Integrative medicine programs may be uniquely positioned to offer exercise counseling services as part of conventional oncology care, which can lead to improved self-reported symptoms and quality of life. We have presented a model of care that successfully integrated an electronic system to support efforts to capture self-reported outcomes as part of routine clinical care. For future studies, we have more to learn about the clinical care effects of providing the exercise counselor (physical therapist) with a symptom report as part of the clinical encounter. We also have more to learn about patient selection for exercise counseling, optimization of exercise plans to better address self-reported symptoms, and the longitudinal effects of such an intervention as part of a formal clinical study with a larger follow-up cohort. The extensive evidence base, along with the findings from this center-based clinical assessment, strongly support further consideration of the role of exercise counseling as part of the standard of care.

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#### **Supplemental Material**

Supplemental material for this article is available online.

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