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Validity and Responsiveness of the Pain Self-Efficacy Questionnaire in Patients With Neck Pain Disorders

Neck pain disorders (NPDs) are a leading cause of disability worldwide⁸⁴ and a cost burden to health care systems and society.^{4,59} The lifetime activity-limiting mean prevalence of neck pain is estimated to be 23%, and the point prevalence is approximately 14%.³⁵ Neck pain disorders include various diagnoses, such as idiopathic neck pain (INP), headache, and whiplash-associated disorders (WADs).³⁸ The clinical course of these disorders

is not favorable for a substantial number of patients who experience persistent symptoms and disability over time.^{73,85}

Several prospective cohort studies have identified the role that psychological factors play as predictors of poor recovery in patients with NPDs.^{6,7,41,70,86} One of the psychological factors that has been extensively studied is pain self-efficacy.⁵⁷ Self-efficacy can be defined as confidence in one's own ability to accomplish a given task or activity.³ In people with pain, the perceived ability to perform certain activities despite the presence of pain has been associated with the level of disability.^{30,89} In patients with NPDs, pain self-efficacy has been found to be a predictor of poor recovery²³ and a mediator in the relationship between pain and disability.^{43,44} Low self-efficacy is also common in patients with WAD⁵ and a more relevant factor in this population than in other posttraumatic musculoskeletal conditions.⁷¹ In chronic WAD, lower self-efficacy has also been associated with more widespread pain.²⁹ Importantly, clinical trials have reported improved self-efficacy following various interventions in people with NPDs, including neck-specific exercise combined with a behavioral approach⁴⁵

• **STUDY DESIGN:** Longitudinal clinimetric study.

• **BACKGROUND:** Pain self-efficacy predicts poor recovery and mediates the relationship between pain and disability in patients with neck pain disorders (NPDs). The Pain Self-Efficacy Questionnaire (PSEQ) is a frequently used instrument to measure pain self-efficacy; however, its measurement properties have never been evaluated in a group of patients with NPDs.

• **OBJECTIVES:** This study aimed to assess validity and responsiveness of the PSEQ in patients with NPDs.

• **METHODS:** Patients with NPDs (n = 161) were included. Confirmatory and exploratory factor analysis was used to assess structural validity. Twelve hypotheses on expected correlations with other instruments were formulated a priori to assess construct validity. Responsiveness was evaluated in 146 patients with NPDs who underwent multimodal rehabilitation by testing 12 hypotheses on expected effect sizes, area under the curve, and correlations with change in other instruments.

• **RESULTS:** Factor analyses showed that the PSEQ is a unidimensional instrument with moderate construct validity and responsiveness (50% to 75% of hypotheses met). Validity was consistent when analyzed separately for patients with whiplash-associated disorders and idiopathic neck pain, and responsiveness was better in patients with idiopathic neck pain.

• **CONCLUSION:** The PSEQ is a unidimensional measure of pain self-efficacy in patients with NPDs, as found by previous studies in other populations. Nevertheless, in contrast with previous studies, its construct validity and responsiveness were found to be suboptimal in NPDs, suggesting that the content validity of the PSEQ and of the comparator instruments used in this study should be better assessed. *J Orthop Sports Phys Ther* 2018;48(3):204-216. Epub 19 Dec 2017. doi:10.2519/jospt.2018.7605

• **KEY WORDS:** cervical spine, factor analysis, idiopathic, whiplash

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and interactive behavioral modification therapy.⁷⁸ Pain self-efficacy is an aspect worth exploring to improve the understanding and management of patients with NPDs.

It is recommended that clinicians assess psychosocial factors when managing patients with NPDs,¹³ and to be able to do so, they need sound measurement instruments. Several patient-reported measurement instruments have been developed to assess pain self-efficacy.⁴⁹ The Pain Self-Efficacy Questionnaire (PSEQ) is the most frequently used in individuals with pain⁸ and may also be the most appropriate, being a widely investigated, short self-reported instrument.⁵⁷ Its measurement properties have been shown to be satisfactory in various countries, languages, and patient populations.^{1,11,12,27,31,47,57,58,61,68,79,83} However, the PSEQ has mostly been tested in samples of patients with chronic pain, including several pain disorders (eg, widespread pain, headache, leg pain),^{1,31,57,58,61,68,79,83} or in samples of patients with chronic low back pain (LBP).^{11,12,27,47,57} No studies have investigated its measurement properties in a sample of patients presenting with NPDs as their primary musculoskeletal complaint.

The measurement properties of an instrument are population specific and context specific, and they should be assessed before use in clinical research and practice in specific populations.²⁵ The validity of a questionnaire refers to “the degree to which a test measures what it claims, or purports, to be measuring,”²⁰ and there is consensus that this measurement property is dependent on the context of a given measurement application.⁴⁶ Responsiveness is defined as “the ability of a measurement instrument to detect change over time in the construct to be measured,” a measurement property that is also population specific and context specific.⁶⁵ Previous research has identified the need to assess the PSEQ measurement properties in populations of patients with the same pain disorder.^{11,58}

Therefore, the aim of the present study was to assess the validity and responsiveness of the PSEQ in patients with NPDs. Considering the important role of pain self-efficacy as a prognostic factor and mediator in NPDs,^{23,43,44} this study can be valuable to clinicians and researchers who intend to measure the pain self-efficacy construct in this patient population.

METHODS

Study Participants and Procedure

PATIENTS INCLUDED IN THE PRESENT study were recruited between April 2012 and December 2015 from 2 clinical settings: an outpatient service of a rehabilitation hospital (Lissone, Italy) and a rehabilitation center (Torino, Italy). Patients were screened by a rehabilitation physician with more than 10 years of clinical experience, or by 2 physical therapists with more than 5 years of experience. Inclusion criteria were being more than 18 years of age, having neck pain with or without arm pain or headache as a primary complaint, and being able to fluently read and speak Italian. Patients with WAD were included only if classified as grade I or II, according to the Quebec Task Force.⁷² Exclusion criteria were specific causes of neck pain (eg, fracture), central neurological signs, fibromyalgia, systemic illnesses such as rheumatoid arthritis, and severe psychiatric diseases.

After signing the informed-consent form, patients were asked to fill out a booklet to collect information on sociodemographic and clinical characteristics. The booklet included the PSEQ and a set of self-reported measurement instruments to assess validity and responsiveness. All participants received a combination of manual therapy and exercise, as chosen by the physical therapists in charge of the treatment. When prescribed, patients also received cognitive-behavioral education, massage, or shortwave diathermy. Four physical therapists with 6, 8, 10, and 11 years of clinical experience were involved in delivering the treatments. Patients receiving

physical therapy combined with cognitive-behavioral education underwent 10 sessions over 5 weeks, while all other patients received 6 sessions over 3 weeks. The cognitive-behavioral component was included because there is evidence suggesting that a multimodal intervention is effective in patients with chronic INP.⁵² All patients were readministered the PSEQ and the other self-reported measurement instruments after the last treatment session.

Ethical approval for this clinimetric study was obtained from the Institutional Review Board of the Scientific Institute of Lissone, Salvatore Maugeri Foundation Institute of Care and Research.

Pain Self-Efficacy Questionnaire

The PSEQ consists of 10 items that represent different daily activities or general aspects of life and ask patients to rate how confident they feel performing these activities, despite the presence of pain.⁵⁷ Each item is rated on a scale ranging from 0 (“not at all confident”) to 6 (“completely confident”), and the total score can range from 0 to 60, with higher scores indicating better self-efficacy. The Italian version of the PSEQ used in this study has been shown to be unidimensional and to have optimal internal consistency, test-retest reliability, construct validity, and responsiveness in patients with chronic LBP.^{11,12}

Comparator Instruments

A set of patient-reported measurement tools were included as comparator instruments. These instruments were chosen to measure constructs representing core domains in patients with spinal pain (disability and pain intensity)⁹ and psychosocial constructs found in previous studies to correlate moderately with pain self-efficacy (pain catastrophizing and fear of movement).^{11,12,17,58,89} To increase the comparability of our findings, we used the instruments that have been more thoroughly investigated⁶⁹ or most frequently used⁸ to measure these constructs. A global perceived effect scale

was administered following treatment to allow a more thorough assessment of responsiveness.²⁶

Two 11-point numeric rating scales (NRSs) ranging from 0 (“no pain”) to 10 (“the worst imaginable pain”) were used to measure pain intensity³⁷ by asking the patients to rate their average neck pain over the last 24 hours and the last 7 days. Two NRSs were adopted, because there is evidence suggesting that pain intensity ratings may be sensitive to different recall periods.³⁹ The NRS has been shown to be a valid, reliable, and responsive tool for use in patients with NPDs.¹⁴

The Neck Disability Index (NDI) was used to assess neck pain-related disability.⁸¹ It includes 10 items that assess pain intensity, personal care, lifting heavy objects, reading, headache, concentration, working, driving, sleeping, and distraction. Each item ranges from 0 to 5, and the total score is converted into a percentage. The NDI is the most frequently investigated questionnaire for neck pain disability, being a reliable, valid, and responsive instrument.⁶⁹ The Italian version showed good measurement properties in patients with INP.^{53,55}

To assess the extent of pain catastrophizing, the 13-item Pain Catastrophizing Scale (PCS) was used.⁷⁴ Each item assesses the frequency of catastrophic thoughts and feelings related to pain on a 5-point Likert scale ranging from 0 (“never”) to 4 (“always”), and the total score ranges from 0 to 52, with higher scores indicating higher pain catastrophizing. There is previous evidence that the total score of the PCS can be used as an interval-level measure.⁸⁷ The Italian version of the PCS exhibited adequate reliability and structural and construct validity in patients with chronic pain.⁵⁴

The Tampa Scale of Kinesiophobia (TSK) was adopted to evaluate patients’ fear of movement.⁸² This 13-item questionnaire asks participants how strongly they agree or disagree with statements regarding pain and movement. Each item is answered on a scale ranging from 1 (“strongly disagree”) to 4 (“strongly

agree”), to provide a total score ranging from 13 to 52. The TSK has shown acceptable internal consistency and test-retest reliability in patients with NPDs,¹⁵ and the Italian version has shown good validity, reliability, and responsiveness in patients with chronic LBP.⁵⁶

A global perceived effect scale was administered to patients following treatment to assess the extent of their perceived improvement. This scale asks the patients, “Compared to how you were feeling at the beginning of treatment, how would you describe yourself now?” The response categories are (1) totally recovered, (2) much improved, (3) rather improved, (4) slightly improved, (5) unchanged, (6) slightly worsened, (7) rather worsened, (8) much worsened, and (9) worse than ever. Patients were specifically asked to indicate only 1 response option. This transition scale was used because it has been shown to be valid and reliable in patients with musculoskeletal disorders.^{40,88}

Validity Assessment

Structural and construct validity are 2 different subdomains of validity. Structural validity assesses the extent to which scores on the instrument reflect the dimensionality of the construct to be measured, and construct validity assesses the extent to which the scores on an instrument are consistent with a priori formulated hypotheses.⁵¹

Structural validity was assessed by testing the hypothesis that the PSEQ is a unidimensional measure of pain self-efficacy in patients with NPDs, where unidimensionality means that all patients’ responses to the items account for the same underlying theoretical construct and not multiple constructs.²⁸ Confirmatory factor analysis was performed to determine whether the data fit our hypothesized measurement model.⁶³ Because the cutoffs of standard confirmatory factor analysis for good fit are rarely met in health outcome assessment,¹⁶ we also ran an exploratory factor analysis to further assess the unidimensionality hy-

pothesis, as suggested and performed by psychometric experts.^{16,18,19,63}

Construct validity was assessed by formulating a set of 12 a priori hypotheses regarding expected correlations between the PSEQ and the comparator instruments and differences in mean scores between relevant subgroups, as suggested by the Consensus-based Standards for the selection of health Measurement INstruments (COSMIN) initiative,^{25,50,51} the Patient-Reported Outcomes Measurement Information System initiative,³⁴ and the International Society for Quality of Life Research.⁶⁴ These hypotheses are presented and explained in **TABLE 1**. Because no studies were available in patients with NPDs, the magnitude and direction of hypothesized correlations with comparator instruments were based on previous studies conducted in patients with chronic LBP and reporting cross-sectional correlations with measures of pain self-efficacy.^{12,17,32,89}

Responsiveness Assessment

As recommended by clinimetric experts,^{25,34,50,51,60,64} a priori hypotheses were also formulated for the evaluation of responsiveness. These hypotheses concerned expected effect sizes, areas under the curve, and expected correlations between the change scores of the PSEQ and the change scores of other instruments (**TABLE 1**). Differences in effect sizes were expected between adjacent categories of the global perceived effect scale, as observed in a previous study of patients with chronic LBP.¹¹ Larger effect sizes were expected in patients receiving the cognitive-behavioral treatment, as there is already evidence suggesting this pattern in patients with NPDs.^{45,78} For assessing the area under the curve, patients classified as “totally recovered,” “much improved,” and “rather improved” on the global perceived effect scale were considered improved, and those rating “slightly improved,” “unchanged,” and “slightly worsened” were considered unchanged.²⁴ Correlations between PSEQ change scores and change scores of other instruments were based on previous studies

TABLE 1

HYPOTHESES FORMULATED A PRIORI TO ASSESS CONSTRUCT VALIDITY
AND RESPONSIVENESS OF THE PAIN SELF-EFFICACY QUESTIONNAIRE
IN PATIENTS WITH NECK PAIN DISORDERS

Construct Validity	Total Sample	WAD Sample	INP Sample
1. The correlation between the PSEQ scores and the NDI scores is negative and >0.60	–	–	–
2. The correlation between the PSEQ scores and the NRS scores is negative and $0.30 \leq 0.60$	–	–	+
3. The correlation between the PSEQ scores and the PCS scores is negative and $0.30 \leq 0.60$	+	+	+
4. The correlation between the PSEQ scores and the TSK scores is negative and $0.30 \leq 0.60$	+	+	–
5. The correlation between the PSEQ scores and the NDI scores is ≥ 0.20 than the correlation between the PSEQ scores and the NRS-7 scores	–	–	–
6. The correlation between the PSEQ scores and the NDI scores is ≥ 0.10 than the correlation between the PSEQ scores and the PCS scores	–	–	+
7. The correlation between the PSEQ scores and the NDI scores is ≥ 0.10 than the correlation between the PSEQ scores and the TSK scores	–	–	+
8. The correlation between the PSEQ scores and the PCS scores is ≥ 0.10 than the correlation between the PSEQ scores and the NRS-7 scores	+	+	–
9. The correlation between the PSEQ scores and the TSK scores is ≥ 0.10 than the correlation between the PSEQ scores and the NRS-7 scores	+	+	–
10. The correlation between the PSEQ scores and the NRS-24 scores is greater than the correlation between the PSEQ scores and the NRS-7 scores	–	–	+
11. The mean PSEQ score is greater in patients who have neck pain only than in patients who also have headache or arm pain	+	+	+
12. The mean PSEQ score is greater in patients who have no comorbidities than in patients who have 1 or more comorbidities	+	+	+
Total hypotheses met, n (%)	6/12 (50%)	6/12 (50%)	7/12 (58%)
Responsiveness			
1. Patients classifying themselves as “much improved” on the GPES display larger ESs than patients classifying themselves as “rather improved”	+	+	+
2. Patients classifying themselves as “much improved” on the GPES display larger SRMs than patients classifying themselves as “rather improved”	+	+	+
3. Patients classifying themselves as “rather improved” on the GPES display larger ESs than patients classifying themselves as “slightly improved”	–	–	+
4. Patients classifying themselves as “rather improved” on the GPES display larger SRMs than patients classifying themselves as “slightly improved”	–	–	–
5. Patients receiving cognitive-behavioral education as part of the intervention exhibit greater ESs than patients not receiving cognitive-behavioral education	+	+	/
6. Patients receiving cognitive-behavioral education as part of the intervention exhibit greater SRMs than patients not receiving cognitive-behavioral education	+	–	/
7. The area under the curve for the PSEQ (using the primary GPES) is above 0.70. Patients were dichotomized into “improved” and “unchanged” to calculate the area under the curve.	–	–	+
8. The correlation between the PSEQ change scores and the NDI change scores is ≥ 0.10 than the correlation between the PSEQ change scores and the NRS-7 change scores	+	+	+
9. The correlation between the PSEQ change scores and the NDI change scores is greater than the correlation between the PSEQ change scores and the PCS change scores	–	–	–
10. The correlation between the PSEQ change scores and the NDI change scores is greater than the correlation between the PSEQ change scores and the TSK change scores	–	+	+
11. The correlation between the PSEQ change scores and the PCS change scores is greater than the correlation between the PSEQ change scores and the NRS-7 change scores	+	+	+
12. The correlation between the PSEQ change scores and the TSK change scores is greater than the correlation between the PSEQ change scores and the NRS-7 change scores	+	+	+
Total hypotheses met, n (%)	7/12 (58%)	7/12 (58%)	8/10 (80%)

Abbreviations: –, unmet hypothesis; /, not applicable hypothesis; +, met hypothesis; ES, effect size; GPES, global perceived effect scale; INP, idiopathic neck pain; NDI, Neck Disability Index; NRS, numeric rating scale; NRS-7, numeric rating scale measuring pain intensity over the last 7 days; NRS-24, numeric rating scale measuring pain intensity over the last 24 hours; PCS, Pain Catastrophizing Scale; PSEQ, Pain Self-Efficacy Questionnaire; SRM, standardized response mean; TSK, Tampa Scale of Kinesiophobia; WAD, whiplash-associated disorder.

reporting the same longitudinal correlations in patients with chronic LBP.^{11,17}

Statistical Analysis

Missing data on the PSEQ and all other assessment tools were checked, and frequencies of missing values were calculated. Missing data were explored to find any recurrent pattern to suggest that data were missing in a nonrandom fashion. Data missing at random were imputed with a 2-way imputation technique.⁸⁰ Descriptive statistics were used to describe sociodemographic and clinical characteristics at baseline, and clinical characteristics following treatment. Change scores of the PSEQ and comparator instruments were obtained by subtracting the posttreatment score from the pretreatment score.

After determining whether Bartlett's test of sphericity was significant ($P < .05$) and the Kaiser-Meyer-Olkin measure of sampling adequacy was greater than 0.80,⁷⁷ a diagonally weighted least-squares estimation procedure was used with confirmatory factor analysis. To determine whether the data displayed a good unidimensional fit, multiple fit indices were used: comparative fit index (CFI) greater than 0.95, Tucker-Lewis index (TLI) greater than 0.95, and root-mean-square error of approximation (RMSEA) less than 0.06.^{25,63} Subsequently, an exploratory factor analysis with a maximum-likelihood extraction method was performed by checking whether the variance explained by the largest factor was at least 20%, the ratio of eigenvalue magnitude of the first and second factors was greater than 4, Cattell's scree test indicated a predominant factor pattern, and the factor loadings were all 0.50 or greater.^{25,63} The Cronbach alpha was used to assess internal consistency and was considered to be adequate when between .70 and .95.⁷⁶

When data were normally distributed (Shapiro-Wilk test $P > .05$), a Pearson product-moment correlation (r) was used to assess correlations between instruments at baseline and between their change scores. A Spearman rank correlation coefficient (r_s) was used when data

were not normally distributed. Correlations of 0.60 or greater were considered strong, those from 0.30 to 0.60 moderate, and those less than 0.30 weak.¹² As suggested by clinimetric experts and previous studies,^{21,22,33,60} construct validity was considered satisfactory when 75% or more of the hypotheses were met, moderate when 50% or more but fewer than 75% were in agreement, and low when fewer than 50% were met.

Effect sizes for responsiveness were estimated by dividing the mean change scores by the respective pretreatment standard deviations. Standardized response means (SRMs) were calculated by dividing mean change scores by the respective standard deviations of the change. Receiver operating characteristic curves were plotted, displaying sensitivity and 1-minus-specificity values on the axes of the curves. The area under the curve was calculated as the probability of correctly discriminating patients as improved or unchanged²⁴ and considered acceptable when greater than 0.70.²⁶ Responsiveness was considered satisfactory when at least 75% of the hypotheses were met, moderate when 50% to 75% were in agreement, and low when fewer than 50% were met.^{33,42,60}

A sample size of at least 100 patients was the recruitment goal, which is considered to be excellent for factor analysis on a questionnaire with 10 items and for assessing construct validity and responsiveness.⁵⁰ A subgroup analysis was preplanned for all measurement properties in patients with WAD and patients with INP. Missing data imputation, descriptive statistics, exploratory factor analysis, correlations, effect sizes, and area under the curve were calculated with IBM SPSS Statistics Version 23 (IBM Corporation, Armonk, NY). Confirmatory factor analysis was performed using the R package lavaan⁶⁷ implemented in Rstudio (RStudio, Inc, Boston, MA).

RESULTS

ONE HUNDRED SIXTY-ONE PATIENTS with neck pain were included in this study, 85 (53%) with WAD and

the remaining 76 with INP. At baseline, 25 patients (16%) had at least 1 missing item on 1 of the self-reported measures (ie, PSEQ, NDI, PCS, TSK); in total, responses to only 51 items (0.7% across the full sample) were missing. Regarding the PSEQ, 2 patients did not complete items 9 and 10 (1.2% of missing responses for each of these items in total), and 1 patient missed the response to item 6 (0.6%). No consistent pattern of missing data was observed, and the imputed data set was used in all subsequent analyses. Baseline characteristics of the included patients are presented in **TABLE 2**.

Fifteen patients with WAD (9% of the total sample) did not complete the intervention period, and their posttreatment data were not collected, leaving a sample of 146 for responsiveness assessment. One hundred patients (68%) received both physical therapy and cognitive-behavioral education, while the others only received physical therapy.

Validity

Confirmatory factor analysis displayed the following fit indices: CFI, 0.997; TLI, 0.996; RMSEA, 0.104 (95% confidence interval [CI]: 0.079, 0.130). These indices indicated a unidimensional pattern; however, because the RMSEA cutoff value was not met, an exploratory analysis confirmed the unidimensionality of the PSEQ in NPDs. One factor with an eigenvalue larger than 1 was able to explain 74.4% of the variance, while the second largest factor explained 5.5%. The ratio between the eigenvalues of these 2 factors

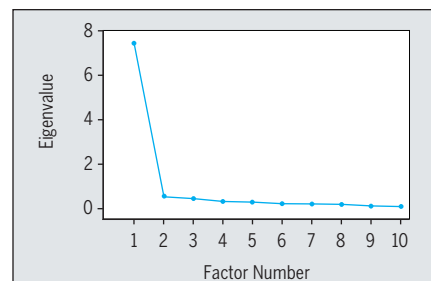


FIGURE. Scree test estimated with exploratory factor analysis of the Pain Self-Efficacy Questionnaire in 161 patients with neck pain disorders.

TABLE 2

BASELINE SOCIODEMOGRAPHIC AND CLINICAL CHARACTERISTICS
OF PATIENTS WITH NECK PAIN DISORDERS INCLUDED IN THIS STUDY

Variables	Total Sample (n = 161)	WAD (n = 85)	INP (n = 76)	Dropouts (n = 15)
Age, y*	44.55 ± 13.81	38.85 ± 12.54	50.93 ± 12.36	37.13 ± 14.22
Sex, n (%)				
Male	57 (35)	37 (44)	20 (26)	10 (67)
Female	104 (65)	48 (56)	56 (74)	5 (33)
Civil state, n (%)				
Married	99 (61)	41 (48)	58 (76)	4 (27)
Unmarried	59 (37)	41 (48)	18 (24)	9 (60)
Missing information	3 (2)	3 (4)	0 (0)	2 (13)
Highest educational level completed, n (%)				
Primary school	25 (15)	1 (1)	24 (32)	0 (0)
Junior high school	49 (30)	25 (29)	24 (32)	5 (33)
Senior high school	67 (42)	43 (51)	24 (32)	8 (53)
University	19 (12)	15 (18)	4 (5)	1 (7)
Missing information	1 (1)	1 (1)	0 (0)	1 (7)
Pain duration, mo				
Median (interquartile range)	5.00 (2.00-24.00)	2.00 (2.00-3.00)	24.00 (12.00-48.00)	2.00 (1.00-3.50)
Pain localization, n (%)				
Neck only	97 (60)	55 (65)	42 (55)	10 (67)
Neck and arm	46 (29)	24 (28)	22 (29)	2 (13)
Neck and head	4 (2)	4 (5)	0 (0)	2 (13)
Only arm	13 (8)	1 (1)	12 (16)	0 (0)
Missing information	1 (1)	1 (1)	0 (0)	1 (7)
Comorbidities, n (%)				
None	97 (60)	63 (74)	34 (45)	13 (87)
Hypertension	25 (16)	6 (7)	19 (25)	0 (0)
Diabetes	15 (9)	4 (5)	11 (14)	0 (0)
COPD	12 (7)	4 (5)	8 (11)	1 (7)
Gastritis	3 (2)	3 (3.5)	0 (0)	0 (0)
Anxiety/depression	3 (2)	3 (3.5)	0 (0)	0 (0)
Renal problems	1 (1)	1 (1)	0 (0)	0 (0)
Cardiovascular problems	4 (2)	0 (0)	4 (5)	0 (0)
Missing information	1 (1)	1 (1)	0 (0)	1 (7)
PSEQ (0-60)*	27.34 ± 13.66	33.27 ± 15.02	20.71 ± 7.80	39.40 ± 11.94
Disability, NDI (0-100)*	26.77 ± 12.77	30.80 ± 13.44	22.26 ± 10.32	33.07 ± 14.85
Pain intensity last day, NRS-24 (0-10)*	4.44 ± 2.14	5.22 ± 2.01	3.57 ± 1.96	5.73 ± 2.22
Pain intensity last week, NRS-7 (0-10)*	4.73 ± 2.08	5.56 ± 2.07	3.80 ± 1.68	6.07 ± 2.02
Pain catastrophizing, PCS (0-52)*	23.65 ± 9.18	19.93 ± 9.90	27.82 ± 6.06	19.47 ± 11.50
Kinesiophobia, TSK (13-52)*	29.91 ± 7.62	27.98 ± 7.61	32.07 ± 7.08	22.87 ± 7.74

Abbreviations: COPD, chronic obstructive pulmonary disease; INP, idiopathic neck pain; NDI, Neck Disability Index; NRS-7, numeric rating scale for pain intensity over the last 7 days; NRS-24, numeric rating scale for pain intensity over the last 24 hours; PCS, Pain Catastrophizing Scale; PSEQ, Pain Self-Efficacy Questionnaire; TSK, Tampa Scale of Kinesiophobia; WAD, whiplash-associated disorder.

*Values are mean ± SD.

was 13.5, and the scree plot indicated a predominant 1-factor pattern (FIGURE). The same results were found when the subgroups of patients with WAD (confirmatory: CFI, 0.997; TLI, 0.997; RMSEA,

0.104; 95% CI: 0.064, 0.143; exploratory: first-factor explained variance, 73.2%; eigenvalue ratio of the first 2 factors = 10.6) or INP (confirmatory: CFI, 0.995; TLI, 0.993; RMSEA, 0.100; 95%

CI: 0.057, 0.141; exploratory: first-factor explained variance, 61.4%; eigenvalue ratio of the first 2 factors = 7.9) were examined separately. Descriptive statistics, communalities, and factor loadings of the

TABLE 3

DESCRIPTIVE STATISTICS, COMMUNALITIES, AND FACTOR LOADINGS FOR THE 10 ITEMS OF THE PAIN SELF-EFFICACY QUESTIONNAIRE IN 161 PATIENTS WITH NECK PAIN DISORDERS

Item	Mean $\pm$ SD	Skewness (SE)	Kurtosis (SE)	Item Total Correlations	Communalities	Factor Loadings
1. I can enjoy things	2.60 $\pm$ 1.59	0.52 (0.19)	-0.26 (0.38)	0.84	0.72	0.85
2. I can do most of the household chores	2.69 $\pm$ 1.59	0.63 (0.19)	-0.22 (0.38)	0.80	0.65	0.81
3. I can socialize with my friends or family members as often as I used to do	3.14 $\pm$ 1.78	0.49 (0.19)	-1.14 (0.38)	0.84	0.73	0.85
4. I can cope with my pain in most situations	2.80 $\pm$ 1.43	0.57 (0.19)	-0.45 (0.38)	0.78	0.61	0.78
5. I can do some form of work	2.63 $\pm$ 1.43	0.47 (0.19)	-0.62 (0.38)	0.83	0.70	0.84
6. I can still do many of the things I enjoy doing	2.45 $\pm$ 1.49	0.47 (0.19)	-0.34 (0.38)	0.80	0.68	0.82
7. I can cope with my pain without medication	2.60 $\pm$ 1.49	0.64 (0.19)	-0.07 (0.38)	0.81	0.69	0.83
8. I can still accomplish most of my goals in life	2.76 $\pm$ 1.64	0.65 (0.19)	-0.58 (0.38)	0.88	0.81	0.90
9. I can live a normal lifestyle	2.75 $\pm$ 1.75	0.61 (0.19)	-0.78 (0.38)	0.90	0.86	0.93
10. I can gradually become more active	2.89 $\pm$ 1.66	0.34 (0.19)	-0.84 (0.38)	0.82	0.70	0.84

Abbreviation: SE, standard error.

10 PSEQ items are presented in **TABLE 3**.

The Cronbach alpha of the PSEQ was .96 for the total sample and in patients with WAD, and .93 in patients with INP. Internal consistency was not adequate for the total sample or for the patients with WAD, as some authors have suggested that a Cronbach alpha greater than .95 may indicate some item redundancy.⁷⁵

Correlations between the PSEQ and the comparator instruments are presented in **TABLE 4**. Ninety-seven patients with neck pain displayed higher PSEQ values (mean, 28.50) than the 64 patients with neck pain and/or pain in other body regions (mean, 25.21). These results were consistent in patients with WAD (34.09 versus 31.17) and in patients with INP (21.19 versus 20.12). The 97 patients with no comorbidities also showed a higher PSEQ mean score than the remaining patients with 1 or more comorbidities (31.13 versus 21.16). This difference was consistent in the 2 subgroups of patients with WAD (35.73 versus 25.14) and patients with INP (22.62 versus 19.17). The construct validity of the PSEQ was moderate in both the total sample and in the WAD and INP subgroups (**TABLE 1**).

Responsiveness

TABLE 5 presents baseline, posttreatment, and change scores of the PSEQ, together

with effect sizes and SRMs in the total sample and in the WAD and INP subgroups. These results were stratified for different response options on the global perceived effect scale, and depending on whether patients received cognitive-behavioral education. The area under the curve for the PSEQ, estimated with the global scale as the external anchor, was 0.69 (95% CI: 0.59, 0.79) in the total sample, 0.53 in the WAD group (95% CI: 0.38, 0.68), and 0.79 in the INP group (95% CI: 0.68, 0.90). Correlations between the change scores of the PSEQ and those of the other tools were also calculated (**TABLE 4**). The responsiveness of the PSEQ was satisfactory in patients with INP and moderate in the total sample and in patients with WAD (**TABLE 1**).

DISCUSSION

TO OUR KNOWLEDGE, THIS IS THE first study to assess the measurement properties of the PSEQ in a sample of patients presenting with NPDs as their primary musculoskeletal complaint. The PSEQ was found to be a unidimensional measure of pain self-efficacy in this population, and its construct validity was moderate according to hypothesis testing. These results were consistent when analyzed separately in patients with

either WAD or INP. Responsiveness was moderate according to hypothesis testing in both the total sample and patients with WAD, whereas it was satisfactory in those with INP.

This study provides valuable information to researchers and clinicians who intend to use the PSEQ in patients with NPDs. Previous studies in either mixed samples of patients with chronic pain or chronic LBP have shown that the PSEQ is a unidimensional tool,^{12,27,31,68,79} in agreement with the findings of the current study. Therefore, summing the scores from the 10 items to obtain a 0-to-60 total score is appropriate in patients with NPDs. Nevertheless, because results for construct validity were suboptimal in this study, clinicians and researchers may need to use some caution in interpreting the PSEQ scores in relation to other instruments, particularly the NDI for disability and the NRS for pain intensity. More research in patients with NPDs is needed to better investigate the PSEQ's validity to ensure that, from a patient's perspective, it is capturing the pain self-efficacy construct. The responsiveness was adequate in patients with chronic INP, consistent with other studies on chronic LBP,^{11,47,58} but was suboptimal in (sub)acute WAD. This is a novel result, considering that this is the first study to assess PSEQ measure-

TABLE 4

CORRELATIONS (SPEARMAN RANK CORRELATION COEFFICIENT) BETWEEN
THE PAIN SELF-EFFICACY QUESTIONNAIRE AND THE COMPARATOR
INSTRUMENTS IN PATIENTS WITH NECK PAIN DISORDERS

	GPES (0-9)	Disability, NDI (0-100)	Pain Intensity Last Day, NRS-24 (0-10)	Pain Intensity Last Week, NRS-7 (0-10)	Pain Catastrophizing, PCS (0-52)	Fear of Movement, TSK (13-52)
PSEQ (0-60)						
Total sample baseline (n = 161)	/	-0.080	0.080	0.186*	-0.538*	-0.380*
WAD baseline (n = 85)	/	-0.128	0.063	0.142	-0.517*	-0.362*
INP baseline (n = 76)	/	-0.569*	-0.390*	-0.382*	-0.415*	-0.193
PSEQ (0-60)						
Total sample change scores (n = 145)	0.401*	-0.375*	-0.129	-0.141	-0.594*	-0.430*
WAD change scores (n = 70)	0.338*	-0.301	-0.157	-0.125	-0.404*	-0.185
INP change scores (n = 75)	0.599*	-0.595*	-0.210	-0.249*	-0.715*	-0.589*

Abbreviations: /, correlation not applicable; GPES, global perceived effect scale; INP, idiopathic neck pain; NDI, Neck Disability Index; NRS-7, numeric rating scale for pain intensity over the last 7 days; NRS-24, numeric rating scale for pain intensity over the last 24 hours; PCS, Pain Catastrophizing Scale; PSEQ, Pain Self-Efficacy Questionnaire; TSK, Tampa Scale of Kinesiophobia; WAD, whiplash-associated disorder.

* $P < .05$.

ment performance in a sample of patients with acute symptoms. The inclusion of patients with acute pain may explain why the results are slightly divergent from previous studies in other samples. Overall, our findings need to be substantiated by other studies of patients with NPDs, especially those with a (sub)acute disorder. Currently, clinicians and researchers may use the PSEQ in patients with chronic INP with greater confidence than in patients with (sub)acute WAD.

The moderate construct validity found in this study is somewhat surprising. While the correlations with psychosocial measures such as the PCS and the TSK were consistent with those found in previous studies,^{11,12,17,30,89} the most substantial difference concerned the correlations with disability and pain intensity instruments (TABLE 4). The baseline correlation with the NDI was substantially lower than correlations found in the previous 4 studies evaluating the association with disability in patients with chronic LBP.^{12,17,32,89} One explanation for this large discrepancy may be the lack of association between pain self-efficacy and disability in patients with NPDs, in contrast with other pain groups. Another possible explanation may be that the disability construct measured by the NDI is different from that of other disability

instruments used in patients with LBP (eg, Oswestry Disability Index, Roland-Morris Disability Questionnaire). In support of this explanation, a qualitative study showed that the content of the NDI does not appropriately cover what it purports to measure.² The correlation with the NRSs for pain in the last week (0.19) was also lower than the correlation between pain self-efficacy and pain intensity found in 3 previous studies (-0.39, -0.46, and -0.40).^{12,17,89} To further explain these differences, it should be noted that the content validity of the NRS has been recently questioned^{36,66} and the content validity of the PSEQ has never been investigated. Content validity is defined as “the degree to which the content of a patient-reported instrument is an adequate reflection of the construct to be measured,”⁵¹ and its evaluation may help to explain the results obtained in this study. Another explanatory consideration for low PSEQ correlations with disability and pain intensity may be that approximately half of our sample (ie, the WAD subgroup) included patients in the (sub)acute phase of a musculoskeletal condition, and all the previous studies included only patients with chronic pain.

Item redundancy might be a challenge for the original 10-item version of the PSEQ, as the Cronbach alpha val-

ues reported in the current study and previous studies^{12,27,31,68,79} were above or very close to the upper limit for acceptable internal consistency.^{64,75,76} This issue could be further explored by using item response theory methods, as these allow item redundancy to be thoroughly investigated.²⁸ In addition, item response theory analysis would allow studying the measurement precision of a questionnaire (operationalized as information and measurement error) along various levels of “ability” of the measured construct.⁶² Various short forms of the PSEQ have been developed and tested, showing very similar measurement properties to the original version.^{11,48,58} Hence, to understand whether deleting some items from the original PSEQ would lead to a substantial loss in measurement precision would require a study directly comparing the original PSEQ and its short forms via item response theory.

The 2 subgroups of patients with WAD and with INP included in this study differed substantially in some characteristics; the INP group displayed older age, longer pain duration, more comorbidities, and more disability and pain intensity, resulting in lower pain self-efficacy (TABLE 2). Despite these differences, we found very similar results for structural validity, construct validity, and internal

TABLE 5

PRETREATMENT SCORES, POSTTREATMENT SCORES, CHANGE SCORES, EFFECT SIZES, AND STANDARDIZED RESPONSE MEANS OF THE PAIN SELF-EFFICACY QUESTIONNAIRE IN PATIENTS WITH NECK PAIN DISORDERS*

Sample	Pretreatment Score*	Posttreatment Score*	Change Score*	Effect Size	Standardized Response Mean
Overall					
Total sample (n = 146)	26.10 ± 13.24	35.82 ± 13.77	9.72 ± 8.46	0.73	1.15
WAD (n = 70)	31.96 ± 15.35	40.67 ± 14.17	8.71 ± 7.99	0.57	1.09
INP (n = 76)	20.71 ± 7.80	31.36 ± 11.83	10.64 ± 8.82	1.36	1.21
Stratification according to the GPES†					
Totally recovered					
Total sample (n = 8)	33.37 ± 19.12	45.50 ± 16.51	12.12 ± 7.04	0.63	1.72
WAD (n = 8)	33.37 ± 19.12	45.50 ± 16.51	12.12 ± 7.04	0.63	1.72
INP (n = 0)	/	/	/	/	/
Much improved					
Total sample (n = 63)	25.65 ± 12.75	38.51 ± 12.57	12.86 ± 8.52	1.01	1.51
WAD (n = 36)	28.83 ± 14.88	39.39 ± 14.00	10.56 ± 8.71	0.71	1.21
INP (n = 27)	21.41 ± 7.54	37.33 ± 10.51	15.93 ± 7.34	2.11	2.17
Rather improved					
Total sample (n = 41)	27.90 ± 13.29	35.61 ± 12.46	7.71 ± 7.80	0.58	0.99
WAD (n = 20)	34.10 ± 15.35	38.35 ± 14.44	4.25 ± 6.21	0.28	0.68
INP (n = 21)	22.00 ± 7.38	33.00 ± 9.88	11.00 ± 7.86	1.49	1.40
Slightly improved					
Total sample (n = 17)	24.06 ± 13.97	34.71 ± 12.15	10.65 ± 5.83	0.76	1.83
WAD (n = 4)	43.50 ± 7.68	51.25 ± 4.86	7.75 ± 4.11	1.01	1.88
INP (n = 13)	18.08 ± 8.99	29.62 ± 8.47	11.54 ± 6.12	1.28	1.89
Unchanged					
Total sample (n = 16)	20.62 ± 8.71	20.75 ± 11.20	0.12 ± 3.79	0.01	0.03
WAD (n = 2)	38.00 ± 15.56	46.50 ± 13.43	8.50 ± 2.12	0.55	4.01
INP (n = 14)	18.14 ± 3.98	17.07 ± 3.77	-1.07 ± 1.98	0.27	0.54
Stratification according to receiving cognitive-behavioral education					
Yes					
Total sample (n = 100)	19.63 ± 6.72	29.84 ± 10.85	10.21 ± 8.76	1.52	1.17
WAD (n = 25)	17.36 ± 3.70	26.36 ± 7.85	9.00 ± 8.46	2.43	1.06
INP (n = 75)	20.39 ± 7.32	31.00 ± 11.50	10.61 ± 8.87	1.45	1.20
No					
Total sample (n = 46)	40.17 ± 13.06	48.83 ± 9.99	8.65 ± 7.76	0.66	1.11
WAD (n = 45)	39.90 ± 12.79	48.62 ± 10.00	8.72 ± 7.81	0.67	1.10
INP (n = 1)	45.00	58.00	13.00	/	/

Abbreviations: /, not applicable; GPES, global perceived effect scale; INP, idiopathic neck pain; WAD, whiplash-associated disorder.

*Values are mean ± SD unless otherwise indicated.

†Data were missing for 1 patient on the GPES; therefore, this analysis was performed in 145 patients.

consistency, whereas responsiveness was found to be better in the chronic INP group. Thus, PSEQ responsiveness has been shown to be satisfactory in patients with a chronic pain complaint, but our findings indicate that more studies on the PSEQ in patients with (sub)acute

pain are needed to evaluate whether all of its measurement properties are as good as they are in samples of patients with chronic pain.

This is the first study to find an area under the curve below 0.70 for the PSEQ, whereas previous studies met the thresh-

old for acceptable validity.^{11,47} The PSEQ not performing as expected could be explained by the generic global perceived effect scale that was used in this study and by the low correlation between the PSEQ and this external anchor, especially in the WAD sample (TABLE 4). In fact, a previous

study showed that it is not easy to define and identify an optimal global perceived effect scale when assessing psychosocial constructs such as pain self-efficacy¹¹; therefore, the challenge remains when assessing responsiveness using the area under the curve. The potential weaknesses of the scale used in this study could also have had an influence on the effect sizes and SRMs (TABLE 5) that did not match all our a priori specified hypotheses on these indices, particularly in patients with WAD (TABLE 1). Just as for construct validity, the mismatch between expected and observed results for responsiveness highlights the importance of future research assessing the validity of the PSEQ, and specifically its content validity, as it is the only measurement property that has not been adequately assessed so far in any patient population. Also, it is fundamental to have other studies assessing the content validity of the NDI and NRS, used in this study, as there is some preliminary evidence^{2,36,66} suggesting that this might also explain why expected correlations were not found.

Test-retest reliability and measurement error could not be assessed in this study, as only a small proportion of patients classified themselves as unchanged following the intervention (TABLE 5). However, while test-retest reliability of the PSEQ was found to be satisfactory in previous studies in other populations,^{12,61,79} the smallest detectable change was found to be slightly above an acceptable margin.^{12,79} Some authors have suggested that the smallest detectable change should not be larger than 20% of the scale range,¹⁰ and other authors state that it should be smaller than the minimal important change, as this would imply that a change beyond the smallest change corresponds to a “true” change in the measured construct.⁷⁶ The minimal important change was not assessed in the current study because the correlation with the global scale was below 0.5, and this scale was not specific to the pain self-efficacy construct. No values of smallest detectable change and minimal important change are available for the PSEQ

in patients with NPDs. However, the smallest change of 15.7 points found in a previous study¹² can be compared to the mean change scores presented in TABLE 5, highlighting that the change scores of this study are all smaller than the smallest change. This result is consistent with a previous PSEQ responsiveness study¹¹ that outlined the limited ability of the PSEQ to discriminate between measurement error and true change.

Other than the limitations listed above, another potential limitation of this study is that the subgroup analyses were performed in samples smaller than 100 patients; nevertheless, a sample between 50 and 100 patients is considered “good,” according to the COSMIN checklist, to assess the methodological quality of validity and responsiveness studies.⁵⁰

CONCLUSION

THIS STUDY EXPLORED THE MEASUREMENT PROPERTIES OF THE PSEQ IN PATIENTS WITH NPDs. Patients’ self-confidence in dealing with their symptoms is very important in NPDs, and a sound measurement instrument is required. Our results are consistent with an existing body of literature regarding the unidimensionality of the PSEQ, which is satisfactory. In addition, we highlighted some challenges regarding the interpretation of the PSEQ scores in relation to other constructs in this patient population, in particular in patients with a (sub) acute WAD. This indicates that qualitative research on PSEQ content validity involving patients and clinicians is warranted to further investigate the construct measured by the PSEQ. ●

KEY POINTS

FINDINGS: This is the first study to assess the measurement performance of the Pain Self-Efficacy Questionnaire (PSEQ) in patients with neck pain disorders and to show that it is a unidimensional measure in this population. Construct validity and responsiveness of the PSEQ were found to be suboptimal

in these patients, but responsiveness was satisfactory in patients with chronic idiopathic neck pain, consistent with previous studies in patients with chronic low back pain.

IMPLICATIONS: The PSEQ total score can be calculated with confidence in patients with neck pain disorders, and the questionnaire could be used in patients presenting with chronic idiopathic neck pain to monitor changes in pain self-efficacy over time.

CAUTION: The PSEQ’s suboptimal results for construct validity and responsiveness may be due to the limited knowledge of the construct measured by the PSEQ and/or the comparator instruments for disability and pain intensity included in this study, or to the inclusion of patients with acute whiplash-associated disorder. Future research on the content validity of the instruments is required, as well as future clinimetric studies in acute pain samples.

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Pragmatically Applied Cervical and Thoracic Nonthrust Manipulation Versus Thrust Manipulation for Patients With Mechanical Neck Pain: A Multicenter Randomized Clinical Trial

Mechanical neck pain, defined as pain exacerbated by cervical spine positions or movements,² is the second most common musculoskeletal complaint.³³ Physical therapists routinely use orthopaedic manual therapy (OMT) as part of a multimodal treatment program to manage patients with neck pain.^{26,72,74} Orthopaedic manual therapy may include nonthrust

manipulation (NTM), defined as a repetitive, rhythmic, passive oscillatory movement applied at an either small or large amplitude,⁴⁷ or thrust manipulation (TM), defined as a high-velocity, low-amplitude movement at or beyond the end of the available range.¹⁵ Both NTM and TM are clinically effective in patients with neck pain when applied to the cervical spine,^{27,70,72,74} the thoracic spine,^{16,78} or the 2 locations in combination.^{19,20,25,26,48,57} However, neither technique has demonstrated consistent superiority in direct-comparison trials.^{6,19,20,25,34,43} Moreover, systematic reviews^{26,27} have reported that both NTM and TM produce similar results on clinical outcomes.

It has been reported that both NTM and TM produce comparable physiological effects that facilitate pain reduction,^{3,30-32,51} change neuromuscular input,^{3,18,51} and alter the inflammatory state caused by injury.⁶⁸ These neurophysiological effects occur locally where the OMT is applied,²¹ segmentally,^{4,11,12,18} and at the supraspinal level.^{17,76} A transient biomechanical effect may also occur.^{13,23} These therapeutic effects may last for minutes⁷³ to hours.^{30,63} Due to the

• **STUDY DESIGN:** Randomized clinical trial.

• **BACKGROUND:** The comparative effectiveness between nonthrust manipulation (NTM) and thrust manipulation (TM) for mechanical neck pain has been investigated, with inconsistent results.

• **OBJECTIVE:** To compare the clinical effectiveness of concordant cervical and thoracic NTM and TM for patients with mechanical neck pain.

• **METHODS:** The Neck Disability Index (NDI) was the primary outcome. Secondary outcomes included the Patient-Specific Functional Scale (PSFS), numeric pain-rating scale (NPRS), deep cervical flexion endurance (DCF), global rating of change (GROC), number of visits, and duration of care. The covariate was clinical equipoise for intervention. Outcomes were collected at baseline, visit 2, and discharge. Patients were randomly assigned to receive either NTM or TM directed at the cervical and thoracic spines. Techniques and dosages were selected pragmatically and applied to the most symptomatic level. Two-way mixed-model analyses of covariance were used to assess clinical

outcomes at 3 time points. Analyses of covariance were used to assess between-group differences for the GROC, number of visits, and duration of care at discharge.

• **RESULTS:** One hundred three patients were included in the analyses (NTM, $n = 55$ and TM, $n = 48$). The between-group analyses revealed no differences in outcomes on the NDI ($P = .67$), PSFS ($P = .26$), NPRS ($P = .25$), DCF ($P = .98$), GROC ($P = .77$), number of visits ($P = .21$), and duration of care ($P = .61$) for patients with mechanical neck pain who received either NTM or TM.

• **CONCLUSION:** NTM and TM produce equivalent outcomes for patients with mechanical neck pain. The trial was registered with ClinicalTrials.gov (NCT02619500).

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• **KEY WORDS:** cervical spine, manual therapy, neck pain, nonthrust, thoracic spine, thrust manipulation

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temporary nature of the treatment effects, it has been recommended that NTM or TM be combined with therapeutic exercise to attain longer-term benefits.^{37,50,74}

The comparative effectiveness between NTM and TM for mechanical neck pain has long been debated and investigated, without resolution. A number of studies that directly compared NTM to TM for mechanical pain have produced conflicting results.^{6,9,19,20,25,34,43} Reasons for the discrepancy may be partially explained by methodological differences, including prescriptive^{6,9,20,65} or pragmatic designs.^{25,34,43}

Prescriptive OMT trials determine the selected spinal level and treatment parameters prior to randomization and fail to account for an individual's clinical presentation. Prescriptive trials often report results favoring TM.^{9,19,20,58} One study investigating the impact of a prescriptive approach of OMT targeting the cervical and thoracic spines in patients with neck pain demonstrated that those receiving TM had superior outcomes.²⁰ Pragmatic trials promote freedom in the clinician's clinical decision-making process, and are arguably more generalizable to actual clinical practice than prescriptive trials.⁵⁴ Pragmatic trial designs permit clinicians to select the OMT technique, dosage parameters, and the segmental level to target. Pragmatic trials that investigated NTM versus TM for mechanical neck pain reported no differences between the interventions.^{25,34,43}

To date, no studies have examined the impact of a pragmatically applied TM versus NTM approach to both the cervical and thoracic spines in patients with neck pain. Previous studies^{34,43} comparing the use of pragmatic TM and NTM have not required the OMT to be applied to both the cervical and thoracic spines, nor have they targeted the TM or NTM to the symptomatic level. The purpose of this study was to compare the effectiveness of pragmatically applied TM to that of NTM, targeting the symptomatic level of both the cervical and thoracic spines in patients with mechanical neck pain.

METHODS

Participants

CONSECUTIVE PATIENTS PRESENTING to 7 participating clinics for the management of neck pain were assessed for eligibility to participate in the study. Patient recruitment occurred over a 12-month period from February 2016 to February 2017. The geographic area encompassed the states of Ohio, Pennsylvania, Texas, South Carolina, Oregon, and Alaska. Patients were eligible if they presented with mechanical neck pain, were between the ages of 18 and 70 years, scored a minimum of 20% on the Neck Disability Index (NDI), and reported 2/10 or greater on the 24-hour numeric pain-rating scale (NPRS). Patients were excluded if they presented with a contraindication to OMT (malignancy, fracture, rheumatoid arthritis, myelopathy, osteoporosis, etc), had a prior surgical history involving the cervical or thoracic spine, presented with spinal nerve root compression (2 or more neurological findings that include myotome weakness, dermatomal sensory loss, and/or deep tendon reflexive changes), were seeking litigation, or were receiving other forms of nonsurgical care. If clinicians were unable to produce the concordant sign in either the cervical or thoracic spine during passive accessory intervertebral motion (PAIVM) testing, then the patient was excluded.

Clinicians performed any clinical tests (cardiovascular, neurological, or orthopaedic) to screen for red flags that could contraindicate study participation. Clinicians were not required to perform the available premanipulative screening tests, as these examination procedures lack adequate sensitivity in detecting compromised blood flow.^{35,40} Instead, clinicians followed the clinical decision-making guidelines for performing cervical TM recommended by the International Federation of Orthopaedic Manipulative Physical Therapists (IFOMPT).⁵⁶ The recommendation includes an individualized patient assessment and contextualizing of the patient's condition

to formulate a risk-benefit analysis.⁵⁶ Evidence suggests that a thorough medical screen and sound clinical reasoning can prevent a number of adverse events from occurring; however, some are not preventable.⁵³ Patient discharge was at the discretion of the physical therapist, as no specific criteria were set to maintain the pragmatic nature of the study.

The Institutional Review Board at Youngstown State University approved this study, and it was registered with ClinicalTrials.gov (NCT02619500). Prior to enrollment in the study, all participants provided informed consent.

Treating Clinicians

Ten clinicians (mean $\pm$ SD experience, 13.4 $\pm$ 10.8 years) provided the OMT interventions. Clinicians were all OMT advanced practitioners as defined by the American Academy of Orthopaedic Manual Physical Therapists.⁵⁵ Clinician characteristics can be found in **TABLE 1**. Each was familiar with identifying the concordant sign and was blinded to outcome data. Concordant sign describes the production of the patient's familiar symptoms through PAIVM testing.¹⁵

Clinical equipoise exists when investigators hold no bias toward one intervention over another,²² and is a necessary ethical principle in clinical research.⁴¹ A lack of equipoise in clinical trials may bias the intervention or data-collection process and could obscure the findings.⁴¹ Our evaluation for detecting clinical equipoise was 2-fold. First, global belief of overall technique effectiveness was measured at the beginning of the clinical trial. Second, following the examination of each patient, the treating clinicians rated their clinical opinion of which OMT technique they felt would be more effective for that patient. A visual analog scale, with gradations ranging from -2 to 0 to +2, was used to quantify potential equipoise and show the extent of preference toward one of the interventions. A 0 indicated that equipoise was present, -2 or -1 indicated a preference toward NTM, and +1 or +2 indicated a preference toward TM.

Examination

Clinicians performed an individualized comprehensive examination of each patient. The required examination procedures for the study included PAIVM testing and deep cervical flexion endurance (DCF). Passive accessory intervertebral motions were performed for the purpose of pain provocation to localize the most involved segment of both the cervical and thoracic spines. The spinal segment targeted for either the NTM or TM was based on the reproduction of the concordant sign with the PAIVM assessment. Although PAIVMs may lack specificity in terms of segmental movement in the spine,^{42,52} pain provocation has been suggested as the most reliable method for isolating the site of the disorder.⁶⁰

For the DCF test,²⁴ patients were positioned supine and instructed to maximally tuck their chin isometrically. Patients lifted their head 2.5 cm and maintained upper cervical flexion simultaneously. A skin fold along the anterolateral neck was monitored, and the investigator's hand remained under the patient's occiput. The timing of the position began once the patient was in the correct position, and stopped when the patient's head dropped into the fingers of the clinician, the patient's head was

elevated greater than 2.5 cm, the patient lost the upper cervical flexion, or the patient ended the test. The interrater reliability of the DCF test has been reported to be moderate (intraclass correlation coefficient [ICC] model 3,1 = 0.67) for clinical testing in patients with neck pain.²⁹ The minimal detectable change is reported as 19.15 seconds.⁴⁵

Outcome Measures

A blinded outcome assessor collected all self-report measures and DCF at visits 1 and 2 and at discharge. The primary outcome of interest was the NDI.⁷¹ The NDI is a self-report measure of perceived disability comprising 10 questions to be answered on an ordinal scale ranging from 0 to 5, for a maximum score of 50 points, which may be expressed as a percent. Higher scores on the NDI indicate greater perceived levels of disability. The NDI has been reported to have acceptable reliability for patients with neck pain,⁴⁶ and has a reported minimum clinically important difference of 7.5 points or 15%.⁷⁷

Secondary variables of interest were also collected. The Patient-Specific Functional Scale (PSFS)⁶⁴ is a patient-identified self-report questionnaire that measures general activity limitations. The scale ranges from 0 (unable to perform)

to 10 (able to perform the activity at the preinjury level). The patient reports 3 activities and rates each activity from 0 to 10, which are averaged for a composite score. The PSFS has excellent test-retest reliability (ICC = 0.92) and a standard error of measurement of 0.43 for patients with neck pain.⁷⁵ The minimal detectable change on the PSFS has been reported to be 2 raw points.⁷⁵ The 24-hour average NPRS score was used to assess the patient's perceived level of pain.⁴⁹ The NPRS is an 11-point scale, ranging from 0 (no pain) to 10 (worst imaginable pain). The patient was instructed to provide his or her current, worst, and best pain scores over the past 24 hours, and a composite average was calculated. The minimum clinically important difference on the NPRS has been reported to be 1.3 points for patients with neck pain.²

The global rating of change scale (GROC)³⁶ is a 15-point scale used to quantify a patient's improvement with treatment or to record the clinical course of a condition over time. Patients were asked to describe their overall condition since the start of treatment until the present time on a scale ranging from -7 ("a very great deal worse") to +7 ("a very great deal better"), with 0 representing "about the same." The GROC was collected at discharge. A score of +5 indicates that a

TABLE 1

TREATING CLINICIAN CHARACTERISTICS AND GLOBAL EQUIPOISE

Clinical Site	Therapist	Global Equipoise	Sex	Degrees and Certifications	Years of Experience	R/F Trained	Practicing State
1	1	Thrust +1	Male	DPT, COMT	9	N	OH
1	2	Equipoise	Male	COMT, OCS, PhD	25	Y (F)	OH
2	3	Equipoise	Male	DPT, COMT, OCS	28	N	PA
3	4	Nonthrust -2	Male	PT, COMT	30	N	PA
4	5	Equipoise	Female	DPT, OCS	4	Y (R)	TX
5	6	Thrust +2	Male	DPT, CSCS	2	Y (R)	OR
6	7	Thrust +1	Male	DPT, OCS	10	Y (R)	AK
6	8	Nonthrust -1	Male	DPT, OCS	3	Y (R)	AK
6	9	Equipoise	Female	DPT, OCS	17	Y (R)	AK
7	10	Thrust +2	Male	DPT, SMT	7	N	SC

Abbreviations: COMT, certified orthopaedic manual therapist; CSCS, certified strength and conditioning specialist; DPT, doctorate of physical therapy; F, fellowship; N, no; OCS, orthopaedic certified specialist; PhD, doctor of philosophy; PT, physical therapist; R, orthopaedic residency; SMT, spinal manipulative therapist; Y, yes.

patient feels that he or she has experienced a dramatic improvement in his or her condition.⁸

Randomization

A computerized random-number generator determined group allocation prior to data collection. Concealed allocation was performed using an opaque envelope and placed in each patient's chart. Following the clinical examination and completion of each individual patient's equipoise scoring, the treating clinician opened the envelope and determined the patient's group allocation.

Interventions

The plan of care was determined by the treating clinician and based on individualized evaluation. The techniques and dosage parameters for the OMT interventions were determined pragmatically. The experimental groups received either NTM or TM, targeting the symptomatic level, to both the cervical and thoracic spines. Clinicians collected information regarding side effects at the start of the second visit.

TM Group The treating clinician performed a high-velocity, low-amplitude thrust to the most symptomatic segment of both the cervical and thoracic spines. The type of TM, direction of thrust, and number of thrusts were at the discretion of the clinician and were based on the individualized evaluation of the patient.^{15,47} The treating clinician recorded the specific parameters for the TM employed during the first 2 sessions.

NTM Group Patients who were allocated to the NTM group received a graded oscillatory technique to both the cervical and thoracic spines. The type of NTM, dosage, and grade were at the discretion of the clinician and based on an individualized evaluation. Clinicians documented the specific parameters for the selected NTM for the first 2 sessions.

Other Interventions In addition to the OMT interventions, a home exercise program was provided to both groups that included active-range-of-motion ex-

ercises for both the cervical and thoracic spines and DCF exercises. The active-range-of-motion exercises were performed for 2 sets of 10 repetitions, twice daily. The parameters of the DCF exercise were based on the patient's ability to perform the exercise correctly. Progression of the DCF exercise was at the discretion of the clinician. Last, patients in both groups received postural education, advice to stay active, and encouragement to participate in their normal activities. No other interventions were added during the course of the study.

Sample-Size Estimation

An a priori sample-size analysis was conducted using G*Power (Heinrich-Heine Universität, Düsseldorf, Germany), selecting a 2-way mixed-model analysis of variance with 2 groups and 3 time points. A calculated sample size of 109 patients provided 80% power to detect a 15% between-group difference on the NDI, with the alpha value set at .05.

Data Analysis

The data for this study were analyzed using SPSS Version 20.0 (IBM Corporation, Armonk, NY). Group comparisons for the NDI, PSFS score, NPRS 24-hour average, and DCF were analyzed with a 2-way mixed-model analysis of covariance (ANCOVA) at baseline, visit 2, and discharge. Separate univariate analyses were performed for each of the clinical outcomes. The between-subject fixed factor was group (NTM or TM), and time served as the random factor. The 2 covariates in the analyses were global and individual patient equipoise. Assumptions for the ANCOVA in the analysis of between-group differences in disability, pain, and motor performance were met, except normality. With a sample size larger than 20 per group, the ANCOVA is robust under moderate deviations of normality.⁶⁷ The original study protocol would have included patients in the final analyses if they were present for at least 2 visits. That protocol was adjusted post hoc to include a true intention-to-treat

procedure, requiring all patient data to be analyzed once randomized. Outliers were identified at the univariate level. An alpha level of significance set at $P < .05$ was used for all analyses.

Separate 2-way ANCOVAs were used to analyze the between-group differences for the GROCC, number of visits, and duration of care at discharge. All assumptions for the use of an ANCOVA were met and the same covariates were used. Missing data for the GROCC, number of visits, and duration of care were managed with multiple imputations. Three data sets were analyzed, providing parameter estimates that were pooled.

RESULTS

ONE HUNDRED FIFTY PATIENTS WERE screened for eligibility at the 7 clinic sites. Thirty participants did not meet the inclusion criteria, and 17 presented with 1 or more contraindications to OMT. **FIGURE 1** provides a flow diagram for participant recruitment and retention processes. Baseline characteristics for both groups are provided in **TABLE 2**. Post hoc interim analysis was completed after data from 103 patients were collected, based on the need to complete recruitment by the grant's timeline for data collection. It was determined that 6 additional patients would not have altered the outcome, based on the small between-group effect sizes.¹⁰ Therefore, the final analyses included 103 patients, 48 randomized to receive TM and 55 to receive NTM.

The results of the 2-way mixed-model ANCOVA revealed no significant interaction effects for time and group on the NDI, PSFS, NPRS 24-hour average, or DCF, while controlling for clinical equipoise. Pairwise comparisons of the estimated marginal means at discharge are reported in **TABLE 3**. Significant main effects for global equipoise ($P < .05$) were observed for the NDI, PSFS score, and NPRS. Significant main effects for individual patient equipoise ($P < .05$) were also observed for the NDI, PSFS score, and NPRS. This effect suggests

that patients treated by clinicians with a preference toward TM for that patient had better outcomes, regardless of treatment group. The significant main effects suggest that outcomes were influenced by clinical equipoise only as independent variables. The magnitude of this effect was nominal, with differences between the adjusted and unadjusted means being small. No significant interaction effects were observed for group and either measure of equipoise.

Within-subject effect for time was significant for the NDI (difference estimate, 17.39; 95% confidence interval [CI]: 4.5, 20.1; $P < .001$), PSFS score (difference estimate, 3.1; 95% CI: 0.695, 3.62; $P < .001$), NPRS (difference estimate, 3.00; 95% CI: 0.769, 3.45; $P < .001$), and DCF (difference estimate, 22.14; 95% CI: 2.6, 29.0; $P < .001$). Pairwise comparisons indicated significant differences for each time point on the NDI and NPRS, presented in **FIGURES 2** and **3**.

Separate ANCOVAs demonstrated no between-group differences for the GROC, number of visits, or duration of care. The estimated means at discharge and between-group differences are provided in **TABLE 4**. Individual patient equipoise had a significant main effect only for number of visits; however, significant interaction effects for group and individual patient equipoise were not observed.

Side Effects and Adverse Events

Twenty-six (25%) of the 103 patients reported experiencing at least 1 minor side effect. An equal number of patients reported having experienced at least 1 minor side effect in each group (NTM, $n = 13$; TM, $n = 13$). Minor side effects reported included aggravation of pain, headache, dizziness, radiating symptoms, muscle stiffness or soreness, and muscle spasm. Participants reported 19 various side effects in the TM group and 15 in the NTM group. The most common side effects included temporary (less than 24 hours in duration) increase in pain and perceived stiffness. No major adverse event was reported.

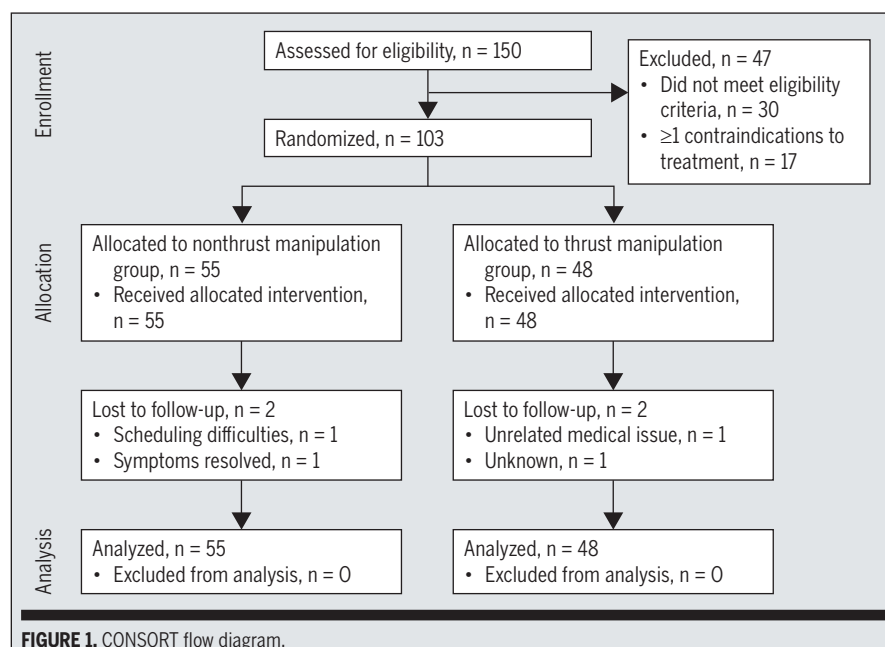


FIGURE 1. CONSORT flow diagram.

TABLE 2

BASELINE CHARACTERISTICS FOR THE NONTHRUST AND THRUST MANIPULATION GROUPS*

	Nonthrust Manipulation Group (n = 55)	Thrust Manipulation Group (n = 48)
Sex, n		
Male	14	13
Female	41	35
Age, y	49.2 ± 15.5	44.8 ± 14.3
Height, m	1.65 ± 0.11	1.66 ± 0.09
Weight, kg	73.7 ± 18.0	78.0 ± 20.7
Body mass index, kg/m ²	27.0 ± 5.1	28.6 ± 4.9
Symptom duration, wk	67.6 ± 108.3	66.2 ± 143.1
Baseline NDI, % [†]	29.6 ± 8.6	29.5 ± 10.1
Baseline PSFS score [‡]	5.1 ± 1.5	4.9 ± 1.6
Baseline NPRS [§]	5.0 ± 1.5	4.3 ± 1.4
Baseline DCF, s	24.4 ± 15.5	25.1 ± 16.9

Abbreviations: DCF, deep cervical flexion endurance; NDI, Neck Disability Index; NPRS, numeric pain-rating scale; PSFS, Patient-Specific Functional Scale.

**Values are mean ± SD unless otherwise indicated.*

[†]0 to 50, with higher scores indicating greater disability.

[‡]0 to 10, with higher scores indicating greater function.

[§]0 to 10, with higher scores indicating more pain.

^{||}Higher timed scores indicate greater motor performance.

DISCUSSION

THIS STUDY FOUND NO BETWEEN-group differences in disability, pain, or motor performance among patients with mechanical neck pain who

received a concordant NTM or TM to both the cervical and thoracic spines. See **TABLE 3** for the between-group adjusted mean difference at discharge. Although a main effect was observed for clinician global and individual patient

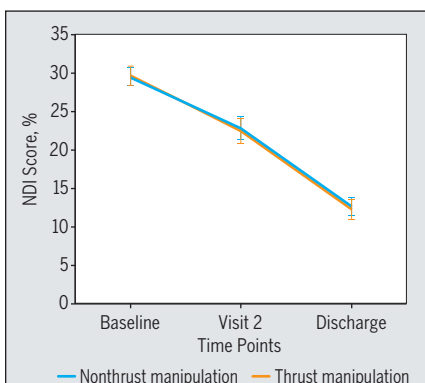


FIGURE 2. Comparison of the adjusted mean differences on the NDI at baseline, visit 2, and discharge. Error bars represent the 95% confidence intervals for each value. No between-group differences were observed; however, both groups experienced significant within-group changes at all 3 time points. Abbreviation: NDI, Neck Disability Index.

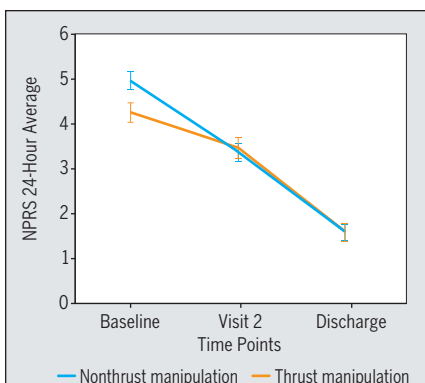


FIGURE 3. Comparison of the adjusted mean differences on the NPRS at baseline, visit 2, and discharge. Error bars represent the 95% confidence intervals for each value. No between-group differences were observed; however, both groups experienced significant within-group changes at all 3 time points. Abbreviation: NPRS, numeric pain-rating scale.

TABLE 3

PAIRWISE COMPARISONS OF THE ESTIMATED MEANS AT DISCHARGE*

Outcome Variable	Nonthrust Manipulation Group (n = 55)	Thrust Manipulation Group (n = 48)	Between-Group Differences		
			Mean Difference [†]	SE	P Value
NDI, % [‡]	12.2 ± 9.4	12.3 ± 9.5	0.47 (-2.7, 1.7)	1.1	.67
PSFS score [§]	8.2 ± 1.5	8.3 ± 1.4	0.20 (-0.15, 0.56)	0.26	.26
NPRS [¶]	1.6 ± 1.3	1.6 ± 1.4	0.20 (-0.15, 0.55)	0.25	.25
DCF, s	46.6 ± 25.7	47.2 ± 31.8	0.50 (-5.8, 5.6)	4.3	.98

Abbreviations: DCF, deep cervical flexion endurance; NDI, Neck Disability Index; NPRS, numeric pain-rating scale; PSFS, Patient-Specific Functional Scale; SE, standard error.

*Values are mean ± SD unless otherwise indicated.

[†]Values in parentheses are 95% confidence interval.

[‡]0 to 50, with higher scores indicating greater disability.

[§]0 to 10, with higher scores indicating greater function.

[¶]0 to 10, with higher scores indicating more pain.

^{||}Higher timed scores indicate greater motor performance.

TABLE 4

GROUP ESTIMATED MEANS AND STANDARD DEVIATIONS FOR THE GROC, NUMBER OF VISITS, AND DURATION OF CARE AT DISCHARGE*

Outcome Variable	Nonthrust Manipulation Group (n = 55)	Thrust Manipulation Group (n = 48)	Between-Group Differences		
			Mean Difference [†]	SE	P Value
GROC	5.0 ± 1.8	4.9 ± 1.7	0.11 (-0.59, 0.81)	0.35	.77
Number of visits	5.7 ± 2.4	6.4 ± 3.1	0.68 (-1.7, 0.40)	0.54	.21
Duration of care, d	35.7 ± 18.0	33.7 ± 16.9	1.96 (-9.8, 5.8)	3.9	.61

Abbreviations: GROC, global rating of change; SE, standard error.

*Values are mean ± SD unless otherwise indicated.

[†]Values in parentheses are 95% confidence interval.

influence between this ethical standard and NTM and TM.¹⁴

Our findings support those of other pragmatic trials investigating the comparative effectiveness between NTM and TM for neck pain. Leaver et al⁴³ investigated clinician-selected NTM and TM for patients with acute neck pain and found that groups had similar results on rate of recovery for neck pain and disability. Hurwitz et al³⁴ performed a large randomized controlled trial (RCT) in a sample of 336 patients that compared NTM and TM, in combination with or without a heat or electrical modality, for patients with neck pain. The authors reported no differences in pain or disability between groups at the 6-month follow-up.

The results of the current study differed from those of OMT trials on patients with neck pain that used a prescriptive design. Cassidy et al⁶ conducted an RCT between NTM and TM on 100 patients with neck pain; those receiving TM reported significantly greater pain reductions. However, the NTM used was a muscle energy technique for 4 repetitions of 5-second holds, which was different from the oscillatory NTM techniques used in the present study.⁶ The results of the present study also differ from those of a multicenter RCT²⁰ on 107 participants presenting with mechanical neck pain over a 48-hour period. The treatment in both groups was standardized and applied to the upper cervical spine and

thoracic spine, regardless of symptom provocation. Results found that TM produced significantly greater reductions in pain and disability. Differences in the application of NTM treatments might explain some of the variation in the results of both studies. In the multicenter RCT conducted by Dunning et al,²⁰ the NTM group received one 30-second bout, applied bilaterally at the C1-2 level, and a 30-second central posterior-to-anterior NTM at the T1-2 level. Clinicians in the present study applied the OMT pragmatically to obtain a desired change in the patient's condition. The total time under load (number of bouts by duration) for the NTM techniques was collected for the first 2 visits. The NTMs applied to the cervical spine lasted, on average, 4.36 ± 2.3 minutes (range, 1-8 minutes). The NTM techniques applied to the thoracic spine, on average, lasted 2.9 ± 1.9 minutes (range, 1-10 minutes). Currently, the optimal dosage for manual therapy in patients with neck pain is unknown²⁷; however, it has been demonstrated that a within-session change is prognostic for between-session changes in patients with neck pain.⁶⁹ Additionally, experimental evidence suggests that the extent of segmental movement, biomechanical alteration, and neurophysiological response may be dependent on force and duration of the OMT techniques.^{13,32,39,62,66}

In the present trial, clinicians provided OMT to the most symptomatic levels. Currently, evidence supporting the need to target the symptomatic level is conflicting.^{1,7,28,38,59} One systematic review reported that a targeted NTM provides greater reductions in pain than random techniques for patients with neck pain.⁶¹ Due to the nonspecific effects shown to occur with OMT,^{3,42,44,51} it may be a matter of relative proximity to the symptomatic level to positively influence pain.

The number of minor side effects reported in this trial was consistent with reports in other studies.^{5,71} An equal number of patients in each group reported having experienced a minor side effect, and no serious adverse events were re-

ported. The screening approach for this study was consistent with the IFOMPT recommendations.⁵⁶

This study is not without limitations. First, we used a sample of convenience and not a more sophisticated type of random sample. As with all OMT trials comparing therapeutic interventions, the treating clinician and patients could not be blinded to group allocation. There were other potential confounding variables that could have impacted our results that were not strictly controlled; however, this is a characteristic of pragmatic trials. We did not stratify our sample based on the duration of symptoms. It is possible that patients who have acute or chronic neck pain may respond differently to the intervention provided in this trial.

CONCLUSION

THE FINDINGS FROM THIS RCT suggest that both NTM and TM produce comparable outcomes on pain, disability, and motor performance for patients with mechanical neck pain when applied in a pragmatic fashion. Patients' perceived level of change, the number of visits, and the duration of care were similar between groups. ●

KEY POINTS

FINDINGS: Patients with mechanical neck pain who received either nonthrust manipulation (NTM) or thrust manipulation (TM) delivered pragmatically to the cervical and thoracic spines experienced similar changes in neck pain, disability, and motor performance when the symptomatic level was targeted.

IMPLICATIONS: When applied pragmatically, both NTM and TM produce similar improvements in pain and disability for patients with mechanical neck pain.

CAUTION: No long-term follow-ups were collected on patient outcomes.

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Posterior Shoulder Tightness: To Treat or Not to Treat?

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Shoulder pain is a common musculoskeletal complaint that is difficult to treat because of the biomechanical complexity of the shoulder region, the interplay between mobility and stability, and the vital role played by the shoulder in moving, positioning, and providing stability for hand function. Despite advances in biomechanics and pain science, there is still much to learn about how impairments influence shoulder function and health. One impairment, posterior shoulder tightness (PST), is often noted in individuals with shoulder pain and consequently has generated much discussion and debate in recent years. The clinical interest in PST evolved from observations of symptomatic throwing athletes with seemingly related deficits in shoulder internal rotation and horizontal adduction (HAD) flexibility of their throwing arm.

Asymptomatic throwing athletes with greater PST are also prone to increased injury rates,^{29,36} prompting discussion regarding preventive strategies. Importantly, PST is also often present in individuals with impingement symptoms or nonspecific shoulder pain and no history of throwing-sport exposure.¹⁴

Range-of-motion shifts and deficits are the clinical indicators of PST, with 3 tissue alterations potentially contributing to these modifications: (1) increased humeral retroversion (retroversion), (2) reduced posterior glenohumeral joint (GHJ) capsule extensibility, and (3) reduced posterior shoulder muscle/

tendon extensibility. The significance of each alteration for shoulder function and the interaction among them remain unclear. It is also unknown if, or to what extent, these impairments can be resolved through interventions. This raises a clinically relevant and straightforward question: when PST is present, should we treat or not treat? In this Viewpoint, we will debate this question and propose that physical therapy interventions have the potential to improve only 1 of the 3 tissue alterations contributing to PST.

Clinical Background

The relatively high incidence of PST in both athletic³ and nonathletic populations¹⁴ suggests its relevance to musculoskeletal shoulder pain. Posterior shoulder tightness is considered a contributor to posterior impingement,³³ rotator cuff tendinopathy,^{3,10} and subacromial impingement syndrome,^{10,18} collectively termed *rotator cuff-related shoulder pain*.¹⁸ The clinical significance of PST is also supported by the observed combination of improved motion and reduced

symptoms following interventions targeting the impairment.^{33,37}

Assessment

The “treat or not treat” question begins with a clinical examination to determine whether PST is present. The assessment of PST requires measurements of shoulder range of motion bilaterally to consider differences related to arm dominance. Measurements for PST include:

1. GHJ internal rotation range of motion measured at 90° of shoulder abduction¹³
2. Shoulder HAD or cross-body adduction¹⁷
3. Low flexion² range of motion
4. Extension plus internal rotation⁷ range of motion

These measures all assess GHJ motion and give insight into shoulder posterior capsule and/or muscle/tendon extensibility. An additional measurement, the bicipital forearm angle (BFA), is used to quantify humeral retroversion.^{6,20}

The measurement of GHJ internal rotation is highly reliable^{13,17} and has been used as the reference standard to evaluate the validity of HAD measurements.³⁴ Horizontal adduction is quantified in sidelying or supine, with measurements in both positions demonstrating excellent reliability and strong correlations with measurements of GHJ internal rotation.^{17,22,34} While GHJ internal rotation and HAD

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are frequently used, the construct validity relating these measurements to posterior shoulder tissue alterations is limited. Low flexion range of motion, quantifying GHJ internal rotation with the shoulder at 60° of flexion, has strong validity and reliability for assessing GHJ posterior capsule extensibility.² Glenohumeral joint extension plus internal rotation, where internal rotation of the GHJ is measured with the shoulder in 60° of extension, may quantify infraspinatus passive stiffness, but further testing is needed to confirm this relationship.⁷

Humeral Retrotorsion: To Treat or Not to Treat? The angle between the lines bisecting the humeral head and through the humeral epicondyles is used to quantify humeral retrotorsion (retroversion).²⁶ Retroversion angle is near 70° in young individuals and is reduced to approximately 30° by skeletal maturity.⁹ When increased retroversion is observed in the dominant shoulder of throwing athletes, it is thought that the high GHJ external rotation torsional forces, such as those generated during throwing, inhibit the reduction in torsion that normally occurs during adolescence. Greater retroversion in adulthood is not clinically modifiable but will impact GHJ range-of-motion rotational measurements,^{1,26} necessitating bilateral assessment.²¹ Failing to identify increased retroversion on the throwing arm may result in false-positive range-of-motion test results and increase the risk of treating a nonexistent soft tissue deficit. Retrotorsion may also be present in nonthrowers, but the prevalence, contribution to symptoms, and mechanism are unknown in these individuals. Because increased retrotorsion is a fixed bony adaptation after skeletal maturation, if the physical examination reveals no deficit in total rotation motion of the GHJ, but a shift in the rotational range instead, then no treatment should be applied. However, when there is a deficit in total rotational range, the clinician must determine whether the deficit is due to lack of external rotation range of motion in a retroverted shoulder or lack of GHJ

internal rotation potentially associated with the presence of PST. The BFA may help inform this decision.

Posterior GHJ Capsule: To Treat or Not to Treat? Decreased posterior shoulder capsule extensibility has long been implicated as the source of PST in throwing athletes,²³ with 2 proposed mechanisms: (1) response to repeated tensile loading during throwing, and (2) response to degenerative joint processes.

In theory, mechanoreceptive cells subjected to repetitive tensile loading during arm deceleration trigger capsule tissue hyperplasia, increasing thickness and reducing extensibility. Imaging confirms increased posterior capsule thickness in throwers' dominant shoulders,^{31,32} but while the mechanism is plausible, support through animal models or longitudinal analyses is lacking.

The construct/meaning of the word *tightness* as it relates to the posterior capsule warrants consideration. The literature uses the term *tightness* to indicate both increased stiffness/loss of extensibility and physical shortening of a tissue. Both interpretations could reduce GHJ motions, but we contend that increased stiffness is the more appropriate interpretation of the alteration seen in the posterior capsule. Increased stiffness is consistent with the idea of hyperplasia in response to mechanical loading and the increased tissue thickness identified on imaging.³² While a large body of evidence describes changes in GHJ kinematics following experimental shortening of the posterior capsule, there is no direct evidence for shortening of the posterior capsule in the presence of hyperplastic change. This raises a dilemma about the validity of using experimental capsule "shortening" to evaluate the effects of capsule "thickening" on joint biomechanics.

The "treat or not treat" question for the posterior capsule is based on 2 considerations: is there an intervention that best "engages" the posterior capsule such that a treatment has the potential to be effective? And, more importantly,

is it theoretically possible for the intervention to be effective in the intended way? We contend that no intervention, regardless of how it engages the capsule, can effectively resolve the hyperplastic changes. Joint mobilization techniques, used clinically, apply forces that are between 3 and 14 kg,³⁸ while the posterior GHJ capsule has a modulus of elasticity of 683 kg/cm².¹² It is therefore unlikely that even our most skillfully applied, capsule-specific mobilizations will reach the elastic limit of the tissue. Even supposing that an intervention can influence only the posterior capsule, any change in tightness of the capsule and its potentially related GHJ range of motion would likely be the result of a temporary viscoelastic effect. This evidence suggests that if the therapeutic goal is to permanently modify posterior capsule extensibility, then manual therapy and exercises are unlikely to be effective and are therefore not indicated. If manual therapy to the posterior capsule proves effective at improving/restoring GHJ range of motion, then the mechanisms are likely through processes other than modified capsule extensibility.

Muscles/Tendons: To Treat or Not to Treat? The posterior rotator cuff and posterior deltoid are potential sources of PST through their functions as GHJ external rotators and restraints to internal rotation. These muscles are particularly vulnerable in overhead throwing athletes because of repetitive eccentric loading demands. While interventions targeting these muscles have restored GHJ motion,^{19,27} the mechanisms underlying these changes remain unclear. Immediate increases in shoulder motion following intervention make structural muscular changes unlikely, suggesting that neuromuscular mechanisms are influencing tissue behavior. Magnetic resonance imaging elastography shows that symptomatic muscles demonstrate increased stiffness,⁵ increased resting electromyographic signal intensity,⁴ and the presence of hypernociceptive chemicals.²⁸ Such features may develop when

muscular demands exceed a muscle's capacity or when articular dysfunction results in afferent reflex activity. Synergistic activity between the shoulder capsule and related muscles exists, such that electrical stimulation of the capsule mechanoreceptors causes shoulder muscle reflex activity, most commonly of the infraspinatus muscle.^{8,11,30} Posterior shoulder tightness in some populations may hypothetically arise from protective reflex activity of the infraspinatus, teres minor, or posterior deltoid in response to afferent discharge from the GHJ capsule. In the absence of an obvious mechanism of tissue overload, this process may partly explain the mechanism of PST generation in nonathletic populations. To treat, in this scenario, may require a multidimensional rehabilitation program aimed at reducing protective muscle activity.

Several recent studies have demonstrated immediate improvement in GHJ motion following interventions targeting myogenic structures of the posterior shoulder. Based on these findings, treatment to these structures is warranted when they are believed to be involved in the range-of-motion deficit. Muscle-based treatments that have been examined include stretching,^{16,24} massage,³⁹ cryotherapy,²⁴ trigger point dry needling,²⁵ instrumented soft tissue mobilization,¹⁵ and muscle-energy techniques.¹⁹ While these muscle-based interventions were not all evaluated using rigorously designed protocols, the range of proposed interventions suggests that of the 3 potential tissue alterations, muscle has the most potential to be responsive and result in improved GHJ motion. How these improvements relate to a muscle's chemical, thermal, structural, cellular, or mechanical environment remains to be determined.

Summary

The current knowledge of PST favors a myogenic cause, especially for throwing athletes.^{1,19,37} While the rapid response to muscle-based interventions in throwing and nonthrowing populations

supports this perspective, the evidence for posterior capsule thickening in throwers suggests that it also influences motion.^{31,32} As is true for many informed dialogs regarding human movement, our Viewpoint on this particular "treat or not treat" question may be part of a normal pendulum swing. For many years, the capsule was considered the main source of PST; however, recent literature suggests that muscle tissues are important structures to consider in the generation of PST. As with many complex problems, the definitive answer will likely be multifactorial and variable across individuals. We propose that a muscle-capsule interaction is quite likely and hypothesize that the relative influence of muscle and capsule on PST lies on a continuum for most individuals.

While the recommendation to consider muscle as the main source of PST may be the safe choice from among the 3 proposed tissue alterations, we also suggest that by treating muscles, other mechanisms are likely to influence joint motion and function. For example, transient changes in posterior capsule mobility, even if only resulting in temporary viscoelastic changes, may also modify GHJ translations, adjust a faulty motor plan, or improve joint arthrokinematics. The likelihood that a "muscle-based" intervention modifies another contributing factor reflects the strategy advocated by Wilk et al³⁵ of focusing on improving GHJ internal rotation motion rather than targeting a specific tissue.

We recommend that clinicians use a cluster of clinical tests to provide the best chance of identifying PST. The use of the BFA, particularly when the deficit occurs in the dominant arm of throwing athletes, may help to identify where in the range the deficit lies. Once identified as PST, a combination of hands-on treatment to the myofascial structures of the posterior shoulder and stretches to the posterior shoulder is recommended. Careful evaluation of measurement outcomes and the application of a measurement-treatment-reassessment approach

when managing PST will help guide the clinician toward the articular, myofascial, or exercise-based intervention most likely to be effective.

Future work to advance our understanding of PST should focus on clarifying the incidence of PST in nonthrowing populations and on determining more precisely the underlying mechanisms/causes of PST, particularly the potential myogenic adaptations. There is a randomized clinical trial currently under way assessing the impact of treating PST as part of a multidimensional treatment program (ClinicalTrials.gov ID: NCT02598947). The results may provide further insight on the interaction between PST and shoulder pain and impairments. ●

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If It Doesn't Work, Why Do We Still Do It? The Continuing Use of Subtalar Joint Neutral Theory in the Face of Overpowering Critical Research

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The use of subtalar joint neutral (STJN) in the assessment and treatment of foot-related musculoskeletal symptomology is common in daily practice and still widely taught.^{2,6} The main pioneer of this theory was Dr Merton L. Root,⁹ and it has been labeled with a variety of names: “the foot morphology theory,” “the subtalar joint neutral theory,” or simply “Rootian theory” or “Root model.”^{2,3,5,6} Throughout the late 1950s and early 1960s, Dr Root conducted hundreds of “biomechanical assessments” and began to understand the importance of the subtalar joint, from which he defined its “neutral” position. From there, he created a classification of foot morphology (eg, forefoot valgus) and linked foot morphology to foot function in gait.¹⁵⁻¹⁷ These core concepts still underpin a common approach to musculoskeletal assessment of the foot, as well as the consequent design of foot orthoses.⁶

The most effective method to create custom foot orthoses has been questioned, and, while disagreements exist,^{2,5,19} the

available literature continues to point to Dr Root's theory as the most prevalently utilized.^{8,11} Concurrently, the worth of Dr Root's STJN theory has been challenged due to its poor reliability^{2,7,10} and, more recently, limited external validity.⁶ Inaccuracies in the interpretation and application of Dr Root's theories have also been proposed.⁹ This critical research spans decades, and it begs the question as to why clinicians who evaluate and treat lower-limb conditions still continue to utilize such a controversial approach.

This Viewpoint briefly but critically reviews the main clinical areas of the STJN theory, and concludes with a possible explanation and concerns for its on-

going use. To support our view, we will discuss (1) historical inaccuracies, (2) challenges with reliability, and (3) concerns with validity.

Historical Inaccuracies

Placing the foot into STJN underpins several areas of the STJN theory: assessment of the non-weight-bearing rearfoot-to-leg angle, measurement of forefoot-to-rearfoot position, and the position in which prescription foot orthoses are cast.^{9,15-17}

The process by which Dr Root's method of foot assessment is researched and utilized is worthy of historical scrutiny. In a historical review of Dr Root's work by Lee,⁹ it is apparent that the main method employed to find STJN in the literature is not the one initially proposed by Dr Root and his coworkers. All research that has continually criticized the reliability and, more recently, the validity of the STJN theory

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has found STJN by palpating the head of the talus and moving the subtalar joint until articular margin congruency with the navicular is determined. This method was not proposed by Dr Root but, rather, by Wernick and Langer in 1972.¹⁸ Dr Root never endorsed this method.⁹

Non-Weight-Bearing STJN Position To achieve the non-weight-bearing STJN position, Dr Root proposed the following procedures:

- A dell of the arc of motion of the subtalar joint is notable when moving from the pronated to the supinated position. The position of this dell is STJN.⁹
- Using bisection lines and calculating the total subtalar joint range of motion. From there, a 2:1 (inversion/eversion) ratio is applied. Moving the calcaneus two thirds from its maximally inverted position would detect the STJN. This method was published in 1971.¹⁵
- If performed correctly, Dr Root proposed that both the procedures noted above would find the same position of STJN.⁹

The non-weight-bearing dell of the arc-of-motion position of STJN does not appear to have been formally published prior to the publication by Lee,⁹ and the reference for this work is quoted as “ML Root, personal communications, 1999.” This method of assessment of STJN position is stated to have been presented in seminars and graduate lectures through the 1950s and 1960s.⁹ However, the lack of formal documentation or publication may explain the dearth of research and apparent use of this examination technique.

Weight-Bearing STJN Position To achieve the weight-bearing STJN position, Dr Root proposed that one pronate and supinate the foot in bipedal stance until there is palpable congruency of the subtalar joint, visual concavity of the lateral surface of the foot to the leg, and a straight line visible in the area of the calcaneocuboid joint. When these

3 observations were noted, STJN was achieved in stance and the rearfoot-to-ground angle recorded.¹⁵

Why the weight-bearing methodology was discarded in lieu of the talar margin palpation method proposed by Wernick and Langer¹⁸ appears less clear. The use of palpation of the talonavicular joint (non-weight bearing and weight bearing) to determine subtalar joint congruency (thus STJN) is anatomically a different position from that proposed by Dr Root and his coworkers.

Applying the STJN theory to foot orthosis prescription demonstrates further possible historical inaccuracies. Dr Root may have been developing foot orthoses in his clinical practice,¹⁶ but no descriptive text on custom orthotic prescription or manufacture was ever made available. Authors have cited Dr Root in their own texts and literature on foot orthosis prescription, often using terminology such as “Rootian” or “modified Rootian” foot orthoses.^{1,12} It may be unwise to assume that Dr Root would agree with the interpretation of his work. Dr Root and his coworkers gave us a theory, in a time without 3-D video gait analysis and computerized plantar pressure examination, by which they believed we could ideally detect “normal” and “abnormal” foot function. They did not follow with any literature relating to the application of this theory to orthosis prescription.

Challenges With Reliability

All available research on the reliability of STJN measurements has found it to be mostly moderate (intratester) to poor (intertester),^{2,7,10,14} including joint positions and recommended bisection-line placement on the lower leg and foot. With regard to orthoses, the most common interpretation of the STJN theory requires a cast or impression of the foot to be taken in a non-weight-bearing STJN position,^{1,9,12,16} resulting in a “neutral negative cast” of the foot. The shape of the neutral cast is of utmost importance, as it is essential to capture the

correct forefoot-to-rearfoot alignment. Without beginning to introduce issues with orthotic manufacture and casting reliability, the problems with STJN position reliability immediately seem to undermine this method.

Concerns With Validity

A recent article⁶ has soundly questioned the validity of the foot morphology observations in Dr Root’s STJN theory relating to gait. In the only paper of its kind, none of the static examinations advocated in Dr Root’s STJN theory related to altered foot kinematics. Areas investigated included the STJN position, the first-ray position, and the forefoot-to-rearfoot angle. This is of prime importance when attempting to relate the STJN position to foot orthosis impression casting and prescription. Jarvis et al⁶ concluded that both the poor reliability and validity of these underpinning STJN theory cornerstones mean that “the Root et al description of foot function and the associated assessment protocol are not a sound basis for clinical evaluation of the foot nor orthotic prescription.”

If It Doesn't Work, Why Is It Still Done?

In the light of this uncertainty about the reliability, validity, and historical accuracy of the STJN theory, we propose that its use for lower-limb musculoskeletal conditions be re-evaluated. However, despite the issues noted above, the outcome of the use of foot orthoses based broadly on this theory appears positive.⁵ The most recent Cochrane Library review on the efficacy of custom foot orthoses⁵ concluded that there is gold-level evidence for the treatment of painful pes cavus and silver-level evidence for foot pain associated with plantar fasciitis, rheumatoid arthritis, and hallux valgus. In 7 of the 11 included articles, STJN was stated as the position from which negative cast impressions were taken. It appears that the STJN theory has become an accepted “clinical fiction,” an

approach for which, although clinicians are not measuring or assessing what they propose and the theory may not describe reality, the net outcome is positive.¹³ In other words, the process that leads to treatment may work, but, considering the above-mentioned critical issues and theoretical failings, not in a way that is commonly believed.

Another explanation for the continued use of the STJN theory is that alternative foot-based theories lack large-population investigations to assess their clinical relevance, and also equally suffer from observer reliability and theoretical validity concerns.^{2,4} Why should clinicians change their approach if there is no proven alternative theory, with a workable clinical assessment and treatment methodology, to adopt?

It is important to recognize that Dr Root's STJN theory is a clinical fiction, because its acceptance as fact may result in practitioner resistance to change and an inability to look outside of this commonly used, although likely incorrect, theory. Such a situation can lead to stagnation and slow development of possibly more effective alternatives. With ongoing theoretical uncertainty in relation to the foot and musculoskeletal injuries, it may benefit the practitioner to be inclusive of all theories within the framework of best evidence rather than remaining dogmatic or exclusive to historical fictional models. ●

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The Influence of Injury Definition on Injury Burden in Preprofessional Ballet and Contemporary Dancers

Across athletic populations, it is recognized that different operational definitions of musculoskeletal injury can impact injury estimates.^{13,15,30} Although there has been considerable investigation of the influence of injury definition on injury estimates in sport,^{19,22,26,37,49} little is known within a dance population.⁵

Dancers are unique to their sporting counterparts. Not only is their movement required to be aesthetically pleasing, but they also typically train from a relatively young age, at high volumes and intensities, and in movement ranges beyond what might be considered normal.^{6,11,14,29,31,42} Additionally, dancers have a very high prevalence of chronic and overuse problems.^{1,5,14,31} Accordingly, injury prevalence and/or incidence may be different in this population compared to sport. Independent investigation of these unique artist-athletes is warranted.

Operational Definitions of Injury

Three different definitions of injury have been employed in sport epidemiological research.⁸ Injuries defined by time loss describe those that lead to an inability to participate fully in training or competition, while those categorized as medical attention result from an athlete seeking care from a medical practitioner. These 2 definitions are well suited to capture acute injuries, which often lead to missed sport participation and/or seeking medical care.^{2,13} In contrast, recurrent and overuse injuries are more appropriately captured with an “all complaints” definition, which encompasses any physical or

STUDY DESIGN: Cohort study.

BACKGROUND: Multiple operational definitions of injury exist in dance research. The influence that these different injury definitions have on epidemiological estimations of injury burden among dancers warrants investigation.

OBJECTIVE: To describe the influence of injury definition on injury prevalence, incidence, and severity in preprofessional ballet and contemporary dancers.

METHODS: Dancers registered in full-time preprofessional ballet (n = 85; 77 female; median age, 15 years; range, 11-19 years) and contemporary (n = 60; 58 female; median age, 19 years; range, 17-30 years) training completed weekly online questionnaires (modified Oslo Sports Trauma Research Centre questionnaire on health problems) using 3 injury definitions: (1) time loss (unable to complete 1 or more classes/rehearsals/performances for 1 or more days beyond onset), (2) medical attention, and (3) any complaint. Physical therapists completed injury report forms to capture dance-related medical attention and time-loss injuries. Percent agreement between injury registration methods was estimated. Injury prevalence (seasonal proportion of dancers

injured), incidence rates (count of new injuries per 1000 dance-exposure hours), and severity (total days lost) were examined across each definition, registration method, and dance style.

RESULTS: Questionnaire response rate was 99%. Agreement between registration methods ranged between 59% (time loss) and 74% (injury location). Depending on definition, registration, and dance style, injury prevalence ranged between 9.4% (95% confidence interval [CI]: 4.1%, 17.7%; time loss) and 82.4% (95% CI: 72.5%, 89.8%; any complaint), incidence rates between 0.1 (95% CI: 0.03, 0.2; time loss) and 4.9 (95% CI: 4.1, 5.8; any complaint) injuries per 1000 dance-hours, and days lost between 111 and 588 days.

CONCLUSION: Time-loss and medical-attention injury definitions underestimate the injury burden in preprofessional dancers. Accordingly, injury surveillance methodologies should consider more inclusive injury definitions. *J Orthop Sports Phys Ther* 2018;48(3):185-193. Epub 13 Dec 2017. doi:10.2519/jospt.2018.7542

LEVEL OF EVIDENCE: Symptom prevalence study, level 1b.

KEY WORDS: dance, epidemiology, injury prevention, injury surveillance

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psychological complaint resulting from relevant sports participation, regardless of its consequences.^{8,9,13} As there are strengths and limitations to each definition, it is important that the appropriate definition for the injury outcome of interest be chosen for injury surveillance research.^{8,45}

In response to the array of descriptions for injury in the dance literature (eg, complaints of pain, financial impact, reduced dance participation, medical attention),^{14,23,30,35,36,40,41} the International Association for Dance Medicine and Science (IADMS) published a consensus statement in 2012 recommending that a dance-related injury be diagnosed by a licensed medical practitioner and result in full time loss.³⁰ Although a time-loss definition is useful for professional dance companies concerned about financial obligations (ie, workers' compensation; hiring temporary dancers to fill contracted positions of injured dancers during the performance season),^{4,5,36} it may not be the most appropriate to estimate the overall injury burden² because it is not sensitive to injuries that are less severe, chronic in nature, or allow for modified participation.⁸ When the most common injuries reported in dance are overuse,¹⁸ using an injury definition that is determined by time away from dance will likely underestimate the injury burden.

Injury Surveillance Methodologies

In sport, it is generally accepted that time-loss and medical-attention injury definitions are the most reliable and accurate.³⁷ Accordingly, standard injury surveillance systems register these injuries via a third party (eg, coaching staff, medical practitioner). The use of multiple personnel for injury registration, however, may introduce systematic bias, depending on the availability and qualifications of the medical practitioners and on interpretation and completeness of data collection.⁸ Additionally, this traditional system may underrepresent the total burden of injury if an athlete does

not report an injury to the appropriate third party.²

Since the IADMS consensus statement, a new method of injury surveillance by which athletes may register injuries themselves has been validated: the Oslo Sport Trauma Research Centre questionnaire on health problems (OSTRCQ).^{9,10} Specifically, over a 3-month period, researchers confirmed that the majority of overuse injuries (90.5%) did not result in medical attention or time loss in sport and were not captured using a standard surveillance system (40 overuse injuries registered by physical therapists versus 419 that were self-reported).⁹ This valid and reliable registration method for self-reported injury provides a more accurate understanding of injury burden and informs the scope of health provision required to best support athletes. Employing this method for injury registration may be particularly useful in dance in that it captures injuries that do not result in time loss and potentially alleviates the avoidance of reporting injuries to a teacher, choreographer, or medical practitioner for fear of not being cast in a specific role or being told to stop dancing.^{3,30,31,51} The online OSTRCQ has been used across sport,^{17,34,38} but has not yet been adapted to or employed in a dance population.

Dance Injury Epidemiology

Existing summary estimates of musculoskeletal injury in dancers are difficult to interpret due to differences in injury definitions, registration methods, duration of injury surveillance, level and style of dance, and geographic locations.^{21,23,30} To move the field of dance injury prevention forward, it is important that injury surveillance methodologies consider injury definitions that are sensitive enough to capture various types of injuries (acute, overuse, recurrent) and not only those impacting dance participation (time loss). The objective of this study was to describe the influence of injury definition (time loss, medical attention, all complaints) on injury prevalence, incidence rates, and severity of musculoskeletal

injury among preprofessional ballet and contemporary dancers.

METHODS

Study Design

GUIDELINES FOR REPORTING COHORT studies (Strengthening the Reporting of Observational Studies in Epidemiology)⁴⁸ were followed. This study was based on data collected in a cohort study investigating potential risk factors for future injury in a preprofessional dance population.

Participants

Participants included a convenience sample of consenting preprofessional ballet and contemporary dance students from 2 dance-training institutions (preprofessional ballet school and university undergraduate dance degree program) in Calgary, Canada. Recruitment occurred in September 2015. To be included, participants had to be registered as full-time students and provide signed informed consent, or assent and parent/guardian consent if under 18 years of age. Participants were excluded if they self-reported an injury resulting in an inability to fully participate in dance training at the start of the study, a current vestibular dysfunction or other medical condition associated with balance impairment, and/or a concussion within the previous 3 months. Ethical approval for the study was granted by the Conjoint Health Research Ethics Board at the University of Calgary, Calgary, Canada (ethics ID: REB14-0897).

Procedures

Baseline characteristics (age, years of dance training, and prior injury history) were collected via questionnaire at study commencement. Body mass index was calculated from height and weight measurements (barefoot, wearing light clothing) to the nearest 0.1 cm and 0.1 kg, using a metric tape measure secured to the wall and a portable digital medical weight scale (BF-350 Body Composition Analyzer; Tanita Corporation, Tokyo, Japan).

Injury Surveillance

Prospective injury surveillance was implemented over 1 academic year to identify all dance-related musculoskeletal injuries and self-reported illnesses. Dancers at the preprofessional ballet school trained for 40 weeks (September-June). Contemporary dancers at the university trained for 31 weeks (September-April). Three definitions of dance-related injury and 2 injury registration methods were utilized.

Injury Definitions

1. Time-loss injury: an anatomic tissue-level impairment that resulted in a dancer not able to complete a class, rehearsal, or performance or a subsequent class, rehearsal, or performance 1 or more days beyond the day of onset^{13,30}
2. Medical-attention injury: an anatomic tissue-level impairment that resulted in a dancer seeking care from a medical practitioner^{13,30}
3. All-complaints injury: any physical complaint leading to difficulties participating in normal dance class, rehearsal, or performance, irrespective of the need for medical attention or time lost from dance activities^{13,30}

Injury Registration Methodologies

Third-Party Injury Registration Preprofessional ballet dancers were regularly monitored for injuries sustained in class, rehearsal, and performance by 2 on-site physical therapists with 4 to 7 years of experience treating dancers. Contemporary university dancers were provided with contact information for 6 medical practitioners at the start of the academic year who had agreed to treat any participants training at the university and requiring medical attention. As the most common medical practitioner from whom dancers typically seek care is a physical therapist,²⁸ we recruited 4 physical therapists (4 to 10 years of experience treating dancers) and 2 chiropractors (2 to 14 years of experience treating dancers).

Medical practitioners documented all dance-related injuries on a standard in-

dividual injury report form (**APPENDIX A**, available at www.jospt.org),¹ which recorded injury status (new, reinjury, exacerbation), type of onset (sudden, gradual, other), mechanism (descriptive), body region, suspected diagnosis, and number of days unable to fully participate in dance. Medical-attention (completed injury report form, yes/no response format) and time-loss (number of days unable to fully participate 1 or more days, yes/no response format) injuries were then distinguished.

Self-report Injury Registration Each week of the academic year, the Research Electronic Data Capture tool (REDCap Version 6.12.0; Vanderbilt University, Nashville, TN)¹⁶ was utilized to e-mail participants a URL to an online questionnaire. Participants were required to complete all questions prior to submitting the online questionnaire. Reminder e-mails were sent to nonresponders every 2 days, up to 3 occasions.

The OSTRCQ was modified for this study (Dance OSTRCQ [**APPENDIX B**, available at www.jospt.org]), as the online questionnaire was originally developed and validated (Cronbach $\alpha = .96$)¹⁰ to monitor the injury and illness patterns among Norwegian Olympic and Paralympic athletes.¹⁰ To ensure dance specificity, changes to sport terminology were made: the phrase “training and competition” was changed to “dance class, rehearsals, and/or performances.”⁴³ With that said, the content and structure of the original questionnaire (ie, the stems of the questions, what the items were asking, the way the items were constructed, the words that were used to address the construct of interest) were not changed. Face validity of the dance-specific terms was determined by consulting 5 preprofessional dancers not included in the study. Questionnaires took less than 5 minutes to complete.

The key content of the questionnaire evaluates perceived consequences of reported health problems (injury, illness, other problem) for dance participation, training volume, dance performance, and symptoms/complaints experienced during the previous week (**FIGURE 1**). If

participants reported full participation without problems, no reduction to the amount of dancing, no impact on dancing, and experienced no symptoms, then the questionnaire was finished. If participants reported a health problem, then they were prompted to define the health problem as an injury or illness and answer further questions pertaining to each. Branch logic procedures have been previously described.¹⁰ Participants sustaining multiple health problems in 1 week were instructed to reflect on the worst problem first. In total, up to 4 health problems could be reported each week.

Dance Exposure

Weekly self-reported exposure-hours (ie, the number of hours spent in class, rehearsal, and performance)^{31,46} were collected online via questions posed following the Dance OSTRCQ.

1. Have you had any difficulties participating in normal dance class, rehearsals, and/or performances due to injury, illness, or other health problems during the past week?
 1. Full participation without health problems
 2. Full participation, but with injury/illness
 3. Reduced participation due to injury/illness
 4. Cannot participate due to injury/illness
2. To what extent have you reduced the amount you dance due to injury, illness, or other health problems during the past week?
 1. No reduction
 2. To a minor extent
 3. To a moderate extent
 4. To a major extent
 5. Cannot participate at all
3. To what extent has injury, illness, or other health problem affected your dancing during the past week?
 1. No effect
 2. To a minor extent
 3. To a moderate extent
 4. To a major extent
 5. Cannot participate at all
4. To what extent have you experienced symptoms/health complaints during the past week?
 1. No symptoms/health complaints
 2. To a mild extent
 3. To a moderate extent
 4. To a severe extent

FIGURE 1. Four key questions of the dance-specific Oslo Sports Trauma Research Centre questionnaire on health problems.¹⁰

Statistical Analysis

Data were analyzed using the statistical software Stata Version 13.1 (StataCorp LLC, College Station, TX). Participant characteristics were summarized by dance style using means and standard deviations, medians and ranges, or frequencies and proportions, as appropriate. For each injury definition (time loss, medical attention, all complaints), injury registration (third party, self-report), and dance style (ballet, contemporary), injury prevalence, incidence rates, and severity were examined. Descriptions of all self-reported illnesses were also summarized. Any weeks missing from the Dance OS-TRCQ and dance-exposure questionnaire were excluded from analyses.

Injury Prevalence and Incidence Rates Seasonal injury prevalence (proportions and 95% confidence intervals [CIs]) was estimated by dividing the number of participants reporting at least 1 injury by the total number of participants at risk.³⁹ Weekly injury prevalence (proportions and 95% CIs) was determined by dividing the number of participants reporting an injury that week by the number of participants who responded to the questionnaire that week, and was plotted over the academic year to illustrate variability over time. The injury prevalence of substantial injuries, defined as those leading to a moderate/severe re-

duction in training volume, moderate/severe dance adaptation (eg, exclude all jumps), or complete inability to participate in dance (injuries reported as 3, 4, or 5 in response to key questions 2 or 3), was evaluated.¹⁰ Incidence rates were expressed as the total number of new injuries per 1000 hours of dance exposure (95% CI).³⁹ Testing for statistical differences between dance styles was beyond the scope of this descriptive study.

Injury Severity Injury severity was based on the total number of days lost from dance class, rehearsal, or performance due to the reported injury.⁴⁶ Additionally, weekly injury severity scores were estimated for each participant based on their responses to 4 Dance OSTRCQ questions (FIGURE 1).⁹ The weighted numeric value allocated to the response to each of these questions followed a published protocol and was summed to determine an overall severity score between 0 (no problem) and 100 (cannot participate) for each injury reported.⁹ Finally, the median (range) of weekly injury severity scores was estimated by dance style.

Agreement Cohen's kappa coefficients, standard error, and percent agreement were used to evaluate agreement between the 2 injury registration methods (third party and self-report). Four categorical variables were compared between med-

ical-attention injuries (yes/no), time-loss injuries (yes/no), new injuries (yes/no), and injury location (20 body locations). Kappa was interpreted based on previously published guidelines: less than 0.00, poor; 0.00 to 0.20, slight; 0.21 to 0.40, fair; 0.41 to 0.60, moderate; 0.61 to 0.80, substantial; and 0.81 to 1.00, almost perfect.²⁷

RESULTS

Participants

IN TOTAL, 145/184 (79%) FULL-TIME preprofessional ballet (n = 85; 77 female; median age, 15 years; range, 11-19 years) and contemporary (n = 60; 58 female; median age, 19 years; range, 17-30 years) dancers participated. At study commencement, 15 dancers did not meet the inclusion criteria (not enrolled full-time, n = 4; currently injured, n = 2; absent, n = 7; parental consent not received by time of preparticipation evaluation, n = 2), and 14 dancers and/or their parents chose not to consent for undisclosed reasons. During the academic year, 10 dancers were lost to follow-up (school attrition, n = 5; withdrew for undisclosed reasons, n = 2; dropped due to noncompliance,³² n = 3). The overall response rate to the weekly Dance OSTRCQ was 99% (5207/5260 weeks of all participant questionnaires completed). Participant characteristics are presented in TABLE 1.

Third-Party Registered Injuries

As only 1 of the university preprofessional contemporary dancers reported to a medical practitioner for a dance-related injury over the course of the study, medical-attention and time-loss injuries for this group were not calculated. On-site physical therapists at the ballet school completed a total of 67 individual dance-related injury report forms from 41 (48%) dancers. Of the 67 individual injuries, 88% (n = 59) were classified as overuse, 13% (n = 9) acute, and 18% resulted in complete time loss (range, 1-45 days). The most commonly injured body parts were the knee (24%, n = 16), ankle

TABLE 1

PARTICIPANT CHARACTERISTICS BY DANCE STYLE*

Characteristic	All (n = 145, 100%)	Ballet (n = 85, 58.6%)	Contemporary (n = 60, 41.4%)
Sex, n (%)			
Female	135 (93.1)	77 (90.6)	58 (96.7)
Male	10 (6.9)	8 (9.4)	2 (3.3)
Age, y	17.9 (11.3-30.5)	15.4 (11.3-19.2)	19.9 (17.9-30.5)
Body mass index, kg/m ² †	20.1 ± 2.9	18.7 ± 2.3	22.2 ± 2.3
Previous training ≥3 times per week, y	9 (1-17)	8 (1-14)	11 (1-17)
Previous injury in last year, %‡	46.9 (38.5, 55.4)	49.4 (38.3, 60.5)	43.3 (30.5, 56.8)

*Values are median (range) or proportion (exact 95% confidence interval) unless otherwise indicated.

†Values are mean ± SD.

‡Previous injury was defined as being dance related and requiring medical attention and/or causing the participant to miss more than 1 day of class, rehearsal, or performance.^{13,30}

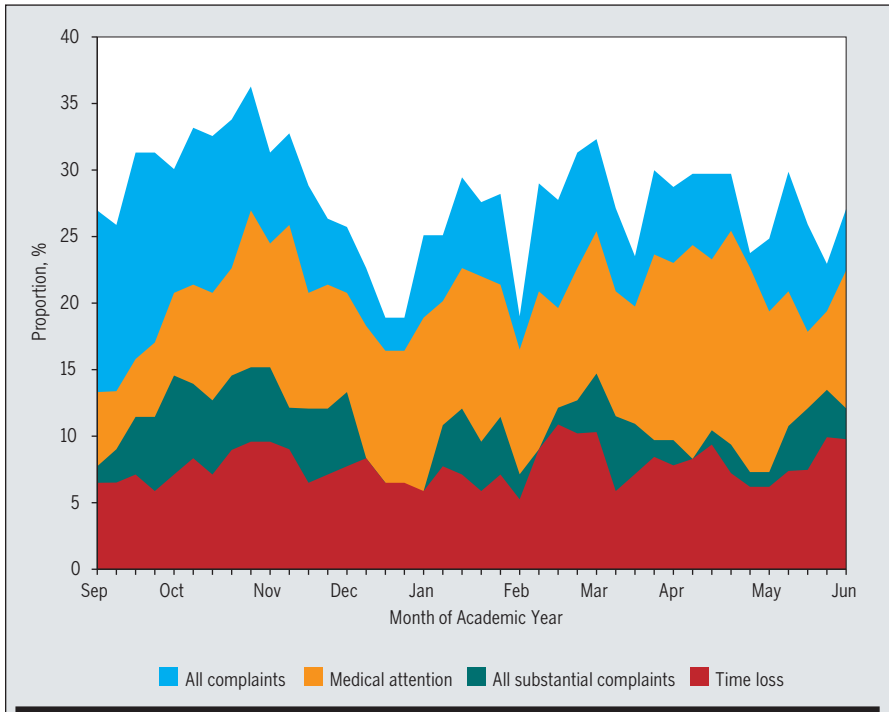


FIGURE 2. Weekly prevalence proportions of self-reported all-complaint injuries (blue), medical-attention injuries (orange), all-substantial-complaint injuries (green), and time-loss injuries (red) over the academic year. Preprofessional ballet dancers trained 40 weeks (n = 85, September-June), and contemporary dancers trained 31 weeks (n = 60, September-April). Prevalence estimates for self-reported all-substantial-complaint and time-loss injuries were the same during December, except for the third week (all-substantial-complaint injuries, 2.1%; time-loss injuries, 2.8%).

(21%, n = 14), and foot (18%, n = 12). Consistent with previous literature,^{6,52} the most common recorded diagnoses were patellofemoral pain (16%, n = 11), posterior ankle impingement (10%, n = 7), and Achilles tendinopathy (9%, n = 6).

Self-reported Injuries and Illnesses
In total, 2005 health problems (1521 injuries, 484 illnesses) were reported by 134 (92%) preprofessional dancers over the academic year. Of these, 590 were classified as substantial (439 injuries, 151 illnesses). Eleven dancers reported no health problems during the year, whereas 45 reported multiple health problems in 1 week at least once during the study period (ie, 39 dancers reported 2 problems in 1 week, 4 dancers reported 3 problems in 1 week, and 2 dancers reported 4 problems in 1 week). The most commonly reported injured body parts were the ankle (22%, n = 342), knee (21%, n = 318), and foot (12%, n = 181). The most commonly reported symptoms from illness included congested/runny nose/sneezing (57%, n = 274), headache (56%, n = 270), and fatigue/exhaustion (54%, n = 260).

TABLE 2 INJURY ESTIMATES BY DEFINITION, REGISTRATION METHOD, AND DANCE STYLE*						
Injury Definition and Registration	Seasonal Prevalence Proportion [†]			Incidence Rate [‡]		
	All (n = 145)	Ballet (n = 85)	Contemporary (n = 60)	All (n = 145)	Ballet (n = 85) [§]	Contemporary (n = 60)
Time loss						
Third-party reported	...	9.4 (4.1, 17.7)	...	...	0.09 (0.03, 0.19)	...
Self-reported	40.7 (32.6, 49.2)	50.6 (39.5, 61.6)	26.7 (16.0, 39.7)	0.72 (0.56, 0.91)	0.65 (0.47, 0.87)	0.91 (0.59, 1.33)
Medical attention						
Third-party reported	...	48.2 (37.2, 59.3)	...	...	0.43 (0.29, 0.62)	...
Self-reported	57.9 (49.4, 66.1)	63.5 (52.3, 73.7)	50.0 (36.8, 63.2)	0.99 (0.79, 1.20)	1.03 (0.80, 1.30)	0.87 (0.56, 1.33)
AC: substantial injury (self-reported)	49.0 (40.5, 57.4)	54.1 (42.9, 65.0)	41.7 (29.0, 55.1)	0.90 (0.71, 1.10)	0.75 (0.56, 0.99)	1.25 (0.87, 1.74)
AC: injury (self-reported)	80.7 (73.3, 86.8)	82.4 (72.5, 89.8)	78.3 (65.8, 87.9)	3.24 (2.88, 3.63)	2.57 (2.20, 2.99)	4.89 (4.10, 5.79)
All health problems (self-reported)	92.4 (86.8, 96.2)	87.1 (78.0, 93.4)	100.0 (94.0, 100.0)	6.45 (5.94, 6.99)	4.61 (4.10, 5.15)	11.00 (9.78, 12.32)
Abbreviation: AC, all complaints.						
*Cells with no values indicate that injury estimates were not calculated because too few contemporary dancers reported to a medical practitioner for a dance-related injury over the duration of the study.						
[†] Values are proportion (exact 95% confidence interval). Seasonal prevalence proportions were estimated as the number of dancers with at least 1 injury during the academic year divided by the total number of dancers at risk.						
[‡] Values are total number of new injuries per 1000 dance-hours (95% confidence interval).						
[§] Total time reported spent in class, rehearsal, and performance for preprofessional ballet dancers was 64901.98 hours over 40 weeks.						
Total time reported spent in class, rehearsal, and performance for preprofessional contemporary dancers was 26363.45 hours over 31 weeks.						

RESEARCH REPORT

Injury Prevalence and Incidence Rates

Depending on the injury definition, registration method, and dance style, seasonal injury prevalence of at least 1 injury ranged from 9.4% (95% CI: 4.1%, 17.7%; third-party registered time loss) to 82.4% (95% CI: 72.5%, 89.8%; all complaints). Incidence rates ranged from 0.1 (95% CI: 0.03, 0.2; third-party registered time loss) to 4.9 (95% CI: 4.1, 5.8; all complaints) injuries per 1000 dance-hours. Detailed injury estimates by injury definition, registration method, and dance style are presented in **TABLE 2**.

FIGURE 2 illustrates the distribution of weekly self-reported injury prevalence across the academic year, by injury definition. The pattern of peaks and troughs for the definitions presented (ie, time loss, substantial complaints, medi-

cal attention, all complaints) coincides with performances and holidays. The proportion of dancers reporting an all-complaint injury was consistently higher than the proportions of dancers reporting an injury resulting in medical attention and time loss.

Injury Severity

Depending on the injury definition, registration method, and dance style, the total number of days lost from dance varied between 111 (all complaints, substantial injury) and 588 days (all complaints, injury) (**TABLE 3**). The median injury severity score for all dancers was 8 (range, 1-43); ballet dancers reported a median score of 8 (range, 1-43) and contemporary dancers reported a median of 7 (range, 1-39) across the academic year.

Agreement

Cohen's kappa coefficients and percent agreement between the 2 injury registration methods are summarized in **TABLE 4**. Among self-reported and third-party registered injuries, kappa coefficients ranged between 0.02 (new injury) and 0.46 (medical attention), with standard errors spanning from 0.003 to 0.103. Percent agreement ranged from 59% (time loss) to 74% (injury location).

DISCUSSION

RESULTS FROM THIS STUDY highlight the considerable variability in injury estimates and severity among preprofessional dancers when different injury definitions and registration methods are utilized.

Injury Prevalence and Incidence Rates

Overall, injury prevalence and incidence rates among preprofessional ballet and contemporary dancers are highest when injury is defined as any complaint leading to difficulties participating in normal dance class, rehearsal, or performance, regardless of any consequences and when dancers self-report. Discrepancies between injury definitions and registration methods have been cited previously in the dance literature. Though direct comparison is difficult, the number of complaints (25.9/1000 dance-hours) among a professional modern dance company was also far greater than injuries resulting in time loss (0.22/1000 dance-hours).⁵ Injury estimates based on third-party injury registration (ie, medical practitioners) have also been found to be lower than self-report (ie, dancer).^{3,31,51} For example, Luke et al³¹ estimated the self-reported incidence rate among preprofessional ballet dancers to be 4.7 per 1000 dance-hours (95% CI: 3.8, 4.6), compared to 2.9 per 1000 dance-hours (95% CI: 2.2, 3.6) reported by an on-site physical therapist. Additionally, among university-level modern dancers, Weigert and Erickson⁵¹ reported injury prevalence to differ between 77% (self-report) and 36% (on-site physician).

TABLE 3

TOTAL DURATION OF TIME LOSS FROM DANCE DUE TO INJURY*

Injury Definition and Registration	Severity		
	All (n = 145)	Ballet (n = 85)	Contemporary (n = 60)
Time loss			
Third-party reported	...	144	...
Self-reported	681	556	125
Medical attention			
Third-party reported	...	144	...
Self-reported	674	521	153
AC substantial injury (self-reported)	522	411	111
AC injury (self-reported)	727	588	139
All health problems (self-reported)	1036	753	283

Abbreviation: AC, all complaints.

*Cells with no values indicate that injury estimates were not calculated because too few contemporary dancers reported to a medical practitioner for a dance-related injury over the duration of the study.

Values are total number of days lost from dance.

TABLE 4

AGREEMENT BETWEEN SELF-REPORTED AND THIRD-PARTY REPORTED INJURY FOR PREPROFESSIONAL BALLET DANCERS (N = 85)

Injury Variable	Kappa	SE	Agreement, %
Medical attention (yes/no)	0.46	0.103	72.9
Time loss (yes/no)	0.18	0.063	58.8
New injury (yes/no)	0.02	0.003	65.7
Injury location (20 categories)	0.03	0.003	74.0

Abbreviation: SE, standard error.

The current study adds to the mounting evidence that the burden of dance-related injury may be underrated when defined by medical attention and/or time loss and registered by a third party. This further challenges the traditional injury surveillance system recommended by sport and dance organizations,^{30,37} particularly when the majority of injuries reported in dance are overuse, as evidenced by this and many other studies.^{1,4-6,14,31} It is well documented in sport that overuse injuries are not often captured by a time-loss injury definition.^{2,19}

It is also important to consider the impact of dancers' accessibility to medical practitioners for third-party injury registration. There is little published about the accessibility of practitioners (on site versus off site) in the dance population. This study found that on-site physical therapists were accessed much more readily than off-site ones. It is possible that dancers who do not have immediate access to trusted medical practitioners are less likely to seek treatment. In response to these challenges, advancements to improve the psychometric properties (ie, feasibility, validity, reliability) of self-reported sport injury registration have been made.^{2,9,10} Findings from this study demonstrate that a self-report injury surveillance system is appropriate in a dance population.

In addition to health care accessibility, dancers may not seek medical attention for an injury due to fear of not being allowed to participate in class or performance.^{3,6,7,24,30,31,50} Accordingly, it is common for dancers to continue training and performing through pain and injury,⁴⁴ which, not surprisingly, often results in further exacerbation and duration of their injury.³¹ The "fear and avoidance" culture is not limited to preprofessional dancers. Among 260 professional ballet and contemporary dancers surveyed, the most common reasons for not reporting a dance-related injury included beliefs that their dancing was not affected, that pain with dance is inherent, that they could cope with the pain, and that they didn't want to stop dancing.²⁰

Injury Severity

Historically, sport-related injury severity has been estimated by the length of time lost from sport.⁴⁶ There are limitations to this approach in a dance population, where time loss is avoided and few time-loss injuries are reported. Therefore, estimations of injury severity based on time loss alone may underestimate the true burden of injuries in dance populations.⁹

The severity score captured by the Dance OSTRCQ represents an alternate approach to assessing injury severity.^{9,10} It is an objective measure of the functional limitations (ie, those impacting participation, volume, dance practice, and other symptoms) self-perceived by a dancer that go beyond time loss.^{9,10} The range of injury severity scores reported illustrates great variability between individuals, which is similar to what has been reported by athletes.⁹ Prospective monitoring of the fluctuating severity of non-time-loss injuries could prove valuable for those responsible for arranging medical practitioner support for preprofessional dancers.²⁵

Agreement

Based on Cohen's kappa statistic, agreement between third-party and self-reported injury registration was poor to fair. However, the kappa statistic is affected by prevalence and can underestimate agreement when categories or items (eg, an uncommon injury occurrence such as time loss, or a new injury) are rare.^{12,47} In contrast, percent agreement between injury registration methods ranged between 59% (time loss) and 74% (injury location). This level of agreement between the 2 registration methods is not surprising given the evidence that dancers do not report all injuries to a medical practitioner.^{3,51}

Strengths and Limitations

The strengths of this investigation include a comprehensive evaluation of multiple injury definitions using a prospective surveillance system, a high response rate (99%) for questionnaire completion, and

minimal loss to follow-up (1%). The high response rate suggests that the Dance OSTRCQ is feasible for preprofessional dance populations, and the minimal loss to follow-up suggests that selection bias from loss to follow-up is not a threat to the internal validity of this study.

The potential for recall bias was minimized by only requiring participants to reflect on the previous 7 days of training. However, as some dancers completed previously missed questionnaires at 1 sitting (eg, up to 4 questionnaires), which required them to reflect on health problems that occurred beyond the previous week, some problems may have been underreported. Dancers may have also perceived negative consequences from reporting a problem, such as being told that they could not participate in a certain performance role. In order to reduce this fear, participant confidentiality was explained in the informed-consent/assent form.

It is important to acknowledge that a comprehensive assessment of the clinimetric properties was not undertaken after the modification of the OSTRCQ with dance-specific terminology. Data collected from the Dance OSTRCQ are reliant on dancers' honesty and accuracy. Although attempts were made to minimize misinterpretation of the injury definitions in the Dance OSTRCQ with the provision of simple and dance-specific language appropriate for younger ages, it is possible that some participants misinterpreted injury definitions, which may have led to an overreporting of these problems. Explicit instructions on how to complete the questionnaire were also given at the start of the study. Overreporting of injuries may also have occurred if dancers perceived "normal" pain impacting their dance participation (eg, delayed-onset muscle soreness).⁹ This may have been particularly relevant for the dancers who reported a physical complaint (32% of dancers).

Despite providing contemporary dancers with access to off-site medical practitioners with expertise in dance, there was little uptake of care, which

precluded a comparison between injury registration methods. This highlights the influence of practitioner accessibility on the interpretation of medical-attention injury burden and is an important consideration for future study design. As comprehensive guidelines for completing individual injury report forms were provided to all therapists, it is assumed that reporting bias by on-site physical therapists at the ballet school was minor. Finally, participants in this study represent preprofessional ballet and contemporary dancers, and therefore findings may only be generalizable to vocational dance training institutions and undergraduate university dance programs with individuals of similar ages and practicing similar levels and styles of dance.

Future Directions

Since the 2012 IADMS recommendation to utilize a time-loss injury definition registered by a medical practitioner,³⁰ a standardized tool to register self-reported physical complaints has been developed (OSTRCQ).¹⁰ A dance-specific version of this tool is feasible for use in a preprofessional dance population. Future investigations assessing the clinimetric properties of the Dance OSTRCQ are needed.

While patterns of dance-related injuries are presented in this study, consensus regarding the risk factors for these injuries remains unknown.²³ There is a need for high-level examinations of the interplay of factors³³ that contribute to the high rate of injury reported in preprofessional dancers. Specifically, the development, implementation, and evaluation of a preparticipation screening program, alongside comprehensive prospective injury surveillance, are warranted to aid the prediction of dance-related injury.

CONCLUSION

THE PREVALENCE, INCIDENCE, AND severity of injuries impacting preprofessional dancers vary depending on the definition of injury, injury reporting methodology, and dance style.

Reports of injuries resulting in time loss and medical attention underestimate the burden of injury in a preprofessional dance population. To understand the full impact of injury on a dance population, it is imperative that injury surveillance systems consider injury definitions that are sensitive enough to capture all injuries. ●

KEY POINTS

FINDINGS: Time-loss and medical-attention injury definitions underestimate the injury burden in a preprofessional dance population.

IMPLICATIONS: To understand the true burden of injury on a dance population, it is imperative that injury surveillance systems consider inclusive injury definitions.

CAUTION: Results must be interpreted within the context of the sample tested and the methods employed.

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[RESEARCH REPORT]

APPENDIX A

INDIVIDUAL DANCE INJURY REPORT FORM

Please complete for **any injury** resulting from dance class, rehearsal, or performance.

1. Dancer name: _____		2. Participant ID: _____	
3. Date of injury (MM/DD/YY): _____		4. Date of assessment (MM/DD/YY): _____	
5. Injury status ☐ New injury (no previous history of this injury) ☐ Reinjury (same injury previously occurred but was healed) ☐ Exacerbation (worsening state of previous unhealed injury)		6. Injury occurred during ☐ Technique class (what style of dance): _____ ☐ Rehearsal ☐ Performance ☐ Other: _____	
7. This injury involved (check all that apply) ☐ Sudden onset and contact with another dancer or props ☐ Sudden onset and NO contact with another dancer or props ☐ Gradual onset/overuse ☐ Unknown ☐ Other: _____		8. Did the dancer return to same class, rehearsal, or performance? ☐ No ☐ Yes ☐ Not available	
9. Describe events surrounding injury (including exact mechanism of injury if possible)			
10. Describe subjective report of cause (overtraining, improper technique, etc)			
11. Injury assessment (eg, right ankle tendinitis)			
Side (right, left, both): _____		Body region (structure): _____	
		Type (diagnosis): _____	
12. Exposure status			
_____ Total number of days dancer was unable to fully participate in any dance activities (full time loss)			
_____ Total number of days dancer was unable to fully participate in daily activities (work, school, other)			

ONLY complete this section once the dancer has fully returned to dancing AND has completed all injury-related care.

1. Date of return to dance (full participation) (MM/DD/YY): _____
2. Confirmed diagnosis
3. Who confirmed diagnosis? ☐ Physician ☐ Chiropractor ☐ Physical therapist ☐ Athletic therapist ☐ Other: _____
4. Name of person who confirmed diagnosis
5. Who provided clearance to return to dance? ☐ Physician ☐ Chiropractor ☐ Physical therapist ☐ Athletic therapist ☐ Other: _____

APPENDIX B

DANCE-SPECIFIC QUESTIONNAIRE ON HEALTH PROBLEMS

The following questions will be completed online by each dancer, each week.

Please answer ALL questions, regardless of whether or not you have experienced health problems in the past week. If you have several illnesses or injury problems, please refer to the one that has been your worst problem this week. Reply with the number that corresponds to your best answer to each question.

1. Have you had any difficulties participating in normal dance class, rehearsals, and/or performances due to injury, illness, or other health problems during the past week?
 1. Full participation without health problems
 2. Full participation, but with injury/illness
 3. Reduced participation due to injury/illness
 4. Cannot participate due to injury/illness
2. To what extent have you reduced the amount you dance due to injury, illness, or other health problems during the past week?
 1. No reduction
 2. To a minor extent
 3. To a moderate extent
 4. To a major extent
 5. Cannot participate at all
3. To what extent has injury, illness, or other health problem affected your dancing during the past week?
 1. No effect
 2. To a minor extent
 3. To a moderate extent
 4. To a major extent
 5. Cannot participate at all
4. To what extent have you experienced symptoms/health complaints during the past week?
 1. No symptoms/health complaints
 2. To a mild extent
 3. To a moderate extent
 4. To a severe extent

*If the participant responds number 1 to the first 4 questions, then he or she will be asked question 13.

*If the participant responds any number except number 1 to the first 4 questions, then he or she will be asked question 5.

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5. Is the health problem referred to in the first 4 questions an injury or an illness?

1. Injury
2. Illness

*If the participant answers number 1 to question 5, then he or she will be asked question 6, then 8 onward.

*If the participant answers number 2 to question 5, then he or she will be asked question 7, then 8 onward.

6. What is the location of your injury? If the injury involves several locations, please select the main area.

- ☐ Head/face
- ☐ Neck
- ☐ Shoulder (including clavicle)
- ☐ Upper arm
- ☐ Elbow
- ☐ Forearm
- ☐ Wrist
- ☐ Hand/fingers
- ☐ Chest/ribs
- ☐ Abdomen
- ☐ Thoracic spine
- ☐ Lumbar spine
- ☐ Pelvis and buttock
- ☐ Hip and groin
- ☐ Thigh
- ☐ Knee
- ☐ Lower leg
- ☐ Ankle
- ☐ Foot/toes
- ☐ Other

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7. What major symptom have you experienced during the past 7 days? Select several symptoms if they are related.

- ☐ Fever
- ☐ Fatigue/exhaustion
- ☐ Swollen glands
- ☐ Sore throat
- ☐ Blocked nose/runny nose/sneezing
- ☐ Cough
- ☐ Breathing difficulty/tightness
- ☐ Headache
- ☐ Nausea
- ☐ Vomiting
- ☐ Diarrhea
- ☐ Constipation
- ☐ Fainting
- ☐ Rash/itchiness
- ☐ Irregular pulse/arrhythmia
- ☐ Chest pain/angina
- ☐ Abdominal pain
- ☐ Other pain
- ☐ Numbness/pins and needles
- ☐ Anxiety
- ☐ Depression/sadness
- ☐ Irritability
- ☐ Eye symptoms
- ☐ Ear symptoms
- ☐ Symptoms from urinary tract/genitalia
- ☐ Other

8. Please state the number of days over the past 7-day period that you have had to completely miss dancing due to this problem.

- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6
- ☐ 7

9. Is this the first time you have reported this problem through this monitoring system?

1. Yes, this is the first time
2. No, I have reported the same problem in 1 of the previous 4 weeks
3. No, I have reported the same problem previously, but it was more than 4 weeks ago

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10. Have you sought medical attention for this problem?

1. Yes
2. No

*If the participant responds number 1 to question 10, then he or she will be asked question 11.

11. Please provide a diagnosis for this problem.

12. Have you experienced any other injuries, illnesses, or other health problems that have restricted you from full participation in class, rehearsal, and/or performances in the past week?

1. Yes
2. No

*If the participant responds number 1 to question 12, then he or she will be asked question 13.

13. Please provide detail on what this injury or illness was.

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Dance-Exposure Questions

1. State the total number of hours you spent in CLASS during the past 7 days.

2. State the total number of hours you spent in REHEARSAL during the past 7 days.

3. State the total number of hours you spent in PERFORMANCE during the past 7 days.

4. State the total number of hours you spent in OTHER PHYSICAL ACTIVITY during the past 7 days.

The End of an Era?

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Nineteen seventy-two was a memorable year. The average price of a home was \$27 600 in the United States and £7400 in the United Kingdom. It was the year of Bloody Sunday in Northern Ireland. It was the year the world watched in awe as Mark Spitz won 7 gold medals in the Olympics and was horrified by the terrorist atrocities at the same Olympics. It was the year the digital watch was introduced and the year the first handheld scientific calculator, the HP-35, became available and was on every scientist's wish list, costing a mere \$395! It was the year *Dirty Harry* was playing in movie theatres and Roberta Flack's "The First Time Ever I Saw Your Face" was on everyone's lips. It was also the year that Don McLean's "American Pie" was the number 1 US hit for 4 weeks and the whole world was trying to decipher its meaning. That same year, President Nixon visited China and ended a quarter century of no diplomatic ties, and the famous American orthopaedic surgeon, Charles Neer, published his seminal paper, "Anterior Acromioplasty for the Chronic Impingement Syndrome in the Shoulder: A Preliminary Report."²⁷

This wasn't a robust scientific paper. By today's terms, we might call it a blog. However, this "blog" changed the direction of orthopaedic practice for the next half century. Neer argued that a primary cause of shoulder pain was attrition of the supraspinatus tendon and related structures, such as the subacromial bursa, from the overlying acromion, especially when the arm was elevated, a position

that is commonplace in throwing sports, swimming, the building industry, hair dressing, and myriad other human activities. In 1983, he wrote, "95% of tears of the rotator cuff are caused by impingement."²⁸ Neer recommended surgical removal to stop the impingement, and over the last half century, based on the available statistics,^{11,32} it could be argued that millions of people around the globe would have undergone acromioplasty surgery to stop this portion of the bone impinging onto the soft tissues located in the subacromial space. Others followed,² implicating the shape of the acromion as a causative factor in the impingement process, with a type 3, downward-sloping or hooked acromion predisposing the individual to a higher risk of impingement and symptoms, due to increased narrowing and encroachment onto the subacromial space.²

However, against the tide of subacromial decompression surgery there has been dissent, and the relationship between the acromion and symptoms has been challenged. Henkus et al⁹ reported that at 2.5-year follow-up, removal of the

acromion and bursectomy were no more beneficial than a bursectomy alone, and in a recent 12-year follow-up, the same findings were reported.¹³

Narrative challenges to the subacromial impingement theory have been published,^{17,19-23} arguing that the anatomy, pathology, poor relationship between imaging and symptoms, and equivalent outcomes obtained with other interventions, such as exercise, even in the presence of a type 3 acromion, compellingly dispute the relevance of the acromion as initially hypothesized. Lewis^{17,22} hypothesized that the reported benefits of acromioplasty may not be due to removal of the anteroinferior aspect of the acromion, but rather to the many weeks of "relative rest" and to the graduated and incremental rehabilitation following surgery.^{5,24} Lewis^{17,19,22} also hypothesized that the benefits of the surgery may be due to the potential benefits of a placebo effect. A substantial body of clinical research now suggests that the reported outcomes of many elective orthopaedic surgical procedures may be attributable to such a response.^{8,10,26,29,30}

The findings of the recently published Can Shoulder Arthroscopy Work (CSAW) study¹ have substantially confirmed these earlier hypotheses. In this randomized 3-group trial, acromioplasty was reported to be no more beneficial than investigational arthroscopy and no intervention at 6-month and

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1-year follow-ups. Although pressured saline would have been introduced into the shoulder in the investigational arthroscopy group, it was designated as a placebo, as no bone or soft tissue was removed. These findings substantially challenge the rationale behind the proposed biomechanical benefit of subacromial decompression surgery and may herald the end of the era for this procedure. At the very minimum, they should challenge surgeons, health funding bodies, insurance providers, clinicians, the media, and those contemplating surgery to reflect on the published literature.

The evidence unequivocally demonstrates that an exercise program is as effective as surgery for what has been termed *subacromial impingement syndrome* at 1-, 2-, 4-, 5-, and 10-year follow-ups,^{7,12} and is as effective as surgery for partial-thickness rotator cuff tears.¹⁵ There is also evidence that 75% of people experiencing symptoms attributed to an atraumatic full-thickness rotator cuff tear who undergo an exercise program will not require surgery.¹⁴ There is also evidence that surgical outcomes for full-thickness rotator cuff tears are not related to the “success” of the surgery.^{3,4} However, there is a fairly large “elephant in the room” here: if surgery can be a placebo, exercise could be a placebo as well, or both interventions may only be mapping the natural course of the condition as the patient’s symptoms regress to the mean.¹⁸ We need to better understand the effect of our nonsurgical interventions, and more research, much more, is needed. However, proponents of evidence-based practice would advocate that if there are 2 interventions of equal clinical effectiveness (even if the basis for that outcome is uncertain), then the choice of the economically competitive treatment should dominate that of the more expensive intervention, allowing the finite resources to be directed in a more appropriate manner. Furthermore, activity- and exercise-based interventions have significant and important health benefits.¹⁶ Different exercise programs may have different

outcomes,³¹ and, although manual therapy may only have a short-term effect³¹ and provide no difference in functional outcome measurements (Shoulder Pain and Disability Index [SPADI] and the shortened version of the Disabilities of the Arm, Shoulder and Hand questionnaire [QuickDASH]), its addition might improve patient-perceived success at 4 weeks and 6 months, and acceptability of symptoms at 4 weeks.²⁵

Finally, what should we call this condition? Impingement is inappropriate; an aberrant acromion is not pushing down onto the underlying tissues. It is important to consider that an individual’s decision to undergo surgery is most strongly predicted by the individual’s low expectation that physical therapy could be of benefit⁶; therefore, framing the need for surgery around an unsubstantiated pathoanatomical model may add to this low expectation. A term that suggests that exercise as an intervention might be of benefit, without the need for surgery as a first-line treatment, may motivate the individual to participate in an active management strategy. This, together with the uncertainty pertaining to the acromial theory, was the main reason the term *rotator cuff-related shoulder pain* was suggested.¹⁹ This body of research should compel all health practitioners to speak with one voice, using carefully constructed language that does not introduce yellow flags by implicating structures that do not appear to be the cause of the symptoms. ●

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The Influence of Exercise Dosing on Outcomes in Patients With Knee Disorders: A Systematic Review

Exercise has been identified as a powerful intervention for many ailments,^{42,66} the best medicine for many prevalent noncommunicable diseases in the developed world,²⁴ and has often been used to treat musculoskeletal disorders.^{66,79} However, exercise delivery varies greatly, and many questions still exist regarding the influence of exercise dose, specifically, whether variations in dose can influence outcomes.¹³ Exercise dosing can be somewhat complex, and may refer to the repetitions, sets, intensity, duration, frequency, number of total exercises, and progression of each exercise. While some aspects of dosing must be tailored to each individual patient, es-

tablishing general parameters of effective dosing can ensure that results in practice align with those found in clinical trials. Identification of optimal doses can help standardize effective care, inform clinical practice guidelines, and decrease dosage variance in clinical trials. Inadequate

dosing can have negative consequences. Similar to the consequences seen with drug therapy, underdosing of exercise may lead to an unrealized therapeutic gain,²⁷ while overdosing may lead to injury or harm.⁵⁰ Both consequences can lead to premature abandonment of a potentially effective intervention.

There is a large body of evidence supporting the use of specific exercise doses in patients with diabetes mellitus,³¹ patients undergoing chemotherapy treatments for cancer,⁸⁴ and postmenopausal women.^{16,77,78} These studies show that particular doses of exercise benefit individuals by lowering C-reactive protein levels, reducing blood pressure, and diminishing fatigue. The American College of Sports Medicine⁶⁷ discusses the dose-response relationship between exercise and conditions such as cardiovascular health; muscle, bone, and joint health; and mental health and well-being. It is known that there is an interaction between the amount of exercise performed and overall health benefits, but the specific amount has never been quantified.⁶⁷ This highlights the importance of determining the optimal exercise dose for a range of health conditions, including musculoskeletal disorders.

Knee disorders, both overuse and chronic, are one of the most common musculoskeletal ailments that benefit from exercise.^{51,81,82} Specifically, evidence abounds to support the use of therapeutic exercise for knee osteoarthritis (OA).^{1,7,10,23,70,74}

STUDY DESIGN: Systematic review.

BACKGROUND: Therapeutic exercise is commonly used to treat individuals with knee disorders, but dosing parameters for optimal outcomes are unclear. Large variations exist in exercise prescription, and research related to specific dosing variables for knee osteoarthritis, patellar tendinopathy, and patellofemoral pain is sparse.

OBJECTIVES: To identify specific doses of exercise related to improved outcomes of pain and function in individuals with common knee disorders, categorized by effect size.

METHODS: Five electronic databases were searched for studies related to exercise and the 3 diagnoses. Means and standard deviations were used to calculate effect sizes for the exercise groups. The overall quality of evidence was assessed using the Physiotherapy Evidence Database scale.

RESULTS: Five hundred eighty-three studies were found after the initial search, and 45 were included for analysis after screening. Physiotherapy

Evidence Database scale scores were “fair” quality and ranged from 3 to 8. For knee osteoarthritis, 24 total therapeutic exercise sessions and 8- and 12-week durations of exercise were parameters most often associated with large effects. An exercise frequency of once per week was associated with no effect. No trends were seen with exercise dosing for patellar tendinopathy and patellofemoral pain.

CONCLUSION: This review suggests that there are clinically relevant exercise dosing variables that result in improved pain and function for patients with knee osteoarthritis, but optimal dosing is still unclear for patellar tendinopathy and patellofemoral pain. Prospective studies investigating dosing parameters are needed to confirm the results from this systematic review.

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KEY WORDS: dose, exercise prescription, exercise therapy, physical therapy, therapeutic exercise

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However, exercise trials for knee OA vary significantly in their dosing. A systematic review identified specific exercise types for knee OA, but reported very little about specific dosing, and instead provided a more generalized conclusion that exercises to address aerobic capacity, quadriceps muscle strength, or lower extremity performance should be prescribed.⁴³ The authors also advocated for a therapeutic exercise program performed 3 times per week to effectively reduce pain.⁴³ Although some information on dosing was extracted for analysis, the authors indicated that heterogeneity across studies did not allow for specific recommendations on dosing beyond their recommended frequency of 3 times per week to reduce pain.

Two common disorders of the knee, patellar tendinopathy and patellofemoral pain (PFP), are also often managed with exercise.^{51,82} Specifically, eccentric strengthening exercises have long been advocated as very effective for patellar tendinopathy.^{40,68} A typical dose reported in the literature (3 sets of 15 repetitions, 1 to 2 times per day, 7 days per week^{41,68}) has been associated with improved pain and function.^{11,41,47} However, Kongsgaard et al⁴⁷ found improvements with either eccentric or heavy, slow resistance exercises. Within that study, the frequency per week and total number of physical therapy sessions were different for each group, yet both groups improved. This highlights the need for an enhanced understanding of the role of dosing. While many exercise programs are effective for treating PFP, details regarding specific dosing are lacking. High-dose, high-repetition exercises, defined as weight-bearing and non-weight-bearing strengthening with various loads and differing ranges of motion, may be more effective than low-dose, low-repetition exercises for this patient population.⁶⁵

Beyond dosing, recent attention has focused on the relationship between effect size and clinical decision making. Studies have reported *P* values that vary based on sample size but indicate that a significant effect exists. However, little is

known about the magnitude of that effect (whether it is small or large). Effect sizes are independent of sample size, and provide the magnitude of an intervention.^{61,76}

These arguably are much more important for guiding clinical decision making by identifying interventions with the greatest impact on improving outcomes.³⁴

Because there is such large variation in reports of exercise dosing for musculoskeletal disorders of the knee, the purpose of this review was to identify and summarize specific exercise dosing associated with improved outcomes in pain and function in patients with common knee disorders. A secondary purpose was to categorize the dosings based on their effect sizes.

METHODS

Search Strategy

CLINICAL TRIALS THAT UTILIZED therapeutic exercise as an intervention for the management of knee OA, patellar tendinopathy, and PFP were identified through database searches in MEDLINE, Embase, CINAHL, Cochrane Database of Systematic Reviews, and SPORTDiscus from January 2005 through June 2016. Studies were included if they (1) were peer reviewed, (2) were either a systematic review or a randomized controlled trial, (3) utilized exercise as one of the primary interventions, and (4) were published from 2005 to June 2016. Studies were excluded if they (1) were not published or translated in the English language, (2) did not include therapeutic exercise as a primary intervention, and (3) did not have an outcome measure for pain and function. Because of the large number of studies associated with exercise and these disorders, limits were placed on the date ranges to focus on more recent literature. Combinations of the following search terms were used with the Boolean operators AND and OR: *physical therapy, physiotherapy, rehabilitation, exercise, exercise therapy, knee pain, jumper's knee, patellar tendon, patellar tendinopathy, patellar tendonopathy, patellar ligament, patellofemoral pain, patellofemoral pain*

syndrome, retropatellar pain, chondromalacia, patella chondromalacia, knee osteoarthritis.

Study Selection and Data Extraction

Titles and abstracts of studies identified by the search terms were screened by 2 reviewers (J.Y. and D.R.). Full-text studies were retrieved when eligible and screened by the same 2 reviewers. Disagreements between authors were resolved by a third reviewer (J.C.). Reference lists of selected studies were manually checked for inclusion. Data were extracted by 2 authors (J.Y. and D.R.) to include exercise type, single-session duration, frequency of intervention, total number of sessions, duration of care, time frame of study, outcome measures assessing pain and/or function, and baseline and end-of-study means and standard deviations associated with each outcome measure.

For the purposes of this review, the following terms were operationally defined: exercise type, single-session duration, frequency of intervention, total number of sessions, duration of care, and time frame of study. Exercise type was defined as an exercise activity prescribed by a health care provider that required physical effort by the patient and was done with the intention of improving health.⁴⁹ Single-session duration was the length of time for 1 exercise session, supervised or as a home exercise program (HEP). Frequency of intervention was how often the patient performed the exercise, supervised or as an HEP. Total number of sessions was the number of exercise sessions performed, supervised or as an HEP, during the study. Duration of care was the total length of time, in weeks, an individual performed exercise. Time frame of study was the length of time for the intervention and final follow-up. This varied among studies, as some had the final follow-up on the last day of treatment and others collected measurements weeks after the last day of intervention.

Data Synthesis and Analysis

To calculate the magnitude of effect, the standardized mean difference (SMD) was

used where data were available, using means and standard deviations at baseline and at the end of the study to provide the longest available follow-up time frame. Cohen's benchmarks (0.2, small; 0.5, medium; 0.8, large) were used to determine the size of effect.¹⁸ TABLES 1 through 3 provide the calculated effect sizes, exercise type, and dosing variables for knee OA, patellar tendinopathy, and PFP.

RESULTS

FOLLOWING THE SEARCH AND SCREENING process, 59 studies were included, and 44 of these studies had the necessary data required for effect-size calculation. Thirty-two studies were identified for knee OA, with 24 reporting the required data for effect-size calculation.^{2,9,12,14,15,22,25,26,33,36-39,48,52-56,58,62,71-73,80,85,88-93} Only 3 of 8 studies for patellar tendinopathy,^{4,11,19,28,41,47,86,95} and 17 of 19 studies for PFP, reported the required data.^{5,6,20,21,29,30,32,35,44-46,57,63-65,69,75,83,94} Corresponding authors were contacted from those studies where data were not avail-

able, and 1 more study was included, resulting in a total of 45 studies.¹⁹ FIGURE 1 outlines the search results.

Methodological Quality Assessment

To assess the quality of the included studies, the Physiotherapy Evidence Database (PEDro) scale was used. The PEDro scale comprises 11 criteria to evaluate internal and external validity of randomized controlled trials, and has been shown to be valid and reliable.^{59,60} Of the 45 studies included in this review, 43 received the same PEDro scale scores by the 2 independent reviewers.^{2,5,6,9,12,14,15,20-22,25,26,29,30,32,33,36,38,39,41,45-48,52-55,57,63-65,69,71,73,75,83,89-94} For the remaining studies, the additional reviewer was consulted to reach consensus.^{11,19} A methodological quality rating was given to all studies. A study having a score of 7 or above was considered to be high quality, 5 or 6 fair quality, and 4 or below poor quality.⁸⁷

The quality assessment score for the included studies is shown in TABLE 4. The 45 studies for knee OA, patellar tendinopathy, and PFP had mean quality scores re-

flecting "fair" quality evidence. The mean quality score was 6.42 (range, 4-8) for the 24 knee OA studies, 5.5 (range, 4-6) for the 4 patellar tendinopathy studies, and 5.65 (range, 3-8) for the 17 PFP studies. Only 2 studies met the criterion for blinding participants.^{19,25} None of the studies met the criterion of blinding the treatment provider. However, this is typical in physical therapy trials, as it is difficult to blind clinicians in studies involving exercise, but does not appear to significantly influence the effect size.³ FIGURE 2 shows the risk of bias across studies.

Effect Sizes

The included studies often used several outcome measures, which led to a wide range of effect sizes within an individual study. All but 1 study related to knee OA exhibited a wide range of effect sizes (small to large) on pain and function.⁹² Large effect sizes were seen in 15 studies,^{2,9,15,36,38,39,48,52-55,71,73,91,93} with the visual analog scale (VAS) for pain,^{2,36,71,73,91,93} Knee Injury and Osteoarthritis Outcome Score (KOOS),^{15,93} and Western Ontario

TABLE 1

DOSING VARIABLES AND EFFECT SIZES FOR KNEE OA STUDIES

Study	Exercise Type	Single-Session Duration	Frequency	Total Sessions, n	Duration of Care	Time Frame of Study	SMD*	Magnitude of Effect
Açılmaş et al ²	Low-impact calisthenics, static stretching, aerobic training, functional strengthening exercises	Total not reported, but did have 10-min warm-up, 15-min cool-down, 20-min aerobic exercise, and unknown time for strengthening exercise	3 times per week, supervised	36	12 wk	12 wk	VAS, 2.44 SF-36, 1.32	Large Large
Bennell et al ⁹	HEP for hip abductor/adductor strengthening plus in-clinic instruction on exercise progression	Not reported	5 times per week, HEP plus 7 times, supervised	60 plus 7	12 wk	12 wk	NPRS, 0.83 WOMAC function, 0.76 Step test, 0.45	Large Medium Small
Brismée et al ¹²	Tai Chi	40 min	3 times per week, supervised for weeks 1-6 and 3 times per week, HEP for weeks 7-12	36	12 wk	18 wk	VAS overall, 0.48 VAS maximum pain, 0.36 WOMAC function, 0.33	Small Small Small
Bruce-Brand et al ¹⁴	HEP for strengthening exercises	30 min	3 times per week, 2 supervised and 1 HEP	18	6 wk	14 wk	SF-36 physical, 0.63 WOMAC pain, 0.40 WOMAC function, 0.01	Medium Small No effect

Table continues on page 149.

TABLE 1

DOSING VARIABLES AND EFFECT SIZES FOR KNEE OA STUDIES (CONTINUED)

Study	Exercise Type	Single-Session Duration	Frequency	Total Sessions, n	Duration of Care	Time Frame of Study	SMD*	Magnitude of Effect
Chaipinyo and Karoonsupcharoen ¹⁵	Balance: stepping forward/backward/sideward and mini-squat exercises Strength: seated isometric knee extension exercises	Not reported	5 d/wk, HEP	20	4 wk	4 wk	KOOS function in ADL: strength, 0.89; balance, 0.45 KOOS pain: strength, 0.69; balance, 0.64	Large, small Medium, medium
Farr et al ²²	Aerobic exercise, flexibility, range of motion, strength and balance exercises	60 min	3 times per week, supervised	108	36 wk	36 wk	WOMAC pain, 0.54	Medium
Foroughi et al ²⁵	High-intensity resistance exercise at 80% of peak muscle strength	Not reported	3 times per week, supervised	72	24 wk	24 wk	WOMAC pain, 0.61 WOMAC total, 0.65	Medium Medium
Foroughi et al ²⁶	High-intensity resistance exercise at 80% of peak muscle strength	Not reported	3 times per week, supervised	72	24 wk	24 wk	WOMAC pain, 0.62 WOMAC total, 0.70	Medium Medium
Hay et al ³³	Aerobic and stretching/strengthening exercises	20 min	3-6 supervised sessions	3-6	10 wk	52 wk	WOMAC pain, 0.40 WOMAC function, 0.35	Small Small
Huang et al ³⁶	I: isokinetic strengthening exercise II: isokinetic strengthening exercise and continuous ultrasound III: isokinetic strengthening exercise and pulsed ultrasound	I: 20 min of heat and 5 min on stationary bike plus unknown time frame for strengthening II: 20 min of heat and 5 min on stationary bike plus unknown time frame for strengthening plus 5 min of continuous ultrasound III: 20 min of heat and 5 min on stationary bike plus unknown time frame for strengthening plus 5 min of pulsed ultrasound	3 times per week, supervised, with 15 min on stationary bike as HEP	24	8 wk	52 wk	VAS: I, 0.87; II, 1.67; III, 1.78 Lequesne index: I, 0.82; II, 2.00; III, 2.24	Large, large, large Large, large, large
Jan et al ³⁸	WB: knee flexion/extension strengthening in WB NWB: knee flexion/extension strengthening in NWB	Not reported	3 times per week, supervised	24	8 wk	8 wk	WOMAC: WB, 1.04; NWB, 1.74	Large, large
Jan et al ³⁹	High: high-resistance strengthening exercises Low: low-resistance strengthening exercises	High, 30 min; low, 50 min	3 times per week, supervised	24	8 wk	8 wk	WOMAC pain: high, 1.01; low, 1.00 WOMAC function: high, 1.34; low, 1.30	Large, large Large, large
Krasilshchikov et al ⁴⁸	Aerobic exercise and progressive resistance strengthening exercises	35 min	3 times per week, supervised	24	8 wk	8 wk	WOMAC: pain, 1.32; function, 1.83	Large, large
Lee et al ⁵²	Tai Chi Qigong	60 min	2 times per week (unclear whether HEP or supervised)	16	8 wk	8 wk	SF-36: 1.19 WOMAC: function, 0.67; pain, 0.54	Large Medium, medium

Table continues on page 150.

TABLE 1

DOSING VARIABLES AND EFFECT SIZES FOR KNEE OA STUDIES (CONTINUED)

Study	Exercise Type	Single-Session Duration	Frequency	Total Sessions, n	Duration of Care	Time Frame of Study	SMD*	Magnitude of Effect
Lim et al ⁵³	Varus: 5 quadriceps-strengthening exercises with ankle weights and black Thera-Band Neutral: 5 quadriceps-strengthening exercises with ankle weights and black Thera-Band	Not reported	5 times per week, HEP plus 7 supervised visits	67	12 wk	12 wk	WOMAC pain: neutral quadriceps, 0.82; varus quadriceps, 0.28 WOMAC function: neutral quadriceps, 0.54; varus quadriceps, 0.13	Large, small Medium, no effect
Lim et al ⁵⁴	Aquatic: aquatic-based aerobic and strengthening exercises Land: land-based aerobic and strengthening exercises	40 min (30 min plus 5-min warm-up and 5-min cool-down)	3 times per week, supervised	24	8 wk	8 wk	WOMAC total: aquatic, 1.34; land, 0.79 SF-36 physical: aquatic, 0.58; land, 0.68	Large, medium Medium, medium
Lin et al ⁵⁵	Proprioception: seated proprioceptive training via computer game program challenging knee movement Strength: seated knee concentric/eccentric quadriceps-strengthening exercise starting at 50% 1RM and progressing by 5% at each visit	Proprioception: 20 min for each lower extremity Strength: not reported	3 times per week, supervised	24	8 wk	8 wk	WOMAC pain: proprioception, 1.20; strength, 1.39 WOMAC function: proprioception, 0.89; strength, 1.93	Large, large Large, large
Salli et al ⁷¹	C-E: isokinetic strengthening exercises Isometric: isometric strengthening exercises	Not reported	3 times per week, supervised	24	8 wk	20 wk	VAS rest: C-E, 1.21; isometric, 1.24 VAS motion: C-E, 2.72; isometric, 2.16 WOMAC function: C-E, 1.64; isometric, 1.13 SF-36: C-E, 1.49; isometric, 0.89	Large, large Large, large Large, large Large, large
Silva et al ⁷³	Aquatic: strengthening and stretching exercises for the lower extremity and gait training Land: same as aquatic group but on land	50 min	3 times per week, supervised	54	18 wk	18 wk	VAS: aquatic, 1.78; land: SMD, 1.38 WOMAC total: aquatic, 1.30; land, 0.78 Lequesne index: aquatic, 1.31; land, 0.76	Large, large Large, medium Large, medium
Wang et al ⁸⁹	Aerobic exercise, flexibility, and strengthening exercises for the lower and upper extremities in water	50 min	3 times per week, supervised	36	12 wk	12 wk	VAS, 0.41	Small
Wang et al ⁹⁰	Aquatic: flexibility and aerobic exercises for the upper and lower extremities Land: same as aquatic group but on land	60 min	3 times per week, supervised	36	12 wk	12 wk	KOOS pain: aquatic, 0.58; land, 0.76 6MWT: aquatic, 0.72; land, 0.58 KOOS (ADLs): land, 0.47; aquatic, 0.17	Medium, medium Medium, medium Small, no effect

Table continues on page 151.

TABLE 1

DOSING VARIABLES AND EFFECT SIZES FOR KNEE OA STUDIES (CONTINUED)

Study	Exercise Type	Single-Session Duration	Frequency	Total Sessions, n	Duration of Care	Time Frame of Study	SMD*	Magnitude of Effect
Weng et al ⁹¹	I: isokinetic strengthening exercises	Not reported	3 times per week, supervised	24	8 wk	52 wk	VAS: II, 1.38; III, 2.07; I, 0.69	Large, large, medium
	II: bilateral static stretching exercises and isokinetic strengthening exercises						Lequesne index: I, 0.47; II, 2.21; III, 2.68	Small, large, large
	III: proprioceptive neuromuscular facilitation stretching and isokinetic strengthening exercises							
Williamson et al ⁹²	Lower extremity strengthening and stretching exercises	60 min	1 time per week, supervised	6	6 wk	12 wk	OKS, 0.06 VAS, 0.17 WOMAC, 0.05	No effect No effect No effect
Yennan et al ⁹³	Aquatic: aerobic warm-up, aquatic stretching/strengthening exercises, cool-down	65 min	Unclear	Unclear	6 wk	6 wk	WOMAC total: aquatic, 1.18; land, 0.19	Large, no effect
	KOOS: aquatic, 1.19; land, 0.99						Large, large	
	Land: same as aquatic but on land						VAS: aquatic, 2.43; land, 0.98	Large, large
Abbreviations: 1RM, 1-repetition maximum; 6MWT, 6-minute walk test; ADL, activities of daily living; C-E, concentric/eccentric; HEP, home exercise program; KOOS, Knee injury and Osteoarthritis Outcome Score; NPRS, numeric pain-rating scale; NWB, non-weight bearing; OA, osteoarthritis; OKS, Oxford Knee Score; SF-36, Medical Outcomes Study 36-Item Short-Form Health Survey; SMD, standardized mean difference; VAS, visual analog scale; WB, weight bearing; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.								
*Calculated for time frame of study.								

and McMaster Universities Osteoarthritis Index (WOMAC)^{38,39,48,53-55,71,73,93} as the most common outcome measures. Medium effect sizes were seen in 12 studies,^{9,14,15,22,25,26,52-54,73,90,91} with the WOMAC pain and function subscales as the most common outcome measures.^{9,22,25,26,52-54,73} Small effect sizes were observed in 10 studies,^{9,12,14,15,22,33,53,89-91} with the pain VAS, WOMAC, and KOOS as the most common outcome measures.^{12,14,15,22,33,53,90,91}

The effect sizes in the studies on patellar tendinopathy varied. The eccentric exercise group in the study by Jonsson and Alfredson⁴¹ exhibited a large effect size on the Victorian Institute of Sport Assessment (VISA) (SMD, 2.03), whereas the concentric exercise group had a small effect size (SMD, 0.31) on the same outcome measure. Kongsgaard et al⁴⁷ reported large effect sizes in both the eccentric and heavy, slow resistance exercise groups for the VISA and pain VAS, whereas Biernat et al¹¹ had a small effect

size with eccentric and concentric exercise on the VISA. da Cunha et al¹⁹ used eccentric exercise and exhibited no or small effect (pain VAS), or medium and large effects (VISA).

Large effect sizes were more common for PFP, reported in 16 of the studies.^{6,20,21,29,30,32,45,46,57,63-65,69,75,83,94} Eight studies reported medium effect sizes,^{5,6,21,30,32,57,64,65} and 3 reported small effect sizes, primarily on function.^{29,30,65} One of the studies reported a small effect size on the numeric pain-rating scale,³⁰ and 3 studies reported no effect size on functional outcomes.^{20,29,65}

Single-Session Duration

Many of the studies for knee OA were either unclear or did not report details of session duration.^{2,9,15,25,26,36,38,53,56,71,91,92} In the studies that did provide session duration, times ranged from 20 minutes to 65 minutes.^{12,14,22,33,39,48,52,54,55,73,89,90,92,93} None of the studies for patellar tendinopathy

reported details of session duration,^{11,19,41,47} and only 6 of the 17 included studies for PFP did.^{20,45,46,63,65,83} Of these 6, 5 studies ranged from 20 to 60 minutes,^{45,46,63,65,83} and 1 from 75 to 120 minutes.²⁰

Frequency of Intervention

Three supervised sessions per week was the most common frequency prescribed to patients with knee OA, with only 1 study prescribing 3 sessions per week as an HEP.^{2,22,25,26,38,39,48,54,55,71,73,89-91} Five studies had combinations of both supervised and HEP sessions.^{9,12,14,36,53} One study reported 1 supervised session per week, another 2 per week (unclear whether supervised or HEP), and 1 study 5 HEP sessions per week.^{15,52,92} Frequency for patellar tendinopathy ranged from 1 to 2 times daily, to 3 times per week supervised, to 1 supervised session and 2 HEP sessions per week, or to 7 days per week as an HEP.^{11,19,41,47} Most of the studies on PFP also utilized the frequency of 3 super-

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vised sessions per week.^{20,29,30,32,45,46,63,65,75,94} One study delivering only an HEP utilized a frequency of 7 days per week.⁵⁷ Four studies had combinations of both supervised and HEP sessions.^{6,21,64,83} Last, 1 study had a frequency of 2 times per day, 7 days per week, but it was unclear whether it was supervised or an HEP.⁵

Total Number of Sessions

The total number of sessions varied greatly. The most common numbers of

sessions for knee OA were 24 and 36 (range, 3-108),^{2,12,22,33,36,38,39,48,54,55,71,89-91} 168 (range, 36-180) for patellar tendinopathy,^{11,19,41,47} and 24 and 36 (range, 12-146) for PFP.^{20,21,32,45,46,65,75}

Duration of Care

For knee OA, the total duration of the exercise program ranged from 4 to 36 weeks (mean, 11.74).^{2,9,12,14,15,22,25,26,33,36,38,39,48,52-55,71,73,89-93} In the small number of patellar tendinopathy studies,

the duration was either 12 weeks or 24 weeks.^{11,19,41,47} The most common duration for PFP was 8 weeks,^{20,21,45,46,75} ranging from 3 to 16 weeks, with an average of 7.57.^{5,6,29,30,32,57,63-65,69,83,94}

DISCUSSION

THERE IS A LARGE VARIATION IN dosing of exercise, making it difficult to discern how specific dosing variables may influence the effects of treatment. However, some observations emerged from this review. For knee OA, (1) 24 total exercise sessions were most often related to large effect sizes, (2) 8- and 12-week durations most often exhibited larger effect sizes, and (3) a frequency of 1 time per week showed no effect. There were no trends associated with patellar tendinopathy or PFP. These findings suggest that the dose of exercise influences the outcome of treatment; however, further prospective trials should validate this before definitive recommendations are made about optimal exercise dosing.

Single-Session Duration

Because session duration was either not reported or unclear for many of the studies, definitive recommendations cannot be provided. There were no particular session durations associated with greater effect sizes. For example, Lin et al⁵⁵ used only 20 minutes of exercise, 3 times per week, for patients with knee OA and showed large effect sizes for the WOMAC pain and function subscales, whereas Farr et al²² used 60 minutes, 3 times per week, and showed a medium effect size on the WOMAC pain subscale. In PFP, large effect sizes were seen with interventions that used 25-minute sessions and 75- to 120-minute sessions,^{20,83} so session duration may not be an important factor in treatment effectiveness. However, individuals who received low-dose, low-repetition exercise for 20 minutes had a small effect size.⁶⁵ Nonetheless, the variation in session duration across all

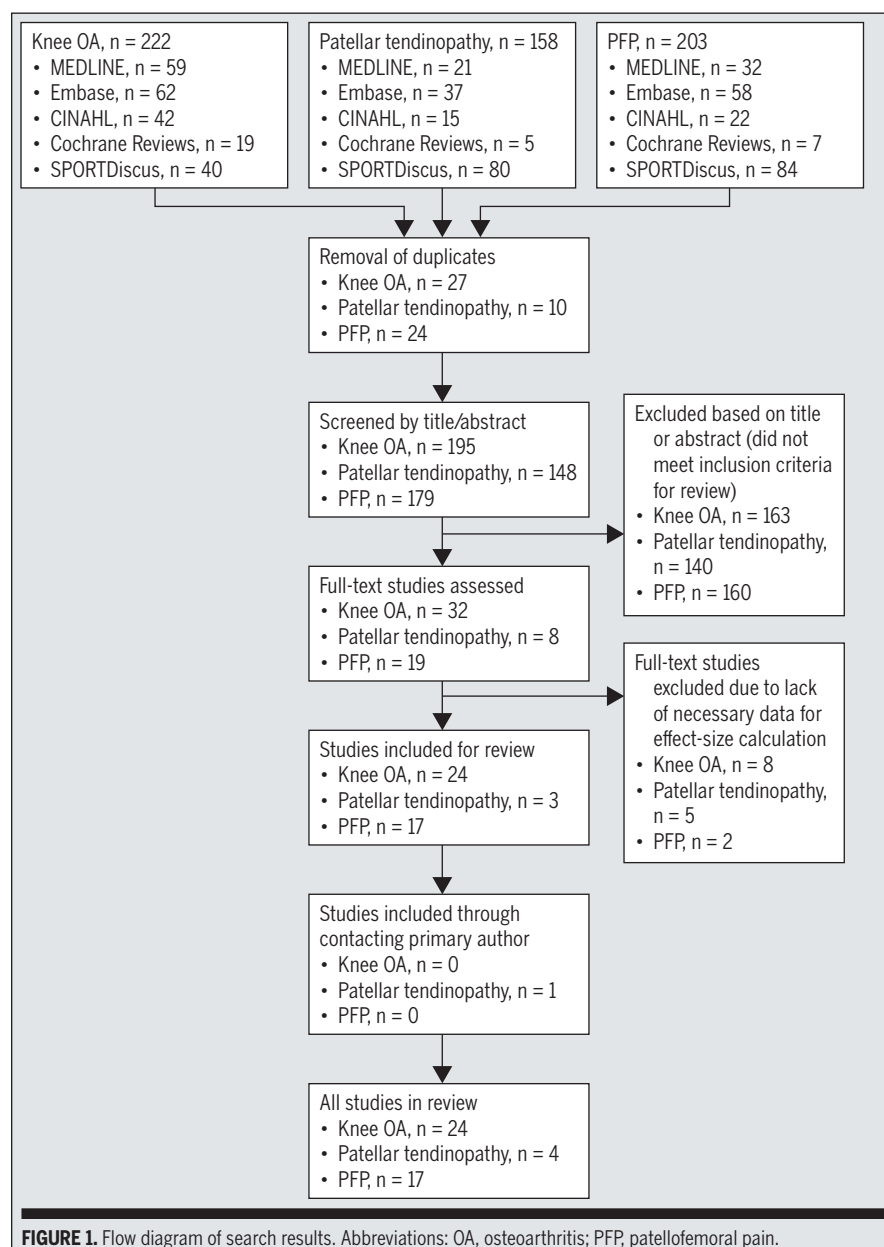


FIGURE 1. Flow diagram of search results. Abbreviations: OA, osteoarthritis; PFP, patellofemoral pain.

studies in PFP did not allow for specific recommendations.

Frequency of Intervention

There was a wide variation in the frequency of sessions, but 2 observations were made. One study on knee OA demonstrated that receiving therapeutic exercise 1 time per week had no effect on the pain VAS, WOMAC, and Oxford Knee Score questionnaire.⁹² It was the only study in this review in which patients received exercise only 1 time per week, and although only 1 study, it suggests that the frequency of exercise intervention might affect treatment outcomes, which warrants further investigation.

Total Number of Sessions

There was a trend between the number of sessions and effect size for knee OA, but not for patellar tendinopathy and PFP. For

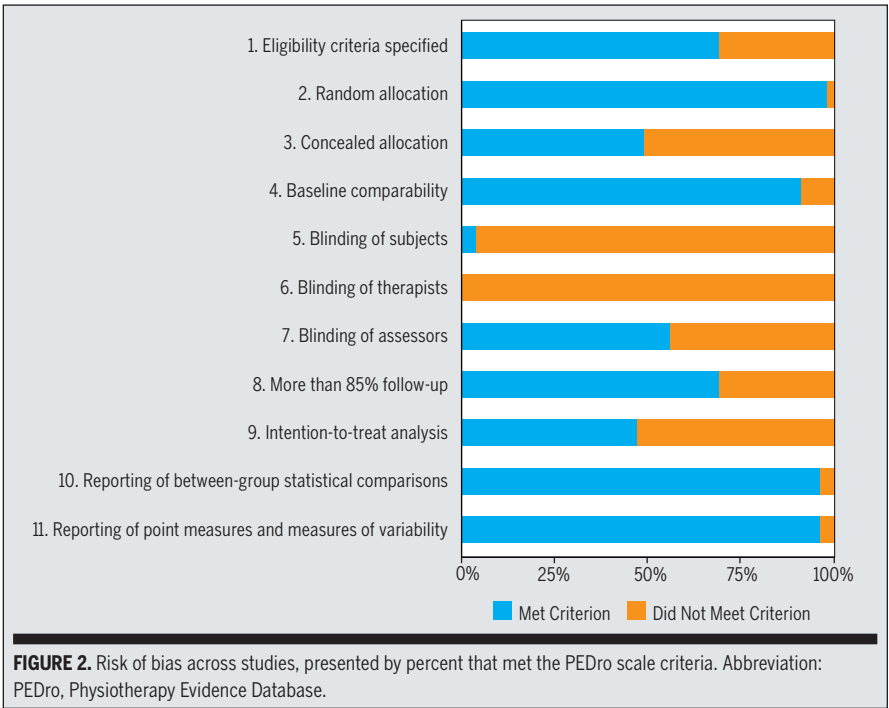


TABLE 2		DOSING VARIABLES AND EFFECT SIZES FOR PATELLAR TENDINOPATHY STUDIES						
Study	Exercise Type	Single-Session Duration	Frequency	Total Sessions, n	Duration of Care	Time Frame of Study	SMD*	Magnitude of Effect
Biernat et al ¹¹	Eccentric quadriceps strengthening on 25° slant board unilaterally and concentric strengthening bilaterally	Not reported	1 time per day, 7 d/wk, HEP	168	24 wk	24 wk	VISA: eccentric, 0.44; concentric, 0.24	Small, small
da Cunha et al ¹⁹	Eccentric, pain: squats on 25° slant board with pain allowed	Not reported	3 times per week	36	12 wk	12 wk	VISA: eccentric, pain, 0.75; eccentric, no pain, 1.02	Medium, large
	Eccentric, no pain: squats on 25° slant board with no pain allowed						VAS: eccentric, pain, 0.00; eccentric, no pain, 0.36	No effect, small
Jonsson and Alfredson ⁴¹	Eccentric or concentric quadriceps strengthening on decline	Not reported	2 times per day, 7 d/wk, HEP	168	12 wk	12 wk	VISA: eccentric, 2.03; concentric, 0.31	Large, small
Kongsgaard et al ⁴⁷	Eccentric: unilateral squats on 25° slant board	Not reported	Eccentric: 2 times per day, 7 d/wk, HEP with 1 supervised session per week	Eccentric: 168, HEP plus 12 supervised HSR: 36	12 wk	26 wk	VISA: eccentric, 1.58; HSR, 2.40	Large, large
	HSR: bilateral squats, leg press, and hack squats		HSR: 3 times per week, with 1 supervised session				VAS: eccentric, 1.99; HSR, 3.10	Large, large
Abbreviations: HEP, home exercise program; HSR, heavy, slow resistance; SMD, standardized mean difference; VAS, visual analog scale; VISA, Victorian Institute of Sport Assessment. *Calculated for time frame of study.								

knee OA, 24 sessions was related to large effect sizes.^{36,38,39,48,54,55,71,91} Although 24 sessions was also seen in 2 other studies exhibiting medium and small effects, 53% of the studies with large effects had 24 sessions, suggesting that this number may impact overall outcomes.^{54,91}

Duration of Care

Larger and smaller durations tended to be associated with large and small or no effect sizes, respectively, but not always. Durations of 8 and 12 weeks were the most common in studies investigating knee OA, and these durations were associated with large effect sizes.^{2,9,36,38,39,48,52-55,71,91} Longer durations of 18, 24, and 36 weeks were also associated with large and medium effect sizes in knee OA studies,^{22,25,26,73} whereas 4- and 6-week durations were often reported to

have medium, small, or no effects.^{14,15,92,93} However, some interventions of 12 or 36 weeks in duration for knee OA had a small or no effect.^{9,12,22,53,90} It is possible that the large effect sizes associated with 8- and 12-week durations were due to the larger number of studies with these durations. Also, a greater number of outcomes were available for calculating effect sizes for these durations, which led to greater potential to show large effect sizes. The largest effect size was an SMD of 2.72 on the pain VAS from Salli et al,⁷¹ and the participants were seen for 8 weeks. This suggests that 8 weeks may be beneficial in reducing pain, but the quality of this study was only “fair,” so the recommendation must be taken with caution.

There was no indication of better effects with specific durations in studies

investigating patellar tendinopathy and PFP. Twelve weeks was the most common duration for patellar tendinopathy, and large effect sizes were seen with eccentric exercises and heavy, slow resistance training,^{41,47} but small effect sizes were also seen with eccentric exercises over a 24-week period.¹¹ Although 8- and 12-week durations were also common for PFP,^{20,21,32,45,46,57,65,75} there was a wide range of durations associated with large, medium, small, or no effect.

Other Factors Affecting Exercise Prescription

Other variables may also lead to different exercise prescription. One is the timing when exercise prescription occurs. Recent literature has examined the effect of booster sessions for knee OA,^{1,10,23} that is, regularly scheduled

TABLE 3

DOSING VARIABLES AND EFFECT SIZES FOR PFP STUDIES

Study	Exercise Type	Single-Session Duration	Frequency	Total Sessions, n	Duration of Care	Time Frame of Study	SMD*	Magnitude of Effect
Bakhtiari and Fatemi ⁵	SLR exercise Semi-squat exercise	Not reported	2 times per day, 7 d/wk (unclear whether supervised or HEP)	42	3 wk	5 wk	VAS: SLR, 0.64; semi-squat, 0.50	Medium, medium
Balci et al ⁶	IR: hip IR strengthening exercises based on 1RM and HEP with strengthening exercises ER: hip ER strengthening exercises based on 1RM and HEP with strengthening exercises	Not reported	20 supervised sessions over 4 wk plus HEP, 3 times per day for 6 wk	20 plus 126 HEP sessions	4 wk plus HEP for 6 wk	10 wk	VAS at rest: ER, 0.99; IR, 0.66 VAS with activity: ER, 1.36; IR, 1.00 Kujala scale: ER, 1.01; IR, 1.08	Large, medium Large, large Large, large
De Marche Baldon et al ²⁰	FST: via motor control and trunk/hip strengthening exercises ST: via stretching and quadriceps strengthening exercises	FST: 90-120 min ST: 75-90 min	3 times per week, supervised	24	8 wk	12 wk	VAS: FST, 4.33; ST, 1.57 LEFS: FST, 2.06; ST, 1.64 Single-leg hop: FST, 0.92; ST, 0.06	Large, large Large, large Large, no effect
Dolak et al ²¹	Hip: hip-specific strengthening exercise and hamstring, quadriceps, and triceps surae stretches Quadriceps: quadriceps-specific strengthening exercises and hamstring, quadriceps, and triceps surae stretches	Not reported	3 times per week (1 supervised, 2 HEP)	24	8 wk	8 wk	VAS: hip, 0.83; quadriceps, 0.74 LEFS: hip, 1.00; quadriceps, 0.88	Large, medium Large, large

Table continues on page 155.

TABLE 3

DOSING VARIABLES AND EFFECT SIZES FOR PFP STUDIES (CONTINUED)

Study	Exercise Type	Single-Session Duration	Frequency	Total Sessions, n	Duration of Care	Time Frame of Study	SMD*	Magnitude of Effect
Fukuda et al ²⁹	Knee: knee stretching/strengthening Knee/hip: knee and hip stretching/strengthening	Not reported	3 times per week, supervised	12	4 wk	52 wk	LEFS: knee/hip, 2.29; knee, 0.24 AKPS: knee/hip, 1.62; knee, 0.21 NPRS (up stairs): knee/hip, 3.48; knee, 0.09 NPRS down stairs: knee/hip, 3.14; knee, 0.18 Single-leg hop: knee/hip, 1.20; knee, 0.18	Large, small Large, small Large, no effect Large, no effect Large, no effect
Fukuda et al ³⁰	Knee: knee stretching/strengthening exercises Knee/hip: knee and hip stretching/strengthening exercises	Not reported	3 times per week, supervised	12	4 wk	4 wk	LEFS: knee/hip, 1.30; knee, 0.66 AKPS: knee/hip, 1.07; knee, 0.77 NPRS (up stairs): knee/hip, 1.29; knee, 0.57 NPRS (down stairs): knee/hip, 1.68; knee, 0.38 Single-leg hop: knee/hip, 0.46; knee, 0.30	Large, medium Large, medium Large, medium Large, small Small, small
Hafez et al ³²	Eccentric: eccentric strengthening exercises, hamstring stretches, and ultrasound Concentric: concentric strengthening exercises, hamstring stretches, and ultrasound	Not reported	3 times per week, supervised	36	12 wk	12 wk	VAS: eccentric, 4.49; concentric, 2.24 WOMAC: eccentric, 2.42; concentric, 0.56	Large, large Large, medium
Khayambashi et al ⁴⁶	Aerobic and hip strengthening exercises	30 min	3 times per week, supervised	24	8 wk	24 wk	VAS, 2.75 WOMAC, 2.53	Large Large
Khayambashi et al ⁴⁵	Hip: hip abductor and external rotator strengthening exercises Quadriceps: quadriceps strengthening exercises	30 min	3 times per week, supervised	24	8 wk	24 wk	VAS: hip, 2.99; quadriceps, 1.32 WOMAC: hip, 2.50; quadriceps, 1.13	Large, large Large, large
Lun et al ⁵⁷	Lower extremity strengthening/stretching exercises	Not reported	1 time per day, 7 d/wk, HEP	84	12 wk	12 wk	VAS: 1 h after sport, 0.81; during activity, 0.56; following 30-min sit, 0.54 Knee Function Scale: 0.56	Large, medium, medium Medium
Moyano et al ⁶³	PNF: proprioceptive and aerobic exercise Stretch: stretching for the hip/knee	20-60 min	3 times per week, supervised	48	16 wk	16 wk	NPRS: PNF, 4.07; stretch, 1.51 Kujala scale: PNF, 1.94; stretch, 5.49	Large, large Large, large
Nakagawa et al ⁶⁴	Stretching/strengthening exercises for the lower extremity and functional training for the abdominals and hip abductors and external rotators	Not reported	1 time per week, supervised; 4 times per week, HEP	30	6 wk	6 wk	VAS: usual pain, 1.64; worst pain, 2.12; stair climb, 1.44; descending stairs, 2.40; squat, 2.79; prolonged sitting, 0.71	Large, large, large, large, medium
Østerås et al ⁶⁵	High dose: high-dose, high-repetition strengthening exercises and aerobic exercise Low dose: low-dose, low-repetition strengthening exercises and aerobic exercise	High dose: 60 min Low dose: 20 min	3 times per week, supervised	36	12 wk	12 wk	VAS: high dose, 1.67; low dose, 0.58 Step-down: high dose, 1.19; low dose, 0.28 FIQ: high dose, 1.10; low dose, 0.03	Large, medium Large, small Large, no effect

Table continues on page 156.

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TABLE 3

DOSING VARIABLES AND EFFECT SIZES FOR PFP STUDIES (CONTINUED)

Study	Exercise Type	Single-Session Duration	Frequency	Total Sessions, n	Duration of Care	Time Frame of Study	SMD*	Magnitude of Effect
Razeghi et al ⁶⁹	Hip/knee strengthening exercises	Not reported	Unclear	Unclear (over 4 wk)	4 wk	4 wk	VAS, 2.12	Large
Song et al ⁷⁵	LPHA: leg-press strengthening exercise at 60% of 1RM with 50-N hip abduction force applied to distal thigh Leg press: leg-press strengthening exercise at 60% of 1RM	Not reported	3 times per week, supervised	24	8 wk	8 wk	VAS: LPHA, 0.91; leg press, 1.10 Lysholm: LPHA, 1.04; leg press, 0.93	Large, large Large, large
van Linschoten et al ⁸³	Aerobic, stretching and strengthening, balance and flexibility exercises	25 min	Total of 9 times over 6 wk, supervised; daily HEP	9 supervised, 84 HEP	6 wk supervised, HEP for 12 wk	52 wk	Function score, 1.31 Pain: at rest, 1.20; with activity, 1.46	Large Large, large
Yilmaz Yelvar et al ⁹⁴	Knee/postural: knee stretching/strengthening exercises and postural stabilization program Knee only: knee stretching/strengthening exercises	Not reported	Knee/postural: 3 times per week, supervised Knee only: 3 times per day, HEP	Knee/postural: 18 Knee only: 126	6 wk	12 wk	VAS: knee/postural, 3.27; knee only, 1.88 Kujala scale: knee/postural, 3.72; knee only, 1.95 TUG: knee/postural, 0.86; knee only, 0.92 1-leg hop: knee/postural, 1.07; knee only, 0.87	Large, large Large, large Large, large Large, large

Abbreviations: 1RM, 1-repetition maximum; AKPS, Anterior Knee Pain Scale; ER, external rotation; FIQ, knee Functional Index Questionnaire; FST, functional strengthening; HEP, home exercise program; IR, internal rotation; LEFS, Lower Extremity Functional Scale; LPHA, leg-press hip abduction; NPRS, numeric pain-rating scale; PFP, patellofemoral pain; PNF, proprioceptive neuromuscular facilitation; SLR, straight leg raise; SMD, standardized mean difference; ST, standard training; TUG, timed up-and-go test; VAS, visual analog scale; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.
*Calculated for time frame of study.

TABLE 4

PEDro SCALE SCORES FOR INCLUDED STUDIES

Condition/Study	Item*											Total Score [‡]	Study Quality
	1†	2	3	4	5	6	7	8	9	10	11		
Knee osteoarthritis													
Ağlarnış et al ²	Y	Y	N	N	N	N	Y	N	N	Y	Y	4	Poor
Bennell et al ⁹	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y	8	High
Brismée et al ¹²	Y	Y	N	Y	N	N	Y	N	N	Y	Y	5	Fair
Bruce-Brand et al ¹⁴	Y	Y	N	Y	N	N	Y	N	N	Y	Y	5	Fair
Chaipinyo and Karoonsupcharoen ¹⁵	Y	Y	Y	Y	N	N	Y	Y	N	Y	Y	7	High
Farr et al ²²	Y	Y	Y	Y	N	N	N	N	N	Y	Y	5	Fair
Foroughi et al ²⁵	Y	Y	N	Y	Y	N	N	N	N	Y	Y	5	Fair
Foroughi et al ²⁶	N	Y	Y	Y	N	N	N	N	N	Y	Y	5	Fair
Hay et al ³³	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y	8	High
Huang et al ³⁶	N	Y	Y	Y	N	N	N	N	N	Y	Y	5	Fair

Table continues on page 157.

TABLE 4

PEDro SCALE SCORES FOR INCLUDED STUDIES (CONTINUED)

Condition/Study	Item*											Total Score [‡]	Study Quality
	1 [†]	2	3	4	5	6	7	8	9	10	11		
Jan et al ³⁸	N	Y	N	Y	N	N	Y	Y	Y	Y	Y	7	High
Jan et al ³⁹	Y	Y	N	Y	N	N	Y	Y	Y	Y	Y	7	High
Krasilshchikov et al ⁴⁸	N	Y	N	Y	N	N	Y	Y	Y	Y	Y	7	High
Lee et al ⁵²	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y	8	High
Lim et al ⁵³	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y	8	High
Lim et al ⁵⁴	Y	Y	N	Y	N	N	Y	Y	Y	Y	Y	7	High
Lin et al ⁵⁵	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y	8	High
Salli et al ⁷¹	N	Y	Y	N	N	N	Y	Y	N	Y	Y	6	Fair
Silva et al ⁷³	Y	Y	N	Y	N	N	Y	Y	Y	Y	Y	7	High
Wang et al ⁸⁹	Y	Y	N	Y	N	N	N	Y	Y	Y	Y	6	Fair
Wang et al ⁹⁰	Y	Y	Y	Y	N	N	Y	Y	N	Y	Y	7	High
Weng et al ⁹¹	N	Y	Y	Y	N	N	N	N	Y	Y	Y	6	Fair
Williamson et al ⁹²	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y	8	High
Yennan et al ⁹³	Y	Y	N	Y	N	N	N	Y	N	Y	Y	5	Fair
Patellar tendinopathy													
Biernat et al ¹¹	N	Y	Y	Y	N	N	N	N	Y	Y	Y	6	Fair
da Cunha et al ¹⁹	Y	Y	N	N	Y	N	N	Y	N	Y	N	4	Poor
Jonsson and Alfredson ⁴¹	Y	Y	N	Y	N	N	Y	Y	N	Y	Y	6	Fair
Kongsgaard et al ⁴⁷	N	Y	N	Y	N	N	Y	Y	N	Y	Y	6	Fair
PFP													
Bakhtiary and Fatemi ⁵	N	Y	Y	Y	N	N	N	N	Y	Y	Y	6	Fair
Balci et al ⁶	N	Y	N	Y	N	N	N	Y	N	Y	Y	5	Fair
De Marche Baldon et al ²⁰	Y	Y	Y	Y	N	N	N	Y	Y	Y	Y	7	High
Dolak et al ²¹	Y	Y	N	Y	N	N	Y	N	Y	Y	Y	6	Fair
Fukuda et al ²⁹	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y	8	High
Fukuda et al ³⁰	Y	Y	Y	Y	N	N	Y	Y	N	Y	Y	7	High
Hafez et al ³²	N	Y	N	Y	N	N	N	N	N	Y	Y	4	Poor
Khayambashi et al ⁴⁶	Y	Y	N	Y	N	N	N	Y	N	Y	Y	5	Fair
Khayambashi et al ⁴⁵	N	N	N	Y	N	N	N	Y	N	Y	Y	4	Poor
Lun et al ⁵⁷	Y	Y	N	Y	N	N	N	N	N	N	Y	3	Poor
Moyano et al ⁶³	Y	Y	Y	Y	N	N	N	Y	N	Y	Y	6	Fair
Nakagawa et al ⁶⁴	N	Y	Y	Y	N	N	Y	Y	Y	N	Y	7	High
Østerås et al ⁶⁵	Y	Y	Y	Y	N	N	N	Y	N	Y	Y	6	Fair
Razeghi et al ⁶⁹	Y	Y	N	N	N	N	N	Y	N	Y	Y	4	Poor
Song et al ⁷⁵	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y	8	High
van Linschoten et al ⁸³	Y	Y	N	Y	N	N	N	Y	Y	Y	Y	6	Fair
Yilmaz Yelvar et al ⁹⁴	N	Y	N	Y	N	N	Y	N	N	Y	N	4	Poor

Abbreviations: N, no (criterion not satisfied); PEDro, Physiotherapy Evidence Database; Y, yes (criterion satisfied).

*1, Eligibility criteria were specified; 2, Subjects randomly allocated to groups; 3, Allocation was concealed; 4, Groups similar at baseline regarding most important prognostic indicators; 5, Blinding of subjects; 6, Blinding of all therapists; 7, Blinding of all assessors who measured at least 1 key outcome; 8, Measures of key outcomes were obtained from more than 85% of those initially allocated to groups; 9, All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data were analyzed by "intention to treat"; 10, Results of between-group statistical comparisons are reported for at least 1 key outcome; 11, Study provides both point measures and measures of variability for at least 1 key outcome.

[†]Not calculated in overall score.

[‡]Out of 10.

follow-up appointments weeks or months after supervised physical therapy is completed. In these cases, physical therapists meet with patients to review their rehabilitation program for modification or progression.²³ This supports the notion that timing may be more important in overall outcomes than the exact specifics of the intervention plan. Abbott et al¹ found that 12 sessions of physical therapy over 1 year in patients with knee OA were more beneficial than 12 consecutive sessions. On the other hand, Fitzgerald et al²³ compared exercise alone to exercise and manual therapy with or without booster sessions. They demonstrated that 3 booster sessions did not improve outcomes at 1 year. Therefore, it is not yet clear whether the addition of booster sessions results in better outcomes.

As mentioned previously, exercise dosing is complex and usually requires some tailoring to individuals based on their unique presentation. Gaps in the literature exist regarding the temporal influence of exercise parameters. Just as it has been recommended that individuals partake in at least 150 minutes of physical activity per week, there may be an ideal amount of total overall exercise time that impacts patient outcomes.¹⁷ Also, an identical bolus of 315 minutes of exercise per week could be disseminated in a variety of ways. Are 7 daily sessions of 45 minutes better than 14 twice-per-day sessions of 22.5 minutes or 21 thrice-per-day sessions of 15 minutes? Outcomes might be better with daily exercise compared to 48 hours between each exercise session, but this comparison would likely also be dependent on the duration and intensity of each daily exercise session. Also, are these sessions supervised or part of an HEP? This could impact the dose, as the patient may not perform the HEP correctly or may not be compliant. Along with large variations in doses that demonstrate large effect sizes, these complexities further illuminate the likelihood that other factors influence

outcomes beyond exercise type and dosing alone.

There are also confounding factors that may dictate the appropriate dose of exercise. Brody¹³ described a variety of factors, including stage of healing, psychosocial issues, ability of the patient to effectively participate in an exercise program, home and work demands, limb dominance, motor control issues, and the presence of wounds, and these are often not reported or accounted for in current exercise trials. An improvement in the quality of reporting exercise dosing in trials, as well as any confounders that could potentially influence the fidelity of the exercise program, is critical. These data can help better inform clinical practice, better allow researchers to fine tune exercise dosage in subsequent trials, and improve our understanding of exercise parameters that work better than others.

There are limitations to this review. First, outcome measures differed across the 45 included studies. Because of this, we chose to include common measures related to pain or function for analysis. However, this could mean that a large effect size based on 1 outcome measure may not equate to a large effect on another measure. The quality of studies in this review rated as fair on the PEDro scale, and this should be taken into account with the overall recommendations. As previously mentioned, many studies did not provide the necessary data to calculate overall effect sizes. It is possible that the results of this review may have differed if all of the studies had incorporated appropriate data for effect-size calculation and could have been included. Also, of 14 studies using an HEP, values for compliance were provided for only 4 (range, 83%-93%).^{6,9,11,12,14,15,21,41,47,53,57,64,83,94} If compliance had been reported for all studies, it might have impacted the overall results of this review. Last, studies were included if published from 2005 to present to include more recent evidence. It is possible that

relevant studies were not included, thus introducing the potential for bias.

CONCLUSION

THERE IS ABUNDANT RESEARCH ON the use of therapeutic exercise to treat musculoskeletal disorders, but to date no research has reported on specific exercise doses to maximize outcomes. This review focused on exercise doses for knee OA, patellar tendinopathy, and PFP. The only trends found were in exercise doses for knee OA, with 24 total sessions and durations of 8 and 12 weeks being the parameters most often associated with large effect sizes, and a frequency of 1 time per week being related to no effect. It is difficult to determine whether these variables were solely responsible for the effect-size results, because there are many factors involved in prescribing exercise. This review demonstrates the need for continued research on exercise dosing, particularly the variables of single-session duration, frequency, total number of sessions, and duration of care, as well as the reporting of effect sizes to assist in determining the clinical impact exercise may have on particular musculoskeletal disorders. ●

KEY POINTS

FINDINGS: In knee osteoarthritis, 24 total sessions and 8- and 12-week durations of care were most often associated with large effects, and a frequency of 1 time per week was related to no effect.

IMPLICATIONS: These exercise dosing variables may provide for more efficient and effective treatments in patients with knee osteoarthritis, and future research should compare the different dosing variables to confirm the results of this review.

CAUTION: The quality of studies included in this review was “fair,” and none of the studies directly compared the dosing variables that were extracted from each study, so readers should use caution when interpreting the results.

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