

Association Between the Single Assessment Numeric Evaluation and the Western Ontario and McMaster Universities Osteoarthritis Index

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Context: Patient-reported outcomes (PROs) evaluate how patients describe symptoms as well as level of physical function or quality of life. The Western Ontario and McMaster Universities Osteoarthritis (WOMAC) Index is one of the most common PROs used to assess disability in patients with knee osteoarthritis (OA), yet the Single Assessment Numeric Evaluation (SANE) is a single-question instrument that may improve the efficiency associated with the measurement of patient function.

Objective: To determine the associations between (1) SANE_{Function} and the physical dysfunction subsection of the WOMAC index (WOMAC_{Dysfunction}) before rehabilitation and after a 4-week therapeutic exercise intervention as well as (2) the percentage change in SANE_{Function} and WOMAC_{Dysfunction} in people with knee OA after 4 weeks of therapeutic exercise.

Design: Cross-sectional study.

Setting: Research laboratory.

Patients or Other Participants: Thirty-six participants (15 men, 21 women) with radiographic knee OA.

Intervention(s): Participants completed 12 sessions (over a 4-week period) of therapeutic exercise to strengthen the lower extremity.

Main Outcome Measure(s): The SANE_{Function} and WOMAC_{Dysfunction} (WOMAC_{Dysfunction} normalized to 100%) scores were collected before and after the 4-week intervention. Percentage change scores over the 4-week intervention were calculated for both measures.

Results: Participants with a higher SANE_{Function} score demonstrated a lower WOMAC_{Dysfunction} score at baseline ($r_s = -0.44, P = .007$) and at the 4-week time point ($r_s = -0.69, P < .001$). There was a nonsignificant and weak association between the changes in the SANE_{Function} and WOMAC_{Dysfunction} scores over the 4 weeks of therapeutic exercise ($r_s = -0.17, P < .43$).

Conclusions: The SANE_{Function} and WOMAC_{Dysfunction} scores demonstrated moderate to weak associations before and after a 4-week exercise program, respectively, whereas the changes in SANE_{Function} and WOMAC_{Dysfunction} scores were not associated. These PROs may be measuring different aspects of self-reported function and therefore should not be used interchangeably to determine a therapeutic response.

Key Words: patient-reported outcomes, disability, physical function, quality of life

Key Points

- The Single Assessment Numeric Evaluation (SANE)_{Function} and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)_{Dysfunction} scores demonstrated moderate to weak associations before and immediately after a 4-week therapeutic exercise intervention in individuals with knee osteoarthritis.
- There was no association between the changes in SANE_{Function} and WOMAC_{Dysfunction} over the 4-week therapeutic exercise intervention period.
- The SANE_{Function} and WOMAC_{Dysfunction} scores should not be used interchangeably to determine a therapeutic response to an intervention.

Patient-reported outcome (PRO) assessments allow clinicians to evaluate how patients describe the intensity or type of symptoms experienced, their level of physical function, and their quality of life.¹ Various PROs have been developed to understand disease-specific patient-reported symptoms or physical limitations.² Similarly, some of the most common PROs in musculoskeletal health care focus on the assessment of disability for a particular region of the body.^{3–5} Conversely, other PROs have been developed to evaluate a patient's overall or general health for the purpose

of providing a more global assessment of functional change.⁶ The collection of PROs is important for various stakeholders involved in the health care system (eg, patients, providers, payers, employers) as data gleaned from PROs are critical for improving clinical decision-making strategies and measuring the efficacy of various therapeutic interventions.^{7–9} The Western Ontario and McMaster Universities Osteoarthritis (WOMAC) Index is one of the most common PROs for assessing pain, stiffness, and function in patients with knee osteoarthritis (OA). The WOMAC Index comprises 24

questions that ask how patients perceive their OA-related knee pain ($n = 5$), stiffness ($n = 2$), and function ($n = 17$) during specific activities,^{10,11} as well as 2 additional questions that allow patients to rate their overall pain in each knee over the past 48 hours. The subsections of the WOMAC individually demonstrate acceptable reliability and construct validity in patients with knee OA^{10–12}; a systematic review of the literature¹³ showed that the WOMAC_{Dysfunction} consistently demonstrated the strongest reliability, followed by the pain and stiffness subsections.

Administering the WOMAC Index in a clinical setting requires additional time in order to accurately collect and effectively use this information to improve health care. Therefore, the Single Assessment Numeric Evaluation (SANE) was developed to assess subjective function in a variety of patient populations using a single question to determine the level of function on a simple scale from 0 to 100.^{14–17} The function subsection of the WOMAC index (WOMAC_{Dysfunction}) evaluates disability, and a greater WOMAC_{Dysfunction} score indicates more patient dysfunction; conversely, the SANE evaluates function, and a greater SANE score demonstrates greater patient function (SANE_{Function}). The SANE has been used to evaluate subjective function in patients who have sustained acute anterior cruciate ligament (ACL) injuries and have undergone ACL reconstruction^{14–16,18} as well as those with chronic patellofemoral pain¹⁷ or patellar fractures.¹⁹ Furthermore, the SANE_{Function} is sensitive to a change in the level of functionality; it has been used to study improvement in function after surgery^{14,15} and the functional decline of patients in longitudinal testing.²⁰

Although the SANE has not been extensively studied in individuals with knee OA, it has been compared with other PROs in patients who have sustained a knee injury or experience knee pain. Specifically, the SANE has demonstrated moderate to strong associations compared with functional status as measured by the Lysholm score (r range = 0.58–0.87),¹⁵ the International Knee Documentation Committee Index (IKDC; r range = 0.65–0.80),²¹ and the activities of daily living subsection of the Knee Outcome Survey ($r = 0.85$)¹⁷ in patients with various traumatic (ACL injury) and chronic (patellofemoral pain) knee injuries. Similar to the distinction between the SANE_{Function} and WOMAC_{Dysfunction} scores, the Lysholm and IKDC instruments use multiple questions that normalize overall function to a total score of 100% rather than the single question on the SANE. The SANE,²¹ Lysholm,²² IKDC,²³ and Knee Outcome Survey²⁴ instruments all demonstrate acceptable reliability, but the association between the SANE_{Function} and other PROs differs within people over time. Williams et al¹⁵ reported that the SANE_{Function} and Lysholm scores fluctuated between moderate and strong associations within the same patients at 3 ($r = 0.58$), 6 ($r = 0.87$), 12 ($r = 0.73$), and greater than 24 months ($r = 0.65$) after ACL reconstruction. Conversely, Winterstein et al²¹ reported that the SANE_{Function} score demonstrated consistently higher self-reported function than the IKDC Index over a 12-month period in female patients with various knee injuries. Therefore, further study is needed to understand exactly how the SANE is associated with other PROs at specific time points, as well as how changes in the SANE are associated with changes in PROs over time and after different therapeutic interventions.

Overall, the current evidence^{15,17,21} demonstrates that the SANE_{Function} score has moderate to strong associations with the level of function assessed by other PROs at single time points in patients with acute knee injuries or surgeries. It remains unknown if the change in function over time is assessed similarly between the SANE_{Function} and more common PROs that use multiple questions to determine functional ability. Although previous authors¹⁵ concluded that the SANE_{Function} should be evaluated in patients with a broad range of knee conditions, no information is available regarding the utility of the SANE_{Function} compared with the function-specific subsection of the WOMAC in individuals with knee OA, which is largely considered the most disabling and costly of all knee conditions.²⁵ Strong associations between the SANE_{Function} and the WOMAC_{Dysfunction} in patients with knee OA who are receiving therapeutic exercise (TE) may allow for the adoption of a time-efficient PRO, such as the SANE_{Function}, into clinical practice. Because the SANE_{Function} specifically addresses the functional status of the individual, we sought to evaluate the relationship between the SANE_{Function} and the function-specific subsection of the WOMAC (WOMAC_{Dysfunction}). The purposes of this study were to determine (1) the associations and the level of agreement between the SANE_{Function} and WOMAC_{Dysfunction} scores before and after a 4-week TE intervention and (2) the percentage change in SANE_{Function} and WOMAC_{Dysfunction} in people with knee OA after a 4-week TE intervention. We hypothesized that strong associations and agreement would exist between PROs before and after the 4-week TE intervention, as well as for the percentage change in SANE_{Function} and WOMAC_{Dysfunction} after the TE intervention. In an effort to better understand our primary purposes, we also performed post hoc analyses to evaluate the associations between the changes in SANE_{Function}, WOMAC_{Pain}, and WOMAC_{Stiffness} scores over the 4-week TE intervention. It is possible that a change in overall function, as measured by the SANE_{Function}, may have been influenced by a change in pain or stiffness (or both), which is separately evaluated by the WOMAC_{Aggregate} but not distinguished within the SANE_{Function}. Our post hoc question was to determine if a change in pain or stiffness may have contributed to the perception of a change in function as measured by the SANE_{Function}. The rationale for these post hoc analyses was to determine if the change in SANE_{Function} score demonstrated a stronger association with a change in other subsections of the WOMAC than with WOMAC_{Dysfunction} score.

METHODS

The current study was part of a double-blinded randomized controlled trial evaluating the augmentation of transcutaneous electrical nerve stimulation (TENS) to a traditional 4-week (12-session) TE program.²⁶ All participants performed the same TE but were randomly allocated to 1 of 3 treatment groups that may have included an additional TENS or sham TENS treatment during the TE and 8 hours each day when physically active (TENS + TE [$n = 12$], sham TENS + TE [$n = 12$], or TE only [$n = 12$]).²⁶ The SANE_{Function} and WOMAC_{Dysfunction} scores were collected before and after the 4-week TE intervention. Participants removed the TENS or sham TENS before any outcome testing. The Institutional Review Board at the

University of Virginia approved the recruiting methods, consenting process, and experimental procedures used in the current study. Sample size for this study was estimated using G*Power Statistical Power Analysis (version 3.1; Heinrich-Heine-Universität Düsseldorf, Germany).²⁷ Previous researchers¹⁵ reported moderate to strong associations (r range = 0.58–0.87) between the SANE_{Function} and Lysholm scores in patients with ACL injury. Conservatively, we estimated a moderate 2-tailed association would be present between the SANE_{Function} and WOMAC_{Dysfunction} outcomes (r = –0.45) and determined that 36 individuals would be needed to detect a significant association with an α of .05 and $1 - \beta$ equal to 0.8.

Participants

Potential participants were recruited from the university community and from participating orthopaedic surgeons within the University Health System. The inclusion criteria for the current study were consistent with the criteria used to enroll patients in the aforementioned randomized controlled trial.²⁶ All participants had a clinical diagnosis of tibiofemoral OA in at least 1 knee and a Kellgren-Lawrence score between 1 and 4 as assessed with bilateral radiographs obtained within the previous 6 months. Additionally, all participants demonstrated a voluntary quadriceps activation of less than 90%,²⁸ which was assessed isometrically at 70° of knee flexion using the burst-superimposition technique.^{26,29} We excluded individuals with a diagnosed heart condition that limited exercise, altered sensation over the anterior knee region, bilateral total knee arthroplasties, or lower body surgery or knee trauma in the previous 6 months. Participants with unilateral knee OA and contralateral total knee arthroplasty were included in the study, but these participants only received targeted TE, TENS, or sham TENS to the limb with knee OA and not to the limb with the total knee arthroplasty. A mandatory 2-week washout period, determined from previously published half-life data, was implemented for all participants who previously had a corticosteroid³⁰ or hyaluronic acid injection.³¹ Participants were asked to not use nonessential pain medication 12 hours before therapy sessions and 24 hours before all testing sessions. Written consent was obtained from the participants before testing.

Self-Reported Disability Evaluations

We used the SANE^{21,32} and WOMAC Index¹⁰ scores, which are reliable measures of self-reported function in people with knee injuries or knee OA, respectively. A single investigator (B.P.) provided instructions to each participant on how to complete each outcome measure and explained the differences among rating pain, stiffness, and function for the entire WOMAC index. Participants completed all 3 WOMAC Index subsections (pain, stiffness, and function). The 17-question WOMAC_{Dysfunction} subsection, in which participants were instructed to rate the degree of difficulty they experienced while performing various activities of daily living, was the primary WOMAC outcome measure for the current study. The WOMAC_{Dysfunction} subsection has strong reliability (interclass correlation coefficient = 0.90) in patients who demonstrated arthroscopically

confirmed knee OA.¹² We chose the WOMAC_{Dysfunction} subsection as our main WOMAC outcome measure because we believed that it aligned most clearly with the information that the SANE_{Function} score sought to capture. For each question, participants indicated their disability as *none*, *slight*, *moderate*, *severe*, or *extreme*, which corresponded to scores between 0 and 4, respectively. The WOMAC_{Dysfunction} was scored between 0 and 68, with a 68 indicating the most physical dysfunction among the examined tasks. Participants completed all 3 traditional WOMAC Index subsections (pain, stiffness, and function). We included 2 additional WOMAC pain questions that assessed pain using the same WOMAC Likert scale and asked, “Please describe the level of pain you have experienced in the last 48 hours for each one of your knees” for both the left and right knees; the WOMAC pain subsection value for the current study was then calculated from a total of 28 possible points (0 = *least pain* and 28 = *most pain*). All participants indicated the level of pain in each knee regardless of the presence or severity of bilateral radiographic knee OA. The WOMAC_{Stiffness} subsection included 2 questions for a total of 8 possible points (0 = *least stiffness* and 8 = *most stiffness*). In addition, we included a variable that analyzed all 3 subsections of the WOMAC score together (WOMAC_{Aggregate} score). We individually normalized each participant’s raw score out of 100% or the total possible points in each WOMAC subsection ([raw score for the participant / total possible score] · 100). The SANE_{Function} was completed after finishing the entire WOMAC Index. Participants were asked, “On a scale of 0 to 100, how would you rate your knee’s function, with 100 being normal?” and instructed to write the number on a piece of paper. When completing the 4-week assessment for both outcomes, participants were not allowed to know their baseline SANE_{Function} or WOMAC_{Dysfunction} score. Percentage change scores over the 4-week intervention period were calculated for the SANE_{Function} score as well as for the WOMAC subsections using the following equation (Percentage change = [(4-week value – baseline value) / baseline value] · 100).

Therapeutic Exercise Intervention

Over a 28-day period, all participants completed 12 sessions of TE supervised by a licensed physical therapist or a certified athletic trainer.²⁶ Exercises focused on improving quadriceps muscle strength, as quadriceps strength is associated with disability in people with knee OA. We used the daily adjustable progressive resistive exercise system³³ to systematically advance open and closed chain strengthening exercises throughout the 28-day intervention as previously described.²⁶ In addition to strengthening exercises, participants performed balance exercises and gait training during each session. Flexibility limitations were individually managed with stretching, and muscle or joint soreness was managed with cryotherapy.

Statistical Analyses

Means and standard deviations were computed for demographics and outcome measures (Table). Frequencies and percentages were calculated for sex and the Kellgren-

Table. Demographics and Mean Outcome Measures

Measure	All Participants, N = 36		With Outliers Removed, n = 33	
	15 Men, 21 Women		14 Men, 19 Women	
	Mean ± SD			
Sex				
Age, y	59.89 ± 11.59		59.58 ± 11.78	
Height, cm	171.18 ± 9.17		171.78 ± 9.22	
Mass, kg	84.28 ± 18.71		85.97 ± 18.57	
SANE _{Function}				
Baseline	57.11 ± 18.53		60.03 ± 16.00	
4 wk	78.22 ± 17.84		77.03 ± 18.09	
WOMAC _{Dysfunction} (out of 100%)				
Baseline	43.89 ± 14.35		42.99 ± 13.29	
4 wk	48.72 ± 12.45		49.72 ± 12.43	
Change (out of 100%)				
SANE _{Dysfunction}	61.66 ± 128.42		32.19 ± 29.59	
WOMAC _{Dysfunction}	-16.97 ± 28.77		-19.69 ± 24.97	
WOMAC _{Stiffness}	-25.66 ± 23.11		-24.21 ± 22.66	
WOMAC _{Pain}	-32.32 ± 10.29		-15.36 ± 24.96	
WOMAC _{Aggregate}	-16.90 ± 14.38		-14.01 ± 10.41	
	No. (%)			
Kellgren-Lawrence score (%)				
1	2 (5.6)		1 (3)	
2	9 (25)		9 (27.3)	
3	12 (33.3)		10 (30.3)	
4	13 (36.1)		13 (39.4)	

Abbreviations: SANE, Single Assessment Numeric Evaluation; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

Lawrence score of radiographic OA severity (Table). Before conducting the primary analyses, we assessed normality of the SANE_{Function} at baseline and at the 4-week time point, WOMAC_{Dysfunction} and WOMAC_{Aggregate} scores at baseline and 4 weeks, and percentage change in SANE_{Function}, WOMAC_{Dysfunction}, and WOMAC_{Aggregate} over 4 weeks using separate Shapiro-Wilk tests. Spearman (r_s) rank order correlations were used to evaluate all associations because at least 1 nonnormally distributed variable was included in all analyses. We separately evaluated the bivariate associations between SANE_{Function} and both WOMAC_{Dysfunction} and WOMAC_{Aggregate} scores at the baseline and the 4-week time points. Next, we determined the bivariate associations between the changes in SANE_{Function}, WOMAC_{Dysfunction}, and WOMAC_{Aggregate} over the 4-week intervention period. The α level was set a priori at .05 for all analyses. To assess agreement, or if the SANE_{Function} provided identical results to the WOMAC_{Dysfunction} and WOMAC_{Aggregate} scores, we calculated the Lin concordance correlation coefficient (R_c) and corresponding 95% confidence intervals (CIs).³⁴ The definitions regarding the strength of the R_c are arbitrary, with 1.00 representing *full agreement* and 0 representing *no agreement*. Therefore, we chose to classify the strength of all associations and agreement statistics for the current study as *negligible* (0.0–0.3), *weak* (0.31–0.5), *moderate* (0.51–0.7), *high* (0.71–0.9), or *very high* (0.9–1.0).³⁵ The Statistical Package for the Social Sciences (version 19.0; IBM Corp, Armonk, NY) was used to assess all bivariate associations.

RESULTS

All initial associations reflected a total of 36 participants with knee OA (Table). Three participants (8.3%) reported a unilateral total knee arthroplasty. We found baseline SANE_{Function} ($W = 0.94$; $P = .05$) and WOMAC_{Aggregate}

scores ($W = 0.84$; $P > .001$), as well as 4-week SANE_{Function} ($W = 0.97$; $P = .001$), 4-week WOMAC_{Dysfunction} ($W = 0.92$; $P = .01$), 4-week WOMAC_{Aggregate} ($W = 0.93$; $P = .03$) scores, and change in SANE_{Function} score ($W = 0.33$; $P < .001$) to be nonnormally distributed; therefore, Spearman rank order correlations were used for all analyses. Participants with a higher SANE_{Function} score demonstrated a lower WOMAC_{Dysfunction} score (weak association: $r_s = -0.44$, $P = .007$; Figure 1) and a lower WOMAC_{Aggregate} score (weak association: $r_s = -0.46$, $P = .005$) at baseline. Similarly, participants with a higher SANE_{Function} score demonstrated a lower WOMAC_{Dysfunction} score (moderate association: $r_s = -0.69$, $P < .001$; Figure 2) and a lower WOMAC_{Aggregate} score (moderate association: $r_s = -0.65$, $P < .001$) at the 4-

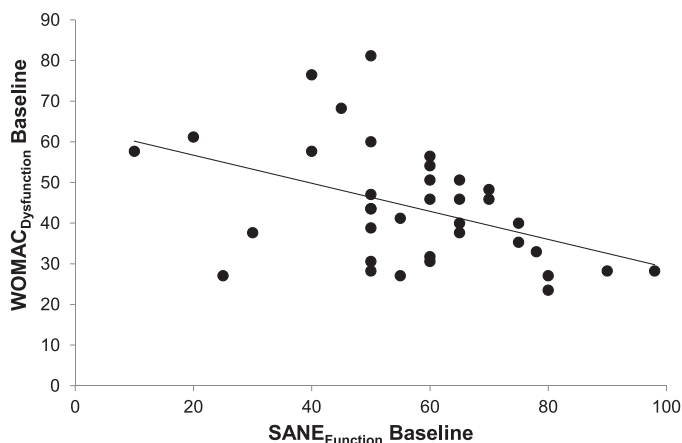


Figure 1. Association between SANE_{Function} and WOMAC_{Dysfunction} scores at baseline. Participants with a higher SANE_{Function} score demonstrated a lower WOMAC_{Dysfunction} score ($\rho = -0.44$, $P = .007$). Abbreviations: SANE, Single Assessment Numeric Evaluation; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

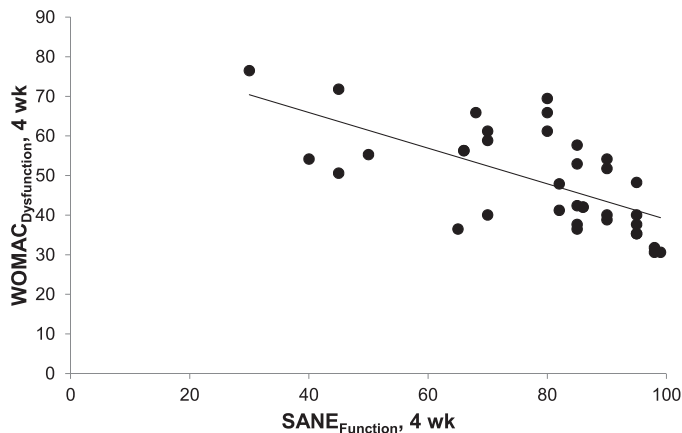


Figure 2. Association between $SANE_{Function}$ and $WOMAC_{Dysfunction}$ scores at the 4-week follow-up. Participants with a higher $SANE_{Function}$ score demonstrated a lower $WOMAC_{Dysfunction}$ score ($\rho = -0.69$, $P < .001$). Abbreviations: SANE, Single Assessment Numeric Evaluation; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

week time point (Figure 2). A non-statistically significant and weak association was present between the change in $SANE_{Function}$ score and the changes in $WOMAC_{Dysfunction}$ (negligible association: $r_s = -0.17$, $P < .43$; Figure 3) and $WOMAC_{Aggregate}$ (negligible association: $r_s = -0.26$, $P < .13$) scores over the 4 weeks of the TE intervention when all participants were considered. After removal of 3 potential outliers who demonstrated a change in $SANE_{Function}$ score of $>130\%$ (visible to the right of the scatterplot in Figure 3), we did not identify an increase in the overall strength of the association between the change in $SANE_{Function}$ and the changes in $WOMAC_{Dysfunction}$ ($n = 33$; negligible association: $r_s = -0.21$, $P < .24$; Table, Figure 4) scores or $WOMAC_{Aggregate}$ ($n = 33$; negligible association: $r_s = -0.19$, $P < .30$) scores over the 4 weeks of the TE intervention. For the entire cohort, agreement was weak between the $SANE_{Function}$ and $WOMAC_{Dysfunction}$ scores ($Rc = -0.32$; 95% CI = $-0.54, 0.07$), as well as between the $SANE_{Function}$ and $WOMAC_{Aggregate}$ scores ($Rc = -0.45$; 95% CI = $-0.68, 0.16$) at baseline. We found negligible agreement between the $SANE_{Function}$ and $WOMAC_{Dysfunction}$ scores ($Rc = -0.21$; 95% CI = $-0.34, -0.07$), as well as between the $SANE_{Function}$ and $WOMAC_{Aggregate}$ scores ($Rc = -0.12$; 95% CI = $-0.20, -0.04$) at the 4-week time point. There was negligible agreement between the change in the $SANE_{Function}$ score before and after removal of the outliers, respectively, for the changes in the $WOMAC_{Dysfunction}$ ($n = 36$; $Rc = -0.11$; 95% CI = $-0.23, -0.01$; $n = 33$; $Rc = -0.19$; 95% CI = $-0.47, -0.13$) and $WOMAC_{Aggregate}$ ($n = 36$; $Rc = -0.001$; 95% CI = $-0.001, 0.00$; $n = 33$; $Rc = -0.00$; 95% CI = $-0.002, 0.001$) scores.

Post Hoc Analyses

The post hoc analyses were conducted without the 3 outliers who demonstrated changes in the $SANE_{Function}$ score of $>130\%$. An increase in $SANE_{Function}$ score was significantly but weakly associated with a decrease in $WOMAC_{Pain}$ score ($r_s = -0.36$, $P = .04$) and nonsignificantly weakly associated with a decrease in $WOMAC_{Stiffness}$ score ($r_s = -0.3$, $P = .1$) over the 4-week TE intervention period.

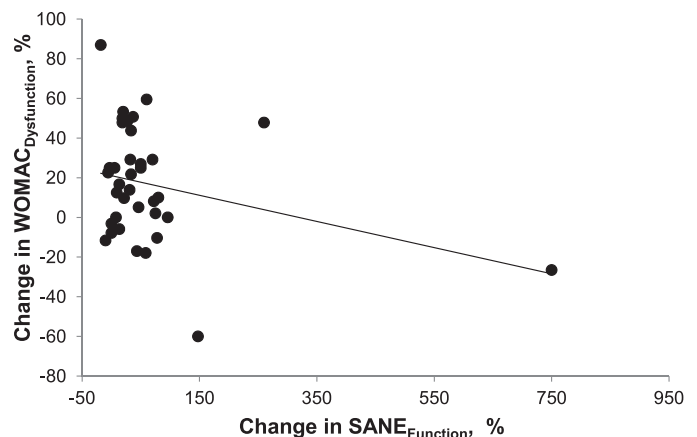


Figure 3. Association between percentage changes in $SANE_{Function}$ and $WOMAC_{Dysfunction}$ scores after the 4-week therapeutic exercise intervention (all participants). There was a nonsignificant and weak association between the changes in the $SANE_{Function}$ and $WOMAC_{Dysfunction}$ scores over the 4 weeks of therapeutic exercise ($\rho = -0.17$, $P < .43$) among all participants. Abbreviations: SANE, Single Assessment Numeric Evaluation; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

DISCUSSION

The main findings of our study were that $SANE_{Function}$ and lesser $WOMAC_{Dysfunction}$ scores demonstrated moderate and weak associations, respectively, before and immediately after a 4-week TE program in individuals with knee OA (Figures 1 and 2). Similar weak and moderate associations, respectively, were evident between the $SANE_{Function}$ and $WOMAC_{Aggregate}$ scores before and immediately after a 4-week TE program suggesting that the $SANE_{Function}$ score had a comparable association with $WOMAC_{Aggregate}$ and $WOMAC_{Dysfunction}$ scores. The negative direction of the association between the

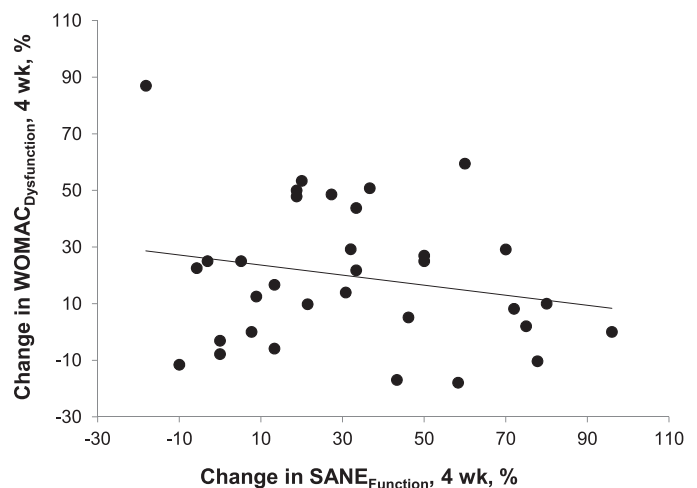


Figure 4. Association between percentage changes in $SANE_{Function}$ and $WOMAC_{Dysfunction}$ scores after the 4-week therapeutic exercise intervention (outliers removed). After removal of 3 potential outliers who demonstrated a change in $SANE_{Function}$ score of $>130\%$, the overall strength of the association between the changes in $SANE_{Function}$ and $WOMAC_{Dysfunction}$ scores did not increase over the 4 weeks of therapeutic exercise in the remaining 33 participants ($P < .24$). Abbreviations: SANE, Single Assessment Numeric Evaluation; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

SANE_{Function} and WOMAC_{Dysfunction} scores reflects the nature of the 2 instruments. A score of 100% on the SANE_{Function} indicates the best possible participant function, whereas a normalized 100% on the WOMAC_{Dysfunction} demonstrates the worst possible function. It is interesting that a decrease in the WOMAC_{Dysfunction} score over the 4-week TE intervention was not associated with an increase in the SANE_{Function} score in the same participants. We found a weak association between a decrease in WOMAC_{Pain} score and an increase in SANE_{Function} score over the 4 weeks, suggesting that a change in the SANE_{Function} score may be influenced by a change in pain when performing activities that compose the WOMAC_{Dysfunction} score. It is possible that a change in overall function, as measured by the SANE_{Function} score, was influenced to some extent by a change in pain after a TE intervention. A change in the WOMAC_{Stiffness} score did not significantly influence the SANE_{Function} score. Additionally, we observed only negligible to weak agreement between SANE_{Function} and WOMAC_{Dysfunction} scores before and immediately after a 4-week TE program, as well as negligible agreement for the change in SANE_{Function} and WOMAC_{Dysfunction} scores over the same time, further indicating that information gleaned from these 2 PROs was not interchangeable.

In our study, the magnitudes of the associations between SANE_{Function} and WOMAC_{Dysfunction} scores in individuals with knee OA were smaller than those shown previously between the SANE and other PROs, such as the Lysholm score¹⁵ and the IKDC Index,²¹ that have been assessed in patients with acute knee injury or surgery. The strength of the association at the 4-week time point ($r_s = -0.69$) in our participants with knee OA was similar to associations between the SANE and IKDC scores at 12 months after knee injury ($r = 0.65$)²¹ as well as between the SANE and Lysholm scores at 24 months after ACL reconstruction ($r = 0.65$).¹⁵ Although the SANE_{Function} has not previously been compared with other PROs in patients with knee OA, the 4-week associations are consistent with those between the SANE and PROs in patients who may demonstrate persistent or chronic disability at 12 months and 24 months after acute knee injury.^{15,21}

Contrary to our hypothesis, an improvement in SANE_{Function} was not associated with a decrease in WOMAC_{Dysfunction} (Figures 3 and 4). Additionally, an improvement in SANE_{Function} was only weakly associated with a decrease in WOMAC_{Pain} ($r_s = -0.36$) or WOMAC_{Stiffness} ($r_s = -0.30$). Therefore, even though the SANE_{Function} score may be a reliable measure of self-reported function, individuals may express a change in overall function (SANE_{Function} score) differently than a change in dysfunction based on specific activities of daily living as measured by the WOMAC_{Dysfunction} score. On average, after the outliers were removed, participants in our study demonstrated greater changes in the SANE_{Function} score than in the WOMAC_{Dysfunction} score (Table). We cannot conclude from our analyses that the change in function evaluated with the SANE_{Function} score was systematically overestimated compared with the WOMAC_{Dysfunction} score. Yet our data suggest that individuals with knee OA described a change in function differently if they were asked a single global question (SANE_{Function}) compared with a series of questions

related to tasks that typically cause pain in patients with knee OA (WOMAC_{Dysfunction}). Individuals may experience significant disability during many of the activities that are included in the WOMAC_{Dysfunction} and therefore decrease their exposure to these activities during daily life. It is possible that the improvements individuals demonstrate in the SANE_{Function} may be specific to a limited number of activities they continue to pursue in daily life. Subsequently, individuals may continue to indicate high levels of disability when specifically asked on the WOMAC about activities they may not have pursued recently due to a previous history of dysfunction.

Furthermore, we were unable to discern whether the SANE_{Function} or WOMAC_{Dysfunction} score was a more valid measure of the change in overall patient-reported function. Our analysis was meant to evaluate if these instruments were related before and after a 4-week TE intervention and if the self-reported response to the TE intervention could be measured similarly with both instruments. Compared with the WOMAC_{Dysfunction} score, the SANE_{Function} score is less burdensome for the patient to complete and for the clinician to administer. Therefore, a strong association between the SANE_{Function} and WOMAC_{Dysfunction} scores would have provided evidence to clinicians that the former could be used to evaluate similar information about physical function and disability as traditionally assessed with the latter. However, our study suggests that the SANE_{Function} and the WOMAC_{Dysfunction} cannot be used interchangeably to evaluate the self-reported functional capacity of individuals with knee OA. Our data indicate that these 2 measures may be assessing different aspects of self-reported disability or that the SANE_{Function} may not be a valid measure of self-reported disability in individuals with knee OA. Yet whether a change in the SANE_{Function} score can be useful for predicting other important outcomes related to knee OA remains unknown. For example, we did not determine whether a change in the SANE_{Function} or WOMAC_{Dysfunction} score is better able to identify the level of patient satisfaction with the intervention, tolerability of the intervention, knee-related confidence, or likelihood of requiring knee arthroplasty.³⁶

Given the study design, we were unable to determine if clinicians should administer the SANE_{Function}. We can conclude only that the SANE_{Function} is not measuring aspects of self-reported function similar to those measured by the WOMAC_{Dysfunction}. We were also unable to determine if a change in either of these PROs (SANE_{Function} or WOMAC_{Dysfunction}) was associated with a change in the physiological progression of OA. Further, the SANE_{Function} does not allow a clinician to determine which activities cause the most disability to the patient or, in the case of a change in SANE_{Function} score, which activities caused an overall change in patient function after an intervention. Therefore, due to the nature of the SANE_{Function}, clinicians may need to follow up with additional questions to fully understand the cause of self-reported disability. It is possible that the order of testing influenced the results of our study, as the WOMAC scores were collected before the SANE score in all participants. Although a potential order bias was consistent at baseline and the 4-week posttest, thereby affecting the change scores equally, future investigators should randomize the order of testing in case

completing 1 PRO influences how participants respond to questions on another PRO. Our study did not exclude participants based on level of patient-reported functionality at the beginning of the study, which is evident from our large range for both the SANE_{Function} (range = 10%–98%) and WOMAC_{Dysfunction} (range = 23.53%–81.18%) scores at baseline. It is possible that SANE_{Function} and WOMAC_{Dysfunction} scores may be associated differently based on the magnitude of functionality in patients with knee OA. We tested a relatively small sample of individuals (N = 36). Future researchers should evaluate larger samples to assess the utility of the SANE_{Function} in different subsets of individuals with knee OA based on level of patient-reported functionality or radiographic knee OA severity. The current study was part of a project that assessed the ability of conventional strength training and TENS to improve muscle function compared with sham TENS with conventional strength training and conventional strength training alone³⁷; we did not find differences in the WOMAC Index or WOMAC subscales between groups³⁷ and, therefore, evaluated all participants together in this study. We lacked a large enough sample to identify differences in associations among patients who underwent specific interventions, yet it is possible that participants whose function improved more over the 4-week intervention would demonstrate different associations between the SANE and WOMAC scores compared with those who had less improvement. Further research is necessary to determine the utility of the SANE_{Function} in the clinical setting for patients with knee OA.

In conclusion, we found that the SANE_{Function} and WOMAC_{Dysfunction} scores demonstrated moderate and low associations, respectively, before and immediately after a 4-week TE program in individuals with knee OA. Changes in the SANE_{Function} and WOMAC_{Dysfunction} scores over the 4-week TE intervention period were not associated. Agreement was negligible to weak between the SANE_{Function} and WOMAC_{Dysfunction} scores, respectively, before and immediately after a 4-week TE program, as well as negligible for the change in SANE_{Function} and WOMAC_{Dysfunction} scores over the 4-week TE program. Therefore, the SANE_{Function} and WOMAC_{Dysfunction} should not be used interchangeably to determine a therapeutic response to an intervention.

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