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Cameron J. Powden

Matthew C. Hoch

Beth E. Jamali
Old Dominion University, bjamali@odu.edu

Johanna M. Hoch

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Cameron J. Powden, PhD, LAT, ATC*; Matthew C. Hoch, PhD, ATC†; Beth E. Jamali, PhD, PT‡; Johanna M. Hoch, PhD, ATC†

*Department of Applied Medicine and Rehabilitation, Indiana State University, Terre Haute; †Division of Athletic Training, University of Kentucky, Lexington; ‡Athletic Training and Physical Therapy, Old Dominion University, Norfolk, VA

Context: The accurate evaluation of self-reported changes in function throughout the rehabilitation process is important for determining patient progression. Currently, how a response shift (RS) may affect the accuracy of self-reported functional assessment in a population with chronic ankle instability (CAI) is unknown.

Objective: To examine the RS in individuals with CAI after a 4-week multimodal rehabilitation program.

Design: Controlled laboratory study.

Setting: Laboratory.

Patients or Other Participants: Twenty adults (5 men, 15 women; age = 24.35 ± 6.95 years, height = 169.29 ± 10.10 cm, mass = 70.58 ± 12.90 kg) with self-reported CAI participated. Inclusion criteria were at least 1 previous ankle sprain, at least 2 episodes of the ankle "giving way" in the 3 months before the study, and a score ≤24 on the Cumberland Ankle Instability Tool.

Intervention(s): Individuals participated in 12 intervention sessions over 4 weeks and daily home ankle strengthening and stretching.

Main Outcome Measure(s): Patient-reported outcomes (PROs) were assessed at 4 times (baseline, preintervention, postintervention, and 2-week follow-up). At the postintervention and 2-week follow-up, participants completed then-test assessments to measure RS. Then-test assessments are retrospective evaluations of perceived baseline function completed after an intervention. The PROs consisted of the Foot and Ankle Ability Measure-Activities of Daily Living and Sport subscales, the modified Disablement in the Physically Active scale physical and mental summary components, and the Fear-Avoidance Beliefs Questionnaire Physical Activity and Work subscales. We used repeated-measures analyses of variance to compare preintervention with then-test measurements. Individual-level RSs were examined by determining the number of participants who experienced preintervention to then-test differences that exceeded the calculated minimal detectable change.

Results: We did not identify an RS for any PRO ($F > 2.338$, $P > .12$), indicating no group-level differences between the preintervention and retrospective then-test assessments. Individual-level RS was most prominent in the Foot and Ankle Ability Measure-Sport subscale (n = 6, 30%) and the Fear-Avoidance Beliefs Questionnaire Physical Activity subscale (n = 9, 45%).

Conclusions: No group-level RS was identified for any PRO after a 4-week multimodal rehabilitation program in individuals with CAI. This finding indicates that traditional assessment of self-reported function was accurate for evaluating the short-term effects of rehabilitation in those with CAI. Low levels of individual-level RS were identified.

Key Words: health-related quality of life, injury-related fear, patient-reported outcomes, rehabilitation


Key Points
- Individuals with chronic ankle instability who participated in a 4-week multimodal rehabilitation program did not experience a group-level response shift, as indicated by similar preintervention and retrospective preintervention evaluations.
- Individual-level response shifts occurred in a group of participants and may affect measurement evaluation.
- Traditional preintervention-to-postintervention testing methods provided an accurate evaluation of the treatment effects after conservative treatment for those with chronic ankle instability.

C hronic ankle instability (CAI) is a condition characterized by residual symptoms, recurrent ankle sprains, and repeated episodes of the ankle "giving way" during functional activities.[1] The repetitive trauma that accompanies CAI is believed to contribute to long-term consequences, such as ankle osteoarthritis[2] and reduced physical activity.[3] Traditionally, CAI investigations have focused on identifying mechanical and sensorimotor deficits from a disease-oriented perspective, such as dorsiflexion range-of-motion restrictions[4] and postural-control impairments.[5] However, the emergence of evidence-based practice has emphasized the importance of patient-oriented evidence that evaluates the effect of a condition or treatment on health status from the patient's perspective. This, coupled with the directive from the International Ankle Consortium[6] to include patient-reported outcomes (PROs) in CAI research, has led to an increased number of studies that incorporate these instruments.

Within clinical practice, accurately determining patient changes using PROs is vital for evaluating patient
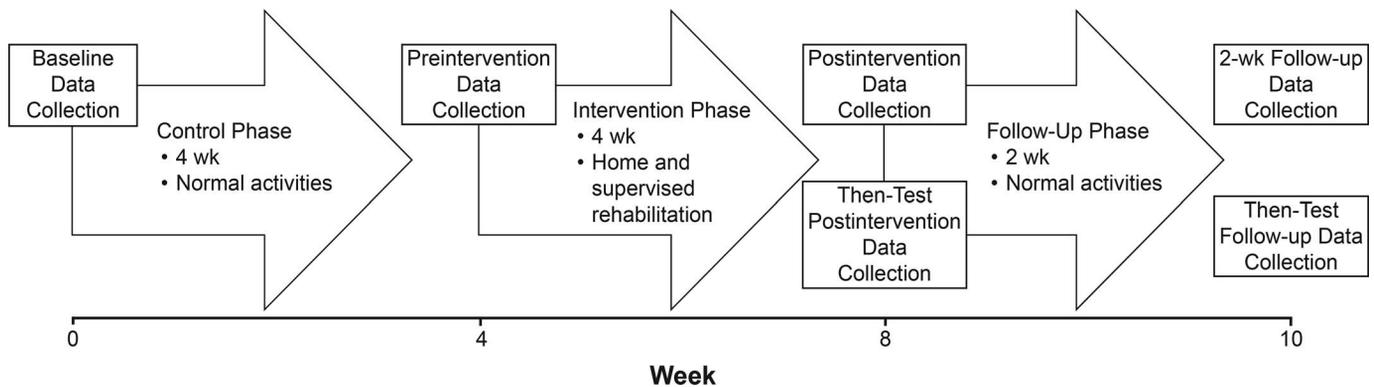
Figure 1. Study timeline representing the 4 data-collection sessions (baseline, preintervention, postintervention, 2-week follow-up), then-test assessments (then-test postintervention, then-test follow-up), and phases of the intervention (control, intervention, follow-up).

progression and making subsequent clinical decisions.[7] Given the subjective nature of the information captured by PROs, researchers have assumed that the intraindividual standards remain stable throughout rehabilitation for measuring true change in these concepts.[8,9] However, this may not be a correct assumption, as patient values can vary as they reconceptualize their conditions during the disease or rehabilitation process.[8,9] This reconceptualization is known as *response shift* (RS) and can alter the manifestation of perceived health-related quality of life (HRQOL).[9] Response shift is a phenomenon by which an individual's self-evaluation of a construct changes due to a change in the internal standards of measurement (scale recalibration), a change in values or priorities (reprioritization), or a personal redefinition of the target construct (reconceptualization) or a combination of these.[8,9] Consequently, an RS may interfere with the ability to accurately detect change in a construct or PRO, leading to improper clinical decisions if encountered during the treatment process.

Traditionally, RS has been observed in individuals with chronic, life-threatening conditions whose physical health deteriorates but whose self-reported HRQOL remains stable.[10] More recently, RS has gained attention as a possible phenomenon[11] after rotator cuff repair,[12] autologous chondrocyte implantation,[13] total knee arthroplasty,[14–16] knee microfracture,[17] lumbar spinal decompression surgery,[18] and unspecified rehabilitation for chronic low back pain,[19] all treatments for chronic musculoskeletal conditions. Response shifts in these populations can potentially affect the evaluation of the rehabilitation process and clinical decision making and lead to the underestimation or overestimation of patient change after treatment. Subsequently, inaccurate assessments of patient change could lead to improper progression, continuation, or cessation of a treatment course.

Individuals with CAI may follow a trend similar to that of patients with chronic low back pain[19] after conservative rehabilitation. Like chronic low back pain, CAI is a condition associated with prolonged modifications in physical activity to avoid reinjury.[3,20] Therefore, if individuals with CAI reconceptualize their health by avoiding activities that promote giving way or have instigated previous ankle sprains, this may affect subsequent treatment decisions and negatively affect rehabilitation progression. Therefore, the purpose of our study was to evaluate the RS phenomenon among individuals with CAI after a 4-week rehabilitation program. We hypothesized that RS would occur and would indicate that detriments in HRQOL may be underestimated in individuals with CAI before rehabilitation.

METHODS

Design

In this controlled laboratory study, all participants completed 4 data-collection sessions (baseline, preintervention, postintervention, and 2-week follow-up) at which PROs were collected and a 4-week intervention (Figure 1). The 4-week intervention consisted of 12 supervised sessions and a daily home-exercise protocol. The PROs were collected traditionally: perceived function was evaluated at the time of PRO completion and with the *then-test method*, which is a retrospective evaluation of perceived function before the intervention that is completed after the intervention. The independent variables were time (baseline, preintervention, postintervention, 2-week follow-up) and PRO administration (traditional, then test). The dependent variables were PRO scores.

Participants

Participants were part of a larger study and have been described in another article.[21]

Procedures

Testing procedures from baseline to the postintervention data-collection session were described in another study.[21] For the period between the postintervention and 2-week follow-up data-collection sessions, participants were instructed to cease all interventions (home and supervised) but to maintain their normal activities of daily living. During each data-collection session, traditional PRO administration was conducted in a counterbalanced order using a Latin square. This order was maintained across all data-collection sessions for each participant. During the last 2 data-collection sessions (postintervention, 2-week follow-up), the then-test PRO was also administered (then-test postintervention, then-test follow-up; Figure 1). The order of traditional and then-test PRO assessment was counterbalanced. All data-collection sessions were conducted by 1 athletic trainer (AT) with 5 years of experience (C.J.P.) who did not have access to previous data during these sessions.

Table 1. Preintervention and Then-Test Assessments (Mean ± SD), Cronbach α, and Minimal Detectable Change[a]

Assessment	Preintervention	Then-Test Postintervention	Then-Test Follow-Up	Preintervention to Then-Test Postintervention	Preintervention to Then-Test Follow-Up	Cronbach α	Minimal Detectable Change
				Response Shift			
Foot and Ankle Ability Measure, %							
Activities of Daily Living subscale	88.63 ± 8.07	86.79 ± 9.66	86.37 ± 9.90	1.85 ± 4.29	2.26 ± 5.32	0.890	5.22
Sport subscale	80.16 ± 10.2	77.97 ± 13.47	76.41 ± 12.88	2.19 ± 8.05	3.75 ± 7.28	0.847	7.99
Modified Disablement in the Physically Active scale							
Physical summary component	13.25 ± 7.75	14.80 ± 8.63	16.45 ± 8.44	−1.55 ± 6.09	−3.20 ± 5.72	0.594	8.05
Mental summary component	2.30 ± 2.62	2.25 ± 2.83	2.30 ± 3.39	0.05 ± 1.32	0.00 ± 2.41	0.667	2.74
Fear-Avoidance Beliefs Questionnaire							
Physical Activity subscale	12.60 ± 4.22	11.50 ± 5.22	10.80 ± 5.31	1.10 ± 4.79	1.80 ± 5.00	0.662	3.89
Work subscale	5.20 ± 6.81	5.00 ± 5.59	6.35 ± 6.54	0.20 ± 5.18	−1.15 ± 6.38	0.704	6.69

[a] Adapted with permission. Powden CJ, Hoch JM, Jamali BE, Hoch MC. A 4-week multimodal intervention for individuals with chronic ankle instability: examination of disease-oriented and patient-oriented outcomes. *J Athl Train*. 2019;54(4):384–396.

Patient-Reported Outcomes

Given the multidimensional profile of self-reported functional deficits in the CAI population,[20] we included ankle-specific, global, and dimension-specific measures.[21] Specifically, the Foot and Ankle Ability Measure–Activities of Daily Living and Foot and Ankle Ability Measure–Sport (FAAM-Sport) subscales,[22] the modified Disablement in the Physically Active scale physical and mental summary components,[23] and the Fear-Avoidance Beliefs Questionnaire (FABQ) Physical Activity and Work subscales[24] were completed by all participants. Further information, including calculated minimal detectable changes (MDCs) for each PRO, can be found in our previous report.[21]

Assessment of Response Shift

For this investigation, we completed the assessment of RS using the then-test method.[13] This approach supplemented traditional preassessment-to-postassessment comparison with a then-test assessment at the same time as the postintervention assessment. For the then-test assessment, participants completed PROs to retrospectively assess their function at preintervention before the intervention ended. During this assessment, participants were instructed to complete the PROs based on how they perceived their function before the intervention.[25] The reason for having patients complete the then-test and traditional postintervention assessments at the same time is that the same frame of reference and standards can be used for both. This would control for shifts in construct interpretation that might develop due to the rehabilitation process.[25] Response shift is calculated as the difference between the then-test and preintervention assessments. It evaluates the potential change in preintervention self-perceived function due to a change in internal standards after an intervention.[25]

Intervention

Details of the 4-week supervised and home exercise program have been reported.[21] In brief, participants completed a home intervention comprising gastrocnemius-soleus complex stretching and ankle strengthening and a 12-session supervised component comprising ankle strengthening, balance training, and joint mobilizations. We based all components of both interventions on established rehabilitation programs for patients with CAI.[26–28] During the supervised interventions, participants were reminded of the home-intervention procedures, and additional patient education was provided if needed. Interventions and instructions were executed by ATs with a minimum of 5 years of clinical experience (C.J.P., M.C.H., and an AT who was not an author). Before the study, the lead investigator conducted a training session to promote treatment consistency among clinicians.

Statistical Analysis

Our method for addressing missing PRO items was described in another study.[21] The possible presence of an RS (preintervention, then-test postintervention, then-test follow-up) was evaluated using separate 1-way analyses of variance for each PRO. Sidak post hoc comparisons were performed when we found main effects or interactions. The α was set a priori for all analyses at .05.

Standardized-response mean effect sizes (ESs) and corresponding 95% confidence intervals (CIs) were calculated for each dependent variable to examine the magnitude of difference between the preintervention and then-test scores.[29] A positive ES indicated greater reported disability on the then-tests than noted in the preintervention scores. We interpreted ESs as *weak* (≤0.39), *moderate* (0.40–0.69), or *strong* (≥0.70).[30] Furthermore, Cronbach α values were calculated for each measure to indicate consistency. Lastly, RS was examined at an individual level by assessing preintervention to then-test postintervention and then-test follow-up differences using MDCs calculated from the larger study.[21] We also evaluated the direction of the individual-level RSs: then-test indicating greater disability, less disability, or no difference compared with preintervention.

RESULTS

The mean (± standard deviation), Cronbach α, and MDC for the preintervention and then-test assessments are displayed in Table 1, and the ESs and 95% CIs are displayed in Figure 2. Overall, 0.22% of all PRO data was imputed using regression imputation due to missing items.[21]
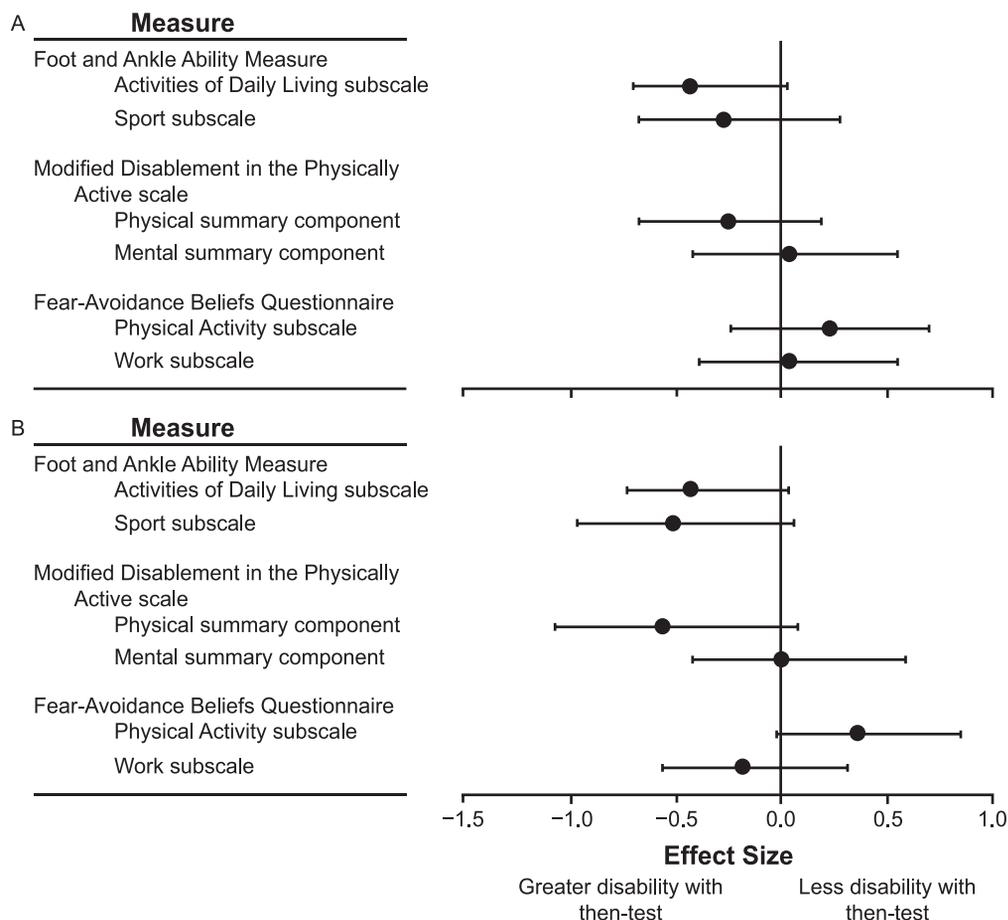
Figure 2. Standardized-response mean effect sizes and 95% confidence intervals. A, Preintervention to then-test postintervention. B, Preintervention to then-test follow-up.

Assessment of Response Shift

When assessing the presence of an RS after the intervention, no differences were detected between preintervention and then-test postintervention or then-test follow-up scores for any PROs (F values > 2.338, P values > .12). These differences did not exceed the MDC[21] (Table 1) and were associated with weak ESs and CIs that crossed zero (Figure 2). The number of participants who had preintervention to then-test postintervention and then-test follow-up changes that exceeded the calculated MDCs is presented in Table 2. The FAAM-Sport subscale had the largest number of participants with individual-level RSs that indicated greater reported disability on the then-test postintervention (n = 5, 25%) and then-test follow-up (n = 5, 25%) evaluations. The FABQ Physical Activity subscale had the largest number of participants with individual-level RSs that indicated less disability on the then-test postintervention (n = 6, 30%) and then-test follow-up (n = 6, 30%) evaluations. Overall, these findings indicated the lack of a meaningful RS or recalibration of the participants' internal standards.

DISCUSSION

We hypothesized that individuals with CAI who participated in a 4-week multimodal rehabilitation program would experience RSs that would result in initially underestimating their HRQOL detriments before rehabili-

tation as determined by then-test assessments associated with greater levels of disability than at preintervention. Our findings did not support this hypothesis, as we observed no differences between preintervention and then-test postintervention or between preintervention and then-test follow-up measures. This indicates that at postintervention, the participants' retrospective assessments of their disabilities before the intervention were similar to their preintervention measurements at the group level. These findings further suggest that after conservative care, patients with CAI did not experience an RS and that traditional preassessment-to-postassessment testing methods provided an accurate evaluation of the treatment effect.

This investigation was one of the first to evaluate the RS phenomenon after a conservative intervention. Nagl and Farin[19] evaluated the effect of RSs in individuals undergoing conservative rehabilitation for low back pain. Whereas their conclusions indicated that an RS in which individuals underestimated their preintervention disability had occurred, these results were associated with weak ESs,[19] suggesting that their identified RS may not have been clinically meaningful. This would support our observations that individuals with CAI did not experience RSs, as we found nonsignificant differences that were associated with weak ESs for all measures. Sprangers and Schwartz[9] proposed that a substantial catalyst is required for an RS to occur. Traditionally, RSs have been identified after surgical interventions, such as knee replacement,[16]

Table 2. Individual-Level Response-Shift Analysis (Rate [%])

Assessment	Preintervention to Then-Test Postintervention			Preintervention to Then-Test Follow-Up		
	Greater Disability With Then-Test	No Difference	Less Disability With Then-Test	Greater Disability With Then-Test	No Difference	Less Disability With Then-Test
Foot and Ankle Ability Measure						
Activities of Daily Living subscale	2 (10)	17 (85)	1 (5)	3 (15)	16 (80)	1 (5)
Sport subscale	5 (25)	14 (70)	1 (5)	5 (25)	14 (70)	1 (5)
Modified Disablement in the Physically Active scale						
Physical summary component	2 (10)	16 (80)	2 (10)	2 (10)	17 (85)	1 (5)
Mental summary component	1 (5)	19 (95)	0 (0)	3 (15)	15 (75)	2 (10)
Fear-Avoidance Beliefs Questionnaire						
Physical Activity subscale	4 (20)	10 (50)	6 (30)	2 (10)	12 (60)	6 (30)
Work subscale	2 (10)	17 (85)	1 (10)	3 (15)	16 (80)	1 (5)

rotator cuff repair,[12] and arthroplasty.[14] Conservative care may not provide a substantial enough catalyst to prime individuals for an RS.[11] As such, our findings support using traditional preassessment-to-postassessment comparison methods to evaluate self-reported function after a conservative intervention for those with CAI. However, this should not be assumed for all treatment courses among patients with CAI. Researchers should evaluate the potential for an RS after surgical intervention, such as lateral ankle repair, among those with CAI.

Individual-level examination of RSs was conducted by determining the number of participants with differences between preintervention and then-test scores that exceeded calculated MDCs.[21] The FAAM-Sport subscale and FABQ Physical Activity subscale scores exhibited the greatest levels of potential individual-level RSs, as an average of 7 (35%) individuals demonstrated differences that exceeded the MDC (Table 2). However, only 5 participants had evidence of RSs on both instruments. Therefore, the RS may be construct specific for an individual patient and not serializable across domains of function and contextual factors. The modified Disablement in the Physically Active scale mental summary component and the FABQ Work subscale scores displayed the lowest levels of potential RS, as the magnitudes of an average of 3 (15%) individuals exceeded the MDC. Furthermore, PROs that demonstrated greater levels of potential individual-level RSs were associated with preintervention-to-postintervention changes.[21] Similarly, PROs that demonstrated lower levels of potential individual-level RSs were associated with a lack of preintervention-to-postintervention changes.[21] In combination, these results may indicate that the potential for RS is greatest in outcome measures that are meaningful to patients and display large amounts of change after an intervention. In addition, 3 (15%) participants at postintervention and 5 (25%) participants at the 2-week follow-up demonstrated RS magnitudes that exceeded the MDC for at least 3 of the 6 PROs. These individual-level findings are similar to those from a previous investigation[13] of RS after autologous chondrocyte implantation that demonstrated individual-level RSs ranging from approximately 20% to approximately 40% of the participants. Furthermore, 17% to 31% of these participants displayed RSs on 3 of the 4 PROs, and the authors[13] did not identify group-level RSs similar to those in our investigation. Lastly, we found that for each PRO, participants exhibited an RS recalibration that demonstrated both an overestimation and underesti-

mation of their preintervention function, which was similar to the results of Howard et al.[13] This incongruence may have contributed to our lack of group-level findings. Ultimately, we did not identify a group-level RS, but we did note low levels of individual RSs. At this time, it is unclear if this level of RS could affect the assessment of patient change in the clinical setting. Further research is needed to explore the effects of potential individual-level RSs on the assessment of patient change and to determine when RS is most likely to occur in populations with a variety of orthopaedic conditions. Innovative and clinician-friendly techniques for assessing individual-level RSs should also be evaluated.

Our investigation had limitations. The major limitations were the lack of a true control group and our relatively short follow-up period of 2 weeks. Time is possibly a factor in evaluating RSs, as many researchers' follow-up periods were 6 to 24 months.[12–15] Participants may need more time to reconceptualize their new level of function, as well as to be exposed to challenging tasks or situations. Also, our participants were not actively seeking care for their ankle conditions at the time of the study, which may have affected their potential for an RS. In previous studies,[13,16,18,19] researchers examining RS have investigated patient groups who were actively seeking health care services in the form of surgery or rehabilitation for their health conditions. Future work is needed to confirm and expand on our findings by including blinding and sham treatments, a longer follow-up period, and participants who are actively seeking treatment. Finally, this study was not powered to observe an RS. Based on our findings, future RS investigations should include between 10 (ES = 0.56) and 51 (ES = 0.23) participants, as indicated by our primary outcomes.

CONCLUSIONS

The results of this research support using traditional preassessment-to-postassessment methods to evaluate the efficacy of conservative treatment for patients with CAI, as no group-level RS was observed. However, some individuals with CAI may demonstrate individual-level RSs. Clinicians may need to develop patient-centered methods of evaluating the potential for RS in their patients when providing individualized care. Not evaluating individual-level RSs in the clinical setting could result in an inaccurate evaluation of patient-reported change during rehabilitation.

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Address correspondence to Cameron J. Powden, PhD, LAT, ATC, Department of Applied Medicine and Rehabilitation, Indiana State University, 567 North 5th Street, Terre Haute, IN 47809. Address e-mail to cameron.powden@indstate.edu.