

Break On Through (To the Digital Side)— JOSPT's Digital Future

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Editor-in-Chief

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Anyone with a web browser can visit the *Journal of Orthopaedic & Sports Physical Therapy* (JOSPT) website (www.jospt.org) and see that the *Journal's* vision is to be the leading international source of knowledge for movement-related health. The JOSPT publishes scientifically rigorous content and promotes application of that content to movement-related health. The purpose of this editorial is to give you a taste of what is to come in 2019 and beyond for #yourJOSPT. To vivify the JOSPT vision and mission statements. To outline the how, when, what, why, and who.

In July 2018, JOSPT readers received an introduction to me as a researcher and clinician.¹ Over the past 12 months, I have been privileged to take a listening and learning tour of the diverse JOSPT community. The tour has been a celebration of orthopaedic and sports practice. I have listened to people sharing their pride in delivering high-quality care to patients and athletes based on clinical research published in the *JOSPT*. Their joy at receiving a fresh copy of the *JOSPT* every month. Their desire for more ways to engage with the important content published in the *Journal*. Their commitment to lifelong learning.

What I have heard from the JOSPT community confirms that now is the right time for JOSPT to advance our digital media offerings. JOSPT is in a strong position because of the editorship of Dr Guy G. Simoneau and Dr J. Haxby Abbott. I thank both

editors for their commitment to JOSPT over the past 17 years. The solid base they have helped establish means we are in good shape to leap into the digital age.

As a beginning clinician, you may have bent your back under the weight of years of knowledge, bound between the hard covers of weighty books, piled high on overflowing desks. Or juggled folders stuffed with reams of paper—relics of the war you waged with the photocopying machine. Just to be sure that you had a copy of every new article and every possible outcome measure.

In 2019, we carry all this information, and more, in our pockets. Exercise programs can be constructed and implemented with a few short screen taps. Outcome measures can be completed and test results reviewed in real time in the clinic. Infographics and podcasts help us efficiently consume and translate the best research into clinical practice. Education is delivered to vast audiences through Massive Online Open Courses (MOOCs). Jobs are sought and won on Twitter.

Do not fear this new age; embrace it! Here are 3 ways that JOSPT is embracing multimedia to add value for our community:

1. Growing our digital media footprint with a JOSPT blog and podcast
2. Creating infographics to help translate research to practice
3. Developing an education platform to deliver high-quality, interactive, clinical case-based continuing education content

In 2020, visitors to the JOSPT website will find a newly redesigned and more interactive platform, focused on helping you translate the great physical therapy-related research we publish into your practice. The revamped website is central to our intention to continue to publish quality research that makes a difference in clinical practice, while building capacity for JOSPT leadership in the key strategic areas of knowledge translation, patient-public partnership, and education.

I am most grateful for the service of the JOSPT Editorial Board, decisively led by our 4 Editors Dr Joshua Cleland, Dr Bryan Heiderscheit, Dr Steven Kamper, and Dr Karin Silbernagel. I am also excited to welcome new members to the team. Dr Christopher Hughes will lead the Education portfolio, Mr Paul Blazey

[EDITOR'S NOTE]

will head up the Engagement portfolio, and Ms Joletta Belton will guide us on patient partnerships in research. Dr Natalia Bittencourt, Dr Hege Grindem, Dr Rachel Jermann, Dr Benjamin Keeton, Dr Martin Mackey, Dr Daniel Pinto, and Dr Kris Porter join the team as Associate Editors. Welcome!

Our team hopes to enlist the support of all those who want to contribute to making JOSPT the premier source of clinically relevant print and digital content for the orthopaedic and sports community.

There are at least 6 ways you can connect with and contribute to the *JOSPT*:

1. Follow our social media channels (@JOSPT on Twitter and @JOSPTofficial on Facebook)
2. Follow the hashtags #yourJOSPT, #globalPT, #sportsPT
3. Send me an e-mail (clare.ardern@ki.se)
4. Talk with me in person (eg, at the Third World Congress of Sports Physical Therapy, Vancouver, October 4-5, 2019)
5. Submit your manuscript (<https://mc.manuscriptcentral.com/jospt>)
6. Join our peer-review team (apply

online at <http://jospt.wufoo.com/forms/reviewer-application/>)

Enjoy this issue, and please keep sharing how we can make the *JOSPT* as relevant as possible to you, and to the patients and athletes with whom you work. ●

REFERENCE

1. Nyland JA. Board of Directors names Clare L. Ardern next *JOSPT* Editor-in-Chief. *J Orthop Sports Phys Ther*. 2018;48:517-518. <https://doi.org/10.2519/jospt.2018.0106>

SEND Letters to the Editor-in-Chief

JOSPT welcomes **letters related to professional issues or articles published in the *Journal***. The Editor-in-Chief reviews and selects letters for publication based on the topic's relevance, importance, appropriateness, and timeliness. Letters should include a summary statement of any conflict of interest, including financial support related to the issue addressed. In addition, letters are copy edited, and the correspondent is not typically sent a version to approve. Letters to the Editor-in-Chief should be sent electronically to jospt@jospt.org. Authors of the relevant manuscript are given the opportunity to respond to the content of the letter.

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Perceived Instability Is Associated With Strength and Pain, Not Frontal Knee Laxity, in Patients With Advanced Knee Osteoarthritis

Over 250 million people worldwide live with knee osteoarthritis.²⁶ Up to half have activity limitations, such as decreased mobility at home and in the community.³ People with knee osteoarthritis are often challenged by muscle weakness,¹⁵ perceived instability,^{8,19} increased pain,¹² and reduced function.¹¹

Increased varus/valgus laxity is common in patients with knee osteoarthritis.^{15,19,23} Altered knee motion associated with knee laxity is hypothesized to contribute to development and progression of osteoarthritis.

There is a biological rationale for a relationship between varus/valgus motion and functional joint instability. However, the relationship between knee laxity and perceived instability is uncertain.^{9,10}

Measures of knee laxity may be affected by the measurement tool used and by guarding in patients who may fear discomfort or pain.¹⁰ Recording passive knee laxity under anesthesia may be a way to overcome measurement challenges⁹ and accurately quantify the relationship of static knee laxity to knee symptoms (eg, perceived instability).

Recent studies have focused on evaluating the relationship between knee laxity and the development and progression of osteoarthritis.¹ Another relevant clinical question is, what factors influence patients' perceptions of knee instability?⁸ The purpose of this secondary analysis⁹ was to assess whether knee extensor strength, varus/valgus laxity, and pain were related to patients' perceptions of knee instability in people awaiting total knee arthroplasty (TKA).

METHODS

THIRTY-NINE PARTICIPANTS (40 KNEES; 33 participants from Freisinger et al⁹) were recruited by orthopaedic surgeons at The Ohio State University and participated after providing Institutional

• **BACKGROUND:** Increased varus/valgus laxity and perceived knee instability are independently associated with poor outcomes in people with knee osteoarthritis. However, the relationship between laxity and perceived instability is unclear.

• **OBJECTIVE:** To assess whether knee extensor strength, pain, and knee laxity are related to perceived knee instability in patients with advanced knee osteoarthritis.

• **METHODS:** This was a secondary analysis of a prospective observational cohort study of 35 patients (24 female; mean $\pm$ SD age, 60 $\pm$ 8 years; body mass index, 33 $\pm$ 5 kg/m²) with knee osteoarthritis awaiting total knee arthroplasty (36 knees). Within 1 month before arthroplasty, we measured isometric knee extension strength and self-reported knee pain (using the Knee Injury and Osteoarthritis Outcome Score pain subscale). Patients rated their perception of knee instability as

moderate to severe ($n = 20$) or slight to none ($n = 15$ patients, $n = 16$ knees) using the Knee Outcome Survey. We measured intraoperative varus/valgus knee laxity.

• **RESULTS:** Lower knee extension strength ($P = .01$) and greater pain ($P < .01$) were associated with the perception of moderate to severe knee instability. Laxity was not related to perceived knee instability ($P = .63$).

• **CONCLUSION:** Knee extension strength and pain were associated with perceived instability in people with advanced osteoarthritis. Varus/valgus laxity was not related to perceived knee instability.

• **LEVEL OF EVIDENCE:** Level 2, prognostic. *J Orthop Sports Phys Ther* 2019;49(7):513-517. doi:10.2519/jospt.2019.8619

• **KEY WORDS:** arthroplasty, function, KOOS, operative

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RESEARCH REPORT

Review Board–approved consent. We aimed to enroll 42 participants to examine the relationships between intraoperative, functional, and patient-reported measures before and after TKA.

Participants had been diagnosed with predominantly medial-compartment tibiofemoral osteoarthritis and were scheduled for primary TKA within 30 days. We excluded patients with a body mass index greater than 45 kg/m², those who were unable to walk 10 m unaided, and those with predominantly lateral-compartment osteoarthritis or revision TKA, because the influence of surgical technique on TKA outcomes was the parent study's primary focus. Four participants were excluded due to sterilization error, prohibiting intraoperative data collection (n = 2), or technical difficulties during preoperative testing, resulting in no available strength data (n = 2).

The clinical assessment, self-reported measures, and intraoperative laxity measurement methods are described in detail in a previous publication.⁹ We measured isometric knee extensor strength during a maximal voluntary isometric contraction in a seated upright position, with the knee held at 60° of flexion (System 3; Biodex Medical Systems, Shirley, NY). We normalized the average peak torque from 2 trials by body mass (Newton meters per kilogram). To assess perceived knee instability, we used a question from the Knee

Outcome Survey–Activities of Daily Living scale¹³: “To what degree does giving way, buckling, or shifting of the knee affect your daily activity?” Respondents rated their instability on a scale ranging from 0 to 5, with 0 as preventing all activity, 1 as affecting activity severely, 2 as affecting activity moderately, 3 as affecting activity slightly, 4 as not affecting activity, and 5 as no instability. We dichotomized scores of 0 to 2 as a moderate or severe effect on activity and scores of 3 to 5 as slight or no effect on activity. We assessed pain using the pain subscale of the Knee injury and Osteoarthritis Outcome Score (KOOS),¹⁷ where a higher score reflected less pain.

We measured intraoperative varus/valgus knee laxity after exposing the distal femur and proximal tibia, but prior to any bone, ligament, or meniscal alterations associated with performing a standard TKA. Kinematics were collected with retroreflective marker clusters rigidly attached to the distal femur and proximal tibia with cortical bone screws.^{9,24} Using a custom testing device,²⁴ the surgeon applied varus and valgus torques with the knee fully extended, and the resulting varus and valgus motions and torques were recorded without any feedback provided to the surgeon. The combined varus/valgus range of motion under ±10 Nm of torque was calculated as the varus/valgus laxity. Surgeons were blind to strength, laxity, and other clinical data.

We used 2-sample Student *t* tests to compare knee extension strength, varus/valgus laxity, and KOOS pain scores between patients who reported moderate to severe knee instability and patients who reported slight to no knee instability. We used backward selection binary logistic regression to identify predictor variables that were significantly associated with the dichotomous perceived knee instability outcome variable. We initially included knee extension strength, varus/valgus laxity, and KOOS pain scores, plus all 2-way interaction terms, as continuous candidate variables for the backward selection process. Statistical analyses were performed in Minitab 17 (Minitab, LLC, State College, PA).

RESULTS

THE STUDY INCLUDED 35 PARTICIPANTS (36 knees) (TABLE 1). Clinical assessments and self-report measures were completed a median of 16 days prior

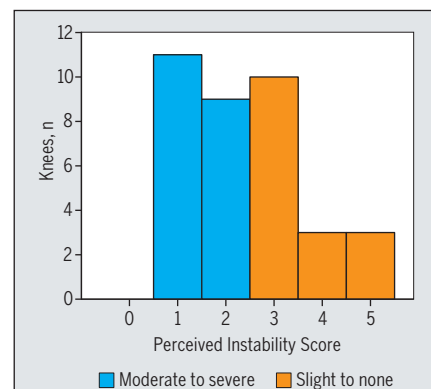


FIGURE 1. Distribution of perceived instability among the participants in the study, based on the response to the question, “To what degree does giving way, buckling, or shifting of the knee affect your daily activity?” from the Knee Outcome Survey.¹³ A score of 0 indicated that instability prevented all activity, 1 indicated that instability affected activity severely, 2 indicated that instability affected activity moderately, 3 indicated that instability affected activity slightly, 4 indicated that instability did not affect activity, and 5 indicated no instability. Scores on the Knee Outcome Survey instability question were then grouped into 2 categories: those who perceived a moderate or severe effect on activity (0, 1, or 2; n = 20 knees) and those who perceived a slight or no effect on activity (3, 4, or 5; n = 16 knees).

TABLE 1

DEMOGRAPHICS OF INVOLVED KNEES OF STUDY PARTICIPANTS

Characteristic	Value*
Sex, n	
Female	24
Male	11
Age, y	59.9 ± 8.0
Body mass, kg	92.2 ± 15.8
Height, m	1.67 ± 0.10
Perceived instability (IKOS)	2.4 ± 1.2
Varus/valgus laxity, deg	5.4 ± 3.0
Knee extension strength, Nm/kg	1.00 ± 0.44

Abbreviation: IKOS, Knee Outcome Survey instability question.
**Values are mean ± SD unless otherwise indicated.*

to surgery (interquartile range, 28 days; range, 2-117 days). Of 35 participants, 20 reported moderate or severe perceived instability and 15 (16 knees) reported slight to no perceived instability (FIGURE 1). There was no difference in varus/valgus knee laxity between those who did and did not report instability. Patients who reported moderate or severe instability were weaker and reported more pain than those who reported slight or no instability (TABLE 2). The final binary logistic regression model included knee extension isometric peak torque ($\beta = 13.5 \text{ Nm/kg}$, $P = .010$), KOOS pain ($\beta = 0.323$, $P = .006$), and the interaction between knee extension maximal voluntary isometric contraction and KOOS pain ($\beta = -0.215$, $P = .031$). Varus/valgus laxity was not associated with perceived knee instability ($P > .25$). FIGURE 2 shows the distributions of KOOS pain, varus/valgus laxity, and knee extension strength.

DISCUSSION

AMONG PATIENTS WITH SYMPTOMATIC knee osteoarthritis, knee extensor weakness and limitations due to knee pain were associated with a greater likelihood of perceiving moderate to severe knee instability. Varus/valgus laxity was not associated with perceived knee instability. These results may support knee extensor strength training as a focus of

treatment for patients with symptomatic knee osteoarthritis. Participants had inferior knee extension strength relative to age-matched controls.² However, participants with stronger quadriceps may have greater ability to develop a neuromuscular control strategy to stabilize the knee, even in the presence of lax passive restraints. For individuals who perceive excessive tibiofemoral motion as instability, activating the quadriceps could lessen excessive frontal plane motion because the line of action of the quadriceps-patella-patellar tendon complex has a moment arm that acts to resist opening of

the lateral compartment.¹⁸ Our previous results are consistent with this theory, as greater varus/valgus laxity was associated with greater knee extension strength.⁹ Muscle-related dynamic stabilization is possible in knees with high laxity, though using the quadriceps as a dynamic stabilizer does result in higher joint reaction forces and a higher risk of osteoarthritis progression.²² While greater passive laxity could theoretically lead to a greater likelihood of “giving way, buckling, or shifting of the knee,”¹³ perceived as an unstable joint, no such relationship has been observed in

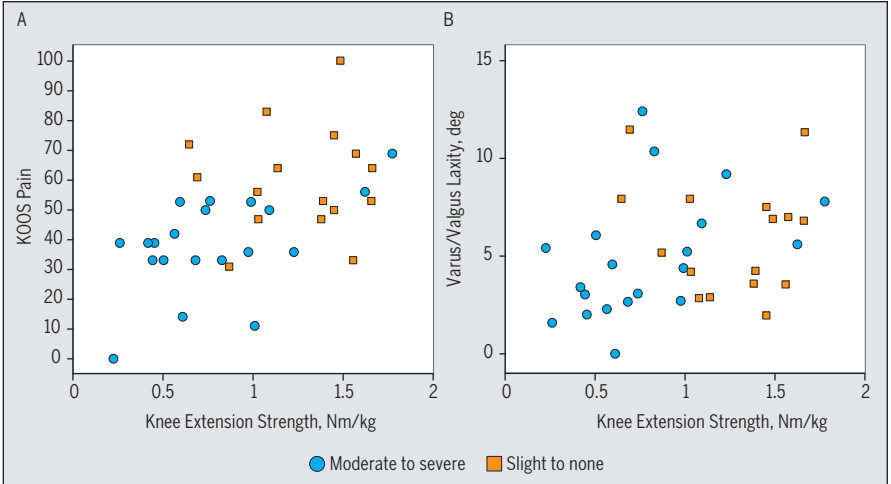


FIGURE 2. Self-reported pain as indicated by the (A) KOOS¹⁷ pain subscale (higher values indicate less pain) and (B) varus/valgus laxity with the knee fully extended and $\pm 10 \text{ Nm}$ of torque applied under anesthesia, versus normalized knee extension maximum voluntary isometric contraction of the involved limb. Orange squares indicate participants who reported slight to no perceived instability, and blue circles indicate participants who reported moderate to severe perceived instability. Abbreviation: KOOS, Knee injury and Osteoarthritis Outcome Score.

TABLE 2	GROUP DIFFERENCES, UNIVARIATE TEST RESULTS, AND BINARY LOGISTIC REGRESSION MODEL FOR KNEE EXTENSION MVIC, VARUS/VALGUS LAXITY, AND THE KOOS PAIN SUBSCALE*				
			Binary Logistic Regression		
	Moderate to Severe [‡]	Slight to None [‡]	Univariate Student t Test P Value	Coefficient (SE)	P Value
KOOS pain (0-100)	38.6 $\pm$ 16.4	59.9 $\pm$ 17.8	.001	0.323 (0.162)	.006
Knee extension MVIC, Nm/kg	0.79 $\pm$ 0.42	1.26 $\pm$ 0.33	.001	13.54 (6.73)	.01
Varus/valgus laxity, deg	4.9 $\pm$ 3.1	6.0 $\pm$ 2.9	.310	NA	NA
Knee extension MVIC-KOOS pain interaction	NA	NA	NA	-0.215 (0.120)	.031

Abbreviations: KOOS, Knee injury and Osteoarthritis Outcome Score; MVIC, maximum voluntary isometric contraction; NA, not applicable; SE, standard error.
*Values are mean $\pm$ SD unless otherwise indicated.
[‡]Scores of 0 to 2 on the Knee Outcome Survey instability question.
[‡]Scores of 3 to 5 on the Knee Outcome Survey instability question.

individuals with either mild to moderate osteoarthritis²⁰ or end-stage osteoarthritis.⁹ Many factors potentially influence the perception of instability in individuals with knee osteoarthritis. Pain and arthrogenic inhibition,¹⁶ followed by inadequate eccentric quadriceps activation, may contribute to a giving-way or buckling sensation. Therefore, our finding of a relationship between pain and perceived instability might warrant further study.

The significant positive interaction coefficient between pain and strength suggests that together, they do more than the sum of their parts in contributing to a perception of instability. Because we only collected data at 1 time point, we cannot determine whether strength training could have reduced pain or reduced perceived instability. However, a dual focus on treating weakness and pain may be beneficial. Addressing knee instability through a comprehensive treatment approach that targets muscle strength, pain, and sensory deficits (such as proprioception and vibratory acuity), with a focus on neuromuscular and stabilization training, may promote favorable outcomes.^{5-7,14,21} However, controlled trials are needed to inform intervention development.

Limitations

Due to large variances, we could not perform subgroup analyses of strength or pain. The desired sample size for the study ($n = 42$) was chosen a priori by identifying correlations between intraoperative and functional measures, not for the secondary subgroup analyses mentioned here. The decision to perform TKA was made between patient and clinician, and thus presents a risk of selection bias. Osteoarthritis severity was based on the patient's and clinician's judgment. Therefore, our results may not apply to all patients with knee osteoarthritis.

Certain characteristics of end-stage disease, such as the presence of osteophytes, could have influenced perceptions of instability. The use of passive varus/valgus laxity under anesthesia also limits

the applicability of the results to all patients with knee osteoarthritis, or to other forms of laxity. Passive laxity was only measured at full extension due to time limitations. Perceived instability could be related to laxity of the joint at other flexion angles. We included a greater proportion of women—who have greater varus/valgus laxity—than men.^{10,23,25}

Perceived instability was only assessed by a single item from the Knee Outcome Survey. While this approach was consistent with our previous work examining instability in patients with medial knee osteoarthritis,^{19,20} other assessments of perceived instability may result in different relationships to laxity, strength, and pain. With the exception of sample size, these limitations are unlikely to have significantly affected the internal validity of the study, because these participants are representative of people living with significant pain and physical limitations due to knee osteoarthritis.

CONCLUSION

KNEE EXTENSION STRENGTH AND pain were independently associated with perceived instability in people awaiting TKA. There was no relationship between varus/valgus laxity and perceived instability. ●

KEY POINTS

FINDINGS: Knee extension strength and pain were associated with perceived knee instability in people awaiting total knee arthroplasty. Varus/valgus laxity measured under anesthesia was not associated with perceived instability. Weakness and pain significantly interacted in their association with perceived instability.

IMPLICATIONS: An intervention that focuses on both strengthening and pain reduction may improve perceived instability in individuals with advanced osteoarthritis.

CAUTION: The study sample included patients with advanced osteoarthritis; therefore, the findings are not generaliz-

able to individuals with other conditions or with osteoarthritis at other levels of severity.

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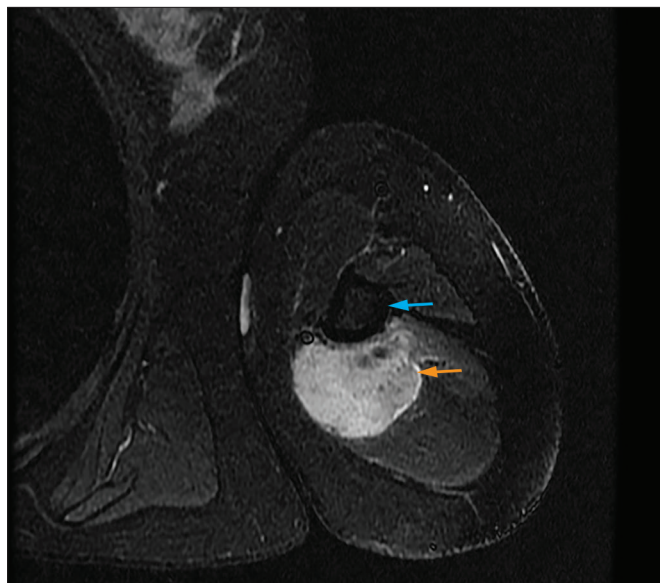


FIGURE 1. T2-weighted, axial magnetic resonance image showing the epithelioid sarcoma (orange arrow) against the posterior aspect of the proximal humerus (blue arrow) in the location of the radial nerve.

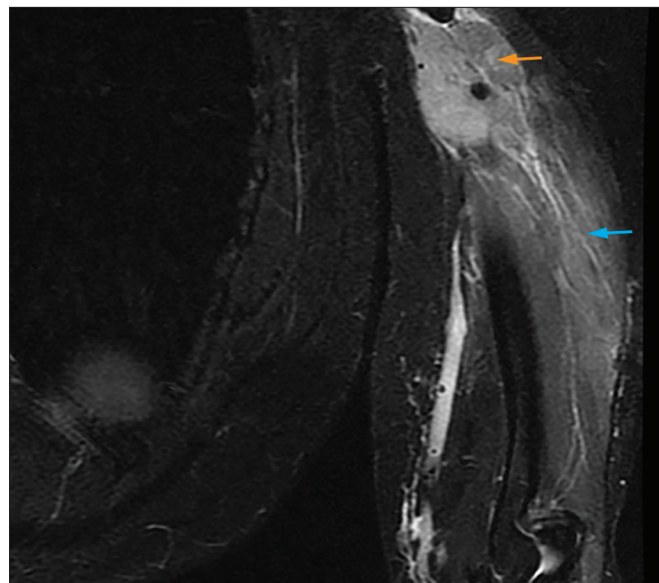


FIGURE 2. T2-weighted, coronal magnetic resonance image showing the primary part of the epithelioid sarcoma (orange arrow) in the proximal arm/axilla, extending laterally. The high-intensity signal extending distally from the tumor (blue arrow) is indicative of acute denervation.

An Unusual Radial Neuropathy

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A 23-YEAR-OLD WOMAN PRESENTED to her physician for left forearm pain of insidious onset 2 weeks prior, inability to extend the wrist, and numbness in the dorsal hand. The patient was prescribed duloxetine and ibuprofen for pain and referred to an occupational therapist. She was treated with a wrist splint and exercise for 3 weeks. An electromyogram (EMG) and nerve conduction study (NCS) within 4 weeks of the primary care visit demonstrated radial neuropathy, with no compression site identified. Magnetic resonance imaging (MRI) of the left elbow/forearm 2 months after the EMG/NCS revealed edema and atrophy of the wrist extensor muscles, but no compressive lesion.

The patient reported trouble sleeping, but denied weight loss or systemic symptoms. With no improvement, the patient was referred to an orthopaedic surgeon, whom she saw 1 week after the MRI.

This surgeon consulted with a physical therapist for a repeat EMG/NCS. The clinical exam revealed severe weakness of radial nerve-innervated muscles distal to the triceps, with no evidence of root or plexus pathology. A second, more detailed EMG/NCS revealed a severe radial motor and sensory neuropathy, with compression between the lateral and long heads of the triceps. Two weeks after the surgeon's consultation, the patient returned for follow-up, at which time the surgeon felt a mass in the proximal upper extrem-

ity not identified previously. Radiographs of the shoulder and humerus taken at this time were unremarkable. This prompted the order of same-day MRI of the arm/axilla region.

The MRI scan showed a 4 × 5-cm mass at the spiral groove compressing the radial nerve (FIGURES 1 and 2). A biopsy (FIGURE 3, available at www.jospt.org) confirmed an epithelioid sarcoma. This rare sarcoma affects young adults, with an affinity to the distal upper extremity, although proximal variants have been described, as in this case.¹ The patient was referred to oncology and began chemotherapy, yet succumbed to the disease 1 year later. ● *J Orthop Sports Phys Ther* 2019;49(7):558. doi:10.2519/jospt.2019.7927

Reference

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Running Themselves Into the Ground? Incidence, Prevalence, and Impact of Injury and Illness in Runners Preparing for a Half or Full Marathon

Running is a popular sport.²⁹ However, runners often sustain running-related injuries (RRIs). The cumulative incidence proportion (the number of new cases divided by the number of runners at risk) and the period prevalence (the number of existing and new cases within a predetermined time period, divided by the total number of runners at risk within the study sample) of RRIs vary greatly.^{4,14,26,34} The reported proportion of injured runners ranges from 7.5% to 58%.¹⁴ This might be explained by differ-

ences in study methodology, heterogeneity across studies, and the use of different RRI definitions.^{14,15}

Recently, consensus was achieved on the definitions of RRIs and illness symp-

toms and on procedures for data collection for use in epidemiological studies of athletics.³² There is a need for epidemiological studies of half marathon and marathon runners (1) using a running-related pain experienced during at least 1 running session definition, and (2) for early identification of RRIs before their impact increases and running performance is compromised. It is also important to register illness symptoms in half marathon and marathon runners, because these symptoms may disrupt regular training or participation in running events.

In runners, RRIs and illness symptoms often do not cause time loss, yet they may last longer and have greater cumulative impact than acute RRIs.⁹ The Oslo Sports Trauma Research Center (OSTRC) questionnaire can be used to register and monitor RRIs before they cause time loss.⁶ The OSTRC questionnaire can also be used to register illness symptoms.⁶

According to the seminal sequence of prevention model by Hlobil et al¹⁰ and van Mechelen et al,³⁵ it is necessary to establish the incidence, prevalence, and impact of RRIs and illness symptoms in half marathon and marathon runners before their etiology or preventive measures can be established. The primary aim of our study

● **OBJECTIVE:** To describe the incidence, prevalence, and impact of running-related injuries (RRIs) and illness symptoms in half marathon and marathon runners during the 16-week period before the Utrecht Marathon.

● **METHODS:** In this prospective cohort study, we used the Oslo Sports Trauma Research Center questionnaire to register RRIs and illness symptoms every 2 weeks during the 16-week study period. When an injury or illness occurred, questions were added regarding its nature. We calculated the incidence proportion (the number of new cases divided by the number of runners at risk) and the period prevalence (the number of existing and new cases within a 2-week period, divided by the total number of runners at risk during that period).

● **RESULTS:** Of the 161 included runners, 9 out of 10 reported an RRI or illness symptom at some time during the study period. In any 2-week period, 5.6% to 14.8% of the runners reported a new RRI, and 6.3% to 13.8% of the runners reported a new illness symptom. The prevalence of RRIs

ranged from 29.2% to 43.5%, and the prevalence of illness symptoms ranged from 28.3% to 71.2%. The most prevalent RRIs were in the lower leg (prevalence range, 5.4%-12.3%) and knee (prevalence range, 2.7%-9.3%). The most prevalent illness symptoms were rhinorrhea/sneezing (prevalence range, 3.9%-12.7%) and coughing (prevalence range, 3.9%-11.9%). The incidence and prevalence of illness symptoms peaked at the same time as the influenza-like illness epidemic of the winter of 2015-2016.

● **CONCLUSION:** Nine out of every 10 runners reported an RRI or illness symptom in the lead-up to a half or full marathon. In any 2-week period, up to 1 in 7 runners reported a new RRI or illness symptom.

● **LEVEL OF EVIDENCE:** 2b. *J Orthop Sports Phys Ther* 2019;49(7):518-528. doi:10.2519/jospt.2019.8473

● **KEY WORDS:** illness symptoms, prevalence, running, running-related injuries, surveys and questionnaires

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was to describe the incidence, prevalence, and impact of RRIs and illness symptoms in half marathon and marathon runners during a 16-week preparatory period before the Utrecht Marathon, for both the half and full marathon events.

METHODS

THIS PROSPECTIVE COHORT STUDY—the SUCces Measurement and Monitoring Utrecht Marathon Study (SUMMUM-2016)—was approved by the University Medical Center Utrecht Ethics Committee (protocol number 15-592).

Participants

Runners were recruited from September 1 to November 21, 2015, during registration for the half or full Utrecht Marathon, via a newsletter and a symposium on RRIs. Runners interested in participating were sent an information letter. Informed consent was obtained before the baseline questionnaire was completed. The study inclusion criteria were being 18 years of age or older at baseline, having an e-mail address, and having adequate Dutch reading and writing skills.

Procedures

The baseline questionnaire was sent to all participants on November 29, 2015, 16 weeks before the Utrecht Marathon (March 20, 2016). We sent follow-up questionnaires every 2 weeks, up to the event. All questionnaires were sent on Friday morning, and participants were allowed 5 days to complete them. Reminders were sent every 2 days to participants who either had not started or had not completed the questionnaire. All questionnaires were sent using NetQuestionnaires (NETQ Healthcare BV, NETQ Insights BV, Utrecht, The Netherlands).

Questionnaires

The baseline questionnaire collected demographic information (sex, age, weight, height), prior half or full marathon experience, and any RRIs during the preceding 12 months. We used a backward/

forward translation method to translate the English version of the OSTRC questionnaire into Dutch.² This Dutch version of the OSTRC questionnaire was used to monitor the incidence, prevalence, and impact of RRIs and illness symptoms in runners every 2 weeks.⁶

The OSTRC questionnaire comprises 4 multiple-choice questions, scored from 0 to 25 (APPENDIX, available at www.jospt.org). For each OSTRC questionnaire response, we calculated an injury severity score for each runner by summing the scores of the 4 questions (maximum score of 100). If the OSTRC severity score was greater than 0, an RRI or illness symptom was considered present, and follow-up questions were asked regarding the anatomical location and type of RRI or type of illness symptom. If questions 2 or 3 of the OSTRC questionnaire were scored 13 or greater, we considered the RRI or illness symptoms to be “substantial” (ie, leading to moderate or severe reductions in training volume, or moderate or severe reductions in sports performance, or complete inability to participate in sport).⁶ Participants then completed a new OSTRC questionnaire and additional questions for each injury or illness symptom.

Injury Definitions

An RRI was any self-reported complaint involving muscles, joints, tendons, and/or bones deemed by the runner to be caused by running. To be classified as an RRI, the complaint (1) had to be present for at least 1 running session, and (2) should have reduced the distance, speed, duration, or frequency of running. Runners were asked not to report blisters or delayed-onset muscle soreness.

Data Analysis

All data were analyzed using SPSS (Version 20; IBM Corporation, Armonk, NY, USA). Baseline characteristics were described using mean $\pm$ SD for continuous data, median and an interquartile range (IQR) of 25% to 75% for numerical data that were not normally distributed, and percentage and frequency for categorical

data. Measurement uncertainty was presented as SD, 95% confidence interval (CI), or range.

Chi-square tests and independent *t* tests (as appropriate) were used to test for differences between the baseline characteristics of the half and full marathon runners. Where continuous variables were not normally distributed, the Mann-Whitney *U* test was used. Alpha was set at .05.

Data from runners who did not report an RRI or illness symptom at baseline were included in the incidence calculations of RRIs and illness symptoms, respectively. The number of incident cases was the number of runners who reported a new RRI or illness symptom (ie, OSTRC severity score greater than 0 and they reported that RRI/illness symptom for the first time in this study) during the 16-week study period. To account for censoring, we calculated cumulative incidence proportions for RRIs and illness symptoms every 2 weeks by dividing the number of athletes with new RRIs or illness symptoms by the total number of athletes at risk during these 2 weeks.²¹ We used Kaplan-Meier survival curves to show the cumulative probability of not having an RRI or illness symptom during the 16-week study period.²⁷ The log-rank test was used to assess whether half and full marathon runners had a similar probability of RRIs or illness symptoms at any time point during the 16-week period.³

We used Cox regression analyses, with data from runners who reported no RRIs or illness symptoms at baseline, to evaluate whether predetermined covariates were associated with the hazard rate ratios (HRRs) for RRIs or illness symptoms (ie, the ratio of 2 hazard rates or injury rates, calculated as the number of RRIs or illness symptoms divided by the exposure time²²). The HRR shows the injury rate for RRIs or illness symptoms during the 16-week study period. Further, survival curves were plotted using the Cox regression. The number of weeks was used as the time variable (maximum follow-up, 16 weeks).

Runners were censored if they did not complete a questionnaire for the first time, or at the end of the follow up period, whichever came first. Reasons why runners did not complete the questionnaire were not registered. Based on the literature, the following covariates were included in our Cox regression models: age, sex, an RRI at baseline, an RRI during the 12 months before the start of this study, and running experience (defined as having run at least 1 half marathon). We hypothesized that older age, female sex, an RRI at baseline, an RRI during the 12 months before the start of this study, and being an inexperienced runner would increase injury risk.^{13,33}

The proportional hazards assumption for the covariates included in the Cox regression was studied by using log-minus-log plots, and by introducing a time-dependent covariate into the Cox regression model separately for each covariate.²² If a covariate did not meet the proportional hazards assumption, a stratified Cox regression was performed.³⁷ Multicollinearity was studied by exploring correlations between the covariates.

Data from all runners were used to calculate the prevalence of RRIs and illness symptoms.⁶ The prevalence of RRIs and illness symptoms was calculated every 2 weeks by dividing the number of RRIs or illness symptoms reported by the total number of respondents.^{6,32} This was also done for each anatomical location separately.

The impact of (substantial) RRIs at each anatomical location and (substantial) illness symptoms was calculated by summing the answers of the 4 OSTRC questions every 2 weeks. The median (IQR) OSTRC severity score was calculated per anatomical location and per illness symptom separately.

Internal Consistency of the OSTRC Severity Score

To test the internal consistency (ie, the interrelatedness) of the 4 OSTRC questions and the OSTRC severity score, we

calculated Cronbach's alpha.¹⁷ A Cronbach's alpha between .70 and .95 was considered adequate.³¹ The assumption of unidimensionality of the 4 OSTRC questions was checked using confirmatory factor analysis using a principal-component analysis.

RESULTS

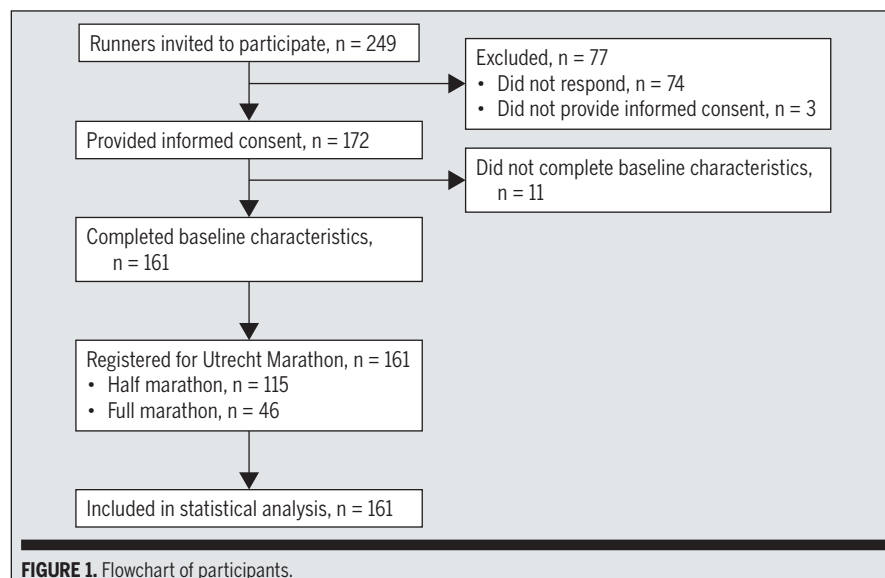
Baseline Characteristics and Response Rate

IN TOTAL, 249 RUNNERS WERE INVITED to participate in this study. Of the 172 runners who provided informed consent, 11 did not complete the baseline characteristics section of the baseline questionnaire and were excluded. We analyzed data from 161 runners (115 half marathon runners, 46 full marathon runners) (FIGURE 1). The average response rate for the questionnaires during the 16-week preparation period was 74.1% (range, 68.5%-79.9%); 72 (44.7%) runners did not respond or did not complete 1 or more questionnaires within the 16-week period. These 72 runners were significantly shorter (mean $\pm$ SD, 175.7 $\pm$ 9.7 cm) than the 89 (55.3%) runners who completed all questionnaires (mean $\pm$ SD, 179.4 $\pm$ 9.0 cm) (P = .013). There were no other significant differences between these groups at baseline.

There were no significant differences in sex, age, height, and weight at baseline between the half and full marathon runners (TABLE 1). Significantly more half than full marathon runners did not have any prior full marathon experience (P < .001), and 44 (27.3%) and 108 (67.1%) runners did not have any prior half or full marathon experience, respectively. Of the half marathon runners, 41 (35.7%) had not participated in a half marathon event before, whereas 20 (43.5%) of the full marathon runners had not participated in a full marathon event before. Significantly more full than half marathon runners ran a half marathon in the 12 months before this study (P = .02).

Internal Consistency of the OSTRC Severity Score

Internal consistency of the 4 OSTRC questions was adequate (Cronbach's α = .91, based on data from 161 runners). The confirmatory factor analysis extracted 1 underlying construct from the 4 OSTRC questions. Eighty-nine runners completed all 9 questionnaires during the 16-week period, and their data were used to calculate the Cronbach's alpha for the OSTRC severity score. The internal consistency of the OSTRC severity score was adequate (Cronbach's α = .81).



Incidence, Prevalence, and Impact of RRIs

History of RRIs During the 12 months before the study, 83 (51.6%) runners reported 1 or more RRIs (TABLE 1), mainly of the lower leg ($n = 29$, 18.0%) and knee ($n = 26$, 16.1%). Of these 83 runners, 56 (67.5%) reported 1 RRI, 22 runners (26.5%) reported 2 RRIs, 4 runners (4.8%) reported 3 RRIs, and 1 runner (1.2%) reported 5 RRIs. The anatomical locations of RRIs did not significantly differ between half and full marathon runners.

RRIs in the 16-Week Preparatory Period Before the Utrecht Marathon During the 16-week preparatory period, 143 runners (88.8%) reported an RRI or illness symptom. Specifically, 106 (65.8%) runners reported 403 RRIs; 201 (49.8%) of these RRIs were classified as substantial (OSTRC question 2 or 3 scored 13 or greater) (FIGURE 2A).

Ninety-three runners reported no RRI at baseline. Of these, 37 runners reported an RRI during the 16-week period; thus, the cumulative incidence proportion was 39.8%. The cumulative incidence proportion per 2 weeks ranged from 5.6% to 14.8%. The highest cumulative incidence proportion was found in week 14 (TABLE 2). FIGURE 3A shows the survival curve for RRIs regarding the half and full marathon runners during the 16-week period. No significant difference was found between these runners in the probability of an RRI at any time point ($P = .128$).

Because the covariate “RRI during the 12 months prior to this study” did not meet the proportional hazards assumption, a stratified Cox regression was performed (TABLE 3). FIGURE 3C shows the survival curves for the half and full marathon runners without RRIs. There was no difference between the hazard rates for RRIs of runners who did or did not have an RRI during the 12 months prior to this study (HRR = 1.74; 95% CI: 0.37, 8.28).

There were minor fluctuations in the prevalence of RRIs (FIGURE 2A) and (substantial) lower-leg and knee RRIs (FIGURE 2B). The prevalence of all RRIs and

TABLE 1

BASELINE CHARACTERISTICS OF THE HALF AND FULL MARATHON RUNNERS*

	All Runners (n = 161)	Half Marathon (n = 115)	Full Marathon (n = 46)	P Value†
Sex, n (%)				.13
Female	71 (44.1)	55 (47.8)	16 (34.8)	
Male	90 (55.9)	60 (52.2)	30 (65.2)	
Age, y	40.7 ± 11.7	39.8 ± 12.0	43.0 ± 10.7	.13
Height, cm	177.7 ± 9.4	177.10 ± 9.7	179.3 ± 8.6	.18
Weight, kg	72.6 ± 12.2	72.6 ± 12.7	72.5 ± 11.1	.94
Participants who had already started training at baseline, n (%)	116 (72.0)	82 (71.3)	34 (73.9)	
Time runners had been training at baseline, wk	10.4 ± 4.71	12.3 ± 5.6.3	6.13 ± 6.13	
Completed half marathons, n (%)				
In total				<.001
0	44 (27.3)	41 (35.7)	3 (6.5)	
1-2	29 (18.0)	24 (20.9)	5 (10.9)	
3-9	47 (29.2)	30 (26.1)	17 (37.0)	
≥10	41 (25.5)	20 (17.4)	21 (45.7)	
In the past 12 mo				.02
0	21 (17.9)	17 (23.0)	4 (9.3)	
1-2	54 (46.2)	35 (47.3)	19 (44.2)	
3-9	29 (24.8)	15 (20.3)	14 (32.6)	
≥10	13 (11.1)	7 (9.5)	6 (14.0)	
Completed full marathons, n (%)				
In total				<.001
0	108 (67.1)	88 (76.5)	20 (43.5)	
1-2	26 (16.1)	18 (15.6)	8 (17.4)	
3-9	15 (9.3)	8 (7.0)	7 (15.2)	
≥10	12 (7.5)	1 (0.9)	11 (23.9)	
In the past 12 mo				<.001
0	23 (43.4)	18 (66.7)	5 (19.2)	
1-2	19 (35.8)	8 (29.6)	11 (42.3)	
3-9	10 (18.9)	1 (3.7)	9 (34.6)	
≥10	1 (1.9)	0 (0.0)	1 (3.8)	
History of RRIs (past 12 mo), n (%)				.34
Yes	83 (51.6)	62 (53.9)	21 (45.6)	
No	78 (48.4)	53 (46.1)	25 (54.3)	
Head, spine, trunk	11 (6.8)	8 (7.0)	3 (6.5)	1.00
Upper extremity	2 (1.2)	1 (0.9)	1 (2.2)	.44
Hip	12 (7.5)	9 (7.8)	3 (6.5)	1.00
Groin	5 (3.1)	4 (3.5)	1 (2.2)	1.00
Upper leg/hamstrings	11 (6.8)	8 (7.0)	3 (6.5)	.89
Knee	26 (16.1)	17 (14.8)	9 (19.6)	.28
Lower leg	29 (18.0)	22 (19.1)	7 (15.2)	.86
Ankle	9 (5.6)	5 (4.3)	4 (8.7)	.22
Foot/toe	10 (6.2)	6 (5.2)	4 (8.7)	.26
Other	2 (1.2)	2 (1.7)	0 (0.0)	.41

Abbreviation: RRI, running-related injury.

*Values are mean ± SD unless otherwise indicated.

†Difference between full and half marathon runners.

[RESEARCH REPORT]

TABLE 2

INCIDENCE PROPORTION PER 2 WEEKS
DURING THE 16-WEEK PREPARATORY PERIOD
BEFORE THE UTRECHT MARATHON

Time Point, wk	RRIs (n = 93)			Illness Symptoms (n = 136)		
	Incident Cases per 2 wk, n	Runners at Risk, n	Incidence Proportion per 2 wk, %*	Incident Cases per 2 wk, n	Runners at Risk, n	Incidence Proportion per 2 wk, %*
2	11	93	11.8	15	136	11.0
4	5	67	7.5	11	105	10.5
6	5	51	9.8	8	82	9.8
8	3	40	7.5	6	67	9.0
10	2	36	5.6	8	58	13.8
12	4	32	12.5	5	45	11.1
14	4	27	14.8	5	37	13.5
16	3	23	13.0	2	32	6.3

Abbreviation: RRI, running-related injury.

*The incidence proportion is expressed as a percentage and calculated by dividing the number of events (ie, runners who reported a new RRI or illness symptom [Oslo Sports Trauma Research Center questionnaire cumulative severity score greater than 0]) by the number of runners at risk.

substantial RRIs ranged from 29.2% to 43.5% and 15.8% to 22.4%, respectively. Lower extremity RRIs had the highest prevalence. Lower-leg, knee, and foot/toe RRIs had the highest number of cases (TABLE 4). During the 16-week period, the prevalence of lower-leg, knee, and foot/toe RRIs ranged from 5.4% to 12.3%, 2.7% to 9.3%, and 2.5% to 7.1%. The most frequently reported substantial lower extremity RRIs were lower-leg, knee, and ankle RRIs. The prevalence of substantial lower-leg, knee, and ankle RRIs ranged from 2.2% to 6.8%, 0.8% to 5.0%, and 2.4% to 3.7%, respectively.

The lower extremity RRIs with the highest OSTRC severity score for all RRIs and substantial RRIs were ankle injuries (median, 60.0; IQR, 34.0-75.0) and substantial groin injuries (90.0; IQR could not be calculated because only 2

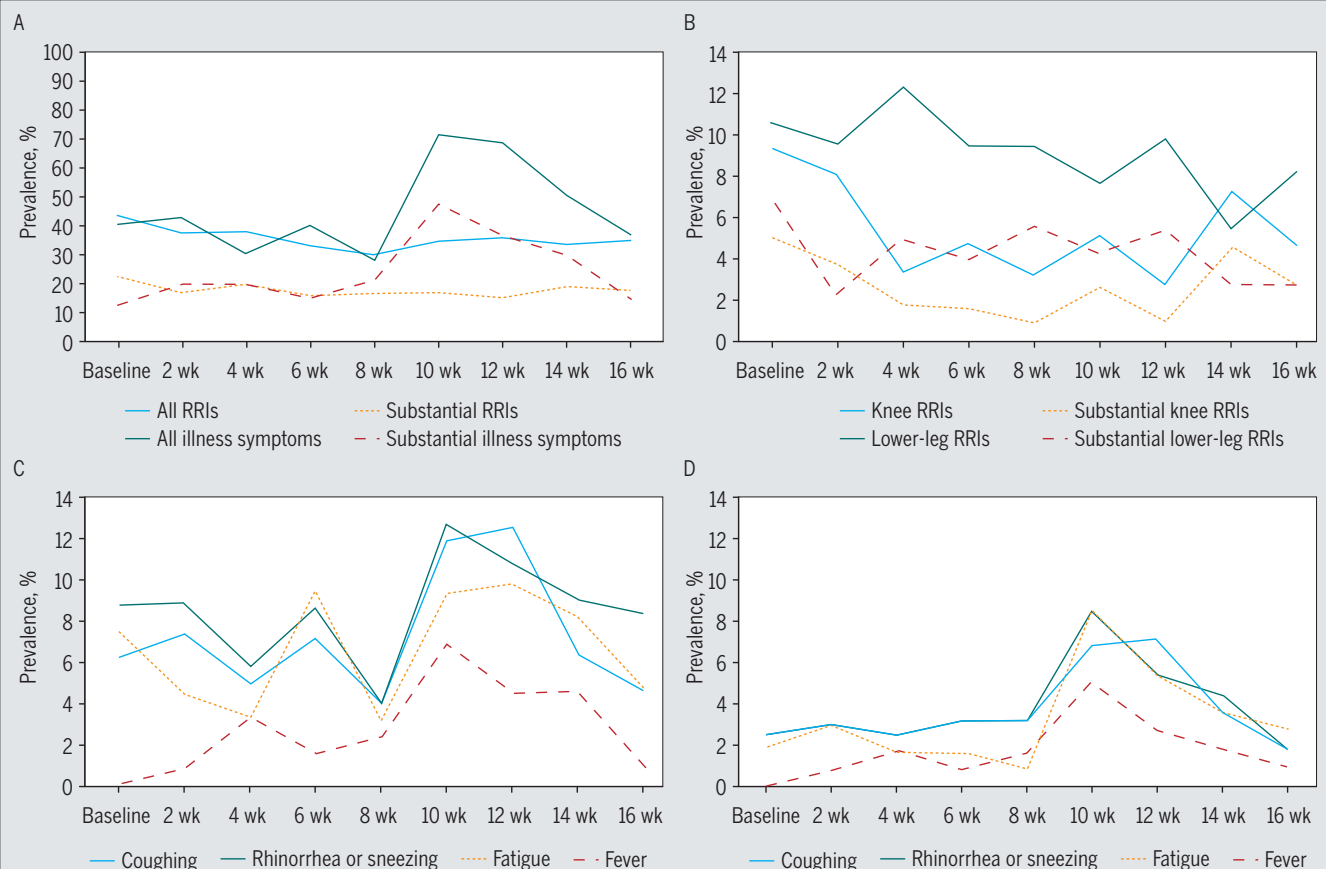


FIGURE 2. Prevalence of (A) all and substantial RRIs and all and substantial illness symptoms, (B) all and substantial knee and lower-leg RRIs, (C) all illness symptoms, and (D) substantial illness symptoms in half and full marathon runners during the 16-week preparatory period before the Utrecht Marathon. Abbreviation: RRI, running-related injury.

cases were reported) (TABLE 4). The most frequently reported types of RRIs were “muscle and tendon RRIs” (all RRIs, $n = 188$ [46.7%]; substantial RRIs, $n = 87$ [43.3%]) and self-reported overuse RRIs (all RRIs, $n = 127$ [31.5%]; substantial RRIs, $n = 58$ [28.9%]) (TABLE 5).

Incidence, Prevalence, and Impact of Illness Symptoms

During the 16-week preparatory period, 84 (52.2%) runners reported 504 illness

symptoms, of which 263 were classified as substantial (FIGURE 2A). One hundred thirty-six runners reported no illness symptoms at baseline. Sixty runners reported illness symptoms during the 16-week period, with a cumulative incidence proportion of illness symptoms of 44.1%. FIGURE 3B shows the survival curve for illness symptoms regarding the half and full marathon runners during the 16-week period. There was no difference in the probability of illness symptoms between

the half and full marathon runners at any time point ($P = .282$).

A stratified Cox regression was performed, because the covariate “RRI during the 12 months prior to this study” did not meet the proportional hazards assumption (TABLE 3). FIGURE 3D shows the survival curves for half and full marathon runners without illness symptoms. There was no difference in the hazard rates for illness symptoms for runners who did or did not have an RRI during the 12 months prior to the study (HRR = 3.02; 95% CI: 0.95, 9.60).

The prevalence of all illness symptoms ranged from 28.3% to 71.2%, and the prevalence of substantial illness symptoms ranged from 12.4% to 47.5%. The most reported illness symptoms were “rhinorrhea or sneezing” and coughing (TABLE 4). During the study period, the prevalence of rhinorrhea or sneezing and substantial rhinorrhea or sneezing ranged from 3.9% to 12.7% and 1.8% to 8.5%, respectively. The prevalence of coughing and substantial coughing ranged from 3.9% to 11.9% and 1.8% to 6.8%, respectively. The prevalence of (substantial) illness symptoms increased from week 10 to week 14 of the 16-week period (FIGURE 2A). During this period, and in the 2 weeks thereafter, the prevalence of (substantial) RRIs did not change. The course of the 3 most frequently reported illness symptoms during the study period and the illness symptom with the highest impact (fever) are shown in FIGURE 2C. The course of the most frequently reported substantial illness symptoms during the study period and the substantial illness symptom with the highest impact (fever) are shown in FIGURE 2D.

The most severe illness symptom was fever (median OSTRC severity score, 61.0; IQR, 37.0-80.0) (TABLE 4). The most severe substantial illness symptoms were shortness of breath (median OSTRC severity score, 80.0; IQR, 66.8-80.0), sore throat (median OSTRC severity score, 80.0; IQR, 60.0-80.0), and coughing (median OSTRC severity score, 80.0; IQR, 62.0-80.0).

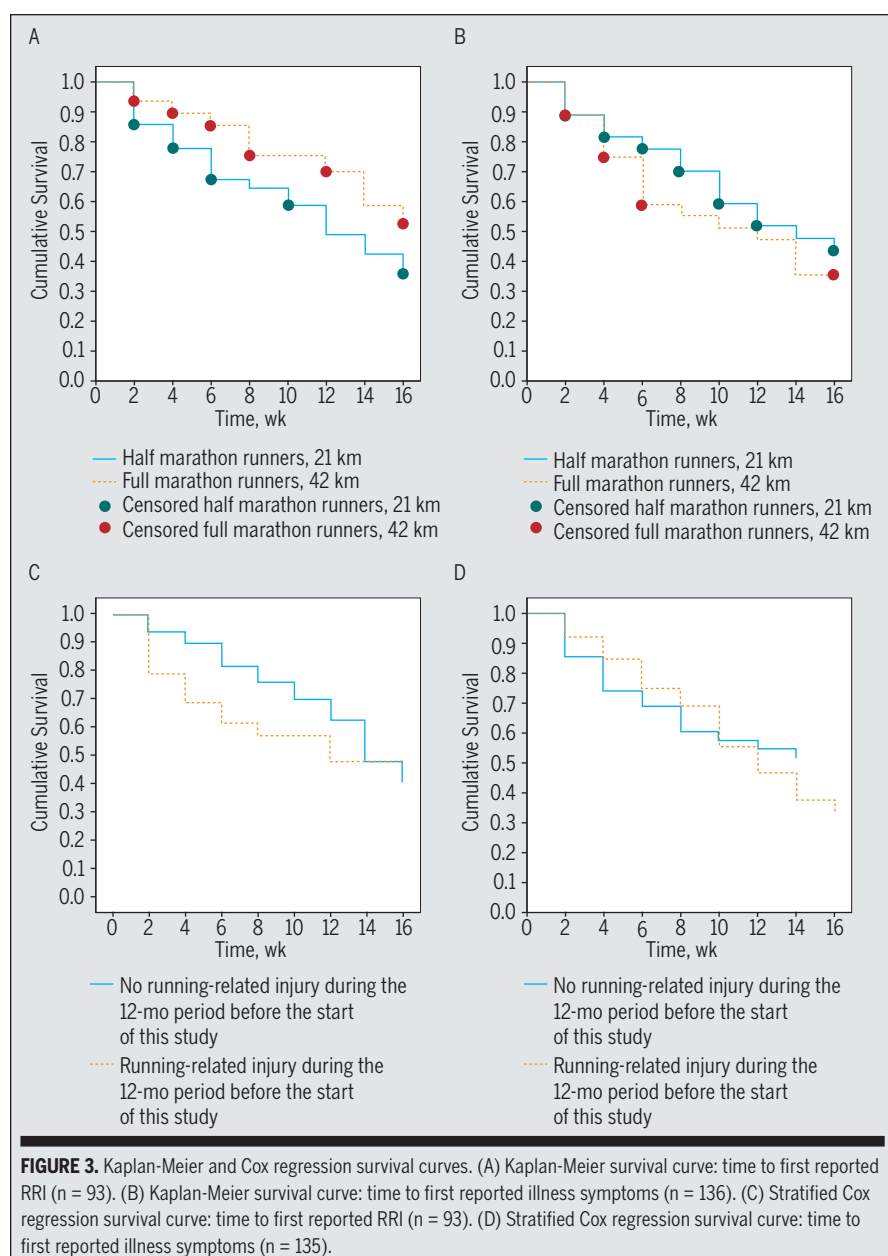


FIGURE 3. Kaplan-Meier and Cox regression survival curves. (A) Kaplan-Meier survival curve: time to first reported RRI ($n = 93$). (B) Kaplan-Meier survival curve: time to first reported illness symptoms ($n = 136$). (C) Stratified Cox regression survival curve: time to first reported RRI ($n = 93$). (D) Stratified Cox regression survival curve: time to first reported illness symptoms ($n = 135$).

DISCUSSION

THIS STUDY DESCRIBED THE INCIDENCE, prevalence, and impact of RRIs and illness symptoms in runners over 16 weeks as they prepared for the half or full Utrecht Marathon. In total, 88.8% of the runners reported an RRI or illness symptom during this period. This study used the recommendations of the athletic consensus group by reporting RRIs as well as illness symptoms in half and full marathon runners.³²

Incidence, Prevalence, and Impact of RRIs

The cumulative incidence proportion of RRIs ranged from 5.6% to 14.8% during the 16-week period, which is compa-

rable to the lower estimate of the range of 7.5% to 58.0% reported in scientific literature.¹⁵ The prevalence of RRIs in half and full marathon runners ranged from 29.2% to 43.5% during this 16-week period. Most RRIs affected the lower extremities. The most common reported lower extremity RRIs affected the lower leg (prevalence range, 5.4%-12.3%), knee (2.7%-9.3%), and foot/toe (2.5%-7.1%). The most common reported substantial lower extremity RRIs affected the lower leg (prevalence range, 2.2%-6.8%), knee (0.8%-5.0%), and ankle (2.4%-3.7%).

Two other prospective cohort studies also used the OSTRC questionnaire to investigate the prevalence of RRIs.^{8,9} One studied runners preparing for a 5-, 10-, or 16-km running event, and re-

ported an average RRI prevalence of 30.8% (95% CI: 25.6%, 36.0%) during the 6-month study period.⁸ The second involved trail runners, and reported an average RRI prevalence of 22.4% (95% CI: 20.9%, 24.0%).⁹ The 95% CIs of the average prevalence of RRIs reported by these studies were similar to those in our study. Both studies used the Orchard Sports Injury Classification System to classify the anatomical location of the RRIs and determine the type of RRIs.²⁵ The reported anatomical locations most affected were similar to the findings of our study. Although lower-leg and knee RRIs had the highest prevalence in the present study, ankle RRIs had the greatest impact (ie, median OSTRC severity score, IQR). These were lower extremity RRIs of the ankle (median OSTRC severity score, 60.0; IQR, 34.0-75.0). Of the substantial lower extremity RRIs, groin RRIs (median OSTRC severity score, 90.0; no IQR could be calculated because only 2 cases were reported) had the highest impact. Hespanhol Junior et al⁸ and Hespanhol Junior et al⁹ reported median (IQR) OSTRC severity scores for RRIs of runners training for a 5-, 10-, or 16-km running event and trail runners of 39.5 (IQR, 22.0-68.0) and 35.0 (IQR, 22.0-55.7), respectively. However, these studies did not report the OSTRC severity scores per anatomical location, so comparisons are not possible.

Incidence, Prevalence, and Impact of Illness Symptoms

The cumulative incidence proportion and prevalence of (substantial) illness symptoms peaked from weeks 10 through 14 (January 2016, weeks 5-9) of the 16-week period before the marathon. This period coincided with the influenza-like illness epidemic of the winter of 2015-2016 in the Netherlands.³⁰ The peak in the self-reported influenza-like illness prevalence of 93/10000 was reported during week 6 of 2016.

There was no increase in the prevalence of RRIs during the influenza-like illness epidemic or thereafter (weeks

TABLE 3

COX REGRESSION TIME-TO-EVENT ANALYSES FOR TIME TO FIRST RRI AND TIME TO FIRST ILLNESS SYMPTOM

Time-to-Event Stratified Cox Regression Models	Hazard Rate Ratio*	P Value
Time to first RRI (n = 93 without RRI at baseline)		
RRI during the 12 mo prior to this study (n = 30)		
Sex (female) [‡]	2.451 (0.775, 70.750)	.127
Age, y	0.980 (0.934, 1.028)	.406
Training goal (full marathon) [‡]	0.919 (0.283, 2.989)	.888
Running experience (at least 1 half marathon) [§]	1.341 (0.377, 4.762)	.650
No RRI during the 12 mo prior to this study (n = 63)		
Sex (female) [‡]	0.649 (0.226, 1.863)	.422
Age, y	1.043 (1.000, 1.089)	.049
Training goal (full marathon) [‡]	0.390 (0.143, 1.064)	.066
Running experience (at least 1 half marathon) [§]	0.524 (0.176, 1.562)	.246
Time to first illness symptoms (n = 135 without illness symptoms at baseline)		
RRI during the 12 mo prior to this study (n = 77)		
Sex (female) [‡]	0.919 (0.460, 1.835)	.810
Age, y	0.994 (0.966, 1.024)	.701
Training goal (full marathon) [‡]	1.706 (0.862, 3.375)	.125
Running experience (at least 1 half marathon) [§]	3.633 (1.226, 10.763)	.020
No RRI during the 12 mo prior to this study (n = 58)		
Sex (female) [‡]	0.518 (0.197, 1.363)	.183
Age, y	0.982 (0.944, 1.022)	.381
Training goal (full marathon) [‡]	0.815 (0.310, 2.138)	.677
Running experience (at least 1 half marathon) [§]	0.477 (0.182, 1.247)	.131

Abbreviation: RRI, running-related injury.

*Values in parentheses are 95% confidence interval.

[‡]Male sex is the reference category.

[§]Half marathon is the reference category.

^{||}No experience (ie, 0 half marathons) is the reference category.

^{||}P < .05.

14-16); however, we did not investigate a potential relationship between symptoms and RRIs. Van Tonder et al³⁶ investigated the effects of symptoms of systemic illness on running performance. They found that runners with self-reported symptoms of systemic illness (ie, fever, cough, general muscle pain, general joint pain, or headache) were 55% more likely not to finish a race compared with healthy controls (relative risk = 1.55; 95% CI: 0.99, 2.44). Runners who were diagnosed with symptoms of an acute systemic illness during the 24 hours prior to the start of a race had a 7-fold (95% CI: 2.37, 20.83) increased risk of not finishing the race compared with healthy controls.⁷ Thus, symptoms of systemic illness affect running performance. However, Van Tonder et al³⁶ and Gordon et al⁷ did not report whether the runners with illness symptoms were unable to finish the race because of their symptoms or per example because of the occurrence of an RRI. Illness symptoms might reduce a runner's performance and load tolerance and increase the risk of sustaining an RRI. However, the relationship between illness symptoms and RRIs is unclear, and might be a focus for future research.

Incidence- Versus Prevalence-Based Analyses of RRIs and Illness Symptoms

Our study was designed in 2015 to determine the prevalence of RRIs and illness symptoms during the 16-week period before the half or full Utrecht Marathon. We used a definition of running-related pain experienced during at least 1 running session and registered illness symptoms using the OSTRC questionnaire and prevalence-based measures, as advised by Timpka et al³² and Bahr.¹

Recently, Nielsen et al²¹ described how both prevalence- and incidence-based measures can be used. Prevalence-based measures are useful when the goal is to describe the proportion of injured athletes at a certain time point or period. Incidence-based measures are useful when examining etiology, prevention, or treatment. Incidence- and prevalence-based mea-

sures are both reported in the sports medicine field.^{8,11,16,18,23} Bahr pointed out that for overuse injuries, prevalence may be more suitable than incidence, because overuse injuries are often not associated with time loss.¹ However, incidence-based measures can be used to perform advanced time-to-event analysis, which allows for time-dependent exposures, time-dependent outcomes, and competing risks.^{19,20,22}

In practice, many exposures, like training parameters, are time dependent. Therefore, using these methods

could enable researchers to more accurately model clinical practice. However, in order to use these incidence-based measures, researchers must design data collection and analysis appropriately. Unfortunately, our data did not allow us to study time-dependent exposures, outcomes, and competing risks.

Internal Consistency of the OSTRC Severity Score

This study investigated the internal consistency of both the 4 OSTRC questions

TABLE 4 NUMBER OF CASES AND OSTRC SEVERITY SCORE OF RRIs AND ILLNESS SYMPTOMS DURING THE 16-WEEK PREPARATORY PERIOD BEFORE THE UTRECHT MARATHON		
	Cases, n (%)	OSTRC Severity Score*
RRIs per anatomical location		
Head, spine, and trunk		
All	26 (6.5)	47.5 (28.8-92.0)
Substantial [†]	18 (9.0)	80.0 (44.0-100.0)
Upper extremity		
All	16 (4.0)	22.0 (8.0-34.8)
Substantial [†]	2 (1.0)	100.0 [‡]
Hip		
All	43 (10.7)	29.0 (14.0-50.0)
Substantial [†]	19 (9.5)	51.0 (43.0-92.0)
Groin		
All	12 (3.0)	29.0 (16.0-35.0)
Substantial [†]	2 (1.0)	90.0 [‡]
Upper leg or hamstring		
All	37 (9.2)	37.0 (22.0-61.5)
Substantial [†]	19 (9.5)	51.0 (42.0-83.0)
Knee		
All	62 (15.4)	37.0 (20.0-66.0)
Substantial [†]	30 (14.9)	66.0 (43.3-80.0)
Lower leg		
All	104 (25.8)	37.0 (22.0-64.5)
Substantial [†]	49 (24.4)	66.0 (49.0-77.5)
Ankle		
All	47 (11.7)	60.0 (34.0-75.0)
Substantial [†]	34 (16.9)	67.5 (52.3-89.0)
Foot/toe		
All	52 (12.9)	49.5 (22.0-74.3)
Substantial [†]	28 (13.9)	72.0 (55.5-80.0)
Other		
All	4 (1.0)	17.0 (9.5-21.5)
Substantial [†]	0 (0.0)	...
Table continues on page 526.		

TABLE 4

NUMBER OF CASES AND OSTRC SEVERITY SCORE
OF RRIs AND ILLNESS SYMPTOMS DURING
THE 16-WEEK PREPARATORY PERIOD BEFORE
THE UTRECHT MARATHON (CONTINUED)

	Cases, n (%)	OSTRC Severity Score*
Illness symptoms		
Rhinorrhea or sneezing		
All	92 (18.3)	37.0 (14.0-67.0)
Substantial†	43 (16.4)	72.0 (60.0-80.0)
Coughing		
All	80 (15.9)	45.0 (14.0-80.0)
Substantial†	41 (15.6)	80.0 (62.0-80.0)
Fatigue		
All	78 (15.5)	37.0 (19.0-67.5)
Substantial†	35 (13.3)	72.0 (51.0-80.0)
Sore throat		
All	65 (12.9)	53.0 (25.0-80.0)
Substantial†	36 (13.7)	80.0 (60.0-80.0)
Headache		
All	44 (8.7)	47.5 (16.0-78.5)
Substantial†	24 (9.1)	73.0 (60.0-80.0)
Shortness of breath		
All	35 (6.9)	60.0 (37.0-80.0)
Substantial†	20 (7.6)	80.0 (66.8-80.0)
Fever		
All	29 (5.8)	61.0 (37.0-80.0)
Substantial†	18 (6.8)	77.0 (64.8-80.8)

Abbreviations: OSTRC, Oslo Sports Trauma Research Center questionnaire; RRI, running-related injury.

*Values are median (25%-75% interquartile range).

†Substantial RRIs or illness symptoms are defined as scores of 13 or greater on questions 2 and/or 3 of the OSTRC questionnaire.

‡The interquartile range could not be calculated because there were only 2 cases.

and the OSTRC severity score. Both were found to be adequate (4 OSTRC questions, Cronbach's $\alpha = .91$; OSTRC severity score, Cronbach's $\alpha = .81$). Clarsen et al⁵ and Jorgensen et al¹² reported similar values for the internal consistency of the OSTRC questionnaire on overuse injuries (Cronbach's $\alpha = .91$) and health problems (Cronbach's $\alpha = .90$), respectively. In the same period as we translated the OSTRC questionnaire into Dutch, Pluim et al²⁴ also translated the OSTRC questionnaire into Dutch, but the internal consistency was not studied.

Limitations

One hundred fifteen half marathon runners and 46 full marathon runners participated in this study. Because this study had a relatively small sample, we could not study the incidence, prevalence, and impact of RRIs and illness symptoms for men and women and half and full marathon runners separately.¹⁸ Muscle and tendon RRIs (eg, jumper's knee or tendinitis) were the most frequently reported type of RRI (n = 188, 46.7%). We measured these injuries as 1 type of RRI. However, they can be separated into muscle RRIs and tendon RRIs, and into traumatic and atraumatic (ie, overuse) RRIs. We used a self-report questionnaire to assess the type of RRI and onset mechanisms. Novice runners can accurately (ie, validly) report the RRI location, but they may inaccurately assess the type of RRI and onset mechanisms.²⁸ Therefore, we might have underestimated the types of RRIs or onset mechanisms.

CONCLUSION

NINE IN EVERY 10 RUNNERS REPORTED an RRI or illness symptom during the 16-week period in the lead-up to a half marathon or full marathon—1 in every 3 runners reported an RRI, and half reported illness symptoms. In any 2-week period, up to 1 in 7 runners reported a new RRI. The most prevalent RRIs affected the lower leg and knee. Ankle and substantial groin RRIs

TABLE 5

TYPE OF RRIs DURING THE 16-WEEK PREPARATORY
PERIOD BEFORE THE UTRECHT MARATHON*

Type of RRI	All RRIs	Substantial RRIs†
Muscle and tendon injuries (eg, jumper's knee or tendinitis)	188 (46.7)	87 (43.3)
Overuse RRIs	127 (31.5)	58 (28.9)
Distortion	22 (5.5)	15 (7.5)
Spinal injury or hernia	15 (3.7)	13 (6.5)
Contusion	8 (2.0)	2 (1.0)
Cartilage injury	6 (1.5)	3 (1.5)
Joint luxation	3 (0.7)	0 (0.0)
Bone fracture	3 (0.7)	1 (0.5)
Other	31 (7.7)	22 (11.0)
Total	403 (100.0)	201 (100.0)

Abbreviation: OSTRC, Oslo Sports Trauma Research Center; RRI, running-related injury.

*Values are n (percent).

†Substantial RRIs are defined as scores of 13 or greater on questions 2 and/or 3 on the OSTRC questionnaire.

had the greatest impact. The most prevalent illness symptoms were rhinorrhea/sneezing and coughing. Fever, substantial shortness of breath, substantial sore throat, and substantial coughing were the symptoms that had the greatest impact. The prevalence and cumulative incidence proportion per 2 weeks of illness symptoms peaked at the same time as the influenza-like illness epidemic peaked in the winter of 2015–2016. ●

KEY POINTS

FINDINGS: Running-related injuries (RRIs) and illness symptoms occurred frequently in half and full marathon runners during a 16-week period in the lead-up to an event. In any 2-week period, up to 15% reported a new RRI and up to 14% reported new illness symptoms. The 2-week prevalence of RRIs ranged from 29.2% to 43.5%, and the 2-week prevalence of illness symptoms ranged from 28.3% to 71.2%.

IMPLICATIONS: Lower extremity RRIs and illness symptoms occur frequently in runners preparing for a half or full marathon event and have an impact on running performance and participation. Future studies must clarify the etiology of these RRIs and identify measures that might help to decrease injury prevalence and impact.

CAUTION: The findings are specific to half and full marathon runners. Therefore, they may not reflect RRI and illness symptom epidemiology in other athletic populations.

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APPENDIX

NEDERLANDSE VERSIE VAN DE OSLO SPORTS TRAUMA RESEARCH CENTER (OSTRC) VRAGENLIJST MONITOREN VAN BLESSURES EN ZIEKTES*

De volgende vragen gaan over de afgelopen twee weken. Gelieve alle vragen te beantwoorden, ongeacht of u gezondheidsproblemen heeft meegemaakt gedurende deze periode. Kies het antwoord dat het beste bij u past. In geval van twijfel, wilt u dan de meest geschikte optie selecteren.

Indien u verscheidene ziekten en/of blessures ondervindt, refereer a.u.b. naar de klacht die u het heftigste ondervond gedurende de afgelopen 2 weken. Aan het eind van de vragenlijst krijgt u de mogelijkheid om additionele gezondheidsproblemen te rapporteren.

Vraag 1: Heeft u problemen ondervonden bij het uitvoeren van een training en/of wedstrijd ten gevolge van een blessure, ziekte of andere gezondheidsproblemen gedurende de afgelopen 2 weken?

- | | |
|---|----|
| ☐ Volledige uitvoering zonder gezondheidsproblemen | 0 |
| ☐ Volledige uitvoering, inclusief blessure/ziekte | 8 |
| ☐ Verminderde uitvoering vanwege blessure/ziekte | 17 |
| ☐ Geen uitvoering vanwege blessure/ziekte | 25 |

Vraag 2: In hoeverre heeft u uw trainingsomvang moeten aanpassen ten gevolge van een blessure, ziekte of andere gezondheidsproblemen gedurende de afgelopen 2 weken?

- | | |
|---|----|
| ☐ Geen vermindering | 0 |
| ☐ In minimale hoeveelheid | 6 |
| ☐ In matige hoeveelheid | 13 |
| ☐ In grote hoeveelheid | 19 |
| ☐ Niet in staat tot uitvoering | 25 |

Vraag 3: In hoeverre heeft een blessure, ziekte of andere gezondheidsproblemen effect gehad op uw prestaties gedurende de afgelopen 2 weken?

- | | |
|---|----|
| ☐ Geen effect | 0 |
| ☐ In minimale hoeveelheid | 6 |
| ☐ In matige hoeveelheid | 13 |
| ☐ In grote hoeveelheid | 19 |
| ☐ Niet in staat tot uitvoering | 25 |

Vraag 4: In hoeverre heeft u symptomen/gezondheidsklachten ervaren gedurende de afgelopen 2 weken?

- | | |
|---|----|
| ☐ Geen symptomen/gezondheidsklachten | 0 |
| ☐ Milde symptomen/gezondheidsklachten | 8 |
| ☐ Matige symptomen/gezondheidsklachten | 17 |
| ☐ Ernstige symptomen/gezondheidsklachten | 25 |

De OSTRC somscore berekent u door de antwoordscores per vraag bij elkaar op te tellen. Indien bij vraag 2 en/of 3 de score ≥ 13 is spreekt men van een "substantiële" gezondheidsklacht.

*Translated from Clarsen et al.⁶ Adapted by permission from BMJ Publishing Group Limited.

Interpreting Outcomes 2—Statistical Significance and Clinical Meaningfulness: Linking Evidence to Practice

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Scores on outcome measures matter in the clinical world because they influence treatment decisions, and because payers are increasingly asking clinicians to justify their treatment decisions. For researchers, scores on outcome measures are the currency in which they trade; outcome scores provide the answers to research questions.

Many outcome constructs might be of interest to clinicians, researchers, patients, and payers: pain, function, disability, physical activity, work, depression, anxiety, quality of life, work productivity, etc. When talking about an outcome, we generally take this to mean the level of the construct (eg, low/medium/high pain intensity or good/poor physical function). We use a score on the outcome measure to give us this information.¹ Physical therapists need to interpret the scores on outcome measures, whether they are collected from their patients in practice or from participants in studies, to help guide clinical care.

The Evidence in Practice series has addressed the important distinction between change and difference.² In clinical practice, measurement usually involves calculating change in outcome scores from pretreatment to posttreatment, and interpreting whether the change is important or meaningful. In research, a study might report mean change in 1 group of people over time, or the mean difference between 2 groups.

Interpreting an outcome score involves making an informed judgment about what a change or difference of that size really means. This involves asking whether the change or difference is clinically meaningful, statistically significant, or both (**TABLE**). For simplicity, this article will refer to between-group differences to illustrate the concepts.

Statistical Significance

What Is a *P* Value? An enduring memory from statistics classes is often that a *P* value less than .05 means something important has happened. The *P* value represents the probability that the true difference between the means of 2 groups is as big as, or bigger than, the difference reported in the study, if the groups came

from the same population and assuming that the data meet various statistical assumptions. A *P* value is not the probability that the 2 groups are different, nor is it the probability that the difference is due to chance.³ If this sounds suspiciously complicated, you are not alone—the concept is not at all user friendly. Traditionally, researchers have interpreted a *P* value of less than .05 in a randomized controlled trial to mean that we are quite confident that the reported difference is not due to random variation and that the reported difference is because of the treatment.

One common, incorrect interpretation of a *P* value less than .05 is that the difference between groups is 95% likely to be “real,” as opposed to a chance finding. This interpretation is not accurate due to the way *P* values are calculated, which means that a *P* value itself is not a good measure of evidence regarding hypotheses about treatment effectiveness. This

TABLE		STATISTICAL SIGNIFICANCE AND CLINICAL MEANINGFULNESS	
		Description	
Statistically significant difference		The probability under a specified statistical model that a statistical summary of the data (eg, mean difference between 2 groups) would be equal to or more extreme than its observed value ³	
Clinically meaningful difference		A mean difference between groups that is large enough for patients to consider the difference important	

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[EVIDENCE IN PRACTICE]

view is gradually gaining acceptance in the world of clinical research. Authors, reviewers, and journal editors are changing the way *P* values are interpreted in published articles; this involves less emphasis on statistical significance to determine treatment effectiveness.

Size of Effect The mathematical process used to calculate *P* values is sensitive to sample size and the precision of the measure. Let's say we conducted 2 randomized controlled trials in the same population, and delivered the same treatment and control interventions. One trial had 50 participants in each group and the other trial had 500 in each group. On the measure of disability, there was a between-group difference of 10 points in the smaller trial and a between-group difference of 5 points in the larger trial. It is possible that the difference (of 5 points) is statistically significant in the larger trial and that the difference (of 10 points) in the smaller trial is not significant, simply because the smaller trial had less statistical power (ie, its ability to detect a statistical difference). So, we might conclude that the same treatment was effective when tested in a large clinical trial, but not effective when tested in a smaller trial. This means, given enough participants, that one can find a statistically significant *P* value but that this sig-

nificant difference may have no clinical meaning or value.

Clinical Meaningfulness

Interpreting change or difference on an outcome score requires considering how large the change or difference actually is and whether it has clinical implications. Researchers have become increasingly interested in the concept of clinical meaningfulness. You might have read terms like *minimal important change*, *minimal clinically important difference*, and *smallest worthwhile effect*. The goal is to determine whether the size of the difference is likely to be worthwhile from the patient's point of view.

Defining a clinically meaningful difference means determining a threshold for an outcome measure (eg, 2 points on a 0-to-10 pain-intensity scale, or 30% improvement from the baseline score). If the difference between groups is larger than this, then the treatment is considered "effective" compared to control. The precision of the treatment effect, usually reported with confidence intervals, is also relevant when interpreting how meaningful a change is. Precision will be the topic of an upcoming Evidence in Practice article.

Just as when assigning a $P < .05$ threshold for statistical significance, there are

real challenges with determining "clinical meaningfulness" thresholds for outcome measures. Defining clinical meaningfulness for assessing treatment effectiveness is complex, and the next Evidence in Practice article takes a deeper dive into the issue.

Conclusion

Measuring outcomes is critical. But measuring is only half the job—data must be analyzed and interpreted appropriately. This is the case in research and in clinical practice. Determining whether a treatment is effective involves making judgments about (1) the size of the reported effect, (2) the precision of the effect, and (3) whether the effect is clinically meaningful. ●

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High-Level Performance After the Return to Run Clinical Pathway in Patients Using the Intrepid Dynamic Exoskeletal Orthosis

Ankle and foot injuries such as fractures, sprains/strains, and crush injuries are common in military servicemembers.^{1,25} For instance, it has been estimated that upward of 221 393 soldiers can seek medical attention for ankle and foot injuries in a 5-year span.²⁵ Treatment of combat-related ankle and foot fractures often involves radical surgical procedures and, at times, amputation.^{6,12,24} Within the military setting, a sports medicine approach is typically utilized for rehabilitation, facilitating early strength and functional training, with the hope of return to high-level

activities and, potentially, to duty.¹⁴ Despite this approach, sprains and fractures of the lower leg, ankle, and foot are some of the leading causes of limited-duty days²⁰ and medical discharge²³ from the military. Ad-



ditionally, return-to-duty rates after foot and ankle injuries remain extremely low, with only 18% to 28% returning to duty after open tibial fractures,⁵ hindfoot injuries,²² and Lisfranc injuries.²

In 2009, a multidisciplinary team of physical therapists, prosthetists, and orthopaedics specialists from the Center for the Intrepid at Brooke Army Medical Center developed the Intrepid Dynamic Exoskeletal Orthosis (IDEO) and a unique rehabilitation program, the Return to Run Clinical Pathway (RTR), with the goal of returning servicemembers with severe limb injuries to running, sports, and possibly military duty.^{15,16} The IDEO (FIGURE 1) is a custom, energy storage and return, carbon-fiber ankle-foot orthosis whose key features include a plantar-flexed, roller-shaped foot plate; proximal ground reaction force cuff; and posteriorly mounted struts with variable stiffness, based on the patient's height, weight, and intended activity level with the orthosis.^{16,21} The RTR is a rehabilitation program that was specifically developed for IDEO users, which includes strengthening and multidirectional agility training as previously described.^{15,16}

• **BACKGROUND:** Severe ankle and foot injuries in the US military can result in high-level functional limitation, lost duty days, and medical discharge.

• **OBJECTIVE:** To assess the effectiveness of the Return to Run Clinical Pathway (RTR) in returning patients with lower extremity fractures who utilized the Intrepid Dynamic Exoskeletal Orthosis (IDEO) to high-level mobility.

• **METHODS:** Thirty servicemembers with lower extremity fractures who utilized the IDEO unilaterally and completed the RTR at Naval Medical Center San Diego were included in this retrospective operational review. The Comprehensive High-level Activity Mobility Predictor (CHAMP) and all subtests were completed prior to and after completion of the RTR as part of routine clinical care. An analysis of covariance (ANCOVA) was used to compare CHAMP scores before and after the RTR.

• **RESULTS:** Significant improvements were found in the T test (mean change, faster by 5.3 seconds; 95% confidence interval: 3.6, 7.1 seconds; $P = .03$) and total CHAMP score (mean change, 4.2 points; 95% confidence interval: 3.0, 5.3 points; $P < .05$). No significant changes were noted in the single-legged stance subtest, the Edgren sidestep test, or the Illinois agility test.

• **CONCLUSION:** The RTR led to improvements in high-level, multidirectional mobility in IDEO users with a history of fractures. Applicability of the intervention used in this study requires further validation before widespread use.

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• **KEY WORDS:** ankle-foot orthosis, military, rehabilitation with orthoses

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When running with this specialized orthosis, a midfoot strike has been hypothesized to maximize the capabilities of energy storage and return; therefore, training the appropriate foot-strike pattern is a focus of the RTR.^{15,16,21}

A comparative study by Patzkowski et al¹⁷ examined functional performance in the IDEO compared to 2 other ankle-foot orthoses (BlueROCKER, posterior leaf spring) and a no-brace condition. Results suggested that the IDEO had superior performance in the 40-yd (36.6 m) dash, 4-square step test, timed stair ascent, and self-selected walking velocity, and was the preferred bracing option for 94.4% of the sample. Using similar performance measures, Bedigrew et al³ found improvements in the 4-square step test, self-selected walking speed, and timed stair ascent after completion of the RTR in individuals who utilized the IDEO. Moreover, Owens and colleagues¹⁵ found subjectively that IDEO users who completed the RTR reported successful return to running, sports, weightlifting,

and even return to duty. On the other hand, Blair et al⁴ suggested that IDEO users with an ankle injury who did not participate in the RTR were less likely to return to duty (12.9%) when compared to those who did complete the RTR (51.3%).

One of the limitations of the previous research on the IDEO and RTR is that the outcome measures used in these studies may not have completely captured the multidirectional agility improvements practiced during the RTR. For instance, measuring a 40-yd (36.6 m) dash and self-selected walking speed requires mainly sagittal plane motion, without the need to change direction. The 4-square step test is commonly utilized to assess fall risk^{7,8}; however, risk of falls would be unexpected in patients with high-level mobility participating in a rehabilitation program such as the RTR. Anecdotally, both patients and providers have highlighted the high-level performance achieved after completion of the RTR since the implementation of the IDEO and RTR at military treatment facilities. Therefore, the purpose of the current study was to assess high-level, multidirectional performance after completing the RTR in individuals with lower extremity fractures who had been prescribed the IDEO at a military treatment facility. We hypothesized that participation in the RTR would result in significant improvements in multidirectional performance, as assessed using the Comprehensive High-level Activity Mobility Predictor (CHAMP) test.

METHODS

THE CURRENT STUDY WAS A RETROSPECTIVE analysis of patients with lower extremity fractures who were prescribed the IDEO unilaterally for ankle and/or foot pain and/or high-level functional limitations from February 2014 through June 2017. As part of standard clinical care, all patients were initially evaluated by a multidisciplinary team, including an orthotist, physical therapist, physical medicine and reha-

bilitation physician, and orthopaedic surgeon, to determine patient eligibility to receive an IDEO. Primary injuries necessitating the IDEO included fractures of the ankle ($n = 16$), foot ($n = 9$), tibial/fibular shaft ($n = 3$), or a combination of these regions ($n = 2$).

Patients were not excluded from this analysis if they had any injuries proximal to or at the knee joint or injuries to the contralateral limb, as this was consistent with the multidisciplinary team's clinical decision making for IDEO prescription. Out of this sample, 27% had proximal injuries and 20% had contralateral injuries that occurred due to the same initial mechanism. Patients were deemed not eligible to receive the IDEO if they presented with progressive degenerative diseases such as multiple sclerosis, proximal weakness due to neurological involvement (peripheral or central nervous system), severe joint laxity or muscle weakness, and/or excessive pain at rest with a diagnosis of complex regional pain syndrome. Mechanisms of injury varied among the patients in this analysis, and included motorcycle accidents, motor vehicle accidents, improvised explosive device, sporting injuries, falls, and unknown/other (which includes stress fracture). This protocol was approved by the Naval Medical Center San Diego's Institutional Review Board (NMCS.D.2014.0026). A total of 30 patients were identified for analysis (TABLE 1).

All patients were casted and fitted for the orthosis by a single certified orthotist. The IDEO design replicated previous studies' descriptions^{15,16}; the posterior strut stiffness was determined by the same orthotist and individualized to each patient's anthropometrics and utilization of the orthosis (walking versus running). An initial test fitting of a "check"/temporary orthosis was performed prior to the fabrication of the definitive orthosis. Once the orthotist achieved optimal fit and alignment of the definitive IDEO, patients were enrolled into the RTR and were trained by a single licensed physical therapy assistant with certification in athletic training.



FIGURE 1. The Intrepid Dynamic Exoskeletal Orthosis.

The RTR started, on average, 4.7 ± 4.0 days after receiving the orthosis. The training program consisted of strengthening of the lower extremities and core, plyometric training, and run retraining, with a focus on multidirectional motions and proper foot strike in the orthosis, as described previously.^{4,15,16} The RTR was held 3 times a week, with an additional day each week used to practice traversing outdoor, inclined, uneven terrain. Session 1 of each week (“linear day”) was mainly dedicated to performing exercises primarily in the sagittal plane, while session 2 (“lateral day”) focused more on exercises performed primarily in the frontal plane. The third session each week (“acceleration day”) then targeted exercises for speed development combined with changing directions.

Strengthening exercises of the lower and upper extremities were progressed over the course of the training, which

began by finding the individual’s 80% 1-repetition maximum. The individual then exercised, using the 80% 1-repetition maximum weight, at a set tempo of a 10-second concentric contraction followed by a 10-second eccentric contraction. Once the individual was able to complete 6 repetitions at this tempo, the weight was increased by 4.5 kg. Speed and agility exercise progression followed a patient-specific model, considering factors such as current level of function and patient goals. The 20-m 6-cone run (FIGURE 2) was a timed exercise performed weekly, in which patients personally tracked their time and strove for weekly improvements.

The APPENDIX (supplemental video available at www.jospt.org) provides a comprehensive list of exercises incorporated into each of the training days. Completion of the RTR program required participation in approximately 12 visits or,

at the discretion of the clinical staff, the patient achieving his or her goals. Multiple IDEO users participate in the RTR at the same time, creating a group rehabilitation environment, with varied levels of experience with the IDEO among users.

Assessment of Multidirectional Performance

The CHAMP test was originally developed to assess high-level functioning in servicemembers with lower-limb amputations.¹⁰ The CHAMP test consists of 4 subtests (FIGURE 3): single-legged stance, the Edgren sidestep test,¹⁹ T test,¹⁹ and Illinois agility test.^{13,19} The test-retest and interrater reliability of the total CHAMP score and subtest scores have been found to be excellent (intraclass correlation coefficient [ICC] range, 0.97-1.00) in servicemembers with lower-limb amputations.¹⁰ As for the Edgren sidestep test, T test, and Illinois agility test, interrater reliability has been found to be excellent (ICC range, 0.92-0.99) and test-retest reliability good to excellent (ICC range, 0.62-0.83) in male servicemembers without injuries.¹⁹

The CHAMP test was collected for all patients in this cohort by physical therapists as part of standard clinical care. The

TABLE 1		PARTICIPANT DEMOGRAPHICS	
		Value*	
Sex, n (%)			
	Male	28 (93)	
	Female	2 (7)	
Branch of service, n (%)			
	Navy	15 (50)	
	Marine Corps	13 (43)	
	Army	1 (3)	
	Air Force	1 (3)	
Mechanism of injury, n (%)			
	Motorcycle accident	15 (50)	
	Motor vehicle accident	2 (7)	
	IED	2 (7)	
	Sporting injuries	1 (3)	
	Falls	2 (7)	
	Unknown/other	8 (27)	
Age at injury, y		27.8 ± 6.3	
Age at time of IDEO, y		30.9 ± 7.1	
Height pre RTR, cm		175.2 ± 6.5	
Weight pre RTR, kg		86.6 ± 15.8	
Body mass index, kg/m²		28.1 ± 4.4	
Abbreviations: IDEO, Intrepid Dynamic Exoskeletal Orthosis; IED, improvised explosive device; RTR, Return to Run Clinical Pathway.			
*Values are mean ± SD unless otherwise indicated.			

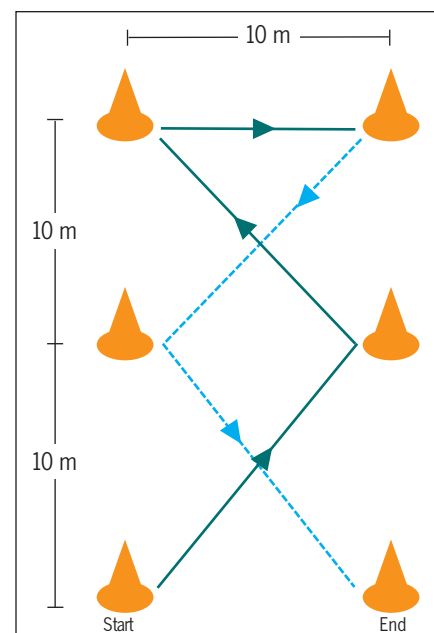


FIGURE 2. Timed 20-m 6-cone run.

[RESEARCH REPORT]

CHAMP test was used in this study and as part of clinical assessments due to its intended use for servicemembers, ability to measure multidirectional high-level mobility, and clinical utilization across military treatment facilities. All participants completed the 4 subtests on a level surface, either in an indoor gymnasium or on an outdoor tennis court, while wearing the IDEO and athletic shoes. Completion of the CHAMP test without the IDEO is not routinely conducted as part of clinical care due to the patients' pain intensity when not using the orthosis and inability to perform high-impact activities without the orthosis; therefore, assessment of the CHAMP test without the IDEO was not included in the current study. The CHAMP test was measured prior to starting the RTR and after completion of the RTR.

Single-legged stance was used to assess static balance and stability. A maximum of 3 trials on each limb were recorded; the best score was used for analysis. Single-legged stance score was recorded in seconds, with an increase in time indicative of improvement and a maximum score of 30 seconds (FIGURE 3A). The Edgren sidestep test (FIGURE 3B) measured unidirectional frontal plane agility by sidestepping in both the left and right directions, while the T test (FIGURE 3C) assessed bidirectional agility in the frontal and sagittal planes (forward and backward) in the navigation of a T-shaped course. The Illinois agility test (FIGURE 3D) was used to evaluate multidirectional, high-level mobility in all 3 planes of motion (sagittal, frontal, and transverse), which included forward sprinting and weaving in S-like motions

between cones. The Edgren sidestep test was scored in number of meters sidestepped in 10 seconds, with a higher score indicative of improvement. In contrast, both the T test and Illinois agility test were scored in seconds to complete each test, with decreases in time indicative of improvement. The best score was used for analysis, from a maximum of 2 trials, for the Edgren sidestep test, T test, and Illinois agility test. Total CHAMP test score was quantified as the sum of converted scores for each subtest, previously described in detail elsewhere.¹⁰ Total CHAMP scores can range from 0 to 40, with 40 representing the highest level of performance.¹⁰

Statistical Analysis

Descriptive statistics were performed for sample characteristics. A repeated-

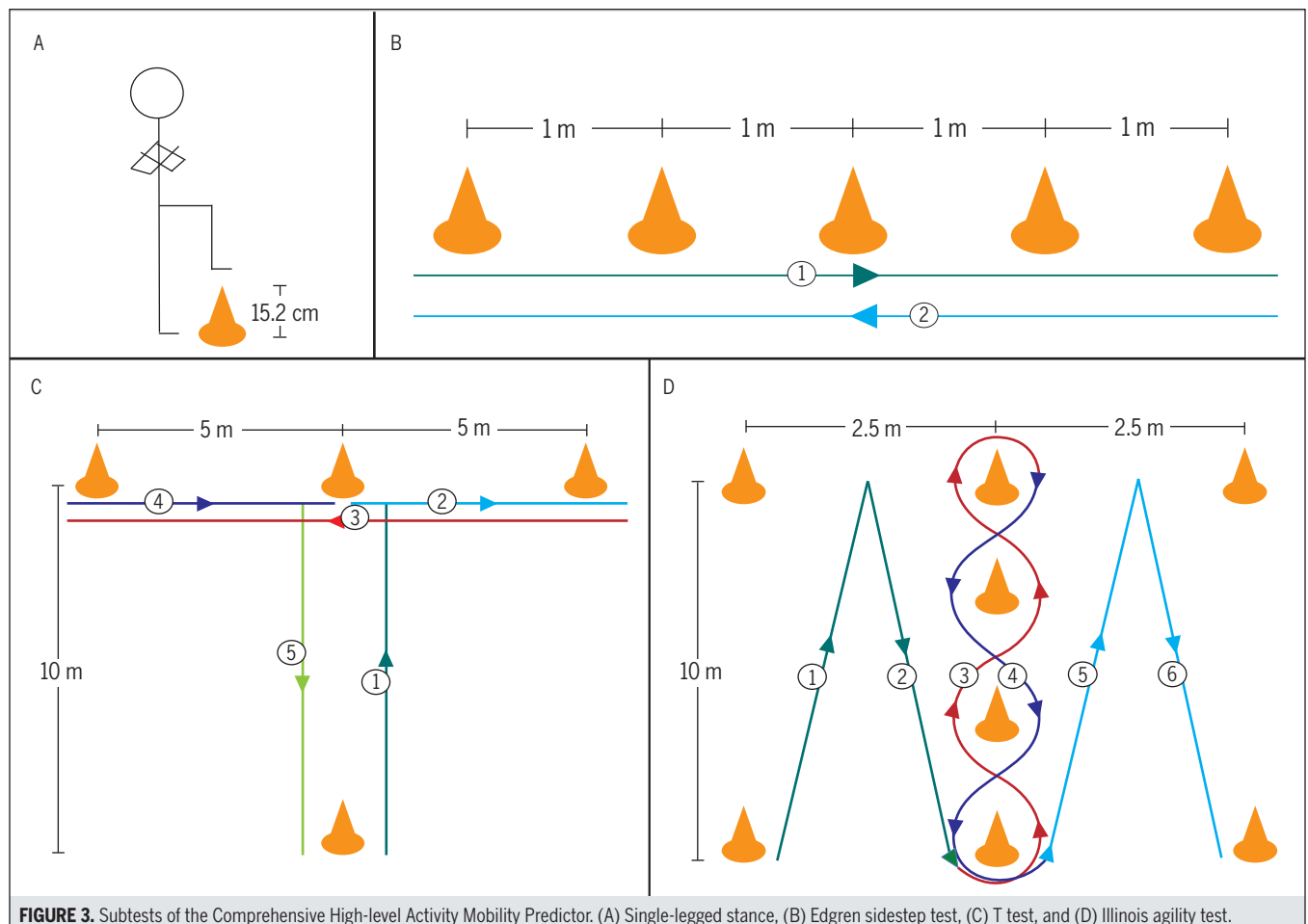


FIGURE 3. Subtests of the Comprehensive High-level Activity Mobility Predictor. (A) Single-legged stance, (B) Edgren sidestep test, (C) T test, and (D) Illinois agility test.

measures analysis of covariance was performed while adjusting the covariates of body mass index and the time between injury and receiving the IDEO. Comparison tests were performed for the CHAMP raw scores and total CHAMP score before and after the RTR ($\alpha = .05$).

RESULTS

THE MAJORITY OF THE STUDY SAMPLE were men (93%) and served in the US Navy (50%) and Marine Corps (43%). Participants included in this sample received their definitive IDEO an average $\pm$ SD of 3.1 ± 4.8 years after their injury or onset of pain, at an average age of 30.9 ± 7.1 years. On average, it took patients 42.5 ± 16.4 days or 6.1 ± 2.3 weeks to complete the RTR. Participants completed 2.5 ± 1.1 RTR visits per week, with an average total number of visits of 13.0 ± 3.8 .

Significant improvements were noted (TABLE 2) in raw scores for the T test and

total CHAMP test score ($P < .05$). Time to complete the T test improved, on average, by 5.3 seconds (95% confidence interval [CI]: 3.6, 7.1 seconds). The total CHAMP score also significantly improved by an average of 4.2 points (95% CI: 3.0, 5.3 points). No significant changes were noted in single-legged stance raw score in the unaffected and affected limbs ($P > .05$). Edgren sidestep test performance improved by 3.7 m on average (95% CI: 2.4, 5.1 m); however, this change was not statistically significant ($P = .34$). Performance on the Illinois agility test also improved, on average, by 5.3 seconds (95% CI: 3.9, 6.8 seconds; $P = .07$).

DISCUSSION

THE FINDINGS FROM THIS STUDY demonstrate clinically important improvements as a result of clinical care provided to this unique patient cohort. The findings from this retrospective observational study support our ini-

tial hypothesis that the RTR is effective at improving multidirectional, high-level performance in patients with prior lower extremity fractures who use the IDEO. This study demonstrated a significant improvement in the raw scores for the T test and the converted total CHAMP scores. Average changes in the T test and converted total CHAMP score exceeded the established minimal detectable change previously reported in the literature (TABLE 2).^{10,19}

These improvements were likely a result of a combination of factors, including the multidirectional agility training that is part of the RTR, increased overall exercise performance, improved patient confidence, interference with the pain cycle, energy storage and return provided by the IDEO, and offloading of the involved limb, through the IDEO design, with appropriate running foot-strike form. Improvement in performance during the Edgren sidestep test and Illinois agility test did exceed the established minimal

TABLE 2

CHAMP SCORES

Test	Unadjusted Means*		ANCOVA				
	Pre RTR	Post RTR	Source	df	F Value	P Value	MDC
Single-limb stance (IDEO side), s	3.5 ± 2.7	5.5 ± 5.8	BMI	1	1.6	.76	NE
			Time [†]	1	0.0		
			Error	27			
Single-limb stance (non-IDEO side), s	30.0 ± 0.0	29.7 ± 1.3	BMI	1	0.4	.56	NE
			Time [†]	1	8.2		
			Error	27			
Edgren sidestep test, m	17.0 ± 3.3	20.7 ± 2.6	BMI	1	0.4	.34	3.19 ¹⁹
			Time [†]	1	0.4		
			Error	27			
T test, s	21.0 ± 5.6	15.6 ± 2.0	BMI	1	1.7	.03 [‡]	1.1 ¹⁹
			Time [†]	1	0.0		
			Error	27			
Illinois agility test, s	27.5 ± 4.5	22.2 ± 2.2	BMI	1	0.2	.07	1.8 ¹⁹
			Time [†]	1	0.1		
			Error	27			
Total CHAMP score	24.7 ± 2.6	28.8 ± 2.7	BMI	1	0.0	.047 [‡]	3.7 ¹⁰
			Time [†]	1	0.3		
			Error	27			

Abbreviations: ANCOVA, analysis of covariance; BMI, body mass index; CHAMP, Comprehensive High-level Activity Mobility Predictor; IDEO, Intrepid Dynamic Exoskeletal Orthosis; MDC, minimal detectable change; NE, not established for 30-second maximum; RTR, Return to Run Clinical Pathway.

*Values are mean $\pm$ SD.

[†]Time between injury and receiving orthosis.

[‡]Significant ($P < .05$).

detectable change¹⁰; however, neither result was statistically significant, which may be due to lack of study power. Additionally, there were no significant improvements in the single-legged stance time for either extremity. For the affected side, this may be impacted by the orthosis shape and design, where positioning the ankle in a relatively fixed plantar-flexed position and a rocker-shaped forefoot can compromise the use of an ankle strategy¹¹ to control balance, as well as little emphasis on static balance during the RTR. A ceiling effect is anticipated to play a role in the lack of significant change in the single-legged stance time of the unaffected limb, where most subjects achieved the maximum score of 30 seconds, leaving no room for improvement.

The CHAMP test was originally developed to measure agility, power, speed, balance, and coordination in servicemembers with lower-limb amputations.¹⁰ Although the individual subtests of the CHAMP have been used in various populations,^{9,13,18,19} to the best of our knowledge, this is the first study to utilize the composite score in a sample of servicemembers with lower-limb trauma other than amputation. When comparing results from this study to prior research,¹⁰ our sample of patients with lower extremity fractures who utilized a unilateral IDEO performed 29% to 48% better than servicemembers with lower-limb loss, but 16% to 25% worse than servicemembers without limb injuries, after completing the RTR program for the CHAMP subtests and the total CHAMP score. The ability to master the CHAMP test in this patient cohort was likely due to a combination of the IDEO and the RTR, as part of the multidisciplinary approach to rehabilitation used at the military treatment facility.

Study Limitations

As a retrospective analysis, limitations to this study include a sample of convenience, lack of control group, multiple raters, and broad inclusion criteria. The CHAMP test was gathered as a functional

outcome measure by 3 trained physical therapists as part of standard clinical care. All physical therapists were trained to provide instructions in the same way to limit intertester variability in the clinical assessments.

Another limitation of the study may be a potential bias toward those who were more likely to have successful outcomes with the IDEO, by including only patients who completed the RTR. A post-RTR CHAMP test was only conducted clinically on patients who completed the RTR program, therefore making it difficult to control for this bias. Some reasons for not completing the RTR include patient noncompliance, time constraints due to work responsibilities, transition out of the military, and receiving military orders requiring a move outside the area. Further assessment of functional outcomes in those who did not complete the RTR is necessary, as well as in those who started but did not complete the full RTR, to determine the effectiveness of the program.

Because this was a retrospective analysis of clinical outcomes, including a control group for comparison purposes was not possible, as it would be unethical to withhold these services from patients who could receive substantial benefits from the treatment. The findings from this study suggest a positive effect of the orthosis within the context of the RTR; however, additional research is needed to prove this. Future research efforts should consider additional comparisons to other widely used ankle-foot orthoses to provide further insight on high-level outcomes unique to orthosis design.

CONCLUSION

HIGH-LEVEL FUNCTIONING IS AN important outcome, in particular for servicemembers and athletes. Findings from this study support the hypothesis that the RTR is an effective treatment approach for individuals with lower extremity fractures who utilize the IDEO for returning to high-level activities. At

this time, abandonment rates as well as long-term outcomes and complications, such as secondary musculoskeletal conditions of the IDEO, remain unknown. Future clinical efforts should focus on providing high functional outcomes for young, wounded military servicemembers while minimizing negative secondary effects. ●

KEY POINTS

FINDINGS: High-level, multidirectional mobility improves after completion of an intensive sports medicine rehabilitation program in patients with lower extremity fractures who utilized a custom, energy storage and return ankle-foot orthosis.

IMPLICATIONS: The patients involved in this study were a unique population and were highly motivated to return to high-level activities. Patient goals, prior activity level, and injury severity should be considered when using this specific ankle-foot orthosis and high-level rehabilitation program.

CAUTION: Limitations of this study include a sample of convenience, absence of a control group, and a potential bias toward those who successfully complete the Return to Run Clinical Pathway.

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APPENDIX

EXERCISES USED IN THE RETURN TO RUN CLINICAL PATHWAY

Exercises on linear days (120 minutes)

- Monster walks, forward/lateral (100 ft)
- Forward/backward lunges (100 ft)
- Dynamic hip swings, forward/backward/lateral (2 sets of 10 repetitions)
- Over/unders (100 ft)
- Nonreciprocal forward ladder drill (100 ft)
- Reciprocal forward ladder drill (100 ft)
- Static split squats (10 repetitions)
- Static lunges (10 repetitions)
- Walking lunges (100 ft × 2)
- Sport-cord running (300 ft)
- Double-legged bridge (10 repetitions)
- Alternating single-legged bridge (10 repetitions)
- Stair runs (2 flights × 3 bouts)
- Inchworm (10 repetitions)
- Quarter-mile run (or longer, if able)
- Dowel runs (3 bouts)
- Lower extremity strengthening
 - Leg press*
 - Knee flexion/extension*
 - Hip abduction/adduction*
 - Hip thrusters (3 sets of 10 repetitions)
 - Deadlift (3 sets of 10 repetitions)

Exercises on lateral days (90 minutes)

- Monster walks, lateral/diagonal (100 ft)
- Slide backs, backward/diagonal (2 sets of 25 repetitions each)
- T drill with resistance (3 bouts)
- S drill (3 bouts)
- Lateral hurdles, right/left (3 bouts each side)
- Hurdle squat jumps (100 ft)
- Wall drives, lateral/forward (10 repetitions each direction)
- Rearfoot elevated squats (2 sets of 10 repetitions)
- Ladder drills, gas/brake, diagonals (4 bouts)

- Cardio (20 min; patient choice of bike, elliptical, treadmill, or stair climber)
- Box jumps (2 sets of 10 repetitions)
- Shadow drill

Exercises on acceleration days (120 minutes)

- Monster walks, lateral/diagonal (100 ft)
- Forward/backward lunges (100 ft)
- Wall drills: single-leg high knees (10 repetitions)
- Wall drills: alternating high knees (10 repetitions)
- Wall drills: dynamic high knees (10 repetitions)
- Supine alternating single-leg raises (10 repetitions)
- Static split squats (10 repetitions)
- Static lunges (10 repetitions)
- Walking lunges (100 ft × 2)
- Seated running arm motions (10 s at slow speed, 10 s at medium speed, 10 s at fast speed; 3 bouts each)
- Planks, forward/right/left (10 repetitions each)
- High-knee folds (10 repetitions per side)
- Dowel runs (3 bouts)
- Falling starts (10 repetitions)
- Timed 20-m 6-cone run (3 bouts)
- Push-up starts (10 repetitions)
- Sled pull (300 ft)
- Pallof press squats, right/left (10 repetitions each side)
- Pallof press tall kneeling, right/left (10 repetitions each side)
- Rope slams (3 sets × 30 s)
- Upper extremity strengthening
 - Bench press*
 - Incline bench*
 - Lat pull-downs*
 - Seated row*
 - Land-mine bus driver (3 sets of 10 repetitions)
 - Land-mine push press (3 sets of 10 repetitions)

**Exercise performed at 80% 1-repetition maximum at a set tempo of a 10-second concentric contraction followed by a 10-second eccentric contraction. Once the individual is able to complete 6 repetitions in 2 minutes at the specified tempo, weight is increased by 4.5 kg.*

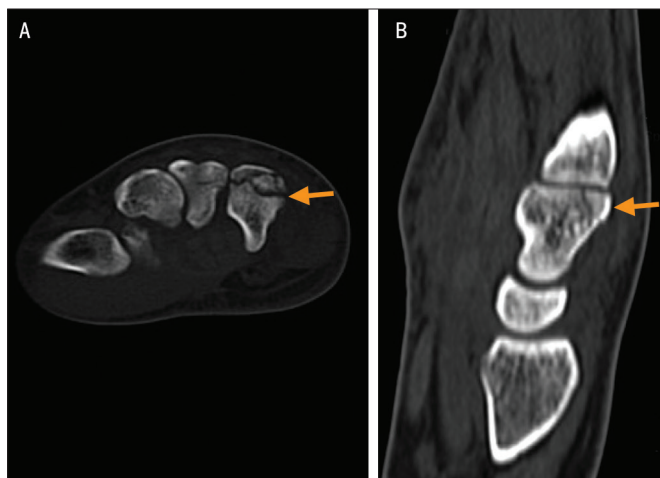


FIGURE 1. Initial computed tomography scan of the right wrist demonstrating a comminuted, nondisplaced dorsal hamate fracture (orange arrows): (A) axial view and (B) sagittal view.

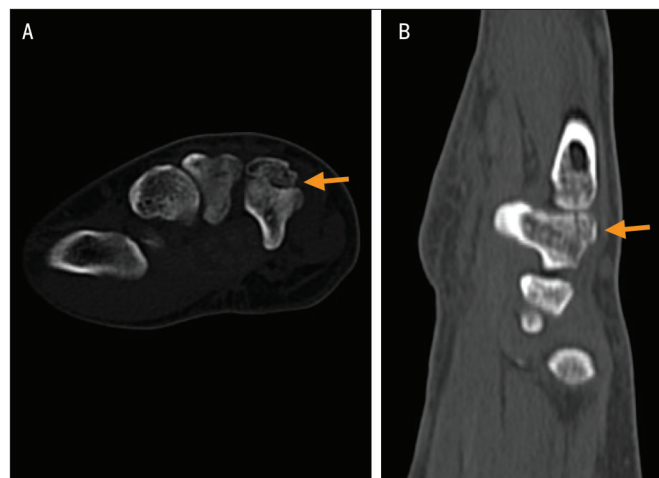


FIGURE 2. Repeat computed tomography scan of the right wrist, performed 12 weeks after the initial injury, demonstrating partial healing of the comminuted hamate fracture (orange arrows): (A) axial view and (B) sagittal view.

Nonoperative Comminuted Hamate Fracture

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A DEPLOYED US NAVY SAILOR WAS seen at a host-nation emergency department after falling on her outstretched hand. A computed tomography (CT) scan was utilized due to the frequent insufficiency of standard radiographs to demonstrate fractures and demonstrated a comminuted, nondisplaced dorsal hamate fracture (**FIGURE 1**). In the absence of displacement or carpometacarpal subluxation, the fracture was treated conservatively with cast immobilization. After 8 weeks of cast immobilization, a CT scan revealed no healing, and the host-nation orthopaedic surgeon recommended a carpectomy. The physical therapist, act-

ing as the patient's musculoskeletal primary care provider, obtained a second opinion remotely from a Navy orthopaedic surgeon, who deemed that there was no indication for delayed surgical fixation because the fracture remained stable, without secondary displacement.

Cast immobilization was discontinued following the remote consultation, and physical therapy was initiated 1 to 2 times per week to regain motion. After 4 weeks of physical therapy, the patient complained of clicking over the ulnar aspect of her wrist. A CT scan was performed and demonstrated partial fracture healing without displacement, so physical

therapy continued (**FIGURE 2**). At the conclusion of physical therapy, 5 months after injury, she exceeded her previous maximum bench press weight and push-ups, meeting the fitness standards of the Navy.

Hamate fractures are rare and account for less than 2% of all carpal fractures.² Classified by their area of involvement, type I involves the hook of the hamate, and the less common type II involves the body.¹ Conservative treatment of nondisplaced body fractures has demonstrated good results, but such fractures require monitoring for secondary displacement.^{1,3} *J Orthop Sports Phys Ther* 2019;49(7):557. doi:10.2519/jospt.2019.8514

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The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or reflecting the views of the US Navy or Department of Defense.

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The 2018 Physical Activity Guidelines for Americans: What's New? Implications for Clinicians and the Public

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Despite the widely publicized health benefits of physical activity, a large proportion of the world's population is insufficiently active or completely inactive.⁶ Every few years, several major national health authorities review the evidence base and release formal advice and guidance on the amount and type of physical activity that people should do. Since the 1996 US Surgeon General's report on physical activity and health, the publication of the US physical activity guidelines has been much anticipated. These guidelines come with bells and whistles for a reason: more than any other country, America places a remarkable effort into systematically synthesizing thousands of studies on physical activity and health.

Like its 2008 predecessor,¹¹ the 2018 edition of the Physical Activity Guidelines for Americans (PAGA18) was a mammoth feat involving nearly 100 committee members, consultants, experts, and personnel, who scrutinized 38 questions and 104 subquestions and graded the evidence based on research consistency and quality. The whole effort took over 2

years to complete and resulted in a 779-page report in early 2018, followed by the publication of the summary guidelines in the *Journal of the American Medical Association*.¹²

In this Viewpoint, we (1) summarize the key components of the PAGA18 with respect to adults, and (2) discuss the implications for the general public and health care practitioners.

Amounts and Types of Physical Activity Recommended for Key Populations

The traditional definition of physical activity is any movement produced by skeletal muscles that results in energy

expenditure.² Guidelines have progressed beyond the classical movement–energy expenditure definition.² For example, aspects of posture, such as large amounts of sitting, are now recognized as relevant to some health outcomes.¹³ Here are the headline recommendations for 4 specific groups of adults.

Adults Aged 18 to 64 Years Able-bodied adults should move more and sit less in daily life. For more substantial health benefits, adults should engage in 150 to 300 minutes of moderate-intensity physical activity, or 75 to 150 minutes of vigorous activity, or equivalent combinations of both. One minute of vigorous activity is approximately equivalent to 2 minutes of moderate activity.¹⁸ Ideally, the activity should be spread throughout the week. There may be extra health benefits of going beyond the recommended amounts. In addition, adults should engage in strength training that involves all major muscle groups at least

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twice a week, although no session duration is specified.¹²

Adults Aged 65 Years and Older In addition to the recommendations for those aged 18 to 64 years, older adults should engage in multicomponent activities that include balance training for fall prevention, and aerobic and muscle-strengthening activities. As fitness and physical limitations in older adults are more common, the appropriate activity intensity should be relative, not absolute.¹²

Physical Activity During Pregnancy and After Giving Birth During pregnancy, and in the postpartum period, women should aim for at least 150 minutes of moderate physical activity per week. Women who regularly engage in vigorous-intensity activities before pregnancy can maintain these activities during and after their pregnancy. Pregnant women should consult a health care practitioner for advice on adjusting their activity level if needed.¹²

Adults With Chronic Conditions or Disabilities In the United States alone, 117 million adults (about half the population) have 1 or more preventable chronic health problems. Most chronic health problems can be managed well with physical activity.¹ Adults with chronic conditions should consult a health care practitioner to ascertain their ability to do regular physical activity. If they are able to, adults with chronic conditions should aim to meet the physical activity recommendations in terms of aerobic activity and strength training. If these chronic conditions do not allow them to meet the recommended amounts, then

they should aim to be as physically active as possible.

What Is New (or Almost New) in the PAGA18?

The PAGA18 is not short of new insights into physical activity and new recommendations (the **TABLE** summarizes the novel elements of the PAGA18, as well as their potential implications). In the next sections, we address 5 elements.

An Upper Boundary on the Recommended Exercise Dose for Adults An upper boundary (ie, 300 moderate-intensity minutes per week) is favored over a single minimum value (150 minutes). An upper limit encourages people to do more than the minimum amount. The upper limit also recognizes that very high volumes of moderate to vigorous activity may not be necessary to maintain health and prevent disease. For many people, somewhere in the recommended range will be a feasible “sweet spot” where they will gain the most health benefit.

No Lower Threshold on the Recommended Exercise Dose Less than 150 minutes of moderate or 75 minutes of vigorous activity per week can still have substantial health benefits. This is a positive message for much of the population, who currently fall well short of the desirable minimum, including many people with chronic health conditions: doing something is better than doing nothing at all.

No More 10-Minute Continuous Bouts Any amount of physical activity can be health enhancing. This opens new avenues for activity prescription and creates opportu-

nities to capitalize on brief and sporadic bouts of incidental physical activity, a kind of activity to which previous guidelines assigned no health value. Incidental physical activity is any activity that is part of one's daily living, not performed specifically with the purpose of recreation or health, and requires no time commitment. Short bouts of incidental activities, such as carrying heavy groceries,¹² walking uphill, or stair climbing, can reach vigorous relative intensity for the majority of middle-aged and older adults. In addition to enjoying the unique health properties of high-intensity physical activity,⁵ as few as 4 brief (1-3 minutes long), high-intensity incidental physical activity sessions per day can contribute a substantial portion of the weekly minimum recommended amounts when repeated on most days of the week (eg, 27%-100% if repeated on 5 days a week).¹⁵

No Need for Activity to Be of at Least Moderate Intensity The PAGA18 introduces flexibility around “intensity” by moving away from the idea that activity has to be of at least moderate intensity to be health enhancing. Emerging evidence suggests that light-intensity physical activity,^{3,9} such as ambulating, slow walking, and low-effort housework, is health enhancing, although there is uncertainty about the optimal amounts and dose response.

Sit Less, Move More Following several countries, which have already introduced nonquantitative guidance on sedentary behavior,¹⁴ the PAGA18 also recommends sitting reductions for all groups. Howev-

TABLE

FOUR NEW KEY ELEMENTS FEATURED IN THE 2018 PHYSICAL ACTIVITY GUIDELINES FOR AMERICANS AND THEIR POTENTIAL IMPLICATIONS

New Recommendations	Key Implications	Users
Desirable range of moderate and vigorous activity	Encourage those who can to be more active; identify a “sweet spot” range	The particularly healthy population, including younger adults
Light activity is beneficial	Recognize the importance of any movement	The whole adult population
Removal of the 10-minute continuous bouts	Encourage brief, sporadic movement into everyday lifestyle; accumulate vigorous physical activity via such sporadic movement	The whole population can benefit, particularly the elderly, obese, and those with comorbidities
Limit sitting (no specific daily threshold specified)	Focus on creating more movement opportunities; any movement matters	Most of the population, especially those with sedentary occupations, work commutes, and leisure practices

er, contrary to current United Kingdom, Norwegian, German, New Zealand, and Australian guidelines¹⁴ that recommend interruptions of long bouts of sitting (also termed “sedentary breaks”⁴), the PAGA18 emphasizes that there is insufficient evidence to support such a recommendation.^{1,12}

Specific Implications for Health Care Practitioners

The PAGA18 provides high-quality evidence to support practitioners working with all patients to encourage sufficient, suitable activity and thus improve their physical and mental health. The new aspects of the PAGA18, specifically the recognition of the importance of light physical activity and activity bouts of any length, are important, and are especially useful for practitioners working with people who have impairments. The role of progressive physical activity volume and intensity (start low, improve fitness, increase gradually) is emphasized, and this is what professionals like physical therapists excel at. Similar to the 2008 guidance,¹¹ physical activity is put into the context of relative intensity, which acknowledges that a given task will require different effort for people of different ages and fitness levels. The PAGA18 encourages health care practitioners to help tailor physical activity programs to meet the needs and goals of patients.

Something many practitioners may find disappointing is that the PAGA18 makes few references to the role of physical activity in musculoskeletal health and the prevention or treatment of musculoskeletal disorders. Instead, the PAGA18 highlights the importance of safe physical activity practice for injury prevention. Injury prevention will continue to be an important area of clinical practice. Increasing awareness of and evidence for benefits of activity for the prevention and management of musculoskeletal disorders should be an area for activity advocacy by physical therapists.

High-quality clinical practice guidelines recommend physical activity for

common musculoskeletal disorders such as knee and hip osteoarthritis and back and neck pain.¹⁰ While these disorders will not lead to premature death, insufficient physical activity as a preventable corollary of musculoskeletal disorders may increase the risk of other, life-threatening health problems.

The Future

All physical activity guidelines are based on evidence generated from self-reported physical activity. Over the last decade, we have seen huge developments in physical activity measurement. Many large-scale population cohort studies are now adopting accelerometer devices to obtain fine-grained assessments of free-living movement across 24 hours per day. As these studies mature with prospective follow-up of health outcomes, we will gain a more nuanced understanding of dose-response associations, including how the behaviors (sleep/sitting/light to moderate to vigorous physical activity) over a full 24 hours interact with one another.

International consortia of accelerometer studies, such as the Prospective Physical Activity, Sitting, and Sleep consortium,¹⁶ can eventually enable what has been called “the next generation of systematic reviews”⁸—individual participant and prospective meta-analyses on the health effects of physical activity and its components. Improved physical activity measurement and evidence synthesis methods will improve our recommendations on issues important to activity prescription, including specific types of activity, as well as activity intensity, duration, frequency, time patterns, and the balance between activity and rest.

There is a growing body of evidence on health outcomes of physical activity for different patient groups. The “Goldilocks principle,” recently proposed for designing work tasks to enhance physical capacity and health,^{7,17} can be used by health care practitioners to prescribe the “just right” amount and type of physical activity for each patient. Together with improved understanding of the interac-

tions between various doses of activity and disease processes enabled by objective time-based measurement of activity, this approach will help physical therapists better tailor activity recommendations to patients across the full range of current capacity and impairment.

Summary

The background work that informed the PAGA18^{1,13} is arguably the most comprehensive source of information on movement and health to date. The PAGA18¹² expands the menu of physical activity prescription options available to health care practitioners. Movement, of any intensity and duration, matters for health.

Key Points

- Physical activity of any intensity and duration is beneficial.
- Adults and older adults should move more and sit less throughout the day.
- Adults and older adults should do 150 to 300 minutes a week of moderate-intensity, or 75 to 150 minutes a week of vigorous-intensity, physical activity, or equivalent combinations of moderate- and vigorous-intensity activity.
- Pregnant women should aim for 150 minutes of moderate physical activity per week.
- Adults should also do muscle-strengthening activities involving all major muscle groups at least 2 days a week.
- Older adults will also benefit from balance training as well as aerobic and muscle-strengthening activities.
- Adults with chronic conditions or disabilities should strive to be as physically active as possible, ideally to meet the recommended amounts for adults when possible. ●

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Identifying and Prioritizing Clinical Guideline Recommendations Most Relevant to Physical Therapy Practice for Hip and/or Knee Osteoarthritis

Osteoarthritis (OA) is a chronic condition that commonly affects the hip and knee joints, causing significant pain and disability in affected individuals.³⁹ Osteoarthritis at these lower-limb sites is the leading contributor to the burden of OA and is often treated with arthroplasty surgery.¹² The burden of OA on the health care system is anticipated to



exponentially increase, due to the aging population and rising obesity rate.^{4,5} Core management of people with OA comprises exercises, self-management education, and weight loss.^{3,35,39}

Physical therapists are thus a key provider of care for this patient population, given the central role of conservative strategies for managing OA.^{58,59}

While evidence-based guidelines on the management of OA^{2,3,16,23,35,39} exist, studies have indicated gaps between physical therapist practice and clinical guideline recommendations for hip and/or knee OA management.^{11,13,24,53} A study among Belgian physical therapists showed that some continued to employ ineffective treatments for the management of knee OA.⁵¹ An Australian cross-sectional survey also identified that some physical therapists used electrotherapy to manage people with hip OA,¹¹ despite insufficient evidence to support its use.^{3,39} These findings suggest a shortfall in the dissemination and implementation of existing recommendations among physical therapists.

● **BACKGROUND:** Physical therapists are key providers of conservative management for hip and/or knee osteoarthritis (OA), yet not all guideline recommendations are tailored to their scope of practice.

● **OBJECTIVE:** To identify and prioritize the most important recommendations relevant to physical therapy practice for hip and/or knee OA.

● **METHODS:** International physical therapists (n = 132) were invited to participate in an online modified Delphi survey, followed by a priority-ranking exercise. A total of 63 recommendations were extracted from 2 recent high-quality clinical guidelines. In 3 Delphi rounds, the panel identified those recommendations they considered to be most relevant to physical therapy practice for hip and knee OA. Any new recommendations were ascertained. For a recommendation to be included, at least 70% of respondents had to rate the recommendation as 7 or above on a numeric rating scale (0 is not important and 10 is extremely important). The panel prioritized

recommendations that remained after the final round using decision-making software.

● **RESULTS:** Of 132 therapists from 14 countries, 62 completed round 1, 52 completed round 2, 45 completed round 3, and 35 completed the priority-ranking exercise. From an initial list of 70 potential recommendations (including 7 new recommendations), 30 were included in the priority-ranking exercise. The top recommendations were related to providing education and prescribing exercise and weight loss as core treatments, followed by individualized OA assessment and treatment and communication strategies.

● **CONCLUSION:** This study identified and ranked the most important recommendations relevant to physical therapy practice for hip and/or knee OA. *J Orthop Sports Phys Ther* 2019;49(7):501-512. doi:10.2519/jospt.2019.8676

● **KEY WORDS:** clinical practice, Delphi, evidence-based care, knowledge translation, priority ranking, quality indicators

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[RESEARCH REPORT]

Improving implementation of hip and knee OA guidelines within physical therapy practice could improve delivery of effective treatments and optimize treatment outcomes for patients. A preliminary step to assist physical therapists to adopt best practices, as outlined in hip and knee OA guidelines, is to identify and prioritize clinical guideline recommendations that are most relevant to physical therapy practice.

Physical therapy management of people with OA does not occur in isolation from other health care providers. Effective management of hip and knee OA typically involves a variety of health care providers, including general practitioners, rheumatologists, and orthopaedic surgeons, as well as a range of allied health professionals, and the role responsible for enacting individual guideline recommendations is often unclear. Furthermore, not all recommendations from current OA guidelines^{2,3,16,23,35,39} are within the scope of physical therapy practice. Although 2 guidelines specific to physical therapy management of people with OA have been previously published, one is now out of date⁴¹ and the other is limited to hip OA only.¹⁰ Thus, there remains the question of what the most important recommendations relevant to physical therapy practice in the management of hip and/or knee OA may be.

This study used 2 high-quality international OA clinical guidelines^{16,39} to identify and prioritize, by international consensus, the most important recommendations for physical therapists to implement when managing all patients with hip and/or knee OA.

METHODS

THE PRESENT STUDY COMPRISED 3 sequential stages: (1) extraction of recommendations from 2 recent, high-quality clinical guidelines; (2) a 3-round Delphi survey to identify, by consensus, which of those recommendations would be relevant for physical therapists; and (3) a priority-ranking exercise

to rank the retained recommendations in order of perceived importance (FIGURE 1). Ethics approval was granted by The University of Melbourne Human Research Ethics Committee (Ethics ID 1750150). Participants gave implied consent by completion of the first survey.

Stage 1: Extraction of Recommendations From Clinical Guidelines

All recommendations from the National Institute for Health and Care Excellence OA guidelines³⁹ and the European League

Against Rheumatism recommendations for the nonpharmacological core management of hip and knee OA¹⁶ were extracted. Although several other OA clinical guidelines^{2,3,23,35} also exist, these 2 were selected because they cover both assessment and treatment for hip and knee OA, and also score highly on methodological quality based on the Appraisal of Guidelines Research and Evaluation II tool.^{7,32,36} For the purpose of this research, the investigators converted all original recommendations from both guidelines into instructional

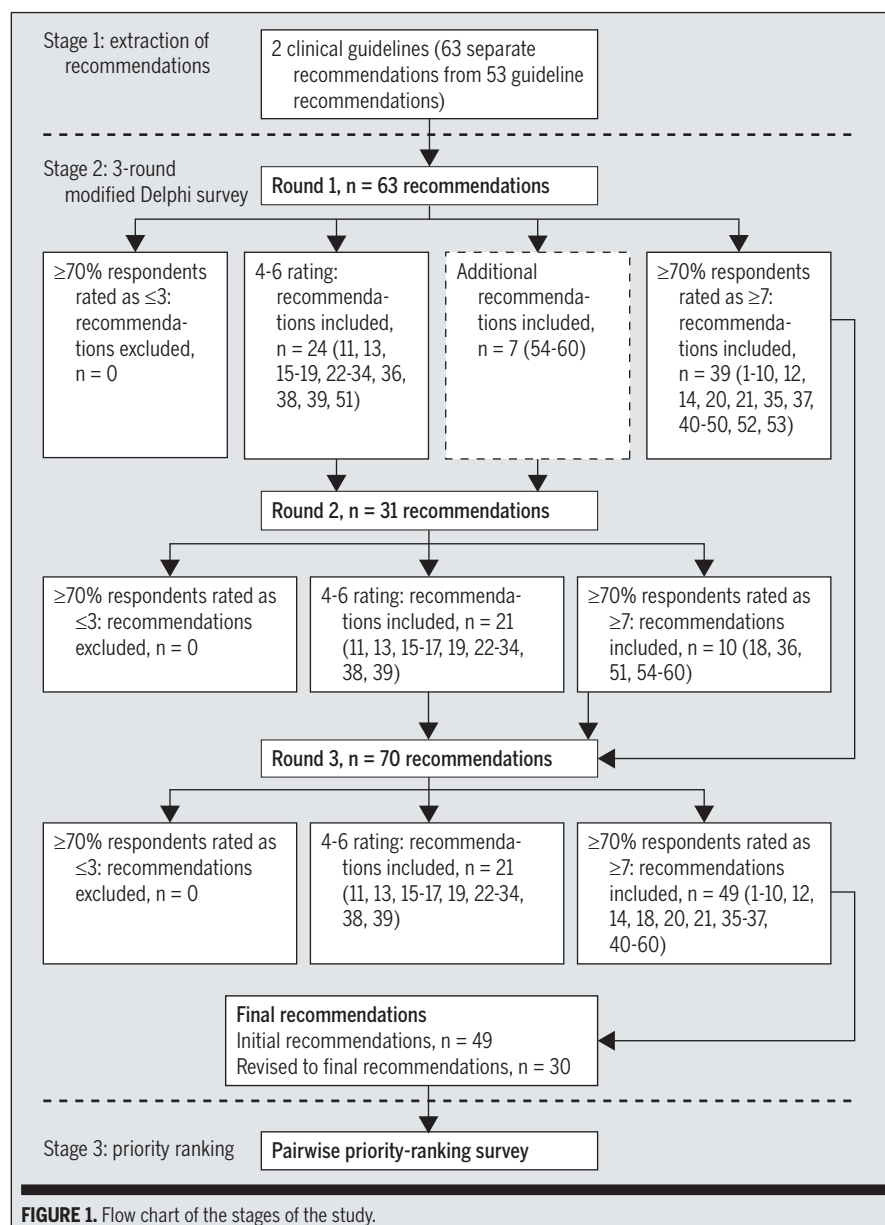


FIGURE 1. Flow chart of the stages of the study.

recommendations, ensuring that the meanings remained the same and were relevant to hip and/or knee OA only, with minimal alterations to wording. A final list was compiled for inclusion in the first round of the Delphi survey in stage 2 (**APPENDIX A**, available at www.jospt.org).

Stage 2: Delphi Survey

A modified Delphi technique³¹ was used to obtain consensus from a panel of experts on the most relevant recommendations for physical therapists. This method was chosen because it does not require face-to-face meetings,^{17,31} thus allowing selection of expert participants from a geographically dispersed population.⁹ In a modified Delphi study, the open-ended round in a classical Delphi panel discussion is replaced by providing the expert panel with relevant statements developed from the existing literature.²² The experts on the panel could, however, provide any additional evidence-based recommendations they felt should be included in the list, given that we only included 2 clinical guidelines in this study.

Sample Size There is no set guidance available on determining sample size for Delphi studies.^{45,55} A larger sample size increases the reliability of a consensus process such as a Delphi study, with a panel size of 12 or above deemed adequate to demonstrate improvement in reliability.³⁸ One study investigated the reliability of outcomes obtained from a Delphi panel of 23 participants and found that as long as the experts have similar training and knowledge, such a sample size is sufficient to ensure reliability and stability of results.¹ Based on previous studies,^{18,49} we estimated a response rate for the first round of 45%, and 70% of the remaining participants for each of the subsequent 2 rounds.^{18,44} We thus invited 132 participants, from whom we estimated that 60 would complete round 1 and at least 29 would be retained by round 3.

Participants An international panel of expert physical therapy clinicians and researchers was invited to participate via

e-mail. A list of potential participants was prepared by the investigators, drawing from their OA networks as well as within the field of published OA research. Contact e-mail addresses were obtained from publicly available sources, such as publications and university or clinical practice websites. The investigators also asked 10 national and international collaborators to provide names and contact details of clinicians from their countries who potentially met the eligibility criteria and might be interested in participating.

To be included as expert clinicians, respondents (1) had to be currently registered to practice as a physical therapist and (2) had to have seen at least 1 patient with hip and/or knee OA per week over the past 6 months. Expert researchers were required (1) to be a physical therapist and (2) to meet at least 1 of the following criteria: (a) first or last author on at least 2 papers per year on primary human research in hip and/or knee OA over the past 5 years; (b) invited to give a plenary or keynote presentation on hip and/or knee OA at an international conference in the last 5 years; or (c) obtained nationally competitive grant funding as the chief investigator for a clinical research project investigating hip and/or knee OA in the past 5 years.

Procedure Three sequential rounds of online surveys were conducted via Research Electronic Data Capture (REDCap) software (Vanderbilt University, Nashville, TN), hosted at The University of Melbourne. Potential participants were first sent an e-mail that contained a link to access further information about the study, confirm eligibility, and complete the questionnaire online. In the first round, participants were also asked to provide basic demographic information such as age, sex, location, education, number of years of clinical/research experience, average number of clinical practice hours per week, and the primary site of clinical practice. In all rounds, participants were required to rate each recommendation on an 11-point numeric rating scale (NRS) that ranged from 0 (not im-

portant) to 10 (extremely important) in response to the statement, "Please rate each of the following recommendations according to how important you believe they are for a physical therapist to implement in managing all people with hip and/or knee osteoarthritis." Participants were reminded in the survey to rate the importance of each recommendation for all patients with hip and/or knee OA rather than for a subset of patients. A final question in the first round asked participants for any additional evidence-based recommendations they felt should be included in the list.

Each Delphi round ran for 2 weeks, with approximately 6 weeks between rounds to allow for data collation and analysis. Each round took approximately 30 minutes to complete and could be done over multiple sessions. Two reminder e-mails were sent to nonresponders at 5-day intervals after the initial mailing in each round. Only participants who completed a survey round were included in the subsequent round.

Defining Consensus Although there is currently no standard threshold for consensus in the Delphi literature,³¹ 70% consensus is a commonly used benchmark.^{14,49} Thus, we defined consensus for the inclusion of a recommendation a priori as 70% or more of respondents rating a recommendation as 7 or above on the NRS. Recommendations were excluded if 70% or more of respondents rated a recommendation as 3 or below. The cutoffs of 7 and 3 on the NRS for the inclusion and exclusion of a recommendation, respectively, were adopted from a recent consensus study.⁴⁹ Recommendations that were rated between 4 and 6 on the NRS were required to be rerated in the subsequent round, regardless of the percentage of respondents rating them. These recommendations did not achieve consensus on inclusion or exclusion (ie, indicating panel uncertainty about an item) and were retained for a revote in the subsequent round, to allow the panel to "rescue" an item for inclusion. Recommendations from round 1 that were rated

as 7 or above by 70% or more of respondents were added directly to round 3 for rerating. Additional recommendations generated from round 1 were included in round 2 for initial rating. Recommendations that were rated between 4 and 6 on the NRS in rounds 1 and 2 were rerated in rounds 2 and 3, respectively. Recommendations from round 2 that were rated as 7 or above by 70% or more of respondents were also added to round 3 for rerating.⁴⁹ Finally, only recommendations that were rated as 7 or above by 70% or more of respondents in round 3 were included in the final list of recommendations. The investigators reviewed duplicative content from the recommendations in the final list and merged it into a single recommendation, as appropriate, for the priority-ranking exercise in stage 3 (FIGURE 1).

Data Analysis For each recommendation, the percentage of respondents rating a recommendation 3 or less, between 4 and 6, or 7 or greater was calculated. The investigators discussed the additional recommendations nominated by the expert panel in round 1 and merged similar recommendations into a single recommendation as appropriate.³¹ However, only recommendations that were deemed evidence based were accepted and included in round 2. A de-identified summary of the panel's responses for each recommendation from the previous round was e-mailed to participants prior to rounds 2 and 3. This process aimed to encourage the panel members to revise their earlier answers in light of the responses of other members.¹⁴

Stage 3: Priority-Ranking Exercise

Participants were required to prioritize the final list of recommendations remaining after round 3 via an online decision survey created in the 1000minds program (1000minds Ltd, Dunedin, New Zealand). The 1000minds program is a multi-attribute decision analysis research tool that prioritizes and quantifies the relative importance of statements, reflecting expert consensus.²¹ Participants

were presented with a series of paired recommendations (known as "pairwise rankings") and asked which of the 2 they believed was more important for physical therapists to implement in the management of all people with hip and/or knee OA. Based on participants' answers, 1000minds used background mathematics to arrive at individuals' rankings of the recommendations and the averaged rankings for the group.²¹

RESULTS

Participant Characteristics

SIXTY-TWO (47%) OF 132 INVITED experts completed round 1 of the Delphi survey. Of these, 20 were clinicians, 27 were researchers, and 15 identified themselves as both clinicians and researchers. Experts originated from 14 countries: Australia (n = 14), Belgium (n = 2), Brazil (n = 6), Canada (n = 4), Denmark (n = 5), Ireland (n = 2), Japan (n = 1), the Netherlands (n = 5), New Zealand (n = 6), Norway (n = 3), Saudi Arabia (n = 1), Singapore (n = 2), the United Kingdom (n = 7), and the United States (n = 4). Participants' characteristics are shown in TABLE 1. Of the 132 invited experts, 52 (39% of the original sample and 84% of round 1 respondents) completed round 2, 45 (34% of the original sample and 87% of round 2 respondents) completed round 3, and 35 (27% of the original sample and 78% of round 3 respondents) completed the priority-ranking exercise. Of the 35 participants who completed the whole study, 18 were researchers, 8 were clinicians, and 9 identified themselves as both clinicians and researchers.

Delphi Survey

Fifty-three recommendations were extracted from the guidelines in stage 1. Two of these recommendations had 6 subcategories each. Thus, these 2 guideline recommendations became 12 separate recommendations, and the total number of recommendations presented to participants in round 1 of the Delphi survey

was 63. Rounds 1 and 2 were conducted from August to September and September to October 2017, respectively, with the final round undertaken from October to November 2017. FIGURE 1 represents the results of each Delphi round. In round 1, 70% or greater of the respondents rated 39 of the 63 recommendations as 7 or above on the NRS. These recommendations covered the diagnosis of OA, the individualized approach to OA management, education, exercise prescription, weight loss, use of aids or devices, vocational rehabilitation, goal setting, offering of core treatments prior to joint surgery, and avoidance of arthroscopic lavage and debridement (APPENDIX B, available at www.jospt.org). No recommendations were excluded in this round. An additional 9 recommendations were generated from the expert panel. After merging similar suggestions, 7 new recommendations (APPENDIX C, available at www.jospt.org) were included in round 2. These additional recommendations addressed depression screening, management of psychological distress, strategies to optimize adherence, personalized exercise and physical activity programs, information on exercising locally, and helping patients to understand the pain experience. The panel also suggested a "do not do" recommendation relating to herbal supplements.

Twenty-four (APPENDIX D, available at www.jospt.org) of the original 63 recommendations, plus 7 new recommendations from round 1, were included in round 2. Ten recommendations were rated as 7 or above on the NRS by 70% or greater of the respondents, and, again, no recommendations were excluded in this round. The 10 recommendations included 7 additional recommendations proposed by the expert panel and 3 relating to appropriate footwear and referral thresholds for joint surgery. Therefore, all original 63 recommendations as well as the 7 new recommendations were included in round 3 for rerating.

In round 3, 70% or greater of the respondents rated 49 of the 70 recommendations as 7 or above on the NRS for

importance (**APPENDIX E**, available at www.jospt.org), excluding 21 recommendations from stage 3 (**FIGURE 2**). Following revision by the investigators to remove duplicative content in the remaining 49 recommendations, a final list of 30 recommendations was generated for the priority-ranking exercise.

TABLE 2 shows the final ranked list of priority recommendations, grouped by content area. There were 8 recommendations related to the principles of treatment planning and delivery, 4 to OA

diagnosis and assessment, 3 to physical therapy core treatments, 3 to adjunctive physical therapy treatments, 9 to review and referral, and 3 to communication.

DISCUSSION

THIS STUDY USED A CONSENSUS method and a priority-ranking exercise to produce and prioritize a list of the most important clinical guideline recommendations relevant to the scope of physical therapist practice when

managing hip and/or knee OA. Of the original 63 recommendations extracted from 2 high-quality OA clinical guidelines, as well as the 7 additional items nominated by the international expert panel, 49 achieved consensus as being important for physical therapists. Several were combined to produce a final list of 30 recommendations. Interestingly, none of the original recommendations reached consensus to be excluded. This implies that all recommendations from the 2 OA clinical guidelines are considered at least somewhat relevant to physical therapists when managing hip and/or knee OA, and highlights the important role physical therapists have in managing this condition. To facilitate communication of the findings, we have summarized the priority guideline recommendations for physical therapy management of hip and/or knee OA in **FIGURE 3**.

Several highly ranked recommendations (ranked 1-3, 8, 9, 11, and 17 in **TABLE 2**) were related to exercise and physical activity. This is not surprising, given that exercise is a core physical therapy intervention and surveys from different countries have found that exercise is commonly used by physical therapists to manage hip and knee OA.^{11,24,25,29,51} These recommendations are supported by high-quality evidence showing that exercise decreases pain and improves function in this patient population.^{19,20} Furthermore, engaging in a physically active lifestyle promotes many other health benefits for people with OA, including reducing risk of developing other major health conditions, such as heart disease and diabetes³⁰; improving muscle strength, aerobic capacity, and mood¹⁵; as well as delaying progression of OA and functional limitations.⁵⁴ Despite the benefits of physical activity, research has shown that people with OA are not as physically active as people without OA.²⁶ People with OA often have comorbidities, such as obesity, heart disease, and diabetes, which increase their likelihood of poorer physical function.^{30,52} Thus, improving exercise and physical activity levels in people with hip and/or knee OA, taking into account

TABLE 1

CHARACTERISTICS OF THE EXPERT PANEL MEMBERS (N = 62)

	Value*
Age, y	
≤30	3 (5)
31-50	43 (69)
51-70	16 (26)
Sex (female)	35 (57)
Highest educational qualification	
PhD	38 (61)
Master's degree (research)	11 (18)
Postgraduate certificate/diploma	7 (11)
Bachelor's degree	4 (7)
Other	2 (3)
Time spent researching osteoarthritis, y (n = 42)	
≤10	19 (31)
11-20	20 (32)
21-30	3 (5)
Time spent in clinical practice, y (n = 35)	
≤10	6 (10)
11-20	17 (27)
21-30	7 (11)
31-40	5 (8)
Average time in clinical practice weekly, h (n = 35)	
0-10	10 (16)
11-20	8 (13)
21-30	2 (3)
31+	15 (24)
Primary site of clinical practice (n = 35)	
Private practice	13 (21)
Public community health center	4 (7)
Hospital	11 (18)
Other†	7 (11)

*Values are n (percent).

†Rheumatology department (n = 1), university clinic (n = 2), home based (n = 2), primary care center (n = 1), and postsecondary institution (n = 1).

TABLE 2

FINAL RANKED LIST OF RECOMMENDATIONS GROUPED BY CONTENT AREA

Content Area/Rank*	Top 30 List of Recommendations [†]	Panel Members Rating ≥7 in Round 3, %	Group Ranking	
			Median (IQR)	Mean
Principles of treatment planning/delivery				
2	Discuss and offer personalized exercise and a physical activity program according to needs, preferences, self-motivation, and ability to perform exercises. An appropriate program may include strengthening, aerobic exercise, land- or water-based exercise, and supervised or unsupervised exercise. The type and dosage should be tailored	100	8.5 (4.8-12.8)	9.9
3	Advise people with OA to exercise as a core treatment, irrespective of age, comorbidity, pain severity, or disability. Exercise should include local muscle strengthening and general aerobic fitness	98	9 (6.3-12.5)	10
8 [‡]	Agree on individualized self-management strategies with the person with OA. Ensure that positive behavioral changes such as exercise, weight loss, use of suitable footwear, and pacing are appropriately targeted (R9, R45)	98	11 (6.3-17.0)	11.5
9	Ensure that self-management programs for people with OA, either individually or in groups, emphasize the recommended core treatments, especially exercise	98	11.5 (7.0-16.8)	11.8
10	When lifestyle changes are recommended, offer people an individually tailored program, including long-term and short-term goals, intervention or an action plan, and regular evaluation and follow-up with possibilities for adjustment of the program	100	11 (6.8-15.5)	11.8
12	Incorporate strategies to optimize adherence to treatment recommendations (eg, offer booster sessions to increase adherence to exercise)	100	12 (7.8-20)	13.4
17 [§]	Select the mode of delivery of exercise education (eg, individual one-to-one session, group classes, etc) and use pools or other facilities according to the preference of the person and local availability and cost (R48, R59)	100	14 (11.3-19.3)	15.1
18	Take into account comorbidities that compound the effect of OA when formulating the management plan	100	16.5 (11.3-21.8)	15.7
Diagnosis and assessment				
7 [§]	Assess the effect of OA on the person's function, quality of life, occupation, mood, relationships, and leisure activities and assess health education needs, health beliefs, and motivation to self-manage (R3, R43)	100	11.5 (6.8-15.8)	11.5
15	Be aware that atypical features, such as a history of trauma, prolonged morning joint-related stiffness, rapid worsening of symptoms, or the presence of a hot, swollen joint, may indicate alternative or additional diagnoses	100	15.5 (8-21)	14.3
21	Diagnose OA clinically without investigations when a person is 45 years of age or older, has activity-related joint pain, and has either no morning joint-related stiffness or morning stiffness that lasts no longer than 30 minutes	93	20 (8.5-25.5)	17.7
26	Screen for depression using an accepted depression screening tool	87	24 (15-28)	20.8
Physical therapy core treatments				
1	Offer advice on the following core treatments to all people with clinical OA: access to appropriate information, activity and exercise, and interventions to achieve weight loss if the person is overweight or obese	100	8.5 (5-12.8)	9.6
11	Teach a regular individualized exercise regimen that includes strengthening (sustained isometric) exercise for both legs, including the quadriceps and proximal hip girdle muscles, aerobic activity and exercise, as well as adjunctive range-of-movement/stretching exercise	89	11 (6.3-20)	12.5
16 [§]	Offer interventions to achieve weight loss as a core treatment for people who are obese or overweight, incorporating individualized strategies that are recognized to effect successful weight loss and maintenance (R14, R50)	84	12.5 (8.5-23.3)	14.7

Table continues on page 507.

TABLE 2

FINAL RANKED LIST OF RECOMMENDATIONS GROUPED BY CONTENT AREA (CONTINUED)

Content Area/Rank*	Top 30 List of Recommendations [†]	Panel Members Rating ≥7 in Round 3, %	Group Ranking	
			Median (IQR)	Mean
Adjunctive physical therapy treatments				
23 [‡]	Consider the use of walking aids, assistive technology, and adaptations at home and/or at work to reduce pain and increase participation (R20, R52)	98	20.5 (11.8-25.5)	18.6
29 [‡]	Offer the person advice on appropriate and comfortable shoes (R18, R51)	84	27 (19.8-28)	23.4
30	Do not offer herbal supplements to people with hip and/or knee OA	80	29.5 (28.5-30)	27.8
Review and referral				
6	Ensure that the person with OA has been offered at least the core (nonsurgical) treatment options before referring the person for consideration of joint surgery	100	11 (6.5-14.3)	11.2
14	When discussing joint surgery, check that the person has been offered at least the core treatments for OA, and give information about the benefits and risks of surgery and the potential consequences of not having surgery, recovery, and rehabilitation	98	12.5 (6.3-21.8)	14.1
19	Consider referral for joint surgery for people with OA who experience joint symptoms (pain, stiffness, and reduced function) that have a substantial impact on their quality of life and are refractory to nonsurgical treatment	96	17 (10.3-24.3)	17.2
20	Manage any psychological distress of the person (eg, referral to another health professional if required)	96	20 (11.8-25)	17.4
22	Do not refer for arthroscopic lavage and debridement as part of treatment for OA, unless the person has knee OA with a clear history of mechanical locking (as opposed to morning joint stiffness, "giving way," or X-ray evidence of loose bodies)	100	20.5 (11.5-26)	18.5
24	For people who are at risk of work disability or who want to start/return to work, provide them with rapid access to vocational rehabilitation, including counseling about modifiable work-related factors	89	20 (13.5-25)	18.8
25	Offer regular reviews to all people with symptomatic OA. Agree on the timing of the reviews with the person	91	21 (16.8-26.3)	20.1
27	Consider an annual review for any person with 1 or more of the following: troublesome joint pain, more than 1 joint with symptoms, more than 1 comorbidity, and/or taking regular medication for OA	84	23 (18.5-25.8)	20.8
28	Base decisions on referral thresholds for joint replacement surgery on discussions between patient representatives, referring clinicians, and surgeons, rather than using scoring tools for prioritization	80	24 (19.3-27)	22.2
Communication essentials				
4 [§]	Agree on a plan with the person (and family members/carers) for managing OA, individualized according to the wishes and expectations of the individual, localization of OA, risk factors, presence of inflammation, structural change, pain, activity restriction, societal participation, and quality of life (R4, R44)	100	8.5 (4.5-13.5)	10.3
5 [§]	Offer accurate verbal and written information to enhance understanding of OA and its management, understanding of pain experience, and to counter misconceptions. Ensure that information sharing is an ongoing, integral part of the management plan rather than a single event at time of presentation (R8, R46, R60)	100	12 (4.8-15.3)	10.5
13	Discuss the risks and benefits of treatment options with the person, taking into account comorbidities. Ensure that the information provided can be understood	100	15 (7.5-19.3)	13.8

Abbreviations: IQR, interquartile range; OA, osteoarthritis; R, recommendation.

*The numbers represent the ordinal ranking of the priority values. For example, 1 is first; that is, this is the top ranking for the group.

[†]The final list of 30 recommendations was generated following revision of the remaining 49 recommendations from round 3. The complete original recommendations can be found in APPENDICES A and C.

[‡]When there were recommendations with duplicative content, the recommendation with the highest agreement was accepted.

[§]Recommendations with similar key characteristics were combined to create this unique recommendation.

[RESEARCH REPORT]

comorbidities, is an important management goal.

The recommendation ranked 12 in **TABLE 2** was related to strategies to enhance exercise adherence. This is important, given that clinical benefits of exercise tend to decline over time due to poor adherence.^{34,42} Adherence is a predictor of the long-term effectiveness of exercises, both within and after a treatment period.^{42,43} Additional booster sessions following supervised treatment have been found to positively influence the outcomes of exercise in the long term.^{40,43}

Patient education is another key component in the management of hip and/or knee OA and was highly ranked (1, 5, 8, 10, and 13 in **TABLE 2**) by the expert panel. Patients should receive information about OA diagnosis, prognosis, and the risks and benefits of treatment options³⁶ in order to promote active participation and allow informed choices to be made. Increased knowledge also gives patients greater control over their own health care

decisions.^{6,27}

Advice about weight loss was included in the recommendation ranked highest by the physical therapists. In addition, a recommendation relating to provision of strategies to support weight loss was ranked 16th. The latter is perhaps surprising, as many physical therapists do not consider tackling weight loss as within their scope of practice.^{48,57} Furthermore, not all physical therapists feel competent to initiate a conversation about weight with patients, or to effectively provide weight-loss interventions to patients who are overweight or obese.^{47,50,57} In light of the importance of weight loss for this patient population and the high ranking of recommendations relating to weight loss by the expert panel, educating physical therapists to provide weight-management advice and interventions, as well as to support behavior change, may be a priority for the profession.

Thirty-three percent (n = 21) of the extracted recommendations did not

reach consensus among the expert panel to be included following round 3. Of note, recommendations regarding pharmacological management of OA were excluded. In contrast and as expected, implementation of recommendations about pharmacological management was identified as the top-priority task for general practitioners when consulting people with OA in a previous consensus study.⁴⁴ These recommendations were not rated highly by the majority of the physical therapists, possibly because not all physical therapists worldwide are able to prescribe medications within their scope of practice.³⁷

Recommendations that proposed thermotherapy, electrotherapy, and manual therapy as adjunct treatments for people with OA were also not ranked highly by physical therapists, even though these treatment modalities are within the scope of physical therapy practice globally and are often used by physical therapists.^{11,25,51,53} A possible reason may be that these treatment modalities have somewhat conflicting evidence of their effectiveness, as reflected by varying recommendations across other clinical guidelines.^{3,23,35} Another reason for the exclusion of these recommendations may be the wording of the question in the consensus exercise, which directs physical therapists to nominate recommendations that would be applicable to all patients with hip and/or knee OA rather than to subsets of patients.

Future Implementation Strategies

There are numerous clinical practice guidelines for OA, but they are not specifically for physical therapists. This study identified and prioritized assessment and treatment recommendations that apply to all patients with hip and knee OA and that were the most relevant for physical therapist practice. Establishing the most relevant physical therapist-specific recommendations can inform the content of educational programs, self-assessment of quality of care, and benchmarking and practice audit tools,^{8,28,33} and may thus

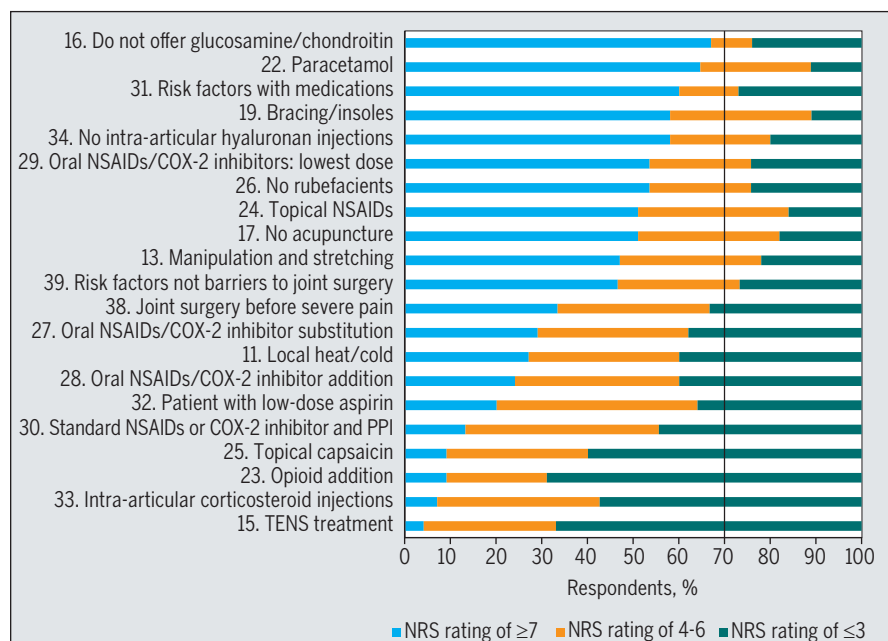


FIGURE 2. The percentage of participants rating the 21 recommendations that were excluded in round 3 (priority-ranking exercise) because they did not reach consensus for inclusion. Recommendations were rated on an NRS as 3 or less, between 4 and 6, or 7 or greater out of 10, where 0 is not important and 10 is extremely important. Inclusion was defined as at least 70% of respondents rating the item as at least 7 on the NRS. Abbreviations: COX, cyclo-oxygenase; NRS, numeric rating scale; NSAID, nonsteroidal anti-inflammatory drug; PPI, proton-pump inhibitor; TENS, transcutaneous electrical nerve stimulation.

help improve practice and reduce the use of ineffective treatments/advice. In addition, the list of ranked recommendations provides a foundation to develop quality indicators for physical therapy care of people with hip and/or knee OA.

In general, the results of this study can inform physical therapists of the recom-

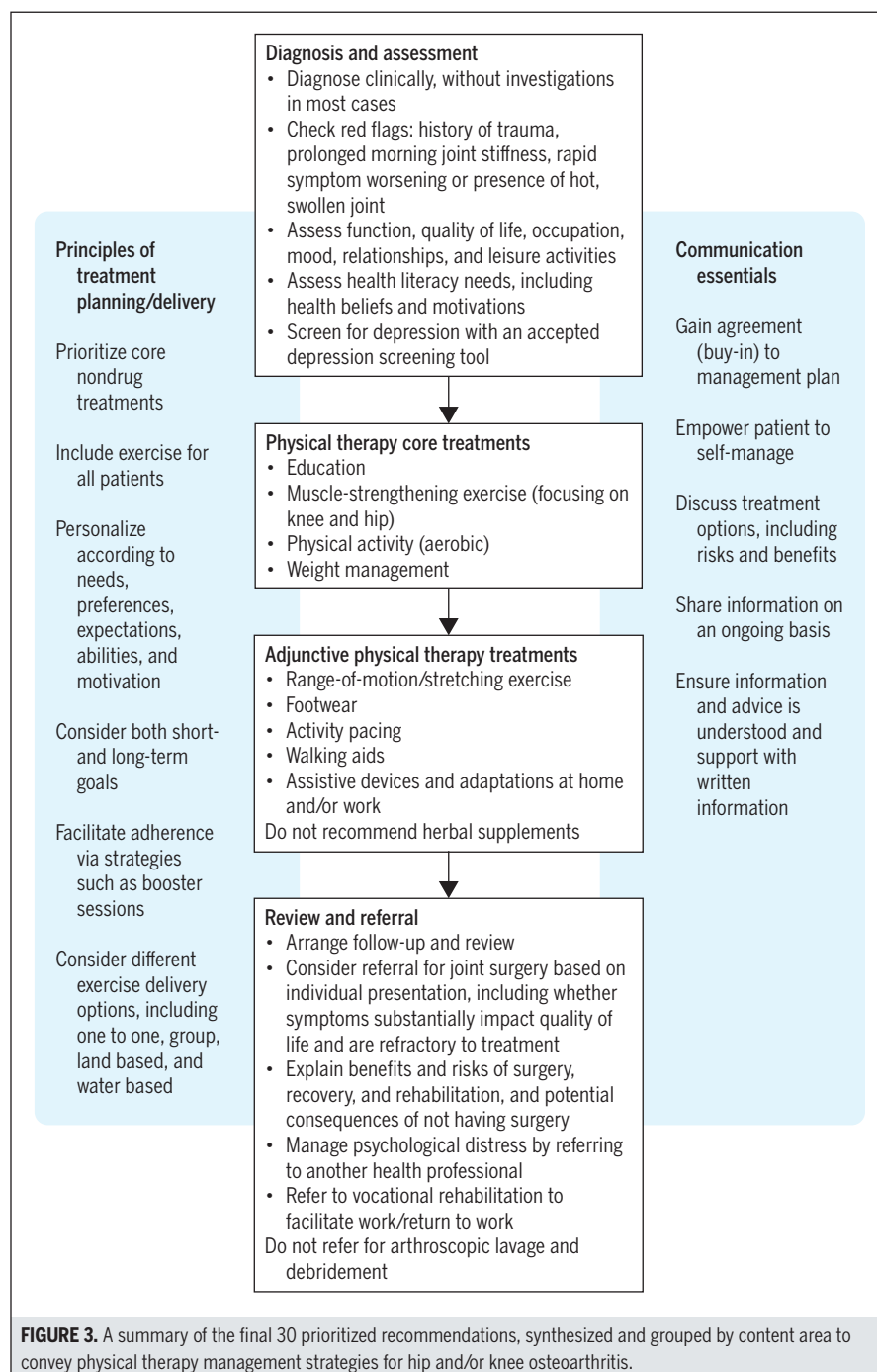
mendations that are important in order to provide optimal care in their physical therapy clinical practice. All 30 recommendations should be considered if comprehensive evidence-based management is to be provided. The results can be useful as a checklist for physical therapists when self-auditing their own practice. They can

also be used when designing new or reviewing existing OA programs/services.

Strengths and Limitations

A strength of this study was the inclusion of physical therapists from diverse geographical locations and with different scopes of practice, cultures, training, and health care contexts to ensure that the findings reflected the potential diversity of opinion. The Delphi expert panel was recruited from 14 countries across several continents to gain an international perspective. There was a mix of researchers and clinicians from various clinical settings. Other strengths include robust methodology that fulfilled proposed quality indicators for a Delphi study (eg, reproducible participant criteria; pre-specification of the number of Delphi rounds, with clear criteria set a priori for dropping or excluding items¹⁴), a large sample size, and good response rates to the Delphi rounds³¹ and priority-ranking exercise.

This study has several limitations. First, the results may not represent best practice for physical therapists working in all contexts and geographical locations. More than 56% of the expert panel identified themselves as clinicians (20 clinicians and 15 clinicians/researchers out of 62 respondents). Thus, over half the panel identified themselves as having a clinical role. Nonetheless, future work would benefit from greater representation of clinicians who manage hip and knee OA. Second, the response rate to the first Delphi round was low (47%), although this was slightly higher than the a priori estimated rate (45%). In addition, the views of the participating physical therapists may differ from those who declined participation and from other physical therapists not contacted. Third, the study was confined to the opinions of physical therapists. The perspectives of patients would have been valuable, as patients differ from physical therapists in their expectations and preferences. Fourth, we extracted recommendations from 2 clinical guidelines and might have



missed important recommendations included in others. Furthermore, we used generic OA clinical guidelines because, at the time of study planning, there were no current physical therapist-specific hip and knee OA guidelines. Since then, the 2009 clinical guideline for hip OA developed by the Orthopaedic Section of the American Physical Therapy Association¹⁰ has been updated. The recommendations relating to weight loss, patient education, individualized exercise and physical activity, as well as use of assistive devices are consistent with the findings of our study. The main differences are that the updated guideline¹⁰ by the Orthopaedic Section of the American Physical Therapy Association provides more recommendations around hip assessment and additionally recommends manual therapy, bracing, and ultrasound. Finally, some of the final recommendations were similar, which created overlap and redundancy. Thus, a useful next step could be to reword the recommendations in order to create a new list without duplication across items. This could be achieved by using focus groups of physical therapists or by using a conceptualization method such as concept mapping.⁴⁶

CONCLUSION

A LARGE PANEL OF RESEARCH AND clinical physical therapists has identified relevant recommendations from clinical guidelines and prioritized those most important for physical therapists to implement when managing all patients with hip and/or knee OA. The findings can help direct evidence-based management to ultimately improve outcome for patients with the condition. The results can also be used to guide training of physical therapy students and graduates in OA management, as well as to contribute to the formulation of quality care indicators and subsequent evaluation of evidence-practice gaps. Future research is required to determine how to best utilize and implement the recommendations in physical therapy clinical practice. ●

KEY POINTS

FINDINGS: Thirty recommendations were identified and prioritized by international physical therapists as those most important for physical therapists when managing all patients with hip and/or knee osteoarthritis (OA). The top recommendations were related to the provision of education, prescription of exercise and weight loss, individualized OA assessment, and treatment and communication strategies.

IMPLICATIONS: Findings can assist physical therapists to implement evidence-based care for patients with hip and/or knee OA in daily practice, facilitate self-evaluation of care provided, and be used to assess care gaps in the future.

CAUTION: As recruitment did not cover all geographical regions and the initial response rate was less than 50%, the views of participants may not fully represent the wider physical therapy population.

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APPENDIX A

Original recommendations extracted from the National Institute for Health and Care Excellence OA guidelines³⁹ and the European League Against Rheumatism recommendations for the nonpharmacological core management of hip and knee OA,¹⁶ after conversion into instructional recommendations.

- R1. Diagnose OA clinically without investigations when a person is 45 years of age or older, has activity-related joint pain, and has either no morning joint-related stiffness or morning stiffness that lasts no longer than 30 minutes.
- R2. Be aware that atypical features, such as a history of trauma, prolonged morning joint-related stiffness, rapid worsening of symptoms, or the presence of a hot, swollen joint, may indicate alternative or additional diagnoses.
- R3. Assess the effect of OA on the person's function, quality of life, occupation, mood, relationships, and leisure activities.
- R4. Agree on a plan with the person (and the family members or carers as appropriate) for managing OA.
- R5. Take into account comorbidities that compound the effect of OA when formulating the management plan.
- R6. Discuss the risks and benefits of treatment options with the person, taking into account comorbidities. Ensure that information provided can be understood.
- R7. Offer advice on the following core treatments to all people with clinical OA: access to appropriate information, activity and exercise, and interventions to achieve weight loss if the person is overweight or obese.
- R8. Offer accurate verbal and written information to all people with OA to enhance understanding of the condition and its management, and to counter misconceptions, such as that it inevitably progresses and cannot be treated. Ensure that information sharing is an ongoing, integral part of the management plan rather than a single event at time of presentation.
- R9. Agree on individualized self-management strategies with the person with OA. Ensure that positive behavioral changes, such as exercise, weight loss, and use of suitable footwear and pacing, are appropriately targeted.
- R10. Ensure that self-management programs for people with OA, either individually or in groups, emphasize the recommended core treatments, especially exercise.
- R11. Consider the use of local heat or cold as an adjunct to core treatments.
- R12. Advise people with OA to exercise as a core treatment, irrespective of age, comorbidity, pain severity, or disability. Exercise should include local muscle strengthening and general aerobic fitness.
- R13. Consider manipulation and stretching as an adjunct to core treatments, particularly for OA of the hip.
- R14. Offer interventions to achieve weight loss as a core treatment for people who are obese or overweight.
- R15. Consider the use of transcutaneous electrical nerve stimulation as an adjunct to core treatments for pain relief.
- R16. Do not offer glucosamine or chondroitin products for the management of OA.
- R17. Do not offer acupuncture for the management of OA.
- R18. Offer advice on appropriate footwear (including shock-absorbing properties) as part of core treatments for people with lower-limb OA.
- R19. Consider assessing people with OA who have biomechanical joint pain or instability for bracing/insoles as an adjunct to their core treatments.
- R20. Consider assistive devices (eg, walking sticks) as adjuncts to core treatments for people with OA who have specific problems with activities of daily living. Refer people with OA who have specific problems with activities of daily living appropriately (eg, occupational therapists).
- R21. Do not refer for arthroscopic lavage and debridement as part of treatment for OA, unless the person has knee OA with a clear history of mechanical locking (as opposed to morning joint stiffness, "giving way," or X-ray evidence of loose bodies).
- R22. Offer paracetamol for pain relief in addition to core treatments; regular dosing may be required. Consider paracetamol ahead of oral NSAIDs, COX-2 inhibitors, or opioids.
- R23. Consider the addition of opioid analgesics if paracetamol or topical NSAIDs are insufficient for pain relief for people with OA. Consider the risks and benefits, particularly in older people.
- R24. Consider topical NSAIDs for pain relief in addition to core treatments for people with knee OA. Consider topical NSAIDs ahead of oral NSAIDs, COX-2 inhibitors, or opioids.
- R25. Consider topical capsaicin as an adjunct to core treatments for knee OA.
- R26. Do not offer rubefacients for treating OA.
- R27. Consider substitution with an oral NSAID/COX-2 inhibitor if paracetamol or topical NSAIDs are ineffective for pain relief for people with OA.
- R28. Consider the addition of an oral NSAID/COX-2 inhibitor to paracetamol if paracetamol or topical NSAIDs provide insufficient pain relief for people with OA.
- R29. Use oral NSAIDs/COX-2 inhibitors at the lowest effective dose for the shortest possible period of time.
- R30. When offering treatment with an oral NSAID/COX-2 inhibitor, the first choice should be either a standard NSAID or a COX-2 inhibitor (other than etoricoxib 60 mg). In either case, coprescribe with a PPI, choosing the one with the lowest acquisition cost.
- R31. Consider individual patient risk factors, including age, when prescribing oral NSAIDs/COX-2 inhibitors, because all oral NSAIDs/COX-2 inhibitors have analgesic effects of a similar magnitude but vary in their potential gastrointestinal, liver, and cardiorenal toxicity. Consider appropriate assessment and/or ongoing monitoring of patient risk factors when prescribing the person with oral NSAIDs/COX-2 inhibitors.
- R32. If a person with OA needs to take low-dose aspirin, consider other analgesics before substituting or adding an NSAID or COX-2 inhibitor (with a PPI) if pain relief is ineffective or insufficient.

APPENDIX A

- R33. Consider intra-articular corticosteroid injections as an adjunct to core treatments for the relief of moderate to severe pain in people with OA.
- R34. Do not offer intra-articular hyaluronan injections for the management of OA.
- R35. Ensure that the person with OA has been offered at least the core (nonsurgical) treatment options before referring the person for consideration of joint surgery.
- R36. Base decisions on referral thresholds on discussions between patient representatives, referring clinicians, and surgeons, rather than using scoring tools for prioritization.
- R37. Consider referral for joint surgery for people with OA who experience joint symptoms (pain, stiffness, and reduced function) that have a substantial impact on their quality of life and are refractory to nonsurgical treatment.
- R38. Refer for consideration of joint surgery before there is prolonged and established functional limitation and severe pain.
- R39. Patient-specific factors (including age, sex, smoking, obesity, and comorbidities) should not be barriers to referral for joint surgery.
- R40. When discussing the possibility of joint surgery, check that the person has been offered at least the core treatments for OA, and give him or her information about the benefits and risks of surgery and the potential consequences of not having surgery, recovery and rehabilitation after surgery, how having a prosthesis might affect him or her, and how care pathways are organized in his or her local area.
- R41. Offer regular reviews to all people with symptomatic OA. Agree on the timing of the reviews with the person.
- R42. Consider an annual review for any person with 1 or more of the following: troublesome joint pain, more than 1 joint with symptoms, more than 1 comorbidity, and/or taking regular medication for OA.
- R43. Conduct initial assessments using a biopsychosocial approach, including physical status, activities of daily living, participation, mood, as well as health education needs, health beliefs, and motivation to self-manage.
- R44. Individualize the treatment of hip and/or knee OA according to the wishes and expectations of the individual, localization of OA, risk factors (eg, age, sex, comorbidity, obesity, and adverse mechanical factors), presence of inflammation, severity of structural change, level of pain and restriction of daily activities, societal participation, and quality of life.
- R45. Offer an individualized management plan (a package of care) that includes the core nonpharmacological approaches, specifically (a) information and education regarding OA, (b) addressing maintenance and pacing of activity, (c) addressing a regular individualized exercise regimen, (d) addressing weight loss if overweight or obese, (e) reduction of adverse mechanical factors (eg, appropriate footwear), (f) consideration of walking aids and assistive technology.
- R46. Information and education for the person with hip and/or knee OA should (a) be individualized according to the person's illness perceptions and educational capability; (b) be included in every aspect of management; (c) specifically address the nature of OA (a repair process triggered by a range of insults), its causes (especially those pertaining to the individual), its consequences, and prognosis; (d) be reinforced and developed at subsequent clinical encounters; (e) be supported by written and/or other types of information (eg, DVD, website, group meeting) selected by the individual; (f) include partners or carers of the individual, if appropriate.
- R47. When lifestyle changes are recommended, offer people with hip and/or knee OA an individually tailored program, including long-term and short-term goals, intervention or an action plan, and regular evaluation and follow-up, with possibilities for adjustment of the program.
- R48. Select the mode of delivery of exercise education (eg, individual one-to-one sessions, group classes, etc), and use pools or other facilities according both to the preference of the person with hip and/or knee OA and local availability.
- R49. Teach a regular individualized (daily) exercise regimen that includes strengthening (sustained isometric) exercise for both legs, including the quadriceps and proximal hip girdle muscles (irrespective of site or number of large joints affected), aerobic activity and exercise, as well as adjunctive range-of-movement/stretching exercise.
- R50. When educating people with hip and/or knee OA on weight loss, incorporate individualized strategies that are recognized to effect successful weight loss and maintenance.
- R51. Offer the person advice on appropriate and comfortable shoes.
- R52. Consider the use of walking aids, assistive technology, and adaptations at home and/or at work to reduce pain and increase participation.
- R53. For people who are at risk of work disability or who want to start/return to work, provide them with rapid access to vocational rehabilitation, including counseling about modifiable work-related factors such as altering work behavior, changing work tasks, or altering work hours, use of assistive technology, workplace modification, commuting to/from work, and support from management, colleagues, and family toward employment.

Abbreviations: COX, cyclo-oxygenase; NSAID, nonsteroidal anti-inflammatory drug; OA, osteoarthritis; PPI, proton-pump inhibitor; R, recommendation.

APPENDIX B



The percentage of participants in round 1 who rated recommendations as 3 or less, between 4 and 6, or 7 or greater on an NRS where 0 is not important and 10 is extremely important. The 39 recommendations displayed were included directly into round 3, as at least 70% of the respondents rated these recommendations as 7 or greater on the NRS. Abbreviations: NRS, numeric rating scale; OA, osteoarthritis. The complete recommendation corresponding to each number can be found in APPENDIX A.

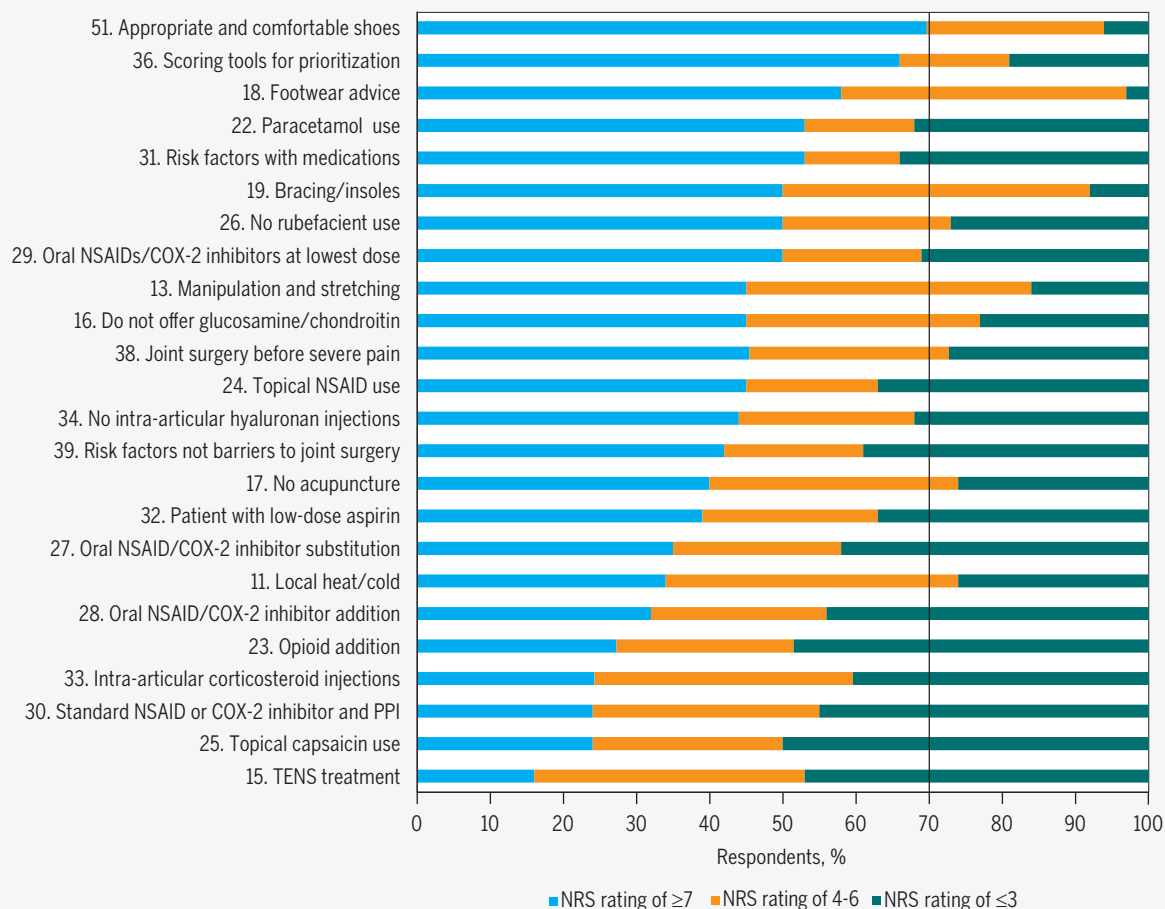
APPENDIX C

The 7 new recommendations nominated by the panel in round 1 and added to round 2 are as follows.

- R54. Do not offer herbal supplements to people with hip and/or knee OA.
- R55. Screen for depression using an accepted depression screening tool.
- R56. Manage any psychological distress of the person (eg, referral to another health professional if required).
- R57. Incorporate strategies to optimize adherence to treatment recommendations (eg, offer booster sessions to increase adherence to exercise).
- R58. Discuss and offer a personalized exercise and physical activity program to people with hip and/or knee OA according to their needs, preferences, self-motivation, and ability to perform the exercises. An appropriate exercise program may include muscle strengthening, aerobic activity, land- or water-based exercise, and a supervised or unsupervised exercise program. The type and dosage of the exercise program should be individually tailored.
- R59. Provide information on opportunities for people to exercise locally at minimal financial cost.
- R60. Offer accurate verbal and written information to enhance understanding of the pain experience, including the neurobiological basis of pain.

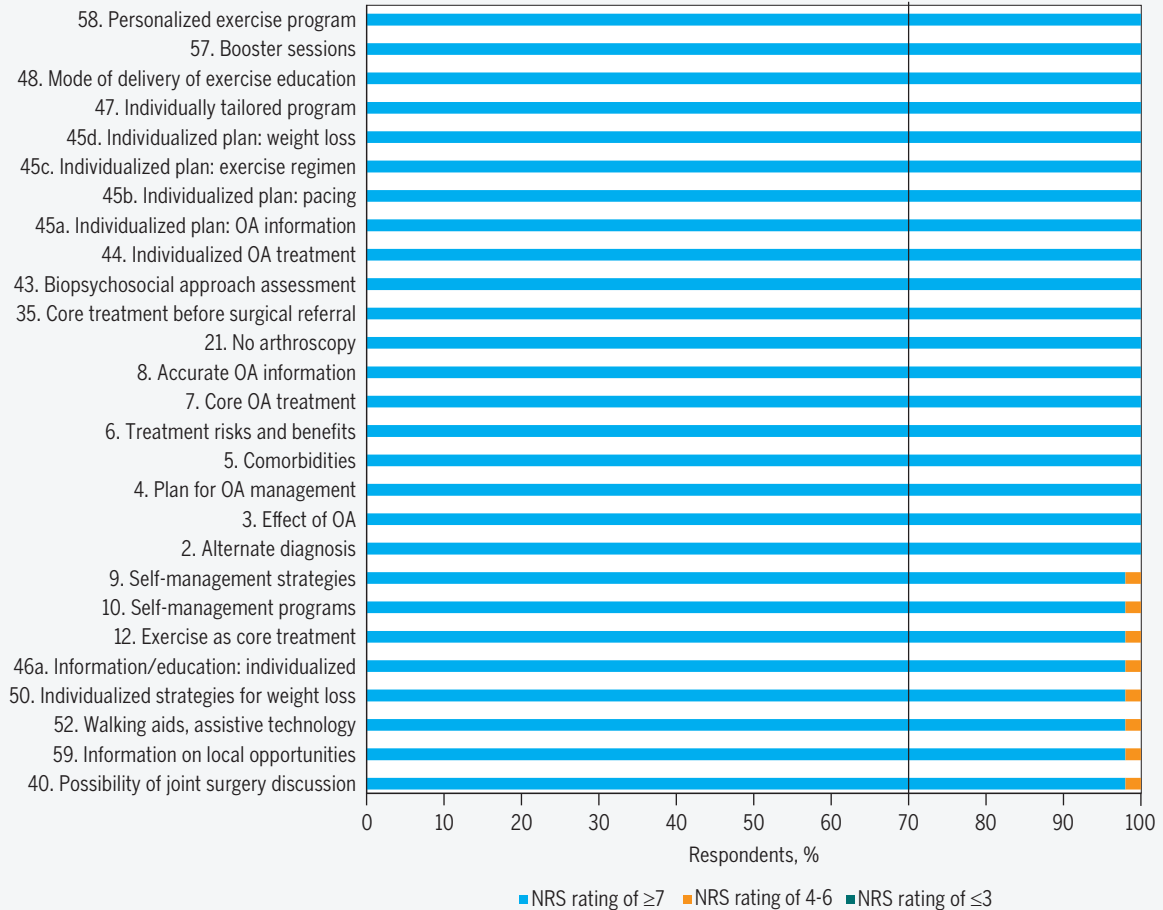
Abbreviations: OA, osteoarthritis; R, recommendation.

APPENDIX D

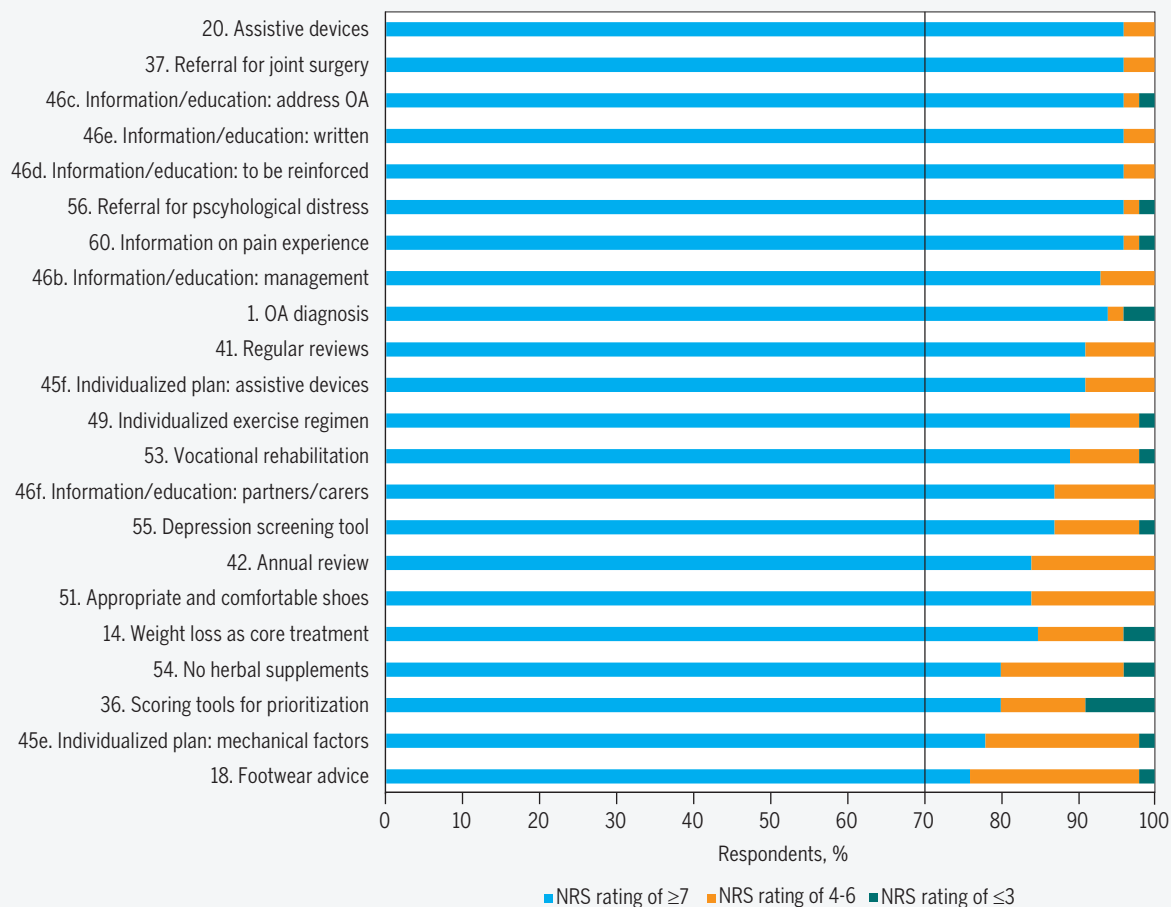


The percentage of participants in round 1 who rated recommendations as 3 or less, between 4 and 6, or 7 or greater on an NRS where 0 is not important and 10 is extremely important. The 24 recommendations displayed were rerated in round 2, as they did not reach consensus for inclusion (defined as at least 70% of respondents rating the item as at least 7 on the NRS). Abbreviations: COX, cyclo-oxygenase; NRS, numeric rating scale; NSAID, nonsteroidal anti-inflammatory drug; PPI, proton-pump inhibitor; TENS, transcutaneous electrical nerve stimulation. The complete recommendation corresponding to each number can be found in **APPENDIX A**.

APPENDIX E



APPENDIX E



The percentage of participants in round 3 who rated recommendations as 3 or less, between 4 and 6, or 7 or greater on an NRS where 0 is not important and 10 is extremely important. Forty-nine recommendations were included in stage 3 (priority-ranking exercise), as at least 70% of the respondents rated these recommendations as 7 or greater on the NRS. Abbreviations: NRS, numeric rating scale; OA, osteoarthritis. The complete recommendation corresponding to each number can be found in **APPENDIX A**.

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Effectiveness of Foot Orthoses Versus Corticosteroid Injection for Plantar Heel Pain: The SOOTHE Randomized Clinical Trial

Plantar heel pain is common in primary care,^{24,30} and plantar fasciitis is its most common cause.³⁹ Prevalence estimates of plantar heel pain in community-dwelling samples range between 3.6% and 6.9%.^{9,12} Previous research has suggested that plantar

heel pain is self-limiting and usually resolves in 1 to 2 years,^{8,43} although a recent longitudinal study found that 50% of participants with plantar heel pain remained symptomatic 5 years after the onset of symptoms.¹¹

Plantar heel pain has been found to cause significant disability and poorer health-related quality of life.^{14,29} Accordingly, effective treatment is essential to minimize its direct effects on pain and disability, as well as its indirect effects on

activities of daily living and productivity. Recommended treatment includes an initial period of simple, low-cost care that involves weight reduction, if appropriate, activity modification, footwear changes, and plantar fascia and calf stretches.^{6,35} If these interventions fail, then further recommendations for treatment may include foot orthoses and/or corticosteroid injection.

Foot orthoses and corticosteroid injection are more effective than control interventions (either placebo/sham or no treatment), although at different time points. A Cochrane review concluded that corticosteroid injection is more effective than a control in the short term (at week 4) but that its benefits are not sustained at week 12.⁷ A meta-analysis found moderate-quality evidence that foot orthoses are more effective than a control in the longer term (at week 12), but not in the short term (at week 4).⁴²

Foot orthoses and corticosteroid injection have been directly compared in 3 randomized trials,^{16,20,45} although their findings are difficult to generalize due to use of a cointervention (oral anti-inflammatories) with corticosteroid injection,²⁰ use of a soft “anti-pronatory pad” rather than a true foot orthosis,¹⁶ and a

● **BACKGROUND:** Plantar heel pain is a common foot complaint that causes significant disability and poorer health-related quality of life. Foot orthoses and corticosteroid injection are effective treatments for plantar heel pain; however, it is unclear whether one is more effective than the other.

● **OBJECTIVE:** The aim of this trial was to compare the effectiveness of foot orthoses and corticosteroid injection for plantar heel pain.

● **METHODS:** In this parallel-group, assessor-blinded, randomized clinical trial, participants received prefabricated, arch-contouring foot orthoses or a single ultrasound-guided corticosteroid injection. The primary outcome measure was the foot pain subscale of the Foot Health Status Questionnaire at 4 and 12 weeks.

● **RESULTS:** One hundred three participants aged 21 to 72 years (63 female) with plantar heel pain were recruited from the community and received an intervention. For the primary outcome of foot pain, corticosteroid injection was more effective at

week 4 (adjusted mean difference, 8.2 points; 95% confidence interval: 0.6, 15.8 points). However, foot orthoses were more effective at week 12 (adjusted mean difference, 8.5 points; 95% confidence interval: 0.2, 16.8 points). Although these findings were statistically significant, the differences between the interventions did not meet the previously calculated minimal important difference value of 12.5 points.

● **CONCLUSION:** Corticosteroid injection is more effective than foot orthoses at week 4, but this effect does not last; and appropriately contoured foot orthoses are more effective than corticosteroid injection at week 12. However, patients may not notice a clinically worthwhile difference between the interventions.

● **LEVEL OF EVIDENCE:** Therapy, level 1b. *J Orthop Sports Phys Ther* 2019;49(7):491-500. Epub 26 May 2019. doi:10.2519/jospt.2019.8807

● **KEY WORDS:** orthotic devices, orthotics, plantar fasciitis, steroid

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short duration of follow-up (4 weeks).⁴⁵ Accordingly, our aim was to evaluate the effectiveness of foot orthoses and corticosteroid injection for the treatment of plantar heel pain.

METHODS

THE STEROID INJECTION VERSUS Foot Orthoses (SOOTHE) Heel Pain Trial was an assessor-blinded, parallel-group randomized trial. The methods for this trial have been reproduced in brief from a published protocol paper,⁴¹ and the findings have been reported in accordance with the Consolidated Standards of Reporting Trials statement³³ and the Template for Intervention Description and Replication checklist.¹³ The trial was prospectively registered with the Australian New Zealand Clinical Trials Registry (registration ACTRN12615001266550). Ethical approval for the trial was obtained from the La Trobe University Human Ethics Committee (approval number 15-120), and all participants provided informed consent.

Participants were included if they were over 18 years of age, had a diagnosis of plantar heel pain of at least 4 weeks in duration,²¹ and reported an average pain over the last 7 days of at least 30 mm on a 100-mm visual analog scale (VAS). Participants were excluded if they had received any

treatment in the past 4 weeks, had worn foot orthoses or received a corticosteroid injection in the heel in the last 6 months, had a history of surgery to the heel, or had a systemic medical condition such as an inflammatory disorder, connective tissue disease, or neurological disorder. All appointments were conducted at a primary care podiatry center at La Trobe University (Bundoora, Australia), apart from the intervention appointment for participants who were allocated to receive a corticosteroid injection, which was conducted at a medical imaging center (Southern Cross Medical Imaging, Bundoora, Australia).

Interventions

The foot orthosis group received a pair of Formthotics (Foot Science International, Christchurch, New Zealand) full-length, prefabricated foot orthoses from a podiatrist with more than 20 years of experience (J.M.G.). The Formthotics were full-length, dual-density devices manufactured from a soft polyethylene foam top layer (Shore type A durometer of 25) and a firm polyethylene foam base layer (Shore type A durometer of 50) (FIGURE 1). For each participant, an appropriately sized orthosis was selected, and each orthosis was placed in the participant's footwear and heated with a device specifically designed for this purpose by Foot Science International.

Following heating and placement in the shoe, participants stood on the orthoses to allow them to conform to the contour of the foot. If participants experienced discomfort, modifications were made by the investigator during the appointment.

The corticosteroid injection group received a single, ultrasound-guided corticosteroid injection at a medical imaging center. The corticosteroid injections were administered by 1 of 3 radiologists, whose experience ranged from 10 to 23 years. Participants were placed in a prone position, with their feet hanging off the end of an examination table (FIGURE 2). A 25-gauge needle was used to inject a solution containing 1 mL of a combination of betamethasone acetate and betamethasone sodium phosphate (Celestone Chronodose; Merck & Company, Inc, Kenilworth, NJ) and 1 mL of bupivacaine (Marcaine 0.5%; Pfizer Inc, New York, NY). The needle was inserted through the medial heel, approximately 1 cm above the weight-bearing line of the skin, in a medial-to-lateral direction, with infiltration surrounding the area of maximum plantar fascia thickening. The needle did not penetrate the plantar fascia, so each injection delivered corticosteroid around the fascia, not within the fascia. The plantar heel was sonographically imaged using

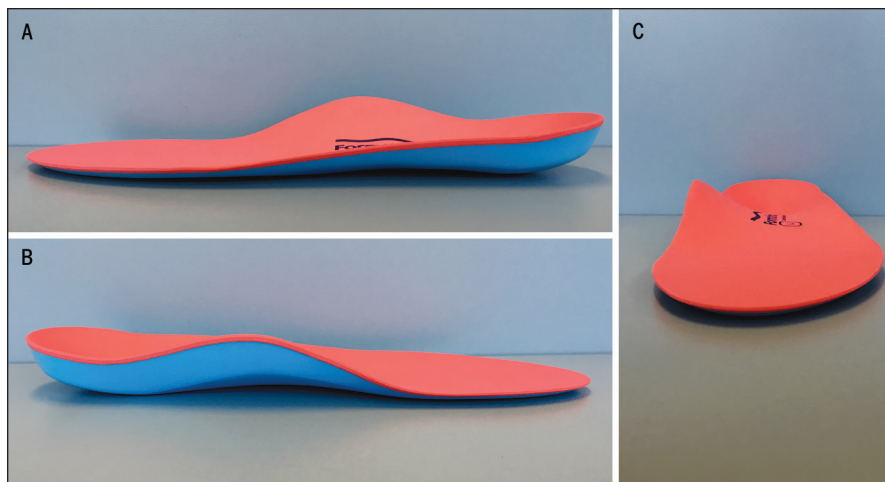


FIGURE 1. The Formthotics full-length, dual-density, prefabricated foot orthosis. (A) View of the lateral orthosis, (B) view of the medial orthosis, and (C) view from the distal to the proximal end of the orthosis.



FIGURE 2. Approach used to administer the ultrasound-guided corticosteroid injection.

a LOGIQ S8 ultrasound system and a linear ML6-15 MHz probe (General Electric Company, Boston, MA).

To reflect clinical practice, participants in both groups also received a plantar fascia- and calf-stretching program (FIGURE 3) and education. A pamphlet outlining the stretching program and education provided to both groups is available in the trial protocol.⁴¹

Adherence to the interventions was assessed at weeks 4, 8, and 12. Participants randomized to the foot orthosis group were asked to report the number of days and hours per day they had worn their orthoses over the last week. In addition, both groups were asked how many days over the last week they had performed the stretches.

Outcome Measures

Outcome measures were collected from participants at weeks 4, 8, and 12. Past research has found that corticosteroid injection is more effective than a control at week 4, but that foot orthoses are more effective at week 12. Therefore, we chose 2 primary time points: weeks 4 and 12.^{7,42} The patient-reported outcome measures were administered to participants on a laptop computer through an online survey platform (Qualtrics, Provo, UT). Questionnaires at week 8 were delivered via an e-mail link that directed participants to the Qualtrics platform; as a result, participants did not visit the podiatry center at week 8.

Primary Outcome Measure The primary outcome measure was the foot pain subscale of the Foot Health Status Questionnaire (FHSQ).⁵ The FHSQ is a 13-item questionnaire used to evaluate foot-specific health-related quality of life. It has 4 subscales (foot pain, foot function, foot-wear, and general foot health), with each scored on a 100-point scale (0 representing the poorest foot health). The minimal important difference has been calculated as 12.5 points for the foot pain subscale in participants with plantar heel pain.¹⁸

Secondary Outcome Measures Severity of “first-step” pain and average pain over the last 7 days were measured on a 100-mm VAS. Foot function was measured using the foot function subscale of the FHSQ.⁵ Overall improvement was measured with a 15-point global perceived rating of change.¹⁵ Participants were considered to have improved if they rated their change as “a little better” or greater. Health-related quality of life was measured with the European Quality of Life-5 Dimensions (EQ-5D)²⁷ questionnaire and the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) version 2.²² The EQ-5D scores were combined into a single “health state” to allow simple comparison between groups. Scores ranged from 5 (the best health state) to 25 (the worst health state). Self-reported physical activity was measured using the 7-Day Physical Activity Recall questionnaire,³² and the results were converted to daily energy expenditure, expressed in kilo-

calories per day.²⁸ Fear-avoidance beliefs were measured using the Fear-Avoidance Components Scale.²⁵ Plantar fascia thickness and hypoechogenicity were measured sonographically by the primary investigator (G.A.W.) using an ACUSON Antares ultrasound system (Siemens AG, Munich, Germany) with a linear 5- to 12-MHz probe. Participants were asked to recall the number of days of work lost and the number of sessions of sports or exercise missed over the previous week, and whether they used any cointerventions for their heel pain. To assess treatment preference, participants were asked at baseline which of the 2 treatments they preferred.³⁶

Randomization and Blinding

Participants were allocated to groups using a random sequence generated by an interactive telephone system. Participants were allocated on a 1:1 ratio after randomization and stratified according to sex, body mass index, and duration of symptoms. Group allocation was concealed; participants were advised of their allocation by a secondary investigator who was not involved with other components of the trial.

Due to the nature of the interventions used in this trial, the participants and the investigators providing the interventions were not blind to group allocation. The assessor (G.A.W.) was blind to group allocation, and this blinding was maintained during data analysis.

Sample Size

The sample size was calculated a priori, based on the primary outcome measure.⁵ A sample size of 100 participants was calculated for adequate statistical power to detect the minimal important difference of 12.5 points (0-to-100-point scale).¹⁸ We selected a standard deviation of 21, consistent with previous randomized trials,^{17,23} a power level of 0.8, an alpha level of .05, and factored in a dropout rate of 10%.

Data Analysis

Primary and secondary outcomes were analyzed using IBM SPSS Statistics Ver-

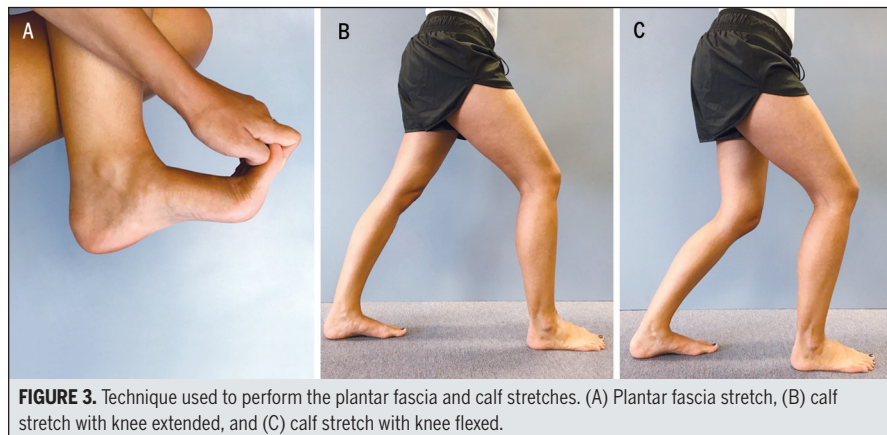


FIGURE 3. Technique used to perform the plantar fascia and calf stretches. (A) Plantar fascia stretch, (B) calf stretch with knee extended, and (C) calf stretch with knee flexed.

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sion 24.0 (IBM Corporation, Armonk, NY), following the intention-to-treat principle. Standard tests of the distribution of continuous data were undertaken, and skewed data were transformed if appropriate. If data were not normally distributed and could not be transformed, then the data were handled nonparametrically. Missing data were replaced using multiple imputation for participants who received their allocated intervention.³⁴ Little's test was performed to ensure that data were missing completely at random and to determine the method for generating the imputed data sets.¹⁹ Regression models were created using group allocation, age, and baseline values as predictors. The estimates from 20 imputed data sets were combined using Rubin's rules.³¹

Continuous data were analyzed using a linear regression approach to analysis

of covariance, with the baseline score for each continuous outcome measure used as a covariate.^{26,38} Dichotomous outcomes were compared using relative and absolute measures,² in addition to the number needed to treat. To assess for differences in adherence between groups, independent-samples *t* tests were used.

RESULTS

PARTICIPANTS WERE RECRUITED BETWEEN May 2016 and June 2017, and their progress through the trial is displayed in **FIGURE 4**. Ten participants withdrew from the trial after being randomized but prior to receiving their allocated intervention, and they were excluded from the trial and the analyses, as recommended by Fergusson and colleagues.¹⁰ A secondary analysis of baseline characteristics was

conducted that included all participants who were randomized (*n* = 113). The withdrawal of these participants did not affect important baseline characteristics of age, sex, body mass index, education, duration of symptoms, and the primary outcome measure of the FHSQ foot pain subscale (**APPENDIX**, available at www.jospt.org). The remaining participants had similar characteristics at baseline (**TABLE 1**).

Primary Outcome

The results for the primary outcome (pain measured with the FHSQ foot pain subscale) are summarized in **TABLE 2**. At week 4, corticosteroid injection was more effective at reducing pain than foot orthoses. At week 8, the groups reported similar pain levels. At week 12, foot orthoses were more effective than corticosteroid injection at reducing pain (**FIGURE 5**). These findings did not reach the minimal important difference value of 12.5 points for the FHSQ foot pain subscale.

Secondary Outcomes

The results of secondary outcomes are summarized in **TABLE 2**. For average pain severity measured using a VAS, corticosteroid injection was more effective than foot orthoses at week 4. This result met the minimal important difference value of 8 points for VAS average pain.¹⁸ At weeks 8 and 12, the groups were similar.

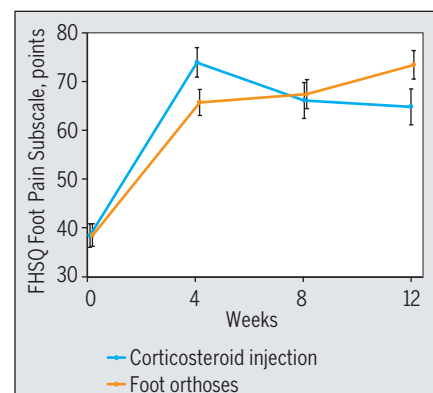
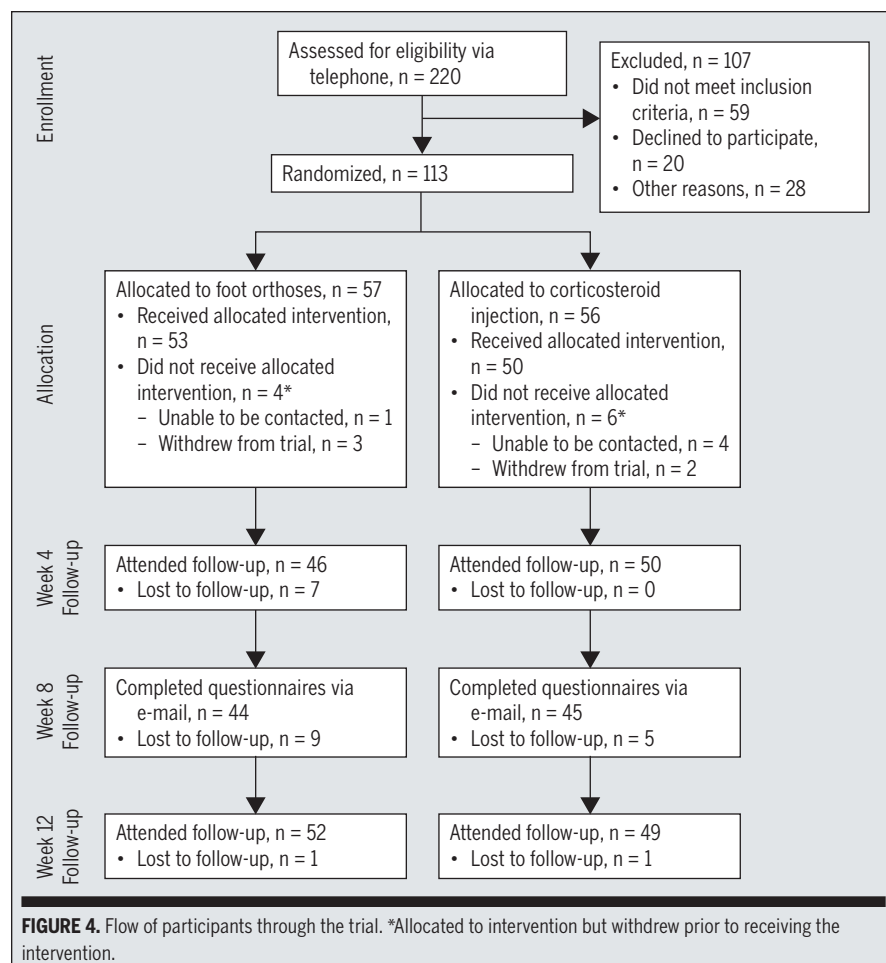


FIGURE 5. The primary outcome measure, the FHSQ foot pain subscale (0-100 points), presented as mean and standard error. A higher value indicates less pain. Abbreviation: FHSQ, Foot Health Status Questionnaire.

For first-step pain measured using a VAS, the groups were similar at weeks 4 and 8. At week 12, however, foot orthoses were more effective than corticosteroid injection. This result did not meet the minimal important difference value of 19 points for VAS first-step pain.

For overall improvement (TABLE 3), participants in the corticosteroid injection group were 18% (95% confidence interval [CI]: 3%, 36%) more likely to report an improvement in their symptoms at week 4. Participants in the foot orthosis group were more likely to report an overall improvement at week 8 (15%; 95% CI: -4%, 31%) and week 12 (16%; 95% CI: -1%, 31%), but this did not reach statistical significance.

For health-related quality of life measured using the EQ-5D, corticosteroid injection was more effective at week 4. However, this was inconsistent with the EQ-5D VAS, which was similar for each group. At weeks 8 and 12, the groups reported similar values on the EQ-5D and the EQ-5D VAS. The groups also reported similar values for each time point on the SF-36 physical and mental component summaries.

The between-group differences were similar on the remaining secondary measures.

Adverse Events

The rate of adverse events is presented in TABLE 4. Adverse events were generally short term (of less than 1 week in duration) and consisted of swelling, a bruised feeling, and pain in the corticosteroid injection group and cramping, discomfort, arch pain, and aching proximal to the feet (eg, ankles or calves) in the foot orthosis group. One participant who was randomized to receive foot orthoses experienced a plantar fascia tear while running. This participant remained in the trial and was managed with activity modification and supportive athletic taping until symptoms were reduced.

Adherence

The groups were similar in their adherence to the stretching program at week 4 ($t_{92} = -0.3$, $P = .773$), week 8 ($t_{85} = 0.6$, $P = .577$), and week 12 ($t_{97} = 0.5$, $P = .628$). Adherence to foot orthoses was consistent at each time point. Participants reported that they used their foot

orthoses for an average of 6.6 ± 0.7 , 6.6 ± 1.0 , and 6.2 ± 1.5 days per week for an average of 10.1 ± 3.5 , 9.2 ± 3.9 , and 9.2 ± 3.7 hours per day at weeks 4, 8, and 12, respectively.

Cointerventions

At week 4, there were 3 participants in the foot orthosis group who used cointerventions, including massage and paracetamol with codeine. At week 8, there were 4 participants in the corticosteroid injection group who reported using an unspecified anti-inflammatory, foot orthoses, massage, and a turmeric supplement. At week 12, there were 4 participants in the foot orthosis group who reported using codeine, diclofenac, paracetamol, and massage. In the corticosteroid injection group, 4 participants reported using diclofenac gel, paracetamol and an offloading walker, unspecified anti-inflammatories, and a tart cherry supplement.

DISCUSSION

THIS TRIAL FOUND THAT CORTICOSTEROID injection is more effective than foot orthoses for reducing pain in the short term (week 4). However, in the longer term (week 12), foot orthoses are more effective. The 8-point between-group difference observed for the primary outcome of the FHSQ foot pain subscale at weeks 4 and 12 is not greater than the minimal important difference value of 12.5 points,¹⁸ which indicates that the difference between these interventions in the short and longer term may not be clinically meaningful on average. As might be expected, the findings of secondary outcomes that measured pain (eg, VAS) support the results of the primary outcome measure. The groups were similar for the other secondary outcomes: foot function, health-related quality of life, self-reported physical activity, fear-avoidance beliefs, and thickness and hypoechogenicity of the plantar fascia.

TABLE 1

PARTICIPANT CHARACTERISTICS AT BASELINE*

Characteristic	Foot Orthoses (n = 53)	Corticosteroid Injection (n = 50)
Age, y	42.9 ± 10.9	44.9 ± 12.8
Women, n (%)	33 (62.3)	30 (60.0)
Weight, kg	88.1 ± 21.5	86.9 ± 21.7
Height, m	1.7 ± 0.9	1.7 ± 1.0
Body mass index, kg/m ²	31.1 ± 6.6	29.7 ± 5.9
Education, y	15.5 ± 2.7	15.1 ± 3.6
Duration of symptoms, mo [†]	6 (8)	6 (8)
Allocated to preferred treatment, n (%)	21 (39.6)	21 (42.0)
Plantar fascia thickness, mm [‡]	5.9 ± 1.1	5.8 ± 1.5
Foot Posture Index [§]	3.6 ± 3.3	3.7 ± 3.7
Ankle range of motion, deg		
Knee extended	40.2 ± 6.9	37.9 ± 6.9
Knee flexed	45.9 ± 8.3	44.7 ± 7.3

*Values are mean ± SD unless otherwise indicated.

[†]Values are median (interquartile range).

[‡]Based on the most painful foot.

[§]Scores range from -12 (highly supinated foot) to +12 (highly pronated foot). A score between 0 and 5 indicates a normal foot posture.

TABLE 2

CONTINUOUS PRIMARY AND SECONDARY OUTCOMES AND ANCOVA-ADJUSTED BETWEEN-GROUP DIFFERENCES

Outcome/Measure	Group*		ANCOVA-Adjusted Estimates of Effect		
	Foot Orthoses (n = 53)	Corticosteroid Injection (n = 50)	Between-Group Difference [†]	t Statistic	P Value
Primary: foot pain					
FHSQ [‡] foot pain subscale					
Baseline	38.4 ± 17.3	38.5 ± 17.0			
4 wk	65.7 ± 19.4	73.9 ± 21.6	-8.2 (-15.8, -0.6) [§]	-2.1	.034
8 wk	67.4 ± 21.9	66.1 ± 26.1	1.2 (-7.8, 10.3)	0.3	.790
12 wk	73.4 ± 20.9	64.8 ± 26.0	8.5 (0.2, 16.8) [§]	2.0	.045
Secondary					
Average pain severity (VAS [§])					
Baseline	51.1 ± 16.7	56.8 ± 17.9			
4 wk	27.8 ± 21.2	20.6 ± 21.1	8.8 (0.7, 16.9) [§]	2.1	.033
8 wk	26.8 ± 25.4	33.6 ± 31.1	-5.2 (-16.2, 5.8)	-0.9	.356
12 wk	20.4 ± 21.7	28.7 ± 26.9	-6.7 (-16.1, 2.7)	-1.4	.164
First-step pain severity (VAS [§])					
Baseline	68.2 ± 14.9	72.5 ± 16.4			
4 wk	30.6 ± 26.6	22.6 ± 22.9	9.2 (-0.4, 18.8)	1.9	.060
8 wk	25.9 ± 25.4	33.7 ± 31.2	-6.4 (-17.4, 4.6)	-1.1	.254
12 wk	19.8 ± 20.0	35.3 ± 30.8	-13.7 (-23.5, -3.9) [§]	-2.7	.006
Foot function (FHSQ [‡] foot function subscale)					
Baseline	63.6 ± 23.3	59.7 ± 24.4			
4 wk	81.5 ± 16.7	84.4 ± 19.0	-4.4 (-10.2, 1.4)	-1.5	.135
8 wk	81.7 ± 19.5	82.4 ± 21.7	-2.1 (-9.2, 4.9)	-0.6	.558
12 wk	87.9 ± 14.7	83.9 ± 20.4	2.3 (-3.4, 8.0)	0.8	.427
Health-related QoL (EQ-5D [¶])					
Baseline	9.2 ± 2.4	9.6 ± 2.3			
4 wk	8.5 ± 2.9	7.3 ± 1.9	1.3 (0.4, 2.3) [§]	2.8	.005
8 wk	8.2 ± 2.8	8.2 ± 2.9	0.2 (-0.8, 1.2)	0.4	.686
12 wk	6.9 ± 1.6	7.5 ± 2.3	-0.4 (-1.1, 0.3)	-1.1	.285
Health-related QoL (EQ-5D [¶] VAS [§])					
Baseline	71.6 ± 17.8	78.7 ± 15.1			
4 wk	77.3 ± 13.9	81.0 ± 14.9	-1.2 (-6.3, 3.9)	-0.4	.648
8 wk	75.9 ± 16.7	76.0 ± 20.9	2.2 (-4.9, 9.4)	0.6	.537
12 wk	79.4 ± 13.9	79.1 ± 17.9	3.1 (-2.7, 8.9)	1.0	.300
Health-related QoL (SF-36 [¶] PCS)					
Baseline	45.2 ± 7.4	45.2 ± 7.5			
4 wk	47.1 ± 7.8	48.1 ± 6.7	-1.1 (-3.5, 1.4)	-0.8	.406
8 wk	48.1 ± 6.8	48.6 ± 7.4	-0.5 (-2.8, 1.9)	-0.4	.689
12 wk	49.5 ± 6.2	48.5 ± 6.6	1.0 (-1.0, 3.1)	0.9	.325

Table continues on page 497

Strengths and Limitations

This was a robust randomized trial in which the groups had similar baseline characteristics, bias was minimized by allocation concealment and blinded outcome assessment, there were few participant dropouts, and there was adequate

statistical power. Furthermore, the findings are generalizable and should be easily implemented. We used appropriately contoured, prefabricated foot orthoses that are relatively inexpensive and easy to access and administer. For the corticosteroid injection, radiologists from the

community administered the injections using a common technique and a widely used corticosteroid.

Due to the nature of the interventions, it was not possible to blind the participants or researchers who provided the interventions, although the therapists were

TABLE 2

CONTINUOUS PRIMARY AND SECONDARY OUTCOMES AND ANCOVA-ADJUSTED BETWEEN-GROUP DIFFERENCES (CONTINUED)

Outcome/Measure	Group*		ANCOVA-Adjusted Estimates of Effect		
	Foot Orthoses (n = 53)	Corticosteroid Injection (n = 50)	Between-Group Difference [†]	t Statistic	P Value
Health-related QoL (SF-36 [®] MCS)					
Baseline	51.4 ± 8.9	52.8 ± 8.2			
4 wk	51.1 ± 11.1	52.8 ± 9.0	-0.5 (-3.1, 2.1)	-0.4	.706
8 wk	51.2 ± 8.9	54.1 ± 7.6	-1.9 (-4.3, 0.4)	-1.6	.100
12 wk	52.6 ± 7.9	53.3 ± 6.8	0.0 (-2.2, 2.3)	0.0	.978
Self-reported physical activity (7-Day PAR ^{**})					
Baseline	4199.0 ± 1657.5	3853.6 ± 1395.6			
4 wk	4332.8 ± 1797.9	3883.9 ± 1701.1	181.9 (-319.3, 683.2)	0.7	.477
8 wk	3762.6 ± 1350.1	3564.2 ± 1313.3	-31.9 (-361.1, 297.1)	-0.2	.849
12 wk	4295.7 ± 2386.9	4001.7 ± 1720.0	-8.8 (-630.3, 612.8)	0.0	.978
Pain-related fear-avoidance beliefs (FACS ^{††})					
Baseline	30.8 ± 18.0	29.6 ± 16.6			
4 wk	22.3 ± 19.1	19.5 ± 16.1	2.0 (-3.4, 7.4)	0.7	.460
8 wk	21.8 ± 18.8	20.2 ± 17.2	0.7 (-4.4, 5.9)	0.3	.773
12 wk	16.5 ± 16.8	18.9 ± 18.3	-3.0 (-8.4, 2.3)	-1.1	.270
Plantar fascia thickness, mm ^{‡‡}					
Baseline	5.9 ± 1.1	5.8 ± 1.5			
4 wk	5.7 ± 1.4	5.3 ± 1.4	0.3 (-0.1, 0.7)	1.7	.083
12 wk	5.7 ± 1.2	5.8 ± 1.6	-0.1 (-0.5, 0.2)	-0.6	.521
Days of work lost					
Baseline	0.1 ± 0.3	0.0 ± 0.1			
4 wk	0.2 ± 1.1	0.2 ± 1.0	0.0 (-0.4, 0.4)	0.4	.690
8 wk	0.7 ± 3.8	0.3 ± 1.9	0.4 (-0.7, 1.5)	-0.5	.603
12 wk	0.2 ± 0.7	0.0 ± 0.4	0.1 (-0.1, 0.3)	1.0	.298
Sessions of sport or exercise lost					
Baseline	2.1 ± 2.5	1.7 ± 2.1			
4 wk	1.3 ± 2.6	1.1 ± 2.6	0.2 (-0.8, 1.2)	0.4	.651
8 wk	2.1 ± 4.6	2.0 ± 4.9	0.1 (-1.8, 1.9)	0.1	.944
12 wk	1.0 ± 3.2	1.5 ± 3.8	-0.5 (-1.8, 0.9)	-0.7	.492

Abbreviations: ANCOVA, analysis of covariance; EQ-5D, European Quality of Life-5 Dimensions questionnaire; FACS, Fear-Avoidance Components Scale; FHSQ, Foot Health Status Questionnaire; MCS, mental component summary; PAR, Physical Activity Recall; PCS, physical component summary; QoL, quality of life; SF-36, Medical Outcomes Study 36-Item Short-Form Health Survey; VAS, visual analog scale.

*Values are mean ± SD.

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

[‡]Scores on the FHSQ range from 0 (most pain/worst function) to 100 (no pain/best function).

[§]Statistically significant finding.

^{||}Scores on the VAS range from 0 (no pain/best health state) to 100 (worst pain/worst health state).

[¶]Scores on the EQ-5D range from 5 (best health state) to 25 (worst health state).

^{‡‡}Scores on the SF-36 range from 0 (worst quality of life) to 100 (best quality of life).

^{***}Scores on the 7-Day PAR are presented as daily energy expenditure (kilocalories per day).

^{††}Scores on the FACS range from 0 (no fear-avoidance beliefs) to 100 (extreme fear-avoidance beliefs).

^{‡‡}Measured sonographically.

not involved with other parts of the trial, such as group allocation, outcome assessment, and data analysis. Because a similar proportion of participants in each group received their preferred intervention, the lack of participant blinding should not

have led to bias from resentful demoralization.³⁷ In addition, the participants recruited into this trial were, on average, younger by approximately 5 to 10 years than those in previous trials,^{3,4,17,23} which may have been due to a method of recruitment (so-

cial media) not used in previous trials. Finally, a true “no-treatment” control group was not included, given that previous trials have demonstrated the effectiveness of both interventions compared to sham or placebo.^{4,23,40,42,44}

RESEARCH REPORT

Comparison of Findings With Previous Research

For the primary outcome of pain, our findings are consistent with those of previous research^{16,20,45} that found corticosteroid injection to be more effective at week 4. The findings of this trial compared with those of previous trials were less clear at week 12, when foot orthoses were found to be more effective than corticosteroid injection. In contrast, Kriss¹⁶ found that corticosteroid injection was more effective than foot orthoses, while Lynch and colleagues²⁰ found that the effectiveness of both interventions was similar. The inconsistency in findings may be explained by the interventions provided. For example, Kriss¹⁶ used a soft “anti-pronatory pad” rather than a true foot orthosis, whereas Lynch and col-

leagues²⁰ used customized foot orthoses and supportive foot taping in combination. In addition, the group sizes in the trial by Lynch and colleagues²⁰ (approximately $n = 30$) were reduced by a high participant dropout rate (approximately $n = 10$ per group), which could have reduced the power to detect differences between groups. Consequently, differences in the foot orthoses and statistical power between our trial and previous trials may explain the inconsistent findings.

Unanswered Questions and Future Research

The findings indicate that corticosteroid injection is more effective than foot orthoses in the short term and that foot orthoses are more effective in the longer term. Future research should evaluate the

additive effect of each treatment to understand whether combining treatments can optimize patient outcomes. Furthermore, to understand the effectiveness in the community, we recommend that future trials be multicentered and community based.

Finally, this trial did not follow participants past week 12, and there are limited data on the effectiveness of each treatment after this time point.^{1,4,23} Only 1 trial that compared foot orthoses to corticosteroid injection followed participants beyond week 12,¹⁶ and this trial found that both groups were similar at week 24. Thus, it is important to understand the long-term effects of corticosteroid injection and foot orthoses for people with plantar heel pain. We recommend that future trials measure outcomes for longer periods.

TABLE 3

DICHOTOMOUS SECONDARY OUTCOMES, RELATIVE RISK, RELATIVE BENEFIT INCREASE, ABSOLUTE BENEFIT INCREASE, AND NUMBER NEEDED TO TREAT

Outcome	Foot Orthoses (n = 53)	Corticosteroid Injection (n = 50)	Relative Risk [†]	Relative Benefit Increase [‡]	Absolute Benefit Increase [‡]	Number Needed to Treat [‡]
Overall improvement [‡]						
4 wk	43 (81)	48 (96)	1.18 (1.03, 1.36) [§]	-0.18 (-0.36, -0.03) [§]	-0.15 (-0.28, -0.02) [§]	-7 (-4, -44) [§]
8 wk	45 (85)	36 (72)	0.85 (0.69, 1.04)	0.15 (-0.04, 0.31)	0.13 (-0.03, 0.28)	8 (-33, 4)
12 wk	47 (89)	37 (74)	0.83 (0.69, 1.01)	0.16 (-0.01, 0.31)	0.15 (-0.01, 0.29)	7 (-216, 3)
Hypoechoogenicity [§]						
Baseline	35 (66)	35 (70)				
4 wk	35 (66)	32 (64)	0.97 (0.73, 1.29)	0.03 (-0.29, 0.27) [¶]	0.02 (-0.16, 0.20) [¶]	49 (-6, 5)
12 wk	25 (47)	27 (54)	1.14 (0.78, 1.68)	-0.14 (-0.68, 0.22) [¶]	-0.07 (-0.25, 0.12) [¶]	-15 (-4, 8)

*Values are event rate (percent). The corticosteroid injection group was considered the experimental group for all calculations.

†Values in parentheses are 95% confidence interval.

‡Measured with a 15-point global perceived rating of change, dichotomized to “improved” (if the participant rated his or her change to be “a little better” or higher) or “not improved” (if the participant rated his or her change to be “about the same, hardly any better at all” or lower).

§Statistically significant findings.

¶Measured sonographically.

*Represents a relative risk reduction and absolute reduction.

TABLE 4

SELF-REPORTED ADVERSE EVENTS, RELATIVE RISK, RELATIVE RISK REDUCTION, ABSOLUTE RISK REDUCTION, AND NUMBER NEEDED TO HARM

Time Point	Foot Orthoses*	Corticosteroid Injection*	Relative Risk [†]	Relative Risk Reduction [‡]	Absolute Risk Reduction [‡]	Number Needed to Harm [‡]
0-4 wk	7/46	9/50	1.18 (0.48, 2.92)	-0.18 (-1.92, 0.52)	-0.03 (-0.18, 0.13)	36 (-6, 8)
5-8 wk	7/44	3/45	0.42 (0.11, 1.52)	0.58 (-0.52, 0.88)	0.09 (-0.04, 0.23)	11 (-22, 4)
9-12 wk	5/52	3/49	0.64 (0.16, 2.52)	0.36 (-1.52, 0.84)	0.03 (-0.08, 0.15)	29 (-12, 7)

*Values are event rate. The corticosteroid injection group was considered the experimental group for all calculations.

†Values in parentheses are 95% confidence interval.

CONCLUSION

OUR FINDINGS INDICATE THAT CORTICOSTEROID injection is more effective than foot orthoses at reducing pain in the short term; however, foot orthoses are more effective at reducing pain in the longer term. Although these findings are statistically significant, they may not be clinically meaningful, which suggests that, on average, patients may not notice a difference between the interventions. Accordingly, based on the findings of this trial, health professionals can advise patients with plantar heel pain that corticosteroid injection is more effective than foot orthoses in the short term but that this effect does not last, and appropriately contoured foot orthoses are more effective than corticosteroid injection in the longer term. ●

KEY POINTS

FINDINGS: At week 4, corticosteroid injection reduced the primary outcome measure of foot pain by a significant difference of 8.2 points (0-to-100 scale) compared to foot orthoses. At week 12, foot orthoses reduced foot pain by a significant difference of 8.5 points compared to corticosteroid injection.

IMPLICATIONS: Health professionals can advise patients with plantar heel pain that corticosteroid injection is more effective than foot orthoses in the short term, but that foot orthoses are more effective than corticosteroid injection in the longer term.

CAUTION: The between-group differences observed for the primary outcome measure of foot pain at weeks 4 and 12 are less than the minimal important difference value of 12.5 points, which indicates that the difference between these interventions may not be clinically meaningful.

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[RESEARCH REPORT]

APPENDIX

COMPARISON OF BASELINE PARTICIPANT CHARACTERISTICS FOR PARTICIPANTS WHO WERE RANDOMIZED (N = 113) VERSUS THOSE WHO RECEIVED AN INTERVENTION (N = 103)*

Characteristic	Participants Who Were Randomized			Participants Who Received an Intervention		
	Foot Orthoses (n = 57)	Corticosteroid Injection (n = 56)	Overall Sample (n = 113)	Foot Orthoses (n = 53)	Corticosteroid Injection (n = 50)	Overall Sample (n = 103)
Age, y	42.5 ± 11.0	44.7 ± 12.9	43.6 ± 11.9	42.9 ± 10.9	44.9 ± 12.8	43.8 ± 11.7
Women, n (%)	35 (61.4)	33 (58.9)	68 (60.2)	33 (62.3)	30 (60.0)	63 (61.2)
Body mass index, kg/m ²	31.2 ± 6.6	29.5 ± 5.7	30.3 ± 6.3	31.1 ± 6.6	29.7 ± 5.9	30.4 ± 6.3
Education, y	15.6 ± 2.8	14.9 ± 3.4	15.2 ± 3.1	15.5 ± 2.7	15.1 ± 3.6	15.3 ± 3.1
Duration of symptoms, mo [†]	6 (8)	6 (8)	6 (8)	6 (8)	6 (8)	6 (8)
FHSQ [‡] foot pain subscale	40.9 ± 16.9	37.1 ± 17.3	39.1 ± 17.2	38.4 ± 17.3	38.5 ± 17.0	38.4 ± 16.9

Abbreviation: FHSQ, Foot Health Status Questionnaire.

*Values are mean ± SD unless otherwise indicated.

[†]Values are median (interquartile range).

[‡]Scores on the FHSQ range from 0 (most pain/worst function) to 100 (no pain/best function).