Electrical Stimulation Therapies for Active Duty Military with Patellofemoral Pain Syndrome: A Randomized Trial

Col Laura A. Talbot, NC, USAFR (Ret.); LTC Zack Solomon, PT, DPT, SP, USA†; Dr. Lee Webb, PT, DPT, OCS, SCCE‡; Dr. Christopher Morrell, PhD§; COL E. Jeffrey Metter, MD, MC USAR (Ret.)**

ABSTRACT

Introduction

Patellofemoral pain syndrome (PFPS) is a common musculoskeletal disorder among military service members that causes knee pain, quadriceps strength loss, and impaired motor performance in otherwise healthy individuals. PFPS poses a threat to the health, fitness, and subsequent readiness of the total force. The goal of rehabilitation for military service members with PFPS is to regain physical capacity of strength and function and to reduce pain, in order to restore readiness in this population. The randomized controlled trial reported here compared an active home exercise program (HEP) alone with three different electrical stimulation treatment regimens implemented concurrently with HEP postulated improvements in lower extremity strength and physical functional performance while also reducing pain in active duty military diagnosed with PFPS.

Materials and Methods

After baseline testing, 130 active duty military members with PFPS were randomized to 1 of 4 treatment groups: (1) neuromuscular electrical stimulation (NMES) with HEP; (2) transcutaneous electrical nerve stimulation (TENS) with HEP; (3) combined NMES/TENS with HEP; (4) active HEP only. The primary outcome measure was degree of change in knee flexion and extension strength over 9 weeks. Secondary outcomes were physical functional performance and knee pain. The primary analyses used repeated measures, linear mixed-effects models with a random effect for subject, time as a continuous variable, group as a categorical variable, and a group and time interaction to test for differences in change over time among the groups.

Results

All three electrical stimulation treatment groups improved in knee extension strength in the PFPS limb to a greater extent than the HEP alone group over the 9-week treatment period. The NMES and NMES/TENS groups improved to a greater extent than the HEP alone group in knee flexion strength in the PFPS limb. The reported pain improved over time for all treatment groups with no significant group differences. All three stimulation groups performed better on the 6-min walk test than the HEP alone group.

Conclusion

The findings from this study showed that all three electrical stimulation with HEP treatment groups showed greater improvement in strength compared to the HEP alone group. These findings could offer alternative forms of rehabilitation for AD military with PFPS as these treatment regimens can be easily implemented at home station or during deployment.

INTRODUCTION

Musculoskeletal injuries are prevalent within military populations posing a threat to the health and fitness of military service members.[1] Of these injuries, patellofemoral pain syndrome (PFPS) is the most common diagnosis among active duty personnel presenting with knee pain in military ambulatory care clinics.[2] Physical training errors, intense physical activity, athletics and sports[3], heavy load carriage,[4,5] military training, and changes in training programs are the contributing factors.

Service members with knee pain limit physical activity and joint motion to reduce pain. Inactivity leads to loss of quadriceps femoris (quadriceps) strength and joint instability: the resulting weakness increases risk for PFPS.[1] These injuries

*Department of Neurology, College of Medicine, University of Tennessee Health Science Center, 855 Monroe Ave, Suite 415, Memphis, TN 38163.

†Physical Therapy Services, Dunham U.S. Army Health Clinic, Carlisle Barracks, PA 17013.

‡Byrd Clinic Physical Therapy, Fort Campbell, KY 42240.

§Department of Mathematics and Statistics, Loyola University Maryland, Baltimore, MD 21210-2699.

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can be long term with recurrence that limits duty time[2], lowers fitness,[3,4] and may lead to medical discharge.[5]

The primary objective of this pilot randomized controlled trial was to compare an active home exercise program (HEP) to three electrical stimulation treatment regimens combined with HEP. These interventions are designed to improve lower extremity strength and physical functional performance in active duty military with PFPS. The treatment groups were HEP alone, neuromuscular electrical stimulation (NMES) combined with HEP, transcutaneous electrical nerve stimulation (TENS) with HEP, and alternating NMES with TENS with HEP. Our central hypothesis was that NMES, TENS, or NMES/TENS with HEP would produce greater increases in lower extremity strength than HEP alone.

METHODS

Participants

Participants were recruited from physical therapy referrals at Blanchfield Army Community Hospital, Ft. Campbell, KY, between April 2016 and February 2018. They were informed of study procedures and provided written consent. The study was approved by the Institutional Review Board at Regional Health Command–Atlantic and registered in ClinicalTrials.gov (Trial of Self-managed Approaches for Patellofemoral Pain Syndrome in Active Duty, ID: NCT 02597673). Table SI presents eligibility criteria.

Study Design

This study was a randomized controlled trial comparing three electrical stimulation therapies of NMES, TENS, and NMES/TENS plus HEP with HEP alone. After baseline testing, participants ($N = 132$) were randomized using blocked randomization with permuted blocks of eight. Treatment assignment was concealed from study staff and participants using sequentially numbered, sealed envelopes, opened after the participant completed all baseline assessments. Blinding after baseline testing was not possible. Knee extension and flexion, function, and pain were assessed at baseline, 3, 6, and 9 weeks. Telephone calls, emails, and/or text messages are checked for compliance and provided reminders of study visits. All groups were matched on treatment time and number of sessions.

Intervention Programs

Active Home Exercise Program

All participants received HEP which teaches quadriceps muscle strengthening exercises and self-management to promote adherence. The exercises consist of straight leg raises, quad sets, step-ups, and squats. A handout, exercise demonstration, and return demonstration of exercises assured participants' comprehension of the protocol. Weekly communication via email, text, or phone encouraged compliance with the protocol.

Neuromuscular Electrical Stimulation Program

In addition to HEP, the NMES group received 9 weeks of NMES strength training. The KneeHAB XP controller, a dual channel device, delivered a preset program using a symmetrical square biphasic waveform with output current that ranged from 0 to 70 mA. Parameters were set at variable pulse duration of 300 to 400 μs; ramp time of 1.0:0.50 s; frequency of 50 Hz; and duty cycle of 5 s-on/10s-off. The controller recorded usage. This provided a total ON time of 6.06 min in each 20-min session. The Conductive Thigh Garment, an attachment to the controller, wrapped around the thigh providing precise placement of four gel pads over the quadriceps. The electrodes and wiring are incorporated into the garment making attachment and removal quick and easy.[6] The NMES protocol consisted of 20 min of NMES stimulation while concurrently performing the HEP. NMES combined with HEP vs HEP alone were alternated daily for 9 weeks for a total of 31 NMES/HEP and 31 HEP sessions (total 62 sessions). To standardize training, stimulation intensity was based on calculated percentages of maximal voluntary contraction (MVC) using current strength readings. Participants were trained at 20–30% of MVC during weeks 1–3, 31–40% weeks 4–6, and 41–50% weeks 7–9. Adjustments to stimulation contraction intensity were made at each visit. Participants received a handout describing NMES device usage, HEP instructions, training goals, and a web link to an instructional video. During at-home sessions, participants adjusted the amplitude required to achieve the desired goal, as tolerated. Daily email logs were used by participants to record date, duration, amplitude achieved, and subjective pain levels. Staff contacted participants weekly by telephone, email, or text messages to record reported pain levels and treatment compliance.

Transcutaneous Electrical Nerve Stimulation Program

The TENS group used a battery-operated KneeHAB XP controller[7] with lead wire TENS applicator. The TENS protocol consisted of 20 min of TENS stimulation performed concurrently with HEP. TENS combined with HEP vs HEP alone were alternated daily for 9 weeks. TENS stimulation via four 2″ round StimTrod electrodes (Axelgaard, Fallbrook, CA) delivered preset pulsed electrostimulation using a symmetrical square biphasic, asynchronous, frequency-modulated waveform. Parameters were a pulse duration of 200 μs with a frequency of 99 Hz. Electrode placement consisted of a crisscross technique around the knee. Data collection during the treatment period was the same as described above.

Alternating NMES and TENS with Home Exercise Program

The group receiving all three treatments (NMES, TENS, and HEP) had electrical stimulation via the KneeHAB XP controller following the protocols described above. NMES and TENS were performed on alternating days concurrently with HEP. This group also used daily email logs and received follow-up contact from study staff.

Outcome Assessments

Outcome measures were collected at baseline and weeks 3, 6, and 9 over the treatment period. Pain levels were measured prior to testing and after each performance test.

Lower Extremity Isometric Strength

Quadriceps muscle strength was measured using the handheld Nicholas Manual Muscle Tester (NMMT) (kg-force) (Lafayette Instruments; Lafayette, Indiana)[8–10] to record peak force and time to peak force during isometric knee extension and flexion. To stabilize the NMMT, an adjustable strap attachment by Ergo-Kit MMT system was used.

Knee flexion and extension were tested with the participant seated, hips flexed at 90 degrees, and knees at 70° flexion. For knee extension, the MMT was placed on the anterior lower leg (LL) at 60% of distance from tibial tuberosity to medial malleolus. For knee flexion, it was placed at the corresponding location on the posterior LL. Participants performed three maximal efforts holding contractions for 4 s, separated by 10-second rest. The highest score was recorded. Test-retest and inter-rater reliability of handheld dynamometry has been demonstrated.[11]

Adherence to Treatments

Treatment adherence was measured by daily email logs and an internal compliance monitor in the KneeHAB XP and TENS controllers. To verify NMES and TENS training, the KneeHAB controller recorded number of sessions, total usage time, and average session time.

Physical Function Measures

We used four performance-based measures of physical functional performance and an overall pain question assessed at baseline, 3, 6, and 9 weeks.

30-Second Chair Stand Test (30-SCST)

The 30-SCST [12] assessed lower-body strength[13] mimicking squatting.[14] Using a standard 18-inch height chair, full sit-to-stand cycles were performed as quickly as possible for 30 s. The number of complete rises was recorded. Validity and reliability have been reported.[15,16]

Timed Stair Climb Test (SCT)

SCT measures lower extremity strength, balance, and power during the task of negotiating stairs.[13,17] Beginning at the bottom of the stairs, participants ascended four steps (6-inch rise, 11.5-inch run) to a concrete landing and then descended without stopping. They were required to touch each step with 1 foot using a fast pace. Use of the handrail was permitted. Validity and reliability have been demonstrated.[13]

Forward Step-Down Test

The Forward Step-Down test[18] is a measure replicating stair descent. Standing on a 20-cm (8″) platform, the participant steps forward and down from a single-leg stance with a straight knee. The stance leg bends at the knee until the opposite foot lightly touches the ground with the heel and then returns to full knee extension (one repetition). The number of repetitions completed over 30 s is totaled. The intraclass correlation for reliability was 0.94 with standard error of the mean 0.53.[18] The correlation between the step-down test and the VAS for pain was 0.57 ($P < 0.01$).[18]

Six-Minute Timed Walk Test (6-MWT)

The 6-MWT[19,20] measures changes over time in performance capacity. Distance walked over 6 min was determined using a measuring wheel and recorded in inches. Participants were instructed to "walk as quickly as you can" using the same indoor layout for all tests. The 6-MWT has established validity and reliability as a submaximal functional test.[21,22]

Current Pain Level and Knee Pain Following Performance Testing

Current knee pain intensity was assessed using the Visual Analogue Scale, an 11-point numeric rating scale ranging from 0 (no pain) to 10 (worst pain imaginable).[23–25] Knee pain intensity was assessed at the beginning of testing and after each performance-based testing.

Sample Size Estimation and Statistical Analyses

Sample size was calculated based on our previous work[26] using simulation of a mixed-effects model[27–29] with 1000 simulated datasets of subjects tested at baseline, 3, 6, and 9 weeks, then testing the interaction between time and group with a naïve likelihood ratio test. For the primary outcome of knee extension strength, 25 subjects per group (100 total subjects) would detect an effect size difference between groups of 0.55 or a weekly change of 1.28 Nm for an alpha of 0.05 and power of ≥ 0.80. Assuming a 45% dropout rate, the adjusted sample size becomes 136 (34 subjects per group). The actual sample size of 130 recruited is consistent with the power to detect an effect size difference of 0.55 considering the actual dropout rate was less (14.6%).

Demographic and baseline characteristics were compared between groups using an ANOVA for continuous variables and Pearson chi-square or Fisher's exact test for categorical variables. The primary analyses used repeated measures, linear mixed-effects models with random effect for subject, time as a continuous variable, group, and a group-by-time interaction to test for change over time between the HEP group and the NMES, TENS, and NMES/TENS groups. An overall effect for the interaction was tested using an F test. When significant, the individual interaction coefficients of the three treatment groups to HEP were compared with a t-test using the Satterthwaite's method. The mixed-effects model was reanalyzed with time as a fixed categorical effect to compare each time point between HEP and the other three groups using a t-test with the Satterthwaite's method and shown in Tables I and II by * or ** where $P < 0.05$ or

TABLE I. Participant Characteristics by Study Group (n = 130)

	NMES/TENS Plus HEP (n = 30)	TENS Plus HEP (n = 33)	NMES Plus HEP (n = 33)	HEP Only (n = 34)	P-Value
Age (mean years)	26.7 (6.8)	26.9 (5.8)	26.5 (6.1)	26.8 (6.6)	0.996[a]
Male (%)	24 (80.0)	26 (78.8)	25 (75.8)	26 (76.5)	0.975[b]
Race (%)					
Caucasian	17 (56.7)	15 (45.5)	21 (63.6)	17 (50.0)	0.133[c]
African American	13 (43.3)	11 (33.3)	5 (15.2)	12 (35.3)	
Asian/Pacific	0 (0.0)	2 (6.1)	2 (6.1)	1 (2.9)	
Am Indian/Alaska	0 (0.0)	0 (0.0)		1 (2.9)	
Native					
Multi-racial	0 (0.0)	4 12.1)	5 (15.2)	3 (8.8)	
Other	0 (0.0)	1 (3.0)	0 (0.0)	0 (0.0)	
Mechanism of Injury (%)					
Sports	1 (3.3)	2 (6.1)	0 (0.0)	4 (11.8)	0.342[c]
Work	2 (6.7)	2 (6.1)	2 (6.1)	2 (5.9)	
Military training	24 (80.0)	25 (75.8)	31 (93.9)	26 (76.5)	
Other	3 (10.0)	4 (12.1)	0 (0.0)	2 (5.9)	
Rank (%)					
Enlisted	28 (93.3)	30 (90.9)	31 (93.9)	33 (97.1)	0.758[c]
Officer	2 (6.7)	3 (9.1)	2 (6.1)	1 (2.9)	
CES-D	5.6 (4.92)	8.0 (5.65)	6.0 (4.08)	7.7 (5.26)	0.134[a]
Current pain	3.98 (1.8)	4.24 (1.8)	3.42 (1.7)	3.48 (1.8)	0.188[a]

[a]ANOVA
[b]Pearson chi-square
[c]Fisher's exact test
Values are mean ± SD except where indicated; percentages may not add to 100% as a result of rounding.
Pain question is "rate your pain now"; HEP, home exercise program; NMES, neuromuscular electrical stimulation; TENS, transcutaneous electrical nerve stimulation program.

$P < 0.01$. All randomized participants were included in the intent-to-treat analyses. Graphs were prepared showing means and standard error at each time point comparing HEP to each treatment with the P-value for the time-by-group interaction from the continuous mixed-effects models. The analysis was performed using R version 3.5.3[30] with mixed-effects models using the lme4[31] and lmerTest[32] packages. A P-value < 0.05 was considered statistically significant.

RESULTS

Enrollment and Study Attrition

The study assessed 1041 military personnel reporting knee pain, with 862 (83%) screened, and 132 meeting inclusion criteria and enrolled (Fig. S1). Two participants who withdrew during baseline testing were not included in the analyses. The randomized sample (N = 130) included 34 participants in the HEP, 33 in the NMES, 33 in the TENS, and 30 in the NMES/TENS groups.

Characterization of Completers

Completers (n = 111) did not differ from non-completers (n = 19) at baseline on age (P = 0.81), gender (P = 0.37), race (P = 0.48), rank (P = 0.33), and injury mechanism (P = 0.64). There were no baseline differences for the outcome measures of overall pain (3.8 vs 3.5, P = 0.44), affected knee extension strength (39.3 vs 38.5 kg., P = 0.84), affected knee flexion strength (21.6 vs 20.0 kg., P = 0.41), unaffected knee extension (44.6 vs 45.4 kg., P = 0.87), unaffected knee flexion (24.1 vs 24.4 kg., P = 0.86), or VAS pain measures after function tests (chair rise, P = 0.88; stair climb test, P = 0.22; 6-min walk test, P = 0.79; step test left, P = 0.63; step test right, P = 0.32).

Adherence

Adherence to the exercise program consisted of participants answering yes/no to a daily email question: Did you complete the full 20-min session of home exercise? Out of 62 days, no group differences were observed with the NMES/TENS group answering "yes" 52% of the time; NMES group 54%; TENS group 58%, and HEP group 59% [F(3, 126) = 0.22, P = 0.89].

The KneeHAB XP controller compliance monitors reported TENS usage and NMES usage separately. NMES group compliance rate was 54%. TENS group was 65.3%. NMES/TENS group was NMES 46.7% and TENS 47%. There was no difference in TENS [F(1,60) = 2.04, P = 0.16] or NMES [F(1,58) = 0.75, P = 0.79] usage between the stimulation groups.

Baseline Participant Characteristics

All groups were similar at baseline for age, gender, race, rank, mechanism of injury, CES-D, and current pain (Table I).

TABLE II. Strength and Pain Outcomes by Study Groups (N = 130)

	Week	PFPS Knee Extension (kg-force)	PFPS Knee Flexion (kg-force)	Unaffected Knee Extension (kg-force)	Unaffected Knee Flexion (kg-force)	Current Pain Severity
HEP only (n = 34)	0	41.58 (16.56)	21.85 (7.61)	45.07 (17.83)	23.89 (7.20)	3.48 (1.84)
	3	41.41 (14.92)	22.07 (8.05)	42.81 (15.79)	24.71 (8.58)	2.99 (1.99)
	6	44.35 (12.40)	22.84 (7.36)	42.74 (14.50)	25.13 (8.80)	2.90 (2.20)
	9	41.78 (13.46)	24.15 (9.67)	43.83 (14.72)	24.54 (8.27)	2.77 (2.22)
NMES plus HEP	0	37.74 (15.39)	20.32 (7.35)	44.56 (18.75)	23.11 (7.30)	3.42 (1.66)
(n = 33)	3	42.70 (18.66)	22.49 (8.76)	47.16 (19.24)	24.93 (8.49)	2.78 (1.71)
	6	43.31 (17.52)	23.72 (7.35)*	47.58 (18.51)	24.64 (7.53)	2.28 (1.50)
	9	46.22 (18.31)**	26.95 (8.17)**	47.87 (20.64)	26.21 (8.16)	2.44 (1.79)
TENS plus HEP	0	37.14 (15.36)	21.33 (7.13)	43.75 (17.33)	24.34 (7.50)	4.24 (1.76)
(n = 33)	3	43.21 (21.49)	22.99 (8.04)	46.64 (18.58)	23.93 (7.95)	3.44 (2.13)
	6	41.67 (20.60)	22.43 (8.76)	46.31 (16.60)	23.65 (8.61)	3.76 (2.05)
	9	45.44 (23.16)**	25.01 (9.11)	46.69 (18.93)	25.30 (8.30)	3.01 (2.33)
NMES/TENS plus	0	40.42 (18.87)	21.95 (9.13)	45.42 (18.67)	25.20 (8.67)	3.98 (1.77)
HEP (n = 30)	3	43.07 (17.80)	22.56 (8.84)	44.61 (18.60)	24.40 (8.43)	3.02 (1.91)
	6	43.03 (16.54)	23.86 (8.47)	46.14 (15.84)	25.20 (7.79)	2.72 (1.80)
	9	46.89 (17.78)**	26.64 (10.02)*	50.62 (18.32)	26.96 (8.53)	3.27 (2.26)
		Mixed-Effects Regression Models F Test P-values[a]				
	Time	<0.0001	<0.0001	0.0001	0.018	<0.0001
	Group	0.65	0.89	0.98	0.93	0.22
	t*g	0.005	0.005	0.08	0.39	0.71

[a]Mixed-effects models with time as continuous

Values are mean (SD) except where indicated.

No group differences at baseline for PFPS knee extension (P = 0.65) or flexion (P = 0.83), unaffected knee Extension (P = 0.98) or flexion (P = 0.75), or VAS (P = 0.19) using one-way ANOVA

*$P < 0.05$ **$P < 0.01$; comparison is NMES, TENS, NMES/TENS groups to HEP alone relative to baseline scores over 9 weeks.

Abbreviations: HEP, home exercise program; NMES, neuromuscular electrical stimulation; TENS, transcutaneous electrical nerve stimulation program

Baseline strength levels for the PFPS knee and the unaffected knee were not significantly different between the four groups for both extension and flexion and for functional measures (Tables II and III). After completing the functional measures, pain was in the mid-moderate range for all groups and not significantly different at baseline except for the 6-MWT for the TENS group (Table III).

Knee Extension and Flexion Strength Levels

The mean and standard deviation of knee strength and current pain for the groups at baseline, 3, 6, and 9 weeks, are shown in Table II. Knee extension strength in the PFPS limb improved for all three treatment groups to a greater extent than HEP alone over the 9 weeks. Figure 1 shows each of the other groups compared to the HEP group.

NMES and NMES/TENS improved to a greater extent than HEP alone for knee flexion strength in the PFPS limb over the 9 weeks. Group differences were not observed over the 9 weeks for the unaffected knee extension (P = 0.08) or flexion (P = 0.39).

Ratings of current pain declined during the interventions for all treatment groups with no significant differences (P = 0.71).

Functional Recovery and Post-Functional Testing Pain

For function measures, only 6-MWT (P = 0.03) showed a difference in the three groups as compared to HEP over time (Table III). The TENS and TENS/NMES groups showed greater improvement in pain after the 6-MWT and Forward Step-Down tests over HEP. All groups performed the 30-Second Chair Stand Test, Timed Stair Climb Test, and Forward Step-Down Test similarly over the 9 weeks.

Pain ratings following the 6-MWT and the Forward Step-Down Test significantly improved over those of the HEP group for TENS and TENS/NMES (Table III).

DISCUSSION

This study demonstrated the effectiveness of three electrical stimulation treatment programs performed concurrently with active exercise compared to active exercise alone in improving knee strength in active duty military personnel treated for PFPS. The strength gains were associated with concurrent improvement in distance walked over 6 min. All groups showed improvement in pain over the 9-week intervention with minimal group differences. These findings may

TABLE III. Function Outcomes by Study Groups (N = 130)

	Week	30-SCST (No. Rises)	SCT (sec.)	Forward Step-Down Test (No. Reps)	6-MWT (inches)	30-SCST Pain	SCT Pain	FSDT Pain	6-MWT Pain
HEP only	0	11.6 (2.8)	3.7 (1.1)	13.2 (3.9)	24612 (2964)	2.9 (1.8)	2.7 (1.9)	4.2 (1.5)	3.2 (1.7)
(*n* = 34)	3	13.2 (3.5)	3.6 (0.8)	15.4 (5.0)	24373 (3053)	2.9 (1.9)	2.6 (2.1)	3.8 (2.0)	3.3 (2.0)
	6	14.2 (3.4)	3.4 (0.6)	17.0 (4.9)	24970 (2582)	2.8 (2.2)	2.7 (2.0)	3.6 (2.2)	3.1 (2.2)
	9	15.3 (4.0)	3.3 (0.7)	17.7 (5.2)	25059 (3073)	2.8 (2.2)	2.7 (2.0)	3.5 (2.2)	3.0 (2.1)
NMES plus	0	11.0 (3.0)	4.0 (1.4)	11.3 (3.6)	23931 (2772)	2.8 (1.7)	2.7 (1.8)	4.2 (2.2)	2.7 (2.2)
HEP (*n* = 33)	3	12.3 (4.0)	3.7 (1.0)	12.9 (4.3)	24919 (2804)	2.2 (1.7)	2.3 (1.5)	3.2 (2.0)	2.5 (1.6)
	6	12.8 (4.4)	3.5 (1.1)	14.0 (5.6)	25772 (3204)	2.3 (1.7)	2.1 (1.7)	3.3 (1.7)	2.9 (2.1)
	9	14.4 (4.4)	3.5 (1.2)	16.3 (5.3)	25892 (3300)*	2.5 (1.9)	2.0 (1.8)	2.8 (2.1)	2.3 (2.0)
TENS plus HEP	0	11.0 (3.1)	4.2 (1.4)	10.8 (4.9)	23999 (2979)	3.9 (1.8)	3.5 (1.9)	5.2 (1.9)	4.5 (1.7)
(*n* = 33)	3	11.7 (3.0)	3.8 (1.0)	11.8 (4.8)	24951 (3407)	3.5 (2.0)	3.4 (2.0)	4.7 (2.0)	4.3 (2.0)
	6	13.0 (2.9)	3.7 (0.9)	13.9 (5.4)	25284 (3426)	3.6 (2.1)	3.6 (2.3)	4.2 (2.1)	3.9 (2.4)
	9	13.4 (3.5)	3.3 (1.0)	14.9 (5.7)	25847 (3763)*	2.6 (2.2)	2.7 (2.3)	3.3 (2.1)*	2.9 (2.3)**
NMES/TENS	0	11.0 (3.8)	4.1 (1.6)	11.2 (4.0)	23174 (2638)	3.6 (2.0)	3.0 (2.2)	5.3 (2.1)	3.6 (2.3)
plus HEP	3	12.6 (4.1)	3.6 (1.3)	14.4 (5.6)	24102 (2996)	2.9 (2.2)	2.4 (2.1)	3.5 (2.3)**	3.2 (2.2)
(*n* = 30)	6	13.6 (3.9)	3.7 (0.9)	15.3 (4.9)	24753 (2311)*	2.9 (2.3)	2.2 (2.1)	3.6 (2.2)*	2.6 (1.9)*
	9	15.1 (4.8)	3.4 (0.9)	18.0 (6.0)	25227 (2655)**	2.6 (2.4)	1.9 (2.1)	3.2 (2.5)**	2.7 (2.5)
		Mixed-Effects Regression Models F Test *P*-values[a]							
	Time	<0.0001	<0.0001	<0.0001	<0.0001	0.0002	0.0008	<0.0001	0.0007
	Group	0.68	0.26	0.08	0.40	0.03	0.09	0.03	<0.0001
	t*g	0.28	0.23	0.09	0.03	0.12	0.16	0.04	0.02

[a]Mixed-effects models with time as continuous

Values are mean (SD) except where indicated.

No group differences at baseline for 30-SCST (P = 0.77), SCT (P = 0.53), Forward Step-Down Test (P = 0.08), 6-MWT (P = 0.26), 30-SCST Pain (P = 0.06), SCT Pain (P = 0.26), Forward Step-Down Test Pain (P = 0.03), or 6-MWT Pain(P = 0.005) using one-way ANOVA.

*$P < 0.05$ **$P < 0.01$; comparison is NMES, TENS, NMES/TENS groups to HEP alone relative to baseline scores over 9 weeks.

Abbreviations: HEP, home exercise program; NMES, neuromuscular electrical stimulation; TENS, transcutaneous electrical nerve stimulation program; COMBO, NMES/TENS program; 30-SCST, 30-Second Chair Stand Test; SCT, Timed Stair Climb Test; FSDT, Forward Step-Down Test (affected leg); 6-MWT, 6-min-walk test; 30-SCST pain, 30-Second Chair Stand Test with subsequent pain rating; SCT pain, 2-min step test with subsequent pain rating; FSDT pain, Forward Step-Down Test (affected leg) with subsequent pain rating; 6-MWT pain, 6-min-walk test with subsequent pain rating

offer alternative treatment approaches for military personnel with PFPS that can be completed at home station, under field conditions, or during deployment. Further, these options afford personal choice and variability in how an active duty member is treated for PFPS. This can be of potential benefit in maintaining medical readiness and readiness to deploy for these military members.

Although military training contributes to a high incidence of PFPS, only a few high-quality intervention studies have examined therapeutic modalities combined with exercise for this at-risk group.[33] In general, standard treatment for PFPS is exercise with a focus on pain relief.[34] However, at least one systematic review noted that evidence for the effectiveness for pain reduction is not strong.[35] The addition of NMES or TENS does not appear to lead to further pain reduction at completion of the treatment program.[33] While pain relief is clearly a goal, for the military, physical readiness, fitness, and injury reduction are equally important and necessary to be maintained in the armed forces.[36] For this reason, maintenance of strength is important in military rehabilitation to optimize fitness and performance. Thus, Capin and Snyder-Mackler[37] recommend including NMES in rehabilitation when there are deficits in quadriceps strength. The addition of NMES can contribute to knee extension strength improvement. The literature on the effectiveness of TENS for PFPS is less clear with few reported studies, although one study reported a potential early advantage of TENS during treatment.[33] The extent to which either NMES or TENS might contribute to improved functional performance is less clear in the literature, particularly in trained athletes, or for rate of functional recovery following PFPS onset. We found that the TENS and TENS/NMES groups showed greater improvement than the HEP group in pain ratings after 6-MWT and Forward Step-Down testing.

Compliance was noteworthy as soldiers were using the NMES and TENS devices during field training exercises. The ease of self-applying the KneeHAB garment made usage during field conditions quite feasible.

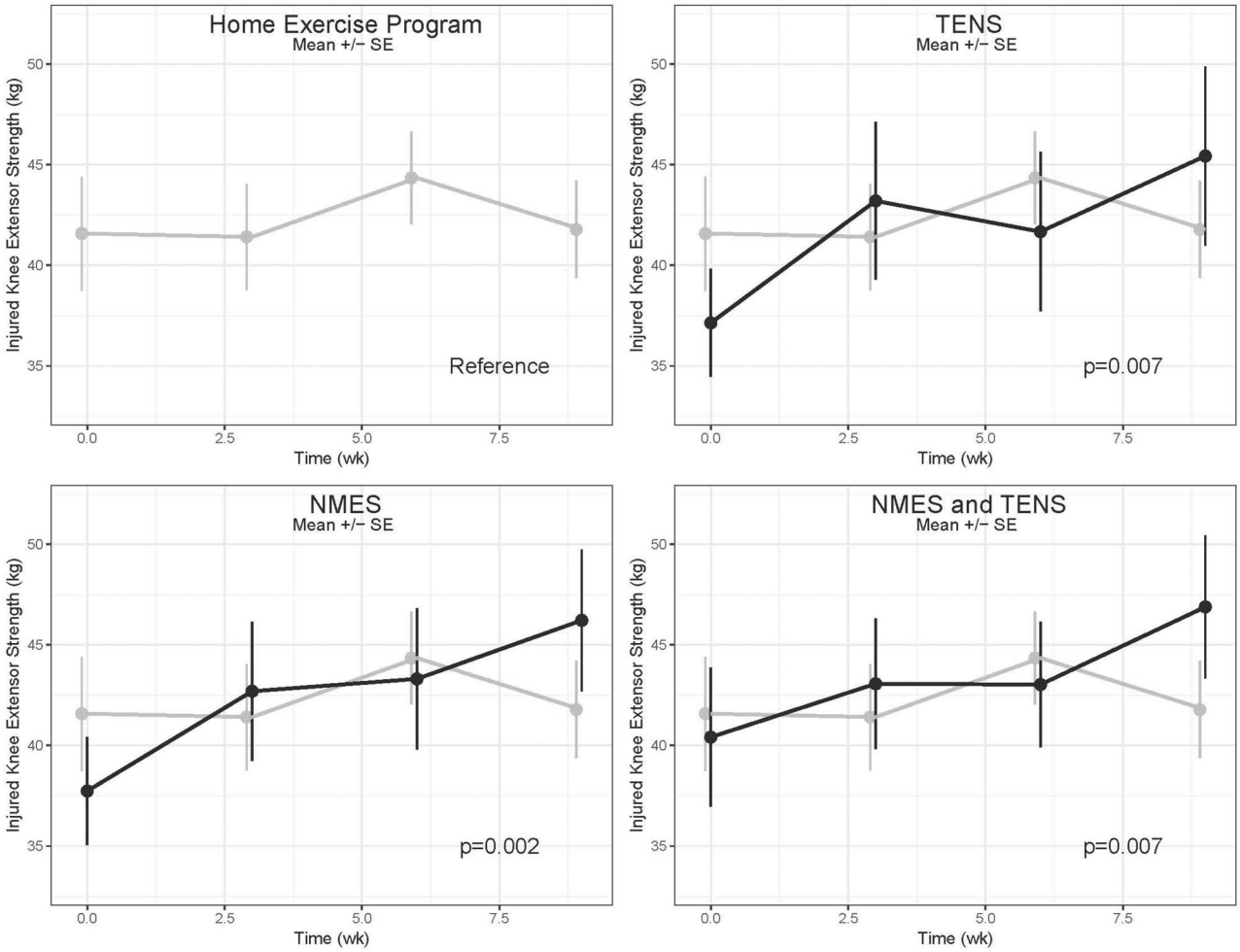

FIGURE 1. Comparison between HEP and electrical stimulation therapies on knee extension strength in the PFPS limb over 9 weeks (*P* for continuous time-by-group interaction).

Several limitations of this study should be noted. We used a handheld dynamometer, function tests, and self-report ratings to measure strength, function, and pain, for which smaller changes might not be detectable. This pilot study was designed and powered to detect what we believed was an important difference in knee strength between the three electrical stimulation interventions as compared to exercise alone. The study was not powered to detect a difference between the three stimulation interventions, assuming each intervention experienced greater gains than exercise alone. The ability to more precisely define which elements caused the greatest increase in strength and reduction in pain would be beneficial for the design of more effective treatment regimens. Further, the study was not powered to detect differences in pain patterns between the groups, nor was it designed to directly assess the treatment impact on return to duty or readiness to deploy by these military members. Further research with larger samples and a more detailed design would be required to address these issues.

CONCLUSIONS

This study contributes to evidence that electrical stimulation therapies using NMES, TENS, or NMES/TENS combined with active home exercise can increase knee extension and flexion strength in the PFPS limb over 9 weeks more than HEP alone. These electrical stimulation therapies are known to be safe (the main complication being skin irritation or burn at electrode site) and may offer alternatives for rehabilitation for active duty military with PFPS as they can be implemented at home station or during deployment.

SUPPLEMENTARY MATERIAL

Supplementary Material is available at *MILMED* online.

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CONFLICTS OF INTEREST

None.

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