ABSTRACT
Introduction:
Low back pain (LBP) is a major cause of visits to ambulatory care, missed duty time, and disability discharge. The subacute phase of LBP presents an opportune time to prevent chronicity and lessen recurrence. The goal of this randomized controlled trial (RCT) was to determine the relative effectiveness of neuromuscular electrical stimulation (NMES) training and a progressive exercise program (PEP) on improving physical performance, pain, and torso strength in U.S. service members with subacute LBP, compared to standard primary care management (PCM) alone.

Methods:
This is an Institutional Review Board–approved protocol for an RCT conducted with active duty military personnel ($n=128$) at Fort Campbell, Kentucky, between April 2018 and March 2020. Participants were randomized to receive NMES ($n=43$), PEP ($n=42$), or PCM ($n=43$) for 9 weeks. Outcome measures of physical performance (sit-ups, push-ups, walking, and torso endurance), torso muscle strength (flexion and extension), and pain were assessed at baseline and after 3, 6, and 9 weeks. Analysis was intent-to-treat using linear mixed effects models. A sensitivity analysis was performed to address the protocol deviations that occurred in response to coronavirus disease 2019 pandemic, which required rescheduling 17 in-person study visits to home assessments at 9-week testing.

Results:
Evidence was found for group differences in physical performance for sit-ups and push-ups, with NMES showing greater improvement than PCM. The two groups showed similar improvements in torso muscle strength, although the NMES groups may show better improvement during early treatment. No group differences in pain levels were observed during the intervention, and all groups improved during the course of the study period. The amount of NMES muscle stimulation was directly related to the level of improvement, which was not the case for the hours reported for PEP exercise.

Conclusion:
In an active duty population with subacute LBP, integrating NMES strength training into the rehabilitation therapy may offer a modest benefit for increasing sit-ups and push-ups and improving torso strength.

INTRODUCTION
Back conditions in U.S. military personnel are a major cause of ambulatory care visits, missed duty time, physical profiles, and disability discharge.1 The incidence of low back pain (LBP) among active duty service members is 40.5/1,000 person-years.2 This rate reflects the military’s high operating tempo and frequent deployments requiring demanding training. Deconditioned back and core muscles from injuries are risk factors for LBP,3–5 with core stability playing a major role in maintaining functional movement.6 LBP episodes are frequently self-limited, with improvements in pain, functional capacity, and return to work within 6 weeks.7 If pain persists beyond 3 months, the problem tends to become chronic and resistant to treatment, leading to inactivity and progressive loss of strength, endurance, and flexibility. Comparing the stage of LBP, normal functionality declines (acute LBP 26.4%, subacute 20.5%, and chronic 15%) as well as those without pain disability (acute 15.7%, subacute 13%, and chronic 8.6%).8 The resulting weakness and pain affects work performance, limits mobility, impacts deployment health, and ultimately leads to disability and early discharge of otherwise healthy service members. To mitigate this progression, treatment during the subacute phase is ideal to prevent recurrence and chronicity through effective interventions.

Non-pharmaceutical home therapies including neuromuscular electrical stimulation (NMES) and progressive exercise vary in their effectiveness in treating subacute LBP versus...
Controls. Poor core strength or endurance contributes to LBP. While military physical training includes core stabilization exercises, the Army Physical Fitness Test (APFT) integrates a 2-min maximal sit-up test to evaluate core strength, endurance, and aerobic fitness. Thus, active duty service members require efficient treatment modalities when rehabilitating LBP to achieve optimal strength, endurance, and fitness.

This randomized controlled trial (RCT) compared physical performance, pain, and torso strength of military service members with subacute LBP who received standard primary care management (PCM) only, NMES training plus PCM, or a progressive exercise program (PEP) plus PCM. Our specific aim was to determine whether NMES plus PCM or PEP plus PCM are more effective than PCM alone to improve physical function, pain, and torso strength.

METHODS

Design and Setting

This trial was a three-group, intent-to-treat RCT of active duty military personnel with subacute LBP recruited from the Blanchfield Army Medical Center (BACH, Ft. Campbell, KY) physical therapy department from April 2018 to March 2020. The trial was registered in ClinicalTrials.gov (“Home-based Approaches for Subacute Low Back Pain in Active Duty: Randomized, Controlled Trial”; ID: NCT-03502187) and received Institutional Review Board approval. Table S1 presents eligibility criteria.

Randomization

Participants were grouped using blocked randomization with permuted blocks of 9. Group assignments were concealed from staff and participants until after completion of intake assessments, by placement in sequentially numbered, sealed envelopes opened after baseline assessments. Due to the nature of the treatment-based study, it was not feasible to blind participants or staff after baseline determination. Compliance checks and visit reminders occurred via telephone calls, emails, and/or text messages.

Interventions

Primary care management

All participants received PCM compliant with LBP clinical practice guidelines. Participants received an information sheet encouraging them to maintain physical activity and minimize extended sedentary behaviors. The military Rx3 website ([https://www.hprc-online.org/page/physical-fitness/rx3-rehab-refit-return-to-duty](https://www.hprc-online.org/page/physical-fitness/rx3-rehab-refit-return-to-duty)) was provided as a supplemental resource. The PCM only group received weekly communications regarding pain status and medication usage to match all groups on time and attention.

Neuromuscular electrostimulation program

The NMES group received a portable rechargeable battery-operated Recovery Back device (Neurotech, Minnetonka, MN) with two integrated conductive site-specific garments for back and abdomen. The Recovery Back controller generated electrical impulses using a pre-set program that delivered a symmetrical biphasic square pulse waveform, eliciting abdominal or lumbar muscle contractions, depending on the garment. Both garments wrap around the waist for accurate torso electrode placements, with only one used during an exercise session. The controller attaches to the appropriate garment via connector socket. The protocol consisted of 30 minutes of NMES stimulation alternating every other day between lumbar and abdominal sites over 9 weeks, as follows:

The abdominal garment produced involuntary contractions of abdominal muscles (obliques, transverse abdominus, and rectus abdominus). Parameters were preset with pulse duration of 250 µs; ramp time of 2:2 seconds; frequency of 55 Hz; intermittent cycling, and a duty cycle of 3 seconds on/5 seconds off maintained throughout the 9-week trial. For consistent placement, the abdominal garment’s center electrode was aligned over the navel.

The lumbar garment produced involuntary contractions to the lumbar paraspinal muscles. The training program consisted of three phases lasting 3 weeks each. Phase 1: work cycle used intermittent cycling parameters, pulse duration 300 µs; ramp time of 1:0.5 seconds; frequency of 50 Hz; and 1:3 duty cycle of 5 seconds on/15 seconds off. Phase 2: strengthening cycle used pulse duration 300 µs; ramp time of 1:0.5 seconds; frequency of 50 Hz; intermittent cycling, 1:2 duty cycle of 5 seconds on/10 seconds off. Phase 3: advanced-strengthening cycle used pulse duration of 300 µs; ramp time of 1:0.5 seconds; frequency of 50 Hz; intermittent cycling, 1:1 duty cycle of 5 seconds on/5 seconds off. Placement was over the lower back between the last rib and iliac crest with garment centered and aligned with the spine. Training time for all phases was 30 minutes.

Training intensity: Participant increased muscle stimulation intensity using the Recovery Back device to the point of muscle contraction then tolerance. Intensity increased for both garments over the 9-week trial, and parameter changes for the lumbar garment (Phases 2 and 3) were made during 3- and 6-week clinic visits. Appropriate usage was maintained by providing participants with individualized instructions for adjusting amplitude settings with return demonstration. The first 5 minutes of each study visit reviewed training logs to determine whether NMES goals were achieved and troubleshoot problems.

Progressive exercise program

PEP is a physical therapist–developed back training program teaching participants to perform controlled, gradual, and progressive exercises. The program consisted of self-management strategies for back fitness at home and standardized muscle strengthening exercises. PEP participants
performed 31 exercise sessions for 60 minutes on alternating days in three sequential phases lasting 3 weeks each. As participants progressed, exercises became more intense and difficult, focusing on stretching and strengthening that progressively loaded and unloaded the lumbar spine through core strengthening exercises. At the baseline visit, participants were provided written instructions and a demonstration of phase 1 exercises to be performed for 3 weeks. The participant performed the exercises during the visit to assure proper form and performance. At each return 3-week visit, the same approach was used to teach phases 2 and 3. Pain status was assessed at each visit.

**Balanced NMES and PEP training**
To balance the treatment hours for the PEP and NMES groups, PEP participants performed 31 hourly sessions on alternating days, while NMES participants performed 62 half-hour sessions daily (31 abdominal and 31 back NMES).

**Adherence to Treatment**
Adherence was measured by participant completion of daily email logs and an internal compliance monitor in the Recovery Back controller. The email logs detailed pain intensity, pain medications taken, amount of time spent on exercise or treatment (PEP and NMES), muscle contractions achieved (NMES), and completion of exercises (PEP). The Recovery Back controller recorded the number of sessions, average session time for abdominal and lumbar garments, and total usage time.

**Outcome Measures**
Outcome measures were collected at baseline and 3, 6, and 9 weeks. The order of physical performance testing was push-ups, sit-ups, six-minute walk, and lumbar muscle tests. Pain levels were assessed before and after testing.

**Physical Performance Tests**
The 2-minute push-up and sit-up tests were completed in accordance with the APFT protocol, consistent with the American College of Sports Medicine Guidelines. Test–retest reliability for a timed push-up test has been reported as 0.93; the sit-up test 0.88-0.94.

**Push-ups**
The 2-minute push-up test evaluates strength and endurance of upper body and the stabilizing abdominal and back muscles. The participant assumes a prone position with hands shoulder width apart on the ground, hips and elbows in extension, toes in contact with the floor, and spine parallel to the floor. The body is lowered as a single rigid unit until the elbows are at a 90° angle and the arms are pushed up to full extension to return to the starting position. The number of push-ups completed in 2 minutes was recorded.

**Sit-ups**
The 2-minute sit-up test determines abdominal muscle endurance and strength. The participant assumes a supine position with knees flexed 90° and fingers interlocked behind the neck, with shoulder blades and soles touching the floor. Abdominal muscles are flexed to propel the upper body toward the knees, and then, the upper body is lowered to the floor. The number of sit-ups completed in 2 minutes was recorded.

**Six-minute walk**
The submaximal 6-Minute Walk Test (6-MWT) evaluates mobility, aerobic capacity, and physical function. Service members walked at a “fast” pace for 6 minutes using a preset circular course. The total distance walked was calculated using a measuring wheel. The 6-MWT has demonstrated submaximal exercise at 72.7% ± 11.6% of VO2max with rank order correlation of 0.49 (P = .001). Test–retest reliability was intra-class correlation coefficients (ICC) = 0.917 [0.862-0.951].

**Lumbar torso muscle**
The Lumbar Torso Muscle Test determines extensor muscle endurance using static, isometric contraction. Participants assume a prone position with the sternum and trunk off the floor (15° extension) and gluteal muscles contracted and hold the pose as long as possible. The performance time was recorded in seconds. Test–retest correlations (r) were 0.93-0.95 for individuals with LBP.

**Current pain level**
The LBP pain intensity was assessed using a Visual Analogue Scale (VAS) containing anchors at each end separated by a horizontal line index that ranges from “no pain” at the far left (0.0 cm) to “worst pain imaginable” at the far right (10 cm). Participants placed a vertical line at the point indicating their current pain level. The score is enumerated from the distance between the “no pain” anchor and the participant’s mark. The VAS pain scale correlated highly with acute pain levels.

**Torso Muscle Strength**
Torso flexion and extension strengths were measured using a modified University of Michigan strength test system (Workability Systems Inc., West Chester, OH) and a Chattanooga–Baseline hand dynamometer (DJO Global, Vista, CA). We used the protocol described by McNeill et al., Nachemson et al., and Chaffin. For trunk flexion, participants stood in the test apparatus with buttocks against the padded board with its superior edge set at the iliac crest. Participants were strapped to the apparatus by a canvas belt placed snugly around the chest and under the arms, horizontal to the dynamometer secured to the apparatus frame. For trunk extension, participants stood with the lower anterior abdomen against the padded board at the iliac crest level with
the belt placed snugly around the back and under the arms and horizontal to the dynamometer.

Participants pulled against the belt as forcefully as possible without using arms for support. For both flexion and extension, participants performed three maximal efforts maintaining voluntary isometric exertion for 5 seconds, separated by 30-second rests; the highest of the three trials was reported in kilograms. Reproducibility by repeat testing differed by a mean of 22% extension and 13% flexion. Intra-individual performance ratios differed by a mean of 20% for extension-to-flexion.

**Sample Size Estimates and Statistical Analyses**

Study sample size was estimated using simulation. Based on 1,000 simulated datasets, 39 subjects per group (117 total subjects) gave an effect size of 0.5-0.9 with power of 0.8 for change in muscle strength or physical function. Planned enrollment was 45 subjects per group (135 total), allowing for approximately 16% drop-out. Simulations based on 34% missing data because of coronavirus disease 2019 (COVID-19) deviations found power of 0.8 to detect a 0.95 effect size.

Group demographics were compared using Pearson’s chi-square test or Fisher’s exact test for categorical and ANOVA for continuous variables. All randomized participants were included in intent-to-treat analyses with outcome measures examined using repeated measures, linear mixed-effects models with random effect for subject, and time treated as continuous, group, and a group-by-time interaction. The primary comparison was the group-by-time interaction to test for change over time between groups. An overall interaction effect used an F-test, and contrasts between NMES + PCM and PEP + PCM groups were evaluated by t-test using Satterthwaite’s method. The mixed-effects model was reanalyzed with time as categorical to compare NMES + PCM and PEP + PCM at each time by t-tests using Satterthwaite’s method. Analysis used R version 4.1.0 with mixed-effects models using the lme4 package and lmerTest packages. A P-value <.05 was considered statistically significant.

**Deviations from registered trial protocol**

Protocol deviations were related to the COVID-19 pandemic and the implementation of the FDA guidance for clinical trials to support the COVID-19 response. Fort Campbell elevated the Health Protection Condition (HPCON) level on March 25, 2020, to CHARLIE, limiting installation access with BACH clinics recommending telehealth therapies and limiting in-clinic care. Active duty personnel received stay-at-home
Enrollment and study attrition

The study screened 4,012 service members reporting unspecified back pain with 133 subjects enrolled and 128 randomized (Fig. 1). As the trial approached completion, the COVID-19 pandemic led to missing performance and strength data culminating in 17 participants with deviations yielding an additional 13% missing for in-clinic tests at the 9-week testing.

Sensitivity analysis

Sensitivity analysis to account for missing data used imputation based on Bayesian inference with outcome data standardized to mean zero and 1 SD. A multivariate mixed effects model included all outcome measures, random subject effects, and group effects at each time point, with adjustments for age, sex, weight, and weight-by-sex. Each missing data point was estimated as a parameter and represented as the mean of 10,000 posterior samples with back-calculation to the appropriate scale. Priors were weakly informative. Graphs were prepared showing means and standard errors for outcome measures at each visit comparing PCM to NMES or PEP. A second sensitivity analysis examined the cumulative time the NMES group used the stimulator and cumulative exercise time by the PEP group. For each of these variables, the other two groups were assigned zero values. Mixed effects models included either of the two variables and time with a random intercept for subject. Study time-adjusted measures were derived by removing the study time effect from the mixed effects model. The adjusted measure was plotted against either the cumulative NMES usage time or the reported PEP time.

RESULTS

Baseline Participant Characteristics

Groups were similar at baseline for age, gender, race, mechanism of injury, CES-D, pain but not rank (Table S2), flexor and extensor torso strength, and physical performance. Table 1 presents means and SDs of the actual data collected for

| Week | Push-ups (no. push-ups) | Sit-ups (no. push-ups) | 6-MWT (feet) | Lumbar muscle test (seconds) | Torso extension (kg) | Torso flexion (kg) | Current pain severity |
|------|------------------------|-----------------------|-------------|-----------------------------|---------------------|-------------------|----------------------|
| 0    | 46.9 (14.4)            | 44.4 (17.6)           | 1940 (253)  | 48.4 (28.7)                 | 54.5 (28.9)         | 51.6 (29.7)       | 4.43 (2.0)           |
| 3    | 46.0 (16.3)            | 44.9 (18.8)           | 2020 (245)  | 48.9 (30.9)                 | 57.5 (33.1)         | 52.1 (29.6)       | 3.88 (2.6)           |
| 6    | 45.9 (14.6)            | 45.6 (18.4)           | 1996 (280)  | 47.1 (35.4)                 | 68.2 (36.9)         | 65.6 (39.9)       | 4.03 (2.5)           |
| 9    | 46.2 (18.1)            | 51.0 (14.5)           | 2041 (271)  | 53.3 (30.9)                 | 69.4 (30.7)         | 65.1 (29.9)       | 3.28 (2.6)           |
| 0    | 43.7 (18.4)            | 41.5 (15.2)           | 1858 (225)  | 39.7 (24.1)                 | 49.2 (27.2)         | 43.7 (23.1)       | 4.78 (2.0)           |
| 3    | 47.4 (16.8)            | 43.2 (15.3)           | 1882 (235)  | 48.3 (24.6)                 | 54.6 (31.0)         | 47.7 (26.3)       | 4.47 (2.2)           |
| 6    | 42.2 (18.7)            | 40.8 (14.9)           | 1904 (257)  | 43.0 (27.3)                 | 53.1 (30.1)         | 44.4 (26.3)       | 4.70 (2.6)           |
| 9    | 46.3 (17.2)            | 45.0 (13.0)           | 1924 (283)  | 46.6 (26.1)                 | 55.1 (23.6)         | 47.9 (22.5)       | 3.93 (2.7)           |
| 0    | 41.1 (18.2)            | 35.5 (21.4)           | 1868 (335)  | 37.4 (21.6)                 | 50.2 (25.4)         | 48.8 (27.7)       | 4.57 (2.2)           |
| 3    | 40.3 (20.4)            | 38.7 (21.5)           | 1889 (320)  | 43.8 (22.7)                 | 61.4 (34.6)         | 57.9 (30.5)       | 4.54 (2.3)           |
| 6    | 42.3 (18.7)            | 43.2 (15.2)           | 1925 (237)  | 42.6 (19.7)                 | 69.0 (33.4)         | 63.7 (29.6)       | 3.96 (2.9)           |
| 9    | 46.0 (22.9)            | 43.5 (18.2)           | 1883 (427)  | 45.9 (22.8)                 | 69.3 (39.3)         | 60.9 (30.9)       | 4.07 (3.1)           |

P-values of mixed effects regression models using F test with time as a continuous variable

| Actual data | Group by time | .06 | .03 | .61 | .41 | .09 | .22 | .57 |
| NMES vs PCM | .02 | .05 | .35 | .19 | .39 | .73 | .29 |
| PEP vs PCM  | .50 | .52 | .88 | .60 | .59 | .19 | .10 | .53 |
| Imputed data | Group by time | .006 | .002 | .30 | .18 | .03 | .08 | .38 |
| NMES vs PCM | .003 | .01 | .17 | .07 | .41 | .38 | .77 |
| PEP vs PCM  | .55 | .34 | .98 | .59 | .07 | .02 | .19 |

Values are mean (SD) except where indicated for the actual data collected.

aGroup by time interaction for collected data.

bMixed effects T-test for group comparisons of actual collected data.

cGroup by time interaction for imputed data.

dMixed effects T-test for group comparisons of imputed data.

Abbreviations: NMES = neuromuscular electrical stimulation; PCM = primary care management; PEP = progressive exercise program; 6MWT = 6-Minute Walk Test.
FIGURE 2. Change in number of push-ups and sit-ups from baseline during 9 weeks of the intervention for the three groups. (A) Push-ups, (B) sit-ups. *P < .05, **P < .01, ***P < .0001 based comparing PCM with NMES + PCM (marks above the lines) and PCM with PEP + PCM (marks below the lines) at each time point adjusted for baseline from the mixed effects model with time as a factor.

physical performance, strength, and current pain measures for groups at baseline, 3, 6, and 9 weeks.

Physical performance
Sit-ups (P = .03) and push-ups (P = .06) showed evidence for group differences over time (Table I), with NMES showing greater improvement than PCM (Table I: sit-ups, P = .05; pushups, P = .02). The difference exhibited by the NMES group was more clearly observable in the imputed data comparisons (Table I: sit-ups, P = .002; pushups, P = .006). Figure 2A illustrates differences in the number of push-ups at week 9 between NMES and PCM (Fig. 2A, P < .01). Figure 2C shows differences in sit-ups at week 6 between NMES and PCM (Fig. 2C, P < .001) with week 9 trending (Fig. 2C, P < .1).

Torso muscle strength and pain
For strength measures, NMES and PCM showed similar improvements over 9 weeks (Table I), although NMES may show earlier improvement at week 3 for flexor strength (Fig. 3C, P < .05) and extensor strength trending (Fig. 3A, P < .10). Current pain scores declined over 9 weeks for all groups with no significant differences (P = .57).

Adherence to interventions
A sensitivity analysis examined the effects of time spent using NMES or performing PEP exercises during the intervention. The NMES group showed a median 9-hour usage (intraquartile range 4.5-16hours), which corresponds to a median of 18 treatment sessions (30 minutes per session). The PEP group reported a median 11 hours of exercise (intraquartile range 1-25 hours), which corresponds to a median 11 exercise sessions (60 minutes per session). Examining the relationship of time in study adjusted outcome measures to hours of NMES or PEP found a significant relationship of time using NMES with improvements in number of sit-ups (Figure S1c: 0.39/hour, P = .009) and extensor strength (Figure S2a: 0.48 kg/hour, P = .03), and a trend for improvements in push-ups (Figure S1a: 0.21/hour, P = .09) and flexor strength (Figure S2c: 0.33 kg/hour, P = .10). No evidence was found for improvement in relationship to reported PEP time.

DISCUSSION
The current study found 9 weeks of NMES core strength training resulted in greater improvement in push-ups and sit-ups compared with PCM in military personnel with subacute LBP. The greatest strength gains from NMES were observed early at week 3, which is consistent with our previous work. Increasing NMES usage showed greater improvement in physical performance and strength that was not observed with PEP. The improved performance of sit-ups and push-ups demonstrated core strength, endurance, and stability that benefitted service members with LBP and were essential for doing daily activities and military relevant tasks. NMES training was safe and feasible using a home-based, telehealth approach during usual military operations and elevated HPCON levels due to COVID-19.

An unexpected finding was the consistent rate of strength improvement in the PCM alone group, with a 21% improvement over 9 weeks. This supports our hypothesis that initiating management of LBP in the subacute phase is effective in the primary care setting, using non-pharmaceutical approaches
that include staying active and gradually increasing the amount and intensity of activities as pain decreases.\(^9\)

Primary limitations of the study were the protocol deviations due to COVID19, when in-person visits shifted to telehealth visits, resulting in missing data for strength and physical performance measures in 17 participants. Also, compliance was limited for the PEP and NMES groups. The majority of participants were perhaps partially compliant. In this study, the effect of the PEP and NMES was thus diluted by those who were not compliant.

CONCLUSIONS
Initiating LBP management of subacute in primary care during the subacute phase was supported in this study. Incorporating NMES strength training into the rehabilitation of subacute LBP may offer a modest benefit for increasing sit-ups, push-ups, and torso strength.

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SUPPLEMENTARY MATERIAL
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CONFLICTS OF INTEREST STATEMENT
The authors have no financial or material support disclosures or conflict of interests to report.

CLINICAL TRIAL REGISTRATION
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INSTITUTIONAL REVIEW BOARD
This study was approved by Regional Health Command-Atlantic (RHC-A) Institutional Review Board (IRB) (RHC-A-18-008).

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