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# REPORT DOCUMENTATION PAGE

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## **INTRODUCTION**

The purpose of this project was to assess the effectiveness of high intensity progressive resistance exercise (HIPRE) training targeting the lumbar extensors to improve lumbar extension muscular strength and endurance in US Army Soldiers. A 2-arm, cluster randomized controlled trial was conducted with US Army Soldiers training to become combat medics from Fort Sam Houston, TX. Soldiers were randomized (by platoon) to receive lumbar extensor HIPRE training (HIPRE, n = 298) or core stabilization exercise training (CORE, n = 284) at 1 set, 1X/week, for 11 weeks. Isometric lumbar extension muscular strength, dynamic lumbar extension muscular endurance, and isometric core muscular endurance were assessed before and after the 11-week intervention. Linear mixed effects analyses were used to assess group differences on these measures at 11-week follow-up.

## **KEYWORDS**

lumbar extensor muscles, exercise, strength, core stabilization, low back pain, military

## **ACCOMPLISHMENTS**

**Specific Aim:** The specific aim of this project was as follows (as described in the approved scope of work): In a controlled clinical trial, assess the effectiveness of a progressive resistance exercise training program to improve lumbar extensor muscle strength and endurance in US Army Soldiers in training to become combat medics.

Key milestones:

Milestone 1: IRB approval - obtained (accomplished for both IRBs - BAMC and USF: May 2012)

Milestone 2: Site, facilities, personnel - established (accomplished June 2012)

Milestone 3: Enrollment, screens, & baseline fitness tests - completed (accomplished: May 2013)

Milestone 4: Exercise training and post-training fitness tests - completed (accomplished: August 2013)

Milestone 5: All study procedures - completed (accomplished: March 2015)

## What was accomplished under these goals?

### SPECIFIC OBJECTIVES

The purpose of this project was to assess the effectiveness of high intensity progressive resistance exercise (HIPRE) training targeting the lumbar extensors to improve lumbar extension muscular strength and endurance in US Army Soldiers.

### MAJOR ACTIVITIES (METHODS)

**Design.** This study was a mixed methods, cluster randomized controlled trial with two intervention arms, an 11-week intervention period, and assessments before and after the intervention period.

**Participants.** All participants were active duty US Army Soldiers stationed at Fort Sam Houston, San Antonio, Texas, US. Soldiers in six consecutively available companies enrolled in Advanced Infantry Training to become combat medics from 2012-2013 were considered for eligibility. To be enrolled in the study, prospective participants first underwent screening and physical examination procedures to evaluate eligibility based on the study's inclusion and exclusion criteria. Screens and physical assessments were directed by licensed healthcare providers. Potential candidates were required to be between 18-35 years of age and English speaking/reading. Potential candidates were excluded from participation if they had any conditions that would preclude their ability to safely complete either of the interventions (e.g., cardiovascular contraindication, orthopedic complaints, systemic inflammatory disease, history of spinal surgery); were currently seeking or receiving treatment for LBP; or were currently performing progressive resistance exercises for the lumbar extensor muscles other than those included in standard military fitness programs. All participants provided informed consent and the study was approved by the San Antonio Military Medical Center Institutional Review Board.

**Sample size.** Based on the hypothesized effect size (25% improvement in lumbar extension strength), cluster size ( $n = 35-36$  Soldiers per platoon), and ICC ( $\leq 0.20$ ), 12 clusters with a total of 426 subjects with evaluable data at follow-up would be needed in order to obtain at least 80% power at the 0.05 significant level with a two-sided test.

**Baseline and follow-up assessments.** Following screening and prior to randomization, all eligible participants underwent baseline assessments, including self-reported questionnaires; body height and weight measurements; and physical fitness tests of isometric lumbar extension muscular strength, dynamic lumbar extension muscular endurance, and isometric core muscular endurance. The same assessments were conducted approximately one week after the 11-week intervention period. Isometric lumbar extension muscular strength was assessed with a lumbar dynamometer (MedX, Ocala, FL) utilizing previously described techniques.<sup>1,2</sup> After the strength test and a five-minute rest, dynamic lumbar extension muscular endurance was assessed with the lumbar dynamometer utilizing a protocol adapted from a previously described protocol.<sup>3</sup>

**Randomization.** A cluster randomization strategy was utilized in which participants were randomized by platoon to either an experimental group (HIPRE,  $n = 298$ ) or control group (core stabilization exercise training - CORE,  $n = 284$ ). The randomization schedule was prepared by computer and balanced to ensure that an equal number of clusters was allocated to each group.

Treatment allocation was performed in a concealed manner at the data coordinating center and was revealed to study staff and participants following baseline assessments.

**Interventions.** The study exercise intervention for both groups (HIPRE, CORE) was initiated approximately one week following completion of baseline assessments and randomization. The intervention for both groups took place outside of (i.e., in addition to) normal US Army physical training. As a result, soldiers electing not to participate in the study were not at risk of being exposed to any of the study interventions. The intervention for both groups was administered one time per week for 11 weeks under supervision of study personnel. Details of the interventions are described in the appendix of this report.

Participants in the experimental group performed lumbar extensor HIPRE training with the lumbar dynamometer (Figure 1).<sup>1,4</sup> Each exercise training session consisted of a warm-up set of submaximal exercise followed by one set of dynamic, full range of motion HIPRE training on the lumbar dynamometer. One set, one time per week of HIPRE training using this protocol has been shown to be sufficient to elicit lumbar extension strength gains in healthy civilians.<sup>5,6</sup>

Participants in the active comparator control group performed core stabilization exercises following a previously established training protocol used in a similar population (Figure 2).<sup>7</sup> Each exercise session consisted of a series of five core stabilization exercises, including the abdominal drawing-in crunch maneuver, horizontal side support, supine shoulder bridge, quadruped alternating arm and leg, and woodchopper.

**Outcome measures.** The primary outcome measure for this study is isometric lumbar extension muscular strength (Nm) defined as the pooled mean value across seven positions of measurement for Maximum Voluntary Isometric Contraction (MVIC): lumbar extension muscular strength =  $(\text{MVIC } 0^\circ + \text{MVIC } 12^\circ + \text{MVIC } 24^\circ + \text{MVIC } 36^\circ + \text{MVIC } 48^\circ + \text{MVIC } 60^\circ + \text{MVIC } 72^\circ)/7$ . Secondary measures included dynamic lumbar extension endurance (number of repetitions) assessed with the lumbar dynamometer and isometric core muscular endurance assessed with the prone static plank test (seconds).

**Blinding.** Blinding participants was not possible because they actively participated in the exercise training interventions. Study personnel who assessed outcomes and the statistician were blinded to group assignment.

**Data analysis.** Means and standard deviations were calculated for baseline demographic variables, and outcome measures at baseline and follow-up. Demographic and baseline variables were compared between the two groups (HIPRE vs. CORE) using independent t-tests for continuous variables and chi-square for categorical variables. For the primary hypotheses, differences at follow-up between the two groups on lumbar extension muscular strength (Nm), lumbar extension muscular endurance (repetitions), and core muscular endurance (sec) were analyzed using linear mixed-effects regression models,<sup>8,9</sup> accounting for the effects of cluster (platoon) and adjusting for baseline measures. The linear mixed-effects model treats the data as two levels (level 1 for individuals, level 2 for clusters), while also taking into account between-cluster variation. To examine differences between the two groups on repeated measures of lumbar extension strength obtained from the seven angles of measurement (72°, 60°, 48°, 36°, 24°, 12°, 0°),

24°, 12°, and 0° of lumbar flexion), we used a three-level linear mixed effects model: level 1 for repeated measures of strength (seven angles of measurement), level 2 for individuals, and level 3 for clusters. All linear mixed effects models were performed using SAS Proc MIXED.<sup>10</sup> Individual specific, within group changes in lumbar extension muscular strength, lumbar extension muscular endurance, and core muscular endurance from baseline to follow-up were analyzed using paired t-tests. All analyses were based on the intention-to-treat principle. All tests were two-tailed and considered to be significant at alpha = 0.05. All analyses were performed using the SAS software, version 9 (SAS Institute Inc, Cary, North Carolina, United States).

## RESULTS

Disposition of participants throughout various stages of the study is shown in Figure 3. Of the 698 soldiers assessed for eligibility, 645 were consented, and 582 were deemed eligible to participate, completed baseline assessments for the primary outcome measure of lumbar extension strength, and were randomized (HIPRE n = 298, CORE n = 284). Reasons for ineligibility were: declined to participate (n = 43), did not meet inclusion criteria (n = 28), and other or unknown reasons (n = 45). Of the 582 participants who were randomized, 522 started the exercise interventions and 447 completed follow-up assessments for the primary outcome measure. Reasons for missed follow-up assessments were: academic reasons related to US Army (n = 5), changed companies (n = 54), discharged from US Army (n = 7), invalid follow-up strength assessment (n = 5), other or unknown reasons (n = 45), profile - unable to complete physical training (n = 14), and voluntary withdrawal (n = 5). Dropout rates were similar between the groups.

No significant differences between the HIPRE and CORE groups were observed in baseline demographics (e.g. age, body height, bodyweight, and sex) or outcome variables (lumbar strength, lumbar endurance, and core endurance) (Tables 1 and 2). Compared with randomized participants who completed follow-up assessments for the primary outcome (n = 447), randomized participants who did not complete follow-up assessments for the primary outcome (n = 135) consisted of a higher percentage of females, and had significantly lower baseline lumbar endurance and core endurance scores.

During the 11-week intervention period, no participant in either group reported that they completed or were exposed to exercises assigned to the other group, suggesting that contamination was not an issue. No participant in either group reported that they started any new exercises for the back and core muscles other than those assigned for the study or as part of the US Army's standard physical training program.

For the participants (n = 447) who completed follow-up assessments for the primary outcome measure, the mean  $\pm$  SD number of exercise sessions completed was  $10.6 \pm 1.2$  sessions, with no significant difference between the HIPRE and CORE groups. For the HIPRE group, the mean  $\pm$  SD dynamic exercise training load at the first and last exercise sessions was  $66.5 \pm 18.0$  kg and  $100.4 \pm 29.0$  kg, indicating a 51% improvement in dynamic exercise load. The mean  $\pm$  SD number of repetitions completed during each set of dynamic exercise training was  $12.8 \pm 1.8$  repetitions. Considering the target range of 8-12 repetitions per exercise set, 33.5% (77/230) of participants had an average number of repetitions per exercise set within the target range. Of the total of 2,454 exercise sets completed (at one exercise set per session) by HIPRE group

participants, 41.4% (1,017/2,454) of the sets were completed within the target range of 8-12 repetitions, 10.9% (267/2,454) were completed with less than eight repetitions, and 47.7% (1,170/2,454) of the sets were completed with greater than 12 repetitions.

No serious adverse events were reported. The observed related or possibly related adverse events were rare and consistent with known side effects of resistance exercise training (e.g. muscle soreness and stiffness). These side effects were generally minor, temporary, self-limiting, and did not impact operations of the soldiers.

Raw isometric lumbar extension muscular strength, dynamic lumbar muscular extension endurance, and isometric core muscular endurance values at baseline and follow-up are found in Table 2. A significant improvement in isometric lumbar extension muscular strength was observed within both groups at follow-up compared with baseline (HIPRE: 13.3% improvement,  $p < 0.001$ ; CORE: 3.3% improvement,  $p = 0.004$ ). Based on the linear mixed effects analyses, adjusted isometric lumbar extension muscular strength (mean  $\pm$  standard error) at follow-up was 9.7% greater for the HIPRE group compared with the CORE group (HIPRE:  $310.2 \pm 6.1$  Nm; CORE:  $282.7 \pm 6.1$  Nm;  $p = 0.001$ ). For the repeated measures of isometric lumbar extension muscular strength across seven angles of measurement, significant effects of group ( $p < 0.001$ ), angle of measurement ( $p < 0.001$ ), and group X angle of measurement interaction ( $p = 0.001$ ) were observed at follow-up (Figure 4). For both groups, isometric lumbar extension muscular strength was linear and descending from  $72^\circ$  (i.e. most flexed position) to  $0^\circ$  (i.e. most extended position). Isometric lumbar extension muscular strength for the HIPRE group was greater than the CORE group at each angle of measurement, with relatively larger differences between the two groups observed at the more extended angles of measurement.

A significant improvement in dynamic lumbar extension muscular endurance was observed at follow-up compared with baseline for the HIPRE group (11.4% improvement,  $p < 0.001$ ), but not for the CORE group ( $p > 0.05$ ). Based on the linear mixed effects analyses, adjusted dynamic lumbar extension muscular endurance (mean  $\pm$  standard error) at follow-up was 12.3% greater for the HIPRE group compared with the CORE group (HIPRE:  $24.6 \pm 1.0$  repetitions; CORE:  $21.9 \pm 1.0$  repetitions;  $p = 0.021$ ). For isometric core muscular endurance, no significant within group improvements and no between group differences were observed at follow-up.

## **DISCUSSION**

The current study indicates that HIPRE training for the lumbar extensors results in significantly greater improvements in lumbar extension isometric muscular strength and dynamic muscular endurance compared with core stabilization exercise among US Army Soldiers completing combat medic training. Lumbar extensor HIPRE training was safely and feasibly implemented as part of this study within the usual operations of US Army Soldiers. These findings suggest that lumbar extensor HIPRE training is useful for effectively improving back muscular capacity in soldiers and could be considered for this purpose in similar military settings.

For participants in the HIPRE group of the current study who completed both baseline and follow-up tests, average pre-training and post-training strength values were 273 Nm and 310 Nm, respectively, representing a 13.6% improvement. This improvement was comparable to strength gains observed in a previous study in which exercise testing and training procedures



were conducted in a similar manner as the current study. In a study with healthy college age civilians who completed a one session per week, 12-week lumbar extensor HIPRE training program,<sup>1</sup> the average pre-training and post-training strength values were approximately 269 Nm and 307 Nm, respectively, representing a 14.1% improvement.

Larger lumbar extension muscular strength gains have been reported in two studies with healthy college age civilians using a different strength testing protocol, whereby a familiarization practice test was performed on a day prior to the actual baseline strength test, and a shorter HIPRE training period of 10 weeks with one session per week.<sup>11,12</sup> In a study by Pollock et al.,<sup>11</sup> the average pre-training and post-training strength values were approximately 307 Nm and 484 Nm, respectively, representing a 57.7% improvement. In a study by Fisher et al.,<sup>12</sup> the average pre-training and post-training strength values were approximately 229 Nm and 278 Nm, respectively, representing a 21.4% improvement. The effect of different testing and training procedures on lumbar extension strength gains in soldiers is unknown and requires further research.

One explanation for the relatively lower lumbar extension muscular strength gains in the current study compared to previous work is that strict adherence to the scheduled one session per week of HIPRE training was not possible for all military participants. The mean number of exercise sessions completed for participants in the HIPRE group was 10.6, indicating that some of the participants did not complete each scheduled weekly exercise session. Another explanation for the relatively lower strength gains is that participants in the current study trained at intensities that were lower than the previously reported studies. In the current study, 47.7% of all HIPRE sets were completed with more repetitions than the target range of 8-12 repetitions to volitional fatigue, indicating that the training load may have been too low to stimulate larger strength gains.

In the current study, a statistically significant improvement in isometric lumbar extension muscular strength was also noted following core stabilization exercise training in US Army Soldiers. To our knowledge, lumbar extension muscular strength gains have not been previously reported following core stabilization exercise. Considering the relatively small strength gain (3.3%), it is possible that this gain is associated with a learning effect with the strength testing protocol rather than actual physiological changes in the lumbar muscles.

In contrast to our hypothesis, lumbar extensor HIPRE training and core stabilization exercise training did not result in significant improvement in core muscular endurance as measured by the prone static plank test. One explanation for this lack of improvement is that a ceiling effect with measurement of core muscular endurance using the prone static plank test in soldiers was likely observed in the current study. The prone static plank test mean score of approximately 170 seconds observed for US Army Soldiers at baseline in the current study was greater than baseline values reported for healthy college age civilians<sup>13</sup> and firefighters.<sup>14</sup> Furthermore, a potential ceiling effect for this test is consistent with findings of a previous study on similar floor based core endurance tests in soldiers.<sup>15</sup>

Potential limitations of the current study should be acknowledged when interpreting its findings. While the observed lumbar extension muscular strength and endurance gains were statistically significant, the clinical relevance of these gains in terms of LBP prevention and treatment of US

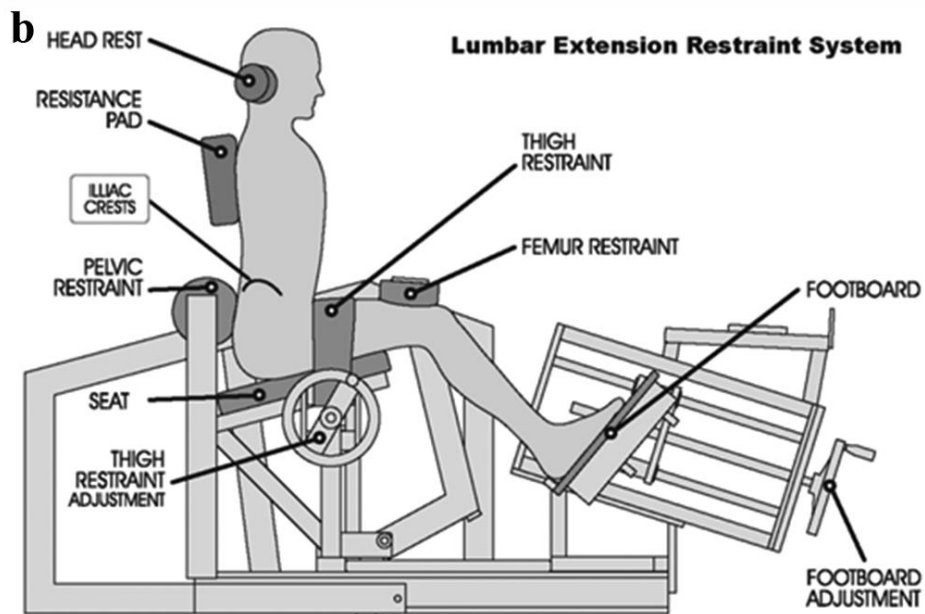
Army Soldiers is unclear. Another limitation of the current study is that exercise training was conducted on the device used for strength testing for participants in the HIPRE group but not for participants in the CORE group. Thus, HIPRE group participants may have had advantages in becoming familiarized with the testing device over the intervention period.<sup>1</sup> Another limitation of the current study is that core stabilization exercise was not administered in the usual frequency of 3-5 sessions per week,<sup>7</sup> which may limit generalizability of the study's findings for this type of exercise training. Moreover, this study did not assess implementation or cost effectiveness. Thus, generalizations regarding implementation or large-scale adoption across the military is not possible for HIPRE, which requires specialized equipment that is relatively costly, and core stabilization exercise.

Future research is needed via a full-scale injury prevention trial to test the hypothesis that a longer-term application of lumbar extensor HIPRE training will reduce the incidence, prevalence, and severity of low back injury both in garrison (i.e., during peacetime) and during deployment to theaters of operations. Also, it may be that the effects of lumbar extensor HIPRE training are further enhanced in the most highly active occupations within the military such as special operation forces. If shown to be successful, longer term studies could then be performed to assess the effectiveness of implementation of lumbar extensor HIPRE training across the US Armed Forces. Future research could continue to explore the potential benefits of HIPRE training in other highly active civilian populations, such as police officers, firefighters, and other first responders. Future research should also consider strategies for improving adherence to the exercise training protocol and maintaining lumbar extension strength gains over longer periods of time in the armed forces.

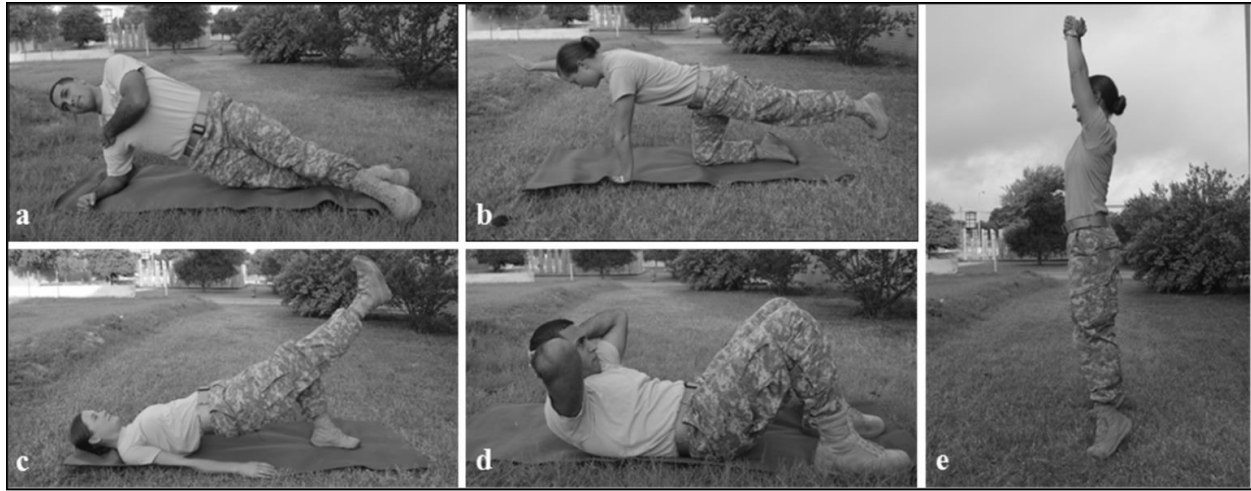
## **CONCLUSION**

In summary, HIPRE training for the lumbar extensors results in significant improvement in isometric lumbar extension muscular strength and dynamic muscular endurance compared with core stabilization exercise in US Army Soldiers. Future research is needed to explore the clinical relevance of these physical performance gains in the long-term incidence of episodes of LBP in this population or other targeted populations.

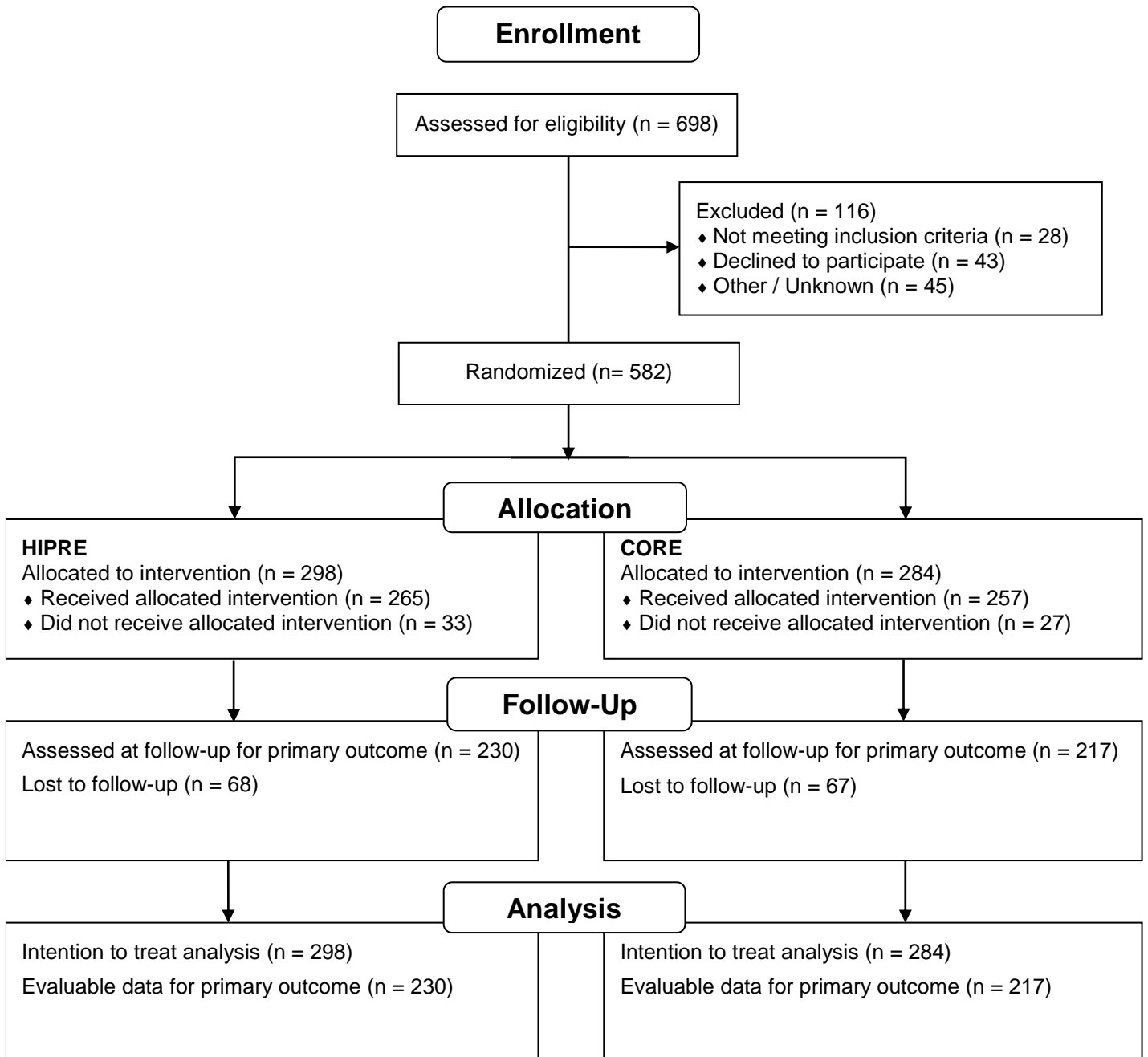
**Figure 1.** Lumbar extensor high intensity progressive resistance exercise (HIPRE) performed by the HIPRE group. a) illustration of participant performing HIPRE with the lumbar dynamometer, b) illustration of the pelvic restraint mechanisms on the lumbar dynamometer (obtained from [www.medexonline.com](http://www.medexonline.com)).



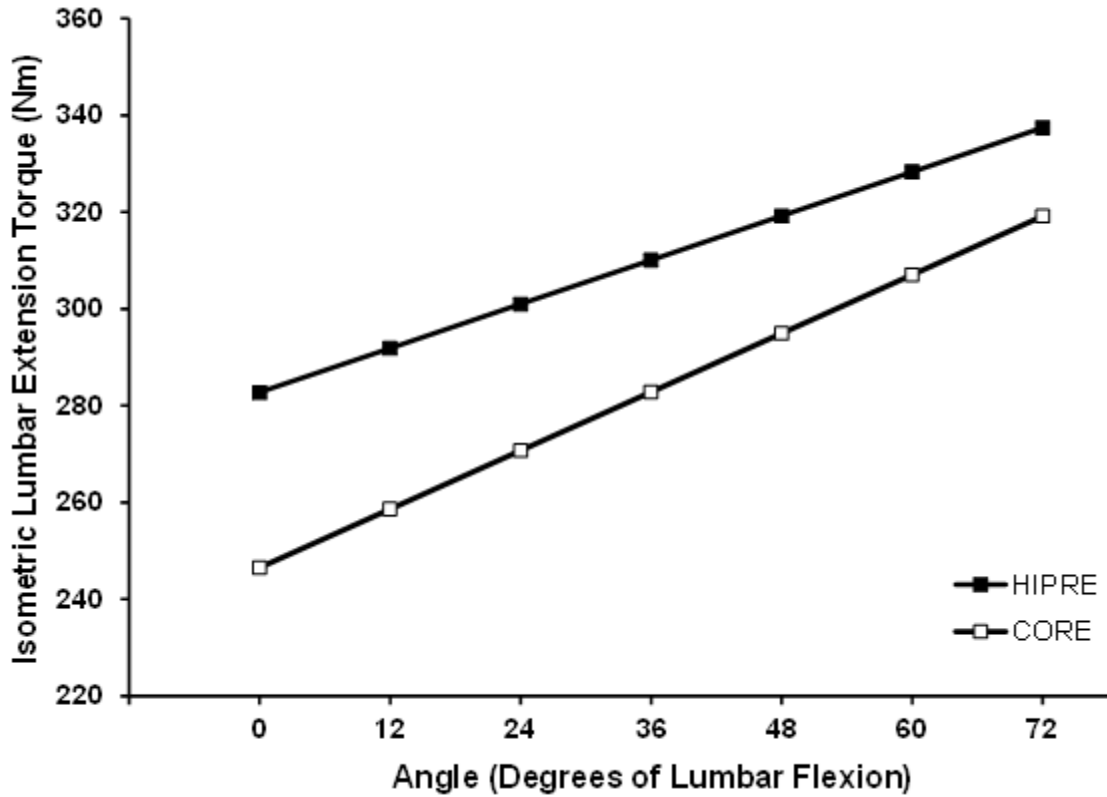
**Figure 2.** Core stabilization exercises performed by the CORE group displaying the end position for each movement. a) side plank, b) quadruped alternating arm and leg, c) supine shoulder bridge, d) crunch with abdominal drawing-in maneuver, and e) woodchopper.



**Figure 3.** Flow diagram of participants through the phases of the study. HIPRE = Lumbar extensor high intensity progressive resistance exercise training. CORE = core stabilization exercise training.



**Figure 4.** Predicted (from regression) isometric lumbar extension strength (torque) mean values (adjusted by baseline and cluster) at follow-up plotted by group and angle of measurement. HIPRE = Lumbar extensor high intensity progressive resistance exercise training. CORE = core stabilization exercise training.



**Table 1.** Baseline characteristics of participants.

	CORE (n = 284)	HIPRE (n = 298)	TOTAL (n = 582)
<i>Continuous variables:</i>			
Age (y)	21.5 ± 3.6	21.8 ± 3.8	21.7 ± 3.7
Body height (cm)	173.7 ± 8.8	174.6 ± 8.5	174.1 ± 8.6
Body weight (kg)	75.4 ± 11.3	76.0 ± 11.5	75.7 ± 11.4
Body mass index (kg/m <sup>2</sup> )	24.9 ± 2.5	24.9 ± 2.7	24.9 ± 2.6
SF-12 physical component score (0-100)	55.0 ± 4.4	55.1 ± 4.4	55.1 ± 4.4
SF-12 mental component score (0-100)	52.5 ± 7.4	52.7 ± 6.8	52.6 ± 7.1
<i>Categorical variables:</i>			
Sex			
Female	68 (23.9)	67 (22.5)	135 (23.2)
Male	216 (76.1)	231 (77.5)	447 (76.8)
History of low back pain			
No	213 (75.0)	231 (77.5)	444 (76.3)
Yes	69 (24.3)	67 (22.5)	136 (23.4)
Exercise routinely prior to military			
No	96 (33.8)	108 (36.2)	204 (35.1)
Yes	188 (66.2)	190 (63.8)	378 (65.0)

Continuous variables expressed as mean ± standard deviation. Categorical variables expressed as n (%). CORE = core stabilization exercise training. HIPRE = lumbar extensor high intensity progressive resistance exercise training. SF-12 = Short Form 12, health related quality of life questionnaire.

**Table 2.** Unadjusted isometric lumbar extension strength (Nm), dynamic lumbar extension endurance (repetitions), and core muscular endurance (seconds) scores at baseline and following the 11-week intervention for all participants.

Variable	CORE		HIPRE	
	n	Mean $\pm$ SD	n	Mean $\pm$ SD
<i>Lumbar Extension Strength (Nm):</i>				
Baseline	284	271.7 $\pm$ 92.8	298	275.4 $\pm$ 87.0
Follow-up	217	282.2 $\pm$ 93.9	230	309.2 $\pm$ 98.0
<i>Lumbar Extension Endurance (repetitions):</i>				
Baseline	271	22.0 $\pm$ 8.0	285	21.8 $\pm$ 7.7
Follow-up	206	22.2 $\pm$ 14.1	212	24.9 $\pm$ 8.2
<i>Core Muscular Endurance (s):</i>				
Baseline	279	172.8 $\pm$ 64.1	296	169.0 $\pm$ 62.4
Follow-up	220	165.5 $\pm$ 66.5	231	163.8 $\pm$ 64.4

CORE = core stabilization exercise training. HIPRE = lumbar extensor high intensity progressive resistance exercise training. SD = standard deviation.



**What opportunities for training and professional development has the project provided?**

Students from the US Army-Baylor Doctoral Program in Physical Therapy and the Department of Physical Therapy at the University of Texas Health Science Center at San Antonio assisted the investigators with data collection, which provided the students with the opportunity to receive training and professional development in exercise testing and prescription for military personnel.

**How were the results disseminated to communities of interest?**

Dissemination of results is ongoing at this time. Scholarly products resulting from this study that have been disseminated to scientific, clinical, and military communities are listed in the “PRODUCTS” section of this report.

**What do you plan to do during the next reporting period to accomplish the goals?**

Not applicable. This document is the final report for this project.

**IMPACT**

**What was the impact on the development of the principal discipline(s) of the project?**

The current study indicates that HIPRE training for the lumbar extensors results in significantly greater improvements in lumbar extension isometric muscular strength and dynamic muscular endurance compared with core stabilization exercise among US Army Soldiers completing combat medic training. Lumbar extensor HIPRE training was safely and feasibly implemented as part of this study within the usual operations of US Army Soldiers. These findings suggest that lumbar extensor HIPRE training is useful for effectively improving back muscular capacity in soldiers and could be considered for this purpose in similar military settings.

**What was the impact on other disciplines?**

Nothing to report.

**What was the impact on technology transfer?**

Nothing to report.

**What was the impact on society beyond science and technology?**

This study (phase 1) demonstrated that a high intensity exercise training protocol for the back muscles efficiently and effectively improves lumbar muscle physical performance in US Army Soldiers. Assuming positive results from future full-scale prevention randomized controlled trials (phase 2) and implementation effectiveness research (phase 3), soldiers who complete this exercise protocol will be inoculated against one of the key physical risk factors (i.e. poor back muscle functional capacity) for low back pain and injury before they are deployed. This will ultimately reduce their risk of developing low back pain and injury during combat and help them to effectively carry out their mission.

Given the magnitude of low back pain and injury in the military, the military benefit of a novel exercise protocol designed to reduce a risk factor for low back pain and injury is difficult to overstate. Soldiers preparing for deployment are in great need of advanced technology to help improve the functional capacity of the lumbar extensor muscles in an effective and efficient manner. Successful implementation of this exercise protocol may maximize back muscle functional capacity and resilience in soldiers at high risk for low back injury, thereby helping them become more physically fit to counteract the extreme physical demands required in combat.

## **CHANGES/PROBLEMS**

Problem:

- The operational flow of the available companies restricted the available time to conduct study procedures.

Corrective actions / Changes:

- Instead of enrolling from all six platoons within the companies, we enrolled from two randomly selected platoons in each company.
- We also scheduled an additional time to make up missed intervention sessions, as needed.
- We implemented other efficiencies in data collection that did not impact our ability to test the study's primary hypothesis.

## **PRODUCTS**

### ***Peer-Reviewed Manuscripts***

- Mayer JM, Childs JD, Neilson BD, Chen H, Koppenhaver SL, Quillen WS. Effect of progressive resistance exercise versus core stability exercise on low back muscle strength and endurance in soldiers (under review).

### ***Other Publications***

- Mayer JM. Improving low back muscular strength and core muscular endurance in US Army Soldiers: preliminary findings from the DOD-funded research grant at the University of South Florida. FCA Journal, 2014;January:14,16.

### ***Scientific Presentations***

#### ***Podium***

- Mayer JM, Childs JD\*, Neilsen B, Koppenhaver SL, Quillen WS. Effects of lumbar extensor progressive resistance exercise versus core stabilization exercise on low back strength and endurance in soldiers: preliminary results of a randomized clinical trial. American Occupational Health Conference, American College of Occupational and Environmental Medicine, San Antonio, TX, April 2014 (\*presenting author).
- Mayer JM, Child JD, Quillen WS. Tutorial lecture - Physical fitness interventions for low back pain in the military. American College of Sports Medicine Annual Meeting, Orlando, FL, May 2014.

- Mayer JM, Childs JD, Libous JL, Chen H, Quillen WS. Effect of lumbar extensor progressive resistance exercise versus core stability exercise on lumbar extension muscular strength and core muscular endurance in soldiers. North American Spine Society Annual Meeting, San Francisco, CA, November 2014.

*Poster*

- Neilson BD, Childs JD, Koppenhaver SL, Francis M, Hurley B, Morgan SC, Stoute SM, Quillen WS, Mayer JM. Relationship between time of day tested and lumbar spine strength and endurance. Academy of Health Sciences Graduate School Research Day, San Antonio, TX, 2013.
- Quillen WS, Childs JD, Mayer JM. Low back pain in the US military: epidemiology, prevention, and future directions. Special Operators Medical Association Annual Scientific Assembly. Tampa, FL, December 2013.
- Quillen WS, Childs JD, Libous JL, Mayer JM. Low back pain in the US Military: epidemiology, prevention, and current Research. University of South Florida Health Research Day. Tampa, FL, February 2014.
- Mayer JM, Childs JD, Libous JL, Neilson BD, Koppenhaver SL, Quillen WS. Factors influencing lumbar extension strength gains in soldiers. American College of Sports Medicine Annual Meeting. San Diego, CA, May 2015 (accepted).

**PARTICIPANTS AND OTHER COLLABORATING ORGANIZATIONS**

**What individuals have worked on the project?**

Name: William S. Quillen  
 Project Role: Principal Investigator  
 Researcher Identifier: None  
 Nearest Person Month Worked: 1.2 calendar months per year  
 Contribution to Project: Dr. Quillen assumed all management, design, implementation, and leadership responsibilities for the experiments of this project. He organized, directed, and planned the scientific and administrative aspects of the project.  
 Funding Support: Not applicable. Funding support was from this award.

Name: John M. Mayer  
 Project Role: Co-Principal Investigator and Project Leader  
 Researcher Identifier: None  
 Nearest Person Month Worked: 4.2 calendar months per year  
 Contribution to Project: Dr. Mayer supervised the day-to-day operations of the study. He directed the development of study protocol and data management plan. He supervised data collection, data management, data analysis, and dissemination efforts.  
 Funding Support: Not applicable. Funding support was from this award.

Name: John D. Childs  
Project Role: Institutional Principal Investigator - AMEDD Center & School (US Army-Baylor Doctoral Program in Physical Therapy)  
Researcher Identifier: None  
Nearest Person Month Worked: 1.2 calendar months per year  
Contribution to Project: Dr. Childs oversaw all study operations at the AMEDD Center & School (US Army-Baylor Doctoral Program in Physical Therapy) at Fort Sam Houston in San Antonio, TX, which was the sole site for data collection. He assisted with interpretation of data analyses, and preparation of scientific presentations and manuscripts for disseminating study results.  
Funding Support: Dr. Childs was a full time federal employee (USAF) during the majority of the project period. Thus, no funding support was allocated to this project.

Name: Brett D. Neilson  
Project Role: Research Coordinator  
Researcher Identifier: None  
Nearest Person Month Worked: 4.2 calendar months per year  
Contribution to Project: Dr. Neilson coordinated all study operations at the AMEDD Center & School (US Army-Baylor Doctoral Program in Physical Therapy) at Fort Sam Houston in San Antonio, TX, which was the sole site for data collection. He conducted enrollment procedures and assessments, coordinated interventions, and conducted preliminary on-site data management, monitoring, and audits.  
Funding Support: Not applicable. Funding support was from this award.

Name: Francis T. Bisagni  
Project Role: Research Assistant  
Researcher Identifier: None  
Nearest Person Month Worked: 2.4 calendar months per year  
Contribution to Project: Dr. Bisagni assisted with study operations at the AMEDD Center & School (US Army-Baylor Doctoral Program in Physical Therapy) at Fort Sam Houston in San Antonio, TX, which was the sole site for data collection. He assisted with enrollment procedures, assessments, interventions, preliminary on-site data management, monitoring, and audits.  
Funding Support: Not applicable. Funding support was from this award.

**Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

Nothing to report (since last reporting period of October 2014 - January 2015).

### **What other organizations were involved as partners?**

- Organization Name: Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc.  
Location of Organization: San Antonio, TX  
Contribution: The organization, the primary partner for this study, provided administrative support for the research team at Fort Sam Houston, TX, and personnel (e.g. research coordinator).
- Organization Name: US Army-Baylor Doctoral Program in Physical Therapy, AMEDD Center & School  
Location of Organization: Fort Sam Houston, TX  
Contribution: The organization contributed personnel (e.g. institutional PI and investigators, student research assistants).
- Organization Name: Fort Sam Houston, TX  
Location of Organization: Fort Sam Houston, TX  
Contribution: The organization provided facilities to administer all recruitment, enrollment, and data collection procedures for the study participants (US Army Soldiers).
- Organization Name: MedX Holdings, Inc.  
Location of Organization: Ocala, FL  
Contribution: The organization provided (via loan) the exercise equipment (4 lumbar extension dynamometers) used for exercise testing and training in this study.

### **SPECIAL REPORTING REQUIREMENTS**

#### **QUAD CHARTS:**

See accompanying file (W81XWH-11-2-0170 Quad\_Chart 2015-05-06.ppt) for Quad Chart.

## **Appendix. Detailed Description of Intervention**

### **1. Experimental Intervention**

#### **High Intensity Progressive Resistance Exercise for Lumbar Extensors**

##### **Background and justification for selecting intervention**

*Back strengthening exercise.* Assessment of lumbar extensor muscle function and isolated strength training of this muscle group is often a dilemma because of the compound movement of the hip, pelvis, and lumbar spine during trunk extension.<sup>4,11</sup> From a position of full trunk flexion, the lumbar extensor, gluteal, and hamstring muscles work together to actively rotate the trunk through approximately 180° in the sagittal plane (i.e. compound trunk extension).<sup>4,11</sup> The lumbar extensors, consisting primarily of the erector spinae and multifidus, extend the lumbo-sacral spine, while the gluteals and hamstrings de-rotate the pelvis and extend the hip. The relative contribution of these individual muscle groups to force production during compound trunk extension is unknown, but it is assumed that the much larger and more powerful gluteals and hamstrings generate the majority of force.<sup>4,11</sup> Therefore, to accurately assess the function of and apply progressive resistance exercise to the lumbar extensors in the ranges required for strength development, torque production from the gluteals and hamstrings must be eliminated.<sup>4,11</sup>

By incorporating a series of pelvic stabilization mechanisms during trunk extension exercise testing and training on a lumbar dynamometer, pelvic and hip rotation can be restricted to less than 3° and the lumbar spine can be isolated.<sup>16</sup> The incorporation of these stabilization mechanisms during testing has resulted in a highly reliable and accurate measure of isometric lumbar extension strength over 72° in the sagittal plane (from a position of full lumbar flexion to a position close to terminal lumbar extension).<sup>16</sup> Moreover, dynamic progressive resistance exercise protocols with a stabilized pelvis and isolated lumbar spine on the dynamometer produces unusually large gains (greater than 100%) in isometric lumbar extension strength in healthy adult civilians with training frequencies as low as one time per week.<sup>4,11</sup> Once gains are realized, these gains are maintained by as little as 1 exercise session per month.<sup>6</sup> Preliminary and unpublished data suggest that gains can also be maintained by incorporating low tech options (e.g. prone trunk extension on a bench, floor, or Roman chair) after the initial 12-week high intensity training period. See Appendix 4 for the instruction manual for the device, which includes full features of the device, software, exercise testing training protocols, and device calibration procedures. See “Facilities & Other Resources” for illustrations of this exercise equipment, which will be utilized in the proposed study.

The large lumbar extension strength gains associated with low frequency training have been attributed to the lack of use of the low back muscles during normal activities. Since the pelvis remains free to move during activities of daily living such as lifting and bending, it is assumed that the small lumbar muscles play only a minor role in trunk extension torque production.<sup>17</sup> Thus, they are considered to be the weak link in trunk extension movements.<sup>17</sup> The rationale behind isolating the lumbar spine during exercise training is to force the lumbar muscles to be the primary trunk extensors, thereby providing the overload stimulus for strength gains.<sup>17</sup> High intensity progressive resistance exercise protocols for the lumbar extensors have not been tested in the US Armed Forces.

Available evidence. In a systematic search of the literature, we uncovered 7 studies<sup>1,4-6,11,18,19</sup> published as refereed full-text articles in which lumbar extension exercise training using protocols similar to that described in this proposal was carried out 1X/week in asymptomatic individuals (see Table 1 of Appendix). In 6 studies,<sup>1,4-6,11,18</sup> the sample consisted of relatively young individuals, described as healthy or sedentary, who were recruited from university settings. The sample in another study consisted of industrial strip mine workers.<sup>19</sup> Of the 6 studies carried out with individuals recruited from university settings, 4 studies,<sup>1,4,5,11</sup> reported original data from the 1X/week exercise training group. The other 2 studies,<sup>6,18</sup> reported 20-week follow-up data from a previous study or the effects of reduced or de-training beyond the initial 12-week training period.

Strength gains. Of the 4 studies with original data (total sample size training at 1X/week = 67), improvements in isometric lumbar extension strength ranged from 24%-120% at 0° (most extended position) and 8%-42% at 72° (most flexed position). The weighted mean strength improvement in these 4 studies was 81% at 0° and 21% at 72° (51% average improvement with these measurements combined).

Exercise dose (volume and frequency). To improve lumbar extension strength using the protocols described in this proposal, 1 set of exercise per session at 1 session per week of training is as effective as multiple sets and multiple exercise sessions per week. Two studies compared 1X/week of exercise training to 2X/week or 3X/week. Lumbar extension strength gains were noted in all 3 training groups, but no significant differences were noted among the groups at 12 weeks or 20 weeks follow-up. The authors concluded that 1X/week of exercise training is as effective as 2X/week or 3X/week of exercise training. In a published abstract, 1 set of exercise training per session was compared with 2 sets and 3 sets of exercise training for 12 weeks. Lumbar extension strength gains were noted in all 3 training groups, but no significant differences were noted among the groups. To our knowledge, no studies have reported relative gains in lumbar extension strength (compared with 1 set, 1X/week training) for multiple set exercise training or multiple sessions per week of exercise training.

Give the above evidence, we believed that 1 set of exercise administered at a frequency of 1X/week for 12 weeks in the target population of Army soldiers in training to become combat medics is sufficient to test the hypothesis of the proposed study.

### **Experimental intervention - methods**

Participants in the experimental group performed a high intensity progressive resistance exercise (HIPRE) program targeting the lumbar extensor muscles, 1 time per week, for 11 weeks, in addition to the usual physical fitness training programs required for soldiers training to become combat medics. Each exercise session was supervised by research personnel and consisted of 1 set of high intensity, dynamic, full range of motion, isolated, progressive resistance exercise training on the lumbar extension exercise machine (MedX, Welltek Inc, Orlando, FL) (Fire 1 of appendix).

As previously mentioned, one set, 1 time per week of high intensity exercise using this protocol has been shown to be sufficient to elicit lumbar extensor strength and endurance gains in healthy civilians.<sup>5,6</sup> Existing data from the peer-reviewed literature do not support the hypothesis that

additional strength benefits can be gained through higher volume training by adding multiple exercise sets per session, or higher frequency training by adding multiple sessions per week. A major component of muscular strength gain appears to be high intensity exercise, whereby heavy weights are used and the subject performs each set to volitional fatigue.

For warm-up the warm-up set and exercise training set, the participant was seated in the lumbar extension dynamometer after removing belts and anything from the pockets that might cause discomfort. The participant lightly gripped the handlebars, a lap belt was secured across the anterior thighs, and a neck pad was positioned to align with the participant's mastoid regions. The participant's feet were placed in the middle of a footboard in slight internal rotation with their knees flexed at approximately 20°. Then, the footboard was tightened to drive the thigh into the femur restraint pad and redirect the femur to push the pelvis into the pelvic restraint pad until there was no rotation in the pelvic restraint pad when the participants flexed to touch their toes.

Prior to performing the training set at each exercise session, each participant performed a warm-up set of exercise on the lumbar extension dynamometer. The warm-up set consisted of dynamic exercise using very low intensity (light weight) for 6-8 repetitions. The dynamic exercise warm-up set was performed at throughout a 72° range of motion in the sagittal plane. The participant performed the concentric contraction (lumbar extension - raising the weight) in two seconds, paused for one second at full extension, and performed the eccentric contraction (lumbar flexion - lowering the weight) in four seconds.

For the actual training set of dynamic exercise, initial resistance for the first session was set at a weight equaling 50% of peak isometric torque determined from the baseline isometric strength test. The dynamic exercise training set was performed at throughout a 72° range of motion in the sagittal plane. The participant performed the concentric contraction (lumbar extension - raising the weight) in two seconds, paused for one second at full extension, and performed the eccentric contraction (lumbar flexion - lowering the weight) in four seconds.

For the training set, the investigator verbally encouraged the participant to perform as many repetitions as possible to volitional fatigue. Visual and auditory feedback was provided by a monitor and speakers attached to the device placed in front of the subject, which provided additional encouragement for the subject to perform repetitions in the prescribed cadence to volitional fatigue. The monitor depicted load movement throughout the range of motion, while the speakers beep at end ranges of motion. Date, time, exercise load, range of motion, and time under load were captured by the dynamometer via its computer software. When the participant completed 12 or more repetitions, resistance was increased in 5% increments with a pin-loaded weight stack on the dynamometer at the next training session. An adjustable 364-kg weight stack provided resistance from 9-182 kg in 0.5-kg increments and variable resistance is accomplished by a cam with a ratio of 1.4:1 (flexion:extension). This exercise protocol is consistent with the American College of Sports Medicine guidelines for progressive models in resistance exercise programs.<sup>20</sup>

## **2. Control Intervention**

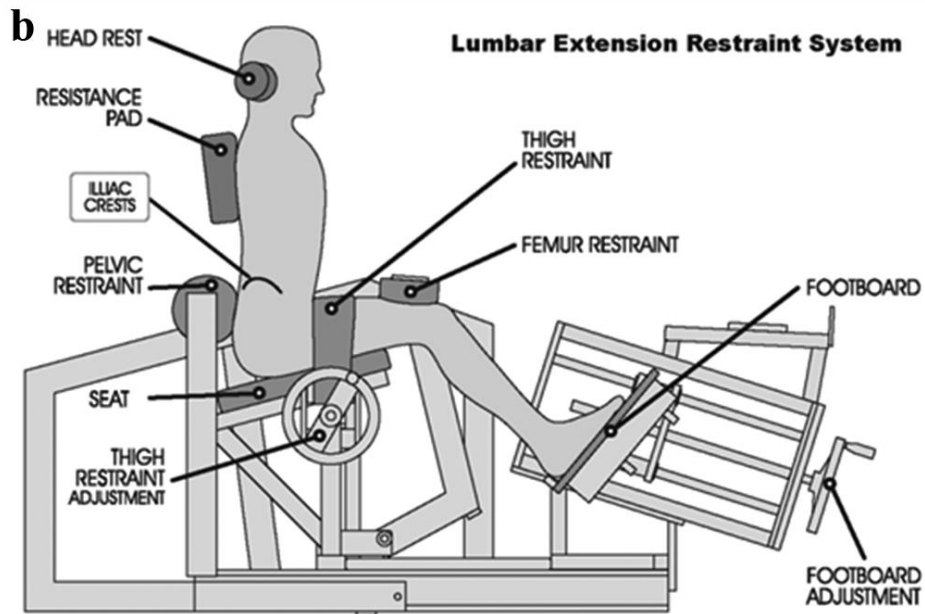
Participants in the control group performed core stability exercises as described by Childs et al. in a previous exercise training study with the same target population.<sup>7,21</sup> Briefly, the participants



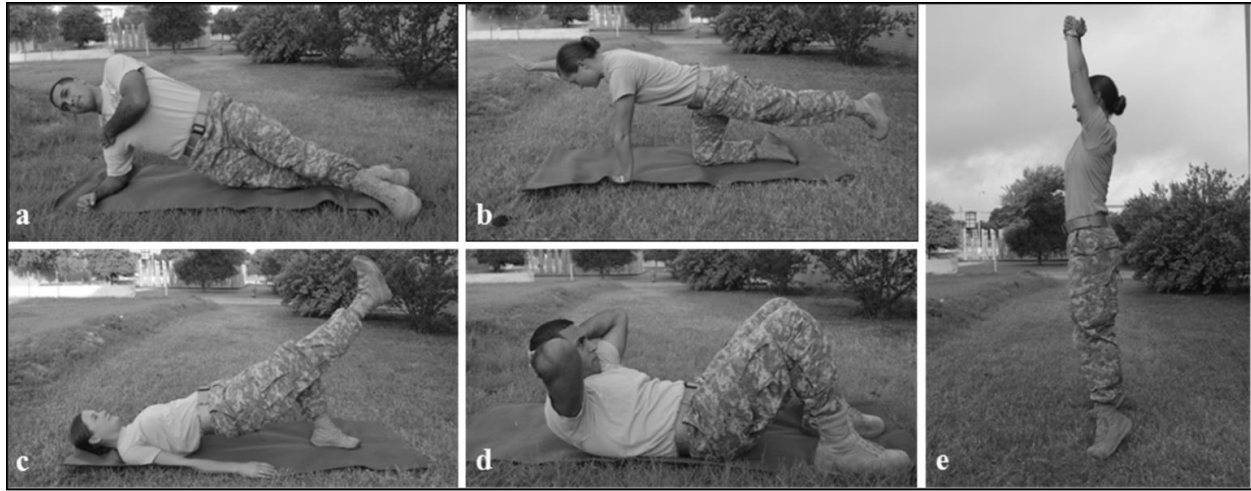
perform a series of 5 core stability exercises, including the abdominal drawing-in crunch maneuver, horizontal side support, supine shoulder bridge, quadruped alternating arm and leg, and woodchopper (Figure 2 of appendix). The participants performed 1 set of 6 repetitions of each exercise within 1 minute with no rest between exercises. This exercise training protocol has been successfully implemented in the target population (but different soldiers from previous years) for the current study.<sup>7,21</sup>

We acknowledge that a frequency of one time per week is not the typical dosage for delivering core stabilization exercise. Nevertheless, core stabilization exercise training was selected as the control intervention for the following reasons: 1) Our intent was to establish a control group to match the attention time provided to the experimental group; 2) Given the proof-of-concept and feasibility nature of this study, we selected a control group that was not hypothesized to improve in the primary outcome measure (lumbar extension strength); and 3) The selected control intervention (core stabilization exercise) was previously shown to be successfully implemented in a large-scale clinical trial with this target population of US Army Soldiers.<sup>7,21</sup>

**Figure 1 (Appendix).** Lumbar extensor high intensity progressive resistance exercise (HIPRE) performed by the experimental group. a) illustration of participant performing HIPRE with the lumbar dynamometer, b) illustration of the pelvic restraint mechanisms on the lumbar dynamometer (obtained from [www.medexonline.com](http://www.medexonline.com)).



**Figure 2 (Appendix).** Core stabilization exercises performed by the control group displaying the end position for each movement. a) side plank, b) quadruped alternating arm and leg, c) supine shoulder bridge, d) crunch with abdominal drawing-in maneuver, and e) woodchopper.



**Table 1 (Appendix).** Evidence summary for lumbar extension exercise training studies in civilians without low back pain.

Author Year Study Design	Subjects Characteristics Age (yr)	Frequency (sessions/week)	Sets/session (number) Repetitions/session (number) Duration (week)	Lumbar extension strength change (%) 0° extended position 72° flexed position
Pollock <sup>11</sup> 1989 RCT	Healthy University setting 32.6 ± 11.4 yr (male) 21.8 ± 1.0 yr (female) n = 25	Exercise1: 1 Control: 0	1 6-15 10	Exercise1 0°: 102%; 72°: 42% Control 0°: -10% (ns); 72°: 2% (ns)
Graves <sup>5</sup> 1990 RCT	Sedentary University setting 31 ± 9 yr (male) 28 ± 9 yr (female) n = 114	Exercise0.5: 0.5 Exercise1: 1 Exercise2: 2 Exercise3: 3 Control: 0	1 8-12 12	Exercise0.5 0°: 105%; 72°: 12% Exercise1: 0°: 54%; 72°: 19% Exercise2: 0°: 100%; 72°: 17% Exercise3: 0°: 130%; 72°: 16% Control: 0°: 8% (ns); 72°: -1% (ns)
Carpenter <sup>18</sup> 1991 RCT	Sedentary University setting 29 ± 10 yr (male & female) n = 56	Exercise0.5: 0.5 Exercise1: 1 Exercise2: 2 Exercise3: 3 Control: 0	1 8-12 12 & 20	12 wk: Exercise0.5 0°: 67%; 72°: 9% Exercise1: 0°: 48%; 72°: 12% Exercise2: 0°: 35%; 72°: 11% Exercise3: 0°: 98%; 72°: 12% Control: 0°: 2% (ns); 72°: 2% (ns)  20 wk: Exercise0.5 0°: 80%; 72°: 8% Exercise1: 0°: 84%; 72°: 23% Exercise2: 0°: 65%; 72°: 10% Exercise3: 0°: 114%; 72°: 15% Control: no data available
Tucci <sup>6</sup> 1992 RCT	Healthy University setting 34 ± 11 yr (male)	1-12 wk all subjects: 1-3	1-12 wk: 1-2 8-12	12 wk all subjects: 0°: 31%; 72°: 9%

	23 ± 11 yr (female) n = 50	13-24 wk: Exercise0.25: 0.25 Exercise0.5: 0.5 Control: 0	12 13-24 wk: 1 8-12 12	24 wk (% change relative to 12 wk): Exercise0.25: 0°: -46%; 72°: -4.2% (ns) Exercise0.5: 0°: -4% (ns); 72°: 7% (ns) Control: 0°: -36%; 72°: -89%
Graves <sup>4</sup> 1994 RCT	Sedentary University setting 33 ± 10 yr (male) 31 ± 9 yr (f) n = 36	Exercise1: 1 Control: 0	1 8-12 12	Exercise1: 0°: 120%; 72°: 14% Control: 0°: 0% (ns); 72°: -2% (ns)
Mooney <sup>19</sup> 1995 Observational cohort study	Strip mine workers age: not reported (male only) n = 197	Exercise1: 1 Control: n/a	1 ≤ 20 20	Exercise1: 0°: 104%; 72°: 54%
Mayer <sup>1</sup> 2002 RCT	Healthy University setting 29 ± 6 yr (male) 36 ± 13 yr (female) n = 18	Exercise1: 1 Control: n/a (other training device)	1 8-12 12	Exercise1: 0°: 24%; 72°: 8%

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