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Original Article

Prevention of low back pain in the military cluster randomized trial: effects of brief psychosocial education on total and low back pain–related health care costs

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Abstract

BACKGROUND CONTEXT: Effective strategies for preventing low back pain (LBP) have remained elusive, despite annual direct health care costs exceeding \$85 billion dollars annually. In our recently completed Prevention of Low Back Pain in the Military (POLM) trial, a brief psychosocial education program (PSEP) that reduced fear and threat of LBP reduced the incidence of health care–seeking for LBP.

PURPOSE: The purpose of this cost analysis was to determine if soldiers who received psychosocial education experienced lower health care costs compared with soldiers who did not receive psychosocial education.

STUDY DESIGN/SETTING: The POLM trial was a cluster randomized trial with four intervention arms and a 2-year follow-up. Consecutive subjects (n=4,295) entering a 16-week training program at Fort Sam Houston, TX, to become a combat medic in the U.S. Army were considered for participation.

METHODS: In addition to an assigned exercise program, soldiers were cluster randomized to receive or not receive a brief psychosocial education program delivered in a group setting. The Military Health System Management Analysis and Reporting Tool was used to extract total and LBP-related health care costs associated with LBP incidence over a 2-year follow-up period.

RESULTS: After adjusting for postrandomization differences between the groups, the median total LBP-related health care costs for soldiers who received PSEP and incurred LBP-related costs during the 2-year follow-up period were \$26 per soldier lower than for those who did not receive PSEP (\$60 vs. \$86, respectively, p=.034). The adjusted median total health care costs for soldiers who received PSEP and incurred at least some health care costs during the 2-year follow-up period were estimated at \$2 per soldier lower than for those who did not receive PSEP (\$2,439 vs. \$2,441,

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Trial registration: NCT00373009 at ClinicalTrials.gov - <http://clinicaltrials.gov/>.

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respectively, $p=.242$). The results from this analysis demonstrate that a brief psychosocial education program was only marginally effective in reducing LBP-related health care costs and was not effective in reducing total health care costs. Had the 1,995 soldiers in the PSEP group not received PSEP, we would estimate that 16.7% of them would incur an adjusted median LBP-related health care cost of \$517 compared with the current 15.0% soldiers incurring an adjusted median cost of \$399, which translates into an actual LBP-related health care cost savings of \$52,846 during the POLM trial. However, it is likely that the unaccounted for direct and indirect costs might erase even these small cost savings.

CONCLUSION: The results of this study will help to inform policy- and decision-making regarding the feasibility of implementing psychosocial education in military training environments across the services. It would be interesting to explore in future research whether cost savings from psychosocial education could be enhanced given a more individualized delivery method tailored to an individual's specific psychosocial risk factors. Published by Elsevier Inc.

Keywords:

Costs; Low back pain; Prevention; Biopsychosocial; Military

Introduction

Next to the common cold, low back pain (LBP) is the most common reason for visiting a physician in the United States and elsewhere [1] and represents a common form of chronic pain [2] and significant cause of disability in society [3,4]. Annual direct health care costs in the United States for spine disorders has been estimated at more than \$85 billion in 2005, corresponding to a 65% increase from 1997 estimates [4]. Moreover, indirect costs from lost work productivity resulting from LBP in the United States are estimated to exceed \$7 billion annually [5]. LBP is also one of the most common forms of chronic pain in the military and has been associated with high rates of medical evacuation for service members participating in Operation Iraqi Freedom or Operation Enduring Freedom in Afghanistan, with return to duty being uncertain [6–8]. It is not surprising then that primary prevention of LBP is a significant research priority for both the general [9] and military populations, where it has been suggested that implementation of preventive measures for service members at highest risk of evacuation could reduce the effect of non-battle-related injuries and disease on military readiness [6]. However, effective strategies for preventing LBP have remained elusive, as highlighted by the European Guidelines for Prevention of Low Back Pain [10] and a recent systematic review on the topic [11].

In response, we recently completed the Prevention of Low Back Pain in the Military (POLM) trial, which was a cluster randomized study with four intervention arms and a 2-year follow-up [12–18]. Based on our primary outcome, there were no differences in low back incidence resulting in the seeking of health care between those receiving traditional versus core stabilization exercise. This negative finding for exercise was somewhat surprising because core stabilization has been advocated as preventive, yet offered no such benefit when compared with traditional military training in this trial [13]. In contrast, a brief psychosocial education program that reduced fear and threat

of LBP [14] reduced the incidence of health care-seeking for LBP regardless of the assigned exercise approach, resulting in a decrease over 2 years (numbers needed to treat=30.3, 95% confidence interval [CI]=18.2–90.9) [13].

A few studies have found that early access to exercise and education approaches during the acute phase of LBP reduces subsequent health care costs [19–21]. However, no studies we are aware of have examined the implications of psychosocial education on subsequent health care costs in a primary prevention model. It would be interesting to understand the economic implications of receiving psychosocial education given the low cost and feasibility of delivering a brief psychosocial education program combined with the fact that this arm of the trial was shown to reduce health care-seeking for LBP. Furthermore, increasing the recognition of pain as a significant public health problem in the United States and exploring population-based methods of delivering pain education were key premises behind the Institute of Medicine's recent report on managing pain in America [22]. The results of this analysis will help to inform whether a military cohort receiving psychosocial education also incurred lower health care costs for LBP, and positive findings could provide important information for future investigations. Therefore, the purpose of this analysis was to determine if soldiers who received psychosocial education experienced lower health care costs compared with soldiers who did not receive psychosocial education. We hypothesized that, consistent with the incidence data, soldiers who received psychosocial education would have lower total and LBP-related costs during the 2-year follow-up period.

Methods

This study reports a planned secondary analysis in the Prevention of Low Back Pain in the Military clinical trial (NCT00373009), which has been registered at <http://clinicaltrials.gov> [12,13]. Consecutive subjects entering

a 16-week training program at Fort Sam Houston, TX, to become a combat medic in the U.S. Army were considered for participation. In the primary trial, 20 companies of Soldiers were cluster randomized to complete one of four training programs: a traditional exercise program including bent-knee sit-ups with ($n=945$) or without ($n=1,212$) a psychosocial education program (PSEP) or a core stabilization exercise program with ($n=1,049$) or without PSEP ($n=1,089$) [13]. The Military Health System (MHS) Management Analysis and Reporting Tool (M2) was used to extract total and LBP-related health care costs associated with LBP incidence over a 2-year follow-up period. To analyze the health care costs for the purpose of this secondary analysis, we collapsed the four groups into two groups (PSEP vs. no PSEP) because there was no difference in health care-seeking for LBP based on the assigned exercise program found in the primary trial [13].

Setting and participants

Research staff at Fort Sam Houston, TX, introduced the study to individual companies of soldiers and obtained written informed consent. Refer to the [Figure](#) for a flow diagram describing the number of companies and soldiers considered for this trial, eventually enrolled into the trial, and the number of evaluable soldiers at the 2-year follow-up period, per the Consolidated Standards of Reporting Trials guidelines [23]. All subjects were recruited during a training orientation session attended by all soldiers as part of their in-processing for combat medic training. For 8 consecutive months, subjects were screened for eligibility according to the inclusion/exclusion criteria. Subjects were required to be 18 to 35 years of age (or a 17-year-old emancipated minor), participating in training to become a combat medic, and be able to speak and read English. Subjects with a prior history of LBP were excluded. A prior history of LBP was operationally defined as LBP that limited work or physical activity, lasted longer than 48 hours, and caused the subject to seek health care. Subjects were also excluded if they were currently seeking medical care for LBP; unable to participate in unit exercise because of an injury in the foot, ankle, knee, hip, neck, shoulder, elbow, wrist, or hand; had a history of fracture (stress or traumatic) in the proximal femur, hip, or pelvis; were pregnant; or if they had transferred from another training group. Other possible exclusions included soldiers who were being accelerated into a company already randomized and recruited for participation in the POLM trial or soldiers who were being reassigned to an occupational specialty other than a combat medic.

Ethics approval

The institutional review boards at the Brooke Army Medical Center (San Antonio, TX) and the University of Florida (Gainesville, FL) granted approval for this project.

All subjects provided written informed consent before their participation.

Exercise programs

Subjects performed the assigned exercise program in a group setting under the direct supervision of their drill instructors as part of daily unit physical training. The subjects' drill instructors received comprehensive training in the study procedures by the staff before the study's initiation. Drill instructors were provided detailed training cards specific to each program. This information was also provided to the drill instructors on the study's website (<http://polm.ufl.edu>) for reference purposes. This training ensured that both the drill instructors and subjects were proficient in their assigned exercise programs and enhanced the ability to accomplish the exercise programs in a standardized manner. Study personnel monitored physical training an average of 2 days per week over the 12-week training period to answer questions and monitor compliance with the assigned exercise program.

The exercise regimen in both groups consisted of five to six exercises, each of which was performed for one minute. Exercise programs were performed daily, for a total dosage time of approximately 5 minutes per day, 4 days per week over a period of 12 weeks. Performing the exercise programs under the supervision of a drill instructor and in a group setting helped to ensure compliance with the assigned program and dosage. Additional details regarding each exercise program can be found elsewhere [12,13,15], but are not included in this article because the focus of this secondary analysis is on health care costs associated with receiving psychosocial education.

PSEP

The dose and format of the PSEP was dependent on the time the investigative team had access to the soldiers outside of the training day, which was limited because of their busy training schedule. As a result, we elected to deliver the PSEP in a single group session during the first week of training that lasted no more than 1 hour. For the education program, the company was divided into two or three groups to accommodate the size of the lecture hall and also to allow for flexibility in scheduling soldiers. Each group received the same information, and the session involved an interactive lecture led by study personnel lasting approximately 45 minutes. The lecture consisted of a visual presentation followed by a question and answer session. The theoretical rationale for and content within the PSEP is described in more detail in a previous POLM publication [14].

Randomization

Military training environments require living in close quarters with other members of the unit, making individual randomization an unfeasible option for this trial because of

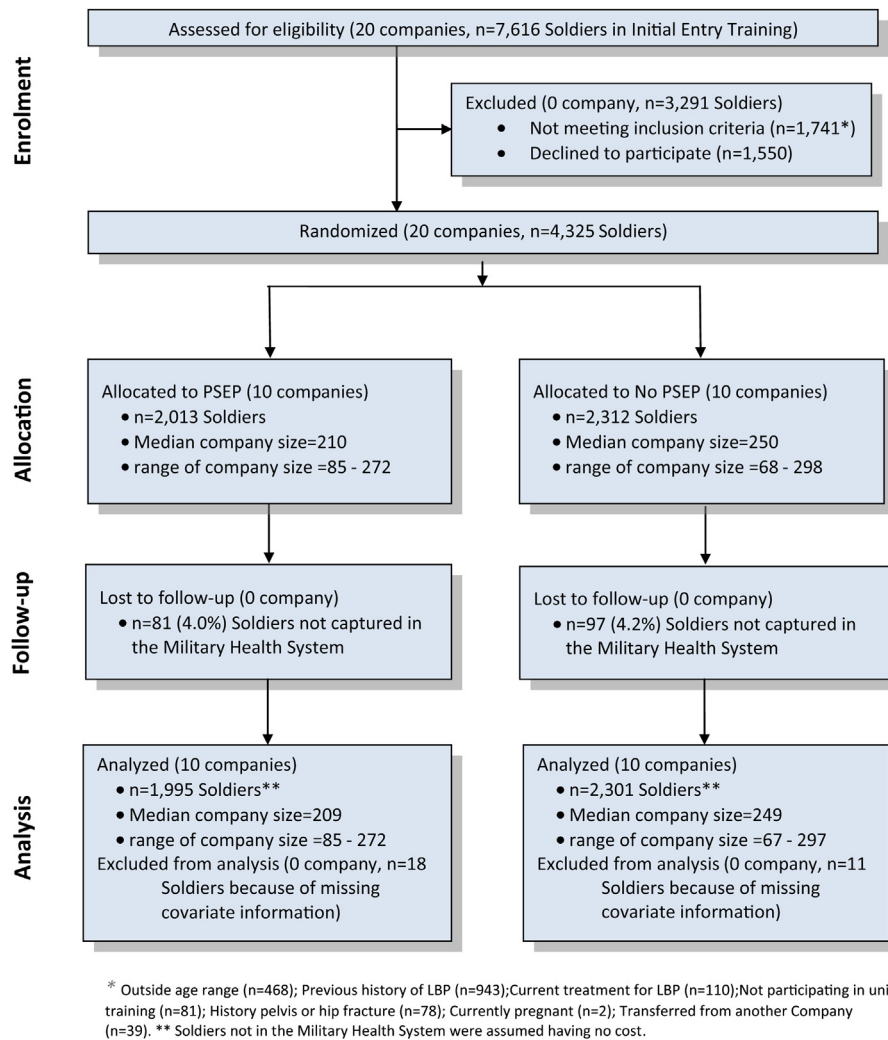


Figure. Flow diagram of clusters and individuals from recruitment to analysis.

concerns related to disruption of normal training schedule and treatment contamination. Therefore, a cluster randomization strategy was used for assigning companies to receive traditional exercise program or core stabilization exercise program. This meant that for a given company, every subject who consented to the study received the same study condition. Cluster randomization is a viable methodological choice that has been effectively used in other large samples of primary prevention [24,25]. The randomization schedule was prepared by computer and was determined before recruitment began. The randomization schedule was balanced to ensure equal allocation to each condition after 12 companies were recruited.

Blinding

It was not possible to mask soldiers because they actively participated in the exercise and education training programs. All outcomes for the primary analysis was assessed by raters blinded to group assignment or were obtained via self-report [13].

Baseline measures

Measures were collected under supervision of research personnel unaware of random company assignment and scored in a masked manner by computer algorithm. Soldiers completed standard demographic information, such as age, sex, medical history, and factors related to military status. Soldiers also completed self-report measures at baseline for physical and mental function [26], anxiety [27], depressive symptoms [28], fear of pain [29], and back beliefs [30].

Sample size estimation and power analysis

The sample size estimates were based on the primary outcome of LBP incidence, which intended to recruit a minimum of 16 companies based on the assumption of 150 consenting soldiers per company. A more detailed sample size estimation and power analysis was published with our trial protocol [12]. The study sample size (N=4,325) could enable us to have 80% power to detect a mean

difference of 0.115 in log-cost (ie, 12% difference in cost) between PSEP and no-PSEP groups, assuming that the log-cost has a within-group standard deviation of 1.35 as observed among the soldiers who incurred health care costs.

Outcomes

M2 is an ad hoc query tool that enhances support to health care managers to oversee MHS operations. The database is updated monthly via an electronic feed from each of the Military Treatment Facility regions worldwide and currently reflects the combined experience of more than 9 million MHS beneficiary members. Maintained by the Tri-care Management Activity, M2 links claims data and demographic data to give a comprehensive view of population, clinical, and financial health utilization and cost data and is integrated with eligibility and enrollment data. M2 was used to extract associated health care costs associated with utilization of health care because of its comprehensive nature. For example, M2 includes data from both the direct care system (care provided in military treatment facilities) and commercial network claims (care provided to MHS beneficiaries at civilian facilities) worldwide. Additionally, the data collected to populate the M2 database include health care use while soldiers are deployed to areas such as Iraq or Afghanistan. Our interest in using a health care-seeking definition of experiencing LBP was driven by studies indicating continuing high rates of health care utilization for LBP [31,32], with trends of greatly increasing cost, but of no obvious benefit to the population [4,33]. In addition, the validity of self-report measures for determining LBP has been questioned for military populations [34], and use of a health care database mitigated these concerns.

Extraction of health care cost data

The M2 database was searched for relevant LBP-related International Classification of Diseases (ICD) codes for soldiers enrolled in the POLM trial. We used similar strategies to operationally define LBP as has been published in other studies, using ICD codes to identify subjects seeking health care for LBP [19,35]. Before being transferred to the investigators, all traceable person-specific identifying factors were transformed into anonymous, coded study numbers to protect subjects' privacy.

Patients were required to be continuously eligible within the database for 6 months before the index date (in addition to 24 months after the index date to define the 24-month episode of care) to identify comorbid conditions that may influence LBP prognosis, including mental health conditions (depression, anxiety, bipolar, or other psychotic disorders), neck or thoracic pain, and fibromyalgia using relevant ICD-9 codes (Table 1). Within this period, we recorded the number of unique ICD-9 diagnoses in any setting and

Table 1
ICD-9 codes that were used to identify comorbid conditions

Code	Description
Comorbid mental health conditions	
296.xx	Affective psychoses
297.xx	Delusional disorders
298.xx	Other nonorganic psychoses
300.xx	Neurotic disorders
301.xx	Personality disorders
308.xx	Acute reaction to stress
309.xx	Adjustment reaction
311.xx	Depressive disorders, not elsewhere classified
Comorbid neck/thoracic pain conditions	
721.0	Cervical spondylosis without myelopathy
721.1	Cervical spondylosis with myelopathy
721.2	Thoracic spondylosis without myelopathy
721.41	Spondylogenic compression of thoracic spinal cord
722.0	Displacement of cervical intervertebral disc without myelopathy
722.4	Degeneration of cervical intervertebral disc
722.51	Intervertebral disc disorder, thoracic, or thoracolumbar region
722.71	Intervertebral disc disorder without myelopathy—cervical
722.72	Intervertebral disc disorder without myelopathy, thoracic region
722.81	Post-laminectomy syndrome—cervical
722.91	other unspecified disc disorder—cervical region
723.xx	Other disorders of cervical region
724.1	Pain in thoracic spine
739.1	Non-allopathic lesions not otherwise specified—cervical region
805	Fracture of cervical spine without spinal cord injury
847.0	Sprains and strains of other, unspecified part of the back—neck
953.0	Injury to nerve root and spinal plexus—cervical
954.0	Injury to other nerves of trunk—cervical
Comorbid fibromyalgia	
729.1	Myalgia and myositis, unspecified

the number of prescription medications based on unique generic product identifiers. We recorded if a hospitalization occurred for any reason, if opioid medications were prescribed, and the total costs for all services during this period including inpatient, outpatient, and prescriptions.

Additional descriptive data were abstracted, as available, to permit risk-adjustment in the data analysis. We recorded the following covariates at the index date: patient's demographic information including age, race, sex, education level, and income; factors related to military status such as active duty status, time in Army; and self-report measures at baseline for physical and mental function, anxiety, depressive symptoms, fear of pain, and back beliefs.

Statistical analysis

All statistical analyses were performed using the SAS software, version 9 (SAS Institute Inc, Cary, NC, USA). Descriptive statistics, including mean, standard deviation, median, and range of all health care costs, were presented by intervention group and type of health care service. Also presented are mean and standard deviation of log-transformed costs. Both Wilcoxon rank sum test (which is based on rank scores of medical costs) and two-sample *t*-test (which is based on log-transformed test) were performed to compare the PSEP and no-PSEP groups across

Table 2
Comparison of baseline characteristics between soldiers who received PSEP versus those who did not

Variable	Label	Overall N=4,325	PSEP n=2,013	No PSEP n=2,312	p Value
Innate Characteristics					
Age (N=4,319)		22.0±4.2	22.3±4.4	21.7±4.0	<.0001
Gender	Male	3,082	1,454 (72.6%)	1,628 (70.6%)	.155
	Female	1,226	549 (27.4%)	677 (29.4%)	
Race	Black or African	420	202 (10.1%)	218 (9.4%)	.354
	Hispanic	426	183 (9.1%)	243 (10.5%)	
	White or Caucasian	3,190	1,496 (74.6%)	1,694 (73.3%)	
	Other	279	124 (6.2%)	155 (6.7%)	
Education	High school or lower	1,935	851 (42.3%)	1,084 (46.9%)	.0019
	Some college	1,998	988 (49.1%)	1,010 (43.7%)	
	College or higher	391	174 (8.6%)	217 (9.4%)	
Income	Less than \$20,000	2,125	922 (45.9%)	1,203 (52.2%)	<.0001
	Greater than \$20,000	2,188	1,085 (54.1%)	1,103 (47.8%)	
Active duty	Active	2,532	1,070 (53.2%)	1,462 (63.3%)	<.0001
	Reserve	1,782	935 (46.5%)	847 (36.7%)	
	Other	8	7 (0.3%)	1 (0.0%)	
Time in Army	<5 months	2,691	1,186 (58.9%)	1,505 (65.2%)	<.0001
	5 months–1 year	969	471 (23.4%)	498 (21.6%)	
	>1 year	661	355 (17.6%)	306 (13.3%)	
Height		68.3±3.9	68.4±3.9	68.3±3.8	.265
Weight		164.8±27.7	165.4±28.0	164.3±27.3	.188
BMI		24.8±3.1	24.8±3.2	24.7±3.1	.480
Psychological					
BDI total		6.4±6.6	6.3±6.4	6.5±6.7	.404
FPQ total		18.1±5.9	18.2±5.7	17.9±6.0	.070
BBQ total		43.4±7.1	43.1±7.1	43.6±7.0	.018
STAI		36.0±9.1	36.0±9.0	36.0±9.2	.864
Baseline health status and physical activity					
PCS total		53.4±5.2	53.3±5.2	53.5±5.2	.092
MCS total		49.2±8.6	49.1±8.6	49.2±8.6	.560
SF12 total		102.6±9.2	102.3±9.2	102.7±9.1	.134
Smoke before entering Army	Yes	1,552	736 (36.6%)	816 (35.3%)	.398
	No	2,771	1,277 (63.4%)	1,494 (64.7%)	
Exercise routinely	Yes	2,220	1,033 (51.3%)	1,187 (51.4%)	.977
	No	2,102	979 (48.7%)	1,123 (48.6%)	

BBQ, Back Beliefs Questionnaire; BDI, Beck Depression Inventory; BMI, body mass index; FPQ, Fear of Pain Questionnaire; MCS, Mental Component Subscale; PCS, Physical Component Subscale; PSEP, psychosocial education program; SF12, Short Form 12; STAI, State Trait Anxiety Index.

all types of health care costs. Demographic and baseline levels of clinical variables were compared between the two intervention groups (PSEP vs. no-PSEP) using analysis of variance for means and chi-square tests for proportions (Table 2). Variables that differed between the groups were considered in the final analyses, in addition to prespecified covariates of gender and age.

Furthermore, we estimated the effect of the intervention group based on a two-part model, adjusting for the baseline variables listed in Table 2 and considering the within-cluster correlation by including a random effect for company. The model consists of two parts: a logistic regression model for the probability of incurring health care costs (ie, having health care cost, yes/no); and conditioned on the event, a log-linear model for the amount of health care costs. Such a two-part model enables us to estimate the total health care costs for each combined levels of the intervention group and other covariates, using the product of

probability of incurring a cost and amount of cost conditioned on the event.

Role of the funding source

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Results

Figure provides information on study enrollment, assignment to the PSEP or no PSEP group, and the availability of health care cost data in the M2 database. Table 2 provides baseline characteristics based on whether soldiers received PSEP or no PSEP. Baseline differences between the groups were found in age, education, income, active duty status,

Table 3

Summary of LBP-related health care costs per soldier by PSEP group for soldiers who incurred LBP-related health care costs for at least one LBP episode during the 2-year follow-up period

Variable	Overall	PSEP	No PSEP	p Value
Number (%) with LBP related cost	n=677 (15.8%)	n=286 (14.3%)	n=391 (17.0%)	.017
Full cost				
Mean±SD	1,006.6±1,673.5	966.5±1,565.1	1,036.0±1,749.9	
Median [minimum, maximum]	431.6 [10.1, 19,029.8]	378.1 [11.4, 10,816.7]	484 [10.1, 19,029.8]	.035
log (full cost)				
Mean±SD	6.21±1.18	6.10±1.25	6.29±1.11	.033
Clinician salary				
Mean±SD	77.2±127.0	73.5±120.7	80.0±131.4	
Median [minimum, maximum]	32.9 [0, 1,069.9]	30.9 [0, 861.1]	35 [0, 1,069.9]	.246
log (clinician salary)				
Mean±SD	3.54±1.31	3.47±1.33	3.59±1.31	.259
Lab cost				
Mean±SD	44.1±66.0	38.7±52.4	48.0±74.2	
Median [minimum, maximum]	24.5 [0, 898.9]	19.5 [0, 419.3]	27.1 [0, 898.9]	.003
log (lab cost)				
Mean±SD	3.13±1.30	2.93±1.40	3.27±1.21	.0008
Other cost				
Mean±SD	474.4±939.1	479.3±987.4	470.8±903.3	
Median [minimum, maximum]	175.2 [0, 7,775.5]	160.4 [0, 7,684.2]	188.1 [0, 7,775.5]	.107
log (other cost)				
Mean±SD	5.29±1.34	5.19±1.44	5.36±1.26	.096
Other ancillary				
Mean±SD	56.0±191.1	46.1±94.2	63.3±238.0	
Median [minimum, maximum]	19.5 [0, 4,362.7]	19.2 [0, 873.8]	22.1 [0, 4,362.7]	.054
log (other ancillary)				
Mean±SD	2.85±1.61	2.72±1.60	2.95±1.62	.068
Other salary				
Mean±SD	185.9±279.8	179.4±256.2	190.7±296.1	
Median [minimum, maximum]	86.4 [0, 3,242.5]	82.8 [0, 1,569.2]	91.8 [0, 3,242.5]	.084
log (other salary)				
Mean±SD	4.54±1.26	4.43±1.37	4.63±1.17	.043
Pharmacy				
Mean±SD	102.2±175.9	88.7±139.6	112.0±197.8	
Median [minimum, maximum]	49.8 [0, 1,997.7]	41.9 [0, 1,184.1]	57.1 [0, 1,997.7]	.016
log (pharmacy)				
Mean±SD	3.71±1.57	3.54±1.62	3.83±1.52	.014
Radiology				
Mean±SD	66.8±104.1	60.6±83.2	71.4±117.0	
Median [minimum, maximum]	34.7 [0, 1,480.4]	34.1 [0, 497.6]	35.6 [0, 1,480.4]	.019
log (radiology)				
Mean±SD	3.52±1.26	3.36±1.36	3.64±1.17	.004

LBP, low back pain; PSEP, psychosocial education program.

time in the Army, company drill instructor, back beliefs, and whether the subject received a ultrasound imaging examination (Table 2); therefore, adjusted estimates were presented in subsequent two-part statistical analyses.

Table 3 presents summary statistics for LBP-related health care costs per soldier by PSEP group for soldiers who incurred LBP-related health care costs for at least one LBP episode during the 2-year follow-up period. Table 4 presents summary statistics for total health care costs per soldier by PSEP group for soldiers who incurred at least some health care costs during the 2-year follow-up period. For both Tables 3 and 4, the mean (standard deviation) and median (range) for the costs are presented. However, we emphasize reporting of median health care

costs rather than the mean because it is a better measure of central tendency when predicting the cost liability. Specifically, the median is influenced less than the mean by a few outliers among individuals who incur extraordinarily high costs. This is consistent with the reporting of health care cost data in the medical literature [36]. LBP-related and total health care costs are further categorized based on the type of health care service that was incurred (clinician salary, other salary, pharmacy, radiology, laboratory, other ancillary, and other). Also presented are the mean and standard deviation of log-transformed costs. Both the nonparametric Kruskal-Wallis test (which is based on rank scores of health care costs) and analysis of variance test (which is based on log-transformed test) are provided.

Table 4

Summary of health care costs per soldier by PSEP group for soldiers who incurred at least some health care costs during the 2-year follow-up period

Variable	Overall	PSEP	No PSEP	p value
Number (%) with Cost	n=3,913 (91.1%)	n=1,821 (91.3%)	n=2,092 (90.9%)	.679
Full cost				
Mean±SD	4,621.0±6,806.8	4,322.9±6,322.4	4,880.6±7,193.4	
Median [minimum, maximum]	2,363.1 [8.1, 109,842.4]	2,199.2 [8.3, 83,874.5]	2,556.4 [8.1, 10,9842.4]	.0001
log (full cost)				
Mean±SD	7.70±1.32	7.62±1.33	7.77±1.30	.0002
Clinician salary				
Mean±SD	378.5±574.2	360.2±553.6	394.3±591.2	
Median [minimum, maximum]	189.4 [0, 8,316.4]	176.3 [0, 8,085.2]	201.4 [0, 8,316.4]	.011
log (clinician salary)				
Mean±SD	5.17±1.35	5.11±1.37	5.22±1.34	.008
Lab cost				
Mean±SD	223.5±326.5	204.5±293.0	240.1±352.3	
Median [minimum, maximum]	113.5 [0, 4,626.3]	103.5 [0, 3,119]	121.6 [0, 4,626.3]	<.0001
log (lab cost)				
Mean±SD	4.64±1.37	4.55±1.37	4.71±1.37	.000
Other cost				
Mean±SD	1,984.5±3,223.7	1,871.3±3,154.0	2,083.0±3,280.7	
Median [minimum, maximum]	988.4 [0, 63,794.3]	931 [2.2, 52,237.1]	1,076.5 [0, 63,794.3]	.0001
log (other cost)				
Mean±SD	6.83±1.33	6.74±1.35	6.91±1.30	.0001
Other ancillary				
Mean±SD	350.2±749.5	324.7±681.2	372.3±803.7	
Median [minimum, maximum]	112.6 [0, 15,561.6]	100.1 [0, 10,053.9]	123.5 [0, 15,561.6]	.006
log (other ancillary)				
Mean±SD	4.66±1.67	4.61±1.63	4.72±1.71	.040
Other salary				
Mean±SD	986.9±1,418.0	911.4±1,281.1	1,052.6±1,524.4	
Median [minimum, maximum]	524.6 [0, 21,734.5]	483.6 [2.2, 13,185.8]	565.4 [0, 21,734.5]	<.0001
log (other salary)				
Mean±SD	6.14±1.37	6.04±1.37	6.22±1.35	.0001
Pharmacy				
Mean±SD	453.2±767.1	422.6±679.7	479.9±835.1	
Median [minimum, maximum]	195.5 [0, 11,237.7]	177.9 [0, 7,570.5]	215.8 [0, 11,237.7]	.002
log (pharmacy)				
Mean±SD	5.14±1.57	5.07±1.56	5.21±1.58	.008
Radiology				
Mean±SD	244.3±347.0	228.1±312.7	258.4±373.8	
Median [minimum, maximum]	126.6 [0, 5,027.6]	115.9 [0, 2,961.3]	136.2 [0, 5,027.6]	.001
log (radiology)				
Mean±SD	4.75±1.36	4.67±1.37	4.81±1.35	.001

PSEP, psychosocial education program.

Summary statistics for health care costs related to LBP

There were 677 (15.8%) soldiers who incurred health care costs for at least one LBP episode during the 2-year follow-up period. As expected and consistent with the primary findings, fewer soldiers who received PSEP incurred LBP-related health care costs (n=286, 14.3%) compared with those who did not receive PSEP (n=391, 17.0%) (p=.017) (Table 3). The median LBP-related health care costs per soldier who incurred costs attributable to at least one episode of LBP during the 2-year follow-up period was \$432 (range=\$10–\$19,030). Soldiers who received PSEP had significantly lower median LBP-related health care costs over the 2-year follow-up period (\$378 [range=\$11–\$10,817]) compared with those who did not

receive PSEP (\$484 [range=\$10–\$19,030]) (p=.035 with Wilcoxon rank sum test) (Table 3).

Summary statistics for total health care costs

Over the 2-year follow-up, the number of soldiers captured in the M2 database was 4,147/4,325 (95.9%). Among the 4,296 soldiers included in the data analysis (after excluding 29 with missing covariate information), 3,913 (91.1%) incurred at least some health care costs during the 2-year follow-up period. No differences existed in the number of soldiers who incurred at least some health care costs based on whether the soldier received PSEP (n=1,821, 91.3%) or not (n=2,092, 90.9%) (p=.679) (Table 4). The median total health care costs per soldier

Table 5
Effect of covariates on LBP-related costs estimated based on a two-part model (PSEP)

Variable	Label	Predicted probability of having LBP related medical cost	Predicted LBP related conditional cost (\$)	Predicted cost by two-part model (\$)	Predicted cost difference from reference (\$)
PSEP	No	0.1665	516.99	86.07	26
	Yes	0.1498	399.04	59.78	0
Gender	Male	0.1665	516.99	86.07	-69
	Female	0.3315	466.49	154.63	0
Race	Black or Africa	0.1917	723.62	138.74	26
	Hispanic	0.1929	591.84	114.15	2
	White or Caucasian	0.1665	516.99	86.07	-26
	Other	0.18	624.77	112.46	0
Education	High school or lower	0.1578	463.51	73.15	5
	Some college	0.1665	516.99	86.07	17
	College or higher	0.1291	530.97	68.57	0
Income	Less than \$20,000	0.1336	471.93	63.07	-23
	Greater than \$20,000	0.1665	516.99	86.07	0
Active duty Status	Active	0.1665	516.99	86.07	42
	Reserve	0.0799	548.16	43.82	0
Smoke before entering Army	Yes	0.2025	555.1	112.4	26
	No	0.1665	516.99	86.07	0
Time in Army	<5 months	0.1665	516.99	86.07	14
	5 months–1 year	0.1372	447.57	61.39	-11
	<1 year	0.1384	520.55	72.03	0
Exercise routinely	Yes	0.1665	516.99	86.07	11
	No	0.1589	470.78	74.81	0
Last APFT score	<150	0.1791	336.01	60.17	-85
	150–200	0.1844	627.11	115.65	-30
	200–250	0.1665	516.99	86.07	-59
	250–300	0.159	611.74	97.29	-48
	>300	0.1674	867.57	145.23	0
Profiled [†]	Yes	0.2012	582.86	117.29	31
	No	0.1665	516.99	86.07	0
Physical/USI exam	No	0.1665	516.99	86.07	-16
	Yes	0.1792	571.16	102.33	0

APFT, Army Physical Fitness Test; LBP, low back pain; PSEP, psychosocial education program; USI, ultrasound imaging.

who incurred at least some health care costs during the 2-year follow-up period was \$2,363 (range=\$8–\$109,842). Soldiers who received PSEP had significantly lower median total health care costs over the 2-year follow-up period (\$2,199 [range=\$8–\$83,875]) compared with those who did not receive PSEP (\$2,556 [range=\$8–\$109,842]) (p=.0001 with Wilcoxon rank sum test) (Table 4).

Statistical analysis results based on two-part model

Tables 5 and 6 present the estimated probability of having any LBP-related and total health care costs, respectively. In addition, they show the predicted conditional cost as well as the product of the two parts, which estimates the expected costs, including all visits. Table 5 presents the results when the costs were restricted to LBP-related visits. Soldiers who received PSEP had LBP-related costs that were \$26 lower per soldier compared with those who did not receive PSEP (\$60 vs. \$86, respectively, p=.034) (Table 5). After adjusting for other factors, soldiers who received PSEP had total health care costs that were only \$2

lower per soldier compared with those who did not receive PSEP (\$2,439 vs. \$2,441, respectively, p=.242) (Table 6).

Discussion

Common chronic pain conditions affect at least 116 million U.S. adults at a cost of \$560 to \$635 billion annually in direct medical treatment costs and lost productivity [22]. A recent report from the Institute of Medicine was published to increase the recognition of pain as a significant public health problem in the United States and provide a roadmap for transforming the way pain is understood, assessed, treated, and prevented [22]. However, despite increasing medical expenditures dedicated toward its management, the prevalence of chronic, disabling LBP in particular continues to increase [4,31] and is among the most frequent causes of medical visits and lost-duty time in the MHS [37]. Moreover, LBP is the primary complaint of 53% of soldiers in Operation Iraqi Freedom/Operation Enduring Freedom who presented to military pain management center [8] and is a leading cause of medical evacuations from Iraq and Afghanistan [6], with only 2% returning to combat

Table 6
Effect of covariates on total health care costs estimated based on a two-part model (PSEP)

Variable	Label	Predicted probability of having LBP related medical cost	Predicted LBP related conditional cost (\$)	Predicted cost by two-part model (\$)	Predicted cost difference from reference (\$)
PSEP	No	0.9556	2,554.29	2,440.98	2
	Yes	0.9631	2,532.14	2,438.72	0
Gender	Male	0.9556	2,554.29	2,440.98	-2,451
	Female	0.9763	5,010.43	4,891.91	0
Race	Black or African	0.9534	2,852.49	2,719.46	141
	Hispanic	0.9565	2,647.15	2,531.91	-46
	White or Caucasian	0.9556	2,554.29	2,440.98	-137
	Other	0.9618	2,680.5	2,578.14	0
Education	High school or lower	0.9507	2,591.26	2,463.53	275
	Some college	0.9556	2,554.29	2,440.98	252
	College or higher	0.9387	2,331.87	2,188.99	0
Income	<\$20,000	0.9553	2,508.65	2,396.41	-45
	>\$20,000	0.9556	2,554.29	2,440.98	0
Active duty status	Active	0.9556	2,554.29	2,440.98	1,818
	Reserve	0.826	754.06	622.83	0
Smoke before entering Army	Yes	0.9589	2,789.22	2,674.59	234
	No	0.9556	2,554.29	2,440.98	0
Time in Army	<5 months	0.9556	2,554.29	2,440.98	-27
	5 months–1 year	0.9536	2,312.58	2,205.19	-263
	>1 year	0.9297	2,654.76	2,468.16	0
Exercise routinely	Yes	0.9556	2,554.29	2,440.98	-99
	No	0.9541	2,662.23	2,539.96	0
Last APFT score	<150	0.8948	2,746.89	2,457.93	86
	150–200	0.957	3,042.64	2,911.7	540
	200–250	0.9556	2,554.29	2,440.98	69
	250–300	0.9582	2,402.67	2,302.13	-69
	>300	0.9735	2,436.07	2,371.55	0
Profiled	Yes	0.9646	3,432.33	3,310.98	870
	No	0.9556	2,554.29	2,440.98	0
Physical/USI exam	No	0.9556	2,554.29	2,440.98	61
	Yes	0.9684	2,458.02	2,380.38	0

APFT, Army Physical Fitness Test; LBP, low back pain; PSEP, psychosocial education program; USI, ultrasound imaging.

duty [8]. A recent study among veterans treated in a Veterans Administration regional health care network also found that LBP was significantly associated with increased risk of high-dose opioid use [38]. Moreover, in fiscal year 2010 (October 1, 2009, through September 30, 2010), approximately 70,000 individuals were recruited into the U.S. Army [39]. Therefore, it is understandable why identifying effective primary prevention strategies and their implications on subsequent health care costs is an important research priority.

In the primary analysis of the POLM trial, brief psychosocial education prevented LBP episodes regardless of the assigned exercise approach, resulting in a 3.3% (95% CI: 1.1–5.5%) decrease over 2 years (numbers needed to treat=30.3, 95% CI=18.2–90.9) [13]. Given the frequency of experiencing LBP and the high costs associated with its management, exploring the magnitude of cost savings with PSEP was an important further consideration. Table 2 illustrates that the two groups were significantly different in several characteristics at baseline. For example, the PSEP group had 2% more male soldiers and 10% fewer soldiers on active duty, two factors that had a meaningful impact on health care costs, both favoring

the PSEP group in the direction of lower health care costs. Therefore, it is important to interpret the results based on the more conservative adjusted estimates derived in the subsequent two-part statistical analyses presented in Tables 5 and 6. Total adjusted median health care costs for Soldiers who received PSEP and incurred at least some health care costs during the 2-year follow-up period were estimated at only \$2 per soldier lower than for those who did not receive PSEP (\$2,439 vs. \$2,441, respectively, $p=.242$) (Table 5). We expect that the relative effect of PSEP on reducing LBP-related costs should be greater than the effect on total health care costs, which makes intuitive sense because PSEP is hypothesized to have a more pronounced and specific effect on LBP-related costs based on the underlying intent of psychosocial education, which in the POLM trial was to reduce the fear and threat of LBP [14]. Although there was indeed more relative effect of PSEP on reducing LBP-related costs, it was only marginally greater than the effect on total health care costs. Total adjusted median LBP-related health care costs for soldiers who received PSEP and incurred LBP-related costs during the 2-year follow-up period were \$26 per soldier lower than for those who did not receive PSEP (\$60 vs. \$86,

respectively, $p=.034$) (Table 6). However, when put into context of actual cost savings in the POLM trial, the results are somewhat unremarkable. For example, had the 1,995 soldiers in the PSEP group not received PSEP, we would estimate that 16.7% of them would incur an adjusted median LBP-related health care cost of \$517 compared with the current 15.0% Soldiers incurring an adjusted median cost of \$399, which translates into an actual LBP-related health care cost savings of \$52,846 during the POLM trial.

Understanding the implications of psychosocial education on the implications of costs associated with specific types of health care services may assist policy-makers in the design of better care processes for patients with LBP. For example, overuse of expensive and often invasive examination procedures and treatments such as drugs and imaging have been shown to be of limited benefit for patients with LBP [33]. In this case, it is important to consider the direct and indirect costs of administering PSEP in the POLM trial. For example, there was negligible lost productivity because the PSEP was delivered within the existing training schedule. Although modest, the direct cost of materials used in the PSEP (ie, Back Book) costs approximately \$1 USD per soldier. Furthermore, given the minimal difference in cost between groups, even a modest estimate of total direct and indirect costs of administering PSEP (eg, instructor and other indirect costs such as space, utilities) may exceed any LBP-related cost savings that could be realized with PSEP. Therefore, more research should be conducted to determine if PSEP should be implemented on a widespread scale, despite our findings from the primary trial results indicating a 3.3% reduction in LBP incidence over 2 years [13].

The results of this analysis in a primary prevention model are more conservative than the results from other studies that have explored the cost-effectiveness of a psychosocial-focused approach in a primary care treatment model for patients already having LBP [40]. Therefore, it may be that secondary prevention strategies currently offer more potential to reduce the epidemic of LBP than primary prevention strategies direct to the broader population, many of whom may develop clinically relevant LBP and/or recover without needing to access the health care system. Another important consideration when interpreting the results of this analysis is that the PSEP was brief because of the soldiers' busy training syllabus; thus, we had limited access to their time outside of training hours. Therefore, to maintain the feasibility of implementing psychosocial education throughout military training environments, we elected to deliver the psychosocial education program in a group setting during a single 1-hour session. One of the potential criticisms of this approach is that the psychosocial education program may have been underdosed. However, despite the pragmatic nature of the trial, the positive effect of the psychosocial education program on reducing health care-seeking for LBP was encouraging [13]. Future research

might consider whether an enhanced dose of PSEP achieves an increased reduction in LBP incidence and potentially a greater cost savings than what was realized in the POLM trial.

One of the strengths of this analysis is that we had a large randomized sample, thus we were able to achieve a high degree of precision in the reporting of the results. Many cost-effectiveness studies with similarly large sample sizes are not randomized or might be randomized but have a small sample. However, given the baseline differences between the groups on several meaningful confounding factors, it is possible that differences on factors that were not collected may also exist. This could contribute to additional confounding that may further attenuate any cost benefit. Another limitation is that we did not calculate cost-effectiveness using commonly reported statistics (ie, quality-adjusted life years) because we were unable to directly assess the cost of delivering the psychosocial education program because it was delivered by the research team. The POLM trial was limited to Army soldiers completing training for a specific occupational specialty (combat medic). It is unknown whether similar findings would be observed in other military services, different occupational specialties, or outside of the training environment.

Conclusion

A brief PSEP achieved only modest savings that were specific to LBP-related health care costs. Furthermore, it is likely that unaccounted for direct and indirect costs might erase even these small cost savings. Therefore, more research is needed to determine if PSEP should be implemented on a widespread scale. The results of this study have important implications on policy- and decision-making regarding the feasibility of implementing psychosocial education in military training environments. It would be interesting to explore in future research whether cost savings from psychosocial education could be enhanced given a more individualized delivery method tailored to an individual's specific psychosocial risk factors.

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