Original Investigation

Early Physical Therapy vs Usual Care in Patients With Recent-Onset Low Back Pain
A Randomized Clinical Trial

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IMPORTANCE Low back pain (LBP) is common in primary care. Guidelines recommend delaying referrals for physical therapy.

OBJECTIVE To evaluate whether early physical therapy (manipulation and exercise) is more effective than usual care in improving disability for patients with LBP fitting a decision rule.

DESIGN, SETTING, AND PARTICIPANTS Randomized clinical trial with 220 participants recruited between March 2011 and November 2013. Participants with no LBP treatment in the past 6 months, aged 18 through 60 years (mean age, 37.4 years [SD, 10.3]), an Oswestry Disability Index (ODI) score of 20 or higher, symptom duration less than 16 days, and no symptoms distal to the knee in the past 72 hours were enrolled following a primary care visit.

INTERVENTIONS All participants received education. Early physical therapy (n = 108) consisted of 4 physical therapy sessions. Usual care (n = 112) involved no additional interventions during the first 4 weeks.

MAIN OUTCOMES AND MEASURES Primary outcome was change in the ODI score (range: 0-100; higher scores indicate greater disability; minimum clinically important difference, 6 points) at 3 months. Secondary outcomes included changes in the ODI score at 4-week and 1-year follow-up, and change in pain intensity, Pain Catastrophizing Scale (PCS) score, fear-avoidance beliefs, quality of life, patient-reported success, and health care utilization at 4-week, 3-month, and 1-year follow-up.

RESULTS One-year follow-up was completed by 207 participants (94.1%). Using analysis of covariance, early physical therapy showed improvement relative to usual care in disability after 3 months (mean ODI score: early physical therapy group, 41.3 [95% CI, 38.7 to 44.0] at baseline to 6.6 [95% CI, 4.7 to 8.5] at 3 months; usual care group, 40.9 [95% CI, 38.6 to 43.1] at baseline to 9.8 [95% CI, 7.9 to 11.7] at 3 months; between-group difference, −3.2 [95% CI, −5.9 to −0.47], P = .02). A significant difference was found between groups for the ODI score after 4 weeks (between-group difference, −3.5 [95% CI, −6.8 to −0.08], P = .045]), but not at 1-year follow-up (between-group difference, −2.0 [95% CI, −5.0 to 1.0], P = .19). There was no improvement in pain intensity at 4-week, 3-month, or 1-year follow-up (between-group difference, −0.42 [95% CI, −0.90 to 0.02] at 4-week follow-up; −0.38 [95% CI, −0.84 to 0.09] at 3-month follow-up; and −0.17 [95% CI, −0.62 to 0.27] at 1-year follow-up). The PCS scores improved at 4 weeks and 3 months but not at 1-year follow-up (between-group difference, −2.7 [95% CI, −4.6 to −0.85] at 4-week follow-up; −2.2 [95% CI, −3.9 to −0.49] at 3-month follow-up; and −0.92 [95% CI, −2.7 to 0.61] at 1-year follow-up). There were no differences in health care utilization at any point.

CONCLUSIONS AND RELEVANCE Among adults with recent-onset LBP, early physical therapy resulted in statistically significant improvement in disability, but the improvement was modest and did not achieve the minimum clinically important difference compared with usual care.

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Lifetime prevalence of low back pain (LBP) is about 70%, and 25% of adults report LBP lasting at least 1 day in the past 3 months.[1] Back pain accounts for 2% to 5% of all physician visits.[1,2] Health care costs for LBP in the United States were approximately $86 billion in 2005,[3] and have been increasing faster than overall health care spending.[3,4] Despite increasing resource use, rates of poor outcomes for LBP are increasing.[5,6]

Most patients with LBP who seek care begin in primary care.[7] Initial management decisions in this setting may be highly influential on outcomes. Early use of magnetic resonance imaging or opioids, which contradicts current practice guidelines,[8] is associated with higher rates of prolonged disability and invasive procedures.[9-11] The effect of early physical therapy is unclear. Guidelines advise delaying referral to physical therapy or other specialists for a few weeks to permit spontaneous recovery.[12] Recent observational studies report early physical therapy is associated with lower costs and reduced risk of invasive procedures when compared with delayed referral,[9,13] suggesting that some patients may benefit from early physical therapy. Prior research has described a decision rule identifying a subgroup of patients who have excellent results from physical therapy involving manipulation and exercise.[14,15] The subgroup defined by this rule includes patients with acute LBP (<16 days duration) without symptoms extending below the knee(s). This subgroup may be particularly likely to benefit from early physical therapy using a protocol of exercise and manipulation.

This study compared the efficacy of early physical therapy of 4 sessions of manipulation and exercise with usual care for patients with LBP seen in primary care fitting the decision rule criteria. Our primary aim was to evaluate change in disability from baseline to 3 months. Secondary outcomes included evaluating changes in disability after 4 weeks and 1 year, and examining change in pain intensity, pain catastrophizing, fear-avoidance beliefs, patient-reported health state and success, and health care utilization.

Methods

Study Design and Participants

Study protocol was approved by the University of Utah and Intermountain Healthcare institutional review boards (Supplement 1). A data and safety monitoring board met annually to review the study. This study was a parallel-group randomized clinical trial. Outcomes were assessed in a blinded manner at 4 weeks, 3 months, and 1 year following enrollment. The primary outcome was disability assessed with the Oswestry Disability Index (ODI) score at 3-month follow-up. Secondary outcomes included change in the ODI score measured after 4 weeks and 1 year, and change in other patient-reported outcomes (described below) measured after 4 weeks, 3 months, and 1 year.

Individuals with LBP visiting a primary care physician in Salt Lake City, Utah, from March 2011 through November 2013 were recruited. Potential participants were informed of the study by clinic staff or by mail using electronic medical records to identify primary care visits with an *International Classification of Diseases, Ninth Revision*, LBP diagnosis (diagnosis codes: 719.55, 721.3, 722.1, 722.52, 722.73, 722.83, 722.93, 724, 729.2, 737.3, 756.11, 756.12, 846, 847.2, 847.3, or 847.9). A letter describing the study was mailed with an opt-out option, followed by telephone contact. Interested individuals were scheduled for evaluation. After providing written informed consent participants underwent a baseline evaluation followed by random assignment to an intervention group.

Eligibility requirements were aged 18 through 60 years with LBP (defined as pain between the 12th rib and buttocks), ODI score of 20 or higher, current symptoms duration of less than 16 days, and no pain or numbness distal to the knee(s) in the past 72 hours. These criteria identified a subgroup of patients likely to respond to the physical therapy protocol in this study.[14] Exclusion criteria were prior lumbar surgery, pregnancy, any other LBP treatment in the past 6 months, clinical signs of nerve root compression (eg, hyporeflexia) or any "red flag" finding suggesting nonmusculoskeletal back pain (eg, infection or neoplasm).

Outcome Assessments

A baseline assessment was conducted before randomization and included all primary and secondary outcomes and demographic information. Patients self-reported race/ethnicity using categories predefined for federally sponsored research. Four-week assessment was conducted in-person by an assessor who was blinded to randomization. Additional assessments were conducted through a study website. The primary outcome was the ODI score, a validated 10-item measure of function for individuals with LBP.[16] Items assessed limitations due to LBP in activities including standing, sitting, walking, pain intensity, lifting, sleeping, social life, employment/homemaking, personal care, and traveling. Scores range from 0 to 100 with higher scores indicating greater disability.[17] The minimum clinically important difference for the ODI was estimated at 6 points for acute LBP.[17]

Secondary outcomes assessed at 4-week, 3-month, and 1-year follow-up included a numeric pain rating of LBP severity (range, 0-10),[18] Pain Catastrophizing Scale (PCS),[19] Fear-Avoidance Beliefs Questionnaire (FABQ) for physical activity, FABQ for work,[20] and a 15-point global rating of change[21] dichotomized to define patient-reported success as occurring when 1 of the top 2 ratings were selected ("a great deal better" or "a very great deal better"). The 5-Dimensional EuroQol (EQ-5D) tool assessed quality of life based on 5 domains (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), each rated on a scale of 1-3, then combined to generate a comprehensive score ranging from 0 (extremely poor quality of life) to 1 (optimal quality of life).[22] Patients self-rated their overall health using the EQ-5D visual analog scale ranging from 0 (worst) to 100 (best imaginable) health. We used monthly online diaries to collect health care utilization for LBP[23] including advanced imaging (computed tomography or magnetic resonance imaging), emergency department or urgent care visit, spine specialist visit (surgeon or physiatrist), spinal injection, or surgery.

Adverse effects of early physical therapy were assessed after 4 weeks with a questionnaire asking "Did you experience any discomfort or unpleasant reaction after any of your physical therapy treatment sessions?" For those responding "yes," adverse effect categories (eg, increased pain or stiffness) were offered. Severity of each adverse effect was rated as light, mild, moderate, or severe.[24]

Randomization

Following baseline evaluation participants were randomized to early physical therapy or usual care following a computer-generated randomization list with randomly varying block sizes of 4 and 8 prepared by the study statisticians prior to beginning enrollment. Sealed envelopes containing the assignment were used to conceal allocation.

Interventions

Following baseline examination but before randomization, all participants were educated about the favorable prognosis of LBP and advised to remain as active as possible. Participants were given a copy of *The Back Book*,[25] and the contents were reviewed with the researcher. *The Back Book* provides messages consistent with LBP guidelines.[8,12,26] All participants were advised to follow-up with their primary care physician as needed. The usual care group received no further intervention.

The early physical therapy group began treatment within 72 hours of enrollment with a physical therapist trained in study procedures. Four treatment sessions were scheduled over 3 weeks (2 sessions in week 1, followed by 2 weekly sessions). Each session began with an assessment. In session 1, the assessment was followed by spinal manipulation using the technique specified in the development of the decision rule.[15] The technique begins with the patient in a supine position. Then the physical therapist side bends and rotates the patient's spine and then provides a high-velocity, low-amplitude thrust to the pelvis. After spinal manipulation, the physical therapist provided instruction in spinal range-of-motion exercises. Participants were instructed to perform 10 exercise repetitions 3 to 4 times throughout the day. Session 2 was scheduled 2 to 3 days after the first session and began with the manipulation followed by a review of range-of-motion exercises and instruction in trunk-strengthening exercises designed to strengthen the primary stabilizing muscle of the lumbar spine, with some evidence of reducing risk of LBP recurrence.[27] The third and fourth sessions were scheduled at 1-week intervals and involved exercise review and progression (eAppendix 1 in the Supplement 2).

Power and Statistical Analysis

Sample size for the primary outcome, change in ODI score from baseline to 3 months after randomization, was based on detecting a 7-point difference (assumed SD, 16)[14,28,29] or an effect size of 0.44. Enrollment of 110 participants per group (N = 220) provided at least 86% power to detect this effect with 2-sided α of 0.05 assuming at least a 90% follow-up rate.

Baseline characteristics were summarized by treatment group. Analyses of primary and secondary outcomes were conducted by intention-to-treat with participants analyzed according to a randomly assigned treatment group irrespective of compliance. Multiple imputation was used for missing observations. Fully sequential imputation[30] was used to generate 10 imputed data sets using available primary and secondary outcome scores, treatment group, employment status, sex, age, marital status, education, prior history of LBP, and smoking. To provide distinct evaluations of treatment effects at different follow-up times, separate analyses of covariance were used to compare mean change in each continuous outcome from baseline with each follow-up between groups controlling for baseline level of outcome. The χ^2 or Fisher exact tests were used to compare proportions of participants self-reporting health care utilization outcomes. Relative risk was used to compare patient-reported success between groups.[31] We conducted a secondary, per-protocol analysis including only participants in the usual care group who did not receive physical therapy during the first 4 weeks, and those in the early physical therapy group who received a protocol-compliant episode defined as attending at least 3 treatment sessions in the first 4 weeks and receiving spinal manipulation at each of the first 2 sessions. Analyses used a 2-sided α of 0.05 without adjustment for multiple comparisons using SAS (SAS Institute), version 9.4.

Results

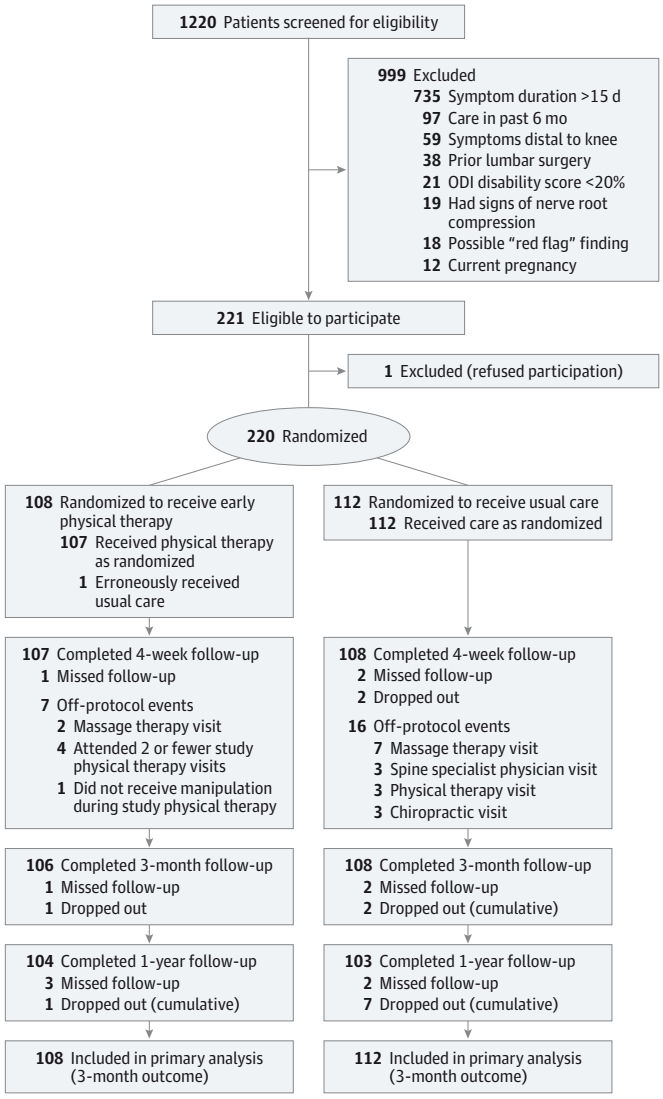
From March 2011 to November 2013, 1220 potentially eligible individuals were identified from which 220 participants enrolled (**Figure**). Randomization assigned 112 participants to usual care and 108 participants to early physical therapy. One participant randomized to early physical therapy was erroneously assigned to usual care. This participant was analyzed with the early physical therapy group for primary analyses. Eight participants (3.6% of the total participants; 7 in the usual care group and 1 in the early physical therapy group) dropped out of the study; 7 participants gave no reason, 1 participant cited family responsibilities. One-year follow-up was completed by 207 participants (94.1%).

The mean age was 37.4 years (SD, 10.3), 115 participants (52.3%) were women, the mean body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) was 29.1 (SD, 7.9), and 16 participants (7.3%) were current smokers (**Table 1**). Table 1 shows characteristics of the 2 groups at baseline.

Intervention Adherence

The early physical therapy group attended 97.2% of the scheduled treatment sessions. Ninety-nine participants (92.5%) attended all 4 sessions, and 8 participants attended 2 or 3 sessions. One participant did not receive the manipulation portion of the protocol and another participant received manipulation at the fourth session in contradiction to the protocol; otherwise sessions were consistent with the protocol. Two participants in the early physical therapy group received massage therapy during the first 4 weeks of the study in contradiction to the protocol. Sixteen participants (14.3%) in the usual care

Figure. Participant Recruitment and Retention



ODI indicates Oswestry Disability Index.

group deviated from the protocol during the first 4 weeks; 7 participants received massage therapy, 3 participants received physical therapy, 3 participants received chiropractic care, and 3 participants received a spine specialist physician visit (2 participants visited a physiatrist and 1 participant visited an orthopedic surgeon).

Early Physical Therapy Adverse Effects

Thirteen participants receiving early physical therapy (12.0%) reported a total of 20 adverse effects from treatment including increased pain (1 mild, 4 moderate, 2 severe, and 1 no severity given), stiffness (2 mild, 3 moderate, 1 severe, and 1 no severity given), spasm (1 severe and 1 no severity given), shooting pain (1 moderate and 1 no severity given), and fatigue (1 mild).

Primary and Secondary Outcomes

Early physical therapy showed significant improvement compared with usual care for the primary outcome (ODI score) at 3 months (mean difference, −3.2 [95% CI, −5.9 to −0.47], P = .02). The ODI score also showed significantly greater improvement for early physical therapy after 4 weeks but not after 1 year (**Table 2**). Some secondary outcomes showed statistically significant differences favoring greater improvement in the early physical therapy group particularly at 3 months. These included PCS score, fear-avoidance beliefs for work, and patients' self-rating of success and self-rating of their overall health (Table 2 and **Table 3**). However, many secondary outcomes showed no statistically significant benefit for early physical therapy at 3 months and/or other follow-up time points (Table 2 and Table 3). For example, there were no significant differences in pain intensity or the FABQ for physical activity at any time point. There was no difference in the FABQ for work score at the 4-week or 1-year follow-up and there was no difference in the EQ-5D quality-of-life score at the 4-week or 3-month follow-up. There were no statistically significant

differences between groups for health care utilization outcomes at any follow-up (Table 3).

Per-Protocol Analysis

Per-protocol analysis excluded 3 participants from the usual care group who received physical therapy in the first 4 weeks and 5 participants in the early physical therapy group who did not receive a compliant physical therapy episode. The participant randomized to early physical therapy who erroneously received usual care was included in the usual care group. Results were similar to primary analyses with a significant difference in the primary outcome ODI score at 3 months favoring greater improvement for early physical therapy (mean difference, −3.7 [95% CI, −0.93 to −6.4], $P = .01$). Per-protocol analyses found significantly greater levels of patient-reported success at 4 weeks and 3 months and significantly greater improvement in pain ratings favoring early physical therapy after 4 weeks and 3 months (eAppendix 2 in the Supplement 2). However, many secondary outcomes showed no statistically significant benefit for early physical therapy at 1 year and/or other follow-up time points. There were no statistically significant differences between groups after 1 year for the ODI score, numeric pain rating, FABQ score for work, PCS score, or patient self-rating of success outcomes. The FABQ score for physical activity and health care utilization outcomes did not differ between groups at any time point.

Table 1. Baseline Participant Characteristics

	No. (%)	
	Usual Care (n = 112)	Early Physical Therapy (n = 108)
Age, mean (SD), y	36.5 (10.2)	38.3 (10.4)
Women	53 (47.3)	62 (57.4)
Race/ethnicity		
White	89 (79.5)	89 (82.4)
Hispanic	13 (11.6)	5 (4.6)
African American	2 (1.8)	3 (2.8)
Other/multiracial	8 (7.1)	11 (10.2)
BMI, mean (SD)	29.2 (8.5)	28.9 (7.3)
Married/live with significant other	69 (61.6)	69 (63.9)
Education		
Completed high school	110 (98.2)	106 (98.1)
Completed degree after high school	49 (43.8)	59 (54.6)
Employment status (employed outside the home)	92 (82.1)	92 (85.2)
Comorbid health conditions		
Diabetes	6 (5.4)	3 (2.8)
Hypertension	10 (8.9)	8 (7.4)
Anxiety/depression	31 (27.7)	28 (25.9)
Upper back/neck pain	37 (33.0)	43 (39.8)
Current medications for back pain		
Nonsteroidal anti-inflammatory	74 (66.1)	73 (67.6)
Opioids	30 (26.8)	29 (26.9)
Muscle relaxers	61 (54.5)	62 (57.4)
Steroid anti-inflammatory	16 (14.3)	10 (9.3)
Other	8 (7.1)	4 (3.7)
Current smoker	7 (6.3)	9 (8.3)
History of treated low back pain	72 (64.3)	74 (68.5)
ODI score, mean (SD)	40.9 (12.1)	41.3 (14.1)
Numeric pain rating, mean (SD)[a]	5.1 (1.9)	5.3 (1.8)
FABQ score, mean (SD)		
Physical activity	15.4 (4.9)	14.8 (4.9)
Work	12.1 (8.9	11.3 (9.0)
PCS score, mean (SD)[b]	13.8 (10.1)	13.9 (11.0)
EQ-5D score, mean (SD)		
Quality of life	0.67 (0.2)	0.65 (0.2)
Overall health self-rating[c]	66.3 (19.4)	68.3 (16.5)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); EQ-5D, 5-Dimensional EuroQol; FABQ, Fear-Avoidance Beliefs Questionnaire; ODI, Oswestry Disability Index; PCS, Pain Catastrophizing Scale.

[a] Three missing scores (1 early physical therapy, 2 usual care), means reflect multiple imputation for missing scores.

[b] One missing score (1 usual care), mean reflects multiple imputation for missing score.

[c] One missing score (1 early physical therapy), mean reflects multiple imputation for missing score.

Discussion

This randomized clinical trial enrolled adults with recent-onset LBP following a primary care visit and compared early physical therapy with usual care (no additional intervention beyond education) during the first 4 weeks. The primary outcome was change in disability, measured by the ODI score, after 3 months. Early physical therapy resulted in statistically significant improvement in disability relative to usual care but the magnitude of the difference was modest and did not achieve the minimum difference considered clinically important at the individual patient level. There was no difference between groups in the ODI score at 1-year follow-up. Results for other secondary outcomes were mixed. Results favored early physical therapy at 3-month follow-up for outcomes of patient-reported success and overall health, PCS score, and fear-avoidance beliefs for work. Most differences between groups were modest. There were no improvements in pain intensity or the FABQ for physical activity outcome at any time point. There was no benefit for the EQ-5D quality-of-life outcome at 4-week or 3-month follow-up and many other secondary outcomes also showed no benefit. Health care utilization at each follow-up did not differ between groups.

Primary care physicians are typically the first-contact provider for patients with LBP in the United States. Guideline-discordant decisions at initial contact are associated with increased risk for prolonged disability and invasive procedures.[10,11,13] Referral to physical therapy is not advised in the first few weeks following initial contact in many guidelines with the rationale that a majority of patients recover rapidly regardless.[12,32] Observational studies involving large Medicare[33] and privately insured[9] samples report higher costs and greater risk for invasive procedure when physical therapy is delayed beyond 2 to 4 weeks, suggesting referral at

Table 2. Primary and Secondary Outcomes for Early Physical Therapy vs Usual Care for Recent-Onset Low Back Pain

Outcome	Visit	Usual Care		Early Intervention		Mean Difference Between Groups in Change from Baseline[a]	*P* Value
		Mean Score	Mean Change From Baseline	Mean Score	Mean Change From Baseline		
Primary Outcome							
ODI score (0-100 scale; higher scores indicate worse function)[b]	Baseline	40.9 (38.6 to 43.1)		41.3 (38.7 to 44.0)			
	4 wk	14.5 (12.1 to 17.0)	−26.6 (−29.0 to −24.1)	11.1 (8.7 to 13.4)	−30.0 (−32.4 to −27.7)	−3.5 (−6.8 to −0.08)	.045
	3 mo	9.8 (7.9 to 11.7)	−31.3 (−33.2 to −29.4)	6.6 (4.7 to 8.5)	−34.5 (−36.4 to −32.6)	−3.2 (−5.9 to −0.47)	.02
	1 y	9.0 (6.8 to 11.1)	−32.1 (−34.3 to −30.0)	7.0 (4.8 to 9.1)	−34.1 (−36.3 to −32.0)	−2.0 (−5.0 to 1.0)	.19
Secondary Outcomes							
Numeric pain rating (0-10 scale; higher scores indicate greater pain intensity)[c]	Baseline	5.1 (4.7 to 5.4)		5.3 (4.9 to 5.6)			
	4 wk	2.1 (1.8 to 2.5)	−3.0 (−3.4 to −2.7)	1.7 (1.4 to 2.1)	−3.4 (−3.8 to −3.1)	−0.42 (−0.90 to 0.02)	.09
	3 mo	1.8 (1.4 to 2.1)	−3.4 (−3.7 to −3.1)	1.4 (1.1 to 1.7)	−3.8 (−4.1 to −3.5)	−0.38 (−0.84 to 0.09)	.11
	1 y	1.4 (1.1 to 1.8)	−3.7 (−4.0 to −3.4)	1.3 (0.94 to 1.6)	−3.9 (−4.2 to −3.6)	−0.17 (−0.62 to 0.27)	.44
PCS score (0-52 scale; higher scores indicate greater pain-catastrophizing beliefs)[d]	Baseline	13.8 (12.0 to 15.7)		13.9 (11.8 to 15.9)			
	4 wk	7.6 (6.3 to 9.0)	−6.2 (−7.6 to −4.9)	4.9 (3.6 to 6.2)	−8.9 (−10.2 to −7.6)	−2.7 (−4.6 to −0.85)	.004
	3 mo	5.2 (4.0 to 6.4)	−8.6 (−9.9 to −7.4)	3.0 (1.8 to 4.2)	−10.9 (−12.1 to −9.6)	−2.2 (−3.9 to −0.49)	.01
	1 y	4.3 (3.0 to 5.5)	−9.6 (−10.8 to −8.3)	3.3 (2.1 to 4.6)	−10.5 (−11.8 to −9.3)	−0.92 (−2.7 to 0.61)	.31
FABQ score for physical activity (0-24 scale; higher scores indicate greater fear-avoidance beliefs)[e]	Baseline	15.4 (14.5 to 16.3)		14.8 (13.8 to 15.7)			
	4 wk	7.9 (6.9 to 8.9)	−7.2 (−8.2 to −6.1)	7.2 (6.2 to 8.3)	−7.8 (−8.9 to −6.8)	−0.67 (−2.2 to 0.81)	.37
	3 mo	5.7 (4.7 to 6.7)	−9.3 (−10.3 to −8.3)	5.2 (4.2 to 6.2)	−9.9 (−10.9 to −8.9)	−0.54 (−2.0 to 0.90)	.46
	1 y	5.7 (4.4 to 6.9)	−9.4 (−10.6 to −8.2)	5.7 (4.5 to 6.9)	−9.4 (−10.6 to −8.2)	−0.02 (−1.70 to 1.74)	.98
FABQ score for work (0-42 scale; higher scores indicate greater fear-avoidance beliefs)[f]	Baseline	12.1 (10.2 to 14.0)		11.3 (9.6 to 13.0)			
	4 wk	9.1 (7.8 to 10.3)	−2.7 (−4.0 to −1.4)	8.0 (6.8 to 9.3)	−3.7 (−5.0 to −2.4)	−1.0 (−2.8 to 0.82)	.28
	3 mo	7.5 (6.2 to 8.8)	−4.3 (−5.5 to −3.0)	5.2 (3.9 to 6.5)	−6.5 (−7.9 to −5.2)	−2.3 (−4.1 to −0.4)	.02
	1 y	6.2 (4.8 to 7.5)	−5.5 (−6.9 to −4.2)	5.2 (3.9 to 6.5)	−6.5 (−7.8 to −5.2)	−1.0 (−2.8 to 0.90)	.31
EQ-5D score for quality of life (0-1 scale; higher scores indicate greater quality of life)[g]	Baseline	0.67 (0.64 to 0.80)		0.65 (0.62 to 0.69)			
	4 wk	0.84 (0.82 to 0.86)	0.18 (0.15 to 0.20)	0.87 (0.85 to 0.89)	0.21 (0.19 to 0.23)	0.03 (0.0 to 0.07)	.05
	3 mo	0.88 (0.86 to 0.90)	0.22 (0.20 to 0.24)	0.91 (0.88 to 0.93)	0.24 (0.22 to 0.27)	0.03 (−0.01 to 0.06)	.10
	1 y	0.88 (0.86 to 0.90)	0.22 (0.20 to 0.24)	0.92 (0.90 to 0.94)	0.26 (0.24 to 0.28)	0.04 (0.01 to 0.07)	.02
EQ-5D score for overall health self-rating (0-100 scale; higher scores indicate greater self-rated health)[c]	Baseline	66.3 (62.7 to 69.9)		68.3 (65.2 to 71.4)			
	4 wk	72.5 (69.3 to 75.7)	5.2 (2.0 to 8.4)	77.6 (74.5 to 80.8)	10.4 (7.2 to 13.5)	5.2 (0.64 to 9.7)	.03
	3 mo	73.3 (69.7 to 76.8)	6.0 (2.5 to 9.6)	79.2 (75.6 to 82.8)	11.9 (8.3 to 15.5)	5.9 (0.91 to 10.9)	.02
	1 y	75.3 (71.9 to 78.7)	8.0 (4.6 to 11.4)	80.9 (77.5 to 84.3)	13.6 (10.3 to 17.0)	5.6 (0.77 to 10.4)	.02

Abbreviations: EQ-5D, 5-Dimensional EuroQol; FABQ, Fear-Avoidance Beliefs Questionnaire; ODI, Oswestry Disability Index; PCS, Pain Catastrophizing Scale.

[a] Mean differences are adjusted for baseline scores of outcome variable.

[b] Missing scores: 0 at baseline, 7 at 4 weeks, 5 at 3 months, and 14 at 1 year; imputed using multiple imputation procedure.

[c] Missing scores: 3 at baseline, 6 at 4 weeks, 5 at 3 months, and 12 at 1 year; imputed using multiple imputation procedure.

[d] Missing scores: 1 at baseline, 6 at 4 weeks, 6 at 3 months, and 13 at 1 year; imputed using multiple imputation procedure.

[e] Missing scores: 0 at baseline, 5 at 4 weeks, 5 at 3 months, and 13 at 1 year; imputed using multiple imputation procedure.

[f] Missing scores: 0 at baseline, 7 at 4 weeks, 6 at 3 months, and 13 at 1 year; imputed using multiple imputation procedure.

[g] Missing scores: 1 at baseline, 6 at 4 weeks, 8 at 3 months, and 13 at 1 year; imputed using multiple imputation procedure.

Table 3. Dichotomous Secondary Outcomes for Early Physical Therapy vs Usual Care for Recent-Onset Low Back Pain

	Participants, No. (%)			
	Early Physical Therapy	Usual Care	Relative Risk (95% CI)	*P* Value[a]
Patient-reported success[b]				
4 wk	60 (55.6)	50 (44.6)	1.24 (0.95-1.63)	.12
3 mo	64 (59.3)	49 (44.0)	1.35 (1.03-1.75)	.03
1 y	65 (59.7)	60 (53.7)	1.11 (0.88-1.42)	.38
Health Care Utilization Outcomes[d]				
Emergency department or urgent care visit[c]				
4 wk	0	1 (0.9)		>.99
3 mo	2 (1.9)	2 (1.8)		.97
Total at 1 y	9 (8.4)	9 (8.1)		.94
Advanced imaging				
4 wk	0	1 (0.9)		>.99
3 mo	2 (1.9)	1 (0.9)		.62
Total at 1 y	3 (2.8)	4 (3.6)		.74
Spine specialist physician visit				
4 wk	0	3 (2.8)		>.99
3 mo	3 (2.8)	7 (6.3)		.23
Total at 1 y	8 (7.5)	11 (9.9)		.53
Spine injection				
4 wk	0	0		
3 mo	1 (0.9)	1 (0.9)		.98
Total at 1 y	2 (1.9)	3 (2.8)		.68
Spine surgery				
4 wk	0	0		
3 mo	0	1 (0.9)		>.99
Total at 1 y	2 (1.9)	1 (0.9)		.62

[a] Relative risks calculated using the Zou method.[31]

[b] Missing scores: 6 at 4 weeks, 5 at 3 months, and 12 at 1 year; imputed using multiple imputation procedure (15-point Likert scale; self-ratings of "a great deal better" or "a very great deal better" defined as success).

[c] *P* values from Fisher exact tests.

[d] One hundred fifty six participants (70.9%) completed 12 monthly online diaries reporting utilization outcomes, 196 participants (89.1%) completed 10 or more, 206 participants (93.6%) completed 8 or more.

initial contact may be preferable, at least for some patients. To our knowledge, no previous studies have tested this hypothesis of early physical therapy vs usual care following initial primary care contact. Effect sizes were small and did not achieve the minimum clinically important difference for the primary outcome. For secondary outcomes, early physical therapy showed benefit across some, but not across all, domains. The potential benefits of early physical therapy should be considered in light of the time and effort required to participate in physical therapy.

Because of the volume of LBP patients and recognition that many improve quickly, efforts have been made to identify patient subgroups most likely to benefit from early physical therapy. This study examined a subgroup described in previous research as responsive to the specific physical therapy protocol used.[34] The subgroup is characterized by at least moderate disability (ODI score ≥20), acute onset (<16 days duration), no symptoms distal to the knee(s) or clinical findings suggesting nerve root compression. We selected this subgroup because it is linked to a specific physical therapy protocol of spinal manipulation and exercise, which are evidence-based LBP treatments.[12] The majority of exclusions resulted from the acuity criterion (<16 days duration). This criterion maximized likelihood of success with this physical therapy protocol in prior research.[34] Patients with somewhat longer symptom durations may benefit from early physical therapy, but further research should investigate this question.

Other strategies to identify patient subgroups who are likely to benefit from physical therapy have been described. A promising approach stratifies patients based on the presence of physical and psychosocial factors using the StarT Back screening tool.[35] Physical therapy is recommended for patients with predominantly physical prognostic factors, whereas therapy augmented with efforts to overcome psychosocial obstacles is recommended for patients with both physical and psychosocial factors.[36] Although our physical therapy protocol did not include explicit interventions to address psychosocial factors (eg, cognitive behavioral therapy), we found greater improvement in important psychosocial constructs including PCS score and fear-avoidance beliefs in this group. This may result from intervening early for acute LBP when adverse psychosocial beliefs may be more amenable to change without specific psychological interventions.[37] However, further study is needed to confirm this theory.

We found that patients in both groups improved rapidly. Rapid and substantial improvement by most patients with acute LBP limits treatment effects in early intervention studies.[38] We detected a modest difference favoring early physical therapy that was better than the natural history of acute LBP for the primary outcome at 3-month follow-up. How-

ever, the between-group difference did not achieve the threshold for minimum clinically important difference. Furthermore, differences were mostly undetectable by 1 year.

We designed our physical therapy protocol for efficiency, focusing on evidence-based treatments (education, exercise, and manipulation).[12] We did not include passive modalities (eg, ultrasound) that are frequently used but are not evidence-based[12] and may prolong physical therapy episodes.[39] Our physical therapy protocol used 4 treatment sessions compared with national averages of more than 7 sessions for acute LBP.[9] We believe this 4-session protocol is practical for routine clinical use. Additional research is needed to evaluate its effectiveness under more pragmatic circumstances.

We provided education to both groups. Our education involved written materials and dialogue focused on encouraging activity and assuaging concerns that imaging should be performed. Although education is recommended by guidelines as a component of primary care practice,[40] our approach was likely beyond what typically occurs.

Our study has limitations. First, although more than 90% of participants provided data after 1 year, there were more patients who dropped out from the usual care group than from the early physical therapy group. Second, results of our secondary outcomes should be interpreted cautiously as we did not adjust for multiple comparisons. Third, we did not include an attention control group. Fourth, we did not assess adverse events in the usual care group.

Conclusions

Among adults with recent-onset LBP, early physical therapy resulted in statistically significant improvement in disability, but the improvement was modest and did not achieve the minimum clinically important difference compared with usual care.

ARTICLE INFORMATION

Author Contributions: Dr Fritz and Ms McFadden had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Fritz, Asche, Brennan.
Acquisition, analysis, or interpretation of data: Fritz, Magel, McFadden, Asche, Thackeray, Meier, Brennan.
Drafting of the manuscript: Fritz, McFadden, Asche.
Critical revision of the manuscript for important intellectual content: Fritz, Magel, McFadden, Asche, Thackeray, Meier, Brennan.
Statistical analysis: McFadden, Asche.
Obtained funding: Fritz, Asche.
Administrative, technical, or material support: Fritz, Magel, McFadden, Thackeray, Meier, Brennan.
Study supervision: Fritz, Thackeray, Brennan.

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Data and Safety Monitoring Board: Roger Chou, MD (Oregon Health and Science University), Anthony Delitto, PhD, PT, FAPTA (University of Pittsburgh), Richard Holubkov, PhD (University of Utah), John Childs, PhD, PT, MBA, FAPTA (US Army-Baylor University Doctoral Program in Physical Therapy), and Lucy Savitz, PhD (Intermountain Healthcare).

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