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The Effect of a Fear-Avoidance–Based Physical Therapy Intervention for Patients With Acute Low Back Pain: Results of a Randomized Clinical Trial

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Study Design. A randomized clinical trial with 4-week and 6-month follow-up periods.

Objective. To compare the effect of a fear-avoidance–based physical therapy intervention with standard care physical therapy for patients with acute low back pain.

Summary of Background Data. The disability reduction strategy of secondary prevention involves providing specific treatment for patients that are likely to have chronic disability from low back pain. Previous studies have indicated that elevated fear-avoidance beliefs are a precursor to chronic disability from low back pain. However, the effectiveness of physical therapy intervention based on a fear-avoidance model is unknown.

Methods. Sixty-six consecutive patients referred to physical therapy with low back pain of less than 8 weeks' duration were randomly assigned to receive fear-avoidance–based physical therapy (n = 34) or standard care physical therapy (n = 32). The intervention period lasted 4 weeks for this study. Disability, pain intensity, and fear-avoidance beliefs measures were recorded before and after treatment. A 6-month follow-up of the same measures was obtained by mail.

Results. An intention-to-treat principle (last value forward) was used for data analyses that tested the primary and secondary hypotheses. The prediction of disability at 4 weeks and 6 months after treatment was significantly improved by considering the interaction between the type of treatment and the initial level of fear-avoidance beliefs. Both groups had significant within group improvements for disability and pain intensity. The fear-avoidance treatment group had a significant improvement in fear-avoidance beliefs, and fear-avoidance beliefs about physical activity were significantly lower than the standard care group at 4 weeks and 6 months after treatment.

Conclusion. Patients with elevated fear-avoidance beliefs appeared to have less disability from fear-avoidance–based physical therapy when compared to those receiving standard care physical therapy. Patients with lower fear-avoidance beliefs appeared to have more disability from fear-avoidance–based physical therapy, when compared to those receiving standard care physical therapy. In addition, physical therapy supplemented with fear-avoidance–based principles contributed to a positive shift in fear-avoidance beliefs. [Key words: randomized clinical trial, acute low back pain, fear-avoidance beliefs, physical therapy, disability] **Spine 2003;28:2551–2560**

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The Fear-Avoidance Model of Exaggerated Pain Perception (FAMEPP)[1,2] was developed by a multidisciplinary clinical team to explain why some individuals with acute low back pain resolve their symptoms, whereas others progress to a state of chronic disability. In this model, pain perception was divided into a sensory component, which was the physiologic response to a nociceptive stimulus, and an emotional reaction component, which was the psychologic response to the stimulus. The FAMEPP proposed that the emotional reaction component, comprised primarily of an individual's fear of pain, was the most important factor in determining whether a confrontation or avoidance response was used during an episode of acute low back pain. It was further hypothesized that an avoidance response was maladaptive and its associated consequences were primary contributors to the development of chronic disability from low back pain.[1,2]

Waddell *et al*[3] developed the Fear-Avoidance Beliefs Questionnaire (FABQ) to investigate fear-avoidance beliefs in the clinical setting and investigated the psychometric properties of the questionnaire on a group of patients with chronic low back pain. Results from the study indicated that the FABQ was a reliable measure and two subscales within the FABQ were identified: a four-item scale measuring fear-avoidance beliefs about physical activity and a seven-item scale measuring fear-avoidance beliefs about work.[3] In addition, Waddell *et al*[3] demonstrated that, after controlling for pain intensity and pain location, fear-avoidance beliefs about work explained a significant amount of variance in disability (23%) and work loss (26%). Subsequent cross-sectional studies in patients with chronic low back pain replicated that fear-avoidance beliefs could be reliably measured and that a strong relationship existed between fear-avoidance beliefs, work loss, and disability.[4–8] These additional findings strengthened Waddell *et al*'s original contention that "fear of pain and what we do about it may be more disabling than pain itself."[3]

The role of fear-avoidance beliefs for patients with acute low back pain has recently been investigated. For example, Vlaeyen *et al*[6] hypothesized that fear-avoidance beliefs are a protective mechanism for patients with acute low back pain, preventing further tissue damage during the initial phases of healing. Evidence exists in the literature, however, to contradict this hypothesis. Klenerman *et al*[9] observed that fear-avoidance beliefs were the best predictor of 2-month disability in general practice patients with acute lumbar pain. Fritz *et al*[10] found that higher fear-avoidance beliefs predicted persistent disability and inability to return to work within 4 weeks of treatment for patients with work-related, acute low back pain. Instead of being protective in nature, these studies suggested that elevated fear-avoidance beliefs during an episode of acute low back pain are predictive of future disability.[9,10]

Secondary prevention, which involves providing specific treatment during an acute episode of low back pain to patients that have been identified as being likely to develop chronic disability, has been endorsed as a viable strategy for reducing disability from low back pain.[11,12] Although the literature indicates that identifying patients likely to develop chronic disability from low back pain is possible,[13–15] interventions that adequately address psychosocial factors related to future disability from low back pain are lacking.[10,16–18] Investigation of a fear-avoidance–based intervention has been advocated in the literature because it appears that fear-avoidance beliefs are a specific psychosocial factor significantly related to chronic disability from low back pain.[9,10,17] The purpose of this clinical trial was to investigate the effect of a fear-avoidance–based physical therapy intervention for patients with acute low back pain.

■ Methods

This study was a randomized clinical trial designed to investigate the effect of fear-avoidance–based physical therapy treatment for acute low back pain. Consecutive patients referred by physicians to outpatient physical therapy for evaluation and treatment of acute low back pain were considered for participation in this study. Patients meeting the inclusion criteria and who consented to the study underwent a standard physical therapy examination and completed self-report forms for disability, pain intensity, and fear-avoidance beliefs. Then, patients were randomly assigned to receive fear-avoidance–based physical therapy or standard care physical therapy for treatment of their low back pain. After 4 weeks of treatment, patients were re-evaluated and self-report forms were completed again. Treatment related to the clinical trial was then discontinued and 6-month follow-up information (self-report forms only) was obtained through the mail.

Hypotheses. The authors hypothesized that fear-avoidance–based treatment would have a differential effect on disability, depending on the amount of initial fear-avoidance beliefs. Therefore, the *a priori* primary hypothesis tested during this clinical trial was: 1) prediction of 4-week and 6-month disability from low back pain would be improved by considering the interaction between the type of physical therapy treatment (*i.e.*, fear-avoidance–based or standard care) and the level of initial fear-avoidance beliefs. The authors also hypothesized that fear-avoidance–based treatment would result in an improvement in fear-avoidance beliefs and developed an *a priori* secondary hypothesis; 2) patients receiving fear-avoidance–based treatment would have lower fear-avoidance beliefs at 4 weeks and 6 months compared to those receiving standard care treatment.

Subjects. For 9 months, 4 physical therapists from 3 different outpatient clinics in the greater Pittsburgh, Pennsylvania, area screened consecutive patients referred for evaluation and treatment of low back pain. The criteria for study inclusion were the patient had to be between the ages of 18 and 55, had to have an onset of low back pain or low back pain and leg pain within the last 8 weeks, and be English speaking/reading. The criteria for study exclusion were having signs of nerve root compression, having low back surgery within the last 6 months, tumor, fracture, osteoporosis, or pregnancy. A patient was determined to have "signs of nerve root compression" if a straight leg raise of less than 45° that reproduced low back pain and leg pain was detected, or if diminished reflex, sensory, and/or muscle testing results were detected in a myotomal or dermatomal pattern.

Refer to Figure 1 for a flow chart describing the number of patients excluded from this trial, meeting the inclusion criteria, and enrolled as participants. The 7 patients excluded for "other" reasons included not having symptoms in the low back and/or leg region (n = 1), having known tumor, fracture, osteoporosis, or infection (n = 3), having had low back surgery within the past 6 months (n = 2), and being pregnant (n = 1). One patient who consented to study participation was randomly assigned to standard care treatment before all the necessary initial data were collected. This study participant was excluded from subsequent data analyses because he did not respond to multiple attempts at collecting the initial data by phone or mail, did not attend any treatment sessions, and did not respond to multiple attempts at collecting 4-week data by phone or mail. Therefore, data analyses for this study are based on 66 study participants, 34 from the fear-avoidance treatment group and 32 from the standard care treatment group.

Randomization. The randomization scheme was prepared by computer and was completed before the start of the study. Randomization was stratified by physical therapist and was balanced to ensure equal allocation to each treatment group. After the randomization list was generated, treatment assignments were contained in sealed, numbered envelopes. Patients were randomly assigned treatment by a physical therapist investigator and envelopes were opened in sequential order, as each patient entered the study.

Intervention. Blinding of the physical therapists was not possible during this clinical trial because of the interactive nature of the treatment. Blinding of the patients was also not possible during this clinical trial because of the informed consent process. All patients were evaluated and treated by physical therapists using a previously described treatment-based classification system (TBC).[19] Treatment-based classification uses key historical and physical examination findings to classify patients with acute low back pain into four separate treatment categories (Table 1).[19,20] Reports in the literature have described the reliability of TBC[20] and the relative effectiveness of TBC compared to generic exercise[21,22] and guideline recommendations.[23]

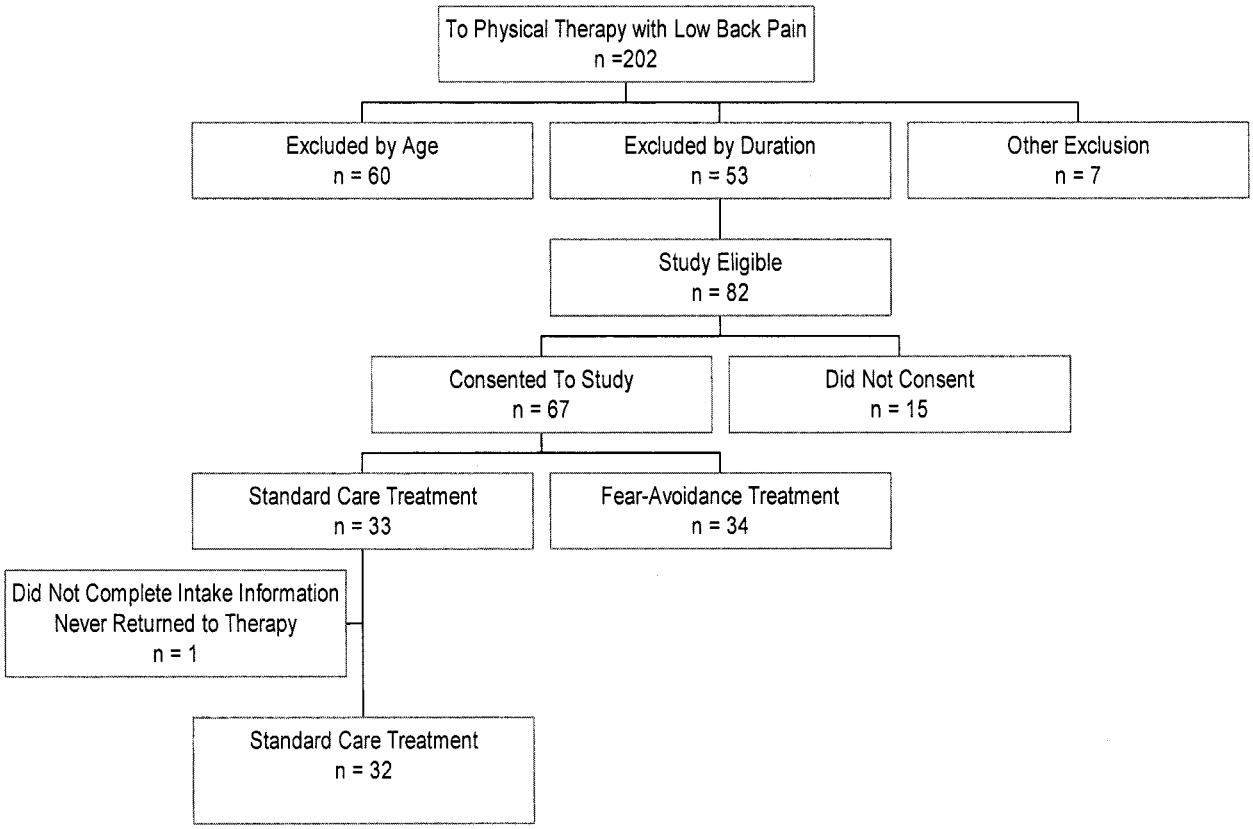

Figure 1. Recruitment and enrollment summary for clinical trial.

After being classified for physical therapy treatment, patients were then randomly assigned (Figure 2) to receive TBC as normally delivered (standard care treatment), or fear-avoidance–based TBC (fear-avoidance treatment). Several steps were taken in an attempt to standardize delivery of the physical therapy treatment. For example, the two treatment groups had required educational components, standard exercise prescriptions and exercise progressions, and total treatment time was limited to 1 hour per patient per therapy session. Physical therapists participating in the trial attended a training session and demonstrated competency in the study protocol by passing a written test.

Standard Care Treatment. Patients randomly assigned to receive standard care treatment were issued the *Handy Hints* educational pamphlet, which takes a traditional approach to patient education by emphasizing spine anatomy and pathology. This pamphlet has been used in a previous clinical trial and patients reading it did not have an improvement in fear-avoidance beliefs.[24] The patient read the pamphlet as part of a home program and self-report of compliance was recorded on an exercise log by the physical therapist. Any follow-up questions the patient had about the pamphlet were answered by the physical therapist in a manner that was consistent with information from the pamphlet. Predefined guidelines based on the

Table 1. Summary of Treatment-Based Classification[19,20]—Examination Findings and Treatment Recommendations

Classification	Examination Findings	Treatment
Mobilization	Unilateral symptoms without signs of nerve root compression	Joint mobilization
	Positive findings for sacroiliac region dysfunction	Joint manipulation
	Positive findings for lumbar region dysfunction	Active range of motion exercises for spine
Specific exercise	Flexion syndrome	
	Patient preference for sitting	Lumbar flexion exercises
	Centralization with lumbar flexion motions	Avoidance of activity involving spinal extension
	Extension syndrome	
	Patient preference for standing or walking	Lumbar extension exercises
	Centralization with lumbar extension motions	Avoidance of activity involving spinal flexion
Immobilization	Frequent previous episodes	Lumbar strengthening exercise
	Positive response to prior manipulation	Lumbar stabilization exercises
	Presence of frontal plane deviation during lumbar movements	
	Lumbar segmental hypermobility	
Traction	Presence of radicular signs	Mechanical traction
	Unable to centralize with lumbar movements	Autotraction
	May have lateral shift deformity	

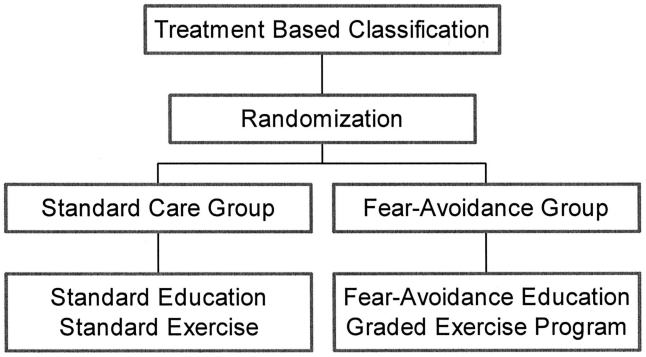

Figure 2. Treatment group components.

patient's reported change in pre- and postexercise pain intensity were used to standardize exercise progression within the standard care group.

Fear-Avoidance–Based Treatment. Vlaeyen and Linton[17] suggested that an intervention based on the FAMEPP[1,2] should educate the patient in a specific manner and utilize an intervention that appropriately addresses the patient's fear avoidance. From these suggestions, a fear-avoidance–based physical therapy intervention was developed for use in this clinical trial. Patient education utilizing a fear-avoidance model differs from the traditional approach because it de-emphasizes anatomic findings, encourages the patient to take an active role in his recovery, and educates the patient to view back pain as a common condition, not a serious disease.[17,24,25] All patients randomly assigned to the fear-avoidance treatment group were issued the *Back Book* educational pamphlet, which utilizes the aforementioned principles. This educational pamphlet has been used in a previous clinical trial and patients reading the pamphlet had a significant decrease in fear-avoidance beliefs.[24] The patient read the pamphlet as part of a home program and self-report of compliance was recorded on an exercise log by the physical therapist. Any follow-up questions the patient had about the pamphlet were answered by the physical therapist in a manner that was consistent with information from the pamphlet.

Graded exercise was used to progress exercise for patients in the fear-avoidance group because it has been endorsed as a potential treatment for individuals with elevated fear-avoidance beliefs.[17] In a graded exercise program, exercise prescription is based on a predetermined quota of intensity of exercise, duration of exercise, or repetition of exercise.[17,26,27] When the established quota is reached, the patient receives positive reinforcement, and a new exercise quota is established.[26,27] Predefined guidelines based on graded exercise principles were used to standardize exercise prescription within the fear-avoidance group. A description of a patient receiving fear-avoidance treatment has been published in a home-study course.[28]

Outcome Measurement. At the time of initial evaluation, study participants completed a standardized demographic information form that included: gender, age, smoking status, marital status, and educational level. Clinical information was collected by a physical therapist blinded to the treatment assignment. Using a standard history form, the physical therapist obtained the type of onset of symptoms, the length of time of the symptoms, the presence of lower extremity symptoms, and the number of previous episodes of low back pain. The physical therapist collected physical impairment data for total lumbar flexion and straight leg raise in a standard manner as proposed by Waddell *et al*.[29] The patient completed self-report forms measuring disability, pain intensity, and fear-avoidance beliefs during the initial evaluation, 4 weeks after treatment, and 6 months after treatment.

Disability. The primary outcome variable for this clinical trial was disability from low back pain, which was measured by the Oswestry Disability Questionnaire (ODQ). The ODQ is a disease-specific measure of functional disability in patients with low back pain.[30–32] Hudson-Cook *et al*[33] developed a modified version of the original questionnaire that consists of 10 different functional items. The subject scores each functional item by rating the difficulty from 0 to 5. The final score is typically expressed as a percentage with higher percentages indicating higher amounts of disability.[31,32] The ODQ has demonstrated high levels of reliability and an expert panel recommends its use as an outcome measure in studies of LBP.[31,34,35]

Pain Intensity. Patients were given anatomically simple pictures that show the front and back of the human body.[36] Patients were asked to rate their present pain intensity using a 0 to 10 ordinal scale located at the bottom of the page. A "0" rating corresponded with no pain and a "10" rating corresponded with maximum pain intensity.[36]

Fear-Avoidance Beliefs. The secondary outcome variable was fear-avoidance beliefs about physical activity, which was measured by the FABQ.[3] The FABQ is a 16-item questionnaire and each item is scored from 0 to 6. Higher numbers on the FABQ indicate increased levels of fear-avoidance beliefs related to low back pain. Two subscales within the FABQ have been identified: a four-item scale measuring fear-avoidance beliefs about physical activity (FABQ-PA) and a seven-item scale measuring fear-avoidance beliefs about work (FABQ-W).[3] The FABQ has demonstrated high levels of reliability in previous studies of patients with low back pain.[3,4]

Statistical Analyses. SamplePower, Release 1.0 (SPSS Inc., Chicago, IL) was used to determine sample size and power estimates based on the primary hypothesis. The criteria used for this analysis were a regression analysis with four covariates and the addition of an interaction term resulting in a 10% increase in R^2. This analysis indicated that 54 subjects were necessary for this study to obtain 80% power. An intention-to-treat principle (last value forward) and an alpha level of 0.05 were used for all data analyses that tested the primary and secondary hypotheses. The continuous variables used in the regression model (disability and fear-avoidance beliefs) were first tested for approximating a normal distribution. Descriptive statistics were calculated for demographic, physical examination, and self-report measures and postrandomization differences were assessed using the appropriate statistical procedures.

A main effects regression model was created using predefined effects: type of physical therapy treatment (fear-avoidance or standard care), treatment-based classification category (specific exercise, mobilization, immobilization, or traction), initial fear-avoidance beliefs, and initial disability. Fear-avoidance beliefs about physical activity were used in this

Table 2. Baseline Characteristics of the Study Participants

	Standard Care Group (n = 32)	Fear-Avoidance Group (n = 34)	*P* Value
Demographic			
Age*	36.8 (10.1)	39.5 (10.0)	0.276
Gender† (# of female subjects)	17/32 (53%)	21/34 (62%)	0.645
Smoking† (# of smoking subjects)	10/32 (31%)	10/32 (29%)	1.000
Marital status† (# of married subjects)	16/32 (50%)	24/34 (71%)	0.145
Education† (# of college graduates)	14/32 (44%)	12/34 (35%)	0.509
Clinical			
Prior history of LBP† (# with prior history)	17/32 (53%)	23/34 (68%)	0.340
Leg pain with LBP† (# with leg pain)	20/32 (63%)	21/34 (62%)	0.951
Onset of LBP† (# with sudden onset)	22/32 (69%)	18/34 (53%)	0.288
Duration of LBP† (# of days, present episode)	27.6 (16.4)	27.1 (16.2)	0.912
Total lumbar flexion* (°)	76.8 (28.2)	76.3 (27.3)	0.943
Average SLR* (°)	67.7 (13.7)	71.4 (12.7)	0.259
Treatment classification†			0.596
Specific exercise	11/32 (34%)	17/34 (50%)	
Mobilization	9/32 (28%)	6/34 (18%)	
Immobilization	9/32 (28%)	8/34 (24%)	
Traction	3/32 (9%)	3/34 (9%)	
Self report			
Oswestry Disability score*	38.6 (16.0)	35.8 (11.4)	0.413
Present pain intensity rating* (0–10 rating scale)	4.6 (2.5)	4.3 (2.4)	0.585
Fear-avoidance beliefs about physical activity*	15.3 (5.5)	15.1 (4.8)	0.899
Fear-avoidance beliefs about work*	14.3 (12.1)	12.9 (11.3)	0.628

All values are reported as mean (standard deviation), unless otherwise indicated.
* Significance tested with independent *t* test.
† Significance tested with χ^2 test.
LBP = low back pain; SLR = straight leg raising.

model because this sample was not anticipated to have a large amount of work-related low back injury and this variable has been used in previous studies of patients without work-related low back pain.[18,24,37] The primary hypothesis was tested by hierarchical addition of first-order treatment interactions to the main effects model. The secondary hypothesis was tested by determining the statistical difference in fear-avoidance beliefs between the two treatment groups at the 4-week and 6-month follow-up periods. Between group differences were also considered for disability and pain intensity. When significant differences were observed for either hypothesis, relative risk (RR) and numbers needed to treat (NNT) were calculated to estimate the magnitude of the difference.

■ Results

The mean age of the 66 study participants was 38.2 (SD = 10.1) years of age, 38 (58%) of the participants were women, and 4 (6%) study participants experienced work-related low back injury. The mean duration of symptoms for the current episode of low back pain was 27.3 (SD = 16.2) days, 40 (61%) of the study participants had a past history of activity limiting low back pain, 41 (62%) of the study participants reported low back and leg pain, whereas 25 (38%) reported only low back pain. The measures of disability and fear-avoidance beliefs were found to approximate a normal distribution by Kolmogorov-Smirnov tests ($P > 0.05$). A summary of baseline characteristics for each treatment group is provided in Table 2. No significant differences were noted between the treatment groups.

Treatment Summary

Sixty-six (100%) study participants reported reading the educational pamphlet at least 1 time and 66 (100%) of the study participants received feedback consistent with the appropriate treatment model during physical therapy sessions. The principal investigator (S.Z.G.) qualitatively reviewed the first three exercise logs for each physical therapist and found that the appropriate exercise prescription guidelines were being followed. At 4 weeks, no significant differences were noted between the treatment groups for follow-up or utilization of physical therapy services (Table 3). At 6 months, no significant differences were noted between the treatment groups for follow-up, selecting same treatment for low back pain, having continued low back pain, or seeking additional treatment from other health care providers. No adverse events were reported during this clinical trial.

Primary Hypothesis

First-order treatment interaction terms were individually added to the main effects model to assess their effect on prediction of disability (Table 4). Addition of the interaction between type of treatment supplement and fear-avoidance beliefs improved prediction of disability at 4 weeks (Model #1, $P < 0.049$) and 6 months (Model #4, $P < 0.034$). At 4 weeks, an F_p test confirmed Model #1 as the "best" model because the main effects model had significantly ($F_p = 5.22$, $P < 0.026$) more residual.[38] At 6 months, an F_p test confirmed Model #4 as the "best" model because the main effects model had significantly ($F_p = 4.41$, $P < 0.039$) more residual.[38] The standardized beta coefficients for the 4-week and 6-month final models are summarized in Table 5.

Table 3. Treatment Summary

	Standard Care Group (n = 32)	Fear-Avoidance Group (n = 34)	*P* Value
4 weeks			
Follow-up completed*	30/32 (94%)	33/34 (97%)	0.957
Days to follow-up†	29.2 (13.3)	28.7 (9.7)	0.503
No. of appointments‡			0.905
Mean	6.7 (2.7)	6.8 (3.1)	
Median	6	6	
Range	2–12	2–17	
Discharged from therapy*	20 (63%)	26 (77%)	0.334
6 months			
Follow-up completed*	28/32 (85%)	30/34 (88%)	0.927
Days to follow-up†	183.7 (10.4)	182.6 (13.0)	0.729
Continued low back pain*	5/28 (18%)	5/30 (17%)	0.915
Same treatment again*	25/28 (89%)	27/30 (90%)	0.929
Additional treatment*	7/28 (25%)	10/30 (33%)	0.485
Low back surgery§	0/7 (0%)	2/10 (20%)	0.486

All values are reported as mean (standard deviation), unless otherwise indicated.
* Significance tested with χ^2 test.
† Significance tested with independent *t* test.
‡ Significance tested with Mann-Whitney U test.
§ Significance tested with Fisher exact test.
Continued low back pain = number of patients who indicated continued low back pain from original episode; same treatment again = number of patients who would choose same physical therapy treatment again; additional treatment = number of patients who have visited an MD, DC, or massage therapist for additional treatment of their LBP; low back surgery = number of patients who had surgery for treatment of LBP, after completing physical therapy.

Table 5. "Best" Regression Models for Prediction of 4-Week and 6-Month Disability

Variable	Beta Coefficient*	*P* Value
4-Week disability		
IFABQ × TREAT	−0.653	0.049
IODQ	0.429	<0.0005
IFABQ	0.292	0.042
TREAT (Fear-Avoidance)	0.520	0.102
CLASS (Mobilization)	−0.202	0.081
CLASS (Immobilization)	0.007	0.944
CLASS (Traction)	0.198	0.071
6-Month disability		
IFABQ × TREAT	−0.736	0.034
IODQ	0.383	0.001
IFABQ	0.469	0.002
TREAT (Fear-Avoidance)	0.589	0.077
CLASS (Mobilization)	−0.090	0.449
CLASS (Immobilization)	0.120	0.301
CLASS (Traction)	0.036	0.753

* Standardized coefficients.
IFABQ = Initial Fear-Avoidance Beliefs about Physical Activity score; IODQ = Initial Oswestry Disability Questionnaire Score; TREAT = treatment group (standard care as baseline); CLASS = treatment classification (specific exercise as baseline).

The nature of the interaction between fear-avoidance beliefs and the treatment group was further investigated by creating separate regression lines using the remaining significant independent variables. Baseline disability remained a significant predictor ($P < 0.05$) of 4-week and 6-month disability for the standard care treatment group and the fear-avoidance treatment group. In the standard care treatment group, fear-avoidance beliefs remained a significant predictor of 4-week disability ($\beta = 1.02$, $P < 0.031$) and 6-month disability ($\beta = 1.27$, $P < 0.016$). In the fear-avoidance treatment group, however, baseline fear-avoidance beliefs were not predictive of 4-week disability ($\beta = -0.63$, $P < 0.377$) or 6-month disability ($\beta = -0.07$, $P < 0.844$). When compared to a pooled

Table 4. Prediction of Disability at 4 Weeks and 6 Months

Dependent Variable: 4-Week Disability Regression Model	R^2	Adjusted R^2	F-ratio for Model Change	Significance of Model Change
Main effects model (IODQ) + (IFABQ) + (TREAT) + (CLASS)	0.40	0.33	NA	NA
Treatment interactions added to the main effects model:				
Model #1				
Main effects model + (TREAT × IFABQ)	0.43	0.37	4.027*	0.049
Model #2				
Main effects model + (TREAT × CLASS)	0.43	0.34	1.084†	0.363
Model #3				
Main effects model + (TREAT × IODQ)	0.40	0.32	0.220*	0.641
Dependent Variable: 6-Month Disability Regression model				
Main effects model (IODQ) + (IFABQ) + (TREAT) + (CLASS) + error	0.33	0.26	NA	NA
Treatment Interactions Added to the Main Effects Model				
Model #4				
Main effects model + (TREAT × IFABQ) + error	0.38	0.31	4.709*	0.034
Model #5				
Main effects model + (TREAT × CLASS) + error	0.37	0.27	1.249†	0.301
Model #6				
Main effects model + (TREAT × IODQ) + error	0.34	0.26	0.563*	0.461

* Calculated with partial F test.
† Calculated with multiple-partial F test.
IODQ = Initial Oswestry Disability Questionnaire score; IFABQ = Initial Fear-Avoidance Beliefs Questionnaire score (physical activity scale); TREAT = treatment group (standard care used as baseline variable); CLASS = treatment-based classification (specific exercise category used as baseline variable).

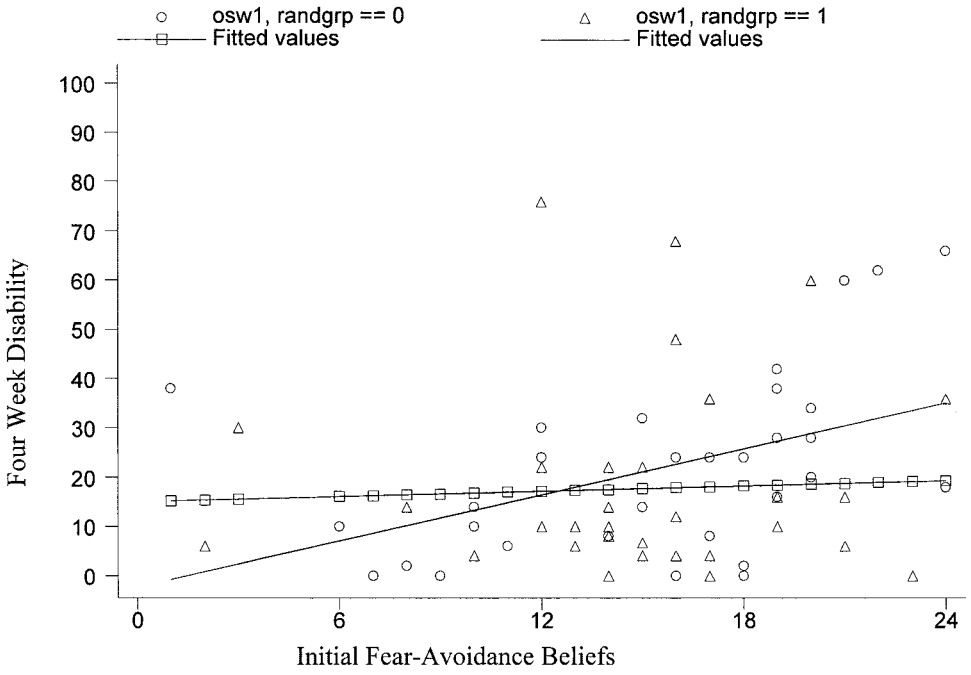

Figure 3. Treatment interaction between initial fear-avoidance beliefs and type of treatment supplement (4 weeks after treatment). y-axis = 4-week Oswestry Disability Questionnaire score (measured by Oswestry Disability Questionnaire). x-axis = Initial Fear-Avoidance Beliefs Questionnaire (physical activity) score. osw1, randgrp==1 = 4-week disability score for fear-avoidance treatment group. osw1, randgrp==0 = 4-week disability score for standard care treatment group.

variance, the slopes of the regression lines for the two treatment groups were found to be significantly different from each other at 4 weeks ($t = 2.84$, $P < 0.004$) and 6 months ($t = 3.19$, $P < 0.002$).[39] Figure 3 is a graphical representation of the significant interaction observed 6 months after treatment. For patients with elevated fear-avoidance beliefs (defined as greater than 15 on the FABQ-PA)[24] the NNT (95% CI) for a clinically important improvement (defined as greater than a 12-point reduction in ODQ)[34] in disability was 5.3 (2.3–infinity) at 4 weeks and 4.0 (2.1–infinity) at 6 months. The RR for patients with elevated fear avoidance beliefs having a clinically important improvement (using the previously described definitions) in disability was 1.4 (1.0–2.0) at 4 weeks and 1.7 (1.2–2.3) at 6 months.

Secondary Hypothesis

Results of 4-week and 6-month outcomes for disability and pain intensity are summarized in Table 6. The 4-week and 6-month outcomes for fear-avoidance beliefs are summarized in Table 7. The standard care treatment group had significant within-group improvements for disability and pain intensity. The fear-avoidance treatment group had significant within group improvements for disability, pain intensity, fear-avoidance beliefs about physical activity, and fear-avoidance beliefs about work. Between-group differences for fear-avoidance beliefs about physical activity were observed at 4 weeks and 6 months. Numbers needed to treat (95% CI) for a clinically important improvement (defined as greater than 4-point reduction)[24] in fear-avoidance beliefs about physical activity was 3.2 (2.0, 12.1) at 4 weeks and was 4.7 (2.4, infinity) at 6 months. Relative risk (95% CI) for a clinically important improvement (same definition) in fear-avoidance beliefs about physical activity was 2.7 (1.2, 5.9) at 4 weeks and 1.6 (0.9, 2.9) at 6 months.

Table 6. 4-Week and 6-Month Treatment Outcomes for Disability and Pain

Measure	Standard Care Group (n = 32)	Fear-Avoidance Group (n = 34)	Between-Group Difference (95% CI)	*P* Value*
Oswestry Disability Questionnaire Score (0–100)				
Baseline	38.6 (15.9)	35.8 (11.4)	2.8 (−4.0, 9.6)	0.413
4 wks	21.5 (18.3)	17.7 (19.5)	3.8 (−5.5, 13.1)	0.422
Mean change† (95% CI)	17.1 (11.8, 22.3)	18.0 (11.9, 24.2)		
6 mos	15.5 (17.9)	11.9 (10.0)	3.6 (−3.5, 10.8)	0.317
Mean change† (95% CI)	23.0 (16.8, 29.3)	23.9 (20.1, 27.6)		
Present pain intensity rating (0–10)				
Baseline	4.6 (2.5)	4.3 (2.4)	0.3 (−.9, 1.5)	0.585
4 wks	2.6 (2.4)	1.9 (2.4)	0.7 (−.5, 1.9)	0.288
Mean change† (95% CI)	2.0 (1.0, 2.9)	2.4 (1.6, 3.3)		
6 mos	1.5 (2.0)	1.7 (2.2)	−0.1 (−1.2, .9)	0.779
Mean change† (95% CI)	3.0 (2.0, 4.2)	2.6 (1.7, 3.5)		

* Significance determined by independent *t* test.
† Mean within-group change determined from baseline score.
CI = confidence interval.

Table 7. 4-Week and 6-Month Treatment Outcomes for Fear-Avoidance Beliefs

Measure	Standard Care Group (n = 32)	Fear-Avoidance Group (n = 34)	Between-Group Difference (95% CI)	*P* Value*
Fear-Avoidance Beliefs Questionnaire (Physical Activity Scale, 0–24)				
Baseline	15.3 (5.5)	15.1 (4.8)	0.2 (−2.4, 2.7)	0.899
4 wks	14.9 (6.5)	10.7 (5.4)	4.2 (1.3, 7.1)	0.006
Mean change† (95% CI)	0.3 (−1.8, 2.5)	4.4 (2.1, 6.7)		
6 mos	13.5 (7.0)	10.1 (5.9)	3.4 (.2, 6.6)	0.037
Mean change† (95% CI)	1.8 (−0.9, 4.4)	5.0 (2.8, 7.2)		
Fear-Avoidance Beliefs Questionnaire (Work Scale, 0–42)				
Baseline	14.3 (12.1)	12.9 (11.3)	1.4 (−4.3, 7.1)	0.628
4 wks	13.4 (12.4)	11.1 (10.5)	2.3 (−3.3, 8.0)	0.409
Mean change† (95% CI)	0.9 (−1.4, 3.1)	1.8 (−.8, 4.4)		
6 mos	12.3 (12.3)	9.7 (10.2)	2.6 (−3.0, 8.2)	0.352
Mean change† (95% CI)	1.9 (−1.1, 5.0)	3.1 (0.7, 5.6)		

* Significance determined by independent *t* test.
† Mean within-group change determined from baseline score.
CI = confidence interval.

■ Discussion

Secondary prevention is a disability prevention strategy that administers treatment to patients with acute low back pain who have been identified as likely to develop chronic symptoms.[12] Studies of secondary prediction have consistently shown that psychosocial variables related to future disability, like fear-avoidance beliefs, are detectable during an acute episode of low back pain.[9,10,40,41] Effective treatment options for patients that are likely to have chronic disability from low back pain have not been as widely reported, however.[42,43] This randomized clinical trial represents an initial attempt to reduce disability experienced by individuals with acute low back pain by integrating physical therapy treatment with principles of a fear-avoidance model. Results of this clinical trial suggest that disability from acute low back pain is dependent on an interaction between the type of physical therapy treatment and the initial amount of fear-avoidance beliefs. This interaction was present at 4 weeks and 6 months after physical therapy treatment for low back pain.

The nature of this interaction was that study participants with higher fear-avoidance beliefs receiving the fear-avoidance treatment had less disability than study participants receiving the standard care treatment. In contrast, study participants with lower fear-avoidance beliefs receiving the fear-avoidance treatment appeared to have more disability than study participants receiving the standard care treatment. This finding suggests that the use of fear-avoidance education and graded exercise may only be an appropriate treatment choice for patients that are more likely to be "avoiders" (*i.e.*, with higher fear-avoidance beliefs). This compliments the fear-avoidance model, because it provides evidence that less disability is expected when education and exercise prescription encourage study participants to engage in activities that are confrontational to their low back pain. This interaction also suggests that the use of fear-avoidance education and graded exercise may not be an appropriate treatment choice for patients that are already more likely to be "confronters" (*i.e.*, with lower fear-avoidance beliefs). The reason for this finding is unclear, but it may be unnecessary to provide confronters with educational material that encourages confronting because the additional, redundant information distracts the patient rather than reinforce the desired message.[44,45] Another possible reason for this finding is that the use of a pain based exercise prescription better approximates the optimal exercise dosage in patients who are confronters, who are more likely to de-emphasize pain associated with exercise and thus have greater exercise tolerance. In contrast, a graded exercise prescription may actually under estimate the optimal exercise dosage for patients with low fear-avoidance beliefs.

These results and those of another clinical trial[24] demonstrate that augmenting routine courses of treatment (primary care, osteopathic, and physical therapy) for acute low back pain with fear-avoidance–based management principles result in decreased disability for patients with elevated fear-avoidance beliefs. The NNT and RR point estimates suggest that the decrease in disability for patients with elevated fear-avoidance beliefs has clinical significance, but the wide confidence intervals associated with these estimates limit their interpretation. We feel that these confidence intervals were observed because the sample size estimates for this clinical trial were based on regression parameters, not on clinical significance parameters, and the sample size was not adequate for a precise estimate of NNT or RR.

A secondary prevention strategy based on a fear-avoidance model still needs to be refined. For example, only one cut-off point for determining the level of fear-avoidance that constitutes an "at-risk" patient has been suggested in the literature.[46] This cut-off point was not utilized in this study because it involved predicting return to work for patients with work-related low back pain. To confirm the apparent beneficial effect on disability for patients with elevated fear-avoidance beliefs and the apparent negative effect on disability for patients with lower fear-avoidance beliefs, larger clinical trials that

stratify randomization based on the level of fear-avoidance are needed.

A randomized clinical trial suggested that combining advice to exercise *and* an information pamphlet was the least effective way to improve pain and function.[45] In addition, it has been suggested that the use of specialty services, like physical therapy, may draw extra attention to the patients' symptoms and focus the goal of treatment to symptom abatement, instead of functional improvement.[47] Others have hypothesized that clinical practices associated with specialty services have the potential to reinforce beliefs that contribute to prolonged disability.[48,49] Therefore, the observation that fear-avoidance beliefs improved in his group of patients is encouraging. The between-group differences in fear-avoidance beliefs about physical activity persisted at 6 months and the magnitude of the between-group differences (RR point estimate at 4 weeks = 2.7, at 6 months = 1.6) were similar to the Burton *et al* study (RR point estimate at 2 weeks = 2.72, at 3 months = 1.53).[24] We believe that the wider confidence intervals observed in this study were due to the smaller sample size, rather than a smaller treatment effect. In contrast to what has been hypothesized, this study demonstrates that with the appropriate modifications, physical therapy treatment consisting of treatment-based classification, educational pamphlets, and exercise results in a positive, clinically meaningful improvement in fear-avoidance beliefs.

Fear-avoidance beliefs about work improved after 6 months for the fear-avoidance group, but did not significantly differ from the standard care group, a finding consistent with a previous study.[37] One reason for this finding could have been that only 6% of this sample had work-related low back pain, and the work scale was not an appropriate measure of fear-avoidance for this sample. Another potential reason is that the fear-avoidance treatment used in this study was too generic to influence the patients' work beliefs. For example, the *Back Book* does not provide information about positive coping and management strategies that can be used in the work place. Similarly, the graded exercise program used in this study may not have adequately exposed the study participants to work situations of which they were fearful. In order to positively change work beliefs, clinicians and researchers may find it necessary to investigate the effect of educational information that is specific to the work place and to investigate the effect of alternate forms of exercise prescription. Graded exposure, which gradually exposes individuals to increasing levels of specific situations that they fear will cause pain to their back, is an example of such an exercise prescription.[50]

■ Conclusion

This clinical trial suggests that disability experienced at 4 weeks and 6 months after an episode of low back pain is dependent on an interaction between the type of treatment received and the level of fear-avoidance beliefs. The nature of the interaction was that only those patients with elevated fear-avoidance beliefs experience less disability with fear-avoidance treatment. This compliments a secondary prevention disability reduction strategy because it suggests that fear-avoidance treatment may be an effective treatment option after patients with an increased risk for chronic disability (*i.e.*, elevated fear-avoidance beliefs) are identified. These findings further compliment secondary prevention because they suggest that patients without an increased risk of chronic disability (*i.e.*, lower fear-avoidance beliefs) do not benefit from fear-avoidance treatment. Before these relationships are confirmed; however, further research to establish sound "cut-off" scores based on fear-avoidance beliefs, and larger clinical trials, stratified by level of fear-avoidance beliefs are necessary. This clinical trial also demonstrated that patients receiving fear-avoidance treatment report lower fear-avoidance beliefs about physical activity. It appears that additional research needs to be completed to find treatment options that effectively reduce work beliefs.

■ Key Points

- The resultant disability at 4 weeks and 6 months after treatment was dependent on an interaction between the type of physical therapy treatment the patient received and the initial level of fear-avoidance beliefs.
- The nature of the interaction suggests that patients with elevated fear-avoidance beliefs benefit from fear-avoidance–based physical therapy, whereas patients with lower fear-avoidance beliefs do not benefit from fear-avoidance–based physical therapy.
- At 4 weeks and 6 months, a significant decrease in fear-avoidance beliefs about physical activity was observed in patients receiving the fear-avoidance–based physical therapy.

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