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High Fear-Avoiders of Physical Activity Benefit From an Exercise Program for Patients With Back Pain

Jennifer A. Klaber Moffett, MSc, PhD, MCSP,* Jane Carr, MSc,* and Elaine Howarth, MSc†

Study Design. A subgroup analysis of patient outcomes from a randomized controlled trial comparing a Back to Fitness program with usual general practitioner care.

Objectives. To test whether patients with high scores on measures of fear-avoidance and distress/depression benefit the most.

Summary of Background Data. A fitness program, ongoing since the 1980s, was developed for use in the community and has been shown to be effective in reducing disability. Detailed analyses are needed to identify patient groups who benefit. Recent evidence points to the potentially important role of fear, distress, and depression.

Method. Data from 98 patients allocated to normal general practitioner care and 89 patients allocated to a group exercise program were analyzed after categorizing baseline scores on fear-avoidance beliefs (high/low) and distress/depression (at risk/normal). The main outcome measure was the Roland Disability Questionnaire. Outcomes were compared between the intervention and control groups at 6 weeks, 6 months, and 12 months.

Results. High fear-avoiders fared significantly better in the exercise program than in usual general practitioner care at 6 weeks and at 1 year. Low fear-avoiders did not. Patients who were distressed or depressed were significantly better off at 6 weeks, but the benefits were not maintained long-term.

Conclusion. Patients with high levels of fear-avoidance beliefs could significantly benefit from the Back to Fitness program. The benefits of the exercise program for patients with high levels of distress/depression appear to be short-term only. Average attendance was only 4 to 5 classes, which may not be sufficient for more recalcitrant cases. Further research is indicated. [Key words: back pain, exercise, fear, depression, randomized controlled trial] **Spine 2004;29:1167–1173**

It is widely recommended that patients with back pain need be encouraged to resume normal activities as soon as possible.[1–3] However, there may be a variety of obstacles that prevent this. A recent systematic review of psychological factors (based on 6 prospective cohorts of patients) found evidence that distress, depressive mood, and somatization at baseline all influence outcome.[4] Also, the theoretical framework for the development of fear-avoidance beliefs and their influence on musculoskeletal disorders has recently been reviewed.[5] Both Pincus *et al*[4] and Vlaeyen and Linton[5] stressed the need for research in this area, as the consequences are likely to be important.

A fitness program has been ongoing since the 1980s at an orthopedic hospital in Oxford, United Kingdom, in recognition that patients with chronic back pain often need help in regaining confidence to use the spine normally. It was designed to be an adjunct to a back school that provided patient education and advice.[6,7] The exercise program consists of 8 1-hour sessions held twice a week in the early evening, so that people who are employed do not have to take time off work. It is designed to encourage movement of the back and strengthens and stretches all the main muscle groups in the body but does not focus on the back. It incorporates cognitive-behavioral principles.

The program was demonstrated in a randomized controlled trial (n = 81) to be significantly more effective in terms of function than a back school on its own.[8] Even 2 years later, patients still reported significantly reduced levels of functional disability on the Oswestry Disability Index.[9,10] This program was more recently developed for use in the community setting, requiring less space and no gym equipment. The details of the *Back to Fitness* program have been documented in a manual for physiotherapists.[11] In a trial (n = 187) of its clinical effectiveness and cost effectiveness, it was compared to general practitioner (GP) management as usual. Small but statistically significant benefits were demonstrated at 6 and 12 months.[12] Immediately after the treatment phase, pain intensity was not reduced but distressing pain was significantly reduced, suggesting that the patients randomized to the intervention were able to cope better. At both 6 and 12 months after randomization, according to scores on the primary outcome measure, the Roland Disability Questionnaire (RDQ),[13] patients allocated to the intervention reported small but significantly improved function. Sick days totalled 607 for the control group compared to 378 in the intervention over the succeeding 12-month period. The mean costs per patient including days off work and extra equipment for the control group was £508 and for the intervention group £360. Because the average number of classes attended was 4 to 5, it seems unlikely that benefits can be attributed primarily to physiologic changes. It has been suggested in relationship to

From the *Institute of Rehabilitation, University of Hull, Hull, and †Applied Statistics Centre, University of Hull, Hull, United Kingdom.
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Address correspondence and reprint requests to Jennifer A. Klaber Moffett, MSc, PhD, MCSP, Institute of Rehabilitation, University of Hull, 215 Anlaby Road, Hull, HU3 2PG, United Kingdom; E-mail: j.k.moffett@hull.ac.uk

another comparable exercise program that benefits may be attributed to changes in psychological factors.[14]

Clearly not every back pain patient needs to be referred to this type of program, and many are not prepared to participate in an exercise program. It is, however, important to establish who could benefit most from the *Back to Fitness* program. Previous research has suggested the potentially important role of fear-avoidance beliefs in the development of chronic back pain.[15–19] In particular, it has been suggested that back pain disability for some patients may be determined more by the fear of pain rather than pain intensity or biomedical factors.[5] Fears of this nature can be observed in the clinical setting. McCracken *et al* reported that anxious patients often overpredict pain when asked to carry out a "straight leg raise."[20] There is some evidence that exposing the patient to what they fear the most, *i.e.*, movement, may be important in treatment regimes. Crombez *et al* found that over prediction of pain was reduced by a gradual repeated exposure to the activity that the person feared.[16] The *Back to Fitness* program that promotes a gradual return to normal activities in a supervised setting may be of particular benefit for this subgroup of patients. Fear of physical activity can be measured on a subscale of the Fear-Avoidance Beliefs Questionnaire.[19]

Psychological distress can often accompany longstanding back pain and can be related to an avoidance of usual activities, leading to a sense of helplessness.[21] Two of the most common causes of distress can be an increased bodily awareness (somatization) and depressive symptoms. These can be measured using the Distress and Risk Assessment Method (DRAM).[22] Recent research has shown that even older patients with recalcitrant depressive symptoms can respond to exercise.[23] It is therefore possible that back pain patients who are distressed might benefit from the *Back to Fitness* program.

The aim of this analysis was to test the following hypotheses:

1. Patients with high baseline fear-avoidance beliefs will benefit most from participation in the exercise classes, in terms of improving by at least 2 RDQ points, compared to those receiving usual GP care.
2. Patients with high baseline fear-avoidance beliefs will benefit most from participation in exercise classes, demonstrating a reduction in fear-avoidance beliefs at 6 weeks followed by an improvement in functional outcome at 12 months, compared to those receiving usual GP care.
3. Patients who are classified as *at risk/distressed* at baseline will benefit most from participation in the exercise classes, in terms of improving by at least 2 RDQ points over time, compared to those receiving usual GP care.

■ Method

Study Design. A subgroup analysis of patient outcomes from a randomized controlled trial comparing an exercise program for patients with back pain with usual GP care in the community setting.[12]

Patients. A total of 187 patients participated in the randomized controlled trial,[12] and all were included for the purposes of the present analysis. They were aged 18 to 60 years, had mechanical low back pain of between 6 weeks' and 6 months' duration, and all had to be declared medically fit by their GPs to participate in classes. Exclusion criteria were constant or persistent severe back pain judged on clinical grounds to be due to nerve root problems, other musculoskeletal disabilities that would affect their ability to cope with the fitness program, systemic conditions, major surgery within the last year, fractures, and pregnancy.

Recruitment and Randomization. Patients were referred by 87 participating GPs in the York area. Potentially eligible patients were invited by telephone to an initial interview to explain the study and its implications. Those who met the eligibility criteria and consented to participate attended a first assessment a week later. This included a physical examination (to exclude possible serious spinal pathology) and collection of baseline data. Patients were randomized using a computer-generated randomization list. Allocation to treatment was concealed from the clinical researchers. All participating patients signed a consent form.

Treatment. Patients were allocated either to exercise classes (8 sessions of 1 hour spread over 4 weeks) or to GP care as usual. Exercises were designed to increase confidence in using the spine normally. This included low-impact aerobic exercises and strengthening and stretching exercises for the main muscle groups. A cognitive behavioral approach underpinned the program.

Questionnaires

- The RDQ was administered at baseline, 6 weeks, 6 months, and 12 months.[13]
- The Fear-Avoidance Beliefs Questionnaire was administered only at baseline and at 6 weeks.[24]
- The DRAM (combined Modified Somatic Perceptions Questionnaire[25] and the modified Zung questionnaire[19]) was only administered at baseline as a predictor of outcome. This method classifies patients into 4 categories: normal, at risk, distressed depressive, and distressed somatic.[22]

The main focus of the current analysis is on the Fear-Avoidance Beliefs Questionnaire, using only the section relating to physical activities. This subsection, referred to as the FABphys, asks to what extent the patient agrees or disagrees with following statements:

My pain was caused by physical activity.

Physical activity makes my pain worse.

Physical activity might harm my back.

I should not do physical activities that (might) make my pain worse.

I cannot do physical activities that (might) make my pain worse.

The fear-avoidance scores of participating patients were split into high and low scores using a cutoff point of 14 or more,

Table 1. Baseline Variables for the Two Groups

Variable	Intervention (n = 89) Mean (SD)	Control (n = 98) Mean (SD)
Age (yrs)	41.1 (9.21)	42.6 (8.62)
No. of women	51 (57%)	55 (56%)
RDQ (range 0–24)	6.65 (4.01)	5.56 (3.94)*
FABphys (range 0–30)	13.79 (5.26)	12.74 (5.47)
Fear-avoidance group	Numbers in each category	
Low fear (0–13 points)	41 (44%)	53 (56%)
High fear (14–24 points)	48 (52%)	45 (48%)
Distress and Risk Assessment Method		
Normal	40 (45%)	56 (57%)
At Risk	34 (38%)	34 (35%)
Distressed Depressive	12 (14%)	4 (4%)
Distressed Somatic	3 (3%)	4 (4%)

Values are mean (SD) unless otherwise stated.
* $P < 0.05$.
RDQ = Roland Disability Questionnaire; FABphys = fear-avoidance beliefs about physical activity.

which was the median baseline score in this study. This cutoff point was used in a similar way in another study of how patients' beliefs were influenced by an intervention, in this case through simple messages in *The Back Book*.[15,26] Patients are referred to as low or high fear-avoiders. The change score of more than 4 on the FABphys was defined as a clinically important score.[19] For the DRAM, there were too few numbers, for analysis purposes, in the *distressed depressive* and *distressed somatic* categories. However, by combining the *at risk* groups with the *distressed* groups, it was possible to compare a proportionate number of those who were at risk or distressed with normal patients. Although collapsing the *at risk* patients with the other 2 categories results in a more heterogeneous group, the reporting of depressive symptoms (*i.e.*, >17 points on the Modified Zung Scale) is a common denominator in this combined group.

Analysis was focused on differences between the intervention and control groups and included analyzing clinically important improvements in individual patients, in particular achieving a 2-point improvement in RDQ at each of the follow-up points from randomization (a score of 2–3 points has been cited as the cutoff point for a minimally important level of clinical change[27]). The sample size (n = 187) of the original study enabled 90% power to detect a 2-point difference in outcome (RDQ). Statistical significance was set at the 5% level. The statistical package SPSS[28] was used.

The statistical analysis used an assessment of odds ratio (OR) to allow for the appropriate presentation of binary logistic regression to account for baseline RDQ scores and enable comparison between unadjusted and adjusted analyses. It was considered necessary to adjust for the baseline RDQ scores, as the mean score was higher in the intervention group. An OR, for example, of 1.5 indicates that the odds of a given occurrence (such as improving by at least 2 RDQ points) for a patient allocated to the exercise program is 1.5 times as great as that for one allocated to the control group. All odds ratios were reported with their corresponding 95% confidence intervals (95% CI).

■ Results

Baseline Characteristics

The baseline characteristics of our study population are shown in Table 1. The 2 treatment groups were similar with respect to age, gender, and baseline FABphys scores. The mean baseline RDQ score for the intervention group was slightly higher than for the control group ($P = 0.048$). Overall, there was no association between treatment group and DRAM category at baseline. However, a small but significantly higher proportion of "distressed depressive" patients were randomized to the intervention group ($\chi^2 = 5.27$, $P = 0.022$).

Clinical Outcomes

Table 2 shows the proportion of (and percentage of) patients who improved by at least 2 RDQ points according to their level of fear-avoidance beliefs (FABphys) at baseline. Within the high fear-avoidance group at baseline, patients randomized to the exercise classes demonstrated statistically significant benefits, compared to the control group, at 6 weeks (unadjusted OR = 3.77), 6 months (unadjusted OR = 2.82), and 12 months (unadjusted OR = 4.80). However, when the baseline RDQ scores were accounted for, within the high fear-avoidance group, patients randomized to the intervention treatment group reported statistically significant benefits, compared to the control group, only at 6 weeks and at 12 months (adjusted OR = 2.74 and adjusted OR

Table 2. Clinically Important Improvement in RDQ (≥2-point Reduction) Over Time, by Level of Fear-Avoidance at Baseline, for the Intervention and Control Groups

Level of Fear-Avoidance at Baseline	Intervention	Control	n	Unadjusted OR	Unadjusted 95% CI	Adjusted OR	Adjusted 95% CI
6 wks							
Low fear	21/39 (54%)	22/51 (43%)	90	1.54	0.66–3.56	1.63	0.65–4.10
High fear	36/46 (78%)	21/43 (49%)	89	3.77*	1.50–9.47	2.74*	1.08–7.35
6 mos							
Low fear	20/35 (57%)	21/48 (44%)	83	1.71	0.71–4.13	1.73	0.58–5.12
High fear	31/42 (74%)	19/38 (50%)	80	2.82*	1.10–7.19	1.98	0.72–5.48
12 mos							
Low fear	20/37 (54%)	24/49 (49%)	86	1.23	0.52–2.88	1.16	0.42–3.18
High fear	37/46 (80%)	18/39 (46%)	85	4.80*	1.83–12.56	3.58*	1.30–9.84

OR = odds ratio; CI = confidence interval.
* Significant at the 5% level.

Table 3. Analysis of Clinically Important Improvements for Those Patients With Complete Data for FABphys at 6 Weeks and RDQ at 12 Months

Group	High Fear Avoiders at Baseline FABphys ≥14 Points	High Fear Avoiders at Baseline Showing Clinically Important Improvements in FABphys at 6 Weeks and in RDQ at 12 Months
Intervention	45	19
Control	39	7

Odds ratio = 3.34; 95% confidence interval = 1.10–10.42.

= 3.58, respectively). In the low fear-avoidance group at baseline, patients randomized to the exercise classes showed greater improvements in RDQ scores compared to the control group at 6 weeks, 6 months, and 12 months but differences were not statistically significant.

Table 3 shows those patients with a high initial FABphys score (≥14 points) who were randomized to the exercise program were significantly (statistically) more likely to achieve a clinically important improvement in RDQ (≥2 points) at 12 months, which was preceded by a clinically important improvement FABphys (>4 points) at 6 weeks.

Table 4 shows the proportion of (and percentage of) patients who improved by at least 2 RDQ points according to their level of distress at baseline (*i.e.*, normal *vs.* at risk/distressed). Within the group classified as *at risk/distressed* at baseline, a statistically significantly higher proportion of patients randomized to the intervention treatment, compared to the control group, improved by at least 2 RDQ points at 6 weeks (unadjusted OR = 3.62) and 12 months (unadjusted OR = 2.78). Adjusting for baseline RDQ scores, patients within the *at risk/distressed* group and randomized to the intervention treatment group had statistically significant benefits compared to the control group at 6 weeks only (adjusted OR = 3.17). For this group of patients who were *at risk/distressed*, benefits of the intervention were not maintained at 6 months and 1 year.

■ Discussion

Encouraging physical activity through an exercise program can be effective in reducing disability and can also be preventive.[29] The results of our analysis have supported the hypothesis that those with high fear-avoidance scores at baseline benefit most from the *Back to Fitness* program (Table 2). High fear-avoiders randomized to exercise classes were over 3 times more likely at 12 months to report reduced disability (based on RDQ scores) compared with those who were randomized to usual GP care. The program was not significantly more beneficial than usual GP care for low fear-avoiders. The relationship between function and fear avoidance was further clarified. Those who improved by more than 4 points on the FABphys at 6 weeks were 3 times more likely to improve on the RDQ at 12 months (Table 3). Of special note is that benefits are maintained 1 year later after an average of only 4 to 5 classes.

Our findings are consistent with recent studies on fear-avoidance. Linton et al[18] found there was a "dose" relationship between the level of fear avoidance beliefs and the performance of activities of daily living. In a recent trial to evaluate *The Back Book*,[15] a reduction in fear-avoidance beliefs preceded a reduction in functional disability.

What may be occurring is a reinterpretation of back pain and a feeling of greater control on the part of the patients. Previous data[12] in the form of pain diaries lend support to this theory. Compared to those receiving GP care only, patients in the *Back to Fitness* program reported significant reductions in levels of distressing pain (but not pain intensity) immediately following the intervention. Similarly, in the Frost *et al* study,[8] pain self-efficacy was significantly improved in the exercise group compared with the control group.

The hypotheses in respect to the DRAM were only in part upheld. Patients who were classified as *at risk/distressed* were 3 times more likely to benefit from the *Back to Fitness* program in terms of function at 6 weeks, but after that the value of the DRAM as a predictor was

Table 4. Clinically Important Improvement in RDQ (≥2-point Reduction) Over Time, by Level of Risk and Distress at Baseline, for the Intervention and Control Groups

Level of Distress and Risk at Baseline	Intervention	Control	n	Unadjusted OR	Unadjusted 95% CI	Adjusted OR	Adjusted 95% CI
6 wks							
Normal	21/38 (55%)	24/54 (44%)	92	1.54	0.67–3.56	1.40	0.54–3.59
At risk/distressed	36/47 (77%)	19/40 (48%)	87	3.62*	1.45–9.05	3.17*	1.20–8.40
6 mos							
Normal	22/37 (60%)	22/52 (42%)	89	2.00	0.85–4.71	1.82	0.67–4.91
At risk/distressed	29/40 (73%)	18/34 (53%)	74	2.34	0.89–6.16	1.78	0.60–5.26
12 mos							
Normal	22/39 (56%)	21/52 (40%)	91	1.91	0.82–4.43	1.80	0.66–4.88
At risk/distressed	35/44 (80%)	21/36 (58%)	80	2.78*	1.04–7.46	2.26	0.81–6.33

OR = odds ratio; CI = confidence interval.
* Significant at the 5% level.

reduced (Table 4). There are several possible explanations for these results. Inevitably, precision will have been lost by collapsing the 3 groups of at risk/distressed depressed/distressed somatic. Main *et al*[22] (1992) found that Type R (at risk) patients were twice as likely as Type N (normal) to have a poor outcome, whereas Type DD (distressed depressed) or DS (distressed somatic) were 3 to 4 times more likely than Type N patients to have a poor outcome. Common to all patients in the *at risk/distressed* groups (>17) are significant scores on the Modified Zung Depression Scale. The association between back pain and depression is well documented.[4] Although good quality research is lacking, there is some evidence that exercise may be beneficial for depression in the short-term (Ernst 2001) and possibly in the longer term if patients continue to exercise on their own after treatment has finished (Babyak et al[30]). Although we have no reliable data on patients' exercise activity following participation in the trial, it is possible that the benefits of exercise for the *at risk/distressed* group were not maintained over the longer term, perhaps because patients stopped exercising. Social support has a central role in depression (Brown and Harris[31]). Possibly, by participating in a group exercise class, depressed patients derived some benefits through social support or simply through a sense of belonging (Hagerty and Williams[32]), which ceased soon after treatment ended.

Due to sample size restrictions, it was not possible to examine the combined effects of both high fear-avoidance and distress in patients. This would be a useful focus for future research. A further limitation of this study is that it was conducted locally in a relatively affluent residential area of the North East of England. These results, therefore, need to be compared with studies conducted elsewhere to include more deprived areas such as inner city populations. Data from a large-scale study, the UK back pain, exercise and manipulation trial (UKBEAM trial) evaluating the efficacy of the *Back to Fitness* program as well as spinal manipulation, will shortly be available.

One strength of the study was that it was carefully conducted, and the recruitment rates were satisfactory, in spite of the usual difficulties of carrying out such a study in the Primary Care setting.[33] The dropout rates were minimal, with a follow-up rate at 12 months of 91%.

Clinical Implications

The findings of this study suggest that different subgroups of patients may require different approaches. This has important clinical implications, and research is needed to further clarify the issues involved. Although the *Back to Fitness* program is unlikely to be suitable for everyone, it seems that there may be particular benefits for those who present with high-fear avoidance beliefs. Overcoming the fear of moving the spine normally may be the key to this program's success for this group of patients. For those with low fear-avoidance beliefs, this type of program may not be as beneficial and therefore not perhaps be necessary. For those patients who are at risk or distressed, there appears to be benefits either through exercise *per se* or through perceived support/group membership. However, the benefits for this group of patients were found to be short term. Strategies for maintaining the feeling of support/group membership and/or exercise activity may be important for more long-term benefits for this group of patients.

■ Key Points

- Patients were randomized to a *Back to Fitness* program or to usual general practitioner care.
- Patients who benefited most from the *Back to Fitness* program appeared to be those who were afraid that physical activity might damage their backs.
- Patients with high fear-avoidance beliefs who were randomized to the *Back to Fitness* program were over 3 times more likely to be functioning well at 1 year compared to those randomized to usual GP care.
- Patients with low fear-avoidance beliefs benefited from the *Back to Fitness* program in terms of function, but not significantly more than patients allocated to usual general practitioner care.
- Patients who were *at risk* or *distressed/depressed* benefited from the *Back to Fitness* program compared to those randomized to usual general practitioner care, but only in the short term.

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Point of View

Tim A. Ahles, PhD

Psychological factors have been implicated in the development and maintenance of chronic pain syndromes in many studies over the last 20 to 30 years. The importance of the study by Klaber Moffett, Carr, and Howarth relates to the examination of 2 specific psychological constructs, fear avoidance and distress/depression, and the relationship of these constructs to treatment outcome in an exercise-based treatment program. Interestingly, outcomes differed depending on the psychological variable examined. Specifically, patients classified as high fear-avoiders who were in the exercise program had significantly better outcomes as compared to patients in the usual care group at 6 weeks and 1 year posttreatment, whereas low fear-avoiders did not differ from patients in the usual care group. Patients classified as distressed/depressed who were treated with exercise had better outcomes than the usual care group at 6 weeks; however, these benefits were not maintained.

An important aspect of these findings is that they have direct clinical relevance, both in terms of the identification of patients who might be more appropriate for an exercise intervention and in terms of further tailoring of the intervention to target the psychological factors identified. As outlined in previous research,[1,2] the intervention focuses primarily on graduated exercise. An exciting next step in the research would be to compare the current treatment with one that includes components that target fear-avoidance (*e.g.*, cognitive strategies to reduce irrational beliefs, graded exposure to feared physical activities, arousal reduction strategies like relaxation exercises, *etc.*) to see if outcomes are further enhanced. Similarly, strategies that target distress/depression (*e.g.*, cognitive-behavioral techniques and/or medications) and specific relapse prevention strategies might enhance outcomes for patients in this group.

Another intriguing finding is the lack of difference in outcomes when comparing intervention patients who were categorized as low fear-avoiders or low distress/depression and usual care controls. One might have predicted that patients with no co-occurring psychological issues would receive maximal benefit from an exercise-based program. Does a structured exercise program not add to standard care for these patients, or does standard care include enough instruction in back exercises or referral to physical therapy such that the 2 interventions are functionally equivalent for patients with no psychological issues? Answers to these questions may lead to approaches for enhancing the efficacy of the exercise intervention for the low fear avoidance, low distress/depression groups or may lead to cost-effective interventions that can be delivered within the context of standard care. As with all good research, more questions are stimulated than are necessarily answered within the context of this study.

From the Department of Psychiatry-Behavioral Medicine, Dartmouth Hitchcock Medical Center, Lebanon, New Hampshire.
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Address correspondence and reprint requests to Tim A. Ahles, PhD, Department of Psychiatry-Behavioral Medicine, Dartmouth Hitchcock Medical Center, One Medical Center Drive, Lebanon, NH 03756, USA; E-mail: Tim.A.Ahles@Dartmouth.edu

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