Graded Exercise for Recurrent Low-Back Pain
A Randomized, Controlled Trial With 6-, 12-, and 36-Month Follow-ups

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Study Design. The study was a randomized controlled trial. Treatment was for 8 weeks, with follow-up posttreatment and at 6-, 12-, and 36-months.

Objective. The purpose was to evaluate the effect of a graded exercise intervention emphasizing stabilizing exercises in patients with nonspecific, recurrent low back pain (LBP).

Summary of Background Data. Exercise therapy is recommended and widely used as treatment for LBP. Although stabilizing exercises are reportedly effective in the management of certain subgroups of LBP, such intervention protocols have not yet been evaluated in relation to a more general exercise regimen in patients with recurrent LBP, all at work.

Methods. Seventy-one patients recruited consecutively (36 men, 35 women) with recurrent nonspecific LBP seeking care at an outpatient physiotherapy clinic were randomized into 2 treatment groups: graded exercise intervention or daily walks. The primary outcome was perceived disability and pain at 12-month follow-up. Secondary outcomes included physical health, fear-avoidance, and self-efficacy beliefs.

Results. Of the participants, 83% provided data at the 12-month follow-up and 79% at 36 months. At 12 months, between-group comparison showed a reduction in perceived disability in favor of the exercise group, whereas such an effect for pain emerged only immediately postintervention. Ratings of physical health and self-efficacy beliefs also improved in the exercise group over the long term, although no changes were observed for fear-avoidance beliefs.

Conclusion. A graded exercise intervention, emphasizing stabilizing exercises, for patients with recurrent LBP still at work seems more effective in improving disability and health parameters than daily walks do. However, no such positive results emerged for improving regard pain over a longer term, or for fear-avoidance beliefs.

Low back pain (LBP) is one of the western world’s greatest socioeconomic medical problems. A 69% lifetime prevalence of LBP in Sweden has been reported. LBP refers to a large heterogeneous group of patients in which nonspecific LBP represents a high proportion, and a recurrence as high as 86% has been proposed. Physical activity in general is considered important for health, depression, and pain experience, and exercise therapy is recommended and widely used in LBP. Uncertainty continues, however, about the most effective exercise approach. Recently, there has been focus on exercises aiming to optimize the control of segmental motion and stabilization of the lumbar spine. Bergmark. Proposed in a biomechanical model that the lumbar spine is stabilized by activation of “the local muscle-system”: segmentally inserted muscles; here, experimental research has reported deficits in m. transversus abdominis (TrA) and m. multifidus (MF) in subjects with LBP compared with healthy persons. In addition, altered motor control of the lateral abdominals seems related to the persistence and chronicity of LBP. At least in the early phases of management, stabilizing exercises targeting these muscles seem to be effective in reducing disability, pain, and recurrence rate in LBP. It has, however, been argued that it is important to involve a combination of several potentially lumbar spine stabilizers in an exercise protocol. Stabilizing exercises differ from general exercises by being more body-specific and requiring more attention and precision from the patient. Importantly, psychosocial factors related to the development of pain and disability, e.g., self-efficacy, and fear of movement, may also affect the persistency and recurrence of pain. The stabilizing exercises, by being individually dosed and graded into functional and loaded positions, might affect self-efficacy beliefs and possible fear of movement. So far, few trials have investigated stabilizing exercises as an isolated factor, whereas others have combined stabilizing exercises with methods such as education, manual therapy, manipulation, and general exercises. These trials report somewhat conflicting results. In addition, few trials distinguish between subjects at work and those who are not. To our knowledge, the usefulness of a graded, individually dosed exercise intervention emphasizing stabil-
lizing exercises has not yet been investigated in recurrent LBP, and no such trial approaches subjects still at work.

The present trial investigated the short- and long-term effects of a graded protocol emphasizing stabilizing exercises in subjects with recurrent nonspecific LBP, all at work on inclusion. This exercise group was compared with a reference group receiving instruction about daily walks. Outcome measures were perceived disability, pain, physical health, and self-efficacy and fear-avoidance beliefs about physical activity.

Materials and Methods

Design

The present single-center, randomized, controlled trial had 6-, 12- and 36-months follow-ups. A fixed allocation randomization procedure guaranteed equal numbers of patients of each sex in each group: the first woman and the first man were allocated by lot to either the exercise group or the reference group. Patients were thereafter consistently assigned to either group. The assignments were presented in sealed, sequentially numbered envelopes, and the assignment list was maintained by the clinic’s secretarial staff. The 2 treating physiotherapists (PT) had no influence on the allocation.

The inclusion of subjects was based on a power of 0.80 (α of 0.05) to detect a reduction in perceived pain (by > 50% from initial status) that was one-third greater in the intervention group than in the reference group at 12-months follow-up. This was based on the hypothesis that (a) one-third of the reference- and intervention group would reduce perceived pain due to regression-to-the-mean and nonspecific treatment effects and (b) one-third greater in the intervention group than in the reference group would reduce perceived pain due to treatment effects. The power calculation was based on a pilot study. In allowing for a 15% drop-out rate in the long-term, this resulted in a sample-size of n = 72.

Participants

Subjects with LBP (n = 369) seeking care at a primary health care setting, a private physiotherapy clinic, between August 2003 and May 2004 were considered for inclusion. Of the subjects, 23% were referred from general practitioners, and the rest sought care by own initiative or by recommendations. Inclusion criteria were: men and women aged 18 to 60 years, still at work despite ongoing recurrent LBP (>8 weeks) but with at least 1 pain-free period during the previous year. LBP was defined as pain, ache or discomfort, localized below the costal margin and above the inferior gluteal folds without referred leg pain. The subjects had mechanically induced LBP with pain on active movement (e.g., extension, flexion, and lateral flexion), paravertebral tenderness, and a positive springing test of at least 1 lumbar segment. The clinical tests used have previously been tested for good interexaminer reliability. 

Exclusion criteria were: first-time LBP, pain radiating to the leg or legs with or without overt neurologic signs, pregnancy, known lumbar disc hernia or fracture, back surgery, diagnosed inflammatory joint disease, known severe osteoporosis, or known malignant disease. Participant recruitment and flow are summarized in Figure 1. Clinical and demographic characteristics were similar between the 2 groups (Table 1).

The patients were allocated to the first available PT at the clinic for a clinical examination. The 12 PTs that examined the subjects had an international certificate in manual therapy and more than 15 years of this specialization, and had clinical experience of mean 21 years. They 2 treating PTs were experienced in stabilization training.

After the clinical examination, if eligible, the patients were informed about the trial and invited to participate. Five declined. Seventy-one (36 women, 35 men) with an average pain duration of mean 11 (range 1–38) years gave their informed consent. After the clinical examination, eligible subjects received a new appointment with either of the 2 treating PTs. Evaluations pre-, posttreatment and follow-ups at 6-, 12-, and 36-months all consisted of self-completed questionnaires, which were returned by post in prepaid envelopes. Baseline demographic data were collected by interview on inclusion. Questions on earlier treatment, expectation of treatment, and on compliance at 6-, 12, and 36-months with the intervention were included in the general questionnaire, presented together with the other instruments. One question evaluated adherence in long-term to continuous exercises/walks; do you go on exercising as instructed during the intervention period? (Yes/No).

Outcome Measures

Primary outcome was perceived disability and pain at the 12-month follow-up. Perceived disability was measured with the Oswestry Low Back Pain Questionnaire (OSD). The OSD is designed to assess how pain affects various activities of daily living. Total score is 100. The instrument is advocated as a core outcome measure in clinical LBP trials. Pain was measured with a 100-mm visual analogue scale anchored by “no pain at all” and “worst pain imaginable.” Secondary outcome included physical health assessed through the Short Form-36 Health Survey. This is a generic health survey not designed for any special patient category but recommended in studies of back pain. The self-efficacy scale assessed self-efficacy beliefs specially related to 8 basic physical activities, and fear-avoidance beliefs were assessed with the modified fear-avoidance-beliefs questionnaire on physical activity.

Interventions

The initial clinical examination lasted for 60 minutes for all included subjects. All subjects were informed on inclusion that physical activity is beneficial for LBP, but not what activity is best. All subjects received information on the importance of continuing normal activities, and basic advice on e.g., lifting, resting, and sitting. The treatment period was 8 weeks; the subjects in the exercise group were individually supervised by a PT weekly for 45 minutes and the subjects in the reference group met the PT for 45 minutes the first (week 1) and last week (week 8).

Exercise Group. The PT individually supervised and used clinical judgment in the progression of the graded stabilizing exercises. First, the subjects were informed of how the stabilizing muscles act, as hypothesized, in healthy people and in those with LBP. The PT demonstrated how the muscles act as stabilizers. It was explained that the “deep inner muscle corset” (i.e., the local muscle system) and the “outer corset” (i.e., the global muscle system) are both important for maintaining good functional stability of the spine. The importance of relearning activation of the deep inner corset (i.e., TrA and the deep MF) was emphasized. To avoid recurrent LBP periods, the importance of contracting the stabilizing mus-
cles in activities of daily-life, especially those that set off pain, was underlined. The progression of the exercises was based on the patients’ pain level and observed movement control and quality. In contrast to strength training, the program used low-load endurance exercises. The first stage consisted of specific exercises to address the stabilizing muscles, after the protocol described by Richardson et al. with instructions to gently draw in the anterolateral abdominal wall (i.e., TrA isolated from the other abdominal muscles) together with a tightening of the MF in different nonpostural positions, together with relaxed breathing. A bio-pressure unit was used in the learning process (Stabilizer; Chattanooga Group, Hixon, TN). In the subsequent phase, the program gradually progressed to performing the exercises posturally more upright and to functionally loaded positions/exercises. Exercises with moderate resistance via pulleys in standing and seated positions were performed to increase the demand on the stabilizing muscle system and to train the “local” and “global” muscle system together. A natural spine position both during the exercises and in daily life was emphasized, avoiding pain-generating postures. The patients were encouraged to perform the low-load exercises at home every day. The home-training program was designed to take approximately 15 minutes, and has previously been reported on. The subjects were instructed to maintain the program indefinitely to avoid recurrence of pain. It was emphasized that although adherence with a home-training program is important, the most important thing is to incorporate activation of the stabilizing muscles in daily life.

**Reference Group.** The subjects in the reference group (n = 35) were informed of the benefits of daily walks as physical activity. They were instructed to take a 30-minute walk every day. The walk might be divided into 2 parts of 15 minutes.
They were instructed to walk at the fastest pace that was convenient and did not set off pain. If their pain persisted or increased they should slow down. They should continue walking taken were recorded in a diary, which was returned to home exercises but with no follow-up instructions. The daily walks increased they should slow down. They should continue walking taken were recorded in a diary, which was returned to home exercises but with no follow-up instructions. The daily walks increased they should slow down. They should continue walking was determined. The subjects were, after treatment and at follow-ups, dichotomized by MCIC in perceived disability and pain. A $\chi^2$ test was used to assess the differences between the groups regarding MCIC. Potential baseline differences between responders and nonresponders through the follow-up course were examined with regression analysis. An intention-to-treat procedure was followed (last-observation-carried-forward). Adherence to the intervention in the reference-group is presented as percentage of performed daily walks as reported in the diaries. In the exercise group, adherence is presented as percentage PT sessions attended. For the long-term result, adherence is presented as percent of individuals reporting continuous training. Statistical significance was set to $P \leq 0.05$.

### Results

Clinical and demographic characteristics were similar between the 2 groups (Table 1). Regression analysis on baseline variables between responders versus nonresponders showed that subjects who responded to all follow-up occasions were associated with better physical health.

At the 12-month follow-up, 55% of the exercise-group and 26% of the reference group had reduced their pain level by 50% or more ($P = 0.01$). Regarding MCIC, 53% of the subjects in the exercise group and 34% in the reference group showed a clinically important change ($\geq 15$ mm) in perceived pain ($P = 0.11$) after the intervention. Regarding perceived disability, 44% in the exercise group and 31% in the reference group showed an MCIC ($\geq 10$ points) ($P = 0.26$) after the intervention. At the 12-month follow-up, the exercise group showed an MCIC regarding perceived disability of 53% and the reference group of 26% ($P = 0.02$).

Regarding primary outcome, Friedman’s within-group ANOVA revealed that both groups significantly improved over time concerning perceived disability ($P < 0.01$) and for pain ($P < 0.001$) (Table 2). For secondary outcome, Friedman’s ANOVA revealed improvement over time concerning physical health in both groups ($P < 0.001$) but regarding fear-avoidance and self-efficacy beliefs only in the exercise group ($P < 0.001$).

Table 2 shows baseline median values and median change scores for each follow-up. Between-group testing (Mann-Whitney $U$ test) showed significant differences in favor of the exercise group for perceived disability at the 6-months [exercise group; $-9$ (md), $-19/-2$ (25th/75th)] and 12-month [exercise group; $-10$ (md), $-20/-2$ (25th/75th)], maintained at the 36-month follow-up [exercise group; $-11$ (md), $-23/-4$ (25th/75th)] (Figure 2). In addition, between-group results for pain showed greater reduction for the exercise group postintervention $[-15$ (md), $-31/-8$ (25th/75th)] (Figure 3).

The exercise group maintained their pain level, but there was no significant group difference in the long-term. Regarding secondary outcome, the results

### Table 2. Median Values (md/25th/75th) Preintervention and Median Change Score Postintervention, and at Each Follow-up Occasion in Exercise Group ($n = 36$), Reference Group ($n = 35$)

<table>
<thead>
<tr>
<th></th>
<th>Preintervention</th>
<th>Postintervention</th>
<th>6 mo</th>
<th>12 mo</th>
<th>36 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pain</strong></td>
<td></td>
<td>$P = 0.025$</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Exercise</td>
<td>32 (18–59)</td>
<td>$-15 (-31/-8)$</td>
<td>15.5 (30/3.5)</td>
<td>$-12 (-34.5/-3)$</td>
<td>$-14 (-40/-4.5)$</td>
</tr>
<tr>
<td>Reference</td>
<td>38 (23–62)</td>
<td>$-8 (-19/-1)$</td>
<td>$-9 (24/0)$</td>
<td>$-12 (-22/0)$</td>
<td>$-12 (-23/-2)$</td>
</tr>
<tr>
<td><strong>Disability</strong></td>
<td></td>
<td>$P = 0.023$</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercise</td>
<td>20 (12–26)</td>
<td>$-7 (-15/-4)$</td>
<td>$-9 (-19/-2)$</td>
<td>$-10 (-20/-2)$</td>
<td>$-11 (-23/-4)$</td>
</tr>
<tr>
<td>Reference</td>
<td>22 (14–28)</td>
<td>$-4 (-10/0)$</td>
<td>$-4 (10/0)$</td>
<td>$-2 (12/2)$</td>
<td>$-6 (-14/0)$</td>
</tr>
<tr>
<td><strong>Physical health</strong></td>
<td></td>
<td>$P = 0.015$</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercise</td>
<td>ns</td>
<td>$-7 (-15/-4)$</td>
<td>$-9 (-19/-2)$</td>
<td>$-10 (-20/-2)$</td>
<td>$-11 (-23/-4)$</td>
</tr>
<tr>
<td>Reference</td>
<td>ns</td>
<td>$-4 (-10/0)$</td>
<td>$-2 (-12/2)$</td>
<td>$-6 (-14/0)$</td>
<td>$-6 (-14/0)$</td>
</tr>
<tr>
<td><strong>Fear-avoidance</strong></td>
<td></td>
<td>$P = 0.005$</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercise</td>
<td>ns</td>
<td>$-1 (-4/0)$</td>
<td>$-3 (-5/0)$</td>
<td>$-3 (-7/0)$</td>
<td>$-3 (-9/0)$</td>
</tr>
<tr>
<td>Reference</td>
<td>ns</td>
<td>$0 (-2/2)$</td>
<td>$-1 (-2/2)$</td>
<td>$-1 (-7/2)$</td>
<td>$-2 (-6/0)$</td>
</tr>
<tr>
<td><strong>Self-efficacy</strong></td>
<td></td>
<td>$P = 0.005$</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercise</td>
<td>49 (43–53)</td>
<td>2.5 (0.6/5)</td>
<td>5 (0/9.5)</td>
<td>7.5 (1–12)</td>
<td>8 (2/13)</td>
</tr>
<tr>
<td>Reference</td>
<td>44 (35–58)</td>
<td>1 (0/5)</td>
<td>3 (0/7)</td>
<td>3 (-9/10)</td>
<td>4 (0/7)</td>
</tr>
</tbody>
</table>

Significant between-group differences are indicated with bold ($P \leq 0.05$). ns indicates nonsignificant.
showed a significant group difference in short- and long-term regarding physical health and group difference in assessed self-efficacy after 12 and 36 months. Regarding fear-avoidance, no such differences emerged.

In the exercise group, there was 96% attendance at the PT sessions, and in the reference group 71% adherence with the daily walks. Long-term adherence with training at the 12- and 36-month follow-ups was 78% and 61% in the exercise group versus 57% and 51% in the reference group, respectively (P = 0.01, P = 0.41). Twenty-two percent in the exercise group and 46% in the reference group reported a recurrent need for new treatment periods at the 12-month follow-up (P = 0.03), whereas at the 36-month follow-up, the proportions were 36% and 40%, respectively (P = 0.73).
Discussion

The present trial sought to evaluate disability and pain parameters in subjects with recurrent ongoing LBP, still at work, after a supervised graded exercise-protocol emphasizing stabilizing exercises. The main results showed a reduction in perceived disability in the short- and long-term in favor of the exercise group while such results emerged only for pain in the short-term. The secondary outcome measures physical health, self-efficacy, and less need for recurrent treatment periods improved in the intervention group, whereas no effects emerged for fear-avoidance beliefs.

Our results are comparable to those of trials evaluating stabilizing exercises as an isolated factor in specific subgroups of LBP. Other clinical trials evaluating these exercises used a more pragmatic approach combining the stabilizing exercises with other methods. This may explain, at least partly, the discrepancies between the studies.

The present group of subjects was well defined. The subjects had nonspecific LBP with localized mechanical LBP, included by PTs with an international degree in manual therapy. A health-care setting with all physiotherapists experienced in clinical examination of LBP disorders might not be generalizable to every clinical setting. This might be considered a limitation to the present study. A majority of the present subjects (67%) sought care in the present primary clinical setting without referral by a general practitioner. This might also not be generalizable to other trials collecting subjects from primary-health-care settings, where patients with pain still may need a referral by a general practitioner.

Patients who remain in primary health care, as in the present study, may be expected to be less disabled than those referred to specialized secondary settings. The present intention was to investigate a subgroup with LBP, which is commonly seen in a primary health-care setting. To investigate a more homogenous group, the present study included subjects still at work. Few clinical trials distinguish between subjects at work and those who are not, which makes it harder to interpret outcomes.

The exercises performed in the present study were intended to change the activity pattern of the stabilizing muscles. The theory is that repeated voluntary activation of a muscle induces plastic change in the nervous system, leading to a modification of the automatic recruitment of the trained muscle during performance of functional tasks. However, few clinical trials present evidence of such a change. Recent laboratory studies evaluating an isolated voluntary contraction of TrA in patients with LBP showed an improvement in motor control 6 months after the intervention. Hall et al reported that nonspecific “core” exercises targeting the abdominals did not change the activity pattern of TrA. These laboratory studies, however, include few subjects; and the importance of whether changes in trunk-muscle activity are a cause or an effect of LBP is not known. We did not control for a possible change in muscle activity pattern using ultrasound or electromyography but aimed, rather, to investigate the patients’ own ratings of pain and disability after an exercise intervention based on this hypothesis. It is, however, not clear that reduced pain and disability after stabilizing exercises is associated with changes in the muscle activity pattern: other underlying explanations are possible.

Behavioral-cognitive treatment emphasizes modification of a behavioral process assuming that pain and disability are influenced not only by somatic factors. Although the present subjects were being gradually coached in exercises and function, a behavioral change might have occurred. Treatment strategies should focus on improving functional abilities using a graded approach, and the use of such an approach seems advisable in LBP. There is also growing evidence that improvement in self-efficacy is associated with disability, more than pain or fear-avoidance. One might therefore assume that, in the exercise group, the enhanced self-efficacy beliefs were associated with the alleviation of disability. An analysis of possible associations between our subjects’ baseline characteristics and the outcome of the present trial is currently in hand.

With respect to intergroup variability, the exercise group reduced disability significantly both in short- and long-term. Although the exercise group did supervise graded exercises and was instructed to activate the stabilizing muscles in pain-generating situations, the reference group was instructed to take daily walks. As a general exercise program does not aim to train specific activity patterns, it might not improve disability in the same way as body-specific stabilizing exercises do. Further, general exercises do not change the activity pattern of the stabilizing muscles, as recently reported. The present trial intended to combine specific exercises with functional exercises in which both “local” and “global” muscles work together. This has previously been proposed to be important in an exercise protocol. Other issues affecting the outcome of the present trial need to be considered when interpreting the results, such as the patients’ expectations, the therapists’ enthusiasm and expertise, and furthermore, subgroups of patients with LBP adopt different self-management strategies to avoid recurrence of pain. However, in the long-term, the effects of such issues should at least partly have faded. At the 36-month follow-up, only self-efficacy and physical health were improved in favor of the exercise group, and this may indicate a possible benefit of the graded exercises.

The adherence to the intervention may be considered high in comparison with other trials investigating stabilizing exercises. The fact that all subjects were at work might be reason. Furthermore, the subjects in the present study were individually supervised during the
intervention and in the long-term instructed to go on with their activation of the stabilizing muscles indefinitely to avoid recurrent pain. This may at least partly explain why the intervention group had higher adherence and also showed a more successful outcome than the reference-group.

At baseline, there was no difference between the groups’ expectations of the intervention. However, after the intervention, the exercise group was significantly more satisfied. The exercise group also reported less long-term need for treatment than did the reference group, and such results have previously been reported. One might assume that the graded intervention provided the participants with a possible self-management strategy. The regression analysis comparing nonresponders and responders on baseline data showed, merely, that nonresponders tended to report lower physical health at baseline, and this may be considered when interpreting the present results.

A possible limitation of the present study may be lack of power. We hypothesized that the intervention group would reduce perceived pain by one-third more than the reference group at the 12-month follow-up, and this was based on previous findings. There is, of course, a chance that the differences between the groups for the outcome measures of interest were not identified because of type II error, particularly when considering the absolute differences between groups. However, a recent trial ran a power calculation in a clinical study similar to ours and arrived at a power of 80% (α 0.05), with 60 subjects randomized into 2 different exercise groups.

Graded stabilizing exercises, as an isolated factor, might not be appropriate for all subgroups in LBP. However, most of these patients often need coaching in pain-generating postures and spinal control using a stabilization strategy. Hence the present outcome must be seen as important for PTs’ working with patients with LBP in primary health-care settings.

The present trial investigated patients with long-term recurrent LBP still at work. Maintenance of working capacity seems to be an important variable in preventing acute, subacute, or recurrent LBP from becoming chronic. Regarding the efficacy of graded stabilizing exercises, further clinical and laboratory studies are required in specified subgroups of LBP, as there is controversy regarding these exercises.

### Conclusion

A graded-exercise intervention emphasizing stabilizing exercises for working patients with nonspecific recurrent LBP seems to improve disability and health parameters such as self-efficacy and physical health, more than do instructions to take daily walks. However, no such positive results emerged for pain over a longer term, or for fear-avoidance beliefs. Although the graded stabilizing exercises seem beneficial in LBP, there is still no clear evidence as to how they affect disability and pain levels. Further studies are therefore needed to clarify related mechanisms.

### Key Points

- A graded exercise intervention emphasizing stabilizing exercises seems to improve perceived disability and health parameters in short and long terms in patients with recurrent LBP.
- No such improvement was seen in the longer terms for perceived pain.
- The exercises, by being individually graded, might change self-efficacy beliefs and thus improve perceived disability.
- The exercise intervention seems to reduce the need for recurrent treatment in long-term.

### References
