Behavioral-Graded Activity Compared With Usual Care After First-Time Disk Surgery: Considerations of the Design of a Randomized Clinical Trial

Raymond W.J.G. Ostelo,a,b Albére J.A. Köke,b Anna J.H.M. Beurskens, PhD,a Henrica C.W. de Vet, PhD,b Maria R. Kerckhoffs,a,b Johan W.S. Vlaeyen, PhD,a,c Pieter M.J.C. Wolters,d M. Willem Berfelos, MD, PhD,e and Piet A. van den Brandt, PhDf

ABSTRACT

Objective: To present the design of a trial on the effectiveness of a behavioral-graded activity model.

Design: Randomized clinical trial.

Patients: Patients undergoing first-time lumbar disk surgery who still have low-back pain at the 6-week neurosurgical consultation.

Interventions: A patient-tailored behavioral-graded activity program that is based on operant therapy. The key elements of this program are baseline measurements, goal-setting, and time-contingency. This program is compared with usual care in physiotherapy, which is pain-contingent.

Outcome Measures: Primary measures are the patient's global impression of the effect and their functional status. Secondary measures are kinesiophobia, catastrophizing, pain, main complaint, range of motion, and relapses. The direct and indirect costs will also be assessed. The effect measures are rated before randomization and 3, 6, and 12 months later.

Discussion: Several trials have been conducted on the effectiveness of behavioral treatments. Subjects were always patients with chronic low-back pain. In this trial, we apply such a treatment in patients after first-time disk surgery in a primary care setting. (J Manipulative Physiol Ther 2000;23:312-9)

Key Indexing Terms: Behavioral Treatment; Intervertebral Disk; Lumbar Vertebrae; Surgery; Physiotherapy; Randomized Clinical Trials

INTRODUCTION

Why Publish a Design?

Publishing the design of a study before the results are available has various advantages. First, it may counteract possible publication bias: a study producing positive results seems more likely to be published than a study showing no difference between the study groups.1,2 Therefore if the design is published but not the results, the study can still be included in a systematic review because data can be retrieved from the researcher. In addition, publishing the design of a study before the results are available provides the researcher (and the reader) an opportunity to reflect critically on the design of the study, irrespective of the results. When results are contrary to the expectations of the researchers, methodologic flaws are examined; however, if results are in line with the expectations of the researchers, methodologic flaws are more likely to be overlooked.2 Furthermore, this article can elaborate on the interventions and theoretic background more extensively than the methods section of an article reporting the results of a study. This difference is of interest to caregivers, who can learn about the intervention in detail, which is especially useful if the intervention is complex or if caregivers are not or not yet familiar with the intervention. In this article, we describe the design of a randomized clinical trial on the effect of a behavioral treatment applied by physiotherapists in patients with low-back pain after first-time lumbar disk surgery. This therapy is not or not yet widely used to treat these patients. We then discuss the background of the study and the methodologic choices.

First-Time Lumbar Disk Surgery

In the Netherlands, 10,000 surgeries are performed each year because of lumbosacral radicular syndrome, which is based on a herniated lumbar disk.3 The success rate in the literature varies from 60% to 90%,4-10 meaning that despite surgery, in 10% to 40% the results are unsatisfactory and symptoms persist. These persistent symptoms mainly consist of pain, motor deficits, and a decreased functional status. In 2% to 19% of all patients who underwent surgery, a recurrent herniated lumbar disk occurs, 74% of which occur within 6 months after the first surgery.11,12 If patients still have these symptoms despite the surgery, they are often referred to physiotherapy.
Theoretic Models of Pain

The biomechanic model assumes a causal relation between tissue damage and pain. However, the definition of pain given by the International Association for the Study of Pain\textsuperscript{13} states that tissue damage is not a necessary condition for pain to occur. The biopsychosocial model, in a significant distinction, holds that when dealing with pain, the complex interaction between biologic, psychologic, and social entities of patients may be greatly important. Both models can be applied to explain the unsatisfactory results of lumbar disk surgery.

**Biomechanic model of disease.** The biomechanic model of disease mainly focuses on somatic issues. The (traditional) biomechanic model is based on the idea that a physical pathologic condition leads to pain and disability. Clinical recognition and diagnosis of the underlying pathologic condition provide the basis for rational physical treatment of the illness. For example, Kahanovitz et al\textsuperscript{14} and Mayer et al\textsuperscript{15} looked at the changes in back muscles caused by the surgery and found that these changes may contribute to problems after surgery. In particular, muscle strength and endurance are considered to prevent the occurrence of low-back pain.\textsuperscript{16-18} Furthermore, intraoperative complications (eg, dural tears, level errors, or root damage) may indicate poor prognosis.\textsuperscript{5} However, even in research that focuses on these somatic issues, there are indications that psychologic, social, and financial factors may be important in the maintenance of persistent symptoms.\textsuperscript{19}

**Biopsychosocial model.** The more recently developed biopsychosocial model emphasizes the role of psychologic and social factors in the development and maintenance of symptoms. Since Fordyce\textsuperscript{20} introduced the biopsychosocial model, this new framework has gained interest in the field of chronic low-back pain. The complex interaction among the biologic, psychologic, and social entities of patients may also be important in how patients respond after first-time disk surgery.\textsuperscript{20-22} The biopsychosocial approach is based on the behavioral equation Stimulus-Organism-Response-Consequences (SORC) (Fig 1).\textsuperscript{22} “R” is the problematic behavior, such as pain. The other components represent controlling variables of which the response (R) is a function. The immediate environmental variables are represented as “S” (the internal or external stimuli that precede R) and “C” (the consequences that follow R). “O” represents the biomedical variables. Within such a biopsychosocial approach, the causes or maintaining factors of behavior in terms of explicit environmental events are objectively identified and manipulated. The equation represents not a static but a dynamic system in which consequences provide new stimuli for subsequent SORC chains. Currently, pain is defined as a sensory and an emotional experience. Emotions are typically subjective, never observable in themselves, and can only be inferred by their effects at some observable level, such as psychophysiologic reactivity, cognitions (eg, beliefs about pain and pain control), and overt pain behaviors. Pain behaviors are sensitive to social consequences. When expressed by patients, desirable things can happen (positive reinforcement) and unpleasant situations can be avoided (avoidance learning). By means of these environmental influences, pain disability can be maintained long after healing has occurred.\textsuperscript{21-24}

**Treatment of First-Time Lumbar Disk Surgery Patients**

Treatment of patients after lumbar disk surgery has been considered important for more than 3 decades.\textsuperscript{25} The content of the treatment ranges from advice to normal physical training to total rehabilitation programs.\textsuperscript{7,25-27} The more recently developed biopsychosocial model often are referred to as cognitive-behavioral therapy. Based on this model, 3 treatment modalities have been proposed (Fig 1). First, cognitive treatment attempts to decrease distorted ways of thinking about pain and increase feelings of self-control with cognitive coping strategies. Second, respondent treatment trains the patient to apply relaxation skills to reduce psychophysiologic reactivity to personal stressors. Third, operant therapy attempts to increase health behaviors with graded activity and positive reinforcement, thereby attempting to decrease pain behaviors and increase tolerance levels.\textsuperscript{20,24} From this perspective, chronic low-back pain in general is approached differently. The guideline is not pain (or the reaction on the previous treatment of the patient) but the functional abilities of the patient. The behavioral-graded activity program assessed in this study is an operant therapy in which principles developed for the treatment of chronic low-back pain are applied to patients after first-time disk surgery.

**DISCUSSION**

**Aim of This Study**

In this study, we aim to assess the effectiveness of a behavioral-graded activity program compared with usual care in patients who still have low-back pain 6 weeks after first-time disk surgery. Thus we assess the behavioral-graded activity not in patients with chronic low-back pain, but in patients with a new start in their low-back pain episode who...
had not yet recovered. These patients might be considered on the threshold of becoming patients with chronic low-back pain. 29

Study Design

The effectiveness of the behavioral-graded activity in comparison with usual care in patients who underwent a first-time disk surgery will be assessed in a randomized clinical trial. The study protocol was approved by the Medical Ethics Committee of the University Hospital Maastricht. Fig 2 shows the outline of the study.

Selection of Patients and Informed Consent

Patients with low-back pain and/or sciatica are referred to a neurosurgeon. If surgery is indicated, the status of the patient, including duration of symptoms, pain, motor or sensitivity deficits, reflexes, and the findings on magnetic resonance imaging or radiography, is documented before the surgery. The policy of participating hospitals in the south of the Netherlands requires that after surgery, the patient is typically hospitalized for 3 to 5 days. In this period, the hospital physiotherapist teaches the patient low-back exercises and how to resume functions of normal daily living. The patient is advised to resume normal activities as soon as possible. Only patients with an antalgic posture, serious motor deficits, and/or the need for prescription analgesics will be referred to a physiotherapist immediately after discharge from the hospital. Each patient will then be seen by the neurosurgeon again after 6 weeks. Patients who still have symptoms that restrict their ADL and/or work are referred to a physiotherapist. These patients are informed about our randomized controlled trial by the neurosurgeon. If they show interest, they are contacted by the research assistant. This experienced physiotherapist (MRK) explains the goal of the study and the implications of participating and checks the eligibility of the interested patients.

Patients are included if they are aged between 18 and 65 years; undergo first-time disk surgery at only one level; have symptoms (pain) that restrict their normal daily living and/or work; and are willing to accept the consequences of participating. Patients are excluded if they experience complications during surgery, which is judged by the neurosurgeon based on preset criteria. These patients may have a worse prognosis than patients who undergo the surgery without complications. In addition, patients with confirmed and relevant underlying diseases that influence ADL (eg, stenosis, malignancies) are excluded. Patients are also excluded if one of the treatments is contraindicated (ie, respiratory symptoms). If a patient meets the selection criteria and is willing to participate, the informed consent procedure is completed.

Sample Size

The study attempts to enroll 200 patients, with 100 patients per treatment arm. This sample size is sufficient to detect a 20% difference in recovery rate (Global Perceived Effect [GPE]) between the behavioral-graded activity program and the usual care. We think that a 20% difference is clinically relevant; this difference is statistically significant at $\alpha = .05$ with a power (1-beta) of 80%. To obtain this study size we are cooperating with 4 hospitals and 75 physiotherapists.

Randomization

An independent examiner prepared the envelopes by coding them according to a random computer-generated list. Although there is concealed randomization, an unequal distribution of prognostic factors over the two therapies may occur. To prevent this, we prestratified based on 2 important prognostic factors. The first prognostic factor was the duration of the symptoms before surgery (less than or longer than 3 months) as a measure of the chronicity of the low-back pain. The second prognostic factor was whether a patient has been referred to a physiotherapist immediately after surgery, which accounts for the severity of the symptoms. One method to prevent unequal treatment-group sizes is block randomization; in this study we chose blocks of four. After every 4th patient, the distribution per stratum of patients allocated to both therapies is equal. If a patient meets all criteria she/he will be handed an opaque, sealed, coded envelope prepared by an independent examiner. In this envelope, there is a list of the names of all physiotherapists who perform the allocated therapy. The principal investigator (RO) contacts the patient by telephone to determine which physiotherapist is most easily accessed by this patient and ensures that the patient starts therapy as soon as possible after randomization.

Blinding

By using these opaque envelopes the research assistant who performs all measurements is blinded to the allocated treatment. The patients are blinded to a certain extent because they are unaware of the exact content of both treatments; these patients may also be termed naive to the content of the treatment not received. The physiotherapists are not blinded but are not involved in the effect measurements.

Fig 2. The study design.
Interventions

Behavioral-graded activity. The behavioral-graded activity program in this study is an operant therapy based on the principles of the biopsychosocial model. Operant therapy attempts to increase health behaviors with graded activity and positive reinforcement, thereby decreasing pain behaviors. The term “behavioral-graded activity” for this program emphasizes the behavioral component rather than merely the physical training principles. The treatments are given by physiotherapists in an outpatient setting, which is common in the Netherlands. Before the start of the study, therapists followed a practical training course in this approach and were updated on the course of the research project.

Behavioral-graded activity is based on contingency management as described in more detail by Fordyce and Fordyce et al and applied by Lindström. The essence of this program is to develop an individually graded exercise program to teach the patient that it is safe to move while increasing the level of activity. What is important in the program is that the level of activity is based on baseline measurements, which are performed at the start of the program. The program starts with two main complaints as reported by the patient (see effect measurements). The main complaints of the patient are activities that are important to the patient and cannot be avoided. First, the patient is asked to perform these activities during the initial baseline measurements until the patient has to stop because of pain. After these baseline measurements, the patient sets his or her individual treatment goals for this activity. The therapist acts only as a coach in this goal-setting, because it is important that the goal is the patient’s internal goal. Starting from baseline and knowing the treatment goal, quotas can be set on time-contingency principles. Then quotas are systematically increased to enable the patient to reach his or her preset goal within 3 months (18 sessions of 30 minutes each) of therapy. The quotas should always be exactly followed, neither overperformed nor underperformed. Thus there is a shift from pain-contingency (baseline) to time-contingency (quotas) management. The first quotas are slightly lower than baseline level to ensure that the first experience of the patient while performing the exercises is successful. Successful completion of the quotas will enhance the patient’s motivation: positive reinforcement is a key principle in operant conditioning theory. In total, the therapist strives to implement 5 activities or exercises in the program, depending on the patient’s wishes and needs. In this way, a patient-tailored, individual behavioral-graded activity program is developed. During the program, a patient must practice at home. As a general rule, all activities or exercises must be practiced at least once a day. Every activity or exercise is documented by the patient on a performance chart. These performance charts are discussed with the physiotherapist, and the patient is reinforced for achievements, disregarding pain behaviors. To facilitate the generalization of change in behavior to the home situation, partners are invited to attend some therapy sessions with the patients to gain clear insight into the rationale behind the therapy. If a patient has difficulty performing the desired activity, the physiotherapist uses another strategy: shaping. Shaping is “developing a new behavior by reinforcing successive approximations toward the terminal response.” This strategy is based on relearning wellness behaviors.

An example of the behavioral-graded activity approach is shown in Fig 3. Suppose walking is one of the main symptoms of the patient. The baseline measurements show an average at which the patient is forced to stop because of pain. After determining this baseline measurement, the patient sets his or her goal for this particular activity. The quotas can then be increased for each session to reach the preset goal, starting below baseline level.

Usual care. Usual care in this study is based on the biomechanic model. As a concept, usual care within physiotherapy is difficult to grasp if examining the individual techniques being used in everyday practice. In usual care, pain is the guideline for therapy. The choice of application and/or exercises strongly depends on the level and severity of the pain. In a survey in the United Kingdom, the most commonly reported modalities were symptomatic treatments. If a patient reports a strong reaction after the previous treatment (eg, pain), the intensity of therapy will be reduced until the patient is able to withstand a higher intensity again. This model is described in the Guidelines of the Dutch Association of Physiotherapy (KNGF). After extensive interviews and discussions with the physiotherapists in the usual care group, we reached consensus about the categories of treatment goals.

The most frequently named goals for the treatment of this particular population are listed in Table 1. The exact techniques used for each treatment goal differ tremendously within and among physiotherapists. Therefore operationalization to the extent of individual techniques is not possible and not desirable. We think that when investigating usual care for a specific population the whole spectrum of treatments used by physiotherapists for this population should be included. On the other hand, techniques are limited to only “usual” techniques (in physiotherapy), with the exclusion of acupuncture, osteopathic techniques, and other alternative
techniques. The techniques allowed are also listed in Table 1. Specific operant-behavioral components are not allowed. There are 18 sessions of 30 minutes duration within a period of 3 months. Contrary to behavioral-graded activity, usual care physiotherapists are allowed to stop treatment when a patient no longer has symptoms and the treatment goals have been reached. This fits the principles of usual care.

**Contrast between interventions.** The contrast between interventions is an important issue in this study because both interventions are performed by a physiotherapist. However, there are some important features that are responsible for the contrast. First, behavioral-graded activity is based on systematically performed baseline measurements. Usual care is based on anamnesis and physical examination of the patient. In addition, in behavioral-graded activity, the management is time-contingent once quotas have been set. Usual care evaluates the reaction of a patient to the previous treatment and possibly adapts the therapy based on this evaluation, which is pain-contingent. Furthermore, in behavioral-graded activity, specific behavioral components are used, including a performance chart systematic reinforcement of health behaviors and extinction of pain behaviors, and specific goal-setting by the patient. Thus what is done in both interventions can be the same (ie, exercises) depending on the patient, but how it is done makes the difference between behavioral-graded activity and usual care.

**Integrity Check**

On a random basis, a whole treatment program of both interventions will be recorded on audiotapes. The first author (RO) and an independent, blinded expert will examine a sample of these recordings to determine if the treatments have been performed as described. In addition, quality assessment will be conducted based on the characteristics of the treatments (pain-contingent vs time-contingent).

**Prognostic Variables and Outcome Measurements**

In a recent consensus meeting in the Netherlands on the lumbosacral radicular syndrome, the lack of reliable clinical measurements was made clear.19 The guidelines on sciatica recommend mainly range of motion and Lasegue’s sign37 for control measurement in normal practice, which will be scored in our baseline measurement. However in our opinion, these are not the most appropriate and sensitive methods of measuring improvement in clinical research. It is known that all kinds of clinical findings correlate poorly with the disability level of a patient.21,38-40 Therefore this study mainly focuses on patient-tailored disability measurements. The primary outcome measures are the most relevant for the patient and clinician. In addition, our measurements focus on some aspects that may be of great importance to the biopsychosocial model, the secondary outcome measures, which reflect on the complex interaction among biologic, psychologic, and social entities. Furthermore, we will assess the costs. Table 2 gives an overview of the data collection.

**Table 1. Treatment goals and techniques/exercises in usual care**

<table>
<thead>
<tr>
<th>Treatment goals</th>
<th>Techniques/exercises</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADL-training, optimize physical fitness, optimize spine/joint mobility, optimize muscle strength, optimize muscle length, optimize muscle tonus, optimize stability in trunk muscles, and combat pain</td>
<td>Back-specific instruction/education, ADL-training program, manipulations, mobility and strength exercises, stability exercises, massage, warmup (packages and ultra short wave), and other modalities</td>
</tr>
</tbody>
</table>

**Table 2. Overview of data collection and measurement**

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Before operation</th>
<th>Baseline</th>
<th>3 months</th>
<th>6 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient and lumbar-sacral characteristics</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Inclusion/exclusion</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Informed consent</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Randomization</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>NEM (prognostic)</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Expectancy (prognostic)</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>

**Outcomes measures**

- Global perceived effect (GPE)
- Roland Disability Questionnaire (RDQ)
- Tampa Scale of Kinesiophobia (TSK)
- Pain Catastrophizing Scale (PCS)
- Pain Observation Scale (POS)
- Pain (VAS)
- Main Complaint (MC) (VAS)
- SF-36
- Cost diary
- Range of motion (ROM)
- Relapses

**NEM, Negative emotionality; VAS, visual analogue scale; SF-36, short-form 36 questionnaire.**
contain items reflecting bodily or somatic symptoms, which might influence the score.

Expectancy is measured as described by Vlaeyen et al. 46 and modified after Borkovec and Nau. 45 After 2 treatments, the patients will be contacted and asked to what extent they believe that this specific treatment is beneficial to them. After these 2 treatments, the patients had sufficient information to score expectancy based on their perception of the treatments and not simply their ideas about them, which would be the case when expectancy would be measured before treatment. Expectancy will be scored on a 10-point scale, where 0 = the patient has no expectancy at all that they will benefit from this treatment and 10 = the patient is absolutely convinced of the benefit. Besides its use as an assessment of the prognostic value, expectancy will be used to compare the level of credibility between the 2 groups at the start of therapy. Thus we can check to what extent the patients were naïve (see earlier discussion of blinding).

Outcome Measurements

**Primary outcome measures.** Global Perceived Effect (GPE) is measured by self-assessment on a 7-point scale (1 = completely recovered and 7 = worse than ever). From the viewpoints of both patients and clinicians, asking patients to assess their perceived benefit is sensible.

Low-back specific functional status is measured by the Roland Disability Questionnaire (RDQ). 47 which has shown to be useful. 48-50 The Dutch translation has proved to be a valid instrument that is sensitive to change over time. 51,52

**Secondary outcome measures.** Fear of movement is measured by the Tampa Scale for Kinesiophobia (TSK). 53 Kori et al. 54 introduced the term “kinesiophobia” to describe the condition in which a patient has an excessive, irrational, debilitating fear of physical movement and activity resulting from a feeling of vulnerability to painful injury or reinjury. The TSK consists of 17 items, each rated on a 4-point Likert scale. The Dutch translation has fair and consistent internal validity. 55,56

Pain catastrophizing is measured by the Pain Catastrophizing Scale (PCS). 57 A patient is said to catastrophize pain, when he or she views pain as extremely threatening. 24 Catastrophizing is considered a maladaptive belief that may intensify pain, depression, and fear. 58

Pain behavior is measured by the Pain Behavior Scale (PBS). The PBS was originally an observation scale scoring 10 pain behaviors with 3-point scales. 59 The ratings of 8 behaviors can be obtained after a relatively short observation time. For these items, excellent reliability coefficients are found. The ratings of 2 other behaviors (“down time” and “medication use”) are only possible after at least 1 day of observation. These items showed poor reliability coefficients and were removed from the scale, resulting in improved internal consistency. Validity of both the 8-item PGS and the Dutch version proved to be sufficient. 60

Pain intensity of the low back or the leg will be scored on a Visual Analogue Scale (VAS). The relevance, validity, and reliability of the VAS are commonly accepted for low-back pain. 61-63

The Main Complaint (MC) 64 will be selected by the patient at baseline in a standardized way. The patient selects 2 frequently performed activities that are important in his or her daily life but are difficult because of low-back pain. The severity will be scored on a VAS. 65

Health status will be evaluated by the short-form 36 (SF-36). 66 The Dutch translation by van der Zee et al. 56 showed satisfactory validity and reproducibility.

Costs will be evaluated with cost diaries. 57 These are kept up to date by the patient. In this way, costs can be calculated and include additional therapies, drug use, visits to health care providers, out-of-pocket expenses, and paid help. In addition, costs that refer to the value of production lost to society because of low-back pain-related absence from work or days of inactivity at home can be calculated.

The range of motion in flexion and extension of the lumbar spine is measured by the Cybex Electronic Digital Inclinometer-320 (EDI-320). The reproducibility of this instrument proved to be satisfactory, especially for flexion. 68-70

Relapses of low-back pain and reoperations are evaluated during the 12-month follow-up period.

Analysis

Baseline comparability will be performed by descriptive statistics to examine if randomization was successful. If necessary, adjustments for prognostic inequalities will be performed. Before these analyses are done, all decisions about which deviations are considered as serious protocol deviations will be made. Differences between baseline measurement and follow-up will be calculated for every individual and will be compared between the 2 treatment groups. Group differences and 95% confidence intervals will be calculated for all outcome measures. Then statistical analyses will be performed according to the intention-to-treat principle, meaning that patients will be analyzed in the treatment group to which they were randomly allocated. In addition, a per-protocol analysis will be performed. This means analyzing only those patients with no serious protocol deviations. Comparing the results of the intention-to-treat and the per-protocol analysis will indicate to what extent protocol deviations might have biased the results. Regression analyses will be conducted both to adjust for baseline differences and to study the influence of the prognostic variables and patient characteristics on the outcome.

CONCLUSION

This article describes the design of a randomized clinical trial. In addition to the method, the interventions were highlighted because a behavioral approach is not or not yet widespread, certainly not for patients after surgery. However, many trials have been conducted concerning behavioral treatment in low-back pain. 71 Most subjects were patients with chronic low-back pain symptoms lasting 6 months or longer. This is justified by the working mechanism of behavioral therapy, which is focused on issues that are prevalent in chronic pain patients. In this study, we are interested in whether a behavioral approach is also effective
when applied to patients undergoing first-time disk surgery, who still have symptoms at their 6-week neurologic consultation.

There are some concluding remarks concerning the method. We did not choose a waiting list control group because the medical ethics committee considered it inappropriate to withhold treatment from patients who had been waiting for recovery for 6 weeks. Patient blinding is a validity criterion in most reviews, which is not possible in this trial. The best available alternative is to check whether both interventions have the same credibility to patients. This will be compared by the expectancy that patients in both groups have about the therapy after 2 sessions. Equal distribution of expectancy between both intervention groups will be regarded as similar credibility for both interventions. Blinding of outcome measurement is another issue. Currently, many people advocate the use of patient-specific measurements because they are considered the most appropriate and sensitive for measuring improvement in clinical research.\(^1\) The advantage is that these outcome measures are the most relevant for the patient and clinician. The disadvantage is that blinding is difficult because the patient must complete the questionnaires.

In this study, we choose to implement the behavioral-graded activity program for primary care physiotherapists, where other studies often use in-patient programs or a hospital-based approach. The advantage to this approach is that if the behavioral-graded activity program proves more effective than the usual care, it can be implemented in the daily practice of the physiotherapist because this is in the context of the research project. A prerequisite, however, is that the physiotherapists receive sufficient training in behavioral techniques. However, if the program does not prove better than usual care, the question remains whether the program will have been conducted in an adequate manner. To investigate this question we will analyze the audiotapes.

REFERENCES


