This paper discusses the rationale for and content of a newly developed treatment for shoulder complaints, and describes a randomised study which is currently being conducted to test effectiveness of the treatment. In current practice, approximately 50% of all patients with shoulder complaints mention limitations in the performance of daily activities and persisting pain after six months. To improve the functional ability of patients with chronic shoulder complaints, despite their pain, we have developed an operant behavioural and time-contingent graded exercise therapy programme for use in a primary care setting. We present the theory and conceptual model underlying this programme, report on its development and content, and describe the design of a randomised clinical trial to evaluate the programme’s effectiveness and cost-effectiveness. One hundred and thirty-two patients who suffer from shoulder complaints for at least 3 months are being recruited in general practice. After inclusion in the study, patients are allocated randomly to the graded exercise therapy programme or to usual care. Questionnaires will be used to measure factors like severity of the main complaint, functional limitations of daily activities, perceived recovery, global health status, shoulder pain, generic health-related quality of life, and costs. These factors will be assessed at baseline, during treatment (6 weeks), and after treatment (12, 26, and 52 weeks). [Geraets JJXR, Goossens MEJB, de Bruijn CPC, Köke AJA, de Bie RA, Pelt RAGB, van den Heuvel WJA and van der Heijden GJMG (2004): A behavioural treatment for chronic shoulder complaints: Concepts, development, and study design. Australian Journal of Physiotherapy 50: 33–38]

Key words: Shoulder; Behavior Therapy; Randomized Clinical Trials; Research Design

Introduction

Shoulder complaints are a very common problem in Dutch primary health care. The community-based one-year prevalence of chronic shoulder pain lasting more than three months was estimated at 15% in 1998 (Picavet et al 2000). The annual incidence of shoulder complaints registered in general practices in the Netherlands has been reported to be as much as 25 per 1000 patients (Sobel et al 1996). Approximately 50% of all patients who visit their general practitioner with a new episode endure complaints for up to six months, and up to 40% report complaints after 12 months (Windt et al 1996). Musculoskeletal disorders, of which shoulder complaints constitute the second largest group after low back disorders, account for the second largest component of healthcare costs (Meerdink et al 1998).

There is little information on the aetiology, diagnosis, and prognosis of shoulder complaints. Biomedical, psychological, and social factors are generally assumed to be involved and to interact in the course of non-specific musculoskeletal pain (Engel 1980, Nielson and Weir 2001, Vlaeyen and Linton 2000). A clear model of pain as a result of interaction between nociceptive stimulation, pain perception, pain experience, and pain behaviour has been described by Loeser (1980). It is unclear, however, whether and to what extent biological, psychological, and social factors have a causal relation with the initiation of shoulder complaints or with the transition from acute to chronic shoulder complaints (van der Heijden 1999). It can be hypothesised, however, that these factors play a role in the course of shoulder complaints, comparable to other non-specific musculoskeletal pain disorders (Linton 1995).

Over the last decades, cognitive and behavioural principles have been integrated into pain management and have proven to be effective (Guzmán et al 2001, Linton 1999, Morley et al 1999, Tulder et al 2001, Vlaeyen and Linton 2000). The focus is primarily on pain behaviour, fear-avoidance beliefs, and the associated disability. Performance and conditioning of physical activities are important features from a behavioural point of view. Most studies on the effectiveness of cognitive behavioural therapy for musculoskeletal pain have been administered for chronic complaints in multidisciplinary settings (Morley et al 1999).

Given the high prevalence of shoulder complaints and the tendency for these complaints to become chronic, we have developed a graded exercise therapy programme for the primary care setting. This programme, administered by physiotherapists, is based on behavioural treatment principles. The programme aims to improve functional abilities in patients with shoulder complaints, largely excluding pain as a primary target. This paper presents the theory and conceptual model underlying the programme, discusses its development and content, and describes the design of a study we are currently undertaking to evaluate the programme’s effectiveness and cost-effectiveness.

Several considerations induced us to publish separate articles on the design of the study and the results. The first is that this allows reflection on the study protocol, independently of the study results. Second, it allows us to identify protocol deviations that might influence study results. Third, it allows publication bias to be avoided.

Concepts of the graded exercise therapy programme

Biomedical approach Traditionally, the management of shoulder complaints has been based on a disease-oriented biomedical
Behavioural activation is assumed to improve functional ability, attention from pain to activity, and provoking healthy behaviour. Biomedical treatments focus mainly on pain relief and the treatment of disability. There is limited evidence that biomedical based interventions speed up recovery in the short term for patients with shoulder complaints, and long-term effects have been rather disappointing (Green 2003, van der Heijden 1999, Kroese 2002).

**Biopsychosocial approach** The Melzack and Wall's gate-control theory of pain has led to broad discussion and new views on pain (Melzack and Wall 1965). Initially, (chronic) pain was considered to be a result of straightforward somato-sensory stimulation. Nowadays, there is general agreement that pain has sensory, affective, and cognitive dimensions. The International Association for the Study of Pain defines pain as ‘an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage’ indicating that pain experience is subjective (Merskey and Bogduk 1994).

This reconceptualisation of pain had led to the development of a new multidimensional biopsychosocial model in which biological, psychological, and social factors contribute to produce pain experience and its persistence (Fordyce 1976, Nielson and Weir 2001, Turk and Okifuji 1997).

**Operant conditioning approach** A behaviourally-oriented operant conditioning approach focuses on environmental reinforcement of pain behaviour and pain-related inactivity in the maintenance of pain. According to learning theory principles, pain behaviour is acquired and can be modified through new learning experiences (Skinner 1953), and pain behaviour is considered to be conditional on the consequences that follow its occurrences. Positive or negative reinforcement may provoke continuation of the pain behaviour.

Fordyce et al first described the theoretical concept of operant behavioural treatments (Fordyce 1976). Characteristics of these treatments are reinforcement, rewarding, target setting, and activity scheduling. To date, the effectiveness of operant behavioural treatment programmes has been documented in several studies (Morley et al 1999). Moreover, graded activity programmes have been shown to improve the level of daily activities and reduce disability in patients with subacute back pain (Fordyce et al 1986, Lindstrom et al 1992), and those with chronic back pain (Turner and Clancy 1999).

**Development of the graded exercise therapy programme**

The graded exercise therapy programme has been developed by experts in the field of operant behavioural treatments for chronic pain, together with a steering committee of primary care physiotherapists. Behaviour change seeks to increase levels of daily activity by goal setting, pacing of progress towards goals, and manipulation of cues for and consequences of behaviours to promote change. The main elements of the graded exercise therapy programme are graded activity, time contingency, and operant conditioning (Fordyce et al 1986, Turk and Okifuji 1999).

**Graded activity** In graded activity, levels of activity increase in a step-wise fashion. Graded activity has biomedical and psychosocial aims: improving functional ability, shifting attention from pain to activity, and provoking healthy behaviour. Behavioural activation is assumed to improve functional ability in patients with chronic musculoskeletal pain (Fordyce 1986).

**Time-contingency** Whereas a disease-oriented pain-contingent approach involves activities that are performed and adjusted according to pain experience, a time-contingent approach involves levels of activity that are structured in time. The intensity of exercises rises gradually over time, irrespective of pain experience, with a fixed quota agreed upon at the start of the programme.

**Operant conditioning** By changing the consequences of behaviour, operant learning principles are used to promote and improve healthy behaviour. Positive reinforcement of the preferred behavioural changes is given to increase and maintain the frequency of graded activities.

External reinforcement is related to social and environmental factors. Reinforcement of healthy behaviour is given directly by the physiotherapist who acts like a coach. Initially, the emphasis is on external positive reinforcement to provoke behavioural changes. When behaviour has changed in the preferred direction, external reinforcement becomes less intensive and internal reinforcement becomes more important for the maintenance of the healthy behaviour. Internal reinforcement depends on the benefits patients experience as a consequence of healthy behaviour. Patients will become more motivated if they succeed in the performance of preferred activities and experience the progress made as a consequence of their own healthy behaviour.

**Characteristics of the graded exercise therapy programme**

The primary aim of this exercise programme is to enable the patient to perform his or her own preferred shoulder activities in daily life at home or at work, irrespective of the pain experience. It does not aim to achieve pain relief. The programme’s activities are related to specific shoulder functions such as reaching, supporting, pushing, pulling, hitting, and stabilising, with work-related activities receiving special attention.

A total of 18 one-hour sessions are held over a period of 12 weeks. The programme is administered in small groups of three to five persons under the supervision of a specially trained physiotherapist. Since not all participants start the programme at the same time, some patients in the group may already have made some progress in their rehabilitation plan while others have just joined the group.

**Content of the graded exercise therapy programme**

The programme consists of a start-up period, and a treatment plus generalisation period.

**Start-up period** The programme starts with history taking, a physical examination, and identification and assessment of the patient’s preferred activities. Special attention is paid to patients’ experiences, beliefs, and behaviour with respect to the complaints, and to possible barriers and obstacles towards recovery and increasing activity levels. At this stage, reconceptualisation of pain and pain-related disability is important to ensure that patients are convinced they are able to control and influence their pain experience (Turk and Okifuji 1999). The treatment rationale is explained and aims of the treatment programme are set in terms of functional goals.

During the start-up period, which lasts two weeks, patients are asked to perform and adjust their preferred activities on the basis of pain-contingency, the assumption being that levels of activity will be high if pain levels are low and vice versa. Levels of activity are registered in graphs that are used to evaluate progress as a consequence of the patients’ actual behaviour.
At the end of the start-up period, the baseline for treatment is determined. Because the experience of pain is assumed to lead to limited progress, the level of activity at the start of the treatment period is set slightly below the average of the patient’s pain-contingent performance, making it likely that the patient can complete the activities successfully. Positive experiences as a consequence of their initial treatment activities are expected to motivate patients to proceed with further exercises.

Goals, quota, and the precise content of the treatment period are determined and agreed upon for every individual patient. Goals are related to the patient’s own preferred daily activities. The patient signs a contract setting out the patient-tailored rehabilitation plan, which defines quota for the treatment period by means of grading, that is, goal setting and time scheduling (Figure 1).

**Treatment plus generalisation period** The second phase, lasting 10 weeks, involves graded activity exercises. In this phase, activities are structured according to a time-contingent approach, and the intensity of the exercises is increased gradually over time.

At the start of the treatment period, positive reinforcement of healthy behaviour is emphasised. Gradually, reinforcement becomes intermittent and less intense. Graphs are used as an instrument to reinforce patient behaviour and to discuss and evaluate the steps that have been achieved. Progress is attributed to the patient’s performance.

Special attention is paid to the application of what has been learned in everyday life, that is, how to deal with new goals and how to manage a relapse. This is called generalisation. Generalisation already starts at the beginning of the treatment period, but is emphasised strongly at the end of the treatment period.

**Design of the graded exercise therapy evaluation study**

**Objectives** The graded exercise therapy trial is designed to study whether graded exercise therapy is a clinically effective and cost-effective treatment for patients with chronic shoulder complaints after 6 and 12 months (Figure 2). Graded exercise therapy is compared with usual care according to the guideline for shoulder complaints issued by the Dutch College of General Practitioners (DCGP) in 1999. The following research questions will be addressed in this study:

1. Is graded exercise therapy clinically more effective than usual care in terms of its effects on performance of daily activities, perceived recovery, global health status, shoulder pain, and generic health-related quality of life after 6 and 12 months in patients with chronic shoulder complaints?

2. Is graded exercise therapy more cost-effective than usual care after 12 months in patients with chronic shoulder complaints?

**Recruitment and allocation of patients** Thirty-two general medical practitioners in the province of Limburg, The Netherlands, recruited patients who suffer from shoulder complaints. The period of enrolment ran from January 2002 until July 2003. Patients who visited their general practitioners and met the selection criteria were asked to participate in the study. A research assistant visited potential participants at home within two weeks of their visit to the general practitioner. Patients were eligible for inclusion if they were at least 18 years of age and had suffered from shoulder pain or complaints in the shaded area shown in Figure 3 for at least three months.

Furthermore, patients had to be suffering from shoulder complaints at the time of intake. Exclusion criteria were: treatment for the shoulder complaint during the three months prior to the initial consultation with the general practitioner; complete rotator cuff tears; serious prior trauma, i.e. fractures or dislocations, or prior surgery of the shoulder, upper limb, neck or thorax; osteoporosis, rheumatoid or bacterial arthritis, tumour, referred pain from internal organs, cervical radicular syndrome, gross shoulder hypermobility, stroke, polyneuropathy, multiple sclerosis, polymyalgia, or ankylosing spondylitis; treatment for serious psychiatric disorders, or inability to complete questionnaires in Dutch.
**Sample size**  Sample size calculations are based on perceived recovery rates as data on rates of performance of daily activities are not available. Recent studies of shoulder treatment in general practice show that six months after the first consultation about 50% of all patients report full recovery or that their complaints are much improved. Since only patients with complaints lasting at least three months participated in the study, we estimate that only 25% of these patients would feel fully recovered or much improved at six months after randomisation. Since we aimed at a 10% dropout rate, we needed 66 persons per treatment group to detect an increase in the recovery rate from 25% to 50% (number needed to treat of four).

**Informed consent and randomisation**  After giving informed consent to participate in the study, patients were randomised to receive either graded exercise therapy or usual care. A random number list generated by a researcher who was not involved in the conduct of the study was used to allocate patients.

**Intervention**  Graded exercise therapy  Graded exercise therapy is implemented as described above. At the start of the intervention, patients are given a short brochure about the rationale behind the therapy, as well as a booklet containing graphs to evaluate progress and a treatment agreement to promote compliance with the programme.

**Usual care**  Usual care is standardised according to the 1999 version of the guidelines for shoulder complaints issued by the DCGP (Winters et al 1999) and consists of information, recommendations, and medical or pharmaceutical therapy. This usual care of shoulder complaints is pain-contingent. The GP makes the specific choice of treatment.

**Physiotherapists and general practitioners**  Prior to the start of the study, physiotherapists participating in the graded exercise therapy group took part in a one-day workshop and two booster sessions under the supervision of experts in the field of cognitive-behavioural treatments (AK and RP). General practitioners participating in the usual care group have been given a refresher course on using the DCGP 1999 guideline for shoulder complaints.

**Baseline and follow-up measurements**  Patients are seen five times for collection of data: before randomisation, during the intervention at 6 and 12 weeks after randomisation, and after completion of the treatment at 26 and 52 weeks after randomisation. At all these moments, the variables shown in Table 1 are assessed.

In addition, demographic variables, disease characteristics, comorbidity, physical activity, workload, and treatment credibility and preferences are documented at baseline. Function of the shoulder girdle and cervicothoracic spine, severity of the main complaint, and psychosocial variables (anxiety, depression, somatization, distress and job content) are regarded as prognostic variables.

**Clinical effectiveness**  Performance of daily activities as the main outcome variable of clinical effectiveness is measured by the severity of the main complaint and functional limitations of daily activities. Perceived recovery is measured on a seven-point ordinal scale. Patients are regarded as recovered if they feel either fully recovered or much improved. Global health status, shoulder pain, and generic health-related quality of life are also assessed as outcome variables of clinical effectiveness. Process measures include kinesiophobia, fear-avoidance beliefs and fear of re-injury, catastrophising, coping with pain, and internal and external locus of control.

**Cost-effectiveness**  To evaluate the short-term and long-term cost-effectiveness of graded exercise therapy, the following socio-economic endpoints are collected: programme costs, direct health care costs, direct non-medical costs, and indirect costs. Costs are measured by means of patient cost diaries (Goossens et al 2000). The effects are measured in terms of generic health-related quality of life descriptions measured with the EQ5D (Brooks 1996).

**Blinding**  Two research assistants who are not involved in the randomisation procedure collect baseline, process, and outcome data. Blinding of patients and health care providers (i.e. physiotherapists and general practitioners) is not possible. Data entry, intention to treat analysis, and cost analysis will be carried out independently and blinded for treatment allocation.

**Data presentation and statistical analysis**  Baseline data, which are relevant for comparability of groups, will be presented. Dropouts and losses-to-follow up will be described.

Analyses will be performed on the primary outcome measures (severity of the main complaint and functional limitations of daily activities), and on other clinical outcome measures (perceived recovery, global health status, shoulder pain, and generic health-related quality of life). *t* or *F* tests will be used to compare groups for outcome variables measured on continuous scales with Gaussian distributions, while Mann-Whitney tests will be used for non-Gaussian distributions. Chi-square tests will be used for ordinal and dichotomous outcome variables.

The primary endpoints, change in performance of daily activities at 6 and 12 months, will be compared using the average changes over time of both groups. Differences between groups and their 95% confidence interval will be calculated. Effect measurements, point estimates and 95% confidence intervals will be presented.

Baseline characteristics considered *a priori* to be possible prognostic factors for performance of daily activities and which differ between the groups after randomisation will be handled as potential confounders. Their influence will be evaluated by means of multivariable regression analyses. In the case of confounding, adjusted effect estimates will also be reported. In the analyses of the differences in change for the primary end point at 6 and 12 months we will account for the repeated measures character of the data.

All data will be analysed primarily according to the intention-to-treat principle. In order to study the influence of protocol violations on the study outcomes, an on-treatment-analysis will be performed. Patients with documented deviations from the study protocol will be excluded from the on-treatment analysis.
Qualitative evaluation

A qualitative evaluation of the trial progress is being undertaken concurrently. Questionnaires completed by both the patients allocated to graded exercise therapy and by the physiotherapists involved, and treatment reports are used to evaluate the content of graded exercise therapy at the end of each treatment period. Interviews with patients allocated to usual care and their usual care providers are used to evaluate the content of the control treatment.

Applicability and suitability of the graded exercise therapy programme will be evaluated at the end of the study. Experiences with and beliefs about the content of the programme, among both patients and physiotherapists, will be evaluated in focus group interviews.

Approval  The design of the study presented here has been approved by iRv/SRLs nationally recognized Medical Ethics Committee.

Discussion

Since it is as yet unclear whether and which patients will benefit from the graded exercise therapy programme, we exclude patients only on the basis of systematic diseases, referred pain, or severe biomedical or psychiatric disorders. We consider the programme most suitable for patients with discrepant pain behaviour and pain beliefs. They might either postpone activities because they believe activity may cause damage or re-injury, or ignore the pain and consequently exceed suitable levels of activity. We hope this study will contribute to further insights into the applicability of behavioural treatments in musculoskeletal pain.

The present study is characterised by randomised allocation, cost-effectiveness evaluation and qualitative process evaluation. However, since blinding patients is not possible in this pragmatic study, information bias has to be taken into account. The contribution of graded exercise therapy towards total effects

<table>
<thead>
<tr>
<th>Table 1. Baseline and follow up measurement.</th>
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<tr>
<td><strong>Variable</strong></td>
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<tr>
<td>Baseline status</td>
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<td>Demographic variables</td>
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<td>Specific disease characteristics</td>
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<td>Co-morbidity</td>
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<td>Physical activity</td>
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<td>Workload</td>
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<td>Treatment credibility and preference</td>
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<td>Prognostic variables</td>
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<td>Function of shoulder girdle</td>
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<td>Function of cervicothoracic spine</td>
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<td>Severity of main complaint</td>
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<td>Psychosocial variables</td>
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<td>Job content</td>
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<td>Outcome variables</td>
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<td>Performance of daily activities</td>
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<tr>
<td>1. Severity of main complaint</td>
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<td>2. Functional limitations of daily activities</td>
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<td>Perceived recovery of complaints</td>
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<td>Global health status</td>
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<td>Shoulder pain</td>
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<td>Quality of life</td>
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<td>Costs</td>
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<td>Process variables</td>
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<td>Kinesiophobia</td>
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<td>Fear-avoidance beliefs</td>
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<td>Catastrophising</td>
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<td>Coping with pain</td>
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<td>Internal locus of control</td>
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<td>External locus of control</td>
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4DSQ: Four Dimensions of psychological Symptomatology Questionnaire (Terluin 1998); SDQ: Shoulder Disability Questionnaire (van der Heijden et al 2000); SPS: Shoulder Pain Score (Winters et al 1996); EuroQol-5D: Quality of life (Brooks & de Charro 1996); TSK-DV: Tampa Scale for Kinesiophobia (Vlaeyen et al 1995); FABQ-DV: Fear-Avoidance Beliefs Questionnaire (Vendrig et al 1998); PCCL: Pain Coping and Cognition List (Berg et al 2001)
cannot be evaluated in absolute terms because the study does not have an add-on design. There is some uncertainty as to required sample size, because calculations are based on rates of recovery and not on rates of performance of daily activities.

Although the graded exercise therapy programme could be embedded in a multidisciplinary approach to shoulder complaints, it was developed to be administered in a primary care physiotherapy setting. It is obvious that professional capacities and attitudes towards shoulder complaints among health care providers are extremely important. Physiotherapists do have capacities in terms of coaching patients in their physical activities, but special training in the treatment of psychological factors of pain and disability appears to be necessary.

**Acknowledgement** This study is funded by the Netherlands Organization for Scientific Research (NWO-MW, grant number 904-65-901) and by the ‘De Drie Lichten’ Foundation, Hilversum, The Netherlands.

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