Physiotherapy for Chronic Neck Pain

Evaluation of a biopsychosocial approach

Frieke Vonk

The work presented in this thesis was financially supported by College voor Zorgverzekeringen, The Netherlands. Deelprogramma Paramedische Zorg.

College voor zorgverzekeringen

Printing of this thesis was financially supported by:
The Department of General Practice of the Erasmus Medical Center, Rotterdam, The Netherlands
Stichting Anna Fonds, Leiden

Anna Fonds

Steunt orthopedische research

Dutch Arthritis Association

Reumafonds
Dutch Arthritis Association

Cover design and photography: Frieke Vonk
Cover realisation: Optima Grafische Communicatie, Rotterdam
Printed by: Optima Grafische Communicatie, Rotterdam
ISBN: 978-90-8559-999-9

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Evaluation of a biopsychosocial approach

Fysiotherapie voor patiënten met Chronische Nek klachten
Evaluatie van een biopsychosociale benadering

Proefschrift

ter verkrijging van de graad van doctor
aan de Erasmus Universiteit Rotterdam
op gezag van de rector magnificus
Prof.dr. H.G. Schmidt
en volgens besluit van het College voor Promoties.

De openbare verdediging zal plaatsvinden op
Woensdag 2 juni 2010 om 11.30 uur

door

Frieke Vonk
Geboren te Oss

Promotiecommissie

Promotor:	Prof.dr. B.W. Koes
Overige leden:	Prof.dr. H.J. Stam
	Prof.dr. J.J. van Busschbach
	Prof.dr. R. Nijhuis- van der Sanden
Copromotor:	Dr. A.P. Verhagen

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1

General Introduction

BACKGROUND

Neck pain

Prevalence

Neck pain is a common complaint that causes substantial morbidity in western countries. Reported prevalence in the general population ranges from 9.5% to 22%, and the 12-month (point) prevalence estimates ranges from 30% to 50% [1 2 3]. It is suggested that two thirds of individuals may at least once in their lifetime experience neck pain; it is more often reported by women than men [4 5]. Patients with neck complaints generally also complain of neck stiffness and reduced mobility [6]. Between 5% and 20% of neck pain patients will have a significant disabling problem [7]. In the Netherlands, neck pain is one of the three most-reported musculoskeletal pains with estimated total related costs in 1996 of US $686.2 million (€526.24 million), representing about 1% of the total Dutch health care expenditure [4 8 9].

Course

Neck pain can have different specific causes of onsets (e.g. herniated disc, tumours, infection etc). However, in most cases no conclusive evidence is found for any specific pathology of the neck pain[10 6]. When no specific pathology is found the pain is labelled as non-specific[11 12].

Non-specific neck pain usually resolves within days or weeks, but can recur or become chronic in some of the patients [13]. Studies show relatively low recovery rates for patients in general practice with a new episode of neck pain; less than one quarter (24%) reported recovery after 3 months [14] and only a third of the patients reported recovery at one year follow-up [14 15].

Moreover, although patients with neck pain may improve, most do not experience complete recovery from their pain and disability [15 16]. These findings contradict the commonly held view that neck pain has a highly favourable prognosis. Rather, they underline the recurrent, fluctuating and persistent nature of neck pain [15 14 4]. When the pain persists for more than 3 months it is defined as chronic [12]. The prevalence of chronic neck pain in the general population in the Netherlands is 14.3% [4]. Although not life-threatening, neck pain can negatively affect the patient's quality of life, and may result in medical consumption, absenteeism and disability [8 9].

Treatment

Most people who suffer from neck pain do not seek care and choose to deal with their pain on their own [17]. Before 2006, patients in the Netherlands seeking care were required to first visit a general practitioner. Of all people registered, approximately 8% consulted their general practitioner (GP) at least once per year with a complaint relating to the neck or upper extremity. This resulted in approximately seven consultations per GP each week for these complaints [18].

There is a large variety of therapeutic interventions available for neck pain, such as 'wait and see', rest, medication (analgesics, NSAIDS), neck collars, physiotherapy (exercise , massage, physical therapy modalities), manual therapy, acupuncture and surgery [19] [6] [20]. In the Netherlands, patients with neck pain are often treated with exercise-oriented physiotherapy. In 1998, about 33% of general population patients with neck, shoulder or back pain sought physiotherapy [4]. For chronic neck pain, moderate evidence is available for the benefit of exercise, stretching and/or strengthening. Additionally, strong evidence is available that exercise combined with manipulation or mobilizations is beneficial for pain, function and global perceived effect. It is unclear, however, what the relative benefit is of the different exercise types [21] [22].

Within physiotherapy, two treatment models are currently known. One is a traditional biomedical model, in which treatment is focussed on pain caused by physiological pathology, leading to a pain-contingent approach [23] [24]. The other is the biopsychosocial model, in which it is assumed that pain can persist long after the initial pathology has healed, and that psychological and social factors are important determinants in development and perpetuation of complaints [25] [26] [27] [28] [29]. One of the treatment approaches applied within the context of the biopsychosocial model is the operant treatment approach [23] [30] [31]. This approach is focussed on decreasing pain behaviour (operants) and increasing healthy behaviour on a time-contingent basis [32] [33]. It has shown promising results in back pain but the effectiveness for neck pain is still unknown [34]. In this thesis a biomedical treatment-conventional exercise - is compared to a biopsychosocial treatment - behavioural graded activity .

Prognostic factors

Neck pain is assumed to be a multifactorial affliction, implying that there are a number of risk factors contributing to its development [35]. While etiologic factors (risk factors) are associated with the onset of the complaint, prognostic factors can potentially predict the future course subsequent to the onset [36]. Previous studies

on effectiveness of physiotherapy in patients with neck pain showed that between 40% and 50% continue to experience persistent neck pain one year after treatment [37 38]. Risk factors for the development of chronic pain (i.e. transition from acute to chronic) are well documented in the literature[39 40 7 14] however once pain has become persistent, outcome is less predictable [13]. Knowledge of the prognostic factors of persistent complaints might help enhance treatment success, as it can facilitate clinical decisions concerning choice of treatment and identification of patients at risk of poor outcome [41]. In the literature, there is little consistency regarding the duration of persistent symptoms or factors that influence outcome once pain becomes persistent [13]. Prognostic factors described there vary depending on the choice of the dependent variables, the stage of pain (acute, sub-acute or chronic) examined [40] and the population under study. The prognostic factors identified included higher age, a higher severity of pain, a history of previous attacks, being off work, low back pain, and cycling [10 42 37]. However, for patients who are in the chronic stage of pain there are no clear determinants and/or prognostic models available for the persistence of complaints. In chapter 5 we therefore examine possible prognostic factors for poor outcome in patients with chronic neck pain in primary care.

Physiotherapists' beliefs or attitude

Since non-specific neck pain has no obvious physical cause and lacks available guidelines, it has been argued that treatment regimens applied may reflect the physiotherapists' attitude, which could have implications for the effectiveness of the treatment [43 44 45 29]. For example, the therapists' attitude is found to influence their view on which medical information is important, and also the recommendations they give to patients [43 44 45]. Although physiotherapists' treatment approach seems important, an explicit description is often missing in studies performed, as is examination of the influence on outcome. Understanding therapists' attitude, however, seems fundamental in developing better ways of managing pain complaints [29], and could have implications for education of therapists and for daily practice.

The Aim of the thesis

The overall objective of this thesis is to examine the effectiveness of behavioural graded activity versus conventional exercise in recovery of complaints and function in chronic neck pain patients, and to examine whether other (external) factors can influence this effectiveness. By examining the prognostic factors for poor recovery

and the possible influence of the physiotherapists' attitude on this recovery, we hope to assist in identifying patients at risk for poor recovery after treatment, and also to point out some factors that could be relevant for the improvement of managing pain complaints in primary care physiotherapy.

Outline of the thesis

Chapter 2 gives an overview of currently available reviews on the effectiveness of conservative treatment for neck pain patients. In **chapter 3** an extensive overview of the methods of the randomised trial and the content of the treatments behavioural graded activity and conventional exercise for non-specific neck pain patients is presented. The results of the randomised trial are presented in **chapter 4**. The aim of **chapter 5** is to identify prognostic factors that are associated with persisting complaints and poor daily functioning. In **chapter 6** we evaluated whether therapists who chose to perform either BGA, CE or manual therapy differ in their treatment approach (or attitude) towards neck pain, and whether a behavioural graded activity training has any influence on the treatment approach. **Chapter 7** describes the influence of the physiotherapists' attitude on the outcome in chronic neck pain patients. **Chapter 8** reflects on the main findings of the previous chapters as well as the study limitations, and gives possible implications for daily practice and future research.

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2

An overview of available evidence for the effectiveness and cost-effectiveness of conservative treatment for neck pain

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Submitted

ABSTRACT

Background

The demand for evidence based medicine (EBM) has increased dramatically in the last decade. In this article, we discuss the benefit of EBM and its role in the treatment of neck pain, and we present an overview of the evidence on effectiveness and cost-effectiveness of conservative treatment for neck pain.

Method

We searched Pubmed, Embase and Cochrane for reviews on conservative treatment in non-specific neck pain, and Pubmed for evaluation of cost-effectiveness. RCTs published after publication of the reviews were also included. Outcomes required were either: pain, overall improvement, satisfaction with treatment, function (e.g. neck specific functional status), well-being (e.g. quality of life), disability (e.g. activities of daily living, work absenteeism) and adverse effects. The methodological quality assessment, data extraction and data analysis of the original systematic reviews were perused in this overview.

Conclusion

The evidence for conservative treatment for neck pain is still inconclusive, however, for chronic neck pain manipulative therapy and/or mobilization in combination with exercise seems to have the most promising results. Additionally, manipulative therapy would appear to be more cost-effective than physical therapy or standard medical care (as administered by the general practitioner).

INTRODUCTION

Neck pain

Neck pain is a common musculoskeletal disorder. The point prevalence of neck pain in the general population of the Netherlands varies between 9% and 22%, with approximately one-third of all adults experiencing neck pain during the course of a year [1]. Some 5-10% of these subjects will develop chronic pain [2].
The main feature of mechanical neck pain is pain in the cervical region, which is often accompanied by restriction of the range of motion and associated with functional limitations [3]. The pain may originate from many structures in the cervical region, especially the spine and soft tissues, but there is no conclusive evidence regarding specific pathology in the majority of cases of acute or chronic mechanical neck pain [4]. Consequently most cases are labeled as non-specific mechanical neck pain or mechanical neck pain of unknown origin [4].
Risk factors for mechanical neck pain are physical load factors, such as vibration, flexion of the neck, sitting posture and heavy lifting [3]. However, psychological factors, such as passive coping, cognition, fear avoidance, depression, anxiety and social factors are also reported to aggravate and perpetuate neck pain [3 5]. High pain intensity and a previous history of neck pain are strongly and consistently associated with an unfavorable prognosis [1 6]. However, it is still difficult to identify a consistent core set of prognostic psychological factors that predict a favourable short and long-term outcome of sub-acute neck pain [7].
Although mechanical neck pain is self-limiting, 40% of patients contact their general practitioner. Of these patients 30% are referred for further diagnosis by a medical specialist, and 32% are referred for conservative therapy consisting of physiotherapy, manual therapy or chiropractic care [2 8].

Evidence-based medicine

The importance of evidence-based medicine (EBM) has steadily increased during the past decade. EBM is defined by Sackett et al. as “Conscientious, explicit and judicious use of current best evidence in making decisions about care of individual patients”. The practice of EBM means integrating individual clinical expertise with the best available evidence derived from systematic reviews [9 10].
However, ‘evidence’ is a rather broad concept. On the one hand, the evidence may refer to new or existing interventions, which may be diagnostic, preventive and /or therapeutic. Evidence on the effectiveness of therapeutic interventions may be obtained through randomised clinical trials (RCTs), while evidence on the

effectiveness of diagnostic interventions may be obtained through either RCTs or specific diagnostic studies. On the other hand, evidence on adverse effects or risk factors associated with a particular treatment are typically obtained from prospective, observational studies due to the lower incidence of adverse reactions. Furthermore, full economic evaluations provide evidence on cost-effectiveness and/or cost-utility.

In EBM, information about the individual patient with his or her individual problem is collected from history taking, physical examination and additional diagnostic evaluation combined with clinical scientific information about diagnostic tools, prognostic factors and effectiveness of interventions. Sackett proposed five steps (See table 1) on how to practice EBM as a clinician [11].

The access to the internet has provided the clinician with a wealth of information to help them in EBM. However, the publication of more than 40.000 biomedical journals, 2.000.000 articles, and 20.000 books each year has clearly led to an overload of information for the clinicians [11]. The consequence is that they can no longer assimilate the best available evidence. Systematic reviews have been conducted in order to resolve this problem. Within the field of therapeutic interventions, for example, systematic reviews pose a specific question, conduct a search strategy aimed at identifying relevant trials, and, conduct a critical appraisal of the methodological quality of the included trials. The result of this procedure is an unbiased and comprehensive view of the literature on that topic. Thus, for the clinician, a systematic review is an efficient manner of obtaining an answer to a clinically relevant question. To date, a substantial number of systematic reviews on neck pain have been published.

Table 1: The 5- step model of EBP (Sackett)

How to practice evidence-based medicine?
1. Ask clinical questions you can answer
2. Search for the best evidence
3. Critically appraise the evidence
4. Apply the evidence in care for your patient
5. Self-evaluation (of the above steps)

The Cochrane Collaboration

The Cochrane Collaboration is an international non-profit organization that prepares, maintains, and disseminates systematic up-to-date reviews of health care interventions. The main purpose of the Cochrane Collaboration is to provide information that is evidence-based, easily accessible, internationally developed, quality controlled, clinically useful, and periodically updated. One of the review groups, the Cochrane Back Review Group, coordinates reviews on back pain, neck pain and other spinal disorders. The Editorial Board of the Cochrane Back Review Group [12] developed guidelines to facilitate a more systematic approach to the literature reviews, decrease the potential for bias, improve the quality of reviews in the field, facilitate comparison across reviews, and enhance consistency among reviewers [13]. These systematic reviews have in turn served as the basis for a number of clinical guidelines for the primary care management of back and neck pain.
The aim of this article is to summarize the available evidence from reviews on the effectiveness of different therapeutic interventions for (mechanic) neck pain. The evidence from trials published after the most recent review are included, further we will discuss some evidence on cost-effectiveness.

METHODS

Reviews were searched in Pubmed, Embase and Cochrane. We performed a search up to 2009. From the Cochrane library we included the most recent review when more than one existed on the same subject. RCTs that were not included in the review because the publishing date was after publication of the review were also searched for. Systematic reviews were included if the main topic was conservative treatment in non-specific neck pain and when they included randomised trials on acute (less than 6 weeks), sub-acute (6-12 weeks), and/or chronic neck pain (more than 12 weeks). Since the focus of this article is conservative treatment all reviews on non-surgical treatment for neck pain were included. Two reviews of the Cochrane Library 2006, Issue 3, concerning surgical or invasive interventions were not included in this present summary [14 15].
Further, one of the following outcome measures was required in order to be included in our analysis: pain, overall improvement or satisfaction with treatment, function (e.g. neck specific functional status), well-being (e.g. quality of life), disability (e.g. activities of daily living, work absenteeism) and adverse effects.
For the evaluation of cost-effectiveness, Pubmed was searched for systematic reviews or economic evaluations using the free text words, 'cost effectiveness' and

'economic evaluation'. The methodological quality assessment, data extraction and data analysis of the original systematic reviews were perused in this overview.

Evidence on therapy for mechanical neck disorders

Manipulation/mobilization

The review from Gross et al.[16] included 33 trials. This review found strong evidence for manipulation and/or mobilization when used in combination with exercises, although the type of exercises which were used was not mentioned in most of the studies Manipulation and/or mobilization alone, however, were not found to be beneficial. Additionally, there is insufficient evidence for the effectiveness of manipulation and/or mobilization for radicular complaints. In an update of this review the conclusion still remains, exercise combined with mobilization/ manipulation, exercise alone, and low-level laser therapy demonstrated either intermediate or long-term benefits. Also, in a more recent study the Cervical Overview Group came to the same conclusion [17].

In yet another review of 12 trials which investigated spinal manipulation (N=7 trials), mobilization (N=4 trials) and a combination of both therapies (N=1 trial), Bronfort et al. [18] concluded that there was moderate evidence that spinal manipulative therapy and/or mobilization was superior to general practitioners care and physical therapy in the short-term for improving physical function in patients with chronic neck pain. However, the therapy was provided by a large variety of therapists, including the chiropractor in 5 trials, a medical doctor in 2 trials, a physical therapist in 4 trials and a manual therapist in 1 trial. For patients with acute neck pain the evidence was inconclusive.

In a review by Ernst of chiropractic manipulation for neck pain [19], only 4 trials met the inclusion criteria and the conclusion was that no effectiveness existed in favor of chiropractic manipulation compared to spinal mobilization or exercise therapy.

Traction

A review by Aker et al. [20] showed no benefit from traction for acute neck pain. The review of Graham at al [21], concluded that the current literature does not support or refute the efficacy or effectiveness of continuous or intermittent traction for pain reduction, improved function or global perceived effect when compared to placebo traction, tablet or heat or other conservative treatments in patients with chronic neck disorders.

Exercises

Kay et al. [22] found strong evidence for a multimodal care approach of exercise combined with manipulation or mobilizations to be beneficial for pain, function and global perceived effect for sub-acute and chronic mechanical neck pain with or without headache. Moderate evidence was found for short and long-term benefit of exercise, stretching and/or strengthening in chronic mechanical neck pain. Also moderate evidence was found for he short-term benefit of vertigo/ eye-fixation exercise imbedded in a more complex program for chronic mechanical neck disorders. Further, Kay et al. found limited evidence of the benefit of strengthening exercise in the short and long-term for chronic mechanical neck disorders. The author could not conclude what the relative benefit of exercise was compared to other treatments and what the relative benefit was of different exercise approaches. Mior [23] concluded that for chronic neck pain the evidence of effectiveness of exercises is limited, but no information is given on which exercises were compared. A review by Aker et al. [20] showed no benefit from stretching, exercise or neck school for acute neck pain. For both sub-acute and chronic mechanical neck disorders a recent review by Gross et al. [24], showed evidence favoring exercise alone or a multimodal strategy (exercise and mobilization/manipulation) for pain, function, and general perceived effect in the short and long-term. The used exercises were shown in an addendum.

Multidisciplinary biopsychosocial rehabilitation

Karjalainen et al. found limited evidence on multidisciplinary biopsychosocial rehabilitation for neck and shoulder pain [25]. Only two relevant studies were included. There was little scientific evidence for the effectiveness of multidisciplinary biopsychosocial rehabilitation compared with other rehabilitation facilities for neck and shoulder pain.

Patient education

Haines et al. found no effectiveness for educational interventions or advice for neck pain of various acuity stages and disorder types and at various follow-up periods, including advice to activate, advice on stress coping skills, and neck school [26].

Physical modalities

Kroeling et al. [27] did not find convincing evidence of a clinically important benefit of electrotherapy modalities for neck pain. Current evidence for pulse electromagnetic field therapy, repetitive magnetic stimulation and transcutaneous electrical nerve stimulation (TENS) shows that these modalities might be more effective than placebo but not compared to other interventions. Galvanic current, iontophoresis, electric muscle stimulation, and static magnetic field did not reduce pain or disability.
Low-level laser therapy has demonstrated benefit in the short and intermediate term for pain and function for neck disorders with associated degenerative changes; however, benefit of laser has not been shown for pain. Laser therapy appears to be effective for only chronic neck disorder with associated degenerative changes. The evidence does not support widespread use in all neck disorders, as it may not be superior to placebo in other types of neck pain[17].

Massage

Ezzo et al. [28] included 19 trials in their review and assessed massage alone or massage in combination with other modalities. They concluded that the effectiveness of massage remains uncertain and they found no significant advantage of massage over no treatment, hot packs, exercises, sham laser, TENS, manual traction, mobilization, education or pain medication.

Acupuncture

Trinh et al. [29] included 10 trials that examined acupuncture treatments on chronic neck pain. They concluded that there was moderate evidence that acupuncture relieves pain better than some sham treatments or waiting list controls. The effects are measured on pain and especially on the short-term. This benefit of acupuncture is supported in the review of Systematic Review and Meta-Analysis of Fu et al. [30]. The found positive results for acupuncture in seven out of nine meta-analyses, in particular for short-term pain reduction. Further they found positive results of real acupuncture with sham acupuncture, which represents the most rigorous control for acupuncture validation. However no proof was found for the effect of acupuncture on disability and long-term pain relief for patients with neck pain

Behavioural graded activity

A behavioural graded activity program (BGA) can be described as a time-contingent increase in activities from baseline towards pre-determined goals. No reviews are yet available on the effectiveness of behavioural graded activity for neck pain. A recently conducted randomised clinical trial evaluates the effectiveness of BGA compared with conventional exercise for patients with chronic neck pain [31]. This trial involved 139 patients and showed no difference in effect between both strategies in the management of chronic neck pain patients. A randomised clinical trial, involving 146 patients with sub-acute non-specific neck pain shows no statistical or clinical difference in effectiveness between a BGA program and manual therapy [32].

Economic evaluations of neck pain

Five economic evaluations of RCTs have been published on cost-effectiveness and cost-utility for conservative treatments of neck pain [33-38]. Two of these studies [33 34 36] did not exclusively include patients with neck pain nor reported results separately for neck pain. Despite this, these studies are included in the summary below. The first Swedish economic evaluation compared chiropractic and physiotherapy for patients with low back- or neck pain visiting a general practitioner [33 34]. In total, 323 patients aged 18 to 60 years who had no contraindications to manipulation and who had not been treated within the previous month were randomised to chiropractic (n=179) or physiotherapy (n=144). Treatment was carried out at the discretion of the therapist. Both direct and indirect costs were measured. There were no differences in outcome or direct or indirect costs between chiropractic and physiotherapy after 6 and 12 months. However, only 22% of the patient population in this study had neck pain.
A recent study conducted in the Netherlands compared the cost effectiveness of physiotherapy, spinal mobilisation, and usual care by a general practitioner for patients with neck pain. Patients were recruited by 42 general practitioners and randomly allocated to manual therapy (n=60, spinal mobilisation), physiotherapy (n=59, mainly exercise), or general practitioner care (n=64, counseling, education, and drugs). Both direct and indirect costs were prospectively measured using cost diaries covering a period of one year. The manual therapy group showed a faster improvement than the physiotherapy group and the general practitioner care group up to 26 weeks, but there were no differences in effectiveness after 52 weeks [6]. The total costs of manual therapy (447 euro) were approximately one-third of the costs of physiotherapy (1297 euro) or the general practitioner care (1379 euro). The cost-effectiveness and cost-utility ratios showed that manual therapy was less costly and more effective than physiotherapy or general practitioner care [39]. See figure 1 and 2.

Table 2: Reviews within framework of the Cochrane Collaboration

Study	Studies included	interventions		evidence	outcome	remarks
Gross 2004 Mechanical neck disorders	33	Manip alone vs sham	5	Moderate evidence of **no** effect	pain	
		Manip vs various comparisons	5	No evidence of benefit	pain, function, GPE	
		Mob alone vs various comp.	4	Moderate evidence of no difference	pain, function,	
		Manip and mob vs placebo	1	No evidence of benefit	pain, function,	
		Manip and mob vs no treatment	5	Short/long term benefit	pain, function, GPE	
		Multimodal + physical agents	6	Moderate evidence of **no** effect	pain, function, GPE,	
		Multimodal + exercises vs non exercise treatment	15	**Strong** evidence of benefit	pain, function, GPE,	
Karjalainen 2003 Neck and shoulder pain	2	Active multidisciplinary treatment vs traditional care	1	No evidence of benefit	pain, sick leave, health related behaviour	Non randomised trial
		Multidisciplinary treatment with psychologist vs multidisciplinary treatment with psychologist as supervisor	1	limited evidence of benefit	pain, costs, functional status, ability to work	
Kay 2005 Mechanical neck disorders	31	Various types of strengthening, stretching and eye-fixation exercises		Limited evidence neck disorders with headache	pain, function, disability, patient satisfaction and GPE	19 % van Tulder criteria to 35 % Jadad criteria were high quality trials
		Active range of motion exercises, home exercise program		Limited evidence acute MND include WAD		
		Eye fixation program		Limited evidence chronic MND short term		
		Stretching and strengthening		Unclear findings in chronic neck disorders		
		Multimodal approach, exercise combined with manipulations or mobilisations		**Strong** evidence subacute and chronic MND with or without headache in short and long term	pain, functions, GPE	
Graham 2008 Neck pain with or without radiculopathy	7	continuous or intermittent mechanical traction		Inconclusive evidence of continuous or intermittent traction for pain reduction, improved function or global perceived effect when compared to placebo traction, tablet or heat or other conservative treatments	Pain, function, GPE	

Study	Studies included	interventions		evidence	outcome	remarks
Haines 2009 Neck pain with or without radiculopathy	10	advice focusing on activation	8	No evidence	Pain	Of the 10 selected trials, only two (20%) were rated high quality
		advice focusing on pain & stress coping skills	2	moderate evidence of no benefit	Pain	
		traditional neck school	1	limited evidence of no benefit	Pain	
Kroeling 2009 Mechanical neck disorders	18	pulsed electromagnetic field therapy (PEMF), repetitive magnetic stimulation (rMS) and transcutaneous electrical nerve stimulation (TENS)		Very low quality evidence compared to placebo	pain	
		permanent magnets (necklace)		Low quality evidence not more effective than placebo	improve function and disability (4 trials)	
		modulated galvanic current, iontophoresis and electric muscle stimulation (EMS)		Very low quality evidence not more effective than placebo		
Haraldson 2006	19	Multimodal application or massage as stand alone treatment	6	Inconclusive evidence no recommendation can be made	Pain, physical functioning, patient satisfaction and cost of care	High quality positive trials not present.
Trinh 2006 Neck disorders	10	Acupuncture for chronic neck pain		Moderate evidence compared to sham post treatment and short term Limited evidence more effective than massage short term Moderate evidence compared to waiting-list controls in short term.	pain	

GPE = General Perceived Effect
MND = Mechanical Neck Disorders
WAD = Whiplash Associated Disorder

Figure 1 indicates the difference in overall improvement between the three intervention groups. The difference between manual therapy and physiotherapy or standard general practice was statistically significant. Results were similar for all other outcomes. Figure 2 shows a cost-effectiveness plane. The graph represents bootstrap replications of cost-effectiveness ratio for pain intensity comparing manual therapy with physiotherapy. Most cost-effectiveness ratios are located in the bottom right quadrant , suggesting that manual therapy is more effective and less expensive than physiotherapy.

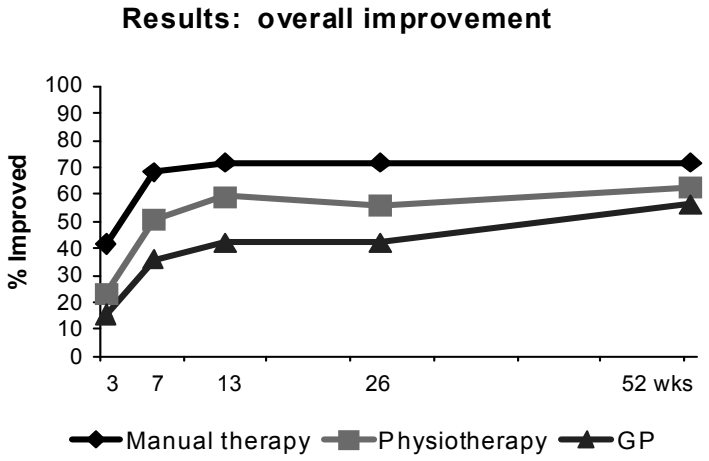

Figure 1: Differences in results between manual therapy, physiotherapy and usual care by the general practitioner (Hoving et al 2002)

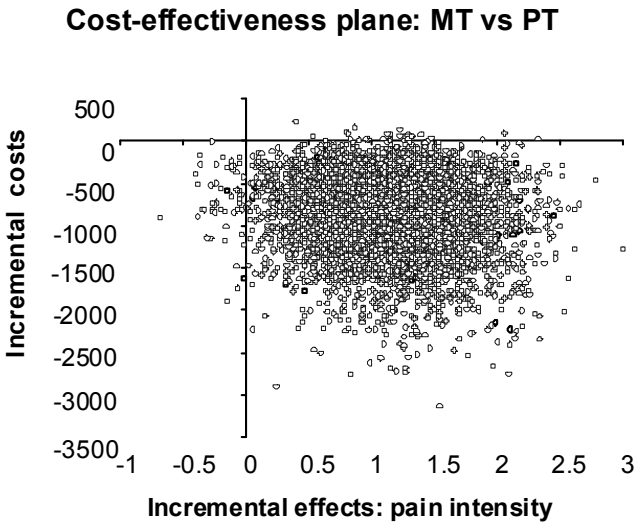

Figure 2: Cost-effectiveness plane, manual therapy versus physiotherapy (Korthals et al 2003)

Jensen et al.[36]conducted an economic evaluation of behavior oriented physiotherapy, cognitive behavioral therapy, a multidisciplinary rehabilitation program combining both, and usual care for patients with back and neck pain. The study population consisted of blue-collar and service/care workers on sick leave, identified in a national health insurance database in Sweden. Approximately 40% of the study population had neck pain. Outcome variables were sick leave, early retirement and health-related quality of life. Both direct and indirect costs were included. The results showed that the multidisciplinary rehabilitation program was superior to the three other interventions, especially in women. However, data on health-related quality of life were not analyzed because of the low response rate and a formal cost-utility analysis was consequently not performed.

A German study assessed the costs and cost-effectiveness of additional acupuncture treatment in patients with chronic neck pain compared to patients receiving 'usual care' [37]. Both direct and indirect costs were included. Since health insurance databases were used, direct costs outside the health care system, for example over-the-counter medication, were not included. Primary outcome was health related quality of life (SF-36). Follow-up was 3 months. A total of 1,753 patients were randomised to acupuncture and 1,698 to usual care. The costs of acupuncture treatment were significantly higher compared to usual care (€926 vs. €648; mean difference: €278 [95% CI: €176 to €379]). The incremental cost-effectiveness ratio (ICER) of acupuncture treatment was €12,469 per QALY. The 'usual care' group included delayed acupuncture treatment after 3 months, which may not be an optimal usual care control group.

An economic evaluation conducted in the United Kingdom assessed the cost-effectiveness of a brief physiotherapy intervention versus usual physiotherapy management of neck pain[40]. A total of 139 patients were allocated to the brief intervention, and 129 to the usual physiotherapy. Only direct costs were included and resource use data were prospectively collected for the follow-up period of one year. Quality-adjusted life years (QALYs) were estimated using EQ-5D data collected at baseline, 3 and 12 months from the start of the treatment. The results showed that the brief intervention was associated with lower costs (£-68; 95% CI £-103 to £-35). There were no differences in QALYs (-0.001; 95% CI, -0.030 to 0.028) compared with usual physiotherapy. The cost-utility ratio showed that the incremental costs of usual physiotherapy compare to the brief intervention were £68,000 per QALY.

DISCUSSION

In summary, the Cochrane reviews conclude that there are few high quality trials, that the effectiveness of many commonly used conservative treatments for neck pain is still unclear, that there are many small trials, and that effect estimates are also small. Manipulation and/or mobilization when used in combination with exercises seems the most promising. Overall, this seems a poor basis to establish clinical guidelines. Which technique or dosage was more beneficial was not possible to determine, neither whether certain subgroups benefit more from exercises than another subgroup. In addition to an overview of the literature, good quality systematic reviews also appraise the methodological quality. However, clinical relevance of the trials is often ignored. In neck pain reviews, there was hardly any focus on the content of the therapy used, failing to describe which techniques were used and whether they were properly performed. Another problem related to the applicability of trial results, is the fact that many interventions evaluated in trials consist of a combination of different interventions or components. As a result, it is often impossible to assess which component of the therapy was successful and why. Additionally, there is little agreement as to what manipulation, manual therapy, and mobilization encompass. We argue that future reports of trials and reviews should spend more attention to aspects of clinical relevance, and clearly describe the type, content and duration of the intervention.

Despite the fact that the content of the interventions in the trials varied widely, the conclusion of this overview of reviews is that manual therapy, i.e. manipulation and/or mobilization, seems to be an effective therapy. Additionally, this overview has shown that there is a conspicuous absence of high quality trials. Finally, economic evaluations on patients with mechanical neck pain are rare. The economic evaluations that have been published showed that manual therapy and a brief physiotherapy intervention, might be more cost-effective than physiotherapy alone, and that acupuncture might be more cost-effective than usual care with delayed acupuncture treatment. The economic evaluations have been conducted in five different countries and results may not be directly generalizable to other countries, because of differences in health care and social systems. We argue that within the framework of EBM there should be more attention on economic evaluations because they give additional information on costs and the consequences of new or existing interventions Given budgetary limitations, it is not only important to know whether an intervention is more effective than another intervention, but also whether this is associated with lower costs.

Conclusions

The evidence on conservative treatment for neck pain still is inconclusive and scarce, therefore, recommendations are usually based upon expert opinion rather than high quality studies. Randomised trials and economic evaluations that have sufficient sample sizes and meet current methodological standards are direly needed. The content of the interventions must be an integrated part of the description of these future trials, so they are more transparent, reproducible and their results generalizable to daily practice. This will also facilitate their role in clinical guidelines and EBM.

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3

Effectiveness of behavioural graded activity compared with conventional exercise in chronic neck pain: design of a randomised clinical trial

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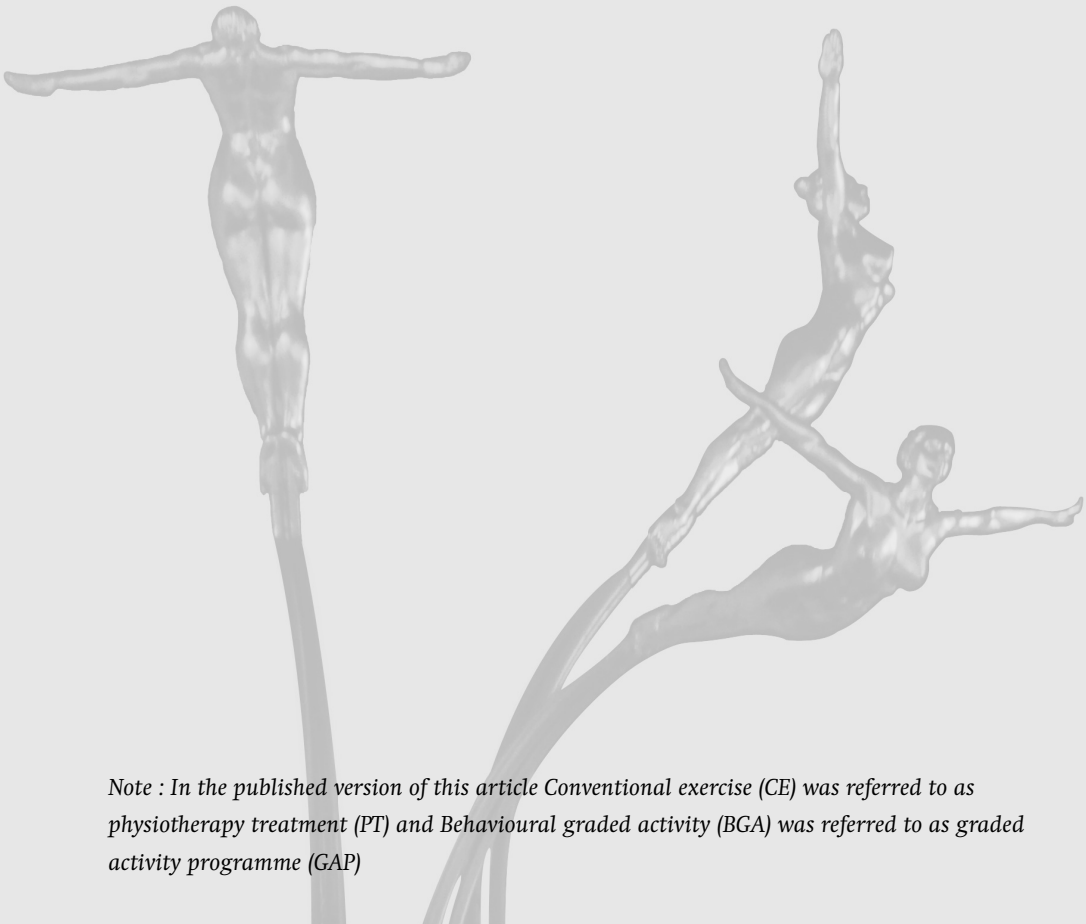
BMC Musculoskeletal Disorders 2004, 5:34



Note : In the published version of this article Conventional exercise (CE) was referred to as physiotherapy treatment (PT) and Behavioural graded activity (BGA) was referred to as graded activity programme (GAP)

ABSTRACT

Background

Chronic neck pain is a common complaint in the Netherlands with a point prevalence of 14.3%. Patients with chronic neck pain are often referred to a physiotherapist and, although many treatments are available, it remains unclear which type of treatment is to be preferred.
The objective of this article is to present the design of a randomised clinical trial, Ephysion, which examines the (cost) effectiveness of behavioural graded activity compared with conventional exercise for patients with chronic non-specific neck pain.

Methods

Eligible patients with non-specific neck pain persisting longer than 3 months will be randomly allocated to either behavioural graded activity or conventional exercise. The behavioural graded activity is based on an operant approach, which uses a time-contingent method to increase the patient's activity level. This treatment is compared with conventional exercise using a pain-contingent method.
Primary treatment outcome is the patient's global perceived effect concerning recovery from the complaint. Global perceived effect on daily functioning is also explored as primary outcome to establish the impact of treatment on daily activity. Direct and indirect costs will also be assessed. Secondary outcomes include the patient's main complaints, pain intensity, medical consumption, functional status, quality of life, and psychological variables. Recruitment of patients will take place up to the end of the year 2004 and follow-up measurement will continue until end 2005.

BACKGROUND

Prevalence and incidence

Neck pain is a common complaint that causes substantial morbidity in western countries with a reported prevalence ranging from 9.5 to 22% [1,2]. Of all musculoskeletal pains in the Netherlands, neck pain is one of the three most reported with a point prevalence of 21%; it is more often reported by women than men [3]. In 1996 total related costs were estimated to be US $686.2 million (€526.24 million), which is about 1% of the total Dutch health care expenditures [4]. Most neck complaints are continuous or recurrent [3]. When the neck pain persists for more than 3 months it is defined as chronic, and the related prevalence is 14.3% [3,5]. Although the prevalence of neck pain is stable over different age groups, the incidence of chronic neck pain increases with age [3,6].

There are many potential causes of neck pain, but mostly no specific underlying pathology is found so that it is designated as non-specific [7]. Although not a life-threatening disease, neck pain can negatively affect patients' quality of life, cause pain and stiffness, and may result in substantial medical consumption, absenteeism and disability [4,8].

In the Netherlands, patients with neck pain are often referred for physiotherapy. Moreover, physiotherapy accounted for 84% of the total direct medical neck pain costs in 1996 [4]. Although physiotherapists can apply various treatments, no formal guidelines are yet available.

Treatment models

Two treatment models have been described in the literature, both of which are applicable within the field of physiotherapy. The first, a biomedical model, considers pain to be a sign of physiological damages and treatment according to this model aims to remove the pathologic condition so that the pain will no longer occur [9,10]. Moreover, treatment is guided by the amount of pain a patient experiences, leading to a pain-contingent approach [11]. According to the second, a biopsychosocial model, pain is not necessarily caused by underlying pathology or impairment but can persist long after the initial pathology has healed; psychological and social factors may be important in the development and maintenance of complaints [12,13]. According to the principles of this biopsychosocial model, behavioural therapies assume that maladaptive behaviours are learned and, therefore, can be modified

through new learning experiences [10 14]. Three different approaches are known: respondent, operant and, cognitive behavioural therapy [9 15 16]. The present study mainly employs an operant behavioural approach, as described by Fordyce and applied by Lindström et al. [11 17]. According to this approach, the treatment focuses on decreasing pain behaviour (operants) and increasing healthy behaviour, and consists of behavioural graded activity on a time-contingent basis [11 18].

Available evidence

Many conservative physiotherapeutic treatments are available for treating neck pain, but there is insufficient evidence to allow to conclude that one type of treatment is more effective then others [19 20].
In a review on chronic pain, operant behavioural therapy was found to be beneficial to waiting list control groups on outcomes such as pain experience, mood effect other than depression, social role, and for the expression of pain behaviour [21]. Compared to other treatments, operant behavioural therapy is only beneficial for the expression of pain behaviour and role functioning [21]. Another review showed little evidence that biopsychosocial multidisciplinary rehabilitation is more effective than other rehabilitation methods for neck and shoulder pain, but the authors found only two relevant studies that satisfied the criteria for their review [22]. When examining the effectiveness of behavioural treatment for chronic pain another difficulty is that no standard protocol exists for the application of these treatments. As a result, a wide range of techniques described in the literature has been labelled as behavioural [23].

In summary, it remains unclear which type of conservative, including behavioural, treatment is to be preferred in the management of chronic neck pain. Therefore, this study, Ephysion (Effectiveness physiotherapy in neck pain), aims to evaluate the (cost) effectiveness of an operant behavioural programme (i.e. behavioural graded activity) compared with conventional exercise in patients with chronic non-specific neck pain. In addition, we aim to identify subgroups of patients who benefit most from one of the two treatments, and to identify the most important determinants for recovery from chronic non-specific neck pain.

Why a design article

Because a biased study design can produce incorrect conclusions, the design of a trial should be carefully examined before adopting its conclusions [24]. A design article allows to examine the design objectively without being influenced by the

study results, to check any resulting articles for protocol deviations, and may also reduce the temptation to search for associations during data analysis rather then presenting hypotheses in advance [25]. Further, a published protocol informs others about which studies are in process thus reducing duplication of research effort [25]. Finally, a design article prevents publication bias in the case that future articles are not published, because study results can be retrieved from the author and the study can therefore still be included in future reviews [25 26].

METHODS

Study design

A randomised clinical trial (RCT) has been designed to assess the effectiveness of behavioural graded activity compared with conventional exercise in patients with chronic non-specific neck pain. The study design has been approved by the Medical Ethics Technical Commission of the Erasmus MC, University Medical Centre in Rotterdam and is in compliance with the Helsinki Declaration.

Selection of patients and informed consent

Forty general practitioners (GP) in region West Brabant in the Netherlands will select the patients. Patients are eligible if they are aged between 18 and 70 years old, have suffered from neck pain for over three months, and have an adequate knowledge of the Dutch language. Excluded are patients diagnosed with a specific disorder (e.g. a slipped disc, a tumour or a lesion in the cervical spine), those who have had physical/manual therapy during the previous six months, those with a chronic disease (e.g. rheumatoid arthritis or coronary artery disease), or those who have to undergo surgery in the near future. Eligible patients will receive an information leaflet from their GP and the GP then informs the research department.
Thereafter, the research assistant contacts the patient, provides additional information about the implications of participation, re-checks the eligibility of the patient, and completes the informed consent procedure.

Sample size

The sample size for this study is calculated according to the global perceived effect (GPE). Based on previous studies, a 20% difference in GPE is expected after completion

of either treatment (9 weeks) and is considered to be clinically relevant; 160 patients are needed to detect this difference. In this calculation a power (1- β) of 80% is taken into account. Thus, the inclusion of 80 patients per treatment group is planned.

Randomisation

An independent examiner using a computer-generated randomisation schema performs randomisation. To prevent unequal distribution, patients are pre-stratified based on three important prognostic factors: gender, age and the severity of the complaint, which are recorded at baseline [27]. Further, unequal group sizes are prevented by using a 6-block randomisation that equalizes allocation to the two treatment groups per stratum after every sixth patient [28]. After randomisation, patients choose a physiotherapist within the allocated treatment group. Then, to ensure that the treatment starts as soon as possible, the research assistant makes the first appointment for treatment.

Blinding

Patients are told to receive physiotherapy but are blinded to allocation of the two treatments; the content of the treatments is not described in the information leaflet. This enhances the quality of the study, because the patients themselves measure the effect of treatment. GPs are also blinded for allocation to prevent accidentally informing the patients of the allocated treatment.
The physiotherapists are not blinded for allocation, but the physiotherapists from each treatment group are kept strictly separate and are not involved in the outcome measurement. Finally, the primary investigator is blinded for patients' allocation but the research assistant is not; neither is involved in the outcome measurement.

Physiotherapists and Interventions

After receiving written information, 34 physiotherapists in region West Brabant will participate in either the conventional exercise (CE) or the behavioural graded activity (BGA). To optimise the contrast between the two treatments, both groups are strictly separated throughout the study. The CE group consists of 16 physiotherapists and the BGA group of 18 physiotherapists. The CE physiotherapists participate in a meeting to standardize the conventional exercise. The BGA physiotherapists are instructed on the behavioural graded activity approach during a two-day theoretical and practical training course.

Both interventions are performed in an outpatient setting. A maximum of 18 treatments per patient is set and each treatment takes about 30 minutes, which is in accordance with medical insurance policy in the Netherlands. Before treatment starts, physiotherapists receive a completed questionnaire about the patient's main complaints [29]; this questionnaire reveals the three daily activities which are considered the most important complaints to the patient. Physiotherapists can use these three activities in the process of formulating the patient's primary therapy aim. In both treatments, the physiotherapist starts with a physical examination of the patient and an anamnesis. Then an individually tailored program will be applied and the process recorded after each treatment session using a specially designed form.

Conventional exercise

The content of conventional exercise is decided by consensus among the participating CE physiotherapists. Treatment is according to a biomedical model, which implies guidance based on the amount and severity of pain that the patient's experiences.
By consensus, the conventional exercise is divided into the patient's primary therapy aim, three general treatment goals, and several techniques to attain those goals. The primary therapy aim is defined as the result the patient wants to achieve by the end of therapy. A general treatment goal is a goal for each single treatment and could, therefore, differ per treatment session. Table 1 shows the three general treatment goals, together with the techniques physiotherapists can choose to attain them. In daily practice a broad spectrum of treatment techniques are available, but in this study the techniques to be used consist of conservative techniques with a strong focus on exercises. Moreover, manipulative techniques, acupuncture and other (alternative) techniques are excluded, as are physiotherapeutic applications such as ultrasound or diathermy.

Behavioural graded activity

An operant approach was the basis of the behavioural graded activity as used in this study. The treatment is according to a biopsychosocial model, which implies that it is guided by the patients' functional abilities and that time-contingent methods are used to increase the activity level of the patient [11]. The behavioural graded activity has three phases; a baseline phase, a treatment phase, and a generalization phase. These phases are not bound to strict time limits but can gradually merge into each other.

Table 1: Treatment goals and techniques that can be used to reach the primary treatment aim

Treatment goals	Techniques
Relaxation and preperation for exercise	- Massage - Relaxation exercise - Thoracal treatment up to thoracal 9. - Localized 3-d mobilization within physiological boundary of the joint capsule - Mobilization in al directions within physiological boundaries. - Traction within physiological boundaries. - Techniques of Mulliken excluding manipulation - Techniques of McKenzie excluding manipulation
Education	Can take place at the same time as the first treatment target. Education includes patient reassurance; explanation of (physiological) load and capability of carrying a load; and encouragement of physical activity
Exercise	- Passive exercise, guided active exercise, and active exercise - Exercise at the physiotherapist - Assign homework

Before starting the baseline phase, the treatment vision and the patient's ideas about pain and its causes are discussed. The development and maintenance of pain will be explained and patients are reassured that it is safe to move and to increase their level of activity [11 13 30]. Both are explained by means of a pain model, which has been derived from the fear-avoiding-model of Vlaeyen et al. [13]. Thereafter primary therapy aims are formulated based on the patient's main complaints, which are described as three daily activities and were revealed in the baseline questionnaire. For each of these activities, a baseline level of intensity is determined based on a pain-contingent measure. This means that patients perform each activity at least three times, each time until they have to stop because of their pain. Afterwards, patient and physiotherapist together set a start quota and time-contingent treatment quotas for each activity. The quotas will be based on the patient's mean baseline scores, primary therapy aims [17], and on the behaviour that can be derived from the baseline measure. If necessary, facilitating disorder-oriented exercises can be added to the treatment as preparation for the activities that were pointed out as main complaints. The same approach as used for the main complaint is used for these exercises.

During the treatment phase, patients systematically increase the time-contingent quotas to enable them to reach their personal aims within a pre-set therapy time period. To ensure a successful experience during the first exercise, the start quota is below the mean baseline score. The pre-set exercise quotas have to be strictly followed; neither over-performance nor under-performance is allowed. During this

phase the patient has to practice at home and document every activity or exercise on a performance chart. These charts will be discussed in the following treatment session and achievements will be reinforced while disregarding pain behaviours. Positive reinforcements of healthy behaviour and the patient's experiences of success are considered to be important to enhance the patient's motivations.

The generalization phase takes place at the end of the treatment phase. In this phase generalization of learned behaviour and management of relapses will be discussed.

Outcome measurement

Baseline questionnaires are sent after inclusion, which is as soon as possible after patients have consulted their GP. Outcome of intervention will be assessed at 4 and 9 weeks after randomisation; however, if the treatment is not finished at 9 weeks, the patients will receive an additional questionnaire (Ts) after finishing the treatment. Follow-up assessments are planned at 26 and 52 weeks after randomisation. All outcome measures are reported by means of mailed questionnaires. Table 2 presents the outcome variables, the instruments used and the moments at which they are measured.

Primary treatment outcome of this study is the global perceived effect, which is used to assess recovery from the complaint [31]. In addition, the global perceived effect in daily functioning was explored in order to also establish impact of treatment on daily activity. Both treatment outcomes (recovery of complaint and functioning in daily activity), are assessed on a 7-point Likert-scale, ranging from completely recovered (1) to worse than ever (7).

Costs are measured using a combination of questionnaires to collect data on direct medical costs (e.g. the amount of received treatment and additional therapy received), and indirect costs due to sick leave and disability.

Secondary outcome measures include main complaints, pain intensity, medical consumption, coping, functional status, quality of life, and psychological variables. Prognostic factors are measured including demographic variables, the baseline variables and the psychological variables (table 2).

Table 2: Overview of variables measured in this study

Variable	Time Measured						Range of unit
	T0	T4	T9	Ts	T26	T52	
Inclusion and exclusion variables	x						
Demographic variables	x						
Baseline variables							
Specific complaint characteristics	x						
Experience of the neck complaint and functioning in daily activities	x						1-7 (Likert scale)
Co-morbidity	x						
Additional complaints	x						
Primary outcome							
'Global perceived effect' (neck complaint and functioning in daily activities)[31]		x	x	x	x	x	1-7 (Likert scale)
Secondary outcomes							
Main complaint [29]	x	x	x	x	x	x	0-10 (Likert scale)
Pain (VAS)[31]	x	x	x	x	x	x	
Medical consumption	x	x	x	x	x	x	Dose per day
Coping with Multi-dimensional pain (MPI) Part I- II [32]	x		x		x	x	0-6 (Likert scale)
Activity (MPI, part III)	x	x	x	x	x	x	0-6 (likert scale)
Specific functional status (NDI) [33]	x	x	x	x	x	x	
Quality of life (SF-36)[34 35]	x		x		x	x	
(EQ-5d)[35 36]	x	x	x	x	x	x	
Work activities	x		x		x	x	Hours/week
Satisfaction about treatment		x	x	x	x		1-5 (Likert scale)
Compliance with treatment exercise		x	x	x	x	x	Number and time per week
Additional treatments		x	x	x	x	x	Discipline and number of treatments
Side-effects		x	x	x	x	x	Yes - No and any additional elucidation
Psychological (prognostic) variables							
Fear of movement (TSK) [37]	x				x	x	1-4 (likert scale)
Catastrophizing (PCS)[38]	x		x		x		1-5 (likert scale)
Depression (CES-D)[39]	x		x		x		1-4 (likert scale)
Self-efficacy (PSEQ)[40]	x	x	x	x	x	x	10-100% (very unsure - very sure)
Stages of change (PSOCQ)[41]	x		x				1-5 (likert scale)

Note: T_0 = baseline measurement, T_4, T_9, (T_S), T_{26}, T_{52} are follow-up measurements at 4, 9, 26 and 52 weeks, respectively, after randomisation. Ts was received at the end of treatment, when treatment lasted longer than 9 weeks. *MPI*, Multidimensional Pain inventory; *NDI*, Neck Disability Index; *SF-36*, Short Form 36; *EQ-5d*, Euroquol 5-Dutch language version; *TSK,* Tampa Scale for Kinesiophobia; *PCS*, Pain Catastrophizing Scale; *CES-D*, Centre for Epidemiologic Studies - Depression; *PSEQ*, Pain Self-Efficacy Scale; *PSOCQ*, Pain Stages Of Change Questionnaire.

Analyses

Descriptive statistics will be used to examine comparability of baseline data between CE and BGA, and to check if randomisation was successful. Before this analysis, decisions about differences considered to be clinically relevant are made and, if necessary, adjustment will be made for these differences in multivariate analysis. Further, all outcome data will be screened for normality and, if necessary, logarithmic transformations or non-parametric methods of analysis will be applied.

The first aim is to evaluate the (cost) effectiveness of BGA compared to CE. Treatment effectiveness will be examined with a Student's t-test (continuous), a Chi-square test (dichotomised) or a Wilcoxon test (not normally distributed) according to the intention-to-treat principle. This means that patients will be analysed in the treatment group to which they are randomly allocated. For missing data, imputation techniques will be used. When the dropout rate is 10 % or more, or loss to follow-up is 20 % or more, per-protocol analysis will be performed.
The results on primary outcome will be dichotomised into improved versus not improved. Improved implies completely recovered and much improved, whereas not recovered implies slightly improved, not changed, slightly worsened, much worsened, and worse than ever [31].
Cost effectiveness will be calculated from a societal perspective. Costs (direct as well as indirect) will be related to the treatment effects, based on the primary outcome measure, by calculating cost-effectiveness ratios.

The second aim is to identify subgroups of patients that benefit most from one of the two treatments. The following subgroups will be investigated: duration and severity of the complaint, depression, and fear of movement.

The third aim is to identify important variables for recovery. For this purpose multivariate analysis will be performed to investigate the influence of prognostic variables and patient characteristics on the outcome. Separate analyses will be conducted to investigate prognostic factors for short-term (3 months) and long-term (12 months) recovery.

DISCUSSION

This study is designed to evaluate the (cost) effectiveness of behavioural graded activity compared with conventional exercise in patients with chronic non-specific neck pain. Since physiotherapists perform both treatments in this study, contrast between the two treatments is a very important issue. There are contrasts both in the composition of the treatment and the way the physiotherapists approach the patient. With regard to the composition, the behavioural graded activity (BGA) starts with a systematically performed baseline measurement; this is in contrast to the conventional exercise (CE), where treatment is based on history taking and physical examination. In BGA quotas are set based on the patient's behaviour, whereas in CE they are set based on pain levels and training principles. After quotas are set BGA uses a time-contingent treatment approach, which involves a pre-set systematic increase in activities. In contrast, CE uses a pain-contingent approach, which means that treatment is adapted to the patient's reaction to previous treatment sessions.

Furthermore, BGA uses a hands-off approach, whereas CE may contain hands-on techniques, such as massage, traction etc (Table 1).

This study addresses an important question because chronic neck pain is a common complaint and it remains unclear which type of physiotherapeutic treatment is most effective. Recruitment of patients will take place until up to the end of 2004; follow-up measurement will continue up to end 2005.

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4

Effectiveness of a behaviour graded activity program versus conventional exercise for chronic neck pain patients

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European Journal of Pain 13, 2009: 533–541

ABSTRACT

Chronic neck pain is a common complaint in the Netherlands with a point prevalence of 14.3%. Patients with chronic neck pain are often referred to physiotherapy and, nowadays, are mostly treated with exercise therapy. It is, however, unclear which type of exercise therapy is to be preferred. Therefore, this study evaluates the effectiveness of behaviour graded activity (BGA) compared with conventional exercise (CE) for patients with chronic neck pain.

Eligible patients with non-specific chronic neck were randomly allocated to either BGA or CE. Primary treatment outcome is the patient's global perceived effect concerning recovery from complaint and daily functioning. Outcome assessment was performed at baseline, and at 4, 9, 26, and 52 weeks after randomization. Effectiveness was examined with general estimating equations analyses.

Baseline demographics and patient characteristics were well balanced between the two groups. Mean age was 45.7 (SD 12.4) years and the median duration of complaints was 60 months. The mean number of treatments was 6.6 (SD 3.0) in BGA and 11.2 (SD 4.1) in CE. No significant differences between treatments were found in their effectiveness of managing patients with chronic neck pain. In both BGA and CE some patients reported recovery from complaints and daily function, but the proportion of recovered patients did not exceed 50% during the 12-month follow-up period. Both groups showed clinically relevant improvements in physical secondary outcomes. International Standard Randomised Controlled Trial Number: ISRCTN88733332.

INTRODUCTION

Neck pain is one of the three most-reported musculoskeletal pains in the Netherlands [1 2]. Reported prevalence in western countries ranges from 9.5 % to 22% [3 4]. When no specific pathology is found the pain is labelled non-specific; when it lasts more than 3 months it is defined as chronic [5]. Although not life-threatening, neck pain can negatively affect the patient's quality of life, and may result in medical consumption, absenteeism and disability [2 6].

In the Netherlands, patients with neck pain are often treated with exercise-oriented physiotherapy. In 1998, 32.8% of patients with neck, shoulder or back pain sought physiotherapy [1]. For chronic neck pain, moderate evidence was found for the benefit of exercise, stretching and/or strengthening. Additionally, strong evidence was found that exercise combined with manipulation or mobilizations was beneficial for pain, function and global perceived effect. It was unclear, however, what the relative benefit was of the different exercise types [7].

Two common treatment models are available. One is the traditional biomedical model, in which treatment is focussed on pain caused by physiological pathology, leading to a pain-contingent approach [8 9]. Problems regarding this model include no causal relationship being found between pathology and the severity of pain a patient experiences, and a failure to acknowledge the influence of behavioural and psychosocial factors in pain experiences [10]. As a consequence a biopsychosocial model has gained increasing support [11-13]. According to this model, pain can persist long after the initial pathology has healed, and psychological and social factors are important determinants in development and perpetuation of complaints [14 15]. Further, maladaptive behaviours are assumed to be learned and, therefore, can be modified through new learning experiences which, in chronic pain, can decrease pain and disability [11]. Three approaches are known: respondent, operant, and cognitive behavioural therapy [8 16 17].
Cognitive behavioural therapy has shown promising results in chronic pain [10 11]. For neck pain, a brief physiotherapy intervention using these principles was slightly less effective than usual care physiotherapy and as effective as McKenzie therapy [18-20]. However, these were brief interventions and a longer more focussed intervention might be more effective.

The present study employs an operant behavioural graded activity approach, in which treatment is focussed on decreasing pain behaviour (operants) and increasing healthy behaviour on a time-contingent basis [21 22]. It has shown promising

results in back pain but the effectiveness for neck pain is still unknown [23]. This study evaluates the effectiveness of behavioural graded activity compared to conventional exercise in patients with chronic non-specific neck pain in primary care.

METHODS

Study design

The study is a randomised clinical trial, and has been approved by the local Medical Ethics Committee. A detailed description of the design, interventions and outcomes is published elsewhere [24].

Patient selection

Patients, from region West Brabant in the Netherlands, who consulted their general practitioner (GP), were eligible for inclusion if they were aged between 18 and 70 years, suffered from neck pain for at least three months, and had an adequate knowledge of the Dutch language. Excluded were patients diagnosed with a specific disorder (e.g. a slipped disc, a tumour or a lesion in the cervical spine), those who had physical/manual therapy during the previous six months, those with a chronic disease (e.g. rheumatoid arthritis or coronary artery disease), or those who had to undergo surgery in the near future. Eligible patients signed an informed consent and were included. Patients who presented themselves in general practice with an episode of neck pain lasting longer than three months were defined as incident cases. In order to improve the recruitment rate we additionally searched the medical files of three GPs for prevalent cases. Prevalent cases were defined to be patients who had visited their GP with chronic neck pain in the previous 2 years. Like the incident cases they were checked on eligibility, signed informed consent and thereafter were treated in the same way as the patients recruited by the GPs.

Randomisation and blinding

An independent person using a computer-generated randomisation scheme randomised the patients. Unequal distribution was prevented by pre-stratification at baseline on gender, age and the severity of the complaint [25]. Further, a six-block randomisation was used, in which allocation to the two treatment groups was equalized per stratum after every sixth patient [26]. Patients were blinded for treat-

ment allocation [24]. They were informed about receiving exercise therapy but the content of the treatment was not revealed. Further, the GPs and the researcher were blinded for allocation. Physiotherapists were not blinded but were not involved in the outcome measurement. The randomisation code was revealed to the researchers once recruitment, data collection and long-term analyses were completed.

Physiotherapists and Interventions

The physiotherapists performed the treatment in the treatment arm they felt most comfortable with: either the behavioural graded activity (n=17) or the conventional exercise (n=13). Before the start of the trial the BGA therapists received a two-day training on the BGA approach and a half-day refresher training after three months. The CE therapists participated in a consensus meeting to standardize the treatment [24]. Table 1 gives the characteristics of the therapists of both treatment arms and the mean number of patients they treated.

Both interventions were performed in an outpatient setting. Both started with a history taking and a physical examination, and applied an individually tailored program.
In accordance with medical insurance policy in the Netherlands, duration of treatment was about 30 minutes and patients could receive up to18 treatments. The therapist decided the number of treatments, but the patient also had the option to stop treatment. Therapists recorded the content of each treatment session on a standardised registration form for either CE of BGA.

Conventional exercise

The content of the conventional exercise (CE) was decided by consensus among the participating physiotherapists and reflects usual care. Treatment was according to a biomedical model, which implies that it is guided by the patient's pain ex-

Table 1: Physiotherapists characteristics and the mean number of patients treated

	CE therapists (n=13)[#]	BGA therapists (n=17) [#]
Male: n (%)	9 (81.8%)	12 (80.0%)
Age in years, mean (SD)	41.7 (10.9)	44.8 (7.0)
Work experience in years (SD)	17.0 (9.2)	20.5 (7.0)
No of patients treated within study, mean (SD)	5.4 (3.7)	4.2 (std. 2.8)

[#] data on characteristics were missing for two therapists

perience. The treatment had a strong focus on exercise but physiotherapists were allowed to use physiotherapy techniques to prepare patients for this CE [24]. The additional techniques allowed were massage, thoracic treatment up to thoracic 9, localized 3-d mobilization within the physiological boundaries of the joint capsule, mobilization in all directions, traction, and non-manipulative techniques of Mulliken or McKenzie. However, each technique was only allowed within physiological boundaries; not as high velocity techniques [24]. Manipulative techniques, acupuncture and other (alternative) techniques were excluded, as were physical applications such as ultrasound or diathermy.

Graded Activity Program

An operant approach was the basis of the behaviour graded activity program (BGA) as used in this study. The treatment was according to a biopsychosocial model, which implies that it is guided by the patient's functional abilities and that time-contingent methods are used to increase the activity level of the patient [22].
The BGA program had three phases; a baseline phase, a treatment phase, and a generalization phase. In the baseline phase, patients' beliefs about pain were discussed by means of a pain model [15], primary therapy aims were formulated and, based on a pain-contingent measure, baseline levels of activities were determined. During the treatment phase patients systematically increase their activities. The time-contingent quotas enable them to reach their personal aims within a pre-set therapy time period and thereby enhance their ability to self-manage their pain. In the generalization phase (at the end of the treatment phase) generalization of learned behaviour to other areas and management of relapses were discussed.

Baseline and outcome measurement

At baseline, patients' demographics, disease characteristics and secondary outcomes were measured. Outcomes were assessed at 4 weeks, at 9 weeks (end of treatment period), and at 26 and 52 weeks. All outcomes were assessed by means of patients' questionnaires.

The primary outcome, i.e. global perceived effect (GPE) has two parts: GPE for recovery from complaints, and GPE for recovery of functioning in daily activities. GPE was assessed on a 7-point Likert scale, ranging from completely recovered (1) to worse than ever (7). Then, the scores were dichotomized into recovered (completely recovered and much improved) versus not recovered (slightly improved, not changed, slightly worsened, much worsened, and worse than ever) [27]. Patients

judged their recovery in comparison to the previous measurement (cumulative recovery). As a consequence patients could remain recovered or relapse into the not recovered category.

The following physical secondary outcomes were assessed:
Patients' main complaint, measured with the main complaints questionnaire. This revealed three daily activities that patients considered most important and which were difficult to perform because of neck pain [28]. The severity of these main complaints was measured with an 11-point numerical rating scale (0-10), in which a higher score indicated more severe main complaints. For this study only the first main complaint was evaluated.
Pain severity during the previous week was evaluated using a similar numeral rating scale (0-10) [28]. A higher score indicated more severe pain. Impediment in daily activities due to neck pain during the last month was measured with a similar scale. A higher score indicated more impediments.
Functional status was measured with the Neck Disability Index [29 30 31]. Calculation of a sum score multiplied by 2 provided the overall NDI score on a scale from 0 to100, in which a higher score indicated greater disability.
Frequency of activity was measured with the activity subscale from the Multi Dimensional Pain Inventory-Dutch Language Version (MPI-DLV) [32]. Scores ranged from 0 to 6 (never to very often).

The following psychosocial secondary outcomes were assessed:
Self-efficacy was measured with the Chronic Pain Self-efficacy Scale (CPSS) [33]. Patients' perceived self-efficacy has been defined as their expectation that they can execute a behaviour required to produce a desirable outcome [34]. The questionnaire identified 3 factors: pain self-efficacy (PSE) for coping with pain management, self-efficacy for coping with symptoms (CSE), and self-efficacy for function (FSE). Higher scores indicated higher self-efficacy.
Pain-related fear of movement or (re)injury was assessed with the Tampa Scale for Kinesiophobia (TSK) [15 35]. Seventeen items were measured on a 4-point Likert scale (strongly disagree to strongly agree). Higher scores indicate a higher amount of pain-related fear of movement or (re)injury.
Pain Catastrophizing was measured with the Pain Catastrophizing Scale (PCS) [36]. Total scores were calculated with a range from 0 to 52. A higher score indicated more catastrophizing.
Depression was measured with the Center for Epidemiologic Studies Depression (CES-D) scale [37]. Total scores on the depression scale range from 0 to 20 in which higher scores indicated more severe depression.

Health-related quality of life was measured with the Euroquol-5D (EQ-5D). The scores range from -1 to 1, in which a higher score indicated a better quality of life [38 39].

Analyses

Descriptive statistics were used to examine patient characteristics and equality of baseline data between the BGA and CE groups to check whether randomisation was successful. Possible differences in patient characteristics between prevalent cases and incident cases were examined with Chi-square ($p<0.05$). To compare patients who were lost to follow-up with the other patients the Mann-Whitney test was used ($p<0.05$).

Treatment effectiveness over time was examined using general estimating equations (GEE). The longitudinal GEE technique takes into account that the observations within one person over time are dependent and uses all available data [40]. The primary dichotomized outcome global perceived effect was examined with the logistic GEE. Further, we examined whether baseline differences, when occurring, influenced the treatment effect. For the secondary continuous outcomes the linear GEE was used, and we adjusted for baseline values to overcome the possible problem of regression to the mean. For both GEE analyses we categorized the time variable in weeks (4, 9, 26, and 52), used an unstructured correlation structure and the 'robust' estimation procedure for the standard errors. All analyses were carried out according to the intention-to-treat principle.

Changes in scores on the 11-point numeric scales were considered clinically relevant when these scores differed by more then two points [41].

Further, descriptive statistics were used to examine the physiotherapists' registration forms in order to assess the delivery of treatment.

RESULTS

Study population

Eligible patients were recruited from February 2003 to December 2005. Figure 1 shows the flow of the study population. The final number of eligible patients was 139. Of these, 121 patients were incident cases and 18 were prevalent cases. Patients were randomised to either the BGA (n=68) or the CE (n=71) group.

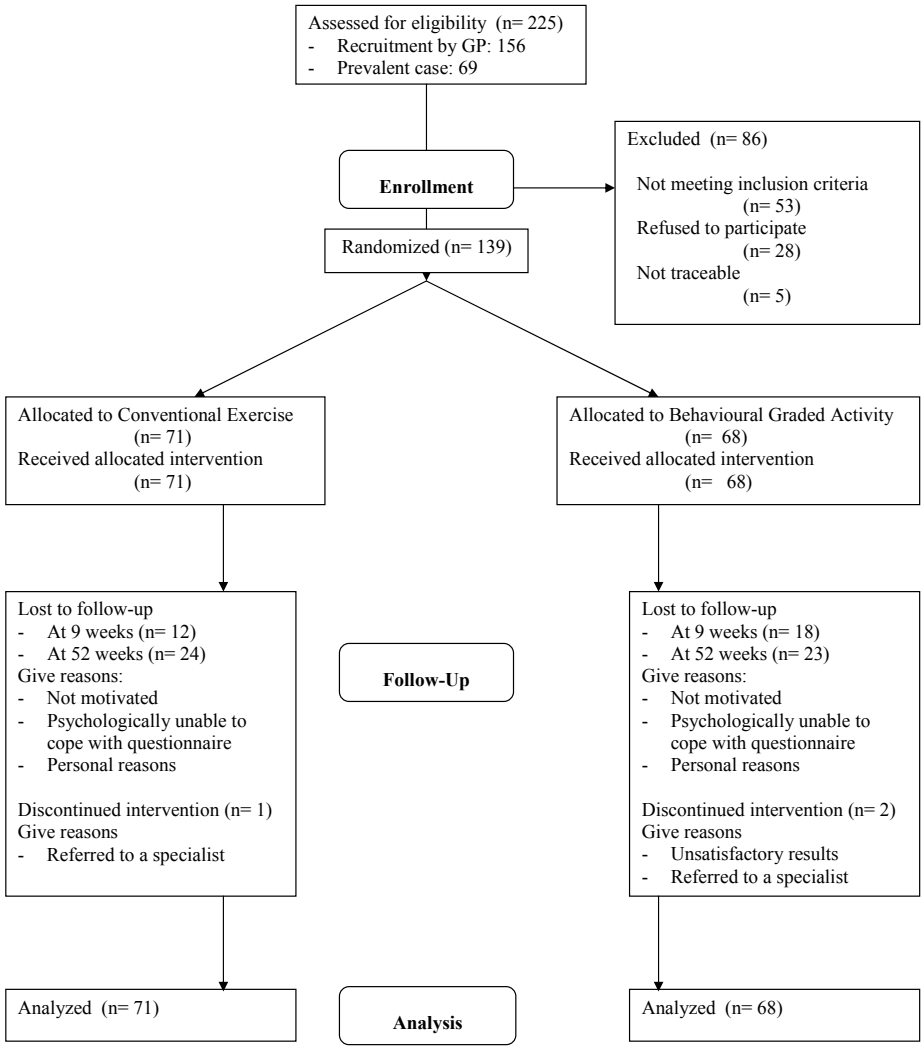


Figure 1: Patient flow through study

Table 2 gives the baseline characteristics of the patients in both treatment arms. It shows that the baseline data were well balanced between the two groups, except that the median duration of complaints was 60 (IQR 96) months for BGA and 54 (IQR 126) months for CE. Mean age is 45.7 (SD 12.4) years and 60% of the participants are female. The mean severity of the complaint is 6.9 (SD 1.8) on a scale ranging from 0 to 10.

After randomisation nine (6.5%) patients did not return the complete package of baseline questionnaires but four of them did return the main complaints questionnaire. At the end of the treatment period (9 weeks) loss to follow-up was 21.6% (n=30).

Table 2: Baseline characteristics of the study population. Values are means (standard deviations) unless stated otherwise

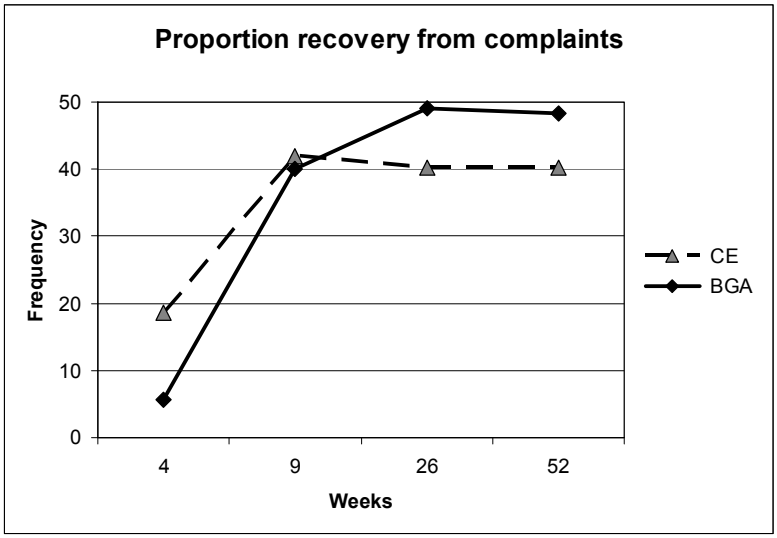
	CE (n=71)	BGA (n=68)
Age in years	45.7 (12.7)	45.7 (12.1)
Female: n (%)	43 (60.6)	43 (63.2)
Duration of complaints in month at inclusion: median (IQR)	54 (126)	60 (96)
Taking pain medication: n (%)	30 (44.1)	31 (50.8)
Had physiotherapy in past: n (%)	51 (75.0)	51 (83.6)
Paid jobs: n (%)	44 (64.7)	43 (70.5)
Outcome measures		
Severity Main complaint (0-10)	7.1 (1.7)	6.5 (2.1)
Pain severity (0-10)	7.0 (1.7)	6.8 (2.0)
Impediment (0-10), median (IQR)	5.0 (4.0)	5.0 (5.0)
NDI (0-100)	30.7 (12.1)	30.3 (12.8)
MPI-DLV: Activities (0-6)	2.8 (0.7)	2.9 (0.8)
PSEQ (0-100)		
PSE. Pain self-efficacy	57.6 (16.5)	57.2 (17.6)
FSP: functional self-efficacy	76.2 (16.4)	75.8 (20.3)
CSE: coping self-efficacy	61.5 (16.6)	60.4 (16.0)
Kinesiophobia TSK (17-68)	36.7 (7.5)	34.8 (7.8)
PCS (0-52)	15.9 (9.5)	15.8 (8.6)
CES-D (0-60) median (IQR)	10.0 (9.0)	10.0 (14.0)
EQ-5d (0-1)	0.7 (0.2)	0.7 (0.2)

* GPE: global perceived effect, PCS: pain catastrophizing scale, PSOCQ: Pain stages of change questionnaire, CES-D: Center for Epidemiologic Studies Depression, PSEQ: Pain self efficacy questionnaire, MPI-DLV: Multidimensional pain inventory- Dutch language version, NDI: Neck disability index, SF-36: Short form quality of life

Of these, only one patient terminated treatment (BGA) because of unsatisfactory results. Another patient (BGA) was referred to a specialist for pulmonary complaints. Further, two patients (one from each group) were referred to a specialist because of specific complaints. Other reported reasons for withdrawal were: not motivated, psychologically unable to cope with the questionnaire, and personal reasons. After 52 weeks loss to follow-up was 33.8%. Patients lost to follow-up were significantly younger: i.e. 39.96 (11.06) years compared to the other patients who were 49.08 (11.87) years (p= 0.00). Further, loss to follow-up was significantly higher among the prevalent patients compared to the incident patients (66.7% vs. 28.9%; p=0.03). However, both the prevalent cases and the patients that were lost to follow-up at 52 weeks were equally distributed between both treatment groups. Before becoming lost to follow-up, 17.4% of the patients in the BGA and 13.3% in the CE group rated themselves as recovered from complaints.

Effect of intervention

The mean number of treatments received was 6.6 (3.0) in BGA and 11.2 (4.1) in CE. In both groups some patients reported recovery in complaints and in daily functioning (Figure 2). However, in both groups the proportion of patients recovered did not exceed 50% during the 12-month follow-up period.



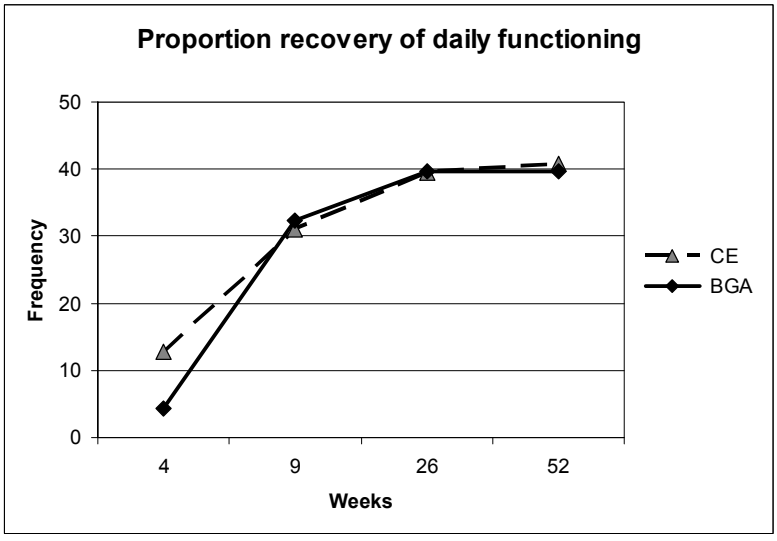


Figure 2: Recovery from complaints and of daily function over time

No significant differences between the groups were found for recovery in complaints or daily functioning. However, the pattern of recovery in complaints differed. At 4 weeks, CE showed significantly more recovery in complaints compared to BGA (OR 0.25 (95%CI 0.06; 0.99), as estimated with GEE analyses (Table 3). At 9 weeks, recovery in complaints was similar for both groups. Thereafter, recovery stabilized in the CE group, whereas in the BGA group it increased until follow-up at 26 weeks. The pattern of recovery in daily functioning was similar in both groups. No significant differences between treatments were found.
Because the duration of complaints differed at baseline between the two groups, we examined whether this influenced the primary outcome. Adjustment for duration of complaints changed the ORs of recovery only slightly and they remained non-significant.

Table 4 gives the results on secondary outcomes. For the physical outcomes no significant differences were found between the two groups at any time point of measurement. However, for the severity of the main complaint, the pain severity, and impediment both treatments showed a clinically significant improvement (>2 points), which was maintained until 52 weeks follow-up and was even enhanced for impediment. For the psychosocial outcomes BGA showed significantly higher improvements compared to CE only for catastrophizing and pain self-efficacy at

Table 3: Results of global perceived recovery (GPE): proportion, odds ratios, and odds ratios adjusted for the duration of the complaint at baseline

	n (%) CE recovered	n (%) BGA recovered	OR [95%CI]*	Adj. OR [95%CI]#
GPE complaints (n=120)				
4 weeks	11 (18.6)	3 (5.6)	0.25 [0.06; 0.99]	0.21 [0.04; 0.99]
9 weeks	26 (41.9)	22 (40.0)	0.95 [0.83; 1.18]	1.01 [0.45; 2.27]
26 weeks	25 (40.3)	28 (49.1)	1.48 [0.71; 3.06]	1.70 [0.76; 3.81]
52 weeks	25 (40.3)	28 (48.3)	1.38 [0.67; 2.86]	1.57 [0.70; 3.51]
GPE daily functioning (n=120)				
4 weeks	9 (15.3)	3 (5.6)	0.33 [0.08; 1.29]	0.34 [0.07; 1.72]
9 weeks	22 (35.5)	22 (40.0)	1.25 [0.59; 2.63]	1.48 [0.64; 3.38]
26 weeks	28 (45.2)	27 (47.4)	1.13 [0.55; 2.33]	1.37 [0.61; 3.09]
52 weeks	29 (46.8)	27 (46.6)	0.99 [0.48; 2.04]	1.16 [0.52; 2.60]

The BGA treatment is compared with conventional exercise (CE). * estimated with logistic GEE analysis. # estimated with logistic GEE analysis and adjusted for the duration of the complaints at baseline. An OR >1 means that over the corresponding period more patients in the BGA group reported recovery than in the CE group.

the end of the treatment period (9 weeks), and for pain self-efficacy at 26 weeks of follow-up. All other secondary measures were not significantly different.

Table 4: Secondary continuous outcomes at follow-up from available case analyses and mean differences over time between intervention groups, including 95% confidence intervals

Continuous secondary outcomes	CE (ACA)	BGA (ACA)	Mean difference (MD)#	95%CI
Severity Main complaint (0-10) ↓				
4 weeks	6.1 (2.0)	5.6 (2.0)	-0.05	-0.62 ; 0.51
9 weeks	4.5 (2.8)	4.1 (2.5)	-0.16	-0.94 ; 0.62
26 weeks	4.1 (2.8)	3.4 (2.7)	-1.75	-2.92 ; -0.58 *
52 weeks	4.0 (2.8)	3.7 (3.2)	-0.01	-1.16 ; 1.13
Pain Severity (0-10) ↓				
4 weeks	5.9 (1.7)	5.9 (2.1)	0.176	-0.38 ; 0.73
9 weeks	4.6 (2.3)	4.4 (2.4)	-0.32	-1.13 ; 0.48
26 weeks	4.3 (2.9)	4.2 (2.4)	-0.21	-1.19 ; 0.78
52 weeks	4.3 (3.0)	4.1 (3.2)	-0.49	-1.71 ; 0.74
Impediment (0-10) ↓ me (IQR)				
4 weeks	4.0 (3.0)	4.0 (4.0)	-0.12	-0.72 ; 0.48
9 weeks	3.0 (3.0)	2.0 (4.0)	-0.08	-0.77 ; 0.61
26 weeks	3.0 (5.5)	2.0 (3.0)	-0.56	-1.42 ; 0.31
52 weeks	2.0 (5.0)	1.0 (5.5)	-.139	-1.24 ; 0.96
NDI (0-100) ↓				
4 weeks	27.9 (11.4)	27.5 (11.6)	-0.99	-4.22 ; 2.24
9 weeks	24.0 (12.9)	22.1 (15.2)	-1.88	-5.60 ; 1.83
26 weeks	26.5 (13.9)	22.5 (14.0)	-2.86	-6.65 ; 0.92
52 weeks	26.6 (14.2)	21.9 (16.5)	-3.35	-8.28 ; 1.58
MPI-DLV Activities (0-6) ↑				
4 weeks	2.7 (0.7)	2.8 (0.8)	0.09	-0.18 ; 0.36
9 weeks	2.8 (0.7)	2.9 (0.8)	0.03	-0.21 ; 0.26
26 weeks	2.8 (0.7)	3.0 (0.7)	0.10	-0.10 ; 0.30
52 weeks	2.9 (0.8)	3.3 (0.7)	0.16	-0.13 ; 0.45
PSE: pain self efficacy (0-100) ↑				
4 weeks	61.1 (18.2)	59.7 (17.3)	-0.48	-6.10 ; 5.14
9 weeks	60.9 (21.7)	67.1 (17.1)	7.25	1.09 ; 13.40 *
26 weeks	59.2 (19.8)	68.1 (18.3)	9.26	2.81 ; 15.71 *
52 weeks	59.6 (20.9)	61.4 (23.7)	2.92	-5.00 ; 10.84
FSE: functional self efficacy (0-100) ↑				
4 weeks	76.1 (14.8)	76.8 (20.7)	2.19	-1.88 ; 6.26
9 weeks	79.2 (16.5)	81.9 (18.9)	1.82	-2.48 ; 6.12
26 weeks	76.4 (19.0)	82.4 (17.1)	4.08	-0.13 ; 8.29
52 weeks	75.0 (17.5)	79.5 (20.0)	2.03	-3.02 ; 7.07
CSE: coping self efficacy (0-100) ↑				
4 weeks	63.9 (16.4)	67.0 (16.7)	3.93	0.43 ; 8.29
9 weeks	64.9 (18.6)	72.2 (15.6)	3.05	-1.76 ; 7.86
26 weeks	66.1 (16.1)	72.4 (15.5)	2.55	-2.68 ; 7.79
52 weeks	65.1 (17.1)	69.3 (19.2)	0.32	-5.84 ; 6.48

Table 4: Secondary continuous outcomes at follow-up from available case analyses and mean differences over time between intervention groups, including 95% confidence intervals (continued)

Continuous secondary outcomes	CE (ACA)	BGA (ACA)	Mean difference (MD)#	95%CI
Kinaesiphobia TSK (17-68) ↓				
26 weeks	34.3 (8.3)	30.7 (8.4)	-1.75	-4.22 ; 0.72
52 weeks	33.3 (7.2)	31.8 (7.7)	2.20	-0.10 ; 4.50
PCS (0-52) ↓				
9 weeks	13.6 (10.2)	10.4 (7.4)	-2.16	-4.30 ; -0.02 *
26 weeks	12.7 (9.2)	9.6 (7.9)	-0.02	-2.19 ; 2.15
52 weeks	12.5 (9.3)	10.0 (9.3)	0.90	1.88 ; 3.68
CES-D (0-60) ↓				
9 weeks	9.0 (10.0)	5.0 (11.5)	-1.02	-3.44 ; 1.40
26 weeks	8.0 (13.0)	4.0 (12.0)	-1.79	-4.30 ; 0.72
52 weeks	8.5 (12.0)	6.0 (12.0)	-1.73	-3.94 ; 0.48
EQ 5d total (-1-1) ↑				
4 weeks	0.7 (0.1)	0.7 (0.2)	.026	-0.03 ; 0.07
9 weeks	0.7 (0.2)	0.8 (0.2)	.012	-0.07 ; 0.09
26 weeks	0.8 (0.1)	0.8 (0.2)	-0.04	-0.10 ; 0.02
52 weeks	0.7 (0.2)	0.8 (0.2)	0.03	-0.05 ; 0.11

ACA= absolute scores from available case analyses, # MD = BGA-CE, adjusted for baseline values and estimated with linear GEE analysis. For example, the MD-score on the NDI at 52 weeks is -3.35, which means that the BGA group mean score is 3.35 lower than that of the CE group. Meaning 3 points less disability on a range from 0-100. *=$p < 0.05$. ↓ = Higher scores on this scale indicate worse results. ↑= Higher scores on this scale indicate better results.

Treatment delivery

Registration forms on the content of the treatment were only available for 44 patients (64.7%) in BGA and for 54 patients (76.1%) in CE.

In CE active exercise was used in 90.7% of the patients, guided exercise was used in 50% ,and passive exercise was used in 57.4 %. Massage was given to 81.5% of the patients. Further, traction techniques and mobilization techniques were used in 44% and 57% of the patients respectively.

In BGA, in the baseline phase the pain model was discussed with 100% of the patients, and time-contingent practice schedules were made with 90.7% of the patients. In the treatment phase active exercise was used in 91.7% of patients, guided exercise was used in 22.7%, and passive exercise was used in 11.6% of the patients. The generalization phase (i.e. generalization of learned behaviour to other areas and prevention and management of relapses) was discussed with 74.4% of the patients.

We also examined medicine use, number of side effects (e.g. headache, dizziness, etc.) and additional treatments used, all as reported by the patients. Further, we examined whether treatment was effective in subgroups (catastrophizing, fear of movements, duration of complaints and pain severity), by dividing each subgroup at the median. No differences between treatments were found (data not shown).

DISCUSSION

This study revealed no differences in recovery between the BGA and CE group in the management of patients with chronic non-specific neck pain. Some patients reported recovery in complaints and daily functioning but the proportion of recovered patients did not exceed 50% in either group. BGA and CE show similar patterns of recovery for functioning but not for complaints. Further, both groups showed short-term and long-term clinically relevant improvements in the secondary outcomes pain severity, severity of the main complaint, and impediment [41].

Comparison to other studies

This study is one of the few to examine the effectiveness of a behavioural graded activity treatment compared to conventional exercise for patients with chronic non-specific neck pain in primary care. The treatment groups showed no differences in recovery in the short-term (9 weeks) and long-term (52 weeks), which is in line with two recent trials on neck pain investigating a brief cognitive behavioural intervention compared to other forms of physiotherapy [18 19]. Our results are also in line with the latest review on exercise in neck pain, in which no conclusive evidence was found to prefer either physiotherapy treatment for patients with chronic neck pain [7 42].

The fact that no difference in short-term and long-term effectiveness is found could be caused by diminished contrast between the two treatment groups. In another study it was suggested that a two-day behavioural training could be too short for a discernible impact on patient treatment outcome [40 43]. This, however, was based on a training for randomised GPs. In this study the BGA treatment was provided by physiotherapists who chose to perform it and were already familiar with the concept. Moreover, the BGA training period in this study was longer than in the study of King et al.. We believe that we took all necessary steps to ensure a good implementation.

The difference in recovery from complaints in favour of CE at 4 weeks was unexpected. Mobilization techniques combined with exercise have been found effective in the latest reviews and could, therefore, have contributed to the fast recovery in CE [44 45]. In this study 57% of the patients received mobilization techniques that were not high velocity. However, recovery was not significantly different between patients who did receive mobilization and those who did not. Another explanation could be that the hands-on method of the CE is perhaps more in line with patients' expectations and preferences, which are known to influence effectiveness of treatment [18].

Further, the proportion of recovered patients in the present study did not exceed 50%, which was lower then expected based on previous results in back pain [23 46]. Also, a trial on less severe neck pain patients (in which only 30% had chronic pain) showed 60% recovery for physiotherapy at 52 weeks [47]. In the present study the duration of complaints at baseline was high and, although it did not change the effectiveness between treatments, patients could have been therapy resistant. It has been suggested that patients who do not respond to treatment and are unable to resume normal activities may need a more intensive approach [19].

In the secondary outcomes only a few significant effects were found. The BGA group showed significantly higher short-term improvements (9 weeks) for catastrophizing and pain self-efficacy compared to the CE group. At 26 weeks the improvements in pain self-efficacy remained significantly higher in BGA but at 52 weeks no difference was found between BGA and CE. These findings might also be due to chance, because of the multiple testing.

Limitations and strengths

Study population

To improve our recruitment rate we added prevalent cases to our population. At baseline, these prevalent patients differed from the incident cases in the physical outcomes (i.e. pain severity, severity of the main complaint and impediment). However, because these patients are equally distributed over both treatment groups they did not disturb the internal validity of the study. Further, the majority of our patients were incident cases recruited by a GP and, therefore, represent the population of patients who in actual practice are referred to physiotherapy for their neck complaints.

Loss to follow-up did occur in this study. At the end of the treatment period 21.6% was lost to follow-up. Only one patient (in BGA) terminated the treatment because of unsatisfactory results. Other known reasons were not related to the treatment; therefore, selective withdrawal from the study is unlikely. At 52 weeks 33.8% of the patients was lost to follow-up but they were equally distributed over the two groups and are unlikely to have disturbed the internal validity of the study.

Delivery of treatment

The participating physiotherapists performed either the BGA or the CE treatment. It could be argued that the treatment effect is, therefore, attributable to the therapists rather than to the treatment itself. However we believe that this is unlikely in this study because the sample of therapists in both treatments is sufficiently large and homogenous (work experience and other characteristics did not differ significantly). By having these two separate therapist groups we created as much contrast between treatments as possible.

With regard to compliance to the treatment it has been suggested that undergraduate training could make it difficult for physiotherapists to consider psychosocial factors above biomedical factors [19]. However, in our the case the attitude of the BGA therapists was less biomedical three months after the BGA training [48]. Based on evidence of treatment delivery it is apparent that some therapists did relapse into biomedical behaviour in some patients by providing passive exercise, which is protocol deviation. Whether guided treatment is protocol deviation is open for discussion. When used at the beginning of the active exercise as reassurance that the activity is possible, it might be acceptable. However, when used as a separate treatment technique it is considered protocol deviation. The information from the registration forms was insufficient to differentiate between these two forms of usage. Both passive and guided exercise were not used in many patients, and if used, they were combined with active exercise. Further, in most patients all the phases of the BGA treatment were performed.

The lower treatment frequency in BGA compared to CE was unexpected and raises the question of whether the intensity was as intended. The baseline requires approximately three treatments, which leaves three to four treatments on average for the treatment phase and generalization phase. A possible reason for the low treatment frequency, found in several remarks of the registration forms, was that the BGA principles were understood and that the patient was able to continue the exercises at home.

Measurement

For the primary outcome (global perceived effect) we used cumulative recovery whereby patients could become or remain recovered compared to the previous measurement; however, they could also relapse into the not recovered category. Because long-term pain conditions are assumed to follow recurrent or fluctuating patterns [49], we assumed that the cumulative recovery rate would better correspond to these patterns than recovery from the beginning of treatment. Further, recovery compared to a previous measure is assumed to be less sensitive to recall bias than recovery compared to the start of treatment.

For the measurement of the main complaints we only evaluated the first main complaint. It can be argued that evaluation of the mean of the three complaints would provide a broader picture of the improvement in these for the patient's relevant complaints. However, in our study no difference was found between results obtained from the mean of the three complaints or from the first complaint only. In such cases one complaint can be a substitute for the three complaints [28]. Further, in this study the second and third complaints were not always treated. For these reasons we chose to only evaluate the first main complaint.

Conclusion

Despite the limitations, this study showed no differences in effectiveness between BGA and CE in the management of patients with chronic neck pain. The proportion of patients that recovered did not exceed 50% in either treatment group. For physical secondary outcomes both groups showed clinically relevant improvements. Both treatments can, therefore, be provided for patients with chronic neck pain. In the present study BGA patients received less treatment compared to the CE group, which could indicate that it is more cost effective than CE. However, further examination that includes direct and indirect costs is necessary.

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5

Prognostic factors for persistent complaints in patients with non-specific chronic neck pain

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Submitted

ABSTRACT

Background

Recent studies show that as many as 50% of chronic neck pain patients still experience complaints one year after physiotherapy.

Method

In this prospective cohort study we used data of a randomised trial to identify prognostic factors for persistence of complaints and poor functioning post-treatment. Persistent complaints are defined as no recovery post-treatment according to the global perceived effect, and was assessed at short-term (9 weeks) and long-term (52 weeks) follow-up. Results were examined with multi-level regression analysis.

Results

Short-term persistence of complaints was associated with more severe pain at baseline and little responsibility for pain self-management. Long-term persistence was associated with lower age, psychosocial variables and exercising before baseline. Short-term persistence in poor functioning was associated with lower activity levels, lower functional status and the presence of pain in the arm or hand. Long-term poor functioning was associated with little responsibility for pain self-management, and a lower self-efficacy on functioning.

Conclusion

The results show that different prognostic factors influence the short-term and long-term outcome. Further it is shown that different prognostic factors influence the outcome in persistent complaints and poor daily functioning.

INTRODUCTION

Although neck pain is not a life-threatening disease, it can negatively affect a patient's quality of life and may result in substantial medical consumption, absenteeism and disability [1,2]. In the Netherlands neck pain is one of the three most often reported musculoskeletal pains. When no specific underlying pathology can be found, the neck pain is designated as non-specific; when the pain persists for more than three months it is defined as chronic [3,4]. Between 40 and 50% of patients with neck pain continue to experience pain one year after treatment [5-7].
Information on the prognostic factors of persistent complaints can facilitate clinical decisions concerning choice of treatment and identification of patients at risk of poor outcome [8]. This knowledge would enable therapists to pay extra attention to these factors prior to or during the treatment and might thus help enhance treatment success. Several prognostic models for neck pain have been described, and the prognostic factors varied depending on the choice of the dependent variables and the stage of pain (e.g. acute, sub-acute or chronic). To our knowledge, the factors found so far are based on heterogeneous groups of patients, including patients in acute, sub-acute and chronic pain stages. The factors found for persistence of neck complaints were higher age, a higher severity of pain, a history of previous attacks, being off work, low back pain and cycling [5,9,10].
However, the influence of the factors can vary at different stages of pain [11]. It is therefore important to examine prognostic factors at each stage of pain.

For the chronic neck pain stage no prognostic models are available; thus it remains largely unknown which factors are important in persisting pain and poor daily functioning. Therefore, this study explores which baseline factors are prognostic factors for the short-term (9 weeks) and long-term (52 weeks) persistence of complaints and poor daily functioning after physiotherapy in patients with chronic neck pain.

METHODS

Design

A prospective cohort study was conducted among participants of a randomised trial on the effectiveness of behavioural graded activity versus conventional exercise in patients with chronic neck pain [7,12]. The Medical Ethics Committee of the Erasmus MC (University Medical Centre Rotterdam) approved the study. A detailed descrip-

tion of the design, interventions and outcomes is published elsewhere [7 12]. For the present study the participants of the trial are evaluated as a cohort and the allocated treatment is considered a potential prognostic variable.

Recruitment

Between February 2003 and December 2005 general practitioners in the region of West Brabant recruited patients. Patients were eligible if their primary complaint was chronic neck pain; this was defined as neck pain for at least three months [4]. In addition, they had to be aged between 18 and 70 years and have an adequate knowledge of the Dutch language. Patients were excluded if they had been diagnosed with a specific disorder (e.g. a slipped disc, a tumour or a lesion in the cervical spine) or a chronic disease (e.g. rheumatoid arthritis or coronary artery disease), had received physical/manual therapy during the previous six months, or had to undergo surgery in the near future. Eligible patients who signed an informed consent were included and randomised. Before randomisation the patients completed an extensive baseline questionnaire which contained questions on possible prognostic factors.

Management of neck pain

Patients were randomised to either conventional exercise (CE) or behavioural graded activity (BGA). Both were standardized treatments performed by physiotherapists; the content of these treatments is extensively described elsewhere [7 12]. In summary, CE corresponds to a biomedical model, meaning that it is guided by patients' pain experience. BGA corresponds to a biopsychosocial model, meaning that it is guided by patients' functional abilities and uses time-contingent methods to increase patients' activity level [13]. Both treatments focussed strongly on exercise, but only in CE were the physiotherapists allowed to use physiotherapy techniques to prepare patients for this [7 12]. The mean age of the performing physiotherapists was 42.33 (sd. 8.3) years with a mean work experience of 18.1 (sd. 8.1) years. Fifty-one percent of therapists had at some time experienced neck pain themselves.

Definition of outcome

For both complaint and poor functioning, 'persistence' was defined as no recovery post- treatment according to the global perceived effect rate at short-term (9 weeks) and long- term (52 weeks) follow-up. Global perceived effect was measured

on a 7-point Likert scale ranging from completely recovered (1) to worse than ever (7). Patients judged their recovery in comparison to the previous measurement (cumulative recovery). The scores were then dichotomized into persistent complaints (slightly improved, not changed, slightly worsened, much worsened, and worse than ever) versus recovered (completely recovered and much improved) [14].

Potential prognostic factors

The fear-avoidance belief model and the transtheoretical model (i.e. the stages of change) were used as a basic framework to decide on which factors to examine [15] [16]. We also searched the literature for known predictors of neck pain, chronic pain in general, and poor treatment outcome.

Demographic and disease-specific variables examined were age (median cut-off), gender, education (cut-off at tertiary education e.g. HBO in the Netherlands), history of complaints (number of episodes in the last 5 years, median cut-off), paid employment (no/yes), back pain: (no/yes), pain in the arm or hand (no/yes), previous week's exercising to decrease pain (no/yes).

Other potential prognostic variables examined were: patients' main complaint patients' most important daily activity that was difficult to perform due to neck pain, as revealed by main complaints questionnaire on a Numeric Rating Scale, NRS: 0-10, with higher scores indicating more severe complaints) [14]; pain severity during the previous week (NRS: 0-10, higher scores indicating more severe pain); last month's impediment in daily activities due to the complaint (NRS: 0-10, higher scores indicating more impediment) [14]; functional status (NDI: 0-100, higher scores indicating greater disability) [17] [18] [19]; frequency of activity (MPI-DLV subscale: 0-6, i.e. never-very often) [20]; self-efficacy on pain, coping and function (CPSS: 0-100%, higher scores indicating higher self-efficacy) [21]; pain-related fear of movement or (re)injury (TSK: 17-68, higher scores indicating more pain-related fear) [22] [23]; pain catastrophizing (PCS: 0-52, higher scores indicating more catastrophizing) [24] [25]; depression (CES-D: 0-20, higher scores indicating more severe depression) [26]; Health-related quality of life (EQ-5D, -0.02 to 1, higher scores indicating a better quality of life [27] [28]; and patients' stage of change (PSOCQ, 1-5) [15]. This last questionnaire measures patients' readiness to adopt a self-management approach to chronic pain. It comprises four scales (pre-contemplation, contemplation, action and maintenance) in each of which a patient's personal responsibility for pain self-management increases. The results of the questionnaire were dichotomised into little responsibility for pain self-management (predominately pre-contemplation and contemplation) versus strong responsibility for pain self-management (predominately action and maintenance).

Statistical analysis

For the continuous outcomes we examined whether a linear relationship could be considered between the potential prognostic factors and the outcomes. If not, the factors were dichotomized by the median (in the case of impediment, severity of the main complaint, activity, quality of life, self-efficacy in pain and coping) or by a biological cut-off score (depression; cut-off score is 16) [26]. Subsequently, univariate logistic multilevel analyses were performed for all potential prognostic factors. In these analyses two levels were used: patients (level 1) and physiotherapists (level 2). This allowed us to take into account that the patients were grouped according to the physiotherapists they were treated by. The relatively small sample size made it impossible to simultaneously add all the possible predictors to the multivariable model. Therefore, the variables that were associated with the outcome ($p<0.20$) were selected for the multivariable multilevel model. We first evaluated the correlation between these variables, and if they were highly correlated (i.e. Spearman or Pearson $r > 0.50$) we retained the variable with the highest univariate association with the outcome. The associated variables were then simultaneously added to the multivariable model. The best prognostic model was constructed using manual backward selection according to the Wald-statistic test, until all included variables were statistically significant, i.e. $p< 0.10$. This p-value is regarded suitable for a relatively small sample size [29]. The odds ratios (ORs), 95% intervals (CI) and p-values are presented.

Discriminative ability of the prognostic models was examined with the area under the curve (AUC), which in logistic regression is identical to concordance (c) statistics. The AUC scores range from 0.5 (chance) to 1.0 (perfect discrimination).

Analyses for characteristics and calculation of the AUC were performed in Statistical Package for Social Science (SPSS) version 15.0. All multilevel analyses were performed with Multilevel analysis for Windows (MLwiN, version 2.02).

RESULTS

The baseline characteristics of the 139 patients enrolled in the study are presented in Table 1.

Outcome

Data on persistence of complaints and functioning in daily activity were available for 117 patients (84.2%) at 9-weeks follow-up and for 120 patients (86.3%) at 52

Table 1 Baseline characteristics of the study group

	Mean	(SD)
Age at randomization (years)	45.7	(12.4)
Gender (% female)	61.9%	
Education (≥ tertiary education)	18.3%	
Paid employment (%)	67.4%	
Therapy (behavioural graded activity)	48.9%	
Exercised before baseline (%)	35.7%	
Back pain comorbidity (%)	45%	
Pain in arm or hand (%)	33.3%	
History of complaints (past 5 years): number of episodes	7-10	
Severity of pain last week (NRS 0-10)	6.9	(1.8)
Impediment because of neck pain last month (NRS 0-10)	4.7	(2.7)
Severity main complaint (NRS 0-10)	6.8	(1.9)
Functional status (NDI 0-100)	30.5	(12.4)
Activity (frequency) (MPI 0-6)	2.8	(0.7)
Health-related quality of life (EQ-5D -0.02-1)	0.7	(0.2)
Pain self-efficacy (0-100%)	57.4	(16.9)
Functioning self-efficacy (0-100%)	76.0	(18.2)
Coping self-efficacy (0-100%)	60.9	(16.2)
Depression (CES-D, 0-20)	11.6	(8.7)
Catastrophizing (PCS, 0-52)	15.8	(9.0)
Fear of movement and (re)injury (TSK 17-68)	35.8	(7.6)
Strong responsibility for PMS (%)	51.2%	

PSM: Pain self-management. Values are means unless stated otherwise.

weeks follow-up. After 9 weeks, 69 patients (59%) reported persistent complaints and 73 patients (62.4%) reported poor functioning. At 52 weeks the number of patients reporting persistent pain and poor functioning was 67 (55.8%) and 64 (53.3%), respectively.

The models for persistent complaints are based on data from 115 patients at short-term and 108 patients at long-term follow-up. The model of functioning was based on data from 116 patients at short-term and 118 patients at long-term follow-up. The differences between the numbers of patients in each model is due to missing values in the prognostic factors.

Prediction of persistence

Short-term follow-up

Table 2 shows associations between potential predictors and unfavourable outcome of neck pain at 9 weeks.

Table 2: Associations between potential predictors and an unfavourable short-term (9 weeks) course of chronic neck pain.

T9	Complaint						Functioning in daily activity					
	Univariate OR (95% CI)		p-value	Multivariable OR (95% CI)		p-value	Univariate OR (95% CI)		p-value	Multivariable OR (95% CI)		p-value
Age	0.84	(0.36; 1.93)	0.68				1.14	(0.50; 2.62)	0.76			
Gender	0.61	(0.25; 1.46)	0.27				0.94	(0.39; 2.24)	0.89			
Education	0.90	(0.32; 2.55)	0.84				0.86	(0.30; 2.41)	0.76			
Paid employment	0.54	(0.22; 1.31)	0.17*				0.51	(0.20; 1.26)	0.14*			
Therapy	0.92	(0.31; 2.76)	0.88				0.75	(0.25: 2.41)	0.60			
Exercised before baseline	1.24	(0.52; 2.92)	0.62				2.04	(0.83; 5.02)	0.12*			
Back pain	1.17	(0.51; 2.71)	0.71				1.06	(0.46; 2.44)	0.89			
Pain in arm/hand	2.42	(0.96; 6.06)	0.06*				2.70	(1.04; 7.01)	0.04*	2.76	(1.04; 7.29)	0.04
History of complaints	0.87	(0.38; 2.00)	0.75				1.41	(0.62; 3.23)	0.41			
Pain severity	2.05	(0.88; 4.79)	0.09*	1.33	(1.03; 1.72)	0.03	1.29	(1.02; 1.64)	0.04*			
Impediment	1.56	(0.69; 3.53)	0.28				0.86	(0.38; 1.93)	0.72			
Severity main complaint	1.35	(1.05; 1.73)	0.02*				1.68	(0.71; 3.97)	0.24			
Functional status	1.01	(0.97; 1.04)	0.76				0.99	(0.95; 1.02)	0.38			
Activity	0.67	(0.29; 1.53)	0.34				0.46	(0.20; 1.08)	0.08*	0.46	(0.19; 1.09)	0.07
Quality of life	0.32	(0.13; 0.82)	0.02*				0.58	(0.24; 1.41)	0.43			
Pain self-efficacy	0.75	(0.33; 1.73)	0.50				0.76	(0.33; 1.75)	0.51			
Functioning self-efficacy	0.99	(0.97; 1.02)	0.51				1.00	(0.98; 1.03)	0.89			
Coping self-efficacy	0.45	(0.19; 1.06)	0.07				1.07	(0.47; 2.43)	0.86			
Depression	1.99	(0.74; 5.35)	0.17				1.30	(0.49; 3.42)	0.60			
Catastophizing	1.04	(0.99; 1.09)	0.15*				1.01	(0.97; 1.06)	0.56			
Fear of movement	1.05	(0.99; 1.11)	0.08*				1.03	(0.97; 1.08)	0.37			
Little responsibility PSM	2.59	(1.12; 6.02)	0.03*	0.40	(0.17; 0.92)	0.02	0.83	(0.37; 1.90)	0.66			

PSM: Pain self-management

* These variables were selected for the multivariable analysis (in case of a correlation >0.5 the strongest univariate predictor was included). Correlations were Depression vs. Quality of life (0.56) and vs. Coping self-efficacy (-0.56); Pain severity vs. Severity main complaint (0.6).

Persistence of complaints was associated with a combination of more severe pain at baseline and little responsibility for pain self-management. Persistence of poor functioning was associated with a combination of lower activity levels and the presence of arm or hand pain at baseline. In both models the found associations were of moderate strength (OR's between 2 and 6 or between 0.17 and 0.5) except for the association between pain severity and persistence of complaints. The AUC for the persistent complaints model was 0.65 and for the poor functioning model 0.63.

Long-term follow-up

Table 3 shows associations between potential predictors and unfavourable outcome of neck pain at 52 weeks.

Persistence of complaints was associated with a combination of lower quality of life, lower self-efficacy on functioning, more severe complaints, age lower than 45.8 years, and exercise before the baseline measurement. Persistence of poor functioning was associated with a combination of little responsibility for pain self-management, age lower than 45.8 years, and lower self-efficacy on functioning. Most associations found in the long-term models were of moderate strength (OR's between 2 and 6 or between 0.17 and 0.5). The AUC for the persistent complaints model was 0.71 and for the poor functioning model 0.65.

DISCUSSION

This study explored the short-term and long-term prognostic factors for persistent complaints and persistent poor daily functioning after physiotherapy for chronic neck pain. In both models the short-term prognostic factors differed from the long-term ones.
At 9 weeks follow-up the two models (persistent complaints and poor functioning) also differed from each other regarding the prognostic factors. At 52 weeks, the models also differed from each other except for the prognostic factor lower self-efficacy on functioning.

Some of the prognostic factors emerging from the present study were reported earlier as prognostic factors for poor recovery of complaints, i.e. more severe pain at baseline [9 30], lower quality of life [30]and presence of arm or hand pain [31 32]. Lower functional status was found to be a prognostic factor for prolonged sick leave [33].

Table 3: Associations between potential predictors and a long-term (52 weeks) unfavourable course of chronic neck pain.

T52	Complaint						Functioning in daily activity					
	Univariate OR (95% CI)		p-value	Multivariable OR (95% CI)		p-value	Univariate OR (95% CI)		p-value	Multivariable OR (95% CI)		p-value
Age	0.44	(0.19; 1.02)	0.55*	0.37	(0.13; 1.07)	0.07	0.58	(0.26; 1.32)	0.19*	0.42	(0.17; 1.07)	0.07
Gender	1.26	(0.55; 2.90)	0.59				1.53	(0.66; 3.54)	0.32			
Education	0.45	(0.16; 1,28)	0.13*				0.54	(0.19; 1.54)	0.24			
Paid employment	0.83	(0.35; 1.94)	0.66				0.68	(0.29; 1.62)	0.39			
Therapy	0.56	(0.19; 1.65)	0.29				0.79	(0.27; 2.34)	0.66			
Exercised before baseline	2.19	(0.95; 5.07)	0.07*	3.66	(1.19; 11.20)	0.02	0.69	(0.30; 1.58)	0.38			
Back pain	2.04	(0.89; 4.66)	0.09*				1.57	(0.69; 3.55)	0.28			
Pain in arm/hand	1.59	(0.68; 3.70)	0.29				1.91	(0.81; 4.51)	0.14*			
History of complaints	1.21	(0.54; 2.70)	0.64				1.63	(0.71; 3.71)	0.25			
Pain severity	2.19	(0.97; 4.98)	0.06*				1.67	(0.74; 3.74)	0.21			
Impediment	1.85	(0.83; 4.11)	0.13*				1.48	(0.67; 3.26)	0.34			
Severity main complaint	1.41	(1.11; 1.81)	0.01*	1.36	(0.98; 1.88)	0.07	1.34	(1.05; 1.70)	0.02*			
Functional status	1.03	(1.00; 1.07)	0.04*				1.03	(0.99; 1.06)	0.13*			
Activity	0.56	(0.25; 1.26)	0.16*				0.52	(0.23; 1.17)	0.12*			
Quality of life	0.30	(0.12; 0.74)	0.01*	0.37	(0.12; 1.13)	0.08	0.34	(0.14; 0.86)	0.02*			
Pain self-efficacy	0.64	(0.29; 1.45)	0.25				0.67	(0.30; 1.50)	0.33			
Functioning self-efficacy	0.97	(0.94; 0.99)	0.01*	0.97	(0.93; 1.00)	0.05	0.97	(0.94; 0.99)	0.01*	0.96	(0.94; 0.99)	0.01
Coping self-efficacy	0.41	(0.18; 0.94)	0.03				0.54	(0.24; 1.21)	0.13			
Depression	3.15	(1.13; 8.79)	0.02				2.96	(1.09; 8.05)	0.03			
Catastophizing	1.04	(0.99; 1.10)	0.09*				1.03	(0.98; 1.08)	0.23			
Fear of movement	1.10	(1.04; 1.17)	0.00*				1.08	(1.02; 1.14)	0.01*			
Little responsibility PMS	0.42	(0.19; 0.94)	0.03*				0.43	(0.19; 0.97)	0.04*	0.41	(0.17; 0.99)	0.05

PSM: Pain self-management

* These variables were selected for the multivariable analysis (in case of a correlation >0.5 the strongest univariate predictor was included). Correlations were Depression vs. Quality of life (0.56) and vs. Coping self-efficacy (-0.56); Pain severity vs. Severity main complaint (0.6).

The importance of self-efficacy in chronic pain has been established in previous studies investigating pain intensity, disability and functioning [34 35 36 37]. Therefore, evaluating and bolstering patients' belief in their own abilities may be an important component of therapy [35]. Our results support this notion since self-efficacy was identified as a prognostic factor for long-term persistent neck complaints and poor functioning.

Having little responsibility for pain self-management was found to be a prognostic factor for short-term persistence of complaints and long-term poor functioning. These results partly support the argument that predominant pre-contemplation attitudes may detrimentally affect outcomes [38] and that patients who remain focussed on medical management benefit less from physical and cognitive-behavioural therapies than patients who are at least partly convinced that managing pain is their responsibility [15]. Our results further support this argument with the association found between patients' lower activity level and poor functioning at 9 weeks follow-up.

Exercise in the week before baseline measurement was a prognostic factor for long-term poor recovery. This was unexpected and contrary to the findings of Vos et al. [33] but similar to those of Hill et al. who found cycling to be associated with poorer outcome [5]. Patients who recover after exercise are not likely to consult the general practitioner, so it is possible that we included a selective group of patients in whom the complaints persisted even though they exercised. However, we have no insight into the content or duration of the exercise of patients. Another possible explanation is that the association between exercise and persistent complaints at 52 weeks could be due to chance (type 1 error), as it was not found in the other multivariable prognostic models in the present study.

In contrast to a recent review reporting younger age to be associated with better outcomes [39], we found it to be associated with poor recovery of complaints and function at 52 weeks. However, our results resembled those of Hill et al. [5], who found patients between 30 and 44 years to be twice as likely, and patients between 45 and 59 years almost four times as likely to report persistent neck pain compared to those under the age of 30 [5]. In our study, the majority of the patients in the youngest age group were aged between 30 and 45.8 (76.8%). Our result confirm the suggestion that the poorest prognosis for neck pain is the middle age years [39].

Our long-term results support the statement that in the persistence of chronic pain, psychological and behavioural factors are usually more important than

biomedical factors[40]. Moreover, the associations found between recovery and these psychological factors were mostly stronger (i.e. of moderate strength) than with other factors, which is in agreement with the latest review[39]. In the short-term however, arm and/or hand pain was also found as a prognostic factor of moderate strength for poor functioning.

It has been argued that complaints (impairment) and function (disability) might be different concepts [8], and that prognostic factors that appear in analysis are associated with the outcome measure that is used [8]. Our results support both these arguments, for we found different prognostic factors for persistent complaints and poor functioning. However, since both persistent complaints and poor daily functioning were measured with the same instrument (GPE) we agree more with the argument that they might be different concepts. This should be taken into account by both therapists and researchers.

Our results may have some practical implications and act as confirmation of previous results. First, because the prognostic factors for persistent complaints differed from those of poor functioning, the therapist should decide whether to address complaints or function during treatment. Based on that decision, different factors should be taken into account.

Second, the results confirmed the importance of awareness of behavioural and psychosocial factors during treatment. However, for short-term poor functioning, arm and/or hand problems were also an important prognostic factor. Further, although less than moderate in strength, the severity of pain was found as a prognostic factor for short-term and long-term persistent complaints. Perhaps therapists should address both these biomedical factors and psychological or behavioural factors at the start of the treatment.

Third, it might be useful to consider the patient's responsibility for pain self-management (stage of change) and self-efficacy in function prior to treatment, since they were found to influence both persistence of complaints and poor functioning. The outcome of treatment might be improved by interventions aimed at increasing the patient's responsibility for pain self-management and self-efficacy. However, increasing the patient's stage of change to a more active stage early in treatment might not be enough to affect outcome in the long term [41]. The action or maintenance stage might need time to consolidate in order to influence the outcome [41]. More research is needed to establish whether a shift towards stronger responsibility for pain self-management can affect the treatment outcome.

The present study has some limitations. One possible limitation lies in the selection of variables. The relatively small sample size made it impossible to simultaneously add all the possible predictors to the multivariable model. Because the multivariable model included only the significant univariate associations, we might have missed some variables that only become important in interaction with other variables. Further, in case of correlation, we chose to include the univariate variable that was most strongly associated with the outcome. If we had chosen a different cut-off for the correlation (e.g. >0.8 instead of >0.5) none of the significant variables would have been excluded from the multivariable model, which might have led to different results. However, the variables included in the multivariable model were selected based on the application of two theoretical models (the fear avoidance model and the transtheoretical model) and are therefore supported by the literature [15 42].

For the primary outcome (global perceived effect) we used cumulative recovery. We chose this because long-term pain conditions are assumed to follow recurrent or fluctuating patterns [43] and cumulative recovery was assumed to better correspond to these patterns. Further, with the use of cumulative recovery, recovery is calculated over time and is therefore a more effective design for comparing people who develop pain to those who do not [11 30]. Lastly, recovery compared to a previous measure is assumed to be less sensitive to recall bias than recovery compared to the start of treatment.

Conclusion

This article shows that different prognostic factors influence the short-term and long term-outcome. Also different prognostic factors were found for the outcomes persistent complaints and poor daily functioning.

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6

Physiotherapists' treatment approach towards neck pain and the influence of a behavioural graded activity training: An exploratory study

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Manual Therapy 14 (2009), 2: 131-137

ABSTRACT

Physiotherapists' treatment approach might influence their behaviour during practice and, consequently, patients' treatment outcome, however, an explicit description of the treatment approach is often missing in trials.

The purpose of this prospective observational study was to evaluate whether the treatment approach differs between therapists who favour a behavioural graded activity program (BGA), conservative exercise (CE) or manual therapy, and whether BGA training has influence on the treatment approach.

Forty-two therapists participated. BGA therapists received a 2-day training. Treatment approach was measured at baseline and at 3-month follow-up, using the Pain Attitudes Beliefs Scale for Physiotherapists. Herewith a biomedical and biopsychosocial approach was generated. Differences were examined with ANOVA and independent Student's t-test. Influence of the BGA training was examined with linear regression.

At baseline, there were no significant differences between BGA, CE or manual therapists use of biomedical or biopsychosocial approaches, but there was a trend for BGA therapists to score higher on the biopsychosocial approach. At follow up, their biopsychosocial score remained higher and their biomedical score was lower compared to CE therapists. Corrected regression analysis showed a 4.4 points (95%CI-7.9, -0.8) greater decrease for therapists who followed the BGA training compared to therapists who did not.

Our results indicate no significant differences in treatment approach at baseline and, that BGA training might influence therapists' treatment approach by decreasing biomedical approach scores.

INTRODUCTION

In the Netherlands, neck pain is one of the three most reported musculoskeletal pains and entails considerable costs for health care [1]. Because generally no specific underlying pathology can be found, the neck pain is designated as non-specific [2]. When musculoskeletal pain cannot be explained by an obvious physical cause and when only few guidelines are available, the treatment regimens may reflect the clinicians' beliefs [3]. Therapists' attitude influences their actual behaviour, which could have implications for the effectiveness of the treatment [4 5 6]. An observational study showed that the treatment style of clinicians (concerning prescription of pain medications or bed rest) was related to treatment outcome in low back pain [7]. Health care providers who were fear avoidant also were more likely to advice a patient to avoid painful movements [6]. Further, it is argued that therapists allegiance and adherence to treatment protocols is a plausible contributor to differences in treatment outcome [8]. Therefore, understanding therapists' beliefs or treatment approach seems fundamental in developing better ways of managing pain complaints [9]. Insight in therapists' treatment approaches and whether or not training can modify them could have implications for education of therapists and for daily practice.

Two different treatment approaches are known in literature. First, the traditional biomedical approach in which treatment is focussed on pain caused by physiological pathology or impairment [10]. Therapists support a pain-contingent treatment approach, where treatment is guided by the amount of pain the patient experiences. Second, the biopsychosocial treatment approach in which psychological and social factors are assumed to be important determinants in the development and maintenance of complaints, and in which pain can persist long after the initial pathology has healed. Therapists support a time-contingent approach in which patients' activities are systematically increased [11 12].
To measure physiotherapists' treatment approach, Ostelo et al. [13] developed the questionnaire 'Pain Attitudes and Belief Scale for Physiotherapists (PABS-PT)', which was further validated by Houben et al. [14] (see Appendix). From this questionnaire two factors can be generated: a biomedical approach and a biopsychosocial approach. The factors are not opposites of the same scale, but both are important in determining therapists' treatment approach [14]. The questionnaire has been used to examine the treatment approach of different therapists, physiotherapy students, and general practitioners [15 14 16]. A recent review on 5 measurement tools for health care providers' attitudes and beliefs concluded that the PABS-PT was one of the two to have undergone the most thorough testing to date [17].

Although physiotherapists' treatment approach may be important, an explicit description is often missing in trials. The aim of this study is to appraise the treatment approach of therapists in two ongoing trials [18] [19]. Therefore, we formulated three research questions. First, do therapists who favour a behavioural graded activity program (BGA) differ in their treatment approach from those therapists who favour conservative exercise (CE) or manual therapy? Second, does the primary specialisation (physiotherapy/manual therapy) influences the treatment approach? This influence is assumed because in the Netherlands certified manual therapists are specialised in manipulation techniques and are allowed to use them, whereas physiotherapists are not. Third, can BGA training, based on the principles of behavioural change as described by Fordyce [12] and as applied by Lindstrom et al. [11], influence therapists' treatment approach?

METHODS

Physiotherapists

Therapists included in this study (n=45) were involved in one of two ongoing randomised clinical trials (RCT) i.e. Ephysion [18] or the Neck Trial [19]. In these trials a BGA program was compared with either conventional exercise (Ephysion) or manual therapy (Neck Trial) in sub-acute or chronic neck pain patients. Before assessment of the treatment approach, participating therapists were given the choice to decide which treatment arm they were most comfortable with to deliver within the trial. As a result, both the BGA and the CE treatment arm in the Ephysion study consisted of both physiotherapists and manual therapists. Three therapists from the Ephysion study were excluded: two applied after baseline measurement and one did not complete the baseline measurement. The BGA therapists from the Neck Trial were excluded because their treatment approach was only assessed after the BGA training. Consequently, insight in the influence of that training on their treatment approach was not possible. The 42 remaining therapists consisted of 30 therapists from the Ephysion study (13 CE therapists and 17 BGA therapists) and 12 manual therapists from the Neck Trial (see figure 1). All participating manual therapists were certified and registered by the Royal Dutch Association for Physical Therapist (KNGF). After baseline measurement, the BGA therapists received a two-day training on the BGA approach. The remaining therapists participated in a consensus meeting to standardise their treatments [18] [19].

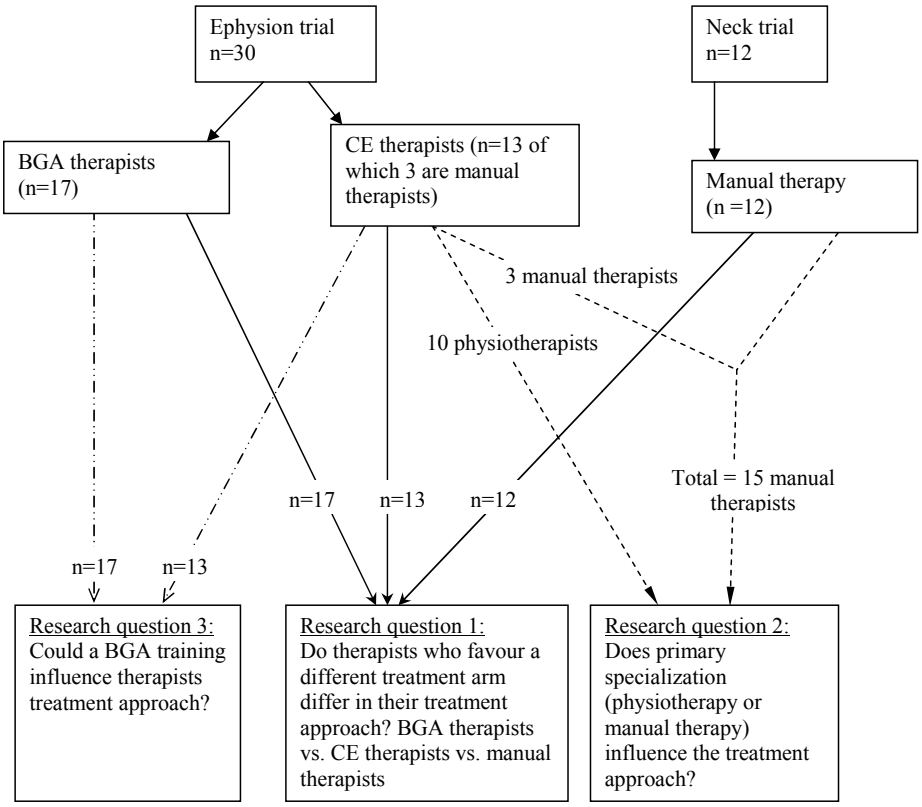

Figure 1: Overview of the compilation of the groups of therapists analysed to answer the research questions.

Questionnaires

First, therapists' characteristics were measured by a questionnaire, including gender, age, primary specialisation, work setting, and years of working experience. Second, therapists' treatment approach towards neck pain was measured with the Pain Attitudes and Belief Scale for Physiotherapists (PABS-PT) [14]. The PABS-PT is a 19-item questionnaire developed by Ostelo et al. [13] and further validated by Houben et al. [14]. It was designed to determine physiotherapists' treatment approach towards chronic low back pain. To make the questionnaire suitable for the present study we replaced 'low back pain' with 'neck pain'. Therapists were asked to rate every item on a 6-point Likert scale ranging from 'totally disagree (1)' to 'totally agree (6)'. From this, two factors were generated i.e. 1) a biomedical approach including 10 items, and 2) a biopsychosocial approach including nine items [14] . Each treatment approach is calculated by the sum of the items ranging from 10-60 on factor 1 and from 9-54 on factor 2. Higher scores on factor 1 indicate a biomedi-

cal treatment approach, and higher scores on factor 2 indicate a biopsychosocial treatment approach.

Data collection

The therapists in the Ephysion study received the PABS-PT twice: once at baseline (one week before either the consensus meeting or the BGA training), and 3 months after the trial started. In the Neck Trial, therapists' treatment approach was evaluated only 3 months after the trial started. Because the manual therapists from the Neck trial showed no differences in demographics or characteristics compared with BGA and CE therapists and because they did not receive any training, their data were regarded as baseline data.

Statistical analysis

Research question 1

First, frequencies (number, mean, standard deviation) were calculated for demographics and characteristics of the participating therapists. To examine baseline differences in treatment approach we calculated scores for the biomedical and biopsychosocial approach and tested them using a one-way ANOVA (research question 1). Figure 1 shows which therapists were compared per research question.
For further exploration of research question 1, we calculated a *global treatment attitude* at baseline, by combining the biomedical and biopsychosocial treatment approach after dividing the scores on these latter approaches into tertiles. Five different global treatment attitudes were derived i.e. 1) Therapists were considered to have a *purely biomedical* treatment attitude when their score was in the highest tertile on the biomedical treatment approach and in the lowest tertile on the biopsychosocial treatment approach, 2) they were considered to have a *more biomedical* treatment attitude when their score on the biomedical treatment approach was one tertile higher than their biopsychosocial score. The same applies vice versa for a 3) '*purely*' or 4) '*more*' *biopsychosocial* treatment attitude, and 5) therapists were considered to have a *neutral* treatment attitude when therapists scored both treatment approaches in the same tertile. The division into the global attitude is descriptive, no further statistical analyses have been carried out because of the small sample size.

Research question 2

Because of education differences, we assumed that primary specialisation (physiotherapy/manual therapy) could influence the treatment approach (research question 2). To examine this, the manual therapists from the CE treatment arm (n=3) were added to the manual therapists (n=12) of the Neck Trial. Then mean scores on the biomedical and biopsychosocial approach were calculated, and both groups were compared with an independent Student's t-test ($\alpha = 0.05$).

Research question 3

Finally, we evaluated whether BGA training could influence the treatment approach (research question 3). We calculated follow-up scores of the treatment approaches and the within-person changes between baseline and follow-up. Differences in follow-up scores were examined with independent Student's t-tests and differences from baseline scores with dependent Student's t-test ($\alpha = 0.05$). Then the possible influence of the BGA training on the within-person changes was evaluated with linear regression. Confounding was checked by separately adding variables that were assumed to influence the treatment approach. Variables were subsequently added to the multivariate model when they were related to both the BGA training (determinant) and the within-person change (outcome), and when they changed the regression coefficient of the BGA training by at least 10%; they were added in a block using the method 'enter'. The examined variables were age (cut-off point 43 years, mean), gender, primary specialisation (physiotherapist/manual therapist), other trainings followed (biomedical/biopsychosocial training), experience of neck pain (yes/no), and work experience (cut-off point 18 years, mean) [13 14].

RESULTS

Research question 1

In total, 42 baseline questionnaires were completed. Table 1 presents the baseline demographics, characteristics and treatment approaches of the three treatments arms.

Table 1: Baseline data on therapists' gender/age, work characteristics and scores on treatment approach

	Ephysion CE therapists (n=13)	Ephysion BGA therapists (n=17)	Neck Trial Manual therapists (n=12)
Male (n)	11	14	9
Age in years, mean (SD)	42.6 (10.8)	44.3 (6.8)	44.2 (7.5)
Registered as manual therapist (n)	3	6	12
Work experience in years (SD)	17.1 (8.6)	19.8 (7.1)	20.3 (7.1)
Weekly hours work, mean (SD)	35.2 (9.7)	40.9 (12.0)	36.9 (11.7)
Biomedical, mean (SD)	27.6 (4.7)	25.6 (5.4)	28.4 (8.7)
Biopsychosocial, mean (SD)	35.1 (4.7)	38.7 (4.5)	36.0 (6.4)

BGA= graded activity program.

There were no significant differences in characteristics between the therapists. The overall mean age was 43.7 (SD 8.3) years and overall work experience was 19.1 (SD 7.5) years.

In general, BGA therapists scored lower on the biomedical approach and higher on the biopsychosocial approach compared to CE therapists and manual therapists. However, when tested with ANOVA, these differences were not significant for either the biomedical approach (p=0.46) or the biopsychosocial approach (p=0.14). The tertile borders (for calculating the global treatment attitude) lay at 24.2 and 29.0 points for the biomedical treatment approach and at 34.0 and 39.0 points for the biopsychosocial treatment approach, respectively. With these, the therapists were divided into 5 global treatment attitudes (Table 2).

Table 2 shows that the majority of the CE therapists and manual therapists have a global biomedical attitude (76.9% and 58.3%, respectively) and the majority of the BGA therapists have a global biopsychosocial attitude (56.3%).

Table 2: The five different global treatment attitudes at baseline and the number (percentage) of therapists with that attitude per treatment arm

	CE therapists (n=13)	BGA therapists (n=17)	Manual therapists (n=12)
1. Purely biomedical attitude	3 (23.1%)	2 (12.5%)	6 (50%)
2. More biomedical attitude	7 (53.8%)	3 (18.8%)	1 (8.3%)
3. Neutral attitude	0	3 (18.6%)	1 (8.3%)
4. More biopsychosocial attitude	1 (7.6 %)	2 (12.5%)	1 (8.3%)
5. Purely biopsychosocial attitude	2 (15.4%)	7 (43.8%)	3 (25%)

The global treatment attitude was revealed by calculation of one overall score, which was done by combining the tertile scores of the biomedical and the psychosocial approach .

Research question 2

No differences were found for the influence of primary specialisation (physiotherapy/manual therapy) on the treatment approach. The mean biomedical score of the manual therapists (n=15) was 27.6 (SD 8.0) compared with 28.6 (SD 4.8) for the physiotherapists (n=10) (MD 1.0, 95%CI -4.8; 6.8). The scores on the biopsychosocial approach were 35.7 (SD 5.9) and 35.3 (SD 5.1) respectively (MD -0.4, 95%CI -5.1; 4.4).

Research question 3

At 3-months follow-up, 27 questionnaires were returned in the Ephysion study. Three therapists (10%) did not return the follow-up questionnaire. They did not differ in demographics, characteristics and treatment approach at baseline compared to the other therapists. The treatment approach scores at follow-up are presented in Table 3.

Table 3 shows significantly lower scores at follow-up on the biomedical approach for BGA therapists compared to CE therapists (MD -6.2 points, 95%CI -11.1; -1.3). The scores on the biopsychosocial approach for BGA therapists compared with CE therapists were significantly higher (MD 5.8 points, 95%CI 1.8; 9.9).
With regard to the within-person changes from baseline to follow-up, the BGA therapists showed a significant decrease of 4.6 (95%CI 1.8; 7.4) points on the biomedical approach but no changes on the biopsychosocial approach. The CE therapists showed no within-person changes on either approach.
Univariately, the BGA training was significantly related to the biomedical approach (B=-3.8, 95%CI -7.4; -0.3). The variables work experience and age were found to be confounders. However, because they were significantly correlated (r =0.88) they could not be considered as separate variables. We considered work experience in physiotherapy a more important contributor to the development of a treatment approach than age and therefore added this variable to the multivariate model.

Table 3: Mean scores on the biomedical and biopsychosocial approach at 3-month follow-up and change scores from baseline to follow-up

	CE therapists (n=12)	BGA therapists (n=15)	Change scores from baseline to follow-up, mean (SD)	
			CE therapists	BGA therapists
Biomedical, mean (SD)	26.9 (4.5)	20.7 (7.1)*	-0.8 (3.7)	-4.6 (4.9) **
Biopsychosocial, mean (SD)	34.5 (4.3)	40.4 (5.6)*	-0.8 (3.5)	0.7 (4.8)

* BGA therapists' scores on both approaches are significantly different from CE therapists' scores
** BGA therapists biomedical score has significantly decreased from the baseline score in table 1.

Table 4: Final multivariate models of the influence of the BGA training on the within-person change on the biomedical and biopsychosocial approaches corrected for work experience

Outcome	Variables	B*	SE	CI
Within-person change on the biomedical approach	Constant	0.81		
	BGA training	-4.37	1.73	-7.95, -0.79
	Work experience (years)	2.43	1.73	-1.15, 6.01
Within-person change on the biopsychosocial approach	Constant	-6.99		
	BGA training	0.67	1.46	-2.35, 3.69
	Work experience (years)	3.87	1.46	0.85, 6.89

BGA training (1) vs. no BGA training (0); work experience ≥18 years (1) vs. work experience <18 years (0). * B = regression coefficient as estimated with multiple linear regression analysis and corrected for work experience.

Table 4 presents the multivariate models for both approaches corrected for work experience. The first model shows that the therapists who followed the BGA training had a 4.4 points higher decrease on the scores on the biomedical approach compared to the therapists who did not follow the training. Further, the second model shows that work experience is a more important variable than the BGA training in explaining the small changes in the biopsychosocial approach. The explained variance of both models is small, 17% for the biomedical and 20% for the biopsychosocial model.

DISCUSSION

This study shows that, at baseline there were no significant differences between BGA, CE and manual therapists' use of biomedical or biopsychosocial approaches. But there was a trend for BGA therapists to score higher on the biopsychosocial approach, and for CE and manual therapists to score higher on the biomedical approach. No significant differences were found between physiotherapists and manual therapists in the treatment approach at baseline. Our results further indicate that the BGA training might influence the therapists' treatment approach, as the scores on the biomedical approach decreased.

Possible limitations

Our study has an observational design and our findings are based on a small sample. Therefore we consider our analysis to be explorative; one should be careful in generalising the results. No significant differences in treatment approach

were found at baseline, but this could be due to a power problem. ANOVA corrects for multiple testing and is therefore less sensitive in small sample sizes.

The questionnaire used to measure treatment approach focussed on neck complaints in general, and does not discriminate between acute and chronic complaints. However, in our aim to measure a general treatment approach we chose not to make the questionnaire more specific. Furthermore, the original PABS-PT also makes no distinction between acute and chronic complaints even though it was constructed for chronic low back pain. Although the questionnaire was constructed for chronic low back pain we considered it suitable for chronic neck pain as well, because the treatment approach is considered to be based on the physiotherapists' beliefs on chronic musculoskeletal problems in general and on their general preference for either the biomedical or biopsychosocial approach. This assumption is supported by a review on chronic pain, in which a heterogeneous group of pain problems was accepted as a whole, because neither the diagnosis, nor the site of pain, nor the medical findings were found to be major sources of variance in the targets of treatment [20]. The suitability of the PABS-PT is further supported in our results by showing that the questionnaire can indicate differences between therapists on both the biomedical and biopsychosocial approach for neck pain as well. The scores found in this study are similar to those found for back pain [15]. However, because the PABS-PT is newly developed no reference data were available, making it difficult to interpret whether the (significant) differences in treatment approach are clinically relevant.

To our knowledge this is the first study to use the PABS-PT longitudinally among physiotherapists. Recently, an adjusted PABS was used longitudinally to measure the treatment approach among general practitioners [16], but the questionnaire has not yet been validated for longitudinal use. Nevertheless, both studies indicate that the questionnaire seems suitable and sensitive to change.

Finally, socially desired answers cannot be ruled out, particularly at follow-up in BGA therapists because the BGA training could have made them aware of desirable answers. However, despite promotion of a more biopsychosocial way of thinking in the training, the scores on this approach did not increase.

Comparison with other studies

The impact of treatment approach on actual behaviour has never been evaluated so far, but our study is the first to show an association between therapists' treat-

ment approach and the treatment they chose to perform in the trials. This could be a relevant factor when performing that particular treatment and for future research.

In earlier studies it was argued that the two-factor structure of the PABS-PT provides more detailed information on a therapists' treatment approach than a measure with only one outcome dimension [13] [14]. Although we agree, we additionally combined the two treatment approaches into one global treatment attitude because we consider this to provide better insight into which treatment approach the therapist actually favours and might therefore be an important predictor for their behaviour.

In the present study we found no influence of the primary specialisation (physiotherapy/manual therapy) on the treatment approach, which is contrary to the findings of Ostelo et al. [13], but similar to those of Houben et al. [14]. Ostelo et al. [13] found a significantly higher biomedical treatment approach for therapists with a biomedical specialty; however, they included both manual therapists and McKenzie therapists in the biomedical specialty. Another explanation for the contrasting findings might be that they used an earlier version of the PABS-PT; although differences between the PABS-PT versions are small they might have caused the different results.

The present study differs from previous studies in that it evaluates whether a two-day BGA training influences the therapists' treatment approach. As expected, we found that therapists who followed the BGA training had a larger decrease in their biomedical approach than therapists who did not follow the training. Contrary to our expectations, the biopsychosocial approach was not affected by the training; work experience seemed to be a stronger contributor to the biopsychosocial change. Perhaps therapists with several years of practice were more biomedically educated and needed to decrease their biomedical treatment approach before being able to adopt a more biopsychosocial one. However, because our study is not a RCT, the results should be further evaluated in larger samples.
In a recent RCT [16] a similar trend was found in the change of the treatment approaches of general practitioners (GPs). At follow-up, they also found a decrease in the biomedical approach for GPs who were randomised to the treatment aimed at psychosocial factors, and also found minimal changes in the biopsychosocial approach. However they evaluated a different type of training, and had a follow-up period of 8 months.

Finally, the question remains what magnitude of change in treatment approach is needed to show a clinically relevant change in therapists behaviour and, even more important, in patient outcome. Earlier studies found only small effects of a short training on the attitude towards cognitive behavioural treatment compared to those not attending training [16] [21]. Consequently the training had no discernible impact on patient treatment outcome. These latter studies, however, used (slightly) different measurements and examined different healthcare providers and complaints compared to the present study. Whether the change in treatment approach, as found in this study, is large enough to change behaviour needs to be investigated.

Conclusions and recommendations

Despite the limitations, this study shows no significant differences between BGA, CE and manual therapists use of biomedical or biopsychosocial approaches at baseline. But there was a trend for BGA therapists to score higher on the biopsychosocial approach, and for CE and manual therapists to score higher on the biomedical approach. Further, therapists specialised in physiotherapy or manual therapy do not differ in treatment approach at baseline. Finally, BGA training might influence the therapists' treatment approach, as the scores on the biomedical approach decreased

Based on the possible trend, it might be advisable in future research to have the participating therapist choose what treatment they want to perform. This could prove beneficial for the performance of that treatment; however, evaluation of our findings in larger samples is recommended.
Whether a change in treatment approach causes changes in therapist's actual behaviour should be further explored. Additionally, when it does, the magnitude of change in treatment approach needed to provide a change in therapist's behaviour and in patients outcome, needs to be determined.
Finally, evaluation of the usage of the PABS-PT is recommended, i.e. to determine whether therapist's actual behaviour corresponds best with the two separate approach scores from the PABS-PT, or whether it is better to calculate one global treatment attitude, based on combining the tertile scores of both treatment approaches.

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7

The influence of physiotherapists' attitude on treatment outcome in chronic neck pain patients

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Submitted

ABSTRACT

Background

Physiotherapists' attitude might influence their behaviour during practice and, consequently, patients' treatment outcome. Insight into therapists' attitude seems fundamental in developing better pain management and could have implications for daily practice. The purpose of this prospective study was to examine whether physiotherapists' attitude influenced patients' short-term and long-term recovery of complaints and daily functioning.

Method

Twenty-seven physiotherapists and 111 patients were examined. Physiotherapists' attitude was measured with the 'PABS-PT' and categorized into a 'biopsychosocial' (BPS), 'biomedical'(BM) or 'neutral' attitude. The influence of physiotherapists' attitude on patients' recovery was examined with logistic regression. Crude and adjusted analyses (for relevant therapists' and patients' characteristics) were performed.

Results

Patients in the BPS or BM attitude groups showed higher adjusted probabilities for recovery of complaints and functioning than those in the neutral attitude group. This was found in both the short-term and long-term, with the sole exception of short-term recovery of complaints where no significant difference was found between BM and neutral groups.

Conclusion

Our results indicate that physiotherapists' attitude influences short-term and long-term treatment outcome in chronic neck pain patients. Recovery seems to fare better when patients are treated by a physiotherapist with a BPS or BM attitude compared to being treated by a neutral therapist.

INTRODUCTION

Neck pain is one of the most frequently reported musculoskeletal pains and entails considerable health care costs [1]. Because generally no specific underlying pathology can be found, the neck pain is designated as non-specific [2].
When musculoskeletal pain cannot be explained by an obvious physical cause and when only few guidelines are available, the treatment regimens applied may reflect the therapists' beliefs [3]. Therapists' beliefs or attitude may influence their actual behaviour, which could have implications for the effectiveness of the treatment [4] [5] [6]. For example, the therapists' beliefs and attitude were found to influence their recommendations to patients [4] [5]. Moreover, healthcare providers who were fear-avoidant were also more likely to advise a patient to avoid painful movements [6]. Further, the attitude was found to influence the therapists' view on which medical information was important [4] [5]. Therefore, understanding therapists' beliefs or attitude seems fundamental in developing better ways of managing pain complaints [3]. Insight into therapists' attitude and their impact could have implications for education of therapists and for daily practice.

Two different attitudes in physiotherapy are currently known. First, the traditional biomedical attitude, in which treatment is focussed on pain caused by physiological pathology or impairment [7]. Therapists with a biomedical attitude support a pain-contingent treatment approach, where treatment is guided by the amount of pain the patient experiences. Second, the biopsychosocial attitude, in which psychological and social factors are assumed to be important determinants in the development and maintenance of complaints, and in which pain can persist long after the initial pathology has healed. Therapists with a biopsychosocial attitude support a behavioural time-contingent approach in which patients' activities are systematically increased [8] [9].

In a previous study we explored whether therapists participating in two trials had different attitudes towards neck pain and its treatment before the trial, and whether the attitude could be changed by behavioural training. We found no differences in attitude between physiotherapists who chose to perform either a biopsychosocial behavioural graded activity treatment (BGA), a biomedical conservative exercise treatment (CE) or manual therapy. Furthermore we found that training based on the principles of behavioural change [8] [9], might have had an influence on the BGA therapists as their attitude,was less biomedical after the training [10].

The aim of this study is to examine whether the physiotherapists' attitude influences patients' short-term and long-term treatment outcome; i.e. recovery of complaints and recovery of daily functioning. We hypothesize that the physiotherapists' attitude will influence the short-term recovery in treated patients, but we cannot predict whether a biomedical attitude or a biopsychosocial attitude will have more effect. This is because any influence of a physiotherapist's attitude may well be modified by the patient's beliefs and attitudes on pain. In the long-term, we expect the recovery to be less influenced by the physiotherapists' attitude compared to the short-term. Moreover, we expect that if any influence is found, this will decrease after correcting for the patients' characteristics and prognostic factors.

METHODS

Study design

A prospective analysis was conducted among participants of a randomised trial on effectiveness of physiotherapy in chronic neck pain [11 12]. A detailed description of the design, patient selection criteria, interventions and outcomes is reported elsewhere [11 12].
In summary, between February 2003 and December 2005 general practitioners in the region West Brabant in the Netherlands recruited patients with chronic neck pain. This was defined as neck pain with a duration of at least three months [13]. Eligible patients were randomised to either behavioural graded activity (BGA) or conventional exercise (CE). Both were standardized treatments performed by physiotherapists [11 12]. Patients completed postal questionnaires at baseline, 4 weeks, 9 weeks (end of treatment period), 26 weeks and 52 weeks. The Medical Ethics Committee of the Erasmus MC (University Medical Centre Rotterdam) approved the study. No significant differences were found between the BGA and CE treatment in their effectiveness in managing patients with chronic neck pain. In both treatments some patients reported recovery from complaints and daily functioning, but the proportion of recovered patients remained between 40% and 50% during the 12-month follow-up period. Both groups showed clinically relevant improvements in some secondary outcomes [12].

Physiotherapists and Patients

Treatments were performed by 30 physiotherapists. They performed the treatment they felt most comfortable with: either BGA (n=17) or CE (n=13). The BGA therapists

received a two-day training in the BGA approach and a half-day refresher training after three months. The CE therapists participated in a consensus meeting to standardize the treatment [11]. Twenty-seven physiotherapists provided information on their attitude and were included in this study (BGA, n=16, CE, n=11).
Eligible patients were between 18 and 70 years old, were not diagnosed with a specific disorder or chronic disease, had not received physical/manual therapy during the previous six months, and would not undergo surgery in the near future. The number of patients included in the trial was 139.

Determinants

Independent variable

The physiotherapist's attitude was measured twice: once at baseline (one week before either the consensus meeting or the BGA training), and once after three months [12]. We used the latter scores since they best represented the physiotherapist's attitude when giving treatment. Attitude was measured with the 'Pain Attitudes and Belief Scale for Physiotherapists' (PABS-PT) [14], which was concluded to be one of the questionnaires to have undergone the most thorough testing [15] (see Appendix). The PABS-PT is a 19-item questionnaire in which the items can be rated from 'totally disagree (1)' to 'totally agree (6)'. From these, the biomedical factor and the biopsychosocial factor can be calculated [14]. Based on a median split of both factors, three different attitudes were derived: (i) the biomedical attitude, BM, (scores were above median in the biomedical factor and below median in the biopsychosocial factor);[16] biopsychosocial attitude, BPS, (scores were above median in the biopsychosocial factor and below median in the biomedical factor); (iii) neutral attitude (scores were either both above or both below the median in both factors).

Outcome (Dependent variable)

Patients' recovery is measured in two parts: (i) global perceived effect (GPE) for recovery from complaints [16], and GPE for recovery of functioning in daily activities. GPE was assessed on a 7-point Likert scale, ranging from 'completely recovered' (1) to 'worse than ever' (7). Patients judged their recovery in comparison to the previous measurement (cumulative recovery). The scores were dichotomized into 'recovered' (completely recovered and much improved) versus 'not recovered' (slightly improved, not changed, slightly worsened, much worsened, and worse than ever) [17].

Possible confounders

Physiotherapist's demographics and characteristics examined for confounding were: gender, age, working experience (years), therapy performed (BGA/CE), primary specialisation (manual therapy/physiotherapy) and whether they had experienced neck complaints themselves in the past.
The patient-related variables examined for confounding were demographic variables and variables that were found to be prognostic factors for persistence of complaints and poor functioning in our multivariable analysis [18]. Clinical characteristics thus found and further examined were pain severity (Numeric Rating Scale, NRS: 0-10, with higher scores indicating more severe pain), and additional complaints (i.e. pain in arm or hand at baseline: no/yes). Other prognostic variables examined were: functional status (NDI, 0-100, higher score indicating greater disability) [19], frequency of activity (MPI-DLV subscale, 0-6, i.e. never-very often) [20], self-efficacy on functioning (CPSS: 0-100%, higher scores indicating higher self-efficacy) [21] [21], health-related quality of life (EQ-5D, -0.02 to 1, higher scores indicating a better quality of life) [22] [23], previous week's exercising to decrease pain (no/yes), and patients' stage of change (PSOCQ, 1-5) [24]. The last questionnaire measures patients' readiness to adopt a self-management approach to chronic pain. It comprises four scales (pre-contemplation, contemplation, action and maintenance) in each of which a patient's personal responsibility for pain self-management increases. The results of the questionnaire were dichotomised into little responsibility for pain self-management (predominately pre-contemplation and contemplation) versus strong responsibility for pain self-management (predominately action and maintenance).

Statistical analysis

Descriptive statistics were used to examine patients' and therapists' characteristics and baseline values of the possible confounders.
The possible influence of the physiotherapists' attitude on the treatment outcome (recovery yes/no) was evaluated with logistic regression analysis. The physiotherapists' attitude was used as a categorical variable, in which the neutral attitude was the reference category. Three analyses were performed: 1) a crude analysis, 2) an analysis adjusted for relevant therapist characteristics and 3) an analysis additionally adjusted for relevant patients' characteristics and prognostic factors [25] [26].

RESULTS

Physiotherapists and Patients

Data on recovery was available for 117 patients (84.2%) at 9-weeks follow-up and for 120 patients (86.3%) at 52 weeks follow-up. Data on the attitude of the physiotherapists was available for 121 patients. As a result, the number of patients for whom a complete set of data was available was 108 at 9 weeks follow-up and 111 at 52 weeks follow-up. Patients' baseline characteristics are presented in Table 1 and the physiotherapists' characteristics are given in Table 2.

Table 1: Baseline characteristics of the study group.

	Mean (SD)
Patient demographics and clinical characteristics	
Age at randomization (years)	45.9(12.4)
Gender (% female)	63.29%
History of complaints (past 5 years): number of episodes	7-10
Severity of pain last week (NRS 0-10)	6.9(1.9)
Pain in arm or hand, yes (%)	32.2%
Prognostic variables recovery	
Therapy (behavioural graded activity)	53.6%
Exercised before baseline, yes (%)	37.3%
Functional status (NDI)	30.7(12.5)
Activity (frequency) MPI	2.8(0.74)
Health-related quality of life (EQ-5D)	0.7(0.2)
Functioning self-efficacy (0-100%)	75.8(18.7)
Strong responsibility for pain control	51.9%

Values are means unless stated otherwise.

Table 2: Characteristics of the physiotherapists (N=27).

	(SD)
Age (years)	42.33 (8.3)
Work experience (years)	18.05 (8.1)
Biomedical attitude scores	22.7 (6.2)
Biopsychosocial attitude score	38.4 (5.2)
Have at some time experienced neck pain (%)	52.5%
Registered as manual therapist (%)	15.3%
Number of physiotherapist per attitude category	
- Biopsychosocial attitude, number (%)	8 (29.6%)
- Biomedical attitude, number (%)	13 (48.1%)
- Neutral attitude, number (%)	6 (22.2%)

Values are means unless stated otherwise.

After 9 weeks, 47 patients (43.5%) reported recovery of complaints and 43 patients (39.8%) reported recovery of functioning in daily activities. At 52 weeks the number of patients reporting recovery of complaints and functioning was 49 (44,1%) and 52 (46.8%), respectively.

The influence of physiotherapists' attitude on recovery

Short-term recovery (9 weeks)

The influence of the physiotherapist's attitude on the patient's short-term outcome is shown in Table 3. Explicit recovery frequencies are given in Table 4.

Table 3: Associations between physiotherapists attitude and short-term recovery (9 weeks) of chronic neck pain complaints and daily functioning.

	Crude OR	(95% CI)	OR [a]	(95% CI)	OR [ab]	(95% CI)
T9 Complaint	(N=108)		(N=106)		(N=106)	
BPS vs. neutral	5.61	(1.89; 16.68)	5.32 [a]	(1.76; 16.06)	6.83 [ab]	(2.10; 22.23)
BM vs. neutral	2.50	(0.82; 7.63)	2.82 [a]	(0.88; 8.99)	2.92 [ab]	(0.90; 9.50)
T 9 Function	(N=108)		(N=106)		(N=105)	
BPS vs. neutral	4.63	(1.57; 13.71)	7.24[c]	(2.08; 25.19)	10.09 [cd]	(2.67; 38.06)
BM vs. neutral	1.99	(0.64; 6.13)	3.97[c]	(0.91; 17.33)	5.79 [cd]	(1.20; 27.96)

BM= biomedical attitude, BPS = biopsychosocial attitude, neutral= neutral attitude.
[a] adjusted for physiotherapists' characteristics: work experience (≥18 years)
[b] adjusted for patients' characteristics and prognostic factors: age (≥45.85 years)
[c] adjusted for physiotherapists' characteristics: work experience (≥18 years), therapy (CE/BGA), experienced neck complaints (yes/no)
[d] adjusted for patients' characteristics and prognostic factors: pain in hand and/or arm (no/yes)

Table 4: Frequency of patients recovered per attitude category at 9 weeks

Attitude	Recovery of complaints Recovered N/total N (%)	Recovery of function Recovered N/total N (%)
T9		
biopsychosocial	26/43 (60.5%)	24/43 (55.8%)
biomedical	15/37 (40.5%)	13/37 (35.1%)
neutral	6/28 (21.4%)	6/28 (21.4%)

Frequencies shown are the patients recovered versus the total number of patients treated within that category. In brackets the percentage recovered patients is shown.

Table 3 shows a significantly higher probability of short-term recovery of complaints in patients who were treated by physiotherapists with BPS attitude compared to a neutral attitude. The difference remains significant after adjusting for the physiotherapists' characteristics and the patients' prognostic variables [OR 6.83 (95%CI 2.10;22.23)]. No significant difference in recovery of complaints was found between patients who were treated by physiotherapists with a BM attitude versus a neutral attitude [OR 2.92 (95%CI 0.90; 9.30)].
Similar results were found for the influence of the physiotherapists' attitude on patients' recovery of daily functioning. Patients treated by a physiotherapist with a BPS attitude had a significantly higher probability of recovery of daily functioning compared to patients treated by a physiotherapist with a neutral attitude, even after adjusting for the physiotherapists' characteristics and the patients' prognostic variables [OR 10.09 (95%CI 2.67;38.06)]. Patients treated by a physiotherapist with a BM attitude had a significantly higher probability of recovery of daily functioning compared to patients treated by a physiotherapist with a neutral attitude, but only after adjusting for both the physiotherapists' characteristics and patients' prognostic factors [OR 5.79 (95%CI 1.20; 27.96)].

Long-term recovery (52 weeks)

The influence of the physiotherapist's attitude on the patient's long-term outcome is shown in Table 5. Explicit recovery frequencies are given in Table 6.

Table 5: Associations between physiotherapists attitude and long-term recovery (52 weeks) of chronic neck pain complaints and daily functioning.

	Crude OR	(95% CI)	OR [a]	(95% CI)	OR [ab]	(95% CI)
T52 Complaint	(N=111)		(N=109)		(N=108)	
BPS vs. neutral	3.79	(1.38; 10.43)	8.47 [a]	(2.39; 30.06)	9.72 [ab]	(2.50; 37.75)
BM vs. neutral	1.71	(0.60; 4.85)	7.81 [a]	(1.68; 36.24)	9.21 [ab]	(1.74; 48.85)
T 52 function	(N=111)		(N=109)		(N=109)	
BPS vs. neutral	4.59	(1.66; 12.74)	7.15 [a]	(2.14; 23.88)	10.32 [ac]	(2.62; 40.66)
BM vs. neutral	1.91	(0.68; 5.39)	5.399 [a]	(1.25; 23.27)	5.11 [ac]	(1.04; 25.16)

BM= biomedical attitude, BPS = biopsychosocial attitude, neutral= neutral attitude.
[a] adjusted for physiotherapists' characteristics: work experience (≥18 years), therapy (CE/BGA), manual therapy (no/yes)
[b] adjusted for patients' characteristics and prognostic factors: severity of pain, pain in hand and/or arm (no/yes)
[c] adjusted for patients' characteristics and prognostic factors: age (≥45.85 years), severity of pain

Table 6: Frequency of patients recovered per attitude category at 52 weeks

Attitude	Recovery of complaints Recovered N/total N (%)	Recovery of function Recovered N/total N (%)
T52		
biopsychosocial	26/44 (59.1%)	28/44 (63.6%)
biomedical	15/38 (39.5%)	16/38 (42.1%)
neutral	8/29 (27.6%)	8/29 (27.6%)

Frequencies shown are the patients recovered versus the total number of patients treated within that category. In brackets the percentage recovered patients is shown.

Table 5 shows a significantly higher probability of recovery of complaints in both the BPS and BM group compared to the neutral group, after correcting for the physiotherapists' characteristics and patients' prognostic factors [OR 9.72 (95%CI 2.50; 37.75) and OR 9.21 (95%CI 1.74; 48.85) respectively]. Similarly, a significantly higher probability was found for the adjusted recovery of daily functioning in both the BPS group [OR 10.32 (95%CI 2.62; 40.66] and the BM group [OR 5.11 (95%CI 1.04; 25.16)] compared to the neutral group.

No significant difference was found between patients who were treated by a physiotherapist with a biomedical versus a biopsychosocial attitude for either recovery of complaints [OR 0.85 (0.24;2.93)] or daily functioning [OR 0.36 (95%CI 0.13; 1,01)].

DISCUSSION

This study is one of the first to examine the influence of physiotherapists' attitude towards neck pain and its treatment on patients' short-term and long-term treatment outcome. After correcting for the physiotherapists' characteristics and the patients' prognostic variables, it shows a higher probability of recovery in patients who were treated by physiotherapists with a BPS attitude or a BM attitude compared to those treated by physiotherapists with a neutral attitude. This was found for both the short-term and long-term recovery of both complaints and daily functioning in both BPS and BM groups, with the sole exception of short-term recovery of complaint where no significant difference was found between the BM and neutral groups.

Findings as related to the hypotheses

As hypothesized, the physiotherapists' attitude had a significant influence on both the short-term recovery of complaints and daily functioning. In contrast to our hypothesis we found that the long-term recovery was still influenced by the physiotherapists' attitude. For the recovery of complaints, the OR's at long-term

are even larger then than those at short-term. Apparently the physiotherapists' attitude has a long-lasting influence after treatment has ended.

How the attitude influences the patients' recovery we can only speculate, since we have neither information on the physiotherapists' actual behaviour during treatment nor on the patients' response to the physiotherapist. In the literature little relevant information can be found. To our knowledge, the actual interaction between physiotherapists and patients has only been examined in one qualitative study [27]. Only a few studies examine the influence of the physiotherapists' belief on their stated behavioural intentions [14 28].
Some evidence has been found on the importance of the interaction between patient and the healthcare provider for a positive patient-provider alliance, which was found to be associated with improved healthcare outcomes [27 29]. Moreover, this collaborative relationship between patient and provider was argued to be essential for effective pain management. This makes it especially important for chronic pain patients, as they are more likely to benefit from developing efforts to manage – rather than 'cure' – their pain [29]. The patient- provider alliance was found to be influenced by the correspondence of the therapist's explanation of treatment recommendations with the patients' existing beliefs [27]. The explanations and recommendations given by therapists were found to be influenced by their beliefs on pain and the cause of their patient's pain [4 27 28]. When the explanation given made sense to the patient in relation to all their previous experiences and beliefs, the patients' belief could be changed, which could have contributed to their good outcome [27]. It is possible that the physiotherapists with a BPS attitude or CE attitude were more convincing in their communication towards the patient regarding the causes of the pain and treatment outcome than the therapists with a neutral attitude.
In the long-term the recovery in both the BPS and the BM groups differed from that in the neutral group. This might suggest that it is better to have a specific attitude than to be neutral. It might also be that the explanation of the neutral therapists corresponded less with the patients' beliefs. According to Daykin et al. [27] a limited explanation can leave many questions unanswered in the patient's mind and seldom convinces the patient of the harmlessness of the symptoms, which could be detrimental to the short-term and long-term recovery. However we have no information on correspondence between the patients' beliefs and the physiotherapists' beliefs, therefore any possible causality remains unclear.

This study showed that the physiotherapists' influence on the patients' treatment outcome should not be ignored. For future research it is recommended that the

physiotherapists' attitude towards the treatment that they are asked to perform is measured, for it could influence the outcome of the treatment. Further research is advised to gain more insight into possible causal links between the therapists' attitude and the patients' outcome, as this insight could have implications for education of therapists and daily practice

Limitations

Although it is an interesting finding that more patients seem to recover when treated by physiotherapists with a BPS or BM attitude compared to a neutral attitude, one should be cautious in drawing strong conclusions from it. This is because only a small number of therapists performed the treatment in the attitude categories (i.e. 8 BPS, 13 BM and 6 neutral). Generalisation of the results to other physiotherapists is therefore not obvious. However, the demographics and characteristics of the physiotherapists in this study are similar to those of Houben et al. [14] who examined a larger group of physiotherapists and found similar results, namely that the biopsychosocial factor influenced the advice given to the patients, and both the biomedical and biopsychosocial factor helped predict stated behavioural treatment intentions. Further research into the influence of therapists' attitude on the outcome in a larger population is recommended.

Conclusion

This study showed that the physiotherapists' attitude can influence the short-term and long-term recovery of complaints and function in chronic neck pain patients. Recovery of both complaints and functioning seemed to fare better when patients were treated by a physiotherapist with a BPS or BM attitude than when they were treated by a neutral therapist. Since the findings were based on a limited sample only, we recommend further examination of this phenomena in a larger study group.

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8

General Discussion

INTRODUCTION

Neck pain is one of the three most reported musculoskeletal complaints in the Netherlands [1 2]. The prevalence of neck pain increases with age, peaking in the middle years and declining in later life [3]. Neck pain can negatively affect the patient's quality of life, and may result in medical consumption, absenteeism and disability [2 4]. When no specific pathology is found the pain is labelled non-specific; when it lasts more than 3 months it is defined as chronic [5]. Patients who suffer from non-specific neck pain are often treated with exercise-oriented physiotherapy. At the start of this study cognitive behavioural and operant therapy had already shown promising results in chronic pain populations [6 7 8]. Further, behavioural graded activity, which is based on cognitive behavioural therapy, was found to be more effective in reducing the number of sick days, improving the level of daily activities and reducing disability in patients with back pain compared to usual care by a physician [9 10]. However, it was still unknown whether BGA is effective in chronic neck pain patients.

The overall aim of this thesis was therefore to examine the effectiveness of behavioural graded activity (BGA) for chronic neck pain patients compared to conventional exercise (CE), i.e. usual care. A secondary aim was to identify prognostic factors for poor recovery and to examine whether the physiotherapist's attitude can influence the treatment outcome.

In this chapter the findings of this thesis are summarised, discussed and possible implications for daily practise and future research are given.

Main findings of this thesis:

- Our review showed that evidence on the effectiveness of many commonly used conservative treatments for neck pain is inconclusive. Manipulation and/or mobilization when used in combination with exercises seems the most promising option (chapter 2).
- We found no difference in effectiveness between BGA activity and CE for patients with chronic neck pain (chapter 3). In both treatment groups the proportion of recovered patients remained between 40 and 50% during the 12-month follow-up period.
- Different prognostic factors were found for poor recovery of complaints and for poor daily functioning in patients with chronic neck pain. Identified prognostic factors for the short-term persistence of complaints were more severe pain at baseline and little responsibility for pain self-management. For the long-term persistence, lower quality of life, lower self-efficacy on functioning, more severe complaints, age lower than 46 years, and having exercised before the baseline measurement were prognostic factors. For the short-tem poor daily functioning factors found were lower activity levels and the presence of arm or hand pain at baseline. For the long-tem, prognostic factors were little responsibility for pain self-management, age lower than 46 years, and lower self-efficacy on functioning (chapter 5).
- No difference in the attitude towards neck pain and its treatment was found at baseline between therapists who applied different forms of therapy. At follow up, after receiving behavioural graded activity training, the BGA therapist scored significantly lower on the biomedical factor compared to baseline. Further, they scored significantly higher on the biopsychosocial factor and lower on the biomedical factor compared to CE therapists at follow-up (chapter 6).
- The physiotherapists' attitude influences both the short-term and the long-term outcome in patients after treatment. Recovery of both complaints and functioning seemed to fare better when treated by a physiotherapist with either a biopsychosocial or biomedical attitude than by a physiotherapist with a neutral attitude (chapter 7).

EVALUATING THE RESULTS

Although promising results for behavioural graded activity had been found for back pain, in our trial no significant difference in effectiveness was found between BGA and CE in patients with chronic neck pain. However, some beneficial effects

of BGA were found for the secondary outcomes catastrophizing and self-efficacy. In chapter 4 some possible explanations for our results were presented. In this section we further discuss factors that could have influenced our results.

Delivery of treatment

Was the number of BGA treatment sessions sufficient?

For both the BGA and the CE a maximum of 18 sessions of 30 minutes was advised. At the start of the study, this was in accordance with the medical insurance policy in the Netherlands (chapter 3). Further, according to the supervisors of the BGA training, this number of treatments was needed to accomplish change in behaviour and to complete all the treatment phases of BGA. However, in both treatment groups the mean number of treatment sessions was lower: 6.6 in BGA and 11.2 in CE. The lower number of treatment sessions in BGA compared to CE was unexpected and raises the question of whether a sufficient number of treatment sessions was given. The baseline phase of BGA requires approximately 3 sessions, meaning that on average only 3 to 4 sessions were available for the treatment phase and generalization phase. No direct relationship between the number of sessions given and treatment outcome can be found in the literature. Effectiveness of brief, moderate and extensive behavioural interventions varies between studies [11] [12] [9] [10] [13] . These studies vary in their complaints examined, therapies compared and outcome measured, therefore no conclusion can be drawn from them concerning the minimal number of BGA sessions needed. It has been suggested that reduction of fear, as aimed at in BGA, will only provide an increase of function when patients receive the opportunity to challenge their personal fears in a behavioural experiment [14]. It is possible that the number of BGA sessions in our study was not sufficient for patients to challenge their fears and experience new behaviour, which could improve self-management of their complaints.
On the other hand in several registration forms the physiotherapist remarked that the BGA principles were understood and that the patient was able to continue the exercises at home. If this is the case than perhaps only a few sessions are needed to experience that it is safe to move and to continue practising without supervision at home. This is supported by the continuing increase, albeit small, in recovery after treatment at 9 weeks in the BGA group. Further, a similar percentage of patients who were recovered was achieved in both treatment groups. The BGA group, however, needed fewer treatment sessions to achieve this percentage of recovered patients. Future studies should focus on the minimal number of treatment sessions which are necessary to change behaviour.

Was the contrast between treatments sufficient?

Since both treatments examined were exercise-based and within the field of physiotherapy, the contrast between them was an important issue. To optimise the contrast between the two treatments, the BGA and CE were provided by different physiotherapists and both groups of physiotherapists were strictly separated throughout the study. In the trial, therapists chose to give the treatment they preferred and thereafter participated in either a BGA training or a consensus meeting. We assumed that choosing the treatment would lead to a better compliance with the treatment and as a result would guarantee the contrast between treatment groups. We believe that we took all necessary steps to ensure a good implementation, but was it enough?

Although most of the BGA patients underwent the different treatment phases in accordance with the protocol (chapter 4), some protocol deviation also occurred. Based on evidence of treatment delivery it is apparent that some therapists did relapse into biomedical behaviour with some patients. Even though active exercise was used with most patients some had also received guided and/or passive exercise; respectively 22.7% and 11.6%. (Guided exercise given as reassurance at the start of the exercise is not seen as protocol deviation in BGA. However, guided exercise used as a separate technique as well as passive exercise are seen as biomedical approaches and therefore deemed to be protocol deviations). Both techniques were also used in CE and therefore could have diminished the contrast between treatments. However in CE these passive techniques were used in half of the patients and in BGA in less than a quarter of the patients, and then always combined with active exercise. Further, in CE most patients were given massage, and 44% to 57% of the patients were given traction techniques and mobilisation techniques, which increased the contrast between treatments. Based on this information, we believe that there was sufficient contrast in techniques applied in BGA and CE.

However, contrast between the treatments was determined not only by the techniques used but also by the behaviour of the therapists. It has been suggested that for the physiotherapists the biggest change in giving behavioural treatment is their expected role [15]. Interpreting the patients' experience of pain and their pain behaviour is difficult, especially when the physiotherapists are used to explaining pain according to a biomedical model. Coaching patients in changing their behaviour demands patience, perseverance and good communication skills of the physiotherapist [15]. Other studies suggest that a two day behavioural training for the physiotherapists could be too short for a discernible impact on patient

treatment outcome [13 16 17]. In chapter 6 we measured the attitude of therapists to gain some insight into their possible behaviour. We found no difference in baseline attitude between the therapists, but at follow-up the BGA therapists were more biopsychosocial and less biomedical than the CE therapists. However, further examination of the physiotherapists' attitude in chapter 7 showed that more physiotherapists in BGA showed an attitude that was not in accordance to the applied therapy (10 out of 16) compared to CE (3 out of 11). This supports the idea that the contrast between treatments could have been diminished by the BGA therapists being more biomedically oriented.
The attitude of the therapist could also have been influenced by the physiotherapy guidelines. No guidelines for neck pain exist, but the guidelines for back pain and whiplash both stimulate behavioural principles. This could have influenced the CE treatment to be more biopsychosocial. However, based on the relatively low number of physiotherapists with a biopsychosocial attitude applying CE, and the fact that the new guidelines were published at the end of the trial period in 2005, we don't think this is likely to have happened.

To summarize, the contrast between BGA and CE was not as large as we had hoped for, because of protocol deviation and attitudes of physiotherapists that were not in accordance with the applied therapy. In theory, a larger contrast could have led to a difference in effectiveness between treatments. However, since this was a pragmatic trial the results are likely to be in accordance with outcomes in daily practise

Were the psychological factors in the BGA pain-model applicable to neck pain patients?

The aim of BGA is to improve functioning and healthy behaviour despite pain and the central idea is that pain behaviour should be the focus of the treatment [14]. In BGA a fear-avoidance model is used to explain and discuss the patients' pain beliefs and how these beliefs influence recovery [18] (chapter 3). In short, the model postulates opposing behavioural responses, confrontation and avoidance, and presents possible pathways by which injured patients get caught in the downward spiral of increasing avoidance, disability and pain [19]. The theory states that avoidance of movements or activities results in the persistence or recurrence of chronic musculoskeletal pain and disability [18 19]. Catastrophic thinking is considered a potential precursor of pain-related fear and was found to be important in predicting pain and disability [19 20]. It is explained to patients that avoidance, although seeming to solve the pain problem at the time, might in the long run increase pain and disability [19]. In the treatment phase of BGA patients exercise according to

a time-contingent schedule which provides them with the experience needed to increase self-efficacy for adaptive coping [21].
In our study where the baseline scores on both fear-avoidance and catastrophic thinking were already relatively low (chapter 4) a decrease in fear-avoidance behaviour and catastrophizing, and therefore an increased level of function, is less likely to occur. This may imply that the participants of BGA were not particularly suitable for this kind of treatment.

Another possibility is that fear-avoidance and catastrophizing are less important in chronic neck pain patients than in back pain patients. This is supported by our finding in chapter 5, that these factors were only univariately associated with poor recovery, suggesting that other variables are more important in the persistence of chronic neck complaints. Moreover, in the general population, low scores on some psychological factors in neck pain patients were also found. This suggests that chronic neck pain represents a distinct group among musculoskeletal syndromes in which psychosocial factors could be less important in neck pain than in some other regional pain syndromes [22]. This is further supported by two reviews [3 23]. However, fear avoidance was found to be associated with the level of activity in acute whiplash patients and with function and pain in sub-acute neck pain, as well as being an important factor for identifying patients who are at risk of developing chronic neck pain [24 25 26]. It therefore seems that the influence of fear avoidance and catastrophizing can be different depending on the stages of pain and on the outcome measured [27 28]. It might be that the pain model used in BGA better suits acute and sub- acute neck pain patients than chronic neck pain patients. In our study however, fear avoidance and catastrophizing decreased in both treatment groups but showed a larger decrease in the BGA group at 9 weeks compared to the CE group (chapter 4).

Patients

Recruitment

It is important to control the process of recruiting patients because errors can lead to selection bias. In our study patients were recruited after consulting their general practitioner for chronic neck pain, and defined as incident cases. During the study, in 2004, the Dutch medical insurance policy changed, meaning that physiotherapy was only covered if patients had additional insurance. As a result the volume of physiotherapy treatment in 2004 was 6.1% lower than in 2003 [29]. In our research we also found a decrease in the number of patients recruited per

month. To improve our recruitment rate we added some (18) prevalent cases to our population (chapter 3). Because they were equally distributed over both the BGA and CE group they did not disturb the internal validity of the study (chapter 4). Furthermore, the majority of our patients (87%) were incident cases recruited by a GP and therefore reasonably represent the population of patients who in actual practice are referred to physiotherapy for their neck complaints.
The number of patients needed to be able to find a significant difference of 20% between treatments was calculated to be 160. Unfortunately, even with the addition of the prevalent cases we did not meet this number of patients. Considering the marginal differences in effectiveness between the treatments, it seems unlikely that there would be any drastic change in results with the inclusion of an additional 21 patients.

Were the patients therapy-resistant?

Treatment effectiveness can be influenced by patient's resistance to treatment. In our study patients had a high mean duration of complaints at baseline and exercising before baseline was found to be a predictor for poor recovery. This leads to the possibility that the population that enrolled in this study consisted of patients with rather therapy-resistant complaints. This idea is further supported by the fact that our study population consisted mostly of middle-aged patients, who have been found to have the poorest prognosis for neck pain [3 22].

Another factor that might influence patients' resistance to treatment, at least in BGA, is whether patients are ready to adopt pain self-management. Little responsibility for pain self-management may detrimentally affect outcomes and patients who remain focussed on medical management benefit less from physical and cognitive-behavioural therapies than patients who are at least partly convinced that managing pain is their responsibility [30 31]. Our results in chapter 5 support this, finding that little responsibility for pain self-management was a prognostic factor for short-term persistence of complaints and long-term poor functioning. To gain more insight, we examined, for each treatment, the influence of readiness to adopt pain self-management with descriptive statistics. In both treatments approximately half of the patients reported little responsibility for pain self-management. Of these patients the majority did not recover in either treatment group (60 to 70%).
However, it might be possible to change patients' readiness to adopt pain self-management. It has been suggested that more effort should be put into preparing the patient for behavioural therapy [14], and the advised techniques are similar to those

used in the baseline phase of BGA. We therefore subsequently examined whether patients' readiness to adopt pain self-management changed during treatment. We found that 35.7% of CE patients and 60.1% of BGA patients with little responsibility for pain self-management at baseline were strongly responsible after treatment at 9 weeks follow-up. This supports the idea that BGA might be more effective in changing patients' readiness to adopt pain self-management. Whether this change in readiness also influences patients' responsiveness to treatment needs further investigation.

Patients' compliance with the treatment is also a factor that can influence responsiveness to treatment. There is very little in the literature on patients' compliance with physiotherapy exercise and with the advice given by the therapist [32]. In our study, the patients of both BGA and CE reported having exercised at 4 weeks and 9 weeks follow up; respectively 87.9% and 76.8% in CE and 98.1% and 95.7% in BGA. Furthermore, at 9 weeks follow up, 43% of the CE patients and 50% of BGA patients reported that they were able to follow the advice given by the physiotherapist. Therefore we believe that most patients were compliant with the treatment exercise, but had more difficulties in following the advice given by the physiotherapist. This inability to follow advice cannot be explained with our data but could affect patients' responsiveness to treatment. Moreover, we believe that both failure to comply and inability to follow advice could be barriers for implementation of exercise treatments and should be further examined.

Physiotherapists' attitude

As mentioned before, the attitude of the physiotherapist can influence the contrast of the treatments. In chapter 7 we examined whether it can influence patients' outcome, and found that patients who were treated by a physiotherapist with either a biomedical attitude or a biopsychosocial attitude had higher probability of recovery. We can only speculate about reasons for this result; perhaps physiotherapists who have a clear attitude are more likely to give patients a credible explanation for the pain problem and the treatment rationale. Earlier studies showed that the credibility of treatment and the patient's understanding of its rationale are important factors for treatment outcome [7 33]. Even though the groups of therapists in our study were small the results imply that the relationship between the therapist and patient is very important.

A possible limitation is our method of categorizing the attitude. In chapter 6 we did this by dividing both the biomedical factor and the biopsychosocial factor of the PABS-PT into tertiles before combining them into an attitude score, resulting

in five different categories. This choice was made in consultation with the developers of the PABS-PT in order to ensure a strong contrast between physiotherapists with a biomedical attitude and those with a biopsychosocial attitude. In chapter 7, however, we combined the biomedical factor and the biopsychosocial factor into an attitude score by dividing at the median rather than into tertiles. This was chosen to optimize the statistical power since a tertile division would result in an insufficient number of patients in each cell, thus rendering further examination impossible. Had we had a larger sample size we would have used the tertiles for categorizing the attitude which might have led to different results.

PROGNOSTIC FACTORS

Knowledge of prognostic factors is important for it can help identifying patients who are at risk for poor treatment outcome. We therefore examined which baseline variables could be prognostic factors for poor outcome (chapter 5). Other studies also have examined prognostic factors but they are mostly based on patients with heterogeneous stages of complaints (acute, sub-acute or chronic). The influence of factors can vary at different stages of pain [28]. Therefore we examined the prognostic factors in a more homogeneous group of chronic neck pain patients. The factors found can in practice help physiotherapists with identifying the subgroups with a higher risk of persistent complaints or persistent poor functioning.
A potential limitation of our prognostic model was that treatment allocation did not resemble daily practice because the study population was randomised for the purpose of the trial. However, because of the recruitment process and the selection criteria used we are confident that the patients that participated in this study reasonably represent the patient population who in actual practice are referred to physiotherapy for their neck complaints. Further, as argued by Schellingerhout et al. [34], the advantage of using a RCT for this type of analysis is that it offers the possibility to introduce treatment as a covariate in the model, without the risk of biased results due to confounding by indication. However, for use the prognostic models found in other populations external validation is advised.

OUTCOME MEASUREMENT

In the development of this study we carefully considered our choice of primary and secondary outcome measures. The trial had to be close to real practice and the chosen outcomes had to be appropriate to the treatments examined.

Primary outcome

The primary outcome 'general perceived recovery' (GPE) is an often-used measure for treatment outcome in musculoskeletal pain. We decided to use it as our primary outcome because it is assumed to cover overall improvement, instead of only one aspect of the complaint (e.g. pain). Further, from both the patients' and clinicians' viewpoint it is seen as relevant and sensible to ask the patients to assess their perceived benefit [35]. We chose to add a second primary outcome measure 'general perceived recovery of daily functioning' because it was believed to be a more appropriate outcome measurement for BGA. This is because BGA is not aimed at recovery of complaints but at improving patients' daily functioning despite their pain. We therefore also expected to find larger improvements in daily functioning in BGA compared to CE. This, however, was not confirmed by our results (chapter 4).

In our study the primary outcomes are used slightly differently from earlier studies. Patients were asked to compare their recovery with the previous measurement instead of comparing it with baseline. Based on these scores we then calculated the cumulative recovery in which patients could remain recovered; however, they could also relapse into the not recovered category. By calculating this cumulative recovery, the scores could then be interpreted as recovery compared to baseline. We chose this method because it better corresponds to the recurrent or fluctuating patterns often seen in long-term pain conditions [36]. Further, recovery compared to a previous measure was assumed to be less sensitive to recall bias than recovery compared to baseline measure, which meets one of the criticisms given of the GPE [37].

Secondary outcomes

The secondary outcomes were also chosen based on their relevance to the treatments. Here we encountered a problem because the examined treatments have different treatment aims and treatment approaches. In CE, treatment is aimed at curing the complaint using a pain-contingent approach, whereas in BGA treatment is aimed at improving patients' daily functioning despite the pain using a time-contingent approach. To measure the outcome of CE, biomedical measurements were needed (i.e. pain severity, impediment because of pain). These measurements could interfere with the BGA treatment because they ask the patient to focus on the pain, which is contrary to the treatment approach of BGA. Therefore they might in theory negatively influence the outcome in BGA. However, patients were asked about their pain only once (at 4 weeks) during the treatment process

and once at the endpoint of treatment (9 weeks), so the effect of interference is considered to be small.

Minimal important change

The results of our study are influenced by our choice on what improvement is considered to be relevant. Like other studies before, we dichotomized the GPE into 'recovered' (completely recovered/much improved) versus 'not recovered' (slightly improved, not changed, slightly worsened, much worsened, and worse than ever) [35 38-40]. This dividing point was chosen based on the suggestion that this point reflects the concept of clinically important change and that patients are likely to give 'slightly improved' as a socially desirable answer even if a relevant improvement is not perceived [35 41 42 43]. However, other authors consider slightly improved to be a minimal important improvement [44 37 45]. Even though we still believe that the risk of socially desirable answers is larger with the dividing point 'slightly improved', we question whether the gap between 'slightly improved' and 'much improved' may be too large for chronic pain patients. Other studies have already indicated that the difference between 'no change' and 'slightly improved' is small and the difference between 'slightly' and 'much' improved is larger [43 42].
Further, a recent study that used GPE as an anchor showed that for 'much improved' chronic pain patients needed a larger change than patients with acute pain [41]. Could this imply that for a similar improvement in pain, the chronic pain patients are less likely to rate themselves as 'much improved'? The finding of de Vet et al. [41] implies that GPE might be less sensitive to change in chronic pain patients. Perhaps 'moderately improved' should be added to bridge the gap between 'slightly improved' and 'much improved' and to make the questionnaire more sensitive to change for chronic pain patients. The finding of de Vet et al. however, could also mean that chronic pain patients need improvements to be larger to be considered clinically relevant. For patients with more severe pain at baseline this has been confirmed; these patients needed a greater absolute change in pain to obtain clinically significant relief [46 41]. As de Vet et al. mentioned, remarkably little research has focussed on the importance of change [41]. We, the researchers and clinicians, set the dividing line of minimal important change; however it is unknown what amount of change is important to patients. Further studies, including qualitative studies, could be useful in examining how large an improvement needs to be for it to be relevant for patients.

Fluctuating pain pattern could influence outcomes

Chronic pain patients often show pain that has a fluctuating nature, with severity of pain alternating between high and low [36]. This fluctuating pattern can affect the treatment outcome as is shown in a study in patients with hip osteoarthritis [47]. Rozendaal et al. found a stable level of pain at group level, but a substantial fluctuation in the individuals pain levels over a two-year period. This individual variation was characterized by a large standard deviation on the pain scores at group level. Rozendaal et al. [47] suggest that due to this fluctuating nature of complaints, baseline and follow-up measures could have given completely different results if the study had started at a different time point. In our study the standard deviations at baseline were only large for impediment by the complaint. In the follow-up scores however they were larger for pain severity, severity of main complaints and impediment. This could indicate that individual variations were also present in our study. Since we did not have a control group that received no treatment at all, it is not possible to say whether this individual variation is caused by the responsiveness of patients to the treatment or whether it is caused by the common fluctuating nature of chronic pain.

IMPLICATIONS FOR PRACTICE

As of 2006, patients who suffer from neck pain can visit the physiotherapist directly without visiting their general practitioner first. This might have consequences for the makeup of the population with acute problems that visit the physiotherapist. Perhaps the patients who would benefit from the 'wait and see' policy of general practitioners [48], might now go to a physiotherapist immediately. However, we think that it will not change the makeup of the population with chronic neck pain, because we assume that they would have been referred to physiotherapy in any case.

- We suggest that no exercise treatment (BGA or CE) should be recommended over the other based on the patients' recovery of both complaints and function. If the secondary outcomes catastrophizing and pain self-efficacy are a treatment aim then BGA is slightly more beneficial than CE. However, still half of the all patients did not improve. Perhaps more intensive approaches might be needed for persistent chronic neck pain.
- Patients' readiness for pain self-management can influence outcome. Little responsibility for pain self-management was found to predict poor outcome. Physiotherapists should be aware of this during treatment. It might be beneficial to put more effort into preparing these patients for pain self-management

before or at the start of treatment. Techniques such as those advised in the baseline phase of BGA might be helpful for this.

- Fear-avoidance and catastrophizing could be less important in chronic neck pain compared to in back pain. Further, the importance of these factors may change depending on the stage of pain the patient is in. Physiotherapists should therefore be cautious when applying treatments that have shown effectiveness in acute or sub-acute neck pain to chronic pain patients, and likewise when appropriating other musculoskeletal pain treatments for neck complaints.
- Patients compliance with treatment can influence treatment outcome. It is therefore advisable to discuss barriers to compliance with the patients throughout the treatment, especially when treatment involves exercising at home. Further, barriers to following the advice given should also be discussed. Insight into these barriers can help in finding solutions to improve compliance.
- To identify chronic neck pain patients who are at risk for poor outcome, the following prognostic factors may be helpful: for the short-term persistence of complaints, severe pain at baseline and little responsibility for pain self-management; for the long-term persistence of complaints, lower quality of life, lower self-efficacy on functioning, more severe complaints, age lower than 46 years, and having exercised before the baseline; for the short-tem poor daily functioning, lower activity levels and the presence of arm or hand pain; for the long-tem poor functioning, little responsibility for pain self-management, age lower than 46 years, and lower self-efficacy on functioning.
- Physiotherapists should be aware of the influence of their own attitude on the patients' treatment outcome. They should be aware that any conflict between their attitude and the treatment they give could have an adverse affect on patients treatment outcome.

IMPLICATIONS FOR FUTURE RESEARCH

- In this study we examined the effectiveness of BGA compared to CE. When we want to know *why* a treatment works, we should examine how factors that are associated with treatment influence the treatment outcome. It could be examined whether the factors are moderators of the outcome or mediators of the effect. This might increase insight into which aspects of treatment work for whom, which could help improve the development of effective treatments.
- The minimal number of BGA sessions needed to change patients behaviour is still unknown. Future study should focus on the question of whether a minimal number of sessions is needed to give patients the opportunity to challenge their

personal fears in treatment sessions or whether it is enough when patients understand the principles of BGA and can practise further at home.

- Little responsibility for pain self-management was found as a prognostic factor for poor outcome. It seems possible to change patients' responsibility for pain self-management better with BGA than with CE. Future research could further test this observation, as well as examining whether more responsibility for pain self-management also leads to better treatment outcome.
- In the pain model of BGA, fear avoidance and catastrophizing are important factors. For chronic neck pain patients, however, they seem to be less important, and therefore the pain model might be less applicable for these patients. Future research could examine whether BGA's applicability is different for the different pain stages.
- Patients' failure to comply with treatment and inability to follow the therapist's advice could be barriers for the implementation of exercise treatment. Barriers to compliance and following advice are unknown and need to be examined.
- The prognostic factors found in this study were based only on chronic neck pain patients. Earlier research however mostly used heterogeneous groups of patients in different pain stages. It is advisable for future research to differentiate between the stages of pain when examining treatments, risk factors or prognostic factors, since the factors that are relevant might differ in the various pain stages.
- Researchers should be aware that the physiotherapist's attitude can influence patients' treatment outcome and therefore might interfere with the effectiveness of treatments examined. It is therefore advised to measure the therapist's attitude so that it can be examined as a confounder of treatment. In this trial we only had information on the physiotherapists' attitude and the patients' treatment outcome and not on the stages between the two. Future research could examine whether the physiotherapists' attitude influences their behaviour during treatment, whether this affects the patient-physiotherapist relationship and how this relationship affects the patients' attitude and behaviour. This could be done by, for example, monitoring actual behaviour during treatment.
- Further examination of the outcome measure GPE is advised for future research. Topics to be examined would include: (i) Whether cumulative recovery, in which recovery is compared to the previous measurement, is preferable to the standard use of GPE, in which it is compared to baseline; (ii) Whether recovery of complaints actually is an overall measurement, including pain, function etc. or only measures part of the problem; (iii) Whether the gap between 'slightly improved' and 'much improved' is too large and whether the inclusion of 'moderately improved' would increase the sensitivity of GPE in chronic pain patients;

(iv) As researchers and clinicians we choose the dividing point of minimal important change. However it is unknown what amount of change is important to patients. Further studies should examine how large an improvement needs to be (on a suitably extended GPE scale) for it to be relevant to patients, and whether the minimal important change on the GPE is different for patients in different stages of pain and with different severity of pain. Qualitative studies as well as quantitative ones would be useful in the examination of these topics.

- In this study we had no control group that had not received treatment at all. Therefore no insight could be achieved into the influence of the natural fluctuating pattern of pain on the treatment outcomes. It is therefore advisable for future research to add a control group without any treatment.
- Use of different outcome measures in other studies has led to differing results. It might be advisable, as a way of making studies more comparable, to assemble a standard set of instruments to be used in such studies in addition to any other outcome measures chosen.

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Summary

Neck pain is a common complaint that causes substantial morbidity in western countries and is one of the three most-reported musculoskeletal pains in the Netherlands. The prevalence of neck pain increases with age, peaking in the middle years and declining in later life. It is more often reported by women than men. In most cases no specific pathology can be found for the neck pain, and the pain is labelled as non-specific; when it lasts more than 3 months it is defined as chronic. There is a large variety of therapeutic interventions available for neck pain, such as 'wait and see', rest, medication (analgesics, NSAIDS), neck collars, physiotherapy (exercise , massage, physical therapy modalities), manual therapy, acupuncture and surgery. In the Netherlands, patients with non-specific neck pain are often treated with exercise-oriented physiotherapy.
Within physiotherapy, two treatment models are currently known. One is a traditional biomedical model, in which treatment is focussed on pain caused by physiological pathology, leading to a pain-contingent approach. The other is a biopsychosocial model, in which it is assumed that pain can persist long after the initial pathology has healed, and that psychological and social factors are important determinants in development and perpetuation of complaints. The biopsychosocial treatment 'behavioural graded activity' (BGA), using a time-contingent approach, has shown promising results in back pain but the effectiveness for neck pain is still unknown. Therefore, in this thesis the effectiveness of behavioural graded activity is compared to conventional exercise (CE) for chronic neck pain patients.

In **Chapter 2** we present an overview of the available evidence on the effectiveness and cost-effectiveness of conservative treatment for neck pain. Further we discuss the importance of 'evidence based medicine' within physiotherapy. We searched Pubmed, Embase and Cochrane for reviews on conservative treatment in non-specific neck pain, and Pubmed for evaluation of cost-effectiveness. RCTs that were published after publication of the reviews were also included. For inclusion in our study, one of the following outcomes was required: pain, overall improvement, satisfaction with treatment, function (e.g. neck-specific functional status), well-being (e.g. quality of life), disability (e.g. inability to perform activities of daily living, absenteeism) or adverse effects. The methodological quality assessment, data extraction and data analysis of the original systematic reviews were perused in this overview.
The overview of evidence showed that the effectiveness of many commonly used conservative treatments for neck pain is still unclear. However, for chronic neck pain manipulative therapy and/or mobilization in combination with exercise seems to have the most promising results. Additionally, manipulative therapy

would appear to be more cost-effective than physical therapy or standard medical care (as administered by the general practitioner).

Chapter 3 describes the detailed study protocol of the randomised trial that we performed to examine the effectiveness of BGA compared to CE in primary care patients with chronic non-specific neck pain. Eligible patients with chronic neck pain were randomly allocated to either the BGA or CE group. The Primary outcome measures were patient's global perceived recovery of complaint and recovery of daily functioning. Secondary outcomes include the patient's main complaints, pain intensity, medical consumption, functional status, quality of life, and psychological variables. Primary and secondary outcomes were measured at baseline and after 4, 9, 26 and 52 weeks.

Chapter 4 describes the short-term and long-term results of the randomised controlled trial (RCT) that we performed to asses the effectiveness of BGA compared to CE for chronic neck pain patients. We included 139 patients who were randomised to either the BGA or CE group.
At baseline, demographics and patient characteristics were well balanced between the two treatment groups. Mean age was 45.7 (SD 12.4) years and the median duration of complaints was 60 months. The mean number of treatments was 6.6 (SD 3.0) in BGA and 11.2 (SD 4.1) in CE. No significant differences between treatments were found in their effectiveness in managing chronic neck pain. In both the BGA and CE groups some patients reported recovery of daily function and from complaints, but the proportion of recovered patients did not exceed 50% during the 12-month follow-up period. Both groups showed clinically relevant improvements in physical secondary outcomes.

Similar to our findings, other studies also showed that many chronic neck pain patients still experience complaints one year after physiotherapy. In **chapter 5** we used the data of the RCT to identify prognostic factors for persistence of complaints and poor functioning post-treatment. Persistent complaints were defined as no recovery post-treatment according to the global perceived effect, and was assessed at short-term (9 weeks) and long-term (52 weeks) follow-up.
We found short-term persistence of complaints to be associated with more severe pain at baseline and little responsibility for pain self-management. Long-term persistence was associated with lower age, psychosocial variables and exercising before baseline. For poor functioning, short-term persistence was associated with lower activity levels, lower functional status and the presence of pain in the arm or hand. Long-term poor functioning was associated with little responsibility for

pain self-management, and a lower self-efficacy on functioning. The results show that different prognostic factors influence the short-term and long-term outcome. Further it is shown that different prognostic factors influence the outcome in persistent complaints and poor daily functioning.

Physiotherapists' treatment approach might influence their behaviour during practice and, consequently, patients' treatment outcome. However, an explicit description of the treatment approach is often missing in trials. The purpose of **chapter 6** was to evaluate whether the treatment approach (corresponding to the biomedical or biopsychosocial model) of therapists differed between therapists who chose to perform BGA, CE or manual therapy. Further we examined whether BGA training had any influence on the treatment approach. Forty-two therapists participated in this study. BGA therapists received a 2-day training and a half-day refresher. Treatment approach was measured at baseline and at 3-month follow-up.
At baseline, we found no significant differences between BGA, CE or manual therapists' use of biomedical or biopsychosocial approaches, but there was a trend for BGA therapists to score higher on the biopsychosocial approach. At follow-up, their biopsychosocial score remained higher and their biomedical score was lower compared to CE therapists. Corrected regression analysis showed a 4.4 points (95%CI -7.9, -0.8) greater decrease for therapists who followed the BGA training compared to therapists who did not. Our results indicate no significant differences in treatment approach at baseline and that BGA training might influence therapists' treatment approach by decreasing biomedical approach scores.

The physiotherapists' attitude is also the subject of **chapter 7**, where we examined whether the physiotherapists' attitude might influence patients' short-term and long-term treatment outcome; i.e. recovery of complaints and recovery of daily functioning. Insight into therapists' attitude and its impact seems fundamental in developing better ways of managing pain complaints, and could have implications for education of therapists and for daily practice. Twenty-seven physiotherapists and 111 patients were examined. Physiotherapists' attitude was measured as being either 'biopsychosocial' (BPS), 'biomedical'(BM) or 'neutral'.
We found a higher probability of recovery in patients who were treated by physiotherapists with a BPS or BM attitude compared to those treated by physiotherapists with a neutral attitude. This was found for both the short-term and long-term recovery of both complaints and daily functioning, with the sole exception of short-term recovery of complaints, where no significant difference was found between the BM and neutral groups. Our results indicate that the physiotherapists'

attitude can influence short-term and long-term treatment outcome in chronic neck pain patients. It would appear from our results that from a patient point of view, it is preferable to have a physiotherapist who has a specific attitude rather than a neutral one.

In **Chapter 8** the main findings of this thesis are summarised and discussed, and possible implications for daily practice and future research are given.

Samenvatting

Nekpijn is een veel voorkomende klacht die veel morbiditeit veroorzaakt in westerse landen. In Nederland is het een van de drie meest gerapporteerde klachten aan het bewegingsapparaat. De prevalentie van nekpijn neemt toe met de leeftijd, met een piek op middelbare leeftijd en een daling op hogere leeftijd. Het wordt vaker gerapporteerd door vrouwen dan door mannen. In de meeste gevallen kan er geen specifieke oorzaak gevonden worden en wordt de pijn als aspecifiek omschreven. Nekpijn die langer duurt dan 3 maanden wordt gedefinieerd als chronische nekpijn. Er zijn veel verschillende therapeutische interventies beschikbaar voor nekpijn, zoals 'afwachtend beleid', rust, medicatie (analgetica, NSAIDS), het dragen van een nekkraag, fysiotherapie (oefentherapie, massage, fysische applicaties), manuele therapie, acupunctuur en een operatie. In Nederland worden patiënten met nekklachten vaak behandeld met oefentherapie.
Binnen de fysiotherapie zijn er momenteel twee behandelmodellen bekend. Het eerste model is een traditioneel biomedisch model, waarbij de behandeling zich richt op de pijn die wordt veroorzaakt door fysiologische pathologie, ofwel er is sprake van een pijn-contingente aanpak. Het tweede model is een biopsychosociaal model, waarbij wordt aangenomen dat pijn kan blijven bestaan lang nadat de initiële pathologie is geheeld en dat psychologische en sociale factoren belangrijke determinanten zijn bij de ontwikkeling en het voortduren van klachten. De biopsychosociale behandeling 'gedragsgeoriënteerde graded activity', die een tijdscontingente aanpak heeft, had veelbelovende resultaten voor rugpijn, maar de effectiviteit voor nekpijn is nog niet bekend. In dit proefschrift wordt daarom onderzocht of er een verschil in effectiviteit is tussen gedragsgeoriënteerd graded activity (BGA) en oefentherapie (CE) voor patiënten met chronische nekpijn.

In **hoofdstuk 2** presenteren we een overzicht van het beschikbare bewijs over de effectiviteit en kosteffectiviteit van conservatieve behandeling van nekpijn. Tevens bespreken we het belang van 'evidence based medicine' voor fysiotherapie. We hebben een zoekactie naar reviews over conservatieve behandeling voor aspecifieke nekpijn uitgevoerd in Pubmed, Embase and Cochrane. Daarnaast hebben we hebben in Pubmed gezocht naar gerandomiseerde trials (RCT) die de kosteneffectiviteit evalueerde. De RCT's die zijn gepubliceerd na de publicatie van de reviews zijn ook geïncludeerd in deze studie. Voor inclusie in onze studie moest één van de volgende uitkomstmaten aanwezig zijn: pijn, algehele verbetering, tevredenheid met de behandeling, functioneren (bijv. nekspecifieke functionele status), welzijn (bijv. kwaliteit van leven), beperkingen (bijv. het onvermogen om dagelijkse activiteiten uit te voeren, afwezigheid op werk) of bijkomende verschijnselen. De evaluatie van de methodologische kwaliteit, de data extractie en de data-analyse is in dit overzicht overgenomen van de originele reviews.

Het overzicht laat zien dat er nog steeds onduidelijkheid is over de effectiviteit van veel van de gebruikte conservatieve behandelingen voor nekpijn. Voor chronische nekpijn worden de meest veelbelovende resultaten gevonden bij manipulatieve therapie en/of mobilisatietherapie in combinatie met oefentherapie. Tevens lijkt manipulatieve therapie meer kosteneffectief te zijn dan fysiotherapie of standaard medische zorg (zoals gegeven door een huisarts).

Hoofdstuk 3 beschrijft het gedetailleerde studie protocol van het gerandomiseerde onderzoek dat we hebben uitgevoerd om de effectiviteit van BGA in vergelijking met CE te onderzoeken voor eerstelijns patiënten met aspecifieke chronische nekpijn. Patiënten met chronische nekpijn die konden deelnemen werden gerandomiseerd naar ofwel de BGA- ofwel CE groep. De primaire uitkomstmaten waren het door de 'patiënt globaal waargenomen herstel van klachten' en het 'herstel van dagelijks functioneren'. Secundaire uitkomstmaten waren: de belangrijkste klacht van de patiënt, pijn intensiteit, medische consumptie, functionele status, kwaliteit van leven en psychologische variabelen. De primaire en secundaire uitkomsten werden gemeten bij aanvang en na 4, 9, 26 en 52 weken.

Hoofdstuk 4 beschrijft de korte- en lange termijn resultaten van de RCT die we hebben uitgevoerd om de effectiviteit van BGA ten opzichte van CE voor patiënten met chronische nekpijn te onderzoeken. Wij hebben 139 patiënten geïncludeerd die vervolgens werden gerandomiseerd naar ofwel de BGA- of de CE groep.
De demografische kenmerken en de patiëntkarakteristieken waren bij de baseline meting evenwichtig verdeeld tussen de twee behandelgroepen. De gemiddelde leeftijd was 45,7 (SD 12,4) jaar en de mediane duur van de klachten was 60 maanden. Het gemiddelde aantal behandelingen was 6.6 (SD 3.0) voor BGA en 11.2 (SD 4.1) voor CE. Er werden geen significante verschillen gevonden in effectiviteit van de behandelingen voor chronische nekpijn. Zowel in de BGA- als in de CE groep rapporteerde sommige patiënten herstel van klachten en herstel van dagelijks functioneren, maar de proportie herstelde patiënten kwam niet boven de 50% gedurende de follow-up periode van 12 maanden. Beide groepen toonden klinisch relevante verbeteringen in de fysieke secundaire uitkomsten.

Net zoals in onze studie, hebben andere studies ook aangetoond dat veel chronische nekpijn patiënten nog steeds klachten hebben een jaar na de fysiotherapeutische behandeling. In **hoofdstuk 5** hebben we de data van de RCT gebruikt om prognostische factoren voor het persisteren van klachten en het slecht functioneren na de behandeling te identificeren. Persisterende klachten werden omschreven als 'geen herstel na de behandeling' volgens de uitkomstmaat 'patiënt globaal

waargenomen herstel' en is onderzocht op korte termijn (9 weken) en op lange termijn (52 weken) .
Op korte termijn waren de persisterende klachten geassocieerd met ernstigere pijn op baseline en weinig verantwoordelijkheid voor pijn zelfmanagement. Langdurig aanhoudende klachten waren geassocieerd met een lagere leeftijd, psychosociale variabelen en het doen van oefeningen vóór de baselinemeting. Voor de uitkomstmaat 'slecht functioneren' was korte termijn persistentie geassocieerd met een lager activiteiten niveau, lagere functionele status en de aanwezigheid van pijn in de arm of hand. Persistentie van slecht functioneren op de lange termijn was geassocieerd met weinig verantwoordelijkheid voor pijn zelfmanagement, en een lagere self-efficacy voor functioneren. Deze resultaten laten zien dat de prognostische factoren op de korte- en lange termijn van elkaar verschillen. Verder is aangetoond dat de persistentie van klachten door andere prognostische factoren wordt beïnvloed dan de persistentie van slecht functioneren.

De attitude van fysiotherapeuten, ten aanzien van behandeling van nekklachten, kan invloed hebben op hun gedrag tijdens de behandeling en kan daardoor invloed hebben op de behandeluitkomst van de patiënt. Toch wordt er in trials vaak geen expliciete beschrijving gegeven van de attitude van fysiotherapeuten. Het doel van **hoofdstuk 6** was te onderzoeken of de attitude (corresponderend met het biomedische of biopsychosociale model) verschilt tussen therapeuten die kozen voor de behandeling BGA, CE of manuele therapie. Daarnaast hebben we onderzocht of een BGA-training deze attitude kan beïnvloeden. Tweeënveertig therapeuten namen deel aan de studie. De BGA therapeuten ontvingen een training van 2 dagen en een herhalingscursus van een halve dag. De attitude werd op baseline en na 3 maanden follow-up gemeten.
Op baseline vonden we geen significante verschillen tussen de BGA, CE en manuele therapeuten in het gebruik van ofwel een biomedische ofwel biopsychosociale attitude. Er was echter wel een trend aanwezig waarin BGA therapeuten hoger scoorde op de biopsychosociale attitude. Bij de follow-up meting was hun biopsychosociale score nog steeds hoger dan die van de CE therapeuten en tevens was hun biomedische score lager dan die van de CE therapeuten. In de gecorrigeerde regressie analyse was een verlaging van de biomedische score te zien die 4.4 punten (95%CI -7.9, -0.8) groter was voor de therapeuten die een BGA training hadden gehad in vergelijking met de therapeuten die de training niet hadden ontvangen. Onze resultaten tonen geen significante verschillen in attitude aan tussen de therapeuten op baseline maar ook dat een BGA training invloed kan hebben op verlaging van de biomedische attitude.

De attitude van de fysiotherapeuten is ook het onderwerp van **hoofdstuk 7**. We onderzochten of de attitude van de fysiotherapeuten het behandelresultaat van de patiënt kan beïnvloeden, dat wil zeggen het korte en lange termijn herstel van klachten en het herstel van dagelijks functioneren. Inzicht in de attitude van therapeuten en de invloed daarvan op het herstel bij de patiënt, lijkt fundamenteel bij het ontwikkelen van beter pijn management. Dit inzicht kan gevolgen hebben voor het onderwijs van therapeuten en voor de dagelijkse praktijkvoering.
Zevenentwintig fysiotherapeuten en 111 patiënten werden onderzocht. De attitude van de fysiotherapeuten werd ofwel gemeten als een 'biopsychosociale' (BPS), 'biomedische' (BM) of als 'neutrale' attitude.
We vonden een hogere waarschijnlijkheid op herstel in patiënten die werden behandeld door een fysiotherapeut met een BPS of een BM attitude in vergelijking met patiënten die werden behandeld door een fysiotherapeut met een neutrale attitude. Dit werd zowel op korte- als lange termijn gevonden en zowel in het herstel in klachten als ook in het herstel van het dagelijks functioneren. De enige uitzondering hierop was het verschil tussen de BM en neutrale groep, waarbij op korte termijn geen verschil in herstel van klachten werd gevonden. Onze resultaten tonen aan dat de attitude van de fysiotherapeuten invloed kan hebben op de korte- en lange termijn behandelresultaten van patiënten met chronische nekpijn. Vanuit het oogpunt van de patiënt, lijkt een behandeling door een fysiotherapeut met een specifieke attitude in plaats van een neutrale attitude de voorkeur te hebben.

In **hoofdstuk 8** worden de centrale bevindingen van dit proefschrift samengevat en bediscussieerd en tevens worden mogelijke implicaties voor de dagelijkse praktijk en voor toekomstig onderzoek beschreven.

Dankwoord

Jeeh, hij is af! Vele vrij uurtjes zijn er in gaan zitten en het was niet altijd eenvoudig om mijn werk te combineren met het afronden van het proefschrift, maar het is gelukt! Veel mensen hebben me tijdens mijn onderzoek en later bij het schrijven van dit proefschrift geholpen. Ik wil dan ook iedereen die een bijdrage heeft geleverd bedanken. Natuurlijk wil ik hier ook nog graag enkele mensen specifiek noemen.

Als eerste wil ik alle patiënten bedanken die een jaar lang hebben meegedaan aan dit onderzoek. Ook de huisartsen die hebben geholpen bij de inclusie van de patiënten en de fysiotherapeuten die enthousiast een jaar lang de therapie verzorgden, bedankt voor jullie inzet en bijdrage aan het slagen van dit onderzoek.

Beste Bart, dank je wel voor je enthousiaste en prettige manier van begeleiden, daardoor kwam ik altijd weer vol enthousiasme en met nieuwe energie bij onze bespreking vandaan. Je adviezen op mijn conceptartikelen werden altijd voorafgegaan door een compliment wat motiverend werkte. Ook je relatieverende kijk op commentaren van reviewers werkte erg prettig. Al met al wil ik je dus bedanken voor de fijne samenwerking, je geduld en voor alles wat je me geleerd hebt.

Arianne, bedankt voor de begeleiding bij het onderzoek. Een bondig artikel schrijven is niet gemakkelijk, maar door je aanwijzingen en je talent voor schrappen heb je me geleerd dat een artikel niet af is als je niets meer kan toevoegen, maar juist als je niets meer kan weghalen.

Marlies, jij mag natuurlijk niet ontbreken! Heel erg bedankt voor al je inzet, je nauwkeurigheid en je enthousiasme als onderzoeksassistente. We hebben samen de leuke en de minder leuke dingen van onderzoek doen meegemaakt en we zijn er steeds vol voor gegaan. Dank je wel voor de fijne samenwerking en voor de gezellige gesprekken.

Jos Twisk, heel erg bedankt voor je hulp bij de statistische analyses van mijn onderzoek. Dank je wel voor je heldere uitleg, je tijd, je snelle reacties op mijn mails met vragen en tevens voor je spoedcursus longitudinale analyse, je enthousiasme daarbij werkt aanstekelijk!

Jan Pool, onze eerste kennismaking vergeet ik niet snel: we zouden elkaar bij Eindhoven in de trein ontmoeten voor een afspraak in Maastricht. Net na het verlaten van het station hoorde we ineens een enorm kabaal en dook iedereen het gangpad in. Kabelbreuk! Maastricht hebben we niet meer gehaald, maar we hadden wel

genoeg tijd om kennis te maken. Dank je wel voor onze inhoudelijke discussies, je positieve instelling, de gezelligheid bij onze afspraken en voor het feit dat je altijd tijd voor me vrij maakte ook al had je zelf ook veel dat je bezighield.

Mario Geilen en Albére Köke, jullie wil ik bedanken voor het opleiden van de 'graded activity' fysiotherapeuten, voor jullie bijdrage aan het onderzoek en bij het design artikel.

René, bedankt voor je interesse en je hulp bij alle personele en financiële zaken!

De afdeling huisartsgeneeskunde heb ik als een leerzame en gezellige afdeling ervaren, hiervoor wil ik alle collega's en oud collega's bedanken. Een aantal collega's wil ik speciaal nog noemen: Esther R., Petra, Rebekka, Esther K, Max, Pim, Janneke, Anita, Celinde en Pepijn. Bedankt voor alle leuke herinneringen, zoals o.a. de tennisavonden afgesloten met eten en deelname aan de Roparun.

Elske, Wilbert en de afdeling Medische Besliskunde van het LUMC, jullie wil ik bedanken voor de mogelijkheid om mijn werk flexibel in te delen zodat ik dit proefschrift kon afronden. Ook wil ik mijn collega's van het LUMC bedanken voor hun interesse en goede tips voor de laatste loodjes van mijn promotie.

Ingrid, van leuke Winnock collega ben je uitgegroeid tot vriendin. We hebben al twee werkgevers gedeeld en ik vind het gezellig dat we nu eindelijk directe collega's zijn. Dank je wel voor je steun, het lezen van stukken, en de gezellige theeafspraken met worteltjestaart.

Cathy, dank je wel voor je steun, interesse en voor onze gezellige etentjes waar we het altijd weer presteerde om als laatste in het restaurant over te blijven

Lieve vrienden, dank je wel voor jullie begrip dat ik niet altijd veel tijd voor jullie had vanwege het werken aan het proefschrift. Maar daarnaast natuurlijk ook erg bedankt voor jullie steun, alle gezelligheid, de goede gesprekken en het plezier dat we samen hebben.

Alle vrienden van musicalgroep 'Rits' en theaterzanggroep 'Prestige', bedankt voor jullie interesse en voor alle leuke herinneringen aan producties en zangvoorstellingen. Het zingen geeft een goede balans tussen creatief en wetenschappelijk bezig zijn.

Lieve Rianne, al heel snel nadat we collega's werden zijn we goede vriendinnen geworden. Niet alleen in het onderzoek hebben we veel gedeeld en leuke herinneringen opgebouwd, maar ook daarbuiten. Ik ben dan ook erg blij dat we nu ook dit traject samen mogen afronden. Met jou als paranimf naast me kan het toch bijna niet anders dan goed gaan.

Andy, dank je wel voor je interesse, goede discussies en steun. Kleine Roan, iedere keer dat ik je zie moet ik lachen en is alle stress vergeten.

Lieve Hielke, dank je wel voor alles! Bedankt dat je altijd voor de volle honderd procent meeleeft met alles, voor onze zussendagen en voor de leuke gesprekken bij een glas wijn. Ik kan me geen betere zus bedenken en ik ben dan ook heel erg blij dat je als paranimf naast me staat op deze bijzondere dag.

Lieve paps en mams, het is teveel om op te noemen waar ik jullie allemaal voor wil bedanken. Bedankt voor jullie steun, enthousiasme, voor de humor die we delen en alle gesprekken die we voeren. Ik heb het erg getroffen met ouders zoals jullie. Dank je wel dat jullie er altijd voor me zijn.

Dear Richard, you have brought music into my life in more than one way. Thank you for everything we share, the fun, the thoughts, the music and thanks for always being there for me. Thank you for changing my Dunglish into proper English in my articles and thesis. Life is fun with you and I hope we will share many more 'next ten minutes' with each other.

Over de auteur

Curriculum Vitae

PhD Portfolio

Curriculum Vitae

Frieke Vonk is op 10 juli 1972 geboren in Oss. Na het behalen van haar HAVO diploma aan het Vincent van Gogh College te Oss begon zij in 1998/90 aan de studie docent lichamelijke opvoeding aan de Christelijke Academie Lichamelijke opvoeding te Zwolle. In 1994 studeerde zij af als 1e graad docent en startte in datzelfde jaar aan de studie Bewegingswetenschappen aan de Rijksuniversiteit in Groningen. Tijdens haar afstudeerproject onderzocht zij de effectiviteit van hartrevalidatie op het bevorderen van sportief actief gedrag ter preventie van een secundair infarct. In december 1997 studeerde zij af in de richting revalidatie en gehandicapten zorg. Na haar afstuderen werkte zij als consulent Topsport voor het Olympisch Steunpunt Zwolle/Flevoland, als assistent in opleiding bij het Noordelijk Centrum voor Gezondheidsvraagstukken en afd. Orthopedie van het AZG te Groningen en als bewegingsdeskundige bij re-integratiecentrum Winnock in Den Bosch.

In juli 2003 begon zij als junior onderzoeker bij de afdeling Huisartsgeneeskunde van het Erasmus Rotterdam. Zij deed een gerandomiseerd onderzoek naar de effectiviteit van twee fysiotherapie behandelingen, 'behavioural graded acitvity' versus oefentherapie (conventional exercise), waaruit de artikelen in dit proefschrift voortkwamen. Sinds 2006 is heeft zij het afronden van haar promotie gecombineerd met andere werkzaamheden, zoals statistisch onderzoeker bij het Centraal Bureau voor de Statistiek en projectmanager/ onderzoeker bij het Centre for Organisational Behaviour.

Sinds Juni 2009 werkt zij bij de afdeling Medische Besliskunde van het Leids Universitair Medisch Centrum aan twee methodologische projecten. Het eerste betreft een validatie onderzoek naar de 'Well-being valuation method', een methode om de kosten voor het verlenen van mantelzorg te bepalen. In het tweede project onderzoekt zij of een verschil in perspectief en framing bij waardering van gezondheid het marginale nut beïnvloedt.

PhD Portfolio

Name PhD student: Frieke Vonk — Promotor: Prof.dr. B.W. Koes
Erasmus MC Department: General Practice — Copromotor: Dr. A.P. Verhagen
PhD period: 2003-2010

Courses	Year	Workload
Post graduate epidemiology	2005-2007	60 ECTS
EMGO Institute for Health and Care Research, Biomedical English Writing and Communication,	2004	40 hours
Conferences/ Presentations		
Annual Conference of the Royal Dutch Society for Physiotherapy (KNGF)	2004	20 hours
EMGO Institute for Health and Care Research,	2005	20 hours
Annual Dutch Symposium of Epidemiology (WEON), Poster presentation	2004	16 hours
Annual Conference of the Royal Dutch Society for Physiotherapy (KNGF), Poster presentation	2004	16 hours
International Conference		
11th World Congress on Pain, IASP Australia, Poster	2005	16 hours
Teaching activities		
Supervising students physiotherapy	2005	80 hours

Appendix

Items van de ‘Pain Attitudes and Belief Scale for Physiotherapists’ (PABS-PT)

Items A zijn biopsychosociaal
Items B zijn biomedisch

		volledig mee **oneens**	in grote mate mee **oneens**	enigszins mee **oneens**	enigszins mee **eens**	in grote mate mee **eens**	volledig mee **eens**
A.	Psychische overbelasting leidt ook bij afwezigheid van weefselschade tot nekpijn	○	○	○	○	○	○
A.	De oorzaak van nekpijn is onbekend	○	○	○	○	○	○
B.	Pijn is het gevolg van weefselschade	○	○	○	○	○	○
A.	Bij een patiënt met veel nekpijn is het juist goed om fysieke oefeningen te doen	○	○	○	○	○	○
A.	Functionele beperkingen bij nekpijn zijn het gevolg van psychosociale factoren	○	○	○	○	○	○
B.	Patiënten met nekpijn kunnen beter alleen pijnvrije bewegingsfuncties oefenen	○	○	○	○	○	○
A.	Ondanks blijvende pijn kan een behandeling toch geslaagd zijn	○	○	○	○	○	○
B.	Nekpijn betekent dat er sprake is van organisch letsel	○	○	○	○	○	○
B.	Bij toename van nekpijn pas ik de fysieke oefeningen in mijn behandeling onmiddellijk aan	○	○	○	○	○	○
B.	Als de behandeling niet leidt tot een afname van nekpijn is er op termijn een groot risico op ernstige beperkingen	○	○	○	○	○	○
B.	Pijnvermindering is een voorwaarde om tot functieherstel te komen	○	○	○	○	○	○
B.	Toename van pijnklachten betekent dat sprake is van nieuwe weefselschade of uitbreiding hiervan	○	○	○	○	○	○
A.	Er bestaat geen effectieve behandeling die de nekpijn wegneemt	○	○	○	○	○	○

		volledig mee **oneens**	in grote mate mee **oneens**	enigszins mee **oneens**	enigszins mee **eens**	in grote mate mee **eens**	volledig mee **eens**
A.	Ook al is de pijn toegenomen, de patiënt kan toch fysieke oefeningen doen	O	O	O	O	O	O
B.	Als patiënten pijn aangeven tijdens oefenen en/of fysieke activiteiten maak ik mij zorgen dat er iets wordt beschadigd	O	O	O	O	O	O
B.	De ernst van de weefselschade bepaalt de hoeveelheid pijn	O	O	O	O	O	O
A.	Leren omgaan met stress bevordert het herstel van nekpijn	O	O	O	O	O	O
A.	In de behandeling moeten oefeningen die de nek belasten niet geschuwd worden	O	O	O	O	O	O
B.	Nekpijn patiënten lopen een groter risico om op den duur nekafwijkingen op te lopen	O	O	O	O	O	O