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Original article

Comparison of the effectiveness of a behavioural graded activity program and manual therapy in patients with sub-acute neck pain: Design of a randomized clinical trial

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Abstract

The objective is to present the design of a randomized clinical trial (RCT) on the effectiveness and cost effectiveness of a behavioural graded activity programme compared with manual therapy in patients with sub-acute neck pain. Sub-acute is defined as pain existing for 4–12 weeks. The behavioural graded activity programme is a time-contingent increase in activities from baseline towards pre-determined goals. Manual therapy consists mainly of specific spinal mobilization techniques and exercises. The primary outcomes are global perceived effect and functional status. Secondary outcomes are kinesiophobia, distress, coping, depression and somatization. The intensity and persistence of the pain and its interference with activities are also assessed. Direct and indirect costs are measured by means of cost diaries. Measurements take place at baseline and 6 and 12 weeks after randomization. To assess the long-term effect, measurements will also take place after 6 and 12 months.

Finally some challenges are discussed concerning the use of a behavioural graded activity programme, manual therapy and outcomes.

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1. Introduction

Neck pain is a common musculoskeletal disorder. The point prevalence for neck pain in the general population of The Netherlands varies between 9% and 22% (Borghouts et al., 1999; Picavet and Schouten, 2003), and approximately one-third of all adults will experience neck pain during the course of 1 year (Croft et al., 2001). Some 5–10% of the neck complaints will develop into a

chronic pain disorder (Borghouts et al., 1999). Once non-specific neck pain becomes chronic, defined as pain existing for more than 12 weeks, 44% of the patients consult their general practitioner (GP) annually (Borghouts et al., 1999). The main feature of neck pain is pain in the cervical region, often accompanied by restriction of the range of motion and functional limitations (Ariens et al., 1999). 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 neck pain (Bogduk and Barnsley, 2000). Consequently most cases are labelled as non-specific neck pain or neck pain of unknown origin (Bogduk and Barnsley, 2000). Risk factors for the occurrence of neck

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pain are physical load factors such as vibration, flexion of the neck, sitting posture and heavy lifting (Ariens et al., 1999), but psychological and social factors are also reported to aggravate and perpetuate neck pain (Ariens et al., 1999; Linton, 2000). Hence, neck pain is a bio-psychosocial problem, in line with the definition of pain formulated by the International Association for the Study of Pain (IASP, 1986).

High pain intensity and a previous history of neck pain is strongly and consistently associated with an unfavourable prognosis (Croft et al., 2001; Hoving et al., 2002). Although neck pain is often self-limiting within a few weeks of onset, 40% of the patients contact their GP; 30% are referred for further diagnosis to a medical specialist and 32% for physiotherapy, manual therapy (MT) or some other type of conservative therapy (Borghouts et al., 1999; Picavet and Schouten, 2003). The evidence regarding the effectiveness of these conservative therapies for neck pain is still inconclusive. A review performed by Aker et al. (1996) showed no benefit from stretching, laser therapy, traction, exercise or neck school for acute neck pain. Gross et al. (2002a, b) concluded that MT is effective for neck pain in the short term, if used in combination with types of other treatment (e.g. exercises). The updated Cochrane review of Gross et al. (2004) concluded that there was strong evidence for manipulation and/or mobilization when used in combination with exercises. Manipulation and/or mobilization alone were not beneficial. For chronic neck pain, randomized controlled trials (RCTs) have reported beneficial effects in favour of physical therapy, acupuncture and MT (van Tulder et al., 2000; Gross et al., 2002a, b). Bronfort (Bronfort et al., 2004) concluded that there was moderate evidence that spinal manipulative therapy and/or mobilization was superior to general practice medical care and physical therapy in the short term for improving physical function in patients with chronic neck pain. For patients with acute neck pain the evidence was inconclusive. Hoving (Hoving et al., 2001) concluded, after an extensive review of reviews, that there is no conclusive evidence for or against any of these treatments. However, recently published results of an RCT carried out by Hoving et al. (2002) in patients with sub-acute or chronic neck pain showed a significant difference in effectiveness in favour of MT, compared to both physiotherapy or usual care from the GP, both for short and long-term follow-up.

One of the shortcomings of a review seems to be the focus on the methodological quality of the trials. The quality of the trials is in most cases poor and there is hardly any focus on the content of the therapy used. If the definition of manipulation and/or mobilization is common, trials are included in the review without knowing if the used techniques are properly used, if there is a treatment protocol and if the techniques are

generally used in daily practice. Despite that MT seems to be an effective therapy.

Among some patients neck pain still becomes chronic. One possible explanation could be the role of psychological and social factors in the awareness of pain. During recent decades there has been an increasing interest in the psychological and social aspects of acute and chronic pain. In addition, psychological and social factors are believed to play a role in the transition from acute to chronic pain and disability (Gatchel, 1996; Linton, 2000). Consequently for patients with sub-acute and chronic pain the emphasis is increasingly focussed on behavioural treatment, based on operant, cognitive or respondent techniques (Turner and Keefe, 2000; Vlaeyen and Linton, 2000; Ostelo et al., 2000; van Tulder et al., 2000). Behavioural treatment focuses on reducing disability through the modification of environmental contingencies and cognitive processes.

Also a transition of a similar trend can be observed for sub-acute and chronic neck pain. Identification of the underlying specific pathology is no longer the primary focus. For this, several reasons are mentioned: (a) medical examinations fails to find specific underlying pathology in the majority of neck pain cases (Bogduk and Barnsley, 2000), (b) the degree of physical disability can be due to inactivity rather than a result of the physical condition (Köke and Thomassen, 2003), (c) the pain can depend on cognitive processes (Cioffi, 1991) and negative thoughts (Dolce et al., 1986), and (d) the patient's condition can depend on the degree of kinesiophobia (Kori et al., 1990). This model suggests possible pathways by which neck pain patients, similarly to low back pain patients or patients with other pain conditions, become enmeshed in a downward spiral of increasing avoidance, disability and pain. Specially in patients who interpret pain as threatening (pain catastrophizing) and exhibit kinesiophobia or fear of movement (Vlaeyen and Linton, 2000; Nederhand et al., 2004). In literature this model has been a topic for research, especially in low back pain patients but not in neck pain patients so far.

Although there are some promising results regarding the effect of cognitive behavioural therapy (CBT) on back pain, arthritis pain, cancer pain and mixed chronic pain (Turner and Keefe, 2000; Keefe, 2000), the effectiveness of CBT for neck pain in a primary care setting is still unknown.

Therefore, we hypothesize that the above mentioned factors are also involved in neck pain patients and we suggest that CBT is also a useful therapy for patients with sub-acute neck pain.

A CBT programme is based on the bio-psychosocial model, which means that not only the nociceptive structures are held responsible for the pain awareness of the patient. Pain can also be seen as an emotion

according to the International Association for the Study of Pain's (IASP) definition of pain. This can lead to a response in one of the following three response systems that characterize emotional experiences (Vlaeyen et al., 1995; Ostelo et al., 2000; Köke, 2002): (i) the *psycho-physiological* system such as feelings, increase muscle tension, etc.; (ii) the *cognitive* system, such as thoughts, catastrophizing, fear, etc.; and (iii) the *motor* system such as pain behaviour, disuse syndrome, etc (Linton and Ryberg, 2001).

Physical therapists are not trained to treat cognitive processes, so a full CBT program is not realistic. Pain behaviour, however, can be treated by PTs using a graded activity (behavioural graded activity, BGA) programme as incorporated in other trials (Lindstrom et al., 1992; Ostelo et al., 2000). The focus is on the motor system and the PT can use operant principles and can act as a coach (Lindstrom et al., 1992; Jensen et al., 1995).

The evidence of this BGA programme is still questionable; however, it is widely practiced in low back pain patients. Some studies are not positive (Ostelo et al., 2003; Steenstra, 2004) others are more promising in improving the level of physical activity at work compared to usual care (Staal, 2003). However, for neck pain patients the affect of a BGA programme is still unknown. In our opinion it is a challenge to assess the effectiveness of this programme in patients with sub-acute neck pain.

In summary, MT, a typical hands-on therapy is an effective therapy for neck pain. It is hypothesized that psychological and social aspects play an important role in the transition from sub-acute to chronic pain. BGA, a typical hands-off therapy, can influence pain behaviour and pain intensity by focussing on those aspects, and shows promising results in other pain conditions.

In order to assess the effects of BGA for neck pain we designed an RCT assessing the following hypothesis:

A BGA programme is more effective than MT in patients with sub-acute neck pain.

Secondly we will assess whether the severity of complaints influences.

The study protocol was approved by the Medical Ethics Committee of the VU University Medical Centre in Amsterdam.

2. Methods

2.1. Selection of patients

The participants in the study are patients with sub-acute non-specific neck pain, defined as pain in the cervical region existing for at least 4 weeks, but no longer than 12 weeks. The neck pain may radiate to the shoulder region or the upper extremities, or be

accompanied by headache, but the main complaint must concern the neck. The inclusion criteria are: non-specific neck pain, age between 18 and 70 years, and a new episode of pain (defined as no neck pain in the previous 4 months). The patients must not have had any therapy for neck complaints in the previous 4 months. The exclusion criteria are specific neck pain, for example due to rheumatoid arthritis, disc herniation, neurological diseases or malignancy. Patients with whiplash-associated disorders are included unless they have an unsettled insurance claim running during the intake period. During the first GP consultation these criteria are assessed and the patient is informed about the study. Eligible patients who are interested in participation are referred to the research assistant, who informs them further about the consequences of participation and re-checks the inclusion criteria. Patients who are eligible and agree to participate are asked to sign the informed consent form and the baseline measurement is performed.

2.2. Randomization procedure

After the baseline measurement the patients are randomly assigned either to the MT treatment or to the BGA programme. The treatment sessions take place in the private practices of the participating therapists. A colleague from the research department who is not involved in recruitment, treatment or data-collection, generated a random list based on a computer-generated sequence. The randomization was pre-stratified for severity of the complaints and age of the patient. Four strata are constructed with a cut-off point for age of 40 years and a cut-off point for severity of the main complaints of 7 on a 0–10 numerical rating scale. The treatment allocation is concealed, as numbered opaque sealed envelopes based on the computer generated list are used, and the research assistant who deals with the inclusion of the patients, is unaware of the content of the envelopes.

2.3. Blinding

The patients are aware of the treatment they receive, so it is not possible to blind them but the research assistant who is responsible for the baseline and the follow-up measurements will be blinded for the treatment allocation. Prior to the measurements, the patients are asked by the research assistant not to mention the treatment to which they were allocated. To evaluate the blinding procedure, at the end of the follow-up period the research assistant will record which treatment she thinks the patients received.

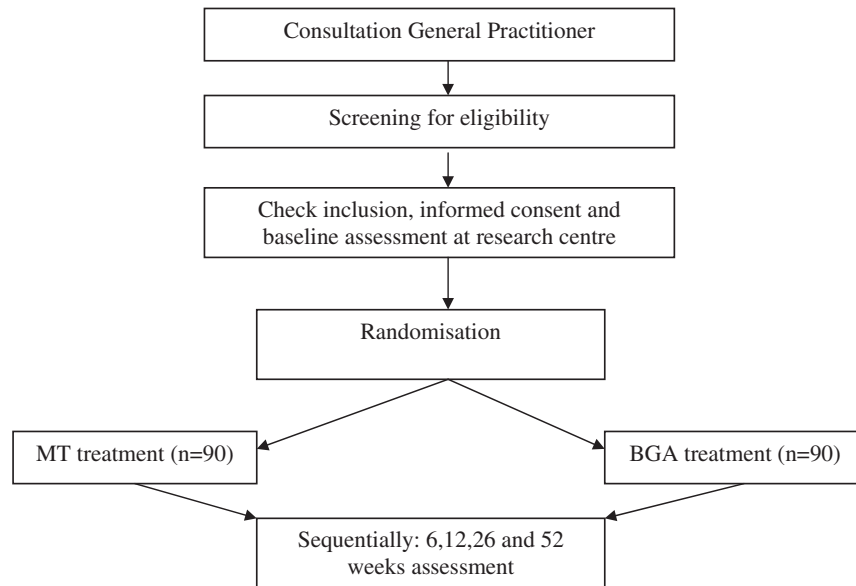


Fig. 1. The study design, patient flow. MT: manual therapy; BGA: Behavioural Graded Activity program.

2.4. Drop-outs

All efforts will be made to avoid drop-outs, such as extra telephone calls and/ or mails and if necessary a visit at the patient's home address.

2.5. Sample size

The study aims to include 90 patients per treatment arm. Although arbitrary this is based on the expectation that in the MT group 70% of the patients will recover (Hoving et al., 2002). To detect a difference of 20% between the two treatment groups, which is considered as clinically important, 84 patients are required for each treatment group. This calculation is based on the dichotomized primary outcome measure "perceived recovery", defined as the percentage of patients who are reported to have recovered. The sample size calculation concerns an α of 0.05 and a power $(1-\beta)$ of 90%. To compensate for drop-outs during follow up, we planned to include 90 patients per treatment group. To obtain the required sample size, patients will be recruited by 70 GPs (Fig. 1).

3. Description of the interventions

3.1. Manual therapy

In the Netherlands, MT is a specialization of physiotherapy. The manual therapists in this study followed 3-year post-graduate courses in manipulation and/or specific mobilization techniques to become

certified and registered by the Royal Dutch Society for Physical Therapy (KNGF) as a manual therapist.

The aim of MT is to recognize and interpret tissue and organ-specific dysfunctions on a local and segmental level. During the physical examination, the musculoskeletal system is examined, while accepting asymmetrical morphology and function and respecting the related individual preference of function. A biomechanical assessment is made to obtain detailed information about the relevant joints, muscles, and surrounding soft tissue. (Van der El and Wagemaker, 1993). The assessment of the cervical spine includes three-dimensional tests within or at the limit of the range of motion of the joints. The aim of the treatment is to restore restricted movement, stimulating natural recovery and adaptive processes in relation to the functionality of movement. Furthermore, the treatment also aims to reduce pain, to increase the patient's level of activities and participation, and to prevent recurrences (Van der El, Wagemaker, 1993; Baumgarten et al., 1996).

The treatment consists of manipulation and specific mobilization techniques. A manipulation is a passive movement of a joint beyond its active and passive limit of motion, but within the limit of its anatomical integrity. It is usually a localized thrust which is a quick movement of small amplitude led by the therapist. The aim of the manipulation is to regain motion, to restore function and to reduce pain.

A mobilization utilizes skilled low-grade passive movement with large amplitude. Passive mobilization can be repetitive or not, varying in amplitude. The aim of mobilization is to restore movement and to relieve pain. The specific technique that is chosen depends on the therapist, and is not yet a topic for research.

Table 1
The content of manual therapy treatment, assessed by manipulative therapist on a registration form (Hoving et al., 2002)

Manual therapy in neck pain patients ($n = 60$)	Median (IQR) ^a
Number of sessions	6 (5, 6)
Physical examination	6 (5, 6)
Muscle techniques	5 (3, 6)
Specific articular mobilisation techniques	6 (4, 6)
Frequently used:	
• Type: traction/translation, 2/3 dimensional specific techniques	
• Location: 2 ^e –3 ^e cervical segment, cervico-thoracic junction-thoracic spine and costo-vertebrale articulations (1st rib)	
Co-ordination and stabilisation techniques	3 (0, 4)
Instruction and exercises	4 (3, 6)

^aIQR (Inter Quartile Range of treatment sessions).

Similar to the Hoving trial (Hoving et al., 2002), MT did not include high velocity thrust techniques in the cervical region. This technique was excluded for ethical reasons because of reported complications of spinal manipulations, and especially vertebrobasilar complications (Assendelft et al., 1996). Despite this exclusion, the overall effect of the MT intervention was promising in favour of MT. Dutch manual therapists use knowledge, methods, and techniques considered unique to MT. In daily clinical practice, physical therapy and MT are often less distinct, because the same person, i.e., the physical therapist with a specialization in MT, provides both. So it is standard practice to use additional exercises and give advice as well in a MT treatment. These are patient tailored and the aim of the exercises is mobilization, stabilization and coordination. This is illustrated by Table 1 which shows the registered content of the MT in the Hoving trial (Hoving et al., 2002).

The content of MT in this trial will be the same as in the Hoving trial.

In summary, in the current RCT the MT intervention is similar to the intervention described in the Hoving trial, which consisted of MT techniques, exercises and advice, we will refer to this therapy as MT. The therapists are also asked to fill in a registration form after each session. The therapists are allowed to provide a maximum of six treatment sessions within 6 weeks. The duration of a single treatment session is 30–45 min.

3.2. Behavioural graded activity programme (BGA)

To emphasize the behavioural component, compared with physical training, the term BGA was introduced (Ostelo et al., 2000). In general, the focus of the treatment is on function and not on the underlying pathology or biological aspects of pain. Physiotherapists

are already trained to treat functional recovery in patients with all kinds of limitations, and they are properly equipped to conduct the intervention in the current trial after a special 2-day training. All PTs participating in this trial have had additional courses in biopsychosocial approach of pain problems. All PTs had more than 10 years of clinical experience. To solve all existing problems and to monitor the treatments, regular days of reflection are organized, furthermore registration forms are used to get insight in the treatments. The therapists' attitude is checked using a health care providers questionnaire, which was adapted for neck pain. (Ostelo et al., 2003; Houben et al., 2004).

The BGA programme, as applied in the present study, is based on time-contingent management, as described in more detail by Fordyce (Fordyce et al., 1973) and applied by Lindstrom and Ostelo (Lindstrom et al., 1992; Ostelo et al., 2000). The emphasis of the treatment in this trial is the operant strategy. Core elements of this programme are: (1) decrease in the pain behaviour and increase in "well" or "healthy" behaviour; (2) improving function and not the reduction of pain; (3) the patient is responsible for the treatment and has an active role; and (4) the therapist acts as a coach.

The BGA treatment can be divided into three phases which will be discussed separately.

3.3. Initial phase

The initial phase first concerns a reconceptualization of the patient's pain model. Central in this is the understanding that pain is not solely the result of underlying tissue damage, but is also influenced by the patient's expectations, beliefs, and fear, as well as activity levels and home and work environment. The patient is then taught that it is safe to move the cervical spine or other parts of the body. Subsequently, the three main complaints are formulated at baseline (Köke et al., 1999). A main complaint is defined as an activity that is very important to the patient, implying that improvement of these activities is highly desirable. During the initial phase the patient is asked to perform these activities until the pain becomes too dominant, in other words pain-contingent. The level, duration or frequency of activities, is registered on a performance chart. A baseline level is constructed, based on these performance charts, thereby determining the average level of each specific activity. From baseline level the patient has to set his/her own individual treatment goals. For example, the patient wants to be able to read his documents for 12 min during work (see example). Once the goal is determined, and knowing the baseline level, quotas are set in order to achieve this predetermined treatment goal within a predetermined time-span (time-contingent) (Fig. 2).

3.4. Treatment phase

Once the treatment phase starts, activities and exercises are no longer performed on a pain-contingent basis, but follow the predetermined quotas. Therefore the key element of the treatment phase is time-contingency, meaning that despite the pain or discomfort the quotas will be adhered to. Initial quotas are set in such a way that they are slightly below the baseline level, to ensure that the first treatment session will be a successful one (Vlaeyen et al., 1995; Kole-Snijders et al., 1999; Köke, 2002). During treatment, the therapist stimulates and encourages the patient and gives positive reinforcement if the quotas are achieved.

3.5. Generalization phase

The aim of this phase is to encourage the patients to proceed with their healthy behaviour during activities of daily living. It is not sufficient to train in a treatment

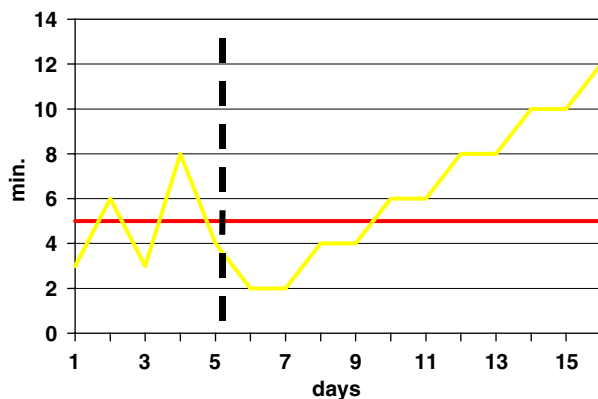


Fig. 2. Example of constructing a baseline measurement of a main complaint.

setting only, but one should also generalize the goals into working or home situations. In this phase the frequency of treatment sessions will be diminished and self-efficacy will be strongly encouraged.

The BGA treatment within the trial period will consist of a maximum of 18 sessions of approximately 30 min.

4. Measurements

The demographic variables as well as primary and secondary outcomes are measured at baseline. Table 2 gives an overview of the data collection.

4.1. Demographic variables

Demographic variables, such as age and gender, will be registered. Furthermore, disease characteristics such as history of the neck pain, possible cause of the complaint, duration of the complaint, irradiation to shoulder or extremity, accompanying headache, shoulder or back pain, will be assessed.

4.2. Primary outcome measurements

Global perceived effect (GPE) (Feinstein, 1987; Beurskens et al., 1996) is measured by self-assessment on a 7-point scale, 1 = completely recovered, 2 = much improved, 3 = little improvement, 4 = no change at all, 5 = slightly worse, 6 = much worse and 7 = worse than ever. The neck-specific functional status is measured according to the Neck Disability Index (Vernon and Mior, 1991). The Dutch translation was found to be a sufficient validly instrument (Heijmans et al., 2002).

Table 2
Overview of data collection

Instrument	Baseline	6 weeks	12 weeks	26 weeks	52 weeks
Inclusion/exclusion	X				
Demographic data	X				
<i>Primary outcome</i>					
Perceived recovery		X	X	X	X
Neck pain disability index (NDI)	X	X	X	X	X
<i>Secondary outcome</i>					
Tampa scale of Kinesiofobia (TSK)	X	X	X	X	X
Pain coping and cognition list (PCCL)	X	X	X	X	X
4 Dimensions of psychological symptomatology questionnaire (4DSQ)	X	X	X	X	X
Numerical rating scale for pain (NRS)	X	X	X	X	X
Patient specific questionnaire (PSQ)					
Graded chronic pain scale (GCPS)	X	X	X	X	X
Sort form 36 (SF-36)	X	X	X	X	X
EuroQol	X	X	X	X	X
Cost-diary		X	X	X	X

4.3. Secondary outcome measurements

These measurements will evaluate all domains of the psychological and social aspects of pain defined in the introduction. Fear of movement is measured according to the Tampa Scale for Kinesiophobia (TSK) (Kori et al., 1990). The Dutch translation of the TSK has a fair and consistent internal validity (Goubert et al., 2000). Pain catastrophizing, pain coping and pain control (external and internal control) is measured by means of the Pain Coping and Cognition List (PCCL) (Stomp-van der Berg et al., 2001). The 4 Dimensions of Psychological Symptomatology Questionnaire (4DSQ) measures factors such as distress, depression, fear and somatization as intermediate factors (Terluin, 1996, 1998). Within the Numeric Rating Scale (NRS) for pain, the patients score their average and maximum pain in the past week and current pain on an 11-point rating scale. The NRS is a valid and responsive scale (Rosier et al., 2002).

The Graded Chronic Pain Scale (GCPS) is designed to assess the intensity, interference with activities and persistence of pain. In the current trial it is used to assess neck pain. All items are either scored on a NRS scale or expressed in days (Von Korff et al., 1992; Von Korff, 2000). The Patient Specific Questionnaire (Beurskens et al., 1996; Beurskens et al., 1999; Köke et al., 1999) is used to score the three most important disabilities on an 11-point numerical rating scale (0 no disability-10 not able to perform this activity).

Health status is evaluated with the Short Form 36 (SF-36). The Dutch translation showed satisfactory validity and reproducibility (Aaronson et al., 1998). Quality of life is measured according to the Euroqol-5D (Feinstein, 1987; The EuroQol Group, 1990). Furthermore, the patients will record any costs due to their neck pain, visits to the therapists, absenteeism from work and use of medication, in a cost diary (Goossens et al., 2000).

5. Analysis

The baseline scores of the patient's demographic (e.g. age, gender, duration of complaints, history of complaints and trauma), primary and secondary outcomes will be used to compare the two intervention groups. Differences between baseline and follow-up measurements will be calculated, and compared between the two intervention groups. If necessary, adjustments for baseline variables will be made, using analysis of covariance. Considering the longitudinal context of the data and possible confounding on the level of the therapist a generalized linear mixed model will be used. The statistical analyses will be performed on the basis of the intention-to-treat principle, i.e. patients will be

analysed in the treatment group to which they were randomly allocated.

Missing data will be replaced by a linear interpolation method for missing measurements, and by a 'last measurement carried forward' method for drop-outs (Twisk and de Vente, 2002). Worse-case scenarios and best-case scenarios for patients with and without missing values for the end-point variables will be compared for the total study population and per treatment group.

6. Discussion

Publishing the design of a study before publishing the results is important for several reasons. Firstly, it yields an opportunity to reflect critically on the design, independently of the study outcomes. Secondly, if the design is published any deviations from the original design can be identified when the study results are published. Thirdly, it may counteract possible publication bias (Dickersin, 1990), because authors of future systematic reviews can identify the study even if its results are never published.

MT seems to be an effective treatment for patients with neck pain (recent reviews of literature). But the exact content of MT is not always clear. In The Netherlands MT consists of specific manual techniques, exercises and advice and is frequently used to treat patients with neck pain. This approach seems to be an effective treatment for these patients (Hoving et al., 2002). However, in a majority of patients with neck pain the complaints are persistent or have recurrences. Cognitive and behavioural factors seem to play an important role (Keefe, 2000). BGA focuses on these factors, but the evidence of the effectiveness of BGA is lacking. Therefore a randomized controlled design was designed to compare the effectiveness of BGA versus MT.

Challenges of this design are:

Treatment BGA: The BGA program used in this trial is an operant therapy based on the principles of the biopsychosocial model. Although physical therapist are skilled to treat patients with neck pain it is not self evident that they are able to provide a BGA program and change their attitude from a pain contingent approach to time contingent approach. To ensure that these principles are adequately used a 2-day training program is provided, supervised by an experienced behavioural therapist and a psychologist. This program consists of a theoretical part in which all the principles of a BGA program are discussed, and a practical part. Although it might be desirable to train PTs more extensively, we choose to train PTs according to the training courses that are normally provided in this approach. The advantage of this strategy is that if this trial provides evidence in favour of the BGA,

the results can easily be implemented. The use of the BGA program by the therapists is evaluated during the trial using a registration form.

Manual therapy: There is an ongoing discussion concerning the content of MT used in trials (Rothstein, 2002). The reaction of many readers of BMJ to the article describing the Hoving trial confirms this (Korthals-de Bos et al., 2003). In the Dutch situation MT is a combination of manipulative therapy, specific mobilization techniques, exercises and advice. In this trial the different components of MT will be described in detail, which will benefit the interpretation of the results.

Outcome measures: Patient satisfaction can be measured using different scales or questionnaires. We choose GPE as a primary outcome measure even though there are some concerns about the reliability and validity of global rating scales. Global ratings typically are correlated with the patient's present status and are not an unbiased measure of change (Norman et al., 1997). However, most authors regard global rating scales as clinically relevant and valid and responsive to measure patient's perceived recovery. From the patient's point of view this subjective scale is perhaps the most sensible method of assessment.

This study is designed as a RCT. The first challenge is to investigate whether BGA is more effective than MT, with focus on a comparison between a mainly hands-on approach, based on the bio-medical model, and a hands-off approach. The second challenge lies in the fact that the study population consists of patients with sub-acute neck pain. The behavioural approach has mainly been tested in chronic pain patients, in whom it is expected that psychological and social factors become more dominant over time. The turning point in pain behaviour, from more nociceptive dominance to more psychological and social dominance, is still unknown, although it is hypothesized that approximately 7–8 weeks after the onset the behavioural factors become dominant (Gatchel, 1996). So the question remains whether MT or a BGA program can prevent sub-acute pain patients from chronicity.

The results of this RCT may be of value for the clinician in choosing the right therapy strategy for each individual patient. Furthermore, this RCT can be used to update systematic reviews, and may contribute to the development of evidence-based clinical guidelines in this field.

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