The effectiveness of manual therapy, physiotherapy and treatment by the general practitioner for chronic non-specific back and neck complaints

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Introduction

Back and neck complaints occur frequently in western countries. It is estimated that some 80% of all people experience back problems during their active life (Nachemson 1976). Neck problems are less frequently reported, but are still a major health problem. In most cases no underlying pathology can be established and thus the causes of the complaints remain unknown (Nachemson 1975). The majority of patients with acute low back pain recover within a few weeks, often with the help of (bed)rest, analgesics and advice about posture and exercises (Nachemson 1979). Within a few months the complaints disappear in about 90% of the cases (Frymoyer 1988, Deyo 1983). When the complaints do not disappear, patients will often be referred to a physiotherapist for treatment with massage, exercises and physical therapy modalities (heat, electrotherapy, ultrasound, short wave etc.). Other patients are referred to a manual therapist for manipulative treatment. Despite the widespread use of physiotherapy for back and neck complaints its effectiveness has been rarely investigated in adequate randomized clinical trials (RCT). Recently an RCT was conducted in the Netherlands that tried to avoid these shortcomings. In this article we present the design of this trial. It focuses on the quantification of the effectiveness of manual therapy and physiotherapy for patients with chronic non-specific back and neck complaints. There have been a number of trials investigating the effectiveness of manipulation and mobilization of the spine for back and neck complaints. The interpretation of the results of these studies is often difficult for methodological reasons. Common problems are the small size of the study population, the criteria for selecting patients, the performance of the manipulative techniques, and the absence of blinded outcome measurements (Greenland et al. 1980, Brunarski 1984, Di Fabio 1986). Recently an RCT was conducted in the Netherlands that tried to avoid these shortcomings. In this article we present the design of this trial. It focuses on the quantification of the effectiveness of manual therapy and physiotherapy for patients with chronic non-specific back and neck complaints. Elsewhere in this volume the theoretical aspects of designing an RCT in this field are explained (Bouter et al. 1990). The results of our trial were not available at the time of writing, but during the presentation of our paper at the conference the first short term results will be discussed.

Selection of patients

Patients (n=300) with pain or self-reported limited range of motion in back or neck were selected actively by general practitioners participating in the study. In addition to this, repeated advertisements in the local press informed patients about the possibility to participate. Patients showing interest were referred to their general practitioner to check the admission criteria. Subsequently, one of the authors (A.E., physiotherapist and manual therapist) performed a physical examination and did a second check with respect to the selection criteria. The purpose of these criteria was to select a (relatively homogeneous) group of patients suitable for treatment with physiotherapy, manual therapy or further treatment by the general practitioner. Patients had to meet the following criteria:

- Complaints were non-specific. No underlying pathology had been established (e.g. malignity, osteoporosis, herniated disc).
- Duration of the complaints was six weeks or longer.
- No physiotherapy or manual therapy treatment for the back and neck complaints had been received during the previous two years.
- Complaints could be reproduced by active or passive physical examination.

The selection of patients started in March 1988 and lasted until December 1989.
Study design

Figure 1 shows the study design. When a patient meets the selection criteria and is willing to participate, the informed consent procedure will be completed. The patient signs a letter which explains all relevant information about the study including the 25% chance for receiving placebo treatment. The outcome of the anamnesis and physical examination are recorded, and the patient fills out certain questionnaires to complete the baseline measurements. After that, randomization per stratum takes place using a list of random numbers. To ensure blindness of the observer, the randomization procedure is carried out by a second research assistant. Prestratification by age (younger than 40 years, 40 years and older) and localization of the complaints (back, neck) is carried out to prevent unequal distributions by chance between the treatment groups. For practical reasons prestratification by residence (four regions) is also carried out. Depending on the outcome of the randomization the patient goes (back) to his or her general practitioner, to a physiotherapist or to a manual therapist in the patient's region.

Study treatments

In the study four treatments are included:

2. Physiotherapy: exercises, massage and physical therapy modalities (e.g. heat, electrotherapy, ultra sound, ultra short wave). Both the manual therapists and the physiotherapists participating in the study were selected by their professional organizations (NVMT and the Royal Dutch Society for Physiotherapy (KNGF). In contrast to the manual therapists, the physiotherapists chosen did not have any training in manipulative techniques.
3. Treatment by the general practitioner: medication, advice about posture, exercises, participation in sports, (bed)rest etc.
4. Placebo treatment: physical examination and simulated ultra short diathermy (10 minutes) and ultrasound (10 minutes) carried out by a physiotherapist. The treatment sessions have a frequency of twice a week for a period of six weeks.

All therapists (except the placebo therapists) are free to choose from their usual therapeutic domain within some explicitly formulated limits of the treatment to which the patient is assigned. All treatments are given for a maximum of three months. For ethical considerations patients return after six weeks to their general practitioner with a written report from the manual therapist or physiotherapist in order to discuss the results and to decide whether to continue, change or stop the treatment. The therapists register the content, frequency and duration of their therapies.

**Measures of effect**

Since the patients are suffering from back and neck complaints, measures recording pain and functional status have been selected (Bergner et al 1981, Kerns et al 1985). In addition, range of motion, physical functioning, patient satisfaction and opinion concerning efficacy and recurrence are measured. Figure 2 shows the operationalization of the most important outcome measures.

**Figure 2: outcome measures**

<table>
<thead>
<tr>
<th>Pain</th>
<th>West Haven-Yale Multidimensional Pain Inventory (WHYMPI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional status</td>
<td>Sickness Impact Profile (SIP)</td>
</tr>
<tr>
<td>Physical functioning</td>
<td>Physical examination by a research assistant (physiotherapist and manual therapist)</td>
</tr>
<tr>
<td>Range of motion</td>
<td>Inclinometer (EDI 320 - CYBEX) X-ray cinematography (cervical spine only)</td>
</tr>
<tr>
<td>Relapse</td>
<td>Physical examination and questionnaire</td>
</tr>
</tbody>
</table>

Pain, functional status and relapse are recorded by means of questionnaires completed by the patients themselves. Physical functioning and range of motion of the spine are measured by the (blinded) research assistant (A.E.). X-ray cinematography (cervical spine only) is carried out for a subgroup of the patients with neck complaints by assistants at the Department of Radiodiagnostics in the university hospital. Patients are blind with respect to the placebo treatment. Figure 3 shows the schedule of the data collection. The scoring of each patient on the sequential follow-up measurements will be compared with his or her score (including individual complaints) at baseline. The four study groups will be compared for the mean difference between the follow-up score at issue and the baseline score.
Figure 3: schedule data collection

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Baseline</th>
<th>3 wks</th>
<th>6 wks</th>
<th>3 mths</th>
<th>6 mths</th>
<th>1 yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information from GP</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Anamnesis</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range of motion, physical function</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>X-ray cinematography</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain (WHYMPI)</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Functional status (SIP)</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Psychologic status (HSCL)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compliance, satisfaction</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information from therapist</td>
<td>X</td>
<td></td>
<td></td>
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</tbody>
</table>

Prognostic information

Information on (other) prognostic variables is collected to assess whether the randomization has been successful and to make subgroup analyses feasible. The latter means that we will perform an exploratory analysis of the effect of treatment for specific subgroups (e.g. localization and duration of the complaints, gender and age). The following information will be obtained:
- history and current complaints (localization, severity etc.), demographic information, work and sport activities, to be obtained by the research assistant at baseline;
- ranges of motion of the spine (EDI 320) and occurrence en severity of pain and limited ROM during active and passive movements by physical examination;
- general health status as measured with the Hopkins Symptom Check List (HSCL) (Derogatis et al 1974);
- compliance and additional treatment (written questionnaire);
- treatment regimen, duration and frequency (collected by the therapists and general practitioners);

Data-management and analysis

After collection the data are stored on a personal computer. Control will be carried out on the inconsistent combinations of answers and the range of possible values. Subsequently, the data will be copied to a VAX 8650 computer for further analysis. The statistical analysis will be carried out according to the 'intention-to-treat' principle. This means that all patients remain in the group to which they were assigned by randomization. This includes drop-outs (insofar as they participated in the effect measurements) and patients with low compliance.

Discussion

There have been a number of trials on the effectiveness of manipulation and mobilization of the spine for back and neck complaints. However, these studies have been criticized for methodological reasons, as was mentioned in the introduction. This study intends to meet these shortcomings. First, the selection criteria were chosen to select a relatively homogeneous group of patients who are suitable for treatment with manual therapy, physiotherapy or (continued) treatment by the general practitioner. Second, the manipulative techniques used are performed by qualified manual therapists who were selected by their professional organization. Third, the outcome measures includes the assessment by a blinded observer. Fourth, the size of the study population seems
sufficiently large to detect treatment differences. Furthermore, for acceptance of the results we believe it to be crucial that physiotherapists and manual therapists are involved at all levels in the design and implementation of a trial like this. The physiotherapists and manual therapists participating in this study agreed fully with the research protocol. The choice of an appropriate placebo treatment in which the patients could trust and which has no specific effects, needed careful consideration. Placebo manipulation, exercises or massage, although desirable, did not appear to be practically feasible. Therefore, our choice became simulated ultrasound and ultrasound as the next best solution. Consequently, the study will focus mainly on the comparison of physiotherapy, manual therapy and (continued) treatment by the general practitioner. Patients who receive placebo treatment may provide an estimation of the effect of referral to a physiotherapist plus the placebo effects of physiotherapy. As was explained in the introduction, no results were available at the time of writing, but at the conference the first short term results of our trial will be presented.

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