

RANDOMIZED CLINICAL TRIAL OF CONSERVATIVE TREATMENT FOR PATIENTS WITH WHIPLASH-ASSOCIATED DISORDERS: CONSIDERATIONS FOR THE DESIGN AND DYNAMIC TREATMENT PROTOCOL

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Background: Whiplash concerns a considerable problem to health care. Available evidence from systematic reviews indicates beneficial effects of active interventions for patients with whiplash injury. In order to evaluate whether a general practitioner or a physiotherapist should provide these active interventions, we have designed a randomized clinical trial.

Objective: The purpose of this article is to present the design of the trial and to provide transparency into the dynamic treatment protocol used.

Patients: Patients with whiplash-associated disorders grade I and II who still have symptoms and disabilities 4 weeks after the accident.

Interventions: A dynamic treatment protocol consisting of 4 different subprotocols. The primary aim is to increase their activities and to improve their quality of life. Content and intensity of treatment are described.

Outcome Measures: The primary outcome measures are pain and disability. The short-term effects are measured at 12 weeks and long-term effects at 1 year after the trauma.

Conclusion: To date, generally the effect of one intervention compared to another intervention has been examined. In our opinion, this cannot be considered as usual care for physiotherapy or general practice. Therefore, a dynamic treatment protocol has been developed to structure the black box of usual physiotherapy and general practice treatment. The results of this trial will be available in 0.5 year. (*J Manipulative Physiol Ther* 2003;26:412-20)

Key Indexing Terms: *Conservative Treatment; Design; General Practice Care; Physiotherapy; Randomized Clinical Trial; Whiplash*

INTRODUCTION

Why publish only the design? Presenting the design at the start of the study provides transparency into the researchers' plan of work. For clinical practice, adequate information of the interventions

used is of the utmost importance, especially when health care providers are not very familiar with the type of treatment. Another advantage of publishing the design of a trial before the results are available is to prevent publication bias.

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There are indications that small clinical trials with negative results are not as easily published as positive trials¹ or will never be published at all. The primary aim of this article is to describe the design, including the theoretical background and the dynamic treatment protocol of our randomized clinical trial (RCT) of conservative treatment for patients with whiplash-associated disorders (WAD).

Theoretical Background

Available evidence. Whiplash has aroused interest for years and still constitutes a major public health problem. The annual incidence of whiplash injury varies in different parts of the world, with rates as high as 70 per 100,000 inhabitants in Quebec² and 94 to 188 per 100,000 inhabitants in the Netherlands.³ Evidence of efficacy for conservative treatment is sparse. We used the results of a systematic review, which assessed the efficacy of conservative treatments for patients with whiplash-associated disorders grade I or II,^{4,5} to select interventions worth studying. The reviewers cautiously concluded that active interventions, such as giving advice "to stay active" and "maintain usual activities," might be effective in acute patients with WAD and rest or immobilization using cervical collars might not.^{4,5} For acute patients with WAD grade I and II, the question remained as to which of the care providers is best able to perform these active treatment strategies and which active interventions are most effective. Table 1 describes the classification of WAD in grades.² The trial aims to determine whether or not there is a difference in effect between active treatment consisting of education and advice given by general practitioners (GPs) compared with education, advice, and active exercise therapy given by physiotherapists (PTs) for patients with WAD grade I and II. Results will be available within 0.5 year.

Biopsychosocial model. Historically, health care was mainly based on biomedical models, with pain as a signal of tissue damage and assumptions that serious tissue damage leads to high levels of pain and disability.⁶ Over the last decade, we have seen a change from a biomedical model toward a biopsychosocial model. In the biopsychosocial model, the patient is seen as a system integrating biological, psychological, and social dimensions.^{7,8} The model emphasizes the role of psychological and social factors in the development and persistence of signs, symptoms, and disabilities. One of the theoretical principles of our study is that acute whiplash trauma may be associated with minor soft tissue damage, which may lead to impairments in physical and mental functions and disabilities. No serious injuries are expected.⁹ In most of these patients, lesions in cervical muscles, ligaments, disks, vertebrae, or nerves cannot be identified, even when sophisticated imaging techniques are used.^{10,11} Because impairments related to whiplash rated WAD I and II share the same presumed etiology as nonspecific neck pain and low back pain,^{12,13} we assume that relations between impairments and disabilities are time-dependent. In acute

Table 1. The Quebec severity classification of whiplash-associated disorders²

Grade	Clinical presentation
0	No complaint about the neck No physical sign(s) only
1	Neck complaint of pain, stiffness, or tenderness No physical sign(s)
2 3 4	Neck complaint and musculoskeletal sign(s)* Neck complaint and neurologic sign(s)* Neck complaint and fracture or dislocation

Grades 1 and 2 indicate the scope of the RCT.

*Musculoskeletal signs include decreased range of motion and point tenderness.

Neurologic signs include decreased or absent deep tendon reflexes, weakness, and sensory deficits. Symptoms and disorders that can be manifested in all grades include deafness, dizziness, tinnitus, headache, memory loss, dysphagia, and temporomandibular pain.

patients, a direct relation between gradual improvement in physical functions and increasing level of activities after whiplash injury is expected. In chronic patients, there are no or only minor relations between improvements in physical or mental functions and activities, and pain will not decrease. In the latter, some psychosocial factors, such as inadequate coping, fear of movement, and job dissatisfaction, may be present and delay recovery, as in other pain conditions.^{14,15} Related to the time period since the accident, treatment should focus primarily on either physical impairments and activities or on psychosocial aspects and activities. Principles of the biopsychosocial model and knowledge of scientific evidence are used as the theoretical basis for the development of the study treatment protocols.

DISCUSSION

General Methodology

Flow chart of study design and human protection. Efficacy of active treatment consisting of education and advice (including advice based on graded activity) given by GPs in comparison with education, advice, and active exercise therapy (including graded activity) given by PTs for patients with WAD I and II is assessed in a randomized clinical trial. Figure 1 shows a flow chart of the study design. The study is approved by the Dutch Advisory Committee on Ethics in Human Experimentation of Nijmegen and Tiel.

Study population. Patients will be recruited from June 1999 to June 2002 by 122 GPs from urban practices and physicians from 3 Emergency Departments of Hospitals in the Middle and South of The Netherlands. The population of our study includes acute patients living in The Netherlands who present with WAD I or II as the result of a whiplash injury after a road traffic accident and who are aged between 18 and 55 years. In The Netherlands, patients with WAD I and II comprise the largest group of patients, and they are normally treated in primary care. To establish an inception cohort, patients with WAD who have symptoms such as

Table 2. Cut off points for functional recovery²

	Not functionally recovered	Functionally recovered*
VAS-pain	30-100	0-29
VAS-work	0-77	78-100
VAS-housekeeping	0-84	85-100
VAS-hobby/sport	0-65	66-100

VAS, Visual Analogue Scale.

*Functional recovery if pain scores are between 0-29 or at least 2 out of 3 activity scores are between the presented borders for functional recovery.

and sampling frame (general practice or emergency department). Block randomization is performed. After allocation, the patient is referred to either a GP or a PT, based on the randomization schedule.

Blinding. Given the nature of the interventions, it is hard to blind patients and care providers. However, the exact content of treatment is not predefined. This way, we may assume that patients are blinded to a certain extent. Outcome assessment is conducted by blinded observers (CWMNS, JCAMH, GGMSP) unaware of the treatment given. To ensure blinding, patients are repeatedly asked not to reveal any information regarding their treatment to the observers. Success of blinding of the observers is evaluated using standardized questionnaires. The blinded observers (CWMNS and GGMSP) will perform data analyses and will be controlled by an independent and blinded researcher (APV).

Interventions

Dynamic treatment protocol. Physiotherapists and general practitioners will both treat the patients according to a dynamic treatment protocol consisting of 4 different subprotocols (A, B, C, and D). Depending on the VAS-pain score and the VAS-activity score, the patient is allocated to protocol A, B, C, or D (Fig 2). Each protocol is characterized by a specific treatment strategy, which is based on consensus between researchers, GPs, and PTs. No strict cutoff points are used. For example, when the point of intersection of the 2 VASs is situated between A and B, the care provider may choose between protocol A and B. Indications for the number of sessions are given per protocol and range from a maximum of 2 times a week during the first 6 weeks to once in 2 months. No maximum or minimum number of sessions are prescribed. Duration of treatment sessions conforms to the Dutch National law and lasts approximately 30 minutes for PT and 10 minutes for GP care. Treatment starts at 4 weeks after the accident. The maximum duration of the intervention period is 9 months (conforming to the Dutch National law). Evaluation of the treatment is planned on fixed time periods. First evaluation is planned after 2 weeks, and if necessary, the protocol choice is reset. Thereafter, there will be an evaluation every 4 weeks. It is possible that a patient's

protocol changes in time. Treatment is terminated when the health problem is resolved or the treatment goals are reached. Treatment is also terminated when no further recovery is to be expected.

Starting points for PT and GP care are similar for all protocols. Protocols A and B start from an activity-related strategy that does not focus on pain. Protocol C starts with a pain-related strategy during the first 2 weeks, followed by an activity-related strategy focusing on increasing activities rather than on pain reduction. Protocol D also starts with a pain-related strategy during the first 2 weeks; patients are recommended to decrease their activities to relieve pain, followed by a graded activity strategy unrelated to pain. The primary aim for all protocols is to increase activities and to improve the quality of life. Only protocols C and D also aim to reduce pain during the first 2 weeks from the start of treatment. The rationale for it is the possible relationship between gradual improvement in physical functions (including pain) and an increasing level of activities. From 2 weeks (6 weeks after the accident), treatment in all protocols becomes focused on activities and psychosocial factors (coping with pain, fear of movement, self-efficacy, self-control) rather than on functions (including pain).

Care providers tailor treatment to the patient's needs by their choice of specific treatment goals within the protocols, and they select their appropriate interventions. Table 3 shows the main treatment goals and interventions for PTs and GPs. Specific information on the GP and PT interventions is described in the next 2 paragraphs.

GP treatment. GP intervention consists of education and advice, including advice on graded activity. The provided information depends on the main treatment goals, which are set in the protocols. Information about the nature of the injury, the absence of serious pathology, the importance of staying active and resuming activities as soon as possible, the expected prognosis, and the risk to develop chronic pain despite the expected benign natural course of whiplash is recommended to be provided to the patient during the first 2 weeks. For example, it is explained to patients that withdrawal from normal activities because of neck pain (within protocols A and C in the first week of treatment) or failure to move the neck might lead to postural impairments with chronic complaints (within protocols A, C, and D in the first week of treatment).^{8,21} Also, dealing with litigation,²² using a soft collar, and relying on medication rather than on activity^{5,21,23} may delay recovery and is discouraged in all protocols. Ergonomic advice about work positioning and pillow size can be given. GPs will encourage patients to increase activities, especially those kinds of activities that the patient tends to avoid within protocols A, C, and D. Activity levels are increased on a time-dependent (and not symptom-dependent) basis, using the graded activity principles.^{24,25} Patients will not perform activities at the GP practice. GPs primarily have a constructive and stimulating role in the graded activity program. To discuss the patient's

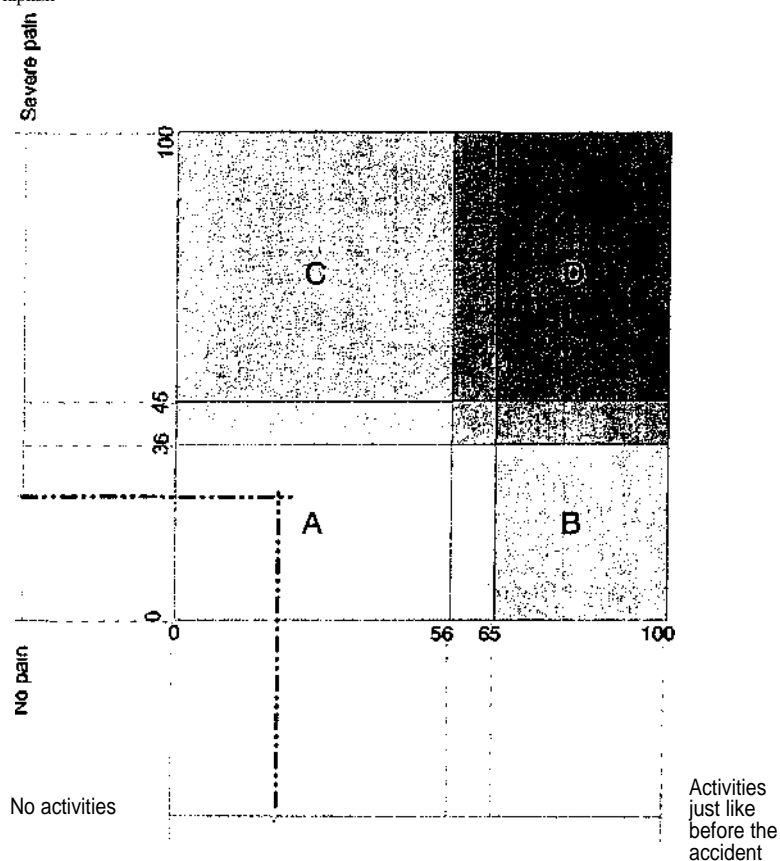


Fig Z. Protocol allocation by VAS scores for pain and activities.

progress and enhance his/her motivation, the patients will document performance charts.

FT treatment. PT intervention consists of education, advice, graded activity, and exercise therapy. Content of education, advice, and general starting points of the graded activity program are similar to GP treatment and are related to the main treatment goals that are set. In contrast with GP treatment, the graded activity program is not only performed at home but also at the PT practice. Activity levels are increased and immediately trained at the PT practice. Direct positive reinforcement is provided to enhance the patient's motivation. Performance charts are documented at home and at the PTs practice. Exercise therapy includes a broad scale of progressive loading exercises for cervical and shoulder muscle functions (stabilization, coordination, strength, endurance, length), articular functions (range of motion), and posture and balance (within all protocols in first 2 weeks; exercises in protocols C and D are performed within the pain limitations). Functional activities such as carrying, lifting, pushing, throwing a ball, and cycling may also be trained (protocols A and C in the first 2 weeks).

Contrast GP and PT treatment. Contrast between 2 intervention groups (GP versus PT) is created by the profession of the care provider (GP versus PT), duration of treatment session

(10 minutes versus 30 minutes), and intervention possibilities (education, advice, and advice on graded activity by GP versus education, advice, graded activity, and exercise therapy by PT).

Black box. Detailed information of treatment is recorded on standardized "care provider" forms to gain insight into the "black box" of treatment goals, allocated interventions, cointerventions, protocol choices, compliance, treatment period, total number of treatment sessions, and reasons for terminating treatment. During the intervention period, the use of cointerventions, such as medication, manual therapy, or medical examinations (computed tomography [CT] scan, magnetic resonance imaging [MRI]) is discouraged. Patients record details on "patient forms" to check allocated interventions, cointerventions, adverse effects, treatment period, and compliance until 1 year after trauma. Forms are recorded weekly (first 4 weeks of treatment), twice a month (4 to 12 weeks), and monthly (> 12 weeks).

Outcome measurements. Baseline measurement is performed at 4 weeks after the accident at the start of treatment (T1). To prevent information bias, accident-related prognostic factors are measured at 2 weeks after the collision (T0). Prognostic factors are chosen with reference to the literature.^{26,28} Our primary outcome measures are pain and activities in

Table 3. Main treatment goals and interventions for PT and GP in protocols A, B, C, and D

Week	Protocol	Main treatment goals	PT treatment	GP treatment
1-2	A	Explaining the natural course of whiplash, absence of pathology, and importance of staying active Improving functions: stability, range of motion, balance, coordination, posture Increasing activities	Education Exercises, advice Functional exercises, advice	Education Advice Advice
1-2	B	Explaining the natural course of whiplash and absence of pathology Improving functions: stability, range of motion, balance, coordination, strength, endurance Increasing activities	Education Exercises, advice Advice	Education Advice Advice
1-2	C	Reducing pain Explaining the natural course of whiplash, absence of pathology, and importance of staying active Improving functions: stability, active range of motion, coordination, posture Decreasing fear of movement Adapting activities	Advice, exercises Education Exercises, advice	Advice Education Advice
1-2	D	Reducing pain Explaining the natural course of whiplash and absence of pathology Improving functions: stability, active range of motion, coordination, posture Decreasing activities	Advice, exercises Education Exercises, advice	Advice Education Advice
3-end	A	Increasing activities Decreasing fear of movement	Functional exercises, advice, graded activity Graded activity	Advice, graded activity Graded activity
3-end	B	Increasing activities	Graded activity	Advice
3-5	C	Improving functions: stability, range of motion, balance, posture, coordination Decreasing fear of movement Improving active coping, decreasing distorted ways of thinking about pain, and self-control Increasing activities	Exercises, advice Education, advice, graded activity Education, advice, graded activity	Advice Advice Education, advice, graded activity
3-5	D	Improving functions: stability, range of motion, balance, posture, coordination, strength, endurance Decreasing distorted ways of thinking about pain and improving self-control Adapting activities	Exercises, advice Education, advice Advice, graded activity	Advice to perform home exercises Education, advice Advice, graded activity
6-10	C	Decreasing fear of movement Improving active coping, self-control and self-efficacy of pain, decreasing distorted ways of thinking about pain Increasing activities	Graded activity Education, advice, graded activity Graded activity, functional exercises, advice	Graded activity Education, advice, graded activity Graded activity, advice
6-end	D	Decreasing distorted ways of thinking about pain Improving self-control and self-efficacy of pain Adapting activities	Education, advice Education, advice Advice, graded activity	Education, advice Education, advice Advice, graded activity
11-end	C	Improving active coping, self-control of pain, self-efficacy, and decreasing distorted ways of thinking about pain Increasing activities	Education, advice, graded activity Graded activity, functional exercises, advice	Advice, graded activity Education, advice, graded activity Graded activity, functional exercises, advice

Table 4. Overview of the data collection and measurements

Outcome measures (instruments)	T0	T1 Baseline	T2	T3 Short-term	T4	T5 Long-term
Prognostic factors						
Age	X					
Sex	X					
Education level	X					
Employment status	X					
Marital status	X					
Insurance type	X					
Comorbidity	X					
Pre-existing headache or neck pain	X					
Seatbelt use	X					
Head restraint	X					
Direction of impact	X					
Position in vehicle	X					
Unprepared for collision	X					
Financial compensation	X	X	X	X	X	X
Neck pain intensity (VAS) ^{17,18,29}	X	X	X	X	X	X
Headache intensity (VAS) ^{17, 18, 29}	X	X	X	X	X	X
Primary outcome measures						
Pain (VAS-pain) ^{17, 18, 29}	X	X	X	X	X	X
Activities (VAS-activities) ^{17, 18, 29}	X	X	X	X	X	X
Secondary outcome measures						
Quality of life (SF-36) ^{30, 31}		X	X	X	X	X
Cervical range of motion (CROM) ³²		X	X	X	X	
Fear of movement (TSK) ³³		X	X	X	X	X
Coping (PCI) ³⁴		X	X	X	X	X
Self-control (MPI) ³⁵		X	X	X	X	
Social support (MPI) ³⁵		X	X	X	X	
Functional disability (NDI) ^{36, 37} (DIP) ³⁸		X	X	X	X	X
Well-being (WBQ) ³⁹		X	X	X	X	X
Dizziness (VAS) ^{17, 18, 29}		X	X	X	X	X
Tiredness (VAS) ^{7, 18, 29}		X	X	X	X	X
Memory problems (VAS) ^{17, 18, 29}		X	X	X	X	X
Medication use (standardized questionnaire)	X	X	X	X	X	X

VAS, Visual Analogue Scale; SF-36, Short Form 36; CROM, Cervical range of motion; TSK, Tampa Scale for Kinesiophobia; PCI, Pain Coping Inventory; MPI, Multidimensional Pain Inventory; NDI, Neck Disability Index; DIP, Disability and Impact Profile; WBQ, Well Being Questionnaire.

daily living (Table 4). Pain intensity and daily activities are measured on a VAS. The VAS is regarded as a reliable, valid, and responsive assessment tool for pain^{17,29} and other observations, such as functioning and activities.^{18,19}

Secondary outcome measures include quality of life, cervical range of motion, fear of movement, coping, self-control, social support, functional disability, well-being, dizziness, tiredness, memory loss, and medication use (Table 4). In Table 4, we have presented the prognostic factors, outcome measures, instruments, and timing of measurement. The quality of measurements is enhanced by randomized sequencing of the questionnaires and regular standardized training sessions for the blinded observers.

Follow-up. Follow-up moments to evaluate treatment are planned at 8, 12, 26, and 52 weeks after trauma. The main short-term follow-up moment is set at 12 weeks (T3); main long-term follow-up is set at 52 weeks (T5) to evaluate the short- and long-term consequences of treatment.

Sample size. The study attempts to enroll 150 patients with 75 patients per treatment group. This sample size is suffi-

cient to detect a difference of 20% in the primary outcome measures (pain and activities) between the GP and PT treatments. A difference of 20% or more is considered to be clinically relevant with a power of 0.8 and a (2-tailed) significance level of 0.05. No interim analyses will be performed.

Statistical analysis. Balance of baseline variables will be presented in a table to evaluate whether randomization was successful. If necessary, adjustments for baseline values will be performed and will be considered as covariates in the analyses. Data of primary outcome measures are screened for normality, and if necessary, logarithmic transformations will be applied or nonparametric methods of analysis will be used. Differences between follow-up and baseline values will be calculated, and mean values and 95% confidence intervals will be presented for the continuous primary outcome measures for the main moments of follow-up (short-term: 12 weeks; long-term: 52 weeks). Analyses between the groups are primarily performed according to the *intention-to-treat* principle using SPSS sta-

tistical software (Benelux bv, Chicago, 111). Patient data are analyzed in the intervention groups to which they are initially assigned, including patients not treated according to the assigned treatment. Additionally, a per protocol analysis excluding all patients who did not receive treatment as allocated will be performed. Comparing the results will indicate to what extent protocol deviations may bias the results.

Finally, multiple regression analyses will be conducted to study the influence of prognostic factors on the outcome such as age, gender, baseline intensity of pain, and cervical range of motion. For all comparisons, a *P* value of .05 (2-tailed) is considered to indicate statistical significance.

CONCLUSION

A new dynamic treatment protocol for patients with WAD I and II is introduced for use in a RCT. All participating care providers have received a training course and an information packet at the start of the study. To assist care providers during the intervention period, a help desk is initiated to provide answers to questions from GPs or PTs about appropriate intervention choices or practical issues as how to record the "care provider forms."

Until now, RCTs have generally investigated the effect of one intervention compared to another intervention. However, we assume that this cannot be considered as usual care. PT (and to a lesser extent GP care) sessions are characterized by a combination of interventions. For example, PTs always provide exercise therapy in combination with patient-related instructions.⁴⁰ Therefore, we have developed this dynamic multimodal treatment protocol. This protocol structures the "black box" of interventions. However, we will not be able to distinguish the effects of different treatment components because their separate and combined effects are not known. We suppose that all these components are part of the everyday GP and PT treatments.

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