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# MEASURING THE CLINICAL COURSE OF LOW BACK PAIN

- using course and indications for care  
to identify subgroups

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**Now this is not the end. It is not even the beginning of the end.**

**But it is, perhaps, the end of the beginning.**

**Sir Winston Churchill, 1942**

# **ABSTRACT**

## **Background**

Non-specific low back pain (LBP) is a very common and costly condition and it is recurrent in a large proportion of cases. However, little is known about the detailed course over time and whether the course varies between individuals or groups of patients. Presumably, several subgroups exist, each with a different course and treatment needs. Exploring the detailed clinical course of LBP is possible with a new method of frequent data collection, short text messages sent and received with mobile phones.

## **Aims**

The overall aim of this thesis was to explore a new method of collecting frequent data by text messaging used to define the clinical course of non-specific LBP in subjects seeking treatment in the primary care sector. The specific objectives were 1) to evaluate this text messaging method, 2) to illustrate various ways of analysing this type of repeated data, 3) to identify clinically relevant clusters on the basis of the clinical course, 4) to investigate the association of common baseline variables with outcomes based on frequently measured data, and 5) to identify clinicians' opinions of the indications for secondary and tertiary prevention of recurrent and persistent LBP.

## **Summary of methods**

In two prospective longitudinal studies, chiropractic LBP subjects were followed for six months/ 18 weeks with weekly text messages. The use of text messages as a data collection tool was scrutinised in terms of response rate, user friendliness and compliance.

Several methods of analysing repeated data were evaluated and illustrated in a model data set with LBP subjects from these studies.

The clinical course of LBP over six months was used to subgroup subjects using hierarchical cluster analysis. The identified subgroups were described in terms of clinical course and demographic characteristics.

The association of baseline variables with outcomes based on weekly text message data was explored.

Preliminary focus groups and a questionnaire survey among Swedish chiropractors determined indications for recommending secondary and tertiary care to patients with LBP.

## **Summary of results**

Using text messages and mobile phones to collect frequent data resulted in a high response rate, 82.5 %. Good user-friendliness is assumed as the drop-outs did not mention the method itself as the reason for discontinuing their participation, and these individuals were not a homogenous group regarding age, gender and LBP characteristics. The method showed high compliance rates; over 70 % of the respondents answered more than 80 % of their text message questions. The appropriate method of analysis will depend on the research question and characteristics of the outcome data. Several methods of analysing repeated data showed that all methods were robust concerning the association of a selected baseline variable with the outcome. Individual courses of LBP over six months showed great variety. The explorative cluster analysis grouped subjects into four clinically relevant units based on their LBP development over time. In predicting future LBP, all the examined variables

interacted with time. Previous duration of the LBP condition predicted LBP at all the investigated time points after the first week. Focus group discussions and the subsequent questionnaire survey identified that the indication for secondary preventive treatment was the presence of previous episodes and that the indication for tertiary prevention was that the treatment was deemed effective.

### **Conclusions**

Text messages can be used to gather frequent data prospectively on large populations. This method has advantages over traditional data collection methods and can be used when repeated information is warranted or when monitoring populations over time. Clinically meaningful clusters could be identified on the basis of course, but these subgroups need further exploration and replication in different populations with more clinical variables added. Similarly, as the predictive ability of some usual clinical baseline factors varies with time, predictors of future LBP needs exploration in detail. Knowledge about subgroups and indications for prevention possible strategies could be used to study the effect of such strategies.

**Keywords:** low back pain, text messages, repeated data, clinical course, subgroups, prediction, prevention

# SAMMANFATTNING

## Bakgrund

Icke-specifik ländryggssmärta är en mycket vanligt och kostsam åkomma som är återkommande i de flesta fall. Kunskapen om utvecklingen över tid och huruvida förloppet skiljer sig mellan individer eller grupper är dock begränsat. Troligen existerar flera subgrupper med olika förlopp och därför olika behov av behandling. Det är nu möjligt att undersöka det detaljerade förloppet av ländryggssmärta med en ny data insamlingsmetod; text meddelanden (SMS) via mobiltelefoner.

## Målsättning

Det övergripande syftet med denna avhandling var att undersöka en ny metod att samla frekventa data med SMS. Genom dessa data definierades sedan det kliniska förloppet av ländryggssmärta hos individer från primärvården. SMS metoden har utvärderats och sätt att analysera frekventa data har illustrerats. Kliniskt meningsfulla subgrupper har bildats baserade på det kliniska förloppet, och prediktorer för förlopp har undersökts. Slutligen har klinikers indikationer för sekundär och tertiär preventiv behandling identifierats.

## Sammanfattning av metoder

Individer med ländryggssmärta som sökt kiropraktor för sina besvär har i två prospektiva material, ett svenskt och ett danskt, följts med SMS varje vecka. Användandet av SMS som data insamlings metod har granskats avseende svarsfrekvens, användarvänlighet samt följsamhet.

Olika metoder för analys av frekventa data är illustrerade med hjälp av data från dessa studier.

Det kliniska förloppet av ländryggssmärta över 6 månader användes till att subgruppera individerna med hierarkisk kluster analys. Subgrupperna beskrevs med kliniskt förlopp samt med demografiska karakteristika. Prediktorer för förlopp undersöktes med ett utfall baserat på frekventa data. Slutligen användes inledande fokus grupper och en enkät studie bland kiropraktorer till att identifiera indikationer för sekundär och tertiär preventiv behandling av återkommande och långvarig ländryggssmärta.

## Sammanfattning av resultat

Att använda SMS och mobil telefoner för att samla frekventa data resulterade i en hög svarsfrekvens, 82,5%. God användarvänlighet antas då avhoppade individer inte uppgav metoden som anledning till att sluta medverka, och dessa individer var inte heller någon homogen grupp med avseende på kön, ålder och besvär. Följsamheten var god, över 70 % av respondenterna svarade vid mer än 80 % av tillfällena.

Vid analys av frekventa data kommer forsknings frågan och egenskaper hos utfalls variabel avgöra vilken analys som är lämpligast.

Det individuella kliniska förloppet av ländryggssmärta varierar mycket. Den explorativa klusteranalysen resulterade i 4 kliniskt relevanta kluster baserade på förloppet över 6 månader.

Prediktion av ländryggssmärta varierar över tid. Tidigare LBP duration predicerar risk för framtida ländryggssmärta, oberoende av tidpunkt.

Fokusgruppdiskussioner och den påföljande enkätstudien visade att indikationen för sekundär preventiv behandling var tidigare besvär, och att indikationen för tertiär behandling var förbättring vid behandling.

## **Konklusioner**

SMS kan användas till att samla in data frekvent och prospektivt i stora populationer. Metoden innebär fördelar jämfört med traditionella insamlingsmetoder och visade att prediktion av ländryggssmärta är beroende av tid. Subgrupperna som identifierats behöver undersökas vidare och replikeras i andra populationer och med flera kliniska variabler. Kunskap om subgrupper och indikationer för preventiva strategier bör användas i studier för att undersöka effekten av dessa strategier.

## LIST OF PUBLICATIONS

- I Iben Axén, Lennart Bodin, Gunnar Bergström, Laszlo Halasz, Fredrik Lange, Peter W. Lövgren, Annika Rosenbaum, Charlotte Leboeuf-Yde, Irene Jensen: **The use of weekly text messaging over six months was a feasible method for monitoring the clinical course of low back pain in patients seeking chiropractic care.**  
*Accepted in Journal of Clinical Epidemiology.*
- II Iben Axén, Lennart Bodin, Alice Kongsted, Niels Wedderkopp, Irene Jensen & Gunnar Bergström: **Analysing repeated data collected by mobile phones and frequent text messages.**  
**An example of Low Back Pain measured weekly for 18 weeks.**  
*Submitted to BMC Medical Research Methodology.*
- III Iben Axén, Lennart Bodin, Gunnar Bergström, Laszlo Halasz, Fredrik Lange, Peter W Lövgren, Annika Rosenbaum, Charlotte Leboeuf-Yde and Irene Jensen: **Clustering patients on the basis of their individual course of low back pain over a six month period.**  
*BMC Musculoskeletal Disorders 2011, 12:99*
- IV Iben Axén & Gunnar Bergström: **The course of low back pain - prediction of bothersome pain and general health** during a six-month period using clinical data and weekly text messages.  
*Submitted to Journal of Clinical Epidemiology.*
- V Iben Axén, Irene B Jensen, Andreas Eklund, Laszlo Halasz, Kristian Jørgensen, Fredrik Lange, Peter W Lövgren, Annika Rosenbaum and Charlotte Leboeuf-Yde: **The Nordic Maintenance Care Program. When do chiropractors recommend secondary and tertiary preventive care for low back pain?**  
*BMC Chiropractic & Osteopathy, 2009 Jan 22;17(1):1*



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## LIST OF ABBREVIATIONS

ANOVA =	analysis of variance
CAM=	complementary and alternative medicine
CI =	confidence interval
EUR =	euro
EQ-5D =	EuroQol 5 Dimensions
GNP =	gross national product
HR =	hazard rate
ICC =	intra class correlation
IIR =	Intervention and Implementation Research
IRR =	incidence rate ratio
LBP =	low back pain
LKR =	Legitimerade Kiropraktorers Riksorganisation
MC =	maintenance care
mm =	millimetre
NRS =	numeric rating scale
OR =	odds ratio
SCA =	Swedish Chiropractors' Association (= LKR)
SD =	standard deviation
SMS =	short message service, synonymous with "text messages"
SRH =	self-rated health
UK =	United Kingdom
US =	United States (of America)
VAS =	visual analogue scale
VRS =	verbal rating scale

# 1: INTRODUCTION

## 1: 1 LOW BACK PAIN

Pain is defined by the International Association for the Study of Pain as “*An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage*” [1]. Low back pain (LBP) is a term applied to pain located between the lower ribs and the gluteal folds. It is a very common condition in the Western world, with a life time prevalence of around 80% [2]. The high prevalence and the disabling nature of the condition make it one of the costliest health care problems of modern times. The highest costs are encountered as indirect costs, i.e. owing to sick leave and loss of productivity [3]. In Sweden alone, the costs were estimated to EUR 1860 million in 2001[4], and in several countries in Europe, the costs amount to 1- 2% of national GNP [5].

LBP is a challenging diagnosis in that, most often, no pathological cause can be identified and the condition is therefore termed non-specific [6]. Thus, the diagnosis is simply stating an area of pain, rather than what structure is injured or what physiological processes are taking place. This also means that in most cases, the pain is not a sign of serious medical pathology. Nevertheless, the patient may be temporarily disabled, incapable of normal activities and work. For a few patients, less than 10%, the pain does not resolve [7].

Several theories exist to explain LBP. Traditionally, LBP was seen as a sprain/strain injury to the back muscles, and rest was often prescribed. In line with this muscular aetiology, inadequate ability to recruit the stabilising muscles of the spine has been a prominent theory to explain LBP. As poor static endurance of the back muscles was shown to predict future LBP [8], this weakness was believed to result in inadequate protection of the spinal structures from injury. Patients with LBP have been found to have altered control of their abdominal muscles [9] and decreased paraspinal muscle activity [10] which could, however, also be the result of disuse and/or misuse in response to pain [11]. Added to this explanatory model of “stability” is the biomechanical theory, according to which altered motion of the spinal joints results from repetitive stress and trauma [12]. This is associated with altered muscle activity [13] and local biochemical reactions [14]. This model has been expanded to include neurophysiological processes of injury and the sustenance of pain [15].

During the past two decades, evidence has shown that psychosocial factors are important in the perception of pain [16, 17]. Patients will interpret and react to the pain sensation based on previous pain experience, occupational demands, social support and health habits [18].

Emotional states such as depression [19] and anxiety [20] will also affect the pain experience and may predict chronicity [21]. Fear of pain may lead to a change in behaviour [22], and create a vicious cycle of decreasing movement leading to increased pain and increased fear. Thus, the development and sustenance of long-lasting pain are associated with the emotional and behavioural consequences of pain [23].

### *Classification*

Traditionally, back pain has been classified into acute, sub-acute and chronic, as has many other conditions. These classifications, used both in the clinical and research settings, were thus differentiated by duration only. This could possibly stem from the fact that in most clinical studies, subjects were not followed for any length of time beyond completion of treatment. If patients were measured when seeking care, i.e. when they experienced relatively intense pain, and straight after an intervention, when the pain had decreased as a result of treatment or because of time, the clinical picture would look benign. Studies that measure subjects in this way have shown that most patients seeking care quickly get better [24].

A recent study has shown that defining LBP on the basis of pain duration alone is not optimal [25]. It has become apparent that LBP is a recurrent condition as about 70-80% of patients experience recurrent episodes of LBP [26, 27]. Further, having had LBP in the past results in a higher risk of getting LBP in the future [28, 29].

The term persistent pain has been introduced to include patients with recurrent as well as long-lasting/ chronic pain. In studies measuring recurrent symptoms, a high proportion of patients will therefore be categorised as having persistent pain [27, 30].

An accurate description of a fluctuating condition such as LBP may require several points of measurement over time. To date, neither natural course (i.e. development without interventions) nor clinical course (i.e. development after an intervention) has been defined in any detail. The trajectory of pain over time has been suggested as an outcome in future clinical trials through consensus processes involving international researchers [31].

### *Prediction*

The presence of a fluctuating condition such as LBP naturally raises the question of prediction of future LBP episodes. Several predictors have been examined and some have been shown to be associated with a poor outcome: high initial pain intensity [32, 33], long duration of the LBP condition [32], psychological distress [34, 35] and poor self-rated health [36]. Some outcomes that have been explored are pain intensity and function [34, 37, 38], and quality of life [39]. However, comparisons are difficult as studies use different outcomes and follow-up times [40]. To further complicate matters, predictors of short term and long term outcome may differ [27]. It has also been proposed that several predictive variables may be measuring the same entity (a more “serious” condition) [41], and that interactions of variables may contaminate the picture.

### *Treatment*

The existing theories have resulted in different treatment approaches such as stabilising exercises to improve stability, behavioural treatment to cope with and manage pain, and manual therapy, postural changes and support to restore or improve function. Thus, different therapists will recommend a treatment that will fit the believed pain

mechanism. In clinical practice these therapies seem to work. The efficacy of these treatments has been studied [42-44]. In most cases, treatment effect is noted but the effect sizes are small [45].

The reasons for the discrepancy between clinical experience and research results are complicated and diverse. In clinical reality and observational studies, there is an issue of patient selection. Self-selection of therapy for back pain has been shown to be associated with perceived benefit [46] and patients choosing complementary and alternative medicine (CAM) treatments for LBP have been shown to be sensitive to educational interventions to self-manage their condition [47]. In a recent study among patients in the United States, the individuals seeking chiropractic care had lower functional limitations, better self-rated health and fewer depressive symptoms compared to patients not utilising chiropractic care [48]. Among chiropractic patients in Sweden less anxiety and depression have been noted [49] compared to other primary care populations.

Patients with non-specific LBP are probably a heterogeneous group. Considering the range of ages, occupations, psychosocial factors, physical status, comorbidities etc. seen in the population of LBP sufferers, this condition is not likely to have one etiological explanation only. Presumably, the diagnosis of non-specific LBP includes several different subgroups of diagnoses, each with its unique course and treatment need. The identification of such subgroups would potentially enhance the tailoring of effective management options to each subgroup and individual case, as opposed to the present situation where all patients are “diagnosed” with the same disorder and treated similarly depending mainly on which type of clinician they approach.

### *Subgroups*

Several attempts have been made to subgroup patients with non-specific LBP. Based on different predictive baseline variables, subgroups have been identified among patients in primary and secondary care.

Some studies have been concerned with psychological characteristics [50-52]. These studies have found relevant subgroups for prediction of a poor long term outcome and risk of chronicity [50], increased sick leave [51] and need for extensive treatment [52]. Thus, it is possible to target patients in need of psychological interventions besides physical treatment to “treat” also their fear and disillusion concerning their LBP.

An attempt has been made to find prognostic subgroups according to a combination of physical and psychosocial work conditions, demographic variables and pain descriptive variables [53]. To detect complex patterns between the selected variables, a cluster analysis was chosen. This stratification aimed to facilitate targeted preventive strategies to the appropriate subgroups.

Recently, researchers have sub grouped patients according to pain course [54-56], based on monthly questionnaires [54], weekly diaries [55] and weekly text messages [56]. These studies all found that some patients’ courses are fluctuating, even though the definitions of these subgroups between studies differ somewhat. Further, they all

defined a group with mild, persistent pain. The two studies conducted in medical settings [54, 55] also found subgroups with severe persistent pain.

Because there is no common definition of episode, because the measurements differ with regard to type and frequency of symptoms and because the studies are performed on different populations, comparisons across studies are difficult. A systematic review concluded that psychological variables, clinical features and work-/health status alone was insufficient to subgroup patients [57]. It is, however, interesting that some of these studies arrived at similar subgroups despite their methodological differences.

### *Prevention*

A logical step in dealing with a recurrent and costly condition is prevention. It would be in the best interests of patients to minimise suffering, disability and time off work, as well as for society in terms of health costs and the loss of productivity. The different types: 1) primary prevention, to stop the condition from actuating: 2) secondary prevention, to minimise recurrence: and 3) tertiary prevention, to minimise the impact of a persistent condition, require knowledge both of the population at risk as well as knowledge of effective preventive strategies.

One intervention that has been shown to have a secondary preventive effect on future episodes of LBP is exercise [58-60] which supports all of the theories mentioned above as exercise is thought to counteract instability and maintain good function. Regarding tertiary prevention, it is recommended that exercise be complemented with psychological treatment [61].

## **1:2 MEASURING LBP**

### *Pain intensity*

Traditionally, when a patient consults for pain, this is the variable of interest. A clinician will typically inquire as to the level (intensity) of pain, and use this as a sign of progress/change.

The most commonly used measures of pain intensity are the visual analogue scale (VAS), the numeric rating scale (NRS) and the verbal rating scale (VRS). In short, VAS offers a continuum of choices as the patient is asked to rate his/her pain intensity on a 10 mm straight line, whereas NRS offers 11 categories (numbers 0 to 10) and VRS offers five categories that are expressed in words from “no pain” to “worst possible pain”. These instruments have been tested quite extensively and are found to be valid and reliable [62, 63]. They have also been subjected to scrutiny concerning responsiveness [64] and clinically meaningful change, showing that a reduction of two points (acute pain) and 30 % (chronic pain) is associated with perceived improvement [65, 66].

However, researches have pointed out that a single measure of pain intensity fails to capture the multidimensionality of the pain experience [67]. Therefore, the patient who



suffers from the condition in question should also be asked regarding his/her impression of change as well as what kind of measure is considered relevant to him/her [68]. Following these observations, a recent qualitative study showed that patients perceive recovery as unrelated to pain intensity and disability, and that the impact of symptoms on the activities of daily living is what makes a difference in this aspect [69].

Pain is a subjective experience, and among patients with LBP, the perception of pain differs [70]. The reason for seeking care may not be the pain intensity, but rather the effects of pain and the restrictions that pain imposes on everyday life [71]. Therefore, measures of pain intensity are often supplemented with measures of functional ability [72], which are responsive to changes in the LBP status [62]. The functional activities of everyday life are, in turn, highly relevant to quality of life; for example being able to sleep at night, to dress oneself or to perform at work [73]. The level of these restrictions has been shown to be the factor that prompts people to seek care for their LBP [74, 75].

#### *“Bothersomeness” as a proxy for the impact of pain*

Bothersomeness was introduced as a summary term to incorporate the functional and intensity aspects of pain in the context of clinical applicability [76]. It has been used in several studies [72, 76, 77] and was introduced to focus groups with LBP patients and found to summarise symptoms and correlate well with the quality of life [39]. It was therefore suggested as part of a standard outcome measure in LBP research [72]. In a recent consensus report to standardise LBP measures, the description “limit your usual activities or change your daily activities” was suggested to measure the severity of pain [78] and adding “for more than one day” was also recommended in the definition of an episode to avoid inflated measures of LBP prevalence.

Even though bothersomeness may mean different things to different patients, this is also the strength of the measure. Patients may experience various levels of pain with resulting disabilities, but the subjective interpretation of the magnitude of the problem is very important to the patient and the clinician. As mentioned, only when the pain impacts on everyday activities does the patient seek care [74] and goes on sick leave, thus utilising the health care and social welfare systems. Thus, the impact of the pain experience is probably captured by “bothersomeness”.

Bothersomeness has been tested against other measures. It has been found to correlate well with pain, disability and psychological health (anxiety and depression) and to predict future work absence and health care consultations [79]. As part of a short questionnaire designed to subgroup patients according to clinical course, the term has been validated against the extensive Örebro Musculoskeletal Pain Screening Questionnaire [80] and found to have similar discriminative properties concerning disability and time off work.

#### *Repeatedly measured data*

Researchers often rely on summary scores of retrospective self-reports of behaviour, pain, depression, etc. These measures assume stability and ignore variations over time and across situations. However, only data collected at frequent points in time would

make it possible to explain the actual course of a disorder and to get a detailed picture of the variations on an individual basis. This is particularly relevant when examining fluctuating conditions over time, such as LBP. Further, contextual associations [81] and temporal sequences can be explored [82]. However, it is impractical and expensive to administer questionnaires to large groups of people repeatedly.

Until recently, frequently repeated data collection was only feasible through self-administered diaries in which patients would provide information at a specific time. In theory, this seems easy. In practice, studies have shown that patients tend to backfill diaries [83], rendering the collected data prone to recall bias. This may be particularly important when studying pain that varies over time, as considerable bias is introduced when the subject is forced to remember particular time points or to average the measure of a certain period from memory [84]. In fact, recall over long periods seems to inflate measures of pain [85] and patients have difficulty remembering fluctuations [84]. Patients with back and neck pain are, however, able to validly recall an “average” pain score for one preceding week [86].

With the Internet, new possibilities exist. A questionnaire or a diary can also be Web-based and interactive between the respondent and the investigator. Reminders can be sent and electronic registration of responses and time of data entry is possible. Web-based questionnaires require the respondent to be computer literate and to be online when data collection is due, which may be considered a limitation. Technical differences between responders’ computers such as processing power and connection speed, might have introduced bias in these studies [87] in the past, as may socioeconomic status [88].

#### *Data collection using mobile phones*

Mobile phone penetration is high in Sweden, 97 % in 2010 [89]. Swedes also use text messages frequently; a third of the population sends between one and 10 messages every day [89]. People keep the phone with them most or all of the time. The system allows messages to be sent as frequently as wanted, on a daily, weekly or monthly basis. When examining a fluctuating condition, such as LBP, with this system, pain, disability, or any outcome of choice can be followed prospectively and in detail. Thus, individual differences, development over time and possible interactions with other variables can be explored. In recent years, this technology has been used in preventive medicine to improve adherence to a vaccination programme [90], and to monitor symptoms in patients with asthma [91].

Answering a research question using a text message requires minimal effort on the part of respondents, who can answer wherever and whenever they find it convenient. Compliance with this method would therefore be expected to be good. In a pilot study from 2007, over 90 % of people of working age (between 18 and 65 years) have mastered the skill of text messaging. Another advantage with this method would be that young men, the study subjects most often lost to follow up [49, 56], would be likely to find SMS data collection fun and easy.

Recall bias is minimised because of short intervals between questions. The question itself can relate to a specific moment (how intense is your pain right now?), or to a recent period, as in Studies I to III, the previous week.

Data handling and errors associated with this are minimised as data are entered directly into a data file suitable for analysis. Finally, the time and cost expenditure of text messages are far less than sending out mailed questionnaires on paper [92].

Data collection through text messages has some limitations. As mobile phones are used as the medium instead of paper, questions cannot be long and it is practically difficult to send more than two or three questions at a time (as each question results in one message, it may get tiresome to receive several messages in a row). Further, the answers should be equally short and preferably only one digit or letter (such as 0 - 7 or Y [yes] / N [no]).

When a new method is introduced, it should be evaluated in a systematic manner to ensure its use in different populations and settings. Besides evaluating recall bias and cost [92], the method has not been scrutinised further.

#### *Analysis of repeated data*

When examining associations between baseline characteristics and an outcome variable measured repeatedly, the major concern is the within-subject correlation. Data measured repeatedly on the same individual are bound to show a high correlation. A method of analysis that models these inherent correlations is most appropriate.

Further, there is also a correlation because of time, as measurements closer in time would show a higher correlation than measurements further apart. Without adjusting for this high covariance, the confidence intervals will be too narrow, falsely indicating a high precision.

Another concern is that of missing data. When subjects are measured repeatedly through self-reports, some data are invariably lost. Some common methods of analysis simply exclude respondents with any missing data, which in studies with long follow up times would mean deleting much of the data. An option to facilitate analysis of repeated data is data imputation, where the last recorded value of that individual, an average or random figure replaces the missing values [93]. Another option is to apply different “cut points” to the data set in relation to a minimal level of measures, and perform the analysis on these different subsets separately to evaluate the effect of the missing data.

## 1: 3 CHIROPRACTIC – PROFESSION AND TREATMENT

Chiropractic is defined by the World Health Organization as “*A health care profession concerned with the diagnosis, treatment and prevention of disorders of the neuromusculoskeletal system and the effects of these disorders on general health*” [94].

The chiropractic profession has existed for over 100 years. Chiropractic has always been synonymous with treatment of the spine [95]. From the beginning, at the time of spiritualism, the chiropractic profession attempted to treat many ailments such as pulmonary, circulatory and digestive problems through a presumed effect on the flow of “bodily energy” [12]. Today, chiropractors concern themselves with the management of musculoskeletal conditions in general [96], with particular emphasis on spinal health [95]. The focus of modern chiropractic lies on function; the theory is that dysfunction of the neuro-musculoskeletal systems may result from the stresses of everyday life, and manifest as disability and pain [12]. Mechanical stress may be caused by trauma, repetitive use or postural stress and psychological stress includes emotional tension of different origins [12]. The modern chiropractor will first rule out serious pathology, then identify any dysfunction amenable to chiropractic treatment. Often, the chiropractor will use manual methods [97, 98] to restore and maintain normal joint function and muscle relaxation [99, 100] in order to reduce pain and disability and to improve quality of life. The techniques used are termed manipulation and mobilisation, and are done with the chiropractor’s hands (hence “manual”), and can be described as using controlled force, leverage, direction, amplitude and velocity applied to specific joints and adjacent tissues [94].

As is the case for all modern health care professions, a chiropractor is aware of the role of the patient’s psychosocial status in the diagnosis and management of patients with musculoskeletal problems and knowledge thereof will influence individual management at the clinical level. Chiropractic care will include informing the patient about the nature of their problem, ergonomic advice and relevant exercises [101], but also advice on general health [102] and stress management [103].

Patients most commonly seek chiropractic care for LBP [97]. For this recurrent and sometimes persistent condition, chiropractic management includes a long term approach known as maintenance care (MC). This is described as “...treatment, either scheduled or elective, which occurred after optimum recorded benefit was reached” [104]. MC is intended in line with the biomechanical theory; if the stresses of everyday life are causing dysfunctions that lead to pain, these stressors need prolonged attention to be correctly identified and properly managed. MC content and purpose have been defined as “optimising health, preventing further ill-health, palliative care and minimising recurrence/ deterioration” [105]. From descriptive studies in the US [105], the UK [104], Norway [27] and Sweden, the prevalence of MC use is around 30 %.

In public health terms, the intentions of chiropractic MC would be termed secondary and tertiary prevention. Secondary prevention, to minimise recurrences of a condition, or to lessen the impact of such an episode, is described in the above definitions. The purpose of tertiary prevention, when a condition is incurable, is to minimise pain and

discomfort or to prevent the condition from deteriorating further: also stated as MC intentions.

The contents of chiropractic MC have also been described [105] and found to consist of passive modalities such as manipulation, but also advice on lifestyle and nutrition (in line with the bio-psychosocial model of health) and advice on exercise (in line with the evidence of prevention).

The indications for MC and the effect of such a regime have not been investigated to any extent in large, randomised studies [106]. A randomised pilot study showed that chiropractic MC had an effect on the disability of subjects with chronic LBP but not on the pain itself [107]. However, a recent randomised study examining the effects of tertiary preventive treatment for chronic neck pain failed to show any statistically significant advantages in pain and disability scores compared to reassuring and advising patients [108]. A study examining an insurance claims register for chiropractic, physician and physiotherapy care for LBP found that subjects under chiropractic care had less recurrence of disability compared to the other types of treatment [109].

In order to investigate the efficacy of MC, it is pertinent that the relevant patient groups are treated. The identification of such subgroups could be based on indications for care. However, the indications for chiropractic MC have not been identified and lie imbedded in clinical experience. This is tacit knowledge, not verbalised, and therefore also difficult to pass on. Through discussions with clinicians, a first step towards a scientific exploration and systematisation of this knowledge in relation to MC can be taken.

## **2: AIMS AND OBJECTIVES**

The overall aim of this thesis was to explore a new method of collecting frequent data by text messaging used to define the clinical course of non-specific LBP in subjects seeking treatment in the primary care sector. The clinical course and clinicians' opinions were the basis for subgrouping patients with LBP.

Study I: The first objective was to critically evaluate the text message method of data collection in terms of response rate, including the association with season, user-friendliness, compliance and generalizability.

Study II: The second objective was to explore and describe different methods of analysing data obtained by the text message technology with a high frequency of repeated measurements.

Study III: The third objective was to investigate whether specific and clinically relevant clusters could be identified among patients with non-specific LBP, based on an explorative cluster analysis on subjects' clinical courses of LBP over a six-month period.

Study IV: The fourth objective was to investigate if some commonly encountered baseline variables were associated with outcomes based on weekly text messages concerning days with bothersome pain over six months as well as a single measure of self-rated health from the six month's follow-up.

Study V: The fifth objective was to explore the decision-making process used by Swedish chiropractors when considering recommending MC for patients with LBP.

### **2:1 COHESION OF STUDIES**

This thesis revolves around the clinical course of non-specific LBP and its measurement. The development of this condition over time is described through frequently measured data, collected with a new method: automated text messages. Study I concerns the evaluation of this new method and study II describes the statistical challenges when analysing such data. Study IV concerns the prediction of LBP, with an outcome based on repeated measurements.

One theme of the thesis is the search for subgroups among patients with non-specific LBP. The clinical course is used as the basis for forming subgroups in study III. Study V is a search for subgroups on the basis of indications for preventive care, as expressed by clinicians.

The evaluation of the method of gathering frequent data with text messages are intended to inform both researchers and clinicians on the strengths and possible limitations of such methods. Further, a consideration for predictive studies is that outcome may be based on repeated measurements. Subgroups could be considered when studying interventions, as these groups may display different courses and outcomes in response to treatment.

## **3: METHODS**

### **3:1 MATERIALS AND RECRUITMENT**

Data in this thesis stems from three materials: two prospective studies and one cross-sectional survey. In the first two studies, chiropractic patients seeking care for non-specific LBP were followed after their initial consultation. Material 1 was gathered in Sweden between May 2008 and June 2009, and the subjects were followed for six months. Material 2 was gathered in Denmark and the subjects were included between February and June 2008, and were followed for 18 weeks. Material 3 was gathered in Sweden between March and June 2007.

#### 3: 1: 1 Material 1

Material 1 was used in Studies I to IV.

The chiropractors collecting data were members of the Swedish Chiropractic Association (SCA), which is the national association for chiropractors with an academic degree. Thirty- five chiropractors from all over Sweden were recruited to collect data on 10 consecutive subjects each from their everyday practices. The sample of chiropractors involved can be described as a convenience sample, as they had stated in the questionnaire survey described below (Material 3) that they wished to participate in further research.

The 262 subjects included in the study had non-specific LBP for which they consulted one of the involved chiropractors. The inclusion criteria were also working age and not having been under chiropractic care for the last three months. The exclusion criteria were pregnancy, not being fluent in Swedish, not having access to a mobile phone and/or not mastering the text message function of their mobile phone.

Subjects were included at the second visit to their chiropractor. The assumption was that patients with specific LBP would be referred out after the initial consultation, leaving only the non-specific cases, suitable for chiropractic treatment as well as inclusion in the study. At the second visit, the patients were informed about the study both verbally and in writing, and signed informed consent forms if they wished to participate. The study was granted approval from the ethics committee at the Karolinska Institutet (2007/1458-31/4).

The chiropractors treated the subjects as they normally would; no ordinations or restrictions were placed upon the treatments. The fourth visit was decided on as the time of the first clinical follow up, as previous studies have shown that most patients visiting a chiropractor will have improved by then [56, 98].

### 3: 1: 2 Material 2

Material 2 was used in Study II

The Danish material recruited patients with LBP from five private chiropractic clinics [56]. Inclusion criteria were: LBP as the main complaint, age between 18 and 65 years and having a mobile phone. Exclusion criteria were: previous back surgery, pregnancy, other significant musculoskeletal problems and inability to speak or read Danish. The project was presented to the local ethics committee and was not found in need for approval.

The chiropractors treated the patients according to their professional judgement, there were no restrictions regarding type and frequency of treatments.

### 3: 1: 3 Material 3

Material 3 was used in Study V.

The chiropractors participating in the focus groups as well as in the questionnaire survey were members of the Swedish Chiropractic Association (SCA). The cross-sectional survey was mailed by ordinary mail to all the members of the SCA (n = 167) in March of 2007. By June 2007, 129 chiropractors had returned their surveys to the research centre. The respondents had the choice of anonymity, but they could also write their names on the questionnaire should they wish to participate in future research.

The study was presented to the local ethics committee, which stated that it did not need approval.

## **3: 2 MEASUREMENTS AND PROCEDURES**

### 3: 2: 1 Material 1

The procedures of this material are illustrated in Figure 1.

At the inclusion visit, the chiropractors recorded baseline characteristics and the subjects were given a questionnaire. At the fourth consultation, the chiropractor noted pain and the subject's self-reported improvement ("definitely improved", "probably improved", "unchanged", "probably worse" or "definitely worse"). After six months, the subjects received a mailed questionnaire with EQ-5D and the single question on self-rated health used at baseline.

#### *Baseline variables*

Age, gender and occupation were recorded by the chiropractor.



### *LBP characteristics*

The LBP characteristics were recorded by the chiropractor: area, intensity, duration and frequency. The presence of leg pain was recorded. The subjects filled in questionnaires with a pain drawing [110], and pain intensity (numeric 11-point scale (NRS), anchors at no pain and worst imaginable)[66].

### *General health*

Two measures of self-rated general health were used; (“How would you rate your health? Excellent, very good, good, fair, poor.”) [111] and the EuroQol, EQ-5D [112], scores ranging from 0 (being death) and 1.0 (being full health).

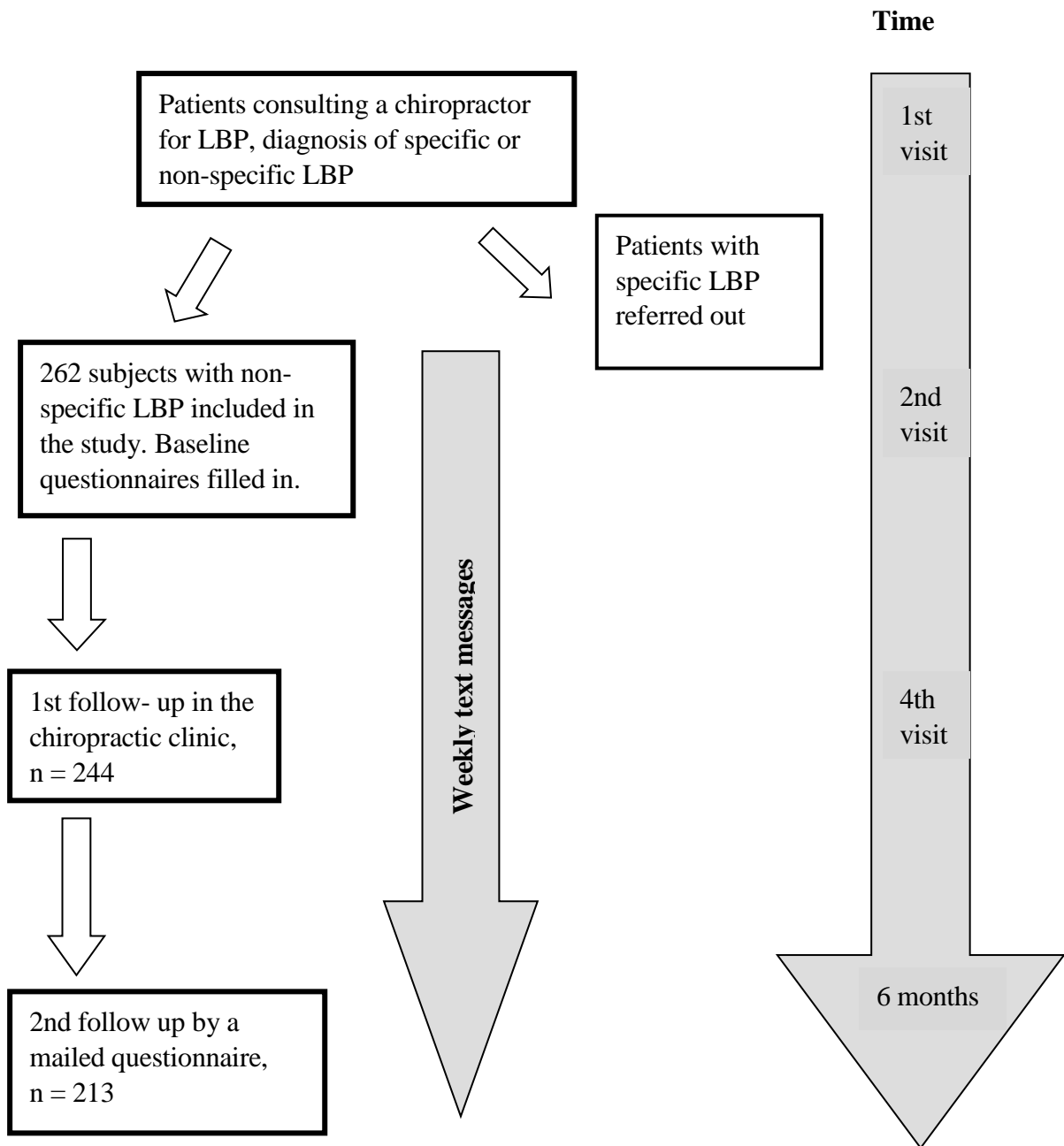
### *Sick leave*

Self-reported sick leave (number of days in the previous year because of LBP) [113] was recorded.

### *Weekly ratings of bothersomeness due to LBP*

The subjects in this study were monitored with a relatively new system: SMS Track® [114]. This software was specifically designed for research in close cooperation with researchers. Every week (Sunday afternoons) the respondents received an automated text message to their private mobile phone, which they were expected to answer by using a text message. The question was: “*How many days during this previous week has your low back pain been bothersome, (i.e. affected your daily activities or routines)? Please answer with a number from 0 to 7.*” ( In Swedish: “Hur många dagar den senaste veckan har din ländrygg besvärat dig, (dvs. påverkat dina dagliga aktiviteter eller rutiner)? Du behöver endast svara med en siffra från 0 till 7.”) Subjects were required to remember their LBP from the past week and answer with a number corresponding to the number of bothersome days. These answers were automatically recorded in a data file, accessible to the first author in real time. Automated reminders were sent to non-responders after three days. Subjects were called by the principal researcher when they missed three responses in a row and kindly reminded to continue answering.

**Figure 1: Material 1**



### 3: 2: 2 Material 2

Subjects received written and verbal information about the study. They had a standardised clinical examination and a mechanical diagnosis was recorded.

#### *Baseline variables*

Information regarding age and gender was recorded by the chiropractor.

#### *LBP characteristics*

The LBP characteristics were recorded by the chiropractor: area, intensity and duration of the problem, as well as the presence of leg pain.

#### *Weekly ratings of bothersomeness due to LBP*

The subjects were followed by weekly text messages for 18 weeks. Every Sunday afternoon, three questions were sent as three text messages. The question used in Study II was:

“Using a number from 0 to 7, please state how many days you have been bothered by your lower back this week.” Thus, as in Material 1 above, the subjects were required to remember their LBP from the past week and answer with a number corresponding to the number of bothersome days. Automated reminders were sent to non-responders the following Thursday.

### 3: 2: 3 Material 3

The procedures for Material 3 can be found in Figure 2.

The focus group discussions took place in conjunction with the general assembly of the SCA, as this is one of the few natural opportunities for chiropractic clinicians to meet. In the written invitation to this meeting, sent out six weeks in advance, the chiropractors were invited to attend the preliminary study to discuss MC.

The preliminary study started with an introduction by the first author explaining the research results [115] leading up to these group discussions. The 36 participants were divided into groups of five (and one with six) participants to enhance dynamic discussions [116]. Each group had a chairperson from the group involved in the design of the study, i.e. a chiropractor presumed to be familiar with the professional language, terminology and topic. The groups were asked to discuss the indications of MC by discussing if the patients in the hypothetical cases described above would be candidates for preventive measures [117]. The chairpersons were instructed to write down, on flip charts, key words from the discussions, and to summarise these notes to the group at the end of each case. The key words were defined as words that came up in sentences describing MC indications. No audio or visual recordings were made during the discussions, and no names were recorded.

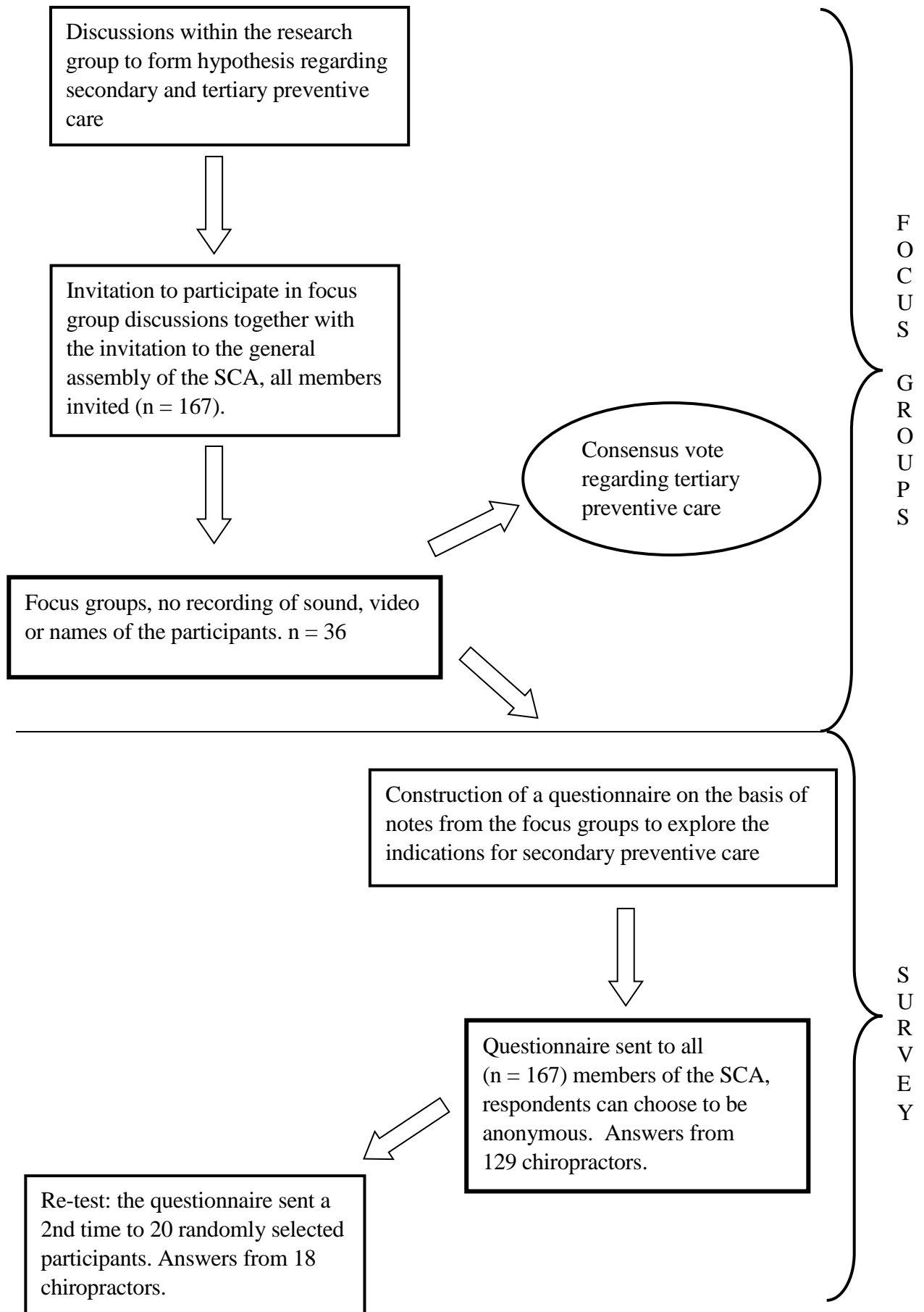
The discussions were semi-structured as they allowed free conversation centred on the hypothetical cases described above. After each case, the notes from each group were read out loud and summarised by the first author. To avoid dominant personalities

taking over, a rotation of group participants was enforced in a systematic manner after each case was discussed.

The initial hypothesis was that past episodes of the LBP would be the determining factor when recommending secondary preventive care for patients with recurrent LBP. However, the clinicians involved in the preliminary focus group discussions mentioned an additional 14 items. Based on these results, a questionnaire was designed to explore the issue further.

The questionnaire started out by describing a summarised hypothetical case from the focus group discussions, and then simply listing the items emerging from the group notes. Beside each item, a straight line was placed, anchored at “not at all important” and “very important”. The use of a line was chosen for being sensitive to change, relative to boxes of the Likert-scale type. Thus, the clinicians were simply asked to mark the line according to their own practice experience.

**Figure 2: Material 3**



### **3: 3 STUDY I**

**The use of weekly text messaging over six months was a feasible method for monitoring the clinical course of low back pain in patients seeking chiropractic care.**

Material 1 was used in this study.

The response rate was evaluated week by week. Further, the response rate was evaluated in relation to season, to see if any bias would result from respondents not answering while on holiday etc. User friendliness was evaluated by asking dropouts about their reasons for discontinuing and comparing their baseline variables with the baseline variables of those who stayed in the study.

Compliance with the method was evaluated by dividing the sample into high compliers (answering more than 80% of the time) and low compliers (answering less than 80% of the time), and comparing their baseline variables as well as their outcomes.

To evaluate the generalizability of the results, external validity was examined for the respondents in the study. As few baseline variables were available, the measure of self-rated health (EQ-5D) was chosen and compared to values from a normative Swedish population as well as to those of a population awaiting back surgery. As a second approach to evaluate the external validity of the population, the mean development over time for the full sample was compared to the clinical course of similar populations described in a systematic review.

In addition to the issues mentioned above, the construct validity of the question on bothersomeness was assessed by correlating the primary outcome (number of days with bothersome LBP) with the pain score (NRS, 0- 10) at baseline as well as the two self-rated health measures from the baseline recording. Likewise the last text message recording (number of days with bothersome LBP from the 26<sup>th</sup> week) was correlated with the six-month follow up recordings of self-rated health [118]. It was decided pre hoc that a Spearman's rank coefficient of between 0.3 and 0.49 would be considered a moderate correlation, and that more than 0.5 would be considered a strong correlation.

The first hypothesis was that the text message answer would correlate moderately to strongly to the NRS measure of pain intensity. The second hypothesis concerned the self-rated health measures; that the simple five-category question of perceived health would correlate positively to the number of days with bothersome pain, as small numbers would mean better health in both instruments. It was expected that this correlation would be moderate. The second measure, EQ-5D taps into several domains of health, with pain and disability represented. Therefore, the correlation of the EQ-5D score and the number of days with bothersome pain was expected to be negative, as greater values in EQ-5D means better health while fewer days with bothersome LBP obviously is better. Also, the correlation was expected to be of moderate strength.

### **3: 4 STUDY II**

#### **Analysing repeated data collected by mobile phones and frequent text messages. An example of Low Back Pain measured weekly for 18 weeks.**

Materials 1 and 2 were used in this study.

A model data set was formed in part with some of the subjects from the Swedish and Danish prospective longitudinal studies described above [56]. By merging two data sets, greater diversity and more respondents with high compliance was intended. Both studies were conducted in the primary sector among patients seeking chiropractic care for LBP with a weekly text message question about the number of days with bothersome pain during the previous week. The two data sets were merged to include weekly pain data for 244 subjects for 18 weeks. This model set was used to exemplify and discuss the possibilities and challenges in analysing repeated data.

The choice of an appropriate analysis depends on the research question. The approach may be variable-oriented, in which a pre hoc hypothesis is based on a specific variable. In the model data set, the overriding hypothesis was that previous duration would predict outcome (e.g. pain days or recovery). The approach may also be person-oriented. In this case, the hypothesis is related to the development or pattern of some variable of the individual participant, which is thought to be similar in groups of patients. In the model data set, the hypothesis was that the development of the LBP might be similar in some individuals, so that homogeneous sub groups based on the course over time could be identified.

Another decision, regardless of study design is that of how to identify the outcome variable as it is this variable that partly determines the analysis depending on its type (nominal, ordinal, interval or ratio data) and its distribution (e.g. normal, Poisson or binominal). In longitudinal studies with many measuring points, the options are to use each point of measure as the outcome or to use some kind of summary measure (such as the sum or mean of all measures).

When each weekly recording is considered an outcome, individual variation is captured but the analysis should accommodate for the within-subject correlation. If a summary measure is used, no problems of within-subject correlation remains, but an oversimplification may be the result.

As illustrations, research questions which were believed to be relevant to medical researchers were chosen. In these examples, all weekly pain data as well as data summaries are illustrated and the outcome is considered both as a count and as a continuous variable with various distributions (as well as having adjusted for skewed distributions). Descriptive measures, incidence calculations, linear models and cluster analyses are illustrated. To illustrate the effects of handling missing data in different ways, the analyses were carried out on three subsets of data. The subsets were: the full data set, those answering 80 % or more of their weekly measures, and those answering all the first eight weeks, respectively.

### **3: 5 STUDY III**

#### **Clustering patients on the basis of their individual course of low back pain over a six month period.**

Material 1 was used in this study.

The weekly measures of LBP from the Swedish prospective longitudinal study were summarised in line diagrams. Thus, a visual picture on the course of LBP was accessible for each subject as well as for the full cohort. These courses were the starting point for an explorative cluster analysis, assuming that the pain course over time would be similar in groups of some individuals and different from the course of other groups. However, it is practically difficult to cluster on 26 weekly variables. Therefore, the clusters were formed on the basis of mathematical descriptions of the individual courses.

Several different approaches were attempted. As most subjects' courses showed a fairly obvious improvement initially, this part of the course was described with a straight (linear) regression line. The most common development after the initial improvement was that of phasing out, i.e. continued improvement at a slower rate. After that, moving towards deterioration and maybe improvement again was relatively common. Therefore, the latter part of the course was described with a second degree line, a curve.

However, from a clinical perspective, the point of change of the crude course, i.e. where the rapid improvement of the first few weeks turns into a slower pace, was also considered important. Therefore, each course was described with two regression lines (one for the first and one for the second part of the course) and the point of intersection between the two, where the pace of improvement changed.

In the final approach, each course was described by four statistical parameter estimates which were then used in the cluster analysis. These parameters were 1) the slope of the regression line describing the early course, 2) the intercept of the regression line describing the early course, 3) the difference in slope between the two regression lines (to describe the change from early to late course), and 4) the intersection estimate (to describe when the change in improvement occurs), the so-called "knot". To secure solid course estimates, only subjects answering more than 80% of the time were included in this analysis.

The cluster method was hierarchical (Ward's) [119], which in short can be described as starting out with as many clusters as there are individuals and then pairing the individuals with others that "match" as closely as possible on the parameters used. This process continues in several steps until finally one cluster remains and contains all the individuals in the sample. This process of uniting smaller groups into larger ones is visually described in a dendrogram. The researcher will then have to scrutinise the



dendrogram to find the optimal cluster solution. Also, the features of the different cluster solutions are evaluated. Generally, a solution of many clusters yields a lot of detail, whereas a solution of fewer clusters will produce a better overview. Therefore, a balance between detail and overview is normally sought to make the final solution comprehensible. A mathematical criterion such as Calinski-Harabasz [119] can be applied to the different solutions, giving the optimal inter- and intra-cluster distances.

Finally, the cluster allocations were revised using the K-means cluster method [119], which is a non-hierarchical method of starting out with a selected cluster solution and involves reallocating the individuals to achieve homogeneity among the clusters. This is done to evaluate the clusters from Ward's method. If only a few individuals are moved (i.e. the same individuals are grouped together using both methods), the formed clusters are considered solid.

The clusters identified were then described also in terms of clinical baseline variables: age, gender, pain intensity, duration of LBP the previous year and self-rated health, as well as the outcome variable, the total number of days with bothersome pain. The clinical variables, the outcome variables excluded, were used in a discriminant analysis (kth-nearest-neighbour) [120] for a multivariate evaluation of cluster differences. Thus, a picture of the subgroup emerges: the individuals in the cluster have a distinct development over time, as well as some common personal characteristics.

### **3:6 STUDY IV**

#### **The course of low back pain - prediction of bothersome pain and general health during a six-month period using clinical data and weekly text messages.**

Material 1 was used in this study.

Some commonly gathered clinical variables were analysed for association with outcomes stemming from the weekly gathered data from text messages as well as a single end-point outcome, collected after 6 months. The available baseline variables were gender, age, pain intensity, the presence of leg pain, previous duration of the LBP condition and self-rated health at baseline. The outcomes were 1) the weekly recordings of days with bothersome pain, 2) the mean number of days with bothersome pain per week and 3) the self-rated health recorded at the final follow-up. The outcomes calculated from the text message data (outcomes 1 and 2) were selected to complement each other. The weekly data give a detailed picture week by week whereas the mean number of days per week summarises the period into a single measure. The single end-point measure of self-rated health was chosen as a comparison, as single measurements are often used as outcomes in clinical studies.

To aid clinical interpretation, the continuous variables were dichotomized according to the cohort mean, i.e. into two groups with less than and more than the group mean, respectively. Thus, all the results are presented as differences between the groups scoring "higher than mean" and "lower than mean".

First, analysis of variance, ANOVA, was used to explore the association of the baseline variables with the mean outcome and the single end-point outcome. Singlefactor models examined each variable separately, and significant associations were further explored in a multi-factor model. If any interactions were present, they were to be explored further.

Then, a multilevel analysis was undertaken to explore the association of the baseline variables with the frequently reported outcome, the weekly recordings of days with bothersome LBP. The outcome was assumed to follow a binomial distribution, and a logit link function described this association. The two levels in this model were 1) the subjects and 2) time (weeks). Again, singlefactor analysis were undertaken to explore one variable at a time. However, as interactions were present between each variable and time, stratification was necessary. A logistic regression analysis was therefore undertaken for separate time points: weeks 1,4,12 and 26. Week 1 was chosen as a “baseline”, week 4 as this is often when an improvement in the LBP condition is noted [121] and weeks 12 and 26 are frequently used as times for follow up in LBP research [32, 37]. Again, each predictor variable was assessed separately and significant variables were then used in a multifactor model.

### **3: 7 STUDY V**

#### **The Nordic Maintenance Care Program. When do chiropractors recommend secondary and tertiary preventive care for low back pain?**

Material 3 was used in this study.

##### **3: 7: 1 Focus group discussions - a preliminary study**

Through initial discussions among the authors, hypotheses concerning indications for care were formulated. The presence of past episodes of the LBP problem was thought to be the main indicator for secondary prevention and improvement with treatment was thought to be a prerequisite for recommending tertiary preventive treatment. To illustrate these hypotheses, nine hypothetical patient cases were constructed from real life cases, as seen in Additional File 1 of Study IV. These cases were kept deliberately simplistic in order to focus on the parameters of interest (i.e. past episodes or improvement). Therefore, the cases were described without any aggravating factors assuming rather uncomplicated clinical pictures. However, the cases were realistic in order for the clinicians to recognise the clinical scenario.

We decided to explore the hypotheses and to expand our knowledge on this matter through a discussion among Swedish chiropractors. Focus group discussions were chosen as the data collection method as group interaction is thought to generate detailed data [116, 122]. Further, this is considered an appropriate way of assessing tacit

knowledge such as shared clinical experience [123] and to be a process of enlightening both consensus and diversity on the topic [123].

The focus group discussions were regarded as a preliminary study [124], and were meant to trigger articulation of attitudes and clinical experiences originating from the nine hypothetical cases described above and, if possible, to reach a consensus vote on whether MC would be appropriate or not in those cases.

If the groups reached a decision during their discussions on whether the case was appropriate for MC or not, these were summarised for each case [117]. These decisions were regarded as “consensus votes” of the initial hypotheses. However, the major contribution of the focus group discussions was the key words noted on the flip charts, as they represented the groups’ reflections when discussing the hypothetical cases. The flip charts were analysed by the authors shortly after the discussions, using a simple form of content analysis.

### **3: 7: 2 Cross-sectional survey**

External validity was evaluated for the chiropractors participating in the study who reported their name through comparison of age, gender and years in practice to the whole SCA.

The response line was divided into quartiles, considered pre hoc to reflect “not important”, “a little important”, “moderately important” and “very important”. If over 70% of respondents marked the same quartile, it was defined by the authors as “good” agreement, “reasonable” if between 50- 69% of the respondents marked the same quartile, and “none” if less than 50% marked the same quartile.

To test the reproducibility of the questionnaire, a test-retest was performed six months after the survey was conducted, on twenty randomly selected respondents who recorded their names on the questionnaire. For the purpose of reliability testing, the marks on the line were interpreted as continuous data by measuring the exact point where the participants had put their mark, in millimetres. Thereafter, because we considered the line a VAS line, a “clinically important difference” of 20% [65] was transferred to the measurement. Thus, any two ratings falling within 20% of each other were considered to be “non-different”.

Agreement, the proportion of equal measurements between the two test occasions, was also calculated.

**Table 1:** A description of the studies in this thesis.

Study	I	II	III	IV	V
Title	The use of weekly text messaging over six months was a feasible method for monitoring the clinical course of low back pain in patients seeking chiropractic care.	Analysing repeated data collected by mobile phones and frequent text messages. An example of Low Back Pain measured weekly for 18 weeks.	Clustering patients on the basis of their individual course of low back pain over a six month period.	The course of low back pain - prediction of bothersome pain and general health during a six-month period using clinical data and weekly text messages.	The Nordic Maintenance Care Program. When do chiropractors recommend secondary and tertiary preventive care for low back pain?
Aim	To critically evaluate the text message method.	To explore and describe different methods of analysing data obtained by the text message technology with a high frequency of repeated measurements.	To investigate whether specific and clinically relevant clusters can be identified on the basis of the clinical course of LBP.	To investigate if some commonly encountered base-line variables were associated with outcomes based on weekly text messages over six months.	To identify clinicians' opinions of the indications for recommending maintenance care (MC) for patients with LBP.
Design & Material	Prospective longitudinal study. Material 1.	Two prospective longitudinal studies, from Sweden/Denmark. Materials 1 and 2.	Prospective longitudinal study. Material 1.	Prospective longitudinal study. Material 1.	Focus groups and a cross-sectional survey. Material 3.
Subjects	n = 262 52 % male Age mean 44 years 57 % had > 30 pain days previous year NRS mean 4.4 50 % had leg pain	n = 244 49 % male Age mean 43.5 years 50 % had > 30 pain days previous year	n = 165 54 % male Age mean 45 years 58 % had > 30 pain days previous year NRS mean 4.4 48 % had leg pain	n = 244 52 % male Age mean 44 years 51 % had > 30 pain days previous year, NRS mean 4.4 49% had leg pain	
Chiro-practicers					n = 129 (survey) 68 % male Age 31-40: 38 % 41-50: 40 % 5-9 yrs in practice: 23% 15+ yrs in practice: 36%
Outcomes	Response rate Compliance User- friendliness		Clinically meaningful clusters	Weekly and mean n of days with bothersome LBP, self- rated health	Indications for secondary and tertiary preventive care
Statistical Analysis	Descriptive Student t X <sup>2</sup> test	Summaries Survival analysis Cox regression Spline regression GEE Multivariate Analysis Visual analysis of courses Cluster analyses	Ward's and K-means cluster analysis	ANOVA Logistic regression	Descriptive Test-retest

### **3: 8 MULTICENTRE STUDIES WITH HIGH COMPLIANCE**

A working group of chiropractic clinicians was formed in Sweden in the mid 1990's. Its purpose was to introduce chiropractors to clinical research through practice-based studies as chiropractic research in Sweden was scarce at that point in time. Over the years, this group has been engaged in several research projects in Sweden [98, 121, 125-127]. The group members have gained practical research competence, up-to-date knowledge of the topic at hand and a true understanding of the rigours of research through these projects.

Through discussions within this group, interesting clinical questions have been raised and debated. Thus, involving clinicians in practise based studies from the planning stages ensures that the topics investigated are relevant to a field practitioner. Recruitment of colleagues to help in the collection of data is much easier when the topic can be presented as one of direct clinical relevance. The guidance of an experienced researcher is, of course, essential to guarantee methodological quality of the final research plan.

Over the years, the group has developed and refined logistical processes to ensure maximal compliance from data collecting clinicians. In short, these processes describe recruitment, encouragement and empowerment in the frequent contact that has to be maintained with the clinicians responsible for the data collection. Considering the high proportions of data-collecting clinicians (ranging from 56% to 91%) and the resulting number of subjects (up to 1500), it appears reasonable to believe that this method is worthwhile considering when planning a multicentre clinical study involving clinicians from any profession.

A detailed manual of the processes described above has been developed (Appendix 1).

## 4: RESULTS

### 4: 1 STUDY I

The patients seeking chiropractic care in Material 1 are described in Study I. In short, the gender distribution was fairly even (52 % male) and the mean age was 44 years. The largest group of subjects (41 % ) had a sedentary job. The average pain was 4.4 on the pain scale, half the subjects reported leg pain in addition to the LBP, and 57 % had experienced pain for more than 30 days during the previous year. Their mean self rated health score was 0.781 (EQ-5D weighted score).

The average response rate was 82.5%, dropping from 90 % during the first week to 79% the 26<sup>th</sup> week. The response rate was fairly constant throughout the study period, and no seasonal variation was noted. Less than 7% of the participants dropped out, and those who were interviewed reported different reasons for doing so. Thus no problem with the method itself was identified. Only one subject raised the issue of cost as a reason for dropping out. However, the dropouts had less severe pain at baseline and had had shorter duration of pain the previous year compared to those who remained in the study.

No baseline differences were found between subjects who were high compared to poor compliers. Thus, using these variables, it is impossible to foresee a highly compliant and a poorly compliant respondent at the outset of a study. However, the poor compliers reported that they experienced more days with bothersome pain during the course of the study.

To evaluate the external validity of the sample, the self-rated health of the subjects was compared to that of a normative Swedish population [128] and to that of subjects awaiting back surgery [129, 130]. The self-rated general health (EuroQol weighted score) of our population (0.78, SD = 0.21) appears to be smaller than the normative value (0.85, SD = 0.20) but higher than that of the surgical patients (0.39, SD = 0.32) and far higher than surgical patients with disc-related sciatica (0.12, SD = 0.35). Further, the development of pain over time on a group level was similar to that reported in a systematic review [24].

The construct validity of the text message question was evaluated by comparing the weekly responses with the initial pain score and the two self-rated health measures at the 4<sup>th</sup> visit and after completion of the study (the 26<sup>th</sup> week). As hypothesised, the Spearman's correlation coefficients of the NRS pain score showed a moderate correlation with the reported number of days with bothersome LBP the first week of the study. For self-rated health, as hypothesised, the Spearman's correlation coefficient ranged from moderate at baseline to strong at six months. The simple 1- 5 score of self-rated health correlated moderately at both time points with the weekly responses. The results are seen in Table 2.

**Table 2.** Spearman’s rank correlation coefficients for the number of days with bothersome pain with the reported pain score (NRS) at baseline and the self-rated health scores (EQ-5D and a single question about general health) at baseline and at the six months follow-up.

Number of days with bothersome pain	Pain intensity NRS Baseline	Self-rated health			
		EQ-5D Baseline	EQ-5D 6 months	General Health Baseline	General Health 6 months
Week 1	0.40	-0.37		0.41	
Week 26			-0.52		0.37

## 4: 2 STUDY II

Study II provides an overview of appropriate methods with which to analyse repeated data. The primary outcome “number of days with bothersome pain” was treated both as a discrete and a continuous variable assuming different distributions. To explore potential differences between groups of subjects, the baseline variable “previous duration” was used to stratify the sample. As these approaches serve as illustrations, the results are not important per se.

An overview of the analytic methods used can be seen in Table 3.

### *Descriptive measures*

Descriptive summaries for the repeated measurements were calculated for the full data set as well as separately for the groups of subjects with short and long previous duration. The mean number of pain days per week was significantly higher for the subjects with long previous duration compared to the subjects with short previous duration.

The proportion of subjects who recovered throughout the course of the study is rapidly increased to the 7<sup>th</sup>/8<sup>th</sup> week, where approximately 50% of the population reported zero days of LBP. During the rest of the study period, this proportion remained rather constant, as seen in Figure 3.

### *Incidence measures*

Incidence calculations were performed by the positive event of “recovery”. There was a statistically significant difference between the groups where the subjects who had short duration of pain the previous year showed a significantly higher rate of recovery compared to those with a long previous duration. This was also found with a Cox regression and a discrete hazard analysis.

### *Course change*

The point of change in the course of LBP was calculated using a spline regression technique, and the group with short previous duration of pain showed a change in their course at 4.5 weeks, whereas the group with long previous duration showed a change at 5.9 weeks.

As previous research has shown that many patients with LBP in primary care have improved by the 4<sup>th</sup>- 5<sup>th</sup> week [56, 98], week 5 was chosen as a clinically relevant point of interest and the proportion of subjects who were recovered at this point in time was calculated using logistic regression. The odds of recovery by the 5<sup>th</sup> week for individuals with short previous duration was significantly higher than for those with long previous duration.

### *Association of baseline variable and outcome*

The association of the selected baseline variable, previous duration, with the outcome, number of days with pain, was illustrated with different linear models. The different



models all showed previous duration to be a predictor for outcome, although estimates varied slightly. These analyses were carried out on two subsets of data to illustrate the effect of missing data: 1) all respondents and 2) the high compliers (individuals responding > 80% of the time), respectively. Estimates varied only marginally between the two subsets.

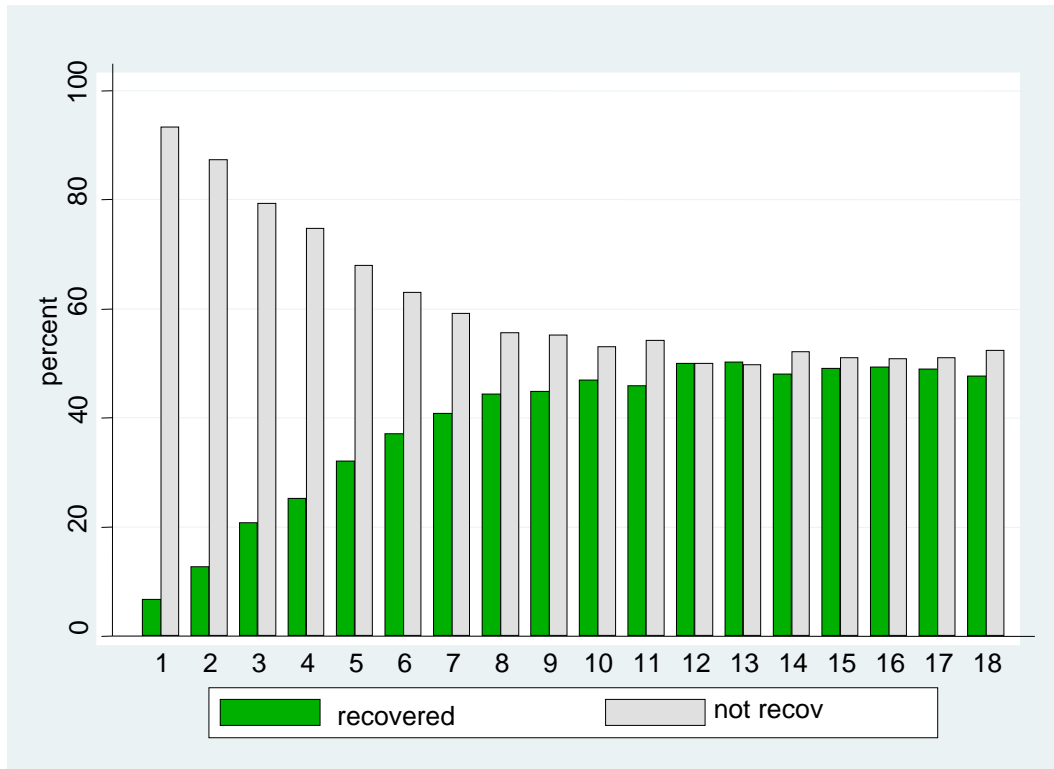
### *Subgroups*

A visual approach to form subgroups on the basis of clinical course resulted in the formation of 13 subgroups, while using the mathematical approach described extensively in this thesis, four clusters resulted. A cluster analysis on the subset of subjects who answered all the eight first weeks, using their actual weekly measurements as clustering parameters resulted in six subgroups.

**Table 3.** A summary of the analytical approaches in Study II.

TYPE OF APPROACH	STATISTICAL ANALYSIS	OUTCOMES
Descriptive	Summaries. Student's t-test. Proportions. Logistic regression.	Total number of days with pain Average number of pain days per week Incidence of recovered patients Proportion of patients recovered
Incidence of recovery	Time to event analysis, with Kaplan Meier curves. Log rank test for differences between groups Time to event analysis with a) Cox proportional hazard regression or b) Discrete hazard regression	Recovery = reporting 0 or 1 pain days in 2 consecutive weeks = Event  AND reporting 0 or 1 pain days in 2 consecutive weeks = Event
Course Change	Spline regressions	The time point of change in the course of pain
Association of baseline variables with outcome	Multilevel mixed- effects logistic regression or generalized estimating equation Multilevel mixed-effects Poisson regression Generalized linear regression or mixed linear model	Multilevel mixed- effects logistic regression or generalized estimating equation Multilevel mixed-effects Poisson regression Generalized linear regression or mixed linear model
Subgroups	Visual inspection Cluster analysis	Subgroups as clusters with low within-cluster variation and high between-cluster variation

**Figure 3.** Percentage of subjects recovered (LBP days = 0) and not recovered in each of 18 weeks following a first visit to a chiropractor.

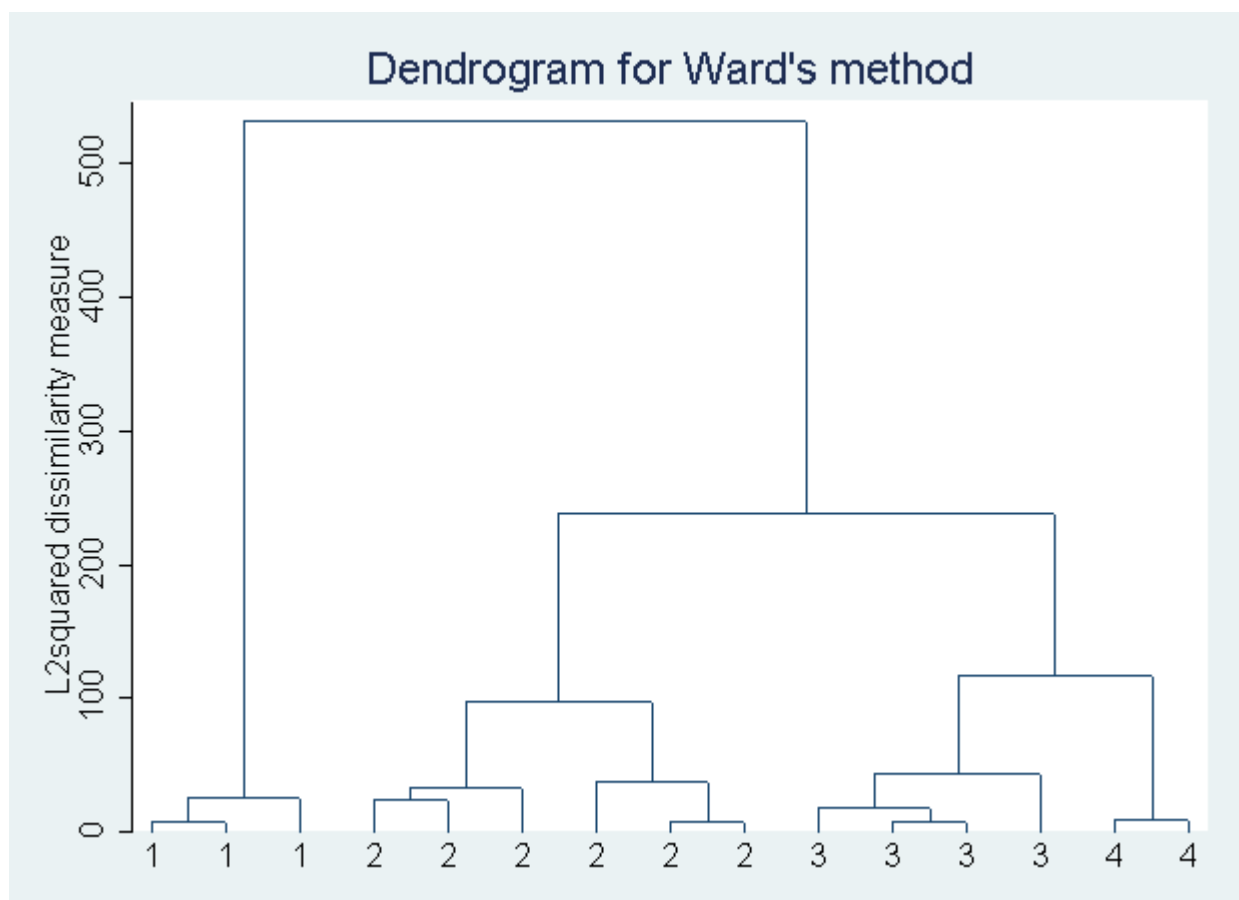


### 4: 3 STUDY III

Of the 176 individual courses eligible for cluster analysis, i.e. answering more than 80 % of the time, four had to be excluded as these courses were constant over the study period and therefore could not be described with regression analysis, as suitable data must exhibit change (slope). A further seven individuals could not be matched with any other individual in the initial step of the clustering, and were also excluded. Thus, 165 subjects were left in the final cluster analysis.

The dendrogram resulting from Ward's hierarchical cluster analysis is presented in Figure 4. The cluster analysis suggested four definite clusters and only 15% of the individuals were reallocated between the Ward's and the K-means methods, indicating solid cluster solutions. The final clusters ranged in size from 23 to 72 individuals.

**Figure 4.** A dendrogram obtained with Ward's method, describing the formation of clusters.



The clusters were described in terms of course (intercept, slope and knot), baseline variables that showed significant differences (age, gender, previous duration of the LBP complaint and self-rated health) and outcome (total number of bothersome days).

Cluster 1 (n= 43) can be described as having a “stable” course over time, a rather constant, low grade problem. It starts off with a few bothersome days initially, and deteriorates slightly before improving in the latter phase of the course. These subjects were the youngest and had the best self rated health of the four clusters.

Cluster 2 (n= 23) contains the subjects who are “fast improvers”. They report most days with bothersome pain but improve at the fastest rate of all the clusters. These individuals reported the highest pain scores initially along with the poorest self rated health of the four clusters.

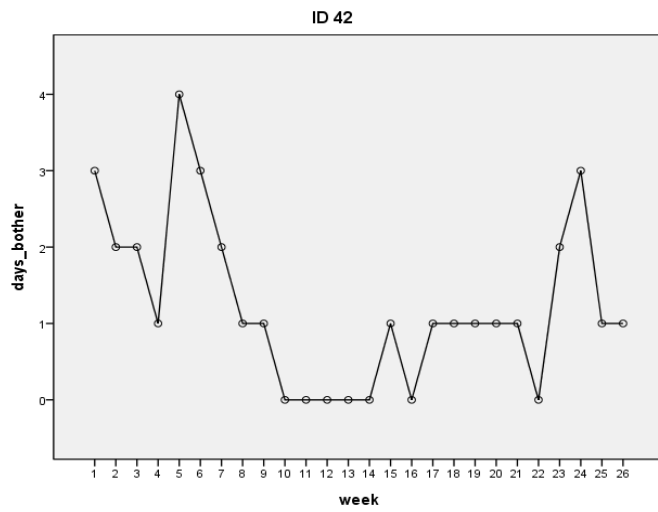
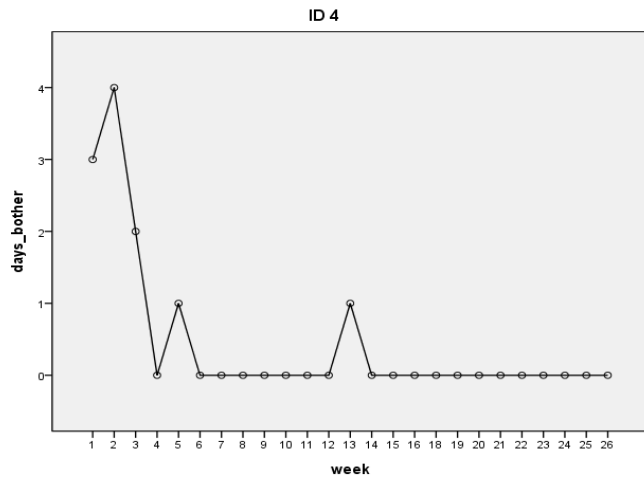
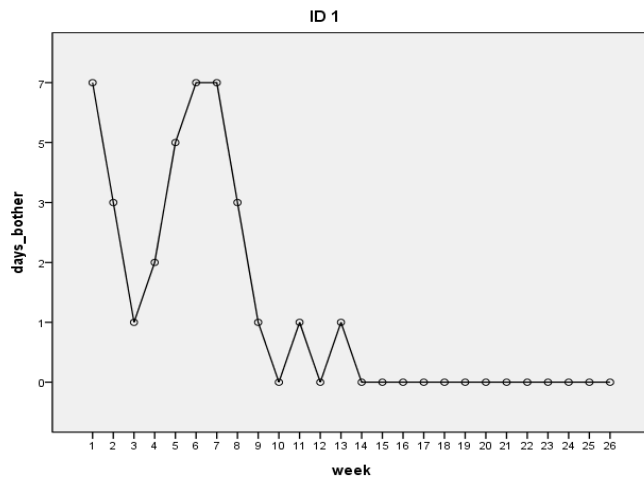
Cluster 3 (n= 72) is the group that most resembles the entire group mean course, it is called the “typical” cluster. As can be expected for the largest cluster, the starting point and the turning point, as well as age, gender, pain intensity and duration resembles that of the entire cohort.

Cluster 4 (n= 27) contains the subjects that are the “slow improvers”. Whereas the turning point for the full cohort is around five weeks, this cluster takes 12 weeks to reach their “knot”. The individuals in this cluster were predominantly older men who had long duration LBP in the previous year before participation in the study.

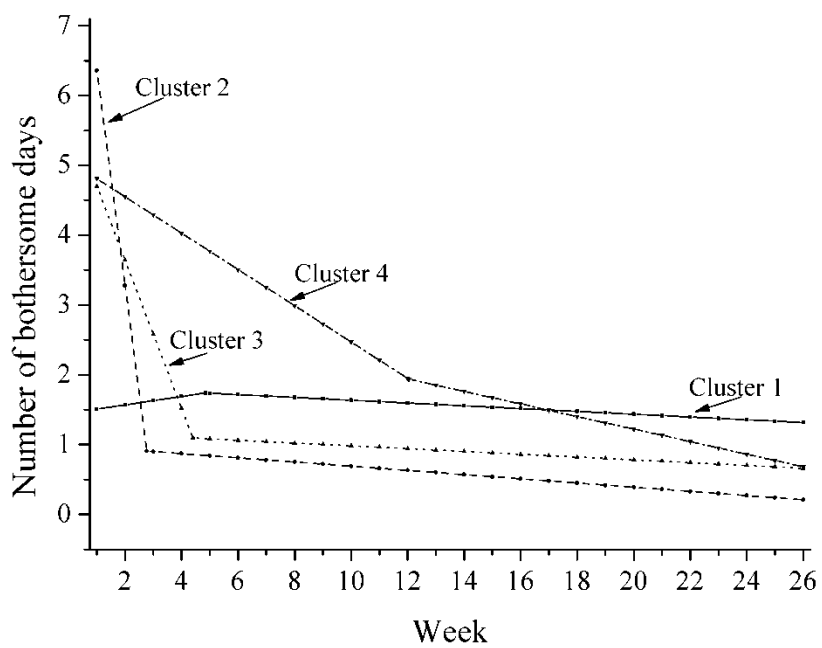
Examples of some individual courses are presented in Figure 5. These are selected to illustrate the variation between individual development over time.

The four clusters are summarised in Figure 6. The multivariate discriminant analysis showed that the error rate in predicting cluster membership based on the clinical variables was 22.4 %.

**Figure 5:** Some examples of individual courses.



**Figure 6.** The average course of each of the four clusters identified on the basis of clinical course.

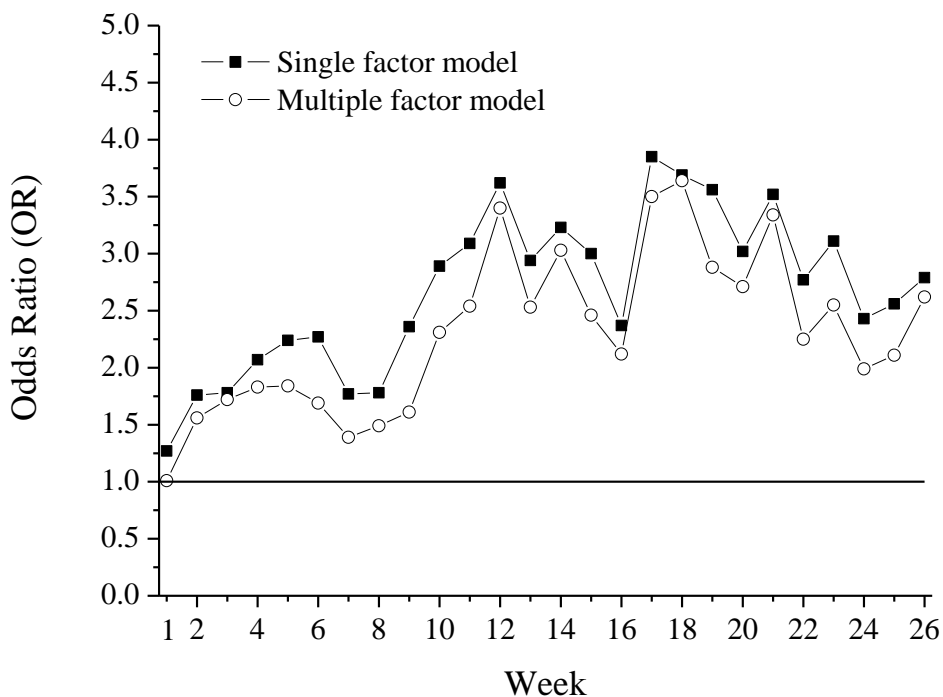


## 4: 4 STUDY IV

The outcomes that summarises the course, the 1) mean number of days with bothersome LBP per week and 2) self-rated health at 26 weeks follow-up, could both be predicted from two clinical variables: previous duration of the LBP condition and self-rated health at baseline.

However, the outcome “weekly measurements “added detail to the prediction model in the logistic regression analysis. The association between most variables and the outcome changed over time. One variable remained significant in all models at all time-points except the first week of the multifactor model: previous duration. Thus, subjects reporting a previous duration of more than 30 days the previous year had equal risk as those with shorter previous duration of reporting bothersome LBP the first week of the study. However, at 12 weeks, these subjects had more than 3 times the odds of reporting bothersome pain, an increased risk that largely persisted throughout the remaining study period. This is illustrated in Figure 7, showing the odds ratios week by week for subjects reporting long previous duration. (Short previous duration serving as the reference category.) It is premature to comment on the importance of these findings, as the interactions need further exploration.

**Figure 7:** Odds ratios (OR) from the logistic regression models showing the difference in risk of reporting bothersome LBP week by week.





## **4: 5 STUDY V**

### *Participating chiropractors*

The characteristics of the identifiable participants of the questionnaire survey are presented in Study IV. In short, they were predominantly male (68 %), between 30 and 50 years (72 %) and 21 % had been in practise for five to nine years, and an additional 33 % for more than 15 years. This profile equals that of the whole SCA.

### **4: 5: 1 Focus group discussions**

During the discussions, the overall impression was that of ease of conversation. For tertiary prevention, the consensus vote suggested that improvement was the main indication for recommending care. When discussing secondary prevention, no clear decision could be extracted from the consensus vote. Thus, the key words noted down on the flip charts were the basis for further analysis through thorough and collective reading, discussion and reflection by the research group. Each key word was written on a whiteboard and condensed into the 14 items [117] seen in Table 4.

These 14 items were then used in the construction of a questionnaire survey that was distributed to all the members of the SCA. In this questionnaire, the chiropractors were asked to rate the importance of each item on a scale from “not at all important” to “very important”. The questionnaire is included as Additional File 2 in Study IV.

**Table 4:** The items extracted from the focus group flip charts with illustrative examples of key words.

ITEM	KEY WORDS
1) Pain intensity	Lot of pain → care more intensive
2) Duration of the LBP episode	Current episode long → lot of compensations occur → MC
3) Trigger factors	Work triggers the problem → MC
4-5) Past episodes–previous year and previous 10 years	Problem recurring → MC
6) Total duration of the LBP problem	Old problem → more MC than short duration
7) Treatment effect	To notice changes due to rehabilitation, stress management or behaviour modification → MC
8) Treatment durability	<ul style="list-style-type: none"> <li>➤ individual frequency MC depending on length of effect</li> <li>➤ treatment effect may last differently between treatments</li> </ul>
9) Patient lifestyle	<ul style="list-style-type: none"> <li>➤ lot of stress</li> <li>➤ if smoking</li> </ul>
10) Patient work	<ul style="list-style-type: none"> <li>➤ lifting and bending</li> <li>➤ stressful situations at work</li> </ul>
11) Psychosocial factors	Kinesiofobia
12) Patient attitude	<ul style="list-style-type: none"> <li>➤ Goal</li> <li>➤ Motivation</li> <li>➤ Expectation</li> <li>➤ Satisfaction</li> </ul>
13) Ability to pay	
14) Need to return to work	

#### **4: 5: 2 Survey**

The questionnaire was completed by 129 (77%) of the intended sample. Only two items reached the pre hoc defined limit of “good agreement” (> 70%) as “very important”. These were the items concerning recurrence of LBP: in the past year and during the past 10 years. A further eight items reached the “reasonable agreement” level as “very important”; duration of LBP (both over the past year and present episode), treatment effect and durability of treatment outcome, lifestyle, work conditions, psychosocial factors and patient attitude.

Seventeen (85 %) of the retest sample returned their re-test questionnaires. Regarding the line as a VAS- line, 71 % (range 53%- 88%) of the retest scores fell within the pre-defined “acceptable difference” of the first score. The items reaching the highest proportions of equal answers between the two ratings were duration of LBP the previous year (88 %), episodes of LBP the previous year and treatment durability (both 83%). Episodes of LBP the previous year was one of the two items that over 70% of the clinicians rated as “very important”.

To obtain agreement by categories (ordinal data), the number of times the respondents marked the same category in the test as in the retest was counted and divided it by the total number of replies. Overall agreement was 60 % (range 41%- 82%). The item reaching the highest agreement (82%) between the two measures was episodes of LBP the last year.

## 5: DISCUSSION

The overall aim of this thesis was to explore a new method of collecting frequent data by text messaging used to define the clinical course of non-specific LBP in subjects seeking care in primary care. The data collection method was found to yield a high response rate, good compliance and was user-friendly. Several methods of analysing repeated data was illustrated. The clinical course was used to subgroup patients, and four clinically meaningful clusters were identified. Indications for secondary and tertiary preventive care for patients with recurrent and persistent LBP were identified.

### 5: 1 GENERALIZABILITY

#### *Generalizability of subjects*

The development of the LBP over time in Material 1 shows that, on a group level, most subjects' LBP rapidly improve after the initial consultation. This finding resembles that described in other studies [24], thus our subjects seem to resemble other populations with LBP in terms of the item studied: pain course. However, as chiropractic treatment is normally not financially reimbursed in Sweden, this type of care may only be available to patients of a higher socioeconomic status. A survey among the inhabitants of Stockholm found that CAM users had a higher education than non-users [131]. A previous study of chiropractic patients in Sweden showed that they had few depressive symptoms [49], which could be indicative of a population that is at an advantage compared to many other patients in the primary sector. However, from the comparison of the self-rated health score (EQ-5D) with that of other populations it was concluded that the subjects rate their health as would be expected for someone with pain of LBP magnitude. Therefore, in terms of health status, the population scores as expected for patients seeking primary care for LBP in Sweden.

#### *Generalizability of the text message method*

To draw any conclusions as to the generalizability of the text message method of collecting data from this study is perhaps somewhat premature. As described above, the external validity of the sample has been evaluated. However, other measures, such as mobile phone penetration and socioeconomic factors probably play a part in participants' possibilities and willingness to comply with a lengthy text message study. Considering the high mobile penetration in Sweden and the fact that only one of the drop outs reported cost as a reason for discontinuing, in countries with similar high use of mobile technology and similar socioeconomic factors, the system should work as well as reported here. Obviously, in different settings, these factors need consideration.

#### *Generalizability of the survey results*

Whether the results of the survey can be generalized to other populations of chiropractors is not known. The focus of the questionnaire survey was aimed at clinical judgement, and as such, should be applicable in other countries as well, at least if the

chiropractic patient populations are similar. As the SCA members received their chiropractic education mainly in England, the US or Denmark, they should share some of the attitudes to management concerning patient care with their colleagues around the world. However, education is probably only a part of what makes up the clinical expertise of a practitioner. Local legislation and financial reimbursement most likely matter when it comes to choosing patients suitable for treatment, particularly long-term regimes such as MC. A later interview study [132] and an anonymous questionnaire study [133] on attitudes towards MC among chiropractors in Denmark has revealed similar indications for secondary preventive treatment: past episodes of LBP, and a common intent to prevent new episodes of LBP.

## **5:2 STUDY I**

The feasibility of the method has been examined in several different domains. In evaluating user friendliness, the reasons given for dropping out were scrutinised. Only a few respondents (< 7 %) dropped out, and some were possible to reach for an explanation. The answers given for discontinuing the study were diverse, and seemed unrelated to the method itself. In many longitudinal studies, drop outs are young men [26, 49, 56], but this was not the case in our study.

After scrutiny of the data collection method, we are confident that collecting weekly data through text messages is a feasible and user-friendly method in a primary care population with LBP in countries similar to Sweden.

The high compliers, decided pre hoc to be those answering 80% or more of the 26 weeks, were evaluated in comparison to the poorly (less than 80%) compliant subjects. As there were no differences in their baseline characteristics, compliance seems unpredictable from the baseline data available herein. However, the course of the less compliant differed from the highly compliant in that the former experienced more days with bothersome pain during the latter part of the study. From the available data, it is not possible to examine this difference further. We speculate that these individuals might actually have a poorer prognosis over time, which is creating a bias in the evaluation of this group, as their answers are fewer and the estimates therefore less reliable. On the other hand, these subjects might have only remembered to answer their text messages when in pain, thus creating an inflated mean value. Had they answered to the extent of the highly compliant responders, their courses might have been quite similar. In future studies, highly and poorly compliant respondents should be evaluated to examine any possible bias arising from answering more or less frequently.

One concern about frequent data collection is an ethical question. Is it sound to remind individuals often of their condition? In most research projects, the variable of interest is negative to the patient involved, such as pain, disability and anxiety. Having to consider repeatedly that one is not well may lead to an increased focus on the pain which may have a negative effect on one's health status. Besides being detrimental to the individual, such attention bias might also affect the outcome variable in our study [134]. However, a study on individuals with rheumatic pain assessed several times a day at random intervals for a month showed no systematic effect on depression scores [135]. On a group level, depression scores actually improved during that study, maybe

attributable to recognition of the amount of time with little or no pain, or to an increased understanding or sense of control over the pain. Therefore, the authors of this study suggest that frequent assessment may actually be positive on symptoms of pain in subjects with chronic pain.

## **5: 3 STUDY II**

According to the research question, the data gathered, the type and distribution of the selected outcome and correlation of measurements, different ways of analysing repeated data are illustrated in this thesis. By using a model data set with an outcome measure that could be interpreted in different ways and applying relevant research questions for LBP researchers, different outcomes could be described and scrutinised. All the analyses performed here point in the same direction: subjects who reported few “< 30” days of LBP the previous year report: 1) fewer pain days during the six months of the study, show 2) a quicker rate of improvement, and 3) have a higher chance of improving during the six month follow-up than those who report more “≥ 30” pain days prior to the start of the study.

These analyses serve as illustrations. The results are not important per se, but as they point in the same direction, they illustrate the robustness of the methods. In other datasets exploring different conditions, the research questions included here may or may not be of relevance. In some instances the choice of analytic method may be straightforward, and the overview presented here may be of help. In other instances, different methods may be appropriate.

## **5: 4 STUDY III**

The cluster analysis resulted in some clinically relevant findings. First, all the final clusters formed in the cluster analysis have a favourable outcome, i.e. they all show a decrease in the number of days with bothersome pain. Further, these clusters seem to represent clinically relevant subgroups. The multivariate analysis for predicting cluster membership had an error rate which can be considered low, further strengthening the solidity of the clusters.

For a clinician, it is useful to be able to predict the probable clinical course and to inform the patient about a likely outcome. It can be argued that, as is known from other studies, most patients who consult for LBP will improve [24]. This is indeed the overall picture from this cohort. However, these clusters bring detail to the overall picture of the rate of improvement while linking this to clinical baseline variables such as age, gender, previous duration and self-rated health. What remains to be seen is whether the different clusters represent different diagnoses, psychological profiles or further distinguishing factors, ultimately leading to differential treatment of patients belonging to different clusters to improve their outcome both in terms of pain, disability and quality of life, but also in terms of cost effectiveness of the interventions provided.

## **5: 5 STUDY IV**

Different outcomes of future LBP could be predicted from some commonly gathered clinical variables. The mean number of bothersome days per week could be predicted by previous duration of the LBP condition and self-rated health, as could the single end point outcome of self-rated health. Thus, using the frequently gathered data to summarise the whole period verifies some previous results [32, 39], but has little value compared to the traditionally used single end-point.

However, the frequently collected data gave a more detailed picture when selecting several time-points and comparing the odds ratios between these measurements. Fluctuations were noted regarding the significance of several predictors. These were probably the results of interactions between variables, and may explain why different studies report different results [40]. Further, long previous duration of the LBP condition was unimportant for risk of reporting bothersome LBP in week 1, but was associated with an increasing risk of bothersome LBP up until 3 months, and remaining high thereafter. Thus, the earliest development of the LBP condition (week 1) is unaffected by previous pain, but as time progresses, this factor is increasingly associated with a high risk of reporting future LBP.

## **5: 6 STUDY V**

The group of clinicians responsible for the study consisted of chiropractors, sharing the same educational background, working under similar circumstances with the same types of patients as the participants of the focus groups and questionnaire survey. As these background factors are shared, they were presumed to create a “common ground”, i.e. these were the variables on which homogeneity was assumed. However, as the members of the research group had been working with research projects for several years, their opinions and points of view may be permeated by knowledge of the evidence in the topic. This may be evident in the hypotheses formed as well as in the interpretation of the results.

To explore the research questions regarding MC, a qualitative method for data collection was chosen. Normally, such methods are chosen to elucidate a specific topic and not for testing specific hypotheses. Ideally, to access the full range of opinions among the target profession, purposely selecting participants with a wide variation of ages, years in practice, practice locations and of both genders would have been ideal to illuminate the topic thoroughly. However, it is our experience that clinicians in private

practice are reluctant to take time off for research purposes. A pragmatic approach was chosen to gather a convenience sample for this preliminary study in the general assembly of the SCA, whilst aware that these participants may not have expressed all opinions of all the chiropractors in Sweden.

Concerning the matter for discussion, MC, a previous study among Swedish chiropractors [115] has shown that the group is relatively homogeneous in this respect. To make any inference of the study results extended to other settings is, however, difficult.

The hypothesis regarding tertiary prevention; that the main indication for such treatment would be improvement, was verified by the consensus vote. However, the hypothesis regarding secondary prevention; that the main indication would be the presence of past episodes, could not be verified. Interpretation of the flip chart notes was done in a systematic way to ensure that the key messages were represented. Thus, the resulting list of contributing items when recommending secondary care generated new hypotheses regarding MC, which in turn were explored in the resulting questionnaire survey.

It is interesting that the very factor hypothesised to influence recommendations for secondary preventive care, i.e. past episodes of LBP, was the most commonly agreed on in the questionnaire survey. It suggests that the initial discussions were correct in concentrating on this factor. In fact, the clinicians in the research group were able to condense the detail of a normal clinical encounter into a factor that was, to a high degree, agreed on by peers.

Equally interesting is the fact that the clinicians participating in the preliminary focus group discussions were unwilling to make this simplistic condensation. Rather, they indicated that past episodes might be important, but broke the measure into two (the presence of episodes over the past year and the past 10 years) as well as mentioning several other elements also to be considered. This discrepancy between the opinions of the research group and those of the full body of the SCA could mean that the actual clinical encounter is never as simple as the hypothesised cases, and that practicing clinicians are fully aware of this fact. However, it is also possible that the clinical picture is confused by too many details, which are impossible to systematise in the reality of a clinical setting.

Adding the indications for preventive care with the characteristics of the clusters, it would seem that the subjects in cluster 4 would be candidates for prevention; they report many days with pain the previous year, and improve during care. Possibly, subjects belonging to clusters 2 and 3 would also be candidates, as they improve, but knowledge concerning past episodes is needed to determine this.



## 5: 7 STRENGTHS AND LIMITATIONS

### *Subjects in the prospective longitudinal studies*

In Material 1 and 2, patients with non-specific LBP seeking care in the primary health care sector were studied. The strengths of a prospective longitudinal study are that, although it is non-experimental, it is based in the clinical setting and mirrors real life. It may therefore have good generalizability because it adequately reflects the interaction between patient, therapist and setting that takes place in real life as there are no restrictions on the content and number of treatments.

A potential limitation is that the subjects were recruited when consulting a chiropractor for their LBP, and were thus self-selected. Self-selection seems to be linked with treatment satisfaction [46], and may introduce bias and limit the generalizability of the findings.

To limit the burden on the participating clinicians, no record of non-included patients was kept, which is a limitation of these studies. If certain groups of patients were not included systematically, this may introduce bias in the samples. Also, to make the study procedures as uncomplicated as possible for the clinicians, questionnaires were kept at a minimum. In hindsight, questions regarding anxiety, depression, fear avoidance behaviour, coping or pain catastrophizing could have added valuable information in the identification of clinically relevant subgroups.

### *Measuring LBP with frequent text messages*

Several aspects of this method of data collection can be viewed as strengths as modern technology in data collection has the potential of overcoming several of the problems encountered in traditional data collection methods. By using a medium accessible to a large majority of the target population - the mobile phone- reach is guaranteed. Moreover, it seems that most people carry their phone with them at all times, so they can be contacted even at weekends, while travelling and on holidays. This also means that the data collection takes place in the subjects' natural environment, in their leisure time as well as at work, and while performing tasks that influence the variable studied. Therefore, context-bound measures, such as pain, may thus be deemed more valid compared to measures done at a research facility, as pain normally fluctuates during the day, the week and according to activity adaptation. This is termed ecological assessment [82], and allows generalization to the respondents' real life.

A limitation of the method may be that the participating subjects were required to be able to use the text function of their phone. In the latest individual survey of the Swedish population [89], only 7 % replied that they never used the text message function. On the other hand, 38% of teenagers send more than 20 text messages per day. Possibly, this new method appeals to young individuals, which we consider a strength, as it could minimise the bias of certain subject categories dropping out. One may assume that knowledge of texting is not a limitation in a few years' time in a working population.

An obvious limitation of this data collection method is that the questions have to be short to fit the limitations of a text message in terms of number of characters. Thus, the question has to be comprehensible as there is no room for explanatory text. A short and extensively tested concept was purposely chosen: bothersomeness, which seems to have been well received in this population. Possibly, compliance would have been poorer had the question been difficult to interpret.

The high overall response rate of this method must be considered a strength: 82.5%. This is high considering the task of answering weekly text messages for six months. In a Danish study monitoring asthma symptoms, subjects were required to text three messages every day for two months, and the response rates was 69% [91]. Further, in a Malaysian study on subjects with irritable bowel syndrome, weekly symptom reports were collected with text messages for 2 months with a 100% response rate [136]. However, in the latter study, the respondents were reminded by telephone calls and even personal contact, which is not practical when studying large populations. In a Danish study [56] no reminders were sent, and the response rate was similar to the asthma study mentioned above, 63%. In the Swedish prospective longitudinal study, subjects were called when they missed three responses in a row, which, in comparison, boosted the response rate by nearly 20%. Thus, some reminders seems necessary to ensure response rates above 60- 70%.

### *Clusters*

A limitation of the clustering procedure is that four individuals were removed from the cluster analysis because they had a constant response throughout and could therefore not be fitted with regression lines. These could be considered a cluster of their own, but were found to be heterogeneous in terms of course (two individuals answering “0” all the time, and two individuals answering “7” throughout), as well as in terms of baseline variables. Thus, these individuals are deemed atypical and removed from further analysis. Possibly, in a larger sample, further inferences can be made about subjects with a constant response.

In addition, another seven subjects’ clinical course could not be matched with any other course in the initial step of the hierarchal cluster analysis. Again, this could simply mean that they were outliers, and that they should be removed from further analysis, as was done in this case. Again, it is possible that a larger sample could have provided additional individuals that would match these subjects’ courses. However, as our sample was found to be similar to other primary care populations, such additional clusters are unlikely to represent any large proportion of patients with LBP.

In the cluster analysis, only responders labelled “high compliers” were included. As the cluster parameters were based on regression lines, this was necessary to secure solid estimates. We concluded that if a respondent had answered, for instance, 10/26 weeks, the resulting regression lines would not necessarily represent the actual clinical course of that subject, and any inference made on such information would be speculative. Thus, the described exclusion strengthened the formation of solid clusters. However, this could also be viewed as a limitation, as the course of the high compliers differed

somewhat from that of the poor compliers. This inclusion choice may have resulted in bias as one might speculate that the inclusion of the poor compliers might have resulted in clusters with a less favourable outcome.

The clusters were found to be associated with some clinical variables, age, gender, previous duration and self-rated health. However, very few clinical variables were gathered at baseline, limiting the inference about clinical meaningfulness of the clusters.

#### *Predictors of LBP*

The use of outcomes based on frequently measured data indicates that the prediction of future LBP is rather complicated. As all the examined variables were found to interact with time in the multivariate analysis, this suggests that the chosen follow-up time is crucial for the study of prediction. However, it may be necessary to study other predictive variables and to do so over time with frequent measurements, to get a full picture of if and how LBP can be predicted.

#### *Indications for MC*

The chiropractors in the preliminary focus groups were anonymous in that no record was kept as to who participated. Therefore these chiropractors cannot be checked for diversity or representativeness, which is a limitation.

Nevertheless, in the questionnaire survey, the chiropractors could write their name should they wish to do so. The majority (71%) recorded their names, and could be checked in the SCA register against the full body of SCA members for representativeness regarding age, gender and years in practice. Thus, a majority of the chiropractors that completed the questionnaire were found to be representative of the SCA in these aspects.

No sound or image recordings were taken during the discussions. Thus, the data gathered depends solely on the written key words. Had sound recordings been available, further factors may possibly have emerged.

Further, one might be concerned that the group moderators would add bias to the discussions as they were all involved in the design of the study. The fact that the participating groups all suggested numerous other elements of importance besides the hypothesised indications, suggests that preconceived ideas of the research group did not influence the discussions to any large degree.

A limitation of the survey was using a line to mark the importance of an item as the reliability testing became rather difficult. A later study exploring patient reported outcomes [137] used an NRS scale to rate the importance of the items using the same anchors as in our study, “not at all important” and “extremely important”, and then simply calculated the mean score. In that article, there was no discussion about the appropriateness of rating importance this way, and no retest was performed. Considering the nature of the measure, it is not surprising that the reproducibility scores were in the 60- 70% range. It is not a detailed and accurate value (such as blood

pressure), but rather an opinion. Naturally, this is not an exact science, even if one would expect such opinions to be relatively stable over time. Therefore, we the results are considered to be acceptable.

## **6: RESEARCH PERSPECTIVES**

The method of gathering data via text messages is recommended for future use in clinical research, specifically in fluctuating conditions and in disease monitoring. What still remains to be studied, is the optimal time between measurements, which could differ between conditions.

Future studies should replicate and explore the identified clusters further. A similar approach, clustering on the basis of clinical course, should be performed in larger populations and both in populations from the primary and secondary sector to see if the clusters can be reproduced and to search for yet other ones. Further, psychosocial data should be collected to see if such variables would add clinical distinction to the clusters. It is, of course, likely that more subgroups exist and that earlier identification is feasible based on demographic, health or psychological variables.

Different potential predictor variables should also be tested using an outcome based on frequently measured data to further illuminate the prediction of future LBP.

Ultimately, different treatment strategies could be tested for each of the subgroups. This may eventually lead to optimal treatment for the individual. From a societal perspective, this is in the interest of cost optimisation.

The identified indications for MC may be used in future studies as inclusion criteria when examining the content and the effect of such strategies. Adding the clinical experience gathered in these recommendations to the information concerning pain course described in the identified clusters could result in recruiting patients who are most appropriate for this treatment.

## 7: CONCLUSIONS

The work in this thesis has scrutinised a new method of gathering repeated data, text messages using mobile phones. It has been found to be promising and will probably be extensively used in the future as many restrictions of common data collection tools are negated. Further, it opens up new possibilities in the research area of clinical course, incidence and disease monitoring.

Data analysis of repeated data is challenging because of within subject correlation and missing data. Depending on the research question and the available data, suitable methods exist and are illustrated herein, to accommodate these difficulties. This may serve as a reference for later studies.

Four clusters could be identified based on the clinical course of non-specific LBP in a patient population in the primary care sector. The clusters each have a unique clinical course and distinguishing clinical characteristics.

The use of outcomes based on frequently measured data indicates that predicting future LBP seems to be rather complex. Long previous duration of the LBP condition is consistently predicting future LBP.

Finally, the indications for preventive treatment of non-persistent LBP have been identified from clinicians' experiences. Secondary preventive care is recommended for patients with recurrent LBP based on previous LBP episodes, and tertiary care is recommended for patients with LBP if the initial care is deemed successful.

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## **APPENDIX 1**

### **HOW TO CONDUCT A PRACTICE-BASED PROJECT AMONG CHIROPRACTORS.**

Iben Axén and Charlotte Leboeuf-Yde

#### **INTRODUCTION**

Over the past 15 years, a number of practise-based research projects have been performed among chiropractors in the Nordic countries in which data on patients have been collected using questionnaires [1-12]. Some of these studies are summarized in “Table for Appendix 1”. In addition, an international study has been carried out [13].

The successful completion of these projects depended on the participation of four groups of people: 1) the professional researchers, 2) the project group members, 3) the data collecting chiropractors, and 4) the patients.

The professional researcher(s) is/are responsible for the methodological aspects of the study, data analysis and the final report. The project group together with the researcher(s) assists both in the conceptual stages and the data collection. It may also be active during analysis and report preparation. The data collecting chiropractors are responsible for the data collection. The patients provide the data needed for the study.

Over the years, we have developed methods to optimize the involvement of all these participants. The purpose of this report is to describe our work in detail. In other words, it can be considered a manual in practice-based research for chiropractors. We explain the importance of having a dedicated project group which is responsible for personal contacts with the data collecting clinicians, how this group should be selected and instructed and how this group should organize the execution of the study. We also provide instructions for dealing with the data collecting practitioners and how these should collect data from their patients. Finally, we describe how the work after data collection could proceed.

We believe that this method can be used to recruit and encourage chiropractors to participate in practise based research in other countries as well, even though it might be necessary to adapt somewhat to different cultural settings. It is likely that this procedure can be applied also to other professional groups.

## **THE PEOPLE INVOLVED**

### **1.1 Researchers.**

One or several researchers may recruit collaborators for a study of a predetermined topic, or a group of clinicians with an interesting research question may enlist the assistance of a qualified researcher (or several).

The researcher will act as the intellectual anchor of the project, the guarantor of the quality of method and the final report. If several researchers are involved in the project, it would be preferable to make use of people with different areas of expertise (knowledge of the literature, methodological experience or statistical expertise, for example).

### **1.2 Research leader.**

A research leader should be formally appointed in the early planning stages of a research project. This person should be a competent researcher and be familiar with the topic at hand. Usually, this is the person with the research idea, the one who “owns” the project, i.e. he/she is intellectually responsible for the research project.

The research leader has the final say on each stage of the research process and must keep a close eye on people, process and progress. This person must be easily available to deal with urgent issues arising during the study process.

### **2.1 Project group.**

Clinical research should be clinically relevant. In order to avoid esoteric “it-would-be-nice-to-know”-projects, the participation of astute clinically active practitioners is primordial. Because practice-based research relies extensively on the assistance of data collecting practitioners it is only possible to enlist their help if the research project they shall help with feels clinically relevant to them.

A project group consisting of clinicians should therefore be formed to help with the research project, both in the planning and the data collection stages. If the project group is also included in the data analysis, or at least in the data interpretation, and has a say in the manuscript phase, an added benefit is that their participation will enlighten them on the rigours of research and make them knowledgeable in this particular research area.

A dedicated and active project group is of great help in the data collection stage, as its members can improve compliance among the data collecting clinicians, as further described below. Their participation also helps improve the quality of data by minimizing errors in procedures and the handling of questionnaires. Another advantage is that if several people donate their time, the onus of the work can be divided between several persons, which will reduce the need for funding.

The participants in the project group need not be qualified in terms of research competence, but being clinicians they will provide many invaluable viewpoints when preparing a study in a clinical setting. In fact, if the research leader is not a clinician, such clinical input is vital for the successful completion of the project. Clinicians can foresee practical issues regarding time expenditure, delegation of tasks to receptionists, willingness of colleagues to donate the necessary time and suchlike.

Only truly dedicated clinicians should be recruited as project group members. Participation should be voluntary and based on a wish to do practise based research and to search for answers to clinically important questions. A letter from the research leader explaining the need for practise-based research and asking those interested to get in touch is a good way to start out but head-hunting may be a better alternative.

An introductory meeting will make it clear who would be willing to dedicate the necessary time and effort, and the first project group can be formed. "Interested" people who cannot make it to such introduction meetings should not be included in the group, as their first difficulty in participation often is indicative of their future level of involvement.

If several projects will follow, recruitment can probably take place by word of mouth. Project group participants may vary over time with the varied requirements of life. Obviously, it is an advantage if the good co-workers stay on in the group as people who are involved in several projects in this manner get proficient, making work in the project group increasingly smooth and effective.

It should be pointed out that practice-based projects can, of course, be carried out without the help of an active project group. This does, however, require that the researcher who is responsible for the recruitment and continued follow-up of the data collecting practitioners will have to work more or less full time over extended periods. This is probably possible only during a Ph.D. project or for a full-time employed researcher.

It is also possible to set up specific research clinics, whose clinicians will receive training in the data collection process and who enter into a contractual position with a researcher or a research institution, with or without financial compensation for their data collection activities. Obviously, if a formal "employment" exists, the situation is different and this manual will not be relevant for such a set up.

## 2.2 Project officer.

The research leader may not necessarily live or work locally, close to the participants of the study. If not, it is necessary to appoint a project officer from within the project group. This is the person who is responsible for the logistics of the study and the only person within the project group who communicates directly with the research leader and the person who ensures communication within the group.

This person must be particularly dedicated to the project, completely trustworthy, and very methodical in his/her approach to the task at hand. He/she must be respected and liked by most colleagues; kind, courteous and positive, yet firm.

If funding is available, this person should receive remuneration for some or all of his/her work, as it is quite time consuming and will sometimes have to take place during clinic hours, which will result in a loss of income.

### 3. Data collecting participants.

In practice-based studies, it is important to collect data from clinicians who are typical for their professional group. It is therefore important to make such “ordinary” clinicians interested in the project. Most clinicians are interested in the future of their profession, and many will agree to participate. In our studies, these clinicians will then be asked to collect standardized information from a number of patients who fulfil some specific inclusion criteria. The number of clinicians needed will depend on the number of patients needed. This in turn depends on the study design. Our experience is that most clinicians will be willing and able to collect data on 10 patients, if the patient category is one frequently seen. If also no follow-up data are required (i.e. data is only collected at one point in time), more patients per clinician can be included (e.g. 20), as the logistics for the individual clinic is easier in such studies. However, the longer time the data collection will take for each patient and the more complicated the inclusion and/or the follow-up procedure, the more difficult it will be to obtain the collaboration from already busy practitioners.

A high participation rate and valid data are key components of a successful data collection. To achieve this, it will be necessary to explain the purpose of the study in such a way that the potential participants will become truly curious about the results. In other words, it is relevant that they understand that the project is about finding answers that will make their clinical work easier but that it is not about proving a preconceived idea.

There are several different ways of recruiting data collecting participants. Clinicians interested in research can sign up for participation, for instance after information is given about the project at a general assembly or professional meeting. A letter or an e-mail can be sent out to all the members of an association explaining the study aims and method, inviting those interested to sign up. Information must be short and to-the-point, including the purpose of the study, the potential benefits of the study, the tasks included for the participants, the number of patients needed and the time (number of minutes) that data collection will take per patient. This letter should be signed by the research leader and project officer, with contact addresses and telephone numbers. Recruitment can also be done by calling all the members of a target group personally and asking them if they are willing to participate, possibly after an explanatory letter has been sent out. If such calls are made, the logistics of the study can be explained during this phone conversation. If the clinicians are asked to make contact to enquire more about the study, more detailed information can be provided at that point.

In clinics with a receptionist, the success of the data collection often depends on the involvement of the receptionist. Therefore, when the initial accept has been given by the chiropractor, the receptionist should usually be the contact person.

In order to obtain a representative sample of clinicians, it is important to give all individuals the opportunity to participate in the study. In reality, however, it will probably be necessary to make do with the more dedicated members of the profession. Regardless whether you attempt to recruit all registered chiropractors, all members of an association, participants at a political meeting, participants at an academic meeting or specially selected chiropractors only, it is unlikely that the data collecting chiropractors will be completely representative of the underlying chiropractic population. It is more likely that there will be a bias towards the more academically inclined, those with a firm “belief”, those with an interest in research, and those who feel that they have the time to participate in the project. Only by collecting obligatory register data would it be possible to obtain a perfectly representative group of chiropractors.

There is usually no way of knowing whether this selection of clinicians will have an effect on the ultimate selection of patients, treatment and outcomes. Therefore, it is useful to obtain some demographic information on the data collecting chiropractors in relation to known factors that can be held up against the whole population of chiropractors. The national chiropractic association or registration board may have some demographic data that can be used for such purposes, such as age, sex, area of practice, school of graduation and years in practice.

#### 4. Patients.

The patients involved in a research project should, of course also be representative of the patients normally seen in a clinical setting. To avoid selection bias, it is important that the patients are enrolled consecutively in the study according to the inclusion criteria. During busy periods in the clinic and prior to major holidays, it is common that suitable patients are not invited into the study. This can be helped by selecting certain days or time of the day, when recruitment should take place, allowing for some time to catch up, in case the inclusion procedure delays the usual clinic procedures somewhat. Ideally, a record should be kept of all patients who are suitable for participation in the study and for all who were invited but declined participation. However, for practical reasons, this will probably not be feasible (as clinicians are busy). Therefore, it is primordial that clinicians are thoroughly informed of the importance of not selecting patients for inclusion in the study for some specific reason of their own but to let chance play the major role.

Patients should receive information about the study, both verbally and in writing, and that they sign informed consent forms. This, of course, may make participation less attractive for patients who are in a hurry to get out to the parking metre or back to work. Hopefully, this should not bias the study in such a way as to have an effect of the results.

## PLANNING THE STUDY

### 1. Meetings.

The project group should meet with the research leader on several occasions to plan the study. These preparatory meetings could start with discussions of the problem at hand. Clinicians are often naive about the lack of documentation for their clinical activities.

At such a meeting, it might therefore be necessary to give an overview of the clinical problem and the lack of or conflicting evidence that exists, and the need for more or better knowledge could be pointed out. The study aims and objectives and the appropriate design and detailed method will then gradually take form. The research leader provides the formal competence, whereas the project group has the knowledge needed for the practical considerations. Together, the group should be able to design a study that is relevant, methodologically sound and practically possible to perform. In addition, this process makes all the group members able to understand the study and defend the method chosen at all stages of the study process. When the preparation phase is over, the whole group should feel that it is "their" project and that the best possible study is being carried out to answer the research question at hand.

It is important that these meetings are conducted in a pleasant environment and during joyful conditions. A positive social experience will make it easier for the project group to conduct the study.

### 2. Designing and using questionnaires.

During the process of planning, it will become apparent what information needs to be collected. If validated questionnaires exist, which is not always the case, it is preferable to use these. The research leader should provide advice on the available questionnaires, their validity, use and previous results. If need be, questionnaires can be designed by the project group.

Our experience with questionnaires is that if data are to be collected during the normal clinical encounter they should be short to enhance compliance. The easiest questionnaires have short and to-the-point questions with yes/no boxes to tick. It is easier to ask clinicians to collect information normally ascertained in the clinical setting than data not included in a standard consultation.

If possible, all information regarding one patient should be filled in on one piece of paper. Sometimes several questionnaires are needed (for example, one for the patient to fill in, two for the chiropractor; at baseline and for follow up). In that case, these should be of different colours. It is easy to refer to the "blue" rather than the "inclusion" questionnaire when communicating with data collecting clinicians.

Patients' anonymity must be retained at all times also for follow-up studies or whenever multiple questionnaires are required. If information is needed from one clinical occasion only, usually no patient identification is required, but if data are collected at several occasions, the clinician must be able to identify the patient on the questionnaire whilst data are collected, in order for the data to be correctly recorded for the "right" patient. In that case, we recommend that the patient's last name and initial is

written at the top or bottom of the questionnaire, at a dedicated space, to be cut off from the paper and destroyed when the data collection is complete.

When follow-up data are needed or when several questionnaires are used, it is necessary to code the questionnaires. We have used a set of three codes: one for the project group chiropractor, one for the data collecting chiropractor, and one for the patient. E.g. 010101 means project group chiropractor number 01, data collecting chiropractor number 01 and his patient number 01. Similarly, 020310 means project group chiropractor number 02, his data collecting chiropractor number 03 and 10 denotes the number 10 patient.

We keep the cost and effort for the data collecting clinicians to a minimum by providing them with a set of stamped and addressed return envelopes. If the patient has to fill in some information themselves, maybe confidential even to their treating chiropractor, they should be provided with an individual envelope also.

In order to have a good return rate on questionnaires filled out by chiropractors in relation to their patients, we have found that completing the questionnaires “in real time” (i.e. when the patient is in the clinic) is preferable. Questionnaires that patients are asked to fill in themselves should also be done whilst in the clinic. Otherwise, the patient may forget, mislay the questionnaire, or forget to return it to the clinic. For logistic and ethical reasons, all questionnaires should be coded (at least in relation to the data collecting chiropractor) at, sent out from, and returned to the “research centre” to be handled by the project officer. This procedure minimizes errors, as all questionnaires are packed and coded the same way. The project group can assist in the packing of questionnaires and addressing envelopes. Only the project officer should have access to the “key” of codes, to ensure anonymity of the data collecting chiropractors and patients. When the project group gathers to analyse the data, no names of colleagues or patients should be available. And if, for some reason, the identity of a particular respondent becomes apparent, it must be explained to and imposed on the project group that this is highly confidential. The researchers must of course lead the way by being perfect role models in this respect.

### 3. Ethical approval and considerations.

All experimental research regarding human beings (and some other forms of data collection) need approval from a regional ethics committee. Normally, if no experimental treatment is carried out, the study will be regarded as a quality assurance project and the ethics committee will return the application with this comment or no application may even be necessary. However, the rules differ from country to country and can also vary over time. It will therefore be necessary to make enquiries as to whether an approval is needed. If a computerized data file is created in which individuals can be identified, it is likely that a permit is needed also for this (data protection).

Whenever individuals can be identified, for example on questionnaires, or if questionnaires are anonymous but there is a list of names that can be related to the individual questionnaires, it is important that such information is kept safely locked up



and that lists of names and corresponding codes not be kept together with the coded questionnaires.

It is a useful experience for the project group members to write an ethics application. It provides an opportunity to consider the ethical aspects of the study; the routines of using codes instead of names, the integrity of the patients and the safe storage of the data collected.

#### 4. Pilot studies.

If necessary, the project group can assist in the pilot testing of questionnaires and study routines in the clinical setting, i.e. in their own clinics. At a later stage, it is essential for the members of this group to be able to answer questions from the data collecting clinicians regarding patients' opinions, receptionists' tasks and time spent on the study procedures. The data collecting clinicians will need information regarding time requirement before agreeing to participate so this aspect is particularly important to settle before starting the main study.

When a new procedure or questionnaire is to be introduced, a pilot study in the clinical setting will provide the necessary measures of face validity and interpretability, and relevant changes can be made before the study commences. Pilot studies can also provide information on the feasibility of the targeted patient category, i.e. if it is common or not. This will decide the length of the enrolment of patients in the study. Generally, we advise against collecting data on rare patient categories, as this takes too long and exhausts both project group members and clinicians.

Based on the results of the pilot study, data collection time can be estimated. However, it is a good idea to provide for more time than expected, according to pilot study results. Always estimate data collection time by at least twice the calculated time.

Various things will work against your study; clinicians go on holidays, their receptionist gets ill, their colleague quits and leaves, that particular patient type suddenly becomes rare. We also recommend that you never start a data collection period in the beginning of summer, when both clinicians and patients will soon go on holidays. Remember that Christmas, Easter and other holidays have a tendency to disrupt routines.

#### 5. Workshops.

The project group should prepare for the recruitment of data collecting clinicians and for helping them through the data collection period. This is done through targeted telephone calls. These contacts require some skills beyond that of an ordinary telephone call. Therefore the project group members should practice the phone calls illustrated in the appendices with another member of the group (role play). All possible "excuse"-scenarios should be tried and all possible encouraging comments should be invented and written down. This exercise will take a couple of hours and should be done with several rotations, i.e. each member of the group gets to train with several others, until the subject is exhausted.

## **THE DATA COLLECTING CHIROPRACTORS**

### **1. Telephone lists.**

Each project group member can be assigned 8-12 participating clinicians as “theirs”. The assigning is best done when the whole group is together at a planning session. If possible (easily done in a small association), friends can be assigned to each group member. This will make participation harder to refuse. People are much less willing to make up excuses when talking to a friend. Similarly, “enemies” should be avoided on anybody’s list.

Each member of the project group will be responsible for making regular calls to “their” data collecting chiropractors. Thus, the same project group member will always call the same data collecting chiropractors unless otherwise decided in conjunction with the research leader.

We suggest making telephone lists in Excel or on a similar paper version, with dates/weeks written in, so it is easy to keep track of who was called when and what the outcome of the call was.

### **2. Telephone calls and why they are important to ensure compliance.**

At every new step in the data collection, human inertia is likely to work against your project. The steps participating clinicians must go through are as follows:

- A. Opening the envelope with your information material.
- B. Having opened the envelope, actually reading it.
- C. Having read it, also having understood it and considered the implications in the clinic.
- D. Starting with the first case.
- E. Continuing with the rest of the cases.
- F. Returning the questionnaires.

The members of the project group will have to work diligently to overcome these obstacles on the way. This is done with systematic and frequent telephone calls. These phone calls follow a special “program” explained in detail in this manual and described in the appendices. Each of the obstacles of data collection should be addressed in an explanatory phone call.

Different types of clinicians will have to be treated differently. Basically, there are three types of data collecting clinicians, in relation to understanding the purpose and process of the study: Those who understand directly, those who understand after some extra explanations, and those who understand only after detailed information.

In relation to performance, there are four different types of participants: A small group who will do what they should do without any problems, a rather large group consisting of those who do what they should do after some prodding and/or with some delay; a somewhat smaller group which needs a lot of encouragement; and a small group

consisting of those who fail to perform either in silence or despite many vivid assurances of active participation. Obviously, the phone calls need to be targeted to these different types, otherwise the minority group of non-performers can grow into a very large group indeed.

The calls should all be friendly, enthusiastic, patient, encouraging and professional. Each telephone conversation must be targeted to deal with the specific hurdle at hand. There is therefore no point in simply phoning the participants up and asking how they are getting on, in a non-specific manner, as the answer invariably will be “good”. Then, as it becomes apparent to the participant that he is not performing, he will stop answering the phone calls and become inaccessible both by phone and e-mail.

## **TELEPHONE CALLS**

### **1. General points.**

The calls should be noted in the Excel sheet as: participating yes/no, next to the date called and the response to the call. If the person called is participating in the study, the date and time for the next scheduled telephone call should be noted. Similarly, all continued telephone encounters should be noted, until data have been successfully returned or the data collecting chiropractor has quit the study. Obviously, it is vital that all “appointments” for future calls are honoured. Any obstacles and the need for a new call in relation to each hurdle should be noted.

### **2. Recruitment calls.**

Each potential participating clinician should be approached by one of the project group members in an introductory recruitment call, approximately 1 month before the study starts. The call should be outlined as described in Appendix 1:1.

### **3. Complete telephone list.**

After this first round of telephone calls, there should be a list of who were contacted, of those refusing, those not reached and those agreeing to participate, and the project group member to whom they are assigned. Each project group member should receive a list of “their” data collecting chiropractors and the research leader should have the complete list of participants.

## **DURING THE STUDY**

### **1. First support call; responding to the hurdles: *have you received the material, opened the letter and read it?***

One week before the study starts, all participating clinicians are contacted again by their contact person. The call is described in Appendix 1:2.

If the clinician did not yet open the envelope, this call has to be repeated, preferably daily, until he/she does. If the clinician has opened the envelope, but has not looked at the material, this part of the conversation should be repeated in the same manner. Most chiropractors are not making this a priority in their daily practice, and therefore it is not uncommon that they have to be called several times. All calls should be noted for future reference.

2. Following support calls; responding to the hurdles: *have you understood the study, have you started, are you proceeding?*

The following two or three (or as many as it takes!) weeks, each participant should be called to make sure they are proceeding as planned. If not, the call described in Appendix 1: 2 is repeated. The important thing is to always call the clinicians back. It is fairly easy to ignore an e-mail or a letter, but a phone call (in particular from a friend) is difficult to ignore. The conversation will now concentrate on the data collection phase as described in Appendix 1:3.

It is, of course, everybody's right to withdraw from an engagement such as this. No negative feelings should be placed on those who do; all you can say is that you are sorry. Further; some people are procrastinators, they postpone and provide all sorts of excuses. You need to be prepared and persevere with your calls. Sadly, you will notice that some promise a lot more than they deliver.

3. Closing calls; responding to the hurdles: *have you finished and sent the questionnaires back to us?*

At the end of the data collection period, the participating clinicians should be reminded to collect data for the remaining patients and when this is done to send in the questionnaires. Some clinicians will not achieve the full number of patients and will have to return whatever data they have achieved at a specific deadline. This phone call is outlined in Appendix 1:4.

4. Reporting and feedback.

The project officer should obtain reports from all the project group members on a regular basis, at least every week. We recommend establishing a record also of this, and since this is quite time consuming, it is a good idea to exempt the project officer from being a contact person for data collecting clinicians.

Based on the feedback information from each group member, the project officer can provide feedback on the study progress to the entire group. Further, the project officer should keep track of patients recruited to the study by means of questionnaires/informed consent-forms coming in to the research centre. This will tell whether the data collecting clinicians are performing as planned. This feedback should then be forwarded to the responsible project group member, so he knows how successful his "team" is. In the case of non-performance by one (or several) data

collecting chiropractors, the project officer is responsible for discussing this with the project group member, who is responsible for the failing data collector.

As soon as it becomes obvious that a data collecting clinician does not get started, despite the relevant encouraging calls, the project officer should be informed and the case discussed. Possibly, such a participant should be removed from the list. This requires a personal contact. Of course, the failing data collector should be told this in an unemotional manner. For example: “Judging by the number of patients you have enrolled in the study, it looks like you have a busy schedule or that you may not see the right patient type for this project at the moment. This may not be the best time for you to participate in a study like this. What do you say, is it better to remove you from our list?”

## **ANALYSIS AND REPORT PREPARATION**

### **1. Initial data inspection.**

The project group should meet with the research leader for a first inspection of the data. All the raw data should be available to the group, literally to the touch. Together, the group can count the number of questionnaires received, and complete the first data cleaning; i.e. decide which questionnaires are too incomplete to be included. These decisions should be written down for future reference and for the final report/research article.

### **2. Summative and descriptive analysis.**

If feasible (up to around 1000 included patients), data can be entered onto a large spreadsheet by hand. Each pair of project group members gets a batch of questionnaires, and is made responsible for summing up one variable at a time, each in the pair checking the quality of the data entry and counts. The estimate count for each variable obtained by this pair is then reported to an appointed “writer” for example on a board for all to see; the number of positives, negatives and missing. In this way, all the data is added up into one final estimate. This is suitable for all descriptive data and can be done also for some simple cross-tabulations. The method provides a feel for the data not otherwise provided in a computer entered equivalent. Further, the members of the project group get to see all the errors possible when filling out a questionnaire, useful knowledge for future projects. These errors should also be noted for reference when designing questionnaires in future studies.

### **3. Computerized statistical analysis.**

Obviously, when the object of the study is to investigate associations or interactions between variables, statistical computer software needs to be used. In such a case, data can be entered by one or several members of the groups with the usual quality assurance methods (double data entry or random checks). The statistical methods can be explained to the group by the research leader or a statistician, in such a way that they understand why they are used and, in particular, how the results are interpreted.

#### 4. Data interpretation.

The results of the analysis should then be presented to the project group, and be the basis for discussions within the group. Are the results as expected? Why or why not? What are the clinical implications? Are any further analyses suitable? These discussions are the base for the final report or research article. It is important to include the project group at this stage, as this is when the fun starts. This is their moment of reward, after all the hard work and tedious phone calls.

#### 5. Writing the research report.

The project group should, after the interpretation of the results, design the crude outline of the scientific study report. Aided by the research leader, the group can decide the outline of the background, methodology, results and discussion sections. Examples from good and bad research reports can be used to make this easier. The project group can also divide the report between them, some members writing the method section, some the results, and some the discussion. The research leader or project officer will ultimately have the responsibility of putting the fragments together and writing the complete manuscript, after which the project group should proofread and comment. Their active participation during this stage will make the final report less technical and more easily understood by ordinary clinicians. This is important, because unless the research article is easily accessible to clinicians, the information it contains will not be included in their conceptual world and useful information will not become generally implemented.

### **MANAGEMENT**

#### 1. Project group.

In the beginning, it might be a good idea to include more participants in the project group than needed, as it is not uncommon that in a group of 5-8, one or two will drop out when they realize that research requires consistency and tedious tasks. Persons with the best personalities to do this type of work are those who are conscientious and socially gifted. It is always a good idea to include in the group at least one realistically critical person, who finds the weak points in the study design and in the data collection process. It is also helpful to have access to somebody who is interested in computer layout, for the successful design of questionnaires.

Individuals less well suited for this work are those who find it difficult to work together in a team and to conform. Luckily, they will soon single themselves out by their constant need to express contrary opinions. Such individuals are more comfortable working on their own and should not be convinced to stay on in the project when they start gliding out.

Sometimes one or several members of the project group do not perform according to the protocol during the crucial data collecting phase. This can take one of two forms: Phone calls are not made or phone calls are not made according to the agreed procedure. This will become apparent early in the process from the lower response rate from "their" data collection practitioners. When the project officer notices such an

anomaly, it will be necessary to ask tactfully if one (or several) data collecting clinician presents a problem. In that case, it might be best to move this/these participants on to another member of the project group, who might be more successful in establishing a positive contact. It will sometimes be necessary for the project officer to take over the task of managing some or all of these data collecting chiropractors, as otherwise the whole study is jeopardized.

If however, the problem seems to lay with the project group member, the project has a problem. Either the failing group member must be made to understand that the agreed upon procedure must be followed or asked to leave the group. If this is difficult, then at least, ensure that this person is not enrolled for your next study. In the meantime the project officer must take over all or some of the failing group member's tasks.

## 2. Data collecting participants.

During recruitment, we suggest that people who are systematically difficult to reach are left out of the study, as they will continue to be unavailable throughout the whole study period and therefore, usually will be non-compliant.

Obviously, there are those who are less suitable participants than others, which needs to be ascertained during the recruitment phone call outlined in Appendix 1:1. Newly graduated chiropractors who are starting up their own clinic may not have enough patients to be able to provide the required number of study subjects. Extremely busy practitioners will not be able to carry through with their commitment, because their practice procedures usually do not allow for any flexibility.

The odd person will want to change the study protocol, and if the comments are relevant should be listened to and perhaps invited to participate in the project group. However, if the comments are uninformed and the person obviously does not trust the research leader's competence, he or she should be excluded from the data collection group, if sabotage of data seems likely

## **FEEDBACK**

### 1. Project group.

The project group will be familiar with the results of the study through the discussions of the results and the final manuscript/ publication. The final discussions should also include the issue of clinical applicability and the next possible steps forward. We have found that many times the wrap up of one study is the start of the next. The project group members' formal reward for participating is that they get their name on a scientific publication. However, the experience of doing practise based research and finding the answers to clinically relevant questions is rewarding in itself and can be a source of great joy for the group members.

## 2. Data collecting participants.

Making the results of the study known to the clinicians involved in the data collection is important if their participation is wanted in future studies. In this matter, one cannot rely on clinicians reading the resulting scientific publication. We suggest that the report/ publication be sent directly to all who collected data, as well as to the members of their national association. One can include an explanatory letter (stating the results of the study in a couple of sentences) for those who are not interested in reading the full paper. Such a letter has double intentions. First the result should reach those who can implement it, i.e. the clinicians. Second, credit is given to those participating, both members of the project group and the data collecting chiropractors.

We also recommend that the research leader or project officer presents the results at a general assembly to alert all those affected by the findings. This is also an excellent opportunity to praise those donating their time and effort, and to try to awake an interest in others to participate in the next study.

To acknowledge the data collecting clinicians, after each study is completed we provide them with a diploma. This diploma reads: “The chiropractor in this clinic is contributing to making chiropractic treatment evidence based through active participation in research”. The reference of the ensuing publication could also be noted in the diploma text. The idea is that this diploma should hang in the involved clinics making patients aware that their chiropractor is involved in research. For some of our participating clinicians, the fact that they can put “participation in research” on their CV has been an advantage when applying for reimbursement plans through insurance and other funding schemes.

## 3. Scientific community.

Of course, the results of any study should be made known to the scientific community as a publication in a peer reviewed journal and as presentations at scientific conferences. In fact, it would be unethical not to do so.

## **ADVANTAGES**

### 1. The clinical perspective.

In completing the process outlined in this manual, the main purpose of the whole exercise, to obtain answers to a number of research questions, should have been achieved. In other words, we will have obtained knowledge of some clinically relevant issues that will benefit our patients.

The described procedure will enlighten the project group members as to the importance of rigours of protocol and the hard work of ensuring compliance among clinicians. Moreover, at the end of execution of a study like this, they will be knowledgeable in the methodology chosen, a valuable experience for any clinician expected to evaluate research as part of their everyday practise.



## 2. The research perspective.

Because of the involvement of several “ordinary” clinicians and patients, and because the study is taking place in the ordinary clinical setting, it is likely that the research conducted in this manner is not only relevant but also representative and generalizable. In a well conducted project you can expect the data to be trustworthy. When the various tasks are divided between many people, who are willing to donate their time to a good cause, the project will also have been cheap to conduct. The end result will, hopefully, be a clinically relevant and interesting publication, a stepping stone towards a better understanding of the clinical work carried out every day in ordinary practice.

## 3. Future projects.

When the study is completed, the project members will know which clinicians to contact for future studies (a convenience sample). Make a list of these! This will be a group of people who are interested in research, willing to donate the necessary time and effort, and who will be competent co-workers when you invite them in the future. They are compliant.

## REFERENCES, APPENDIX 1

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TABLE FOR APPENDIX 1: Some studies and the resulting compliance rates carried out using the herein described procedures.

Study title	Country	Year	Method	Number of included patients	Compliance, chiropractors	Compliance, patients
<b>Chiropractic in Sweden: a short description of patients and treatment.</b>	Sweden	1997	Cross-sectional	628	78%	73%
<b>The types and frequencies of improved nonmusculoskeletal symptoms reported after chiropractic spinal manipulative therapy.</b>	Sweden	1999	Cross-sectional	1504	81%	86%
<b>The Nordic back pain subpopulation program: demographic and clinical predictors for outcome in patients receiving chiropractic treatment for persistent low back pain.</b>	Norway	2004	Prospective outcome	875	56%	76%
<b>Can patient reactions to the first chiropractic treatment predict early favorable treatment outcome in persistent low back pain?</b>	Sweden	2002	Prospective outcome	615	74%	58%
<b>The Nordic back pain subpopulation program: can patient reactions to the first chiropractic treatment predict early favorable treatment outcome in nonpersistent low back pain?</b>	Sweden	2005	Prospective Outcome & predictive validity	674	86%	56%
<b>The Nordic Back Pain Subpopulation Program: validation and improvement of a predictive model for treatment outcome in patients with low back pain receiving chiropractic treatment.</b>	Sweden	2005	Prospective Outcome & predictive validity	1057	91%	61%

## APPENDIX 1:1

### **The recruitment call.**

- Hello, this is .....I am calling about a research project at .....Have you got a few minutes?
- No? I understand. When will be a good time to call you back?  
OR
- Yes? Great! I would like to briefly tell you about this project: I am working in a group lead by ...
- The aim of the study is....
- and we are going to collect data in the clinics throughout ....and we are starting in the month of .....
- What we would like your help with, is collecting data on 10 patients.....with.....
- It will take up ....minutes of your time per patient and
- you will have to fill in questionnaires regarding .... on the 1<sup>st</sup> and .....visit.
- Do you think that this is something you would like to participate in? Is it feasible, with your workload and clinical setting, that you will be able to collect data as outlined?
- No? That is completely OK, thanks for your time!  
OR
- Yes? Thank you, we will send you the necessary information and material, and I will get in touch with you during....in due time before the study starts.
- What time is usually the best to call you (day and time of day)?
- Here is my telephone number if you have any questions. I will be your contact person.
- OK then, thank you once again. I will be calling you on.....at..... Bye!

APPENDIX 1:2

**The first support call.**

- Have you received the material yet?
- No? I'll send you a new set!
- OR
- Yes? Good! Did you look at the material yet?
- No? I'll call tomorrow then, when you've had a chance to look through it.  
What will be a good time?
- OR
- Yes? Let's go through the study procedures and questionnaires:
  - The patients should have the symptom /diagnosis of...
  - They should be in the ages of...
  - They should be new patients or....
  - They should be able to understand the language of....
  - When the patient comes in, you fill in the yellow form. As you can see, the information we want is.....
  - On the first visit, the patient is also asked to fill in the green form, and put it in the enclosed envelope. We would like your receptionist to mail these to us on a daily basis.
  - Then, when the patient returns on the ...visit, you fill in the blue form..
- I'll call you next week to hear how you're getting along. Please don't hesitate to call me if you have any questions. Good luck!

## APPENDIX 1:3

### **Following support calls.**

- Did you start to collect data yet?
  - No? Do you have any questions? It is important to get started this week! Do you think you will get started tomorrow? Good, I'll call you tomorrow evening (or the decided day)...
- OR
- Yes? Excellent! How is it working out? Are targeted patients coming in? Do you have any questions regarding any of the questionnaires/ procedures?
  - Thank you for participating! Keep up the good work!

#### APPENDIX 1:4

##### **The closing calls.**

- Did you finish collecting data?
- No? I'll call you back next week to hear how you're getting on. It is important that you collect the final cases now, we need to finish up.  
OR
- Yes? Great! Now all you have to do is to put the questionnaires in the provided envelope and mail it to us. Thank you so much!  
OR
- No? Well, we have met the time limit for data collection, so I would like you to send in the data that you have collected. You just put the questionnaires in the provided envelope and mail it to us. Thank you so much!