

# Treating Spinal Pain

Behandelen van wervelkolom gerelateerde klachten

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Bohn  
Stafleu  
van Loghum

# Treating Spinal Pain

Behandelen van wervelkolom gerelateerde klachten

Proefschrift

ter verkrijging van de graad van doctor aan de  
Erasmus Universiteit Rotterdam  
op gezag van de  
rector magnificus

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en volgens besluit van het College voor Promoties.  
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## TABLE OF CONTENTS

Chapter 1;	General introduction .....	6
Chapter 2;	Patient nonadherence to guideline-recommended care in acute low back pain .....	18
Chapter 3;	Validity and reproducibility of the STarT Back Tool (Dutch version) in patients with low back pain in primary care settings .....	34
Chapter 4;	Validity and reproducibility of the modified STarT Back Tool (Dutch version) for patients with neck pain in primary care .....	58
Chapter 5;	Can primary care for back and/or neck pain in the Netherlands benefit from stratification for risk groups according to the STarT Back Tool-classification? .....	78
Chapter 6;	Clinical practice guideline for physiotherapy assessment and treatment in patients with non-specific neck pain .....	98
Chapter 7;	General discussion .....	120
Chapter 8;	Summary .....	136
	Samenvatting .....	142
Appendix;	Dankwoord .....	148
	Curriculum Vitae .....	152
	PhD Portfolio .....	154
	List of publication .....	156

# Chapter 1

## General introduction

## **GENERAL INTRODUCTION.**

Spinal pain is a major public health problem. The Global Burden of Disease Study from 2010 showed that globally, low back pain is the most prevalent musculoskeletal disorder causing disability and neck pain is the fourth most prevalent, out of 289 diseases and injuries.<sup>1</sup> A Dutch study in 2003 showed a self-reported point prevalence for low back pain of 27% and for neck pain of 21%.<sup>2</sup> The Dutch institute for health service research (NIVEL) found that in 2015 neck pain is the most prevalent disorder (10.2%) and low back pain the second (8.1%) disorder in Dutch physical therapy practice.<sup>3</sup> The NIVEL also found that in 2016 the prevalence of (non radiating) low back pain in Dutch general practitioners practice was 30.4 per 1000 patient years and for neck pain this was 20.8 per 1000 patient years.<sup>4</sup>

Both low back pain and neck pain are associated with financial burdens to society. In the Netherlands the costs for low back pain decreased from 4.2 billion euro in 1991 to 3.5 billion in 2002. This decrease is mainly attributed to lower indirect costs due to a change of policy in regards to sickness benefits and reintegration in the Netherlands.<sup>5</sup> The 2002 low back pain costs consisted of 385 to 455 million euro's in direct medical costs and between 3 and 3.1 billion euro's in indirect costs.<sup>5</sup> In 1996 the annual cost of neck pain in The Netherlands was estimated to be 668 million US dollars.<sup>6</sup> A study performed in the United States compared healthcare costs of patients with and without spinal pain in 1997 and then compared these with data from 2005. Spinal related problems were responsible for 9% health care costs in the United States. Results from this study showed a faster increase of health costs in patients with spinal pain.<sup>7</sup> It may be assumed that the Dutch healthcare costs are likely to have been increased since 1996.

### Low back pain

Low back pain is often classified as being either specific or non-specific. Specific low back pain refers to a specific objectively assessed condition or underlying pathology such as: tumors, fractures and infections. Nerve root compression as a result of a stenosis or herniated disc is often considered as a non-serious specific low back pain condition instead of a non-specific condition although the relation between herniated discs and low back pain is unclear.<sup>8,9</sup> This is enforced by studies showing a large proportion (36%) of people without back pain having signs of a herniated disk on a MRI.<sup>10</sup> The majority, over 85%, of patients with low back pain the condition is regarded non-specific, meaning there is no known underlying disease or pathology.<sup>11-13</sup>

Non-specific low back pain is regarded as being a self-limiting condition. Recovery usually occurs within a few weeks after the onset of pain.<sup>14,15</sup> Recent prognostic studies however showed that around 40% of patients with low back pain will take longer than 12 weeks to recover.<sup>13,16,17</sup>

### *Guidelines*

The Royal Dutch Society for Physical Therapy (KNGF) guideline for low back pain categorises patients based on the course of recovery, that is patients are considered to have either a normal or a deviant course of recovery. Deviant course of recovery is defined when over a period of three weeks there is no increase in activities or participation.<sup>14</sup> The course of recovery of the low back pain determines the treatment. In case of a normal recovery there seems to be no reason to provide physiotherapy treatments as the pain is likely to resolve.<sup>14</sup> When recovery is regarded deviant, factors responsible for this deviant course are identified and they can be either psychosocial or non-psychosocial. The American Physical Therapy Association (APTA) also recommends a classification system in their clinical guideline on low back pain but this classification system differs from the one proposed in the KNGF guideline. The APTA classification is based on the International Classification of Functioning, Disability, and Health (ICF). These include; a) acute or sub-acute low back pain with mobility deficits; b) acute, sub-acute, or chronic low back pain with movement coordination impairments; c) acute low back pain with related (referred) lower extremity pain; d) acute, sub-acute, or chronic low back pain with radiating pain; e) acute or sub-acute low back pain with related cognitive or affective tendencies, and f) chronic low back pain with related generalized pain.

The Dutch general practitioners guideline, as well as other international guidelines, includes three management components: (a) reassurance of patients that there is no serious cause for their back problem and the pain is likely to resolve rapidly, (b) simple analgesia to help control symptoms and (c) advice patients to stay active and avoid bed rest.<sup>18–20</sup> Unfortunately there is evidence that large proportions of general practitioners and physical therapist do not adhere to clinical practice guidelines.<sup>21–23</sup> When general practitioners do adhere to the guideline and the previous mentioned advice is given we hope patients to adhere to this advice because non-adherence could delay recovery and/or lead to higher health related costs. Knowledge on patients' non-adherence is often limited to medication. Therefore we need more insight in the non-adherence to the advice and insight in aspects related to the non-adherence. For example; can we predict which patients are likely to not adhere? This knowledge may help clinicians to improve these patients' compliance.

### *Prediction models*

Several tools are available to screen, or predict persisting low back pain. The most common is the Keele STarT Back Tool (Subgroups for Targeted Treatment) (SBT).<sup>24</sup> In 2008 the SBT was developed in the United Kingdom as a brief and user-friendly tool. A questionnaire consisting of nine items using treatment modifiable factors, such as function, psychosocial and comorbid factors for subgrouping. This tool aims not only to subgroup patients as low risk, medium risk, or high risk for persisting low back pain. The primary aim of the tool is to provide a targeted treatment for each



subgroup. The advised targeted treatment for the SBT is for all patients to receive information and advice; in addition, both “medium-” and “high-risk” patients receive standardized physiotherapy to address symptoms and function, and “high-risk” patients also receive psychologically informed physiotherapy to address the psychosocial obstacles to recovery.<sup>25</sup> The SBT approach shows great similarities with the general practitioners’ guideline with the difference that the general practitioners approach is a stepped care meaning that every step is taken in a timely fashion: the first step is that reassurance and/or advice is given, when this is insufficient the next step is taken; the patient is referred to a physiotherapist and so on. The SBT approach is a stratified care meaning that at the first consultation the appropriate therapy is determined.

The SBT has been translated in 2011 into Dutch and some practitioners in Dutch primary care have implemented it. No studies are done on the reliability and validity of the Dutch SBT. It is unknown if the tool can predict persisting disability in the Netherlands and if the tool is able to stratify patients between low, medium, and high risk. Due to the similarities between the SBT and the available guidelines it can be argued if we need a tool like the SBT. Maybe Dutch clinicians can provide the correct stratified care based on their own clinical experience or gut feeling.

### Neck pain

Globally, neck pain is the fourth largest musculoskeletal disorder causing disability.<sup>1</sup> The estimated one-year incidence of neck pain varies between 10.4 to 21.3%.<sup>26</sup> In patients with acute neck pain, pain and disability decrease in the first six weeks with approximately 45%, but little or no decrease in pain and function limitations can be found afterwards.<sup>27</sup> A Dutch cohort study found that after one year 76% of patients reported to be fully recovered or much improved, indicating that still in many patients the complaints persist over time and or are recurrent.<sup>28</sup>

Neck pain is described as ‘an unpleasant sensory and emotional experience associated with actual or potential tissue damage’ in the neck region.<sup>29</sup> The Neck Pain Task Force (NPTF) divides neck pain into four grades.<sup>30,31</sup>

Grade I	Neck pain and associated disorders with no signs or symptoms suggestive of major structural pathology and no or minor interference with activities of daily living
Grade II	No signs or symptoms of major structural pathology, but major interference with activities of daily living
Grade III	No signs or symptoms of major structural pathology, but presence of neurologic signs such as decreased deep tendon reflexes, weakness, or sensory deficits
Grade IV	Signs or symptoms of major structural pathology. Major structural pathologies include (but are not limited to) fracture, vertebral dislocation, injury to the spinal cord, infection, neoplasm, or systemic disease including the inflammatory arthropathies.

Grades I thru III can be divided include two specific subgroups of patients with neck pain: trauma-related neck pain (previously known as whiplash or whiplash associated disorder (WAD) and work-related neck pain, based on patient' statement on the cause or onset of pain.<sup>32,33</sup>

### *Guidelines*

Dutch general practitioners and Dutch physical therapists do not have a clinical practice guideline on neck pain. Other general practitioner and physical therapy guidelines are available but only cover a subgroup of the neck pain population, such as WAD or CANS (Complaints on Arm Neck or Shoulder).<sup>34–36</sup> International guidelines are available that cover neck pain including WAD.<sup>37,38</sup> These guidelines use the grading systems as proposed by the Neck Pain Task Force to classify patients.<sup>37</sup> Alternatively the classification is made by means of International Classification of Functioning, Disability, and Health (ICF). These classify patients into one of the following impairments: Neck pain with mobility deficits, neck pain with headaches, neck pain with movement coordination impairments, or neck pain with radiating pain.<sup>38</sup>

In the bone and joint decade from 2000 to 2010 the United Nations and World Health Organization initiated “The task force on neck pain and its associated disorders”. In that period members from the task force produced a best evidence synthesis from 552 scientific papers.<sup>39</sup> With this evidence available and the high prevalence of neck pain in the Dutch primary care it is due time for a clinical practice guideline on neck pain.

### *Prediction models*

Models such as the SBT often focus on low back pain and to a lesser extend on neck pain. The SBT has been modified in the United Kingdom (UK) to fit patients with other musculoskeletal conditions including neck, upper limb, lower limb or multisite pain to become the SBT-MSK (musculoskeletal).<sup>40,41</sup> A study in the UK on the SBT-

MSK found that it was not yet ready for clinical implementation.<sup>41</sup> The authors of the SBT also developed an alternative to the SBT to fit other musculoskeletal conditions such as the neck pain. The Arthritis Research UK Musculoskeletal Health Questionnaire (MSK-HQ) has been developed in four cohorts it was found to have good completion rates, test–retest reliability and convergent validity with reference standards.<sup>42</sup> Further validation studies are necessary to determine the predictive validity for persisting disability and the applicability in patients with neck pain. These screening tools are all developed in the UK and validated in their health care system. As there are large differences between the healthcare systems in the UK and the Netherlands, cultural differences, and of course the language difference the screening tools need to be translated and validated in the Netherlands before we can determine if it can be used in the Dutch population.

### Scope and aim of the study

The common goal of the studies in this thesis is to provide insight in prognosis and optimal care for patients with spinal pain in primary care (general practitioners and physical therapists). We aim to:

- Describe non-adherence to guideline-recommended care of patients with acute LBP and to explore factors associated with non-adherence. (Chapter 2)
- Translate, and investigate the reliability and validity of the SBT in the Dutch primary care setting among patients with non-specific low back pain. (Chapter 3)
- Modify and evaluate the reliability and validity of the Dutch Version of the SBT for patients with neck pain. (Chapter 4)
- Evaluate whether current Dutch primary-care clinicians offer tailored treatment to patients with lower-back pain or neck pain according to their risk stratification, based on the SBT. (Chapter 5)
- Provide a clinical practice guideline for physical therapists for the assessment and management of patients with neck pain in Dutch primary care. (Chapter 6)

In **Chapter 2** we describe the results of a secondary analysis of the PACE-trial and concerns data of 1642 patients in 235 primary care centres in Sydney, Australia, gathered between November 11, 2009 and March 5, 2013. The PACE-trial studied the efficacy of paracetamol taken regularly or as-needed compared with placebo to improve time to recovery from acute low back pain. Patients were randomised in one of three groups and Australian general practitioners provided guideline-recommended care. This care consists of advise against bed rest, continue normal daily activities, advise against other treatments and tests and the use of study-medication. This could be paracetamol in a time-contingent dosing, or an as-required dosing, or placebo. We analysed and described the magnitude of patient reported

non-adherence with guideline-recommended care for acute low back pain, and to explore possible factors associated with non-adherence.

Chapter 3 through 5 report on the PRINS study; Prevalence of Risk groups in Neck- and back pain patients according to the STarT back screening tool. This is a prospective cohort study including 284 patients whose primary complaint was low back pain or neck pain that consulted the physiotherapist or general practitioner. A questionnaire was sent to the patient at baseline and at follow-up at three days and three months. The construct validity, content validity, reproducibility, and predictive validity for persisting complaints were assessed. The clinicians were blinded for the results of the questionnaire and provided usual care. **Chapter 3** investigates whether the Dutch version of the SBT for low back pain has the ability to predict persisting low back pain in primary care patients in the Netherlands. For this we analysed 184 patients with low back pain. In **Chapter 4** we describe the changes we made to the SBT to fit patients with neck pain. We report about the ability of the SBT-neck to predict persisting neck pain. For this we analysed 100 patients with neck pain. In **Chapter 5** we report on the data we collected on the clinicians' usual care. We determined at baseline whether the patient was low, medium or high risk for persisting low back or neck pain according to the SBT. We analysed the clinicians' data concerning the management of these patients and determined whether the clinicians provided corresponding targeted treatments according to the SBT to these patients. We describe the usual care for patients with neck pain or low back pain separately.

In **Chapter 6** we describe the current available evidence for diagnosing, and treating patients with neck pain as reported in the clinical practice guideline on adult patients with neck pain treated by physiotherapists in the Netherlands. The guideline focuses on non-specific neck pain and cervical radiculopathy. Interventions include: cognitive behavioral treatment, cervical collar, dry needling, education, electrotherapy, exercise, joint mobilization, kinesiotape, low level laser therapy, manipulation, massage, neurodynamics, pillow, thermal agents, traction, shockwave, and workplace interventions.

In **Chapter 7** the main findings of this thesis are summarized and discussed and recommendations for research and clinical practice are presented.

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## **Chapter 2**

# **Patient Nonadherence to Guideline-Recommended Care in Acute Low Back Pain**

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Christopher M. Williams

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## **ABSTRACT**

### Objective:

To describe the magnitude of patient-reported nonadherence with guideline-recommended care for acute low back pain.

### Design:

Secondary analysis of data from participants enrolled in the PACE trial, a randomized controlled trial evaluating the effectiveness of paracetamol for acute low back pain.

### Setting:

Primary care, General practitioner

### Participants:

Data from participants with acute low back pain (N=1643).

### Interventions:

Guideline-recommended care, including reassurance, simple analgesia, and the advice to stay active and avoid bed rest. Also, advice against additional treatments and referral for imaging.

### Main Outcome Measures:

Proportion of nonadherence with guideline-recommended care. Nonadherence was defined as (1) failure to consume the advised paracetamol dose, or (2) receipt of additional health care, tests, or medication during the trial treatment period (4wk). Multivariable logistic regression analysis was performed to determine the factors associated with nonadherence.

### Results:

In the first week of treatment, 39.7% of participants were classified as nonadherent. Over the 4-week treatment period, 70.0% were nonadherent, and 57.5% did not complete the advised paracetamol regime. Higher perceived risk of persistent pain, lower level of disability, and not claiming workers' compensation were associated with nonadherence, with odds ratios ranging from .46 to 1.05.

### Conclusions:

Adherence to guideline-recommended care for acute low back pain was poor. Most participants do not complete the advised paracetamol regime. Higher perceived risk of persistence of complaints, lower baseline disability, and participants not claiming workers' compensation were independently associated with nonadherence.

## BACKGROUND

Globally, low back pain (LBP) causes more disability than any other condition.<sup>1</sup> In the United States estimated costs attributable to LBP range from \$86 billion to \$238 billion per year.<sup>2–4</sup> It is mostly managed in primary care with 12% to 32% of patients with LBP consulting a general practitioner (GP).<sup>5–7</sup> International clinical practice guidelines recommend a similar management approach for the first-line care of patients with acute nonspecific LBP: (1) reassurance that there is no serious cause for their back problem and the pain is likely to resolve rapidly, (2) simple analgesia (eg, paracetamol) to help control symptoms, and (3) advice to stay active and avoid bed rest.<sup>8,9</sup> There is evidence that providing additional treatments to first-line care does not provide additional benefit.<sup>10–12</sup> Guidelines recommend that additional treatments should be reserved for patients who do not recover. Referral for imaging (eg, radiographs, computed tomography scans, magnetic resonance imaging) is discouraged because it offers no diagnostic benefit, nor does it improve clinical outcomes; in fact, it may be associated with poorer outcomes (eg, lower quality of life).<sup>8,13</sup>

There is an extensive body of literature focusing on adherence to guideline-recommended care because this has been shown to result in better outcomes for patients.<sup>14–18</sup> Much of this evidence focuses on clinician prescribing behaviour and provision of care. However, little has been published on the extent to which patients adhere to guideline-recommended care when it is provided. Research to date has identified some factors associated with nonadherence to medication, including; age, gender, baseline disability, perceived health, fear of side effects, limited English proficiency, lack of a social support, and forgetfulness.<sup>19–23</sup> The few studies on chronic pain suggest nonadherence to recommended medication can lead to worsening of symptoms, higher disability and higher utilisation of healthcare.<sup>20,24</sup> Although providing guideline-recommended care to patients does lead to improved outcomes and concurrent lower costs of care for LBP, delivering this care is redundant if patients do not adhere to recommendations.

Understanding the aspects of care that patients do not adhere to, and the characteristics of nonadherent patients, can help in design of targeted strategies to address suboptimal adherence. The primary aim of this study was to describe the degree of nonadherence to guideline-recommended care of patients with acute LBP, in terms of early nonadherence (during the first week of treatment), and over the 4-week treatment period. A secondary aim was to explore possible factors within the available data set, associated with non-adherence.

## METHOD

### Data source

This is a secondary analysis of the PACE study; a randomised placebo-controlled trial which aimed to assess the efficacy of paracetamol in patients with acute LBP.<sup>9</sup> The PACE study included 1643 patients who attended a primary care clinic (Sydney, NSW, Australia) for acute LBP. Detailed description of the trial methods and analysis plan are published elsewhere.<sup>25,26</sup> The PACE study found no differences in recovery time or pain intensity between the paracetamol and placebo group.<sup>9</sup>

### Study Procedure

All participants received information from a trained clinician about the favourable prognosis of their LBP, the low likelihood of a serious disease, and reassurance that complete recovery is highly likely. They were advised against bed rest and to continue their normal daily activities, and informed that the study medication would assist this. Study personnel reinforced these messages over the telephone at baseline assessment. Participants and clinicians were asked not to undertake other treatments and tests because these were unlikely to provide any benefit at this stage.

The trial used a double dummy design to compare the effects of time-contingent dosing of paracetamol, as-required dosing of paracetamol, and placebo<sup>25,27</sup> (table I).

**Table I; Medication schedule for all treatment arms**

Pack	Schedule	Group		
		Time-contingent Paracetamol	PRN Paracetamol	Placebo
Regular	Morning	2 active tablets	2 placebo tablets	2 placebo tablets
	Noon	2 active tablets	2 placebo tablets	2 placebo tablets
	Night	2 active tablets	2 placebo tablets	2 placebo tablets
As required		1-2 placebo tablets max 8 per 24 hours	1-2 active tablets max 8 per 24 hours	1-2 placebo tablets max 8 per 24 hours

### Data collection

Participants completed questionnaires at baseline, and at weeks 1, 2, 4 and 12. A medication diary was used to record daily pain (on a 0-10 numerical pain rating scale) and the number of each type of study tablet taken.

Baseline characteristics included days since onset of pain, perceived risk of persistent pain, presence of pain beyond the knee, number of days of reduced activity, disability (Roland Morris Disability Questionnaire; range, 0-24), worker's compensation, health insurance status, income level, treatment credibility (range 3-27) and expectation score (range, 3-27) both taken from credibility expectancy

questionnaire, feelings of depression in the past week (range, 0-10)<sup>28</sup>, number of previous episodes and good sleep quality

Follow-up items at week 1 and 2 included: pain intensity, recovery, sleep quality, disability, patient specific complaints, additional treatments and GP visits and adverse events. At week 4 additional items included a patient reported inventory of all treatments utilised (health services, medications and community services) over the past 4 weeks, quality of life, the number of hours of reduced work time (each week for previous 4 weeks).

After week 4, participants were asked to return unused study medication packages and to complete a self-reported medication adherence rating scale (Brief Adherence Rating Scale).

### Outcome measurement

The primary outcome for the current study was 'overall nonadherence' to guideline-recommended care. We considered 'overall nonadherence' at 2 time points: (1) early nonadherence, defined as nonadherence to the study medication or the use of additional treatments (ie, other than the study treatments) in the first week; and (2) 4-week nonadherence defined as nonadherence to study medication, or the use of additional treatments (ie, use of other medication or health services) over the 4 weeks of the study treatment period.

We also described the individual aspects of nonadherence separately for each time point: for early nonadherence, nonadherence to (1) the study medication and (2) the use of additional treatments; for 4 week nonadherence, nonadherence to (1) study medication, (2) use of other medications, and (3) use of other health services.

The criterion for nonadherence to study medication in the first week was defined as taking <70% of the recommended regime of the regular study medication in the first week. The criterion for 4-week nonadherence to study medication was taking <70% of the recommended regime for <70% of the recommended treatment days (ie, until recovery or the end of 4wk).

### Statistical analysis

We calculated descriptive statistics for baseline characteristics and non-adherence.

Because worsening of symptoms could initiate additional medication or referral for other treatment,<sup>8</sup> we also calculated nonadherence, which was adjusted for worsening of symptoms. In this analysis, participants who had worsening symptoms and used additional treatments, tests, or medications were considered adherent.

Worsening of symptoms was defined as an increase in pain  $\geq 2$  points and deterioration on the Global Perceived Effect scale (score, -2 to -5).<sup>29,30</sup>

We performed a multivariate logistic regression analyses to determine the associations between the baseline characteristics (independent variables) and 4 dependent variables: the 4-week (1) overall nonadherence, (2) nonadherence to study medication, (3) use of other health services, and (4) use of other medications.

We performed a manual backward stepwise regression process where all candidate variables (table II) were included in the initial model. Nonsignificant variables at the .05 level were subsequently removed to determine independent associations with non-adherence. We report the odds ratio (OR) and the 95% confidence interval (CI) for all variables that remained in the final model.

A sensitivity analysis was conducted to assess the impact of worsening of symptoms in the first week (as defined above) on the results of the regression model. Regression coefficients were compared to assess the impact of this variable. To prevent overfitting and reduce random errors, we needed at least 10 participants per variable.<sup>31</sup> With 15 baseline characteristics (variables) we needed at least 150 participants. This study was performed on 1643 participants.

**Table II; Characteristics of the baseline variables used in the logistic regression model**

Characteristic	n=	Value
Days since onset of pain	1651	9.85 (9.94)
Perceived risk of persistent pain, (0-10)	1648	4.55 (2.78)
Presence of pain extending beyond the knee, n (%)	1646	323 (19.6)
The number of days of reduced usual activity	1648	3.58 (5.86)
Disability measured, (0-24)	1648	13.06 (5.50)
Pain intensity, (0-10)	1650	6.26 (1.90)
Back pain episode not compensable, n (%)	1644	1526 (92.8)
No health insurance status, n (%)	1648	877 (53.2)
Income level under \$88,399 per year, n (%)	1610	1238 (76.9)
Credibility score, (0-37)	1633	26.65 (6.43)
Expectation score, (0-19)	1638	13.69 (3.75)
Feelings of depression in the past week, (0-10)	1648	3.12 (2.93)
Good sleep quality, n (%)	1649	826 (50.1)
Number of previous episodes	1644	6.88 (15.17)
Worsening in week 1, n (%)	1519	26 (1.7)

*Values are mean (SD) unless stated otherwise*

## RESULTS

### Descriptive analysis

The PACE trial included 1643 participants; 53% were male, mean pain intensity  $\pm$  SD at baseline was  $6.3 \pm 1.9$  on a 0 to 10 scale and mean disability  $\pm$  SD was  $13.1 \pm 5.5$  on a 0 to 24 scale (table III). The mean number of days since onset of pain was  $9.9 \pm 9.9$ ; 36.7% of the participants recovered within 1 week and 84.4% within 4 weeks.

**Table III; Episode characteristics over the first four weeks**

<b>Characteristics</b>	<b>Baseline (N = 1653)</b>	<b>Week 1 (N = 1519)</b>	<b>Week 2 (N = 1510)</b>	<b>Week 4 (N = 1515)</b>
Pain intensity, (NPRS, 0-10)	6.26 (1.90)	3.70 (2.62)	2.60 (2.54)	1.70 (2.35)
Recovery (GPE, -5 to 5)	-0.05 (2.11)	2.04 (2.16)	2.79 (2.13)	3.41 (2.09)
Worsening of symptoms, N (%)	N/A	26 (1.7)	15 (1.0)	11 (0.7)

*Values are means (SD) unless stated otherwise, RDQ = Roland Moris Disability Questionnaire, NPRS = Numeric Pain Rating Scale, GPE = Global Perceived*

Overall early nonadherence was 39.7% in the first week, and overall 4-week nonadherence was 70.0%. Early nonadherence to study medication was 30.6%, 4-week nonadherence was 57.5%. Early nonadherence due to use of additional treatments in the first week was 15.9%, 4-week nonadherence due to the use of additional medication was 14.2%, and 25.3% used additional health care. Less than 2% of the participants reported worsening in the first week and there were no differences in nonadherence rates in the sensitivity analysis (table IV).

**Table IV; Nonadherence over the first week and first four weeks of the PACE trial\***

<b>Characteristics</b>	<b>Early nonadherence</b>	<b>Four-week non-adherence</b>
<b>Non-adherence</b>		
Overall non-adherence, N (%)	608 (39.7)	1049 (70.0)
Use of other treatment, N (%)	247 (15.9)	NA
Use of other health services, N (%)	ND	388 (25.3)
Use of additional medication, N (%)	ND	217 (14.2)
Following study medication protocol, N (%)	482 (30.6)	888 (57.5)
<b>Non-adherence, adjusted for worsening;</b>		
Overall non-adherence, N (%)	589 (38.6)	1028 (69.6)
Use of other treatment, N (%)	231 (15.0)	NA
Use of other health services, N (%)	ND	368 (24.3)
Use of additional medication, N (%)	ND	203 (13.4)
Following study medication protocol, N (%)	472 (29.9)	888 (57.5)

#### Multivariable logistic regression analysis

Variables that remained significant in the final multivariate logistic regression models for overall 4-week nonadherence were higher perceived risk of persistence (OR, .93; 95% CI, .89-.97), lower baseline disability (OR, 1.05; 95% CI, 1.05-1.07) and participants not claiming workers' compensation (OR, .46; 95% CI, .27-.77) (Table V). Outcomes for separate aspects of 4-week nonadherence (study medication, additional medications and additional health care use) are presented in tables 6 to 8. Worsening of symptoms in the first week was associated with using additional

healthcare (OR. 6.10; CI, 2.57 to 14.46) and using additional medication (OR, 5.78; 95% CI, 2.41-13.81) but not with nonadherence to the study medication.

**Table V; Results of the multi regression analysis for overall nonadherence over four weeks**

<b>Characteristic</b>	<b>OR (95% CI)</b>
Perceived risk of persistent pain, (0-10)	0.93 (0.89-0.97)
Disability measured, (0-24)	1.05 (1.05-1.07)
No workers compensation	0.46 (0.27-0.77)

**Table VI; Results of the multi regression analysis for study-medication nonadherence over four weeks**

<b>Characteristic</b>	<b>OR (95% CI)</b>
No health insurance	1.37 (1.11-1.68)
Days of pain	0.98 (0.97-0.99)
Perceived risk of persistent pain, (0-10)	0.90 (0.87-0.94)
Disability measured, (0-24)	1.03 (1.01-1.05)
No workers compensation	0.59 (0.38-0.90)

**Table VII; Results of the multi regression analysis for using additional healthcare over four weeks**

<b>Characteristic</b>	<b>OR (95% CI)</b>
Number of days of reduced usual activity	1.03 (1.01-1.05)
Pain intensity, (0-10)	1.11 (1.04-1.19)
No workers compensation	0.42 (0.28-0.65)
No health insurance	0.49 (0.39-0.63)
Worsening in the first week	6.10 (2.57-14.46)

**Table VIII; Results of the multi regression analysis for using additional medication over four weeks**

<b>Characteristic</b>	<b>OR (95% CI)</b>
Pain intensity, (0-10)	1.23 (1.13-1.35)
Worsening in the first week	5.78 (2.41-13.81)
No health insurance	0.73 (0.54-0.99)
Presence of pain extending beyond the knee	0.66 (0.46-0.94)
Expectancy score (3-27)	0.95 (0.91-0.98)

## **DISCUSSION**

### Summary

In the first week of treatment almost 40% of the participants were non-adherent with the recommended care. Over the 4-week treatment period, 70.0% of participants were nonadherent. Failure to comply with the study medication regimen was the main contributor to nonadherence over the early and 4-week periods. Higher



perceived risk that symptoms will be persistent; lower baseline disability and participants not claiming workers' compensation were independently associated with 4-week overall non-adherence. Worsening in the first week was strongly associated with using additional healthcare or medication.

Patient nonadherence in this study was high, despite the fact that participants were well informed and received regular prompts from study personnel. This shows that even recommending simple treatments to patients with LBP requires close monitoring and better support strategies may be required to increase adherence to treatment recommendations.

The results also show that many participants access other treatments despite recommendations that these are not useful. In our study just over 25% of the participants used additional healthcare over the 4-week period. It is not clear why participants did not take the study medication as advised, or used additional tests or treatment. Specifically, it is unknown whether participants requested additional tests or accessed the treatment themselves, or clinicians advised participants to do so. Several studies suggest that typical adjunct treatments and tests provided to patients with acute LBP (eg. massage, acupuncture, McKenzie treatment, diclofenac or manipulative therapy treatments) do not improve outcomes in these participants.<sup>10–</sup>

<sup>12,32,33</sup> Given the fast recovery rate of participants in the study (median time to recovery of 17d), the high rate of ancillary treatments would seem particularly unnecessary. Understanding why patients elected to use additional health care, medications and tests, even when well informed of their limited value, could be important to inform strategies to reduce excessive cost of low back pain management.

### Strengths and limitations

Our study is based on a large dataset, collected in primary care. The GPs and study personnel gave all participants the same advice about the study treatment. Medication usage was self-reported through a diary and confirmed through 2 other methods. We also collected healthcare utilisation measurements at several different time points to improve reliability of these data.

The fact that the outcomes were self-reported (use of other treatment, health services or additional medication) might be considered a limitation. Further, despite the training and instructions that trial GPs received, their adherence to the study protocol is unknown. For participants who underwent additional tests and treatments, or who used other medications, we do not know why, or who initiated the decision. In some cases, a participant could have been complying with the GP's advice to use additional treatments. Also we do not know about adherence to all components of the treatment recommendations, (eg. the advice to stay active and avoid bed rest). Finally, we were unable to evaluate various other factors that might have an impact on patients' adherence, as this was not the primary aim of the original study (PACE

trial). The factors included in our analysis are the ones that were gathered in the PACE trial.

#### Comparison with existing literature

The rate of nonadherence to study medication is not dissimilar to that of other trials. In a randomised controlled trial (RCT) of patients with acute LBP, adherence to at least 75% of prescribed medications was 54% for diclofenac and 48% for paracetamol.<sup>10</sup> Another randomized controlled trial of patients with chronic LBP found much higher adherence to Duloxetine (80% - 120% of the recommended dose of one pill per day) of 85-93%.<sup>34</sup> Our threshold was lower at 70% with a dosage that was higher (6 pills a day). However we asked the participants in our study to use paracetamol on a time-contingent basis, which is a factor known to be related to nonadherence.<sup>21,23</sup>

With respect to concomitant healthcare, 1 randomized controlled trial comparing manipulative therapy with diclofenac reported that 12% of the patients with acute LBP used additional interventions.<sup>10</sup> Other studies have found that 3% to 25% of new patients with LBP received diagnostic imaging.<sup>35,36</sup> A comparable proportion of participants in our study used other therapies or tests in the first 4 weeks. Use of concomitant analgesics in our study (14%) was higher than that in another paracetamol study (3%).<sup>37</sup>

The influence of baseline characteristics on nonadherence was not consistent with previous studies. Characteristics reported in other studies where either not significantly related (age, gender, baseline disability and perceived health) or unavailable in our dataset (fear of side effects, limited English proficiency, lack of a social support or forgetfulness).<sup>19-23</sup>

#### Implications for research and/or practice

This study gives insight into patient nonadherence to guideline-recommended care for acute LBP, and some of the factors associated with non-adherence. The results suggest adherence to simple and clear instructions, especially regarding medication usage, is poor in this population. More research into the complex nature of nonadherence is required to understand why patients do not comply with this advice. Future research could include interviews with patients to better understand their reasons for nonadherence.

## **CONCLUSION**

When given guideline-recommended care consisting of simple analgesics, reassurance and physical advice, patients with acute LBP tend to not adhere to the recommended regimen of prescribed paracetamol and to refrain from using extra health services and additional medication. This study found that a lower baseline

disability and participants not claiming workers' compensation contribute to patients' non-adherence.

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## **Chapter 3**

# **Validity and Reproducibility of the STarT Back Tool (Dutch Version) in Patients With Low Back Pain in Primary Care Settings**

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Physical Therapy, 2017, March 9



## **ABSTRACT**

### Objective:

The purpose of this study was to translate and to investigate the reliability and validity of the STarT Back screening tool (SBT) in the primary care setting among patients with nonspecific low back pain (LBP).

### Design:

The SBT was formally translated into Dutch following a multistep approach for forward and backward translation. General practitioners and physical therapists included patients with LBP.

### Methods:

Patients completed a baseline questionnaire and a follow-up at 3 days and 3 months. The construct validity was calculated with Pearson's correlation coefficient. The reproducibility was assessed using the quadratic weighted kappa and the specific agreement. Predictive validity was assessed using relative risk ratios for persisting disability at 3 months. Content validity was analyzed using floor and ceiling effects.

### Results:

In total, 184 patients were included; 52.2% were categorized in the "low-risk" subgroup, 38.0% "medium-risk," and 9.8% "high-risk." For the construct validity we found, as expected, a moderate to high Pearson's correlation for questions 3 to 9 and a low correlation for questions 1 and 2 with their respective reference questionnaires. The reproducibility had a quadratic weighted kappa of 0.65 and the specific agreement of 82.4% for "low-risk," 53.3% for "medium-risk," and 33.3% for "high-risk." For the predictive validity for persisting disability we found a relative risk ratio for "medium-risk" of 1.8 (95% confidence interval [CI]: 1.0–3.1) and 2.7 (95% CI: 1.4–4.9) for "high-risk" compared with "low-risk." For the content validity, we found that no floor and ceiling effects were present.

### Limitations

There was a relatively small sample size for the retest reliability study. Patients were not compared between physical therapist and GP, as there were not enough patients in both groups. For practical reasons, the patients filled out the baseline questionnaire after receiving the first treatment/consultation; however, the questionnaire is intended to be filled in before the first consultation/treatment.

Conclusion:

The SBT has been successfully translated into Dutch. The psychometric analysis showed acceptable results and, therefore, the SBT is a valid screening tool for patients with LBP in Dutch primary care.

## BACKGROUND

Low back pain (LBP) is a major public health problem. Globally it is the most prevalent musculoskeletal disorder causing disability.<sup>1</sup> In the Netherlands the point prevalence of LBP is found to be 26.9%.<sup>2</sup> LBP is a condition that is broadly divided into three major subgroups. First, LBP with a specific (serious) underlying pathology, such as: tumors, fractures and infections. Second, LBP caused by nerve root compression as a result of a stenosis or herniated disc. The third group, the majority of people with LBP (85 - 90%), is called non-specific LBP as no cause can be found.<sup>3,4</sup> Despite the fact that non-specific LBP is regarded self-limiting as it often resolves within 6 weeks, more recent prognostic studies concluded that for ~40% of patients with LBP recovery will take longer than 12 weeks.<sup>4-6</sup> LBP is a burden on the health care system consuming in the Netherlands between €385-€455 million in direct medical costs and between €3-€3.1 billion in indirect costs.<sup>7</sup> In the United States reports on combined direct and indirect costs for LBP vary between \$86 billion and \$238 billion.<sup>8-10</sup>

Although it has been suggested that patients with non-specific LBP are not a homogeneous patient group, defining subgroups is challenging but important for targeting treatment to the individual patient.<sup>3,11,12</sup> So far sub-grouping based on a patho-anatomical source of the pain appears to be of limited value because often an anatomical structure as cause of pain cannot be found.<sup>4</sup> Certain psychosocial factors are known to influence patients' recovery. Subgrouping patients based on psychosocial factors may result in successful risk stratification. The Keele STarT Back Tool (Subgroups for Targeted Treatment) (SBT) is a tool using different function, psychosocial and comorbid factors for subgrouping. It is developed in England, to allocate primary care patients with LBP into three subgroups concerning their prognosis: low, moderate or high risk for persisting disability<sup>13</sup> and to apply the appropriate stratified care.<sup>14</sup>

The SBT consists of 9 questions, 8 true/false questions and 1 question with a 5-point Likert scale as answer option. The validity of the SBT is often studied using a principal component factor analysis. In the United Kingdom (UK) study, as well as the Finnish, French, German and Persian studies it resulted in 2 subscales: biological (question 1 to 4) and psychosocial (question 5 to 9).<sup>13,15-18</sup> The psychosocial subscale is then viewed as a distress subscale with a Cronbach's alpha ranging from 0.52 (Finnish), 0.55 (German), 0.72 (UK), 0.74 (French), and 0.81 (Persian).<sup>13,15-18</sup> The discriminant validity has been determined by calculating the area under the curve (AUC) of the overall score with the Roland Disability Questionnaire (RDQ) (0.76-0.92).<sup>13,16</sup> The psychosocial subscale of the Pain Catastrophizing Scale (PSC) (0.70-0.83) or the Tampa Scale of Kinesiophobia (TSK) (0.81).<sup>13,18</sup> Other studies calculated the AUC for each separate question resulting in AUCs ranging from 0.74 to 0.86.<sup>16,19</sup> The SBT is a questionnaire formed by combining known factors for delayed recovery of back pain. Based on these

independent factors it aims to predict poor disability with each factor adding to the likelihood of a poor prognosis, this is called a formative model. In our formative model approach it is unnecessary to calculate internal consistency and the AUC against the overall score or the psychosocial subscale as we approach it as independent factors and not as a coherent factors.

The SBT's ability to predict poor disability at 6 months had sensitivity scores ranging between 39.6% and 80.1% and the specificity scores ranging from 65.4% to 94.6%.<sup>13</sup> The English SBT has been found to be a reliable tool in the UK with a quadratic weighted kappa of 0.79.<sup>13</sup> It has been translated in several languages since its initial English publication in 2008.<sup>16–22</sup> No study has been published on the SBT to evaluate the validity and reliability in Dutch primary healthcare. Our aim is to evaluate the validity and reliability of the STarT Back Tool Dutch Version in Dutch primary care.

## **METHOD**

### Translation of the SBT

The original SBT<sup>13</sup> (Appendix A and B) was formally translated following the multistep approach of Beaton et al.<sup>23</sup> and the guidelines of Streiner and Norman.<sup>24</sup> Two Dutch native speakers independently performed a forward translation. After synthesis of a draft Dutch translation of the SBT, this version was backward translated into English by both a Dutch and an English native speaker. An expert committee was formed consisting of one translator who is also a clinical epidemiologist, one backward translator and one clinician (orthopedic spine surgeon). The group examined the forward and backward translations and consolidated these to produce a “pre-final” version of the Dutch SBT. As it became apparent that two different study groups were preparing Dutch translations a second expert meeting, consisting of a representative of each study group (R.O. and M.vH.) was held. A “combined pre-final” version was compiled based on all previous documents and differences were resolved through consensus. The only difference was found in the translation of question 1 “spread down my leg(s)”. We discussed whether to use ‘naar één of beide benen’ (ie. “to one or both legs”) or “naar mijn benen” (ie. “to both legs”). As in the original English version the “s” of “legs” is written between brackets, consensus was reached to use “naar één of beide benen” (ie. “to one or both legs”) in the “combined pre-final” version.

### Pre-final testing

To test the “combined pre-final” version, 20 consecutive Dutch-speaking patients with LBP at the outpatient department of a secondary and tertiary spine referral center, completed this version. In addition, a possibility was made to give comments and suggestions to improve. After completion, they were briefly interviewed about

their thoughts of what was meant by each question and the chosen answer. They were also asked for their general comments on the questionnaire (eg. lay-out, wording, ease of understanding and completion, ambiguities). As no further comments or suggestions to improve were given, the expert group upgraded the 'pre-final' version to the final version.<sup>25</sup> The Dutch version of the SBT is found in Appendix A and B

### Design

The final translated version was subsequently used in this clinimetric study as part of a prospective cohort (PRINS study; Prevalence of Risk groups in Neck- and back pain patients according to the STarT back screening tool) including patients with LBP (and neck pain for a parallel study) of any duration in primary care. This is the first article published on this cohort. Patients received regular care by their general practitioner (GP) or physical therapist. In the Netherlands patients have direct access to physical therapist care and therefore this is regarded primary care as is GP-care. Patients were asked to answer baseline and follow-up questionnaires. A power analysis power showed that 100 patients were needed for a reliability study. The study was approved by the medical ethics committee of the Erasmus University, Rotterdam, The Netherlands. (MEC-2014-256). For this study we only use the data of the LBP patients of the PRINS-cohort.

### Participants

#### *General practitioners and physical therapists.*

We asked GP's and physical therapists that had previously showed their interest in the SBT to participate in the study and asked them to invite colleagues. Information about the study protocol was given through several meetings, by phone, or by digital/paper documentation. Participating GP's and physical therapists received the study protocol and a folder with patient information brochures and informed consent forms.

#### *Patients*

The inclusion period for patients started November 2014 to May 2015. When a patient consulted their GP or physical therapist for their back pain they were asked to participate in the PRINS study. Other inclusion criteria were that the patient was 18 years or older, could speak, read and write in Dutch and had an email address. Patients were excluded if during the consultation the GP or physical therapist found red flags indicating a possible specific underlying pathology (eg. infection, fracture, cauda equina or tumor) responsible for the LBP.

Patients were given oral and written information about the procedure of data collection and the aim of the study. They were given an informed consent form. When the patient signed the informed consent form and handed it back to their GP or physical therapist they registered the patient online. The patient immediately

received an email with a link to the baseline questionnaire. When necessary a reminder was sent within a few days.

### Treatment

The clinician was blinded for the results of the questionnaires including the score on the SBT. The patients received usual care by their GP or physical therapist. We asked the clinician to treat their patient according to their guideline. The guideline advises the GP provide advice and, if necessary, analgesics to patients in the acute phase. In case of persisting pain GPs can refer the patient to the physical therapist. Guideline recommendations for Physical therapists differ based on the course of pain. In a normal course of pain the physical therapist is advised to give reassurance and information to the patient. In case of an abnormal course of pain the physical therapist should provide evidence based interventions such as exercise therapy, mobilization, manipulation and/or massage.<sup>26,27</sup>

### Measurements

#### *Baseline*

At baseline (T0) patients filled out a questionnaire consisting of demographic variables (eg. age, sex) and the SBT. Furthermore, we measured the average pain in the past week using the 11-point Numeric Pain Rating Scale (NPRS)<sup>28</sup> ranging from 0 (no pain) to 10 (worst imaginable pain). Disability was operationalized using the RDQ<sup>29,30</sup> consisting of 24 statements with a “yes” or “no” answer option. The total score ranges from 0 to 24, a higher score indicating more disability. We measured Fear of movement/(re)injury using the TSK<sup>31</sup> consisting of 17 statements with four answer options varying from “highly disagree” to “highly agree”. The total score ranges from 17 to 68, a higher score indicating a higher level of kinesiophobia. To assess the level of catastrophizing we used the PCS, which consists of 13 statements with each a 5-point Likert scale answers option ranging from “not at all” to “always”.<sup>32</sup> The total score ranges from 0 to 52, a higher score indicating a higher level of catastrophizing. Finally we assessed quality of life using the EQ-5D<sup>33</sup> consisting of six questions. The first five questions have a 3-point Likert scale answer options ranging from “no problems” to “severe problems” and the sixth question is a health status question ranging from “worst imaginable health” to “best imaginable health”, score ranges from 0 to 100.

#### *Follow-up*

Three days after inclusion (T1) a repeat-questionnaire was sent in order to investigate the retest reliability of the SBT. It consisted of the SBT, the NPRS and the General Perceived Effect (GPE) scale to measure recovery: “To what degree have you improved since filling out the baseline questionnaire?” The answer options range from “fully recovered” to “worse than ever” on a 7-point likert scale. The time interval was considered long enough to reduce recall bias and short enough to prevent

substantial improvement.<sup>34</sup> This repeat-questionnaire was sent to patients that were included during the last 3 months of the inclusion period.

Three months after inclusion (T2), the patients received a follow-up questionnaire consisting of the GPE and RDQ. At the same time we sent a questionnaire to the GP to ask about the number of visits, prescribed medication, referrals to physical therapist medical professionals and requested diagnostic imaging and blood tests. We sent a similar questionnaire to the physical therapist to ask about treatment data such as date of first and last treatment, number of treatments, questionnaires used and the aim and means of treatment. All questionnaires were handled and stored through LimeSurvey 2.05 (Lime Survey GmbH, Hambrug, Germany)

### Statistical analysis

First we analyzed the data to describe the characteristics of the GP's, physical therapists and the patient population using frequencies, means and standard deviations. The prevalence of the 3 risk profiles according to the SBT-scores are reported

For the *construct validity* we first analyzed at the characteristics across SBT risk profile to determine the discriminant validity. Next, we calculated the Pearson's correlation coefficient between specific items of the SBT and their respective reference questionnaires based on the comparability of the domains of measurement.<sup>35,36</sup> *A priori* we expected a moderate ( $r \geq 0.3$ ,  $<0.5$ ) to high ( $r \geq 0.5$ ) correlation between the SBT activity-questions 3 and 4 with the RDQ, kinesiophobia-question 5 with the TSK, catastrophizing-question 6, 7 and 8 with the PCS and the bothersome-question 9 with the NPRS. We expected a low correlation ( $r < 0.3$ ) between question 1 and 2 and the NPRS as these focus on the location of the pain and not the intensity of pain.

We calculated the *reproducibility* (evaluating the agreement between 2 measurements) in the patient group that remained stable between baseline (T0) and T1. We asked the patients after 3 days to fill out the questionnaire a second time. Patients were considered stable when they scored "slightly improved", "no change" or "slightly worsened" on the GPE at second measurement. As there is some doubt in the literature whether the GPE actually can detect change, we combined the stable GPE score with a stable pain score meaning the NPRS on T1 was plus or minus one point compared to baseline.<sup>3</sup> We calculated the quadratic weighted kappa and the specific agreement. The quadratic weighted kappa will be interpreted as  $\leq 0$  = poor agreement; .01–.20 = slight; .21–.40 = fair; .41–.60 = moderate; .61–.80 = substantial and .81–1 = almost perfect agreement.<sup>37</sup> The specific agreement is calculated for each risk profile separately.<sup>35</sup> For example; patients who are "low-risk" on baseline and follow-up are calculated as a proportion of patients that were "low-risk" on either of the two measurements. In collaboration with Henrika de Vet we modified the specific agreement to fit a 3 x 3 table as shown in table I because the original method is done in a 2 x 2 table.

**Table I; Specific agreement**

		Follow-up (T1)		
		Low	Medium	High
Baseline (T0)	Low	7 (A)	2 (B)	0 (C)
	Medium	1 (D)	4 (E)	0 (F)
	High	0 (G)	4 (H)	1 (I)

“Low-risk”  $A/(A+(B+C+D+G)/2) = 7/8,5 = 82.4\%$

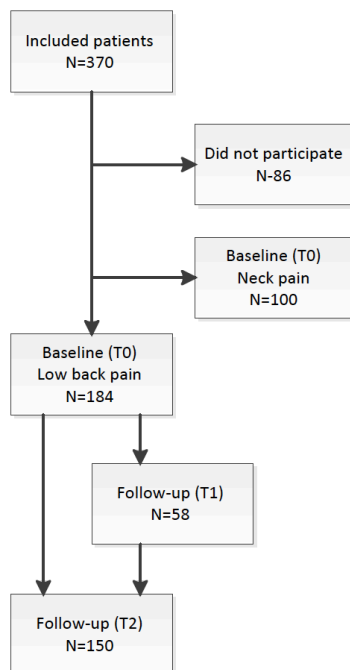
“Medium-risk”  $E/(E+(B+H+D+F)/2) = 4/7.5 = 53.3\%$

“High-risk”  $I/(I+(C+F+G+H)/2) = 1/3 = 33.3\%$

We determined the *predictive validity* by reporting the relative Risk Ratio (RR) for “medium-risk” and “high-risk”, both compared to “low-risk” in their ability to predict the outcome on three months. We defined persisting disability as a RDQ of  $\geq 7$ , this is equal to the cut-off used in the original study where it was the median of the baseline scores.<sup>13</sup> Persisting pain is defined as a NPRS above the baseline median and recovery is defined as either “completely recovered” or “much improved” on the GPE. Limited *content validity* is indicated by the presence of more than 15 percent of the patients reached either the floor (0/9 points) or ceiling effects (9/9 points) on the SBT.<sup>34</sup>

To measure the construct validity and reliability a sample size of at least 50 persons is advised.<sup>34</sup>

**Figure I, patient flow**





## RESULTS

### Patient population

In total, 41 GPs and 70 physical therapists signed up to participate and 12 GPs and 33 physical therapists actually included patients. They included 370 patients of which 184 with LBP and 100 with neck pain for the parallel study, 86 patients did not fill out the baseline questionnaire and were excluded from the analysis. Loss to follow up at three months was 34 (18%) (Figure I). Patients that were lost to follow up showed comparable baseline characteristics compared to the responders. Of the LBP patients, at baseline 96 (52%) patients were categorized as "low-risk", 70 (38%) as "medium-risk" and 18 (10%) as "high-risk" (table II). We found no differences between the groups concerning age, gender or whether they were included by the GP or physical therapist.

### Validity and reproducibility

#### *Construct validity*

For each increase in the risk profile we found a corresponding increase in pain, disability, catastrophising and kinesiophobia (Table III) showing that the SBT has good discriminant validity. Next we found a high correlation, between SBT question 9 and the NPRS ( $r = 0.6$ ), question 3 and 4 with the RDQ and question 8 with the PCS (all  $r = 0.5$ ). We found a moderate correlation ( $r = 0.4$ ) between question 5 and the TSK and question 6 and 7 and the PCS (both  $r = 0.3$ ). The correlation between question 1 and 2 was absent to low and scored  $r = 0.28$  and  $r = -0.05$  respectively (Table IV). The correlations are as was expected *a priori* and therefore we conclude that the construct validity is good.

#### *Reproducibility*

The average time between first (T0) and second (T1) questionnaire was 6 days (range 3-10). In total, 58 patients completed the second questionnaire of which 19 patients were regarded stable compared to baseline. The quadratic weighted kappa for the SBT of 0.65 (95% CI: 0.34 – 0.96) showed a substantial reproducibility. The "low-risk" group had a specific agreement of 82.4%, "medium-risk" of 53.3% and "high-risk" of 33.3% showing an excellent to fair reproducibility.

**Table II; baseline characteristics of the study population**

	<b>Study population (n=184)</b>	<b>UK-validation sample (n=500)</b>
Female	103 (56.0)	293 (58.6)
Age in years, mean (SD)	44.6 (14.6)	45 (9.7)
SBT risk profile		
Low	96 (52.2)	234 (47.4)
Medium	70 (38.0)	186 (37.7)
High	18 (9.8)	74 (15.0)
Episode duration		
<1 month	53 (28.8)	83 (16.9)
1 to 3 months	26 (14.1)	94 (19.1)
4 to 6 months	12 (6.5)	77 (15.7)
7 months to 3 years	36 (19.6)	125 (25.5)
>3 years	57 (31.0)	112 (22.8)
SBT score, mean (SD)	3.60 (2.0)	3.83 (2.3)
Pain intensity		
Mild (0-5)	63 (34.2)	325 (66.1)
Moderate (5-7)	88 (47.8)	113 (23.0)
Severe (8-10)	33 (17.9)	54 (10.1)
Disability (RDQ), mean (SD)	9.5 (5.9)	9.1 (5.9)
Referred leg pain	54 (29.3)	303 (60.6)
Comorbid pain in neck/shoulder	124 (67.4)	276 (55.2)
Very or extremely bothered by back	94 (51.1)	276 (55.2)
Fear (TSK), mean (SD)	34.8 (7.1)	39.5 (6.9)
Catastrophizing (PCS), mean (SD)	13.7 (10.3)	

Values are numbers (percentage) unless otherwise indicated. SBT = STarT Back Tool (0-9), RDQ = Roland Disability Questionnaire (0-24), TSK = Tampa Scale of Kinesiophobia (17-68), PSC = Pain Catastrophizing Scale (0-42). Pain intensity is measured on a Numeric Pain Rating Scale (0-10). UK Validation study preformed by Hill in 2008<sup>13</sup>

### *Predictive validity*

In total 150 patients completed the T2 questionnaire, of which 76 were regarded as “low-risk” at baseline, 58 as “medium-risk” and 16 as “high-risk”. In all 3 risk profiles a decrease in NPRS and RDQ scores over time was seen. The number of patients with a decrease that met the threshold (RDQ < 7) was highest in the “medium-risk” group (Table V). Persisting pain is set as a NPRS ≥ 6. The RR for “medium-risk” at three months as compared to the “low-risk” were 1.8 (95% CI: 1.0 – 3.1) for persisting disability, 1.6 (95% CI: 0.9 – 3.0) for persisting pain and 1.0 (95% CI: 0.7 – 1.3) for recovery. For “high-risk” compared to the low-risk group the RR were 2.7

(95% CI: 1.4 - 4.9) for persisting disability, 3.4 (95% CI: 2.3 – 6.8) for persisting pain and 0.6 (95% CI: 0.3 – 1.2) for perceived recovery. An RR of 3.4 means that patients with “high-risk” had 3.4 times higher chance for persisting low back pain compared to patients with “low-risk”. Some confidence intervals include 1 (= equal risks) making it statistically insignificant.

#### *Content validity*

We analyzed 184 baseline questionnaires concerning the SBT in determining floor and ceiling effects. Nine patients (4.9%) scored zero and 2 patients (1.1%) scored 9 points implying no floor or ceiling effects are present and therefore the SBT showed a good content validity.

**Table III, characteristics of patients in the risk profiles\***

<b>Characteristic</b>	<b>Low risk</b>	<b>Medium risk</b>	<b>High risk</b>
SBT, N (%)	96 (52.2)	70 (38.0)	18 (9.8)
RDQ	6.5 (4.9)	11.8 (5.1)	16.7 (3.1)
NPRS	5.2 (1.8)	6.5 (1.5)	7.2 (1.6)
TSK	32.4 (5.9)	35.4 (6.6)	44.6 (6.2)
PCS	10.0 (7.9)	15.0 (9.5)	28.6 (10.6)

*Values are mean scores (SD) unless otherwise indicated. SBT = STarT Back Tool (0-9), RDQ = Roland Disability Questionnaire (0-24), NPRS = Numeric Pain Rating Scale (0-10), TSK = Tampa Scale of Kinesiophobia (17-68), PCS = Pain Catastrophizing Scale (0-52).*

**Table IV; Pearson’s correlation between the STarT Back Tool and their reference questionnaires**

SBT and reference		Correlation		
	A priori	r		Expected
Q1 - NPRS	$r < 0.30$	0.28	low	Yes
Q2 - NPRS	$r < 0.30$	- 0.05	low	Yes
Q3 - RDQ	$r \geq 0.30$	0.48	moderate	Yes
Q4 - RDQ	$r \geq 0.30$	0.49	moderate	Yes
Q5 - TSK	$r \geq 0.30$	0.38	moderate	Yes
Q6 - PCS	$r \geq 0.30$	0.34	moderate	Yes
Q7 - PCS	$r \geq 0.30$	0.28	low	No
Q8 - PCS	$r \geq 0.30$	0.46	moderate	Yes
Q9 - NPRS	$r \geq 0.30$	0.63	high	Yes

*r = Pearson’s correlation, NPRS = Numeric Pain Rating Scale, RDQ = Roland Disability Questionnaire, TSK = Tampa Scale of Kinesiophobia, PCS = Pain Catastrophizing Scale.*

## DISCUSSION

### Main findings

The SBT is a formative model aiming to give a prognosis on poor disability. The construct validity showed correlations as *a priori* was expected between SBT items with their respective reference questionnaires (NPRS, RDQ, TSK and PSC). The retest reliability is moderate to good, and the RR demonstrates an increased chance for persisting disability and pain with an increase of the risk profile. An expert committee found the questions to be relevant and 20 patients used the SBT and comprehended all questions. Furthermore the absences of floor and ceiling effects confirmed a good content validity.

**Table V, Three month follow-up results**

	Persisting pain		Persisting disability		Recovery	
	NPRS (SD)	RR (95% C.I.)	RDQ (SD)	RR (95% C.I.)	GPE (SD)	RR (95% C.I.)
Low Risk	3.14 (2.38)		3.67 (5.09)		2.28 (0.89)	
Medium Risk	3.38 (2.64)	1.59 (0.85 - 2.96)	5.34 (5.79)	1.80 (1.04 - 3.11)	2.53 (1.17)	0.96 (0.72 - 1.29)
High Risk	5.13 (2.68)	3.39 (2.31 - 6.76)	9.19 (7.54)	2.67 (1.44 - 4.93)	2.56 (0.96)	0.63 (0.33 - 1.22)

*Values are mean scores (SD) unless otherwise indicated. NPRS = Numeric Pain Rating Scale (0-10), RDQ = Roland Disability Questionnaire (0-24), GPE = General Perceived Effects (1-7)*

### Interpretation of findings

The specific agreement, as a measurement to determine the reproducibility, shows a fairly accurate intra-observer consistency for patients with a “low-risk” score. The accuracy decreases as the risk-profile increases. This might be due to the relatively low number of patients in this high-risk category. Also, in “high-risk” patients multiple psychosocial factors are present, which can be influenced during therapy by addressing an active health behavior and the unlikelihood of a serious underlying condition.<sup>38</sup> The latter is probably less of influence as the questionnaire at baseline is given after the first treatment during which the psychosocial factors and the active health behavior are likely to have been addressed. Patients might have been influenced by this information during the primary consultation and therefor shifted from the “high-risk” to the “medium-risk” group before completing the baseline questionnaire. A previous study suggests that assignment to a risk category following a short delay may more successfully predict final outcomes than when administered during initial assessment.<sup>39</sup>

For the reproducibility analysis the conditions (time, pain, perceived recovery) were set *a priori* to ensure 'stable patients'. Due to the natural course of the pain, patients might be recovering between both measurements, shifting to a lower risk-profile and explaining the higher score in the "low-risk" group. The Kappa is influenced by a skewed distribution due to the large proportion of patients with "low-risk". Nevertheless the Kappa shows that the SBT is able to distinguish sufficiently between risk groups.<sup>35</sup> Within the reproducibility analysis we found that four out of the five patients shifted from "high-risk" to "medium-risk" within the first week. These patients had only one consultation in this period and therefore might have been susceptible to change.

We used RR to calculate the additional risk of "high-risk" and "medium-risk" compared to "low-risk". Predicting persisting disability gave the best results, in accordance with the developers aim. Poor disability is defined as a RDQ score of 7 or more, like the original study and other comparable studies.<sup>13,15–18,38</sup> When interpreting the predictive value it has to be taken into account that clinicians applied 'usual care'. There was no standardized or stratified therapy protocol for the clinicians to use. We asked the GP or physical therapist to follow the national guidelines, but recent studies show that guidelines are often not followed by the clinician or the patient.<sup>40,41</sup> The clinician was free to apply their usual care and adjust their therapy in the way they seemed fit.

The confidence intervals of the "medium-risk" and "high-risk" risks for persisting pain and disability show some overlap, which might suggest a lack of independence, but may also be the result of a lack of power. Furthermore, it has to be taken into account that clinicians applied "usual care" and not the advised approach possibly influencing the outcome, which might explain the overlap.

#### Findings in the context of other literature

When comparing our results with the results from the UK study we have to keep in mind that the healthcare system is different between the countries. Despite these differences, we included, in line with the UK study, all LBP patients disregarding duration of complaints or previously provided healthcare. In contrast to the UK study, in our study not all patients were seen by their GP as the physical therapist also included and treated patients via direct access.

The distribution in risk-profiles in our study was well comparable with the distribution in the UK study.<sup>13</sup> All other cohorts all had a shift towards "high-risk" at the expense of "low-risk".<sup>16–19,21</sup> For each increase in risk profile we found an increase in pain, PCS and TSK, this discriminant validity is also found in another studies.<sup>42–44</sup> Other validation studies such as the Finnish, German, French, and Persian followed the same method as the initial UK study by using the Area Under the Curve (AUC) to determine the validity thus making it easier to compare.<sup>16,18</sup> In our study we refrained from using the AUC because we chose not to dichotomize the scores of the questionnaires. We used the Pearson's correlation coefficient giving us the

correlation information needed, although this made it more difficult to compare our results to other studies. We compared individual questions with their reference questionnaire; the UK study used the total SBT score or the psychosocial subscale to calculate the AUC.

The quadratic weighted kappa for the retest reliability in our study is lower than the one in the UK study (0.79 for the stable patients), but comparable to the German version (0.67).<sup>13,18</sup> This might be due to our small sample size of 19 compared to 295 and 410 in the previous mentioned studies. Our data is also more skewed towards “low-risk” as a result of a higher percentage of patients in this group, which influences the kappa. Besides using the quadratic weighted kappa we also calculated the specific agreement.<sup>35</sup> No other studies used this measurement therefore we can’t compare results. Our findings are in accordance with all other studies that evaluated translations of the SBT to be a reliable and valid instrument.<sup>13,15,16,18,19</sup>

### Strengths and limitations

The strength of this study is that we successfully translated the SBT into Dutch and determined the construct validity, reproducibility, predictive validity and content validity. The advised minimum sample size was met for the validity section. A limitation is that we had a relatively small sample size for the retest reliability study. Also we were not able to compare patients between GP and physical therapist, as we did not have enough patients in both groups. Another limitation is that for practical reasons the patient filled out the baseline questionnaire after receiving the first treatment/consultation. The questionnaire is intended to be filled in before the first consultation/treatment because the patient might change its cognition and therefore influence the results.

### Clinical and/or research implications

The STarT Back tool has been translated and validated for use in Dutch primary care. It can be used to, in an early stage, predict persisting disability. More important is that it can be used to match the patient to the advised treatment. Further research is needed to determine if this stratified care leads to a faster recovery and in its turn leads to lower healthcare consumption and lower costs. To further determine the predictive validity future studies might include a non-intervention (natural course) group.

## **CONCLUSION**

The SBT is successfully translated in Dutch and according to the psychometric analysis it showed to be a sufficiently valid and reliable instrument.

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## Appendix A; the original English version of the STarT Back Tool

### The Keele STarT Back Screening Tool

Patient name: \_\_\_\_\_ Date: \_\_\_\_\_

Thinking about the **last 2 weeks** tick your response to the following questions:

	Disagree 0	Agree 1
1 My back pain has <b>spread down my leg(s)</b> at some time in the last 2 weeks	<input type="checkbox"/>	<input type="checkbox"/>
2 I have had pain in the <b>shoulder or neck</b> at some time in the last 2 weeks	<input type="checkbox"/>	<input type="checkbox"/>
3 I have only <b>walked short distances</b> because of my back pain	<input type="checkbox"/>	<input type="checkbox"/>
4 In the last 2 weeks, I have <b>dressed more slowly</b> than usual because of back pain	<input type="checkbox"/>	<input type="checkbox"/>
5 It's not really safe for a person with a condition like mine to be physically active	<input type="checkbox"/>	<input type="checkbox"/>
6 <b>Worrying thoughts</b> have been going through my mind a lot of the time	<input type="checkbox"/>	<input type="checkbox"/>
7 I feel that <b>my back pain is terrible</b> and <b>it's never going to get any better</b>	<input type="checkbox"/>	<input type="checkbox"/>
8 In general I have <b>not enjoyed</b> all the things I used to enjoy	<input type="checkbox"/>	<input type="checkbox"/>

9. Overall, how **bothersome** has your back pain been in the **last 2 weeks**?

Not at all	Slightly	Moderately	Very much	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
0	0	0	1	1

Total score (all 9): \_\_\_\_\_ Sub Score (Q5-9): \_\_\_\_\_

## Appendix B; the translated Dutch version of the STarT Back Tool

### The STarT Back Screening Tool: Dutch Version

Rugscreenings Instrument

Auteur: M van Hooff, W van Lankveld, P Anderson, A Apeldoorn, F van Hartingsveld, R Ostelo (2011)

Naam: \_\_\_\_\_

Datum: \_\_\_\_\_

Antwoord u alstublieft ieder onderdeel. Kruis bij ieder onderdeel het vakje aan dat op u van toepassing is. Soms is het moeilijk om tussen twee vakjes te kiezen, kruis dan het vakje aan dat uw probleem het beste beschrijft. Kruis niet meer dan één vakje per onderdeel aan!

Denk bij het beantwoorden van de volgende vragen telkens aan de situatie **in de laatste 2 weken**.

		Oneens 0	Eens 1
1	In de laatste 2 weken <b>straalde</b> mijn rugpijn wel eens <b>uit naar één of beide benen</b> .	<input type="checkbox"/>	<input type="checkbox"/>
2	In de laatste 2 weken heb ik wel eens pijn in mijn <b>schouder</b> of <b>nek</b> gehad.	<input type="checkbox"/>	<input type="checkbox"/>
3	Vanwege mijn rugpijn <b>liep</b> ik alleen <b>korte afstanden</b> .	<input type="checkbox"/>	<input type="checkbox"/>
4	In de laatste 2 weken <b>kleeedde ik me trager</b> dan gewoonlijk <b>aan</b> vanwege mijn rugpijn.	<input type="checkbox"/>	<input type="checkbox"/>
5	Voor iemand in mijn toestand is het echt niet veilig om lichamelijk actief te zijn.	<input type="checkbox"/>	<input type="checkbox"/>
6	<b>Ongeruste gedachten</b> gingen vaak door mijn hoofd.	<input type="checkbox"/>	<input type="checkbox"/>
7	Ik vind dat mijn <b>rugpijn verschrikkelijk</b> is en ik geloof dat <b>het nooit meer beter zal worden</b> .	<input type="checkbox"/>	<input type="checkbox"/>
8	Over het geheel genomen heb ik <b>niet genoten</b> van alle dingen waar ik vroeger wel van genoot.	<input type="checkbox"/>	<input type="checkbox"/>

9. Over het geheel genomen, hoe hinderlijk was uw rugpijn in de laatste 2 weken?

In het geheel niet	Een beetje	Matig	Erg	Extreem
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
0	0	0	1	1

Totale uitslag (alle 9) : \_\_\_\_\_ Sub Uitslag (Q5-9): \_\_\_\_\_

This is a licensed tool (©2007 Keele University) that may not be modified. The copyright (©2007) of the STarT Back Tool and associated materials is owned by Keele University, the development of which was part funded by Arthritis Research UK:  
i) the tool is designed for use by health care practitioners, with appropriate treatment packages for each of the stratified groups;  
ii) the tool is not intended to recommend the use of any particular product. For further information please see <http://www.keele.ac.uk/sbst/>  
No license is required for non-commercial use. If you would like to incorporate the Dutch version of the STarT Back Tool in any way into commercial product materials, please contact Miranda van Hooff for further advice.

## **Chapter 4**

### **Validity and reproducibility of the modified STarT Back Tool (Dutch version) for patients with neck pain in primary care**

Jasper D. Bier, Raymond W.J.G. Ostelo, Bart W. Koes, Arianne P. Verhagen

Musculoskeletal Science and Practice, 2017

## **ABSTRACT**

### Objective:

To evaluate the reliability and validity of the Dutch version of the STarT Back screening Tool (SBT), for patients with neck pain.

### Methods:

We modified the SBT to fit patients with neck pain. General practitioners and physiotherapists included patients who completed both a baseline and a follow-up questionnaire at 3 days and 3 months, respectively. The construct validity was assessed using Pearson's correlation between the SBT and the reference questionnaires. The reproducibility was assessed in the first week using the quadratic weighted kappa and the specific agreement. Predictive validity was assessed using a relative-risk ratio (RR) for, amongst others, persisting disability at 3 months. Content validity was analysed using both floor and ceiling effects.

### Results:

In total, 100 patients were included; 58% were categorised as being at "low risk" for persisting disability, 37% at "medium risk" and 5% at "high risk". As expected for the construct validity, we found a moderate to high correlation for all questions except for activity question 3. The reproducibility had a quadratic-weighted kappa of .58, and a specific agreement of 90.9% for "low-risk" and 66.7% for "medium-risk" patients. The RRs for persisting disability for "medium-risk" against "low-risk" patients were 1.5 (95% C.I. 0.9 - 2.4) and 1.5 (95% C.I. 0.5 - 4.1) for pain. The sample size for high-risk patients was low.

### Conclusion:

The original SBT is modified to fit patients with neck pain in Dutch primary care. The psychometric analysis indicates sufficiently reliable outcomes, although the predictive validity showed statistically insignificant results.

## BACKGROUND

Globally, neck pain is the fourth largest musculoskeletal disorder causing disability.<sup>1</sup> Numbers from NIVEL, the Netherlands institute for health-services research, found that, in 2015, neck pain was the most prevalent disorder in Dutch physical therapy.<sup>2</sup> The estimated one-year incidence of neck pain varies between 10% and 21%.<sup>3</sup> In patients with acute neck pain, pain and disability decrease in the first six weeks by approximately 45%; however, little or no decrease can be found afterwards.<sup>4</sup> A Dutch cohort found that after one year, 76% of patients with neck pain reported to be fully recovered or much improved, indicating that, in many patients, complaints still persist over time and/or are recurrent.<sup>5</sup> The annual cost of neck pain in the Netherlands was estimated to be \$668 million in 1996; unfortunately, more recent data are not available.<sup>6</sup>

The Neck Pain Task Force and the Dutch physiotherapists' guideline on neck pain classify neck pain into four grades based on the following factors: interference with activities of daily living, the presence of neurological signs (grades I - III), or signs and symptoms of major structural pathology (grade IV).<sup>7,8</sup> The course of the pain (normal or delayed recovery) often determines whether physiotherapeutic treatment is advised; when the course of the pain is normal, treatment is often not advised. Subgrouping patients is becoming an increasingly popular method for applying targeted treatment, since it has the potential to optimise treatment benefits and maximise healthcare efficiency. For low-back pain (LBP), the SBT is probably the best-known tool for subgrouping back-pain patients in primary care combined with a targeted treatment. The SBT focuses on the combination of limitations in patients' activity and pain as well as several psychosocial factors known to influence patients' recovery. It was developed to assign primary-care patients with LBP to one of three subgroups based on their prognosis—low, moderate or high risk for persisting disability—and to apply the appropriate stratified care.<sup>9,10</sup> The SBT consists of nine questions: eight true/false questions and one question with a 5-point Likert-scale as the answer option. It aims to predict persisting disability based on these independent factors, with each factor adding to the likelihood of a poor prognosis. For each subgroup, a targeted treatment is advised. In short, “low-”, “medium-” and “high-risk” patients receive information and advice; in addition, both “medium-” and “high-risk” patients receive standardised physiotherapy to address symptoms and function, and “high-risk” patients also receive psychologically informed physiotherapy to address the psychosocial obstacles to recovery.<sup>11</sup> The SBT has been validated for LBP in the UK<sup>9</sup>, and translated into several other languages, including Dutch.<sup>12–19</sup> A few preliminary studies were performed for other musculoskeletal pain conditions, such as lumbar stenosis, knee pain, shoulder pain and neck pain; however, these findings are not ready for clinical implementation.<sup>20–22</sup> Our aims are to modify the SBT for patients with neck pain, and to evaluate the validity and reliability of the modified SBT in Dutch primary care.



## METHOD

### Developing the SBT-Neck

The Dutch SBT for LBP was initially a combined SBT tool for both patients with neck pain and LBP.<sup>19</sup> It was used as a basis for the neck version. Next, we performed a preliminary field test with two general practitioners (GPs) and one physiotherapist (PT) working in primary care to analyse the instrument's feasibility in 140 patients with neck pain or LBP of any duration. Of the 140 patients, 24.3% experienced neck pain, 42.1% experienced back pain and 32.9% experienced both. We found that patients who suffered from both neck and LBP ( $n = 46$ ), in particular, had difficulty in answering the questions: they could not distinguish between neck pain and LBP.

During a subsequent expert meeting, we decided to return to the initial LBP version and develop a separate neck-pain version. In most questions, "back" was replaced with "neck" and radiating pain in the legs was modified to radiating pain in the arms. Question 3 was changed to "I have used my arms and neck less due to my neck pain" instead of "I have only walked short distances because of my back pain". The changes were based on consensus in the working group. The Dutch SBT is included in Appendix 1. Appendix 2 illustrates the comparison between the original SBT, the Dutch neck-pain version and its English translation.

### Design

We performed a clinimetric sub study—the prevalence of risk groups in neck- and back-pain patients study (PRINS)—as part of a prospective cohort according to the SBT.<sup>19</sup> All patients that consulted primary care for low-back or neck pain were asked to answer both baseline and follow-up questionnaires, and received usual care from their clinicians. The study was approved by the medical ethics committee of the Erasmus University, Rotterdam, the Netherlands. (MEC-2014-256). For this study, we only utilise the data of the patients with neck pain (with or without concurrent back pain) from the PRINS cohort.

### Participants

#### *Clinicians*

We invited clinicians who had previously expressed interest in evaluating the SBT to participate in this study. They all attended a meeting in which the study was explained, and they received the study protocol. They also received posters, information brochures and informed-consent forms for the patients.

#### *Patients*

We included patients from November 2014 until May 2015. When a patient consulted a GP or PT through referral or direct access for their neck pain, they were asked to participate in the PRINS study. Patients with non-specific neck pain (grade I - III), and who were 18 years or older, could speak, read and write in Dutch, and had an

email address, were included. Patients were excluded if, during the consultation, the GP or PT found red flags indicating a possible specific underlying pathology (grade IV), for example, an infection, a fracture, cauda equina or a tumour. Patients were given oral and written information about the procedure of data collection and the aim of the study. When a patient was willing to participate, he or she signed an informed consent and handed it back to the clinician, who registered the patient online. The patient immediately received an email with a link to the baseline questionnaire.

### Treatment

Patients received usual care from their clinicians, who were unaware of the results of the baseline questionnaire, including the SBT score.

### Measurements

#### *Baseline*

At baseline (T0), patients filled out a questionnaire consisting of demographic variables, such as age and gender, and the SBT-Neck. We measured the average pain in the past week using the 11-point Numeric Pain-Rating Scale (NPRS)<sup>23</sup>, ranging from 0="no pain" to 10="worst imaginable pain". Disability was assessed using the Neck Disability Index (NDI)<sup>24</sup>, which consists of 10 statements with a 6-point scale ranging from 0="not limited" to 5="completely limited". The score was doubled to obtain a total score, ranging from 0 to 100, with a higher score indicating greater disability. We measured fear of movement or (re)injury using the Tampa Scale of Kinesiophobia (TSK)<sup>25</sup>, which consists of 17 statements with four answer options varying from 1="highly disagree" to 4="highly agree". The total score ranges from 17 to 68, with a higher score indicating a higher level of kinesiophobia. To assess the level of catastrophising, we used the Pain Catastrophising Scale (PCS), which consists of 13 statements, each with a 5-point Likert-scale as an answer option ranging from 0="not at all" to 4="always".<sup>26</sup> The total score ranges from 0 to 65, with a higher score indicating a higher level of catastrophising. Finally, we assessed quality of life using the EQ-5D<sup>27</sup>, which consists of six questions. The first five questions each have a 3-point Likert-scale answer option ranging from 1="no problems" to 3="severe problems", and the sixth question is a health-status question with answer options ranging from 0="worst imaginable health" to 100="best imaginable health".

#### *Follow-up*

Three days after inclusion (T1), a follow-up questionnaire was sent to the patients to investigate the reliability of the SBT-Neck. The questionnaire consisted of the SBT-Neck, the NPRS and the General Perceived Effect scale (GPE) to assess pain and recovery, respectively, and the answer options on the GPE range from 1="fully recovered" to 7="worse than ever". We considered 3 days short enough to prevent substantial improvement, and long enough, in combination with all other baseline

questionnaires, to reduce recall bias.<sup>28</sup> For practical reasons, the test-retest questionnaire was added only for patients that were included during the last 3 months of the inclusion period.

Three months after inclusion (T2), the patients received a follow-up questionnaire consisting of the GPE and NDI; we simultaneously sent a questionnaire to the GPs to inquire about the patients' number of visits, prescribed medication, referrals to physiotherapists or medical professionals, and requested diagnostic imaging and blood tests. We sent a similar questionnaire to PTs to inquire about treatment data, such as the dates of the patients' first and last treatments, the number of treatment sessions, any questionnaires used, and the aim and means of treatment.

### Sample size

Terwee et al. advise a minimum sample size of 50 persons for all aspects of the clinimetric study; we aimed for a minimum of 100 persons.<sup>28</sup>

### Statistical analysis

We analysed the data to describe patients' characteristics, which were expressed using frequencies, means and standard deviations. The risk-profiles distribution and their characteristics are reported. For *construct validity*, we first analysed the characteristics across the SBT risk profile to determine the discriminant validity. Next, we calculated the Pearson's correlation coefficient for each item of the SBT-Neck and its reference questionnaire, based on the comparability of the domains of measurement.<sup>29,30</sup> We expected a moderate ( $r \geq .3$ ,  $< .5$ ) to high ( $r \geq .5$ ) correlation between the following items: the first question of the SBT-Neck and the single-item question on 'referred pain', the third and fourth activity items and the NDI, the fifth kinesiophobia question and the TSK, the sixth and seventh catastrophising questions and the PCS, and the ninth bothersome question with the NPRS. We included no reference questionnaire for the second question, and no questionnaire to measure depression (question 8).

For *reproducibility*, we selected the patients that remained stable between T0 and T1. Patients were considered stable when they scored "slightly improved", "no change" or "slightly worsened" on the GPE at T1. Since there is some doubt in the literature regarding whether the GPE can actually detect change, we combined a stable GPE score with a stable pain score measured on the NPRS—meaning the same score plus or minus one point compared to the baseline score.<sup>31</sup> We calculated the quadratic-weighted kappa for the ability to distinguish between groups, and the specific agreement for each risk profile separately.<sup>29</sup> The kappa will be interpreted as  $\leq 0$  = poor agreement,  $.01 - .20$  = slight,  $.21 - .40$  = fair,  $.41 - .60$  = moderate,  $.61 - .80$  = substantial, and  $.81 - 1$  = almost perfect agreement.<sup>32</sup> For example, patients who are at "low risk" on T0 and T1 are calculated as a proportion of patients that were at "low risk" on either of the two measurements. In collaboration with de Vet, we

modified the specific agreement to fit a 3x3 table, as illustrated in table I, because the original method employs a 2x2 table.

We determined the *predictive validity* by reporting the RR for “medium-risk” and “high-risk” patients, compared to those at “low-risk”, in their ability to predict the outcome at 3 months. The outcomes are 1) persisting disability, defined as an NDI equal to or higher than the median of the NDI on baseline, and 2) persisting pain, defined as an NPRS equal to or higher than the median of the NPRS on baseline, corresponding to the method that Hill used in the original study.<sup>9</sup> For patients’ individual recovery we analysed 3) disability non-recovery—an NDI score that decreased to below the minimal clinically important difference (MCID) of 4 points<sup>33</sup>, 4) pain non-recovery—an NPRS that decreased to below the MCID of 2 points<sup>34</sup>, and 5) perceived recovery—defined as either “completely recovered” or “much improved” on the GPE.<sup>35</sup>

Limited *content validity* is indicated by more than 15% of the patients reaching either the floor (0/9 points) or ceiling (9/9 points) effects of the SBT.<sup>28</sup>

**Table I; specific agreement**

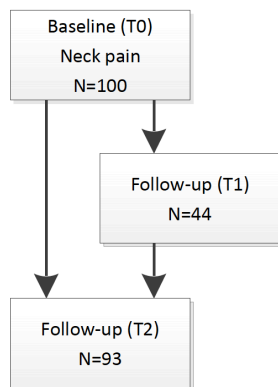
		Follow-up (T1)		
		Low	Medium	High
Baseline (T0)	Low	15 (A)	2 (B)	0 (C)
	Medium	1 (D)	3 (E)	0 (F)
	High	0 (G)	0 (H)	0 (I)
“Low-risk” $A/(A+(B+C+D+G)/2) = 15/16.5 = 90.9\%$				
“Medium-risk” $E/(E+(B+H+D+F)/2) = 3/4.5 = 66.7\%$				
“High-risk” $I/(I+(C+F+G+H)/2) = 0$				

## RESULTS

In total, 12 GPs and 33 PTs included 100 patients with neck pain in the PRINS study. Loss to follow up at 3 months was 7 (7%) (figure I). At baseline, we found that 58 patients (58%) were categorised as “low risk”, 37 (37%) as “medium risk” and 5 (5%) as “high risk” (table 2). We found no differences between the risk groups concerning age or gender. For each increase in the risk profile, we found an increase in the pain, disability, catastrophising and kinesiophobia scores (see table II).

Overall, PTs treated patients in line with the guideline on neck pain: applying mobilisation, utilising exercise therapy and providing information.<sup>8</sup> GPs do not have a guideline on neck pain, and they referred 22 (out of 26) patients to a PT. In total, five patients were prescribed pain medication, one was referred for imaging, and two were referred to medical specialists due to persisting pain.

**Figure 1, patient flow**



### Construct validity

We found a low correlation between activity-question 3 and the NDI scores ( $r = .13$ ); a moderate correlation between activity-question 4 and the NDI, kinesiophobia-question 5 and the TSK, and catastrophising-questions 6 and 7 and the PCS; and a high correlation between SBT-question 1 and the single-item question ( $r = .55$ ), and bothersome-question 9 and the NPRS ( $r = .50$ ) (table III). All correlations were a priori, as expected, regarding the direction of the correlation and the magnitude, with the exception of activity-question 3. We conclude that the construct validity is sufficient.

### Reproducibility

In total, 44 patients completed the second test-retest questionnaire, and 21 of them were regarded as stable. On average, there were 12 days between T0 and T1.

The quadratic kappa of .58 for the SBT-Neck indicated a moderate reproducibility. Distribution is skewed due to the large proportion of patients at “low risk” and the absence of a stable “high-risk” group. For the “low-risk” group, we found a specific agreement of 90.9% and a 66.7% agreement for the “medium-risk” group. We were unable to calculate the specific agreement for the “high-risk” group as there were no patients in this ‘reproducibility sample’. The overall agreement indicated excellent reproducibility for the “low-risk” group and fair reproducibility for the “medium-risk” group.

**Table II; baseline characteristics of the study population**

	<b>Neck pain</b> (N=100)	<b>Low risk</b> (N=58)	<b>Medium risk</b> (N=37)	<b>High risk</b> (N=5)
Female	65 (65.0)	39 (65.5)	23 (62.2)	4 (80.0)
Age in years, mean (SD)	45.6 (14.3)	45.5 (14.1)	44.8 (13.7)	52.8 (21.1)
SBT risk profile				
Low	58 (58.0)	NA	NA	NA
Medium	37 (37.0)	NA	NA	NA
High	5 (5.0)	NA	NA	NA
Episode duration				
<1 month	27 (27.0)	15 (25.9)	11 (29.7)	1 (20.0)
1 to 3 months	18 (18.0)	12 (20.7)	6 (16.2)	0 (0.0)
>3 months	55 (55.0)	31 (53.4)	20 (54.1)	4 (80.0)
SBT score, mean (SD)	3.4 (1.8)	2.1 (0.8)	4.9 (0.9)	7.6 (1.1)
Pain intensity, mean (SD)	5.5 (1.9)	4.7 (1.8)	6.6 (1.4)	7.0 (0.7)
Mild (0-5)	41 (41.0)	34 (58.6)	7 (18.9)	0 (0.0)
Moderate (5-7)	46 (46.0)	24 (41.4)	18 (48.6)	4 (80.0)
Severe (8-10)	13 (13.0)	0 (0.0)	12 (32.4)	1 (20.0)
Disability (NDI), mean (SD)	28.2 (13.6)	22.0 (9.8)	34.6 (12.2)	57.8 (14.2)
Referred pain	33 (33.0)	15 (25.9)	15 (40.5)	3 (60.0)
Comorbid pain	69 (69.0)	36 (62.1)	28 (75.7)	5 (100.0)
Bothersome	48 (48.0)	12 (20.7)	31 (83.8)	5 (100.0)
Fear (TSK), mean (SD)	32.2 (5.9)	29.7 (4.9)	34.8 (4.3)	42.6 (6.9)
Catastrophizing (PCS), mean (SD)	12.7 (10.0)	8.8 (7.3)	16.1 (8.7)	32.6 (15.2)

*Values are numbers (percentage) unless otherwise indicated. pain is measured on the Numeric Pain Rating Scale (0-10). SBT = STarT Back tool, NDI = Neck Disability Index (0-100), TSK = Tampa Scale of Kinesiophobia (17-68), PSC = Pain Catastrophizing Scale (0-65)*

**Table III; Correlation between the STarT Back Tool and their reference questionnaires using the Pearson's correlation**

SBT and reference		Correlation		
	A priori	r		Expected
Q1 – single item	$r \geq 0.30$	0.55	high	Yes
Q3 - NDI	$r \geq 0.30$	0.13	low	No
Q4 - NDI	$r \geq 0.30$	0.37	moderate	Yes
Q5 - TSK	$r \geq 0.30$	0.42	moderate	Yes
Q6 - PCS	$r \geq 0.30$	0.46	moderate	Yes
Q7 - PCS	$r \geq 0.30$	0.35	moderate	Yes
Q9 - NPRS	$r \geq 0.30$	0.50	high	Yes

*SBT = STarT Back Tool, Q = Question, r = Pearson's correlation, NDI = Neck Disability index, TSK = Tampa Scale of Kinesiophobia, PCS = Pain Catastrophizing Scale, NPRS = Numeric Pain Rating Scale*

#### Predictive validity

In total, 93 patients completed the T2 questionnaire. In all three risk profiles, we found a decrease in pain and disability over time (see table IV).

We found that, with an increase in the risk-profile, patients experienced a higher level of pain and disability at 3 months. The baseline median scores for pain and disability, which were an NDI  $\geq 13$  and an NPRS  $\geq 6$ , respectively, were used as a cut-off point. More patients experienced persisting pain or disability in the “medium-risk” group than in the “low-risk” group; however, in both groups, an equal number of patients experienced a significant decrease in pain and disability in 3 months.

The “high-risk” group comprised a small sample size ( $N = 3$ ), resulting in unrepresentative results. The RRs for the “medium-risk” group compared to the “low-risk” group were 3.0 for persisting disability and 3.9 for persisting pain. An RR of 3.9 means that patients at “medium risk” were 3.9 times more likely to experience persisting neck pain, compared to patients at “low risk”. The RR confidence intervals for patients' individual recovery and perceived recovery all include 1 (= equal risks), making it statistically insignificant.





**Table IV; relative risk of pain, disability or recovery at three month follow-up**

	Persisting pain			Persisting disability			MCID in pain		MCID in disability		Perceived recovery	
	N (%)	NPRS (SD)	RR (95% CI)	N (%)	NDI (SD)	RR (95% CI)	N (%)	RR (95% CI)	N (%)	RR (95% CI)	N (%)	RR (95% CI)
Low Risk (N=55)	5 (9.1)	2.64 (1.94)		7 (12.7)	12.32 (9.60)		24 (43.6)		36 (65.5)		37 (67.3)	
Medium Risk (N=34)	12 (35.3)	4.26 (2.59)	3.88 (1.50 - 10.06)	13 (38.2)	22.00 (15.04)	3.00 (1.33 - 6.78)	15 (44.1)	0.99 (0.68 - 1.45)	17 (50.0)	1.45 (0.88 - 2.38)	16 (47.1)	0.70 (0.47 - 1.05)
High Risk (N=4*)	1 (33.3)	5.00 (3.46)	3.67 (0.60 - 22.30)	3 (75.0)	35.00 (24.24)	5.89 (2.41 - 14.41)	1 (33.3)	1.18 (0.51 - 2.72)	2 (50.0)	1.45 (0.51 - 4.12)	3 (75.0)	1.11 (0.61 - 2.02)

*Persisting pain is NPRS  $\geq 6$ , persisting disability is NDI  $\geq 13$  "MCID in pain" is a decrease of  $< 2$  points, "MCID in disability" is a decrease of  $< 14$  points, Recovery is a GPE score of 1 or 2. MCIC = Minimal Clinical Important Change, GPE = General Perceived Effects (1-7), NPRS = Numeric Pain Rating Scale (0-10), NDI = Neck Disability Index (0-100)*

*\*N=3 for pain measure due to missing value*

### Content validity

We analysed the data of 100 patients concerning the SBT-Neck to determine floor and ceiling effects. One patient (1%) scored zero, and one patient (1%) scored nine points, implying no important floor and ceiling effects, and therefore, a good content validity.

## **DISCUSSION**

### Main findings

The SBT-Neck is a formative model that aims to give advises for targeted treatment. The construct validity is sufficient, although activity-question 3 did not meet the expected a priori correlation with the NDI. For the test-retest reliability the specific agreement is moderate to almost perfect and the kappa is moderate. The absence of floor and ceiling effects confirmed a good content validity. However the predictive validity, based on the MCID, demonstrated statistically insignificant results. The results for the "high-risk" group are based on a too small population to draw conclusions.

### Interpretation of findings

The specific-agreement analysis that was used to determine the reproducibility reveals highly accurate consistency for patients with a "low-risk" score; the accuracy decreases, although it is still good, for the "medium-risk" group. The conditions were set to ensure 'stable patients' based on time, pain and reported recovery. Unfortunately, patients took 12 days, on average, to respond, instead of the aimed 3 days, and the delay in response, in combination with the ranges in pain (NPRS +/-1) and recovery (GPE 'no change' +/- 1), could result in patients improving slightly, and therefore, changing to a lower risk profile. This might explain the lower score in the specific agreement for the "medium-risk" group. In interpreting the kappa, we must

keep in mind that the distribution is skewed due to the large proportion of patients at “low risk” and the absence of a “high-risk” group. Nevertheless, the SBT-Neck is fairly able to distinguish between risk groups.<sup>29</sup>

We utilised RRs to calculate the increased risk of the “medium-risk” and “high-risk” groups, compared to the “low-risk” group. All RR calculations using either the MCID of the NPRS, the NDI or the GPE were found to be statistically insignificant. The RRs with cut-off points based on the baseline median of the NPRS and the NDI offered better results; however, they did not represent the patients’ actual persisting pain or disability. The predictive validity was determined while the clinician applied ‘usual care’. In our cohort, no standardised therapy protocol was used as the clinician did not have access to the SBT score. In contrast to LBP, no stratified-care approach is available for patients with neck pain, and we expected the GP or PT to follow the guidelines when available.<sup>36,37</sup> In other cases, clinicians were free to apply their therapy in the ways they deemed fit.

#### Findings in the context of other literature

This is the first publication on the SBT for patients with neck pain. One study published a version of the SBT that can be used for neck pain; however, it was specifically designed for multiple body regions.<sup>20</sup> Also, no stratified care was applied to these patients. Other studies that make use of the SBT focus on LBP.<sup>9,12–19</sup> The validation process of this study is comparable to that of the Dutch LBP version, which is also carried out within the PRINS study, and the results are largely comparable.

For the construct validity, the scores are comparable with the LBP results except for question 3 (correlation with the NDI), where the correlation was lower than expected. This might be because we changed the answer option for questions 3 from the original version: in the original version, the answer option was “I have only walked short distances because of my back pain”, whereas in the modification, we altered the answer option to “I have used my arms and neck less due to my neck pain”, since the expert group considered this to be more relevant. However, this question is not covered by the NDI and possibly explaining the low correlation.

For the reproducibility, we found that the quadratic kappa is slightly lower in this study—with .58 for neck pain, compared to .65 for LBP—and the specific agreement is slightly higher in neck pain.

The initial SBT study that Hill et al. conducted, as well as all the translations, used an internal-consistency analysis and a psychosocial subscale, and calculated a discriminant validity using an area under the curve.<sup>9,12,13,38,39</sup> In our study, we approached the tool as a formative model, making this calculation redundant.

#### Strengths and limitations

The strength of this study is that it is the first one to have successfully modified the SBT to a neck-pain version. Whilst the construct validity, reproducibility and content validity are all moderate to good, the predictive validity is insufficient when using

'usual care' as treatment instead of a targeted treatment. The advised minimum sample size was met, except for the reproducibility (44 instead of 50), and our aim for a minimum of 100 persons was not met for the predictive validity.

Another limitation of this study is that, for feasibility reasons, the baseline questionnaire was filled in after the first consultation instead of before. During the initial consultation, a patient's cognition might be altered, which would influence the results.

#### Clinical and/or research implications

The SBT-Neck requires further research to determine whether current questions and cut-off points are optimal. Also whether stratified care could be added and would then lead to a faster recovery.

### **CONCLUSION**

The SBT is modified to fit patients with neck pain in Dutch primary care. The predictive validity is insufficient on individual prognosis for the instrument to be used in the present form.



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## Appendix 1; The Dutch version of the STarT Back Tool for patients with neck pain.

### The STarT Back Screening Tool: Dutch Neck Version

Auteur: J.D. Bier, B.W. Koes, R.W.J.G. Ostelo, B. Mutsaers, N. Wildervanck, A.P. Verhagen (2014)

Naam: \_\_\_\_\_ Datum: \_\_\_\_\_

Antwoord u alstublieft ieder onderdeel. Kruis bij ieder onderdeel het vakje aan dat op u van toepassing is. Soms is het moeilijk om tussen twee vakjes te kiezen, kruis dan het vakje aan dat uw probleem het beste beschrijft. Kruis niet meer dan één vakje per onderdeel aan!

Denk bij het beantwoorden van de volgende vragen telkens aan de situatie in de **laatste 2 weken**.

	Oneens 0	Eens 1
1. In de laatste 2 weken <b>straalde</b> mijn nekpijn wel eens <b>uit naar één of beide armen</b> .	<input type="checkbox"/>	<input type="checkbox"/>
2. In de laatste 2 weken heb ik, naast mijn nekpijn, wel eens pijn <b>ergens anders</b> gehad.	<input type="checkbox"/>	<input type="checkbox"/>
3. In de laatste 2 weken <b>bewoog</b> ik mijn nek en/of armen <b>minder</b> vanwege mijn nekpijn	<input type="checkbox"/>	<input type="checkbox"/>
4. In de laatste 2 weken <b>kleepte ik me trager</b> dan gewoonlijk <b>aan</b> vanwege mijn nekpijn.	<input type="checkbox"/>	<input type="checkbox"/>
5. Voor iemand in mijn toestand is het echt <b>niet veilig</b> om lichamelijk actief te zijn.	<input type="checkbox"/>	<input type="checkbox"/>
6. <b>Ongeruste gedachten</b> gingen vaak door mijn hoofd.	<input type="checkbox"/>	<input type="checkbox"/>
7. Ik vind dat mijn <b>nekpijn verschrikkelijk</b> is en ik geloof dat <b>het nooit meer beter zal worden</b> .	<input type="checkbox"/>	<input type="checkbox"/>
8. Over het geheel genomen heb ik <b>niet genoten</b> van alle dingen waar ik vroeger wel van genoot.	<input type="checkbox"/>	<input type="checkbox"/>
9. Over het geheel genomen, hoe hinderlijk was uw nekpijn in de laatste 2 weken?		

In het geheel niet	Een beetje	Matig	Erg	Extreem
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
0	0	0	1	1

Totale uitslag (alle 9) : \_\_\_\_\_ Sub Uitslag (Q5-9): \_\_\_\_\_



**Appendix 2; The comparison between the original SBT, the Dutch neck pain version and its English translation.**

	Original SBT	Dutch neck version	English translation of the Dutch neck version
1	My back pain has spread down my leg(s) at some time in the last 2 weeks	In de laatste 2 weken straalde mijn nekpijn wel eens uit naar één of beide armen.	In the past 2 weeks my neck pain sometimes radiated in one or both arms.
2	I have had pain in the shoulder or neck at some time in the last 2 weeks	In de laatste 2 weken heb ik, naast mijn nekpijn, wel eens pijn ergens anders gehad.	In the past 2 weeks I had pain in other parts of my body next to my neck pain.
3	I have only walked short distances because of my back pain	In de laatste 2 weken bewoog ik mijn nek en/of armen minder vanwege mijn nekpijn.	In the past 2 weeks I moved my neck and / or arm less because of my neck pain.
4	In the last 2 weeks, I have dressed more slowly than usual because of back pain	In de laatste 2 weken kleeedde ik me trager dan gewoonlijk aan vanwege mijn nekpijn	In the past 2 weeks I dressed more slowly than usual because of my neck
5	It's not really safe for a person with a condition like mine to be physically active	Voor iemand in mijn toestand is het echt niet veilig om lichamelijk actief te zijn	For someone in my condition it's really not safe to be physically active
6	Worrying thoughts have been going through my mind a lot of the time	Ongeruste gedachten gingen vaak door mijn hoofd.	Worrying thoughts often went through my head.
7	I feel that my back pain is terrible and it's never going to get any better	Ik vind dat mijn nekpijn verschrikkelijk is en ik geloof dat het nooit meer beter zal worden	I think my neck pain is terrible and I believe it will never get better
8	In general I have not enjoyed all the things I used to enjoy	Over het geheel genomen heb ik niet genoten van alle dingen waar ik vroeger wel van genoot	Overall, I have not enjoyed all the things I used to enjoy
9	Overall, how bothersome has your back pain been in the last 2 weeks?	Over het geheel genomen, hoe hinderlijk was uw nekpijn in de laatste 2 weken?	Overall, how bothersome was your neck pain in the past 2 weeks?

## **Chapter 5**

Can primary care for back and/or neck pain in the Netherlands benefit from stratification for risk groups according to the STarT Back Tool-classification?

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## **ABSTRACT**

### Objective:

To evaluate whether current Dutch primary-care clinicians offer tailored treatment to patients with lower-back pain (LBP) or neck pain (NP) according to their risk stratification, based on the Keele STarT (Subgroup Targeted Treatment) Back-Screening Tool (SBT).

### Design:

Prospective cohort study with 3 month follow-up.

### Setting:

Primary care.

### Participants:

General practitioners (GPs) and physiotherapists included patients (N=284) with non-specific LBP, NP or both.

### Interventions:

Patients completed a baseline questionnaire, including the Dutch SBT, for either LBP or NP. A follow-up measurement was conducted after 3 months to determine recovery (using Global Perceived Effect Scale), pain (using Numeric Pain Rating Scale), and function (using Roland Disability Questionnaire or Neck Disability Index). A questionnaire was sent to the GPs and physiotherapists to evaluate the provided treatment.

### Main outcome measures:

Prevalence of patients' risk profile and clinicians' applied care, and the percentage of patients with persisting disability at follow-up. A distinction was made between patients receiving the recommended treatment and those receiving the non recommended advised treatment.

### Results:

In total, 12 GPs and 33 physiotherapists included patients. After 3 months, we analyzed 184 patients with LBP and 100 patients with NP. In the LBP group, 52.2% of the patients were at low risk for persisting disability, 38.0% were at medium risk, and 9.8% were at high risk. Overall, 24.5% of the patients with LBP received a low-risk treatment approach, 73.5% a medium-risk, and 2.0% a high-risk treatment approach. The specific agreement between the risk profile and the received treatment for patients with LBP was poor for the low-risk and high-risk patients (21.1% and 10.0%, respectively), and fair for medium-risk patients (51.4%). In the

NP group, 58.0% of the patients were at low risk for persisting disability, 37.0% were at medium risk, and 5.0% were at high risk. Only 6.1% of the patients with NP received the low-risk treatment approach. The medium-risk treatment approach was offered the most (90.8%), and the high-risk approach was applied in only 3.1% of the patients. The specific agreement between the risk profile and received treatment for patients with NP was poor for low-risk and medium-risk patients (6.3% and 48.0%, respectively); agreement for high-risk patients could not be calculated.

#### Conclusion:

Current Dutch primary care for patients with nonspecific LBP, NP, or both does not correspond to the recommended stratified-care approach based on the SBT, as most patients receive medium-risk treatment. Most low-risk patients are overtreated, and most high-risk patients are undertreated. Although the stratified-care approach has not yet been validated in Dutch primary care, these results indicate there may be substantial room for improvement.

## INTRODUCTION

Low back pain (LBP) and neck pain (NP) are major public health problems; they are the primary and fourth causes, respectively, of disability worldwide.<sup>1</sup> With regard to health-seeking behavior for LBP and NP, approximately 55% of patients seek healthcare, and between 12% and 32% visit a general practitioner (GP).<sup>2-4</sup>

Nonspecific LBP and NP are the main focus of most primary-care guidelines.<sup>5,6</sup> The guidelines from both the Dutch General Practitioners Society and the Royal Dutch Physiotherapists Society divide patients with nonspecific LBP and NP into roughly two subgroups: (1) normal recovery, which is defined as a decrease in pain and function limitation prior to consultation; and (2) a (suspected) delayed recovery.<sup>5,7,8</sup>

The Keele STarT (Subgroup Targeted Treatment) Back-Screening Tool (SBT) is a tool, developed in England, to allocate primary-care patients with LBP to 3 prognostic subgroups: patients at either low, medium or high risk for persisting disability.<sup>9</sup> This allocation aims to ensure that the appropriate stratified care is applied to patients at risk for persistent LBP in order to prevent it.<sup>10</sup> This tool's questions are based on known negative-prognostic factors that can be influenced by treatment. Furthermore, the SBT has been found to be a valid and reliable tool for subgrouping patients in the United Kingdom<sup>9</sup>, and it has been translated and validated in several languages, including Dutch<sup>11</sup>, since its initial English publication in 2008.<sup>12-18</sup> The Dutch version of the SBT has been modified to fit patients with NP.<sup>19</sup> The SBT, and corresponding targeted treatment, has yet to be implemented in the Netherlands. Recommended care for normal recovery is to reassure the patient and inform him or her of the positive prognosis, and to advise the patient to stay active, which might be supported with the prescription of pain medication. If the pain persists or worsens, the GP can refer physiotherapy to the patient. Where current guidelines advise a stepped approach for patients with a delayed recovery, the SBT advises a stratified-care approach; the difference between these 2 approaches relates to the timing of (effective) interventions. Implementing the SBT in the United Kingdom has led to higher quality-adjusted life years for patients and lower health costs, and superior outcomes in the high-risk group using stratified care.<sup>20,21</sup> No studies have been published on stratified care for patients with NP; however, we expect that it will not differ from the approach for LBP. Before advising on implementing the SBT in the Netherlands, we need more insight into the current usual care because implementation of the SBT might be unnecessary if usual care provides comparable or better outcomes. Therefore, the aim of this study is to evaluate current Dutch primary care for spinal pain and whether it corresponds to the advised stratified-care approach based on the SBT.

## METHOD

### Design

The prevalence of risk groups in neck- and back-pain patients according to the SBT (PRINS) study is a prospective cohort study, which includes patients with LBP or NP of any duration that consulted a GP or physiotherapist. The study was approved by the medical ethics committee of the Erasmus University, Rotterdam, the Netherlands (METC-2014-256).

### Participants

#### *Care providers*

We asked GPs and physiotherapists, who work in the primary-care sector and had displayed interest in the SBT during pilot projects, to participate in the PRINS study. Information about the study protocol was provided through several meetings, by phone or by digital/paper documentation, and participating GPs and physiotherapists received the study protocol and a folder with patient information and informed consent forms. The majority of these GPs and physiotherapists work in small clinics in the region of Rotterdam (a maximum of 50 kilometers).

#### *Patients*

The inclusion period for patients started in November 2014 and continued through to May 2015, and patients consulting their GP or physiotherapist for LBP or NP during that period were invited to participate. Other inclusion criteria were that the patient had to be 18 years old or over, could speak and read Dutch and had an email address.

Patients were excluded if, during the consultation, the GP or physiotherapist found “red flags” indicating a possible serious underlying pathology (eg. infection, fracture, cauda equine, tumor) responsible for the LBP or NP.

Patients were provided with oral and written information about the aim of the study and the procedure of data collection, and each patient signed an informed consent, which was handed back to the GP or physiotherapist who subsequently registered the patient online. The patient immediately received an e-mail with a link to the baseline questionnaire, and if necessary, a reminder to complete the questionnaire was sent after a few days. Patients who did not complete the baseline questionnaire within 7 days were excluded from the cohort.

### Treatment

The patients received usual care from their GPs or physiotherapists, who were kept blind for the results of the patients’ baseline questionnaire.

### Baseline measurements

The baseline questionnaire consisted of questions on demographic data, the SBT (either the back or neck version) and the Numeric Pain Rating Scale (NPRS)<sup>22</sup> to



assess pain; the Neck Disability Index (NDI)<sup>23</sup> or the Roland Disability Questionnaire (RDQ)<sup>24,25</sup> to assess disability; the Tampa scale<sup>26</sup> for kinesiophobia; and the pain-catastrophizing scale<sup>27</sup> and the EQ-5D (European Quality of Life-5 Dimensions)<sup>28</sup> to assess quality of life. The NPRS options range from 0 (no pain) to 10 (worst imaginable pain), the RDQ consists of 24 statements with a “yes” or “no” answer option and a total score ranging from 0 to 24, and the NDI consists of 10 statements with a 6-point scale ranging from 0 (not limited) to 6 (completely limited) and a total score ranging from 0 to 50.

### Outcome measure

Three months after inclusion, the patients received a follow-up questionnaire to assess pain (Numeric Pain Rating Scale), disability (RDQ or NDI) and recovery, using the Global Perceived Effect Scale. The answer options on the GPE range from 1 (fully recovered) to 7 (worse than ever). Persisting LBP disability was defined as an RDQ score  $\geq 7$ , based on the mean of the baseline score as used by Hill et al.<sup>9</sup>, while persisting NP disability was defined as an NDI score  $\geq 13$ , based on the median baseline score in this cohort.

Three months after inclusion, the GP was sent a questionnaire to inquire about the number of visits, prescribed medication, referrals to physiotherapists or medical professionals and requested imaging and blood tests. The physiotherapist received a questionnaire to inquire about treatment data such as the number and period of treatments, and the aim and means of treatment. The investigator sent and received all questionnaires digitally, and they were handled and stored through LimeSurvey 2.05.

### Analysis

#### *Treatment categorization*

The 2 authors utilized the following criteria to independently categorize the treatments applied by the GPs and/or physiotherapists (in case of differences between the authors, the categories were determined by consensus):

- **Low-risk approach** – the GP provided information, advice and some analgesics or 1 or 2 physiotherapy consultations, and the treatment was hands-off and consisted of offering information, advice and exercises.
- **Medium-risk approach** – in addition to the low-risk approach, the GP referred the patient to a physiotherapist, and the physiotherapist performed an evidence-based intervention.
- **High-risk approach** – in addition to the medium-risk approach, the GP referred the patient to either a physiotherapist specialized in treating patients with a psychosomatic approach, a psychologist or equivalent, and the physiotherapist assessed bio-psychosocial risk factors and used cognitive behavioral principles as interventions.<sup>29</sup>

### Statistical analysis

We described the characteristics of the clinicians and patient population using frequencies (means with SDs). Next, we calculated the frequencies of patients per SBT risk profile and the clinicians' treatment approaches. The specific agreement calculates percentages of recommended treatment approaches for each risk profile separately.<sup>30</sup> For example, patients who were "low-risk" at baseline and treated as such are calculated as a proportion of patients that were "low-risk" on either of the 2 measurements. We modified the specific agreement to fit a 3x3 table, as illustrated in Table I, because the original method is done in a 2x2 table. We rated a specific agreement < 40% as poor, 40% to 59% as fair, 60% to 74% as good and 75% to 100% as excellent. Lastly, we calculated the percentage of patients with persisting disability per risk profile; this was done for the groups receiving the recommended and non-recommended treatments.

**Table I; specific agreement**

		Follow-Up (T1)		
Baseline (T0)	Risk	Low	Medium	High
	Low	(A)	(B)	(C)
	Medium	(D)	(E)	(F)
	High	(G)	(H)	(I)

*NOTE. Low-risk,  $A/(A+(B+C+D+G))/2$ ; Medium-risk,  $E/(E+(B+H+D+F))/2$ ; High-risk,  $I/(I+(C+F+G+H))/2$ .*

## **RESULTS**

### Study population

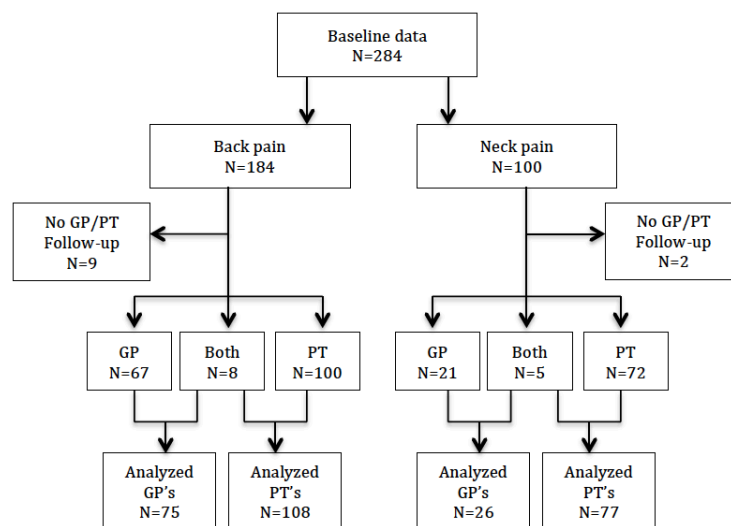
The GPs and physiotherapists originally included 370 patients; however, 86 patients failed to fill in the baseline questionnaire and were excluded. The characteristics of the 284 remaining patients are presented in Table II. The 12 GPs included 103 patients (26 with NP and 77 with LBP) and the 33 physiotherapists included 181 patients (74 with NP and 107 with LBP). The 4 groups (NP/LBP stratified for GP/physiotherapist) are largely comparable in gender, age, fear of movement, pain catastrophizing and pain intensity, and the percentages of SBT-risk profiles of each of the 4 groups are also comparable: the low-risk profile percentage ranges from 50.0% to 60.8%, the medium-risk profile percentage ranges from 35.1% to 42.3% and the high-risk profile percentage ranges from 4.1% to 11.2%. General practitioners tend to see a higher proportion of chronic patients with LBP compared to physiotherapists (68.8% vs. 48.6%).

## Follow-up

The follow-up questionnaire for GPs and physiotherapists had a non-response of 3.9% (n = 11), and the follow-up questionnaire for patients had a failure to follow-up of 14.4% (n = 41). Thirteen patients were seen by both a GP and a physiotherapist; in this analysis, these patients are analyzed in both groups. Figure I (patient flow) displays all patients analyzed despite patients' failure to follow-up.

Due to the clinicians' non-response, the specific-agreement analysis was performed on 273 patients (175 with LBP and 98 with NP), and due to the patients' non-response, the persisting disability analysis was performed on 243 patients (150 with LBP and 93 with NP). Due to both the clinicians' and patients' non-response, the treatment analysis was performed on 234 patients (142 with LBP and 92 with NP).

**Figure I; Patient flow**



## Treatments

The 2 authors independently categorized the treatments that the physiotherapists applied, and, in 90.5% of the cases, agreed on their categorization. The categorization of the GPs' treatments was performed in SPSS (version 24). The authors decided that the treatment offered by a GP, whereby he performed manipulations himself, is categorized as medium-risk (comparable to referring the patient to a physiotherapist, irrespective of the number of manipulations).

### *Lower back pain*

In the specific-agreement analysis, the majority of the patients with LBP were at low risk for persisting disability (n = 95; 54.3%). Thirteen (13.7%) of these patients received the SBT-recommended low-risk treatment approach, which resulted in a specific agreement of 22.4% (Table III). According to the SBT, all other patients (n = 82) were over-treated. Receiving the treatment approach for medium or high risk did not result in a lower percentage of persisting disability (Table IV).

We found that of the 64 (36.8%) patients who were considered to be at medium risk,

55 (85.9%) received treatment corresponding to this risk profile (specific agreement = 51.4%), 7 patients received a low-risk treatment (undertreated) and 2 a high-risk treatment (over-treated). Both over- and undertreated patients had a higher percentage of persisting disability compared to the group that was treated in accordance with its risk profile.

In the group of patients that were considered to be at high risk for persisting disability (n = 16; 9.2%), only 1 patient (6.3%) received the high-risk treatment approach (specific agreement = 10.0%). According to the SBT, all other patients (n = 15) were undertreated. We found that these undertreated patients had an average of 6.5 physiotherapy sessions, and the patients treated as high risk received 8.5 physiotherapy sessions on average.

**Table II; baseline characteristics**

Characteristics	Total		GP		PT	
	Neck (n=100)	Back (n=184)	Neck (n=26)	Back (n=75)	Neck (n=74)	Back (n=108)
Woman	65 (65.0%)	103 (56.0)	17 (65.4)	42 (54.5)	48 (64.9)	61 (57.0)
Age in years, mean (SD)	45.6 (14.3)	44.7 (14.6)	45.4 (12.5)	40.7 (14.7)	45.7 (14.9)	47.5 (13.9)
SBT <sup>§</sup> risk profile						
Low	58 (58.0)	96 (52.2)	13 (50.0)	42 (54.5)	45 (60.8)	54 (50.5)
Medium	37 (37.0)	70 (38.0)	11 (42.3)	29 (37.7)	26 (35.1)	41 (38.3)
High	5 (5.0)	18 (9.8)	2 (7.7)	6 (7.8)	3 (4.1)	12 (11.2)
SBT score, mean (SD)	3.4 (1.8)	3.6 (2.0)	3.7 (2.0)	3.4 (2.0)	3.3 (1.8)	3.7 (2.1)
Episode duration						
<1 mo	27 (27.0)	53 (28.8)	7 (26.9)	15 (19.5)	20 (27.0)	38 (35.5)
1 to 3 mo	18 (18.0)	26 (14.1)	5 (19.2)	9 (11.7)	13 (17.6)	17 (15.9)
>3 mo	55 (55.0)	105 (57.1)	14 (53.8)	53 (70.7)	41 (55.4)	52 (69.3)
Pain intensity <sup>l</sup> , mean ± SD	5.5 (1.9)	5.9 (1.8)	5.4 (1.9)	5.7 (1.9)	5.6 (1.9)	6.0 (1.8)
Mild (0-5)	41 (41.0)	63 (34.2)	14 (53.8)	27 (35.1)	27 (36.5)	36 (33.6)
Moderate (5-7)	46 (46.0)	88 (47.8)	8 (30.8)	38 (49.4)	28 (51.4)	50 (46.7)
Severe (8-10)	13 (13.0)	33 (17.9)	4 (15.4)	12 (15.6)	9 (12.2)	21 (19.6)
Disability (NDI) <sup>¶</sup> , mean (SD)	14.1 (6.8)	NA	14.2 (8.8)	NA	14.1 (6.1)	NA
Disability (RDQ) <sup>#</sup> , mean (SD)	NA	9.5 (5.9)	NA	8.9 (5.7)	NA	10.0 (6.1)
Fear (TSK) <sup>*</sup> , mean (SD)	32.2 (5.9)	34.8 (7.1)	33.8 (5.6)	35.2 (6.3)	31.7 (5.9)	34.4 (7.6)
Catastrophizing (PCS) <sup>†</sup> , mean (SD)	12.7 (10.0)	13.8 (10.3)	16.5 (12.4)	14.6 (11.2)	11.4 (8.7)	13.1 (9.6)
Referral	NA	NA	NA	NA	17 (23.6)	23 (23.2)

**NOTE.** Values are numbers (percentage) unless otherwise indicated.

<sup>§</sup> SBT = STarT Back Tool (total score range 0-9)

<sup>l</sup> Pain intensity is measured on a Numeric Pain Rating Scale (0-10)

<sup>¶</sup> NDI = Neck Disability Index (0-50)

<sup>#</sup> RDQ = Roland Disability Questionnaire (0-24)

<sup>\*</sup> TSK = Tampa Scale of Kinesiophobia (17-63)

<sup>†</sup> PCS = Pain Catastrophizing Scale (0-65)

**Table III; Specific agreement analysis between baseline risk profile and treatment as provided**

Baseline	Treatment profile			
	Low	Medium	High	Specific Agreement (%)
<b>LBP (n=175)</b>				
Low-risk	13	81	1	22.4
Medium-risk	7	55	2	51.4
High-risk	1	14	1	10.0
<b>NP (n=98)</b>				
Low-risk	2	55	0	6.3
Medium-risk	3	30	3	48.0
High-risk	1	4	0	NA

*NOTE. Values are n or as otherwise indicated. Analysis based on patients' baseline-data and clinicians treatment-data. Specific agreement is interpreted as the proportion of patients that had that specific risk profile on either baseline or in the treatment profile.*

**Table IV; treatment analysis for low back pain\***

Baseline	Treatment	N (%)	Persisting Disability, n (%)
<b>LBP (n=142)</b>			
Low-risk	Low	9 (12.0)	2 (22.2)
	Medium	65 (86.7)	13 (20.0)
	High	1 (1.3)	1 (100.0)
Medium-risk	Low	6 (11.3)	3 (50.0)
	Medium	45 (84.9)	15 (33.3)
	High	2 (3.8)	2 (100.0)
High-risk	Low	0 (0.0)	0 (NA)
	Medium	13 (92.9)	7 (53.8)
	High	1 (7.1)	1 (100.0)
Under treated		19 (13.4)	10 (52.6)
Rightfully treated		55 (38.7)	18 (32.7)
Over treated		68 (47.9)	16 (23.5)

*NOTE. Analysis based on patients' baseline-data and follow-up data, and clinicians treatment-data. 'Persisting Disability' is the amount and percentage of patients with persisting disability in the corresponding treatment group. Abbreviation: NA, not applicable*

### *Neck pain*

In the specific-agreement analysis, 57 (58.2%) of the 98 patients with NP were considered to be at low risk for persisting disability. Two of these patients (3.5%) received the corresponding low-risk treatment approach (specific agreement = 6.3%); other patients were considered to be over-treated (Table III) and had a higher percentage of persisting disability at 3 months (Table V).

We found that while 36 patients (36.7%) were considered to be at medium risk for persisting disability, only 30 patients (83.3%) received care that corresponded to their medium-risk profile (specific agreement = 48.0%); the remaining 6 patients were equally divided between receiving the low- and high-risk treatment approach.

Of the 98 patients with NP, the smallest group contains the patients considered to be at high risk for persisting disability (N = 5; 5.1%). None of these patients received the high-risk treatment approach, making it impossible to calculate the specific agreement. On average, these patients underwent 7.2 physiotherapist sessions, while patients treated as high risk in this study received 8.8 sessions on average.

**Table V; treatment analysis for low neck pain\***

<b>Baseline</b>	<b>Treatment</b>	<b>N (%)</b>	<b>Persisting Disability, n (%)</b>
NP (n=92)			
Low-risk	Low	2 (3.7)	0 (0.0)
	Medium	52 (96.3)	7 (13.5)
	High	0 (0.0)	9 (N/A)
Medium-risk	Low	3 (8.8)	0(0.0)
	Medium	28 (82.4)	10 (35.7)
	High	3 (8.8)	3 (100.0)
High-risk	Low	1 (25.0)	1 (100.0)
	Medium	3 (75.0)	2 (66.7)
	High	0 (0.0)	0 (N/A)
Under treated		7 (7.6)	3 (42.9)
Rightfully treated		30 (32.6)	10 (33.3)
Over treated		55 (59.8)	19 (34.5)

*NOTE. Analysis based on patients' baseline-data and follow-up data, and clinicians treatment-data. 'Persisting Disability' is the amount and percentage of patients with persisting disability in the corresponding treatment group. Abbreviation: NA, not applicable*

### *Physiotherapy treatments*

In the specific-agreement analysis, we found that 86.2% of the patients with LBP and 90.8% of the patients with NP received a medium-risk treatment approach, which suggests a one-size-fits-all approach in current usual care. Only 7 patients (3.0%) received a high-risk approach, over half of the patients were over-treated (47.9% for

LBP and 59.8% for NP), and between 32.6% (NP) and 38.7% (LBP) received the targeted treatment. The LBP and NP patients that were given the correct treatment had almost the same percentage of persisting disability in 3 months (32.7% for LBP and 34.5% for NP).

#### *General practitioners referral*

The GPs referred 10 patients (9.9%) for imaging: 7 to rule out serious pathology and 3 at the request of the patient. Three other patients were referred to a neurologist or an orthopedic surgeon due to persisting complaints; 1 of these referrals was at the request of the patient. In 27 cases, the GPs prescribed analgesic drugs; for 15 patients (55.5%) this was time-contingent (compared to pain-contingent). Furthermore, we found an (almost) absence of a psychosocial approach or related referrals by the GP (eg. the high-risk approach).

## **DISCUSSION**

### Main findings

GPs and physiotherapists treat the majority of their patients as medium-risk patients even though this majority is actually at low risk for persisting complaints. No large differences are found between NP or LBP patients. The minority of patients (36.7%) received care that corresponds to the recommended care according to the SBT approach; 52.2% of the patients were considered over-treated and 11.0% were undertreated.

### Interpretation

The SBT approach advises 1 consultation with information or education for low-risk patients. We considered an intervention to match the low-risk profile if the GP or physiotherapist gave information or education in either 1 or 2 consultations. The GP also had the option to offer additional analgesics to the patient within the low-risk treatment approach. The United Kingdom healthcare system recommended an average of 4 interventions. In our cohort (LBP and NP combined), we found an average of 6.8 physiotherapy sessions and 8.7 sessions in the patients with a high-risk profile. Furthermore, we found an (almost) absence of a psychosocial approach or related referrals (for example, the high-risk approach). This study clearly demonstrates that clinicians tend to treat the majority of their patients as medium-risk patients; they do not stratify and treat patients based on the perceived risk of persistent complaints, and over half of the patients are over-treated. In low-risk patients with LBP, we see that the majority of the patients recover, irrespective of a low or medium-risk intervention. We expect the same for NP; however, due to the small proportion of patients receiving a low-risk approach, we could not evaluate this. Also, no conclusions can be drawn from the high-risk population due to the small sample size.

One Irish study conducted a non-randomized clinical trial in 332 LBP patients who were included in a historical cohort.<sup>21</sup> This group received a generic 12-week group education or exercise program, comparable to the medium-risk approach, while an intervention group of 251 LBP patients received a stratified-care approach. Stratified care demonstrated a superior effect on the high-risk group; however, the study did not analyze the usual care, as was done in this study.

In the original SBT study, stratified care was the intervention that was compared to a usual-care approach and found that the intervention group displayed a higher mean change in disability compared to the control group; however, no information about the specific contents of usual care was provided.<sup>20</sup> No other studies have been found that analyze unprotocolled usual care in contrast to the SBT approach.

Other remarkable findings are that the GPs referred 10 patients for imaging even though they were labeled as nonspecific LBP or NP, meaning that there were no signs or signals indicating serious pathology. The GP guidelines advise against diagnostic imaging in these instances<sup>31,32</sup>, since imagery may lead to higher healthcare costs due to additional tests and treatment, but may not improve clinical outcomes and may even lower the quality of life.<sup>33,34</sup> While analgesics were prescribed to 44.5% of the patients on a pain-contingent basis, the GP guidelines advise doing so on a time-contingent basis.<sup>31</sup>

### Strengths and limitations

This is the first study that compares current usual care with the advised stratified-SBT approach in the Netherlands, and provides insight into the question regarding whether specific implementation of stratified care is required or whether usual care already properly categorizes patients.

Our results have limited generalizability for the group of high-risk patients because this group was quite small. At the moment, the SBT approach is only available for LBP patients, and so far, no study has been conducted on an SBT approach for patients with NP; however, the conditions are rather comparable. Our categorization of usual care was based on the information that physiotherapists provided. They wrote their (primary) treatment goals and means, and we may have missed certain psychosocial factors that were addressed but not reported in the patient files.

In the United Kingdom, the SBT has the potential to predict persisting disability in clinical practice. We found differences between usual care and the recommended stratified care, since most patients received the therapy recommended for medium-risk patients. Educating clinicians on the SBT approach, especially for the low and high-risk groups, is necessary for this approach to be effective in reducing pain, function and sick leave in the Netherlands. However, prior to making efforts to change the working method, it is essential to determine what causes clinicians to treat patients as they do. A qualitative study should be undertaken to gain insight.



## **CONCLUSION**

Current Dutch usual care does not correspond to the recommended stratified-care approach based on the SBT for patients with nonspecific LBP or NP. Clinicians tend to treat the majority of their patients as medium-risk patients even though most of them were found to be low-risk patients.

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## **Chapter 6**

# **Clinical Practice Guideline for Physiotherapy Assessment and Treatment in Patients With Non- specific Neck Pain**

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## **ABSTRACT**

The Royal Dutch Society for Physiotherapy (KNGF) issued a clinical practice guideline for physical therapists that assess and treat patients with non-specific neck pain including cervical radiculopathy in Dutch primary care. Recommendations are based on a review of published systematic reviews.

During the intake the patient is screened for serious pathologies and analysing the corresponding patterns. Patients with a cervical radiculopathy can be in- or excluded through corresponding signs and symptoms and possibly diagnostic tests (Spurling, traction/distraction, and Upper Limb Tension Test). History taking is done to gather information about patients' limitations, course of pain, and prognostic factors such as coping style and health related questions.

In case of a normal recovery (profile A) management should be hands-off and patients should receive advice from the Physiotherapist (PT) and possibly some simple exercises to supplement 'acting as usual'.

In case of a delayed/deviant recovery (profile B) the PT is advised to use, in addition to profile A, forms of mobilization and/or manipulation in combination with exercise therapy. Other interventions may be considered in addition. The PT is recommended not to use dry needling, low-level laser, electrotherapy, ultrasound, traction and/or a cervical collar.

In case of a delayed/deviant recovery with clear and/or dominant psychosocial prognostic factors (profile C) these should first be addressed by the PT where possible or referred to a specialist where necessary.

In case of neck pain grade III (profile D) the therapy resembles profile B but the use of the cervical collar may be considered in for pain reduction. The advice is to use it sparsely: only for a short period per day and only for a few weeks.

## BACKGROUND

In 2012 the global burden of disease study stated that neck pain is globally the 4th largest physical complaint regarding years lived with disability.<sup>1</sup> The estimated one-year incidence of neck pain has been reported to vary between 10.4 to 21.3%.<sup>2</sup> Data from 2003, in the Dutch population aged 25 years and over, showed that the neck is the third most common musculoskeletal complaint, after the lower back and the shoulder region.<sup>3</sup> The total costs of spinal pain in the Netherlands in 2011 were 1.3 billion euros (1.5% of the total healthcare costs and 0.2% of the gross domestic product): 40% of these costs are thought to be related to neck pain and 29% of the total costs are related to primary care of which physiotherapy is a part.<sup>4</sup>

### Definition of Neck pain and Scope of the Guideline

Neck pain is described as ‘an unpleasant sensory and emotional experience associated with actual or potential tissue damage’ in the neck region which starts at the superior nuchal line and down to the level of the scapular spine.<sup>5</sup> This includes Whiplash Associated Disorder (WAD), cervicogenic headache, and cervical radicular syndrome. Neck pain has been classified by the Neck pain Task Force (NPTF) four grades, see table I.<sup>6</sup>

**Table I; Neck Pain Task Force classification**

Grade I	Neck pain and associated disorders with no signs or symptoms suggestive of major structural pathology and no or minor interference with activities of daily living.
Grade II	No signs or symptoms of major structural pathology, but major interference with activities of daily living.
Grade III	No signs or symptoms of major structural pathology, but presence of neurologic signs such as decreased deep tendon reflexes, weakness, or sensory deficits.
Grade IV	Signs or symptoms of major structural pathology. Major structural pathologies include (but are not limited to) fracture, vertebral dislocation, injury to the spinal cord, infection, neoplasm, or systemic disease including the inflammatory arthropathies.

The Neck pain guideline covers neck pain grades I to III. Grade I and II include two specific subgroups: trauma-related neck pain (previously known as whiplash or WAD) and work-related neck pain, based on patient’ statement on the cause or onset of pain.<sup>7,8</sup>

### Clinical Course and Prognosis

In a general population 50 to 85% of the patients with neck pain will report neck pain 1 to 5 years later.<sup>9</sup> A Dutch cohort study of patients with neck pain in primary care found that after one year 76% of the patients stated to be fully recovered or much



improved, although 47% reported still to have (some) neck pain.<sup>10</sup> In patients with acute neck pain the pain and disability decrease in the first six weeks with about 45%, but no further decrease can be found afterwards.<sup>11</sup> Neck pain in the working population seems to be quite persistent and takes a recurrent course.<sup>12</sup> 60 to 80% of workers with neck pain will report neck pain one year later.<sup>12</sup> In the trauma related neck pain subgroup improvement in pain and disability mainly occurs within the first three months following the accident.<sup>13</sup> A systematic review found recovery rates range from 16% to 99%.<sup>14</sup> Roughly 50% of people with neck pain continue to experience some degree of neck pain 6 to 12 months following an accident.<sup>15,16</sup>

Prognosis is important in the process of clinical decision-making. When the prognosis of a patient is favorable the intervention may be limited to education and advice, while a patient with a poor prognosis might need an in-depth evaluation followed by a specific therapy or intervention.<sup>13</sup>

### Prognostic Factors

Knowledge about the prognosis and the prognostic factors is essential for determining an indication for physiotherapy and/or an intervention strategy. When the current course of neck pain is favorable and there are no (or a limited amount of) negative prognostic factors there is no indication for physiotherapy besides giving information and advice. When the current course is delayed and the physiotherapist (PT) can influence the negative prognostic factors, there might be an indication for physiotherapy. Despite the multiple research and reviews there are a number of predictors that provide low or very low confidence or inconclusive results.<sup>13</sup> A large survey suggests a gap between current best-evidence and actual practice in establishing a prognosis in neck pain.<sup>17</sup> Factors frequently found to be prognostic for persisting neck pain are, amongst others, history of other musculoskeletal disorders, passive coping style, and psychosocial distress.<sup>9,12,13,15,17-19</sup>

The Royal Dutch Society for Physiotherapy (KNGF) issued and funded a guideline for PT and manual therapists who treat patients with non-specific neck pain and related health complaints in Dutch primary care.<sup>20,21</sup> It aims to (1) increase uniformity and quality of physiotherapy health care, (2) define the boundaries and the domain of the PT in relation to patients with neck pain, (3) ensure that patients receive the optimal care and (4) support the PT in making decisions in the choice of diagnostic and therapeutic interventions.

## **METHOD**

The guideline committee was formed in September 2013. The guideline committee consisted of neck-pain experts, PT's and epidemiologists. Members were chosen for their expertise on the subject and their experience in previously published guideline development committees. The first author was responsible for collecting the data and drafting the guideline. The other authors were responsible for verifying the

statements made in the clinical practice guideline (CPG). The CPG was developed according to the method used for physiotherapy guidelines issued by the KNGF.<sup>20</sup> The method consists of five different phases: (1) preparation, (2) development, (3) validation, (4) implementation (5) evaluation and update. This article focuses on phase one to three. The AGREE II instrument has been used to assist development.<sup>22</sup>

We searched for studies on prognosis of neck pain, accuracy of diagnostic tests, and effectiveness of therapeutic interventions within the domain of physiotherapy and manual therapy.<sup>21,23–25</sup> These interventions have all been described by the KNGF and are (in alphabetical order): cognitive behavioral treatment, cervical collar, dry needling, education, electrotherapy, exercise, joint mobilization, kinesiotape, low level laser therapy, manipulation, massage, neurodynamics, pillow, thermal agents, traction, shockwave, and workplace interventions.<sup>25</sup>

Best evidence was sought from recent systematic reviews, randomized controlled trials (RCTs) and prospective observational studies.<sup>20</sup> We used recent documents from the Neck Pain Task Force (NPTF)<sup>6–9,12,15,26–35</sup>, the International consensus on Neck (ICON)<sup>13,16–18,36</sup>, recently published guidelines such as the guideline from the Canadian Chiropractic Association and the American Physiotherapy Association.<sup>37,38</sup> and Cochrane reviews.<sup>39–50</sup> Additional relevant articles were searched through Pubmed searches using MESH-headings or free text words in combination with the central search term 'neck' or 'cervical'.

### Critical Appraisal Process

The authors appraised all included articles for its quality. Articles were assessed using generally accepted and appropriate tools; e.g. QUADAS for diagnostic tests, PEDro for randomized controlled trials. All intervention studies were assessed as having high, unclear or low risk of bias and subsequently appraised for quality using the Grading of Recommendations Assessment, Development and Evaluation (GRADE)-system.<sup>51</sup> The levels of evidence are presented in table II.<sup>51</sup> Evidence based on randomized controlled trials begins as high quality evidence, but the confidence in the evidence may be decreased for several reasons, including:

- Study limitations (studies were suffering from high risk of bias)
- Inconsistency of results (studies showed clinical or statistical heterogeneity)
- Indirectness of evidence (the study population differed from the target population of the guideline)
- Imprecision (too few studies or included patients; e.g. less than 300 patients or events)
- Reporting bias, publication bias or a fatal flaw.

**Table II; Quality of evidence and definitions**

Level of quality	Definition
High	Further research is very unlikely to change our confidence in the estimate of effect
Moderate	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Low	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Very low	Any estimate of effect is very uncertain

Once evidence was graded, the evidence was translated into recommendations for clinicians. When clinical experience of the guideline committee had a role in the recommendations this is explicitly stated. Cost-effectiveness did not influence the recommendations and none of the guideline committee members had any conflict of interest besides partially working in the primary care. The recommendations were formulated reflecting the evidence into strong recommendations using terms as “is recommended” (evidence indicates that the intervention is effective) or “is not recommended” (evidence indicated that the intervention is not effective). In case of weak or unclear evidence recommendations are formulated as “may be considered”.<sup>52</sup> Where possible these recommendations are stated separately for patients with trauma-related neck pain, work-related neck pain or neck pain grade III.

#### External review by stakeholders

After finalizing the first draft the board of directors of the KNGF gave feedback on the guideline. This did not result in any changes in the recommendations in the guideline.

The guideline then underwent a review from external stakeholders. These organizations were: The Dutch Patients and Clients Federation (NPCF), The Dutch Association of Manual Therapists (NVMT), Dutch General Practitioners Association (NHG), The Dutch Society for Psychosomatic Physiotherapy (NFP), Dutch Association for Occupational Physical Therapists (NVBF), Dutch Association of Orthopedic Surgeons (NOV), Dutch Association of Rehabilitation Physicians (VRA), Dutch Association of Anesthesiology (NVA) and the Association of Dutch Healthcare Insurers (ZN).

Next, the KNGF issued a work field analysis, which was performed under 93 PT to review their opinion of the guideline and its feasibility through a written feedback form. A second method was used to measure 20 PT's provided care through performance indicators before and after attending a presentation about the guideline. A focus-group meeting with the latter group was to evaluate the results and experiences. Revisions were made to the document based on the feedback.

The comments from the work field analysis and an update of the search resulted in the final guideline. The guideline and the supporting documents have been published in Dutch on [www.fysionet-evidencebased.nl](http://www.fysionet-evidencebased.nl) and are accessible for members and non-members of the KNGF.

## RESULTS

### Summary of the content of the clinical practice guideline

In the Netherlands a patient with neck pain can be referred to a PT by a general practitioner or medical specialist. It is also possible that the patient can consult a PT without referral; this is called direct access to PT services. The guideline was constructed according to the different phases of the physiotherapy assessment: intake, physical examination, analysis, treatment, and evaluation of treatment.

### Intake

During the first consultation the patient will undergo a 'screening procedure' to assess whether physiotherapy treatment is indicated. The PT first evaluates complaints and symptoms and checks for any red flags. Red flags are patterns of signs or symptoms (warning signs) that may indicate serious pathology, requiring further medical diagnostics. When red flags (table III) are present it might be an indication for a specific pathology (e.g. Neck Pain Grade IV).

The PT analyses, within the clinical reasoning process, whether the red flags are consistent with the patient's complaints based on age, gender, incidence and prevalence, information on onset of complaints, signs and symptoms. If present and not explicable by a known pattern of neck pain the patient has to be referred to or returned to their general practitioner.<sup>56</sup> The evidence supporting the red flags for neck pain is weak and inconsistent since many red flags are rather generic (such as unexplained weight loss) and suffer from high false positive rates.<sup>29,43,57</sup> When no red flags are present, the diagnostic process continues with an intake. Dutch PTs cannot refer patients for diagnostic imaging, this is reserved for general practitioners or medical specialists. The use of diagnostic imaging to rule-in or rule-out a specific serious pathology (Grade IV) has a low to moderate reliability.<sup>34</sup> A remarkable situation in diagnostic imaging is the relatively high proportion of positive findings in healthy people.<sup>58,59</sup>

The initial aim in the diagnostic process is to identify the patient's problems by formulating initial hypothesis/hypotheses about the diagnosis and further refining this hypothesis (clinical reasoning).<sup>60</sup> During history taking the PT is able to gather information about the patients' deficits in body structure and functions, the patients' limitations in daily activity and restriction in participation. Also it is important to gather information about the patient's environmental and personal factors that can lead to chronicity. It is known that certain psychosocial factors can negatively influence the

neck pain. In this diagnostic process the PT helps the patient to structure treatment goals and health management strategies based on clinical data, patient's preferences, and professional knowledge and judgment.<sup>61</sup> The PT tries to objectify the information from the intake where necessary, with measurement instruments if available. The PT is recommended to use the Numeric Pain Rating Scale (NPRS)<sup>62,63</sup> to objectify pain and the Patient-Specific Functional Scale (PSFS)<sup>62,64</sup> to objectify limitations in activity.

During the intake it is important to identify a possible Grade III neck pain because the approach and policy are different from neck pain Grade I and II. A possible Grade III neck pain will be accompanied by certain signs and symptoms in addition to neck pain<sup>65</sup>: sensory symptoms in the arm such as paraesthesia, numbness, sensory changes, a cervical range of motion described as limited and painful and motor disturbances such as upper limb weakness and/or muscle atrophy.

**Table III; Red flags per possible serious pathology**

Possible pathology	Corresponding red flags
Fracture	Older age <sup>53</sup> , History of trauma <sup>34,53</sup> , corticosteroid use, osteoporosis. <sup>34</sup>
Vertebral dissection	Cerebrovascular symptoms or signs <sup>54</sup>
Injury to the spinal cord or cervical myelopathy	Neurological symptoms e.g. widespread neurological signs in both arms or in the leg(s) such as sensory deficits or loss of muscle strength in the limbs, and bowel and bladder dysfunction. <sup>34</sup>
Infection (including urinary tract infection or skin infection)	Symptoms and signs of infection (e.g. fever, night sweats), risk factors for infection (e.g. underlying disease process, immunosuppression, penetrating wound, intravenous drug abuse, exposure to infectious diseases). <sup>34</sup>
Neoplasm	Past history of malignancy, failure to improve with a month of treatment, unexplained weight loss, <sup>34,38</sup> age >50yr, dysphagia, headache, vomiting. <sup>34</sup>
Systemic disease (Herpes Zoster, Ankylosing spondylitis, inflammatory arthritis, rheumatic arthritis)	Headache, fever, unilateral skin rash, burning pain, itching. <sup>55</sup>

### Physical examination

Differentiating between neck pain grades I/II and grade III can be done during physical examination where specific provocation or reduction tests can be used. Research showed that the following tests are the most valid: the Upper Limb Tension Test A (ULTT) for the nervus medianus, the Spurlings' test, in the combination of side bending and extension of the cervical spine, and the traction/distraction test.<sup>66</sup> A negative ULTT is found valid as a high sensitive test (sensitivity range 0.72 – 0.97, specificity range 0.11 - 0.33) to rule patients out, meaning these patients probably do not have a cervical radiculopathy.<sup>66,67</sup> The Spurlings' test (sensitivity range 0.90 – 1.00, specificity range 0.94-1.00) and the traction/distraction test (sensitivity 0.44, specificity range 0.90 – 0.97) are regarded valid as a specific test to rule in, meaning the patient probably has a cervical radiculopathy.<sup>66–68</sup>

Other clinical tests are not recommended in the physical examination of the neck as they vary and are not very standardized. That is why their accuracy is quite variable and overall insufficient.<sup>34</sup> This does not mean that it should not take place. In the clinical reasoning process, the physical examination aims to further refine the diagnostic hypothesis based on the findings from the intake e.g. to rule-in or rule-out a certain hypothesis. Furthermore it also aims to objectify the level of physical functional limitations and to assess secondary factors that could negatively influence the recovery process. Common forms of physical examination are inspection in rest, inspection during movement, and assessing physical functions such as joint function, muscle control and movement patterns. When evaluating the validity of physical examination or provocation tests the reliability of the procedure is also an issue. Studies evaluating the reliability of physical examination of the neck often find low to moderate reliability (Kappa 42-82%).<sup>69,70</sup>

### Analysis

When during the intake the PT finds no reason to suspect a neck pain grade IV the PT will have to differentiate between neck pain Grade I, II or III. If during the intake the presence of neurological signs such as numbness, paraesthesia, muscle weakness are found and in addition of the physical examination the patient is likely to suffer from neck pain grade III, radiculopathy. In this case the PT is recommended to consult the patient's general practitioner to report the findings and discuss the treatment options.

The PT uses the information from history taking to analyse the pain severity, limitations in activities and restriction in participation. Based on the data collected, the patients' health problem can be analysed. When the PT assumes that the patient will suffer from a delayed recovery, he or she should check for any factors that might explain the persistent nature of the neck pain episode. The PT will assess if the prognostic factors, found during history taking, can be influenced and/or if the therapy can be given according to the guideline. The use of questionnaires to objectify psychosocial prognostic factors may be considered.<sup>71–74</sup>

Based on the history taking and the findings of the physical examination, the PT assigns the patient to a profile: The guideline committee recommends the use of the following patient profiles. Profile A; Neck Pain Grade I/II-normal course. Profile B; Neck Pain Grade I/II, delayed course without dominant psychosocial influence. Profile C; Neck Pain Grade I/II, delayed course with dominant psychosocial influence. Profile D; Neck Pain Grade III.

### Treatment

For treatment profile A the PT will inform the patient about the expected course of pain and provide some take home exercises. It is recommended that the PT limits the treatment to three sessions.

For treatment profile B the PTs' goal is to guide the patient to a quick return to normal daily activities and the prevention of chronicity. The following treatments have, on average, a moderate level of evidence showing a positive effect in contrast to a placebo or other treatments, and are therefore recommended to be used: mobilization<sup>75</sup>, manipulation<sup>75-77</sup> and exercise therapy<sup>78</sup>. The recommended intervention is a combination of these.<sup>79</sup> There is very low quality evidence that information and education for patients with neck pain is effective but in the opinion of the working group it is an essential part of the therapy.<sup>18,50</sup>

The following treatments may be considered by PTs in treating patients with neck pain preferably in addition to the advised treatment. These treatments have a low or very low level of evidence. The evidence shows small effects in contrast to other treatments or placebo: cognitive behavioural treatment / graded activity<sup>80</sup>, cervical collar for patients with neck pain grade III<sup>18,50</sup>, massage<sup>45</sup>, neurodynamics or neural tissue management<sup>41</sup>, pillow<sup>18</sup>, (kinesio) tape<sup>81-83</sup>, thermal agents<sup>36</sup>, and workplace interventions<sup>84</sup>. The studies reporting on these treatments are either of low quality, show small effect sizes or show conflicting evidence.

The following treatments have a low or very low level of evidence. They show no effects in contrast to other treatments or placebo. These treatments are recommended not to be used by PTs in treating patients with neck pain: dry needling<sup>85-87</sup>, low-level laser<sup>36,88,89</sup>, electrotherapy<sup>36,48,90</sup>, ultrasound<sup>36,42,90</sup>, traction<sup>47</sup> and cervical collar for neck pain grade I and II<sup>18,50</sup>. Studies on these interventions did not show any additional benefit when compared to a placebo or another intervention.

For treatment profile C the therapy will correspond with profile B. The difference is the dominant psychosocial influence (psychosocial prognostic factors). These factors should be addressed prior to (or simultaneously with) applying other interventions as these factors are regarded as being 'responsible' for the delayed course of the neck pain. It may considered to be addressed by the PT where possible or referred to a specialist where necessary.

For treatment profile D the therapy resembles profile B but differs on the use of the cervical collar that may be considered in this patient population for pain reduction but only when used sparsely; for a short period per day for a few weeks.

### Evaluation of treatment

The treatment is ended as soon as the agreed treatment goals have been achieved. Even if the goals have not been achieved, the treatment will have to be concluded at some stage. For instance, it is not useful to continue the treatment if no progress has been made after six weeks, as the chances of achieving progress after this period are small. This must be discussed explicitly with the patient before the final treatment session including whether the patient will be referred (back) to the general practitioner or not.

The course of the treatment must be evaluated during the treatment, and at the final session. Besides evaluating the patient's goals it is recommended to use the following measurement instruments at intake: the NPRS for pain and the PSFS for patient specific complaints, also the other instruments used during the intake provided these are suitable for evaluation. Both NPRS and PSFS have a minimal clinical important change of two points. This cut-off point is used to measure patients' improvement.<sup>62,91</sup>

## **DISCUSSION**

### Limitations of the Guideline

The CPG is primarily based on systematic reviews performed by the Cochrane, the ICON and NPTF. A choice made due to limitations in time and funds. Other stakeholders, including patients, were invited after the first concept was finalized. To strengthen the support it would be better to include these stakeholders in an earlier stage. This guideline reserved a group, profile C, for patients where recovery was delayed based on psychosocial factors. No evidence was available for this choice and no evidence is available that addressing these psychosocial factors will lead to recovery from neck pain. The same can be said for addressing other prognostic factors.

The guideline is issued to fit the Dutch physiotherapy practice. This means that only the interventions are included that are within the professional domain of the Dutch PT, as defined by the KNGF. The validation process is also only done in the Netherlands. Both may influence the international generalizability of the guideline.

### Similarities and differences with international guidelines

A recently updated CPG on Neck pain issued by the orthopedic section of the APTA shows great similarities concerning treatment advice, but differs on the subgrouping of patients.<sup>92</sup> Where we use the Grade I-IV as advised by the NPTF the APTA guideline uses the international classification of disease and related health problems (ICD). The prognostic factors can be found in both guidelines where the APTA-CPG advises on more tools to appraise these constructs. Also there is more emphasis on clinical prediction rules where the Dutch PT CPG does not address these at all, as they are not regarded valid enough to be advised. Both guidelines address the same treatments; manual therapy, exercise, multimodal, education and physical agents



(dry needling, laser, ultrasound, TENS (transcutaneous electrical nerve stimulation)). The Dutch PT CPG gives less direction to the form of manipulation, exercise or other modalities and when to use which form. Differences in treatment recommendations is that dry needling and laser are not recommended in the Dutch CPG.

The Ontario Protocol for Traffic Injury Management (OPTIMa) published a guideline in 2016.<sup>93</sup> This guideline focuses on the same grades of neck pain but limits the duration of neck pain to 6 months. In the recommendations of treatments OPTIMa makes a distinction between 0-3 months and 3-6 months. The Dutch guideline does not make that distinction. The OPTIMa guideline also advises on the use of non-steroidal anti-inflammatory drug, electro acupuncture, and botulin toxin injections. These treatments are not regarded as PT-treatments in the Netherlands. Two differences in recommended treatments are that in the OPTIMa laser is a treatment for consideration and the Dutch guideline advises against its use. Also the use of a cervical collar may be considered in the Dutch guideline, in contrast to in the OPTIMa guideline.

This clinical practice guideline is available in full text (in Dutch) on [www.fysionet-evidencebased.nl/](http://www.fysionet-evidencebased.nl/)

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# **Chapter 7**

## General Discussion

## **GENERAL DISCUSSION**

The aim of this thesis is to provide insight into the prognosis and optimal care for patients with spinal pain in primary care – general practitioners (GPs) and physical therapists (PTs). In the previous chapters, we reported the results of all studies conducted. In this general discussion, we will present our main findings and discuss their interpretations. We will discuss the limitations and provide an overview of the literature with their similarities and contradictions. Finally, we will present recommendations for clinical practice and further research.

## **KEY FINDINGS**

### **Chapter 2**

- When a GP offers guideline recommended care over a 4-week treatment period to patients with acute low back pain (LBP) in Australia, the majority (70%) of patients do not adhere to this advice, more specifically to the study medication.
- Non-adherence is positively associated with higher baseline disability and negatively associated with a higher perceived risk that symptoms will be persistent, and with participants not claiming worker's compensation.
- Worsening of the complaint in the first week after consulting the GP is strongly associated with using additional healthcare or medication.

### **Chapter 3**

- The Keele STarT (Subgroup Targeted Treatment) Back-Screening Tool (SBT) is successfully translated into Dutch, and it is regarded as a valid and reliable screening tool for patients with LBP in Dutch primary care

### **Chapter 4**

- The SBT is modified to fit patients with neck pain in Dutch primary care.
- The validity of the SBT for neck pain (in the present form) is not yet sufficient for use in clinical practice.

### **Chapter 5**

- The majority of patients who consult primary care in the Netherlands are regarded as being at low risk for persisting complaints.
- Clinicians treat the majority of their patients as medium-risk patients even though they are regarded as being at low risk or high risk for persisting complaints.
- Fifty-two percent of the patients with LBP or neck pain are considered to be over-treated according to the SBT approach.

### **Chapter 6**

- A clinical-practice guideline (CPG) is provided for Dutch PTs to assist in their diagnostic and therapeutic processes in patients with neck pain.

- The advised physical therapy treatment for patients with neck pain at grades I and II with a normal recovery is to offer information and advice. A wait-and-see policy is likely to be sufficient.
- The advised physical therapy treatment for patients with neck pain at grades I and II with a deviant recovery is a combination of mobilisation (or manipulations) with exercise therapy.
- The advised physical therapy treatment for patients with a grade III neck pain is a combination of mobilisation (or manipulations) with exercise therapy. The short-term use of a soft collar may be considered. If pain increases or therapy is ineffective, then the patient should be referred to his or her GP.

## **DISCUSSION OF THE MAIN FINDINGS**

### Usual care

In our study (chapter 5), usual care for patients with neck pain and/or LBP is described and compared to the SBT approach (targeted treatment). The researchers did not inform the clinicians about the patients' risk profile; these clinicians were completely free to apply care as they saw fit. We expected the clinicians to provide guideline-recommended care or, in the absence of a guideline, evidence-based interventions. Knowledge on the difference between the advised stratified care and the usual care is essential before both deciding on the implementation of the SBT and developing an implementation plan.

We found that the majority of the patients (55%) were at low risk for persisting LBP, but the majority of these patients (88%) received a moderate-risk approach. It seems that a one-size-fits-all approach is applied. In our study, we also found that low-risk patients (in the case of LBP as well as neck pain) received 6.5 physical therapy sessions, medium-risk patients 6.7 and high-risk patients 8.5 sessions. The overall mean for patients with neck pain or LBP was 6.8 sessions, while the mean for musculoskeletal conditions in the Netherlands in 2015, according to the Dutch institute for health-services' research (NIVEL), was 7.8 with a median of 6.<sup>1</sup> To a large extent, these numbers correspond to each other; however, they differ from the results found in the UK. An implementation study from the UK found that, in 201 patients treated by 29 PTs, a mean of 2.7 National Health Service (NHS) physical therapy sessions were given after implementation of the SBT.<sup>2</sup> The implementation of the "improve patient care through targeted treatment (IMPACT) back" study reported an average of 3.8 sessions prior to implementation, and 4.2 sessions after implementation of the SBT.<sup>3</sup> Both studies report a substantially lower number of sessions in the UK in comparison to the Dutch findings, implying large differences in approaches and possibly also due to differences in healthcare system between the two countries. The differences between the amounts of sessions also suggest there is room for more efficiency in the approach of low back pain and possibly also in neck pain.

Another remarkable finding in our study is the overall absence of a psychosocial approach. No differences are found between the approaches on LBP and neck pain. Recovery from these two forms of spinal pain are both known to being influenced by psychosocial factors, as discussed in chapter 6, the CPG on neck pain, but also in other CPG.<sup>4-6</sup> The knowledge that these modifiable factors may lead to persisting spinal pain is the reason that Hill et al., included them in the SBT.<sup>7</sup> In this study, usual care was described based on reports in the patient file. It might be that the clinician addressed the psychosocial factors but did not report on this, or just simply did not address these factors during consultation. If the latter is the case, then this requires thorough training, especially when implementing the SBT. Alternatively, or additionally, referral between colleagues should be facilitated. In the Netherlands there are PTs with an additional degree in a psychosomatic approach. These psychosomatic physical therapists could well fill the need for therapists willing to implement the SBT but are not additionally trained to address the patients with the high-risk of persisting pain.

The main purpose of the SBT is to fast-track patients to the appropriate care. In this study, we found that, on the one hand, current care tends to overtreat patients (low-risk patients), and on the other hand, it demonstrates that Dutch clinicians only sparsely apply a psychosomatic approach in treating patients with spinal pain (high-risk patients). Of course, we still need to study whether the stratified approach leads to better and quicker recovery, and whether this also leads to lower costs. However, this study does indicate that we do need a tool to better serve our patients instead of using a one-size-fits-all approach. There is clearly room for improvement. I would argue that the improvement can be found in the SBT by allocating patients to the appropriate treatment; however, the tool would work better if the system does not facilitate overtreatment by means of a financial incentive for the PT where they get paid more when they deliver more treatments.

### Keele SBT

The SBT is a nine-item questionnaire aiming to stratify patients into one of three risk profiles (low, medium, or high-risk), and it is part of a stratified-care model for managing LBP. The SBT has been translated into several different languages since its initial publication in 2008.<sup>8-20</sup> Overall, the validation process demonstrated great similarities. The initial validation study of the SBT in the UK, along with later studies, preformed a factor analysis to confirm two constructs. Other studies did not perform a factor analysis but used the known subgroups to perform an internal consistency analysis by means of the Cronbachs alpha.<sup>7,12,13,15,19,21</sup> We did not preform a factor analysis or calculate the internal consistency. The main argument for this is that we expect the internal consistency to be neither high nor low because we expect all questions or factors to independently influence the outcome. Also, we did not calculate the specificity and sensitivity of the instrument. Calculating these would mean that we had to combine two groups to be able to compare them (low versus

medium/high or low/medium versus high). We chose to calculate the relative risk (RR) to determine the persisting disability. The RR is, in our opinion, more relevant for clinicians when using the instrument, and it offers us the ability to analyse each group separately.

In calculating the predictive validity for the SBT for LBP, we used the outcome measure “persisting disability”, which was defined as a Roland Morris disability questionnaire score (RDQ) of  $\geq 7$  at 3 months. This cut-off score between yes/no persisting disability was arbitrarily chosen as the median of the baseline scores in the initial SBT study.<sup>7</sup> In validating the SBT for neck pain, we used the same method of defining persisting disability as a neck disability index (NDI) score equal to or higher than the median of the NDI on the baseline. We also analysed patients at a more individual level where we used the RR of patients’ recoveries defined as an NDI score that decreased more than the minimal clinically important difference (MCID) of 4 points. The latter method seems most appropriate because it detects the improvement of disability and not a patient’s disability level compared to the group’s mean level.

For the SBT for neck pain, the predictive validity could be regarded as good when looking at the population level, using the median of the baseline score. However, the predictive validity is insufficient at an individual level, using the MCID. Choosing the analysis method can determine whether the tool is regarded as suitable or not.

The overall score and the psychosocial subscale of questions, as determined by Hill et al., determines a patient’s risk profile. When the overall score is  $\leq 3$ , the risk profile results in a low risk for persisting disability; an overall score  $> 4$  and the subscale score (questions 5-9) lead to medium and high risk categorisations. In all international validation studies, we found that these cut-off points were the same as the original study. Only in one of the Danish validation studies did the author report on changing the cut-off points to examine their influence on the odds ratios.<sup>22</sup> The preliminary results of a secondary analysis on the PRINS (Prevalence of Risk groups in Neck- and back pain patients according to the STarT back screening tool) data demonstrates that changing the cut-off points influences the distribution in risk profiles, resulting in a higher percentage of high-risk patients and an improvement in the RR. (Article under preparation)

A Danish study on the SBT found that episode duration influenced the outcome, and that the SBT was less reliable in patients in the first two weeks of their back pain.<sup>17</sup> In our study of patients with LBP, 21% had these complaints for two weeks or less, and 19% of the patients with neck pain had these complaints for two weeks or less. Besides the episode duration at the baseline, the moment of applying the SBT may influence the results. In the original SBT study, the questionnaire was administered prior to the first consultation, and in our study, the SBT was administered after the first consultation. In the UK study, the percentage of patients in the high-risk profile is 15, whereas in our study, it was 10%. The preliminary results from the PRINS-II study confirm this difference. The SBT in this study is administered prior to the first

consultation, resulting in a shift towards a higher risk profile. One explanation might be that during the first consultation, a patient's beliefs about his illness, cognitions, medical knowledge, and coping style may already have been influenced or altered. When the psychosocial factors are addressed or even altered within the first consultation, these factors might be irrelevant to the patient being at risk for persisting disability, and therefore he or she might not be a true high-risk patient. Applying the SBT after the first consultation may lead to a practical obstacle when a patient is at low risk for persisting disability and, according the stratified-care model, only in need of one consultation. Therefore, I would advise using the SBT prior to or during the first consultation mainly for practical reasons as it gives the PT the option to let the SBT determine or influence the treatment plan.

Initially, the SBT was developed to cater for patients with non-specific LBP; however, the SBT has also been validated for patients with a lumbar central canal stenosis.<sup>19</sup> The SBT has been modified to fit patients with other musculoskeletal conditions, including neck, upper limb, lower limb or multisite pain.<sup>23-26</sup> In our studies, we included patients with LBP, neck pain, or both. In a previous study, where we used the SBT for both LBP and neck pain, we noticed that patients had trouble prioritising their complaints, and were not able to distinguish between LBP and neck pain when they had both. We interpreted the combined SBT to be invalid, since we did not know whether the patient was answering the questionnaire for their neck pain or their back pain. We could also have made the choice not to distinguish between the two and interpret these as multi-site pain instead. Our aim was to develop a neck-pain version rather than a multi-site version; therefore, we separated the SBT. We kept the original version for LBP and modified it to fit patients with neck pain.

In developing the neck-pain version, our starting point was that we wanted to stay as close as possible to the LBP version and only replace items that were specific to LBP. Based on the outcome of a single focus-group meeting, we changed the wording of questions that stated "low-back pain" to "neck pain". Question 1 "radiating pain in the legs" was modified to "radiating pain in the arms". Question 3 was changed to "I have used my arms and neck less due to my neck pain" instead of "I have only walked short distances because of my back pain". The previously mentioned modified SBT (for back, neck, upper limb, lower limb or multisite pain) had a different approach to altering the questions. It based the replacement items on the available proxy items from the data set that it was tested on.<sup>26</sup>

We chose our method because we wanted to stay as close to the original SBT as possible. In doing so, we did not perform an analysis to look for factors related to persisting neck pain; therefore, we could have included unrelated factors in the modified SBT. The SBT for neck pain would benefit from a more thorough approach in analysing factors related to persisting neck pain. As the data-set is now available, further analysis of this data, in looking for replacement items, might lead to a more valid instrument.

### Clinical practice guideline

The *Royal Dutch Society for Physical Therapy* (KNGF) issued the development of a CPG on neck pain in 2013. The aim of the CPG is to assist PTs when assessing and treating patients with non-specific neck pain, including cervical radiculopathy in Dutch primary care. It is the first guideline on neck pain as a whole in the Netherlands. Previous guidelines focused on a specific neck pain, for example, whiplash-associated disorders (WAD) or disorders such as complaints on arm, neck and shoulder (CANS).

The CPG on neck pain demonstrates great similarities to the CPG on LBP when it comes to the classification of patients. Both these guidelines primarily explore the current course of pain and/or disability. It determines whether the course is normal or deviant, and, when the course is deviant, it focuses on the presence of psychosocial factors that influence this deviant course. In treating patients with spinal pain, we find similarities to the approach of the SBT and the CPG. The CPG's normal course of pain or disability corresponds to the SBT's low-risk profile. In both subgroups, the focus is on information and advice. The deviant course in the CPG corresponds to the SBT's medium-risk profile; in both subgroups, the advised approach is an evidence-based physiotherapeutic intervention. The deviant course of pain or disability with psychosocial factors demonstrates similarities to the SBT's high-risk profile in which it is advised that a patient receives a psychosomatic approach from a PT who is skilled in this field. Apart from these similarities, there is an essential difference between the CPG and the SBT: the moment at which the intervention is applied. The SBT stratifies patients at the baseline without the need to analyse the course of pain and disability, making the SBT an instrument to fast-track the patient to the appropriate care. However, it must be noted that one Danish study found that the SBT for LBP might not have the ability to stratify patients in the acute phase. If the clinician has to wait two weeks before applying the SBT, then he is also able to analyse the course of pain or disability. However, this is mainly applicable to low-risk analysis. In analysing the difference between medium- and high-risk profiles, the SBT might be a useful supplement to the Dutch CPG to determine whether a psychosocial approach is indicated – an area in which the current guideline offers little or no direction.

While the CPG demonstrates similarities to the LBP's CPG in its classification, it differs from other guidelines in its methods of recommendations. During the first guideline committee meeting, we chose to include all interventions within the domain of the PT. This includes interventions for which there is little to no evidence or interventions that seem illogical when used in the cervical region. These 17 interventions were consensus-based by the KNGF.<sup>27</sup> Data was collected and assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.<sup>28</sup> The recommendations were formulated, reflecting the evidence, into strong recommendations using terms such as "is recommended" when the evidence indicated that the intervention is effective, or "is not



recommended” when the evidence indicated that the intervention is not effective. In cases of weak or unclear evidence, recommendations are formulated as “may be considered”.<sup>29</sup> The majority of interventions are in the category of “may be considered”. We also have interventions that were “not recommended”, since we chose to include all interventions. To our knowledge, this is the second guideline (out of the 17 CPGs currently available) that advises against certain interventions.

The recommendations against electrotherapy, low-level laser therapy, and ultrasound (including shockwave) therapy were accepted by the PTs without comments or remarks. Recommendations against dry needling were met with some resistance due to personally assumed or experienced effects.

The list of 17 interventions included relatively new interventions, such as the previously mentioned dry needling and shockwave therapies. These interventions are gaining popularity amongst Dutch PTs without clear evidence of efficacy. In the absence of evidence, the guideline cannot recommend the use of these interventions. We know that, on average, clinicians’ adherence to guidelines is quite low.<sup>30–32</sup> Advising against popular interventions with personally assumed effects may lead to a lower adherence. We must keep in mind that it is expected that more evidence will arise regarding relatively new interventions. This evidence must be incorporated in the guideline on a regular base. The guideline must be a dynamic document that is frequently subjected to (small) updates, with the users of the guidelines – the clinicians – being informed.

### Patients’ adherence

There is an extensive body of literature focusing on the adherence of GPs to the guidelines for treating LBP. Depending on the focus of the study, we found that up to 50% of GPs do not adhere to the guidelines.<sup>30–32</sup> These results are comparable to PTs where adherence is as low as 7% to 50%.<sup>33,34</sup> Non-adherence often leads to increased diagnostic workups, such as the use of X-rays, CT scans, and MRIs. The use of these techniques is discouraged in the guidelines as they often offer no diagnostic benefit and may be associated with a lower quality of life.<sup>31,35</sup> The ‘unnecessary’ diagnostic interventions are also reported in chapter 5 where we describe usual care in the Netherlands. We found that 10% of the patients (with non-specific neck pain or non-specific LBP) who consulted their GP were referred to a medical specialist, and in 45% of the patients, GPs prescribed the pain medication on a pain-contingent basis rather than on the advised time-contingent basis. When the clinicians were asked why patients got referred to a medical specialist or went for an X-ray, we found that, in half of the cases, this was at the request of the patient. Chapter 2, which focuses on patients’ adherence to guideline recommended care, concluded that 70% of the patients did not adhere to the guideline recommendations. Combining both clinicians’ and patients’ non-adherence would result in an even lower percentage of overall guideline adherence. Therefore, studies focusing on either patients’ or clinicians’ non-adherence lead to a one-sided view.

In the PACE-trial (paracetamol for low back pain) analysis, the majority of patients' non-adherence was due to not taking the medication as prescribed. These patients were asked to take a maximum dose of study medication; therefore, non-adherence was defined as taking less than 70% of the recommended dose. The 70% threshold allowed room for the patient to forget to take his or her medication a few times without regarding him or her as non-adherent. The study protocol requested that patients continue taking the pain medication until they were pain-free for seven consecutive days.<sup>36</sup> This seems quite long and does not correspond to pain guidelines or LBP guidelines.<sup>5,6,35</sup> I would argue that this seven-day period would also contribute to the non-adherence.

## **IMPLICATIONS AND RECOMMENDATIONS**

### Recommendations and research

The SBT has been validated for LBP; however, the risk ratios are determined on an arbitrarily chosen cut-off point of an RDQ  $\geq 7$ . Since the SBT aims to offer a targeted treatment, it would be a better fit to determine the cut-off point on patients' individual levels. For example, in the SBT for neck pain, we used an improvement of less than the MCID or worsening to define "persisting disability". This method of calculating the risk ratios could also be applied to the SBT for LBP. Another analysis that could be performed to improve the SBT in the Netherlands is to determine the ideal cut-off points for distinguishing between low, medium, and high risk and for improving the risk ratios. When these analyses are done, we need to determine whether the SBT with targeted treatment would lead to better and quicker recovery at lower costs. In the UK, this analysis has been performed; however, results cannot be extrapolated to the Netherlands, mainly due to the large difference in healthcare systems between the two countries. A Dutch replication study of the RCT performed in the UK would seem fit.

For the SBT neck, we performed a study to determine whether it had the potential to perform as well as the original SBT. It does have the potential; however, the tool needs further development and testing. We could analyse whether the prognostic validity improves when certain questions are replaced. In the dataset gathered in the PRINS-study, we have the results of the NDI, the Tampa Scale for Kinesiophobia (TSK), the Pain Catastrophising Scale (PCS) and the quality of life questionnaire (EQ-5D). This dataset can be used in a secondary analysis. Also, an analysis, as suggested for the SBT for LBP, could be performed to change cut-off points to improve predictive validity.

In regards to the guideline adherence it is known to be low, both by clinicians and patients. The actual non-adherence is a result of both clinician and patient non-adherence. I would suggest that CPG non-adherence is studied in combination, with the aims of gathering not only quantitative data on the amount of non-adherence and the analysis of factors known to contribute to this non-adherence, but also qualitative

data of clinicians and patients to determine the reason of why non-adherence took place.

### Recommendations for clinical practice

#### *STarT Back Tool*

Usual care in the Netherlands is a time-based, stepped-care approach that is based on the available CPG (for LBP), a related CPG (WAD/CANS/pain management) or own clinical experience.<sup>4,5,37,38</sup> The SBT is ready to be used in the Netherlands in patients with LBP to assist clinicians in making decisions regarding treatment. In the Netherlands, we need to determine how to apply stratified care. One of the steps is to improve the quality of the information given to patients. The information that a PT gives a patient should contain the same core message that the GP offers and that the patient finds online or in information brochures. In the UK, this information is provided in the form of a booklet – ‘the back book’ – and a supplementary film. In the Netherlands, a paper information booklet, an e-book, a website and a 10-minute film are developed for patients with LBP as part of a second cohort for the SBT (PRINS-II). The information is based on interviews with patients and clinicians to determine the core messages. The same products are developed for patients with neck pain as part of the implementation of the CPG. Because high-quality information, uniformly delivered by clinicians, is essential. In this stage the information is used, when applying the CPG on neck pain, and hopefully in a later stage when using the SBT for neck pain. In the Netherlands, all information products are available to clinicians and patients with LBP or neck pain.

Clinicians in England have the option to receive training to apply stratified care. This training is available for all risk profiles; however, the most training is needed regarding the high-risk approach, and is described as psychologically informed interventions.<sup>7</sup> Whether Dutch PTs require additional training must be determined, since there are differences between English and Dutch PTs. In the Netherlands I would recommend that patients who need a high-risk approach for their LBP should be referred to a psychosomatic PT. This is also advised in the CPG for neck pain when psychosocial factors are limiting recovery.

#### *Clinical practice guideline*

The CPG has been issued by the KNGF. In addition to writing the CPG, the authors were asked to provide lectures on this topic; however, they were not involved in the implementation of the guideline. Furthermore, they were only sparsely updated on the actions undertaken by the KNGF regarding the implementation. In the Netherlands, the KNGF not only serves and represent Dutch PTs and issues the guidelines, but also facilitates trainings for PTs. When these trainings match the guideline, this would benefit implementation. Currently, strange contradictions exist regarding the KNGF policy: on the one hand, the KNGF publishes a guideline that advises against the use of dry needling in patients with neck pain, and on the other

hand, it facilitates and promotes dry needling training for neck pain. The KNGF should develop an implementation plan in collaboration with the authors. It should also focus on delivering the core message to the users of the CPG and avoid presenting mixed messages. The CPG is an easy-to-use document that should be adopted by all Dutch PTs.

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# Summary

## **SUMMARY**

**Chapter 2** describes the magnitude of patient reported nonadherence with guideline-recommended care for acute low back pain. The data from 1643 participants enrolled in the PACE trial evaluating the effectiveness of paracetamol for acute low back pain was used for the analysis.

Patient received guideline recommended care; reassurance, simple analgesia, and the advice to stay active and avoid bed rest. The analgesia consisted of a time-contingent paracetamol, a paracetamol as required dosing of paracetamol, or placebo. Also advice against additional treatments and referral for imaging was given. Patients completed questionnaires and a medication diary. Nonadherence was defined as (1) failure to consume the advised paracetamol dose, or (2) receipt of additional healthcare, tests, or medication during the trial treatment period (4 weeks). Multivariable logistic regression analysis was performed to determine the factors associated with nonadherence.

In the first week of treatment, 39.7% of the participants were classified as nonadherent. Over the 4-week treatment period 70.0% were nonadherent, 57.5% did not consume the advised paracetamol dose. Higher perceived risk of persistent pain, lower level of disability and not claiming workers' compensation were independently associated with nonadherence with odds ratios ranging from .46 to 1.05. We concluded that the adherence to guideline-recommended care for acute low back pain was poor. Most participants do not take the advised paracetamol dose.

**Chapter 3** describes the translation of the Keele STarT (Subgroup Targeted Treatment) Back-Screening Tool (SBT) into Dutch. Next it describes the reliability and validity of the SBT in Dutch primary care setting among 184 patients with non-specific low back pain.

The SBT was formally translated in Dutch following a multistep approach for forward and backward translation. General practitioners and physiotherapists included patients with low back pain, which completed a baseline questionnaire and follow-up questionnaires at three days and three months. Of the 184 patients 52.2% were categorized in the low-risk subgroup, 38.0% medium-risk and 9.8% in the high-risk subgroup. For the construct validity we found a moderate to high Pearson's correlation for question 3 to 9 and a low correlation for question 1 and 2 with their respective reference questionnaires. The reproducibility had a quadratic weighted kappa of 0.65 and the specific agreement of 82.4% for low-risk, 53.3% for medium-risk and 33.3% for high-risk. For the predictive validity for persisting disability we found a relative risk ratio for medium-risk of 1.8 (95% CI 1.0 – 3.1) and 2.7 (95% CI 1.4 – 4.9) for high-risk compared to low-risk. For the content validity we found that no floor and ceiling effects were present. We concluded that the SBT is successfully translated in Dutch. Furthermore, the psychometric analysis showed acceptable

results and therefore we regard it as a valid screening tool for patients with low back pain in Dutch primary care

**Chapter 4** evaluates the reliability and validity of the Dutch version of the SBT for patients with neck pain. General practitioners and physiotherapists included 100 patients who completed both a baseline and a follow-up questionnaire at 3 days and 3 months.

Out of 100 patients 58.0% were categorised as being at low risk for persisting disability, 37.0% at medium risk and 5.0% at high risk. As expected for the construct validity, we found a moderate to high correlation for all questions except for activity question 3. The reproducibility had a quadratic-weighted kappa of .58, and a specific agreement of 90.9% for low-risk and 66.7% for medium-risk patients. The risk ratios for persisting disability for medium-risk against low-risk patients were 1.5 (95% CI. 0.9 - 2.4) and 1.5 (95% CI. 0.5 - 4.1) for pain. The sample size for high-risk patients was low.

In conclusion, we regard the original SBT is modified and able to fit patients with neck pain in Dutch primary care. The psychometric analysis indicates sufficiently reliable outcomes, although the predictive validity showed statistically insignificant results.

**Chapter 5** evaluates whether current Dutch primary-care clinicians offer tailored treatment as usual care to patients with low-back pain or neck pain according to their risk stratification, based on the SBT.

General practitioners and physiotherapists included 184 patients with non-specific low back pain and 100 with neck pain. Patients completed a baseline questionnaire, including the Dutch SBT, for either low back pain or neck pain. A follow-up measurement was conducted after 3 months to determine recovery using the global perceived effect scale, pain using the Numeric Pain Rating Scale and function using the Roland Disability Questionnaire or the Neck Disability Index. A questionnaire was sent to the general practitioners and physiotherapists to evaluate the provided treatment.

In the low back pain group, 52.2% of the patients were at low risk for persisting disability, 38.0% were at medium risk and 9.8% were at high risk. Overall, 24.5% of the patients with low back pain received a low-risk treatment approach, 73.5% a medium-risk and 2.0% a high-risk treatment approach. The specific agreement between the risk profile and the received treatment for patients with low back pain was poor for the low-risk and high-risk patients (respectively 21.1% and 10.0%), and fair for medium-risk patients (51.4%). In the neck pain group, 58.0% of the patients were at low risk for persisting disability, 37.0% were at medium risk and 5.0% were at high-risk. Only 6.1% of the patients with neck pain received the low-risk treatment approach.

The specific agreement between the risk profile and received treatment for patients with neck pain patients was poor for low-risk and medium-risk patients (resp. 6.3% and 48.0%). Agreement for high-risk patients could not be calculated. Overall, the medium-risk treatment approach was offered the most (90.8%) and the high-risk approach was applied in only 3.1% of the patients.

We concluded that the current usual Dutch primary care for patients with non-specific low back pain and/or neck pain does not correspond to the advised stratified-care approach based on the SBT as the majority of patients receive medium risk treatment. The majority of low-risk patients seem to be over-treated and the majority of high-risk patients are possibly undertreated. Although the stratified-care approach has not yet been validated in Dutch primary care, these results indicate that there may be substantial room for improvement.

**Chapter 6** The royal Dutch society of physiotherapists issued a clinical practice guideline, this guideline focuses on diagnosing and treating adult patients with neck pain.

The guideline recommends that physiotherapists classify patients as: Grade I - neck pain and associated disorders with no signs or symptoms suggestive of major structural pathology and no or minor interference with activities of daily living; Grade II - no signs or symptoms of major structural pathology, but major interference with activities of daily living; Grade III - no signs or symptoms of major structural pathology, but presence of neurologic signs such as decreased deep tendon reflexes, weakness, or sensory deficits or Grade IV - signs or symptoms of major structural pathology. Major structural pathologies include (but are not limited to) fracture, vertebral dislocation, injury to the spinal cord, infection, neoplasm, or systemic disease including the inflammatory arthropathies.

In the diagnostic process neck pain grade IV may be excluded using 'Red flags' as a mean to suspect serious pathological conditions. Neck pain grade III may be ruled in using the Spurlings test and/or traction-distraction test or ruled-out by means of the Upper Limb Tension Test. Neck pain grade I and II are combined as the treatment does not differ between these grades. Next the course of the neck pain will be determined as in case of normal recovery there is no clear indication for physiotherapy. For normal recovery, neck pain is expected to decrease in the first 3 weeks, limitation in daily activity will decrease within the first 6 weeks. The next step is establishing the subgroup when applicable: trauma-related or work-related neck pain. These subgroups are known to have different prognostic factors that might influence their recovery. Factors that might influence a delayed recovery should be identified and, when modifiable, be addressed in the course of treatment. The Numeric Pain Rating Scale and the Patient-Specific Functional Scales are recommended to objectify patient's baseline status relative to pain, function and disability and to monitor patients' course throughout the course of treatment.

For patients with grade I or II neck pain with deviant recovery physical therapists are recommended to primarily apply cervical mobilisation or manipulation combined with exercise therapy. For patients with neck pain grade III physical therapists are also recommended to primarily apply cervical mobilisation or manipulation combined with exercise therapy. The cervical collar may be considered in patients with neck pain grade III for pain reduction but only when used sparsely.

Physical therapists may consider the use of cognitive behavioural treatment / graded activity, massage, neurodynamics or neural tissue management, pillow, (kinesio) tape, thermal agents, and workplace interventions for patients with neck pain grade I, II and III when the primarily advised treatments are ineffective or not sufficiently effective. The use of dry needling, low-level laser, electrotherapy and ultrasound, and traction for patients with neck pain grade I, II and III and cervical collar for patients with grade I or II neck pain are recommended against.

# Samenvatting

## **SAMENVATTING**

**Hoofdstuk 2** omschrijft de mate waarin patiënten de in richtlijn geadviseerde zorg bij acute lage rugpijn niet opvolgen (nonadherence). Gegevens van 1643 deelnemers aan de PACE-trial is gebruikt voor nadere analyse. De PACE-trial is een studie naar de effectiviteit van paracetamol bij lage rugpijn. Patiënten ontvingen richtlijn geadviseerde zorg welke bestond uit: geruststelling, pijnmedicatie, het advies om in beweging te blijven en het vermijden van bedrust. De pijnmedicatie bestond uit tijd-contingent paracetamol, pijn-contingent paracetamol, of placebo. Tevens kregen de patiënten het advies om geen andere therapie te volgen of beeldvormend onderzoek te laten verrichten.

De patiënten vulden een vragenlijst in en hielden een medicatie dagboek bij. Nonadherence was gedefinieerd als (1) het niet gebruiken van de geadviseerde dosis paracetamol, of (2) het gebruik van aanvullende zorg, onderzoeken, of medicatie gedurende de duur van het wetenschappelijk onderzoek (4 weken). Een multivariabele logistische regressie analyse is uitgevoerd om te bepalen welke factoren geassocieerd zijn met deze nonadherence.

In de eerste week van het onderzoek is 39.7% van de deelnemers geclassificeerd als nonadherent. In de totale 4 weken van het onderzoek was 70.0% nonadherent, 57.5% gebruikte niet de hoeveelheid geadviseerde paracetamol. De factoren: een hogere mate van veronderstelde risico op blijvende pijn, een lagere mate van beperkingen in activiteiten en het niet ontvangen van een inkomens compensatie waren onafhankelijk geassocieerd met nonadherence met odds ratio's van .46 tot 1.05.

We concluderen dat het opvolgen van de in de richtlijn geadviseerde zorg bij acute lage rugpijn laag is. Het merendeel van de nonadherence in de PACE-trial het gevolg van het niet volgen van de juiste dosering van de paracetamol.

**Hoofdstuk 3** beschrijft de vertaling van de Keele STarT (Subgroup Targeted Treatment) Back-Screening Tool (SBT) in het Nederlands. Daarnaast beschrijft het de betrouwbaarheid en de validiteit van de SBT in de Nederlandse eerstelijns zorg onder 184 patiënten met specifieke lage rugpijn.

De SBT is formeel heen en terug vertaald volgens de multistep benadering. Huisartsen en fysiotherapeuten includeerde patiënten met specifieke lage rugpijn, de patiënten vulde vragenlijsten in op baseline, na 3 dagen en na 3 maanden.

Van de 184 patiënten had 52.2% een laag risico voor blijvende rugklachten, 38,0% een gemiddeld risico en 9.8% hoog risico. Voor de constructvaliditeit vonden we een gemiddeld tot hoge Pearson's correlatie voor vraag 3 tot en met 9 en een lage correlatie voor vraag 1 en 2 met hun referentie vragenlijsten. De betrouwbaarheid had een kwadratisch gewogen kappa van .65 en een specifieke overeenkomst van 82.4% voor patiënten met een laag risico, 53.3% voor patiënten met een gemiddeld risico en 33.3% voor patiënten met een hoog risico.

Wat betreft de predicatieve validiteit vonden we een relatieve risico voor gemiddeld-risico van 1.8 (95% CI: 1.0 – 3.1) en 2.7 (95% CI: 1.4 – 4.9) voor een hoog-risico voor blijvende beperkingen in activiteiten in vergelijking tot een laag risico.

Wat betreft de inhoudsvaliditeit vonden we dat er geen ‘floor and ceiling’ effecten aanwezig waren.

Wij concluderen dat de SBT succesvol vertaald is in het Nederland en dat de psychometrische eigenschappen acceptabel zijn. We beschouwen de SBT als een valide en betrouwbaar instrument voor patiënten met specifieke lage rugpijn in de Nederlandse eerstelijns zorg.

**Hoofdstuk 4** evalueert de betrouwbaarheid en validiteit van de Nederlandse versie van de SBT voor patiënten met nekpijn klachten. Huisartsen en fysiotherapeuten includeerde 100 patiënten met nekpijn welke op baseline en bij follow-up op 3 dagen en 3 maanden vragenlijsten hebben ingevuld.

Van de 100 patiënten was 58.0% gecategoriseerd als laag risico voor blijvende nekpijn klachten, 37.0% gemiddeld risico en 5.0% als hoog risico. Zoals verwacht vonden we voor de constructvaliditeit een gemiddeld tot hoge correlatie met de referentie vragenlijst bij alle vragen met uitzondering van vraag 3

De reproduceerbaarheid had een kwadratisch gewogen kappa van .58, en een specifieke overeenstemming van 90.9% bij laag risico en 66.7% bij gemiddeld risico. De relatieve risico's voor blijvende beperkingen in activiteiten voor gemiddeld risico ten opzichte van laag risico was 1.5 (95% CI: 0.9 - 2.4) en 1.5 (95% CI: 0.5 - 4.1) voor blijven pijnklachten. De sample size voor hoog risico was te klein om relatieve risico's te kunnen berekenen.

We beschouwen de gemodificeerde SBT geschikt voor patiënten met nekpijn klachten in de Nederlandse eerste lijn. De psychometrische eigenschappen laten zien dat het instrument voldoende betrouwbaar is echter de predictieve validiteit laat geen statistisch significante resultaten zien.

**Hoofdstuk 5** evalueert of de huidige in Nederland gebruikelijke eerstelijnszorg, gerichte zorg is in lijn met de geadviseerde risico gestratificeerde zorg volgens de SBT bij patiënten met lage rug of nekpijn.

Huisartsen en fysiotherapeuten hebben 184 patiënten geïnccludeerd met specifieke lage rugpijn of nekpijn. Patiënten hebben een vragenlijst ingevuld, met onder andere de SBT, op baseline. Een vervolg vragenlijst op 3 maanden is afgenomen om herstel te meten middels de GPE (Global Perceived Effect scale). Daarnaast is pijn gemeten met de NPRS (Numerieke Pijn schaal) en is de mate van beperking in activiteiten gemeten met de RDQ (Roland Disability Questionnaire) of de NDI (Neck Disability Index). Een vragenlijst is gestuurd naar de huisartsen en fysiotherapeuten om te bepalen welke therapie er is gegeven.

Bij de patiënten met lage rug pijn was 52.2% laag risico voor chronische klachten, 38.0% was gemiddeld risico 9.8% had een hoog risico. Slechts 24.5% van de



patiënten met lage rugpijn kreeg een behandeling passend bij laag risico patiënten, 73,5% ontving een behandeling passend bij een gemiddeld risico en 2.0% ontving een behandeling passend bij het hoog risico beleid. De specifieke overeenstemming tussen het risico profiel van de patiënt met lage rugpijn en gegeven behandeling was laag voor laag en hoog risico (respectievelijk 21.1% en 10.0%) en redelijk voor gemiddeld risico patiënten (51,4%)

Bij patiënten met nekpijn had 58,0% een laag risico voor blijvende neklachten, 37.0% een gemiddeld risico en 5.0% een hoog risico. Slechts 6.1% van de patiënten ontving een behandeling passend bij het laag risico beleid, 3.1% ontving een behandeling passend bij het hoog risico beleid. De meeste patiënten (90.8%) ontvingen een behandeling passend bij het gemiddeld risico beleid. De specifieke overeenstemming tussen het risico profiel van de patiënt met nekpijn en de gegeven behandeling was laag voor laag en hoog risico (respectievelijk 6.3% en 48.0%) en niet te bepalen voor hoog risico door een te kleine populatie.

We concluderen dat de huidige, in Nederland gebruikte, eerstelijnszorg voor patiënten met lage rugpijn of nekpijn niet overeenkomt met het gestratificeerde beleid volgens de SBT. De meerderheid van de patiënten ontvangt een behandeling passend bij een gemiddeld risico op aanhoudende klachten. De meerderheid van de laag risico patiënten lijkt derhalve over-behandeld en de meerderheid van de hoog risico patiënten lijkt onder-behandeld te worden. Ondanks dat de risicostatificatie met passend behandelbeleid nog niet is gevalideerd in de Nederlandse eerste lijns zorg, impliceren deze resultaten dat er ruimte is voor verbetering.

**Hoofdstuk 6** Het Koninklijk Nederlands Genootschap voor Fysiotherapie heeft een richtlijn uitgegeven welke zich focust op de diagnose en behandeling van patiënten met nekpijn.

De richtlijn adviseert fysiotherapeuten om patiënten te classificeren in een van de volgende gradaties. Graad I: Nekpijn zonder tekenen of symptomen die kunnen wijzen op grote structurele pathologie en die niet of nauwelijks invloed heeft op activiteiten in het dagelijks leven. Graad II: Nekpijn zonder tekenen of symptomen die kunnen wijzen op grote structurele pathologie, maar die wel een forse invloed heeft op activiteiten in het dagelijks leven. Graad III: Nekpijn zonder tekenen of symptomen die kunnen wijzen op grote structurele pathologie, waarbij wel neurologische symptomen aanwezig zijn, zoals verminderde peesreflexen, spierzwakte of sensibiliteitsstoornissen (hypo- of hyperesthesie) in de bovenste extremiteit, bijvoorbeeld als gevolg van een cervicale hernia of stenose. Graad IV: Nekpijn met tekenen of symptomen die kunnen wijzen op ernstige structurele pathologie. Ernstige structurele pathologie omvat (maar is niet beperkt tot): fracturen, vertebrale dislocaties, schade aan het ruggenmerg, infecties, tumoren of systemische ziekten, waaronder gewrichtsontstekingen.

In het diagnostisch proces wordt nekpijn graad IV uitgesloten door middel van 'Rode vlaggen' welke kunnen wijzen op ernstige pathologie. Nekpijn graad III kan bepaald

worden met behulp van de Spurlings test en/of de traction-distraction test of uitgesloten worden met behulp van de Upper Limb Tension Test. Nekpijn graad I en II zijn in de richtlijn gecombineerd omdat de behandeling niet verschillend is tussen deze twee gradaties. De volgende stap in het proces is het bepalen van het beloop van de nekpijn, omdat er bij een normaal beloop geen duidelijke indicatie is voor fysiotherapie. Bij een normaal beloop verwachten we een afname van pijn in de eerste drie weken en een afname van beperking in activiteiten in de eerste 6 weken. De derde stap is het bepalen welke subgroep van toepassing is; werk-gerelateerde nekpijn of trauma-gerelateerde nekpijn. Deze subgroepen kennen andere prognostische factoren welke een negatieve invloed hebben op het herstel. Deze factoren dienen geïdentificeerd te worden en, wanneer beïnvloedbaar, dienen ze geadresseerd te worden in de behandeling. De NPRS (numerieke pijnschaal) en PSK (Patient Specifieke Klacht) worden geadviseerd om objectief op baseline de status van de patiënt in kaart te brengen met betrekking tot pijn, functie en participatie. Tevens kunnen deze metingen gebruikt worden om het beloop van het beloop te bepalen gedurende de therapie.

Bij patiënten met graad I of II nekpijn en een afwijkend beloop worden de fysiotherapeuten geadviseerd om primair cervicale mobilisaties of manipulaties uit te voeren in combinatie met oefentherapie. Bij patiënten met nekpijn graad III worden fysiotherapeuten geadviseerd om primair cervicale mobilisaties of manipulaties uit te voeren in combinatie met oefentherapie. Eventueel kan een halskraag worden overwogen bij patiënten met nekpijn graad III voor pijnreductie maar enkel voor kortdurend gebruik.

Fysiotherapeuten kunnen gebruik maken van; cognitieve gedragstherapie, graded activity, massage, neurodynamica, advies voor een ergonomisch kussen, (kinesio) tape, warmte of koude therapie, of werkplek interventies bij patiënten met nekpijn graad I, II of III. Deze interventies kunnen worden toegepast wanneer de primaire interventie onvoldoende of geen effect heeft gehad. Het gebruik van dry needling, low-level laser, elektrotherapie en ultrageluid (en/of shockwave), en tractie bij patiënten met nekpijn graad I, II en III en een halskraag bij nekpijn graad I en II worden afgeraden.

# Dankwoord

## **DANKWOORD**

Het mogen schrijven van een dankwoord betekend dat het afronden van het proefschrift en de verdediging dichtbij begint te komen. Terugkijkend op hoe het begon en wie er in het traject belangrijk zijn geweest wil ik enkel mensen bedanken. Natuurlijk met het risico dat ik mensen vergeet wil ik er toch enkele bij naam noemen. Bij het bedanken van sommige personen hoort soms ook een stukje achtergrond informatie.

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Ik wil enkele mensen uit de werkgroep van de PRINS-study bedanken; Bert en Nynke bedankt voor jullie input bij het opzetten van de studie en jullie contacten die we hebben mogen gebruiken. Miranda bedankt voor het vertalen van de STarT Back Tool van het Engels naar het Nederlands. Natuurlijk ook een bedankje voor de huisartsen en fysiotherapeuten die hun best hebben gedaan om zoveel mogelijk deelnemers te krijgen voor de studie en dan in het bijzonder de mensen die zich extra hebben ingezet om mij te helpen met includeren: Steven, Guido, Joost en

Frans. Jan, bedankt voor je technische ondersteuning aan de PRINS-study. En als laatste alle 284 anonieme deelnemers aan het PRINS-project.

I'd like to thank Chris and Steve for giving me the opportunity to come to Australia to work on the PACE-trial data. I liked working with you both, (And thanks for the BBQs and beers. Also thanks to Chris Maher for his feedback on the article and all three of you for helping me with my academical English. And while on this topic thanks to Barbara and Zeger for their linguistic support and Neshika for copy-editing.

In het verlengde van de PRINS-study heb ik een implementatie gedaan van de STarT Back Tool. Hiervoor wil ik Steunpunt KOEL bedanken en in het bijzonder Adja en Laura voor de samenwerking. Als onderdeel van de implementatie van de STarT Back Tool (en later ook bij de implementatie van de richtlijn) heb ik twee films, voorlichtingsfolders en websites gemaakt. Ik wil filmmaker Martijn bedanken voor de twee mooie informatieve filmpjes en de acteurs die hier belangeloos aan hebben meegewerkt: Bart, Arianne, David, Marco, Marleen, Carl, Ina, Niels, Ingrid, Barbara en Ilse. Carl bedankt voor het maken van de websites. Vanessa bedankt voor de tekstuele controle van de voorlichtingsboekjes en Suzanne bedankt voor de opmaak van deze boekjes.

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Voordat ik de laatste personen ga bedanken wil ik nog een persoon bedanken waarvan ik helaas de naam niet meer weet, maar een bedankje aan mijn biologie leraar van de MAVO, tijdens mijn diploma uitreiking zei je tegen mij; "gefeliciteerd jongen, je hebt het toch nog gehaald". Ik weet niet met welke reden je deze woorden sprak, waarschijnlijk omdat je niet had verwacht dat deze luie jongen het zou halen. Maar deze woorden zijn mij altijd bijgebleven en hier haal ik mijn motivatie uit en doorzettingsvermogen om dingen af te ronden. Ik heb wellicht de lange route genomen vanaf de MAVO naar dit punt; maar de eindstreep ziet er hetzelfde uit.

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er bij te blijven tot mijn promotie. En bedankt aan de rest van mijn familie en vrienden voor jullie interesse en steun.

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Stephanie, bedankt voor het doorlezen van mijn stukken, bedankt voor de steun en bedankt dat je me de ruimte hebt gegeven om dit te kunnen doen. Alle avonden en weekenden achter de computer, een maand naar Australië zonder jullie, congresbezoeken in Engeland en Zuid-Afrika, en alle lezingen en scholingen in Nederland. Bedankt ook dat je me af en toe hebt tegen gehouden niet nog meer projecten te starten en hooi op mijn vork te nemen. Bedankt. Ik hou van je.

# Curriculum Vitea

## **CURRICULUM VITAE**

Jasper Daniël Bier is geboren in Bangert (Noord-Holland). Na het behalen van zijn MAVO diploma aan de Johannes Calvijn Mavo in Gouda in 1996 heeft hij de VHBO opleiding gezondheidszorg afgerond aan de Albeda College in Rotterdam.

Aansluitend is hij in 1998 gestart met de opleiding Fysiotherapie aan de Hogeschool van Rotterdam. In 2002 heeft hij zijn diploma behaald en is hij gaan werken in een particuliere fysiotherapie praktijk. In 2003 is hij gestart met de deeltijdopleiding gezondheidswetenschappen aan de Erasmus Universiteit Rotterdam, richting Beleid en Management Gezondheidszorg waar hij in 2005 zijn diploma voor heeft behaald. Van 2006 tot 2009 heeft hij de master opleiding Manueeltherapie gedaan aan de SOMT in Amersfoort.

In 2011 heeft Jasper de stap gemaakt naar het onderwijs bij Avans Hogeschool in Breda waar hij deeltijd les gaf aan de opleiding fysiotherapie. In die periode heeft hij een factsheet over nekpijn geschreven voor de NVMT (Nederlandse Vereniging voor Manuele Therapie). Aansluitend kreeg hij de kans om als secretaris aan de slag te gaan bij het schrijven van de richtlijn nekpijn voor het KNGF (Koninklijk Nederlands Genootschap voor Fysiotherapie). Initieel bij Avans Hogeschool en later bij het Erasmus Universiteit Rotterdam, afdeling Huisartsengeneeskunde.



# PhD Portfolio

## PHD PORTFOLIO

	Year	Hours
<b><u>Course / training</u></b>		<b><u>96</u></b>
BROK (Basiscursus Regelgeving Klinisch onderzoek)	2015	30
CPO (Consultatiecentrum voor patiëntgebonden onderzoek)	2015	8
STarT Back Tool, Keele, UK	2015	32
Cervicale radiculopathie: diagnostiek en behandeling	2016	2
IFOMPT Framework: klinisch redeneren bij klachten in de hoogcervicale wervelkolom	2016	2
Klinisch redeneren bij schouderklachten: van topsport tot geriatrie	2015	2
De conservatieve behandeling van heupartrose deel 1: pathologie	2015	3
Patiëntenvoorlichting	2015	3
Perifeer arterieel vaatlijden (PAV)	2015	6
Chronische pijn bij artrose	2015	2
Implementatie Nederlandse Praktijkrichtlijn Frozen Shoulder voor fysiotherapeuten	2015	2
Monitoring Cervical Manipulations	2015	2
EBP/Praktijk gericht onderzoek	2015	2
<b><u>(Inter)national conferences</u></b>		<b><u>140</u></b>
Congress on Neck pain, Amersfoort, NL	2014	8
NHG wetenschapsdag, Rotterdam, NL	2015	8
Symposium neck pain, Hogeschool Rotterdam, Rotterdam, NL	2015	8
CME congress, CME. Utrecht, NL	2015	8
Neck and low back Forum, Keele University, Buxton, UK	2016	32
Network meeting E-health, Hogeschool Rotterdam, Rotterdam	2016	8
Headache and Physiotherapy	2015	4
Wetenschapsdag Fysiotherapie, KNGF, Baarn	2014	8
Wetenschapsdag Fysiotherapie, KNGF, Baarn	2015	8
Wetenschapsdag Fysiotherapie, KNGF, Baarn	2016	8
Wetenschapsdag Fysiotherapie, KNGF, Baarn	2017	8
World Congress on Physical therapy	2017	32
<b><u>Presentation</u></b>		<b><u>240</u></b>
Presentation Guideline on Neck pain, Amstelveen, NL	2015	8
Presentation Guideline on Neck pain, Hoorn, NL	2015	8
Poster, NHG wetenschapsdag. NHG, Rotterdam, NL	2015	4
Poster, NHG wetenschapsdag. NHG, Rotterdam, NL	2015	4
Focus group meeting, Hogeschool Rotterdam, Rotterdam, NL	2015	16
George institute, Sydney, AUS	2015	8
Presentation Guideline on Neck pain, NHG symposium	2016	8
Presentation PRINS-study, NHG symposium	2016	8
Poster, Neck and low back pain Forum, Buxton, UK	2016	4
KNGF "Lezing richtlijn nekpijn" presentation guideline (Rotterdam, NL)	2016	8
KNGF "Lezing richtlijn nekpijn" presentation guideline (Alkmaar, NL)	2016	8
KNGF "Lezing richtlijn nekpijn" presentation guideline (Nijmegen, NL)	2016	8
KNGF "Lezing richtlijn nekpijn" presentation guideline (Nijmegen, NL)	2016	8
KNGF "Lezing richtlijn nekpijn" presentation guideline (Hogeschool Leiden, NL)	2016	8
KNGF "Lezing richtlijn nekpijn" presentation guideline (Hogeschool Rotterdam, NL)	2016	8
KNGF "Lezing richtlijn nekpijn" presentation guideline (Avans Hogeschool, NL)	2016	8
Steunpunt Koel, Course SBT low risk (2x)	2016	16
Steunpunt Koel, Course SBT Medium and High risk (2x)	2016	16
KNGF workshop 'dag van de fysiotherapeut'	2016	8
Poster, KNGF 'dag van de fysiotherapeut'	2016	4
Poster, KNGF 'dag van de fysiotherapeut'	2016	4
BSL web-TV	2016	8
NPI webcast	2016	4
KNGF "Lezing richtlijn nekpijn" presentation guideline (Thim vd Laan, NL)	2017	8
KNGF "Lezing richtlijn nekpijn" presentation guideline (Amsterdam, NL)	2017	8

KNGF "Lezing richtlijn nekpijn" presentation guideline (Spier, NL)	2017	8
KNGF "Lezing richtlijn nekpijn" presentation guideline (Bergen op Zoom, NL)	2017	8
KNGF "Lezing richtlijn nekpijn" presentation guideline (Enschede, NL)	2017	8
KNGF "Lezing richtlijn nekpijn" presentation guideline (Amersfoort, NL)	2017	8
Poster, World Congress on Physical therapy, Kaapstad, Zuid Afrika	2017	4
Poster, World Congress on Physical therapy, Kaapstad, Zuid Afrika	2017	4
<b><u>Intern</u></b>		<b><u>160</u></b>
George institute, Sydney and Newcastle, Australia	2015	160
<b><u>Other</u></b>		<b><u>488</u></b>
Writing Guideline, KNGF, Neck pain	2014-2016	416
Student physiotherapy science	2015	10
Student teaching science	2015	10
Assessor Hogeschool Rotterdam, 31 reviews	2016 / 2017	62
Assessor Hogeschool Rotterdam, Skills,	2016 / 2017	30
<b>Total</b>	<b>1124 hours = 40 ECTS</b>	

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## List of publications

## **LIST OF PUBLICATIONS**

### This thesis

Bier JD, Ostelo RWJG, Hooff ML van, Wildervanck N, Koes BW, Verhagen AP, et al. Validity and Reproducibility of the STarT Back Tool (Dutch Version) in Patients With Low Back Pain in Primary Care Settings. *Phys Ther* 2017;97:561–70.

Bier JD, Scholten-Peeters GGM, Staal JB, Pool JJ, Van Tulder M, Beekman E, et al. Clinical Practice Guideline for Physiotherapy Assessment and Treatment in Patients With Non-specific Neck Pain. *Phys Ther*; pending publication

Bier JD, Sandee-Geurts JJW, Ostelo RWJG, Koes BW, Verhagen AP. Can primary care for back and/or neck pain in the Netherlands benefit from stratification for risk groups according to the STarT Back Tool-classification? *Arch Phys Med Rehabil* 2017. [Epub ahead of print]

Bier JD, Ostelo RWJG, Koes BW, Verhagen AP. Validity and reproducibility of the modified STarT Back Tool (Dutch version) for patients with neck pain in primary care. *Musculoskelet Sci Pract* 2017;31:22–9.

Bier JD, Kamper SJ, Verhagen AP, Maher CG, Williams CM. Predictors of non-adherence to guideline recommended care in acute low back pain. *Arch Phys Med Rehabil* 2017. [Epub ahead of print]

### Other publication

Bier JD, Spaanderman JP, Fockert LH de, Verhagen AP. Factsheet “Manuele therapie bij Nekpijn.” NVMT 2013.

Bier JD, Scholten-Peeters GGM, Staal JB, Pool JJ, Van Tulder M, Beekman E, et al. KNGF-richtlijn Nekpijn. KNGF-Richtlijn 2016 <https://www.fysionet-evidencebased.nl/>