

**TOWARDS A NEW TREATMENT FOR CHRONIC
LOW BACK PAIN PATIENTS**

USING ACTIVITY MONITORING AND
PERSONALIZED FEEDBACK

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TOWARDS A NEW TREATMENT FOR CHRONIC LOW BACK PAIN PATIENTS, USING ACTIVITY MONITORING AND PERSONALIZED FEEDBACK

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CHAPTER 1

General introduction

General introduction

Low back pain (LBP) is a major problem in the western industrialized countries.^{1,2} The one-year prevalence of self-reported low back pain is about 42%³ and the life time prevalence is 60-85%.⁴ LBP is defined as pain localised between the 12th rib and the inferior gluteal folds, with or without leg pain.^{5,6} LBP can be divided into acute and chronic pain. *Acute* low back pain occurs suddenly after a period of a minimum of 6 months without LBP and lasts for less than 12 weeks. *Chronic* LBP (CLBP) has a duration of more than 3 months.^{7,8} The majority of people recover from acute LBP, but in 5-10% of all people with acute LBP symptoms do not resolve and develop into chronic complaints.⁹ Besides being acute or chronic, LBP can be divided into specific or non-specific pain. *Specific* back pain involves degenerative conditions, inflammatory conditions, infective and neoplastic causes, metabolic bone disease, referred pain, psychogenic pain, trauma and congenital causes.¹⁰ *Non-specific* LBP is defined as back pain with no underlying pathology and occurs in about 85% of patients.⁹

The societal costs attributed to LBP are high¹¹ and these costs are mainly attributed to productivity loss, work absenteeism and work-disability.^{3,12,13} The direct medical costs account for only 0.9% of the total costs for health care.³ The prevalence and incidence of LBP is still moderately increasing, probably as a result of the ageing of the population, the increasing prevalence of obesity and an increasing sedentary lifestyle.³ Therefore, LBP continues to be a major problem for our society.

The management of CLBP is difficult because of insufficient knowledge about the causes of CLBP as well as the mechanisms by which pain is maintained. Starting from a bio-psycho-social perspective, a

multidimensional approach of CLBP has now been widely recognized and consequently a variety of multidisciplinary treatments have been developed. The effectiveness of these treatments have been investigated and a best evidence synthesis from several reviews¹⁴⁻²⁰ shows that these treatments have positive short-term effects in functional status, but no long-term effects.²¹ This seriously affects these patients, because recurrence of symptoms (such as pain) and loss of function often has a negative impact on their quality of life. Besides, it has a negative impact on our society and it is disappointing for professionals.

A few explanations can be given for the limited effectiveness of current treatment programs. A first explanation is the heterogeneity of the CLBP population which makes it unlikely that all patients will benefit from the same treatment. Subjects with the same medical diagnosis of CLBP might be different in how they cope with their pain and how this is reflected in their daily behavior. This would suggest striving for more individually tailored treatments.^{22,23}

Secondly, the focus on self-management of patients in traditional care is low and the reliance of the patient on the healthcare professional is very high. In traditional care, there is usually face-to-face contact between the health care professional and the patient, where the professional gives the patient direct feedback on how to do their exercises and gives the patient the opportunity to adjust his functioning accordingly and immediately. Once being at home the patient has to take the total responsibility of keep doing the exercises himself. He is not used to this with the consequence that the compliance to exercising decreases substantially. A patient-centered approach, in which the patient is invited to participate in decision making and takes more responsibility for solving his problem, has shown to be more effective than the

traditional clinician-centered care.^{24,25} One way to make patients more self-responsible and to empower him to do the exercises is by introducing a new service²⁶ that replaces part of the face-to-face feedback from the professional by feedback provided by technology.²⁷

Thirdly, traditional treatment has an insufficient focus on the daily life situation of the patient; patients learn cognitive and motor skills in the artificial setting in the rehabilitation centre. Subsequently, patients find it difficult to translate these skills learned at the treatment setting to their home environment because the home situation doesn't match the treatment environment and they receive no help and feedback of the health care professional. Treatment directly in the own home environment is expected to overcome this problem of translation as skills are directly learned in the daily life situation.

Summarizing this, it is hypothesized that the effectiveness of treatment of CLBP patients can be increased by (1) personalizing the treatment by providing treatments that enable individual goal setting and are based on the patients needs and capacities; (2) using technology to make the patient less dependent on the healthcare professional and give him more responsibility for his treatment outcome and; (3) making the treatment ambulant, so that it becomes possible to treat the patient in his own daily environment.

Starting from this hypothesis, this thesis focuses on:

the development and testing of an ambulant personalized treatment for patients with CLBP that uses technology to support the patient to improve his health status.

For the realization of such treatment, three key elements are considered important: (1) *clinical content*, (2) *design* and (3) *outcome*.²⁸

Concerning the clinical content, it is important that the service is able to monitor relevant aspects of a patient's health status in the daily environment and to give proper feedback to the patient about his actual health status and changes in his status when they occur. Concerning the design, the treatment should be designed in such a way that it fits the needs of the users. Outcome refers to the aspect that the system needs to have positive effects on care in terms of effectiveness and efficiency.

1. Clinical content

Theoretical models explaining the development and maintenance of chronic pain, like the cognitive behavioral fear-avoidance model²⁹ and the avoidance-endurance model³⁰, assume that physical activities are a key aspect, although in various directions. The fear-avoidance model proposes that catastrophic interpretations about pain and elevated pain-related fear levels might lead to avoidance behavior, resulting in low activity levels. According to the avoidance-endurance model, chronic pain patients can display two alternative activity-related strategies: an avoidant strategy which is characterized by low activity levels or a strategy showing persistence in activities^{30,31} characterized by normal or high activity levels.

For both directions there is scientific evidence: some studies show lowered activity levels in chronic pain patients^{32,33} and another study shows similar activity levels compared to controls.³⁴ Not only from theoretic models and experimental studies but also in clinical practice of patients with chronic pain normalizing physical activities is considered a key aspect.³⁵ As such, physical activity is chosen as starting point in the treatment to be developed.

Considering the feedback that needs to be provided to the patient by technology, it is important to define the aim(s) of feedback. Normalizing

physical activity levels can be considered as a process of changing behavior. According to the Trans Theoretical Model³⁶ and the Theory of Planned Behavior³⁷ changing a behavior is a staged process in which at least four stages are discerned to come to actual change: awareness, motivation, intentions, and changes followed by maintenance of the changed behavior. These stages are considered to be important when supporting the patient in achieving a change and as such will be addressed in the feedback provided to the patient. However, at this point there is little knowledge about how feedback strategies should be provided by technology and which feedback strategies are effective to change the activity behavior of CLBP patients. Studies concerning effective feedback strategies are mainly focusing on teaching motor skills which are performed in a controlled laboratory setting and most of these studies concern healthy persons or patients with cardiovascular diseases.³⁸⁻⁴⁰ There is little evidence about effective feedback in chronic diseases like patients with chronic pain and how these simple tasks in the laboratory relate to more complex situations in the daily living, like behavioral change.

2. Design

The treatment should be designed in such a way that it fits the needs of the users being both the professional and the patient. As described above, it was chosen to focus on monitoring physical activity and providing feedback to the patient to enable him to change his activity level and pattern. Starting from these high level requirements, choices for design need to be made. Design aspects that need to be considered are the sensors and sensing technique used that will enable ambulant monitoring as well as the actuators and strategies used to give proper feedback to the patient himself. Monitoring and feedback constitute the personalized interaction between the patient and the system. For this

purpose, a wearable computing device that enables wireless communication between several miniaturized Body Sensor Units and a single Body Central Unit worn at the human body also called Body Area Networks (BAN) is expected to be very useful.⁴¹⁻⁴³ In this thesis, a simple BAN will be used that exists of an Mt-x movement sensor for objectively measuring the patient’s activity level and a Personal Digital Assistant (PDA) for providing feedback to ensure mobility of the patient (see figure 1). Communication between the sensor and the PDA is established with a Bluetooth connection.



Figure 1: Body Area Network of the new ambulant treatment

3. Outcome

Outcome refers to the aspect that the system needs to have positive effects on care in terms of effectiveness and efficiency. To evaluate whether a new kind of treatment has potential for clinical purpose, DeChant et al.⁴⁴ proposed a framework for evaluation in which the type of assessment is tailored to the development life cycle of the technology. It is an iterative process where the evaluation is used for improving the system and more and more endpoints are taken into account as the system becomes more mature. This so-called staged approach differentiates between evaluation at application (stage 1-2) and global levels (stage 3-4). The first two stages are applicable in immature

applications and the last two stages are only suitable for mature applications. According to this approach, the evaluation should be matched to the goals of the intervention and assessment should eventually address technical validation (including user satisfaction), clinical validation (effectiveness), efficiency of the application and generalizability. A stage 1-2 evaluation of an application starts with an evaluation of the technical efficacy (accuracy and reliability) of the application and is used to improve the system for further development. At first, it focuses on the technical aspects and compliance of the system and evaluates the primary objective of the service. As in this, the new treatment module that is being developed will be a first prototype and will be evaluated on its technical efficacy and compliance and focuses on the primary objective specified in different treatment outcomes, namely creating awareness, normalization of activity patterns and decreasing pain intensity levels. During the subsequent deployment a comprehensive evaluation is necessary, using multiple endpoints such as quality, accessibility and cost of care (stage 3). The last step is to examine whether the overall evaluation of a technology in one system, applies in other settings (stage 4).

Outline of this thesis

To get a better understanding of the state of the art of knowledge concerning activity levels of patients with chronic pain, this thesis started with a systematic review (*chapter 2*). This review pointed out that different experimental studies show different results for different patient groups and that there are differences between objective and subjective outcome instruments. Therefore, a cross sectional experimental study was performed to get more insight into differences in activity patterns over the day between CLBP patients and controls (*chapter 3*), but also into the relationship between objectively and

subjectively assessed activity patterns (*chapter 4*). The results of chapter 2-4 are used as a starting point for the development of the new treatment. Chapter 5 and 6 describe and evaluate the new ambulant treatment. As there is little knowledge about how feedback should be provided by technology and which feedback strategies are effective to change the activity behavior of CLBP patients, a study was performed to explore the feedback strategy used in this new treatment by investigating the response to the individual feedback tips given, in terms of changes in activity patterns by the patient (*chapter 5*). Chapter 6 subsequently describes the results of a study in which a stage 1-2 evaluation has been performed focusing on the potential value of the system in terms of technical performance, compliance with the system and the changes in clinical outcomes (*chapter 6*). In the final chapter, the main findings of these studies are integrated and evaluated in the context of existing literature and the aim of this thesis (*chapter 7*).

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CHAPTER 2

Daily physical activities of patients with chronic pain or fatigue versus asymptomatic controls. A systematic review

Van Weering M, Vollenbroek-Hutten MM, Kotte EM, Hermens HJ. Daily physical activities of patients with chronic pain or fatigue versus asymptomatic controls. A systematic review. Clin Rehabil. 2007 Nov;21(11):1007-23

ABSTRACT

The present study was performed to gain an insight in the daily activity level of chronic pain patients compared to asymptomatic controls. A systematic, computerized database search of the medical databases up to September 2006 was performed. In addition, an informal hand search was carried out. Appropriate studies reported on daily physical activities of adult patients with chronic pain or fatigue and included an asymptomatic control group. Two reviewers independently carried out the methodological quality assessment and data extraction of the studies. A qualitative analysis was performed.

Twelve studies were included, involving five different syndromes. Results show large heterogeneity in methods used and syndromes investigated, which limited evidence. Eleven different methods were used to assess daily physical activities resulting in 16 different outcome parameters. Eight studies reported a lower physical activity level in patients compared to controls, but results are different between pain syndromes. There seems to be a difference in results between studies using objective versus those using subjective methods.

Results reported in literature with respect to the activity level of patients with chronic pain or fatigue compared to controls were too heterogeneous to give sufficient evidence and were not conclusive.

1. INTRODUCTION

Chronic pain and fatigue are important health problems due to the high impact on disability, sickness absence and health care costs. Chronic pain of moderate to severe intensity occurs in 19% of adult Europeans and seriously affects their quality of social and working lives.¹ Common chronic pain complaints include headache, low back pain, cancer pain, arthritis pain, neurogenic pain and psychogenic pain. Chronic fatigue occurs in 0.3% of adult Europeans and the cause of this disease is unknown² and it also puts a great burden on our western industrialized society.

Regular physical activity is widely believed to have important health benefits, such as improving quality of life and mobility, and reducing disabilities.³ Conversely, lack of physical activity is considered a risk factor for increasing chronic diseases, functional dependence and mortality.⁴ In many theoretical research models on pain and fatigue, a decreased level of physical activities (physical disuse) is assumed an important factor leading to and maintain chronicity of pain and fatigue.⁵⁻⁸ These models suggest that, as a consequence of long-term physical disuse, the condition of the patient gets worse, resulting in tiredness and pain during daily activities. This increases the fear of movement and thus the patient ends up in a vicious circle, characterized by a decrease in activities and an increase in psychological complaints.⁹ This theory is supported by several studies reporting on activity avoidance and physical functioning (e.g. muscle strength) in patients with chronic pain and fatigue.¹⁰⁻¹⁴ In line with these models, a lot of treatment methods for these patients aim to break through this circle and achieving a normalization of activities of daily living.^{1,6}

However, in addition to the decreased activity levels, Hasenbring¹⁵ postulates in her avoidance-endurance theory that for patients with pain

there is also a group of patients who suppress or ignore pain in order to finish all activities they started and who are unable to integrate phases of relaxation into their daily routine. These patients are expected to show comparable activity levels as asymptomatic controls. The existence of such behavior is supported by Verbunt et al¹⁶ and Spenkeliink et al¹⁷ who both showed similar mean activity levels during the day in chronic low back pain patients compared to asymptomatic controls. However, not only for chronic pain, Kop et al¹⁸ found that chronic fatigue patients also revealed similar average activity levels compared to controls. In addition, also clinicians often indicate that not every patient with chronic pain or fatigue seen in clinical practice shows a deconditioning. There are apparently patients who are very and maybe too active.

To be able to design adequate treatment procedures and to develop an optimal treatment allocation process, it is very important to get a better understanding of the activity levels of patients with chronic pain or fatigue. The objective of this study is to gain an insight in the activity level of chronic pain and fatigue patients compared to asymptomatic controls by a systematic review of the literature. As a main outcome the daily activities of patients is used compared to asymptomatic controls.

2. METHODS

Literature search

An extensive search was conducted consulting the following electronic databases till September 2006: MEDLINE (www.pubmed.com), EMBASE (www.embase.com), PsycINFO (www.ebsco.com), Picarta (picarta.pica.nl) and the Cochrane Controlled Trials Register that is included in the Cochrane Library. In addition, a manual search of relevant journals: Clinical Journal of Pain, Pain and European Journal of Pain was carried out up to September 2006. Finally, for the already selected studies, the function "related articles" in PUBMED was used for an additional check and reference tracking was performed on all included studies. The computerized search strategy was based on the following keywords: pain, chronic, physical activity, daily activities, activity level, disuse, deconditioning and combinations thereof.

The inclusion criteria were that the study should: 1) report on subjects with chronic pain or fatigue, 2) report a control group of asymptomatic controls, 3) evaluate outcomes in terms of daily activities, 4) include patients of 18 years and older, 5) be written in English, German or Dutch.

The first screening of eligible studies was based on the abstract and title. If abstract and title satisfied the inclusion criteria, the study was included. If the information provided by the title and abstract was insufficient to conclude if the inclusion criteria were met, full-text versions were retrieved and read. Final inclusion was made based on the full text versions of the studies.

Methodological quality

The methodological quality of each study was independently assessed by two authors (MvW, EK). Review authors were not blinded with respect to

authors, institution and journal because they were familiar with the literature. Consensus was used to resolve disagreements and an independent third author (MV) was consulted if disagreements persisted. To assess methodological quality, items were scored on a methodological criteria list. For this, a part of the criteria list recommended by the Cochrane Back Group and described by van Tulder et al¹⁹ was used. The list consists of internal validity criteria, descriptive criteria and statistical criteria. The internal validity criteria (n=4) refer to characteristics of the study that might be related to selection bias, attribution bias, detection bias and performance bias. The descriptive criteria (n=3) refer to the external validity of the study and may be used for the subgroup and sensitivity analyses. The statistical criteria (n=2) indicate whether calculations can be made and conclusions can be drawn independently of the opinion of the authors of the original study.

To determine the methodological quality of the studies, each item was graded. Every criterion of the quality list was scored as "yes", "no", "don't know" or "not applicable", with the final quality score being the sum of "yes" scores. The following was used to rate the overall quality of each study against the criteria list: "high" if more than seven of the items were answered "yes"; "medium" if five to seven of the items were answered "yes"; "low" if less than five of the items were answered "yes".¹⁹

Data extraction

For each included study, data were extracted on: age, gender, sample size, work status, duration of complaints, methodological quality, measurement devices, measurement period, outcome measures and the reported results and conclusions of the study. Subsequently, the studies were divided by the different pain syndromes described. The data extraction was again conducted independently by the same reviewers

(MvW, EK) who performed the quality assessment using a data extraction sheet.

Data analysis

For every study, means and standard deviations (SD) of patient and control groups were extracted for the different outcome parameters used. In addition, the coefficient of variation (CV; (standard deviation/mean) x100) has been calculated for each group within each study, if possible. The CV is a useful statistic to gain an insight in the variability within groups and for comparing the degree of variation between groups, even if the means are drastically different from each other. If subgroups in chronic pain patients exist, it is expected that the CV of the patients is higher than those of controls, due to more variability in the patient group.

The different outcome measures used were described separately on psychometric characteristics and subdivided into objective and subjective methods. Objective methods are methods undistorted by emotion or personal bias. Subjective methods are methods that are based on personal interpretations. It was investigated whether the outcome parameter used is related to the differences in activity level between patients and controls. The same was done for high versus low quality studies.

We preferred to pool the results of individual studies. Clinical homogeneity among the studies was assessed by comparing the retrieved studies with respect to outcome measures. If statistical pooling was not possible, the analysis was restricted to a qualitative overview.

3. RESULTS

Literature search

The literature search resulted in a list of circa 1903 citations. After the first screening of abstracts and titles, 86 studies were retrieved for closer inspection. Of these, 12 articles were judged to meet the inclusion criteria and were included in this review (see figure 1). The additional hand search of the journals and references did not show relevant articles. Screening the reference lists of the included studies provided no new articles. There were two main reasons for articles being excluded. The first was that in these studies physical functioning was measured instead of physical activity. Physical functioning involved fitness parameters, such as VO^2 max and muscle strength. The second reason was lack of a control group to compare the results of patients with.

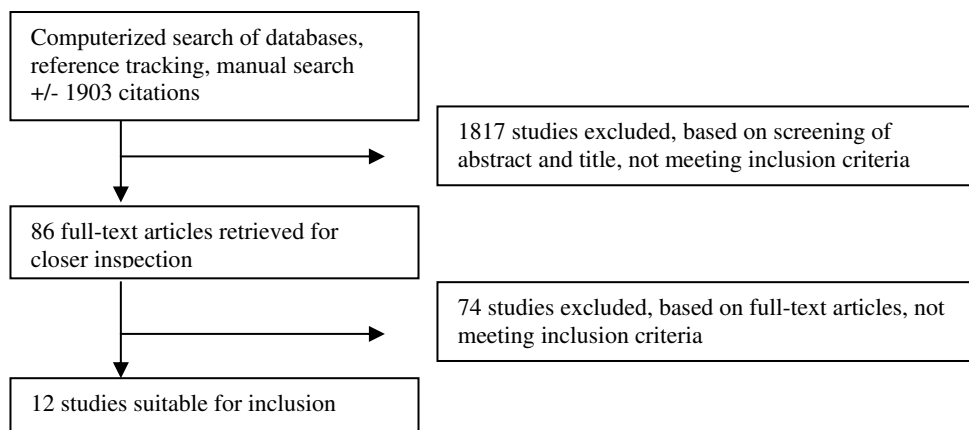


Figure 1: Flow diagram of included studies

Target studies

The 12 selected articles covered a considerable range of different pain syndromes. Of the 12 studies, five concerned patients with chronic fatigue syndrome²⁰⁻²⁴, three studies a mixed group of chronic pain syndromes^{12,18,25}, two studies concerned low back pain patients^{16,17}, one

study involved migraine patients²⁶ and one study concerned fibromyalgia patients²⁷. The control group was insufficiently defined in nine studies; six studies use the term "healthy", without defining this term.^{16,18,22,23,24,27} Bazelmans et al²¹, Nielens et al²⁵ and Farrell et al¹² did not use any in- or exclusion criteria for their controls, meaning that the health conditions of these controls were unknown. Only Black et al²⁰, Stronks et al²⁶ and Spenkeliink et al¹⁷ defined the control group as healthy with no such conditions as the experimental group, for at least six months prior to the study.

Study characteristics

The group characteristics of the studies are displayed in table 1.

The male-to-female ratio differed per study. Seven studies included more females than males^{12,18,21,22,24,25,26}; two studies included more males than females^{16,17}; two studies included females only^{23,27} and one study did not state the gender studied²⁰. The average age in the studies was approximately 35-45 years, however there was a great variability in age in the studies. The range of the mean age in the studies was 33.6 years²³ to 71.8 years¹².

The sample size of the studies varied from 13 cases in the study of Black et al²⁰ to 324 cases in the study of van der Werf et al²².

Only two studies reported the work status of patients^{16,25} and only one reported the work status of both patients and controls.²⁴ There was a great variability in the reported work status in these studies. In Nielens' study²⁵, 20-34% of the patients had a paid job, whereas in Verbunt's study¹⁶ 77% of patients had a paid job. Vercoulen et al²⁴ reported a work status in 28% of the patients and in 47% of the controls. In the study of Spenkeliink et al¹⁷ and Stronks et al²⁶, the work status of both patients and controls is equal, but the amount of working patients and controls is unknown. The mean duration of complaints was reported in

eight of the eleven studies, varying from 6 months in the study of Spenkelink et al¹⁷ to 12 years in the study of Verbunt et al¹⁶.

Methodological quality

The methodological quality between the studies varied with a range from low to high (see table 1). The mean score for methodological quality of all the included studies was seven with a range of three till nine. Six studies had a high methodological quality.^{16,17,22,23,24,26} Five studies had a medium methodological quality^{12,18,20,21,27} and one study had a low methodological quality²⁵.

In more detail; the internal validity of seven of the included studies was good.^{16,17,20,21,22,26,27} Four studies had a moderate internal validity^{12,18,23,24} and one study had a bad internal validity²⁵. The reason for scoring negative on one of the items of the internal validity was most of the times due to not reporting the dropout rate in the study, or there were important outcome measures missing, such as work status.

By scoring the items of the descriptive criteria, the external validity of the studies can be judged. Six studies had a good external validity.^{12,16,17,21,24,27} Three studies had a moderate external validity.^{18,20,23} Three studies had a bad external validity.^{22,25,27} The reason for scoring negative on one of the items of the descriptive criteria was that the groups were not similar at baseline, for example in age or gender, or that the eligibility criteria were insufficiently specified.

The statistical criteria were judged well in 10 of the 12 studies, except for the study of Nielens et al²⁵ and Stronks et al²⁶. In the study of Nielens et al²⁵, no general characteristics of controls were described, such as age or gender. In the study of Stronks et al²⁶, point estimates were missing.

Table 1: Summary of characteristics of all included studies divided by the different pain syndromes

Study population	First author of report	Patients population	Controls	Work status	Duration of complaints mean(SD)	Methodological quality ¹
Chronic fatigue syndrome (CFS)	Bazelmans E 2001 ²¹	CFS N=20 60% female mean age 34 yrs	Neighbors N=20 60% female mean age 32.8 yrs	Unknown	3.2 (2.5) yrs	1,2,3,5,6,8,9
	Black CD 2005 ²⁰	CFS N=6 mean age 43 yrs	Healthy controls, no disease conditions N=7 mean age 43 yrs	Unknown	Unknown	1,2,4,5,7,8,9
	Sisto SA 1998 ²³	CFS N=20 100% female mean age 33.6 yrs	Healthy, sedentary controls N=20 100% female mean age 33.0 yrs	Unknown	8 months to 6 yrs	2,3,4,5,6,7,8,9
	Vercoulen JH 1997 ²⁴	CFS N=51 76% female mean age 36 yrs	Healthy controls, matched on educational level N=53 76% female mean age 37.1 yrs	Pts 28% Controls 47%	5 yrs	1,2,4,5,6,7,8,9
	Van der Werf SP 2000 ²²	CFS N=277 79% female mean age 37.5 yrs	Healthy controls N=47 49% female mean age 40.1 yrs	Unknown	Unknown	1,2,3,4,5,7,8,9
Mixed chronic pain conditions	Farrell MJ 1996 ¹²	Older chronic pain patients N=248 73% female mean age 71.8 yrs	Older controls N=72 69% female Mean age 73.1 yrs	Unknown	Unknown	1,3,6,8,9
	Nielens H 2001 ²⁵	Low back pain, fibromyalgia, other pain syndromes N=55 64% female mean age 44 yrs	Age matched controls, derived from literature on a normative population	20% of male pts 34% of female pts 29% of total pts	> 1 year	2,7,8
	Kop WJ 2005 ¹⁸	Fibromyalgia and/ or CFS N=38 74% women, mean age 41.5 yrs	Healthy, sedentary controls N=27 44% female mean age 38.0 yrs	Unknown	Unknown	1,2,4,5,7,8,9
Chronic low back pain (CLBP)	Spengelink CD 2002 ¹⁷	CLBP N=47 43% female, mean age 36.6 yrs	Healthy controls no CLBP during the last 6 months N=10 60% female	Work situation equal in the patient and	> 6 months	1,2,3,4,5,6,7,8,9

			mean age 29.2 yrs	control group		
	Verbunt JA 2001 ¹⁶	CLBP N=13 33% female mean age 45 yrs	Healthy controls N=13 33% female mean age 45.7 yrs	Pts 77%	12 (7) yrs	1,2,3,4,5,6,7,8,9
Migraine	Stronks DL 2004 ²⁶	Migraine N=24 96% female mean age 39.8 yrs	Healthy controls, free from drugs, no history of headache complaints N=24 96% female mean age 39.6 yrs	Comparable regarding occupation	> 3 months	1,2,3,4,5,6,7,8
Fibromyalgia	Korszun A 2002 ²⁷	Fibromyalgia N=16 100% female mean age 49.2 yrs	Healthy controls N=28 100% female mean age 53.4 yrs	Unknown	Unknown	1,2,3,4,7,8,9

¹Items of methodological quality scored positively in the studies; 1, Is the compliance acceptable in both groups; 2, Are the outcome measures relevant and measures reliable and valid; 3, Is the withdrawal/dropout rate described and acceptable; 4, Is the timing of the outcome assessment in both groups comparable; 5, Are the inclusion and exclusion criteria specified; 6, Are the groups similar at baseline; 7, Is the procedure explicitly described; 8, Is the sample size for each group described; 9, Are point estimates and measures of variability presented for the primary outcome measures

Yrs= years, pts= patients

Overall result on activity level

The results of the included studies specified in five pain syndromes are displayed in table 2. In total, eight of the 12 studies reported a lower physical activity level in chronic pain patients compared to asymptomatic controls. Two studies showed a similar level of physical activity^{16,27} and in two studies a similar mean activity level during the day was reported, with patients having a lowered activity level in the evening¹⁷, lower peak activity levels and less time spent in high level activities compared to controls.¹⁸

Table 2: Results of included studies specified in five pain syndromes.

Study population	First author of report	Measurement device for assessing physical activity	Measurement period	Outcome measures	Results mean (SD)	Conclusion
Chronic fatigue syndrome (CFS)	Bazelmans E 2001 ²¹	Actometer	14 days	Mean number of accelerations per 5-min period, during daytime	Pts 58.2(27.2) ; CV=46.7 C 99.5(25.0) ; CV= 25.1 P=0.00	Significantly lower activity level of CFS patients compared to controls.
	Black CD 2005 ²⁰	Actigraphy , Computer Science and Applications monitor (CSA)	14 days	Average daily activity counts, two-minute epochs, waist-mounted	pts162.5(51.7) CV=31.8 C 267.2(79.5) ; CV=29.7 P=0.017	CFS patients had significantly lower daily activity counts than healthy controls.
	Sisto SA 1998 ²³	Actigraphy (CSA)	7 days	Daily average activity level per minute, waist-mounted	Pts 7.3 (0.89) ; CV=12.2 C 8.6 (0.89) ; CV=10.3 F=8,94 (1,38), P<0.01	CFS patients had a significantly lower average daily activity level compared to healthy controls.
	Vercoulen JH 1997 ²⁴	Actometer	12 days	Mean score of all 5 min epochs, day and night	Pts 23.3(10.7) ; CV=45.9 C 35.5(10.8) ; CV=30.4 P<0.05	CFS patients were significantly less active than healthy controls.
		Self-observation list		Mean score for the two week period, rated daily on a 7-point scale	Pts 3.8(1.3) ; CV=34.2 C 5.4(1.0) ; CV=18.5 P<0.05	The daily observed activity is significantly lower in CFS patients as compared to healthy controls.
		Physical Activity Rating Scale (PARS)		Mean score of time spent on 20 different activities, during the past two weeks scored on a 5-point scale.	Pts 2.1 (0.4) ; CV=19 C 2.7 (0.5) ; CV=18.5 P<0.05	CFS patients had significantly lower daily activities scores compared to healthy controls.
Van der Werf SP 2000 ²²	Actometer (Actilog V3.0)	12 days	Mean number of accelerations per 5-min period, during daytime	Pts 66(22); CV=33.3 C 91(25) ; CV=27 P=0.00 F=39.7 Degrees of freedom 3.320	The CFS patients were significantly less active than healthy controls, with less intense and shorter activity peaks that were in turn followed by longer rest periods. Female patients with CFS were significantly less active than male patients.	
	Self-report daily ratings		Mean reported daily activity, measured four times a day on a 5-point (0-4) scale	Pts 4.6(1.7) ; CV= 37 C 6.1(2.4) ; CV= 39.3 P=0.00	CFS patients report themselves physically less active than healthy controls do.	
Mixed group of pain conditions	Farrell MJ 1996 ¹²	Human Activity Profile (HAP)	-	Adjusted activity score	Pts 37.5(2.1) ; CV=5.6 C 59.1(2.5) ; CV=4.2 P<0.001	Chronic pain patients have a significantly lower activity level than controls.
	Nielens H 2001 ²⁵	Baecke-questionnaire	7 days	Three activity indexes: occupation, sports, non-sports leisure time. Total baecke score= sum of indexes	Pts Males 4.5(SD 1.5) ; CV= 33.3 Pts Females 5.5(SD 1.8) ; CV= 32.7 C males 8.2(SEM 0.1) C females 8.4(SEM 0.1)	Patients of both genders seem to present a significant reduction in total physical activity as compared with data of controls.

		Five-City Project Questionnaire		Average daily energy expenditure rate of the preceding week (kcal/day/kg)	Pts Males 34.4(4.15) ; CV= 12.1 Healthy males 41(6.5) ; CV= 15.9 Males p<0.001 Pts Females 34.1(3.77) ; CV= 11.1 Healthy females 36(6.5) ; CV= 18 Females p=0.09	Male patients are significantly less active than healthy male subjects of the same age.
	Kop WJ 2005 ¹⁸	Actigraphy	5 days	Average daily activity counts summed per 5 minutes epochs, wrist-mounted Peak activity level	Pts 1525 (432) ; CV=28.3 C1602(281) ; CV=17.5 P=0.47 Pts 8654(527) C12913(1462) P=0.003	Patients had similar average activity levels as those of controls. Patients had significantly lower peak activity levels and spent less time in high-level activities when compared with healthy controls.
Chronic low back pain (CLBP)	Spence-link CD 2002 ¹⁷	Dynaport	5 days, no weekends	Overall level of activity combining static or dynamic activity, intensity of trunk movements and walking step frequency, average per hour	Daytime pts 1.40(0.26) ; CV=18.6 controls 1.29(0.20) ; CV=15.5 t-value= 0.44, p=0.66 Evening pts 1.08(0.45) ; CV=41.7 controls 1.30(0.26) ; CV=20 t-value= 2.78, p=0.01	Physical activity levels of CLBP patients are similar compared to healthy controls during the day, but patients were significantly more lying than controls and had a lowered activity level during the evening.
	Verbunt JA 2001 ¹⁶	Doubly labeled water technique (DLWT)	14 days	Average daily metabolic rate/resting metabolic rate <1.6 low activity level >1.85 high activity level	Pts male 1.66(0.30) ; CV=18.1 C male 1.77(0.32) ; CV=18.1 Pts female 1.77(0.21) ; CV=11.9 C female 1.73(0.22) ; CV=12.7	There are no significant differences in activity level between low-back pain patients and healthy controls.
Migraine	Stronks DL 2004 ²⁶	Four uniaxial accelerometers	Migraine-free two-day period	Values of four accelerometer sensors, average per minute	difference between pts and controls: morning p=0.047 afternoon p=0.016 evening p= 0.025	Patients with migraine were found to be significantly less physically active than healthy controls in the morning, afternoon and evening.
Fibromyalgia	Korszun A 2002 ²⁷	Actigraphy	5-7 days	Activity counts per minute, wrist-mounted	Pts 191.44(34.12) ; CV=17.8 C 192.38(22.59) ; CV=11.7 p>0.05	Fibromyalgia patients have similar mean daytime activity compared to healthy controls.

Pts= patients; C= controls; SD= standard deviation; SEM= standard error mean; CV= coefficient of variation

Different pain syndromes

Table 2 summarizes the methods used to assess physical activities, the results and conclusions of the selected studies, grouped for five different pain syndromes; chronic fatigue syndrome, mixed pain conditions, low back pain, migraine and fibromyalgia.

Chronic Fatigue Syndrome (CFS)

Five studies concerned CFS patients²⁰⁻²⁴. All five studies showed a significant difference in activity level between CFS patients and asymptomatic controls. Patients were significantly less active than controls, had lower average peak amplitude and the average duration of the peak amplitudes were shorter for CFS patients. These peak amplitudes were followed by more minutes spent in rest periods.²²

Mixed chronic pain syndromes

Three studies involved a heterogeneous group of pain patients. The study of Kop et al¹⁸ showed a similar average activity level for patients and controls, but CFS and fibromyalgia patients spent less time in high-level activities (>8000 units/5 minutes; e.g. running, gardening) and had lower peak activity levels (highest level of activity in a 5-minute period during the 5 day observation period).

Two other studies of Nielens et al²⁵ and Farrell et al¹² showed a significant lower activity level of patients compared to asymptomatic controls.

Low back pain

Two studies concerned patients with CLBP. Of these two, one showed a similar physical activity level of CLBP patients compared to asymptomatic controls¹⁶ and the other study showed a similar activity level during the day, but a lowered activity level during the evening in CLBP patients compared to controls.¹⁷

Migraine

One study concerned migraine patients. This study reported that patients with migraine were significantly less physically active than controls during a 2-day migraine free period.²⁶

Fibromyalgia

One study concerned fibromyalgia patients. This study showed a similar average activity level of fibromyalgia patients compared to asymptomatic controls.²⁷

Assessments methods

Eleven different methods were used to measure the daily physical activity level of chronic pain patients, resulting in 16 different outcome parameters (see table 2). Five of the 11 assessment instruments used were found to be reliable and valid in a chronic pain population, namely the Dynaport²⁸, Doubly Labeled Water Technique²⁹ (DLWT), actigraphy³⁰, the Baecke questionnaire³¹ and four-sensor accelerometry³² (see table 3). These methods were used in seven of the 12 studies. Only one study used the DLWT (determines the average daily metabolic rate and provides a reliable measure of energy expenditure), considered the “gold standard” for physical activity assessment in daily living.¹⁶ The Dynaport was used in one study and the main outcome was time spent on different activities and body positions. Four studies used actigraphy (uni-axial accelerometer, indirect measurement of energy expenditure), which expressed daily activity level in activity counts (based upon the magnitude of a change in velocity during a given time period). The Baecke questionnaire was used in one study and measures the work-, sports- and leisure time index of patients and controls. Four-sensor accelerometry was used in one study, using four uniaxial accelerometers employed to classify static and dynamic activity.

Three of the 11 methods, used in four studies, had some limitations concerning their reliability and validity; the HAP questionnaire¹², self observation list²⁴ and the actometer³³. Self observation lists and the HAP

questionnaire require subjective interpretations. The less an instrument requires subjective interpretations the better the reliability and validity is.²⁴ The actometer tends to underestimate the level of activity when the percentage of intense activity (e.g. running) is high. Three of the 11 methods, used in three studies, had not been tested for their reliability and validity in a chronic pain population; self-report ratings, the Five City Project Questionnaire and the Physical Activity Rating Scale (PARS).

Subjective versus objective instruments

Eight studies used objective methods, whereas two studies used subjective methods^{12,25} and two studies combined objective with subjective methods^{22,24} to assess physical activities. In total, five different objective methods and six different subjective methods were used in the studies (see table 3).

Table 3: Validity and reliability of methods used for assessing physical activity in a chronic pain population, including references for the noted scores.

	Measurement device	Validity	Reliability	Reference
Objective methods	Dynaport	+	+	Munneke et al 2001 ²⁸
	Doubly Labeled Water Technique	+	+	Schoeller et al 1996 ²⁹
	Actigraphy, CSA	+	+	Warms et al 2004 ³⁰
	Actometer	-	-	Morrell et al 1988 ³³
	Four-sensor accelerometry	+	+	Bussmann et al 1998 ³²
Subjective methods	Self-observation list	-	-	Vercoulen et al 1997 ²⁴
	Self report daily ratings	?	?	Unknown
	Five City Project Questionnaire	?	?	Unknown
	HAP Questionnaire	+/-	+/-	Farrell et al 1996 ¹²
	Baecke Questionnaire	+	+	Jacob et al 2001 ³¹
	PARS	?	?	Unknown

+: good, +/-: moderate, -: bad, ?: unknown

Measurement period

The measurement periods in the studies differed from 1 to 14 days. Three studies had a measurement period of 14 days^{16,20,21}, two studies had a measurement period of 12 days^{22,24}, five studies measured for 5-7 days^{17,18,23,25,27} and one study has a measurement period shorter than

five days²⁶. Ten of the 12 studies included the weekends, two did not^{16,24}. The evenings were included in all studies.

Coefficient of variation

The CV was calculated to investigate the variability within the different groups and to compare the variation between the patient and the control groups. In one study the CV could not be calculated because necessary parameters were missing.²⁶ In eight of the remaining 11 studies the CV was higher in the patient group as compared to controls (see figure 1). The CV of all objective methods used, was higher in the patient groups as compared to controls. In two studies, using the subjective methods, the CV was lower in patients than in controls.^{22,25} In the study of Verbunt et al¹⁶ the CV of patients and controls was the same

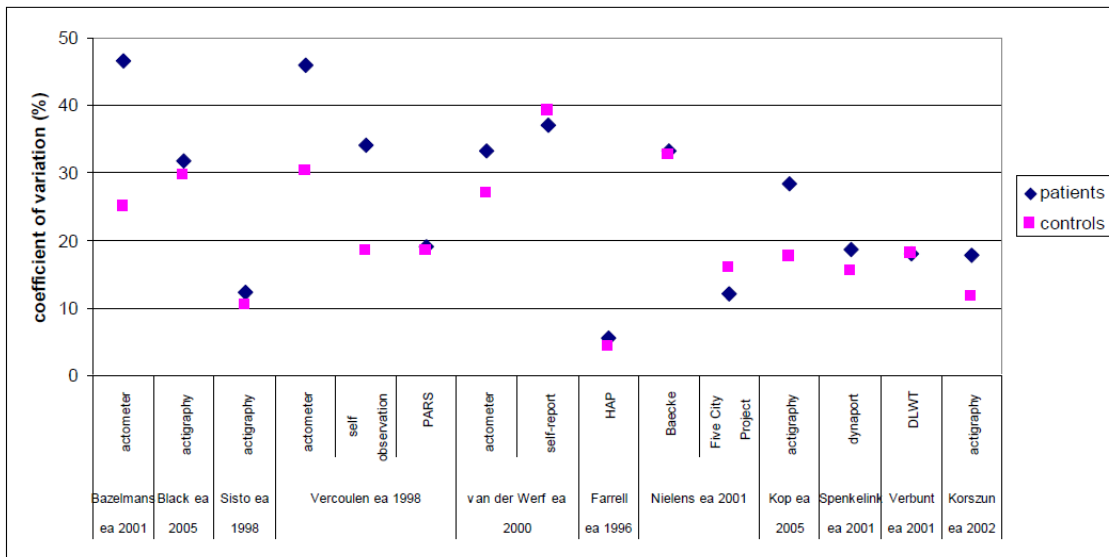


Figure 2: Coefficient of variation of both patients and controls for each method and study

Qualitative analysis

Looking at the small number and heterogeneity of the included studies; e.g. great variability in the studies of methods, pain syndromes and different outcome parameters used, the results could not be statistically pooled. Therefore, the analysis was restricted to a qualitative overview.

4. DISCUSSION

The results of this systematic review seem to indicate that patients with chronic fatigue or pain have lower activity levels compared to healthy controls. However, a number of shortcomings within and comparability problems between the selected studies weaken this conclusion.

To assess physical activity level, 11 different measurement devices were used, five being objective and six being subjective. Only one study used the gold standard³⁴ being the doubly labeled water technique. This study reported no significant difference in activity level of low back pain patients and asymptomatic controls.¹⁶ In addition, four of in the total ten studies that used objective measures also showed no difference in activity level between patients and controls. In contrast, all four studies that used subjective measurements showed a lower physical activity level of patients compared to asymptomatic controls. This might indicate that patients' self-reported levels of physical activity were estimated lower than those actually measured. This is in concurrence with literature³⁵⁻³⁷ and might indicate that subjective instruments do not measure actual behavior. Maybe patients compare their actual activity level with their physical activity level before their pain started, which they overestimate. Mood can also be an explaining factor for underestimating the activity level as Haythornwaite et al³⁸ found that depressed chronic pain patients reported themselves less active than non-depressed patients. Besides, most of the subjective methods had problems with reliability and/or validity which may be responsible for the differences compared to objective measures.

There were four studies with low and medium methodological quality, reporting a lowered activity level of patients compared to controls and four studies with a high methodological quality reporting a lowered

activity level of patients compared to controls. In addition, there were two studies with a medium methodological quality and two studies with a high methodological quality reporting no differences in activity level between controls and patients. Therefore, it seems that the methodological quality has no influence on the results concerning activity level.

Different measurement periods have been used in the studies, varying from 2 days in the study of Stronks et al²⁶ up to 14 days in the studies of Black et al²⁰, Bazelmans et al²¹ and Verbunt et al¹⁶. Three of the five studies that used a measurement period of seven days or less, showed a similar mean activity level of patients compared to controls. Five of the six studies with a measurement period longer than seven days, showed a lowered activity level of patients as compared to controls, but all five studies used subjective or unreliable methods. Based on these results, it is still unclear what the best measurement period is. To represent normal daily life, we would advise to measure at least seven days, including the weekend and evenings.

The work status of patients and controls could play a role in the outcome of activity level, because persons who are still working will have at least during this time the ability to meet the physical demands that the job charge them to do and might therefore be similar to controls. In this review the percentage of working patients was only mentioned in three of the 12 studies. Because of the minority of studies reporting on work status together with the differences in methodological quality, different methods used, different syndromes between the three studies who reported on work status, no conclusions can be made concerning work status and activity level. We recommend for future

research to control for this condition and take into account the impact of work-status on daily activities.

By comparing the different syndromes there are differences noticeable between the groups. Two of the five syndromes (CFS, migraine) report a lowered activity level of patients compared to asymptomatic controls. In the subgroup of chronic low back pain both studies report a similar mean activity level during the day compared to controls. In the mixed pain condition groups the results were inconsistent; two studies showed a lowered activity level of patients compared to controls and one study showed a similar average activity level of patients and controls. The only study concerning fibromyalgia patients, showed a similar mean daytime activity level. Although the number of studies for each group is limited, these differences might be important and could indicate that the theoretical models are different for subgroups of pain patients. For CFS patients deconditioning described in the fear-avoidance theory of Vlaeyen et al⁷ seems to be important, whereas in CLBP patients, the avoidance-endurance model of Hasenbring et al¹⁵ might provide a better fit. In the majority of studies the CV was higher in patients compared to controls. A high coefficient of variation could indicate that daily activity levels are highly variable between the various subjects in the group and this could mean that there are patients with high levels of daily activity and patients with low levels of daily activity. With the cognitive behavioral models as background information we hypothesize that this could resemble with subgroups of patients, a group of patients with high activity levels, a group of patients with low activity levels and possibly a group of patients with activity levels comparable to those of controls. However, the magnitude of the CV can be caused by many other factors also, that might not be equal between the patients and their controls. As for example hardly any information about working

status and social environment is available, groups might not have been sufficiently matched. So the variability might be attributable to many other factors for which were not controlled.

In summary, results reported in literature with respect to the activity level of chronic pain patients compared to controls were too heterogeneous and were not conclusive. A lot of subjective methods had problems with reliability and validity and objective methods report different results compared to subjective. Differences between different syndromes have been reported.

Further research seems necessary to gain more insight in the activity level of (subgroups of) chronic pain patients but also for validation of the methods.

Limitations of the review

Some limitations of our review should be noted. It is possible that we have omitted important studies by searching only Dutch, English and German- language literature. No effort was made to identify unpublished studies, since they are hard to find and some studies are not published for a number of reasons linked to bias. Also our analysis was limited because of heterogeneity among patient populations and outcome measures. Our assessment of the methodological quality of observational studies was based on a part of the Cochrane criteria list. However, these criteria are developed for randomized controlled trials and not for observational studies. The use of quality assessment tools to appraise observational studies included in systematic reviews is less well established than in systematic reviews on randomized controlled trials. As no accepted gold standard exist³⁹, we continued using parts of the Cochrane criteria list and we believe that the items we assessed are the most important to the validity of these types of studies.

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CHAPTER 3

Daily physical activities in chronic lower back pain patients assessed with accelerometry

van Weering MGH, Vollenbroek-Hutten MMR, Tönis TM, Hermens HJ. Daily physical activities in chronic lower back pain patients assessed with accelerometry. *Eur J Pain*. 2009 Jul;13(6):649-54.

ABSTRACT

The objective of the present cross-sectional study was to gain more insight into the daily activity pattern of CLBP patients compared to controls, using accelerometry. Daily activities were assessed by measuring body movement with a tri-axial accelerometer that was worn for seven consecutive days during waking hours. Measurements were performed in the daily environment (in-doors and out-doors) of the participant. Differences between activity level, time of day and work status were tested.

Data were obtained from 29 CLBP patients and 20 controls. Results show that the overall activity levels of patients (mean 0.75; sd 0.43) are not significantly different from those of controls (mean 0.71; sd 0.44). However, patients show significantly higher activity levels in the morning ($p < 0.001$) and significantly lower activity levels in the evening ($p < 0.01$) compared to controls. No significant differences in activity levels were found between leisure time and working days within either group; furthermore no significant differences in activity levels were found between patients with different work status.

In conclusion, overall activity levels do not differ significantly between CLBP patients and controls, but the distribution of activities over the day differs significantly.

1. INTRODUCTION

Chronic lower back pain (CLBP) is an increasingly important health problem. Picavet and Hazes (2003) showed that 27% of the Dutch population suffers from lower back pain (LBP). In most subjects these symptoms disappear quickly, in less than six weeks. In a small group of patients with LBP (10%), complaints are not resolved within six weeks and these patients might develop CLBP. Yet this small group of CLBP subjects accounts for up to 90% of all medical and societal costs for LBP (Nachemson AL 1992).

The management of LBP is difficult because of insufficient knowledge about the causes of CLBP and the mechanisms by which pain is developed and maintained. As a result, a multidimensional approach of CLBP has now been widely recognized and a variety of multidisciplinary treatments have been developed. For years, enhancement of a patient's level of physical fitness and normalization of activities of daily living has been an important goal in rehabilitation treatment in CLBP, merely based on the hypothesis that physical deconditioning contributes to the chronification of LBP (Vlaeyen et al., 1995). However, clinicians indicate that not every patient with CLBP seen in clinical practice shows a deconditioning and that there are apparently some patients who are (too) active. In addition to the clinical observations, a recent review on daily activities of patients with chronic pain and/or fatigue showed that for CLBP the results were inconclusive (van Weering et al., 2007). Of the twelve studies included in this review, two described CLBP. One study showed a similar physical activity level in patients with CLBP over the whole day compared to a control group (Verbunt et al., 2001). The other study showed a similar activity level during the day, but a lowered activity level during the evening in patients with CLBP compared to controls (Spenkeliink et al., 2002). Another more recent study, which

was not yet published at the time of the review, showed a lower intensity of everyday physical activity in patients with LBP compared to controls (van den Berg et al., 2007). Based on these results, it can be concluded that more insight into differences in activity patterns over the day between patients and controls is needed. All three studies hypothesize that work status of patients might be an explanatory factor for the differences found in activity levels between patients and controls, which means that this relationship needs to be explored further. Therefore, the aim of this study was to investigate whether there is a difference in daily activity patterns, in terms of activity level assessed by accelerometry, between patients with CLBP and non-symptomatic controls, and whether work status influences these activity patterns.

2. METHODS

2.1 Participants and setting

Patients with non-specific CLBP were recruited from the Roessingh Revalidation Centre Enschede in the Netherlands. CLBP was defined as continuous or recurrent episodes of pain that persist longer than 12 weeks. Non-specific means that no specific cause for the complaints was known. Other inclusion criteria for patients were: (1) aged between 18 and 65 years; (2) non-specific LBP was the primary complaint; (3) no structural pathology; (4) not yet in treatment. The inclusion criteria for healthy controls were: (1) aged between 18 and 65 years; (2) subjective report of being healthy; (3) no history of back pain in the last six months. The exclusion criteria were (1) wheelchair-bounded patients or controls; (2) surgery in the last six months and (3) terminal or progressive disease.

Controls were recruited by asking the patients to inform their spouses about the study and ask them to participate. Additional controls were recruited by advertising. Care was taken that the two groups were comparable in terms of mean age and gender.

The experimental protocol was approved by the Medical Ethics Committee of the Roessingh, Enschede.

2.2 Design

A cross-sectional study was performed. The measurements were performed between February 2006 and December 2006.

2.3 Measures

All participants completed a series of standard measures.

- A form for information about personal characteristics (age, gender), duration of pain complaints, work status and self-indicated physical load during work (Baecke et al., 1985).
- The Dutch version of the Roland Morris Disability Questionnaire (RMDQ) which measures perceived low back pain disability. The questionnaire consists of 24 items with "yes" or "no" answers and a total score ranging from 0-24. The total score is the sum of all questions answered in the affirmative, ranging from 0 (no disability) to 24 (severe disability). The RMDQ is sufficiently valid and reliable in patients with CLBP (Jensen et al., 1992, Roland et al., 2000).
- A MT9 inertial 3-D motion sensor was used in combination with a MOBI8-MT9 data logger to measure the activity level objectively. The MT9 sensor contains three uniaxial piezoelectric accelerometers. It weighs 35 grams and was attached to the lower back by means of an elastic belt, measuring accelerations in the anteroposterior, mediolateral, and longitudinal axes of the trunk. The acceleration (sampled with a frequency of 128 Hz) was bandpass filtered with a 4th order butterworth filter with cut-off frequencies of 0.01 and 20 Hz, integrated over time periods of 60 seconds and thereafter summed over the three axes (Bouten et al., 1996). The resulting measure of physical activity was expressed as mean acceleration per minute. Data collection from the MT9 continued for seven days, during waking hours. The output was stored in a data memory card and read out by a computer after one week.
- A self-constructed activity diary was used, in addition to the accelerometer. This diary was used for defining working days and

days of leisure time. Patients filled in their daily activities specified in terms of morning, afternoon and evening activities.

2.4 Procedures

On the morning of the first day, the procedure was explained, questionnaires were filled in and the activity sensor was attached to the hip. Instructions were given regarding the use of the equipment and the activity diary was explained. Participants wore the activity monitor as much as possible for seven consecutive days, for a maximum of 17 hours each day (7.00 to midnight). Measurements were performed in the daily environment of the participant and they were instructed to continue their daily lives. All measurements were performed before the patients started their rehabilitation programs and therefore no interference with treatment occurred.

2.5 Data analysis

For the measurements of daily activity, the mean activity level over 60 minutes was used and calculated from the three accelerometer signals measured by the MT9 sensor.

To get insight into daily activity patterns, line graphs were made showing the average mean acceleration for each hour in both groups. Only those hours for which at least 25% of the total data for that particular hour was available, were included in the analysis. As a consequence of this approach, the hours 7.00-8.00 and 22.00-24.00 o'clock were excluded from analysis.

For the remaining hours, three periods of the day were compared in the analysis: morning, afternoon and evening. The following time periods were used for the three times of day:

- ❖ Morning from 8.00-12.00
- ❖ Afternoon from 12.00-18.00
- ❖ Evening from 18.00-22.00

Work status was defined in two different ways: first by occupational level, by defining five different occupational groups: employed, housekeeping, invalidity benefits/ sick leave, retired and college. "Employed" is defined as patients working despite their back pain, "housekeeping" as patients/controls who choose to be engaged in housekeeping and patients receiving invalidity benefits were those forced to stop working because of their back pain. When the number of patients or controls in one of the five occupational groups was less than five, this occupational group was excluded from relevant analyses. Second, work status was defined as leisure time versus working time. Leisure time days were defined as days when patients and controls are not working at all during that day. Working days were defined as days when patients and controls are working for at least one day part during that day. This is considered important as not all leisure time days are in the weekends and comparison of activities on leisure time days with working days gives insight in whether the activity patterns shown are influenced by work.

2.6 *Statistical Analysis*

For statistical analysis, the Statistical Package for the Social Sciences (SPSS11.5) was used. Descriptive data were expressed as means \pm standard deviation (SD). Normality of the scores was tested using the Kolmogorov-Smirnof test, normal-plots and histograms. The α level was set at 0.05 for all analyses.

To obtain insight into the daily activity patterns, line graphs were made showing the average mean acceleration for each hour in both groups.

Differences in mean acceleration on variables with a normal distribution, such as differences between the seven days of the week, time of day (morning, afternoon, evening), work status (occupational level and leisure time versus working time) were tested using a univariate General Linear Model (GLM), including two-way and three-way interactions. GLM provides regression analysis and analysis of variance for one dependent variable by one or more factors. Mean acceleration was used as the dependent variable and the fixed factors were: day, time of day, occupational level and leisure time/working time. Independent samples t-tests were used for Post Hoc analysis.

3. RESULTS

3.1 Participants

Data were obtained from 29 patients with CLBP and 20 non-symptomatic controls. Only two of the included controls were spouses, the other 18 controls responded to the advertisement. No participants reported adverse events in the monitoring week (such as disturbance in daily activity) and none dropped out. The general characteristics of both patients and controls are shown in table 1. Mean age and gender were not significantly different between patients and controls. The mean score for subjective disability on the RMDQ was 13, meaning a high level of disability. Work status differed significantly, with more working controls than patients, but there were no significant differences between working patients and working controls in mean hours of work during a week as well as in the subjectively experienced physical load during work. Educational level differed significantly, with controls having on average a higher level of education than patients.

Table 1: Characteristics of the study population. Values expressed as mean (SD).

	Patients (N= 29)	Controls (N= 20)	P
Gender	55% men 45% women	45% men 55% women	0.494
Age (years)	44.41 (13.64)	40.63 (14.61)	0.422
Disability level (RMDQ)	13.00 (5.08)	-	
Duration of complaints (months)	59.25 (52.42)	-	
Physical load during work	3.01 (.36)	3.07 (.50)	0.659
Occupational level (frequencies)	Employed 8 <i>Part-time/full-time</i> 5/3 Mean hours work a week 25	Employed 18 <i>Part-time/full-time</i> 8/10 Mean hours of work a week 30	0.000
	Housekeeping 6 Invalidity benefits /sick leave 13 Retired 1 College 1	Housekeeping 1 Retired 1	0.075
Educational level (frequencies)	Lower education 7 Intermediate education 19 Higher education 3	Lower education 1 Intermediate education 3 Higher education 16	0.000

3.2 Error analysis

During data gathering, technical failures with the equipment were experienced which causes loss of data. The technical failures did however not relate to failing accelerometers, but were mostly due to breaking cables. When the cable was broken, no data was stored on the memory card. As such an error is more likely to occur when the system is worn for longer periods of time, more failures occurred at the end of the week which resulted in less data available for analysis for the weekend. Besides, in some cases the memory card failed also resulting in unstored data of the participant. Although these technical failures decreased the amount of data, it did not influence the reliability of the data.

3.3 Differences between days

To compare the differences in activity level between days, table 2 shows the mean activity levels of the seven days for both patients and controls. Patients had a slightly higher activity level than controls on Wednesdays, Thursdays and Fridays, but none of these differences in days were significant between or within groups. Controls had a non-significant higher activity level during the weekend as compared to weekdays, whereas patients showed comparable activity levels during both the weekend and weekdays.

Table 2: Means and standard deviations for both patients and controls for each day. Values expressed as mean (SD).

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Total	F	P
Controls	.69 (.58)	.73 (.47)	.70 (.40)	.71 (.33)	.73 (.43)	.88 (.55)	.76 (.46)	.74 (.46)	1.002	0.423
Patients	.64 (.30)	.72 (.34)	.72 (.38)	.87 (.54)	.79 (.50)	.71 (.43)	.74 (.56)	.74 (.44)		

3.4 Differences between weekdays

Figure 1 shows the mean activity level over all weekdays for each hour separately for both patients and controls. The mean activity level of patients and controls was comparable, however when compared according to time of day the activity levels of patients and controls differed significantly.

Table 3 shows the activity level for both patients and controls, specified in morning, afternoon, evening and mean activity level during weekdays. Mean activity levels in all groups were comparable. However, in the morning the activity level of patients was significantly higher and in the evening the activity level of patients was significantly lower as compared to controls, independent of occupational level. The patients showed slightly more variability in activities during the morning and less variability in activities during both the afternoon and evening as compared to controls.

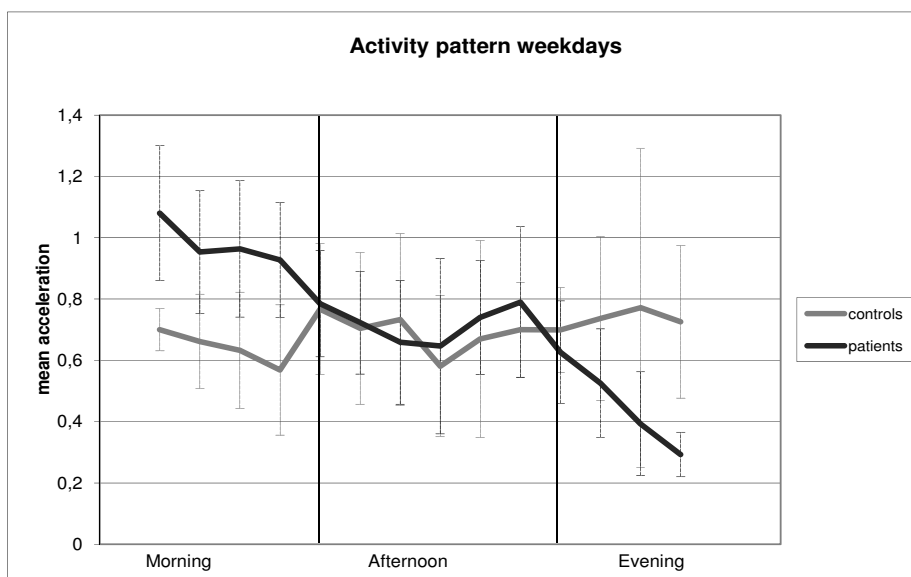


Figure 1: Activity pattern with standard deviations during weekdays for both patients and controls, expressed in mean acceleration per hour.

3.5 Differences between times of day during weekend and weekdays

Figure 2 shows the comparison of the activity patterns over the days both for weekdays and weekend days for both patients and controls.

In the control group, the activity level of the three times of day in the weekend was reversed compared to week days; the activity level in the weekend was significantly higher in the morning ($p=0.001$) and significantly lower in the evening ($p=0.001$) as compared to weekdays, and resembled the activity pattern in the patient group.

In the patient group, the activity level of the three times of day during the weekend was comparable to the activity pattern during weekdays, with no significant differences.

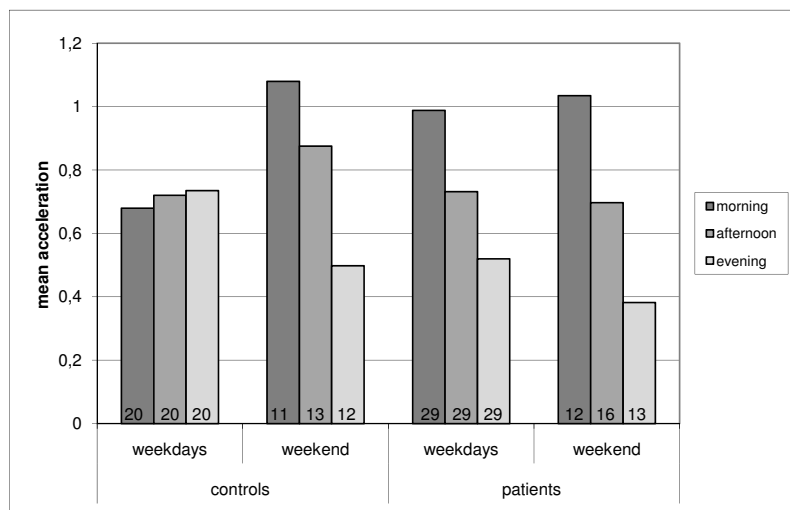


Figure 2: Comparison of the activity pattern of both patients and controls during weekdays and weekend. N (participants) at the bottom of the bar.

3.6 Impact of work status

Table 3 also shows the results for the three occupational groups (n>5), namely: employed, housekeeping, invalidity benefits/ sick leave that can be discerned within the patient group. This table shows no significant differences between the three occupational groups in mean activity levels, and that all groups showed the same kind of pattern during the day, with higher activity levels in the morning and lower activity levels in the evening. We also looked at work status as leisure time/ working time. Almost all controls were employed, except for one who was retired and one who was a housewife. In the patient group, many were on sick leave or received invalidity benefits. As not all working patients and controls had a full-time job, the activity pattern during working days and days of leisure time could be compared.

Table 3: Mean accelerations during weekdays specified in morning, afternoon, evening and average total activity level (mean) for both groups. Values expressed as mean (SD).

	Morning	Afternoon	Evening	Mean	F	P
Controls (n=20)	.68 (.41)	.72 (.44)	.74 (.48)	.71 (.44)	6.163	0.002
Patients (n=29)	.99 (.41) **	.73 (.32)	.52 (.44) *	.75 (.43)		
Working (n=8)	1.01 (.37)	.75 (.29)	.47 (.21)	.76 (.36)		
Housekeeping (n=6)	1.11 (.39)	.75 (.21)	.46 (.21)	.71 (.35)		
Invalidity benefits/ sick leave (n=13)	1.04 (.43)	.76 (.39)	.61 (.61)	.80 (.50)		

*=p<.05 **=p<.001

Figure 3 shows the activity pattern of patients and controls during leisure time and working days from Monday till Friday.

Within groups, this figure shows that on working days controls were more active at all three times of day compared to leisure time, but not significantly.

Patients in contrast showed more activity in the afternoon and less in the evening during working days, but the activity patterns during leisure time compared to working time were comparable, with high activity levels in the morning and low activity levels in the evening.

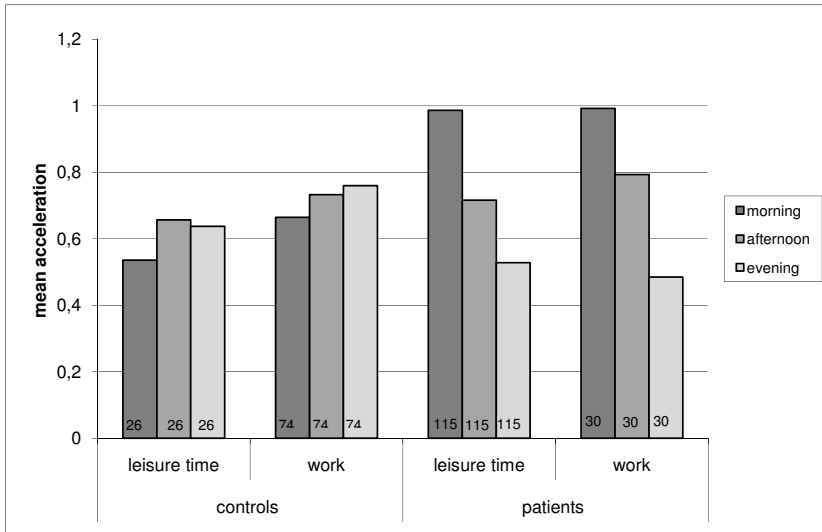


Figure 3: The activity pattern of patients and controls during leisure time and working days from Monday till Friday. N (days) at the bottom of each bar.

4. DISCUSSION

This study aimed to investigate whether there is a difference in daily activity patterns, in terms of activity level, assessed by accelerometry, between patients with CLBP and non-symptomatic controls, and whether work status influences these activity patterns. This study shows that on average patients have similar mean levels of activity as compared to controls, but different patterns of activity over the day. Patients had a significantly higher activity level in the morning and a significantly lower activity level in the evening as compared to controls. This deviating activity pattern was mainly observed during weekdays. During the weekend, the pattern of both groups was comparable with patients showing the same behavior as during weekdays and controls changing their behavior in the direction of patients.

A possible explanation for the deviating activity pattern of patients over the day may be the change in pain intensity during the day. When patients experience low pain intensity in the morning, they might feel able to do a lot, but when the pain intensity increases during the day the ability to be active is expected to decrease. This assumption is supported by the literature showing that systematic trends in pain intensity were found within one day. The most frequent observation was an increase in pain intensity from the morning to the evening (Glynn and Lloyd 1976a,b, Jamison and Brown 1991, Peters et al., 1999). Peters et al. (1999) found a linear increase of pain intensity in 47% of patients with pain from various causes. Jamison and Brown (1991) also reported the same pattern in 33.8% of patients with LBP. The study of Glynn and Lloyd showed the largest increase in pain over the day in female patients and in patients who did not work outside the house (Glynn and Lloyd 1976). This was also supported by the findings of our study, as patients with only household tasks (mostly women) showed

the most deviating activity pattern during the day, with highest activity levels in the morning and lowest activity levels in the evening. So, although direct evidence is lacking, it could be that the increase of pain is a dominant factor causing the decrease of activity over the day.

Mean activity levels were comparable between patients and controls in the present study. However, cognitive behavioral theories concerning the development and maintenance of CLBP, hypothesize that individual differences in physical functioning might exist as a result of individual differences in coping strategies (Vlaeyen et al., 1995, Hasenbring et al., 2001). According to these models, differences in coping strategies such as catastrophizing or suppressing may result in different behavior towards daily activities. For example, patients who catastrophize their pain, are afraid to move and might tend to underload whereas patients who suppress or ignore their pain, might tend to overload. As such, it could be possible that group differences in mean activity level do not exist whereas differences on subgroup level might be present. As such, further exploration of the relationship between cognitive aspects and physical activity level is desired.

The second question was whether work status influences the activity level of patients. Our results of measuring lower activity levels in the evening are in line with the study reported by Spenkeliink et al. (2002). However, their assumption that working patients might have less capacity left for activity in the evening is not confirmed in our study. Our results show that patients have a comparable activity level on working days as during leisure time days in the evening. Furthermore, our results show that the three occupational groups discerned in the patient group did not differ in total activity level as well as in the pattern during the day. This is in contrast with the study of Vercoulen et al. (1997), who found that working situation and housekeeping tasks significantly

influenced the activity level of patients with chronic fatigue syndrome. So, the results of our study do not confirm the hypothesis that work status influences the activity pattern of patients.

Cognitive behavioral models of CLBP, such as the fear-avoidance model (Vlaeyen and Linton, 2000) and the avoidance-endurance model (Hasenbring et al., 2001), ascribe a crucial role to inadequate physical activity levels, such as under or overloading, in causing disabilities. In our study, patients felt disabled because of their back problems, as shown in their RMDQ scores. The patients' RMDQ scores (13.0 +/- 5.1) were above the mean RMDQ scores (9.5 +/- 5.8) in a comparable population of 338 persons with CLBP (Gommans et al. 1997). However, their average daily activity levels were not significantly higher or lower in comparison with the daily activity levels of healthy controls. Also Smeets et al. (2006) found that although patients state that they are moderately or severe disabled, they still perform activities at a normal level. An explanation for the high disability level in the patient group could be that a lot of people with chronic pain do feel themselves disabled, as they are not able to perform social activities in their leisure time, which is in most cases during the evening. Therefore, it could be hypothesized that the disability level as a factor in the cognitive behavioral models might not be related to the average daily activity level but maybe more to the declining activity pattern over the day.

On the basis of the results discussed above, one could hypothesize that treatment of LBP should also aim at restoration of the balance in activities over the day. We expect that by adapting the activity patterns of patients during the day by doing less in the morning, patients might have more capacity left for the evening for doing social things which might reduce their level of disability. For future research it seems

important to explore the possibility of influencing these daily activities and decreasing the imbalance in activity patterns of patients with CLBP during the day. One way of doing this is through ambulant feedback training in the daily environment of the patient. Frequent feedback about deviations in activity patterns will make patients aware of their imbalance and could motivate them to change their pattern. A few studies have investigated the effects of ambulant feedback training in chronic pain patients. Voerman et al. (2006) showed that ambulant myofeedback training was beneficial in reducing pain and disability levels in patients with chronic whiplash and female workers with work-related neck-shoulder complaints. In addition, a study by Newton-John et al. (1995) also showed beneficial results of biofeedback training in patients with CLBP.

Conclusion

The overall summed activity levels of patients with CLBP were not significantly different compared to controls, but the distribution of activities during the day differed significantly. Work status does not seem to have an influence on the activity pattern of CLBP patients.

5. ACKNOWLEDGEMENTS

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CHAPTER 4

The relationship between objectively and subjectively measured activity levels in people with chronic low back pain

van Weering M, Vollenbroek-Hutten M, Hermens H. The relationship between objectively and subjectively measured activity levels in people with chronic low back pain. Clin Rehabil. 2011 Mar;25(3):256-63.

ABSTRACT

The objective of this study was to compare self-report measures of daily activities with objective activity data to determine whether patients with chronic lower back pain (CLBP) report their activity levels as accurately as controls do.

A cross-sectional study was performed in patients and controls. The study was carried out in the daily environment of the subjects. A tri-axial accelerometer was worn for five weekdays and the Baecke Physical Activity Questionnaire was filled in. Pearson's correlation was calculated to get insight in the awareness of patients and controls. Comparisons of the relationship between the objective and subjective scores of each individual patient with those of the group of controls were used to allocate each patient into subgroups; overestimators, underestimators and aware patients. Physical and psychological characteristics of these groups were explored.

Thirty-two patients and 20 healthy controls participated. Patients showed weak correlations between the objective and subjective scores of physical activity and appear to have problems in estimating their activity levels ($r=-.27$), in contrast to controls who showed strong correlations between the objective and subjective scores ($r=.66$). Comparison of the individual relationships of patients with those of controls showed that 44% of the patients is not aware of their activity level. There are relatively more underestimators (30%) than overestimators (14%). Physical characteristics between the three groups tend to be different.

It can be concluded that patients' self-reports about their activity level are relatively inaccurate when compared to objective measurements.

1. INTRODUCTION

Chronic lower back pain (CLBP) is a common health complaint with high societal burden ^{1, 2} and patients with chronic lower back pain frequently report high disability scores.^{3,4} Cognitive behavioral models of CLBP, such as the fear-avoidance model ⁵ and the avoidance-endurance model ⁶, hypothesize that both over- and underactivity, dependent on the cognition of the patient, result in disabilities and as such contribute to the development and maintenance of chronic pain.

Clinically, the activity levels of patients are commonly determined using patients' self-reports. A review concerning activity levels in chronic pain and fatigue patients showed different results for the subjective and objective methods used in several studies, indicating a discrepancy between both methods.⁷ Although both methods have not been compared directly in one study, results of these earlier studies do suggest that in a chronic pain population, self-reported levels of physical activity can be subject to both underestimating and overestimating. As rehabilitation is focused on normalizing the activity pattern of CLBP patients^{8, 9}, it is important to consider this when treating patients. For example, in case a patient is overestimating he might think his daily physical activity is sufficient and his intention or motivation to change his activity behavior would be low.¹⁰ Intention or motivation to change is one of the most important predictors of behavioral change according to commonly applied theoretical models.^{11, 12} So making patients aware of their activity behavior may be an important first step to motivate them to change their unhealthy behavior.

At this moment, there are no studies found in the last twenty years comparing self-reported activity levels of CLBP patients with objective data in daily life. Therefore, the aim of this study was to compare self-report measures of daily activities with daily activities as measured

objectively by means of accelerometry in both patients and asymptomatic controls. For healthy subjects it was shown that only 57-67% of a general healthy population is realistic about their physical activity level.^{13,14,15} Based on this, it is hypothesized that patients show a discrepancy between subjective and objective measured activity to a greater extent than a non-patient population. A further aim was to explore whether those patients showing a discrepancy differ in psychological and physical characteristics like fear of movement, coping with pain, disability levels, aerobic capacity and physical performance compared to those patients who don't show a discrepancy.

2. MATERIALS AND METHODS

A cross-sectional study was performed in the daily environment of the participant and before the patients started the actual rehabilitation program so no interference of treatment occurred. Patients with non-specific CLBP were recruited from the Roessingh, center for rehabilitation in Enschede, the Netherlands. Controls were recruited by asking the patients to inform their spouses about the study and ask them to participate. Additional controls were recruited by advertising. Care was taken that the two groups were comparable in terms of mean age and gender. CLBP was defined as continuous or recurrent episodes of pain in the lower back lasting for more than 12 weeks. Non-specific means that no specific cause for the complaints was known. Other inclusion criteria for patients were: 1) age between 18 and 65 years, 2) no structural pathology, 3) not in treatment yet. The inclusion criteria for healthy controls were: 1) age between 18 and 65 years, 2) subjectively reporting being healthy, 3) no history of back pain in the last six months. The exclusion criteria were wheelchair-bound patients or controls, surgery in the last six months, terminal or progressive disease and any other musculoskeletal condition which may affect activity and movement. The experimental protocol was approved by the Medical Ethics Committee of the Roessingh, center for rehabilitation in Enschede, the Netherlands.

On the morning of the first day, the procedure was explained and for each participant the age, gender and duration of complaints (for patients) were recorded. Thereafter the following questionnaires are filled in and tests in the laboratory were carried out:

- The Dutch version of the Roland Morris Disability Questionnaire (RMDQ) was used to assess perceived low back pain disability. The questionnaire consisted of 24 items with yes or no answers. The total score was the sum of all questions answered in the affirmative and ranges from 0 (no disability) to 24 (severe disability). The RMDQ is sufficiently valid and reliable in CLBP patients.^{16,17}
- The Baecke Physical Activity Questionnaire (BPAQ) was used to quantify the amount of physical activity and assesses the level of physical activity over one year. This questionnaire consisted of 19 items addressing the three main types of physical activity: work, sport and leisure time. Three indexes were calculated based on the scores given by the participants: a work index, a sports index and a leisure time index. The total BPAQ score (BPAQ total) was obtained by summing these three indexes. The BPAQ is a reliable instrument to subjectively measure habitual physical activity in patients with CLBP.¹⁸
- The Coping Strategies Questionnaire (CSQ) was used to assess coping strategies.¹⁹ It is a self-report measure containing 44 items and seven subscales (denial of pain, diverting attention, positive self-talk, increasing activity, reinterpreting pain sensations, catastrophizing, praying or hoping). The CSQ also comprises 2 single-item scales that assess individual's perceptions of their control over pain and confidence in their ability to decrease pain (coping self-statements).²⁰ Patients mark on 10 cm visual analogue scales with the endpoints defined in the same way as the original Likert-type scale, "never do" and "always do". Higher scores on each of the subscales indicate greater use of that particular coping strategy.²⁰
- The Tampa Scale of Kinesiophobia (TSK) has frequently been used to assess fear of movement in studies of chronic pain.^{2, 21, 22} The Dutch version of the TSK has been reported to be reliable and valid.^{23, 24}

The TSK is a 17-item scale and the total score can vary between 17 and 68, whereas a total score >37 means high fear of movement.

- A single-stage sub maximal treadmill walking test was performed to test the VO^2_{max} of the patient. This test is suitable for testing people with various diagnoses in clinical and research settings²⁵ and is proven reliable and valid²⁶. The test starts with a warming-up at a walking speed of 3.2-7.2 km/hour to elicit a heart rate between 50% and 70% of age-adjusted heart rate ($220 - age$). Following this four minute warming-up, the grade is elevated to 5% for four minutes. Heart rate (HR) is measured in the last minute and used with speed, age and gender in a formula to predict VO^2_{max} .²⁵ A higher VO^2_{max} score indicates a higher aerobic capacity of the subject.
- A Timed Up and Go (TUG) Test was performed to assess the physical performance and dynamic balance of the patient and is proven reliable and valid.²⁵ The patient sits on a standard arm chair and walks to a line on the floor 3 m away, turns, walks back to the chair, and sits down again. Patients choose their own comfortable and safe walking speed. A stopwatch is used to time the performance (in seconds). The higher the score, the worse the physical performance of the subject is.

The objective activity level is measured by an MT9 inertial 3-D motion sensor in combination with a MOBI8-MT9 data logger. The MT9 sensor contains three uni-axial piezoelectric accelerometers and measures acceleration. Accelerometers have been found to be reliable and valid in a variety of laboratory and free-living settings for assessing daily activity levels.^{27,28} The sensor weighs 5 gram and was attached on the hip by means of an elastic belt, measuring accelerations in the anteroposterior, mediolateral, and longitudinal axes of the trunk. The acceleration (sampled with a frequency of 128 Hz) was bandpass filtered with a 4th

order Butterworth filter with cut-off frequencies of 0.11 and 20 Hz, integrated over time periods of 60 seconds and thereafter summed over the three axes.²⁷ The resulting measure of physical activity was expressed as mean acceleration per minute. Data collection from the MT9 continued for five weekdays, during waking hours. Five days is expected to give a good view about ones activity level.²⁹ For calculating the activity level per day, only those hours for which at least 25% of the total data for that particular hour was available, were included in the analysis. As a consequence of this approach, the hours 7.00–8.00 and 22.00–24.00 o'clock were excluded from analysis. This means that the mean activity level presented in this study, is the mean activity level from 8.00 till 22.00 o'clock.

Statistical Analysis

For statistical analysis, the Statistical Package for the Social Sciences (SPSS11.5) was used. Descriptive data were expressed as means \pm standard deviation (SD) and the alpha level was set at 0.05 for all analyses. Normality of the scores was tested using the Kolmogorov-Smirnov test, normal-plots and histograms.

We used Pearson's correlations to explore the correlations between the subjective scores and the objective scores. Correlations were considered weak when $\rho < 0.30$, moderate when $0.30 \leq \rho \leq 0.50$ and strong when $\rho > 0.50$.³⁰

Strong correlations are not equivalent to strong agreement between the two measures. In addition, a scatter plot was made to gain more insight in the subgroups. To be able to investigate the level of awareness of patients compared to controls, we calculated the tolerance interval of the control group. This tolerance interval is the interval in which there is some level of confidence that a specified fraction of the population's values lie, based on a sample that is measured from this population. It

was expected that some controls may not be realistic about their activity level.^{10,13} Therefore, the tolerance interval of the controls was chosen quite arbitrary and set at 80%.

To be able to get insight in the patients who have the tendency to under or overestimate compared to controls, we displayed the scatter plot of the patients over the tolerance interval of controls. Patients with values above this tolerance interval of controls were defined as overestimators and patients with values below this tolerance interval were defined as underestimators. Patients with values within the tolerance interval were defined as aware. In addition, we explored the differences in psychological (TSK, RDQ, CSQ) and physical variables (TUG, VO²max) between those subgroups, by calculating the median and range. The results between these subgroups were compared with the Kruskal-Wallis test. A trend was defined as a p value <.10.

3. RESULTS

Data were obtained from 32 CLBP patients and 20 non-symptomatic controls. The general characteristics of both patients and controls are shown in table 1. Groups were comparable with respect to gender and age. The mean score for subjective disability on the RMDQ was 13, indicating a moderate level of disability.

Table 1: Characteristics of the study population, objective and subjective activity scores and Pearson's correlations between objective activity level and subjective activity level, for both patients and controls. Values expressed as mean (SD).

	Patients (N= 32)	Controls (N= 20)	P
Gender	18 men 14 women	9 men 11 women	0.429
Age (years)	44.5 (12.9)	41.2 (14.4)	0.387
Disability level (RMDQ)	13 (5)	-	
Duration of complaints (months)	63.7 (58.3)	-	
BPAQ Total	8.6 (1.2) (n=27)	8.9 (.9)	0.332
Accelerometer data	.77 (.26) (n=27)	.74 (.38)	0.720
Pearson's correlations objective and subjective activity scores	-.269 (n=27)	.663(**)	

** p<.001

Objective and subjective activity level

Table 1 presents the subjective perceived and objectively measured activity level of both patients and controls. In five patients, the BPAQ total score could not be calculated as five values of one of the three indexes of the questionnaire were missing. These patients were excluded from further analysis. Patients scored on average the same as controls on both the subjective and objective scales.

Correlations between objective and subjective activity level

In table 1, the correlations between the subjective activity level and the objective activity level are presented. It shows that, in the patient group, a weak correlation exists between the subjectively reported activity level and the objectively measured activity level. For the controls, the Pearson's correlation between the objective activity level and the BPAQ total score was strong and significant.

BPAQ Total score and objective activity level, tolerance interval

Figure 1 presents the scatter plots of patients and controls, with the corresponding tolerance interval of controls plotted in both graphs. There was one outlier in the data of the controls (BPAQ total score above 10 and accelerometer data above 2.0 m²), however the regression coefficient with ($r^2 = 0.44$) and without ($r^2 = 0.46$) this participant was similar.

The figures showed that twelve patients (44%) fell outside the tolerance interval of controls, of which four patients (14%) scored above this interval (tend to overestimate) and eight patients (30%) below this interval (tend to underestimate).

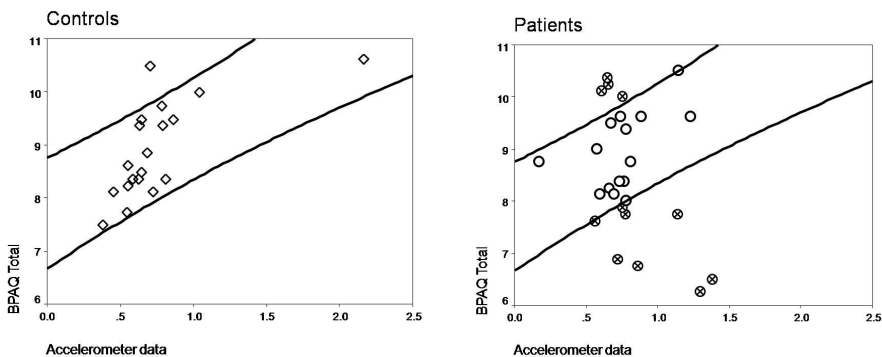


Figure 1: Relationship between objective and subjective activity level for each participant with the tolerance interval of controls included in both scatter plots; on the left controls and on the right patients (blank dots: patients who fell inside tolerance interval; dots with cross: patients who fell outside tolerance interval).

Characteristics of patients between subgroups

Table 2 presents the characteristics of the underestimators, overestimators and aware patients. All groups had a comparable age distribution.

Patients who underestimate tend to score lowest on the coping scale increasing activity (CSQ) compared to the other two groups. Patients, who overestimate, tend to have the lowest VO²max score. The group that was defined as aware of their activity level tend to score highest on the VO²max test and on the coping scale increasing activity (CSQ).

Table 2: Characteristics of patients divided into subgroups. Values expressed as median (range).

		Overestimators (n=4)	Aware (n=15)	Underestimators (n=8)	P
Individual characteristics	Age (years)	44.5 (18)	45.5 (52)	38.5 (41)	.901
	Duration of complaints (months)	45 (165)	33 (182)	65 (186)	.232
	Fear of movement (TSK)	32 (7)	37 (30)	36.5 (13)	.154
	Disability level (RMDQ)	15 (7)	15 (18)	14.5 (12)	.788
Physical characteristics	VO ² max	27.1 (12.4)	33.9 (26.8)	30.1 (11.3)	.095*
	TUG (seconds)	7.6 (6.4)	6.0 (7.9)	5.6 (2.5)	.320
	Objective activity level (m ²)	.65 (.15)	.74 (1.1)	.82 (.82)	.149
	Subjective activity level (BPAQ total)	10.2 (.38)	8.8 (2.5)	7.3 (1.6)	.000*
Psychological characteristics (CSQ)	Catastrophizing	28 (23)	16.5 (49)	16.5 (41)	.550
	Praying and hoping	24 (19)	18 (37)	16.5 (33.0)	.669
	Increasing activity	24.5 (29)	34.5 (41)	20 (33)	.091*
	Reinterpreting pain sensations	11 (7)	13.5 (47)	15 (22)	.768
	Positive self-talk	30.5 (32)	43 (53)	25 (32)	.379
	Diverting attention	12 (24)	20 (40)	11 (30)	.422
	Denial of pain	14 (17)	34.5 (47)	24 (36)	.324
	Coping self-statements	13 (16)	12.5 (18)	6 (15)	.322

* p<.10, indicating a trend between the characteristics of the three subgroups.

4. DISCUSSION

Results of this study show that the self-report measures of physical activity of patients do not correlate at all with their objective measurement of activity. This means that patients with CLBP are generally badly aware of their current activity level. In contrast, data of asymptomatic controls reveal strong correlations, meaning that they are able to better estimate their activity levels compared to patients. This study also showed that the percentage of patients that are badly aware of their activity level is 44% and this can be interpreted in terms of patients who have the tendency to subjectively overestimate and patients who have the tendency to subjectively underestimate their activity level. In this study there were more underestimators (30%) than overestimators (14%).

The existence of a gap between what patients think they do and what they actually do may be important to consider in terms of treatment of patients with chronic pain as different theoretical models for behavioral change^{11,12} assume that the extent to how a person perceives his behavior is an important predictor of achieving behavioral change and as such effect of treatment. The idea behind this is that misconceptions can lead to less intention or motivation to change¹² and might eventually affect treatment outcomes. As such, treatment should aim at decreasing the discrepancy between the perception of these patients and their real activity level. Literature shows that activity feedback in different patient groups is one possible way to make patients aware of their activity behavior and to change this behaviour.³¹⁻³³ Once patients have adapted their perceptions in line with their real activity level, treatment could focus on getting the patient motivated to change their activity level. Further research seems necessary to investigate the possibility of

activity feedback to increase the awareness and to change activity behavior of CLBP patients.

This study also explored the differences between the overestimators, underestimators and aware patients. Although the number of subjects available in the subgroups was low, an interesting trend in physical characteristics could be observed, with the lowest aerobic capacity score found in the overestimator group. The characteristics of these overestimators seem similar to the fear-avoidance responses to pain as assumed by Hasenbring⁶, which according to Hasenbring lead to disability via physical inactivity, disuse of muscles and deconditioning. It was hypothesized that the way patients cope with their pain influences the awareness about their activity level. However, more research is needed to underline this assumption, which could be of real value for clinicians to identify and manage these subgroups of patients.

Limitations

The Baecke questionnaire used in this study to define the subjective activity level of both patients and controls is designed to measure activity in the last year. The objective activity level is measured over a time period of five days. Those time periods do not match. This could have led to a bias in the data, however we couldn't find a better reliable and valid alternative for the Baecke questionnaire at that moment.

In our study, patients were included that have pain for at least three months, which means that there might be patients included that were still pain free during the reference period of the Baecke questionnaire. However, excluding the data of four patients having a pain duration less than one year did not influence the results of the correlations between the Baecke questionnaire and objective activity level. There was still a

weak correlation between both methods when excluding those patients ($\rho=-.214$).

The tolerance interval used in this study was chosen quite arbitrary and set at 80%, as we expected some controls not being realistic about their activity level. However, we also looked at the results when changing this tolerance interval to 70%. The lower the interval, the more cases fell outside the interval and more trends in psychological and physical characteristics between the three groups are visible (TUG and duration of complaints). This makes it clear that some caution is needed in interpreting the results of the present study. The sample size in our study was limited and therefore the subgroups we made can only be interpreted explorative. More research is necessary to understand the value of the results found here.

In conclusion, 44% of the patients with CLBP had difficulties in estimating their activity levels accurately. Thirty percent of the patients reported themselves less active than they were in real life and 14% reported themselves more active than they were in real life. For treatment settings, it seems important to combine currently used self-report with objective activity data to define the starting points of treatment and as such improving the chance to reach positive effects of treatment.

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CHAPTER 5

Do personalized feedback messages about activity patterns stimulate patients with chronic low back pain to change their activity behavior on a short term notice?

ABSTRACT

The aim of this study was to explore whether patients responded to personalized feedback messages on top of continuous visual feedback in terms of changes in activity patterns and to explore whether this response is related to the stage of change and the pain intensity levels of the patient. Patients wore a tri-axial accelerometer and a PDA for two weeks and received continuously and time-related personalized feedback to influence activity behavior. The time-related feedback messages consisted of discouraging, encouraging and neutral messages. The response to the feedback messages was calculated based on the activity 30 minutes before and after the message. In addition, the readiness to change the physical activity behavior was measured with the Stage of Change questionnaire. Pain intensity levels were measured three times a day using a visual analogue scale.

Data were obtained from 16 patients, receiving a total of 517 feedback messages. Overall, patients responded to both the encouraging ($p=.049$) and discouraging ($p<.000$) feedback messages, with a higher response in the morning. Patients in different stages of change responded differently to the feedback messages ($p=.009$), with patients in the preparation phase having the highest response. The response to the feedback messages was significantly related to the pain intensity of the patient ($-.226$) in the second week of feedback.

This study suggests that personalized feedback messages have the potential to influence activity behavior. In addition, it seems to be relevant to take time of the day, the stages of change and pain intensity levels of the patient into account to further optimize the feedback strategy used.

1. INTRODUCTION

Low back pain remains a condition with a relatively high incidence and prevalence. The etiology is not always obvious and 5-10% of the complaints are non-specific.¹ Chronic pain is a multidimensional problem in which bio-psycho-social aspects play a role², which resulted in the existence of various multidisciplinary treatments. For several decades, physical reconditioning has been an important sub goal in these treatments, however nowadays the question rises whether deconditioning in chronic pain patients really exists.^{3,4} Several studies showed that the mean activity level of patients with chronic low back pain (CLBP) does not differ from that of healthy individuals⁵⁻⁷ but the distribution of activities over the day seems to differ, with patients having higher activity levels in the morning⁷ and lower activity levels in the evening compared to controls.^{7,8} Another study showed that patients were more likely to over- or underestimate their activity levels compared to controls.⁹ Therefore we hypothesize that objective monitoring of daily activities along with feedback could be beneficial for CLBP patients to make them aware of their activities and to help them balancing their activities during the day. As such, a new activity-based feedback treatment has been developed for CLBP patients that is used in the daily environment of the patient and that is designed to guide the patient to reach a healthy distribution of activity over the day. The system consists of a 3D- accelerometer for objectively measuring the patient's activity and a Personal Digital Assistant (PDA) for providing feedback. The potential value of the system was tested in an earlier study in CLBP patients, evaluating the compliance with the system and the changes in clinical outcomes¹⁰, showing positive results. Also another study in healthy subjects showed that a PDA with an integrated accelerometer giving feedback was able to influence activity levels.¹¹ A

crucial aspect to influence a patient's behavior with such systems is the way feedback is provided to the patient. Up till now there is little evidence about how this feedback should be provided via technology.

Changing a person's behavior is according to various models considered a staged process.^{12,13} The stages discerned are: (1) precontemplation; (2) contemplation; (3) preparation; (4) action; followed by (5) maintenance of the changed behavior. According to these models, awareness, motivation and intentions are important for subjects to change from one stage to another. These stages are considered to be important to address when feedback is provided via technology as is the case in present study. The feedback used consists of continuously visual feedback to bring the patient awareness about his activity pattern and individual feedback messages. These individual feedback messages are thought to stimulate the patients to change their activity behavior on a short-term.

The aim of this study was to explore whether patients are able to respond to the feedback messages given on top of the continuously visual feedback. As we assume that behavioral change occurs via a staged-approach, we explore whether patients in different stages show a different response to the feedback messages. In addition, as pain, the main complaint of the patients, is according to theoretical models related to activity behavior^{14,15}, it is explored whether the pain intensity level is related to the degree patients are able to respond on the feedback messages.

2. MATERIALS AND METHODS

2.1 Participants and setting

Patients with non-specific CLBP were recruited from the Roessingh, center for rehabilitation and from physiotherapist practices in the surroundings of Enschede. Inclusion criteria were: age between 18 and 65 years; continuous or recurrent episodes of pain in the lower back lasting for more than 12 weeks (chronic); no specific cause for pain complaints; no other pathologic complaints or immobility and sufficient knowledge of the Dutch language. The exclusion criteria were wheelchair-bound patients, surgery in the last six months, terminal or progressive disease and any other musculoskeletal condition which may affect activity and movement. The experimental protocol was approved by the Medical Ethics Committee of the Roessingh, center for rehabilitation in Enschede, the Netherlands. All patients gave their informed consent prior to participation in the intervention.

2.2 Intervention

Patients wore a body area network (BAN) that consisted of an Mt-x movement sensor and a Personal Digital Assistant (PDA) (see figure 1) for measuring daily activities. Patients wore the BAN during their everyday lives, for a maximum of 14 hours each day (8.00 till 22.00 o'clock).

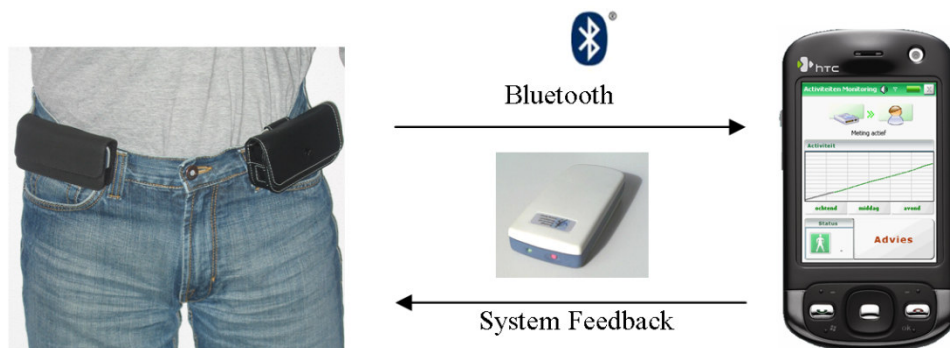


Figure 1: Health Body Area Network of the patient

The feedback given by the BAN consisted of (1) visual real-time feedback and (2) time-related personalized feedback every hour.

2.2.1 Visual real-time feedback

For the visual real-time feedback the PDA shows a reference line on the screen. This reference line was based on a database of the mean activity patterns of 60 healthy controls who were measured earlier with the same equipment. The mean activity of each hour of those controls from 8.00 till 22.00 o'clock was calculated and thereafter cumulated and displayed as a reference line on the PDA. Next to this reference line, the cumulative activity data of the patient every minute is shown as a line on the PDA. As such, patients could look at the display of the PDA at all times to see their current activity pattern in relation to the reference value, which brings the patient awareness about his activity pattern. Patients were instructed to follow the reference line as good as possible in order to better balance their daily activities.

2.2.2 Time-related feedback messages

The time-related feedback messages were provided every hour and were automatically generated by the PDA. The feedback was based on

the difference between the activity pattern of the patient at that moment and the reference value, which enabled them to adjust their activities in an adequate way. The feedback messages consisted of a percentage number, which is the deviation of the activity pattern of the patient compared to the reference value and a specific personal message. Based on the deviation from the reference line, advises were given to the patient in which direction to change his activity level and suggestions which activities he could perform to achieve the change (see figure 2). Patients could receive three types of feedback messages: encouraging, neutral and discouraging feedback messages. When the activity level of the patient was above that of the reference line (deviation $>10\%$), he received a discouraging feedback message. When the activity level was below the activity level of the reference line (deviation $>10\%$), he received an encouraging feedback message. When the deviation from the reference line was less than or equal to 10%, he received a neutral feedback message. An example of an encouraging message is: "We advise you to become more active, e.g. go for a walk" and an example of a discouraging message is "we advise you to take some rest, e.g. read the newspaper". In addition, neutral messages were generated to reinforce when the patient was doing the right thing (e.g. "well done, keep up the good work!"). These messages were defined by the researcher in order to be motivating for the patient.

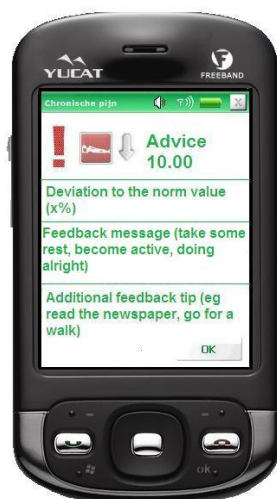


Figure 2: Hourly time-related feedback message

2.3 Procedures

The design was a prognostic cohort study. On the morning of the first day, the procedure was explained, questionnaires were filled in and instructions were given regarding the use of the BAN. The study was performed before patients started the actual rehabilitation program and therefore no interference of rehabilitation treatment occurred.

2.4 General measures

For each patient the age, gender, duration of complaints and working hours were recorded. In addition, the disability level of each patient was measured using the Dutch version of the Roland Morris Disability Questionnaire (RMDQ) that assesses perceived low back pain disability. The questionnaire consisted of 24 items with yes or no answers. The total score was the sum of all questions answered in the affirmative and ranges from 0 (no disability) to 24 (severe disability). The RMDQ is sufficiently valid and reliable in CLBP patients.^{16,17}

Activity level

To investigate the activity level of the patients objectively, patients wore the BAN. The movement sensor measures 3D accelerometer data (x, y and z-axes, sampled at 100 Hz) which is transmitted to the PDA using a wireless Bluetooth connection. The 3D accelerometer data was filtered further using a 4th order Butterworth filter (0.11 – 20 Hz). The absolute value of each of the axis is integrated over 60 seconds and summed thereafter; resulting in a measure of physical activity.¹⁸ Activity data were expressed as counts per minute (cpm) and more cpm indicated a higher activity level. This data was stored on the PDA and downloaded on a computer after the patients returned the BAN.

Pain intensity

The pain intensity was measured three times a day on a Visual Analogue Scale (VAS). The VAS was generated automatically as a pop-up on the PDA in the morning (12.00 o'clock), in the afternoon (16.00 o'clock) and in the evening (20.00 o'clock). The VAS consists of a line drawn with an interval scale from zero (0) to ten (10).¹⁹ Zero represents "no pain" and ten represents "the worst pain possible". The patient was instructed to rate the pain on the PDA by pointing to an interval that represented his pain experience. A higher VAS-score indicated a higher pain intensity level. The VAS has been reported to be reliable and valid in a low back pain population.²⁰

Stages of change

To measure the motivation of the subjects to change the physical activity behavior the validated Stage of Change (SoC) questionnaire was used before the study started.²¹ This questionnaire is based on the trans- theoretical model of change.¹² Behavioral change occurs through a series of stages. Participants were asked to rate their own stage of

change by choosing one out of five statements, one for each stage of change, that best fitted their intention to change physical activity and their current physical activity level. Stage 1 (precontemplation) meaning no physical activity at all and no intention to change this in the next six months, stage 2 (contemplation) meaning no physical activity at all but thinking about becoming physical active in the next six months, stage 3 (preparation) meaning no physical activity at all but thinking about becoming physical active in the next month, stage 4 (action) meaning being physical active but started that less than six months ago, stage 5 (maintenance) meaning being physical active for more than six months.

2.7 Data-analysis

To see how people respond to the feedback messages, we use a response measure which compares the amount of activity performed in the 30 minute interval before the feedback event ($\Delta 1$), with the amount of activity performed in the 30 minute interval after a feedback event ($\Delta 2$) for the encouraging and discouraging feedback messages. Neutral feedback messages were not taken into account, because no changes are to be expected after a neutral feedback message. By comparing these values we could see if a subject was more active after an encouraging feedback message (F_{enc}) or less active after a discouraging feedback message (F_{dis}). Response is expressed in counts per minute (cpm). To be sure at what time the feedback message was noted by the patient, he had to click an "OK" button when the message had been read and at that time the response has been calculated. Response after a discouraging feedback message was defined as $F_{dis} \Delta 1 - F_{dis} \Delta 2$. Response after an encouraging feedback message is defined as $F_{enc} \Delta 2 - F_{enc} \Delta 1$. This means that in both cases a higher response means a better response to the feedback messages. The magnitude of the response was expressed as percentage of the change in activity before and after the

feedback event. For F_{dis} we expect a decrease in activity, and as such a negative percentage of change. For F_{enc} we expect an increase in activity and as such a positive percentage of change. A response of 0-10% was considered no response, 10-30% as a moderate response and a response of more than 30% was considered high. An interval of 30 minutes was chosen, so that no overlap in activity occurred because every 60 minutes a feedback message was given. Morning was defined as hours between 8.00 and 12.00 o'clock, afternoon as the hours between 12.00 and 17.00 o'clock and evening as the hours between 17.00 and 22.00 o'clock.⁷ The feedback days were divided into feedback week 1 (first seven measurement days) and feedback week 2 (last 7 or more measurement days). The results of patients who dropped out of the study were included in the analysis of pain intensity and response for the days those patients wore the system.

2.8 Statistical Analysis

For statistical analysis, the Statistical Package for the Social Sciences (SPSS11.5) was used. Descriptive data were expressed as means \pm standard deviation (SD). The alpha level was set at 0.05 for all analyses. A trend has been defined as $p < .15$.

Normality of the scores was tested using the Kolmogorov-Smirnof test, normal-plots and histograms. A bar chart was made, to get insight in the sort of feedback messages given to the patients during different day parts and feedback weeks.

The response after a feedback message for each feedback week and the whole feedback period was tested using paired t-test for F_{enc} and F_{disc} separately, with the activity before the feedback event and the activity after the feedback event being a pair. To investigate differences in response during different day parts and both feedback weeks, we used GLM univariate analysis, with response being the dependent variable

and day part and week being the factors. Bonferroni post-hoc tests and plots were made to gain insight in which factors differed.

Differences in response for the different stages of change of the patients were measured using one-way Anova, with response being the dependent variable and stages of change being factor. Bonferroni post-hoc tests were performed to investigate which factors differed. We used a Pearson's correlation to explore the level of agreement between response and pain intensity levels during different day parts and both feedback weeks. Correlations were considered weak when $\rho < 0.30$, moderate when $0.30 \leq \rho \leq 0.50$ and strong when $\rho > 0.50$.²²

3. RESULTS

3.1 Participants

Sixteen patients with CLBP participated in this study. The general characteristics of the patients are shown in table 1. The mean score for subjective disability on the RMDQ was 11, meaning a moderate level of physical disability. Four patients dropped out of the study prematurely, of which three due to technical problems and one due to private reasons.

Table 1: Characteristics of the patient group. Values expressed as mean (SD).

	CLBP patients (n=16)
Age (years)	54 (11)
Gender (frequencies)	7 male/ 9 female
Duration of complaints (months)	222 (218)
Work (hours)	13 (16)
Disability level (RMDQ)	11 (4)

3.2 Feedback messages

Figure 1 shows the number of feedback messages at each day part given to the patients during both feedback weeks. A total amount of 1547 feedback messages were given to all patients, with 480 messages in the morning, 645 messages in the afternoon and 422 messages in the evening. Most feedback messages were neutral (58%), followed by discouraging (36%) and encouraging (6%) feedback messages.

Of all encouraging messages most were given in the morning (n=52; 60%). For the neutral (n=372; 41%) and discouraging (n=251; 45%) the highest number of feedback messages were given in the afternoon. This pattern is similar during both feedback weeks.

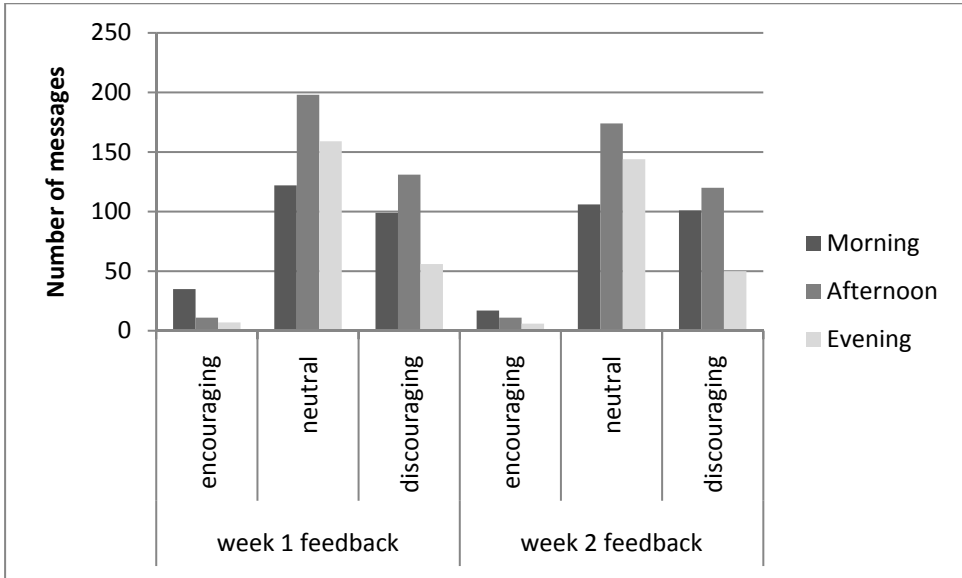


Figure 3: Number of feedback messages at each day part given during both feedback periods.

Table 2 shows the different feedback messages given to each patient and shows that there is a lot of variation between patients. Ten patients received many discouraging feedback messages ($\geq 25\%$ of total) and two patients received many encouraging feedback messages ($\geq 25\%$ of total), in addition to the many neutral feedback messages that patients received.

Table 2: Feedback messages specified by patient. Values expressed as n(%). Grey shadows: patients having $\geq 25\%$ encouraging or discouraging messages.

ID	Encouraging	Neutral	Discouraging	Total
1	5 (3.6)	39 (27.9)	96 (68.6)	140
2	1 (3.2)	16 (51.6)	14 (45.2)	31
3	4 (11.1)	11 (30.6)	21 (58.3)	36
4	1 (0.9)	42 (39.6)	63 (59.4)	106
5	5 (3.4)	39 (26.7)	102 (69.9)	146
7	6 (4.4)	92 (68.1)	37 (27.4)	135
8	15 (32.6)	30 (65.2)	1 (2.2)	46
9	0 (0)	31 (83.8)	6 (16.2)	37
10	21 (13.9)	103 (68.2)	27 (17.9)	151
11	6 (4.6)	109 (83.2)	16 (12.2)	131
12	12 (42.9)	9 (32.1)	7 (25.0)	28
13	1 (0.6)	84 (53.5)	72 (45.9)	157
14	1 (0.9)	105 (89.7)	11 (9.4)	117
15	8 (6.3)	69 (53.9)	51 (39.8)	128
16	0 (0)	30 (55.6)	24 (44.4)	54
17	1 (1)	94 (90.4)	9 (8.7)	104
Total	87 (5.6)	903 (58.4)	557 (36.0)	1547

3.3 Response

To get insight in the response to messages only discouraging and encouraging feedback messages were taken into account in the response measure. In addition, due to gaps in the sensor data or sometimes two messages would be noted by the patient too close to each other, rendering one of them useless, we could use 517 feedback messages for analysis.

Table 3 shows the overall response to the feedback messages. Patients decreased their activity level significantly after a discouraging feedback message ($p < .000$) during both feedback weeks. After an encouraging feedback message, patients increased their activity level significantly ($p = .049$) when looking at the whole feedback period. The overall response to both feedback messages was considered moderate. Looking at the individual level, twelve patients (75%) had a positive response to the feedback messages and four patients (25%) had a response in

another direction as expected. A lot of variability in the magnitude of the response was seen between patients.

Table 3: The response in cpm and magnitude of the response after an encouraging or a discouraging feedback message. Values expressed as means. -: decrease in activity after a feedback message; + increase in activity after a feedback message. Grey shadows: response of patients in another direction as expected.

Sort of feedback	ID	Response (cpm)	Magnitude response (%)	P-value
Discouraging	1 (n=91)	2613,9	-11	
	2 (n=10)	-8278	+36	
	3 (n=12)	4988,6	-22	
	4 (n=49)	4857,6	-13	
	5 (n=91)	5878,8	-17	
	7 (n=32)	-270,4	+1	
	8 (n=1)	31123,0	-52	
	9 (n=6)	30215,6	-49	
	10 (n=15)	8375,9	-16	
	11 (n=14)	15406,1	-36	
	12 (n=5)	13741,6	-36	
	13 (n=65)	6378,8	-13	
	14 (n=9)	14282,2	-33	
	15 (n=40)	10941,4	-22	
	16 (n=15)	3392,5	-9	
	17 (n=7)	50471,0	-81	
	Total (n=462)	5658	-17	
Encouraging	1 (n=2)	-13231,5	-46	
	2 (n=1)	-8,0	0	
	3 (n=3)	1058,7	+4	
	4 (n=1)	-5335,0	-49	
	5 (n=4)	20395,5	+80	
	7 (n=4)	-6917,0	-31	
	8 (n=13)	4125,5	+16	
	10 (n=7)	7692,1	+24	
	11 (n=5)	25103,4	+107	
	12 (n=6)	1739,2	+6	
	13 (n=1)	6654,0	+15	
	15 (n=7)	8573,3	+26	
	17 (n=1)	86471,0	+293	
	Total (n=55)	7670	+29	

* p<.05

Concerning the different day parts, table 4 shows that there is a trend in differences in response between different day parts (p=.105). Post-hoc analyses showed that the response in the morning was significantly

higher than the response in the afternoon ($p=.048$). There were no differences in response between the first and second week of feedback ($p=.419$). There was no interaction effect between day part and feedback week, indicating that the differences shown in response during different day parts, were not different for both feedback weeks ($p=.256$).

Table 4: The response after a feedback message

	Response (cpm)	P-value
Day part		
Morning (n= 207)	9590	.105*
Afternoon (n=230)	4598	
Evening (n=80)	4572	
Week		
Week 1 (n=274)	7174	.419
Week 2 (n=243)	5937	

* $p<.15$ (trend)

3.4 Response and stages of change

Table 5 shows that most patients were in the maintenance phase (50%) or the preparation phase (38%) of the stages of change model. Looking at the response, patients in the maintenance phase showed a positive response to the feedback messages, in contrast to the patient in the action phase (6%), who showed a negative response. Statistically, the response to the feedback messages of patients in the preparation phase was significantly higher compared to the response of the patient in the contemplation ($p=.029$) and action phase ($p=.033$), however this is based on only one patient in both the contemplation and the action phase.

Table 5: Stages of change the patients are in and the mean response specified for each stage

Stages of change	CLBP patients (frequencies)	Mean response (cpm)	P
Precontemplation	0	-	.009
Contemplation	1	2273	
Preparation	6	12369	
Action	1	-1009	
Maintenance	8	6989	

3.5 Response and pain intensity levels

Table 6 shows the correlation between the response to the feedback messages and pain intensity levels. There was a weak, but significant, overall negative correlation between the response of the patient and their pain intensity levels in the second week of feedback (-.226). Concerning the day parts, a moderate significant correlation was found in the morning in the second week of feedback (-.332). These negative correlations indicate that when the pain intensity levels were lower, the response to the feedback messages was higher.

Table 6: The correlation between response and pain intensity levels

Week	Day part	Pearson's correlation
Week 1	Morning (n=54)	-.107
	Afternoon (n=51)	.026
	Evening (n=20)	-.346
	Total (n=125)	-.118
Week 2	Morning (n=40)	-.332*
	Afternoon (n=39)	-.204
	Evening (n=19)	.037
	Total (n=98)	-.226*

* p<.05

4. DISCUSSION

The aim of this study was to explore the feedback strategy used in an ambulant activity-based feedback system by looking at the response to the individual feedback messages and the relation between the response to these feedback messages, and the patients' stages of change and pain intensity levels.

Overall, patients responded to both the encouraging and discouraging feedback messages, with no differences in response between the two weeks. It seems that the feedback reaches its effect already in the first week and lasts in the second week of feedback. In addition, the response to the feedback messages was significantly higher in the morning, compared to the afternoon. Time of the day seems therefore important to consider in when and how to give feedback to patients. A possible explanation for this might be that in the morning, patients received other, more encouraging, feedback messages compared to the afternoon and evening. However, looking at the overall reaction on the encouraging and discouraging messages, the reaction on discouraging messages seems to be stronger than on the encouraging messages. It could also be that in the morning patients feel the ability to respond to the feedback messages and have the capacity/energy left to respond whereas there is less capacity left during the afternoon and evening. To come to a better spread of response on messages over the day a possible solution might be to adjust the reference line per day part i.e. different goal settings for different day parts, for example by lowering the goal in the morning. That will make it easier to follow the line in the morning to save energy for the other day parts to reach the reference line and respond to the feedback messages. There might be a third explanation for the higher response in the morning and that is the systematic trends found in literature that the pain intensity levels

fluctuate within one day. The most frequent observation was an increase in pain intensity from the morning to the evening.²³⁻²⁵ It could be that when patients feel less pain in the morning, they might feel more able to respond to the feedback messages compared to when pain intensity levels are higher, resulting in a lower response to the messages in the afternoon and evening. This is in line with the moderate relationship we found in the present study between pain and response. However, there might be other explanations for this relationship. It might be that when listening to the feedback messages and as such adjusting activity patterns accordingly, pain intensity levels decrease. However, causality cannot be proven from the results obtained in our study. Or an explanation for this might be that how patients cope with their pain influences their activity behavior. Patients who have a passive coping strategy withdraw themselves from what they are doing when they experience pain and give up control about their pain.²⁶ When these patients experience high pain levels, they might ignore the feedback. On the other hand, when they feel less pain, they might feel able to follow the feedback messages. Unfortunately, we did not define coping strategies in this study and for future research it seems important to explore the relationship between pain intensity levels and activity behavior.

Looking at the individual patients, twelve patients adhered to the feedback messages (75%). Four patients (25%) did not adhere to the feedback messages, however in three of these patients this was based on a small number of messages ($n \leq 4$). These results are positive and suggest that the feedback messages stimulate the majority of patients to directly adjust their activity levels after a feedback message and as such enable patients to change activity behavior. This is important because self-endorsement and motivated behaviors are more likely to

result in meaningful, long-lasting behavioral changes²⁷ and will therefore promote long-lasting positive treatment-effects.

Patients received mostly discouraging and neutral feedback messages during the two weeks of feedback. This indicates that CLBP patients in this study have comparable or even higher activity levels during the day as compared to healthy controls. This is in line with an earlier study⁷ and suggests that not all CLBP patients are deconditioned in the sense of physical inactivity. This is in favor of the avoidance-endurance model of Hasenbring¹⁴ where it is assumed that different subgroups of patients exist, with different activity behavior and it therefore questions the existence of a disease syndrome that assumes that physical deconditioning contributes to the chronification of lower back pain.¹⁵

Another important finding of our study is the trend that patients in different stages of change respond differently to the feedback messages. Half of the CLBP patients (50%) were in the maintenance phase of the stages of change model, which means that patients intend to maintain their activity behavior for an extended period and think that the current activity behavior is fine.²⁸ Overall, these patients received mostly neutral feedback messages, which means that most feedback messages are in line with their expectations and this might explain the high response to the few encouraging and discouraging feedback messages they receive. Another 38% of the patients were in the preparation phase; not physically active but thinking about becoming physical active in the next month. These patients have the intention to change behavior which was also reflected in a high response to the feedback messages. One patient was in the contemplation phase, which indicates the intention to change, but not on a short-term (next six months), explaining the low response to the feedback messages. One patient was in the action phase and

showed a low response to the feedback messages. This was not in line with our expectations, because patients in this stage normally have the intention to change. One explanation for this could be that the feedback messages for this patient who is probably doing his best to change are formulated too negatively which is demotivating and as such the patient does not respond. This pleads for developing different feedback messages for different stages of change and probably more positively formulated feedback messages for patients in the action phase. This is also in line with a recent review of Norcross et al²⁹, suggesting that the stage of change of each patient should be assessed and that treatment should be tailored accordingly. They recommend focusing on insight or awareness for the early stages, and focusing on change processes for the later stages. Therefore, for the feedback strategy it is important that the information that is provided to the patients should be tuned to the stage they are in for optimal effect.

Conclusion

It can be concluded that the feedback messages have an additional value over the continuous visual feedback that patients receive during the day. This indicates that the feedback strategy chosen is able to change behavior on a short-term notice. However, it seems to be relevant to take time of the day, pain intensity levels and the stages of change of the patient into account to further optimize the feedback strategy used.

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CHAPTER 6

**Potential value of an activity-based feedback
system for treatment of patients with chronic
low back pain**

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ABSTRACT

The aim of this study was to evaluate the potential value of a new personalized activity-based feedback treatment. Patients wore a tri-axial accelerometer and a PDA for 15 days. Patients received continuously and time-related personalized feedback and were instructed to follow the activity pattern as displayed on the PDA (norm value). The technical performance and compliance with the system were rated. Objective and subjective activity scores were compared for exploring awareness. The absolute difference between the activity pattern of the patient and the norm value was calculated and expressed as mean difference. Changes in mean differences and pain intensity levels were tested for exploring the effect of the feedback.

Data were obtained from 17 patients. The technical performance and compliance with the system were rated moderate. More than half of the patients were aware of their activity level during the feedback days (67%). A positive effect of the feedback was seen in a trend in a decrease in mean differences ($p=.149$) and a significant decrease in pain intensity levels ($p=.005$).

This study suggests that an individual-tailored feedback system that focuses on the activity behavior of the patient has potential as treatment of patients with CLBP.

1. INTRODUCTION

Chronic low back pain (CLBP) is an increasingly important health problem. Picavet and Hazes showed that 27% of the Dutch population suffers from low back pain (LBP).¹ In most subjects these symptoms disappear, but a minority (5-10%) of subjects with nonspecific LBP eventually develops CLBP. However, this small group of CLBP subjects accounts for up to 90% of all medical and societal costs for LBP.^{2,3}

Regular physical activity is widely believed to have important health benefits for many chronic diseases. It improves quality of life and mobility and reduces disabilities.⁴ Also in the management of LBP, the significance of physical activity is generally accepted.⁵ However, clinically, the activity levels of patients are commonly determined using patients' self-reports and an earlier study showed that subjective perceptions of activity can be subject to under or overestimation⁶, showing the importance of quantitative and objective monitoring of daily activities. In addition, different studies suggest that the activity pattern during the day seems to be a more important parameter to focus on in treatment of CLBP patients, rather than the overall activity level.^{7,8,9} We hypothesize that balancing activities during the day is beneficial and that strategies focusing on creating these balanced patterns should be part of the treatment of CLBP patients. To be able to balance the activity pattern of each patient individually, objective monitoring and personalized feedback is essential to make patients aware of their activity pattern and to coach them when and how to change their activity pattern. Changing a person's behavior is considered a staged process which should be taken into account when developing this feedback. According to the Trans Theoretical Model¹⁰ and the Theory of Planned Behavior¹¹ at least four stages are discerned to come to actual change: awareness, motivation, intentions, and changes followed by

maintenance of the changed behavior. In line with this, a new treatment system has been developed that addresses these stages. The system visualizes and interferes with the activity pattern of the individual patient. Patients receive continuously and time-related feedback about their activity to make them aware of their (in) adequate behavior and motivates and enables patients to change.

The aim of this study was to evaluate the potential value of this new personalized activity-based feedback treatment using the methodology proposed by DeChant et al.¹² Following DeChants' so-called staged-approach, we performed a stage 1-2 evaluation, aiming to prove the quality of the system. In the present study, the quality of the system has been specified by its (1) technical performance; evaluated in terms of correctly received feedback messages and received pop-ups for scoring pain intensity and subjective activity; (2) compliance to the system; evaluated in number of days and duration the system is worn; and (3) changes in the clinical outcome measures being awareness, pain intensity and activity patterns.

2. MATERIALS AND METHODS

2.1 Participants and setting

Patients with non-specific CLBP were recruited from the Roessingh, center for rehabilitation and from physiotherapist practices in the surroundings of Enschede. Inclusion criteria were: 1) age between 18 and 65 years; 2) continuous or recurrent episodes of pain in the lower back lasting for more than 12 weeks (chronic); 3) no specific cause for pain complaints; 4) no other pathologic complaints or immobility and 5) sufficient knowledge of the Dutch language.

The experimental protocol was approved by the Medical Ethics Committee of the Roessingh, center for rehabilitation in Enschede, the Netherlands. All patients gave their informed consent prior to participation in the study.

2.2 Intervention

Patients wore a body area network (BAN) that consisted of an Mt-x movement sensor and a Personal Digital Assistant (PDA) (see figure 1). Patients wore the BAN during their everyday lives, for a maximum of 14 hours each day (8.00 till 22.00 o'clock).

The intervention consisted of a *monitoring* and a *feedback* part. During the *monitoring part*, patients were monitored for four days in their own environment to establish a baseline daily activity pattern. No feedback was given to the patient during this part. During the *feedback part*, patients were instructed to deploy the same activity pattern as displayed visually on the PDA (norm value) for 15 days. This norm value was based on a database of the mean activity patterns of 60 healthy controls that were measured with the same equipment. The mean activity of those healthy controls of each hour from 8.00 till 22.00 o'clock was calculated, cumulated and displayed as a line on the PDA. Patients

received feedback on their activity pattern in relation to the norm value, which enables them to adjust their activities in an adequate way.

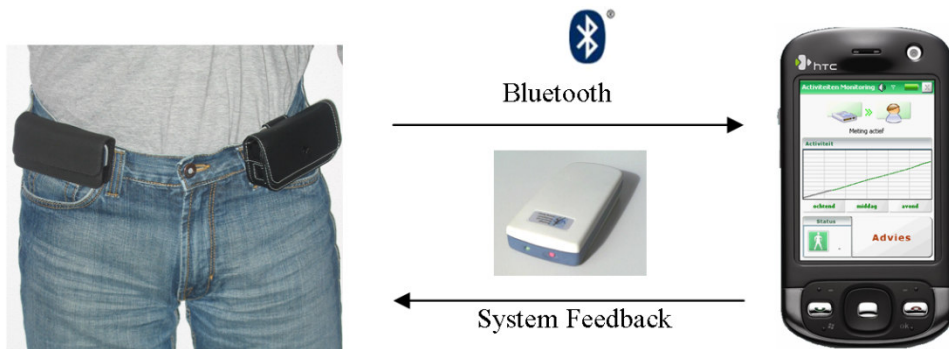


Figure 1: Health Body Area Network of the patient

The feedback given by the BAN consisted of (1) visual real-time feedback and; (2) time-related personalized feedback every hour. The visual real-time feedback consisted of a graphical presentation of the cumulative activity data of the patient every minute. At any time, patients could look at the display of the PDA to see their current activity pattern in relation to the norm value. The time-related feedback was provided every hour and was automatically generated by the PDA, based on the difference between the activity pattern of the patient at that moment and the norm value of healthy controls. The feedback consisted of concrete personalized advises to the patient in which direction to change, getting more or less active, and suggestions which activities he can perform to achieve such changes. When the activity level of the patient was more than 10% above the norm value, he received a message to take some rest (e.g. have a cup of tea). When the activity level was more than 10% below the norm value, he received feedback to become more active (e.g. take a walk). When the deviation from the

norm value was less than 10%, he received feedback that he is doing alright.

2.3 Procedures

The design was a prognostic cohort study. On the morning of the first day, the procedure was explained, questionnaires were filled in and instructions were given regarding the use of the BAN. The study was performed before patients started the actual rehabilitation program and therefore no interference of rehabilitation treatment occurred.

2.4 General measures

For each patient the age, gender, duration of complaints and working hours were recorded. In addition, the disability level of each patient was measured using the Dutch version of the Roland Morris Disability Questionnaire (RMDQ) that assesses perceived low back pain disability. The questionnaire consisted of 24 items with yes or no answers. The total score was the sum of all questions answered in the affirmative and ranges from 0 (no disability) to 24 (severe disability). The RMDQ is sufficiently valid and reliable in CLBP patients.^{13,14}

2.5 Evaluation of the quality of the system for clinical use

2.5.1 Technical performance

The technical performance of the system was evaluated by counting the missing time-related feedback messages and the missing Visual Analogue Scale (VAS) scores during the feedback part of the treatment. The first time-related feedback message was generated at 9.00 o'clock and the last feedback message at 21.00 o'clock. This means that in total, when the system was worn the whole day possible, a maximum of

13 feedback messages were generated by the system during one day. The *missing feedback messages* were defined as the percentage of feedback messages that were not generated by the system while it was worn during the feedback part. *Missing VAS scores* were defined as the percentage of VAS scores concerning pain intensity and subjective perceived activity (see 2.5.3) that were not generated when the system was worn during the feedback part.

2.5.2 Compliance

The compliance with the system was evaluated by calculating the number of feedback days, useful feedback days and duration the system was worn. The *number of feedback days* was defined as a day when the system has been worn and feedback has been given at least one time during that day. *Useful feedback days* were defined as feedback days when the system has been worn for at least 8 hours during that day (>50% of the day). *Duration* was defined as the total amount of hours and minutes the system has been worn during the whole feedback part by the patient.

2.5.3 Clinical outcome measures

Pain intensity

The pain intensity was measured three times a day on a VAS in the morning, afternoon and evening. Zero represents “no pain” and ten represents “the worst pain possible”. The patient was instructed to rate the pain by pointing to an interval that represents his pain experience. The VAS has been reported to be reliable and valid in a low back pain population.¹⁵

Activity pattern

To investigate the daily activity pattern of the patients objectively, patients wore the BAN. The movement sensor measures 3D accelerometer data (x, y and z-axes, sampled at 100 Hz) which is transmitted to the PDA using a wireless Bluetooth connection. The 3D accelerometer data was filtered further using a 4th order Butterworth filter (0.11 – 20 Hz). The absolute value of each of the axis is integrated over 60 seconds and summed thereafter, resulting in a measure of physical activity.¹⁶ Activity data were expressed as counts per minute (cpm) and more cpm indicated a higher activity level. This data was stored on the PDA and downloaded on a computer after the patients returned the BAN.

In addition, at the end of each day, all patients received a pop-up on their PDA asking them about their activity level during that day, using a VAS with zero meaning no activity at all and ten meaning maximal activity during that day. Patients gave an indication about how active they think they were that day by means of a number on the VAS.

2.7 Data-analysis

We defined the technical performance during the feedback part as "good" if the feedback messages and both VAS scores had less than 20% missing values, "bad" if all three had more than 20% missing values and "moderate" if one or two had more than 20% missing values and at least one less than 20% missing values.

Compliance has been defined as "good" when the system was worn for 12 days or more (>80% of the feedback part) and with a minimum of 12 useful feedback days. A "bad" compliance was defined as a duration of less than 8 days (<50% of the feedback part) and less than 8 useful feedback days. The patients that did not fit these ranges of "bad" or "good" compliance were defined as "moderate" compliance.

Only useful feedback days were included in the analysis of awareness and activity patterns. The feedback days were divided into feedback week 1 (first seven measurement days) and feedback week 2 (last 7 or more measurement days).

The results of patients who dropped out of the study were included in the analysis of clinical outcome measures for the days those patients wore the system. To get insight into the effect of the feedback on the activity patterns of the patients, the absolute difference between the activity pattern of the patient and the norm value during the day and in the morning, afternoon and evening was calculated and expressed as mean difference. A lower mean difference indicated that the patient was better following the norm value and thereby better balancing his activity level to the level that controls do. Morning is defined as hours between 8.00 and 12.00 o'clock, afternoon as the hours between 12.00 and 17.00 o'clock and evening as the hours between 17.00 and 22.00 o'clock.

2.8 Statistical Analysis

For statistical analysis, the Statistical Package for the Social Sciences (SPSS11.5) was used. Descriptive data were expressed as means \pm standard deviation (SD). The alpha level was set at 0.05 for all analyses. A trend has been defined as $p < .15$

Normality of the scores was tested using the Kolmogorov-Smirnof test, normal-plots and histograms.

Mean group differences between the feedback and monitoring part were tested statistically on group level with GLM univariate analyses (in case of normal distribution) and post hoc testing, with pain intensity levels and mean differences being dependent variables and day parts and week being factors.

In addition to this group level analysis, individual patterns were explored for those patients for whom at least three monitoring days were available. For these patients the mean differences were displayed graphically (scatter plots) for each monitoring day as well as feedback days, to gain insight in the individual patient trends. In addition, for each of these individuals the mean pain intensity levels were calculated over the monitoring days and both the feedback weeks and subsequently individual changes in pain intensity levels were calculated. These individual changes were considered small when the increase or decrease in pain intensity levels were between 5 and 10%, moderate when between 10 and 30% and high when $>30\%$. A change of one point on a maximum score of 10 was considered a clinically relevant change in pain intensity.¹⁷

To gain some insight into the levels of awareness of patients about their activity level, we used Spearman's' correlations to explore the level of agreement between the subjective scores and the objective scores. Awareness was considered low when $-1 < \rho < 0.30$, moderate when $0.30 \leq \rho \leq 0.50$ and high when $\rho > 0.50$.¹⁸

In addition, as changing a patients' behavior is considered a staged process with awareness being the first step¹⁰, we also explored the correlations between (1) awareness and mean differences and (2) awareness and pain intensity levels. Correlations were considered weak when $\rho < 0.30$, moderate when $0.30 \leq \rho \leq 0.50$ and strong when $\rho > 0.50$.¹⁸

3. RESULTS

3.1 Participants

Seventeen patients with CLBP participated in the intervention. The general characteristics of the patients are shown in table 1. The mean score for subjective disability on the RMDQ was 11, meaning a moderate level of physical disability.

Table 1: Characteristics of the patient group. Values expressed as mean (SD).

ID	Age	Gender	Pain duration (months)	Work status (hours a week)	Disability level (RMDQ)
1	.	Female	.	0	10
2	48	Female	480	15	11
3	59	Female	120	24	5
4	58	Female	168	0	15
5	57	Male	240	0	11
7	61	Male	108	32	13
8	37	Female	36	28	12
9	52	Male	120	0	16
10	35	Male	24	36	10
11	68	Female	648	5	7
12	69	Female	564	0	14
13	56	Female	60	0	7
14	66	Male	504	0	16
15	48	Male	12	40	14
16	60	Female	228	0	3
17	34	Male	12	30	6
Total	54 (11)	7 male/ 10 female	222 (218)	13 (16)	11 (4)

3.2 Technical performance

On average, 16% of the feedback messages were missing and 10% of the VAS for pain intensity and 34% of the VAS for subjective perceived activity were not generated when the system was worn during the whole feedback part (see table 2). Based on the predefined criteria, the technical performance was rated good in nine patients (56%), moderate in four patients (25%) and bad in three patients (19%).

During data gathering, technical failures with the equipment were experienced which causes loss of data. The technical failures did however not relate to failing BANs, but were mostly due to Bluetooth

connection problems between the PDA and movement sensor or to human failure, such as wrong loading of the sensors resulting in less power capacity. Although these technical and human failures decreased the amount of data, it did not influence the reliability of the data.

3.3 Compliance

As can be seen in table 2, ten patients completed the whole intervention by wearing the system for 15 feedback days or longer (63%). The system was worn on average for 13 feedback days, with a minimum of 4 days and a maximum of 17 days. Five patients dropped out of the study prematurely. One of those patients had to end the study due to private problems (ID 16) and four patients dropped out due to technical problems (ID 6, 8, 9, 12). One patient wore the movement sensor in her bra (ID 6) and this data is defined as unreliable and deleted from further analysis. Drop-outs did not differ in age, gender, duration of complaints, disability and work hours from those fulfilling the intervention.

The average of useful feedback days during the feedback part was 11, with a minimum of 4 and a maximum of 17 useful feedback days and patients wore the system on average 10 hours a day. The overall compliance was rated good in seven patients (44%), moderate in five patients (31%) and bad in four patients (25%).

Table 2: Compliance and technical performance of the feedback system during the feedback part

ID	Technical performance (%)			Overall technical performance	Compliance			Overall Compliance
	Missing feedback messages (range 0-100%)	Missing VAS scores pain intensity (range 0-100%)	Missing VAS scores activity (range 0-100%)		Feed-back days	Useful Feed-back days	Duration (h:m) (range 0-210)	
1	1	0	0	+	15	11	140:35	+/-
2	26	12	42	+/-	17	7	148:15	+/-
3	16	2	0	+	15	14	164:36	+
4	30	35	71	-	17	10	175:20	+/-
5	13	11	28	+	16	13	178:48	+
7	21	14	25	+/-	17	17	203:23	+
8	11	0	25	+	7	5	53:20	-
9	25	29	50	-	8	6	79:59	-
10	26	5	37	+/-	15	10	160:47	+/-
11	17	14	7	+	17	13	180:16	+
12	20	21	100	-	7	6	58:30	-
13	6	4	7	+	16	14	187:15	+
14	9	6	9	+	12	11	118:53	+/-
15	9	0	20	+	13	12	130:47	+
16	22	0	100	+/-	4	4	57:16	-
17	6	7	18	+	15	15	159:70	+
Mean	16%	10%	34%	+/-	13	11	132:42	+/-

3.4 Clinical outcome measures

3.4.1 Awareness

Due to many missing VAS scores during the monitoring week, the awareness expressed by the correlation between objective and subjective scores could not be calculated for this monitoring part ($n \leq 2$). During the feedback part, the amount of VAS scores were sufficient ($n > 2$) in twelve patients meaning that for those patients an estimate of awareness could be assessed (see table 3). Results showed that six patients were well aware of their physical activity level (50%), two patients were moderate aware (17%) and four patients had a low awareness of their activity level (33%).

Table 3: Spearman’s correlation between subjective perceived activity level and objective activity scores for each patient (n=12)

ID	Awareness during feedback period
1	.882(**) (n=11)
2	.678(*) (n=10)
3	-.024 (n=15)
4	.530 (n=4)
5	-.420 (n=10)
7	.660(*) (n=12)
10	.472 (n=7)
11	.256 (n=13)
13	.636(*) (n=13)
14	.337 (n=10)
15	-.278 (n=6)
17	.608(*) (n=14)

* p<.05

** p<.001

Of the sixteen patients, nine patients were eligible for the individual data analysis.

3.4.2 Activity pattern

Looking at group levels, the differences between the activity level of the patients and the norm value of controls showed that mean differences are the lowest during the afternoon both during the monitoring part and feedback part ($F=6.272$; $p=.003$), meaning that during this day part the activity pattern is least deviating.

Comparing the feedback days with the monitoring days showed a non-significant trend in a decrease in mean differences ($F=1.932$; $p=.149$), with no interaction effects for day parts and week (see figure 2), meaning that the decrease in mean differences during different day parts weren’t different between weeks.

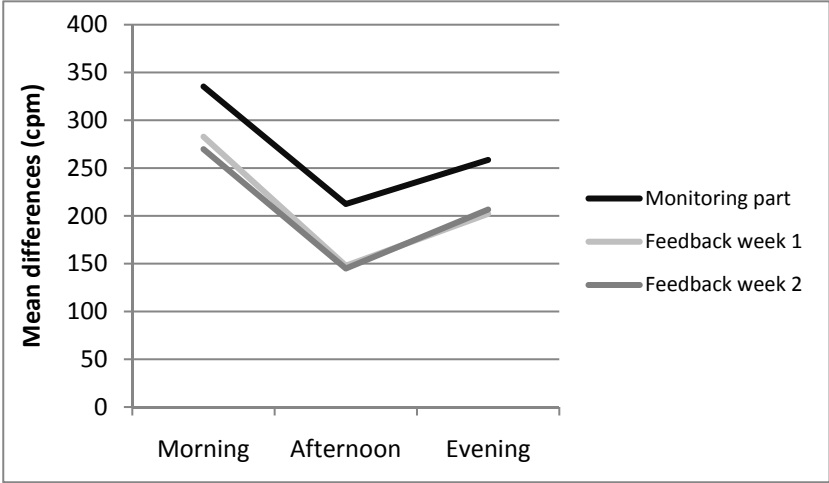


Figure 2: Mean differences specified in day parts, during different treatment periods (n=16).

Looking at the individual scatter plots for the daily mean differences during the monitoring and feedback part, it becomes clear that for most patients the difference varies between 0 and 400 whereas for some patients the variability is much higher and much more variable between the consecutive days. Taking in mind that the average activity of patients is 1014 cpm, differences up to 400 are considered large (40%) (see figure 3).

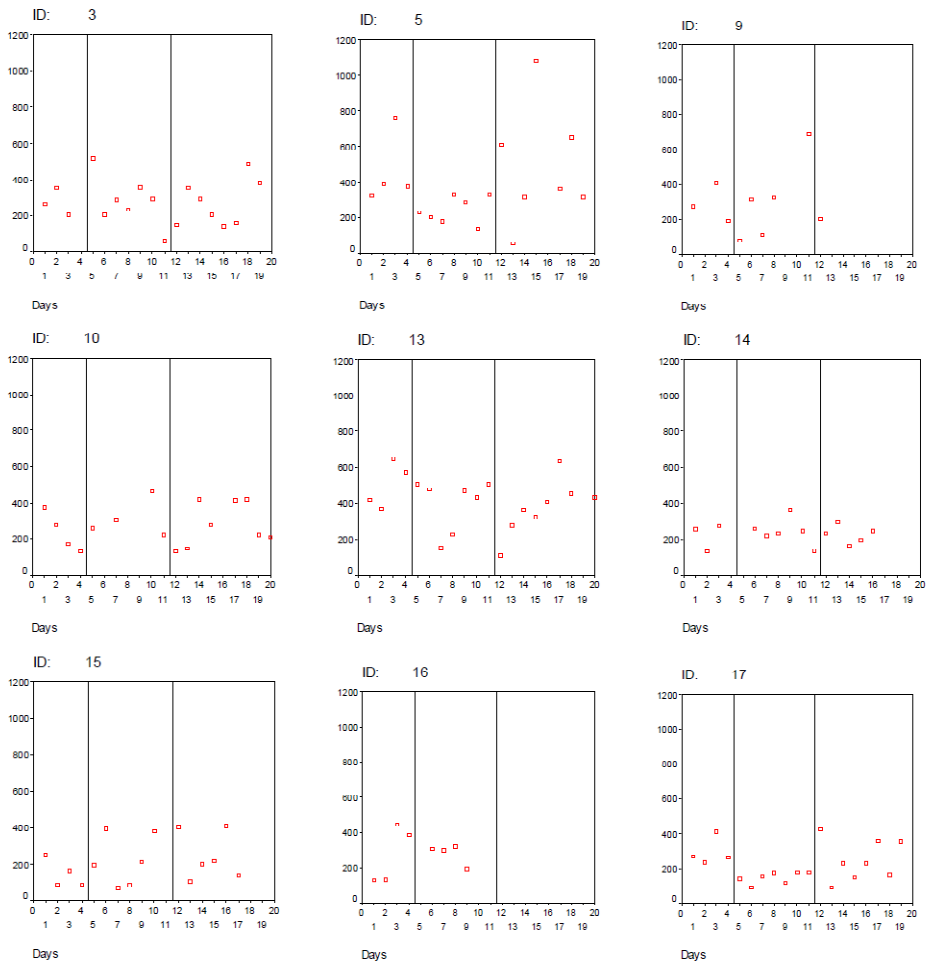


Figure 3: Daily mean differences during monitoring days (first block; days 1-4), feedback week 1 (second block; days 5-11) and feedback week 2 (third block; days 12-20) for each patient separately.

Looking in more detail at the individual patterns over the feedback days compared to the monitoring days than four patients showed a decrease in mean differences during the feedback part, compared to the monitoring part (ID 5, 9, 13, 17), two patients showed an increase in mean differences (ID 10, 15) and three patients had similar mean differences during the feedback part compared to the monitoring part (ID 3, 14, 16). These data are also shown in table 4.

Table 4: Mean differences for each patient during monitoring and the first and second week of feedback. Values expressed as mean (SD). Dark grey shading: increase in mean differences; light grey shading: decrease in mean differences

ID	Monitoring	Feedback week 1	Feedback week 2
3	275,5 (74,7)	278,7 (141,4)	270,3 (129,4)
5	461,8 (199,6)	241,5 (76,6)	484,5 (329,2)
9	290,9 (108,9)	304,0 (244,3)	201,0 (-)
10	240,9 (111,3)	313,4 (107,3)	280,6 (123,1)
13	502,7 (128,2)	396,0 (145,5)	375,6 (151,1)
14	221,5 (79,0)	243,7 (75,5)	227,0 (51,0)
15	149,3 (78,8)	223,0 (140,6)	247,0 (130,3)
16	275,3 (165,7)	283,6 (60,4)	-
17	299,1 (78,9)	151,3 (33,4)	252,8 (118,1)
Total	305,5 (155,0)	267,6 (135,0)	306,8 (178,3)

3.4.3 Pain intensity

Looking at group levels, a trend becomes visible for the pain intensity levels during the different day parts both during the monitoring part and feedback part ($F_{2,533}$; $p=.080$) (see figure 4). Pain intensity levels are significantly higher in the afternoon compared to the morning ($p=.046$). Comparing the feedback part with the monitoring part showed that the pain intensity levels decreased significantly after the second week of feedback compared to the monitoring part and compared to first week of feedback ($F=5.401$; $p=.005$). No significant interaction effect between day part and feedback week was found, meaning that the decrease in pain intensity levels during different day parts wasn't different between both feedback weeks.

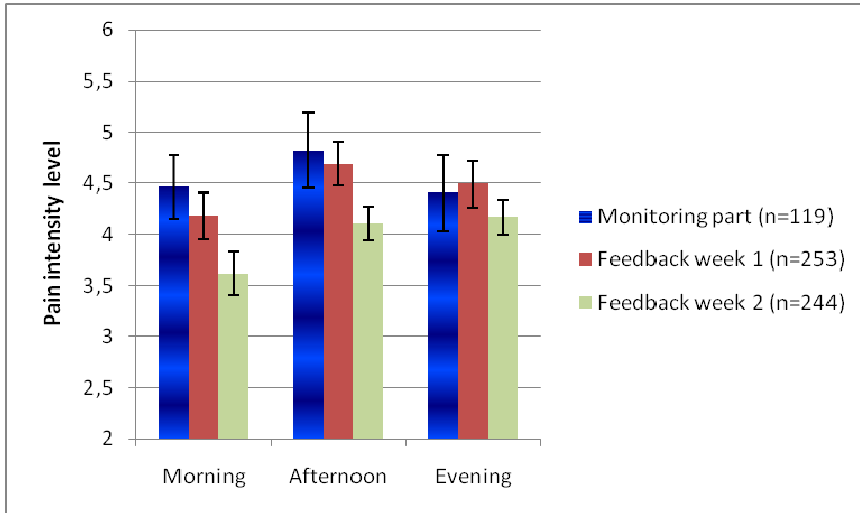


Figure 4: Mean pain intensity and standard errors of the mean at three day parts during the monitoring and feedback part (n=16)

Table 5 shows the individual mean pain intensity levels for the monitoring part and the two feedback weeks. During the first week of feedback, pain intensity levels decreased in four of the nine patients. The decrease varied in magnitude from large in one patient (clinically relevant reduction), moderate for one patient (clinically relevant reduction), to small for two of the patients. An increase in pain intensity levels was seen in three patients (range 8-34%) and two patients showed no change in pain intensity levels.

During the second week of feedback, pain intensity levels decreased in three patients compared to the monitoring part. The magnitude varied from large in two patients (clinically relevant reduction), to moderate in one patient. An increase in pain intensity levels was seen in three patients (range 8-30%) and one patient showed no change in pain intensity levels.

Overall, a small decrease (-9%) in pain intensity levels was found in the first week of feedback, with two patients showing a clinical relevant reduction (ID 10 and 16). A moderate decrease in pain intensity levels

in the second week of feedback (-24%) compared to the monitoring part was found, with two patients showing a clinical relevant reduction (ID 5 and 10).

Table 5: Mean pain intensity levels (scale 0-10) for each patient during monitoring and the first and second week of feedback. Values expressed as mean (% change). Dark grey shading: increase in pain intensity levels, light grey shading: decrease in pain intensity levels.

ID	Monitoring	Feedback week 1	Feedback week 2
3	1.78	2.38 (+34%)	2.27 (+28%)
5	6.67	7.31 (+10%)	4.58 (-31%)
9	7.20	6.75 (-6%)	-
10	6.83	4.71 (-31%)	2.67 (-61%)
13	3.50	3.19 (-9%)	2.77 (-21%)
14	7.00	6.69 (-4%)	6.67 (-5%)
15	3.82	3.83 (+3%)	4.14 (+8%)
16	3.67	2.62 (-29%)	-
17	1.91	2.06 (+8%)	2.48 (+30%)
Total	4.61 (n=82)	4.16 (-10%) (n=148)	3.5 (-24%) (n=139)

3.4.4 Correlation between awareness, mean differences and pain intensity

Awareness of activity levels was calculated for each patient, as was shown in table 3. As this is thought to be the first step towards behavioral change, we looked whether awareness correlates with mean differences in activity pattern and pain intensity levels. Table 6 shows that there was a moderate negative correlation between awareness and mean differences, indicating that a higher awareness correlated with lower mean differences. There was a weak negative correlation between awareness and pain intensity levels meaning that there is no relationship between the variables.

Table 6: Pearson's correlation between awareness, pain intensity and mean differences during the feedback part

		Mean differences	Pain intensity levels
Awareness	Pearson Correlation	-,367	-,182
	Sig. (2-tailed)	,085	,406
	N	23	23

4. DISCUSSION

The present study evaluated, using the theory of DeChant, the technical performance, compliance and changes in clinical outcome of a personalized activity-based feedback treatment.

Both the technical performance and compliance with the system were rated moderate and the adherence to the system decreased over time. The drop-out rate (29%) was slightly higher than the dropout rate found in a study of Voerman et al. using a four-week myofeedback teletreatment intervention.¹⁹ Moderate compliance was mostly due to technical and human failures. Looking at the technical aspects of this study in more detail, Bluetooth connections and charging of the sensors caused the most problems. A first evaluation of the system as done in this study is considered very important as technical problems as experienced here are a major barrier for successful implementation of telemedicine systems and can limit the usefulness and perceived effectiveness of technology.²⁰ By evaluating this in advance, the technical performance can be improved, increasing the chance of successful implementation in the future.

More than half of the patients (67%) had a moderate or strong positive correlation between self-rated and objective activity scores when receiving feedback. When comparing this to results of an earlier study with CLBP patients, this percentage is higher than during days when patients were only monitored (56%).⁶ The higher percentage of aware patients in this study could be interpreted as a positive result of the treatment. However, caution is needed interpreting these results, because the awareness during the monitoring part was based on results

of an earlier study and not known in this study. This hampers direct comparisons.

Another promising result is the moderate correlation between awareness and mean differences in activity level. Patients with a higher awareness seemed better able to follow the norm value of controls, resulting in lower mean differences. This is in line with theoretical models explaining the process of achieving behavior changes^{10,21}; awareness is assumed to be the first step towards achieving behavioral change and once patients have adapted their perceptions in line with their real activity level, they will be more motivated to actually change their inadequate behavior. However, the correlation between awareness and mean differences doesn't imply directly a causal relationship, indicating the need for more research.

Pain intensity levels decreased over time which suggests that the treatment is beneficial in the group of CLBP patients treated in this study and three of the nine patients (30%) showed a clinically relevant decrease in pain intensity levels. However, no significant changes in activity patterns were shown in this study. An explanation for this might be that changes in pain intensity levels are more likely brought about by cognitive changes rather than by a change in activity behavior. This is in line with a study of Woby et al.²² showing that there is a strong correlation between cognitive factors and pain levels in CLBP patients and especially self-efficacy emerged as a strong predictor of pain levels. Lower functional self-efficacy beliefs seem associated with higher pain levels.²³ The intervention used in this study might have increased self-efficacy beliefs of the patients, by teaching them how and when to change their behavior, resulting in a decrease in pain intensity levels.

Concerning the activity level a trend, however not significant, was seen revealing a more balanced activity pattern during the feedback part compared to the monitoring part. Looking in more detail, four of the nine patients showed a decrease in mean differences during the feedback compared to the monitoring days. An explanation for the non-significance might be that the variability between patients was high, resulting in high standard deviations. As such, large differences are needed to show significance. This also indicates the need for a larger sample size in the future.

Another explanation might be that changing behavior as activity is complex and takes time. Therefore, the two weeks of intervention might have been too short to induce further changes in activity patterns. Another explanation might be that the feedback strategy chosen was not strong enough to induce strong changes. In this study, the time-related feedback was given every hour and the frequency of this additional feedback was chosen arbitrary. The idea behind this was that patients would have the opportunity to change their behavior during a certain time-period. However, maybe more warnings should have been given when the deviation to the norm value became too high and patients should have been more notified of the consequences of their inadequate behavior. Therefore, more research is necessary to be able to find a good feedback strategy.

Overall, the positive results of this study are consistent with the self-management literature, which emphasizes the benefits of providing cues to action as well as helping patients to better visualize the outcome of their specific actions.^{24,25,26} It seems positive that the treatment is given in the patients' own environment, giving him the opportunity to train and learn in his daily situation. This way, the patient is responsible for his own behavior and he can be guided and treated much more intensive

compared to a therapeutic setting, increasing the change of positive health outcomes.²⁷ However, because of the small sample size included and the uncontrolled nature of this study, the clinical findings need to be interpreted with caution. In addition, looking at individual differences between patients, results were not positive for all patients. For some patients the trends found were as hoped for, with patients being better able to balance their activity patterns and reducing pain intensity levels. In contrast to other patients showing no differences in activity patterns and pain intensity levels. More research is necessary focusing on gaining more insight for which patients such an activity-based feedback intervention might be beneficial.

Conclusion

This study suggests that an individual-tailored feedback system that focuses on the activity behavior of the patient has potential as treatment of patients with CLBP. The staged-approach for evaluating the potential of such treatment was successful, because specific improvement points have emerged increasing the change for successful implementation in the near future.

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CHAPTER 7

General discussion

The aim of this thesis was *to develop and test an ambulant personalized treatment for patients with CLBP that uses technology to support the patient to improve his health status.*

To do so, this thesis started with a systematic review (*chapter 2*) followed by a cross sectional patient – control study to get a better understanding of the activity levels of patients with chronic pain (*chapter 3*) as well as of the individual relationship between objectively and subjectively assessed activity patterns (*chapter 4*). The results of these chapters were used as starting points for the development of a new treatment that aims at making the patient aware of his inadequate activity pattern and supports the patient with normalizing and balancing his activity pattern over the day. To enable this, a technology supported treatment with feedback on the activity levels was developed and implemented. The feedback strategy was first explored in terms of changes in activity patterns deployed by the patients as response to individual feedback tips (*chapter 5*). This exploration was followed by a study to investigate the potential value in terms of technical usability for clinical use, patients' compliance to the system and the changes in clinical outcomes (*chapter 6*). In this final chapter, the main findings of these studies are integrated and evaluated in the context of existing literature and the aim of this thesis.

Clinical content

Daily activities of patients with CLBP

The systematic review shows that there are differences in daily activity levels between different pain syndromes, however results were too heterogeneous and consequently not conclusive. Beside this, the objectively measured activity levels show different results compared to

subjective measured activity levels (chapter 2). Therefore, the activity level of CLBP patients and the relationship between objectively measured and subjectively perceived activity patterns of CLBP patients was further explored. Compared to healthy controls, the mean activity level was found to be similar. Despite a high disability level¹, patients still perform activities at a rather normal level compared to healthy controls. Results of our study show however that the activity pattern over the day of CLBP patients is deviating, which is reflected in a significantly higher activity level in the morning and a decreased activity level during the evening (chapter 3). These results are in line with the results of Huijnen et al², who showed that activity fluctuations rather than the mean activity level over time contributed significantly in explaining disability in CLBP patients. However, Lin et al³ found in his review that CLBP patients with high levels of disability were also likely to have low levels of physical activity. Based on this, it can be concluded that activity patterns are indeed deviating in patients with CLBP but that there is still no consistent evidence about which activity parameter is most related to their experienced disability. For clinical practice, it is important that this is further researched as it would require a different treatment strategy. For the patients who have low activity levels, treatment will promote increased physical activity to reduce disability. However, patients having deviating activity patterns will benefit more from learning strategies to balance their activities during the day.

Another important finding in relation to clinical practice is the fact that the objectively measured activity patterns are hardly correlated to the subjectively reported activity patterns (chapter 4). This can be interpreted as patients being not well aware of their actual activity level. Further exploration of the results shows that there are both patients who underestimate as patients who overestimate their activity level. This is important to know as different theoretical models for inducing

changes assume that the extent to how a person perceives his behavior is an important predictor of achieving behavioral change and as such the effects of treatment.^{4,5} It is assumed that misconceptions lead to less motivation to change and thus that creating awareness is the first step to achieve behavioral changes. This provides arguments for using quantitative and objective monitoring of daily activities during treatments so that it not only relies on subjective assessment methods and should start with creating awareness about deviating activity patterns.

Another important finding was that activity levels and activity patterns were similar for both working patients and non-working patients and also that working patients show similar activity levels and activity patterns during leisure time and work time (chapter 3). Combining these findings suggests that the characteristics of CLBP are more dominant than the work status of patients. This also suggests that for treatment of CLBP patients, only offering a structured environment such as work won't be sufficient for improving activity patterns, but treatment should focus more on balancing activity patterns during both work and leisure time.

Technology supported feedback

Monitoring of daily activities of CLBP patients shows that the activity pattern over the day is deviating compared to controls and that patients are badly aware of their activity pattern. Therefore, the feedback strategy should serve two purposes: inform the patient about his activity pattern to make him aware of his activity pattern and motivate patients to change to a more balanced activity pattern. There is hardly any evidence about the effectiveness of different feedback strategies. Only Kosterink et al⁶ showed that continuously visual feedback on the daily

muscle activity patterns of patients with chronic neck and shoulder pain was effective in decreasing pain intensity levels and disability. With respect to our feedback strategy, the choice was also made for continuously feedback on activity patterns. On top of that, personalized feedback messages on results and advices how to behave were added, as an extra motivation of the patient. We found that patients responded within 30 minutes to both encouraging and discouraging feedback messages given and that 75% of the patients adhered to these messages. This suggests that the individual feedback messages are effective in stimulating patients to adjust their activity levels on a short-term notice. This is in line with other studies indicating that personally tailored messages have greater impact on health behavior change than untailored or bulk messages.^{7,8} The other 25% of the patients that did not respond to the feedback messages can be characterized by having received only a small amount of feedback messages.

An important finding was that the response to the feedback messages was significantly higher in the morning, compared to the afternoon. Time of the day seems therefore important to consider in when and how to give feedback to patients. It could be that in the morning patients still have the capacity/ energy left to respond to the feedback messages, whereas there is less capacity left during the afternoon and evening. This suggests for more individual goal setting and adjusting the reference line to the capacities of the patient, to come to a better spread of response during the day. By adjusting the reference line for each day part, for example by lowering the goal in the morning, it will be easier for the patient to follow the line in the morning to save energy for the other day parts to reach the reference line and respond to the feedback messages.

As changing behavior is considered a staged approach, it was explored whether patients in different stages responded differently to the feedback messages (chapter 5). Results show that patients in the preparation phase and the maintenance phase have a high response to the messages and patients in the contemplation and action phase have a relatively low response. Although preliminary, we suggest that for the feedback strategy it is important that the information provided to the patients should be tuned to the stage they are in for optimal effect.⁹ Although based on a small number of patients in all stages, the results plead for developing different feedback messages for different stages of change. Feedback messages might be more negative oriented to increase awareness of the current behavior. However, when the aim is to influence behavior, more positive feedback messages will be needed to stimulate and motivate patients. This is in line with the results of Norcross et al¹⁰ who suggest in a recent review that the stage of change of each patient should be assessed and that treatment should be tailored accordingly. They recommend focusing on insight or awareness for the early stages, and focusing on change processes for the later stages.

Despite the high percentage of patients adhering to the personalized feedback messages, the overall effect, as measured in a more balanced activity pattern, was limited. An explanation for the limited effectiveness of the feedback strategy might be that the time-related feedback was given every hour, which was chosen quite arbitrary, with the idea that patients would have enough time to respond to the messages. Maybe more warnings should have been given or messages should not be generated based on time, but based on an event. For example when the deviation in activity pattern becomes too high and change in behavior is necessary. This means that when receiving a message, the patient

knows that a change in behavior is really required instead of receiving a lot of neutral messages as was the case in our study. It might be hypothesized that event-related feedback might be more effective than time-related feedback, because it is more understandable and more compulsory. However, more research is necessary to investigate the effect of time-related versus event-related feedback in changing behavior of CLBP patients.

Design

To be successful, the technology should be designed in such a way that it fits the needs of the users being both the professional and the patient. One of the requirements for the design of our BAN was that it should be ambulant and as such be integrated in the daily living of the patient. Results show that the BAN seemed to be applicable in the patients' daily environment; both during work and leisure time. However some patients found it difficult to adhere to the feedback messages during work time (non-published results). Data concerning the usage of the system revealed interesting information about the technical performance and compliance of patients with the new system. The technical performance and compliance was rated moderate and the system shows a low or moderate technical performance in seven patients and six of these patients also show a low or moderate compliance with the system. Three of them dropped out due to these technical problems (chapter 6). According to the Theory of Reasoned Action¹¹ subjects rationally choose non-compliance when the barriers (eg efforts, costs) outweigh the expected benefits.¹² The fact that the overall technical performance and compliance were rated moderate could indicate that some patients found that the effort of using the system out weighted the clinical benefits they experienced. However, despite these stability problems, we encountered that all patients participating in the trials were very enthusiastic about

the concepts developed. When the system is further improved, the patients think positive about using such an application for their diseases in the near future (non-published results).

To be accepted by its users, being both patients and professionals, it is important that the treatment fits the needs of those users¹³ and for this it is very important to have a good definition of the requirements for the treatment at the start of the development. In our study, we didn't define the requirements systematically. However, there are methods to do this, like scenario-based requirements analysis¹⁴ that uses scenarios as a starting point. Functional and non-functional specifications can be defined from these scenarios that subsequently can be translated into technical specifications before developing a prototype which will be tested with users to explore whether the application fits the requirements.¹⁵ Using such a structured method for the current treatment could have improved the fit and consequently a better acceptance by its users.

Outcome

To evaluate whether the new kind of treatment has potential for clinical purpose, DeChant et al¹⁶ proposed a framework for evaluation in which the type of assessment is tailored to the development life cycle of the technology. In this thesis, we performed a stage 1-2 evaluation that focused on technical performance for clinical use, as discussed above, but also on the changes in the clinical outcomes being awareness, activity behavior and pain intensity levels.

Awareness

In chapter 4 we explored whether patients were able to estimate their activity patterns accurately. Results show that 44% of the patients were

not aware of their current activity pattern. This underlines the assumption that creating awareness is important. Our feedback was designed to make patients aware of their activity pattern by means of visual continuously feedback and personalized feedback messages. Results of chapter 6 show that during the feedback treatment, more than half of the patients (67%) are able to estimate their activity levels quit well (moderate correlation) during the feedback period. Although not directly compared by baseline awareness with awareness after a feedback period, these results sound promising and are in line with other studies concerning tailored physical activity interventions which showed positive results for increased awareness.^{17,18} In addition, a moderate correlation was found between this awareness and the way patients were able to follow the reference line. Patients with a higher awareness seemed better able to follow the reference line of controls and as such to change their behavior. The results suggest that creating awareness is essential as a first step before being able to change activity behavior, being in line with the theoretical models explaining the process of achieving behavioral changes.^{4,5} Once a patient has adapted his perceptions in line with his real activity level, he will be more motivated to actually change his incorrect behavior.

Activity behavior

The activity behavior of patients didn't change significantly, although a trend was visible in more balanced activity patterns (chapter 6). This could be a consequence of the high variability between the patients in baseline activity patterns (chapter 6) inducing very different treatment goals between the patients as the reference line to be achieved was the same for all patients. As a consequence, treatment goals might for some patients have been too difficult and for others too easy. Several studies show that goals should not be too easy or too difficult and that goals

should be specific and sufficiently challenging, realistic and achievable.¹⁹⁻²¹ This goal-setting is important to take into account when further developing the feedback strategy. It might be important to consider adjusting the reference line to the individual baseline activity pattern of each patient, instead of using an overall mean reference line. This increases the motivation of the patient which is thought to increase treatment outcomes. Secondly, the two weeks of wearing the system might have been too short to induce sufficient changes in activity behavior as changing behavior takes time. It is possible that the continuous and intense monitoring and feedback provided by the system in our study lead to increased motivation and perceived self-control, which in turn can diminish fear-avoidance beliefs during the course of the intervention.²² This in turn, might lead to a change in activity behavior when wearing the system for more than two weeks. Knowledge regarding the process-factors of the new treatment is essential for obtaining a better understanding of the underlying working mechanisms.

Pain intensity

Chapter 6 shows that overall pain intensity levels significantly decreased over time especially in the second week of feedback. In addition, a moderate inverse relationship between pain and response to the feedback messages was found in chapter 5. It might be that when complying with the feedback messages and as such adjusting activity patterns accordingly on short term notice, pain intensity levels decrease. Or patients with low pain intensity levels feel more able to respond to the feedback messages compared to patients with high pain intensity levels. However, causality cannot be proven from the results obtained in our study and needs to be further explored.

The significant changes in pain are in contrast to the activity patterns that didn't change significantly. Results from earlier ambulant feedback

studies showed that the effects were largely explained by changes in cognitions and behavioral characteristics, such as catastrophizing and avoidance behavior, rather than by changes in physiological parameters.^{6,22,23} Also from the theoretical models like the fear-avoidance model²⁴ and the avoidance-endurance model²⁵ cognitive factors like catastrophizing play an important intermediate role between pain and avoidance behavior which in turn affects disability and pain intensity. Another factor that might be an important mechanism that needs to be explored is related to self efficacy/self management capacity of the patient. Treatment tries to focus on reducing feelings of helplessness and assists the patient to gain control over the pain experience.²⁶ The focus of the new treatment was on how the patient himself could reduce the complaints in an active way, by improving activity patterns which might have increased personal goal-setting and decreased feelings of helplessness and as such might have induced changes in cognitions and behavioral characteristics. Based on this, it is hypothesized that the ambulant treatment might positively influence the vicious circle of cognitions and behavior, but this hypothesis needs to be further explored.

Recommendations for future research

Clinical content

Pain intensity significantly decreased on average, but only 33% of all patients showed clinically relevant improvements. In addition to measuring activity levels of CLBP patients, more aspects might be considered important to take into account for future development of the treatment. We hypothesize that by extending the clinical content of the new treatment with motor skills and cognitive aspects by measuring these skills on the PDA in the daily environment of the patient,

effectiveness of treatment might increase. A few studies have shown that myofeedback in the treatment of chronic pain might be beneficial in reducing pain intensity and disability levels^{26,27}, but also for increasing awareness of unnecessary muscle activity levels.²⁸ In addition, activity behavior is influenced by coping strategies of patients and improvements in both self-efficacy beliefs related to exercise and activity avoidance beliefs are associated with improvement in disability.²⁹

Feedback strategies

Although the studies show promising results, other feedback strategies might be helpful in motivating patients to change behavior. Op den Akker et al³⁰ are investigating how to improve feedback compliance in patients by taking into account various contextual features. This will make the feedback smarter, more efficient and more personalized. It also enables optimization of timing and content of feedback messages to the patient, instead of generating feedback messages at fixed time intervals. This adaptive and automatic feedback is expected to be more motivating and as such might be more able to change the behavior of patients.

Furthermore, it seems useful to include more fun elements into the feedback strategy, which is thought to increase the motivation of the patient. One way of doing this is by using elements of gaming for the feedback.³¹⁻³⁴ The use of gaming in rehabilitation is still in its early stages and often used for training motor skills.³⁵⁻³⁷ However, it might be worthwhile to use for changing behavior of CLBP patients as well.

Design

In this thesis, we made a choice for a simple BAN, which fitted the clinical content that was needed. However, when more information is

required, a number of intelligent physiological sensors can be integrated into a wearable wireless BAN, enabling monitoring of different health functions. For example, using electrocardiography (ECG) in combination with the movement sensor, to enable prediction of the physical condition of patients. This will allow a more accurate and reliable view of the subject his health status. In addition to this BAN, other modules might be integrated that make it possible to train in the home situation of the patient. For example, web-based treatment, where patients perform exercises in their home environment and are supervised by their health care professional. This might be beneficial for the patients, as the intensity of training is thought to be beneficial for treatment outcomes.³⁸ However, it requires that the data of the patient becomes more accessible for the health care professional. This would upgrade the effectiveness of the treatment as it enables the professional to supervise the patient and in addition has the opportunity to give extra feedback to the patient about his performance.

In addition, to increase compliance to the system, the BAN might become even more invisible, for example by integration of sensors in textiles or in the surroundings of the patient. This will make the new treatment less obtrusive and as such will allow a better integration into the daily living of the patient.

Outcome

DeChant et al¹⁶ proposed a framework for evaluation in which the type of assessment is tailored to the development life cycle of the technology. In chapter 6, a stage 1-2 evaluation was conducted. The benefit of small scale testing is that valuable end-user input is obtained that can result in product refinement within a reasonable period of time.³⁹ However, in line with the methodology of DeChant et al¹⁶, future research should focus on evaluating the global impact of the new service on health care.

In these evaluations, sample size should be large enough to obtain scientific evidence in all domains of interest (quality, access, costs) and when comparing the effect of such new treatment to conventional treatment, a control group should be included.

As the results show that the new treatment was not effective for every patient, in terms of awareness, activity behavior and pain intensity levels, it is important to gain further knowledge of prognostic factors besides studying the overall effectiveness. It has been suggested that successful treatment of musculoskeletal pain depends on identifying the patient at the right time and providing the right intervention, or in other words, that a certain intervention will be more beneficial within a subgroup of patients defined by certain characteristics.⁴⁰⁻⁴² Knowledge of prognostic factors will as such facilitate individual selection of the most suitable treatment. The question "who is likely to benefit from the activity-based feedback treatment module" was not part of the research in this thesis, however very valuable to be further explored to be able to make the treatment more tailored and effective in the future.

Conclusion

Patients with CLBP show deviating activity patterns compared to controls and were insufficiently aware of their current activity behavior. An ambulant treatment for patients with CLBP has been developed that uses personalized feedback provided by technology to support the patient to improve his activity behavior. The feedback strategy chosen is able to change behavior on a short-term notice. However, the feedback strategy might be further optimized to induce behavioral changes on the long-term. Results suggest that an individual-tailored feedback system that focuses on the activity behavior of the patient has potential as treatment of patients with CLBP. Specific improvement points have

emerged increasing the chance for successful implementation in the near future.

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Summary

Chronic low back pain (CLBP) is a major problem in the western industrialized countries and the societal costs attributed to CLBP are high and mostly attributed to productivity loss, work absenteeism and work-disability. The management of CLBP is difficult because of insufficient knowledge about the causes of CLBP as well as the mechanisms by which it is maintained. As a result, various treatments have been developed, but unfortunately with a limited effectiveness. A few explanations can be given for this. First, the heterogeneity of the CLBP population makes it unlikely that all patients will benefit from the same treatment. Secondly, the focus on self-management of patients in traditional care is low and the reliance of the patient on the healthcare professional is very high with the consequence that the compliance to exercises decreases when the patient is on his own, without the help of a professional. Thirdly, traditional treatment has an insufficient focus on the daily life situation of the patient which results in problems of translating skills learned in the treatment environment to the home situation. It is hypothesized that the effectiveness of treatment of CLBP patients can be increased by (1) personalizing the treatment by providing treatments that enable individual goal setting and are based on the patients' needs and capacities; (2) using technology to make the patient less dependent on the healthcare professional and give him more responsibility for his treatment outcome and (3) making the treatment ambulant, so that it becomes possible to treat the patient with a high intensity in his own daily environment. Starting from this hypothesis, the aim of this thesis was to develop and test an ambulant personalized treatment for patients with CLBP that uses technology to support the patient to improve his health status. For the realization of such

treatment, three key elements are considered important: clinical content, design and outcome.

Concerning the clinical content, theoretical models like the cognitive behavioral fear-avoidance model and the avoidance-endurance model, assume that physical activities are a key aspect in explaining the development and maintenance of chronic pain. However, these physical activities can be expressed in various directions with high and low activity levels, dependent on how patients cope with their pain. As such, physical activity is chosen as a focus for the treatment to be developed. Chapter 2 describes a systematic review to get a better understanding of the state of the art of knowledge concerning activity levels of patients with chronic pain and fatigue. A systematic search of the medical databases was performed, resulting in the inclusion of twelve studies, involving five different pain syndromes. Eleven different methods were used to assess physical activity and results reported in literature with respect to the activity level of chronic pain patients compared to controls showed different results between subjective and objective measured activity levels and differences in activity levels between pain syndromes. The two studies concerning CLBP patients showed similar activity levels during the day and one of these studies showed lower activity levels in the evening compared to controls. A higher variability in the activity levels in the patient group compared to controls was noticeable in eight studies, which supports the existence of subgroups in activity levels as explained by the theoretical models.

Chapter 3 describes a cross sectional experimental study designed to get a better insight into differences in activity patterns over the day between CLBP patients and controls. Daily activities were assessed in the daily environment of the participant by measuring body movement with a tri-axial accelerometer that was worn for seven consecutive days

during waking hours. Data were obtained from 29 CLBP patients and 20 controls. Results show that the overall activity levels of patients are not significantly different from those of controls. However, patients show significantly higher activity levels in the morning and significantly lower activity levels in the evening compared to controls. No significant differences in activity levels were between patients with different work status. Based on this, balancing the daily activity patterns of patients is suggested to be the starting point for treatment.

Changing activity behavior is considered, just as all other behavioral changes, a staged approach. This means that different stages are discerned to come to actual change and awareness is considered a first step in achieving this behavioral change. For this, it is important to know whether patients are aware of their (in) adequate activity behavior. Chapter 4 compares self-report measures of daily activities with objective activity data to determine whether patients with CLBP report their activity levels as accurately as controls do. Patients showed weak correlations between the objective and subjective scores of physical activity and appear to have problems in estimating their activity levels, in contrast to controls who showed strong correlations. Comparison of the individual relationships of patients with those of controls showed that 44% of the patients are not aware of their activity level and there are relatively more underestimators (30%) than overestimators (14%).

Concerning the design of the treatment, it was chosen to focus on monitoring physical activity in the daily environment of the patient. Feedback about the activity level of the patient is thought to create awareness about his (in) adequate behavior and as such, feedback is provided to the patient to enable him to change his activity behavior. Starting from these high level requirements, choices for design have

been made. In the context of this thesis, a simple Body Area Network was used that exists of an Mt-x movement sensor for objectively measuring the patient's activity level and a Personal Digital Assistant (PDA) for providing feedback to ensure mobility of the patient. As there is little knowledge about how feedback should be provided by technology and which feedback strategies are effective to change the activity behavior of CLBP patients, chapter 5 explores the feedback strategy used in this new treatment by investigating whether patients responded to personalized feedback messages (discouraging, neutral and encouraging messages) on top of continuous visual feedback and to explore whether this response is related to the stage of change and the pain intensity levels of the patient. Data were obtained from 16 patients, receiving a total of 517 feedback messages. Results of this study show that 75% of the patients adhered to the feedback messages (encouraging and discouraging) and the response to the feedback messages was highest in the morning and seems to be related to pain intensity levels. In addition, patients in different stages of change responded differently to the feedback messages. These results indicate that the feedback strategy chosen is able to change behavior on a short-term notice. However, it seems to be relevant to take time of the day, pain intensity levels and the stages of change of the patient into account to further optimize the feedback strategy used.

Concerning the outcome of the treatment, the new system needs to have positive effects on care in terms of effectiveness and efficiency. To evaluate whether such a new kind of treatment has potential for clinical purpose, a staged-approach methodology of DeChant will be used. Chapter 6 describes the results of a study in which a stage 1-2 evaluation has been performed focusing on the potential value of the system in terms of technical performance, compliance with the system

and the changes in clinical outcomes. Data were obtained from 17 patients and the technical performance and compliance with the system were rated moderate. More than half of the patients were aware of their activity level during the feedback days (67%). A positive effect of the feedback was seen, reflected in a tendency into more balanced activity patterns and a significant decrease in pain intensity levels. This suggests that an individual-tailored feedback system that focuses on the activity behavior of the patient has potential as treatment of patients with CLBP.

In the final chapter (chapter 7), the main findings of these studies are integrated and evaluated in the context of existing literature and the aim of this thesis. Results of this thesis suggest that CLBP patients have different activity patterns during the day compared to controls and that they are insufficiently aware of their activity behavior. An ambulant individual-tailored treatment that uses technology to monitor and give feedback on the activity behavior of the patient seems to have potential as treatment of patients with CLBP. Specific improvement points have emerged concerning the clinical content, design and outcome, increasing the chance for successful implementation in the near future. For the clinical content: it is recommended to focus on more aspects than activity levels alone and to make the feedback smarter, more personalized and more fun. For the design: the BAN might be improved by extending it with more sensors to increase reliability about the health status of the patient and by making it less obtrusive in daily life. For the outcome: a next stage evaluation is recommended and more knowledge needs to be gained about prognostic factors indicating for who the treatment will be effective.

Samenvatting

Chronische lage rugpijn (CLRP) vormt een groot probleem in de westerse geïndustrialiseerde landen en de maatschappelijke kosten van CLRP zijn hoog en veelal het gevolg van verlies van productiviteit, arbeidsverzuim en beperkingen op het werk. Het management van CLRP is moeilijk, omdat er onvoldoende kennis over de oorzaken van CLRP is en de mechanismen die het in stand houden. Als gevolg hiervan zijn er verschillende behandelingen ontwikkeld, maar helaas is de effectiviteit van deze behandelingen beperkt. Er kunnen hiervoor een paar verklaringen worden gegeven. De eerste is dat de heterogeniteit van de CLRP populatie het onwaarschijnlijk maakt dat alle patiënten zullen profiteren van dezelfde behandeling. In de tweede plaats is de focus op de zelfmanagement van de patiënten in de traditionele zorg laag en is de patiënt erg afhankelijk van de therapeut. Dit heeft als gevolg dat patiënten sneller stoppen met het uitvoeren van de oefeningen wanneer de therapeut niet meer aanwezig is. Ten derde heeft de traditionele behandeling onvoldoende focus op de dagelijkse leefsituatie van de patiënt. Dit resulteert in problemen tijdens het vertalen van geleerde vaardigheden in de behandelomgeving naar de thuissituatie. Er wordt verondersteld dat de effectiviteit van de behandeling van CLRP patiënten kan worden verhoogd door (1) de behandeling individueler te maken door individuele doelen te stellen die zijn gebaseerd op de behoeften en capaciteiten van de patiënt, (2) gebruik te maken van technologie die ervoor zorgt dat de patiënt minder afhankelijk van de therapeut wordt en hem meer verantwoordelijkheid geeft voor zijn behandeluitkomst en (3) de behandeling ambulant te maken, zodat het mogelijk wordt om de patiënt te behandelen in zijn eigen dagelijkse omgeving. Vanuit deze hypothesen is het doel van dit proefschrift om een ambulante gepersonaliseerde behandeling voor patiënten met CLRP te ontwikkelen

en te testen, die gebruik maakt van technologie ter ondersteuning van het verbeteren van de gezondheidsstatus van de patiënt. Voor de realisatie van een dergelijke behandeling zijn drie elementen van belang: de *klinische inhoud*, het *ontwerp* en het *resultaat*.

Betreffende de klinische inhoud gaan veel theoretische modellen ervanuit dat lichamelijke activiteiten een belangrijke rol spelen bij het verklaren van de ontwikkeling en instandhouding van chronische pijn, zoals het "*fear-avoidance model*" en het "*avoidance-endurance model*". Maar de manier waarop lichamelijke activiteiten een rol spelen in deze modellen is verschillend en afhankelijk van hoe patiënten omgaan met hun pijnklachten wat kan resulteren in hoge en lage activiteitsniveaus. Als zodanig is lichamelijke activiteit gekozen als de focus voor de behandeling die wordt ontwikkeld in dit proefschrift. Hoofdstuk 2 beschrijft een systematische review om een beter begrip te krijgen van de huidige stand van zaken betreffende lichamelijke activiteiten van patiënten met chronische pijn en vermoeidheid. Hiervoor zijn de medische databases systematisch doorzocht, wat resulteerde in de inclusie van 12 studies met vijf verschillende pijnsyndromen. In deze 12 studies zijn 11 verschillende methoden gebruikt om lichamelijke activiteit te meten en de resultaten toonden verschillen tussen subjectief en objectief gemeten activiteit en verschillen in activiteit tussen de vijf pijnsyndromen. De twee studies over CLRP patiënten toonden een gelijk activiteitsniveau gedurende de dag in vergelijking met gezonden en een van deze studies toonde minder activiteit in de avond in vergelijking met gezonden. Acht van de 12 studies lieten een hogere variabiliteit in activiteitsniveau in de patiëntengroep zien vergeleken met gezonden, wat het bestaan van subgroepen in activiteitsniveau ondersteunt, zoals uitgelegd door de eerder genoemde theoretische modellen.

In hoofdstuk 3 is een experimenteel onderzoek uitgevoerd om een beter inzicht te krijgen in de verschillen in de lichamelijke activiteit tussen CLRP patiënten en gezonden. De lichamelijke activiteit werd gemeten in de dagelijkse omgeving van de deelnemer door middel van een bewegingssensor die gedurende zeven opeenvolgende dagen werd gedragen. Aan het onderzoek hebben 29 CLRP patiënten en 20 gezonden deelgenomen. Resultaten tonen aan dat de totale activiteit van de patiënten niet significant verschillend is van die van gezonden, maar dat er wel een verschil te zien was in het activiteitenpatroon over de dag. Patiënten hadden een significant hogere activiteit in de ochtend en een significant lagere activiteit in de avond vergeleken met gezonden. De werkstatus van patiënten en gezonden leken geen invloed te hebben op deze verschillen in activiteitenpatroon over de dag. Op basis hiervan wordt het balanceren van de activiteiten over de dag beschouwd als uitgangspunt voor de nieuwe behandeling.

Verandering van activiteitengedrag wordt, net als alle andere gedragsveranderingen, beschouwd als een gefaseerde aanpak. Dit betekent dat verschillende fasen zijn te onderscheiden om te komen tot daadwerkelijke verandering en bewustwording wordt beschouwd als een eerste stap in de verwezenlijking van deze gedragsverandering. Daarom is het belangrijk om te weten of patiënten zich bewust zijn van hun activiteitengedrag. Hoofdstuk 4 vergelijkt zelfrapportage (subjectief) van de dagelijkse activiteiten met objectieve gegevens over de activiteiten om te bepalen of patiënten met CLRP hun activiteitsniveau net zo kunnen inschatten als gezonden dat doen. Patiënten laten zwakke correlaties zien tussen de objectieve en subjectieve scores van lichamelijke activiteit en lijken problemen te hebben met het schatten van hun activiteitsniveau. Dit in tegenstelling tot de gezonden die een sterke correlatie toonden. Na vergelijking van de individuele relaties van patiënten met die van de gezonden bleek dat 44% van de patiënten zich

niet bewust is van hun activiteitsniveau en dat er relatief meer onderschatters (30%) dan overschatters (14%) zijn.

Betreffende het ontwerp van de behandeling werd gekozen voor het monitoren van de lichamelijke activiteit in de dagelijkse omgeving van de patiënt. Feedback over de activiteit van de patiënt wordt gedacht het bewustzijn over zijn (in) adequate gedrag te vergroten en als zodanig wordt feedback verstrekt aan de patiënt om hem in staat te stellen zijn gedrag te veranderen. Uitgaande van deze high-level eisen zijn er keuzes voor het ontwerp gemaakt. In dit proefschrift wordt een eenvoudig Body Area Network gebruikt dat bestaat uit een MT-x bewegingssensor voor een objectieve meting van het activiteitsniveau van de patiënt en een Personal Digital Assistant (PDA) voor het geven van feedback om de mobiliteit van de patiënt te waarborgen. Er is weinig kennis over hoe feedback moet worden gegeven door middel van technologie en of die feedbackstrategieën effectief zijn om het activiteitengedrag van CLRP patiënten te veranderen. Daarom wordt in hoofdstuk 5 onderzocht of patiënten reageren op persoonlijke feedbackberichten (ontmoedigende, neutrale en bemoedigende berichten) die ze bovenop de continue visuele feedback ontvingen. Daarnaast wordt gekeken of deze reactie gerelateerd is aan de fase van gedragsverandering waarin de patiënt zich bevindt en de mate van pijnintensiteit van de patiënt. Er hebben 16 patiënten aan het onderzoek deelgenomen, die in totaal 517 feedback berichten ontvingen die geanalyseerd konden worden. Uit resultaten van deze studie blijkt dat 75% van de patiënten op de feedbackberichten (aanmoedigende en ontmoedigende) reageerden. Deze reactie op de feedbackberichten was het hoogst in de ochtend en lijkt gerelateerd te zijn aan de pijnintensiteit van de patiënt. Bovendien reageerden patiënten in verschillende stadia van verandering verschillend op de

feedbackberichten. Deze resultaten geven aan dat de gekozen feedbackstrategie in staat is om gedrag op korte termijn te veranderen. Voor het optimaliseren van de feedback strategie lijkt het belangrijk om rekening te houden met de tijd van de dag, pijnintensiteit en de fasen van verandering van de patiënt.

Betreffende de uitkomst van de behandeling moet het nieuwe systeem een positief effect hebben op de zorg in termen van effectiviteit en doeltreffendheid. Om te beoordelen of een dergelijke nieuwe vorm van behandeling potentie heeft voor klinische doeleinden, zal een gefaseerde benaderingsmethodologie van DeChant worden gebruikt. Hoofdstuk 6 beschrijft de resultaten van een studie waarin een fase 1-2 evaluatie is uitgevoerd gericht op het onderzoeken van de potentiële waarde van het systeem in termen van technische prestaties, de naleving van het systeem en de veranderingen in de klinische uitkomsten. Zeventien patiënten hebben aan het onderzoek deelgenomen en de technische prestaties en de naleving van het systeem waren matig gescoord. Meer dan de helft van de patiënten waren zich bewust van hun activiteitsniveau tijdens de feedback dagen (67%). Een positief effect van de feedback werd gezien in een tendens naar meer evenwichtige activiteitenpatronen en een significante afname van pijnintensiteit. Dit suggereert dat een gepersonaliseerd feedback systeem dat zich richt op het activiteitengedrag van de patiënt potentie heeft voor de behandeling van CLRP patiënten.

In het laatste hoofdstuk (hoofdstuk 7), zijn de belangrijkste bevindingen van deze studies geïntegreerd en geëvalueerd in het kader van de bestaande literatuur en het doel van dit proefschrift. Resultaten van dit proefschrift suggereren dat CLRP patiënten verschillende activiteiten patronen hebben gedurende de dag in vergelijking met gezonden en dat

zij zich onvoldoende bewust zijn van hun activiteitengedrag. Een ambulante individuele behandeling op maat, dat technologie gebruikt om het activiteitengedrag van de patiënt te monitoren en hierop feedback te geven, lijkt potentie te hebben als behandeling van patiënten met CLRP. Specifieke verbeterpunten zijn naar voren gekomen betreffende de klinische inhoud, het ontwerp en het resultaat, die de kans op succesvolle implementatie in de nabije toekomst vergroten. Voor de *klinische inhoud* is het aan te raden om op meer aspecten dan alleen de lichamelijke activiteit te richten en de feedback slimmer, persoonlijker en leuker te maken. *Het ontwerp* kan worden verbeterd door de BAN minder opvallend te maken in het dagelijks leven. Voor *de uitkomst* wordt een volgende fase evaluatie aanbevolen en zou er meer kennis moet worden opgedaan over de prognostische factoren die aangeven voor wie de behandeling effectief zal zijn.

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Over de auteur

Marit van Weering werd geboren op 30 oktober 1980 in Groningen. De middelbare school volgde zij in Groningen op het Wessel Gansfort College, waar ze in 2000 haar VWO diploma haalde. Daarna begon ze aan haar opleiding Bewegingswetenschappen aan de Rijksuniversiteit in Groningen, met als afstudeerrichting revalidatie en gehandicaptenzorg. In juni 2005 werd ze als junior onderzoeker aangesteld op het *Awareness* project bij Roessingh Research and Development (RRD) in Enschede, waarbinnen een groot gedeelte van haar promotietraject is uitgevoerd. Momenteel is zij werkzaam op het *Telerevalidatie.nl* project, waarbij een internet-gebaseerd thuisstrainingsprogramma voor het reconditioneren van chronische patiënten wordt geïmplementeerd in drie revalidatiecentra.

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Progress Range

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