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FEAR OF MOVEMENT

**Epidemiological and clinical evaluation
in the Finnish general population and chronic
musculoskeletal pain patients and relevance
for rehabilitation**

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ACADEMIC DISSERTATION

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To Emma and Sara

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ABSTRACT

The purpose of the research project was to develop a functional assessment tool for the assessment of pain behaviour and to investigate the relationship between pain behaviour, fear of movement (TSK-FIN), physical function, and disability (I), and to study the association between fear of movement and leisure time physical activity (LTPA) among chronic pain patients attending a multi-disciplinary bio-psycho-social pain management program (II), and to estimate the measurement properties of the Finnish version of the Tampa Scale of kinesiophobia (TSK-FIN) among chronic pain patients (III), and to investigate fear of movement among the general population and to create reference values for the TSK-FIN in the Finnish general population (IV).

For the intra- and inter-observer reliability, a high percentage of agreement and good to excellent levels of kappa scores for agreement were demonstrated. There was a strong correlation between pain behaviour and subjective pain report and disability ($P < 0.01$). The TSK-FIN had the strongest correlation ($r = 0.60$) to depression (Modified Zung), moderate correlations to pain behaviour ($r = 0.34$) and disability (Oswestry Disability Index, ODI) ($r = 0.37$) and low correlation to subjective pain ($r = 0.30$). The correlations between total pain behaviour and physical function tests are strong ($P < 0.01$). Only grip strength was not correlated with pain behaviour (I).

The level of kinesiophobia was associated with disability ($p = 0.013$) and depressive symptoms ($p = 0.028$). Kinesiophobia and leisure time physical activity were inversely associated. At baseline, the mean LTPA index of the high kinesiophobia group was lower than in the low and medium kinesiophobia groups ($p = 0.012$). At the 6-month follow-up, patients with high kinesiophobia had increased their physical activity to the same level as the other groups. This change was maintained up to the 12-month follow-up. The mean change in the physical activity score was 4 ($p = 0.008$). The mean change in the TSK-FIN score was -2.0 ($p = 0.01$). The effect sizes of the change in the LTPA index and pain intensity at the 12-month follow-up were both moderate in the high kinesiophobia group while they were small in the low and medium kinesiophobia groups (II).

Subjects scored higher on the computer version, mean (SD) 37.1 (8.1), compared to the paper version, mean 35.3 (7.9). The mean difference between the computer and the paper version was 1.9 ($p = 0.001$). The test-retest reliability (ICC) for the paper version of the TSK-FIN was 0.89 and for the computer version 0.88, which indicates excellent reliability. The internal consistencies were 0.80 and 0.82 respectively. The ICC for comparability was 0.77, indicating good reliability between the different

methods. The reproducibility coefficient indicated that there is a 95% expectation that the paper and computer versions differ by less than 11 points. In terms of individual variability, 62% varied by less than 3 points and 44% by less than 2 points (III).

The TSK-FIN score and age were associated in both sexes ($p < 0.01$ for men and $p < 0.001$ for women). Men over 55 and women over 65 had higher scores than younger ones. The presence of cardiovascular disease, musculoskeletal disease or mental disorder was significantly associated with a higher TSK-FIN score compared to the absence of the aforementioned disorders. The cumulative distribution of the TSK-FIN showed that, of all subjects, 14.2% scored 40 points or more. If the cut-off point for kinesiophobia is set at 37 points, 24.5% of the subjects are considered to have kinesiophobia (IV).

The results of this research project suggest that the assessment of pain behaviour demonstrated acceptable reliability. The TSK-FIN also demonstrated acceptable reliability and internal consistency. Among patients with musculoskeletal pain, the TSK-FIN and LTPA are inversely related. A pain management program seems to have favourable effect on the fear of movement and LTPA. Among patient samples (I-III) the mean scores of the TSK-FIN were significantly higher ($p < 0.001$ – $p = 0.007$) compared to the general population (IV). In the present study, men had higher mean values in the total TSK-FIN score in the all samples overall. Further studies are needed to evaluate the validity and factorial structure of the TSK-FIN with all the 17 items and also the widely used 11 -item version of the TSK. Also, studies of measurement properties such as test-retest reliability, predictive validity and internal consistency within the general population are warranted. Content validity of the TSK clearly needs to be explored with a larger sample including measures of disability and functioning as well as psychosocial dimensions, Health Related Quality of Life, and factors related to the Fear Avoidance Model. In addition, further research is required to study the minimal detectable change in the TSK-FIN.

TIIVISTELMÄ

Tutkimuksen tarkoituksena oli kehittää toiminnallinen arviointimenetelmä kipukäyttäjien arviointiin sekä tutkia kipukäyttäjien, liikkumisen pelon (TSK-FIN), fyysisen toimintakyvyn ja toimintakyvyn haitan välisiä yhteyksiä (I), ja tutkia liikkumisen pelon ja vapaa-ajan liikunta-aktiivisuuden (LTPA) yhteyttä moniammatilliseen kipukuntoutukseen osallistuvilla kroonisilla kipupotilailla (II), ja arvioida suomenkielisen Tampa Scale of kinesiophobia (TSK-FIN) – mittarin ominaisuuksia kroonisilla kipupotilailla (III), sekä tutkia liikkumisen pelkoa normaaliväestössä ja luoda suomalaiset väestöarvot TSK-FIN- mittarille (IV).

Kipukäyttäjien arviointimenetelmän toistettavuutta kuvaavat prosentuaaliset osuudet (agreement percentage) ja kappa-kertoimet osoittivat hyvää toistettavuutta. Kipukäyttäjien arvioinnilla oli vahva yhteys koettuun kipuun ja toimintakyvyn haittaan ($P < 0.01$). Liikkumisen pelolla oli vahvin yhteys ($r = 0.60$) masennukseen (Mod. Zung), kohtalainen yhteys kipukäyttäjien arviointiin ($r = 0.34$) ja toimintakyvyn haittaan (ODI) ($r = 0.37$) sekä heikko yhteys koettuun kipuun ($r = 0.30$). Kipukäyttäjien ja fyysisen toimintakyvyn testien väliset yhteydet olivat vahvoja ($P < 0.01$). Vain puristusvoima ei ollut yhteydessä kipukäyttäjien arviointiin (I).

Liikkumisen pelko oli yhteydessä koettuun toimintakyvyn haittaan ($p = 0.013$) ja masennusoireisiin ($p = 0.028$). Liikkumisen pelon ja vapaa-ajan liikunta-aktiivisuuden yhteys oli käänteinen. Kuntoutuksen alkutilanteessa keskimääräinen LTPA -indeksi oli matalampi korkean liikkumisen pelon -ryhmässä kuin matalan ja keskitason liikkumisen pelon -ryhmissä ($p = 0.012$). Kuuden kuukauden seurannassa korkean liikkumisen pelon – ryhmään kuuluvien liikunta-aktiivisuus lisääntyi samalle tasolle kuin muilla ryhmillä. Tämä muutos säilyi 12 kuukauden seurannassa. Keskimääräinen muutos liikunta-aktiivisuudessa oli 4 pistettä ($p = 0.008$). Keskimääräinen muutos TSK-FIN mittarissa oli -2.0 ($p = 0.01$). Kahden kuukauden seuranta-aikana vaikutuksen suuruus LTPA -indeksiin ja kivun intensiteetti muutoksessa oli kohtalainen korkean liikkumisen pelon ryhmässä, kun vaikutuksen suuruus oli pieni matalan ja keskitason kinesiophobia ryhmissä (II).

TSK-FIN:n keskiarvo tietokoneella täytettynä oli korkeampi (37.1 (8.1)) kuin paperiversiossa (35.3 (7.9)). Keskimääräinen ero tietokoneen ja paperin versio oli 1.9 ($p = 0.001$). Test-retest toistettavuus (ICC) oli paperiversiolla 0.89 ja tietokoneversiolla 0.88, mikä osoittaa erinomaista toistettavuutta. Sisäiset johdonmukaisuudet olivat vastaavasti 0.80 ja 0.82. Menetelmien välinen ICC vertailtavuudelle oli 0.77, joka osoittaa hyvää luotettavuutta. Toistettavuuskerroin osoittaa 95 %:n odotusarvoa paperi ja tietokoneen versioiden eron olevan vähemmän kuin 11 pis-

tettä. Yksilöllisestä vaihtelusta 62 % oli vähemmän kuin kolme pistettä ja 44 % vähemmän kuin kaksi pistettä (III).

TSK-FIN pistemäärä ja ikä olivat yhteydessä molemmilla sukupuolilla ($p < 0.01$ miehille ja $p < 0.001$ naisilla). Yli 55 – vuotiailla miehillä ja yli 65 –vuotiailla naisilla oli korkeampi pistemäärä kuin nuoremmilla. Sydän- ja verisuonitaudit, TULE-vaivat tai mielenterveyden häiriöt olivat yhteydessä suurentuneeseen TSK-FIN pistemäärään. Kumulatiivinen TSK-FIN jakauma osoittaa, että kaikista osallistuneista 14.2 % ylitti pistemäärän 40 pistettä tai enemmän. Jos liikkumisen pelon raja-arvo asetetaan 37 pisteeseen, 24.5 %:lla koehenkilöistä voidaan katsoa olevan liikkumisen pelkoa (IV).

Tutkimustulosten mukaan kipukäyttäytymisen arviointimenetelmän toistettavuus on hyväksyttävällä tasolla. Myös TSK-FIN -mittarin luotettavuus ja sisäinen johdonmukaisuus ovat hyväksyttävät. Tule potilailla TSK-FIN ja LTPA ovat käänteisesti yhteydessä. Kipukuntoutuksella näyttää olevan edullinen vaikutus liikkumisen pelon vähenemiseen ja LTPA lisäämiseen. Potilassarjoissa (I-III) TSK-FIN keskiarvot olivat merkittävästi korkeammat ($p < 0.001$ - $p = 0.007$) verrattuna normaali väestöön (IV). Tässä tutkimuksessa miesten TSK-FIN:n keskiarvo oli korkeampi. Lisätutkimuksia tarvitaan TSK-FIN:n validiteetin ja faktorirakenteen arvioimiseksi sekä TSK -17 lomakkeesta, että myös laajalti käytetystä TSK -11 versiosta. Myös mittausominaisuuksien, kuten test-retest toistettavuuden, ennustekyky ja sisäisen johdonmukaisuuden tutkiminen normaaliväestössä ovat perusteltuja. Sisällöllisen pätevyyden arvioimiseksi tarvitaan lisätietoa suuremmasta otoksesta, jolloin voidaan arvioida liikkumisen pelon yhteyttä toimintakyvyn haittaan, toimintaan sekä psykososiaalisiin tekijöihin, kuten elämän laatuun ja, pelko-välttämismalliin liittyviin tekijöihin. Olisi tarpeen myös arvioida TSK-FIN mittarin muutosherkkyyttä.

LIST OF ORIGINAL PUBLICATIONS

This thesis is based on the following original publications, which are referred to in the text by their roman numerals.

- I Koho P, Aho S, Watson P, Hurri H. 2001. Assessment of chronic pain behaviour: reliability of the method and its relationship with perceived disability, physical impairment and function. *J Rehabil Med.* Mar;33(3):128-132.
- II Koho P, Orenius T, Kautiainen H, Haanpää M, Pohjolainen T, Hurri H. 2011. Association of fear of movement and leisure-time physical activity among patients with chronic pain. *J Rehabil Med.* Sep;43(9):794-799.
- III Koho P, Aho S, Kautiainen H, Pohjolainen T, Hurri H. 2014. Test-retest reliability and comparability of paper and computer questionnaires for the Finnish version of the Tampa Scale of Kinesiophobia. *Physiotherapy.* Dec;100(4):356–362.
- IV Koho P, Borodulin K, Kautiainen H, Kujala UM, Pohjolainen T, Hurri H. 2015. Finnish version of Tampa Scale of Kinesiophobia. Reference values in the Finnish general population and associations to Leisure Time Physical Activity. *J Rehabil Med.* Feb, 47(3):249-255.

In addition, some unpublished results are presented.

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ABBREVIATIONS

ACC	Anterior Cingulate Cortex
ANCOVA	Analysis of co-variance
ANOVA	Analysis of Variance
FABQ	Fear-Avoidance Beliefs Questionnaire
FPQ	Fear of Pain questionnaire
CI	Confidence Interval
CLBP	Chronic Low Back Pain
ES	Effect Size
FAM	Fear-Avoidance Model
ICC	Intra-class Correlation Coefficient
ICF	International Classification of Functioning, Disability and Health
HRQoL	Health related quality of life
LBP	Low Back Pain
LTPA	Leisure Time Physical Activity
LoA	Limits of Agreement
mPFC	medial Prefrontal Cortex
OA	Osteoarthritis
ODI	Oswestry Disability Index
TSK	Tampa Scale of Kinesiophobia
VAS	Visual Analogue Scale
WHO	World Health Organization

1 INTRODUCTION

In primary care, 40% of the reasons for visiting a physician are due to pain. A half of the pains arise from musculoskeletal disorders. Taken together with the facts that 20 % of patients have chronic pain, 25 % of the patients of active working age receive sick leave due to their complaint, one in four people aged over 30 have at least one diagnosed musculoskeletal disease or syndrome, and, one in six of the working population has reported severe physical impairment at work, pain can be considered a major health care and public health problem (Mäntyselkä et al. 2001, Kaila-Kangas 2007).

The most common disorders among working subjects are low back, neck and shoulder syndromes of which back related disorders are a major reason for the use of health services, sick leave, and of early retirement. In about 85 % of patients with low back pain (LBP) precise pathoanatomical diagnose is lacking. The majority of nonspecific LBP related costs (> 70 %) is generated by a small subgroup (< 10 %) of patients (Dionne et al. 2005). Early retirement, sick leave, use of healthcare services and disability at work causes most of the expenses. Several factors are recognized to be associated with back pain, including socioeconomic background, physical workload, mental distress, anxiety, fear-avoidance and many life-style variables (Heistaro et al. 1998, Riihimaki and Viikari-Juntura 2000, Swinkels-Meewisse et al. 2006b).

Psychological factors are implicated in the transition from the acute phase to chronic low back pain (Pincus et al. 2006). Earlier studies have demonstrated that fear of movement and fear of (re)injury are better predictors of functional limitations than biomedical parameters (Swinkels-Meewisse et al. 2006b). Crombez et al. (1999) showed that pain-related fear was the best predictor of behavioural performance in trunk extension, flexion and weight-lifting tasks when filtering out the effects of pain intensity. High levels of fear avoidance beliefs relate to increased levels of disability (Cook et al. 2006, Leeuw et al. 2007b). In particular, fear of movement is significantly associated with disability in chronic low back pain (Schiphorst Preuper et al. 2008) and pain-related fear can be more disabling than the pain itself (Vlaeyen et al. 1995a, Crombez et al. 1999). High pain related fear has shown to be the most powerful predictor of disability (Swinkels-Meewisse et al. 2006a).

Pain has an important protective function for people. Typical protective behaviours are reflex-like withdrawal functions away from the noxious stimulus, verbal and nonverbal expressions. The importance of pain has been shown to predict the extent to which individuals engage in these protective behaviours rather than the pain itself (Beecher 1946, Arntz and Claassens 2004).

The aims of the management of patients with chronic pain problems differ in the management of those with acute problems in that treatment focuses on the reduction of disability, alleviation of psychological distress and reducing pain behaviour (Watson 1999a). Decreasing the fear of movement is one goal in pain management and rehabilitation; a reduction in pain-related anxiety seems to predict improvement in functioning, affective distress, pain and pain-related interference of activity (McCracken and Gross 1998). However, although this goal is widely accepted, the authors of earlier studies have not determined whether the decrease in fear of movement increases physical activity among participants in pain management programs. It has been shown that a low level of physical activity in back pain patients is associated with a high level of fear-avoidance beliefs (Elfving et al. 2007), that high fear-avoiders benefit more from an exercise program in terms of disability (Klaber Moffett et al. 2004), and that fear of movement decreases during an intensive physical therapy program in chronic low back pain (Kernan and Rainville 2007).

2 REVIEW OF LITERATURE

2.1 MUSCULOSKELETAL PAIN

2.1.1 Acute pain

The International Association for the Study of Pain (IASP) has defined pain as ‘An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage’. According to the definition pain has two dimensions; a sensory-discriminative one and affective-motivational one. Although acute pain is an unpleasant experience, it has biologically relevant meaning as it serves as a warning mechanism of potential tissue damage and leads towards action by which damage can be minimized. Acute pain might be caused many by events e.g. by a disease or a trauma such as a sprained ankle, broken bones, burns or cuts. Regardless of the origin, acute pain usually resolves as the involved tissues heal. Acute pain typically lasts less than six weeks and its intensity is usually related to tissue damage.

2.1.2 Subacute pain

The term subacute pain is used especially in patients with low back pain or neck pain. Subacute pain refers to pain which has lasted from six weeks up to three months. The subacute phase is seen essential in order to recognize patients in risk of developing chronic pain (Melloh et al. 2011).

2.1.3 Chronic pain

The majority of musculoskeletal tissue damages heal within three to six months, e.g. chronic back pain is widely defined as symptoms persisting for more than three months, whereas in whiplash the timeframe of chronic pain is six months (Scholten-Peeters et al. 2002). Within that context, chronic pain can be considered as pain that lasts after the initial tissue damage has healed. This time-bound definition leaves the pathomechanism of pain unresolved. Chronic pain may be caused by a variety of diseases, or it may be the result of an injury such as back strain, a nerve entrapment or nerve injury. Chronic pain can affect anyone, regardless of age or background, and can occur in almost any part of the body.

2.1.4 Transition from acute to chronic pain, from physiological pain to pathophysiological pain

The other option regarding the categorizing of pain is physiological and pathophysiological pain, which refers directly to whether the nervous system from peripheral nociceptive stimuli to the perception of pain is functioning properly. Transition from acute pain to chronic pain is not simply an on-off type of behavioural change in the pain system. Transition of pain-type is rather a process with discrete pathophysiological steps which means physical remodelling of neuronal cytoarchitecture i.e. neuroplasticity (Voscpoulos and Lema 2010). Changes may occur in both the peripheral and central nervous system. Transition can be affected by biomedical, occupational and psychosocial risk factors (Chou and Shekelle 2010). Biomedical factors include duration and intensity of the initial pain stimulus, which both are capable of leading to both peripheral and central sensitization that aggravate pain perception (Voscpoulos and Lema 2010).

Inflammation of peripheral nociceptors or lesion in peripheral nerves may lead to increased flow of pain impulses to the spinal cord which may lead to damage of inhibitory interneurons. Furthermore, interneurons may become more sensitive to stimuli leading to central sensitization (Torebjörk et al. 1992). As a result, distorted peripheral and central information impinges on the limbic circuitry (hippocampus; nucleus accumbens; and amygdala) (Apkarian et al. 2013).

Transition from physiological i.e. nociceptive pain to pathophysiological pain i.e. neuropathic pain requires a prolonged ongoing sensitization caused either by constant afferent stimulation from injured nerves or functional changes in the dorsal root (McLachlan et al. 1993, Sheen and Chung 1993). As a result of inflammatory and pathological pain, noxious stimuli are no longer required to generate pain, and pain may arise spontaneously in the absence of any stimulus.

An interesting point of view is the notion that genes may play an important role in hypersensitivity and transition from acute to chronic pain, which opens new points of view into finding out who are at risk of developing chronic pain as well as into developing new treatment options (Hartvigsen et al. 2009, Costigan et al. 2010, Williams et al. 2010).

Emotional effects include depression, anger, anxiety, and fear of re-injury. Such a fear might hinder a person's ability to return to normal work or leisure activities (Eccleston et al. 2001). Brain imaging studies have shown that variations in pain characteristics are distinct for different types of chronic pain and those variations cannot be seen among healthy subjects pretending to have pain (Foss et al. 2006). Recent brain imaging studies have also pointed out that the localization of pain is different in acute and chronic pain. High intensity chronic low back pain was localized to the medial prefrontal cortex (mPFC) and the anterior part of anterior cingulate cortex (ACC). In acute pain, portions of the insula and mid-ACC were

active only transiently when the intensity of back pain was on the increase (Apkarian et al. 2011). Thus, chronic pain is associated with the brain's emotional learning circuitry. And furthermore, the strength of synchrony between the medial prefrontal cortex and nucleus accumbens has been shown to predict transition to chronic pain although the involvement of this circuitry in pain is still not fully explored (Apkarian et al. 2013).

The interaction of the limbic circuitry with prefrontal processes is shown to be associated with the transition of a pain condition to a more emotional state (Apkarian et al. 2013). It has been proposed that the prefrontal cortex facilitates fear memory through the integration of sensory and emotional signals and through the coordination of memory storage in an amygdala-based network (Gilmartin et al. 2014).

2.1.5 Disability in musculoskeletal disorders

Chronic pain has many physical and emotional consequences. Physical consequences include increased muscle tension, decreased muscle function, limited mobility and limited range of motion in joints or general poor functioning. Self-rated disability at work and during leisure time is strongly associated with the presence of musculoskeletal disorders or diseases. In the Finnish population, aged 30 years or older, the prevalence of at least one musculoskeletal disease or syndrome is 27.8%. Musculoskeletal disorders are more common among the non-working population (35%) compared to the working population (20%). Among the working population, the prevalence of self-reported severe (6 or more on the 0 to 10 scale) disability at work is 13% in men and 21% in women, and during leisure time it is 12% and 17%, respectively. Among the non-working population, the prevalence of severe disability during leisure time is 23% in men and 24.5% in women. The most common disorders among the working population reported to cause physical impairment at work or during leisure time were low back, neck and shoulder pain. In both genders, the level of education is associated with disability at work. The lower the education, the more commonly the subjects had impairment. (Kaila-Kangas 2007)

2.1.6 Prevalence and occurrence of common musculoskeletal disorders

Based on a Finnish health survey in 2000 (Kaila-Kangas 2007), back pain is the most common musculoskeletal disorder among the Finnish population. The lifetime occurrence of back pain for men is 76.7% and 75.8% for women. The occurrence of sciatic pain was greater among women, 39.5% of women and 30.4% of men have had sciatic pain sometime during their life. Women seem to have more neck pain than men, lifetime occurrence being 54% in men and 68% in women. Also

in lifetime occurrence of shoulder pain there is a gender difference. Of the men, 42.5% and of the women 50.8% reported shoulder pain sometime during their life (Kaila-Kangas 2007).

Age-adjusted prevalence of back pain during the past 30 days among the Finnish population over 18 years of age has increased during the past ten years from 28.2% to 34.6% in men and from 33.1 to 41.4% in women. The prevalence of neck pain during the past 30 days has increased from 24% to 27.2% in men and from 37 to 41.2% in women. The proportion of those suffering from shoulder pain during the last 30 days was higher among men (28.5%) than women (25.7%). The prevalence of shoulder pain increased with age in both genders (Viikari-Juntura et al. 2012). The prevalence of elbow joint pain during the past 30 days was higher among women; 6.0% on the right and 4.5% on the left compared to men with 4.0% and 3.4% respectively. The prevalence of self-reported wrist joint pain and finger joint pain during the preceding month was slightly higher on the right side than the left both in men and women. The prevalence for wrist joint and finger joint pain was at least two-fold in women compared with men, (wrist joint; 9.7% on the right and 8.9% on the left in women and 4.8% and 4.2% in men, finger joint; 13.1% on the right and 11.9% on the left compared to men with 5.8% and 5.3%) (Kaila-Kangas 2007). The prevalence of hip pain and knee pain increased with age in both genders. The age-adjusted prevalence of self-reported hip pain during the past month was 7.9% in men and 11.5% in women (Kaila-Kangas 2007). The age-adjusted prevalence of knee pain during the past 30 days was 28.8% in men and 32.7% in women (Viikari-Juntura et al. 2012).

According to the Finnish health survey (Kaila-Kangas 2007), chronic low back syndrome was diagnosed in 11% of subjects in both genders. Chronic neck syndrome was diagnosed in 7.3% of the women and in 5.5% of the men. Chronic shoulder pain was diagnosed in the right shoulder for 5.3% of the subjects and in the left shoulder for 3.2% of the subjects. Lateral epicondylitis was diagnosed in 1.1%, with 0.7% on the right and 0.5% on the left side. Carpal tunnel syndrome was diagnosed in 3.8% of the subjects with 2.4% on the right side and 2.5% on the left side. Carpal tunnel syndrome was more common in women compared to men as the women/men ratio is 3:1. (Kaila-Kangas 2007)

The age-adjusted prevalence of clinically diagnosed hip osteoarthritis (OA) was 5.7% in men and 4.6% in women. The age-adjusted prevalence of clinically diagnosed knee OA was 6.1% in men and 8.0% in women. Both hip and knee OA are associated with age. Only a few in the age group 30-44 years have OA. In the age group 85 years or over 40% of men have hip OA and 44% have knee OA. Of women 36% have hip OA and 25% have knee OA. (Kaila-Kangas 2007)

2.1.7 From biomedical to bio-psycho-social model of pain

The traditional biomedical models of clinical medicine had embraced a dualistic viewpoint, which was mainly focused on pathophysiology and other biological aspects of disease and separated the mind and body as functioning independently like a machine as Descartes proposed in the 16th century (Engel 1977). Even in the 1980s pain was categorized as ‘organic’ or ‘psychic’. Furthermore, the biomedical model is tightly linked to linear cause–effect thinking, where the intensity of pain is thought to have a linear and direct relationship to tissue damage or activity of a disease. Symptoms have been seen as a cause of the pathophysiology, which are hoped to be identified by medical examinations such as X-RAY or MRI and which can be treated or resolved with drugs, specific treatment targeted to pathophysiology or operation. Especially degenerative changes are present in high proportions of asymptomatic individuals increasing with age. Many imaging-based degenerative features are likely part of normal aging and unassociated with pain (Brinjikji et al. 2015). Although the biomedical actions have resolved many medical problems, there is a large number conditions where the specific cause remains unclear. In brief, the biomedical model of pain is very ‘narrow’ and insufficient to identify a large number of complaints (Engel 1977).

The physiological background of the bio-psycho-social model of pain lies on the gate-control theory (Melzack and Wall 1965). By applying Skinner’s principles of operant conditioning (1953) and the gate-control theory, the goal of treatment was shifted from the reduction of pain intensity towards the impact of pain on life and the restoration of functional behaviour (Fordyce 1982). The bio-psycho-social model of pain took a step forward by widening the perspective from biological factors to psychological and social factors and began to see pain and suffering as complex and multifactorial phenomena (Gatchel et al. 2007). The bio-psycho-social model focuses on both disease and illness, with illness being viewed as the interaction of biological, psychological, and social factors (Crombez et al. 2012). According to (Gatchel et al. 2007), disease refers to a disturbance of body structures or organ systems caused by anatomical, pathological, or physiological changes and illness is seen as a patient’s and his or her family members’ subjective experience of a disease and how they cope with the disease and disability. The bio-psycho-social model has proven particularly useful in extending our knowledge about pain in cases where pain persists in the absence of tissue damage or organic pathology (Gatchel et al. 2007).

2.2 FEAR-AVOIDANCE MODEL OF PAIN (FAM)

The terms fear, anxiety and avoidance have a long history in medical literature. Aristotle was one of the first who linked pain with fear: 'Let fear, then, be a kind of pain or disturbance resulting from imagination of impending danger, either destructive or painful' (Aristotle 2004). The term fear-avoidance model was first by introduced by Lethem et al. (1983). They presented fear and pain to be associated with behaviour through avoidance learning. Fear-avoidance conditioning was suggested by Vlaeyen and Linton (2000) as a process where a classical component and an operant component can be distinguished.

The fear-avoidance model (FAM) was suggested by Vlaeyen et al. (1995b) as a cognitive-behavioural model of fear of movement/(re)injury for patients with low back pain. The resulting vicious circle: 'pain' – 'fear of movement/(reinjury)' – 'avoidance' – 'disability/disuse/depression' – 'pain' was presented as a cyclic chain of events. Later Vlaeyen and Linton (2000) updated the model further adding 'catastrophizing' to the vicious circle and rephrasing 'fear of movement' by 'pain-related fear' and further adding 'hypervigilance' alongside 'avoidance'. Asmundson et al. (2004) differentiated between fear and anxiety and they added an anxiety pathway to the model. Vlaeyen and Linton (2012) further supplemented the model by adding an explanation on how pain-related fear occurs in the first place via learning and motivational processes.

The FAM suggests (Figure 1) the mechanism by which patients' interpretation about pain may contribute to the maintenance of chronic pain and disability. When pain can be confronted and considered as nonthreatening, patients will return back to the physical activities of daily life. Those patients can correct their expectations about pain and keep them in line with their actual experiences promoting functional recovery (Crombez et al. 2002, Trost et al. 2008).

Some patients may become trapped in a vicious circle of chronic disability and suffering regardless of the origin of acute pain. The vicious circle results in a behavioural pattern that is not in synchrony with the underlying biomedical pathology, and further leads to an exaggerated perception of pain (Philips 1987), and thus, pain-related fear can be more disabling than pain itself (Vlaeyen et al. 1995a). Catastrophic cognitions may occur if a patient erroneously interprets pain as a sign of serious injury or pathology or if a patient has painful experiences that are worsened during movement or activities. The patients who catastrophize are more likely to be fearful (Vlaeyen et al. 1995b). It has shown that catastrophizing influences pain reports through supraspinal mechanisms (memory, report bias, attention) and do not affect the transmission of spinal nociceptive signals (Rhudy et al. 2009). Catastrophizing leads to an excessive fear of pain and injury that gradually extends to a fear of physical movement so that people will avoid those physical activities

that are presumed to worsen their problem. This leads to increased avoidance of physical activities and in the long run to disuse, depression and increased disability (Philips 1987, Council et al. 1988).

Catastrophic thinking refers to the process where pain is interpreted as being extremely threatening (Crombez et al. 1998). Catastrophizing has been shown to be associated with pain disability in pain patients (Peters et al. 2005, Sullivan et al. 2005), as well as in the general population (Severeijns et al. 2004). Catastrophizing is associated with disability and pain intensity in various pain problems (Severeijns et al. 2001, Turner et al. 2002, Peters et al. 2005, Sullivan et al. 2005). The initial level of catastrophizing has been demonstrated to be associated with higher pain intensity in prospective studies (Sullivan et al. 1995, Vlaeyen et al. 2004, Pavlin et al. 2005) and furthermore, in study a by Leeuw et al. (2007a), catastrophizing was found to predict fear of movement at six month follow-up, even after accounting for other contributing variables such as initial levels of fear of movement.

Both depression and disuse are known to be associated with decreasing pain tolerance levels and hence promoting painful experiences (Romano and Turner 1985, McQuade et al. 1988). In addition, some patient tends to scan their bodies almost continuously for putative signs of pain or injury. This selection of pain related information is introduced in the model as 'hypervigilance'. Together with avoidance, hypervigilance makes sense in the short-term as they provide time to heal thus protecting the individual. In the short term, avoidance is rewarding as pain often diminishes by avoiding physical activities and resting. However, in the long term that may lead to deconditioning and furthermore to increased pain and disability and decreased levels of physical activity and further social isolation (Crombez et al. 2012).

When pain is perceived as nonthreatening, recovery is likely to happen after a period of diminished physical activities. Interpreting pain as threatening (pain catastrophizing) may give raise to pain-related fear. This leads further to avoidance behaviours and hypervigilance and in the long run to disability, disuse and depression. This makes patients more vulnerable to further pain and fuels the vicious circle of increasing fear and avoidance. Pain catastrophizing is associated with negative affectivity and threatening illness information.



Figure 1. The fear-avoidance model (Vlaeyen and Linton 2000).

If pain, possibly caused by an injury, is interpreted as threatening (pain catastrophizing), pain-related fear evolves. This leads to avoidance behaviors, and hypervigilance to bodily sensations followed by disability, disuse and depression. The latter will maintain the pain experiences thereby fueling the vicious circle of increasing fear and avoidance. In non-catastrophizing patients, no pain-related fear and rapid confrontation with daily activities is likely to occur, leading to fast recovery. Pain catastrophizing is assumed to be also influenced by negative affectivity and threatening illness information.

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2.3 KINESIOPHOBIA, FEAR OF MOVEMENT, FEAR-AVOIDANCE BELIEFS AND PAIN RELATED FEAR

Lundberg et al. (2011a) have stressed that in the literature regarding the FAM, constructs of kinesiophobia, fear of movement, fear-avoidance beliefs and pain related fear have been used interchangeably to describe the complex association of pain and fear, although the above mention terms are not synonyms. The term kinesiophobia was introduced by Kori et al. (1990) who defined it as a condition in which a patient has ‘an excessive, irrational, and debilitating fear of physical movement and activity from a feeling of vulnerability to painful injury or reinjury’. They pointed out the phobic nature of fear of pain and avoidance. The construct ‘Fear of movement’ was introduced by (Vlaeyen et al. 1995b) and defined as ‘a specific fear of movement and physical activity that is (wrongfully) assumed to cause reinjury’. In the fear-avoidance-model fear of movement is recognized as a factor which can maintain a vicious circle of pain and disability (Leeuw et al. 2007b). However, Lundberg et al. (2011a) could not identify any instrument to measure the construct of ‘fear of movement’. The constructs ‘kinesiophobia’ and

'fear of movement' are quite closely related to each other and the Tampa Scale of Kinesiophobia (TSK) has also been used as a measure of fear of movement (Vlaeyen et al. 1995a, Vlaeyen et al. 2002).

The construct 'fear-avoidance beliefs' can be measured by the Fear-avoidance beliefs questionnaire (FABQ) (Waddell et al. 1993). The construct 'pain-related fear' incorporates 'fear of pain', 'fear of injury', 'fear of physical activity' (Asmundson and Taylor 1996) and can be assessed by the Fear of pain questionnaire (FPQ) (McNeil et al. 1986) or by the Pain anxiety symptoms scale (PASS) (McCracken et al. 1992). However, neither Lethem (1983) when describing association between fear and pain nor the above-mentioned authors, have offered conceptual definitions for the questionnaires.

Lundberg et al. (2011a) concluded in their critical review that for most FAM related questionnaires, the conceptual model of the questionnaire's construct was poorly described. The criticism is based on the weaknesses of questionnaire's reliability and especially validity. Comparison of different questionnaires and different versions of same questionnaire is complicated due to unequal evaluation methods of psychometric properties and the fact that there are currently no 'golden standards' of measure for the constructs of FAM. Moreover, based on weak construct validity it is doubted whether by the available measures it can currently be identified who is actually fearful.

2.3.1 Definitions of fear, phobia and anxiety

Fear refers to an emotional reaction to a specific, identifiable and immediate danger (Rhudy and Meagher 2000). It initiates a protective survival mechanism by activating the fight or flight behaviours (Lang et al. 2000, Davis 2006). Through classic conditioning, after the experience of a low back pain episode, anticipated or actual exposure to the same kind of experience may bring up a fear response. Observing others with low back pain may lead to the learning of fear through vicarious exposure (Askew and Field 2007). Individual response when exposed to fearful stimuli may depend on contextual variables. Fearful stimuli may not cause as much avoidance in a safe environment, such as being surrounded by other people, whereas when being alone with the same stimuli, excessive protective behaviours may occur. Such avoidance behaviours may reduce the level of fear in the short term, but in the long term, fear may strengthen (Crombez et al. 2012).

Phobia is an intense and irrational fear of something that poses little or no real danger (Rachman 2004). Phobias are common and can develop of virtually anything at any age. In most of phobic situations, one realizes that the feeling of fear is unreasonable, but they cannot however control their feelings which are by and large, automatic and overwhelming.

Anxiety resembles fear, but is a more future-orientated cognitive-affective state without a clear focus (McNaughton and Gray 2000, Rhudy and Meagher 2000). The threat is not detected but is anticipated, so anxiety is associated with preventive behaviours such as catastrophic thinking and hypervigilance. Hypervigilance refers to a situation where an individual monitors the environment for potential sources of threat and then selectively follows the threat-related rather than neutral stimuli (Eysenck 1992). Hypervigilance may reduce anxiety in the short term, but in the long run, it may be counterproductive (Crombez et al. 2012). The theoretical distinction between fear, anxiety and phobia is correct, but in a clinical context these terms frequently used interchangeably in regard to pain. Fear, anxiety and phobia can be caused by external signs of danger or by internal threats and furthermore, they all are accompanied by similar reactions e.g. muscle tension or pounding of the heart (Rachman 2004).

2.3.2 Assessment of fear of movement

The Tampa Scale of Kinesiophobia

The Tampa Scale of Kinesiophobia (TSK) was introduced by Miller et al. (1991) in order to discriminate between non-excessive fear and anxiety among patients with persistent musculoskeletal pain. It should be noted that the TSK was introduced prior to the fear-avoidance model. The TSK has become one of the most frequently employed measures for assessing pain-related fear. It has been translated into Dutch (Vlaeyen et al. 1995b), French (French et al. 2002), Swedish (Lundberg et al. 2004, Bunketorp et al. 2005), Norwegian (Damsgard et al. 2007), Portuguese (Siqueira et al. 2007), Italian (Monticone et al. 2010), Spanish (Gomez-Perez et al. 2011), Chinese (Wong et al. 2010), Persian (Askary-Ashtiani et al. 2014) and German (Rusu et al. 2014). The original version consists of 17 items, in which each item has a four-point Likert scale with the following alternatives: strongly disagree, disagree, agree and strongly agree. After inverting items 4, 8, 12, and 16, a sum score is calculated. The range of the score is from 17 to 68, with a higher number indicating greater fear of movement.

A number of different versions of the TSK, with 4, 11, 12, 13 and 17 items, have been presented since the original scale was published (Lundberg et al. 2009). Lundberg et al. (2009) also pointed out that in eight out of the eleven different factor solutions for the TSK the reversed items have been removed due to their low factor loadings. Different factor solutions of the TSK have been found with a number of factors ranging from one to five (Lundberg et al. 2009), which suggests that the found factor solutions are highly dependent on the population studied. The observed variability might be due to the applied statistical methods and sample

sizes across studies. Performing factor analyses with populations of less than 200-300 subjects may lead to difficulty in interpretation and in generalizing results (Tabachnick and Fidell 2006).

The two-factor model by Clark et al. (1996) (13 items) has shown a better fit compared to the one-factor model and the four-factor model (Heuts et al. 2004, Woby et al. 2005, French et al. 2007). Clark's two-factor model has been found to be invariant across patients with low back pain and patients with fibromyalgia (Goubert et al. 2004, Roelofs et al. 2004). Recent studies (Tkachuk and Harris 2012, Walton and Elliott 2013, Rusu et al. 2014) have provided support for the two-factor model of the TSK-11, which is based on studies by Woby et al. (2005) and (Roelofs et al. 2007). This model has been found to be invariant across pain diagnoses and countries (Roelofs et al. 2007, Roelofs et al. 2011).

These two factors are named as 'somatic focus' and 'activity avoidance' although there is variation across studies regarding the items included into factors. The two-factor model has been recently supported in a mixed method analysis by (Bunzli et al. 2014). They identified 'damage beliefs' and 'suffering/functional loss' groups. As expected the 'damage beliefs' group agreed more strongly with the somatic focus items. The 'Suffering/functional loss' group fails to discriminate between the two factors.

High scores on the TSK have been found to be associated with pain severity (Sullivan et al. 2009), pain duration (Picavet et al. 2002) and disability in patients with low back pain (Crombez et al. 1999, Picavet et al. 2002). Wideman et al. (2009) have shown that reductions in catastrophizing and the TSK scores predict reductions in disability. The smallest detectable change in the TSK has been found to be 9.2 points (Ostelo et al. 2007). In addition, the clinically meaningful change in the level of kinesiophobia has been determined to be a 4-point difference in TSK-11 scores (Woby et al. 2005). Overall, the TSK is the oldest and still the most frequently applied evaluation tool for fear of movement in research and clinical work.

2.3.3 ICF and the Tampa Scale of Kinesiophobia

The aim of the International Classification of Functioning, Disability and Health (ICF) is to provide a framework for the description of health and health-related states (WHO 2001). The terms health domains and health-related domains are used in order to describe all aspects of health and health-relevant components of well-being. The ICF has two parts, each with two components. Part 1) consists of functioning and disability with the components a) body functions and structures, b) activities and participation. Part 2), contextual factors, has the components c) environmental factors and d) personal factors. The latter are not classified in the ICF due to large social and cultural variance (WHO 2001). Interactions between the components of the ICF are presented in figure 2.

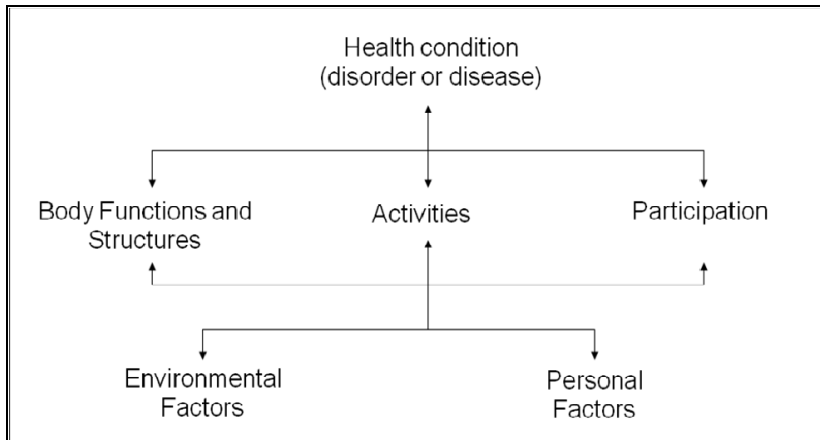


Figure 2. Interaction between the components of the ICF (WHO 2001).

The ICF can serve as a solid theoretical background for conceptualizing each of the assessment instruments and measurement tools used for the assessment of individual functioning or disability. Each measure can be classified in relation to the ICF thus providing construct validity to the measure. This puts assessment in context and provides the focus for selecting relevant aspects of functioning and disability for assessment.

Lundberg et al. (2011a) suggests that the TSK is the best available method to measure 'kinesiophobia', although the conceptual model of the questionnaire's construct was poorly described. As the focus of the present research project was to study fear of movement and the measurement properties of the TSK, only the TSK and not all the FAM related measures were classified into ICF codes in order to study validity of the TSK. There are limitations regarding the Tampa Scale of Kinesiophobia as an ICF-classification. In terms of the ICF, a two-level classification can be made for pain and fear. Pain can be classified as body functions, more specifically to sensory functions and pain (ICF code b280). Respectively, fear can also be classified as emotional functions (ICF code b152). However, as subjective and personal factors are not classified in the ICF, specific coding of the TSK items is not possible.

2.4 PAIN BEHAVIOUR

Loeser & Fordyce (1983) have defined pain behaviours as 'any and all outputs of the individual that a reasonable observer would characterise as suggesting pain. Such as (but not limited to) posture, facial expression, verbalising, lying

down, taking medicines, seeking medical assistance and receiving compensation'. These behaviours are real and are affected by many actual expected factors. And furthermore, they can be quantified by others. Existence of nociception, pain and suffering can be inferred from pain behaviours, history and physical examination (Loeser and Melzack 1999).

Initial physiotherapy assessment of chronic low back pain patients involves an assessment of self-reported disability, physical impairment and current physical capacity using simple functional tasks (Harding et al. 1994, Simmonds et al. 1998). During such assessment, and in particular during the functional capacity evaluation, patients frequently demonstrate a variety of pain associated behaviours (Watson and Poulter 1997). Furthermore, erratic performance of clinical assessment variables has been demonstrated to be influenced by psychological and behavioural factors (Pope et al. 1980, Watson 1999b).

Overt pain behaviours are observable in individuals in pain. Alterations in posture, limping and the demonstration of guarded movements are obvious examples of overt pain behaviours. Others include facial grimacing, rubbing or touching the affected area and groaning or sighing (Keefe et al. 1987). Observational measures often depend on the observation of the subject over a period of time by trained observers (Richards et al. 1982, Vlaeyen et al. 1987). These rely on the identification, by trained observers, of pain behaviours in a number of categories such as mobility, posture, verbal pain report, and non-verbal pain report. These have usually been used in an in-patient setting and observations are taken through the course of a day. This approach is time consuming and requires training large numbers of personnel (Vlaeyen et al. 1987) and may be inappropriate for many clinical settings.

A videotaped behavioural observation measure was developed by Keefe & Block (1982) which relies on the observation of overt pain behaviours such as grimacing, limping and rubbing the affected area. This method has been used in a wide variety of painful conditions (McDaniel et al. 1986, Keefe et al. 1987, Baumstark et al. 1993) and has demonstrated an excellent (agreement 93-99%) level of reliability (Keefe and Block 1982). However, this video rating system and other observational measures have been criticised for not presenting the subject with functional tasks. Patients may only demonstrate pain behaviour during the execution of a task that they perceive as potentially painful or dangerous (Keefe and Dunsmore 1992). Therefore, task-orientated behavioural analyses, where subjects perform a number of everyday activities and specific tasks have been developed (Watson and Poulter 1997). An acceptable ($\kappa=0.40-0.83$, ICC=0.99, agreement 89-97%) level of intra and inter-observer reliability has been demonstrated and the total scores were highly correlated with other pain behaviour measures, disability and fear/avoidance beliefs in patients with low back pain (Jensen et al. 1989, Watson and Poulter 1997), non-cancer chronic pain (McCahon et al. 2005) and multiple sclerosis (Cook et al. 2013).

2.5 AVOIDANCE BEHAVIOUR AND CONSEQUENCES OF AVOIDANCE

The fear-avoidance model predicts that fear of movement leads to avoidance behaviour and avoidance is suggested as the most prominent component of pain behaviour (Philips 1987). In acute pain, avoidance behaviour is adaptive (Philips 1987) as it serves an appropriate protective function for tissues by aiding healing. In a chronic pain state, avoidance behaviour is learned and by nature maladaptive due to pain-related fear (Vlaeyen and Linton 2000).

It has been demonstrated that individuals showing more avoidance were more afraid of pain, more afraid of (re)injury and reported more disability than those classified as confronters (Crombez et al. 1998) and that a low level of physical activity in patients with back pain is associated with a high level of fear-avoidance beliefs and catastrophizing (Elfving et al. 2007). In their review, Zale et al. (2013) concluded that the development and maintaining of chronic pain and pain-related disability may be influenced by pain-related fear. In addition, the relationship between pain-related fear and disability is relative large and it is not moderated by pain intensity or duration. Further, pain-related fear has been shown to be associated with reduced physical performance and pain expectancy (Vlaeyen and Linton 2000). Fear of general physical activity is a stronger predictor of pain-related disability than fear of work related-activities (Zale et al. 2013). Long lasting avoidance and physical inactivity have many negative consequences. They may lead to the decrease of physical performance, limitations on social interaction, more disability and depression.

Earlier studies have demonstrated that fear of movement and fear of (re)injury are better predictors of functional limitations than biomedical parameters (Swinkels-Meewisse et al. 2006a). Pain-related fear predicts behavioural performance in trunk extension, flexion and weight-lifting tasks when filtering out the effects of pain intensity (Crombez et al. 1999), physical functioning and disability (Vlaeyen et al. 1995a, Gheldof et al. 2006).

In earlier literature regarding pain-related fear the role of pain intensity is seen as a secondary factor in avoidance behaviour or disability (Vlaeyen and Linton 2000). Crombez et al. (1999) have stated that 'pain-related fear is more disabling than pain itself.' However, there is a growing body of evidence that high pain intensity is in itself a threatening experience that may contribute avoidance behaviour (Eccleston and Crombez 1999) and that pain has shown be strongly related to functional disability during the acute stage of LBP (Sieben et al. 2005b, Gheldof et al. 2006) and that future disability was best predicted by previous LBP history and pain intensity (Sieben et al. 2005a). Also, during chronic stages of pain the association between pain and disability may be more important than previously suggested (Mannion

et al. 2001, Boersma and Linton 2005, Peters et al. 2005, Leeuw et al. 2007b). In their study, Gheldof et al. (2010) concluded that pain-related fear is rather a consequence than an antecedent of pain severity.

From the FAM it can be predicted that reductions in pain-related fear may improve pain-related disability. It has been shown that a low level of physical activity in patients with back pain is associated with a high level of fear-avoidance beliefs (Elfving et al. 2007), that high fear-avoiders benefit more from an exercise program in terms of disability (Klaber Moffett et al. 2004), and that kinesiophobia decreases during an intensive physical therapy program in chronic low back pain (Kernan and Rainville 2007). And furthermore, cognitive-behavioural therapy decreases pain-related fear among patients with chronic pain (Bailey et al. 2010).

Patients with chronic low back pain related disability have been shown to have a lower level of aerobic fitness. Fear avoidance model factors, e.g. the TSK subscales, somatic focus, activity avoidance, and catastrophizing, were not associated with aerobic fitness. However, aerobic fitness was associated with the level of leisure time physical activity (Smeets et al. 2009). Low back pain patients with high pain related fear demonstrated about half of the peak force of abdominal muscles during isometric exertion compared to patients with low pain related fear suggesting specific activity avoidance to flexion (Thomas et al. 2008). From a therapeutical point of view an interesting note by Keller et al. (2008) was that at a 12 month follow-up after receiving lumbar fusion or cognitive-behavioural therapy (Brox et al. 2006) and exercises (Brox et al. 2003), change in muscle strength was not associated with change in cross-sectional area or density. Almost half of the change of muscle strength was explained by change in pain, change in fear-avoidance beliefs, change in self-efficacy for pain and treatment (cognitive behavioural therapy and exercises) suggesting the central role of pain and treatment in patients with low back pain.

High levels of fear avoidance beliefs have been demonstrated to have a relationship with increased levels of disability (Cook et al. 2006, Leeuw et al. 2007b). In particular, fear of movement is significantly associated with disability in chronic low back pain (Schiphorst Preuper et al. 2008). In addition to fear of movement, pain intensity and depression predicts disability in both patients with specific and nonspecific CLBP explaining 67% of disability related variance (Lundberg et al. 2011b). Furthermore, catastrophizing and pain-related fear are important predictors of present pain intensity and disability in patients with low back pain (Peters et al. 2005, Lundberg et al. 2011b).

3 AIMS OF THE STUDY

The general aim of this study was to learn more about fear of movement: how it can be evaluated, its prevalence in Finland and association to pain behaviour and physical activity. For these general aims four specific aims were set:

1. To develop a new, reliable assessment of pain behaviour performed during the execution of a range of functional assessment measures that could be carried out by physiotherapists and to investigate the relationship between pain behaviour, distress, physical function and impairment (I).
2. To study the association between fear of movement and physical activity and to study the association of change of fear of movement and physical activity among chronic pain patients attending a multi-disciplinary bio-psycho-social pain management program (II).
3. To estimate the internal consistency, test-retest reliability and comparability of paper and computer versions of the Finnish version of the Tampa Scale of kinesiophobia (TSK-FIN) among chronic pain patients and to study patients' personal experiences of completing both versions of the TSK-FIN and preferences between these two methods of collecting data (III).
4. To investigate fear of movement among the general population and create reference values in the Finnish general population, to estimate the prevalence of high kinesiophobia in Finnish men and women; and to examine the association between fear of movement and leisure-time physical activity and the impact of co-morbidities on fear of movement (IV).

4 MATERIAL AND METHODS

4.1 STUDY POPULATIONS

Study I

Fifty-one patients (24 men and 27 women, mean age 44.6 years, SD 8.1) were referred by the Social Insurance Institute (SII) to the chronic pain management programme at ORTON Rehabilitation Centre in Helsinki, Finland. The pain management programme was developed for patients who have serious or prolonged low back problems.

For the initial reliability study, 18 subjects who were consecutive referrals with chronic pain were assessed. The subjects were observed performing the following actions: sitting; a timed 5 minute walk; lying down prone on the floor and rolling over 360° and standing up; bending and reaching; filling, lifting and carrying a box of weights; stair climbing. Two observers assessed the videotapes on two separate occasions with approximately four weeks between ratings. The observers were required to identify the occurrence of pain behaviours on the videotapes. The occurrence of the following behaviours were recorded : distorted gait, audible pain behaviour (groaning, sighing), facial grimacing, touching or holding the affected body part, stopping or resting, verbal complaints about pain, support and leaning, adopting a guarding tense stiff posture.

Inter- and intra-observer reliability over the 4-week period was established on these data. A second group of 33 subjects was assessed in exactly the same way and these data were analysed to identify the relationship between pain, pain behaviour, physical function and disability. There were no significant differences among the groups. The subjects completed a battery of physical performance tests including range of spinal motion repetitive flexion, repetitive arching, repetitive squatting and hand-grip strength.

Study II

Altogether 134 consecutive patients with chronic musculoskeletal pain referred by the SII to the inpatient pain management program or some other individual rehabilitation program between the years 2005 and 2006 at Orton Rehabilitation Centre, were recruited. None of the patients declined to participate. Due to overlapping activities in the rehabilitation programme (e.g. individual meetings with rehabilitation experts), complete data was received for 94 patients. The main goal of the pain management and individual rehabilitation program was for the patients to regain their overall ability to function. Other goals included mitigating

of the inconvenience of pain and strengthening their own means of survival. The group rehabilitation design consisted of physical and functional exercises, an evaluation of the social situation, a psychological assessment of pain-related stress factors and personal pain management training. The program was conducted by a multidisciplinary rehabilitation team, including a physician, psychologist, social worker, two physiotherapists and an occupational therapist.

The exclusion criteria of the pain management program were primary fibromyalgia and major psychiatric disorders. Prior the pain management program the pain problem had been carefully examined to identify conditions for specific treatment by a specialist in the pain clinic of Helsinki University Hospital. The pain and other medication of the patients had also been planned and adjusted there according to the best practices.

All patients participated in the routine rehabilitation and they volunteered to participate in the study and gave their informed consent. The patients did not get any compensation for participating in the rehabilitation program.

Study III

The sample comprised 93 chronic musculoskeletal pain patients who had been referred to a pain management program at ORTON Rehabilitation Centre by specialists at Helsinki University Hospital between 2003 and 2007. The exclusion criteria were primary fibromyalgia and a diagnosed psychiatric disorder. The pain problem of the patients had been thoroughly examined by an anaesthesiologist, neurologist or specialist of physical and rehabilitation medicine at the pain clinic of Helsinki University Hospital in order to identify conditions for specific treatment. Pain medication and other conditions had been optimized. The purpose of the pain management program was to increase the functional capacity of the patients after the medical treatment.

All patients participated in the routine pain management program and all measurements were part of the rehabilitation. SII both funded the rehabilitation services of the patients and provided income security (rehabilitation allowance) during participation in the rehabilitation. The patients did not get any extra compensation for participation in the rehabilitation.

The ethics committee of the Hospital District of Helsinki and Uusimaa and the review board of the ORTON Research Institute approved the study protocol. All patients gave their informed consent for participation in the study.

Study IV

The study was part of the National FINRISK Study 2007 survey. The FINRISK 2007 Study was carried out in six areas in Finland: the cities of Helsinki and Vantaa, the areas of Turku and Loimaa, and the provinces of North Savo, North Karelia, Oulu,

and Lapland. A random sample from the Finnish population register consisting in total of 11 953 persons in the age group 25-74 stratified by area, sex and 10-year age groups was obtained for the study. The survey protocol followed the WHO MONICA protocol (WHO 1998) closely and the later recommendations of the European Health Risk Monitoring Project (Tolonen et al. 2002).

The kinesiophobia study was carried in the Turku and Loimaa area. The sample included 1714 participants, and 1054 (61%) completed the TSK-FIN questionnaire. After excluding 10 subjects with no TSK data and 10 subjects with incomplete TSK data, the final study population comprised 455 men and 579 women. The coordinating ethics committee of the Hospital District of Helsinki and Uusimaa approved the study protocol, and each participant gave a written informed consent.

4.2 MEASUREMENTS

Disability. Self-report of disability was assessed using the Finnish versions of the Oswestry Disability Index (ODI) (Grönblad et al. 1993). The ODI contains 10 items: pain intensity, personal hygiene, lifting, walking, sitting, standing, sleeping, sexual activity, social activity and travelling. Each item is scored on a 6-point scale, where 0 represents no limitation and 5 represents maximal limitation. From this, a percentage score (0–100) is calculated, with a higher score indicating greater disability. The Finnish version of the ODI has been found to be reliable and valid (Pekkanen et al. 2011).

Pain intensity. The average pain intensity during the past week on a 0–100mm was assessed by a visual analogue scale (VAS) ranging from “no pain” to “worst possible pain”. The VAS has been widely used and has shown an acceptable reliability (Williamson and Hoggart 2005).

Depression was assessed in study I using the modified Zung depression index, which consists of 23 items with four response options [rarely or none of the time (less than 1 day per week), some or little of the time (1-2 days per week), a moderate amount of the time (3-4 days per week), or most of the time (5-7 days per week)]. Scores may range from 0 to 69, with higher scores indicating a greater risk of depression. The cut point for depression is a modified Zung score of 34 or higher (Main et al. 1992).

In study II, depressive symptoms were assessed using the 21-item Beck Depression Inventory, version II, (BDI-II) (Beck and Beamesderfer 1974). The 21 items are scored 0–3, the total ranging from 0 to 63. According to the reference levels given in the BDI-manual, 0–13 equals minor depression, 14–19 mild depression,

20–28 moderate depression, and 29–63 severe depression. The Finnish version has shown acceptable levels of reliability and validity (Mattlar et al. 1988).

Somatic perception was assessed using the modified somatic perception questionnaire (MSPQ), which consists of 13 items reflecting heightened autonomic or somatic awareness. Such dysregulation may also be termed “somatic anxiety” or “somatization.” There are four response options for each item: (not at all; a little, slightly; a great deal, quite a bit; or extremely, could not have been worse). The MSPQ scores may range from 0 to 39, with higher scores indicating a greater risk of somatization. The cut point for somatization is an MSPQ score of 12 or higher (Main 1983).

Kinesiophobia/Fear of (re)injury was assessed using the Tampa scale for kinesiophobia (TSK) (Kori et al. 1990). TSK is a 17-item questionnaire, with four possible responses for each item (strongly disagree, disagree, agree and strongly agree). After inverting items 4, 8, 12, and 16, a sum-score is calculated. The range of score is 17–68, with a higher number indicating greater fear of movement. In studies II-IV, The Finnish version of the Tampa Scale of Kinesiophobia (TSK-FIN) was used to assess fear of movement/(re)injury. The original English version (Kori et al. 1990) was translated into Finnish and then translated back into English by authorized translators. The English versions were then compared, and both the translators and the original author of the article resolved differences via the consensus procedure.

The psychometric properties of the TSK have been tested widely in different patient populations. Its internal consistency (Cronbach’s alpha, α) has been found to be acceptable within the general population ($\alpha=0.78-0.79$) (Houben et al. 2005) and in patients with acute low back pain ($\alpha=0.70-0.76$) (Swinkels-Meewisse et al. 2003a, Swinkels-Meewisse et al. 2003b), chronic low back pain ($\alpha=0.73-0.80$) (Vlaeyen et al. 1995b, Goubert et al. 2004, Woby et al. 2005, Monticone et al. 2010, Rusu et al. 2014), fibromyalgia ($\alpha=0.71-0.78$) (Goubert et al. 2004, Burwinkle et al. 2005) and chronic fatigue syndrome ($\alpha=0.68-0.80$) (Silver et al. 2002, Nijs et al. 2004, Nijs and Thielemans 2008), as well as among mixed acute pain population ($\alpha=0.81$) (Gomez-Perez et al. 2011) and chronic pain populations ($\alpha=0.79$) (Cohen et al. 2003, Gomez-Perez et al. 2011), neck pain ($\alpha=0.77-0.89$) (Cleland et al. 2008, Askary-Ashtiani et al. 2014) and in older people ($\alpha=0.74-0.87$) (Larsson et al. 2014).

The test-retest reliability of the scale has been acceptable in patients with acute low back pain ($R=0.78$) (Swinkels-Meewisse et al. 2003a), chronic low back pain ($ICC=0.91-0.96$, $R=0.91$) (Lundberg et al. 2004, Woby et al. 2005, Monticone et al. 2010), mechanical neck pain ($ICC=0.80$) (Cleland et al. 2008) Askary-Ashtiani et al. 2014, shoulder pain ($ICC=0.84$) (Mintken et al. 2010) chronic fatigue syndrome ($ICC=0.83-0.91$) (Nijs and Thielemans 2008) and in older people ($ICC=0.75$) (Larsson et al. 2014).

The validity of the TSK has been demonstrated within the general population (Houben et al. 2005) and in patients with acute low back pain (Swinkels-Meewisse et al. 2003a), chronic low back pain (Lundberg et al. 2004, Woby et al. 2005, Monticone et al. 2010, Rusu et al. 2014), neck pain (Cleland et al. 2008) (Askary-Ashtiani et al. 2014), chronic fatigue syndrome (Silver et al. 2002, Nijs et al. 2004), fibromyalgia (Burwinkle et al. 2005), shoulder pain (Mintken et al. 2010) and temporomandibular disorders (Visscher et al. 2010), among mixed acute and chronic pain populations (Gomez-Perez et al. 2011) as well as after spinal surgery (Archer et al. 2014) and in older people with chronic pain (Larsson et al. 2014).

For the purpose of study II, the patients were classified into tertiles based on distribution of the TSK-FIN in the study population. The TSK tertile I (low kinesiophobia, range 17–33) consists of 30 subjects, the II tertile (medium kinesiophobia, range 34–40) consists of 29 subjects and the III tertile (high kinesiophobia, range 41–68) consists of 34 subjects. The estimates of cut-off points for the TSK in study IV were based on studies by Vlaeyen et al. (1995a) and Lundberg et al. (2004). A TSK value greater than 37 as a cut-off point for high fear of movement was originally proposed by Vlaeyen et al. (1995b). Later, Lundberg et al. (2004) concluded that a TSK value greater than about 40 is an indication of high fear of movement.

Computer use and preferred method in future Subjects were asked how often they used a computer each week, with the possible responses of never, once a week, two to three times a week, four to five times a week or daily. Subjects were also asked which data collection method they would prefer to use in the future, with the possible responses of paper, computer or no preference. The ease of use of both methods was evaluated using a five-point scale (very difficult, somewhat difficult, not difficult or easy, somewhat easy and very easy).

Physical activity. In study II, LTPA was measured according to the recommendations by Sallis et al. (1985), using a questionnaire that included items for frequency and intensity of average number of LTPA bouts, which last at least 20–30 min. Frequency was measured by means of multiple-choice questions that assessed the number of physical activity sessions on a 5-level scale. Intensity was assessed with a multiple choice question in which subjects indicated the type of LTPA on a 4-level scale. The LTPA index was used for the final analysis, taking into account both the frequency and intensity of LTPA according to the MET-values (1 MET = 1 metabolic equivalent = 1 kcal/kg/h). One MET (1 kcal/kg/h) is consumed when reading or watching TV, 4 METs (4 kcal/kg/h) when walking, riding a bike or doing light gardening, 7.5 METs (7.5 kcal/kg/h) when jogging, cross-country skiing, swimming or playing ball games, and 12 METs (12 kcal/kg/h) when training for competitive sports such as

running or cross-country skiing (Sallis et al. 1985). The LTPA index is calculated by multiplying the weekly frequency of LTPA sessions by the MET-value of the intensity of LTPA. The range of the index is from 0 to 60. A value of 60 represents a daily (computed as 5 times per week) LTPA of the highest intensity. LTPA has proven to be a reliable and valid estimator of cardio-respiratory fitness (Tuero et al. 2001). LTPA has been shown to be associated with a lower risk of overweight, hypertension, musculoskeletal disorders (Pihl et al. 2002) and cardiovascular risk (Sofi et al. 2007) and improved quality of life (Vuillemin et al. 2005).

In study IV, the level of leisure-time physical activity was measured with the question: “How much do you exercise and strain yourself physically in your leisure time?” The response options were as follows: (1) In my leisure time, I read, watch TV and do other activities where I do not move much and do not strain myself physically; (2) In my leisure time, I walk, cycle and move in other ways at least 4 h per week; (3) In my leisure time, I exercise at least 3 h per week, and; (4) In my leisure time, I practice regularly several times per week for competition. Response option (1) was considered the “low” category, response option, (2) was considered the “medium” category, and response options (3) and (4) were merged into the “high” category. This instrument has shown good internal validity for measuring all-cause and cardiovascular mortality (Tuero et al. 2001).

Questionnaires completed at the time of admission to the rehabilitation programme provided baseline and clinical data (studies I-III), before any interventions. In study II, six-month follow-up data was completed during the last 2 days of the third phase of the pain management programme and follow-up data at 12 months was collected via a postal questionnaire. In study III, during the rehabilitation programme, all subjects completed paper and computer versions of the TSK-FIN on two consecutive days with an interval of 7 to 8 hours. The two versions of the TSK-FIN were introduced in blocks of five to eight patients in a random order on the morning of day 1. If a subject completed the paper version in the morning of day 1, they subsequently completed the computer version in the afternoon of the same day. On day 2, the order was reversed. In study IV, the participants received a self-administered questionnaire asking about their socio-demographic factors, leisure-time physical activity, co-morbidities and kinesiophobia. They completed the questionnaire at home and returned it to the study site, where anthropometric measurements, blood pressure measurements, blood sampling and a balance test were carried out.

Co-morbidities. Participants were asked if during the last 12 months they had any co-morbidities that were identified or treated by a medical doctor. The answers were coded as “yes” or “no” in the analyses and classified as cardiovascular disease, musculoskeletal disease and mental disorder. In addition, participants were asked

if they had a road traffic accident, an accident at work or at home, a sports-related accident or an accident during their leisure time that required medical treatment.

4.3 STATISTICAL ANALYSES

Statistical analyses were performed with the Statistical Package for Social Sciences (SPSS), version 10 (I), Stata version 10 and SPSS version 15 (II), Stata version 11.1 and SPSS version 15 (III, IV) (SPSS inc, Chigaco, Illinois, USA), (StataCorp LP, College Station, Texas, USA). Shapiro-Wilk test was used to test normality of variables. Frequencies with percentages, medians with interquartile range (IQR), mean and standard deviations were used as descriptive statistics. In addition, 95 percent confidence intervals (95% CI) were used in studies II – IV. Pearson chi-square, t-tests or bootstrap-type t-test (IV) and analysis of variance were used in analysing data between groups. In the case of violation of the assumptions (e.g. non-normality), a bootstrap-type test was used. The bootstrap method is significantly helpful when the theoretical distribution of the test statistic is unknown or in the case of a violation of the assumptions (Efron and Tibshirani 1993). Cronbach's alpha was applied to calculate internal consistency. Bonferroni correction was performed to adjust for multiple comparisons. The statistical significance level was set at 0.05 in all studies.

Study I

The pain behaviour measures represent categorical data. Kappa statistics was chosen for calculation for both intra-observer reliability and inter-observer reliability. Kappa is a measure of “true” agreement, that is agreement beyond expected by chance (Cohen 1960). In addition, the percentage agreements are given, as it was not always possible to calculate Kappa values. The threshold for the acceptability of the Kappa score was set at >0.6 as Landis and Koch (1977) suggested. The relationships between the measures of pain behaviour, self-reported pain and physical function variables were investigated by Pearson product moment correlation using a Bonferroni correction for the large number of variables involved. Multiple regression analysis was used to determine the relative importance of physical impairment, pain and pain behaviour on self-report of disability. The variables were entered in blocks. Self-reported pain was entered first followed by pain behaviour, physical impairment variables and then physical function variables.

Study II

A bootstrap-type (Efron and Tibshirani 1991) (5000 replications) random coefficient regression was used for statistical comparison of the changes in repeated measurements. Confidence intervals (CI) for the mean of changes were obtained by bias-corrected bootstrapping (5000 replications). The effect size ('d') was calculated by using Cohen's method (Cohen 1988) for paired samples. An effect size of 0.20 was considered to be small, 0.50 was medium, and 0.80 was large. CIs for the effect sizes were obtained by bias-corrected bootstrapping (5000 replications). Multivariate linear regression analyses were used to identify the appropriate predictors of the TSK-FIN score using adjusted standardized regression coefficients Beta (β). The Beta value is a measure of how strongly each predictor variable influences the criterion (dependent) variable. The beta is measured in units of standard deviation. Cohen's standard for Beta values above 0.10, 0.30 and 0.50 represent small, moderate and large relationships, respectively.

Study III

The Intra-class Correlation Coefficients (ICC) for test-retest reliability (i.e. repeatability/stability over time) and for comparability (reproducibility) were calculated using a two-way random effects model (ICC 2.1). The difference between the two methods was assessed using a reproducibility coefficient with 95% bias-corrected bootstrap (5000 replications) confidence intervals and Bland - Altman method for limits of agreement (LoA). The Bland-Altman method (Bland and Altman 1986) was used for both methods to show the variability of results at the individual level. The differences between test and retest measurements were plotted against the corresponding mean for each subject. Statistical comparison of the difference in variance between two methods was performed using Pitman's test (Pitman 1939) for paired variances.

Study IV

The adjusted statistical significance between groups was evaluated by bootstrap type analysis (5000 replications) of co-variance (ANCOVA) with appropriate contrast. The cumulative distribution was calculated to estimate the prevalence of high kinesiophobia. The association between kinesiophobia and age was investigated using the Pearson correlation coefficient.

5 RESULTS

5.1 KINESIOPHOBIA, GENDER AND AGE (I, II, III AND IV)

The total number of the participants of this study was 1277 individuals. In study group IV, both men and women were older compared to the other study groups and subjects in sample III were older than in samples I and II (Table 1). The mean score (SD) of the TSK-FIN was 34.3 (7.1). Men had higher ($p < 0.001$) scores [mean (SD) 35.5 (7.4)] in the TSK-FIN compared to women [mean (SD) 33.3 (6.7)]. Among patient samples (I-III) the mean scores of the TSK-FIN were significantly higher ($p < 0.001 - p = 0.007$) compared to the general population (IV) (Table 2). Figure 3 shows the distributions of the TSK-FIN for men and women and figure 4 shows the distribution of the TSK-FIN for patients and the general population. A Shapiro-Wilk test indicated non-normality ($p < 0.001$). Among the general population (IV), a higher TSK-FIN score was significantly associated with the presence of cardiovascular disease ($p = 0.039$), musculoskeletal disease ($p = 0.018$) or mental disorders ($p = 0.015$) compared to the absence of the aforementioned after adjusting sex and age. The presence of an accident during the last 12 months was not associated with the TSK-FIN score. Internal consistency was high in the samples of studies I and III, and moderate in the samples of studies II and IV (Table 2).

Table 1. Number of males (%) and mean (SD) age of men and women across study samples.

	I N=51	II N=93	III N=94	IV N=1039	p
Men (%)	24 (47)	26 (33)	39 (42)	457 (44)	0.40
Age, Mean (SD)	45 (8)	44 (8)	47 (8)	50 (14)	
Men	44 (7)	44 (9)	46 (8)	51 (14)	<0.001
Women	45 (9)	44 (7)	47 (8)	50 (14)	

Table 2. Sample size, TSK score (mean, SD) and Cronbach's alpha of each study sample.

Study	N	TSK (mean, SD)	Alpha
I	51	36.8 (8.7)	0.83
II	93	37.9 (7.9)	0.80
III	94	37.2 (8.2)	0.82
IV	1039	33.6 (6.6)	0.72
Total	1277	34.3 (7.1)	0.75

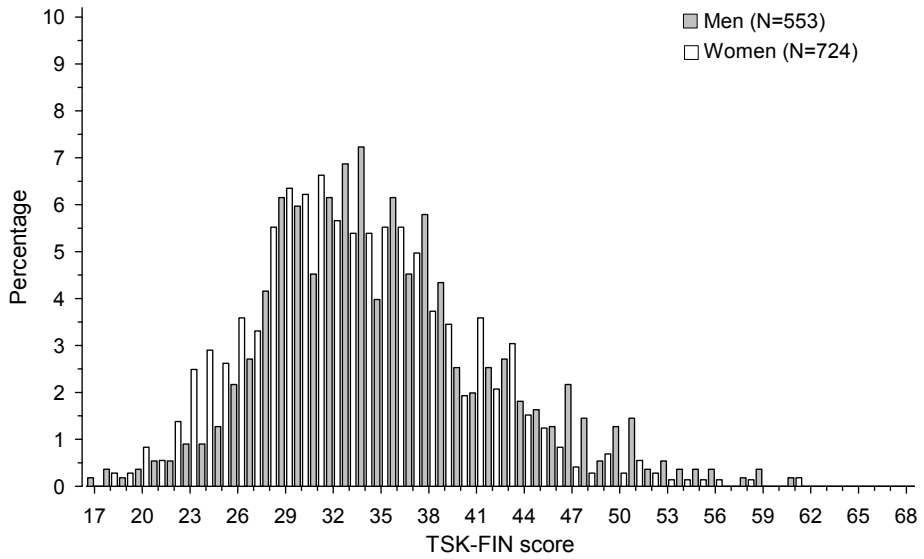


Figure 3. Distribution of the TSK-FIN score for men and women.
 TSK-FIN = The Finnish version of the Tampa Scale of Kinesiophobia

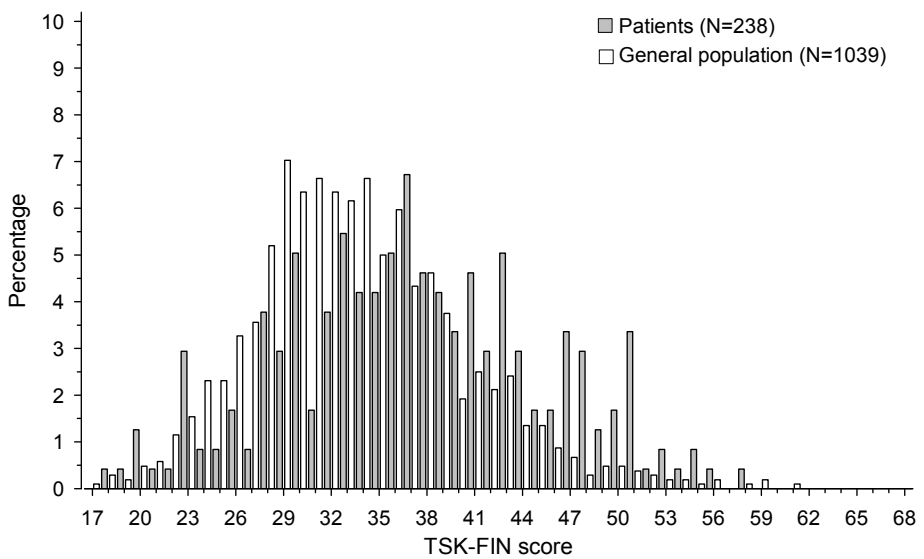


Figure 4. Distribution of the TSK-FIN score for patients and the general population.
 TSK-FIN = The Finnish version of the Tampa Scale of Kinesiophobia

Among the general population the TSK-FIN score and age were associated in both sexes (men: $R=0.17$, $p<0.01$; women: $R=0.19$, $p<0.001$). Men over 55 and women over 65 had higher TSK scores compared to younger persons. Among patient samples, there was no association between the TSK score and age ($R=0.18$, $p=0.78$) (Figure 5). Among men the TSK-FIN scores in each age group were higher in the patient samples compared to general population ($t=2.0$, $p=0.05$ - $t=6.8$, $p<0.001$). Among women the TSK-FIN scores were higher in patients in age group 35 - 44 yrs ($t=2.7$, $p=0.007$) and age group 45 - 54 yrs ($t=3.2$, $p=0.002$) compared to the general population.

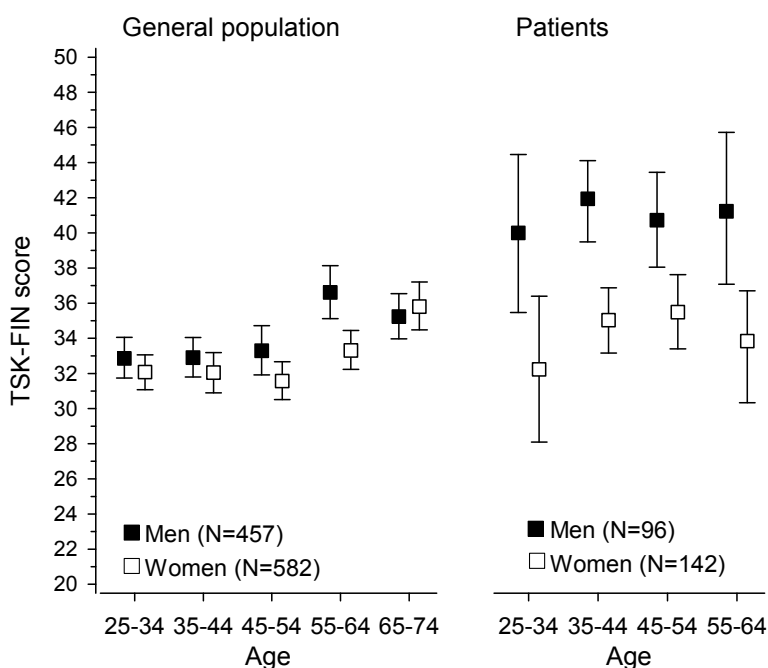


Figure 5. Mean and 95% CI's of the Tampa Scale of Kinesiophobia (TSK-FIN) scores for men and women by age groups.

TSK-FIN = The Finnish version of the Tampa Scale of Kinesiophobia

5.2 RELIABILITY AND COMPARABILITY OF THE PAPER AND COMPUTER VERSION OF THE TSK-FIN (III)

In study III, subjects scored higher in the computer version of the TSK-FIN, mean (SD) 37.1 (8.1) [95% CI 35.5 to 38.8], than in the paper version, mean (SD) 35.3 (7.9) [95% CI 33.7 to 36.9]. The mean difference between the computer and paper version was 1.9 [95% CI 0.8 to 2.9] ($p=0.001$). However, the Pitman's variance ratio of 1.04 [95% CI 0.92 to 1.18] ($p = 0.53$) indicates that variances in the computer and paper versions did not differ.

The test-retest reliability indicates excellent reliability. The internal consistencies were 0.80 (0.73 to 0.84) and 0.82 (0.75 to 0.86) respectively. The ICC for comparability was 0.77 (95% CI 0.66 to 0.85), indicating good reliability between the different methods. The reproducibility coefficient indicated that there is a 95% expectation that the paper and computer versions differ by less than 11 points (95% CI = 9 to 12). Figure 6 shows Bland-Altman plots for the 95% LoA between test and retest measures for both the computer and paper versions. In terms of individual variability, 62% varied by less than 3 points and 44% by less than 2 points.

Both the paper and the computer versions of the TSK-FIN were equally easy or difficult to complete. Sixty-eight per cent of subjects considered that the paper version of the TSK-FIN was easy to complete, 11% considered it difficult to complete and 21% did not consider it to be either difficult or easy to complete. For the computer version, the percentages were 69%, 11% and 20%, respectively. In the future, slightly more than half of the subjects would prefer to answer the questions using the computer version, whereas 17% would prefer the paper version; twenty-nine per cent of the subjects did not show any preference as to which version they would use. There was no association between the preferred method for future use and how much the subject used a computer. Also, there was no association between the preferred method for future use and how easy or difficult the paper and computer versions were to complete.

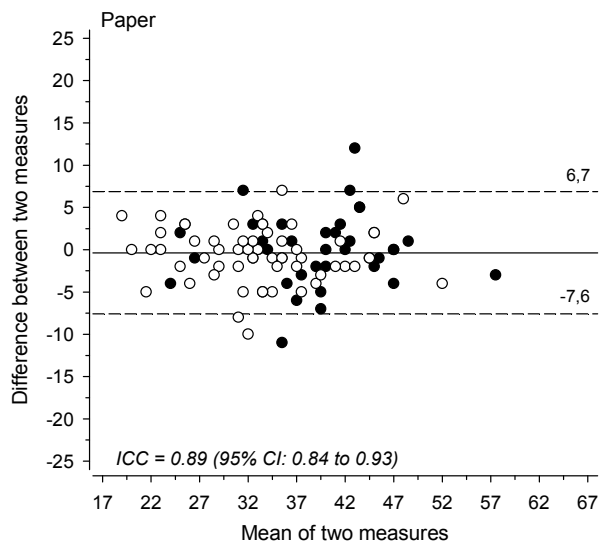
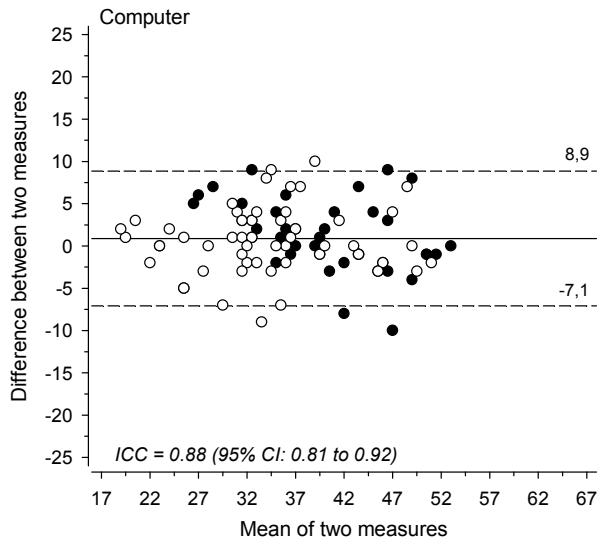


Figure 6. The difference between test and retest measures for both the computer and paper versions of the TSK-FIN plotted against the mean for each patient. The dotted line shows the 95% limit of agreement. Solid circles indicate men and open circles indicate women.

5.3 ASSOCIATION BETWEEN KINESIOPHOBIA AND SELF-REPORTED QUESTIONNAIRES (I, II)

There was a strong correlation between pain behaviour and subjective pain report and disability ($r=0.37$, $p<0.01$). The TSK-FIN had the strongest correlation ($r= 0.60$, $p<0.001$) to depression (Modified Zung), moderate correlations to pain behaviour ($r= 0.34$, $p=0.01$) and disability (ODI) ($r= 0.37$, $p=0.008$) and low correlation to subjective pain ($r= 0.30$). In study II, the level of kinesiophobia was associated with disability ($r=0.28$, $p=0.006$) and depressive symptoms ($r=0.27$, $p=0.01$). The low kinesiophobia group showed lower scores in ODI (mean 31, SD 11) than the medium (mean 37, SD 9) and high (mean 39, SD 14) kinesiophobia groups ($p=0.013$). The high kinesiophobia group had more depressive symptoms (mean 16, SD 7) than the medium and the low kinesiophobia groups ($p=0.028$), (mean 14, SD 8) and (mean 12, SD 6), respectively.

The relationship between subjective report of pain and the physical impairment measures was very poor. Subjective pain report correlated more closely with measures of physical function e.g. repetitive arching, timed walk and lifting. The correlations between total pain behaviour and physical function tests: performance of dynamic trunk exercises, repeated sit to stand, timed walk, and lift was strong ($P<0.01$). Only grip strength was not correlated with pain behaviour.

Pain intensity was the most important variable explaining disability (36% of the variance), pain behaviour contributed a further 14% and somatic perception 8% of the variance. Physical impairment and physical function variables failed to add to the explanation of disability. Kinesiophobia also did not contribute to the explanation of the initial levels of disability (I). In study II, the TSK-FIN accounted for only 4% of the variability of the pain intensity (Figure 7), 12% of the variability of self-rated disability (Figure 8), and 7% of the variability of self-rated depression (Figure 9).

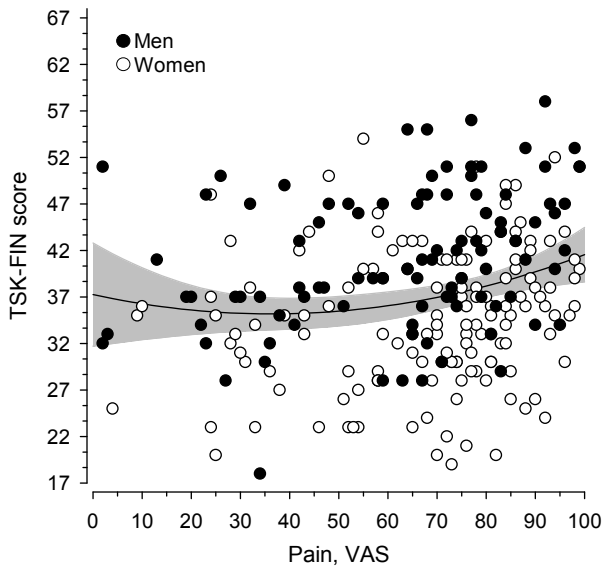


Figure 7. Quadratic relationship with 95% confidence intervals between TSK-FIN score and pain.
 TSK-FIN = The Finnish version of the Tampa Scale of Kinesiophobia
 VAS = Visual Analogue Scale

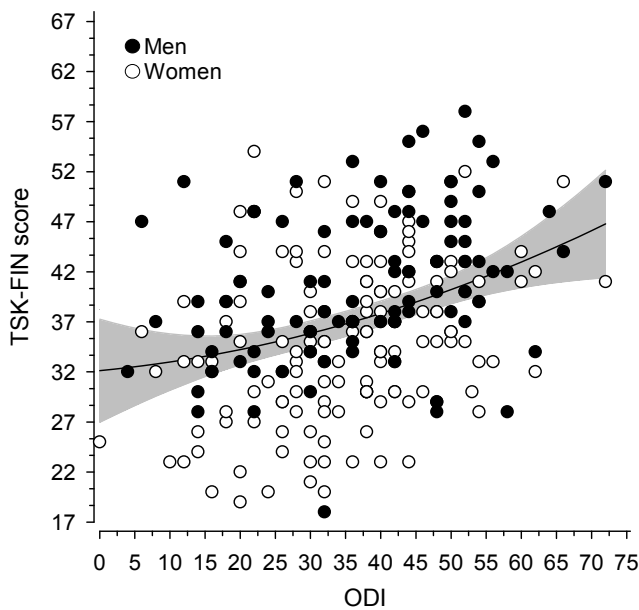


Figure 8. Quadratic relationship with 95% confidence intervals between TSK-FIN score and self-rated disability.
 TSK-FIN = The Finnish version of the Tampa Scale of Kinesiophobia
 ODI = Oswestry Disability Index

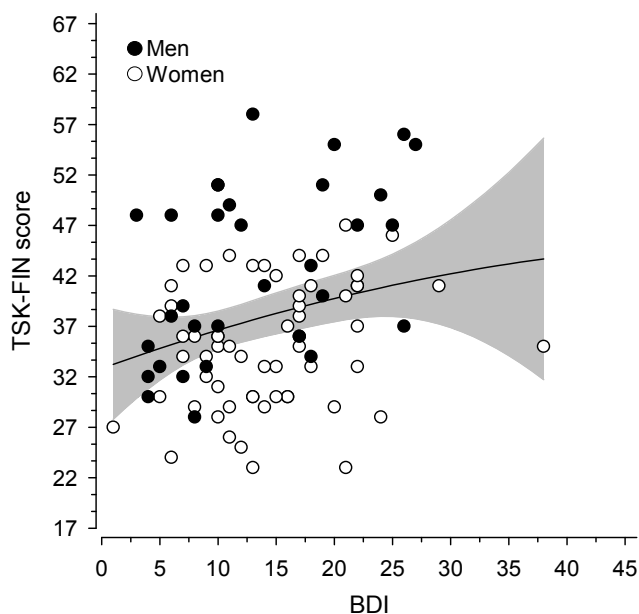


Figure 9. Quadratic relationship with 95% confidence intervals between TSK-FIN score and depression.

TSK-FIN = The Finnish version of the Tampa Scale of Kinesiophobia

BDI = Beck Depression Index

5.4 THE ASSOCIATION OF KINESIOPHOBIA TO LEISURE TIME PHYSICAL ACTIVITY (II, IV)

Among the general population (IV), there was a significant ($p < 0.001$) inverse linear association between kinesiophobia and leisure-time physical activity in both sexes after adjustment for age, whereas among patients (II), linear association was non-significant ($p = 0.46$) (Figure 10). However, kinesiophobia and the LTPA index were inversely associated among the patient sample. Among patients, the mean LTPA index of the high kinesiophobia group was lower (mean 17, SD 13) than in the low and medium kinesiophobia groups, (mean 26, SD 16) ($p = 0.012$). In the subgroup analyses among ‘only musculoskeletal disease’, ‘only accident during last 12 months’ or ‘presence of two or more diseases’ groups, the TSK-FIN score was inversely associated with physical activity. This association was not observed in the ‘apparently healthy’, ‘only cardiovascular’ or ‘only mental disorder’ subgroups.

Among men, patients in each LTPA group had higher ($t = 4.3$, $p < 0.001$ - $t = 5.3$, $p < 0.001$) mean TSK scores compared to general population, while among women there was significant difference ($t = 3.7$, $p < 0.001$) in the mean TSK score only in high LTPA group (Figure 10).

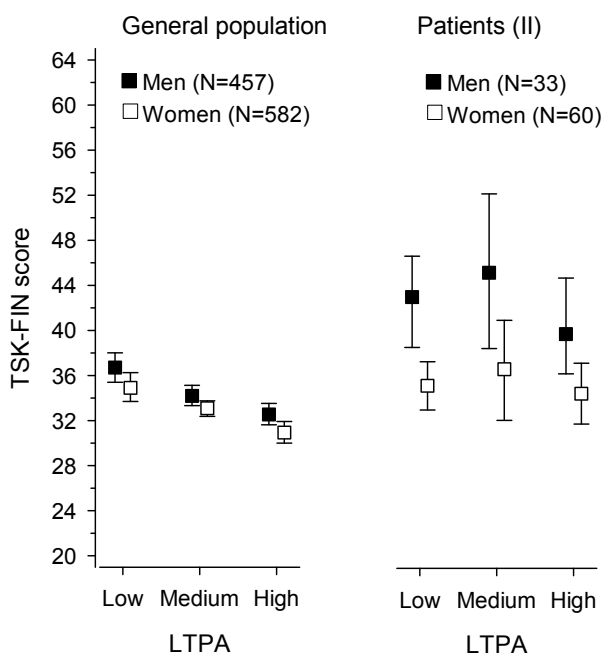


Figure 10. Mean with 95% confidence intervals of the TSK-FIN across LTPA groups for men and women among the general population and patient sample II.

TSK-FIN = Finnish version of Tampa Scale of Kinesiophobia

LTPA = Leisure-Time Physical Activity

At the 6-month follow-up patients among sample II with high kinesiophobia had increased their physical activity to the same level as the low and medium kinesiophobia groups. This change was maintained up to the 12-month follow-up. There were no changes in the low and medium kinesiophobia groups at the 6-month or 12-month follow-up. The mean change in physical activity in the whole sample was 4 (95% CI 1 to 7) ($p=0.008$). The mean change in the LTPA index among patients with high kinesiophobia was 8 (95% CI 3 to 13) ($p=0.023$), while patients with low kinesiophobia showed a mean change of 1 (95% CI -3 to 5) and the mean change for patients with medium kinesiophobia was 2 (95% CI -3 to 6). The mean change in TSK was -2.0 (95% CI -3.5 to -0.5) ($p=0.01$). The effect sizes of the change in the LTPA index and pain intensity at the 12-month follow-up were both moderate in the high kinesiophobia group while they were small in the low and medium kinesiophobia groups.

At the 12-month follow-up, there was no association between the change of kinesiophobia and the change of physical activity when exploring the whole sample ($r=0.10$). However, the association of change in kinesiophobia and physical activity was different in the three kinesiophobia sub-groups. Among patients with low

kinesiophobia, the association was strong ($r=0.48$), but only four (13%) patients had increased their physical activity and showed a decrease in kinesiophobia. In the medium and high kinesiophobia group the associations were weak ($r=0.10$ and $r=0.23$), but favourable changes in physical activity and kinesiophobia was observed in 10 patients (35%) in the medium kinesiophobia group, and in 14 patients (41%) in the high kinesiophobia group.

The strongest explaining variable for fear of movement was the male gender (standardized beta 0.33, $p<0.001$), followed by depression (Beta 0.22, $p=0.019$) and disability (Beta 0.21, $p=0.026$). Physical activity, pain and age did not reach significance. For the model, $r^2 = 0.24$ (95% CI: 0.07 to 0.35) (Figure 11).

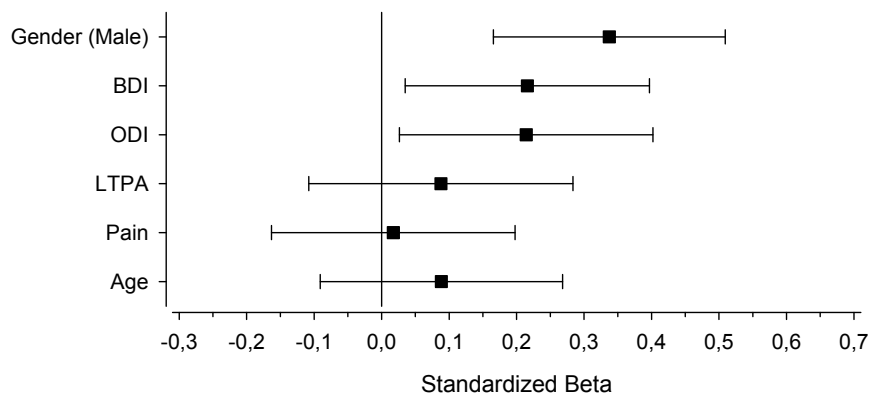


Figure 11. Multivariate relationships between TSK-FIN related factors (β -values with 95% confidence intervals). Beta values above 0.10, 0.30 and 0.50 represent small, moderate and large relationships, respectively.

BDI = Beck Depression Index

ODI = Oswestry Disability Index

LTPA = Leisure Time Physical Activity

5.5 PREVALENCE OF KINESIOPHOBIA AMONG THE GENERAL POPULATION (IV)

The cumulative distribution of the TSK-FIN was calculated for men and women separately in order to estimate the cut-off point of kinesiophobia within the general population (study IV). Of all subjects, 14.2% scored 40 points or more. There were no significant differences between men (15.3 %) and women (13.3 %). If the cut-off point for kinesiophobia is set at 37 points, 24.5% of the subjects are considered to have fear of movement (Figure 12).

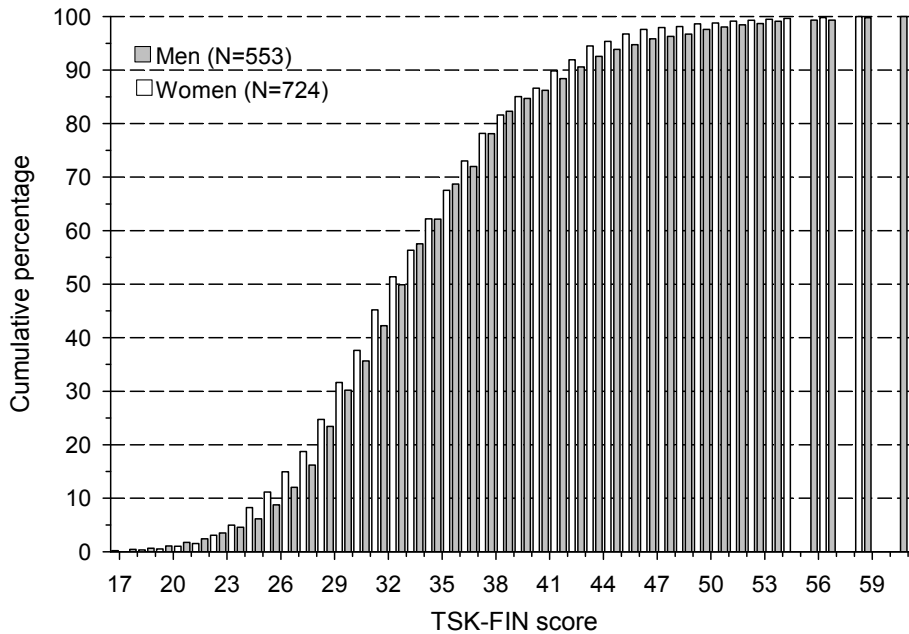


Figure 12. Cumulative distribution of the TSK-FIN scores for men and women among general population. TSK-FIN = Finnish version of the Tampa Scale of Kinesiophobia

5.6 RELIABILITY OF ASSESSMENT OF PAIN BEHAVIOUR

For the intra- and inter-observer reliability, a high percentage agreement and good to excellent levels of kappa scores for agreement were demonstrated (Table 3). The exceptions to this are facial expression (kappa 0.29) and verbal report of pain, which only just failed to reach the acceptable threshold with a kappa score of 0.58. Facial expression was therefore excluded from the final measurement instrument and verbal report of pain was retained in the measure.

After the exclusion of the facial grimacing score, the Cronbach's alpha for the total scores was 0.73, which demonstrates an acceptable level of internal consistency. The exclusion of the Verbal report of pain did not affect the alpha score (0.73) and it was retained in the final measure. The total score of pain behaviour was created for each subject by summing the total number of each category of pain behaviour.

Table 3. Inter- and intra-observer reliability of pain behaviour measure (n=18).

Variable	Observer one			Observer two			Observer one vs two		
	% agreement	Kappa	P	% agreement	Kappa	P	% agreement	Kappa	P
Distorted Gait	88.9	n/a	0.001	83.3	0.67	0.004	83.3	0.67	0.004
Audible pain behaviour	83.3	0.74	0.001	83.3	0.73	0.001	77.8	0.67	0.001
Facial Expression	72.2	0.29	0.18	88.9	0.60	0.01	72.2	0.29	0.18
Stopping/Resting	88.9	0.84	0.001	88.9	0.83	0.001	94.4	0.92	0.001
Touching/Holding	94.4	0.82	0.001	100	1.00	0.001	88.9	n/a	0.001
Verbal reports	88.9	0.61	0.005	88.9	0.73	0.002	83.3	0.58	0.02
Support/Leaning	83.3	0.71	0.001	93.3	n/a	0.001	77.8	0.68	0.001
Guarding/Bracing	83.3	0.74	0.001	88.9	0.85	0.001	83.3	0.69	0.001

6 DISCUSSION

Psycho-social factors are widely recognized to be responsible in the transition from acute to chronic pain and also in the maintaining of chronic pain. According to the fear avoidance model of pain, pain-related fear and avoidance behaviours may play an important role in those processes. Asymmetries and non-coordinated movement patterns 'guarded movements' in gait have been found to be associated with low back pain (Arendt-Nielsen et al. 1996) and asymmetries in gait are correlated with pain behaviour (Keefe and Hill 1985). Main and Watson (1996) and Watson et al. (1997) have suggested that pain-related fear plays a more important role in the development of guarded movements than pain severity or disability levels. One aspect of pain-related fear is fear of movement / kinesiophobia, measured by the Tampa Scale of Kinesiophobia (TSK). Avoidance behaviours may also be evaluated by the TSK or by pain behaviour assessment measures. For clinical rehabilitation practice, reliable and valid assessment tools and outcome measures are needed.

The aim of this study was to examine fear of movement among the Finnish general population and in patients with chronic musculoskeletal pain: how it can be evaluated, its prevalence and its connection to pain behaviour and physical activity. At first, an assessment tool for pain behaviour was developed and its reliability was studied. The relationship between pain behaviour, distress and physical function and impairment were also investigated. Secondly, the association between fear of movement and physical activity among chronic pain patients was studied in a multi-disciplinary bio-psycho-social pain management setting. Thirdly, the internal consistency, test-retest reliability and comparability of the paper and computer versions of the Finnish version of the Tampa Scale of kinesiophobia (TSK-FIN) among chronic pain patients were estimated. Fourthly, fear of movement among the general population was investigated and reference values in the Finnish general population were created.

6.1 TSK-FIN VALUES IN FINNISH PATIENT SAMPLES AND GENERAL POPULATION

Patients with musculoskeletal pain had significantly higher mean values in the total TSK-FIN score than the general population. Among various musculoskeletal pain patient samples, the differences of the total TSK-FIN score between samples with various locations of pain were statistically non-significant. In addition, among the general population, the presence of cardiovascular disease, musculoskeletal disease

or a mental disorder was associated with a higher TSK-FIN score compared to the absence of the aforementioned disorders. The TSK scores found in the Finnish population are in line with those from earlier studies. Houben et al. (2005) reported a mean TSK of 32.9 without back complaints and 33.6 for those with back complaints among the Dutch general population. However, they used re-phrased questions, which might have affected the results. Lundberg et al. (2009) reported a median value of 30 among the aerobics group and 44 for a patient group in respect to the TSK scores. In the current study, presence or absence of an accident during in the last 12 months did not have impact on the TSK-FIN score contrary to study of Turk and Holzman (1986), who reported that patients with traumatic onset of pain had higher score on the TSK. The observed difference of the total TSK score between patient and general population samples suggest the construct validity of the TSK-FIN.

In the present study, men had higher mean values in the total TSK-FIN score in all samples overall, which is in line with previous studies of various populations and countries (Vlaeyen et al. 1995b, Branstrom and Fahlstrom 2008, Roelofs et al. 2011, Luning Bergsten et al. 2012). In the general population sample, but not in the patient samples, age and the TSK-FIN score were significantly associated with one another in both sexes. Among patient samples, there was no association between the TSK-FIN score and age. Earlier, Roelofs et al. (2011) have noted that age was associated with the TSK score among Dutch patients, but not in Canadian and Swedish samples. Comparing the results of the current study to earlier studies more deeply among the general population is difficult because Houben et al. (2005) did not separately report the TSK scores for men and women or the association between fear of movement and age.

6.2 PSYCHOMETRIC PROPERTIES OF TSK-FIN

Reliability, validity and suitability to clinical use or research are essential properties for any measurement. The cultural adaptation process of the TSK-FIN was started by examining reliability (i.e. repeatability and reproducibility), internal consistency and also the comparability of two different methods of completing the TSK-FIN questionnaire. The acceptable reliability of the TSK-FIN questionnaire is a prerequisite of the validity for its clinical use. Furthermore, validity is a wider concept than reliability requiring data gathered from different situations for proper examination.

6.2.1 Internal consistency

The internal consistencies for the total scale of the TSK-FIN across patient samples were good (George and Mallery 2003) and they are consistent with previous studies. The internal consistencies (0.80 to 0.83) found in the present study in patients with chronic pain were somewhat higher than in studies of patients with chronic low back pain (Vlaeyen et al. 1995b, Woby et al. 2005) and acute low back pain (Swinkels-Meewisse et al. 2003a, Swinkels-Meewisse et al. 2003b, Woby et al. 2005). The internal consistency was at the same level as in studies on patients with chronic fatigue (Nijs et al. 2004), low back pain (Goubert et al. 2004), and mixed-pain patients (Cohen et al. 2003, Lundberg et al. 2004). Patients with neck pain have demonstrated a somewhat higher Cronbach's alpha (0.89) (Cleland et al. 2008) than in the present study. For the general population the internal consistency in this study was substantial but somewhat lower than among the general population in the study by Houben et al. (2005).

6.2.2 Reliability

Both methods to complete the TSK-FIN demonstrated good inter-test reliability and excellent test-retest reliability (Fleiss 1999). For both methods, LoA for test-retest reliability were acceptable suggesting suitability for clinical use. However, subjects had a tendency to score higher on the computer version, which suggests that the paper and the computer versions should not be used alternately. This observation of the present study slightly differs from the meta-analytic review by Gwaltney et al. (2008), who concluded that paper and computer versions of different patient-reported outcomes are overall equivalent.

The intra-class correlation coefficients found in this study were lower than among subacute and chronic LBP patients (Monticone et al. 2010) and musculoskeletal pain patients (Lundberg et al. 2004), but higher than among patients with chronic LBP (Woby et al. 2005), neck pain (Cleland et al. 2008) shoulder pain (Mintken et al. 2010) and in older people with chronic pain (Larsson et al. 2014).

The difference in the mean values between the paper and computer method might be due to the difference in lay-out. In the paper version, all items are visible all the time, so one can create an overall impression of the questionnaire before choosing the appropriate response option for each item. In addition, the paper version allows the opportunity to freely change/correct responses. In the computer version, only one item is visible at a time and it is not possible to go back to change any previous answers. On the other hand, having only one item visible at a time is an advantage of the computer version. The subject must respond to the question; the software used in this study did not allow the respondent to move on without answering the question. This is an advantage in respect to clinical rehabilitation

and research as it reduces missing information. Hanscom et al. (2002) found that computer versions of disability (ODI) and quality of life (SF-36) questionnaires had approximately half the missing response rates compared to paper versions. Cook et al. (2004) compared electronic and paper versions of two pain assessment scales (Short-form McGill Pain Questionnaire and Pain Disability Index) and found no significant difference between the versions. They also found that there was no association between computer use and the ease or difficulty of completing the computer version. Most subjects reported that it was easier to complete the computer version and that they would prefer to use the computer version in future, which was also observed in the present study. Furthermore, in clinical rehabilitation, it is a major advantage that members of the rehabilitation team have access to the collected information simultaneously.

Richard and Lauterbach (2004) listed the main advantages of computerized questionnaires: 1) there is less missing data, which can be reduced further by requiring the completion of an item before the subject can move on; 2) it is relatively easy to handle complex skip patterns; 3) out-of-range and ambiguous data can be eliminated; 4) computerized questionnaires reduce the effort and errors involved in entering data from paper sheets to a computer database, for example complex indices are calculated instantly; and, 5) compliance can be increased. Stone et al. (2002) reported that the actual compliance in computer diaries is 90% or better, whereas in paper diaries the actual compliance is 11% to 20%. Gwaltney et al. (2008) have suggests that subjects with little computer experience might have difficulties completing computer version of questionnaires, resulting biased measure. In this study, both versions of the TSK-FIN were equally easy or difficult to complete The fact, that there was no association between the preferred method for future and how much the subject used a computer and that there was no association between the preferred method for future use and how easy or difficult the paper and computer version were to complete, suggests that subjects' experience of computer use has not affected results.

Both Woby et al. (2005) and Roelofs et al. (2007) have suggested revising the original TSK by removing the reversed items (items 4, 8, 12 and 16) due to problematic psychometric properties. They have shown poor correlation with other items and internal consistency has been increased by the removal of these items. Based on factorial analyses, researchers have suggested additionally removing one or two items, resulting in a TSK12 (Vlaeyen 1995b) or a TSK11 (Woby et al. 2005, Roelofs et al. 2007). They found that the internal consistency and test-retest reliability of the revised TSK has been at the same level as with the original TSK17. In the present study, preliminary analyses shows that the test-retest reliability of the paper versions of the TSK-FIN17 and the TSK-FIN11 were equal (ICC = 0.89). In the computer version of the TSK-FIN11, the ICC was somewhat lower than in the

TSK-FIN17 (0.83 vs. 0.88). Also, Cronbach's alpha was lower in both versions of the TSK-FIN11 when compared to the TSK-FIN17. This preliminary finding suggests that removing certain items from the TSK-FIN would not necessarily increase the reliability or internal consistency of this scale.

6.3 STRUCTURE OF THE TSK

One explanation for the previous might lie in structure of the TSK. Some items may not be specifically related to fear of movement. There are different factor solutions (Vlaeyen et al. 1995a, Clark et al. 1996, Lundberg et al. 2004) of the TSK. The most popular seems to be the two factor solution proposed by Clark et al (1996), where one factor is named as 'activity avoidance', which reflects the belief that activity may result in (re)injury or increased pain. The second factor was named as 'pathological somatic focus', relating to beliefs about underlying and serious medical problems. However, preliminary factor analyses of the present data provided a five-factor solution. This might be due to the particular study sample, or there might be cultural reasons.

Vlaeyen et al. (1995b) originally proposed using TSK values greater than 37 as the cut-off point between low and high fear of movement. A number of different cut-off values, ranging from greater than 35 to greater than 44, have been used later (Lundberg et al. 2004). This reflects the fact that the distribution of the TSK might be sample specific. Many studies have used the mean or median as the cut-off point for high fear of movement, which makes sense from a statistical point of view. However, this may result in overestimating the number of patients with elevated or harmful fear of movement. Moreover, the assessment of an individual patient's level of fear of movement may be misleading if it is based on data drawn from a specific patient sample. Therefore, the cut-off point drawn from a large sample might give a more precise view. Based on the findings of the present study, when an individual patient's score in the TSK is greater than 40, clinicians should pay attention to the possibility of fear-avoidance related issues in the patient's manifestation of complaints. Regarding the assessment of fear of movement, the use of the TSK questionnaire is suggested because clinicians' ability to identify fear of movement in real-time e.g. during clinical assessment is limited (Calley et al. 2010).

There are only a few studies that connect diseases other than musculoskeletal diseases to fear of movement. Back et al. (2012) have reported a high level of kinesiophobia (TSK over 37 points) in patients with coronary artery disease. They used a modified questionnaire (TSK-SV Heart), which makes it difficult to compare the results with those from other studies. HajGhanbari et al. (2012) found that patients with chronic obstructive pulmonary disease have a higher level of

kinesiophobia than healthy people. In addition to musculoskeletal disease, the presence of cardiovascular disease and mental disorders was significantly associated with a higher TSK-FIN score than the absence of the aforementioned disorders in this study. Hence, fear of movement may reflect even more generally our tendency to react to various health conditions beyond musculoskeletal disorders. Whether or not the participant had been in an accident in the last 12 months was not associated with the TSK-FIN score.

6.4 FEAR OF MOVEMENT AND PHYSICAL ACTIVITY IN THE GENERAL POPULATION AND PATIENTS WITH CHRONIC PAIN

Among the general Finnish population, a significant inverse linear association between fear of movement and leisure-time physical activity in both sexes after adjusting for age was found. The association between fear of movement and the leisure time physical activity (LTPA) was more complex in patients. Linear association between fear of movement and leisure time physical activity was non-significant but the LTPA- index was significantly lower in patients with a high TSK-FIN score than in patients with a low or medium TSK-FIN score.

One explanation to the observed difference may be due to the fact that the LTPA-index is more precise as it pays attention not only to the intensity of physical activity but also to the frequency of activity. Furthermore, low physical activity in patients may be related to musculoskeletal or other problems itself. The second explanation for this issue might be that not all pain patients who have a high TSK score are fear-avoiders who reduce their activity due to pain. Hasenbring et al. (2001) has pointed out that some patients tend to complete their activities despite pain, thus further aggravating the pain themselves. In low back patients, the relationship between physical activity and pain is U-shaped rather than linear. Both inactivity and excessive activity represented an increased risk for low back pain (Heneweer et al. 2009). In addition, Huijnen et al. (2009) have shown that activity fluctuations over time are common and may increase disability in low back patients. This might also be the case with other musculoskeletal problems. A noteworthy point of view regarding literature is that pain-related fear has been measured by different questionnaires in various studies. Although researchers have found the correlation between the TSK and the fear avoidance beliefs questionnaire (FABQ) to be significant (de Souza et al. 2008, Askary-Ashtiani et al. 2014) the TSK and the FABQ measure different dimensions of pain-related fear. The FABQ is probably a more generic measure, while high scores in the TSK might be due to fear of a specific movement or movement direction.

Pain related fear has been inversely associated with lower physical activity (Elfving et al. 2007), weakened muscle strength (Crombez et al. 1999, Al-Obaidi et al. 2000, Goubert et al. 2004), decreased walking speed (Al-Obaidi et al. 2003) and with diminished performance on physical tasks (Geisser et al. 2000, Vowles and Gross 2003). However, this connection is not yet clear. Associations between pain related fear and functional capacity evaluations were generally weak or non-significant (Reneman et al. 2007). And further, study by Demoulin et al. (2013) shows that neither a task-specific tool (fear visual analogue scale) nor non-task-specific questionnaires (TSK and Photograph Series of Daily Activities, PHODA) correlated significantly with the physical spine tests for patients with chronic LBP. Taken together, the association between physical capacity and pain-related fear has not been thoroughly studied.

6.5 THE IMPACT OF THE PAIN MANAGEMENT PROGRAM ON FEAR OF MOVEMENT

The pain management program used in study II seems to produce positive effects in terms of physical activity among patients with a high level of kinesiophobia. At the 6-month follow-up, the high kinesiophobia group had increased their leisure time physical activity to the level of the low and medium kinesiophobia groups and maintained the change at the 12-month follow-up. The results are in line with studies by Kernan and Rainville (2007) and van Wilgen et al. (2009), who found that multidisciplinary rehabilitation decreases fear of movement, disability, pain and also increases walking distance (Sullivan et al. 2008). Luninggen Bergsten et al. (2012) found that decrease of fear of movement and activity limitations are in conjunction especially in patients who improve their scores on the TSK by eight points or more. In patients with anterior knee pain improvement in pain and disability is associated with a reduction in catastrophizing and fear of movement (Domenech et al. 2014). In addition, (Archer et al. 2014) found that after spinal surgery early postoperative fear of movement predicted pain intensity, pain interference, disability, and physical health at 6-month follow-up in patients with degenerative neck or lumbar conditions.

The observed favourable changes may be due to several reasons. There are one-to-one meetings with team members, lectures and discussion groups which provide information, cognitive and other rehabilitative elements. Most patients are aware of the benefits of exercising and physical activity but they do not feel safe enough to start or continue their activities without external support or guidance. The pain management program provides positive experiences on various physical activities (e.g. walking, water gymnastics, gym and Pilates-type exercise) in a safe environment. In addition, individual home exercise programs are guided. Also, via

peer support of the rehabilitation group one may learn how others have managed to solve problems related to the activities of daily living, physical activity and exercise. The observed changes confirm assumptions about rehabilitation mechanisms among chronic pain patients: by decreasing fear and increasing physical activity, it is possible to break the vicious circle of pain and disability (Vlaeyen et al. 1995b).

6.6 ASSESSMENT OF PAIN BEHAVIOUR

The current study tried to develop a pain behaviour measure using standardized every day functional tasks which might be perceived as challenging by those with back pain. The main advantages of standardized situations are 1) different patients can be compared as the demands on the patients are similar and 2) behaviours can be assessed during specific tasks that the patient may ordinarily avoid. However, results from specific structured situation may not be generalized other patient groups or other setting. Another potential source of bias is that patients may alter their behaviour because they know they are being observed (Keefe and Dunsmore 1992). However, using natural situations for assessment of pain behaviour may be more problematic. First, observations carried repeatedly over time require more resources i.e. more costs and they can be impractical in clinical settings. Secondly, patients may avoid painful tasks resulting fewer pain behaviours.

The results of the intra- and inter-observer reliability study demonstrated that the behaviours could be reliably recorded. Percentage agreement statistics are in line and the Kappa statistics in present study are in line with study by Prkachin et al. (2002) with the exception of facial expression. Low Kappa scores of facial expressions in the present study might be due to technical reasons. Videotapes were recorded so that the whole posture and gait of the subject was visible all the time. It was not always possible see their facial expression clearly on a video screen. Due to the unacceptably low Kappa score this item was removed from the final measure. Due to the borderline result (Kappa 0.58), falling only just outside the threshold set, it was decided that verbal reports would be retained in the final analysis and in the construction of the total pain behaviour score.

6.7 ASSOCIATION OF PAIN BEHAVIOUR WITH PERCEIVED DISABILITY, PHYSICAL IMPAIRMENT AND FUNCTION

The relationship between pain and pain behaviour has been demonstrated to be rather equivocal in other studies with reports for concordance, (Keefe and Block 1982, Romano et al. 1992) and discordance, (Richards et al. 1982, Kleinke and

Spangler 1988, Watson and Poulter 1997). In this study the association between pain and pain behaviour was strong. This may be a result of the nature of the tasks the subjects were required to undertake i.e. lift heavy weights, perform repeated exercises involving the low back and walk for a prolonged period. The subjects would tend to avoid physically challenging tasks in a routine clinical setting and pain behaviour might thus not be observed. Furthermore, pain behaviour observed in a setting not involving the performance of functional tasks may not adequately reflect the difficulty a subject experiences. Pain behaviour was associated with all using standardised range of motion and physical performance tests except maximal grip strength. This indicates that pain behaviour is specific to tasks which would be expected to stress the back, such as lifting, bending and walking.

In the present study, the associations between disability and pain behaviour, and disability and pain report were very similar. Earlier studies, (Richards et al. 1982, Keefe et al. 1987, Romano et al. 1992, Watson and Poulter 1997) have found close relationships between disability and pain behaviour and the correlations between disability and pain behaviours have been consistently higher than the correlations between report of pain and pain behaviours. This might be due the fact that patients in this study reported very high levels of disability and pain. Other studies into the relationships between pain, disability and function have not reported such high levels of pain and disability (Gronblad et al. 1997, Simmonds et al. 1998). Also, disability in those with back pain is highly influenced by psychological factors. The levels of depression and psychological distress in particular have been demonstrated to be highly associated with disability (Main et al. 1992, Averill et al. 1996, Glombiewski et al. 2010, Bener et al. 2013).

The regression analysis in the present study shows that pain intensity explained 36% of the variance in the self-report of disability. When adding pain behaviour and somatic anxiety to the model this increased to 48% and 56%, respectively. Depression and fear of movement did not contribute to the model. The physical impairment and physical function variables failed to add additional explanation of variance to the model. This does not mean that they are simply another measure of pain behaviour, they are the product of a number of influences of which pain behaviour is just one; fear/avoidance beliefs, pain expectancy and self-efficacy beliefs are also influential (Watson 1999b). Quite obviously, the intercorrelations between pain and other factors related to disability are so high that it is hard to distinguish the true impact of each variable on disability.

6.8 LIMITATIONS AND STATISTICAL CONSIDERATIONS

Study I. The relationships demonstrated between the variables in this study may not be representative of patient groups reporting lower levels of pain and disability. Also, the results from a low back pain patient group should be generalized with caution regarding other patient groups.

Kappa statistics is a robust index of agreement as it does not make distinctions among various types and sources of disagreement. Kappa is influenced by distribution and base-rates. Therefore, the magnitudes of kappa's are seldom comparable across different scales, procedures, or populations (Thompson and Walter 1988, Feinstein and Cicchetti 1990). Kappa may be low even though there are high levels of agreement and even though individual ratings are accurate. Whether a given kappa value implies a good or a bad rating system or diagnostic method depends on what model one assumes about the decision-making of the raters (Uebersax 1987).

Study II. There are a few limitations in collecting physical activity data. Firstly, only leisure time activity was registered and measures of occupational physical activities were not included in baseline questionnaires. However, if occupational activities had been taken into account, the sample size would have been remarkably smaller, as 38% of subjects were out of work. Secondly, the LTPA index is based on self-reporting of physical activity frequency and intensity, and people have a tendency to over-report their physical activity (Sallis and Saelens 2000). Motion sensors, such as a pedometer or an accelerometer are more objective methods of assessing physical activity. These devices tend to underestimate walking and overestimate jogging activity and they fail to detect arm movements, resistance exercise and the performance of external work, which might have an effect on the result (Bassett et al. 2000). Moreover, chronic pain patients most often favour to carry out physical exercises in water, where motion sensor devices cannot be used. Heart rate measurement devices can be used in water and energy expenditure can be calculated for the assessment of physical activity. Furthermore, the 12-month follow up data of physical activity would have been lost if motion sensors or heart rate measurement had been used. In addition, the data for physical activity among the general population would have been lost as using motion sensors or a heart rate monitor would have caused expenses far beyond the budget.

In any case, the information on leisure time physical activity was collected using the same method for all patients at every time-point. At the six month and 12 month follow-up the low and medium kinesiophobia groups reported no change in physical activity. In the case of a strong tendency towards over-reporting, one would also have expected an increase in physical activity also in the low and medium

kinesiophobia groups. It should also be noted that the patient sample included mixed pain syndromes, which may have influenced the assessment of disability.

Study III. Test-retest reliability data was collected over two consecutive days. There is a risk that the short time span between the measurements might have caused recall bias. However, the order of completing the paper and computer versions of the TSK-FIN was randomized and the order had no effect on reliability. Deyo et al. (1991) have proposed that the best time span for gathering test-retest reliability data is 1-2 weeks. Marx et al. (2003) have shown that there were no statistically significant differences in the test-retest reliability at 2 days and 2 weeks for four knee-rating scales and the eight domains of the Short Form-36 -questionnaire. Furthermore, a longer time span might also have caused bias. The subjects took part in the normal rehabilitation program, which consisted of three to four hours of physical activity and two to three hours of sitting during health education and group discussions. Some individuals reported more pain as a consequence of physical activity and prolonged sitting, which might have had an influence on their pain-related fear. In addition, the use of pain medication was not controlled. However, there was no difference in the test-retest reliability between patients with high and low pain intensity. In addition, the rehabilitation program could have decreased fear of movement while, on the other hand, physical exercise and participation in the rehabilitation program might have increased pain-related fear in some patients. Both of these may have an effect on individual ratings of fear of movement and reliability.

The statistical methods had pros and cons as well. There are different options for calculating IntraClass Correlation Coefficient (ICC) for different measurement situations. ICC combines information about bias and association as it reflects both the degree of correspondence and agreement among ratings, takes into account of the actual magnitude of the score (Portney and Watkins 2000) and it can be calculated so that it is sensitive to systematic bias in data (Atkinson and Nevill 1998).

One disadvantage is that ICC is strongly influenced by variance, which means that one cannot compare ICCs for samples with different between-subject variance. Furthermore, interpretation of ICC values is not simple although an ICC value closer to 1 indicates higher reliability. However, a coefficient is just a point estimate of the sample in question. In addition, ICC gives no indication of the magnitude of disagreement between measurements. According to the widely-used reference (Fleiss 1999), ICC values between 0.40 and 0.75 represent fair to good reliability and values above 0.75 represent excellent reliability. Atkinson and Nevill (1998) have stated that no clear definition of cut-off points has been presented for practical use. Therefore the calculation of confidence intervals would be more informative.

The Bland-Altman method for limits of agreement (LoA) has some advantages over ICC: the degree of agreement is easily detected visually and easy identification

of bias, outliers and any relationship between variance of measures with the size of the mean can also be detected. The complexity interpretation compared to a single reliability index and the need for a sample set of over 50 subjects to avoid a very wide 95% CI for LoA are the major disadvantages of the method (Rankin and Stokes 1998).

Cronbach's alpha value has been criticized for being sensitive to the number of items: the higher the number of items, the higher the alpha value will be (Cortina 1993). High alpha values (> 0.95), indicate that the items are too closely related. The calculation of the alpha value is based on an assumption of normal distribution, which is seldom observed (Svensson 2001), and therefore bias-corrected bootstrap confidence intervals for alpha were used.

Study IV. The participants consisted of a random sample from the Finnish population register in the Turku and Loimaa area. The response rate for the TSK-FIN was 61%. Harald et al. (2007) have pointed out that younger men with a low socio-economic status in particular are over-represented among non-responders. This was also observed in the present study, and it may have biased the results. If the non-participants were included, the studied associations could have been even stronger, particularly for the age-related increase in the score. There are limitations in using self-report questionnaires to assess physical activity. People have a tendency to overestimate their physical activity (Sallis and Saelens 2000). Motion sensors, such as pedometers or accelerometers, would have yielded more objective data on physical activity. However, these devices have limitations as stated earlier.

The information on co-morbidities was also based on self-reports. The participants were asked if they have had any co-morbidities during the last 12 months that were identified or treated by a medical doctor. Respectively, the participants were asked if they have been in a traffic accident, had an accident at work or at home, had a sports-related accident or had an accident during leisure time that has required medical treatment. Therefore, subgroup analyses regarding the association between kinesiphobia and leisure-time physical activity should be considered as preliminary; in addition, some of the subgroup sizes were small.

6.9 FURTHER STUDIES

Further studies are needed to examine the validity and factorial structure of the TSK-FIN with all the 17 items and also the widely used 11 item version of the TSK among patient samples with different musculoskeletal disorders and different pain modalities, such as neuropathic pain as well as among the general population. Also, studies of measurement properties such as test-retest reliability, predictive validity

and internal consistency within the general population are warranted. The content validity of the TSK clearly needs to be explored with a larger sample including measures of disability and functioning as well as psychosocial dimensions: health related quality of life, and factors related to the FAM e.g. catastrophizing, self-efficacy and pain behaviour. In addition, further research is required to study the minimal detectable change of the TSK-FIN.

To study the validity of the TSK more deeply, the association between fear of movement and its subscales and physical activity should be replicated in a larger sample, providing an opportunity to study different subgroups of pain syndromes more closely among the general population and use novel methods to document physical activity by means of direct measurements. In further studies direct measurements of the level of activity would give a more reliable estimation of the connection between fear-avoidance and physical activity.

A larger study regarding assessment of pain behaviour is required. The relative importance of pain behaviour and fear-avoidance related variables in the development, maintenance and resolution of disability following rehabilitation interventions will be the subject of further research. An interesting link between pain behaviour and fear-avoidance is guarding, which need to be explored. Also, the development of an on-line pain behaviour assessment method is warranted.

7 MAIN FINDINGS AND CONCLUSIONS

Study I: The results demonstrate that, in this group of highly disabled individuals reporting high levels of pain, pain report and the subject's consequent pain behaviour were the most important determinants of disability, physical impairment and physical function. This functional, video-based assessment of pain behaviour is a reliable measure of pain behaviour in back pain. The total scores for pain behaviour correlate very strongly with functional performance and specific impairment (the range of motion of the low back) but only for tasks that involve the back; tests involving the upper limb (grip strength) were not affected. This indicates that this particular test of pain behaviour is suitable for the assessment of those with back pain problems, but probably not other conditions.

Study II: The pain management program seems to produce positive effects in terms of physical activity among patients with high kinesiophobia. At the 6-month follow-up, the high kinesiophobia group had increased their leisure time physical activity to the level of the low and medium kinesiophobia groups and maintained the change at the 12-month follow-up. There were no significant changes in the subjects with low and medium kinesiophobia at the 6-month or 12-month follow-up. Furthermore, the decrease in pain intensity was greatest in the high kinesiophobia group, although the difference between the groups was not statistically significant. The effect sizes of the change of pain intensity were moderate in the high kinesiophobia group and small in the low and medium kinesiophobia groups. The association of the change of fear of movement and physical activity was different in the three kinesiophobia groups. In the high kinesiophobia group, physical activity increased and fear of movement decreased in 41% of the subjects. The respective change was observed in 35% of the subjects in the medium kinesiophobia group, whereas in the low kinesiophobia group this change occurred in only 13% of the subjects. As far as the author knows, this is the first time that an increase in physical activity has been demonstrated in conjunction with a decreased fear of movement in patients with moderate disability.

Study III: Based on the findings in this study, the Finnish version of the TSK has acceptable reliability for assessing kinesiophobia in a mixed musculoskeletal pain population and the TSK-FIN is suitable for clinical use. In order to enhance the comparability of the paper and computer versions of any questionnaire, the versions should have a similar layout (all items on each page should be visible all the time) and the computer version must include the option to go back and make changes

to previous answers, when necessary. It is concluded that the paper and computer versions are highly comparable methods for collecting data as almost two-thirds of the subjects' scores differed by less than three points. Most of the subjects in the present study preferred to complete the computer questionnaire, which should be taken into account when planning future studies. In an ideal situation, the data should be collected in a similar manner during the course of rehabilitation or clinical research.

Study IV: Patients had significantly higher mean values in the total TSK-FIN score than the general population. Among various musculoskeletal pain patient samples the differences of the total TSK-FIN scores between samples were statistically non-significant. In addition, among the general population, the presence of cardiovascular disease, musculoskeletal disease or a mental disorder was associated with a higher TSK-FIN score compared to the absence of the aforementioned disorders.

Reference values for the TSK- FIN have been presented. Earlier studies have shown that there is no clear single cut-off point for kinesiophobia, and different cut-off points have been suggested. The findings of the present study support the suggestion of Lundberg et al. (2004) that a TSK score of over 40 points should direct clinicians' attention towards the possibility of pain-related fear and adjust the treatment plan to address specific needs. Age and the TSK-FIN score were associated with one another in both sexes; older age groups had higher scores than younger ones. Men had higher mean scores overall and there were also gender differences in an item-by-item comparison. Kinesiophobia and leisure-time physical activity were associated with one another; likewise, the presence of co-morbidities was associated with the TSK-FIN score. The relevance of fear of movement in daily practice among musculoskeletal patients is quite evident.

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APPENDICES

APPENDIX 1. Suomenkielinen liikkumisen pelko/TSK -lomake

Nimi:	Hetu	Pvm:
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Tähän on kerätty ilmaisuja joita henkilöt ovat käyttäneet kuvaamaan olotilaansa. Ole hyvä ja rastita kunkin lauseen kohdalla vaihtoehto, joka kuvaa parhaiten mielipidettäsi.

		Täysin eri mieltä	Jonkin verran eri mieltä	Jonkin verran samaa mieltä	Täysin samaa mieltä
1.	Pelkään loukkaavani itseni, jos harrastan liikuntaa	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	Jos yrittäisin voittaa kivun, se vain pahenisi	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.	Kehoni viestii, että minussa on jotain pahasti vialla	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.	Kipu todennäköisesti helpottaisi, jos harrastaisin liikuntaa	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.	Terveystilaani ei oteta tarpeeksi vakavasti	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.	Onnettomuus on lisännyt loukkaantumisalttiuttani pysyvästi	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.	Kipu on aina merkki siitä, että olen loukannut itseni	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.	Vaikka jokin pahentaisi kipua, se ei välttämättä ole vaarallista	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.	Pelkään, että loukkaan vahingossa itseni	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.	Paras tapa estää kipua pahenemasta on olla varovainen ja varoa turhia liikkeitä	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.	Minulla ei olisi näin paljon kipua, ellei kehossani olisi jotain pahastikin vialla	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12.	Vaikka minulla on kipuja, oloni olisi parempi, jos olisin fyysisesti aktiivinen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13.	Kipu kertoo, milloin on syytä lopettaa liikunta, jotta loukkaisi itseäni	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14.	Minun tilassani olevalle ihmiselle ei todellakaan ole terveellistä olla fyysisesti aktiivinen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15.	En voi tehdä kaikkea mitä normaalit ihmiset tekevät, koska loukkaan itseni liian helposti	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16.	Vaikka jokin tuottaa minulle paljon kipua, en pidä sitä varsinaisesti vaarallisena	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17.	Kenenkään ei pitäisi joutua harrastamaan liikuntaa silloin kun on kipuja	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>