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SECONDARY PREVENTION OF LOW BACK PAIN IN OCCUPATIONAL HEALTH SERVICES

LONG-TERM EFFECTIVENESS AND COST-EFFECTIVENESS OF EARLY INTERVENTIONS

Jarmo Rantonen

ACADEMIC DISSERTATION

To be presented for public examination with the permission of the Faculty of Medicine of the University of Helsinki, in Auditorium Porthania PIII, Yliopistonkatu 3, Helsinki, on 13th of December 2019, at 12 noon.

Helsinki 2019
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ISBN 978-951-51-5658-7 (paperback)

ISSN 2342-3161 (print)
ISSN 2342-317X (online)

Hansaprint; Turenki 2019
“Believe those who are seeking the truth. Doubt those who find it” André Gide
ABSTRACT

Background: Four out of five people will experience low back pain (LBP) during their lives. Most LBP episodes pass within one to three months, but about one third reoccur within one year. One in ten people suffer from chronic LBP. Because LBP mainly affects the working-age population, it often leads to serious socio-economic consequences at the personal, employer and societal level. Therefore, it is the most common disabling condition on a global scale. To prevent LBP from developing into a recurrent, chronic and potentially disabling condition, risk-based assessment and targeted interventions should be carried out in the early stage. Hence, the main questions regarding the prevention of LBP and its consequences are: At whom should preventive actions be targeted, how and when?

Aims: This thesis evaluates the effectiveness of early-stage interventions offered to employees who reported disabling pain and stiffness in their low back area but were still able to work.

Methods: An employee survey, recruitment of participants and secondary preventive interventions were carried out in an occupational health (OH) setting. Employees were selected for the study cohort and later categorized into ‘mild’ and ‘moderate’ LBP subgroups according to their responses in the employee survey, based on pre-defined, low back specific criteria. After this, the study participants were allocated into two randomized controlled trials, either the patient information option or the active rehabilitation option. A random sample represented the natural course of LBP as a no-intervention control for both trials. The effectiveness of the interventions was evaluated on the basis of low-back-specific outcomes and sickness absence in comparison to the those of the controls. In addition, health care resource utilization was evaluated in the patient information group.

Results: In both subgroups, a secondary preventive approach showed improvements in some low-back-specific outcomes and quality of life in comparison to controls. In the ‘mild’ subgroup, health care costs decreased at the societal level in both patient information arms and booklet information was cost-effective. Sickness absence also decreased. Although
absolute improvements were minor, the effects were substantial with respect to the low baseline levels.

Conclusions: Early interventions are recommended for pre-defined, symptom-based employee groups as a preventive management strategy for disabling LBP in OH settings.

Tavoitteet: Tämä väitöstutkimus selvitti varhaisen vaiheen toimenpiteiden tehoa työntekijöillä, jotka raportoivat toimintakykyä heikentävää alaselkäoireita siinä määrin, että sen arvioitiin olevan riskitekijä alaselkäkivun kroonistumiselle.

**Tulokset:** Riskiryhmien mukaisesti suunnatut, ennaltaehkäisevät interventiot vähensivät alaselkäoireita ja paransivat elämänlaatua molemmissa interventio-optioissa, verrattuna selkäsairauden luonnolliseen kulkuun. Lieväoireisten optioissa, yhteiskunnan tasolla mitatut terveydenhuollon kustannukset vähenivät molemmissa potilasinformaatioryhmissä ja potilasinformaatio pelkän selkäkirjan muodossa oli kustannusvaikuttavaa. Vaikutukset sairauspoissaoloihin olivat marginaalisia. Vaikka interventioiden absoluuttiset tulokset olivatkin pienet, ne olivat merkittäviä suhteessa mataliin lähtöarvoihin.

**Johtopäätökset:** Alaselkäkivun kroonistumista ehkäisevät varhaisen vaiheen interventiot kohdistettiin oireiden perustella etukäteen määritellylle joukolle työntekijöitä, jotka raportoivat alaselkäkivun heikentävän heidän toimintakykyään. Interventiot osoittautuivat tehokkaiksi ja ne soveltuvat työterveydenhuollon toimintaympäristöön.
ACKNOWLEDGEMENTS

The basis of this research project goes back to 1990s when I was working as an OH physician. I found myself wondering why several employees repeatedly came to my surgery complaining about LBP. Usually, I offered them pain killers and a sickness absence note, and only occasionally more advanced procedures such as self-care advice, tempered work or low back-specific rehabilitation. There was no systematic policy to manage recurrent LBP. I saw a need for change.

This intervention study started in September 2001, but a substantial number of arrangements were made before this; for example, the design of the study using employee survey and questionnaires, the ethics review board assessment, and approvals of and agreements with other stakeholders. Without the help and guidance of my supervisors, Simo and Jaro, and the excellent co-operation with the UPM Kaukas directors, I would never have accomplished this work.

My deepest gratitude goes to my honoured supervisors, Docent Simo Taimela and Professor Jaro Karppinen, who patiently and persistently guided me throughout the research project which lasted so many years. I owe you both so much! My warmest thanks go to my co-writers, Satu Luoto, Markku Hupli, Antti Malmivaara, Aki Vehtari and Eira Viikari-Juntura, for their invaluable support, expertise and guidance throughout this study.

I also wish to thank the personnel of the physiotherapy outpatient unit of Lappeenrannan Fysikaalinen Hoitopalvelu and the South Karelian Central Hospital’s Physical Medicine unit, the worker’s union representatives, the OHS unit personnel, and the HR department of UPM Kaukas, especially my former superiors Mr Markku Korpela and Dr Pekka Helo.

Several organizations, colleagues and co-workers encouraged me to continue with this study, and kindly offered their help and support. Thank you, directors and colleagues at the Finnish Institute of Occupational Health (FIOH), Attendo and Lappeenranta University of Technology (LUT). I express my special gratitude to Dr Rahman Shiri and Director Irma Welling (retired) from FIOH and Professor Ari Jantunen (LUT). Special thanks go to Dr Katja Ryynänen and Mrs Annu Voutilainen. Preliminary examiners,
Docent Marja Mikkelsson and Docent Helena Miranda, thank you both for being very thorough and constructive in your comments. I received my first grant for the study from the Centenary Foundation of Kymi Corporation – after which there was no turning back. Financial support was later received also from other organizations that I greatly respect. Thank you all!

Although this project took me away from home so many times, my family tirelessly supported me and encouraged me to carry on. Thank you my dearest Päivi, my children Karoliina, Janne-Perttu, Otso-Pekka, Juho-Paavo, and Unna-Maria. I hope you will all be able to live your lives and careers according to your best aspirations. Sadly, my parents were not able to see the completion of this study, but I rest assured of their faith in me from the very beginning.

All my dear friends, thank you for believing in me.

Lappeenranta, November 1st, 2019

Jarmo Rantonen
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**ABBREVIATIONS**

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<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>15-D</td>
<td>15-dimensional, health-related, quality of life questionnaire</td>
</tr>
<tr>
<td>Advice</td>
<td>Back Book® information and advice; RCT2 intervention arm (also shown in articles and figures as BB)</td>
</tr>
<tr>
<td>BB</td>
<td>Back book®; RCT2 intervention arm</td>
</tr>
<tr>
<td>BB+A</td>
<td>Back book® and advice; RCT1 intervention arm</td>
</tr>
<tr>
<td>BMI</td>
<td>Body mass index</td>
</tr>
<tr>
<td>Booklet</td>
<td>Back Book® information booklet; RCT1 intervention arm (also shown in articles and figures as BB)</td>
</tr>
<tr>
<td>CBT</td>
<td>Cognitive behavioural therapy</td>
</tr>
<tr>
<td>CEA</td>
<td>Cost-effectiveness analysis</td>
</tr>
<tr>
<td>CEAC</td>
<td>Cost-effectiveness acceptability curve</td>
</tr>
<tr>
<td>CE-pane</td>
<td>Cost-effectiveness plane</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence Interval</td>
</tr>
<tr>
<td>Combined</td>
<td>Back Book® and advice ; RCT1 intervention arm (also shown in articles and figures as BB)</td>
</tr>
<tr>
<td>DBC</td>
<td>Documentation-basedCare; RCT2 intervention arm</td>
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<tr>
<td>DEPS</td>
<td>Depression scale</td>
</tr>
<tr>
<td>e.g.</td>
<td>exempli gratia - ‘for the sake of example’</td>
</tr>
<tr>
<td>et al.</td>
<td>et alia (lat.), meaning ‘and others’</td>
</tr>
<tr>
<td>FAB</td>
<td>Fear avoidance beliefs</td>
</tr>
<tr>
<td>FABQ</td>
<td>Fear Avoidance Beliefs Questionnaire</td>
</tr>
<tr>
<td>FABQ_{ph}</td>
<td>Fear Avoidance Beliefs Questionnaire, physical activity subscale</td>
</tr>
<tr>
<td>FABQ_{w}</td>
<td>Fear Avoidance Beliefs Questionnaire, work subscale</td>
</tr>
<tr>
<td>FU</td>
<td>Follow-up</td>
</tr>
<tr>
<td>GP</td>
<td>General practice</td>
</tr>
<tr>
<td>HC</td>
<td>Health care</td>
</tr>
<tr>
<td>HRQoL</td>
<td>Health-related quality of life</td>
</tr>
<tr>
<td>i.e.</td>
<td>id est - ‘that is to say’</td>
</tr>
<tr>
<td>IC</td>
<td>Incremental cost</td>
</tr>
<tr>
<td>ICER</td>
<td>Incremental cost-effectiveness ratio</td>
</tr>
<tr>
<td>IE</td>
<td>Incremental effect</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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<tr>
<td>--------------</td>
<td>-----------</td>
</tr>
<tr>
<td>LB</td>
<td>Low back</td>
</tr>
<tr>
<td>LBP</td>
<td>Low back pain</td>
</tr>
<tr>
<td>LOCF</td>
<td>Last observation carried forward</td>
</tr>
<tr>
<td>MI</td>
<td>Multiple imputation</td>
</tr>
<tr>
<td>MSD</td>
<td>Musculoskeletal disease(s)</td>
</tr>
<tr>
<td>NC</td>
<td>Natural course of LBP</td>
</tr>
<tr>
<td>NC_mild</td>
<td>Natural course of LBP, control arm of Mild</td>
</tr>
<tr>
<td>NC_moderate</td>
<td>Natural course of LBP, control arm of Moderate</td>
</tr>
<tr>
<td>NICE</td>
<td>National Institute for Health and Clinical Excellence</td>
</tr>
<tr>
<td>ODI</td>
<td>in this thesis: the sum value of Oswestry Disability Index (also: OSW)</td>
</tr>
<tr>
<td>OH</td>
<td>Occupational health</td>
</tr>
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<td>OHS</td>
<td>Occupational health services</td>
</tr>
<tr>
<td>OP</td>
<td>Occupational (health) physician</td>
</tr>
<tr>
<td>OR</td>
<td>Odds ratio</td>
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<tr>
<td>PHI</td>
<td>Physical impairment</td>
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<td>Physio</td>
<td>Documentation-based Care; RCT2 intervention arm (also shown in articles and figures as DBC)</td>
</tr>
<tr>
<td>PMU</td>
<td>Physical medicine unit; RCT2 intervention arm</td>
</tr>
<tr>
<td>PT</td>
<td>physiotherapy</td>
</tr>
<tr>
<td>p</td>
<td>(p-value) probability of error when null hypothesis is rejected (level of statistical significance)</td>
</tr>
<tr>
<td>QoL</td>
<td>Quality of life</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomized Controlled Trial</td>
</tr>
<tr>
<td>Rehab</td>
<td>Physical medicine unit; RCT2 intervention arm (also shown in article and figures as PMU)</td>
</tr>
<tr>
<td>RM-18</td>
<td>(also RMDQ) Roland-Morris 18-item Disability Questionnaire</td>
</tr>
<tr>
<td>SA</td>
<td>Sickness absence(s)</td>
</tr>
<tr>
<td>SD</td>
<td>Standard deviation</td>
</tr>
<tr>
<td>SF-36</td>
<td>36-Item Short Form Survey - Quality of life measure</td>
</tr>
<tr>
<td>VAS</td>
<td>Visual Analogue Scale</td>
</tr>
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</table>
Low back pain (LBP) is one of the leading causes of disability all over the world (Hoy et al. 2014) and is extremely common among the Finnish workforce. The lifetime prevalence of LBP varies between 38% and 84% in adult populations (Burton et al. 2006, Hoy et al. 2010a, Hoy et al. 2010b) and mainly affects people during their active years. Acute LBP is basically a benign and self-limiting condition, but symptoms often recur and sometimes lead to chronic disability; conditions that have serious socio-economic consequences at the personal, employer and societal level (Steenstra et al. 2006b, Hoy et al. 2014).


However, according to several systematic reviews (Mairiaux and Loomis 2012, Schaafsma et al. 2015, Steffens et al. 2016, Foster et al. 2018), randomized controlled studies (RCT) that have focused on the secondary prevention of LBP in OH settings have been few. To prevent LBP from developing into a chronic, potentially disabling condition, early stage assessment of LBP symptoms and tailored interventions according to patients’ symptom levels seem to promote a more efficient secondary preventive approach (Burton et al. 2006, Choi et al. 2010).

In this thesis, I focus on non-acute, non-specific LBP and its related symptoms among the workforce. ‘Non-acute LBP’ means recurrent or persisting LB symptoms for which the patient has not immediately sought care. Non-specific LBP also excludes traumatic origins and specific causes
that may lie behind LBP; for example, disc herniation, malign manifestations or rheumatic disease. Therefore, this study is also limited to non-surgical treatment of LBP (Chou et al. 2017).

I present an extensive, multiphasic intervention study that was conducted in a large forestry company in Lappeenranta, Finland, in 2001–2005. This pragmatic study began with an employee survey that enabled the modelling of a cohort of employees suffering from potentially disabling, recurrent or subacute LBP. Eligible employees were categorized into subcohorts according to their symptom levels. Later, a twofold randomized controlled intervention study was executed among these employees. Intervention groups and corresponding natural course (NC) control groups were followed up over one, two and four years.
Review of the Literature

2 REVIEW OF THE LITERATURE

2.1 LOW BACK PAIN

2.1.1 DEFINITIONS AND CLASSIFICATION

‘Low back pain’ refers to symptoms (pain and stiffness) that are located in the area between 12th ribs and inferior gluteal folds on the posterior part of the human body (Engers et al. 2008). (Figure 1)

![Figure 1](image)

Figure 1. Location of low back pain (‘x-back’ in Finnish). Illustration of upper body with ‘x’ used in study questionnaires, information leaflets and articles throughout the study.

The common definition of LBP is grounded in the aetiology of symptoms. Specific LBP (about 5% of all LBP) is caused by, for example, rheumatic disease, herniated intervertebral disc, spinal stenosis, malignancy in the LB area, osteoporotic or traumatic fracture, polymyalgia rheumatica, or abdominal aneurysm (Dionne et al. 2008, Majid and Truumees 2008, Hoy et al. 2010a). In contrast, non-specific LBP (about 95% of all LBP) seems to have no single identifiable cause or its cause is often multifactorial.

The historic classification of LBP is based on the duration of symptoms (Table 1). Sub-acute LBP is often missing from definitions (Airaksinen et al. 2006, Krismer et al. 2007, Hayden et al. 2010).
Table 1. Historic classification of LBP.

1. **Acute LBP** – symptoms last less than 6 weeks
2. **Sub-acute LBP** – symptoms last at least 6 weeks but no longer than 12 weeks
3. **Chronic LBP** – symptoms last more than 12 weeks

Although still largely used, the classic definition of LBP may often be misleading and is not always completely adequate in different cultural surroundings, populations or patient groups (Deyo et al. 2015).

In addition to previous classifications, *recurrent LBP* is generally used when the iterative occurrence of LB symptoms is emphasized. Evidence shows that recurrence is the major characteristic of non-specific LBP (Costa Lda et al. 2009). Recurrence rate may vary between 24% and 80% over one year, but figures depend on, for example, the length of the symptom-free period between LBP episodes and the way in which we determine the iterative rate over a period of time (Hoy et al. 2010a). Highly prevalent and recurrent LBP is difficult to distinguish from the subacute or chronic condition (Stanton et al. 2009, Stanton et al. 2010, Stanton et al. 2011).

Recently, the National Institute of Health (NIH) Task Force in the United States (Deyo et al. 2015) recommended a more comprehensive definition of chronic LBP, which includes not only the assessment of pain intensity, but also the estimation of the patient’s activity and physical function.

For many scientists and experts in this field, *back pain* means the same as *low back pain* and therefore *back pain* should not be used when other parts of the spine are affected. Some experts have recommended the use of a ‘minimal definition’ of LBP (Figure 2) or a more complicated ‘optimal definition’ in LBP prevalence studies (Dionne et al. 2008).

In this thesis, I use the classic definitions of LBP, i.e. acute, subacute and chronic pain in the LB area (Table 1). For simplicity, LBP also occasionally refers to stiffness, physical impairment and disability.
Review of the Literature

A) In the past 4 weeks, have you had pain in your low back (in the area shown on the diagram)?

Yes ☐  No ☐

If yes, was this pain bad enough to limit your usual activities or change your daily routine for more than one day?

Yes ☐  No ☐

B) In the past 4 weeks, have you had pain in your low back?

Yes ☐  No ☐

If yes, was this pain bad enough to limit your usual activities or change your daily routine for more than one day?

Yes ☐  No ☐

Figure 2. Minimal definition of LBP. Adapted from Dionne et al. (Balagué et al. 2012). Used in: A. Face-to-face interviews and paper or online questionnaires B. Telephone interviews

2.1.2 EPIDEMIOLOGY AND NATURAL COURSE OF LBP

LBP is a very common condition across the globe, and greatly associates with human suffering and the high usage and costs of health care (HC) resources, especially among working-age individuals (Airaksinen et al. 2006, Hoy et al. 2010a, Balagué et al. 2012, Hoy et al. 2014). Point estimates may vary between 1.0% and 58.1% (mean 18.1%) and one-year prevalence between 22% and 65% (Hoy et al. 2012, Hoy et al. 2014). Lifetime prevalence has even been estimated to be as high as 84%, and peak ages range between 35 and
55 years (Airaksinen et al. 2006). The great variation in prevalence estimates has been mainly explained by the heterogeneity of research, i.e. study design, population, definition of LBP and its outcomes (Hoy et al. 2010a, Hoy et al. 2014). However, mean and median estimates typically converge (Hoy et al. 2010a). One-year incidence of LBP also varies greatly across studies conducted in various settings and among different nationalities. In three studies conducted in Denmark and the UK, one-year incidence rates ranged from 6.3 to 19.3 (Biering-Sorensen 1982, Croft et al. 1999, Hestbaek et al. 2003).

According to the National Health 2011 Survey in Finland, 35% of men and 41% of women reported back pain during the preceding 30 days. The symptom prevalence rate has not decreased in the last ten years; in fact, it has increased (Koskinen et al. 2012).

An acute LBP period usually improves within a few weeks, but pain and disability may linger and episodes tend to recur (Pengel et al. 2003). Although patients often recover from a period of LBP within six weeks, a substantial proportion of them (60%) still report low to moderate levels of pain and disability even one year later (Kent and Keating 2005, Costa et al. 2012).

![Figure 3. Median prevalence of LBP (with interquartile range) in relation to prevalence period.](image)

*Figure 3. Median prevalence of LBP (with interquartile range) in relation to prevalence period. (According to Hoy, Bain et al.: A systematic review of the Global Prevalence of Low Back Pain (2012), Arthritis & Rheumatism (Hoy et al. 2012).)*
Recent evidence indicates that often, LB symptoms date back to childhood or adolescence, i.e., some individuals suffer LB symptoms throughout their lives. Symptoms that worsen iteratively may even give the expression of recurrence; but although they are strongly related to each other, they probably belong to the same manifestation of ‘chronic LBP’ (Kaaria et al. 2006, Dunn et al. 2013).

Two main features of the ‘natural course of LBP’ are that most people experience LBP at least once during their lives and only about one third of them seek medical consultation. Moreover, disability rather than pain drives people to seek professional help (Balagué et al. 2012). LBP may seriously affect functioning and health-related quality of life (HRQoL), especially among those with chronic LBP symptoms (Hoy et al. 2012, Hoy et al. 2014, Steffens et al. 2016).

According to recent research, the prevalence of disabling LBP seems to be rising all over the world (Buchbinder et al. 2013) and recurrent LBP is more prevalent than previously acknowledged (Tamcan et al. 2010, Manchikanti et al. 2014). In addition, 15–34% of LBP patients have a fluctuating pain pattern, but most of them suffer from steady levels of pain (Macedo et al. 2014, Kongsted et al. 2016).

2.1.3 ECONOMIC BURDEN OF LBP

LBP is the leading cause of activity limitations and therefore has an enormous economic impact on society, communities, employers and individuals through work absence and increased HC usage (Airaksinen et al. 2006, Sjoberg 2017). A comprehensive economic evaluation includes both direct HC costs and indirect costs. Direct HC costs are mainly the costs of HC utilization (visit to a doctor, nurse, physiotherapist etc.), radiological procedures, different therapeutic modalities and medication costs. Indirect costs typically consist of work loss, worker replacement and reduced productivity due to illness. Indirect losses may be estimated from the employer, individual or societal perspectives.
In the US, LBP causes about USD 149 million lost work days per year and total HC costs (direct and indirect) of USD 100–200 billion per year (Becker et al. 2010, Hoy et al. 2010a, Duthey 2013). In the UK, total costs (direct and indirect) were estimated to be GBP 11 billion already in 2000 (Hoy et al. 2010a). Almost concurrently, the total costs of LBP were estimated to be EUR 211 per person in Sweden and EUR 260 per person in the UK. Over time, these costs have steadily increased. The costs of work loss are, however, estimates and only give us an idea of the severity of the problem (Maher et al. 2017).

More recent figures have been gathered from official databases in Finland. In 2017, The Social Insurance Institution of Finland (Kela) paid a total of EUR 764 million in sickness allowances, of which EUR 171 million were for ‘back illnesses’ (cervical spine excluded) (Kela 2017). These figures do not include part-time sickness allowances. Respective sickness absence (SA) days were 14.1 million (total days) and 3.0 million days (due to back illnesses). Back illnesses attributed about 22% of all allowances and 70% of all musculoskeletal allowances, which shows the great role of LBP among these (Kela 2017). However, the total costs arising from work loss are substantially higher. The State Treasury and Confederation of Finnish Industries have estimated that the cost per SA day is around EUR 351–425 for an employer (Valtiokonttori 2012, Suomen_Akatemia 2017). Given that the average cost per SA day is EUR 370, the annual cost of SA days related to back pain were as high as EUR 1.1 billion for Finnish employers in 2017. Although high, these figures clearly underestimate total expenditure, because only SA episodes that were longer than ten days were reimbursed by Kela, and these figures do not take into account the comorbidity of LBP.

According to the National Institute for Health and Welfare (THL), a total of 14.2 million visits were made to all primary care physicians in 2015 (6.8 million to municipal HC physicians, 3.6 million in private HC and 3.7 million in OHS) (THL 2017). About 4% of all primary care physician’s appointments and about 26% of musculoskeletal-related visits are due to LBP, which amounts to about 0.52 million visits per year in primary care. These figures are comparable with visits due to all skin diseases, all oto-laryngological diseases or type II diabetes visits (Kela 2017, THL 2017). As previously stated, official statistics probably underestimate these figures, because not all diagnoses are reported. Given that the cost of a single physician’s visit is
about EUR 63.5 (Hujanen et al. 2008) in Finland, the total costs of all LBP-related visits were estimated to be around EUR 33.4 million in 2015.

According to Statistics of Finland (Eläketurvakeskus 2018) in 2017, 19,674 individuals were entitled to work disability pension for back disorders (most of these originating from low back), which amounts to about 9.7% of total disability pensions. Given the total expenditure of disability pensions (EUR 2,556.3 million), the share of back disorders was around EUR 248 million in 2017. Back-related disability pensions are quite equally distributed between men and women but are highly prevalent among the age group of 55–64 years (Eläketurvakeskus 2018).

Although secondary HC plays an important role in the management of the few serious consequences of LBP, most visits, as well as the economic and therapeutic burden of LBP, lie in the hands of primary HC. For working-age citizens in Finland, the main primary care operator is occupational health services (OHS).

The costs of presenteeism (i.e. going to work in spite of illness) have been evaluated as being high as the costs of SA (Rissanen and Kaseva 2014, STM 2019). However, economic evaluations are mere estimates. Total costs are also highly dependent on what costs are included in the calculations. In summary, the highest costs of LBP are due to SA, presenteeism, early disability pensions and high HC resource usage.

2.2 WORK ABILITY AND DISABILITY

2.2.1 DEFINITIONS

Work ability means that a person has the health, skills and virtue to complete a task (Tengland 2011). In contrast, disability means that a person has an impairment (or several impairments), that limit(s) their senses, activity or functioning. Disability may be permanent or temporary and due to cognitive, developmental, intellectual, mental, physical, or sensory limitation – or a combination of these. Thus, work disability means that a
person is unable to cope with the demands of their work because of disabling condition(s) (Costa-Black et al. 2010, Saunders and Nedelec 2014).

The social insurance system in Finland provides social service benefits for all Finnish residents. SA benefits usually cover lost income due to a medically certified disease until the insured person is able to return to work. The public insurance system is administered by Kela, and insurance covers a maximum of about 330 days of allowance. After this, a disability pension scheme operated by private pension insurance companies covers lost income for those who are insured by their present or previous employers, according to certain criteria.

### 2.2.2 WORK DISABILITY AND PRESENTEEISM

In 2015, according to Kela, around 1.9 million SA days were compensated due to back illnesses in Finland, which is about 41% of all musculoskeletal diseases (MSDs) (Kela 2017). Even though this is high, these figures are an underestimation, because Kela does not compile statistics or reimburse SA until the deductible (=own risk) days have passed (usually one plus nine days). In general, MSDs constitute a major part of work disability among employees, and LBP is the largest diagnostic entity among all MSDs.

Work disability is a complex phenomenon and has a substantial impact on the workplace, families, communities and individuals. Inability to work because of symptoms related to LBP often leads to SA. LBP-associated SA, especially longer episodes, usually coincides with other morbidities such as depression or multisite pain in the musculoskeletal system (Haukka et al. 2014). Psychosocial factors may contribute to work absence; one Finnish study found that low job control increased the risk of all-cause SA among women and job dissatisfaction among men (Laaksonen et al. 2010).

Exposure to hazardous work and physical workload seems to increase the risk of all-cause SA among both women and men (Laaksonen et al. 2010). Recent evidence also suggests that SA is triggered when a variety of non-medical factors occur simultaneously with the medical condition. Low life satisfaction is a predictor of sick leave (Rolli Salathé et al. 2012, Melloh et al. 2013). Non-medical factors may relate to the illness itself but also to work motivation, lack of skills or the psychosocial situation of the employee.
Society’s compensation system also has an impact on SA (Haukka et al. 2013, Odeen et al. 2013, Haukka et al. 2014).

Employees who experience multisite musculoskeletal pain need more work ability support from their supervisor and OHS in order to maintain their work ability (Haukka et al. 2015). Longer absence periods increase the risk of elevated disability and finally, disability pension. In addition to human suffering, early disability pensions cause high costs to society and are a huge financial risk to larger employers.

On the other hand, several modifiable, work-related or lifestyle factors (non-strenuous work, high supervisor and co-worker support, being able to adjust work day length, no exposure to lifting or repetitive hand movements, normal weight etc.) were positively associated with good work ability among employees who reported multisite musculoskeletal pain (Pensola et al. 2016, Haukka et al. 2017).

Inability to work does not always lead to SA. Presenteeism means that an employee feels disabled and (at least partly) unable to work because of a medical condition but continues working. Being disabled but still present at work often leads to productivity loss, poor health and exhaustion and may also slow down recovery from illness. Presenteeism is difficult to measure, and only a few high-quality trials have addressed it (Bergstrom et al. 2014) so far. The economic impact of presenteeism in Finland in 2014 was estimated to be around the same as that of SA, at EUR 3.4 billion (STM 2019).

### 2.3 RISK FACTORS AND DETERMINANTS OF LBP

The risk factors of LBP depend on how LBP is defined, i.e. acute or persistent. Risk factors or determinants also relate to the aims of this thesis: preventing the first or further LBP episodes or chronification of LBP. Elimination of risk factors may prevent future LBP episodes or their worsening, so it is worthwhile considering which risk factors are modifiable and which are not.

The multifactorial nature of LBP enables us to classify its risk factors or predictors into the following main groups:
1. Intrinsic (individual) risk factors
   a. Non-modifiable predictors (e.g. gender, age, genetics, previous LBP)
   b. Modifiable behavioural risk factors (e.g. smoking, obesity, lack of physical activity)
   c. Individual psychosocial factors (e.g. attitudes, beliefs, anxiety, depression, catastrophizing, kinesiophobia)

2. Extrinsic risk factors
   a. Exposures at work (physical and psychological load, lifting, twisted postures and vibration, low job control, job dissatisfaction, etc.)
   b. Other exposures such as trauma

It has been suggested that previous LBP episodes (Kaaria et al. 2012), some other chronic conditions (asthma, headache, diabetes) (Hartvigsen et al. 2018), obesity, greater age, female gender (Coggon et al. 2017) and sleep problems (Miranda et al. 2008, Lusa et al. 2015) increase the risk of future LBP. Heritability may contribute to spinal pain at least (Hartvigsen et al. 2018). Low leisure time physical activity and manual occupational class seem to raise the risk of LBP among Finnish workers (Kaaria et al. 2006, Kaaria et al. 2011). Although the evidence of risk factors is not consistent and depends on the definition of LBP (Elders et al. 2003), previous LBP episodes are the most significant risk factor for future LBP on the individual level (Bergstrom et al. 2007).

Physical workload, for example, manual material handling, static or awkward work postures body postures, heavy work, lifting, bending and twisting of the trunk (Borenstein et al. 1995), whole body vibration (Hoogendoorn et al. 1999, Sterud 2014) and blue collar work (Bergstrom et al. 2007) increase the risk of LB symptoms. Borenstain et al. also suggest that static body postures include long-term sitting and standing (Borenstein et al. 1995). Esquirol et al. confirmed that exposures at work (e.g. carrying heavy loads) contribute to future LBP but that psychosocial risks may also increase the incidence of chronic LBP. In addition, determinants such as the severity of LBP symptoms and depression were the main factors behind the persistence of chronic LBP. Opportunities to change jobs during one’s
working career, however, may decrease the incidence of LBP on the individual level (Esquirol et al. 2017).

A Finnish study also concluded that high physical workload, kneeling or squatting, whole body vibration, heavy lifting, arm elevation and awkward trunk posture contribute more than 20% of future LBP among male employees. Women tend to underestimate these risk factors, especially whole-body vibration (Solovieva et al. 2012). In addition, Lallukka et al. concluded that physically heavy work, already at a young age, seems to increase the risk of radicular LBP (Lallukka et al. 2017).

2.4 PREVENTION OF LBP

Prevention here means a principle or actions that aim to prevent illness from occurring for the first time (primary prevention) or to counteract its further consequences (secondary and tertiary prevention) (Burton et al. 2006). However, according to European LBP prevention guidelines (Burton et al. 2006), the terms primary, secondary and tertiary prevention may be misleading because these levels are difficult to distinguish from each other. Prevention may also be understood from either a societal or individual level. Interventions in the clinical environment do not specifically target prevention.

To simplify this confusing terminology, in this thesis, I mostly address the term ‘secondary prevention’, which primarily means preventing new episodes of LBP and the disabling and chronic consequences of recurrent or long-term LBP.

2.4.1 PRIMARY PREVENTION

Primary prevention aims to avoid the first occurrence of LBP or its symptoms. For employees, primary prevention mainly focuses on identifying the personal or workplace risk factors that may contribute to LBP. However, given the high incidence of LBP in the worker population and the difficulty in identifying and excluding the work-related risk factors that increase the risk of LBP on the personal level, successful prevention of the
first onset of LBP is limited (Frank et al. 1996, Burton et al. 2005, Bell and Burnett 2009). A systematic review by Poppel et al. found only low-quality evidence that supported exercise as the primary prevention of LBP at the workplace (van Poppel et al. 2004). Back schools have also failed to be effective in acute LBP (Poquet et al. 2016, Straube et al. 2016). Bell et al. in turn found that the studies in this area were of poor quality and that they varied greatly (Bell and Burnett 2009).

A Cochrane review showed that advice for manual material handling and assistive devices did not prevent or treat back pain (Martimo et al. 2010, Verbeek et al. 2012). Transfer technique training or stress management did not reduce LBP among elderly care personnel (Jensen et al. 2006).

Brief workplace counselling by an OH physician reduced pain, fear related to physical activity, risk of SA and improved physical functioning among LBP patients in a Danish study (Jensen et al. 2012). However, ergonomic interventions alone were neither effective nor cost-effective (Russell et al. 2004, Driessen et al. 2011b, Driessen et al. 2012).

2.4.2 SECONDARY PREVENTION – EXERCISE AND WORKPLACE INTERVENTIONS

Secondary prevention of LBP aims to prevent the new onset of a previously experienced LBP episode. It is usually carried out by removing or lowering the impact of LBP-related risks or improving individual resilience through, for example, rehabilitation, information or other therapy. Therefore, it is important to screen employees at a high risk of LBP before beginning actual secondary prevention procedures (Frank et al. 1996).

According to a Cochrane review by Choi et al., post-treatment exercises can prevent recurrences of LBP, but the authors also called for more high-quality studies in this field (Choi et al. 2010). Evidence suggests that exercise alone or in combination with education can reduce the risk of further LBP episodes (Steffens et al. 2016).

Table 2 shows recent high-quality RCTs that have recruited adult participants from primary care populations or from workplaces (i.e. an occupational setting). These studies have focused on the prevention of LBP, i.e. preventing new LBP episodes and the reduction of pain, disability or HC
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costs and on improving HRQoL. Most of the studies referred to include a physical exercise programme, either alone or in combination with information, education or alongside an ergonomic or workplace intervention. Studies that included only military personnel (George et al. 2007, Childs et al. 2014) or focused solely on workplace intervention (IJzelenberg et al. 2007) were not included in the analysis.
<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Country</th>
<th>Participants/gender</th>
<th>FU time</th>
<th>Inclusion/exclusion</th>
<th>Interventions/groups</th>
<th>Main results</th>
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</thead>
<tbody>
<tr>
<td>Suni et al 2018</td>
<td>FIN</td>
<td>3 sub-studies. HC workers volunteered from workplace. 439 responded; eligible 56%, finally 173 participated, mean age 47, 100% female. FU 12 months.</td>
<td>Aged 30-55, working, pain intensity &gt; 2/10 during past 4 weeks. Exclusion: e.g., chronic LBP.</td>
<td>Neuromuscular exercise (57), Back care counselling (55) by CB learning theory. Combined i.e. previous together (53), Control (54). Interventions 6 months, F/U up to 12 months.</td>
<td>LBP, FAB and Work interference; Cost-effective ness;</td>
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<tr>
<td>Chakat-Valayer et al 2016</td>
<td>F</td>
<td>Of 10 hospitals (9,000 emp.), HC workers recr. by OP or campaign. 353 assessed, 342 randomised, mean age 47; 77% female. Basically chronic LBP. FU 1-2 years.</td>
<td>Present LBP; over the previous 3 years 100% participated, mean age 47, 77% female.</td>
<td>NT: Group exercise program: 2h education, group training a’ 90 minutes x 5 times weekly + home based Back Book. C: no intervention.</td>
<td>Physical work de mands (lifts); and maladaptive behaviour (FABQ, F), but not work ability or SA due to LBP.</td>
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<tr>
<td>Reimussen et al 2016</td>
<td>DK</td>
<td>Nurse’s aids, recruited in info sessions (1099). 1074 eligible, 159 responded, Age 47, Finally 594 randomised 92% female. FU 12 months.</td>
<td>Working &gt;20h/week, 18-65 y, no limit of LBP and Neck pain. INT: Stay@work advice to rest as much as possible. C (68): advice to stay active as much as possible.</td>
<td>NT: 12 weeks of physical training, (12 sessions), CBT (2 sessions) and participatory ergonomics (5 sessions): C: no intervention.</td>
<td>Physical work de mands (lifts); and maladaptive behaviour (FABQ, F), but not work ability or SA due to LBP.</td>
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<tr>
<td>Roussel et al 2015</td>
<td>B</td>
<td>Grouping workers (2 hospitals) after info campaign. 68 subjects, mean age 41, 83% female. FU 6 months.</td>
<td>Working &gt;20h/week, 18-65 y, no limit of LBP and Sciatica. INT: Group exercise program: 2 h educat., group training a’ 90 minutes x 5 times weekly + home based Back Book. C: no intervention.</td>
<td>NT: 12 weeks of physical training, (12 sessions), CBT (2 sessions) and participatory ergonomics (5 sessions): C: no intervention.</td>
<td>Passive coping;</td>
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<tr>
<td>Whitehurst et al 2012</td>
<td>UK</td>
<td>All workers at 37 departments (5798 workers). Finally, 1472 and 1575 were in INT and C groups. Age 42, 42% female. FU 12 months.</td>
<td>Low back strain during the last year, ≥ 1 pain-free period in the last 6 months. INT: Stay@work advice to stay active as much as possible. C (68): advice to rest as much as possible.</td>
<td>NT: 3 x 45-sec educational mode about the prevention of LBP and neck pain. INT: Stay@work participatory ergonomics (PE) program, no exercise. C: no intervention.</td>
<td>RMDQ, health-care use, sickness absence; and QALY and cost savings in the intervention group (stratified groups) vs. control.</td>
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<tr>
<td>Hill et al 2011</td>
<td>UK</td>
<td>Many surveys, 641 employees, various occupations. 310 responded (67%): 380 (72%) included, intervention: 100 subjects, 77% female. FU 12 months.</td>
<td>Low back strain during the last year, obtained physician care.</td>
<td>INT (22): advice to stay active as much as possible. C (95): advice to rest as much as possible.</td>
<td>Control group: ↑ LBP strain and ↓ risk of LBP.</td>
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<tr>
<td>Driessen et al 2011a and Driessen et al 2012</td>
<td>N</td>
<td>385 (72%) included, intervention: 100 subjects, 77% female. FU 12 months.</td>
<td>Low back strain during the last year, obtained physician care.</td>
<td>INT (20): advice to stay active as much as possible. C (95): advice to rest as much as possible.</td>
<td>Control group: ↑ LBP strain and ↓ risk of LBP.</td>
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<td>Matsudaira et al 2011</td>
<td>JAP</td>
<td>GP practices (internal, records), 754 suit, assessed, finally 705 randomized. Age 53-54. Practically chronic, at least moderate LBP patients, 60%. female, 50% were employed. FU 12 months.</td>
<td>Moderate, moderate subacute or chronic LBP &gt; 6 weeks, LBP consultation in primary care within 6 months. Only 50% were employed.</td>
<td>INT: ↑ LBP strain and ↓ risk of LBP.</td>
<td>CBT program: RM-24, von Korff pain and QALY. Cost-effectiveness was gained.</td>
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<td>Lamb et al 2010</td>
<td>UK</td>
<td>369 patients, recurrent LBP seeking care at PT clinic. 71 subjects (36 mm. 35 women) rand. in 2 groups. Age 37-40, 50% male, 100% employed. FU 12 months.</td>
<td>LBP (35), / Back book. INT: CBT intervention. Back Skills Training: 1h individual + 61h group session= advise + guided activity, 50 dropped out; C (232): no intervention.</td>
<td>CBT program: RM-24, von Korff pain and disability; + HPPQL-: Cost-effectiveness was gained.</td>
<td>Graded exercise was more effective in disability and health parameters than daily walks.</td>
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<td>Author(s)</td>
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<td>Pillastrini et al 2009</td>
<td>I</td>
<td>Nursery school teachers (N=71) in 9 buildings. Age 44, 100 % female. FU: 2 months.</td>
<td>Nursery school teachers, all women</td>
<td>INT: 6 graded exercise sessions, 2-times/week, for 3 weeks at 1st; Lumbar extension, stabilizing exercises. Self-activity exercises. Education +</td>
<td>INT: disability (Nev red RM) and Low Back related discomfort (VAS)</td>
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<td>Ewert et al 2009</td>
<td>D</td>
<td>Nursery school teachers (N=71) in 9</td>
<td>Nurses with ≥ one episode of LBP during previous 2 years, not present LBP, 18-65 yrs, BMI &lt; 35; Exclusion: radiating pain, &gt; 30 days LBP in 12 months, or 8-10 days leave, inpatient rehab for LBP in 3 years</td>
<td>EP: 11 group sessions, 1 h: intro, exercises, selfcare program. MP: EP + 17 group lessons at 1.75 hours (CB approach, psychological, ergonomic, workplace, stabilization).</td>
<td>No difference between EP and MP. Both interventions; pain interference and intensity</td>
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<td>Suni et al 2006</td>
<td>FIN</td>
<td>Nursery school teachers (N=71) in 9</td>
<td>Nursery school teachers, all women</td>
<td>INT: 2 times/week neuromuscular training (lumbar control) and stabilization (Cognitive-behavioral model); C: no intervention</td>
<td>INT: disability (Nev red RM) and Low Back related discomfort (VAS)</td>
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<td>Maul et al</td>
<td>CH</td>
<td>Nursery school teachers (N=71) in 9</td>
<td>Nursery school teachers, all women</td>
<td>INT: 2 times/week neuromuscular training (lumbar control) and stabilization (Cognitive-behavioral model); C: no intervention</td>
<td>INT: disability (Nev red RM) and Low Back related discomfort (VAS)</td>
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<td>von Koff et al 2005</td>
<td>USA</td>
<td>Nursery school teachers (N=71) in 9</td>
<td>Nursery school teachers, all women</td>
<td>INT: 2 times/week neuromuscular training (lumbar control) and stabilization (Cognitive-behavioral model); C: no intervention</td>
<td>INT: disability (Nev red RM) and Low Back related discomfort (VAS)</td>
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<td>Liet et al 2002</td>
<td>CAN</td>
<td>Nursery school teachers (N=71) in 9</td>
<td>Nursery school teachers, all women</td>
<td>INT: 2 times/week neuromuscular training (lumbar control) and stabilization (Cognitive-behavioral model); C: no intervention</td>
<td>INT: disability (Nev red RM) and Low Back related discomfort (VAS)</td>
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<td>Katgelyzhe et al 2003 (3) and 2004 (9)</td>
<td>FIN</td>
<td>Nursery school teachers (N=71) in 9</td>
<td>Nursery school teachers, all women</td>
<td>INT: 2 times/week neuromuscular training (lumbar control) and stabilization (Cognitive-behavioral model); C: no intervention</td>
<td>INT: disability (Nev red RM) and Low Back related discomfort (VAS)</td>
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<td>Alexandre et al 2001</td>
<td>BRA</td>
<td>Nursery school teachers (N=71) in 9</td>
<td>Nursery school teachers, all women</td>
<td>INT: 2 times/week neuromuscular training (lumbar control) and stabilization (Cognitive-behavioral model); C: no intervention</td>
<td>INT: disability (Nev red RM) and Low Back related discomfort (VAS)</td>
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<tr>
<td>Linton, Andersson 2000</td>
<td>S</td>
<td>Nursery school teachers (N=71) in 9</td>
<td>Nursery school teachers, all women</td>
<td>INT: 2 times/week neuromuscular training (lumbar control) and stabilization (Cognitive-behavioral model); C: no intervention</td>
<td>INT: disability (Nev red RM) and Low Back related discomfort (VAS)</td>
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<tr>
<td>Soukup et al 2001</td>
<td>N</td>
<td>Nursery school teachers (N=71) in 9</td>
<td>Nursery school teachers, all women</td>
<td>INT: 2 times/week neuromuscular training (lumbar control) and stabilization (Cognitive-behavioral model); C: no intervention</td>
<td>INT: disability (Nev red RM) and Low Back related discomfort (VAS)</td>
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As regards the design of the 22 most recent secondary prevention studies presented in Table 2, they were executed in 14 different countries, and five of them were conducted in Finland.

The screening of eligible participants was generally based on a large target population, for example, one big or several workplaces, public calls (newspaper advertisements or social media campaigns) or a large set of primary care physicians or physiotherapists.

These studies used variable inclusion criteria concerning low-back-related symptoms (pain intensity over 2/10, back pain of any duration, at least one LBP episode in the preceding three years etc.). Lack of consistent inclusion criteria prevented deeper comparisons of these studies.

In all the reviewed studies, the eligible participants were screened using a questionnaire, information sessions or (telephone) interviews.


Eight studies included only or mostly women (70–100%) (Alexandre et al. 2001, Ewert et al. 2009, Pillastrini et al. 2009, Matsudaira et al. 2011, Roussel et al. 2015, Chaleat-Valayer et al. 2016, Rasmussen et al. 2016, Suni et al. 2018), seven were from the HC sector, one study included only men
(railroad personnel) (Suni et al. 2006), eleven studies had almost equal numbers of men and women (women 42–70%) and one study did not report the gender of its participants (Maul et al. 2005).

More than half of the examined studies that were performed in an occupational setting were limited to specified occupations or occupational sectors, for example, HC or railroad personnel, making the generalizability of their results questionable. Although the search category for the studies was active exercise interventions or patient education interventions, the studies also included a large variety of other interventions and their combinations.

Driessen et al. found that brief patient information decreased LBP intensity and the number of LBP-affected days in the same way as a participatory ergonomics programme among employees who reported LBP at baseline (Driessen et al. 2011a, Driessen et al. 2012). Matsudaira et al. reported that brief advice to stay active prevented an increase of LB strain and the risk of future LBP compared to the advice to rest (Matsudaira et al. 2011). However, cognitive behavioural therapy (CBT) programmes were more effective than simple information on LBP and the Back Book® booklet (Linton and Andersson 2000, Lamb et al. 2010a). Mini-interventions that included patient information, education and an exercise programme reduced pain, sickness absence and costs after 12 months (Karjalainen et al. 2003a), but after two years, only costs and bothersomeness of pain had decreased (Karjalainen et al. 2004). Worksite visits were not effective (Karjalainen et al. 2003a).

In summary, exercise or patient information, either alone or in various combinations, seem to be effective in secondary prevention of LBP in occupational settings.

2.4.3 TERTIARY PREVENTION - RETURN TO WORK INTERVENTIONS

Tertiary prevention of LBP aims to inhibit or limit the consequences of already chronic, negative aspects of the disease, such as long-term or permanent disability.

Previous interventions focusing on work organizations (Stock et al. 2018) or ergonomic interventions (van Vilsteren et al. 2015, Sultan-Taieb et al. 2017) have been insufficient for preventing LBP-related disability. In a Danish study, a multifaceted workplace intervention (participatory ergonomics, physical training and CBT) decreased fear avoidance and work demands among employees who reported LBP but whose work ability did not improve or SA due to LBP did not decrease (Rasmussen et al. 2016).

However, workplace interventions may facilitate return to work and reduce the duration of SA, pain and physical functioning, especially among patients who report MSD, although the evidence was not consistent (van Vilsteren et al. 2015).

Generally, the existing evidence on workplace interventions (van Oostrom et al. 2009, Madan and Grime 2015, Schaafsma et al. 2015, van Vilsteren et al. 2015) does not support their use for reducing work-related LBP disability. Multidisciplinary rehabilitation and graded exercise improve return to work after SA (Bell and Burnett 2009, Schaafsma et al. 2013, Schaafsma et al. 2015, Saragiotto et al. 2016, Qaseem et al. 2017), but workplace interventions that were arranged after only a short absence (≤ 15 days) from work showed only limited effectiveness (Vargas-Prada et al. 2016). However, part-time sick leave seems to increase work participation (Viikari-Juntura et al. 2012), improve self-assessed health and quality of life (QoL) among employees with persistent musculoskeletal pain. About 27% of
the participants suffered from back pain in these studies (Viikari-Juntura et al. 2012, Shiri et al. 2013).

2.5 LBP TREATMENT GUIDELINES

2.5.1 ACUTE AND SUBACUTE LBP

Recent international guidelines consistently recommend (Qaseem et al. 2017, Stochkendahl et al. 2017, Wong et al. 2017) staying active in cases of acute LBP. Bed rest is not only ineffective; it is also harmful for acute and subacute LBP (McIntosh and Hall 2011). In addition, activity seems to be more beneficial than pain medication, and physiotherapeutic treatments have not proven to be effective. However, there is not enough evidence to recommend back schools for acute or subacute LBP (Poquet et al. 2016). The American College of Physicians also recommends superficial heat, massage, acupuncture or spinal manipulation for acute and subacute LBP (Chou et al. 2016, Qaseem et al. 2017). Others do not recommend acupuncture or imaging (Bernstein et al. 2017).

In the UK, the National Institute for Health and Clinical Excellence (NICE) recommend risk stratification using a suitable risk assessment tool (e.g. STarT Back Tool). Risk-based and targeted treatment, including patient information, group exercise, manual therapy or a combined physical and psychosocial programme, is more effective than non-targeted care in cases of acute and subacute LBP.

The Current Care Guidelines for LBP (updated 5th May 2017) in Finland recommend multidisciplinary rehabilitation or graded exercise for the management of subacute or chronic LBP and avoiding bed rest for acute LBP (Leinonen et al. 2017). The Council for Choices in Health Care in Finland also recommends biopsychosocial assessment of the patient if LBP symptoms do not improve in six weeks. Modern practice already recommends direct access to a physiotherapist instead of consulting a physician for non-specific, acute or subacute LBP (Scheele et al. 2014, Bishop et al. 2017).
2.5.2 CHRONIC LBP

The latest European guideline for chronic LBP dates back to 2006 and neglects recent evidence. However, cognitive-behavioural therapy (CBT), supervised exercise, brief education and multidisciplinary treatment were recommended (Airaksinen et al. 2006) in line with more recent evidence.

Updated evidence suggests non-pharmacological treatment over medications for chronic LBP. Clinicians should also assess the impact of fear of pain and psychosocial factors in the management of subacute or chronic LBP. Pharmacological therapy may be considered a second line therapy or be combined with, for example, biopsychosocially oriented rehabilitation (Chou et al. 2017, Qaseem et al. 2017).

The recent guidelines of the American College of Physicians (ACP) include exercise, multidisciplinary rehabilitation, acupuncture and mindfulness-based stress reduction for chronic LBP (Qaseem et al. 2017). Some other therapies, for example, tai-chi, motor control exercise, progressive relaxation or cognitive behavioural treatment, were also recommended. Canadian clinical practice guidelines mainly include the same recommendations as the ACP guidelines, and emphasize exercise, education, reassurance and self-management for all LBP patients (Wong et al. 2017). Healthy lifestyle interventions (Williams et al. 2018) or back schools are not effective in chronic LBP (Straube et al. 2016). Several complementary and alternative treatments for LBP have been studied, but their effectiveness has been either short term (Furlan et al. 2010) or evidence of it has been lacking (Furlan et al. 2012).

NICE recommends risk evaluation (e.g. STarT Back Tool) and targeted interventions for chronic LBP. Interventions may include simple and less intensive patient information, a group exercise programme, manual therapy or a combined physical and psychosocial programme according to risk-based stratification (Bernstein et al. 2017).
According to Foster et al.’s latest review, advice to remain active, education, exercise therapy and CBT were recommended as first line therapy for persistent LBP, and spinal manipulation, massage, acupuncture, yoga, mindfulness-based stress reduction or interdisciplinary rehabilitation were recommended as second-line or adjunctive therapies (Foster et al. 2018).

2.6 SELF-CARE, PATIENT INFORMATION AND EDUCATION

HC professionals usually deliver patient information to improve patients’ understanding of the medical condition and its prognosis. Patient information can also help patients cope with their medical condition and
provide reassurance of their prognosis by enhancing the self-management of symptoms (Laher et al. 1981, Burton et al. 1996, Burton et al. 1999, Pellise et al. 2009). Face-to-face contact and personal information are often reinforced with educational booklets. Such a combination seems to increase patients’ motivation to self-care (Vuorma et al. 2003, Humphris and Field 2004). Therefore, educational booklets have been used across specialities, for example, in the prevention of oral cancer (Humphris and Field 2004) and type 2 diabetes (Tuomilehto et al. 2001), hypertension (Laher et al. 1981) and LBP (Roland and Dixon 1989). To promote efficient self-care, the content should be evidence-based or at least concurrent with existing guidelines (Coulter 1998, Coudeyre et al. 2007, Frost et al. 2007, Pellise et al. 2009). The optimal patient group and type of information (personal or group, oral or written etc.) should also be determined. Moreover, it should be clear who is mainly responsible for the delivery of the information (Engers et al. 2008). Educational booklets have been used to mediate general patient information, either alone or combined with, for example, personal verbal advice or educational group sessions (Engers et al. 2008). The Back Book® is probably the most widely used guideline-based LBP patient information booklet (Burton et al. 1999, Udermann et al. 2004, Coudeyre et al. 2007, Brox et al. 2008, Albaladejo et al. 2010).

Patient education includes, in addition to the information itself, systemic intervention and either psychosocial or behaviour modification in personal contact with the patient (Engers et al. 2008, Pellise et al. 2009). A combination of booklet and individual advice is believed to have many advantages: patients may become more aware of treatment options and make the most of their consultation. Usually, they also recall the whole content better when they receive information both in writing and verbally (Burton et al. 1999).

The Back Book® is based on the bio-psychosocial model. It focuses on attitudes and unsuitable behaviour and includes information on how to cope with and avoid re-exacerbation of LBP (Burton et al. 1996, Borrell-Carrio et al. 2004). It also emphasizes that one should continue normal activities and return to work as soon as possible (Burton et al. 1999). As the booklet is easy to deliver, safe and cheap (Coudeyre et al. 2007), it has become widely used and is also considered feasible in the treatment and promotion of self-care among LBP patients (Burton et al. 1996, Coudeyre et al. 2006, Henrotin et
al. 2006, Liddle et al. 2007). Although the Back Book® was introduced already a few decades ago and hard evidence on its effectiveness is still lacking (Burton et al. 1999), its content is well in line with general LBP guidelines (Airaksinen et al. 2006, Burton et al. 2006, van Tulder et al. 2006).

Educational booklets are most suitable instruments for primary care and OHS because they are cheap, easy to deliver and safe, and may be used alone or as an aide to personal information.

Already available in several regions of Finland, direct access to a physiotherapist serves as an easy-access consultation and patient education service. It seems to improve primary care response to non-specific LBP and results in better self-care attitudes, decreasing visits to physicians and even the costs of LBP (Scheele et al. 2014, Lautamaki et al. 2016, Bishop et al. 2017).

2.7 OCCUPATIONAL HEALTH SERVICES IN FINLAND

According to the Finnish Occupational Health Care Act, all employers are obliged to arrange OHS for their employees. The main objectives of OHS in Finland are to prevent work-related morbidity and symptoms among employees, to promote and maintain work ability and health and to restore diminished work ability. These objectives are achieved by improving the work environment and the functioning of the work community cooperatively with other stakeholders, inside or outside the workplace, and influencing individuals in the workplace: both employers and employees.

Typically, OHS in Finland evaluates, prevents and resolves work-related health risks; protects and enhances the workplace safety, work ability and general health of the workforce by preventing the consequences of general illnesses; and manages specific occupational hazards and diseases. Employers generally expect easy access to OHS and also value reliable, long-term relationships, workplace knowledge and continuous dialogue with the OHS provider (Stahl et al. 2015).

OHS is an essential part of primary HC in Finland and has been mainly responsible for the primary care of the workforce in Finland for several decades. In spite of good coverage however, OHS contracts and coverage
varies somewhat in Finland. For instance, big companies may offer wide-ranging OHS, whereas small enterprises sometimes provide only minimal OHS for their employees. In some areas of Finland, a lack of OH professionals may also reduce the amount and quality of OHS.

In 2016, approximately 1.83 million employees (87% of the total workforce) were covered by OHS (THL 2017). In addition to 1.2 million health examinations, OHS also had about 4.75 million illness-related visits (Kela 2017). MSDs cause a great deal of work disability (Haukka 2010, Haukka et al. 2015). Therefore, OHS professionals continually face the challenge of how to manage the LBP-related disability of employees (Rasanen et al. 1993, Rasanen and Husman 2003, Kimanen et al. 2011). Evidence-based means for the (secondary) prevention of LBP and subsequent work disability are urgently needed in OHS (Burton et al. 2006).
3 BACKGROUND OF THE STUDY – RESEARCH QUESTIONS

The main task of the OHS system in Finland is to manage the work ability and disability of the workforce.

In order to reduce the high impact of LBP, OHS already operates on several levels (Hoy et al. 2010a), for example, treatment for and management of acute to chronic LBP, disability prevention and rehabilitation, workplace ergonomics and finally, workplace adjustments of LBP-affected employees.

At the time of designing the present study, only a few trials had evaluated the effectiveness of interventions among non-sick-listed workers in an OH setting (Suni et al. 2006). One Cochrane systematic review (Guzman et al. 2001) recommended at least 100 hours of multidisciplinary rehabilitation, graded activity or other exercise programmes for chronic LBP (Lindstrom et al. 1992, Kankaanpaa et al. 1999). It also recognized the effectiveness of simple information and advice, although not for non-acute LBP (Burton et al. 1999). Moreover, there was only scarce evidence of effective and cost-effective interventions for recurrent LBP in an OH setting (Burton et al. 2006, Driscoll et al. 2014).

Therefore, the main questions concerning the secondary prevention of LBP were on whom preventive actions should focus, as well as how and when. The research questions of this thesis were thus formulated as follows:

1. Who and when – Is an employee survey feasible for identifying and categorizing employees at risk of disabling LBP?

2. How – How effective and cost-effective is low-back-specific information in the management of mild-level LB symptoms?

3. How – How effective are low-back-specific active interventions and patient information for moderate level LBP?
4 AIMS OF THE THESIS

Research questions 1–3 of this thesis were evaluated through the following studies:

1. Is an employee survey feasible for identifying and categorizing employees at risk of disabling LBP?

   All studies (I–IV). The design, eligibility criteria and employee categorization in all the studies of this thesis were based on the employee survey results.

2. How effective and cost-effective is low-back -specific information in the management of mild-level low back symptoms?

   a. Study I: Evaluation of the effectiveness of personal face-to-face information in comparison to LB-specific booklet alone among employees reporting non-acute, mild LBP in a randomized controlled trial (RCT).
   The study hypothesis was that low-back -specific self-care advice would reduce LBP symptoms and the related SA. It was expected that personal face-to-face contact with the patient would increase the power of information.

   b. Study II: Examination of the effectiveness and cost-effectiveness of personal advice (either face-to-face information with a booklet or a booklet alone) in comparison to natural course of LBP in mild, non-acute LBP.
   The hypothesis was that both early-phase LB-specific interventions would reduce symptoms and SA and lower costs. Two secondary preventive patient information methods were compared to natural course of LBP.

3. How effective is a combination of low-back -specific active interventions and patient information for moderate level LBP?
Aims of the thesis

a. Study III: Evaluation of the effectiveness of two active rehabilitation interventions in comparison to OH physician’s advice to employees with moderate-level, non-acute LBP in an RCT. The hypothesis was that low-back -specific interventions would reduce both symptoms and SA among employees reporting moderate LBP.

b. Study IV: Examination of the effectiveness of three low-back -specific interventions in comparison to natural course of LBP in moderate, non-acute LBP. The hypothesis was that all three low-back-specific interventions would reduce symptoms and SA when they were offered as secondary prevention.
5 PARTICIPANTS AND METHODS

Two randomized trials and the respective NC control groups were embedded in a multiphasic, prospective cohort study executed in an OH setting among the personnel of a large forestry industry compound in Lappeenranta, Finland. The recruited employees reported non-acute, recurrent and disabling LBP but were still able to work.

5.1 ETHICS

The South Karelian Central Hospital Research Ethics Board approved the study on 13th September 2001. All participants received both verbal and written information about the study, in accordance with the Declaration of Helsinki. Participants who gave their signed informed consent were included in the study. All documents that relate to the information and consent of the participants are stored with the other study material, in accordance with general study regulations.

5.2 PARTICIPANTS

The study population was the entire personnel of the UPM-Kymmene forestry industry compound (‘Kaukas’) in Lappeenranta, Finland. At the start of the study (September 2001), the Kaukas compound consisted of a sawmill, a wood product refinement factory, a pulp mill, a chemical mill, a paper mill, and two plywood mills. Its personnel included that of the forest management unit, the lumberjacks, OHS, the research centre, the administrative units and the ‘Global Head Office’ department of the UPM-Kymmene corporation, and totalled 2480 employees. The employees in the production units were mostly two- or three-shift-workers, but the supervisors and employees in the administrative and commercial units had daytime working hours. The physical demands of the employees varied from
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those of white-collar day-time office work to manually strenuous, irregular three-shift work in the process industry.

All individuals who were registered in the UPM-Kymmene Kaukas company in Lappeenranta were invited to respond to a postal employee survey.

5.2.1 EMPLOYEE SURVEY

A file that included the names and addresses of the personnel (N = 2480) was received from the company staff magazine office. The address list included some already retired employees, whose responses were later excluded from the study.

The employee survey questions and measures (Appendix 1) related to low back syndrome had been previously validated and used in surveys and studies in Finland (Heliovaara et al. 1989, Heliovaara et al. 1993). The included LB-specific measures had been previously validated and used extensively in LBP research (Million et al. 1982, Stratford and Binkley 1997). The first low-back -specific employee survey was posted on 25th September 2001 and was to be returned in two weeks. Only one reminder was sent to those who did not respond to the first postal survey.

Well before the employee survey, information on the study was shared among the main stakeholders of the company (e.g. employer, supervisors, employees, study personnel and trade union representatives). The study personnel paid special attention to the amount, extent and repetition of the general information on the study to suppress doubts and improve the response rate of the survey and the follow-up attendance of the participants. The study information was updated and repeatedly distributed on the company intranet and bulletin boards before and during the survey period, as well as during the follow-up visits. Topical information on the course of the study was also published in seven consecutive articles in the company magazine in 2001–2003.

A total of 1754 (71%) questionnaires were returned to the study centre. Questionnaires that included missing key values (age, gender, LBP history etc; N=7) and responses that reported no previous (ever) LBP (414) were
excluded (24%). Finally, a total of 1333 (76%) responses were included in the eligibility analysis of the intervention study.

5.2.2 INTERVENTION STUDY

Eligibility, inclusion and exclusion criteria

Survey respondents were eligible for the study if they had ever experienced LBP, were regularly employed and under 57 years of age (1333 respondents). SA was neither an inclusion nor an exclusion criterion in this study.

To be included in the study, employees had to fulfil at least one of the following four criteria and also report experiencing LBP intensity of 10 mm or more (VAS 0–100mm) during the preceding week in the survey:

1. Radiating LBP (below knee level) in the last 12 months or
2. Prolonged LBP (two weeks or more) in the last 12 months or
3. Recurrent LBP (two or more episodes) in the last 12 months or
4. Work absence due to LBP (self-reported) in the last 12 months

Exclusion criteria were retirement during the follow-up (two years), pregnancy, presence of acute nerve root compression symptoms, suspicion of a malignant tumour, recent fracture, severe osteoporosis, or any other specific disease that might prevent the employee from continuing in the follow-up.

The employees included in the study were able to continue working despite their LBP symptoms.
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Table 3. Inclusion and exclusion criteria for study according to employee survey responses. (LBP = Low back pain)

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
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<tbody>
<tr>
<td>Permanent employment</td>
<td>No permanent employment</td>
</tr>
<tr>
<td>Male or female, age ≤ 56 years</td>
<td>Age ≥ 57 years</td>
</tr>
<tr>
<td>LBP during preceding week ≥ 10 mm with VAS (Visual Analogue Scale). Mild subcohort: 10 mm ≤ VAS ≤ 34 mm; Moderate subcohort: VAS ≥ 35 mm</td>
<td>LBP intensity VAS (during last week) &lt; 10 mm or retirement during the study (2 years).</td>
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</table>

At least one of the following criteria is fulfilled during the last 12 months:
1. "Sciatica" - LBP radiating below the knee level
2. "Prolongation" - LBP lasting for two weeks or more
3. "Recurrency" - LBP has recurred twice or more
4. "Work absence" - LBP-related sickness absence

Presence of any of the following conditions:
- Pregnancy
- Acute nerve root compression symptoms
- Suspicion of a malignant tumour
- Recent fracture or severe osteoporosis
- Any other disease or treatment that might prevent participation in the follow-up

Study participants and random sample

After the inclusion and exclusion criteria were set, the eligible employees (1333) were categorized into three I according to their self-assessed LBP intensity: ‘no LBP’ (N = 828, VAS < 10 mm), low level (n = 312, 10 mm ≤ VAS ≤ 34 mm; Mild subcohort) and moderate-level subcohort (n = 193, VAS ≥ 35 mm; Moderate subcohort). The ‘No pain’ subcohort was not included in the study interventions and is not reported in this thesis. The Mild and Moderate I together were defined as the main Study cohort (505).

Before the interventions started, a random sample (133) was extracted from the Study cohort and divided into two NC control arms according to their pain intensity levels, NC_{mild} (n = 83; 10 mm ≤ VAS ≤ 34 mm) and NC_{moderate} (n = 50; VAS ≥ 35 mm). Hence, both NC arms were control arms for the study intervention I (Figure 5).

In summary, the eligible employees (N = 1333) were categorized into one of the following three I:

1. Mild = low-level LB symptoms – employees who reported experiencing ‘some’ LBP, i.e., pain intensity between 10–34 mm
on the VAS scale during the preceding week (n = 312). This subcohort included the RCT 1 intervention arm (n = 229) and the corresponding NC control arm (n = 83) (Figure 6).

2. **Moderate** = moderate LB symptoms – employees who reported LB experiencing symptoms that ‘potentially hamper work’, determined as VAS ≥ 35mm during the preceding week (N=193). The Moderate subcohort included the RCT intervention arm 2 (n = 143) and the corresponding NC arm (n = 50) (Figure 7).

3. ‘No LBP’ subcohort = VAS below 10mm during the preceding week or other negative criteria (N = 828)

A final total of 505 employees (28.7% of all respondents) met the study inclusion criteria and were invited to take part in the intervention study (Figure 5).

In summary, the Study cohort included employees who had experienced LBP at some point in their earlier lives and reported experiencing either radicular LB symptoms, prolonged or recurring LBP or SA due to LBP during the preceding year. In addition, they reported experiencing LBP intensity of more than 10 mm during the preceding week. The Mild subcohort consisted of participants who reported low levels of pain; 10 ≤ VAS ≤ 34 mm (Figure 6) and the Moderate subcohort consisted of participants with higher pain intensity; VAS ≥ 35 mm (Figure 7).
Figure 5. Flow diagram of participants in thesis.
5.3 RANDOMIZATION AND BLINDING

An independent biostatistician allocated the Mild subcohort into two intervention arms using a computer-generated randomization table with a block size of eight prepared well before the randomization visit. A research assistant prepared sealed envelopes based on the randomization scheme, which contained referrals to the two intervention options.

The independent biostatistician had also prepared a randomization scheme for the Moderate subcohort using a computer-generated randomization table. To prevent unequal randomization of participants by age and gender into the treatment arms, scripted four-digit identification codes were sorted by gender and age (≤ 45 years, > 45 years), resulting in four strata. Block randomization (with blocks of 15) was applied to ensure equal group sizes within each stratum. On the basis of the randomization scheme, a research assistant had prepared sealed envelopes containing referrals to the three intervention options before the start of the study.

5.3.1 PROCEDURES DURING RANDOMIZATION VISITS

At the beginning of the randomization visit, the study design, implications of the trial and alternative treatment options were explained to all the study participants personally, with an emphasis that taking part in the trial was voluntary and employees who did not want to participate would still receive the best treatment and full attention of the OH physician. Participants were free to withdraw from the trial at any point, and this would not prejudice their treatment.

The same information was written in the informed consent form. After the employee had signed their informed consent, they opened a sealed envelope that contained their group assignment.

During the randomization visit, the OH nurse in RCT1 or the OH physician in RCT2 explained the study procedure individually and in detail to the participant. They also performed basic low-back-specific clinical tests to confirm the absence of medical conditions that would prevent participation in the study. These tests included the evaluation of the general
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posture and structure of the patient, basic clinical tests of the LB area (including vibration, palpation), reflexes, blood pressure, general LBP provocative tests, straight leg rises (SLR) and two balance tests. Some participants were sent to x-ray examinations after individual evaluation but not as a standard procedure. The participants’ height and weight were measured and additional information on previous LBP episodes, prior treatments, rehabilitation, and SAs were also gathered during the first visit.

5.3.2 RCT1 – MILD SYMPTOMS (STUDY I)

After the NC\textsubscript{mild} control group (N = 83) was extracted from the Mild subcohort (N = 312), the remaining employees (N = 229) were invited to participate in the RCT1 study. Forty-seven employees declined, leaving a total of 182 employees who were randomized into two intervention arms: Combined, N = 90 and Booklet, N = 92. After randomization, but well before the first three-month follow-up visit, one person in the Combined group retired and was excluded from the study. Thus, from a total of 182 randomized participants, 181 participants were finally included in the study (Figure 6).
Figure 6. Flow diagram of Mild subcohort, showing number of participants at different phases of study and differentiation of NC\textsubscript{mild} and RCT1.

5.3.3 RCT2 - MODERATE SYMPTOMS (STUDY III)

After the NC\textsubscript{moderate} group (n = 50) was extracted from the Moderate subcohort (N = 193), the remaining employees (143) were invited to see the OH physician. Only 17 of the eligible employees refused and eventually 126
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participants were randomized into Rehab (n = 43), Physio (n = 43) or Advice (n = 40) intervention arms (Figure 7).

Figure 7. Flow diagram of Moderate subcohort, showing number of participants at different phases of study and differentiation of NCmoderate and RCT2

5.3.4 BLINDING

The research assistants, OH nurse, OH physician or other researchers were unable to identify the participants or the group assignments before
randomization. Due to the nature of the interventions, it was not possible to blind the participants and OH professionals of the interventions. SA and questionnaire data were gathered and entered into the computer by separate research assistants, ensuring the researchers’ blinded analysis of the data.

5.4 VARIABLES

5.4.1 EMPLOYEE SURVEY

The employee survey included the following items (Appendix 1):

1. Employment status in the company, work (physical and mental) strain, previous LB operations and history of LB symptoms.
2. LBP risk factors: Sciatica (radicular pain), recurrence of LBP (more than once per year), previous SA and prolonged LBP episodes (lasting more than two weeks) were self-assessed over 12 months.
3. Outcome variables:
   a. Intensity of LBP (pain during preceding week) (Million et al. 1982),
   b. Physical impairment scale (Roland-Morris Disability Questionnaire-18 items) (Stratford and Binkley 1997, Macedo et al. 2011),
   c. Pain-related fear (Fear Avoidance Back Questionnaire) (Waddell et al. 1993) in relation to LBP,
   d. Self-assessment of work ability (not analysed).

5.4.2 INTERVENTION STUDIES

The intervention groups and the NC groups received questionnaires that covered:

1. The respondent’s demographics: employment, basic and occupational education, working hours, additional work, work satisfaction, self-assessed health status, support of superior, work atmosphere, work strain (physical and mental), medication usage,
smoking, physical activity, and satisfaction with previous LB treatment.

2. LBP risk factors: LBP history, sciatica (radicular pain), progression of LBP, family history of LB operations, pain drawings.

3. Outcome variables: questionnaire outcomes and HC utilization data

**Questionnaire outcomes**

The participants received the following outcome scales during the randomization visit and before the follow-up visits (3, 6, 12 and 24 months), see Appendices 2 (Items 1–5) and 3 (Item 6):

1. LBP intensity (VAS, Visual Analogue Scale, range 0–100mm) – pain during preceding week (Million et al. 1982)
2. Physical impairment - Roland-Morris 18-item Disability Questionnaire (RM; range 0–18) (Stratford and Binkley 1997)
3. Pain-related fear - Fear Avoidance Beliefs Questionnaire (FABQ, range 13–78) (Waddell et al. 1993) and its subscales FABQ work (FABQ_w, range 6–36) and FABQ physical activity (FABQ_ph, range 4–24) (Waddell et al. 1993, Wertli et al. 2014)
4. Low-back-related disability - Oswestry Disability Index (ODI; 0–100) (Fairbank et al. 1980)
5. Depression scale – DEPS (range 0–30) (Poutanen et al. 2008)
6. Health-related quality of life (HRQoL; range 0–1) - 15-D QoL Questionnaire (Sintonen 2001)

The following collected items were not used in the study analyses: present LBP, pain during the last three months, HRQoL by RAND-36 (Hays and Morales 2001), Waddell’s Inappropriate symptoms (psychological components) of LBP (Waddell et al. 1980) and work ability self-assessment scales.

**Sickness absences**

SA data were obtained from the OHS electronic medical records at 6, 12, 24, 36 and 48 months. The records were carefully checked for inconsistencies.
Neither maternity or paternity leave nor absence due to caring for a sick child were included. The individual date of inclusion in the study was defined as the starting point for SA data collection. In the intervention groups, the inclusion date was the date of randomization and in the NC groups, the postal date of the employee survey. The SA data in this study were comprehensive and highly reliable because they were based on the employer’s administrative payroll system. There were no missing values in the SA data.

Typically, SA data are highly skewed, over-dispersed with zeros and include some extremely high values. Each SA episode in the data holds one or two specific ICD-10 diagnosis codes (WHO 2003), as well as the first day and last day of the period. The number of SA periods and days were collected at 3, 6, 12, 24, 36 and 48 months after randomization.

SA days and periods were analysed from two perspectives:

1) Low-back-specific SA days and periods
LB-specific SA included all SA episodes and days, regardless of their length, if their ICD-10 (WHO 2003) numbers were as follows: M43.0 Spondylolysis, M43.1 Spondylolisthesis, M45 Spondylarthritis ancylopoetica, M47 Spondylosis, M47.1 Alia spondylitisum cum myelopathia, M48 Aliae spondylopathiæ (including M48.0 Spinal stenosis, M48.8 and M48.9), M51 Aliae morbositates discorum intervertebræ (including 51.1, M51.2, M51.3, M51.8, M51.9), M54 (excluding M54.2 and M54.6) and S33.5 Distorsio partis lumbalis columnæ vertebræ. In summary, all LB-specific SA days and periods were included, regardless of their length.

2) All-cause (total) SA days and periods
The all-cause (total) SA days and periods included SA from all the diagnostic groups. However, long-term, non-low-back-specific SA episodes may interfere with statistical analysis, because these episodes typically originate from, for example, severe diseases or sequels of injury that are not connected to low-back symptoms. It is also assumed that they are not connected with the effectiveness of the interventions. Therefore, all non-low-back-specific episodes that lasted longer than 30
Participants and methods

days were excluded from this data. The 30-day cut-off limit was chosen arbitrarily before conducting any of the analyses. In summary, the all-cause SA days and periods included all low-back-specific SA days and periods, regardless of their length and all other-cause SA that lasted less than 31 days.

HC utilization data

The HC utilization questionnaire (Appendix 4) included the number of visits to a physician, nurse, physiotherapist or other HC professional. Each professional therefore represented a HC unit (four units). In addition, these items were all collected in the following HC categories (six categories): OHS, public (primary) HC, private HC, hospital outpatient and inpatient clinics (separately) and rehabilitation institutions or clinics. The number of radiological procedures during the preceding 12 months and the visits that related to alternative or complimentary HC (acupuncture, massage, chiropractor etc.) were also included (two items). Overall, 26 items were collected.

The costs of some radiological tests were calculated manually and therefore also transferred manually to the database because of the variable unit costs of the different radiological tests. The unit costs of each collected item were obtained from the national working paper of the Finnish Ministry of Social Affairs and Health (Hujanen et al. 2008), expressed in euros, and converted to the 2004 level (the final follow-up visit was in 2004). HC utilization data were analysed in Study II.

Total HC resource usage was available in the intervention groups for the whole two-year follow-up period (0, 3, 6, 12 and 24 months). However, HC utilization in the NC arm was only gathered at the 24-month time point, and thus only covered the preceding 12 months (months 13 to 24 from the initial study start date). Therefore, in order to retain comparability between the intervention arms and the control, 24-month follow-up data were calculated in all the study arms.

Following information was also gathered during the randomization and follow-up visits: previous illnesses, medication, previous rehabilitation,
factors that may worsen LBP (e.g. posture), blood pressure, results of some basic LB tests and two balance tests.

5.5 INTERVENTIONS

Two separate intervention studies were performed in both subcohorts:

1. Mild – Low-level symptoms (Studies I–II): Interventions were executed as planned during January 2002 and September 2002 and follow-up visits continued until October 2004.
2. Moderate – Moderate symptoms (Studies III–IV): Interventions were executed as planned during January 2002 and June 2002, and follow-up visits continued until August 2004.

5.5.1 MILD – LOW-LEVEL SYMPTOMS

After randomization, participants received information and advice during their first visit, according to which intervention arm they were allocated to.

I. Booklet – The Back Book® intervention arm (N = 92)
   The participants received the Back Book® information booklet from the OH nurse. The key messages of the booklet are in line with national LBP management guidelines. The booklet was translated into Finnish from the original English version well before the study began. The information is based on the biopsychosocial model and focuses on attitudes and non-recommended behaviour in terms of LBP. It also contains information on how to cope with LBP, avoid re-exacerbation of LBP, and emphasizes that one should resume normal activities, including work, as soon as possible. The participants in the Booklet arm received no other intervention.
Participants and methods

II. Combined – The Back Book® with Advice intervention arm (N = 89)
The participants received the Back Book® from the OH nurse, but she also reviewed the booklet with them in detail, face-to-face, using a slide show that was prepared in accordance with the Back Book®. Apart from the additional face-to-face information, there were no other differences between the Combined and Booklet intervention arms. The participants in the Combined arm received no other intervention.

Table 4. Summary of interventions and follow-up in Mild subcohort

<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention</th>
<th>Scheduled timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Both intervention arms</td>
<td>Randomisation visit by the occupational health nurse, clinical tests, balance tests</td>
<td>Baseline (=randomisation) visit</td>
</tr>
<tr>
<td></td>
<td>OH nurse follow-up visits: questionnaires, clinical tests, balance tests</td>
<td>3, 6, 12, 24 months after the baseline</td>
</tr>
<tr>
<td>Booklet intervention</td>
<td>Back Book booklet by the Occupational Health nurse (5 minutes)</td>
<td>Baseline visit</td>
</tr>
<tr>
<td>Combined intervention</td>
<td>Face-to-face advice by the Occupational Health nurse and Back Book booklet (about 30 minutes)</td>
<td>Baseline visit</td>
</tr>
<tr>
<td>Natural course (NC) control</td>
<td>One postal questionnaire</td>
<td>24 months after the baseline</td>
</tr>
</tbody>
</table>

All the returned questionnaires were checked, and the participants were given their next appointment date according to the follow-up procedure of the study. The first visit lasted about 60 minutes for the Booklet group, but for the Combined group, the face-to-face information required an additional 20 minutes. The follow-up visits lasted about 30 minutes each.

All participants had unlimited access to usual OHS throughout the study period and were free to obtain additional HC services if needed.
5.5.2 MODERATE – MODERATE SYMPTOMS

During the randomization visit, the OH physician performed a clinical examination and explained the findings to the employee. The participants received information and advice as well as referrals to the Rehab and Physio groups during the first visit according to their allocation into Rehab, Physio or Advice intervention arms.

I. Rehab – Physical medicine unit (N = 43) intervention arm
An intensive, bio-psychosocial and multidisciplinary LBP rehabilitation was carried out at the physical medicine outpatient unit of the South Karelian Central Hospital in the city of Lappeenranta, Finland (Hupli 1998). The rehabilitation team consisted of a specialist in physical medicine and rehabilitation, a psychologist, a social worker and several physiotherapists. The programme included a three-week preliminary course of 1.5-hour sessions three days per week. The pre-course programme included light mobilization and exercises, followed by a three-week intensive course period that comprised progressive exercises and multidisciplinary information on low-back -syndrome and pain management. The rehabilitation programme lasted a total of 6.5 hours per day for five days per week, i.e. 15 days in total. The whole intervention lasted about 111 hours over 6 weeks and was performed in five groups consisting of 8 to 10 individuals.

Finally, a personal maintenance exercise programme was designed for the participants and they were later invited to one follow-up visit six months after the initial course. The participants were not sick-listed during the three-week intensive period, but because they were absent from work, they received compensation from Kela. The costs of the course were covered by the public HC budget. Outpatient rehabilitation in a hospital’s physical medicine and rehabilitation unit is a widely used method for persistent LBP in some physical medicine and rehabilitation clinics in Finland.
II. Physio – Progressive back exercises (N = 43) intervention arm
A graded, bio-psycho-social, low-back -specific exercise programme was carried out in a physiotherapy outpatient clinic (Taimela and Harkapaa 1996, Kankaanpaa et al. 1999). It consisted of a one-hour session two or three times per week, over a period of 12 weeks, supervised by a specially trained physiotherapist. The whole intervention lasted about 24 to 36 hours.
The guided rehabilitation programme included measurements and exercises targeted at the trunk muscles using specific equipment, stretching and relaxation. The physiotherapists emphasized the ‘good prognosis’ of LBP during the treatment sessions and the participants were taught low-back -exercises to perform at home. The importance of the home exercises was emphasized during the programme. The programme also involved a follow-up measurement and visit after six months.

III. Advice – Self-care Advice by an OH physician (N = 40) intervention arm
During the first study visit, participants received the Back Book® (Burton et al. 1999) booklet and their OH physician also explained the contents of the booklet to them individually, face-to-face. The Back Book® contents follow the general LBP guidelines by emphasizing the benign nature and good prognosis of non-specific LBP and suggesting rapid return to normal activities (Burton et al. 1999). The booklet also offers practical advice for patients suffering from an acute or subacute LBP episode. The self-care advice was implemented as a low-cost control intervention.
The baseline visit, which also included the randomization procedure, lasted about 60 minutes in all the intervention arms, but in the Advice arm, the first visit took an additional 20 minutes because of the Back Book® information session. The participants of all the intervention arms were free to use all the HC services during the study interventions and follow-up, as normal. There were no other general or low-back-specific health interventions going on at the company during the study. The OHS unit of the company operated as usual during the study period.

### 5.5.3 NATURAL COURSE (NC) ARMS

The eligibility of the employees in the NC arms was assessed in the same way as that of their fellow employees who were assigned to the intervention arms. The NC participants received no interventions or visits whatsoever. They were sent one follow-up questionnaire, two years after the employee survey.

---

<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention</th>
<th>Scheduled timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>All intervention arms</td>
<td>Randomisation visit by the occupational physician, clinical tests, balance tests</td>
<td>Baseline visit</td>
</tr>
<tr>
<td></td>
<td>OH physician follow-up visits: questionnaires, clinical tests, balance tests</td>
<td>3, 6, 12, 24 months after the baseline</td>
</tr>
<tr>
<td>Rehab intervention</td>
<td>Multidisciplinary, biopsychosocial and LBP specific rehabilitation (altogether 111 hours)</td>
<td>3 + 3 weeks (scheduled after the baseline visit)</td>
</tr>
<tr>
<td>Physio intervention</td>
<td>Graded, bio-psycho-social, low back specific exercise program (altogether 24 - 36 hours)</td>
<td>12 weeks (scheduled after the baseline visit)</td>
</tr>
<tr>
<td>Advice intervention</td>
<td>Face-to-face advice and Back Book booklet by the Occupational Health physician (20 - 30 minutes)</td>
<td>Baseline visit</td>
</tr>
<tr>
<td>Natural course (NC) control</td>
<td>One postal questionnaire</td>
<td>24 months after the baseline</td>
</tr>
</tbody>
</table>

---

Table 5. Summary of interventions and follow-up in Moderate subcohort
Participants and methods

The NC arm members were contacted as little as possible during the follow-up; for example, they only received one reminder if they did not respond to the first postal survey.

In summary, the NC arms followed the NC of LBP throughout the follow-up period. Like the intervention arm participants, the NC group members were also free to use all available HC resources as normal.

5.6 FOLLOW-UP VISITS

All the intervention arms had four scheduled follow-up visits at 3, 6, 12, and 24 months after the randomization visit. The employees were instructed to fill out their follow-up questionnaires during the week prior to their visit date. In both RCTs, the intervention groups were comparable in terms of follow-up intervals, visit activity and time (30 minutes) spent at the follow-up visits. During the follow-up visits, the researcher collected the LB questionnaires and performed the balance tests. None of the intervention procedures, such as collecting patient information, were repeated during the follow-up visits. The follow-up visits lasted about 30 minutes each.

After the follow-up tests were completed and the questionnaires were returned, the next follow-up appointment date was scheduled. If any visit was missed, a new appointment date was scheduled, and the participant was informed via post or a phone call. Some participants returned their questionnaires if they were not able to attend the follow-up visit.

5.7 STATISTICAL METHODS

5.7.1 POWER CALCULATIONS

Power calculations were made before the study started using the main outcome variable in each study.

A power calculation for the difference in LBP intensity (VAS) was made in the Moderate subcohort (Studies III–IV). The standard deviation was expected to be 15 units (mm). The calculations showed that 10 mm
differences in LBP intensity between groups were detectable with 80% power in two-tailed tests with a significance level of 0.05 for a sample of 40 employees in each group.

In the Mild subcohort, the standard deviation of the RM-18 score was estimated to be four units (Studies I–II). A difference of two units between the treatment arms was detectable with 85% power in two-tailed tests with an alpha of 0.05 for a sample of 73 employees in each group; the standardized effect size was 0.50.

5.7.2 PROCESSING THE DATA

To ensure blinding, all the data were entered into the data file by people who were independent of the research personnel.

Missing values and imputation procedure

About 29% of the questionnaire follow-up data were reported missing, mostly due to some completely missed follow-up visits or a single missing item in a multi-component questionnaire. Without imputation, several visits or questionnaire outcomes would have been excluded from the final analysis. Imputation methods are recommended in the management of questionnaire data (Spratt et al. 2010, Vergouw et al. 2012, Gomes et al. 2013, Rezvan et al. 2015). Missing values in the self-administered questionnaire data were imputed using the last observation carried forward (LOCF) principle in Studies I and III and using the multiple imputation method in Studies II and IV.

We are not aware of any systematic reasons, motives or circumstances that would explain the missed visits or non-response in any of the study groups. All the participants of this study had equal opportunity to attend follow-up visits during their working hours and were also offered several alternative appointments if needed. Some participants sent their questionnaire data to the study personnel if they were unable to attend personally. Based on our best knowledge, the missing questionnaire data was missing at random.
Participants and methods

Last observation carried forward

LOCF was formerly one of the most popular imputation methods in follow-up studies. In Studies I and III, the missing values in the questionnaire outcomes were imputed using the previous value of the same variable, LOCF. The imputed value in LOCF can also be determined in other ways, for instance the mean of the previous values. Sometimes, the mean of the same intervention group may also be used.

However, the LOCF method generally causes bias by underestimating the variability of the estimated results (Ranstam et al. 2012).

Multiple imputation

Multiple imputation (MI) is largely recommended as an imputation method in modern research. MI uses sophisticated and multiphasic calculation methods and is generally based on a large amount of available data. In addition, the imputation process is repeated many times before the imputed value is determined (Sterne et al. 2009, Spratt et al. 2010, Ranstam et al. 2012, Vergouw et al. 2012, Gomes et al. 2013).

In Studies II and IV, the missing values in the questionnaire-based outcome variables were imputed using the MI method (Burton et al. 2007) of the IBM SPSS Statistical Package version 24.0 for Windows © (IBM Inc., Chicago, IL, USA). The following items were used as determinants in the MI procedure: age, gender, marital status, education, smoking, lifetime duration of LBP, self-assessed health status, working status, shift work, physical workload, mental workload, self-assessed work ability, job satisfaction, physical impairment, LBP, pain-related fear, all-cause SA at 12 months prior to employee survey, and all-cause SA over the first follow-up year. MI can be used when missing values are missing at random.
5.7.3 OUTCOME VARIABLES

All statistical analyses were performed at the employee level, according to the intention-to-treat principle. The intervention arms were pooled for comparison to the NC arm, when appropriate.

Low back-specific outcomes

Baseline characteristics were compared using descriptive statistics. The effectiveness of an intervention was primarily estimated by the difference between the questionnaire variables of the intervention group and the controls (e.g. Combined versus Booklet or Rehab versus NC). In Studies I and III, group comparisons were calculated at 3-, 6-, 12- and 24-month time points and in Studies II and IV they were examined at the 24-month time-point. Respective baseline values were used as covariates. In Studies II and IV, the baseline values originated from the employee survey, whereas the two RCT (Studies II and III) baseline values were calculated from the randomization visit values. The 95% confidence intervals (95% CI) for the mean differences between the groups were computed using the generalized linear model (GLM). The statistical package of IBM SPSS, versions 22–24 were used (SPSS Inc, Chicago, IL, USA).

In Study II, the effect sizes were estimated using Cohen’s d (Ellis 2010).

SA data

SA data were gathered 12 months before baseline and at 6, 12 and 24 months after baseline, beginning from the individual baseline date of each study participant. The SA data, already from a one-year sequence, were highly skewed, with some very high values and an excess of zeros (Figure 8A). Although the accumulation of the SA data over four years resulted in a smaller amount of zero values, the data remained skewed (Figure 8B). Of the employees, 130 or 40 had no SA days during the first follow-up year or none accumulated over four years, respectively. Zero values have been erased from Figures 8 A and B for clarity.
Participants and methods

Figure 8: (A and B). Total number of total SA days > 0, of study cohort (n = 505): A. During first follow-up year B. Accumulated over 1–4 follow-up years in total. Zero values (A: 130; B: 40) have been erased for clarity.

As regards the SA variables in all four studies, different observational (linear and non-linear) models and hierarchical latent regression models were tested. Count data are commonly modelled using Poisson, negative binomial and corresponding zero inflated models. The previous year’s SA data, i.e. one-year SA days and periods before the study, were used as covariates.
Studies I and III used the Hurdle model (Mullahy 1986), which corresponds to a two-stage process in which the first process determines whether a person has any SAs and the second determines the number of SA periods or days. In the zero part (first process), the latent function models the logit of the probability that the number of SA days or periods is larger than zero. In the count part (second process), the latent function models the log of the mean parameter of the zero-truncated negative binomial. The linear and non-linear models were both tested with different hierarchical structures. The final choice for both latent models was a hierarchical Gaussian process model with a neural network covariance function (Rasmussen and Williams 2006, Vanhatalo et al. 2013). The constructed hierarchical model (Gelman and Hill 2006) contained a common effect, an effect for baseline, effects for each intervention group, and effects for each person (also called random effects). For the logistic model, the probability of SA (days and periods) and odds ratios (OR) for the group differences were reported. For the zero-truncated negative binomial model, the mean SA days or periods and mean ratios of the group difference were reported. All the reported values included 95% confidence intervals (95% CI). The method is described in more detail elsewhere (Vanhatalo et al. 2013).

Finally, in Study III, the best model for SA distribution was achieved using the negative binomial model with a logarithmic link function.

In Study II, to equally comply with the timeframe of HC costs in all the study groups, SA data were gathered in a timeframe of 12–24 months from baseline.

**HC utilization data**

Study II presented and analysed HC utilization data. The cost-effectiveness of the study interventions was analysed and compared to that of the NC group.

A one-way sensitivity analysis, a probabilistic sensitivity analysis (Monte Carlo method and Bayesian, non-parametric bootstrapping with 10 000 replicates) of the comparisons between the intervention and the NC groups were performed to assess the uncertainty of the cost-effectiveness analysis (CEA).
Participants and methods

The incremental cost-effectiveness ratio (ICER) is the cost difference of two interventions divided by the difference of their effects. Hence, ICER summarizes the cost-effectiveness of an HC intervention by representing the average incremental cost (EUR), which associates with one additional unit of effect (SA day).

One-way sensitivity analysis shows how the change in one-unit cost influences the ICER (EUR per SA day), when other values remain at their base level.

The results of the main CEA are presented as cost-effectiveness planes (CE-plane), mean incremental costs (IC) and effects (IE) with corresponding 95% CI and the ICER. The uncertainty of CE-planes was evaluated using cost-effectiveness acceptability curves (CEAC), which are presented in the additional files. The one-way sensitivity analyses for the ICERs are presented in tornado diagrams.

In addition to the results of the imputed main analysis, the complete case analysis (original data) were also presented.

HC costs were first calculated at the 2004 level and later converted to the present time level.
6 RESULTS

6.1 LOSS TO FOLLOW UP

As regards the Mild subcohort, within the first three months, four Combined arm participants and five Booklet arm participants withdrew from the study due to personal reasons but granted permission to use their data. At the end of the two-year follow-up, 18 Combined arm participants, and 20 Booklet arm participants failed to return their questionnaires, resulting in missing data. The reasons for withdrawing from the study remained mostly unknown to the researchers. In both intervention arms, 67 participants continued to the end of the two-year follow-up (activity rates: Combined 73% and Booklet 75%). In the NC_{mild} arm, 32 of the eligible 83 participants did not return the postal questionnaire, meaning that complete data were available for only 51 (61%) participants.

In the Moderate subcohort, one Advice group participant withdrew from the study due to personal reasons before the end of the follow-up but granted permission to use their data. At the end of the two-year follow-up, six Rehab group participants, 10 Physio group participants and 11 Advice group participants failed to return their questionnaires, resulting in missing data. One Physio group participant died three months before the final visit.

A final total of 99 participants (Rehab, n = 37; Physio, n = 33 and Advice, n = 29) continued to the final visit, resulting in participation rates of 86%, 77% and 73%, respectively. In the NC_{moderate} arm, data were available for 31 (62%) participants.

As regards the HC utilization data, complete case analysis included the participants who returned their HC utilization questionnaires during the 24-month visit. However, the main analysis examined the SA data, as well as the multiply imputed questionnaire data of all the study participants.
Results

6.2 EMPLOYEE SURVEY

The response rate of the total employee survey (2480 questionnaires sent) was 71% (1754 responses).

Of all respondents (1754):
- The mean age was 45 years (18-64 yr)
- 72% were male
- 69% were blue-collar workers
- 37% were hired for shift work (two- or three-shift work)
- 20% reported heavy, 37% moderate, and 43% light physical work strain.
- 32% reported heavy, 49% moderate, and 19% light mental work strain.
- 76% reported having previously suffered LBP during their lives (1333 respondents with positive working status and age between 18 and 56 years)
- 14% reported previous SA due to LBP during the preceding 12 months
- 3.5% had a history of LB operation
- 42% reported current LBP
- 29.5% reported radicular LBP during the preceding year
- 18% reported subacute LBP (lasting over 2–12 weeks)
- 60% reported recurrent LBP (more often than once/year)

- Finally, 505 respondents (29%) met the study inclusion criteria – risk of disabling LBP in two subcohorts
  o 312 (18% of all respondents) reported mild-level LBP according to study criteria
  o 193 (11% of all respondents) reported moderate LBP according to study criteria
6.3 MILD-LEVEL SYMPTOMS (STUDIES I – II)

The effectiveness of the interventions in the Mild subcohort were estimated in two studies, Study I, which was the RCT of the Mild subcohort interventions and Study II, which mainly evaluated the cost-effectiveness of the interventions in comparison to the NC.

The main results of Studies I and II are presented below.

6.3.1 BASELINE CHARACTERISTICS

Study I (RCT1)

Table 6 shows the main characteristics of the participants in the RCT1 intervention arms (BB+A=Combined; BB=Booklet).

Study II

Table 7 shows some basic characteristics of the Study II participants. The data were collected from the employee survey data in order to retain comparability between the arms of the study.
### Results

**Table 6. Baseline characteristics of RCT1.**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Combined (N=89)</th>
<th>Booklet (n=92)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographic features</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, yrs.</td>
<td>45 (8)</td>
<td>43 (7)</td>
</tr>
<tr>
<td>BMI, (kg/m²)</td>
<td>27 (4)</td>
<td>26 (4)</td>
</tr>
<tr>
<td>Male, %</td>
<td>79</td>
<td>66</td>
</tr>
<tr>
<td>Married, %</td>
<td>75</td>
<td>73</td>
</tr>
<tr>
<td>Smoking, %</td>
<td>30</td>
<td>28</td>
</tr>
<tr>
<td>High school/vocational degree, %</td>
<td>79</td>
<td>75</td>
</tr>
<tr>
<td><strong>General health</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of LBP, yrs</td>
<td>12 (10)</td>
<td>11 (7)</td>
</tr>
<tr>
<td>Previous low back operation, %</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Physical activity ≥ 2/week, %</td>
<td>80</td>
<td>67</td>
</tr>
<tr>
<td><strong>Work related features</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blue collar, %</td>
<td>69</td>
<td>64</td>
</tr>
<tr>
<td>At shift work, %</td>
<td>41</td>
<td>37</td>
</tr>
<tr>
<td>Satisfied with own work, %</td>
<td>91</td>
<td>88</td>
</tr>
<tr>
<td>Influence on own work, %</td>
<td>81</td>
<td>75</td>
</tr>
<tr>
<td>Physical workload (1-5)²</td>
<td>3.3 (1.0)</td>
<td>3.4 (0.9)</td>
</tr>
<tr>
<td>Mental workload (1-5)²</td>
<td>2.8 (0.8)</td>
<td>2.8 (0.8)</td>
</tr>
<tr>
<td>Work ability, self rated (0-10)³</td>
<td>8.0 (1.5)</td>
<td>8.3 (1.4)</td>
</tr>
<tr>
<td>Total SA days/previous year**</td>
<td>12 (18)</td>
<td>9 (11)</td>
</tr>
<tr>
<td><strong>Outcome variables at baseline</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RM-18 (0-18)</td>
<td>3.0 (3.6)</td>
<td>2.8 (3.4)</td>
</tr>
<tr>
<td>15-D (0-1)</td>
<td>0.92 (0.07)</td>
<td>0.92 (0.07)</td>
</tr>
<tr>
<td>LBP Intensity/VAS (0-100), mm</td>
<td>18 (17)</td>
<td>21 (19)</td>
</tr>
<tr>
<td>ODI (0-100), %</td>
<td>10.8 (8.2)</td>
<td>9.4 (7.4)</td>
</tr>
<tr>
<td>FABQ (13-78)</td>
<td>26.6 (9.7)</td>
<td>27.8 (9.5)</td>
</tr>
<tr>
<td>DEPS (0-30)</td>
<td>3.2 (3.9)</td>
<td>3.4 (3.5)</td>
</tr>
<tr>
<td><strong>Screening criteria</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LBP intensity/VAS (0-100), mm</td>
<td>21 (11)</td>
<td>18 (10)</td>
</tr>
<tr>
<td>Referred pain, %</td>
<td>32</td>
<td>32</td>
</tr>
<tr>
<td>Subacute LBP ≥ 2 wk, previous year, %</td>
<td>38</td>
<td>33</td>
</tr>
<tr>
<td>Recurrent LBP, ≥ 2 times/year, %</td>
<td>92</td>
<td>96</td>
</tr>
<tr>
<td>LBP related SA previous year, %</td>
<td>23</td>
<td>21</td>
</tr>
</tbody>
</table>

* mean when applicable (standard deviation), unless otherwise stated.

¹ Range (when applicable) is presented after the variable name in parenthesis

² register data

³ two-shift or three-shift work

range 1-5 indicates the self rated level of load: 1=very heavy, 2=moderate, 3=intermediate, 4=rather light, 5=very light

³ range 0-10, when 0 is the lowest possible work ability and 10 is the best possible work ability
Table 7. Basic characteristics of study participants in Mild subcohort according to employee survey data.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Combined (n=89)</th>
<th>Booklet (n=92)</th>
<th>NC (n=83)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% mean SD</td>
<td>% mean SD</td>
<td>% mean SD</td>
<td></td>
</tr>
<tr>
<td>Demographics</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>44 8</td>
<td>43 7</td>
<td>45 8</td>
<td>0.52</td>
</tr>
<tr>
<td>Male</td>
<td>79 .</td>
<td>66 .</td>
<td>76 .</td>
<td>0.55</td>
</tr>
<tr>
<td>Smoking</td>
<td>30 .</td>
<td>28 .</td>
<td>31 .</td>
<td>0.35</td>
</tr>
<tr>
<td>High school/vocational degree</td>
<td>79 .</td>
<td>75 .</td>
<td>76 .</td>
<td>0.87</td>
</tr>
<tr>
<td>General health</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of LBP, years</td>
<td>12 9</td>
<td>11 7</td>
<td>14 9</td>
<td>0.09</td>
</tr>
<tr>
<td>SA days before baseline 1</td>
<td>12 18</td>
<td>9 12</td>
<td>14 19</td>
<td>0.10</td>
</tr>
<tr>
<td>Work-related features</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blue collar worker</td>
<td>69 .</td>
<td>64 .</td>
<td>78 .</td>
<td>0.05</td>
</tr>
<tr>
<td>Shift worker (2- or 3-shift work)</td>
<td>41 .</td>
<td>37 .</td>
<td>40 .</td>
<td>0.73</td>
</tr>
<tr>
<td>Physical workload (1-5)</td>
<td>3 1</td>
<td>3 1</td>
<td>3 1</td>
<td>0.13</td>
</tr>
<tr>
<td>Mental workload (1-5)</td>
<td>3 1</td>
<td>3 1</td>
<td>3 1</td>
<td>0.51</td>
</tr>
<tr>
<td>Work ability (0-10)</td>
<td>8.1 1.5</td>
<td>8.3 1.5</td>
<td>7.8 1.6</td>
<td>0.07</td>
</tr>
<tr>
<td>Outcome variables at baseline</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PHI; RM-18 (0-18)</td>
<td>4.2 4.6</td>
<td>2.5 3.2</td>
<td>3.9 3.6</td>
<td>0.34</td>
</tr>
<tr>
<td>LBP intensity; VAS (0-100)</td>
<td>20 7</td>
<td>20 7</td>
<td>19 7</td>
<td>0.52</td>
</tr>
<tr>
<td>Other LB specific variables</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FABQ (13-78)</td>
<td>29 10</td>
<td>29 11</td>
<td>31 11</td>
<td>0.15</td>
</tr>
</tbody>
</table>

1 all cause sickness absence days during 12 months prior to baseline (register data)
2 1-5 indicates self-rated load: 1=very heavy, 2=moderate, 3=intermediate, 4=rather light,
3 range 0-10, when 0 is lowest possible work ability and 10 is best possible work
4 Higher value indicates higher impairment, pain or fear of pain, resp
5 for the comparison between Booklet and NC, mean difference of PHI is significant (p=0.01).

Means (SD=standard deviation) or percentages when applicable. Intervention arms were pooled for comparison between the intervention and NC. [Combined=Back Book and Advice intervention arm; Booklet=Back Book intervention arm; NC=Natural Course control arm; BMI=Body mass Index; SA=sickness absence; LBP=low back pain; VAS=Visual Analogue Scale; RM-18=Roland-Morris 18-item Disability Questionnaire; PHI=Physical impairment; p=P-value]. Missing values (concerning smoking, duration of LBP and shift work) were imputed using the multiple imputation procedure.
Results

There were more blue-collar workers in the NC arm, but comparisons to the pooled intervention arms found no other differences (Table 7). The comparability remained good between the intervention arms and the NC arms.

NC_mild participants

Fifty-one of the 83 eligible NC_mild participants responded (61%) to the study questionnaire. Table 8 shows the baseline characteristics of the NC_mild respondents and non-respondents and their comparisons. Those who did not respond to the questionnaire were more educated and experienced more physical workload.

Table 8. Characteristics of NC_mild control arm respondents and non-respondents.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Not included (32)</th>
<th>Included (51)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male, %</td>
<td>72 . .</td>
<td>78 . .</td>
<td>0.34</td>
</tr>
<tr>
<td>High school/vocational degree, %</td>
<td>100 . .</td>
<td>61 . .</td>
<td><strong>0.00</strong></td>
</tr>
<tr>
<td>Blue collar, %</td>
<td>88 . .</td>
<td>73 . .</td>
<td>0.09</td>
</tr>
<tr>
<td>Age (years)</td>
<td>43 10</td>
<td>45 7</td>
<td>0.27</td>
</tr>
<tr>
<td>Duration of LBP, yrs</td>
<td>14 9</td>
<td>13 9</td>
<td>0.84</td>
</tr>
<tr>
<td>Physical workload (1-5)^1</td>
<td>2.8 1.0</td>
<td>3.3 0.9</td>
<td><strong>0.01</strong></td>
</tr>
<tr>
<td>Mental workload (1-5)^2</td>
<td>3.0 0.8</td>
<td>2.8 0.9</td>
<td>0.42</td>
</tr>
<tr>
<td>Work ability (0-10)^2</td>
<td>7.4 1.9</td>
<td>8.1 1.3</td>
<td>0.06</td>
</tr>
<tr>
<td>Outcome variables at baseline</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PH; RM-18 (0-18)</td>
<td>4 4</td>
<td>4 4</td>
<td>0.98</td>
</tr>
<tr>
<td>LBP intensity; VAS (0-100), mm</td>
<td>20 8</td>
<td>19 6</td>
<td>0.63</td>
</tr>
<tr>
<td>Other LB specific variables</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FABQ (13-78), #</td>
<td>32 11</td>
<td>31 11</td>
<td>0.74</td>
</tr>
<tr>
<td>SA variables before baseline</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LB SA days 1 year before baseline</td>
<td>5 22</td>
<td>4 11</td>
<td>0.64</td>
</tr>
<tr>
<td>All SA days 1 year before baseline</td>
<td>18 24</td>
<td>12 14</td>
<td>0.18</td>
</tr>
<tr>
<td>SA variables after baseline</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total SA days in the first year</td>
<td>21 40</td>
<td>13 20</td>
<td>0.24</td>
</tr>
<tr>
<td>Total SA days in the second year</td>
<td>14 22</td>
<td>17 23</td>
<td>0.60</td>
</tr>
<tr>
<td>Cumulative total SA days in 2 years</td>
<td>35 56</td>
<td>30 32</td>
<td>0.60</td>
</tr>
</tbody>
</table>

* mean when applicable (standard deviation), unless otherwise stated.

1 1-5 indicates the self rated level of load: 1=very heavy, 2=moderate, 3=intermediate, 4=rather light, 5=very light
2 range 0-10, when 0 is the lowest possible work ability and 10 is the best possible work ability
### 6.3.2 QUESTIONNAIRE OUTCOMES

**Study I (RCT1)**

There were no differences between the study arms in terms of PHI, LBP intensity or HRQoL at any time point during the 24-month follow-up (Table 9).

**Table 9. Results of Study I questionnaire variables (RCT1).**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Time Point</th>
<th>Combined mean</th>
<th>Combined SD</th>
<th>Booklet mean</th>
<th>Booklet SD</th>
<th>Combined vs. Booklet MD(95% CI)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical impairment (RM-18)</td>
<td>3mo</td>
<td>2.7</td>
<td>3.2</td>
<td>2.3</td>
<td>3.1</td>
<td>0.2 (.0.5 - 0.9)</td>
<td>0.54</td>
</tr>
<tr>
<td></td>
<td>6mo</td>
<td>1.9</td>
<td>2.6</td>
<td>1.8</td>
<td>2.8</td>
<td>-0.0 (-.7 - 0.6)</td>
<td>0.97</td>
</tr>
<tr>
<td></td>
<td>12mo</td>
<td>2.3</td>
<td>3.3</td>
<td>2.0</td>
<td>3.2</td>
<td>0.2 (-0.5 - 1.0)</td>
<td>0.54</td>
</tr>
<tr>
<td></td>
<td>24mo</td>
<td>2.3</td>
<td>3.6</td>
<td>2.0</td>
<td>3.4</td>
<td>0.2 (-0.7 - 1.1)</td>
<td>0.74</td>
</tr>
<tr>
<td>QoL, (15-D)²</td>
<td>3mo</td>
<td>0.92</td>
<td>0.07</td>
<td>0.93</td>
<td>0.06</td>
<td>-0.01 (-.02 - .00)</td>
<td>0.07</td>
</tr>
<tr>
<td></td>
<td>6mo</td>
<td>0.92</td>
<td>0.09</td>
<td>0.93</td>
<td>0.07</td>
<td>0.00 (-.02 - .01)</td>
<td>0.63</td>
</tr>
<tr>
<td></td>
<td>12mo</td>
<td>0.92</td>
<td>0.09</td>
<td>0.93</td>
<td>0.06</td>
<td>-0.01 (-.02 - .01)</td>
<td>0.34</td>
</tr>
<tr>
<td></td>
<td>24mo</td>
<td>0.91</td>
<td>0.10</td>
<td>0.92</td>
<td>0.07</td>
<td>0.00 (-.02 - .02)</td>
<td>0.99</td>
</tr>
<tr>
<td>Low back pain (VAS), mm</td>
<td>3mo</td>
<td>16</td>
<td>16</td>
<td>20</td>
<td>21</td>
<td>-3 (-8 - 2)</td>
<td>0.21</td>
</tr>
<tr>
<td></td>
<td>6mo</td>
<td>14</td>
<td>16</td>
<td>17</td>
<td>17</td>
<td>-2 (-7 - 2)</td>
<td>0.32</td>
</tr>
<tr>
<td></td>
<td>12mo</td>
<td>19</td>
<td>20</td>
<td>17</td>
<td>19</td>
<td>3 (-2 - 8)</td>
<td>0.30</td>
</tr>
<tr>
<td></td>
<td>24mo</td>
<td>20</td>
<td>23</td>
<td>18</td>
<td>20</td>
<td>3 (-3 - 8)</td>
<td>0.37</td>
</tr>
<tr>
<td>Disability (ODI), %</td>
<td>3mo</td>
<td>9.3</td>
<td>8.8</td>
<td>9.0</td>
<td>8.4</td>
<td>-0.7 (-2.6 - 1.2)</td>
<td>0.46</td>
</tr>
<tr>
<td></td>
<td>6mo</td>
<td>8.8</td>
<td>7.9</td>
<td>7.8</td>
<td>8.3</td>
<td>0.1 (-1.8 - 2.0)</td>
<td>0.90</td>
</tr>
<tr>
<td></td>
<td>12mo</td>
<td>9.1</td>
<td>9.2</td>
<td>6.7</td>
<td>6.9</td>
<td>1.4 (-0.4 - 3.1)</td>
<td>0.13</td>
</tr>
<tr>
<td></td>
<td>24mo</td>
<td>10.7</td>
<td>10.6</td>
<td>8.4</td>
<td>9.6</td>
<td>1.3 (-1.2 - 3.7)</td>
<td>0.31</td>
</tr>
<tr>
<td>Pain-related fear (FABQ)</td>
<td>3mo</td>
<td>27.9</td>
<td>11.2</td>
<td>26.1</td>
<td>10.0</td>
<td>2.1 (-0.1 - 4.3)</td>
<td>0.06</td>
</tr>
<tr>
<td></td>
<td>6mo</td>
<td>25.2</td>
<td>10.4</td>
<td>25.3</td>
<td>10.0</td>
<td>0.2 (-1.8 - 2.2)</td>
<td>0.83</td>
</tr>
<tr>
<td></td>
<td>12mo</td>
<td>26.5</td>
<td>10.7</td>
<td>25.2</td>
<td>9.0</td>
<td>1.7 (-0.2 - 3.6)</td>
<td>0.08</td>
</tr>
<tr>
<td></td>
<td>24mo</td>
<td>26.5</td>
<td>12.1</td>
<td>25.5</td>
<td>9.4</td>
<td>1.4 (-0.8 - 3.5)</td>
<td>0.22</td>
</tr>
<tr>
<td>Depression, (DEPS scale)</td>
<td>3mo</td>
<td>3.3</td>
<td>4.5</td>
<td>2.9</td>
<td>3.4</td>
<td>0.4 (-0.4 - 1.2)</td>
<td>0.33</td>
</tr>
<tr>
<td></td>
<td>6mo</td>
<td>3.1</td>
<td>4.9</td>
<td>3.1</td>
<td>3.6</td>
<td>0.1 (-0.8 - 0.9)</td>
<td>0.91</td>
</tr>
<tr>
<td></td>
<td>12mo</td>
<td>3.1</td>
<td>4.5</td>
<td>2.9</td>
<td>3.4</td>
<td>0.2 (-0.6 - 1.1)</td>
<td>0.60</td>
</tr>
<tr>
<td></td>
<td>24mo</td>
<td>3.5</td>
<td>4.8</td>
<td>2.9</td>
<td>3.4</td>
<td>0.6 (-0.3 - 1.5)</td>
<td>0.19</td>
</tr>
</tbody>
</table>

1 mean, standard deviation (SD), mean difference (MD), 95% confidence interval (95%CI), p-value

2 range (0-1); bigger value represents better quality of life

₃Time point: 6mo=6 month follow-up point, 12mo=12 month follow-up point etc.
Results

Study II
According to the main analysis, at two years from baseline, the mean difference between the PHI, of the Booklet and NC arms was -2.5 [95% CI -3.8 – -1.3] and of the Combined and NC arms, -1.5 [95% CI -2.8 – -0.3] (Table 10).

Table 10. Results of Study II outcome variables. Reproduced with permission from BioMed Central.

<table>
<thead>
<tr>
<th>Outcomes / analysis</th>
<th>Combined</th>
<th>Booklet</th>
<th>NC</th>
<th>Total</th>
<th>Combined vs. NC</th>
<th>Booklet vs. NC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mean</td>
<td>SD</td>
<td>mean</td>
<td>SD</td>
<td>mean</td>
<td>SD</td>
</tr>
<tr>
<td>PHI</td>
<td>3.0</td>
<td>3.6</td>
<td>2.0</td>
<td>2.9</td>
<td>4.5</td>
<td>3.8</td>
</tr>
<tr>
<td>LBP</td>
<td>21</td>
<td>22</td>
<td>20</td>
<td>20</td>
<td>23</td>
<td>19</td>
</tr>
<tr>
<td>SA first year</td>
<td>12</td>
<td>22</td>
<td>12</td>
<td>18</td>
<td>16</td>
<td>30</td>
</tr>
<tr>
<td>SA second year</td>
<td>16</td>
<td>38</td>
<td>12</td>
<td>34</td>
<td>16</td>
<td>23</td>
</tr>
<tr>
<td>SA total in two years</td>
<td>27</td>
<td>50</td>
<td>24</td>
<td>48</td>
<td>32</td>
<td>43</td>
</tr>
<tr>
<td>HC costs in 12 months, €</td>
<td>195</td>
<td>700</td>
<td>108</td>
<td>142</td>
<td>303</td>
<td>577</td>
</tr>
<tr>
<td>Complete case analysis</td>
<td>2</td>
<td>PHI</td>
<td>2.6</td>
<td>3.8</td>
<td>1.5</td>
<td>3.1</td>
</tr>
<tr>
<td></td>
<td>LBP</td>
<td>20</td>
<td>23</td>
<td>17</td>
<td>22</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td>SA first year</td>
<td>13</td>
<td>25</td>
<td>12</td>
<td>19</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>SA second year</td>
<td>16</td>
<td>42</td>
<td>13</td>
<td>39</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>SA two years</td>
<td>29</td>
<td>55</td>
<td>25</td>
<td>54</td>
<td>30</td>
</tr>
<tr>
<td>HC costs in 12 months, €</td>
<td>188</td>
<td>808</td>
<td>73</td>
<td>151</td>
<td>370</td>
<td>730</td>
</tr>
</tbody>
</table>

1Main analysis includes 264 participants in Combined (89), Booklet (92) and NC (83) arms.
2Complete case analysis includes 185 participants in Combined (67), Booklet (67) and NC (51) arms.

The main analysis included the multiply imputed data of 264 cases and the complete case analysis included the original, available data (n = 185). The table shows the means and standard deviations in all the study arms and the comparisons of the intervention arms (Combined and Booklet) and control (NC=natural course arm). [Mean, standard deviation (SD), mean difference (MD), 95% confidence interval (95%CI), p-value of the group comparison, PHI=Physical impairment using the Roland-Morris 18-item Disability Questionnaire (range 0–18), LBP low back pain in Visual Analogue Scale (VAS, range 0–100mm), SA=sickness absence (days), HC=health care].
6.3.3 SICKNESS ABSENCE

**Study I (RCT1)**
In comparison to the booklet information alone, Combined information did not reduce the probability or the number of total or LB-specific SA days (see Study I) at any follow-up point during the four years in comparison to Booklet information. SA days increased in both intervention groups during the last two years of the four-year follow-up.

**Exploratory subgroup analyses of SA (Study I)**
An exploratory subgroup analysis examined the SA data (Study I). Figure 9 shows the *a priori* selected items that were tested. Previous all-cause SA (one year prior to baseline) and shift work predicted the probability of total SA during the follow-up. However, the group difference was not statistically significant for shift work (Figure 9).

![Figure 9. Subgroup analysis of sickness absence in Study I.](image-url)
Results

Study II
All-cause SA days over two years were lower only trend-wise in both intervention arms than in the NC.

6.3.4 USE OF HC RESOURCES (STUDY II)
About 24 months after the employee survey (i.e. baseline), the participants in all the study arms reported their HC utilization during the preceding 12 months, i.e. 13–24 months after baseline. The questionnaire included the following cost items, each of which represents one unit of HC usage.

Cost items (abbreviations refer to Table 11 and Figure 10):
1. Number of visits to a physician (Dr)
2. Number of visits to a nurse (Nurse)
3. Number of visits to a physiotherapist (Phys)
4. Number of visits to another HC professional (else)

These four cost-items were all calculated under the following HC categories 1–4 and categories 5 – 8 were calculated as itself.

Categories (abbreviations refer to Table 11 and Figure 10):
1. OHS (OH-Dr, OH-Nurse, OH-Phys, OH-else)
2. Public (primary) HC (GEN-Dr, GEN-Nurse, GEN-Phys, GEN-else)
3. Private HC (PRIV-Dr, PRIV-Nurse, PRIV-Phys, PRIV-else)
4. Hospital outpatient clinics (HOSP-Dr, HOSP-Nurse, HOSP-Phys, HOSP-else)
5. Hospital inpatient care (Hosp-Days)
6. Rehabilitation clinics (REHAB-Days)
7. Number of radiological procedures during the preceding 12 months (RAD-Cost)
8. Visits related to alternative or complimentary HC (acupuncture, massage, chiropractor etc.) (ALT-Med)

Altogether, twenty (20) cost items were reported.
The HC usage data shows visits to OHS, public HC and private HC separately, because their unit costs are different (Table 11). The unit costs were obtained from the national working paper of the Finnish Ministry of Social Affairs and Health (Hujanen et al. 2008), expressed in euros, and converted to the 2004 level (the final follow-up visit was in 2004). Table 11 shows the use of HC resources over 12 months, scheduled at 13–24 months after baseline.

The focus of this study was on direct HC costs, and SA is considered the primary outcome of the CEA. Travelling costs and productivity losses (i.e. when employees were not working because they were attending study nurse or doctor appointments during their working hours) were not included in the costs. All the study participants worked in the same industrial complex area. The intervention cost was evaluated according to the time required for the verbal patient information during the OH nurse’s visit (EUR 20/person). Both costs and SA days were calculated for 12 months (12 months, timeline of 13–24 months from baseline) in the CEA. Cost-effectiveness was evaluated from the HC perspective.

The direct HC cost per person (not imputed) in the Combined arm was EUR 188, EUR 73 in Booklet arm and EUR 370 in the NC arm (2004 level). The corresponding totals in the two intervention arms and the control arm (missing participants included) were EUR 16 711, EUR 6 700 and EUR 30 699 per year (N = 89, 92 and 83), respectively.

In addition, because total HC costs (all participants included) could be calculated in the Combined and Booklet arms for the whole two-year follow-up period and corrected to the 2018 level (EUR 39, EUR 322 and EUR 17 601, respectively), the NC group estimate for the two years (twice the one-year estimate) would be EUR 75 636 in total.
<table>
<thead>
<tr>
<th>Variable</th>
<th>Description</th>
<th>Unit cost</th>
<th>Combined (n=67)</th>
<th>Booklet (n=67)</th>
<th>NC (n=51)</th>
<th>mean (STD) / €</th>
<th>Combined vs. NC (€)</th>
<th>Booklet vs. NC (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OH-Dr</td>
<td>Visit to a doctor in the OH care</td>
<td>57 €</td>
<td>25</td>
<td>14</td>
<td>44</td>
<td>1 425 €</td>
<td>798 €</td>
<td>2 508 €</td>
</tr>
<tr>
<td>OH-Nurse</td>
<td>Visit to a nurse in the OH care</td>
<td>65 €</td>
<td>4</td>
<td>5</td>
<td>47</td>
<td>2 258 €</td>
<td>323 €</td>
<td>3 035 €</td>
</tr>
<tr>
<td>OH-Phys</td>
<td>Visit to a physiotherapist in the OH care</td>
<td>77 €</td>
<td>5</td>
<td>9</td>
<td>8</td>
<td>1 931 €</td>
<td>348 €</td>
<td>3 039 €</td>
</tr>
<tr>
<td>OH-else</td>
<td>Visit to other professional in the OH care</td>
<td>29 €</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Subtotal - Occupational Health visits</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2 176 €</td>
<td>1 446 €</td>
<td>5 881 €</td>
</tr>
<tr>
<td>GEN-Dr</td>
<td>Visit to a doctor in the public HC</td>
<td>57 €</td>
<td>2</td>
<td>1</td>
<td>12</td>
<td>114 €</td>
<td>57 €</td>
<td>688 €</td>
</tr>
<tr>
<td>GEN-Nurse</td>
<td>Visit to a nurse in the public HC</td>
<td>25 €</td>
<td>0</td>
<td>2</td>
<td>12</td>
<td>-</td>
<td>50 €</td>
<td>302 €</td>
</tr>
<tr>
<td>GEN-Phys</td>
<td>Visit to a physiotherapist in the public HC</td>
<td>39 €</td>
<td>0</td>
<td>5</td>
<td>40</td>
<td>17 €</td>
<td>193 €</td>
<td>1 546 €</td>
</tr>
<tr>
<td>GEN-else</td>
<td>Visit to other professional in the public HC</td>
<td>60 €</td>
<td>0</td>
<td>0</td>
<td>13</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Subtotal - Public health care visits</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 114 €</td>
<td>398 €</td>
<td>5 881 €</td>
</tr>
<tr>
<td>PRIV-Dr</td>
<td>Visit to a doctor in private HC</td>
<td>57 €</td>
<td>2</td>
<td>2</td>
<td>10</td>
<td>114 €</td>
<td>114 €</td>
<td>570 €</td>
</tr>
<tr>
<td>PRIV-Nurse</td>
<td>Visit to a nurse in private HC unit</td>
<td>65 €</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>PRIV-Phys</td>
<td>Visit to a physiotherapist in private HC unit</td>
<td>39 €</td>
<td>0</td>
<td>5</td>
<td>40</td>
<td>2 203 €</td>
<td>1 198 €</td>
<td>2 030 €</td>
</tr>
<tr>
<td>PRIV-else</td>
<td>Visit to other professional in private HC unit</td>
<td>60 €</td>
<td>0</td>
<td>0</td>
<td>13</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Subtotal - Private Health care visits</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2 317 €</td>
<td>1 332 €</td>
<td>2 757 €</td>
</tr>
<tr>
<td>HOSP-Dr</td>
<td>Visit to a doctor in a hospital clinic</td>
<td>177 €</td>
<td>5</td>
<td>4</td>
<td>5</td>
<td>884 €</td>
<td>707 €</td>
<td>884 €</td>
</tr>
<tr>
<td>HOSP-Nurse</td>
<td>Visit to a nurse in a hospital clinic</td>
<td>25 €</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>-</td>
<td>25 €</td>
<td>-</td>
</tr>
<tr>
<td>HOSP-Phys</td>
<td>Visit to a physiotherapist in a hospital clinic</td>
<td>85 €</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>HOSP-else</td>
<td>Visit to other professional in a hospital clinic</td>
<td>60 €</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Subtotal - Hospital outpatient care visits</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>884 €</td>
<td>707 €</td>
<td>909 €</td>
</tr>
<tr>
<td>HOSP-days</td>
<td>Central hospital inpatient days</td>
<td>612 €</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>-</td>
<td>2 447 €</td>
<td>-</td>
</tr>
<tr>
<td>REHAB-days</td>
<td>Inpatient rehabilitiation center or unit / days</td>
<td>234 €</td>
<td>21</td>
<td>0</td>
<td>5</td>
<td>-</td>
<td>4 913 €</td>
<td>-</td>
</tr>
<tr>
<td>RAD-Cost</td>
<td>Radiological procedures</td>
<td>*</td>
<td>6</td>
<td>0</td>
<td>3</td>
<td>590 €</td>
<td>137 €</td>
<td>590 €</td>
</tr>
<tr>
<td>ALT-Med</td>
<td>Visit to a professional in alternative care</td>
<td>*</td>
<td>16</td>
<td>32</td>
<td>45</td>
<td>1 546 €</td>
<td>1 091 €</td>
<td>2 185 €</td>
</tr>
<tr>
<td><strong>Subtotal - other costs</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6 049 €</td>
<td>1 091 €</td>
<td>5 999 €</td>
</tr>
<tr>
<td><strong>Total - Direct health care costs</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>11 240 €</td>
<td>4 880 €</td>
<td>18 863 €</td>
</tr>
<tr>
<td>Face-to-face information costs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 340 €</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>TOTAL Health care Costs</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>12 580 €</td>
<td>4 880 €</td>
<td>18 863 €</td>
</tr>
</tbody>
</table>

* a collection of inconsistent units and unit costs (e.g. radiological procedures like lumbar x-ray or MRI). Number of units show the total number of different units with no specification of the procedure or visit.
Number of units per arm, unit cost, total costs per arm and the mean cost (mean) with standard deviation (STD). Subtotals show the costs in some basic HC categories. [OH: Occupational health; HC: health care, Booklet: Back Book arm, Combined: Back Book and Advice arm, NC: Natural course arm]

6.3.5 COST-EFFECTIVENESS (STUDY II)

Using the imputed cost data (main analysis) of 264 participants, the Booklet intervention was less costly and more effective than the NC arm in the timeframe of 13–24 months after baseline. The Combined intervention only modestly reduced HC costs.

The ICER of the Booklet intervention versus the NC arm was EUR 54 and of the Combined intervention versus the NC arm EUR 315, which means the amount of money required for the intervention per each avoided SA day according to the 2004 level. The estimated mean monetary savings over two years would be EUR 467 and EUR 310 per person (whole group savings: EUR 42 990 and EUR 27 615), corrected to the 2018 level for Booklet and Combined, respectively.
Table 12. Results of two CEA, based on multiply imputed data (main analysis) and complete case analysis (original data). Reproduced with permission from BioMed Central.

Table 12 also shows the mean monetary savings per person in the comparisons between the intervention arms (Combined and Booklet) and the control (NC=natural course of LBP arm) as well as the distribution of bootstrapped, simulated cases across the CE-plane quadrants (in percentages). [mean; 95%CI=95% confidence interval; ICER=incremental cost-effectiveness ratio; incremental costs and effects]

**One-way sensitivity analyses (Figure 10)**

The Booklet intervention was not sensitive to any cost variable in comparison to the NC. The ICER varied from EUR -71 to EUR -45 per SA day avoided (Figure 10). Cost items are explained on Page 68.
However, in the Combined intervention versus the NC, the ICER varied from EUR -530 to 15, showing that the result was sensitive to a single expensive cost item (rehabilitation days).

**Probabilistic sensitivity analysis (Figure 11)**

For the Booklet intervention versus the NC, the mean incremental cost (with 95% CI) was EUR -196 (-308 – -96), (negative figure indicates savings) and the mean incremental effect -3.5 (95% CI -10 – 3.8), representing avoided SA. According to the CE-plane (Figure 11 A), the base case and 81% of the simulated cases were situated in the south-eastern (SE) quadrant, suggesting that the intervention was both cost-saving and more effective (Table 12). All the bootstrapped, simulated cases were located below the horizontal line, showing that the intervention clearly reduced HC costs.

For the Combined intervention versus the NC, the mean incremental cost (with 95% CI) was EUR -107 (-258–61), (negative figure indicates savings), but the mean incremental effect was only marginal, at -0.4 days (-7.5 – 7.8),
Results

representing avoided SA (Table 12). Although the base case was in the SE quadrant (Figure 11 B), suggesting greater effectiveness and fewer costs, only about 54% of the simulated, bootstrapped cases fell in this quadrant. Still, about 87% of the simulated cases lay in the two southern quadrants, which indicate reduced HC costs.

Cost-effectiveness acceptability curve (CEAC) (Figure 12)

According to CEAC, at any level of willingness to pay for an avoided SA day, the probability of the Booklet intervention being acceptable is 81% (for any positive cost of an SA day) (Figure 12).

According to the CEAC, at any level of willingness to pay for an avoided SA day, the probability of the Combined intervention being acceptable is between 62% and 57% (from zero cost to all costs above EUR 200) (Figure 12).

Sensitivity analysis using two datasets

The results and the conclusions drawn from the complete case analysis were largely comparable with the main analysis (Table 12).
Figure 11. Cost-effectiveness planes of Booklet vs NC (3A) and Combined vs. NC (3B).
Results

Figure 12. Cost-effectiveness acceptability curve (CEAC) of Booklet vs NC and Combined vs NC. Reproduced with permission from BioMed Central.

6.3.6 SUMMARY OF THE RESULTS (I – II)
The long-term results of the LB-specific variables indicate that the Booklet and Combined interventions reduced physical impairment but not LBP intensity in comparison to the NC control group. Both patient information methods reduced SA in comparison to the NC control group over one year.

Both patient information methods reduced direct HC costs over one year. Booklet information alone was also cost-effective in comparison to the NC control group.
6.4 MODERATE SYMPTOMS (STUDIES III – IV)

The effectiveness of interventions in the Moderate subcohort were estimated in two studies: Study IV, which emphasized the effectiveness of interventions in comparison to the NC control group, and Study III which was the RCT of the Moderate subcohort interventions.

6.4.1 BASELINE CHARACTERISTICS

Study III (RCT2)

Employees in the Moderate subcohort were randomized into three intervention arms: Rehab, Physio and Advice. The interventions were executed as planned in January 2002 and June 2002. The effectiveness of the interventions was evaluated by comparisons of Rehab and Advice, and Physio and Advice at all follow-up points for two years.
Results

Table 13. Baseline characteristics of participants *" ```

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Rehab (n=43)</th>
<th>Physio (n=43)</th>
<th>Advice (n=40)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographic features</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, yrs.</td>
<td>45 (9)</td>
<td>44 (8)</td>
<td>45 (7)</td>
</tr>
<tr>
<td>Male, %</td>
<td>65</td>
<td>72</td>
<td>68</td>
</tr>
<tr>
<td>Married, %</td>
<td>81</td>
<td>84</td>
<td>70</td>
</tr>
<tr>
<td>Body mass index, kg/m²</td>
<td>26</td>
<td>28</td>
<td>28</td>
</tr>
<tr>
<td>Smoking, %</td>
<td>31</td>
<td>40</td>
<td>40</td>
</tr>
<tr>
<td>High school diploma or vocational degree, %</td>
<td>67</td>
<td>56</td>
<td>58</td>
</tr>
<tr>
<td><strong>General health</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self rated health status moderate or better, %</td>
<td>95</td>
<td>88</td>
<td>95</td>
</tr>
<tr>
<td>Previous low back operation, %</td>
<td>5</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Duration of LBP, yrs</td>
<td>13</td>
<td>10</td>
<td>14</td>
</tr>
<tr>
<td>Previous rehabilitation for LBP or active self care, %</td>
<td>28</td>
<td>35</td>
<td>35</td>
</tr>
<tr>
<td>Chronic morbidity at the medical history, other than LBP, %</td>
<td>33</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>Physical activity before LBP, two times / week or more , %</td>
<td>77</td>
<td>65</td>
<td>68</td>
</tr>
<tr>
<td><strong>Work related features</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blue collar, %</td>
<td>74</td>
<td>77</td>
<td>90</td>
</tr>
<tr>
<td>At shift work, %</td>
<td>43</td>
<td>28</td>
<td>39</td>
</tr>
<tr>
<td>Physical workload (1-5)²</td>
<td>3.2 (1.0)</td>
<td>3.1 (0.8)</td>
<td>2.7 (0.8)</td>
</tr>
<tr>
<td>Mental workload (1-5)²</td>
<td>2.5 (0.9)</td>
<td>2.8 (0.8)</td>
<td>2.9 (0.8)</td>
</tr>
<tr>
<td>Work ability (0-10)³</td>
<td>6.8 (2.0)</td>
<td>7.1 (1.7)</td>
<td>6.8 (2.4)</td>
</tr>
<tr>
<td>Influence on own work some or better, %</td>
<td>65</td>
<td>72</td>
<td>68</td>
</tr>
<tr>
<td>Total sickness absence days in previous year**</td>
<td>16</td>
<td>21</td>
<td>19</td>
</tr>
<tr>
<td><strong>Screening criteria</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intensity of pain (past week) / VAS (0-100), mm</td>
<td>60</td>
<td>55</td>
<td>60</td>
</tr>
<tr>
<td>LBP radiating below knee, %</td>
<td>51</td>
<td>51</td>
<td>45</td>
</tr>
<tr>
<td>Subacute LBP, i.e. two weeks or more, previous year, %</td>
<td>56</td>
<td>44</td>
<td>53</td>
</tr>
<tr>
<td>Recurrent LBP, i.e. more than once / year, %</td>
<td>86</td>
<td>95</td>
<td>93</td>
</tr>
<tr>
<td>Work absence due to LBP (self reported) in the last 12 months, %</td>
<td>33</td>
<td>37</td>
<td>40</td>
</tr>
<tr>
<td><strong>Outcome variables at the randomisation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intensity of pain (past week), VAS (0-100), mm</td>
<td>43 (23)</td>
<td>39 (24)</td>
<td>34 (25)</td>
</tr>
<tr>
<td>Physical impairment, RM-18 (0-18)</td>
<td>8 (5)</td>
<td>6 (5)</td>
<td>6 (5)</td>
</tr>
<tr>
<td>Disability, ODI (0-100), %</td>
<td>21 (13)</td>
<td>17 (12)</td>
<td>16 (11)</td>
</tr>
<tr>
<td>Fear of pain, FABQ (13-78)</td>
<td>37 (14)</td>
<td>35 (11)</td>
<td>32 (12)</td>
</tr>
<tr>
<td>Depression, DEPS (0-30)</td>
<td>6 (4)</td>
<td>4 (5)</td>
<td>4 (4.0)</td>
</tr>
<tr>
<td>Health related quality of life, score of the 15-D (0-1)</td>
<td>0.8681</td>
<td>0.8884</td>
<td>0.8932</td>
</tr>
</tbody>
</table>

* mean when applicable (standard deviation), unless otherwise stated.

² Range (when applicable) is presented after the variable name in parenthesis

³ register data

1 two-shift or three-shift work

2 range 1-5 indicates the self rated level of load: 1=very heavy, 2=moderate, 3=intermediate, 4=rather light, 5=very light

³ range 0-10, when 0 is the lowest possible work ability and 10 is the best possible work ability

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Study IV

The two-year follow-up started with the employee survey. The effectiveness of the interventions (Rehab, 43; Physio, 43 and Advice, 40 participants) was assessed by comparing them to the NC control group (50) using questionnaire outcomes at two years and SA outcomes at four years. Table 14 shows the baseline characteristics of all three intervention arms and the NC control arm. There were no differences between the intervention arms and the NC arm.

Table 14. Baseline characteristics of study participants according to data from employee survey. Reproduced with permission from BioMed Central.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Rehab (n=43)</th>
<th>Physio (n=43)</th>
<th>Advice (n=40)</th>
<th>Control (n=50)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographic features</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, years</td>
<td>45.9</td>
<td>44.8</td>
<td>45.7</td>
<td>46.7</td>
<td>0.44</td>
</tr>
<tr>
<td>Male, %</td>
<td>85.0</td>
<td>72.0</td>
<td>68.0</td>
<td>60.0</td>
<td>0.30</td>
</tr>
<tr>
<td>High School diploma/vocational degree, %</td>
<td>67.0</td>
<td>56.0</td>
<td>58.0</td>
<td>70.0</td>
<td>0.23</td>
</tr>
<tr>
<td>Health related features</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of LBP, years</td>
<td>13.9</td>
<td>10.9</td>
<td>14.9</td>
<td>11.9</td>
<td>0.51</td>
</tr>
<tr>
<td>Smoking</td>
<td>31.0</td>
<td>40.0</td>
<td>40.0</td>
<td>23.0</td>
<td>0.14</td>
</tr>
<tr>
<td>Work-related features</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blue collar worker, %</td>
<td>74.0</td>
<td>77.0</td>
<td>90.0</td>
<td>84.0</td>
<td>0.56</td>
</tr>
<tr>
<td>Shift worker, %</td>
<td>43.0</td>
<td>28.0</td>
<td>39.0</td>
<td>32.0</td>
<td>0.68</td>
</tr>
<tr>
<td>Physical workload (1-5)</td>
<td>3.0</td>
<td>3.1</td>
<td>3.1</td>
<td>3.1</td>
<td>0.48</td>
</tr>
<tr>
<td>Mental workload (1-5)</td>
<td>3.0</td>
<td>3.1</td>
<td>3.1</td>
<td>3.1</td>
<td>0.07</td>
</tr>
<tr>
<td>Work ability (0-10)</td>
<td>7.2</td>
<td>7.2</td>
<td>7.2</td>
<td>7.2</td>
<td>0.84</td>
</tr>
<tr>
<td>Total SA days / previous year</td>
<td>16.23</td>
<td>21.28</td>
<td>19.26</td>
<td>22.49</td>
<td>0.62</td>
</tr>
<tr>
<td>Total SA periods / previous year</td>
<td>4.5</td>
<td>4.4</td>
<td>4.4</td>
<td>4.5</td>
<td>0.99</td>
</tr>
<tr>
<td>LB specific SA days / previous year</td>
<td>6.14</td>
<td>9.25</td>
<td>9.22</td>
<td>9.41</td>
<td>0.92</td>
</tr>
<tr>
<td>Outcome variables at baseline</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LBP intensity, LBP (0-100)</td>
<td>60.17</td>
<td>55.14</td>
<td>60.18</td>
<td>60.18</td>
<td>0.47</td>
</tr>
<tr>
<td>Physical impairment, PH (0-18)</td>
<td>8.5</td>
<td>8.5</td>
<td>8.5</td>
<td>5.7</td>
<td>0.19</td>
</tr>
<tr>
<td>Pain related fear, FABQ (13-78)</td>
<td>38.14</td>
<td>38.12</td>
<td>37.12</td>
<td>35.12</td>
<td>0.26</td>
</tr>
<tr>
<td>FABQ work, FABQw (8-36)</td>
<td>18.7</td>
<td>16.7</td>
<td>16.7</td>
<td>16.7</td>
<td>0.61</td>
</tr>
<tr>
<td>FABQ physical activity, FABQph (4-24)</td>
<td>13.5</td>
<td>14.5</td>
<td>13.5</td>
<td>12.4</td>
<td>0.09</td>
</tr>
</tbody>
</table>

Means (SD=standard deviation) or percentages when applicable. [Rehab=Outpatient rehabilitation at the physical medicine unit; Physio=Progressive back-specific exercises;
Results

Advice=Self-care advice by an OH physician; Control=Natural course control arm; SA=sickness absence; LBP=low back pain; VAS=Visual Analogue Scale; RM-1=Roland-Morris 18-item Disability Questionnaire; PHI=Physical impairment; FABQ=Fear Avoidance Beliefs questionnaire; FABQw=Fear Avoidance beliefs questionnaire, work subscale; FABQph=Fear Avoidance beliefs questionnaire, physical activity subscale.

6.4.2 QUESTIONNAIRE OUTCOMES

Study III (RCT2)
All the results of the questionnaire variables are presented in Table 15. At 3 and 6 months, the Rehab arm was more effective than the Advice arm in terms of pain intensity, and the Physio arm was more effective at 12 months. HRQoL (15-D) improved in the Physio arm towards the end of the follow-up, at 12 and 24 months. However, the active intervention arms (Rehab and Physio) were not effective in reducing physical impairment.

Disability (ODI) and pain-related fear (FABQ) were lower in both active treatment arms compared to self-care information towards the end of the 24-month follow-up.
Table 15. Results of questionnaire variables and comparisons between active intervention groups and control group (Advice). Reproduced with permission from BMJ group.

<table>
<thead>
<tr>
<th>Outcome variable</th>
<th>Time point</th>
<th>Rehab (n=43)</th>
<th>Physio (n=43)</th>
<th>Advice (n=40)</th>
<th>Rehab vs. Advice</th>
<th>Physio vs. Advice</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>MD(95% CI)</td>
<td>p</td>
<td>MD(95% CI)</td>
<td>p</td>
<td></td>
</tr>
<tr>
<td><strong>Primary outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain (VAS), mm</td>
<td>3mo</td>
<td>29 (27)</td>
<td>31 (20)</td>
<td>35 (28)</td>
<td>-10 (-19 - -1)</td>
<td>0.04</td>
</tr>
<tr>
<td></td>
<td>6mo</td>
<td>29 (26)</td>
<td>33 (22)</td>
<td>35 (26)</td>
<td>-10 (-20 - -1)</td>
<td>0.04</td>
</tr>
<tr>
<td></td>
<td>12mo</td>
<td>35 (27)</td>
<td>29 (21)</td>
<td>39 (26)</td>
<td>-7 (-21 - 2)</td>
<td>1.14</td>
</tr>
<tr>
<td></td>
<td>24mo</td>
<td>27 (22)</td>
<td>27 (19)</td>
<td>30 (21)</td>
<td>-5 (-13 - 4)</td>
<td>0.27</td>
</tr>
<tr>
<td>Physio impairment (RM-18), #</td>
<td>3mo</td>
<td>5 (5)</td>
<td>4 (5)</td>
<td>4 (4)</td>
<td>-1 (-2 - 1)</td>
<td>0.39</td>
</tr>
<tr>
<td></td>
<td>6mo</td>
<td>4 (5)</td>
<td>4 (5)</td>
<td>4 (5)</td>
<td>-1 (-3 - 1)</td>
<td>0.27</td>
</tr>
<tr>
<td></td>
<td>12mo</td>
<td>6 (6)</td>
<td>4 (5)</td>
<td>5 (5)</td>
<td>0 (-2 - 3)</td>
<td>0.86</td>
</tr>
<tr>
<td></td>
<td>24mo</td>
<td>4 (5)</td>
<td>4 (4)</td>
<td>5 (5)</td>
<td>-1 (-3 - 0)</td>
<td>0.15</td>
</tr>
<tr>
<td>QoL / 15-D², #</td>
<td>3mo</td>
<td>.89 (.09)</td>
<td>.90 (.07)</td>
<td>.89 (.07)</td>
<td>.01 (-.01 -.04)</td>
<td>0.26</td>
</tr>
<tr>
<td></td>
<td>6mo</td>
<td>.87 (.10)</td>
<td>.90 (.07)</td>
<td>.90 (.08)</td>
<td>.00 (-.03 -.02)</td>
<td>0.78</td>
</tr>
<tr>
<td></td>
<td>12mo</td>
<td>.87 (.09)</td>
<td>.90 (.08)</td>
<td>.88 (.08)</td>
<td>.01 (-.01 -.03)</td>
<td>0.43</td>
</tr>
<tr>
<td></td>
<td>24mo</td>
<td>.87 (.10)</td>
<td>.90 (.07)</td>
<td>.87 (.08)</td>
<td>.02 (-.01 -.04)</td>
<td>0.18</td>
</tr>
<tr>
<td><strong>Secondary outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disability (ODI), %</td>
<td>3mo</td>
<td>15 (14)</td>
<td>14 (11)</td>
<td>16 (10)</td>
<td>-4 (-8 - 0)</td>
<td>0.03</td>
</tr>
<tr>
<td></td>
<td>6mo</td>
<td>14 (14)</td>
<td>13 (12)</td>
<td>14 (12)</td>
<td>-3 (-8 - 1)</td>
<td>0.15</td>
</tr>
<tr>
<td></td>
<td>12mo</td>
<td>15 (14)</td>
<td>12 (10)</td>
<td>14 (13)</td>
<td>-2 (-6 - 3)</td>
<td>0.43</td>
</tr>
<tr>
<td></td>
<td>24mo</td>
<td>13 (12)</td>
<td>12 (11)</td>
<td>15 (13)</td>
<td>-5 (-10 - -1)</td>
<td>0.01</td>
</tr>
<tr>
<td>Pain related fear (FABQ), #</td>
<td>3mo</td>
<td>32 (16)</td>
<td>31 (12)</td>
<td>32 (12)</td>
<td>-3 (-7 - 0)</td>
<td>0.08</td>
</tr>
<tr>
<td></td>
<td>6mo</td>
<td>31 (14)</td>
<td>32 812</td>
<td>32 (14)</td>
<td>-5 (-8 - -1)</td>
<td>0.02</td>
</tr>
<tr>
<td></td>
<td>12mo</td>
<td>33 (14)</td>
<td>31 (12)</td>
<td>33 (13)</td>
<td>-4 (-8 - -1)</td>
<td>0.02</td>
</tr>
<tr>
<td></td>
<td>24mo</td>
<td>31 (15)</td>
<td>31 (11)</td>
<td>35 (15)</td>
<td>-8 (-12 - -3)</td>
<td>0.00</td>
</tr>
<tr>
<td>Depression (DEPS scale), #</td>
<td>3mo</td>
<td>5 (5)</td>
<td>4 (5)</td>
<td>4 (4)</td>
<td>0 (-2 - 1)</td>
<td>0.56</td>
</tr>
<tr>
<td></td>
<td>6mo</td>
<td>6 (5)</td>
<td>4 (5)</td>
<td>4 (4)</td>
<td>0 (-2 - 2)</td>
<td>0.94</td>
</tr>
<tr>
<td></td>
<td>12mo</td>
<td>6 (5)</td>
<td>3 (4)</td>
<td>5 (6)</td>
<td>0 (-2 - 1)</td>
<td>0.65</td>
</tr>
<tr>
<td></td>
<td>24mo</td>
<td>6 (5)</td>
<td>4 (4)</td>
<td>6 (6)</td>
<td>-1 (-3 - 1)</td>
<td>0.22</td>
</tr>
</tbody>
</table>

1 means (standard deviations), mean difference (MD) and 95% confidence intervals (95%CI); p-value for the MD
2 range (0-1); bigger value represents better quality of life
3 Time point: 6mo=6 month follow-up point, 12mo=12 month follow-up point etc.

Study IV
In comparison to NC_{moderate}, physical impairment, pain intensity, QoL and all secondary outcomes improved in the Rehab intervention arm. The Physio arm also improved physical impairment, QoL, FABQ\_work and disability in comparison to NC_{moderate} (Table 16). Advice was not effective.
Results

Table 16. Results of questionnaire outcome variables after 2 years. Reproduced with permission from BioMed Central.

<table>
<thead>
<tr>
<th>Outcomes / analysis</th>
<th>Rehab (43)</th>
<th>Physio (43)</th>
<th>Advice (40)</th>
<th>Control (50)</th>
<th>Rehab vs. Control</th>
<th>Physio vs. Control</th>
<th>Advice vs. Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mean SD</td>
<td>mean SD</td>
<td>mean SD</td>
<td>mean SD</td>
<td>MD 95% CI p</td>
<td>MD 95% CI p</td>
<td>MD 95% CI p</td>
</tr>
<tr>
<td>Primary outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical impairment</td>
<td>4.7 4.5</td>
<td>4.7 4.4</td>
<td>5.9 4.8</td>
<td>7.4 4.4</td>
<td>-3 -5 -1 0.00</td>
<td>-3 -5 -1 0.00</td>
<td>-2 -3 -0 0.07</td>
</tr>
<tr>
<td>LBP intensity</td>
<td>27 19</td>
<td>29 20</td>
<td>32 23</td>
<td>40 26</td>
<td>-13 -24 -1 0.03</td>
<td>-13 -29 -2 0.08</td>
<td>-10 -27 -0 0.24</td>
</tr>
<tr>
<td>Quality of Life - QoL</td>
<td>0.832 0.137</td>
<td>0.841 0.141</td>
<td>0.795 0.136</td>
<td>0.771 0.145</td>
<td>0.06 0.08 -0.12 0.04</td>
<td>0.07 0.01 -0.13 0.02</td>
<td>0.02 -0.03 -0.08 0.42</td>
</tr>
<tr>
<td>Secondary outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain related fear - FABQ</td>
<td>33 15</td>
<td>35 13</td>
<td>40 16</td>
<td>41 13</td>
<td>-8 -14 -2 0.01</td>
<td>-5 -12 -1 0.09</td>
<td>-1 -7 -6 0.82</td>
</tr>
<tr>
<td>Pain related fear - FABQw</td>
<td>15 7</td>
<td>16 8</td>
<td>18 8</td>
<td>19 8</td>
<td>-5 -8 -1 0.01</td>
<td>-4 -7 -0 0.03</td>
<td>-1 -5 -2 0.49</td>
</tr>
<tr>
<td>Pain related fear - FABQph</td>
<td>11 5</td>
<td>12 5</td>
<td>13 6</td>
<td>13 4</td>
<td>-2 -4 -0 0.06</td>
<td>-1 -3 2 0.57</td>
<td>0 -2 -3 0.76</td>
</tr>
<tr>
<td>Disability - OSW sum</td>
<td>8 7</td>
<td>9 8</td>
<td>12 8</td>
<td>14 8</td>
<td>-6 -10 -2 0.00</td>
<td>-5 -8 -0 0.03</td>
<td>-2 -6 -2 0.60</td>
</tr>
</tbody>
</table>

1Analysis includes 176 participants in Rehab (43), Physio (43), Advice (40) and Control (50) arms.

Table 17 shows that the effect sizes between the Rehab and Physio active intervention arms were medium to large in comparison to the NC arm (regarding LBP intensity, PHI, QoL, FABQ, FABQw and OSW) (Table 17).
Table 17. Effect sizes of primary and secondary outcomes in all study group comparisons according to Cohen’s d⁴. Reproduced with permission from BioMed Central.

<table>
<thead>
<tr>
<th>Analysis</th>
<th>Effect size (d)</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rehab vs.</td>
<td>Physio vs.</td>
<td>Advice vs.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>Control</td>
<td>Control</td>
<td></td>
</tr>
<tr>
<td><strong>Primary outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical impairment (PHI)</td>
<td>0.7</td>
<td>0.7</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>LBP intensity (VAS)</td>
<td>0.6</td>
<td>0.6</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>Quality of Life (QoL)</td>
<td>0.4</td>
<td>0.5</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td>Sickness absence² days</td>
<td>0.1</td>
<td>0.0</td>
<td>0.1</td>
<td></td>
</tr>
<tr>
<td><strong>Secondary outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain related fear - FABQ</td>
<td>0.6</td>
<td>0.4</td>
<td>0.1</td>
<td></td>
</tr>
<tr>
<td>Pain related fear - FABQw</td>
<td>0.6</td>
<td>0.5</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td>Pain related fear - FABQph</td>
<td>0.4</td>
<td>0.1</td>
<td>0.1</td>
<td></td>
</tr>
<tr>
<td>Disability - OSW sum</td>
<td>0.8</td>
<td>0.6</td>
<td>0.3</td>
<td></td>
</tr>
<tr>
<td>Sickness absence² periods</td>
<td>0.4</td>
<td>0.0</td>
<td>0.2</td>
<td></td>
</tr>
</tbody>
</table>

¹Cohen’s d effect size is interpreted as follows: d < 0.5 small effect size; 0.5 ≤ d < 0.8 medium; 0.8 ≤ d < 1.2 large; d ≥ 1.2 very large effect size. Medium or larger effect sizes are bolded.

²Sickness absence = accumulated, all cause sickness absence during two years.
Results

6.4.3 SICKNESS ABSENCE

Study III (RCT2)
Figures 13 and 14 show the results, which use the following abbreviations: PMU=Rehab, DBC=Physio, BB=Advice.

In comparison to the Advice arm, the Rehab arm reduced the probability of total SA during the first (Odds Ratio (OR) 0.34 [95% CI 0.14 - 0.81]) and second (OR 0.41 [95% CI 0.19 - 0.88]) follow-up year (Figure 13B).

Figure 13. Probability of total SA days (A) and odds ratio (OR) of group comparisons (B). Reproduced with permission from BMJ group.

Among those with any (total) SA, the number of SA days was lower in the Rehab arm than in the Advice arm during the fourth year (mean ratio (MR) 0.53 [95%CI 0.31 - 0.92]) (Figure 14B).
In comparison to the Advice arm, the Physio arm reduced the probability of LB-specific SA during the third (OR 0.42 [95% CI 0.20 - 0.89]) and fourth (OR 0.35 [95% CI 0.17 - 0.79]) follow-up year (Study III).

Among those with any SA, the Rehab arm reduced the number of total SA periods during the third (MR 0.6 [95% CI 0.41 - 0.89]) and fourth (MR 0.44 [95% CI 0.27 - 0.71]) year in comparison to the Advice arm (Study III).

**Study IV**

In four years, the total number of accumulated SA days in the Rehab, Physio, Advice and Control (=NC) arms were 3223, 3611, 3819 and 4602, respectively. None of the three intervention arms (Rehab, Physio, Advice) were effective in comparison to the NC arm in terms of total, cumulative SA days in 48 months (Table 18).

---

**Figure 14. Number of all (total) SA days (A) and ratio (R) of group comparisons (B). Reproduced with permission from BMJ group.**
Results

Table 18. Number of accumulated sickness absence (SA) days and periods over 4 years\textsuperscript{1,2,3}. Means, mean differences (MD) and 95% confidence intervals (95%CI). Reproduced with permission from BioMed Central.

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Rehab</th>
<th>Physio</th>
<th>Advice</th>
<th>Control</th>
<th>Rehab vs. Control</th>
<th>Physio vs. Control</th>
<th>Advice vs. Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mean</td>
<td>95%CI</td>
<td>mean</td>
<td>95%CI</td>
<td>mean</td>
<td>95%CI</td>
<td>MD</td>
</tr>
<tr>
<td>Primary Outcome</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SA days</td>
<td>67</td>
<td>950 – 91</td>
<td>74</td>
<td>54 – 99</td>
<td>84</td>
<td>61 – 114</td>
<td>72</td>
</tr>
<tr>
<td>Secondary Outcome</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SA periods</td>
<td>8</td>
<td>6 – 11</td>
<td>12</td>
<td>9 – 17</td>
<td>15</td>
<td>11 – 21</td>
<td>13</td>
</tr>
</tbody>
</table>

\textsuperscript{1}Main analysis includes 176 participants in Rehab (43), Physio (43), Advice (40) and Control (51) groups.

\textsuperscript{2}Analyses were calculated with IBM SPSS 24 version’s Generalised linear models Negative binomial with loglink procedure.

\textsuperscript{3}SA days and periods during one year before the intervention were used as covariates, respectively.

In four years, the total number of accumulated SA periods in the Rehab, Physio, Advice and NC arms were 434, 614, 702 and 740, respectively. In the Rehab arm, the mean difference was -5 periods [-10 – 0], representing a small reduction in total SA periods (Table 18).

6.4.4 SUMMARY OF THE RESULTS (III – IV)

Pain, physical impairment, disability and pain-related fear decreased, and QoL improved in comparison to that in the NC arm over two years. Rehab was effective in all outcomes (Study IV). Advice alone was not effective (Study IV). Active interventions (Rehab and Physio arms) reduced pain intensity at up to 6 and 12 months (respectively) and in comparison to the Advice and Physio arms, also improved HRQoL at 24 months (Study III).

The intensive, active rehabilitation clinic intervention reduced the probability of total SA during the first two years and the number of SA days during the fourth year of follow-up in comparison to the Advice arm (Study III). The physiotherapist’s active intervention reduced the probability of LB-specific SA during the third and fourth year (Study III). In the Rehab arm, SA periods were lower than those in the NC arm (Study IV) over the four-year follow-up.
7 DISCUSSION

7.1 MAIN FINDINGS BY RESEARCH QUESTIONS

1. Is an employee survey feasible for identifying and categorizing employees at risk of disabling LBP? (Studies I–IV):
In all the studies of this thesis, the design, eligibility criteria and employee categorization were based on the employee survey results. The employee survey included previously validated questionnaires and measures that had been used in many studies before. The survey had a very good response rate and the outcomes of the survey complied well with other previous population-based studies. The employee survey seemed feasible for collecting LB-related data from among employees and provided a basis for classifying employees into different target options.

2. How effective and cost-effective is LB-specific information in the management of mild-level LB symptoms? (Studies I–II):
A simple, LB-specific information booklet provided by an OH nurse reduced physical impairment and HC costs and was cost-effective. Patient information also improved QoL. Face-to-face oral information did not increase the effectiveness of the booklet.

3. How effective is a combination of LB-specific active interventions and patient information for moderate level LBP? (Studies III–IV):
The active interventions reduced pain, disability, pain-related fear and physical impairment. QoL improved in comparison to NC. However, physician’s advice alone was not effective among these individuals.

4. As regards Research questions 2 and 3, the absolute effects were rather small in both options, which may be explained by the low baseline levels of the outcome variables and the early management design of the study (Studies I–IV).
7.2 STRENGTHS AND WEAKNESSES OF THE THESIS

7.2.1 PARTICIPANTS AND SETTING

The main strength of this population-based study lies in its multiphasic design; basically, its pragmatic approach and participant-recruiting strategy. All the company employees were invited to participate in the questionnaire survey (N = 2480). The response rate was particularly high (71%). The study base (2480 employees) represented the general distribution of the Finnish workforce reasonably well (age, gender, socio-economic class, physical and mental workload). The participants were both male and female employees from all age-groups and different occupations and faced various physical demands at work.

The selection of eligible employees for the trial was based on straightforward and widely used criteria: LBP frequency, duration, intensity and self-reported SA due to LBP. The included participants suffered from periodical or chronic LBP that could potentially hamper their work but had not yet cause disability to work. Although the study population was somewhat heterogenous in terms of LBP severity, compared to most studies in this field, both subcohorts had rather mild symptoms on average.

Although all the participants reported non-acute, yet mild- or moderate-level and chronic LBP in the screening phase, they were all primarily able to work. They were not seeking care but were expected to benefit from proactively assigned interventions. The control group was selected as a random sample from the same cohort of eligible employees, prior to the randomization procedure of the intervention arms. The participants’ characteristics and the inclusion criteria for the study suggest good generalizability of the results. The study setting fostered the secondary preventive approach of the study.

However, quasi-experimental study design may be considered a weakness in the studies, including the NC control. Moreover, because of the pragmatic study design, employees who were suffering from LBP in the recruitment phase were also included in the study, which has considered as
a weakness in a recent systematic review on the prevention of LBP (Shiri et al. 2018).

Of all the 372 eligible participants in the five intervention arms, 64 (17%) refused to take part in the study. Randomization was successful: the treatment arms were comparable as regards the relevant demographic factors. Random sampling was also successful because the NC control groups were comparable to the respective RCT treatment arms. All the participants received their intervention as intended and about 75% continued to the final visit. Adherence to follow-up visits and the response rate to the questionnaires were quite high throughout the two-year follow-up. The follow-up rates were satisfactory in all groups. In contrast with the good follow-up activity in the intervention groups (73–86%), the response rate in the Control group was somewhat lower (62%), which could potentially indicate selective participation and cause bias. However, there was no difference between the baseline variables of the Intervention groups and the Control group or between the basic characteristics of the respondents and non-respondents in the Control group. This indicates that the lower response rate in the Control group did not actually hamper the comparability of the groups.

It is likely that the procedures of this study cannot be adopted as such to other occupational health organizations or different client industries because OH resources and OH contracts or cultures vary so much. However, even minimal, statutory OHS may enable preventive actions if they are properly justified.

As the data of this study were collected about 16–18 years ago, they may be considered old. Treatment guidelines, rehabilitation and assessment of LBP has developed a great deal in the last 20 years, especially in terms of the psychosocial aspects of the LBP syndrome. However, the prevalence of non-specific LBP has not decreased during this time, and today the evidence of the global burden of LBP and its related disability is even greater.
7.2.2 INTERVENTIONS

The employees’ own OH physician carried out the baseline clinical examination and provided advice in the self-care intervention (Studies III and IV). Adherence to the trial was reasonably good, although the loss-to-follow-up was somewhat unequal between the treatment arms (Figures 6 and 7). All the interventions were based on existing clinical practices, i.e., no experimental methodologies were introduced. Two representative samples, 18% (Mild) and 11% (Moderate) of all the respondents were selected in the intervention cohort.

Possible group contamination in RCT1 (Mild) cannot be ruled out because the study participants worked in the same industrial area. All the scheduled follow-up visits in this study should be considered part of the intervention, but there were no differences between the groups in follow-up visit activity, intervals or frequency. On the other hand, no systematic attempts were made to determine whether the study participants in the Booklet group actually read and understood the booklet. However, these facts originate from the pragmatic approach of the study, i.e., these concerns cannot be ruled out in common practice either.

7.2.3 OUTCOME VARIABLES

SA data has good coverage, accuracy, and consistency as salaries and other employee benefits are based on the same information. Still, this study is obviously underpowered as regards SA variables, which can be seen from, for example, the broad CI in the differences between the treatment arms.

At the national Finnish level, during the study follow-up (2002–2005), the number of LB-specific SA was stable or slowly increasing (Kela 2013). At the same time, according to company registers, the total SA rate remained stable at about 5–5.5% of the theoretical working hours per year. The employees or the financial competence of the company faced no major personnel cuts or other threats during the study follow-up. The turmoil that affected the whole Finnish forestry industry effectively started shortly after
our data collection ended. Nevertheless, any potential external confounding factor would have equally influenced the treatment arms.

The questionnaire outcomes are based on well-described, validated LB-specific instruments, although they have shown to function best in their mid-range. As the study focus was on mild LBP, physical impairment values were relatively low at baseline. Previous studies have suggested that RM-18 is rather insensitive to change when impairment levels are low (Stratford and Binkley 2000, Jordan et al. 2006, Hall et al. 2011, Chiarotto et al. 2016). Nevertheless, a small yet significant mean difference in the group comparisons with the NC group was noted. Although the effect sizes were modest in absolute values, the proportional effects were 36–60% of the corresponding baseline values in both comparisons. The results were also long-lasting (Artus et al. 2014).

All the study participants were familiar with the study questionnaires, having already responded to the employee survey at the beginning of the study. The NC group members were also able to respond to their questionnaires in the same way as their fellow participants. Hence, there was no systematic reason or occurrence that would explain the missed follow-up visits.

### 7.3 METHODOLOGICAL ASPECTS

#### 7.3.1 PARTICIPANTS

As LB symptoms are very common and on the other hand heterogenous, population-based, pragmatic studies are highly recommended (Dunn and Croft 2004, Kent and Keating 2005, Hoy et al. 2010a).

This pragmatic study was conducted in the OHS of a large forestry company in Lappeenranta, Finland. The OHS unit was adjacent to the factory area, similarly to any other primary care unit serving its customers. The participants were men and women, aged between 24 and 56, who reported various physical and psychological demands in their work. At baseline, all the participants reported their LBP history and symptoms.
Discussion

These high LBP risk individuals represented 11% of the total number of respondents to the employee survey. Only 12% (n = 17) of the invited employees were excluded or declined to participate in the study. Therefore, we consider external validity to be good. The participants’ mean total pain level was 59 mm (SD 17 mm; VAS: 0–100 mm) and physical impairment was 8 units (SD 5 units; Roland-Morris: 0–18 units) at baseline. Such individuals are at risk of recurrent, progressing LBP (Kaaria et al. 2006). Although their work ability was already reduced, they were still working during inclusion in the study, which suggests that our target group was suitable for secondary prevention of LBP.

In addition to response rate, the most important biases in questionnaire studies lie in wording (ambiguous or complex questions etc.), missing or inadequate data for the intended purpose (belief vs behaviour, insensitive measure etc.), faulty scales (forced choice, leading questions etc.), formatting problems, or study personnel not being objective (Choi and Pak 2005). An example of recall bias is that prior musculoskeletal symptoms are poorly remembered after some years have passed (Miranda et al. 2006).

Some explanation for the good response rate in this study may be that the whole study, including the employee survey, received a great deal of positive support from the company and other stakeholders, including the personnel. The questions related to screening criteria, as well as all the outcome measures, have also been previously validated. Due to the RCT design, possible bias would probably act similarly across all groups. The NC control group was selected as a random sample. There were no differences between the Advice arm and the NC control arm results in the Moderate subcohort. Therefore, it seems that neither booklet information nor follow-up visits affected the outcomes per se.

A literature search of secondary prevention RCTs of LBP in the adult population using a population-based approach in the last 10 years identified studies that evaluated outcomes in relation to different occupations (nurses or similar HC professionals (Alexandre et al. 2001, Warming et al. 2008, Pillastrini et al. 2009, Kamioka et al. 2011, Roussel et al. 2015, Chaleat-Valayer et al. 2016), office workers (Sihawong et al. 2014), military personnel or conscripts (Larsen et al. 2002), railway workers (Suni et al. 2006)), only women (Warming et al. 2008, Pillastrini et al. 2009, Kamioka et al. 2011, Chaleat-Valayer et al. 2016) or only men (Larsen et al. 2002),
young adults (Larsen et al. 2002), or larger age groups. In addition, these studies were conducted in many different countries (Canada (Loisel et al. 2002), Thailand (Sihawong et al. 2014), Sweden (Rasmussen-Barr et al. 2009), Denmark (Rasmussen et al. 2016), Netherlands, Belgium (Roussel et al. 2015), the UK (Hill et al. 2011, Whitehurst et al. 2012), France (Alexandre et al. 2001), Japan (Kamioka et al. 2011) and Finland (Suni et al. 2006, Suni et al. 2017, Suni et al. 2018)). The extensive variability in terms of inclusion criteria, interventions and restricted employee groups in these studies prevents straightforward comparisons with this thesis.

7.3.2 OUTCOME MEASURES

Instead of choosing LB-specific SA as an outcome measurement in this study, we chose all-cause SA because it is generally considered a measure of health in the working population when health is understood as a mixture of social, psychological and physiological functioning (Marmot et al. 1995, Kivimaki et al. 2003). Recorded SA data have several advantages: the quality of the data in terms of coverage, accuracy and consistency over time is superior to that achievable via self-reports. Our SA data was skewed and included several outliers, which are typical phenomena in the analyses of SA (Kivimaki et al. 2003, Thorsen et al. 2015).

7.3.3 DATA MANAGEMENT

Multiple imputation is a modern method for dealing with missing values in longitudinal intervention studies (Sterne et al. 2009, Spratt et al. 2010). Analysing only original data would mean substantial parts of the data being left out of the analyses and would risk losing essential information. However, our study results (using multiple imputation) were consistent with the results based on original data (data not shown).

In this study, about 29% of the study visits were missing in the Mild subcohort after two years. Multiple imputation attenuated the cost-effectiveness results of the Booklet group and the results of the Combined group became less apparent. However, the main conclusions of the study
remained the same, whether analysed using the imputed or the complete case data (Table 13).

The HC usage data in this study covered the number of visits to many HC systems that seem different from each other. However, all public, private and occupational HC visits in the data may be considered primary care resource usage. Our pragmatic study design and the real-life OH organization with comprehensive SA data suggest that the results of this thesis can be easily transferred to OH practice and to some extent also to primary care.

The HC utilization data in Study II was gathered over 13–24 months, because the NC group received only one follow-up questionnaire, scheduled at 24 months after the study began. The same form was used for all participants and HC utilization information covered only the last 12 months. This may be considered a weakness, but the main idea was not to intervene in the NC group by any means during the two-year follow-up. In addition, the patient’s recall period could not exceed 12 months. Recall bias is considered similar in all groups, due to the uniform data collection.

Because of the HC perspective in our study, we omitted non-medical costs such as travel time, time expenses of HC visits or out-of-pocket costs. As some previous studies have shown, the impact of these costs is minor.

7.3.4 INTERVENTIONS

The few prior RCTs of non-sick-listed populations in an OH setting (Suni et al. 2006, Taimela et al. 2008b, Taimela et al. 2010) have dealt with general symptoms or risks to work disability, not only LBP. A population-based study in Denmark showed that a psychosocially-oriented educational booklet with no personal contact was unsuccessful in reducing work absence due to general musculoskeletal pain (Frost et al. 2007). Interventions in two other studies (Taimela et al. 2008b, Taimela et al. 2010) were more intensive than the provision of simple patient information and the study participants were already at risk of work disability.

A systematic review (Henrotin et al. 2006) concluded that simple patient information for participants with chronic LBP increases patient knowledge of LBP and reduces pain, disability, and fear, but not employee absenteeism.
A positive result was strongly related to the consistency of the information and personal contact as well as to trust between the information provider and the patient.

Obviously, the concept of self-care is quite different from the traditional care-giving concept in HC (Wilkinson and Whitehead 2009). Patients may gather information from various sources of their own choice and for their individual purposes. The quality of such information may range from non-factual to proper evidence-based information.

When OH professionals promote the self-care of LBP patients, written information seems to be superior to oral information alone (Burton et al. 1999, Coudeyre et al. 2006, Marty and Henrotin 2009). On the other hand, the additional face-to-face information in Study I showed no effectiveness, which may be explained by the fact that face-to-face information is a rather tenuous complement to booklet information.

As in some other studies (Lotters et al. 2005, Bergstrom et al. 2007, Alexopoulos et al. 2008, Andersen et al. 2012), previous SA also predicted future work loss in this study. In an OH setting, there is an obvious need for simple, reliable LB-specific patient information that can be delivered to employees during their health surveillance visits.

### 7.3.5 RESULTS

The sensitivity analysis in Study II showed that the cost-effectiveness results in the Combined group were sensitive to rehabilitation centre inpatient costs. The data showed that the cost was due to a single inpatient episode of only one person. If this cost was neglected as an outlier, HC costs in the Combined group would fall to around the same level as those in the Booklet group. On the other hand, even though some high cost categories (rehabilitation centre days and hospital inpatient days) were neglected in the NC group, HC usage and costs remained high in the NC group, because HC usage was higher in almost all the HC categories than in the intervention groups.

Though outpatient rehabilitation at the hospital showed slightly better results in reducing SA than the other interventions, its cost-effectiveness must be further evaluated before recommending the intervention for use in
this kind of population. Further research on this topic is required. To find the most suitable participants for secondary prevention, patient selection criteria and optimal intervention strategy need to be confirmed.

7.3.6 SCREENING, SUB-GROUPING

Because LBP definitions contribute to study inclusions and exclusions in reviews and reflect directly on participant recruitment in intervention studies, there is a need to find a new consensus on more advanced and specific, standardized definitions of LBP (Dionne et al. 2008). Otherwise, insufficient or unsuitable definitions may still affect study designs in a way that weakens the generalizability of results (Karran et al. 2017).

The risk of disabling LBP in this thesis was measured using a screening questionnaire that emphasized previous SA due to LBP, recurrent LBP, LBP lasting over two weeks or radicular pain during the preceding 12 months as part of the risk assessment. In addition, LBP intensity subdivided eligible employees into high (Moderate) or low (Mild) risk groups. In comparison, internationally relevant screening tools such as the Start Back Tool (Hay et al. 2008, Hill et al. 2009, Hill et al. 2010, Foster et al. 2011, Hill et al. 2011, Whitehurst et al. 2012) and the Örebro Musculoskeletal Pain Screening Questionnaire (Linton and Boersma 2003, Hill et al. 2010, Karran et al. 2017), also include referred leg pain and bothersomeness of pain and emphasize comorbid pain, fear, anxiety and catastrophizing components of pain as well as depression.

Subgrouping and matched care seem to be efficient strategies among working populations (Hay et al. 2008, Hill et al. 2009, Hill et al. 2010, Foster et al. 2011, Hill et al. 2011, Whitehurst et al. 2012). However, there is still a need to improve screening instruments to achieve more specific and reliable subgrouping, and treatment or secondary prevention according to these subgroup definitions (Karran et al. 2017, Unsgaard-Tondel et al. 2018).
7.4 COMPARISON WITH OTHER STUDIES

7.4.1 STUDY SETTING

On average, all the study participants had a history of LBP or ancillary symptoms for about 12 years and about 12 (Mild) or 20 (Moderate) total SA days in the year prior to study inclusion, of which about 10% were LB-specific. Most had a history of LB treatment, e.g., a self-care programme. Based on the study group characteristics and the pragmatic approach, the results are most applicable in the OH or even wider primary care setting. The Mild subcohort was especially suitable for the trial on the basis of their self-care information because of their low-level symptoms. Only a few other studies in an OH setting are comparable with this study setting, recruitment strategy and symptom level altogether (Table 3). In a comparable inclusion strategy, physician’s advice to stay active reduced LBP strain in acute LBP (Matsudaira et al. 2011). Information and advice have earlier shown to have positive effects on LBP-specific outcomes or recovery, both alone (Burton et al. 1999, Roberts et al. 2002) or as an adjunct to other therapies (Cherkin et al. 1998, Henrotin et al. 2006, Whitfill et al. 2010) in various other settings.

7.4.2 PARTICIPANTS

Some recent studies have shown that an LBP management strategy that is based on a patient-level risk-assessment (e.g. low, medium or high risk of LBP) in primary care is more efficient and cost-effective than a non-stratified approach (Hill et al. 2008, Hill et al. 2011, Whitehurst et al. 2012). Hill et al. (Hill et al. 2011) found that interventions (patient information and physiotherapist consultations) were cost-effective for medium- and high-risk patients. The low-risk subgroup only received one patient information session (educational video and the Back Book). As a result, work loss decreased in the low risk intervention group in comparison to the control group (usual care). Although their recruitment strategy was different that of this study, the main characteristics of the participants in the low- and moderate-risk groups were comparable. Whitehurst et al. later analysed the
Discussion

results of a low-risk group (Whitehurst et al. 2012) and found that the intervention was also cost-effective.

Most prior RCTs concerning LBP in an OH setting have focused on employees who are already off work (Indahl et al. 1998, Hazard et al. 2000, Hlobil et al. 2005, Anema et al. 2007), i.e. tertiary prevention. Engers et al. (Engers et al. 2008) concluded in their recent systematic review that at least 2½ hours is required for the effectiveness of individual patient education concerning return to work. The studies in the review included patients who suffered from moderate to severe pain and physical impairment and were already off work. Such a lengthy intervention would not be applicable in an OH setting for employees with only minor LBP and limitations. In addition, the authors state that ‘... research is also needed to evaluate what type of education is most effective or most efficient with respect to intensity and duration, and which HC professional can best provide patient education’ (Engers et al. 2008).

A classic RCT in Finland studied male railroad employees with LBP based on OH registers (Suni et al. 2006). The participants were randomized into physical training or usual care. The baseline pain and disability levels were even lower than those in this study. The main results were a slight decrease in pain at 12 months and an increase in subjective work ability (Suni et al. 2006). The inclusion criteria were somewhat comparable in both studies, as were the results, i.e., some effectiveness in symptoms among moderately symptomatic participants.

Another Finnish study of female health care workers recently concluded that a combination of physical exercise and counselling reduced the intensity of LBP work interference and fear of pain due to LBP (Suni et al. 2018).

7.4.3 INTERVENTIONS

After the start of the present study, only a few comparable studies have randomized employees with non-acute LBP into active exercise interventions in an OH setting (Ewert et al. 2009, Driessen et al. 2011a, Driessen et al. 2012, Roussel et al. 2015, Chaleat-Valayer et al. 2016, Rasmussen et al. 2016). A previous systematic review of the secondary prevention of LBP found only low-quality evidence that exercise alone and
moderate-quality evidence that exercise combined with education lowers the risk of future LBP episodes among employees (Steffens et al. 2016). However, a more recent systematic review concluded that exercise alone reduces the risk of LBP and disability due to LBP, suggesting that exercise 2–3 times per week is recommended to prevent LBP in the general population (Shiri et al. 2018). Although most earlier studies are not completely comparable to our study, the results of this thesis are in line with the latest evidence in this field.

A Cochrane review on the treatment of chronic LBP about 10 years ago concluded that LBP-specific physical exercise, alone or together with a psycho-social intervention or pain management were effective in reducing both clinical symptoms and SA (Karjalainen et al. 2003b). Recent studies (Loisel et al. 1997, Anema et al. 2007, Jellema et al. 2007, Lamb et al. 2010a) have included patients that were initially more symptomatic than the participants in this thesis. Recruitment in these prior studies was based on work absence records or back clinic consultations (Steenstra et al. 2006a, Choi et al. 2010, Lamb et al. 2010b, Kamper et al. 2015). Different recruitment strategies, higher symptom level and the large variety of interventions make comparison between these studies and this thesis difficult.

The present study assumed that LB-specific patient information could be delivered by an OH nurse, especially when symptoms are minor. In most previous LBP studies, however, personal patient information has been provided by a physician. In some other fields of medicine, self-care has also been promoted by a nurse or other HC professional and the intervention has not lost its effectiveness (Cherkin et al. 1996, Laurant et al. 2005).

### 7.4.4 RESULTS

Primary care interventions for sub-acute or recurrent LBP have been cost-effective in many cases (Lin et al. 2011). However, these studies have not consistently or even properly defined ‘usual care’ as a control group. In addition, these interventions have generally been carried out by a physician or in collaboration with a physiotherapist and are therefore not entirely comparable with this study.
Discussion

It seems surprising that the cost-effectiveness of combined patient information was weaker than the booklet information alone. Some characteristics of the verbal information might explain at least part of this controversy. According to Henrotin et al., patient information should be consistent despite being delivered to patients through various means (Henrotin et al. 2006) such as verbal, written or video methods. Distracting information may cause confusion among patients and diminish its intentional effect. Verbal advice is very sensitive to inconsistency or disturbances per se. The physical and social environment of the patient and nurse, nurse-patient interaction, or intrapersonal characteristics can disturb the fragile connection between the patient and the health service provider. Other possible explanations include individuals in the Booklet group possibly having read the booklet more intensively than those in the Combined group and therefore, complying more closely with the content, or having also used the booklet later as a guideline.

Numerous studies on the (secondary) prevention of LBP have resulted in reduced pain, recurrence of LBP or disability after exercise; psycho-educational, multidisciplinary interventions; or combinations of these (Von Korff et al. 1998, Lonn et al. 1999, Soukup et al. 1999, Linton and Andersson 2000, Glomsrod et al. 2001, Karjalainen et al. 2003a, Von Korff et al. 2005, Vahtera et al. 2009). However, evidence is scattered and inconsistent due to variable recruitment strategies and settings (Choi et al. 2010).

Taimela et al. found that an early OH intervention (SA risk assessment, OH evaluation and early specialist consultations) was effective in reducing SA (Taimela et al. 2008b) and that it saved HC costs (Taimela et al. 2008a) among workers at a high risk of SA in comparison to usual care. Although the participants suffered from a variety of medical conditions, not only LBP, this study is an example of effective, proactive disability management in OH. The intervention was especially effective for workers who were certain that they would not be able to continue working in their current jobs for health-related reasons, or who had co-morbidities or severe physical impairments at work (Taimela et al. 2010).
7.4.5 SUMMARY OF ALL RESULTS

Only a few other RCTs in an OH setting have managed to identify non-sick-listed employees at risk of LBP-related disability and subsequently set up an intervention for these individuals. Yet, the few studies attempting to do so all point in the same direction, i.e., show at least some effectiveness, despite the effect sizes being rather small. Optimal strategies for the secondary prevention of LBP-related disability still need to be found.

In order to reduce recurrent, sub-acute and chronic LBP at the personal, workplace or community level, current evidence suggests a targeted and stratified approach (Hill et al. 2011), but also the ability to adopt multiple management strategies. Especially when facing heterogenic patient groups in primary HC or OHS, successful management strategy includes the whole spectrum of exercise interventions, holistic assessment of employees (Choi et al. 2010), mini-intervention (Karjalainen et al. 2003a, Karjalainen et al. 2004), advice and patient information (Liddle et al. 2007), return to work procedures (van Oostrom et al. 2009, Rolli Salathé et al. 2012) and ergonomic or workplace interventions (Driessen et al. 2010, Haukka 2010) according to current needs.

In general, the lack of consistency in reporting LBP trial results makes it difficult to make definite conclusions or recommendations. In the future, the use of comparable outcomes, larger datasets and consistent LBP definitions would facilitate better reporting (Deyo et al. 2015).
7.5 CLINICAL IMPLICATIONS OF THE RESULTS

Secondary prevention of LBP as part of OH strategy is recommended: The results indicate that proactive, targeted LBP management with appropriate patient information leads to positive outcomes and reduced costs in an OH setting. Targeted, early management of LBP is possible only after early stage detection and classification of symptoms.

Targeted management options are recommended. Low-level symptoms may be managed with minimal interventions, but the same information and advice was not effective with more severe symptoms. There is still a need for advanced risk-assessment of LBP and targeted management of LBP among employees.

A simple, cheap information booklet, provided by an OH nurse, was effective and cost-effective. Self-care information may, for pre-defined employee groups, be delivered by a nurse without losing the intervention losing its effectiveness. However, the local HC team must totally agree on the whole idea of self-management and the contents of patient information, because any disagreement might reflect directly on the patient and even compromise the results. Other studies have suggested that a well-trusted, familiar information provider would also improve these outcomes.

A pragmatic study in an OH setting enables good generalizability of results: Based on the study group characteristics and the pragmatic approach, results are most applicable in OHS or an even wider primary HC setting. Narrow study inclusion criteria may exclude important employee groups from the interventions.

Occupational health plays an important role in the management of disabling LBP among employees: In this study, the vast majority of all primary care consultations were performed in OHS. One of the main tasks of OHS is to safeguard employees from identifiable health risks in their work. The Finnish OHS system already has the required resources and ability to bring secondary preventive actions into practice.
This thesis shows that:

1. A substantial proportion of employees experience LB symptoms but are still able to work.

2. Employees at risk of disabling LBP can be identified by collecting data on LBP history, sickness absence and disability and categorizing them into separate subgroups according to pain intensity, simply using an employee survey questionnaire.

3. Active, early-phase LB-specific interventions resulted in the long-term reduction of several LBP-related symptoms and improvement in QoL.

4. A simple LB-specific patient information booklet reduced several LBP symptoms, improved HRQoL and was cost-effective among employees who reported mild-level LBP.

5. Although the absolute effects of the LB-specific outcomes were rather modest, the results were substantial in comparison to the low baseline levels.
9 RECOMMENDATIONS FOR THE FUTURE

9.1 MANAGEMENT OF LBP IN OCCUPATIONAL HEALTH SERVICES

1. OHS should more actively plan and carry out preventive actions for LBP among the working population. OH professionals in Finland already have the means and resources to execute preventive procedures.

2. More evidence on preventive actions and practical means and measures are still needed for OH personnel to be able to select and categorize employees into different levels of LBP when arranging, for example, health check-ups and employee surveys. OHS should also be familiar with local rehabilitation resources and co-operate with other stakeholders in the area.

3. Multifactorial health problems require a multifactorial risk assessment method. Early management of disabling LBP may be compared to the management of, for example, high blood pressure, blood glucose or cholesterol levels – actions that OH professionals are quite familiar with already.

4. All OH professionals should be involved in early management of LBP, because LBP is a very common health problem and has various levels among employees.

5. A LB-specific patient information booklet is cheap, safe and easy to deliver and can be provided by an OH nurse, for example.

6. There is a need for evidence-based, easily accessible LBP self-care material.

7. Preventive management of LBP may also be expanded to apply to all primary care.
9.2 RESEARCH

1. Future research should address the question of which selection criteria and intervention approach would bring the best results in different settings and industries in terms of the long-term effectiveness and cost-effectiveness of LB management.

2. Further studies that use pragmatic design of non-sick-listed employees (at risk of disabling LBP condition) are needed. They should aim at larger patient samples and introduce a genuine randomized design, also for the control group.

3. More epidemiological data are needed on the prevalence and recurrence of LBP as well as on the heterogenic nature of LBP among the working population.

4. Advanced, but practical classification/categorization criteria of various phenotypes of LBP are needed. Updating LBP classification should be a research priority and main task also at the international level.
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The following foundations, institutions and associations supported this research at different phases of the trial:

1. The Centenary Foundation of Kymi Corporation
2. The Yrjö Jahnsson Foundation
3. The Juho Vainio Foundation
4. The Finnish Cultural Foundation
5. The Finnish Work Environment Fund (grant number 114047)
6. The Etelä-Karjalan Lääkäriseura association
7. The Kymenlaakson Terveyden Turva foundation
8. The Viipurin tuberkuloosisäätiö foundation

The author’s work has been independent of these funders.
APPENDICES

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Appendix 1. Employee survey questionnaire
Oirekysely

Selkätutkimus

1. Sukupuoli
   1 mies
   2 nainen

2. Ammatti / vakanssinimike
   Olen:
   1 työntekijä
   2 toimihenkilö
   3 ylempi toimihenkilö tai johtohenkilö

3. Alaselkävaivalla tarkoitetaan kipua, särkyä tai toimintahäiriötä oheisten kuvien osoittamalla kehon alueella. Onko sinulla ollut koskaan alaselkäavaa?
   1 kyllä
   2 ei

4. Onko Sinulla ollut sairauspoissaoloja työstäsi selkävaivan vuoksi viimeisen vuoden (1v) aikana?
   1 ei
   2 kyllä  Jos kyllä, kuinka monta päivää? ______ päivää (jos et tiedä tarkasti, arvioi)

5. Millaiseksi arvioit nykyisen työsi ruumiillisen (=fyysisen) rasittavuuden kannalta?
   1 erittäin raskasta
   2 melko raskasta
   3 sopivan raskasta
   4 melko kevyttä
   5 erittäin kevyttä

6. Millaiseksi arvioit nykyisen työsi henkisen rasittavuuden kannalta?
   1 erittäin raskasta
   2 melko raskasta
   3 sopivan raskasta
   4 melko kevyttä
   5 erittäin kevyttä

Jos Sinulla ei ole ollut lainkaan alaselkäavaivoja, voit lopettaa lomakkeen täytön tähän ja postittaa lomakkeen ohjeiden mukaan. Kiitos!

HUOM! Jos Sinulla on joskus ollut vähäisiäkin selkäavaivoja, pyydämme jatkamaan lomakkeen täyttämistä.

Antamasi vastaukset ovat luottamuksellisia ja tulevat vain tutkimuksen käyttöön. Vastaaminen ei velvoita sinua millään tavalla. Suuret kiitokset vaivannäöstäsi!
7. **Kuinka pitkään** olet kärsinyt alaselkävaivoista (*arvio, esim. 8 vuotta, 4 kuukautta*):

   Vuosia: ________
   Kuukausia: ________

   Alaselkävaivalla tarkoitetaan ristiselän kipua, särkyä tai toiminnallista haittaa, joka ilmenee työssä tai vapaa-aikana.

8. Onko selkäsi leikattu (välilevytyrän, nikamasirrämän tms. takia)?

   0 ei ole
   1 kyllä; kuinka monta kertaa? ________ kertaa.

9. Onko sinulla **alaselkäkipua tällä hetkellä**?

   0 Kyllä
   1 ei

10. Mikä on alaselkäkipujesi määrä **tällä hetkellä**? **Merkitse kivun määrä rastilla “x”** oheiselle viivalle (-----x---) : (vasemmalla (0) on täydellinen kivuttomuus, oikealla pahin mahdollinen kipu (10)) :

   ![Diagram](image)

   0 täysin kivuton 10 pahin mahdollinen kipu

11. Kuinka pitkään nykyinen selkävaivasi (kipu, särky, toiminnallinen haitta) on kestänyt?

   ________ päivää

12. Säteileekö selkäkipusi polven alapuolelle (sääreen, nilkkaan tai jalkaterään)?

   1 ei
   2 kyllä

13. Pyydämme Sinua **merkitsemään rastilla “x”** oheiselle viivalle (-----x---) keskimääräisen selkäkipujesi määrän viimeisen viikon aikana: (vasemmalla (0) on täydellinen kivuttomuus, oikealla laidalla pahin mahdollinen kipu (10)) :

   ![Diagram](image)

   0 täysin kivuton 10 pahin mahdollinen kipu

   Antamasi vastaukset ovat luottamuksellisia ja tulevat vain tutkimuksen käyttöön. Vastaaminen ei velvoita sinua millään tavalla. Suuret kiitokset vaivannäöstä !
Selkätutkimus Oirekysely


<table>
<thead>
<tr>
<th>Kysymys</th>
<th>täysin eri mieltä (1)</th>
<th>täysin samaa mieltä (6)</th>
</tr>
</thead>
<tbody>
<tr>
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<td>1 2 3 4</td>
<td>5 6</td>
</tr>
<tr>
<td>Ruumiillinen aktiivisuus saa kipuni pahenemaan</td>
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<td>5 6</td>
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<td>Työni vaikeutta kipujani</td>
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<td>5 6</td>
</tr>
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<td>Työni on liian raskasta minulle</td>
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<td>5 6</td>
</tr>
<tr>
<td>Työni tekee kipuni pahemmaksi</td>
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<td>5 6</td>
</tr>
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</table>
15. **Millaista haittaa selkävaiva on aiheuttanut sinulle viimeksi kuluneen vuorokauden aikana?**

Ympyröi (O) kunkin väittämän kohdalla parhaiten sopiva vaihtoehto (numero 1 tai 2).

<table>
<thead>
<tr>
<th>pitää paikkansa</th>
<th>ei pidä paikkaansa</th>
</tr>
</thead>
<tbody>
<tr>
<td>selkävaivan vuoksi vietin suurimman osan ajastani kotona</td>
<td>1</td>
</tr>
<tr>
<td>kävelen tavallista hitaammin</td>
<td>1</td>
</tr>
<tr>
<td>selkäni vuoksi</td>
<td>1</td>
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<tr>
<td>selkäni vuoksi asetun makuulle lepäämään tavallista useammin</td>
<td>1</td>
</tr>
<tr>
<td>joudun selkäni vuoksi ottamaan tukea päästäkseni ylös nojatuolista</td>
<td>1</td>
</tr>
<tr>
<td>yritän selkäni vuoksi saada muita tekemään asioita puolestani</td>
<td>1</td>
</tr>
<tr>
<td>pukeudun selkävaivani vuoksi tavallista hitaammin</td>
<td>1</td>
</tr>
<tr>
<td>nousen ylös seisaalleni vain lyhyeksi aikaa selkävaivani vuoksi</td>
<td>1</td>
</tr>
<tr>
<td>yritän olla kumartumatta tai polvistumatta selkävaivani vuoksi</td>
<td>1</td>
</tr>
<tr>
<td>minun on vaikea nousta tuolista selkävaivani vuoksi</td>
<td>1</td>
</tr>
<tr>
<td>selkäni on kivulias kaiken aikaa</td>
<td>1</td>
</tr>
<tr>
<td>minun on vaikea kääntyä vuoteessa selkävaivani vuoksi</td>
<td>1</td>
</tr>
<tr>
<td>minun on vaikea vetää sukkia jalkaani selkävaivani vuoksi</td>
<td>1</td>
</tr>
<tr>
<td>nukun huonosti selkävaivani vuoksi</td>
<td>1</td>
</tr>
<tr>
<td>vältän raskaita hommia vapaa-aikanani selkävaivani vuoksi</td>
<td>1</td>
</tr>
</tbody>
</table>

**jatkuu seuraavalla sivulla**
Selkätutkimus

jatkoa edelliseltä sivulta

pitää paikkansa (1)
ei pidä paikkaansa (2)

olen selkävaivani vuoksi tavallista ärtysämäksi ja pahantuulisempi seurustellessani muiden ihmisten kanssa ..... 1 ...................... 2..
kuljen portaita ylös tavallista hitaammin

selkävaivani vuoksi ............................. 1 ...................... 2..

...............

16. *Kuinka usein* sinulla on ollut alaselkävaivoja *viimeisen 12 kuukauden aikana*?

1. ei lainkaan

2. _____ kertaa

17. Kun sinulla on alaselkävaivoja, *kuinka pitkään ne* tavallisesti kestävät (keskimäärin, arvio)? (valitse yksi vaihtoehto)

1. alle viikon

2. _____ viikkoa (1-4) viikkoa

3. _____ kuukautta (1-12 kuukautta)

4. _____ vuotta


00 01 02 03 04 05 06 07 08 09 10

*Suurkiitokset avustasi!*

Palauta lomake oheisessa vastauskuoressa. Postimaksu on maksettu. Kiitos!

Tilaa vapaaehtoiselle palautteelle (tarvittaessa myös lomakkeen kääntöpuolelle):

_____________________________________________________________________________________

_____________________________________________________________________________________

_____________________________________________________________________________________

Antamasi vastaukset ovat luottamuksellisia ja tulevat vain tutkimuksen käyttöön. Vastaaminen ei velvoita sinua millään tavalla. Suuret kiitokset vaivannäöstä! 

Appendices

Appendix 2. Study questionnaire – basic information
Selkätutkimus

Peruskyselylomake

Potilasnumero

Seulonnan koodi........

Päiväys ___________ Syntymäaika ___________ Ikä vuosina ___________

1. Sukupuoli
   1 mies
   2 nainen

2. Perhesuhteet
   1 naimaton
   2 avio- tai avoliitossa
   3 eronnut
   4 leski

3. Ammatti / vakanssinimike
   1 työntekijä
   2 toimihenkilö
   3 ylempi toimihenkilö tai johtohenkilö
   4 eläkkeellä
   5 Opiskelija tai työssä UPM-Kymmene Oy:n ulkopuolella

4. Peruskoulutus (vastaa viimeisimmän koulutuksen mukaan)
   1 kansa- tai kansalaiskoulu
   2 keskikoulu tai peruskoulu
   3 ylioppilas
   4 ammattikoulu tai oppisopimuskoulutus
   5 opistoasteen loppututkinto
   6 korkeakoulututkinto

5. Työnantaja
   1 Kaukas
   2 Schaumann Wood Oy Kaukaan Vaneritehdas
   3 Yhtyneet sahat Oy Kaukaan saha
   4 Yhtyneet sahat Oy Timber
   5 UPM-Kymmene Oy, mutta muu kuin edellä mainittu
   6 Muu työnantaja kuin UPM-Kymmene Oy
   7 Ei mikään edellisistä

6. Työaikamuoto päätyössä
   1 kokopäiväinen päivätyö
   2 kaksivuorotyö
   3 kolmivuorotyö
   4 osa-aikainen päivätyö
   5 osa-aikainen vuorotyö
Selkätutkimus
Peruskyselylomake
0kk
Potilasnumero _______

7. Työtilanne tällä hetkellä
   1 työssä täysipäiväisesti
   2 sairaslomalla; alkamis- ja mahdollinen päätymispäivämäärä
   ___________________________________________________________
   3 lomautettu; alkaen______________________________________
   4 osa-aikatyössä; alkaen____________________________________
   5 täysaikaisella eläkkeellä
   6 muu; mikä _____________________________________________

8. Lisäansiot
   1 en tee palkallista lisätyötä
   2 teen palkallista lisätyötä n ___ tuntia viikossa

9. Kuinka tyytyväinen olet nykyiseen työhösi (pääasiallinen työsuhde)?
   1 erittäin tyytyväinen
   2 melko tyytyväinen
   3 en tyytyväinen, mutta en tyytymätönkään
   4 melko tyytymätön
   5 erittäin tyytymätön

10. Uskotko, että terveytesi puolesta pystyisit työskentelemään nykyisessä ammatissasi kahden vuoden kuluttuaakin?
   1 tuskin
   2 en ole varma
   3 melko varmasti
   4 vaikea sanoa, todennäköisesti olen silloin jo eläkkeellä
   5 pystyn vain, jos saan terveydentilani kohentumaan

11. Mikä seuraavista vaihtoehtoista kuvaavat parhaiten nykyistä työtäsi?
    YMPYRÖI YKSI VAIHTOEHTO

   1 KEVYT ISTUMATYÖ. Työ on pääasiassa istumista pöydän, koneen, ohjauslaitteen tms. ääressä, missä tehdään vain kevyttä työtä käsillä (esim. henkinen työ, istuen tehtävää toimistotyö, keveiden esineiden käsittely)
   jatkuu seuraavalla sivulla....
Selkätutkimus

Peruskyselylomake

Potilasnumero _______

...jatkoa...

2 MUU ISTUMATYÖ. Työ on pääasiassa istumista, mutta työssä joudutaan käsittelemään kohtalaisen raskaita esineitä (esim. teollisuustyö "liukuhihnan" ääressä)

3 RUUMIILISESTI KEVYT SEISOMATYÖ TAI KEVYT LIIKKUVA TYÖ. Työ on pääasiassa seisomatytöä ilman raskaita työliikkeitä tai työ on liikkumista paikasta toiseen ilman jatkuvia raskaita kantamuksia (esim. nosturikuljettajan/trukinkuljettajan työ, liikkuva toimistotyö, liikkumista edellyttävä opetustyö)

4 RUUMIILISESTI KEVYEHKÖ TAI KESKIRASKAS LIIKKUVA TYÖ. Työ on pääasiassa liikkuvaa työtä, missä joudutaan kävelemään paljon portaissa tai liikkumaan suhteellisen nopeasti pitkiä matkoja (esim. kevyehkö teollisuustyö, lähetin työ, siivoojan, myyjän/myymäläapulaisen työ)

5 RASKAS RUUMIILLINEN TYÖ. Työ on joko pääasiassa seisomatytöä, johon kuuluu jatkuvaa keveiden esineiden nostelua, kampien yms. kääntämistä tai työssä nostetana kannetaan raskaita esineitä, kairataan, kaivetaan, moukaroidaan tms., mutta välillä myös istutaan tai seisotaan (esim. raskaat metalliteollisuuden työt, rakennustyöt, raskaitten työkalujen, tavaroiden tai osien käsittely, tavan takaa tapahtuva siirtäminen tai kokoaminen, konein tehtävää maataloustyö)

6 ERITTÄIN RASKAS RUUMIILLINEN TYÖ. Työ on pääasiassa jatkuvaa tai melko jatkuvaa raskaiden työliikkeiden suorittamista, mitä tehdään usein pitkään yhteen menoon (esim. metsätyö, raskas maataloustyö ilman koneita, raskas rakennustyö, kaivamistyö ilman koneita)

12. Millaisena pidät terveydentilaasi tällä hetkellä ikäisisi verrattuna?

1 erittäin hyvänä
2 hyvänä
3 keskitasoisena
4 huonona
5 erittäin huonona

13. Voitko vaikuttaa itseäsi koskeviin asioihin työpaikallasi?

0 Hyvin paljon
1 Melko paljon
2 Jonkin verran
3 Hyvin vähän
4 En lainkaan
Selkätutkimus

Peruskyselylomake

0kk

Potilasnumero __________

14. Saatto tarvittaessa tukea ja apua esimiehellesi?

0  Erittäin paljon
1  Melko paljon
2  Jonkin verran
3  Melko vähän
4  Erittäin vähän
5  Minulla ei ole esimiestä

15. Millainen on suhteesi esimieheesi?

0  Erittäin hyvä
1  Kohtalaisen hyvä
2  Ei hyvä mutta ei huonokaan
3  Hiukan ongelmallinen
4  Huono (kireä, kaunainen tms.)
5  Minulla ei ole esimiestä

16. Minkälaiset ovat työtovereiden välit työpaikallasi?

0  Erittäin hyvät
1  Kohtalaisen hyvät
2  Ei hyvät mutta ei huonotkaan
3  Hiukan ongelmalliset
4  Huonot (kireät, kaunaiset tms.)
5  Työskentelen yksin

17. Mikä on alaselkäkipujesi määrä tällä hetkellä? Merkitse kivun määrä rastilla “x” oheiselle viivalle (-----x---) : (vasemmalla (0) on täydellinen kivuttomuus, oikealla pahin mahdollinen kipu (10)) :

"Kipu tällä hetkellä"

|----------------------------------|  |
| täysin                           | 0 |
| kivuton                          | 10|
| pahin                            |   |
| mahdollinen kipu                 |   |

18. Kuinka pitkään nykyinen selkävaivasi (kipu, särky, toiminnallinen haitta) on kestänyt?

_______ päivää
Selkätutkimus

19. Säteileekö selkäkipusi polven alapuolelle (sääreen, nilkkaan tai jalkaterään)?

0  ei
1  kyllä

20. Pyydämme Sinua merkitsemään rastilla “x” oheiselle viivalle (----x---) keskimääräisen selkäkipujesi määrän viimeisen viikon aikana: (vasemmalla (0) on täydellinen kivuttomuus, oikealla laidalla pahin mahdollinen kipu (10)) : "Kipu 1 viikon aikana"

<table>
<thead>
<tr>
<th>täysin kivuton</th>
<th>pahin mahdollinen kipu</th>
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<tbody>
<tr>
<td>0</td>
<td>10</td>
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jatkuu seuraavalla sivulla....
**Selkätutkimus**

**Peruskyselylomake**  

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22. **Millaista haittaa selkävaiva on aiheuttanut sinulle viimeksi kuluneen vuorokauden aikana?** Ympyröi (O) kunkin väittämän kohdalla parhaiten sopiva vaihtoehto (numero 1 tai 2).

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</tbody>
</table>

*jatkuu seuraavalla sivulla....*
<table>
<thead>
<tr>
<th>23. Onko selkävaivasi mielestäsi viime aikoina ollut</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  paranemassa</td>
</tr>
<tr>
<td>2  muuttumaton, pysyvä</td>
</tr>
<tr>
<td>3  pahenemassa</td>
</tr>
<tr>
<td>4  minulla ei ole ollut vaivoja</td>
</tr>
</tbody>
</table>
24. Pyydämme Sinua **merkitsemään rastilla “x” oheiselle viivalle (---x--) keskimääräisen selkäkipujesi määran viimeisen 3 kuukauden aikana:** (vasemmalla (0) on täydellinen kivuttomuus, oikealla laidalla pahin mahdollinen kipu (10)) : "Kipu 3kk"

<table>
<thead>
<tr>
<th>täysin</th>
<th>pahin</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>10</td>
</tr>
</tbody>
</table>

25. Onko lähisukulaisillesi (veljet, siskot, omat vanhemmat) tehty selkäleikkausta (välilevytärän, nikamasiirtymän tms. takia)?

- 0 ei ole
- 1 kyllä


**KIVUN VOIMAKKUUS JA SÄRKYLÄÄKKEET**

- 0 voin sietää kipuni käyttämättä särkylääkkeitä
- 1 kipuni on kovaa, mutta selviyden ilman särkylääkkeitä
- 2 särkylääkkeet vievät kipuni täysin
- 3 särkylääkkeet helpottavat kipujani huomattavasti
- 4 särkylääkkeistä ei ole paljoakaan apua kipuihini
- 5 särkylääkkeistä ei ole mitään apua kipuihini, enkä niitä käytä

**OMATOIMISUUS (PUKEUTUMINEN, PESEYTYMINEN JNE.)**

- 0 selviyden näistä toiminnoista normaalisti ilman, että siitä aiheutuu lisää kipuja
- 1 selviyden näistä toiminnoista normaalisti, mutta siitä aiheutuu ylimääräistä kipua
- 2 näistä toiminnoista selviytyminen aiheuttaa melkoisesti kipuja ja vaatii aikaa ja varovaisuutta
- 3 tarvitsen apua, mutta selviyden useimmilla toiminnoilla on normaali käyttävyys
- 4 tarvitsen apua joka päivä useimmilla omatoimisuuteen liittyvissä toiminnoissa
- 5 en yleensä pukeudu tai peseydy lainkaan, pysyttelen vuoteessa

**NOSTAMINEN**

- 0 voin nostaa raskaita taakkoja jotakuinkin kivuttomasti
- 1 voin nostaa raskaita taakkoja, mutta se aiheuttaa jonkin verran kipuja
- 2 kipu estää minua nostamasta raskaita taakkoja lattialta, mutta voin nostaa niitä, jos ne on sijoitettu sopivasti, esim. pöydälle
- 3 kipu estää minua nostamasta raskaita taakkoja, mutta voin nostaa kevyitä taakkoja, jos ne on sopiastu raskaiden
- 4 voin nostaa ainoastaan hyvin kevyitä taakkoja
- 5 en voi nostaa tai kantaa mitään
Selkätutkimus

Peruskyselylomake

Potilasnumero 0kk

KÄVELY
0 kipu ei estä kävelyäni missään määrin
1 kipu estää minua kävelemästä kahta kilometriä enempää
2 kipu estää minua kävelemästä yhtä kilometriä enempää
3 kipu estää minua kävelemästä puolta kilometriä enempää
4 voin kävellä vain käyttäen keppiä tai kynänsauvoja
5 olen enimmäkseen vuoteessa ja minun on usein ryömittävä WC:hen

ISTUMINEN
0 voin istua millaisessa tuolissa tahansa niin pitkään kuin haluan
1 voin istua miten pitkään tahansa vain määritellyissä tuolissa
2 kipu estää minua istumasta tuntia pidempään
3 kipu estää minua istumasta puolta tuntia pidempään
4 kivun takia en voi istua kymmentä minuuttia pidempään
5 kivun takia en voi istua ollenkaan

SEISOMINEN
0 voin seisoa miten pitkään tahansa ilman, että se aiheuttaa kipuja
1 voin seisoa niin pitkään kuin haluan, mutta se on kivuliasta
2 kivun takia en voi seisoa tuntia pidempään
3 kivun takia en voi seisoa puolta tuntia pidempään
4 kivun takia en voi seisoa 10 minuuttia pidempään
5 kivun takia en voi seisoa lainkaan

NUKKUMINEN
0 kipu ei vaikuta yöuneeni lainkaan
1 nukun kivuista huolimatta käyttämättä lääkkeitä
2 vaikka käytän lääkkeitä, nukun alle kuusi tuntia
3 vaikka käytän lääkkeitä, nukun alle neljä tuntia
4 vaikka käytän lääkkeitä, nukun alle kaksi tuntia
5 kivun takia en saa ollenkaan nukuttua

SUKUPUOLIELÄMÄ
0 sukupuolielämäni on entisellään, eikä siitä aiheudu kipuja
1 sukupuolielämäni on entisellään, mutta se lisää kipujani
2 sukupuolielämäni on lähdes entisellään, mutta hyvin kivulloista
3 kipu rajoittaa huomattavasti sukupuolielämääni
4 kivun takia sukupuolielämäni on lähes olematonta
5 kipu estää minulta kaiken sukupuolielämän

SOSIAALINEN ELÄMÄ (YSTÄVYYSSUHTEET, VAPAA-AJAN HARRASTUKSET YMS.)
0 sosiaalinen elämäni on normaalia, eikä siitä aiheudu minulle merkittävää kipua
1 sosiaalinen elämäni on normaalia, mutta se lisää kipujani
2 kivulla ei ole merkittävää vaikutusta sosiaaliseen elämääni lukuun ottamatta liikunnallisia harrastukseja kuten hautaamista ja tanssimista jne.
3 kipu on rajoittanut sosiaalista elämääni, harrastuksen ovat vähentyneet aiemmasta merkittävästi
4 kivun takia sosiaalin elämäni on rajoitunut kotiirii
5 kivun takia minulla ei ole mitään sosiaalista elämää
MATKUSTAMINEN
0 voin tehdä miten pitkiä matkoja tahansa ilman merkittävää kipua
1 voin tehdä miten pitkiä matkoja tahansa, mutta siitä aiheutuu kipuja
2 selviydyin yli kahden tunnin matkoista, mutta siitä aiheutuva kipu on ikävä
3 kivun takia minun on rajoitettava matkani alle tunnin kestäviksi
4 kivun takia voin tehdä vain alle puolen tunnin kestäviä välttämättämiä matkoja
5 kivun takia en voi matkustaa minnekään muualle kuin lääkärin vastaanotolle tai sairaalaan

27. Oletko viimeksi kuluneen vuoden (12 kk) aikana tupakoinut?
Mikä seuraavista vaihtoehdoista kuvaa parhaiten tupakointiasi?

1 en ole koskaan tupakoinut
2 olen lopettanut, milloin ? ________________________
3 tupakoin joskus, mutta en säännöllisesti
4 poltan säännöllisesti päivittäin alle 20 savuketta tai sikaria
5 poltan säännöllisesti päivittäin yli 20 savuketta tai sikaria
6 poltan säännöllisesti päivittäin muita tupakkavalmisteita; mitä ja kuinka paljon
päivittäin? ________________________________

28. Mitä lääkkeitä käytät tällä hetkellä päivittäin (muutkin kuin särkylääkkeet)
lääkseen nimi ____________________________ _______ kertaa päivässä
lääkseen nimi ____________________________ _______ kertaa päivässä
lääkseen nimi ____________________________ _______ kertaa päivässä
lääkseen nimi ____________________________ _______ kertaa päivässä

(tarvittaessa lisälehдель)

29. Mitä lääkkeitä käytät tarvittaessa?
lääkseen nimi ____________________________ _______ kertaa päivässä
lääkseen nimi ____________________________ _______ kertaa päivässä
lääkseen nimi ____________________________ _______ kertaa päivässä

(tarvittaessa lisälehдель)
Selkätutkimus

Peruskyselylomake

0kk

Potilasnumero ______

LIIKUNTA

30. Kuinka monta kertaa viikossa keskimäärin olet harrastanut liikuntaa viimeisten 12 kuukauden aikana ennen nykyisen selkäkipujakson alkamista (vähintään 20 min. kerrallaan, esim. pyöräily, uinti, voimistelu, juoksu, hiihto, pallopelit, reipas kävely)?

- 0 En lainkaan
- 1 Vähemmän kuin kerran viikossa
- 2 Kerran viikossa
- 3 2 - 3 kertaa viikossa
- 4 4 - 6 kertaa viikossa
- 5 Päivittäin

31. Kuinka monta kertaa viikossa keskimäärin olet harrastanut liikuntaa selkäsi kipeydyttyä (vähintään 20 min. kerrallaan, esim. pyöräily, uinti, voimistelu, juoksu, hiihto, pallopelit, reipas kävely)?

- 0 En lainkaan
- 1 Vähemmän kuin kerran viikossa
- 2 Kerran viikossa
- 3 2 - 3 kertaa viikossa
- 4 4 - 6 kertaa viikossa
- 5 Päivittäin


- 00 täysin työkykytön
- 01 työkyky
- 02 parhaimmillaan
- 03 työkyky
- 04 parhaimmillaan
- 05 työkyky
- 06 parhaimmillaan
- 07 työkyky
- 08 parhaimmillaan
- 09 työkyky
- 10 parhaimmillaan

33. Kuinka tyytyväinen olet yleisesti ottaen ollut selkäavaivasi hoitoon?

Rengasta oikea vaihtoehto.

- 00 täysin tyytymätön
- 01 tyytymätön
- 02 tyytymätön
- 03 tyytymätön
- 04 tyytymätön
- 05 tyytymätön
- 06 tyytymätön
- 07 tyytymätön
- 08 tyytymätön
- 09 tyytymätön
- 10 tyytymätön
35. DEPS-seula (Mielialakysely). Ympyröi se vaihtoehto, joka lähinnä vastaa tilannettasi viimeisen kuukauden aikana.

<table>
<thead>
<tr>
<th></th>
<th>ei lainkaan</th>
<th>jonkin verran</th>
<th>melko paljon</th>
<th>erittäin paljon</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kärsin unettomuudesta</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Tunsin itseni surumieliseksi</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Minusta tuntui, että kaikki vaatii ponnistusta</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Tunsin itseni tarmottomaksi</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Tunsin itseni yksinäiseksi</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Tulevaisuus tuntui toivottomalta</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>En nauttinut elämästäni</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Tunsin itseni arvottomaksi</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Tunsin, että kakki ilo on hävinnyt elämästä Minusta tuntui, ettei alakuloisuuteni hellittänyt edes perheeni ja ystävieni seurassa</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>
Lisäksi toivon, että merkitset alla olevaan piirrokseen ne kohdat, joissa Sinulla on tällä hetkellä kipuja.

Kiitos yhteistyöstä!!
Appendix 3. HRQoL questionnaire (RAND-36 and 15-D)
Elämänlaatu –kysymykset

Nro: __________

Päiväys:____________ Syntymäaika: __________

RAND 36-ITEM HEALTH SURVEY 1.0

STAKES/KTL
Elämänlaatu –kysymykset

1. Onko terveytenne yleisesti ottaen .  (ympyröikää yksi numero)
   1 erinomainen
   2 varsin hyvä
   3 hyvä
   4 tyydyttävä
   5 huono

2. Jos vertaatte nykyistä terveydentilaanne 3 kuukauden (3kk) takaiseen,  onko terveytenne yleisesti ottaen .  (ympyröikää yksi numero)
   1 tällä hetkellä paljon parempi kuin 3kk sitten
   2 tällä hetkellä jonkin verran parempi kuin 3kk sitten
   3 suunnilleen samanlainen
   4 tällä hetkellä jonkin verran huonompi kuin 3kk sitten
   5 tällä hetkellä paljon huonompi kuin 3kk sitten

Seuraavassa luetellaan erilaisia päivittäisiä toimintoja.  Rajoittaako terveydentilanne nykyisin suoriutumistanne seuraavista päivittäisistä toiminnoista? Jos rajoittaa, kuinka paljon?  (ympyröikää yksi numero joka riviltä)

   3. huomattavia ponnistuksia vaativat toiminnat (esimerkiksi juokseminen,
   raskaiden tavaroiden nostelu,
   rasittava urheilu) ............ ......................... 1 .................. 2 .................. 3

   4. kohtuullisia ponnistuksia vaativat toiminnat, kuten pöydän
   siirtäminen, imurointi, keilailu ......................... 1 .................. 2 .................. 3

   5. ruokakassien nostaminen tai kantaminen............. 1 .................. 2 .................. 3

   6. nouseminen portaita useita kerroksia ................. 1 .................. 2 .................. 3

   7. nouseminen portaita yhden kerroksen ................. 1 .................. 2 .................. 3

   8. vartalon taivuttaminen,
   polvistuminen, kumartuminen............................ 1 .................. 2 .................. 3

   9. noin kahden kilometrin matkan kävely ................ 1 .................. 2 .................. 3

   10. noin puolen kilometrin matkan kävely ............... 1 .................. 2 .................. 3

   11. noin 100 metrin  matkan kävely .................... 1 .................. 2 .................. 3

   12. kylpeminen tai pukeutuminen .......................... 1 .................. 2 .................. 3
Elämänlaatu –kysymykset

Onko teillä viimeisen 4 viikon aikana ollut ruumiillisen terveydentilanne takia alla mainittuja ongelmia työssänne tai muissa tavanomaisissa päivittäisissä tehtävissänne? (ympyrökää yksi numero joka riviltä)

kyllä  ei

13. Vähensitte työhön tai muihin tehtäviin käyttämäänne aikaa ...... 1 ............... 2
14. Saitte aikaiseksi vähemmän kuin halusitte ................. 1 ............... 2
15. Terveydentilanne asetti teille rajoituksia joissakin työ- tai muissa tehtävissä ............................................. 1 ............... 2
16. Töistänne tai tehtävistänne suorituminen tuotti vaikeuksia (ollette joutunut esim. ponnistelemaan tavallista enemmän) ............................................. 1 ............... 2

Onko teillä viimeisen 4 viikon aikana ollut tunne-elämään liittyvien vaikeuksien (esim. masentuneisuus tai ahdistuneisuus) takia alla mainittuja ongelmia työssänne tai muissa tavanomaisissa päivittäisissä tehtävissänne? (ympyrökää yksi numero joka riviltä)

kyllä  ei

17. Vähensitte työhön tai muihin tehtäviin käyttämäänne aikaa ............................................. 1 ............... 2
18. Saitte aikaiseksi vähemmän kuin halusitte ................. 1 ............... 2
19. Ette suorittanut töitä tai muita tehtäviänne yhtä huolellisesti kuin tavallistaesti ............................................. 1 ............... 2

20. Missä määrin ruumiillinen terveydentilanne tai tunne-elämän vaikeudet ovat viimeisen 4 viikon aikana häirinneet tavanomaista (sosiaalista) toimintaanne perheen, ystävien, naapureiden tai muiden ihmisten parissa?

(ympyrökää yksi numero)

1  ei lainkaan
2  hieman
3  kohtalaisesti
4  melko paljon
5  erittäin paljon

1 ei lainkaan  
2 hyvin lieviä  
3 lieviä  
4 kohtalaisia  
5 voimakkaita  
6 erittäin voimakkaita

22. Kuinka paljon kipu on häirinnyt tavanomaista työtänne (kotona tai kodin ulkopuolella) viimeisen 4 viikon aikana? (ympyrökää yksi numero)

1 ei lainkaan  
2 hieman  
3 kohtalaisesti  
4 melko paljon  
5 erittäin paljon

Seuraavat kysymykset koskevat sitä, miltä teistä on tuntunut viimeisen 4 viikon aikana. Merkitä kuninka kysymyksen kohdalla se numero, joka parhaiten kuvaa tuntemuksianne.

23. tuntenut olevanne täynnä elinvoimaa ...     ...     .......     ....... 1 ............ 2 ........... 3 ............ 4 ............ 5 ........... 6

24. ollut hyvin hermostunut ...     ...     .......     ....... 1 ............ 2 ........... 3 ............ 4 ............ 5 ........... 6

25. tuntenut mieliläiselle niin matalaksi, ettei mikään ole voinut teitä piristää. ...     ...     .......     ....... 1 ............ 2 ........... 3 ............ 4 ............ 5 ........... 6

26. tuntenut itsenne tyyneksi ja rauhalliseksi ...     ...     .......     ....... 1 ............ 2 ........... 3 ............ 4 ............ 5 ........... 6

27. ollut täynnä tarmoa ...     ...     .......     ....... 1 ............ 2 ........... 3 ............ 4 ............ 5 ........... 6

28. tuntenut itsenne alakuloiseksi ja apeaksi ...     ...     .......     ....... 1 ............ 2 ........... 3 ............ 4 ............ 5 ........... 6

29. tuntenut itsenne "loppuunkuluneeksi" ..     ...     .......     ....... 1 ............ 2 ........... 3 ............ 4 ............ 5 ........... 6

30. ollut onnellinen.....     ...     .......     ....... 1 ............ 2 ........... 3 ............ 4 ............ 5 ........... 6

31. tuntenut itsenne väsyneeksi.....     ...     .......     ....... 1 ............ 2 ........... 3 ............ 4 ............ 5 ........... 6
32. **Kuinka suuren osan ajasta** ruumiillinen terveydentilanne tai tunne-elämän vaikeudet ovat viimeisen 4 viikon aikana häirinneet tavanomaista sosiaalista toimintaanne (ystävien, sukulaisen, muita ihmisten tapaaminen)?
   (ymyröikää yksi numero)
   1) koko ajan
   2) suurimman osan aikaa
   3) jonkin aikaa
   4) vähän aikaa
   5) ei lainkaan

Kuinka hyvin seuraavat väittämät pitävät paikkansa teidän kohdallanne?
(ymyröikää yksi numero joka riviltä)

33. Minusta tuntuu, että sairastun jonkin verran helpommin kuin muut ihmiset
   . . . . . . . . . . 1 . . . 2 . . . 3 . . . 4 . . . 5

34. Olen vähintään yhtä terve kuin kaikki muutkin
   . . . . . . . . . . 1 . . . 2 . . . 3 . . . 4 . . . 5

35. Uskoon, että terveyden
   tulee heikkenemään
   . . . . . . . . . . 1 . . . 2 . . . 3 . . . 4 . . . 5

36. Terveyteni on erinomainen
   . . . . . . . . . . 1 . . . 2 . . . 3 . . . 4 . . . 5

37. **Elämänlaadun kyselylomake (15-D)**

   Ohje: Lukekaa ensin läpi huolellisesti kunkin kysymyksen kaikki vastausvaihtoehdot. Ympyröikää (O) se vaihtoehto, joka parhaiten kuvaa terveydentilaanne tään.

   **KYSYMYS 1. Liikuntakyky**  (Valitse yksi vaihtoehto)
   1) pystyn kävelemään normaalisti (vaikeuksitta) sisällä, ulkona ja portaissa
   2) pystyn kävelemään vaikeuksitta sisällä, mutta ulkona ja tai portaissa on pieniä vaikeuksia
   3) pystyn kävelemään ilman apua sisällä (apuvälinein tai ilman), mutta ulkona ja tai portaissa melkoisin vaikeuksin tai toisen avustamana
   4) pystyn kävelemään sisälläkin vain toisen avustamana
   5) olen täysin liikuntakyvytön ja vuoteenoma
TERVEYTEEN LIITTYVÄN ELÄMÄNLAADUN KYSEYLOMAKE (15-D)

KYSYMYS 2. Näkö (Valitse yksi vaihtoehto)

1) näen normaalisti eli näen lukea lehteä ja TV:n tekstejä vaikeuksitta (silmälaseilla tai ilman)
2) näen lukea lehteä ja/tai TV:n tekstejä pienin vaikeuksin (silmälaseilla tai ilman)
3) näen lukea lehteä ja/tai TV:n tekstejä huomattavin vaikeuksin (silmälaseilla tai ilman)
4) en näe lukea lehteä enkä TV:n tekstejä ilman silmälaseja tai niiden kanssa, mutta näen (näkisin) kulkea ilman opasta
5) en näe (näkisi) kulkea oppaatta eli olen lähes tai täysin sokea

KYSYMYS 3. Kuulo (Valitse yksi vaihtoehto)

1) kuulen normaalisti eli kuulen hyvin normaalia puheääntä (kuulokojeen kanssa tai ilman)
2) kuulen normaalia puheääntä pienin vaikeuksin
3) kuulen normaalia puheääntä melkoisin vaikeuksin, keskusteluissa on käytettävä normaalia kovempaa puheääntä
4) kuulen kovaakin puheääntä heikosti; olen melkein kuuro
5) olen täysin kuuro

KYSYMYS 4. Hengitys (Valitse yksi vaihtoehto)

1) pystyn hengittämään normaalisti eli minulla ei ole hengenahdistusta tai muita hengitysvaikeuksia
2) minulla on hengenahdistusta raskaassa työssä tai urheilussa, reippaassa kävelyssä tasamaalla tai lievässä ylämäessä
3) minulla on hengenahdistusta kävellessä muiden samanikäisten vauhtia tasamaalla
4) minulla on hengenahdistusta pieninkin rasituksen jälkeen, esim. peseytyessä tai pukeutuessa
5) minulla on hengenahdistusta lähes koko ajan, myös levossa

KYSYMYS 5. Nukkuminen (Valitse yksi vaihtoehto)

1) nukun normaalisti eli minulla ei ole mitään ongelmia unen suhteen
2) minulla on lieviä uniongelmia, esim. nukahtamisvaikeuksia tai heräilen satunnaisesti yöllä
3) minulla on melkoisia uniongelmia, esim. nukun levottomasti, uni ei tunnu riittävältä
4) minulla on suuria uniongelmia, esim. joudun käyttämään usein tai säännöllisesti unilääkettä, herään säännöllisesti yöllä ja/tai aamuisin liian varhain
5) kärsin vaikeasta unettomuudesta, esim. unilääkkeiden runsasta käytöstä huolimatta nukkuminen on lähes mahdotonta, valvon suurimman osan yöstä

KYSYMYS 6. Syöminen (Valitse yksi vaihtoehto)

1) pystyn syömään normaalisti eli itse ilman mitään vaikeuksia
2) pystyn syömään itse pienin vaikeuksin (esim. hitaasti, kömpelösti, vavisten tai erityisapuneuvoin)
3) tarvitset hieman toisen apua syömisessä
4) en pysty syömään itse lainkaan, vaan minua pitää syöttää
5) en pysty syömään itse lainkaan, vaan minua pitää syöttää joko letkulla tai suonen sisäisellä ravintoliuoksella
TERVEYTEEN LIITTYVÄN ELÄMÄNLAADUN KYSELYLOMAKE (15-D)

KYSYMYS 7. Puhuminen ___ (Valitse yksi vaihtoehto)

1) pystyn puhumaan normaalisti eli selvästi, kuuluvasti ja sujuvasti
2) puhuminen tuottaa minulle pieniä vaikeuksia, esim. sanoja on etsittävä tai ääni ei ole riittävän kuuluvaa tai se vaihtaa korkeutta
3) pystyn puhumaan ymmärrettävästi, mutta katkonaisesti, ääni vavisten, samaltaen tai äntyttäen
4) muilla on vaikeuksia ymmärtää puhettani
5) pystyn ilmaisemaan itseäni vain elein

KYSYMYS 8. Eriyystoiminta ___ (Valitse yksi vaihtoehto)

1) virtsarakon ja suoliston toimivat normaalisti ja ongelmitta
2) virtsarakon ja/tai suoliston toiminnassa on lieviä ongelmia, esim. minulla on virtsampilis vaikeuksia tai kova tai löysä vatsa
3) virtsarakon ja/tai suoliston toiminnassa on melkoisia ongelmia, esim. minulla on satunnaisia virtsanpidätysvaikeuksia tai vaikea ummetus tai ripuli
4) virtsarakon ja/tai suoliston toiminnassa on suuria ongelmia, esim. minulla on säänollisesti ”vahinkoja” tai peräruiskeiden tai katetroinnin tarvetta
5) en hallitse lainkaan virtsaamista ja/tai ulostamista

KYSYMYS 9. Tavanomaiset toiminnot ___ (Valitse yksi vaihtoehto)

1) pystyn suoriutumaan normaalisti tavanomaisista toiminnoista (esim. ansiotyö, opiskelu, kotityö, vapaa-ajan toiminnot)
2) pystyn suoriutumaan tavanomaisista toiminnoista hieman alentuneella teholla tai pienin vaikeuksin
3) pystyn suoriutumaan tavanomaisista toiminnoista huomattavasti alentuneella teholla tai huomattavin vaikeuksin tai vain osaksi
4) pystyn suoriutumaan tavanomaisista toiminnoista vain pieneltä osin
5) en pysty suoriutumaan lainkaan tavanomaisista toiminnoista

KYSYMYS 10. Henkinen toiminta ___ (Valitse yksi vaihtoehto)

1) pystyn ajattelemaan selkeästi ja johdonmukaisesti ja muistini toimii täysin moitteetomasti
2) minulla on lieviä vaikeuksia ajatella selkeästi ja johdonmukaisesti, tai muistini ei toimi täysin moitteetomasti
3) minulla on melkoisia vaikeuksia ajatella selkeästi ja johdonmukaisesti, tai minulla on junkin verran muistinmenetystä
4) minulla on suuria vaikeuksia ajatella selkeästi ja johdonmukaisesti, tai minulla on huomattavaa muistinmenetystä
5) olen koko ajan sekaisin ja vailla ajan tai paikan tajua
KYSYMYS 11. Vaivat ja oireet (Valitse yksi vaihtoehto)
   1) minulla ei ole mitään vaivoja tai oireita, esim. kipua, särkyä, pahoinvointia, kutinaa jne.
   2) minulla on lieviä vaivoja tai oireita, esim. lievää kipua, särkyä, pahoinvointia, kutinaa jne.
   3) minulla on melkoisia vaivoja tai oireita, esim. melkoista kipua, särkyä, pahoinvointia, kutinaa jne.
   4) minulla on voimakkaita vaivoja tai oireita, esim. voimakasta kipua, särkyä, pahoinvointia, kutinaa jne.
   5) minulla on sietämättömiä vaivoja ja oireita, esim. sietämätöntä kipua, särkyä, pahoinvointia, kutinaa jne.

KYSYMYS 12. Masentuneisuus (Valitse yksi vaihtoehto)
   1) en tunne itseäni lainkaan surulliseksi, alakuloiseksi tai masentuneeksi
   2) tunnen itseni hieman surulliseksi, alakuloiseksi tai masentuneeksi
   3) tunnen itseni melko surulliseksi, alakuloiseksi tai masentuneeksi
   4) tunnen itseni erittäin surulliseksi, alakuloiseksi tai masentuneeksi
   5) tunnen itseni äärimmäisen surulliseksi, alakuloiseksi tai masentuneeksi

KYSYMYS 13. Ahdistuneisuus (Valitse yksi vaihtoehto)
   1) en tunne itseäni lainkaan ahdistuneeksi, jännittyneeksi tai hermostuneeksi
   2) tunnen itseni hieman ahdistuneeksi, jännittyneeksi tai hermostuneeksi
   3) tunnen itseni melko ahdistuneeksi, jännittyneeksi tai hermostuneeksi
   4) tunnen itseni erittäin ahdistuneeksi, jännittyneeksi tai hermostuneeksi
   5) tunnen itseni äärimmäisen ahdistuneeksi, jännittyneeksi tai hermostuneeksi

KYSYMYS 14. Energisyys (Valitse yksi vaihtoehto)
   1) tunnen itseni terveeksi ja elinvoimaiseksi
   2) tunnen itseni hieman uupuneeksi, väsyneeksi tai voimattomaksi
   3) tunnen itseni melko uupuneeksi, väsyneeksi tai voimattomaksi
   4) tunnen itseni hyvin uupuneeksi, väsyneeksi tai voimattomaksi, lähes "loppuun palaneeksi"
   5) tunnen itseni äärimmäisen uupuneeksi, väsyneeksi tai voimattomaksi, täysin "loppuun palaneeksi"

KYSYMYS 15. Sukupuolielämä (Valitse yksi vaihtoehto)
   1) terveydentilani ei vaikeuta mitenkään sukupuolielämääni
   2) terveydentilani vaikeuttaa hieman sukupuolielämääni
   3) terveydentilani vaikeuttaa huomattavasti sukupuolielämääni
   4) terveydentilani tekee sukupuolielämäni lähes mahdottomaksi
   5) terveydentilani tekee sukupuolielämäni mahdottomaksi
Appendices

Appendix 4. Health care utilization questionnaire
Selkätutkimus Palvelut ja kustannukset lomake
Potilasnumero ………………

TERVEYDENHUOLTopalvelut ja kustannukset pvm: …/…200..

Tutkimuksessa selvitetään selkäsairauksien vaikutusta yhteiskunnallisiin kustannuksiin. Tämän vuoksi pyydämme, että kirjaisit tiedot nykyisen selkäkipusi vuoksi käyttämistäsi terveydenhuoltopalveluitsa ja niistä aiheutuneista kustannuksista edellisen selkätutkimuskäynnin tai kyselyn jälkeen.

Nämä, kuten kaikki muutkin tutkimuksessa käytettävät tiedot, käsitellään ehdottoman luottamussellisesti.

Tee merkintä jokaiseen kohtaan ja merkitse – (viiva), jos kysyttyjä käyntejä tai kustannuksia ei ole ollut.

1. TERVEYSKESKUKSESSA

Käynnit edellisen selkätutkimuskäynnin jälkeen
a) Terveyskeskuslääkärillä _______kertaa
b) Terveydenhoitajalla _______kertaa
c) Fysioterapeutilla _______kertaa
d) Muun terveydenhuoltoalan henkilön vastaanotolla – kenen?

________________________________________________________________________

Käynneistä kertyneet kustannukset yhteensä
(Omavastuuosuus ilman matkakuluja) _________ €

Matkakulut: _________km _________ €

2. TYÖTERVEYSEASEMALLA

Käynnit edellisen selkätutkimuskäynnin jälkeen
a) Työterveyslääkärillä _______kertaa
b) Työterveyshoitajalla _______kertaa
c) Fysioterapeutilla _______kertaa
d) Muun terveydenhuoltoalan henkilön vastaanotolla – kenen?

________________________________________________________________________

Käynneistä kertyneet kustannukset yhteensä _________ €
(Omavastuuosuus ilman matkakuluja)

Matkakulut: _________km _________ €
3. YKSITYISELLÄ LÄÄKÄRIASEMALLA

Käynnit edellisen selkätutkimuskäynnin jälkeen

a) Lääkärillä _______ kertaa

b) Terveydenhoitajalla _______ kertaa

c) Fysioterapeutila _______ kertaa

d) Muun terveydenhuoltoalan henkilön vastaanottolla – kenen?
   __________________________________________________________          ___________ kertaa

Käynneistä kertyneet kustannukset yhteensä _________€
(Omavastuuosuus ilman matkakuluja)

Matkakulut: _________km _________€

Onko työnantajasi osallistunut kustannuksiin?

0  Kyllä
1  Ei

Kuinka paljon? _________€

4. SAIRAALAN POLIKLINIKALLA

Sairaalan nimi __________________________________________________________

Käynnit edellisen selkätutkimuskäynnin jälkeen

a) Lääkärillä _______ kertaa

b) Terveydenhoitajalla _______ kertaa

c) Fysioterapeutila _______ kertaa

c) Muun terveydenhuoltoalan henkilön vastaanottolla – kenen?
   ____________________________________________________________          _________ kertaa

Käynneistä kertyneet omat kustannukset yhteensä (ilman matkakuluja) _________€

Matkakulut: _________km _________€
Selkätutkimus Palvelut ja kustannukset lomake

Potilasnumero ……………….

5. RÖNTGEN- JA LABORATORIOTUTKIMUKSET
Mitä röntgen-, laboratorio- yms. tutkimuksia sinulle on tehty terveysasemilla, yksityisillä lääkäriasemilla tai sairaalan poliklinikoilla edellisen selkätutkimuskäynnin jälkeen?

____________________________________________________________________________
____________________________________________________________________________

Tutkimuksista kertyneet omat kustannukset yhteensä (ilman matkakuluja) ___________€
Matkakulut: ___________km ___________€

6. SAIRAALAN VUODEOSASTOHOITO
Sairaalan nimi _______________________________________________________
Hoitopäiviä edellisen selkätutkimuskäynnin jälkeen on ollut yhteensä ___________ kpl
Sairaalalahoidosta kertyneet kustannukset yhteensä ___________€
(Omvastuuosuus ilman matkakuluja ja Kelan korvausosuus vähennettynä)
Matkakulut: ___________km ___________€

7. KUNTOUTUSLAITOSHOITO
Kuntoutuslaitoksen nimi _______________________________________________________
Hoitopäiviä edellisen selkätutkimuskäynnin jälkeen on ollut yhteensä ___________ kpl
Kuntoutuslaitoshoidosta kertyneet kustannukset yhteensä ___________€
(Omvastuuosuus ilman matkakuluja ja Kelan korvausosuus vähennettynä)
Matkakulut: ___________km ___________€

8. LÄÄKKEET
Mitä lääkkeitä olet käyttänyt selkäkivun takia edellisen selkätutkimuskäynnin jälkeen?
Merkitse lääkkeiden nimi, vahvuus, päiväannos sekä käyttöpäivien lukumäärä mahdollisimman tarkasti.

1. Lääke ________________________________________________________________
2. Lääke ________________________________________________________________
3. Lääke ________________________________________________________________

Paljonko nämä lääkkeet ovat yhteensä sinulle maksaneet? _________________________ €
Selkätutkimus  Palvelut ja kustannukset lomake

Potilasnumero …………………

9. MUUT TUTKIMUKSET JA HOIDOT, JOITA EI OLE SISÄLLYTETTY EDELLISIIN LÄÄKÄRI- TAI SAIRAALAKÄYNTIEIHIN
(Sisältäen myös esim. hieronta-, aromaterapia-, akupunktio-, vyöhyketerapia-, kiropraktiset-, ja erilaiset vaihtoehtoishoidot)

Tutkimukset / Hoito  Paikka ja maksaja (esim. työnantaja tai itse)
(edellisen selkätutkimuskäynnin jälkeen)

1.___________________________  _______________________________________________
2.___________________________  _______________________________________________
3.___________________________  _______________________________________________
4.___________________________  _______________________________________________
5.___________________________  _______________________________________________

Käynneistä aiheutuneet omat kustannukset yhteensä (ilman matkakuluja) ______________ €

Matkakulut:         _________km                  ___________ €

10. Kuinka monta tuntia olet saanut käyttää työaikaasi hoitoihin ja tutkimuksiin edellisen selkätutkimuskäynnin jälkeen?

        __________ tuntia

11. ULKOPUOLINEN APU

Oletko saanut apua nykyisen selkäkipusi vuoksi edellisen selkätutkimuskäynnin jälkeen?

Jos olet, arvioi kuinka monta tuntia olet saanut apua

A.  Omaiselta, ystävältä tai naapurilta  __________tuntia
B.  Kunnalliselta työntekijältä (esim. kotiapu)  __________tuntia
C.  Yksityiseltä (maksulliselta) avustajalta  __________tuntia

Kuinka paljon nämä palvelut ovat Sinulle maksaneet?  _________________ €

Joutuivatko Sinua avustaneet omaiset, ystävät tai naapurit olemaan pois ansiotööstään?
Mikäli joutuivat, merkitse, kuinka monta tuntia tai päivää yhteensä he olivat pois työstään:
        _________________ tuntia / päivää  (alleviivaa oikea määritelmä)
12. MUUT KUSTANNUKSET

(Kirjaa tähän muut mahdolliset selkäkivustasi aiheutuneet kustannukset edellisen
selkätutkimuskäynnin jälkeen, esim. apuvälineet, tukiliivit ym.)

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<th>Mikä</th>
<th>Kustannukset / €</th>
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Matkakulut:  

__________km  

__________€
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