Pregnancy-related pelvic girdle pain

Prognosis, risk factors, consequences, and chiropractic management

by

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Scientific environment

The work presented in this thesis was carried out in association with the Norwegian Centre for Movement Disorders and Department of Obstetrics and Gynecology at Stavanger University Hospital, Stavanger, Norway.

The Research Department at Stavanger University Hospital has organized the necessary office facilities at Forskningens Hus and Forskertua.

I was enrolled as a PhD student in 2014 and was affiliated with the Faculty of Social Sciences up to 2018, and since then with the Faculty of Health Sciences, Department of Caring and Ethics at the University of Stavanger.

My supervisor has been Inger Økland, MD PhD, obstetrician, Associate Professor II at the University of Stavanger, and Head of research at Stavanger University Hospital. My co-supervisor has been Ingvild Dalen, PhD, biostatistician, Associate Professor II at the University of Stavanger, and Head of the section of Biostatistics, Department of Research, Stavanger University Hospital.

Jan Petter Larsen, MD PhD, neurologist and Professor at the University of Stavanger, and chiropractors Knut Andersen, PhD, Inger Kjærmann King, MSc, Stefan Malmqvist, MSc, have been part of the pelvic girdle pain research group. Stefan Malmqvist is the first author of three other papers based on the data sample and is currently working on his thesis.

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Summary

Background

Pelvic girdle pain (PGP) is a common musculoskeletal disorder during pregnancy; affected women experience various degrees of pain, disability, and reduced quality of life. In addition, PGP is a frequent cause of sick leave during pregnancy. Although most women recover from PGP after delivery, some women struggle with persistent PGP for months and years. There is still limited knowledge about etiology, occurrence, risk factors, consequences, and treatment options for PGP during pregnancy and after delivery.

Objectives

The overall aim of this thesis was to provide more knowledge about the recovery and persistence of PGP, including risk factors and consequences of persistent PGP. Furthermore, to investigate the effect of chiropractic management for women with PGP during pregnancy and after delivery.

Methods

The four papers in this thesis are based on two separate data collections at Stavanger University Hospital. Paper I and II originate from a retrospective cohort study conducted in 2009.

In Paper I, women with persistent PGP 3–6 months after delivery (n=330), underwent a clinical examination and filled in questionnaires to examine the frequency of persistent PGP, its influence on the women´s daily life, and potential risk factors for persistent PGP.

The pilot study, Paper II, aimed to investigate the feasibility of conducting a randomized clinical trial for women with persistent dominating one-sided PGP. The study included 11 women. Six women

received individualized rehabilitation and chiropractic treatment, and five women were offered individualized rehabilitation alone.

Papers III and IV originate from a prospective longitudinal cohort study carried out in 2010. Inclusions took place at the second-trimester routine ultrasound examination. All eligible women (n=503) filled in questionnaires and answered a weekly SMS question during pregnancy and up to six weeks after delivery. Women with pain in the pelvic area underwent a clinical examination.

Those who were diagnosed with dominating one-sided PGP during pregnancy were included in a randomized clinical trial to investigate the effect of chiropractic treatment compared to conventional health care, presented in Paper III.

In Paper IV, we included women that reported PGP during pregnancy and met for a clinical examination six weeks after delivery. We investigated the subjective recovery from pregnancy-related PGP and detected possible risk factors for a poor recovery. The SMS replies from the final 10 weeks of pregnancy and first six weeks after delivery were used to analyze the proportions of women with substantial recovery and women with either no, transitory or incomplete recovery, based on individual graphs of weekly number of bothersome days due to PGP.

Results

In Paper I, we found that 16% of women reporting pelvic pain (PP) during pregnancy were diagnosed with persistent PGP 3–6 months after delivery. Women with persistent PGP reported mild and moderate pain, and minor disability, but a reduced quality of life. Risk factors for persistent PGP were age ≥ 30 years, moderate or high disability during pregnancy, and combined PP and low back pain (LBP) during pregnancy.

In Paper II, the small number of women with persistent dominating one-sided PGP, and the additional drop-outs, resulted in a low number of

women in the clinical trial. Both groups reported improvement in disability and pain after 20 weeks of intervention.

The randomized controlled trial (RCT) study (Paper III) showed no statistically significant differences in sick leave, pain intensity of PGP, disability, and health related quality of life between the treatment group and the control group during pregnancy or after delivery.

In Paper IV, four out of five women experienced a substantial recovery from PGP within six weeks after delivery. Evident risk factors for a poor recovery were multiparity, PGP the year before pregnancy, and a high pain intensity of PGP during pregnancy.

Conclusions

Most women recovered from pregnancy-related PGP after delivery. However, six weeks after delivery, one out of five women reported persisting PGP, and 3–6 months after delivery, one of out of six women were diagnosed with persistent PGP after a clinical examination. Several risk factors for a poor recovery were found. Women with persistent PGP after delivery reported mild and moderate pain and a reduced quality of life, but seemed to cope fairly well with their daily activities. The results from the clinical trials were inconclusive.

List of papers

This thesis is based on the following papers and they will be referred to by their Roman numerals.

I Gausel AM, Kjærmann I, Malmqvist S, Dalen I, Larsen JP, Økland I. Pelvic girdle pain 3–6 months after delivery in an unselected cohort of Norwegian women. Eur Spine J. 2016; 25(6):1953–9.

II Gausel AM, Kjærmann I, Malmqvist S, Andersen K, Dalen I, Larsen JP, Økland I. Adding chiropractic treatment to individual rehabilitation for persistent pelvic girdle pain 3 to 6 months after delivery: a pilot randomized trial. J Manipulative Physiol Ther. 2019;42(8):601–607.

III Gausel AM, Kjærmann I, Malmqvist S, Andersen K, Dalen I, Larsen JP, Økland I. Chiropractic management of dominating one-sided pelvic girdle pain in pregnant women; a randomized controlled trial. BMC Pregnancy Childbirth. 2017;17(1):331.

IV Gausel AM, Kjærmann I, Malmqvist S, Andersen K, Dalen I, Larsen JP, Økland I. Subjective recovery from pregnancy-related pelvic girdle pain the first 6 weeks after delivery: a prospective longitudinal cohort study. Eur Spine J. 2020; 29(3):556–563.

Abbreviations

ASLR	Active straight leg raise
B.C.	Before Christ
CI	Confidence interval
EDD	Estimated date of delivery
EQ-5D	EuroQol 5-dimension
LBP	Low back pain
ODI	Oswestry disability index
P4	Posterior pelvic pain provocation
PGP	Pelvic girdle pain
PGQ	Pelvic girdle questionnaire
PP	Pelvic pain
NRS	Numeric rating scale
RCT	Randomized controlled trial
RMDQ	Roland-Morris disability questionnaire
SIJ	Sacroiliac joint
SMS	Short message service
SMT	Spinal manipulative therapy
SPSS	Statistical Package for the Social Sciences

Terminology

The author group has had several discussions regarding terminology, and throughout the project opinions have varied on how to best refer to **pelvic girdle pain** (PGP) in accordance with the proposed, "golden standard" definition (1). Existing literature uses various terms for pregnancy-related pain in the lumbopelvic area (Figure 1), and the response from peer-reviewers have also been conflicting. The European guidelines for the diagnosis and treatment of PGP emphasize in the proposed definition of PGP that a lumbar cause of pain should be excluded and that the pain or functional disturbance must be reproduced by specific clinical tests (1). Because of this definition, we have used the term **pelvic pain** (PP) when the pain was self-reported (Papers I–III). However, as the guidelines point out, the term PP also refers to visceral pain in gynecological and/or urological disorders. Therefore, the author group decided to use the term PGP, regardless of PGP being self-reported and without a clinical examination in the last paper (Paper IV). This explains why the terminology in the four papers are inconsistent.

In this thesis, unless otherwise described in the studies referred to, the term PGP will be used regardless of a clinical examination, and **lumbopelvic pain** will be used when women report **low back pain** (LBP) in addition to PGP.

Figure 1 – Different terms used in literature to describe pregnancy-related pain in the lumbopelvic area (2, 3).

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1 Background

The pelvic girdle pain (PGP) project group in Stavanger was established in 2008, and chiropractors Stefan Malmqvist and Inger Kjærmann conducted two separate data collections at Stavanger University Hospital in 2009 and 2010. The 2009 study was a retrospective study, with a follow-up 3–6 months after delivery, whereas the study in 2010 was a prospective study from 18 weeks of pregnancy until six weeks after delivery. Due to various reasons, the project was delayed, and I was introduced to it in 2013. At that point, I had worked as a chiropractor in private practice for nearly 8 years and had met many women with PGP during and after pregnancy. I was still puzzled by the condition and was thankful to join the research group in the autumn of 2013.

In this thesis, the introductory section will refer to and discuss literature published before the submission of my first paper in December 2014. This represents the "state of the art" when I started my research. More recent studies will be addressed in the discussion section. Although this approach is disputed, I believe an introduction referring mostly to recent research would not reflect why the specific research questions were chosen (4).

2 Introduction

The experience of a new life developing in one´s body is amazing, and pregnancy is a time for big emotions and expectations. However, for many women, discomfort and pain overshadow the joy of the antenatal period. About half of all women experience pain in the lumbopelvic area during pregnancy, causing disability and reduced quality of life (1-3, 5). In addition, PGP during pregnancy is a major cause of sick leave (6-8). Some women also struggle with persistent PGP for months and years after giving birth, and many of these are excluded from normal work life due to pain and disability (9-12). Consequently, some women eventually receive disability pension (information on request from the Norwegian Labour and Welfare Administration). Hence, PGP has a major impact on many pregnant women's personal and family life and is a considerable cost to society both during and after pregnancy.

Many health care professionals offer rehabilitative therapy for PGP during and after pregnancy. Some studies have been conducted that investigate the effect of exercises for lumbopelvic pain during pregnancy and after delivery (13-19). However, many studies are not randomized controlled trials (RCTs) and have a low methodological quality, and in addition the studies are not homogeneous regarding to type and duration of interventions. Nevertheless, the European guidelines for the diagnosis and treatment of PGP recommend exercises during pregnancy, and individualized treatment programs focusing on specific stabilizing exercises after delivery (1). Manual therapy is also a common treatment modality (1, 20-22) for PGP. However, the evidence for treatment effect is still limited, and the European guidelines for the diagnosis and treatment of PGP conclude that there is a need for more studies on the effect of manipulative treatment for PGP (1).

More knowledge about the recovery and persistence of PGP, including risk factors and consequences of persistent PGP, is needed to identify

women at risk for chronicity. Moreover, it is essential that the treatment offered to women with PGP during pregnancy and after delivery is safe and effective.

2.1 Anatomy of the pelvic girdle

The pelvic girdle consists of the two pelvic bones (ilium), the sacrum and the coccyx. Together they form a girdle, also described as a closed ring, which serves as a platform with three large levers acting on it – the spine and the two legs (23). In front, the two pelvic bones connect in a unique joint consisting of a fibrocartilaginous disc, sandwiched between the articular surface of the two bones, the symphysis (24). Although the symphysis resists shearing and compressive forces it is capable of a small amount of movement, up to 2 mm shift and 1 degree of rotation (24).

In the posterior aspect of the pelvic ring, the pelvic bones create joints with the sacrum, the sacroiliac joints (SIJs). A synarthrosis joint is immobile and a diarthrosis joint is a joint with free movement, and the SIJs have elements of both. Therefore, the SIJs is also described a

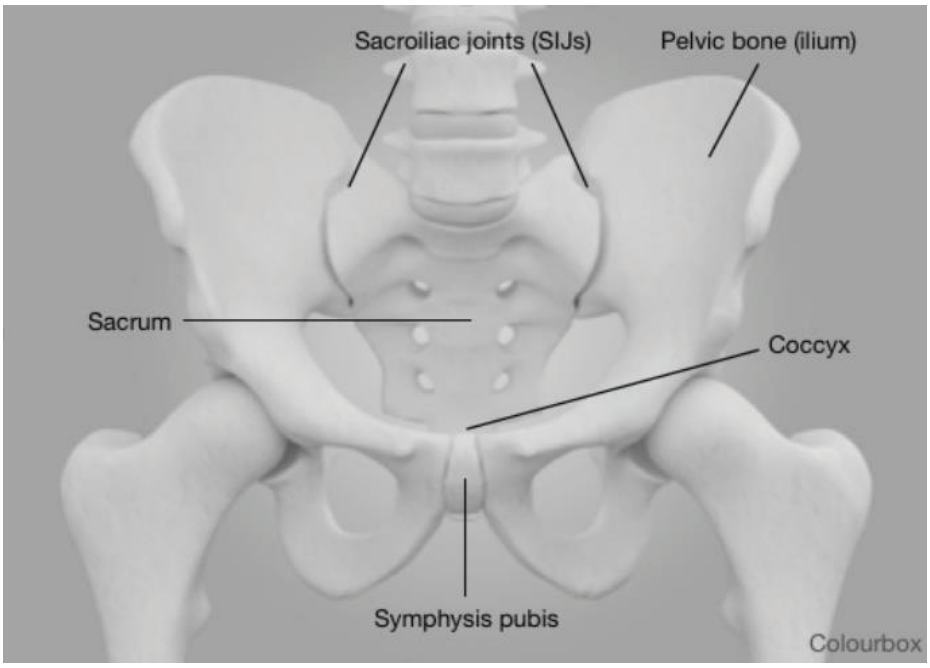


Figure 2 – Anatomy of the pelvic ring.

a amphiarthrosis joint indicating a slightly movable articulation (23). The potential movement in the SIJs has been thoroughly discussed, and there is evidence for a limited motion, average 2 degrees in all the three planes of the sacroiliac joint (23).

The bony structure of the SIJs with a dorso-cranial wedging of the sacrum into the ilia, the ridges and grooves of the articular surface, and the strong ligaments, all contribute to stability via a form closure. In addition, the stability of the joints are a result of force closure, which is a caused by tensing the ligaments, fasciae and muscles (23). Figure 2 shows an illustration of the anatomy of the pelvic ring.

2.2 Definition of PGP

Many different theories and definitions have been presented to explain and describe pregnancy-related PGP. Even today we cannot fully explain

the etiology for PGP. This is also reflected in the number of terms used to describe the condition. Table 1 presents an overview of different terms used to describe pregnancy-related PGP (2, 3, 5, 25).

Table 1 – Different terms used in literature to describe pregnancy-related PGP.

Pelvic arthropathy
Osteitis pubis
Pelvic insufficiency
Pelvic relaxation pain
Pelvic instability
Pelvic girdle pain
Pelvic girdle relaxation
Pelvic pain
Posterior pelvic pain
Low back pain
Lumbopelvic pain
Symphysis pain
Symphysis pubis dysfunction
Pregnancy-related pelvic girdle pain
Relaxation of the pelvic joints in pregnancy
Pelvic osteo-arthropathy
Insufficientia pelvis gravidarum et puerperarum
Spinal and pelvic insufficiency
Symptom-giving pelvic girdle relaxation
Pelvic pain and pelvic joint instability
Peripartum pelvic pain
Backache during pregnancy
Back pain postpartum
Pregnancy-related pain in the pelvis

In 2008, the working group behind the European guidelines for the diagnosis and treatment of pelvic girdle pain proposed a definition for pelvic musculoskeletal pain (1):

> *Pelvic girdle pain generally arises in relation to pregnancy, trauma, arthritis, and osteoarthritis. Pain is experienced between the posterior iliac crest and the gluteal fold, particularly in the*

> *vicinity of the sacroiliac joint (SIJ). The pain may radiate in the posterior thigh and can also occur in conjunction with/or separately in the symphysis. The endurance capacity for standing, walking, and sitting is diminished. The diagnosis of PGP can be reached after the exclusion of lumbar causes. The pain or functional disturbances in relation to PGP must be reproducible by specific clinical tests.*

This definition excludes gynecological and urological disorders and identifies PGP as a pure musculoskeletal disorder. The localization of PGP is limited to the proximity of the SIJs and symphysis and not the lower back. For affected women, but also for the clinicians, the differentiation between PGP and low back pain (LBP) can be difficult, and many women suffer from both conditions simultaneously (5). The recommended clinical tests are pain provocation tests for the SIJs and symphysis, in addition to being functional tests of the pelvic girdle (1). Many studies are restrained from using this strict definition for PGP because they lack a clinical examination. Therefore, both before and after this definition was introduced, many researchers have used the terms pelvic pain (PP) and lumbopelvic pain (26-30), as discussed in the Terminology paragraph, page Xiii.

Lumbopelvic pain includes both PGP and LBP. A proposed definition of LBP is: “Low back pain is pain and discomfort, localized below the costal margin and above the inferior gluteal folds, with or without leg pain” (31, 32).

The subgrouping of PGP was first presented in the study by Albert et al. (33). They classified affected women into five subgroups depending on the localization of the pain and clinical tests (33). Because research has shown that different subgroups of PGP have different prognoses (12), paying attention to subgroups of PGP may contribute to a better understanding of PGP. In addition, a strict use of the PGP definition will make it easier to compare and analyze research in the field.

2.3 History of PGP

In a publication on the historical perspective on pregnancy-related LBP and/or PGP, it is shown that PGP in pregnancy was already known and recognized centuries ago (25). The researchers refer to papers describing how Hippocrates (ca. 400 B.C.) described symphysis pubis dysfunction in relation to pregnancy (25, 34). Hippocrates`s theory was that the widening of the symphysis pubis only occurred during the first parturition and remained widened for later childbirths (25, 34). Following Hippocrates, several medical professionals have discussed the physiology associated with the relaxation of the pelvis that women encounter during pregnancy. In 1870, Snelling described that the symptoms could be explained by relaxation, and described it as following (35):

> *The affection appears to consist of a relaxation of the pelvic articulations, becoming apparent suddenly after parturition, or gradually during pregnancy; and permitting a degree of mobility of the pelvic bones which effectually hinders locomotion, and gives rise to the most peculiar, distressing and alarming sensation.*

Several cases of pelvic syndrome in connection with pregnancy and delivery were described, and in addition to bed rest, the use of a pelvic support belt was a common treatment strategy (35).

Later, the hormone relaxin was recognized to relax ligaments during pregnancy and the hypothesis was that the pelvic joints undergo normal characteristic changes during pregnancy (36). The main focus was, however, still on the symphysis, and not the SIJs (34, 36). In the beginning of the twentieth century, estimates on the frequency of PGP were first investigated, and a Norwegian study from 1929 revealed that painful relaxation of the symphysis and SIJs was present in 17% at the end of pregnancy (37).

In 1962, Walde described the differences between PGP and LBP during pregnancy (38). Based on several studies, including radiological investigations, he concluded that women with long-lasting pain after delivery had degenerative disc lesions and sclerotic changes in the symphysis and SIJs, provoked by pregnancy (38). From the 1970s, the research included more subjective symptoms, questionnaires, pain drawings, clinical testing, and X-rays (25, 39). The researchers had no consensus on terminology; however, the interest and awareness of the possible impact PGP has on quality of life and the costs for society have been investigated since the 1980s (2, 25). In the 1990s, several papers were published on the role of the hormone relaxin in relation to PGP (40-42). Although showing conflicting results, the majority of the studies found no association between serum levels of relaxin and PGP. Since the 1990s, researchers more frequently conducted prospective follow-up studies to investigate the incidence of PGP during pregnancy, prognosis and related risk factors (12, 43-48).

In summary, the literature describes how women have always had discomfort and pain in the pelvic girdle in relation to pregnancy, but the etiology remains unknown.

2.4 Recent PGP research

This section reflects the most relevant research conducted before the beginning of my PhD project.

Modern PGP research focuses on epidemiology, etiology, consequences, and strategies for prevention and treatment of PGP during pregnancy and after delivery. Several Nordic researchers have contributed substantially to the field and parts of the research have been PhD projects. Table 2 presents an overview of Norwegian PhD projects where PGP was a central part of the project.

Table 2 – Overview of Norwegian PhD projects on PGP.

Name	**Year of public defense**	**Title of the thesis**
Britt Stuge	2005	Physical therapy for pregnancy-related pelvic girdle pain. Underlying principles and effects of treatment
Hilde Stendal Robinson	2010	Pelvic girdle pain and disability during and after pregnancy. A cohort study
Elisabeth K. Bjelland	2012	Pregnancy-related pelvic girdle pain: reproductive risk factors and prognosis
Eva Haukeland Fredriksen	2012	Pregnant: Healthy or sick? "Normal pregnancy complaints" and eligibility to protection
Thomas Johan Kibsgård	2014	Radiostereometric analysis of sacroiliac joint movement and outcomes of pelvic joint fusion

One of the most experienced PGP researchers is Britt Stuge. Her PhD project focused on physical therapy and stabilizing exercises for PGP (17, 18, 27). In addition, she is the first author of the Pelvic Girdle Questionnaire (49).

In the late 1990s, a large clinical study was undertaken at two different hospitals in Denmark. The study identified four different subgroups of PGP in women with different incidence, clinical characteristics, pain patterns and prognosis (33). Identifying subgroups, in addition to predictors for PGP was also central in Swedish research (50).

A study from 2010 found home-based specific stabilizing exercises not to be more effective than a natural course for persistent PGP after delivery (51). However, this study lacked individual guidance and adaption. On the other hand, whether to treat or not to treat women with postpartum PGP with exercise has been investigated and the conclusion is that effective treatment may be achieved when exercises for the entire spinal musculature are included, individually guided, and adapted (52).

Factors related to PGP and disability during pregnancy were also investigated (53-55). One of the studies identified clinical risk factors for more severe PGP in late pregnancy (53). In addition, specific pain provocation tests, and a number of pain sites were found to be associated with pain intensity and to have the potential to identify women with a poor prognosis (54).

The Norwegian mother and child cohort study (1999–2008) was a population study of more than 100,000 women in pregnancy and after delivery and several papers originating from the large population study have also focused on PGP (56-61). One of the studies revealed that the risk of developing PGP increased with the number of previous deliveries and it was suggested that parity-related factors play a role in explaining PGP (57). In addition, no association was found when investigating pre-pregnancy hormonal contraception and the development of PGP during pregnancy (56).

In the Netherlands, researchers have conducted several studies on biomechanical aspects in relation to PGP, for example the mobility of pelvic joints and the role of the transverse abdominal muscle during the active straight leg raise (ASLR) test (16, 29, 62-67). The application of a pelvic belt was discovered to decrease the mobility of the sacroiliac joints (63). In a review paper, the researchers conclude that the increased motion of the pelvic joints is one of the factors that cause lumbopelvic pain, and that this justifies the treatment with measures to reduce the increased motion (29).

Radiostereometric measuring of the movement of the sacroiliac joints and the long-term outcome of surgical sacroiliac and symphysis joint fusion has also been investigated (68-71). In a prospective follow-up, seven out of eight patients experienced positive and significant results following SIJ fusion. However, surgical fusion of the SIJ was associated with complications such as infection and nerve damage (71).

Lately, and especially in Scandinavia, more attention has been given to the individual woman's experience of dealing with PGP, and several qualitative studies are presented (72-75). Pregnant women's expectations and experiences in relation to PGP has been explored through internet discussions and interviews (72, 73). Most likely, more qualitative research will add another dimension to the testing of hypotheses in quantitative studies.

Only a few researchers have so far addressed on current, recent research aspects when investigating musculoskeletal disorders, e.g. catastrophizing, fear-avoidance beliefs, and psychosocial factors (28, 76).

Several review papers, guidelines and updates have been published, contributing to an overview of current research, and these are useful for both researchers and clinicians (1-3, 25, 27, 43, 77).

2.5 Prevalence of PGP

2.5.1 Prevalence of PGP during pregnancy

The exact prevalence of PGP is still uncertain. Researchers have estimated the number of women with PP and LBP in pregnancy to range from 4 to 76% (1). This variance is caused by the different methodological approaches and various definitions of PP, lumbopelvic pain and PGP. Some studies are retrospective and based on

questionnaires, while other are prospective studies including a clinical examination with specific clinical tests.

Although the many studies conducted on PGP in Scandinavia indicate a higher prevalence of PGP than in other countries over the world, the impression that PGP is more common in Scandinavia is probably incorrect. One study investigated whether perceived PP among pregnant women differed between affluent and poor societies, and found no geographical differences, irrespective of the socioeconomics of the countries (30). In addition, PGP is reported and investigated worldwide, reflecting the fact that this is not just a Scandinavian problem (78-82).

Perhaps the awareness of PGP in the Scandinavian countries is brought about by the advantageous social benefits. In Norway, full pay during sick leave and free physical therapy treatment (up to 2016) has been given to pregnant women when diagnosed with PGP (83). In addition, Norway has a high proportion of women in paid work, and many women are on sick leave due to PGP during pregnancy, making the condition a socioeconomic burden (8).

Overall, about half of all women have lumbopelvic pain during pregnancy and 20% of pregnant women are afflicted with PGP alone (1).

2.5.2 Prevalence of PGP after delivery

Most women recover spontaneously from PGP after delivery, but for some the PGP is persistent. In a review study of 18 papers on the postpartum prevalence of PP and PP/LBP, the average prevalence of sustained pain was 25%, albeit with a large range from 0 to 67% (2). The variation indicates the need for more high quality studies on how many women struggle with persistent PGP after delivery. Scandinavian researchers have found that 8–20% of women suffering from pregnancy-related lumbopelvic pain during pregnancy still have symptoms two to three years after delivery (12, 84).

2.6 Etiology of PGP

The cause of PGP is thought to be multifactorial, and this is reflected in the many different theories presented over the years to explain the condition (1, 3). The female body undergoes both physiological and anatomical changes during pregnancy. The center of mass is gradually displaced anteriorly due to the enlarging gravid uterus and an increase in body mass of approximately 10–15kg (85, 86). The alteration in hormones during pregnancy is likely to cause ligamentous laxity (85). These normal changes cause an increase of the thoracic kyphosis, lumbar lordosis, and an anterior tilt of the pelvis (85, 86). In addition, the changes lead to increased tension in the posterior core muscles, along with stretching of the anterior abdominal core muscles and laxity of the anterior and posterior ligaments of the spine (85, 86). The joints of the pelvis become more flexible during pregnancy as the mother´s body prepares of for the delivery (86). In general, spinal and pelvic stability is reduced during pregnancy (85). After delivery, the uterus gradually returns to its normal size, and hormone levels quickly return to normal. Impairment in strength, tone, and endurance of the anterior abdominal and low back muscles may account for changes in posture after delivery (85).

In nonpregnant women, relaxin plays an integral role in the remodeling of multiple tissues of the musculoskeletal system (87), whereas in pregnant women it is found to remodel pelvic connective tissue and to inhibit uterine contractility (88). The hormone was long thought to be the cause of pelvic instability, and thus pain. A relationship between relaxin levels and scores of the ASLR test has been shown, but no associations with pain provocation tests and self- reported pain were discovered (89). One theory is that laxity of pelvic joints in pregnancy is compensated by mechanisms to improve force closure and reduce mechanical instability and friction in the joints (89). A systematic review investigating the relationship between pregnancy-related PGP and relaxin levels during pregnancy could not conclude on a positive association (90-92).

Progesterone and estrogen hormone levels also change significantly during pregnancy and in the postpartum period (93). These hormones also affect the musculoskeletal system through modulation of bone, cartilage, ligaments and nervous system (93). However, a possible association with PGP has hardly been investigated (94)

A study on the characteristic gait during pregnancy found increased rotational amplitudes of the pelvis, the lumbar segment, and the thorax in women with PGP (95). Also, a systematic review on the mobility of the pelvic joints revealed that the motion of the pelvic girdle joints was larger in women with pregnancy-related lumbopelvic pain, and suggested that the findings support the idea that enlarged motion is one of the factors that cause pain (29). On the other hand, the movement in the sacroiliac joints during a single-leg stance is small and almost undetectable by precise radiostereometric analysis in women with long-lasting and severe PGP (69), in contrast to the theory that instability is the main cause of pain.

Another theory is based on the findings that most patients with PGP have normal results on imaging techniques (CT, MRI, ultrasound, scintigraphy) (96). Because imaging is normal, it is hypothesized that PGP is not derived from the skeleton or from major soft-tissue changes, such as edema and inflammation, but more likely to originate from the large, stabilizing muscles around the pelvis (96). This is somewhat in line with the theory that optimal stability is provided by form closure, as a result of joint anatomy, and force closure, which are external compressive forces acting on the joint by the muscles, ligaments and thoracolumbar fascia that support the pelvis (91).

Psychosocial factors have the potential to both increase or decrease pain, but have only been investigated to a limited extent in connection with PGP (97). However, some studies find various psychosocial factors to be risk factors for lumbopelvic pain (43, 44, 98, 99). Bad work conditions and poor work satisfaction have been linked to pregnancy-related

lumbopelvic pain (43, 44, 98, 99). Daily stress was found to be a risk factor for pregnancy-related lumbopelvic pain (99), and women with postpartum depressive symptoms were three times more likely to report lumbopelvic pain compared with those without (100). Reduced force closure has been associated with cognitive impairment, such as faulty beliefs, elevated anxiety levels and passive coping strategies (97). Catastrophizing and fear-avoidance beliefs in connection with lumbopelvic pain during and after pregnancy have also been investigated (28, 76). In addition, exaggerated negative thoughts about pain experiences and fear-avoidance beliefs in relation to pregnancy seemed to be associated with lumbopelvic pain and postpartum physical ability (76).

2.7 Clinical examination

According to the European guidelines for the diagnosis and treatment of pelvic girdle pain, the definition of PGP can only be reached after a lumbar cause of pain has been excluded (1). In addition, the pain or functional disturbances in relation to PGP must be reproduced by specific tests (1). Clinical history and neurological and orthopedic examination must therefore be performed in order to rule out red flags and lumbar causes of pain (31). The examination should include the ASLR test, followed by a neurological examination of the lower extremities, including muscle and reflex testing, sensation, and nerve tension tests (101). In addition, in order to exclude hip problems as a cause of positive testing, a rotation range-of-motion test should be performed (101).

Despite the physiological and biomechanical changes during pregnancy, the prevalence of disc degeneration and sciatica do not appear to be increased in pregnancy (102). Even so, bulging disks and herniation are not uncommon in asymptomatic women of childbearing age and this should be kept in mind when examining pregnant women (103).

The European guidelines for the diagnosis and treatment of pelvic pain present several pain provocations tests of the SIJs and the symphysis in addition to a functional test of the pelvic girdle (1). In addition, it has been suggested to include Gaenslen test as a pelvic pain provocation test in a standardized classification system for lumbopelvic pain in pregnancy (101). In order for a provocation test to be considered positive, it has to reproduce the woman's recognizable pain regarding location and quality (1, 101).

2.8 Risk factors

2.8.1 Risk factors for the development of PGP during pregnancy

In order to develop prevention strategies for PGP, it is necessary to investigate risk factors. Knowledge of evident risk factors may also contribute to understanding the of etiology of PGP. The European guidelines for the diagnosis and treatment of PGP include an overview of current research on risk factors for PGP in relation to pregnancy (1). In summary, a history of previous LBP and previous trauma to the pelvis are risk factors for PGP. The evidence is conflicting for multiparous women and those with manual work-load. In addition, the guidelines present factors not associated with PGP; these are contraceptive pills, time interval since last pregnancy, height, weight, smoking and age (1). Unfortunately, except for a few studies with a strict epidemiological design, many studies had insufficient design and inadequate statistical analyses. Furthermore, the wide variation in the definitions for PGP may contribute to conflicting results when investigating risk factors for development of PGP.

In addition to the traditional investigation of risk factors based on epidemiological and clinical information, in the last decade, researchers in the field of musculoskeletal disorders have in the last decades raised

awareness of psychosocial factors associated with the development of chronicity and poor treatment outcomes. These factors are recognized as yellow flags which in back pain research are found to be risk factors of developing long-term disability and poor treatment outcomes (104). Examples of yellow flags include unhelpful beliefs about pain, expectation of poor recovery, worry, fears, anxiety, avoidance of activities due to expectations of pain, and possible reinjury (104). The European guidelines for the diagnosis and treatment of PGP presents no research on yellow flags among PGP patients and state that "based on the limited knowledge, the impression is that yellow flags are less common among PGP patients than among LBP patients" (1). However, because PGP is considered a multifactorial condition and many of the recognized risk factors are conflicting, recognition and further studies on yellow flags and comorbidities are important.

2.8.2 Risk factors for persistent PGP

Risk factors for persistent PGP are even less investigated than risk factors for PGP during pregnancy and are also difficult to assess due to the inconsistent use of terminology. In traditional musculoskeletal research pain is described as chronic when lasting more than 12 weeks (105). In this project we do not know anything about chronicity and we decided to use the term persistent PGP for pain lasting more than six weeks after delivery.

Pain in all three pelvic joints late in pregnancy have been associated with a poor prognosis (12). Furthermore, the number of positive clinical provocation tests were associated with disability and pain intensity 12 weeks after delivery (54). In addition, pre-pregnancy LBP was significantly associated with disability 12 weeks after delivery (54). Having both LBP and PGP in pregnancy has also been associated with persistent PGP (11). The clinical test, ASLR and poor belief in improvement were predictors in another study for both disability and pain one year after delivery (106). Age has been suggested a risk factor

for persistent PGP (2, 10), including both younger age (48) and older age (10, 11). Knowledge about risk factors for persistent PGP is important to develop strategies for prevention of persistent PGP.

2.9 Consequences of PGP during and after pregnancy

Earlier studies have primarily focused on the prevalence and etiology of PGP, and there seems to be little research on consequences beyond pain and disability, up to the year 2000.

There is a vast variation in the PGP intensity that women report, from minor transitory to severe persistent pain (44). In addition to pain and disability, women with PGP report a reduced quality of life (107). In an interview study investigating women with PGP during pregnancy, it was reported that pain negatively affected the experience of being pregnant (75). Moreover, women with severe PGP symptoms reported the frequent use of crutches during pregnancy, and a poor sleep quality due to pain (108). A Norwegian study revealed that three out of four women had been on sick leave at some point during pregnancy, and that PGP together with fatigue, sleep problems and nausea were the largest contributors to sick leave measured as total weeks away from work (6).

Not many studies have looked into on the consequences of persistent PGP. A Swedish study showed that women with persistent PGP and lumbopelvic pain 14 months after delivery reported low self-rated health (9). In another study, women with persistent PGP reported feelings such as discouragement, isolation, and loneliness as part of a daily life with pain and limited physical activity (109). In Norway, approximately 40 women per year were granted disability pensions due to PGP in 2012–2014. In 2014, a total of 648 women received disability pensions with persistent PGP as the the primary or secondary diagnosis (numbers from the Norwegian Labour and Welfare Administration).

Hence, future research should investigate consequences of PGP in terms of persistent pain, disability, health-related quality of life, sick listing, and disability pension. We need more knowledge on how, and to what degree PGP afflicts women during and after pregnancy.

2.10 Chiropractic

The Norwegian Chiropractic Association was established in 1935, and the main reason for the establishment was to seek authorization of professional status (110). At that time, the government was working on a new "quack law" to preclude medical practice without professional education and authorization (111). An authorization of chiropractors was not achieved until 1988 (112). Already in 1974, however, the government determined that patients who were referred by medical doctors for chiropractic treatment could get a partial reimbursement from the national health care system (112). Since 2006, all authorized chiropractors are recognized as a part of the primary health care system in Norway (112). Their rights include the possibility to prescribe sick leave and to refer patients directly for radiological procedures or to other medical specialists for further assessment (111, 112)

At the end of 2018, the chiropractic profession in Norway consisted of approximately 900 individuals, and an average of 85% were members of the national association (113). For many years, the national association has been working to establish a chiropractic education in Norway. Undoubtedly, this would have improved both the academic profile and research activity. The chiropractic profession can still be considered a relatively young profession in Norway.

Chiropractic research in Norway was at a starting point in 2014 with only three completed PhD degrees. In the following years, three additional PhD degrees have been completed, and 10 chiropractic PhD students are currently engaged in ongoing PhD-projects.

The World Federation Of Chiropractic defines chiropractic as:

> *A health profession concerned with the diagnosis, treatment and prevention of mechanical disorders of the musculoskeletal system, and the effects of these disorders on the function of the nervous system and general health. There is an emphasis on manual treatments including spinal adjustment and other joint and soft-tissue manipulation. (114)*

The spinal manipulation of joints was for a long time the central aspect of chiropractic, and this included identifying restricted areas of movement in the spine and vertebrae out of alignment (115). However, a more recent survey reported that, in addition to spinal manipulation, soft tissue techniques, instruction, and advice on exercise were important modalities in clinical practice (116). Overall, the evidence for manipulative therapy for pregnancy-related PGP is emerging. A systematic review stated that the evidence for the use of spinal manipulative therapy (SMT) in pregnancy to reduce lumbopelvic pain was limited (20). The conclusion was however, that clinicians should consider SMT as a treatment option if no contraindications are present (20). Another systematic review, investigating chiropractic treatment of pregnancy-related LBP found that chiropractic care was associated with improved outcomes (21). However, the six included studies were of low-to-moderate quality and all studies lacked randomization and control groups (21). When considering the safety of manipulative treatment, a critical review of the literature revealed only a few reported cases of adverse events following SMT during pregnancy and the postpartum period (117). Although the authors emphasize that improved reporting of such events is required in the future, it may be that such injuries are relatively rare (117).

2.11 Exercises for prevention and treatment of PGP

It is uncertain whether exercises can prevent and treat PGP during pregnancy (5). A well-designed study did not find pelvic stabilizing exercises to decrease pain intensity or shorten the recovery period after delivery (14). Nevertheless, exercises have been shown to be beneficial in women with LBP during pregnancy (13, 118). It is hypothesized that this is because the transverse abdominal muscle cannot be trained during pregnancy (5).

After delivery, women have been found to benefit from specific pelvic girdle stabilizing exercises (18). However, a standardized program with regard to type and duration of exercises does not exist. The European guidelines for diagnosis and treatment of PGP recommend an individualized treatment program, aiming specifically at stabilizing exercises for control and stability, as part of a multifactorial treatment for persistent PGP after delivery (1).

3 Aims of the thesis

The overall aim of this thesis was to provide more knowledge about the recovery and persistency of pregnancy-related PGP including risk factors and consequences of persistent PGP, and to investigate the effect of chiropractic management for women with PGP during pregnancy and after delivery.

The specific aims of the papers were:

- To investigate the occurrence of persistent PGP, its influence on the women's daily life, and potential risk factors for persistent PGP (Paper I).
- To assess the feasibility of conducting a randomized controlled trial (RCT) examining the influence of adding chiropractic treatment to individual rehabilitation for women with persistent dominating one-sided PGP 3–6 months after delivery (Paper II).
- To evaluate the effect of chiropractic management for a subgroup of pregnant women with dominating one-sided PGP (Paper III).
- To assess the subjective recovery from pregnancy-related PGP during the first 6 weeks after delivery, and to detect possible risk factors for a poor recovery (Paper IV).

4 Methods

4.1 Study design

4.1.1 Retrospective cohort

This cohort study was conducted at the maternity ward at Stavanger University Hospital over the period from March to June 2009. All women giving birth at the hospital were asked to participate and to fill out a questionnaire within 24 hours after delivery. Midwives gave verbal and written information about the study. The inclusion criteria were a singleton delivery after 36 completed pregnancy weeks and a good competence in the Norwegian language.

4.1.2 Prospective longitudinal cohort

All women who had a routine ultrasound examination at around 18 weeks of pregnancy at Stavanger University Hospital were asked to participate in a prospective cohort study. Inclusion criteria were a low risk, singleton pregnancy and comprehension of the Norwegian language. The inclusion period was from mid-March to mid-June 2010.

Women willing to participate in the prospective cohort study were asked to fill out a questionnaire. In addition, women reporting pain in the pelvic area at 18 weeks of pregnancy were asked to come for a clinical examination.

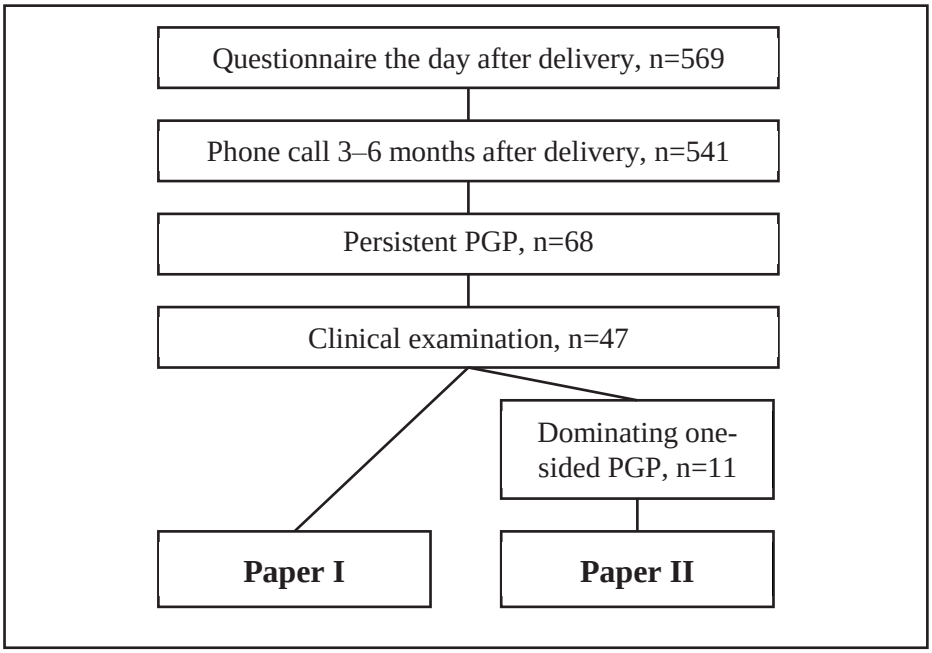
In the prospective cohort study, both symptomatic and asymptomatic women were asked to reply to a weekly short message service (SMS) question asking about the number of days with bothersome PGP the previous week. In addition, women who were asymptomatic at 18 weeks of pregnancy were asked to come for a clinical examination and to fill out questionnaires if they, according to the SMS survey, later in pregnancy reported more than four days of bothersome PP the last week.

Symptomatic women were asked to meet for examinations and to fill out questionnaires at 30 weeks of pregnancy and six weeks after delivery.

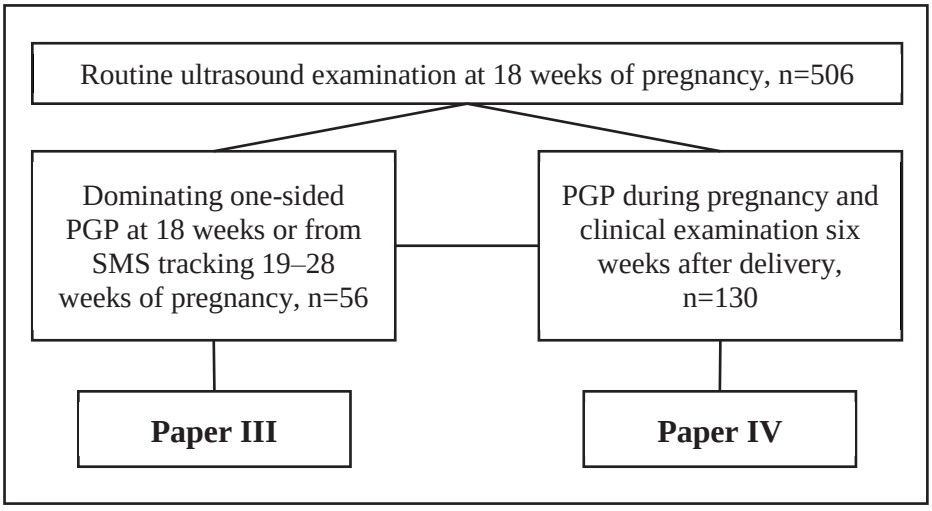
4.1.3 Overview of the PGP project

The papers in this thesis are based on the two data collections conducted at Stavanger University Hospital in 2009 and 2010. The retrospective cohort from 2009 had a follow-up 3–6 months after delivery, whereas the study in 2010 was a prospective study from 18 weeks of pregnancy until six weeks after delivery.

Retrospective cohort 2009



Prospective longitudinal cohort 2010



4.2 Variables

4.2.1 Questionnaires

The questionnaires were developed by the project group and were based on previous studies and the experience of the research team. They consisted of demographic features, manual work load, sick leave during pregnancy, previous pregnancies, PGP and LBP the year before pregnancy, exercising habits before and during pregannncy, and depression during pregnancy. The women were also asked to illustrate the location of pain, using a pain-drawing. Furthermore, a numeric rating scale (NRS) was used for retrospective reporting on monthly PGP intensity (119). In addition, the Norwegian versions of the Oswestry Disability Index (ODI) (120), EuroQol-5D (EQ-5D) (121), and Pelvic Girdle Questionnaire (PGQ) (Paper I) (49) were filled in. All questionnaires are included as appendices.

The NRS is a 11-point numerical pain rating scale (119). The patients were are asked to report pain ranging from zero (no pain) to 10 (worst imaginable pain) (119).

The ODI is a questionnaire to quantify disability due to LBP. It contains 10 items: pain, personal care, lifting, walking, sitting, standing, sleeping, sex life, social life, and traveling. Each item is to be answered with a value between 0 and 5, where 0 represents no disability and 5 represents severe disability. The score is then recalculated into a percentage (120). The Norwegian version has been investigated for reliability and construct validity, and was found acceptable for assessing functional status of Norwegian-speaking patients with LBP (122).

The EQ-5D investigates health-related quality of life. It consists of five items: mobility, self-care, activity level, pain/discomfort, and anxiety/depression. The version included in our studies contained three levels on each item. Each level ranged from no problem to extreme

problems. Calculation of the total score was based on the European set of preference weights (123). After recalculating, the possible values ranged from -7 to 100, where -7 represents extreme problems (worse than death) and 100 is the best health status and quality of life (121). The EuroQol Foundation permitted the use of the EQ-5D questionnaire.

The PGQ is a condition-specific measure for PGP and consists of 20 items related to activity: problems with standing, sitting, lifting, walking, carrying, etc. In addition, two items investigate pain: morning and evening, and another three items investigate disability: dressing ability, movements, and night sleep. Each item has four levels, from "not at all" to "a great extent". The scores are summarized and recalculated to percentages from 0–100, where 100 represents the greatest extent of disability (49). The PGQ has been found to have acceptably high reliability and validity in women with PGP both during pregnancy and after delivery (49).

In the retrospective cohort study the questionnaire handed out at the hospital, within 24 hours after delivery, obtained information on disability at its worst during pregnancy (ODI); health-related quality of life the week before delivery (EQ-5D; and monthly self-reported PP (NRS) during pregnancy. In the follow-up questionnaire 3–6 months after delivery, the women were asked to report PP (NRS) the last week. The ODI, EQ-5D and PGQ were answered according to how they were feeling at the moment.

In the prospective study, the questionnaires filled out at 18 and 30 weeks of pregnancy and six weeks after delivery collected information on present disability (ODI) and health-related quality of life (EQ-5D). Information about PP intensity was retrospective in monthly periods.

4.2.2 Clinical examinations

The clinical examination consisted of a gait analysis, a neurological and an orthopedic examination. The neurological examination consisted of a straight leg raise test to exclude lumbosacral nerve root irritation, and testing of the deep tendon reflexes and sensitivity of the lower extremities.

The orthopedic tests were those recommended by the European guidelines for the diagnosis and treatment of PGP (1) and consisted of:

Posterior pelvic pain provocation (P4) test: The woman lies supine with a 90-degree flexion at the hip and knee on the examined side. The examiner stabilizes the contralateral side of the pelvis over the superior anterior iliac spine. Light manual pressure is applied on the patient`s flexed knee along the longitudinal axis of the femur. The test is to be performed bilaterally (101).

FABER test: The woman lies supine. One leg is flexed, abducted, and externally rotated so that the heel rests on the opposite kneecap. If the test results in pain in the knee and femur or in the inguinal region, this indicates that the hip joint is affected. If pain is experienced in the pelvic joints, it is diagnostic for PGP (124).

Palpation of the symphysis: The woman lies supine and the examiner gently applies direct pressure on the symphyseal joint space to determine the presence of pain. If the palpation causes pain that persists for more than five seconds after removal of the examiner`s hand, it is recorded as pain. If the pain disappears within five seconds, it is recorded as tenderness (125).

Modified Trendelenburg test: The woman is standing with her back towards the examiner and, standing on one leg, flexes the other at 90 degree (hip and knee). The test is considered positive if the hip is

descending on the flexed side. If pain is experienced in the pelvic joints, the test is diagnostic for PGP (124).

Active straight leg raise (ASLR): The woman lies supine with straight legs and feet 20 cm apart. The test is performed after the instruction: "Try to raise your legs, one after another, above the couch for 20 cm without bending the knee". The woman is asked to score impairment on six-point scale: not difficult at all = 0; minimally difficult = 1; somewhat difficult = 2; fairly difficult =. 3; very difficult = 4; unable to do = 5. The scores of both sides are added together so that the summed score ranges from 0–10 (67).

As recommended by Gutke et al., the Gaenslen test was also performed.

Gaenslen test: The woman is lying supine near the edge of the table. One leg is hanging over the edge of the table and the hip and knee of the other leg is flexed towards the patient`s chest. The examiner applies pressure to the flexed knee towards the chest and counter pressure to the knee of the hanging leg towards the floor. The test is to be performed bilaterally (101).

In addition, a hip examination (range of motion) was performed in order to rule out hip problems as the cause of pain in the pelvic area.

Based on the clinical examination, women with a verified PGP diagnosis were subgrouped according to Albert et al. (33). The five groups were:

1. Pelvic girdle syndrome: daily pain in all three pelvic joints confirmed by objective findings.
2. Symphysiolysis: daily pain in the pubic symphysis only, confirmed by objective findings.
3. One-sided sacroiliac syndrome: daily pain from one SIJ alone, confirmed by objective findings.

4. Double-sided sacroiliac syndrome: daily pain from both SIJs, confirmed by objective findings.
5. Miscellaneous: daily pain from one or more pelvic joints, but inconsistent objective findings from the pelvic joints – for example, pain history from the pubic symphysis and objective findings from one SIJ.

4.2.3 SMS-tracking

All women included in the prospective longitudinal cohort, both symptomatic and asymptomatic, were sent questions via SMS (126). Every Sunday from 18 weeks of pregnancy and until six weeks after estimated date of delivery (EDD), the women were asked to reply to the SMS: "How many days during the last week has your pelvic pain been bothersome?". If there was no reply, the question was repeated 24 hours later. The question was to be answered with one single number between 0 and 7, and the response was automatically entered into a database where continuous information from each woman was saved.

4.3 Specific papers — methods

4.3.1 Paper I

A total of 1204 women were invited to participate in the retrospective study, with 994 women fulfilling the inclusion criteria and consenting to participate. However, 336 women did not return the questionnaire and 89 returned an empty or incomplete questionnaire. Hence, the study population in the retrospective cohort consisted of 569 women.

All the women who participated in the retrospective study were contacted by telephone 3–6 months after delivery. Nineteen women did not respond to repeated approaches and nine women declined participation, resulting in 541women, who were interviewed by

telephone. They were asked if they had persistent PP, and if their complaints affected daily activities such as walking, sitting, or standing (yes/no). The data were collected between September 2009 and January 2010.

Of the 541 women who were interviewed, 211 had not reported any PP during pregnancy and were not included in the analyses. Of the 330 women who reported PP during pregnancy, 68 women experienced persistent PP affecting their daily activities 3–6 months after delivery. They were invited to undergo a clinical examination and to fill out new questionnaires. Of these, 21 women did not want to be clinically examined and five of them also declined fill out the questionnaire. A flow chart of the recruitment process is shown in Figure 3.

The outcome was self-reported persistent PGP verified by clinical tests.

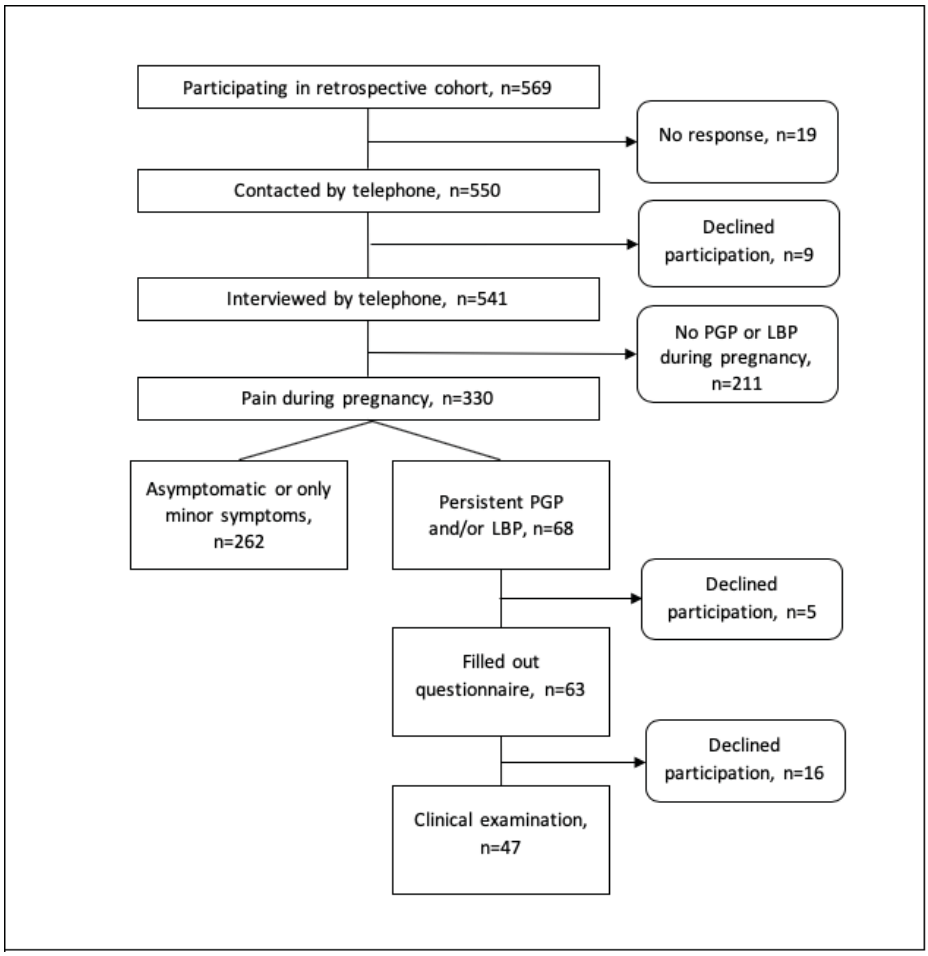


Figure 3 – Flow chart of the recruitment process (Paper I).

4.3.2 Paper II

Of the 47 women who underwent clinical examination 3–6 months after delivery, 13 women were diagnosed with dominating one-sided PGP. Two women declined participation, hence only 11 women were eligible to participate in the study.

In the intervention studies, we included women with dominating one-sided PGP. By isolating subgroups of PGP it might be possible to

differentiate the women who could favor from chiropractic treatment from those who will not. For example, previous studies shown that women with isolated symphysiolysis have a much better prognosis after delivery compared with women with pain in all three pelvic joints (12). A flow chart of the inclusion process into the pilot study is shown in Figure 4.

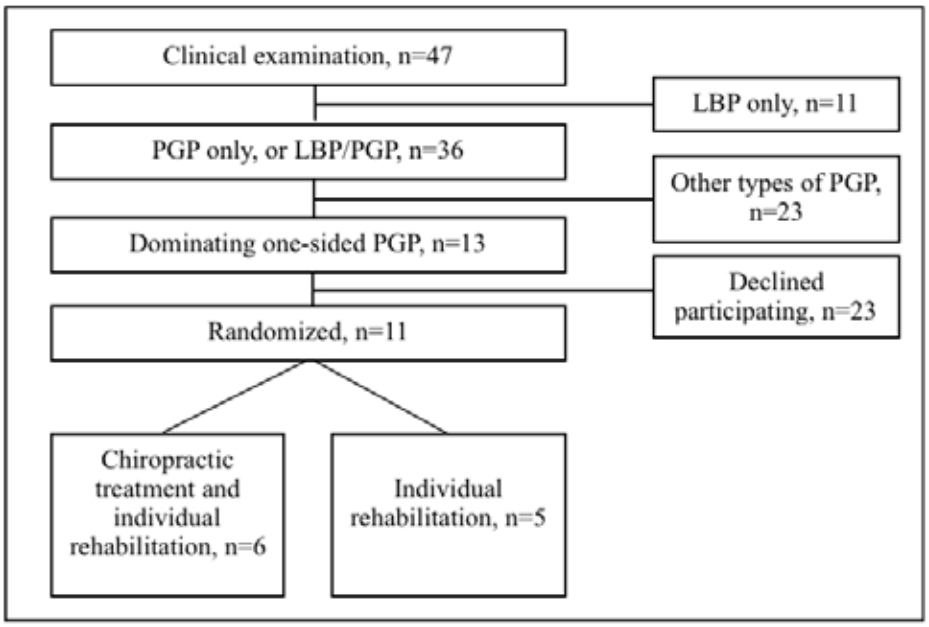


Figure 4 – Flow chart of the recruitment process into the pilot study.

Because of the low number of women with persistent dominating one-sided PGP, we initiated an additional recruitment process in 2014 in a private chiropractic practice in Stavanger. In addition, we advertised

the study to all health clinics and general medical practices in the region. However, the interest for the study was low and we did not manage to include additional women.

The 11 women included in the study were randomized into those receiving chiropractic treatment and individualized rehabilitation (six women), and those receiving individualized rehabilitation alone (five

women). The treatment was free of cost for the participants and the women did not get any remuneration, for example, for traveling expenses.

The randomization process was carried out using closed envelopes containing information about allocation. The envelope contained a randomly assigned number. Women with a number that ended with an even digit joined the treatment group, whereas women with an odd digit were enrolled in the individualized rehabilitation alone group. Four envelopes were prepared and handed out, before a new set of envelopes were distributed (not described in the paper). The examiner performing the clinical examination was blinded for group allocation, before and after the intervention. Additional blinding or placebo was not implemented.

The treatment group received chiropractic treatment in a private clinic in addition to individualized rehabilitation. The chiropractic treatment was chosen by the chiropractor to fit each woman individually and could involve manipulation, for example, as well as mobilization, soft tissue treatment and advice. The number of consultations were decided by the chiropractor but were limited to a maximum of 12 treatments during the 20 weeks of intervention. Women were asked at each consultation if they had experienced any side effects or negative reactions following the previous treatment.

All women were offered a maximum of 10 consultations for rehabilitative training sessions. In addition, the women were given a program with exercises to perform at home at least three times per week. The training program was standardized, but which exercises to do and the number of repetitions was decided by the chiropractor to fit each woman individually. If the women improved quickly, they were given additional exercises in addition to those in the standardized program. All women were also asked to keep track of the training program by keeping a training diary (Appendix 3).

After the 20 weeks intervention period, the women were asked to fill out questionnaires and undergo a clinical examination.

The primary outcome measure was disability measured by the ODI. The secondary outcome measures were the specific orthopedic tests ASLR and P4, pain intensity (NRS), activity limitations and symptoms of PGP (PGQ), and health-related quality of life (EQ-5D).

4.3.3 Paper III

Of the 506 women recruited for the prospective cohort study, 196 women reported pain in the pelvic area. After the clinical examination, 48 women were diagnosed with dominating one-sided PGP. An additional eight women were recruited from the SMS-tracking before pregnancy week 29 and diagnosed with dominating one-sided PGP. Hence, 56 women were included in the intervention study. They were randomized to 28 women in the treatment group, and 28 women in the control group. Three women in the treatment group did not attend the scheduled appointments, resulting in 25 women undergoing chiropractic treatment. In addition, seven women in the control group reported having chiropractic treatment as part of conventional care. Because of this, we conducted both intention-to-treat and per-protocol analyses. In the per-protocol analyses, women who were assigned to the treatment group but did not receive chiropractic treatment, and women in the control group seeking chiropractic treatment were excluded. Another five women in the control group reported that they underwent other types of treatment: one naprapathy, two manual therapy, two physiotherapy. These women were included in the analyses. A flow chart of the inclusion process is shown in Figure 5.

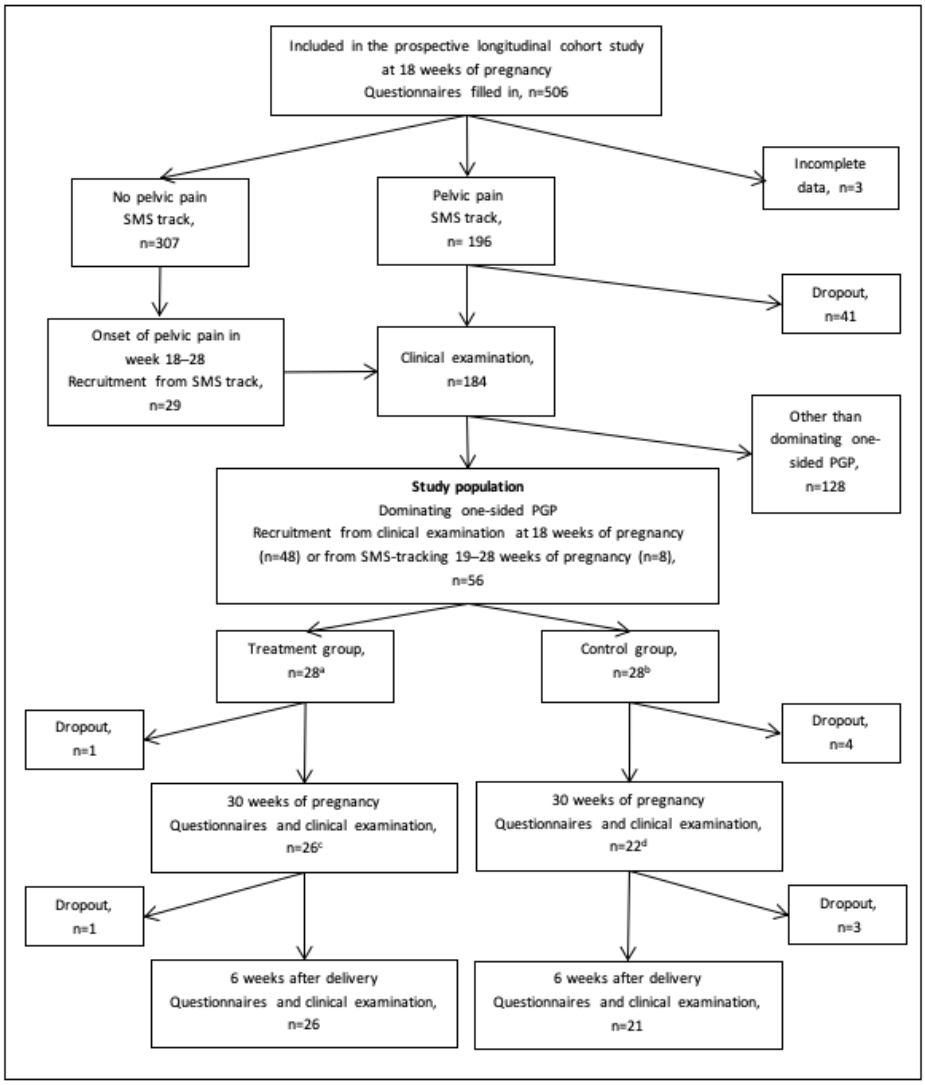


Figure 5 – Flow chart of the inclusion process into the RCT. a. Three women did not meet for scheduled appointment for treatment and did not respond to several attempts of contact. They were included in the intention-to-treat analysis, but excluded from the per-protocol subanalyses. b. Seven women underwent chiropractic treatment as conventional care. They were included in the control group in the intention-to-treat analyses, but excluded in the per-protocol subanalyses. c. One missing observation. The woman did not fill out questionnaires nor attend the clinical examination at 30 weeks of pregnancy, but returned to the study six weeks after delivery. d. Two missing observations. The women did not fill out questionnaires nor attend the clinical examination at 30 weeks of pregnancy, but returned to the study six weeks after delivery.

The randomization process was carried out using closed envelopes containing information about allocation. To implement block randomization, the examiner handed out a set of four envelopes, two envelopes for each group, and for the next four women a new set of envelopes were distributed. The envelope contained a randomly assigned number. Women with a number that ended with an even digit joined the treatment group, whereas women with an odd digit were enrolled in the individualized rehabilitation alone group. The examiner was blinded for group allocation.

The treatment group received manipulation, mobilization, soft tissue treatment, exercises and/or advice chosen by the chiropractor to fit each participant individually. The frequency and number of visits were determined by the chiropractor to fit each woman individually. At each session, the women were asked if they had experienced any negative reactions or adverse events following the previous treatment. The women in the control group were asked to return to conventional primary health care without any restrictions or recommendations. At the follow-ups at 30 weeks of pregnancy and six weeks after delivery, the women were asked in the questionnaire if they had sought any treatment, for example, chiropractic, physiotherapy or massage.

The primary outcome measure was new occurrence of full time and/or graded sick leave due to PGP and /or LBP in the periods of 19–30 weeks and 31–36 weeks of pregnancy. Because the women reported several different reasons for sick leave during the first trimester, and continued to do so, we excluded women who reported sick leave for any reason in pregnancy weeks 1–18.

4.3.4 Paper IV

Of the 506 women included in the prospective longitudinal cohort, a total of 130 women attended the clinical examination on around six weeks after the EDD. However, because information on date of the delivery was

missing for 10 women, we were not able to prepare graphs involving the specific final 10 weeks of pregnancy and the first weeks after delivery, resulting in 120 women eligible for further assessment. In the data analysis we assessed the SMS response from 10 randomly selected women. The pain patterns were visualized in graphs, including the final 10 weeks of pregnancy and the six first weeks after delivery. From a clinical perspective, a first proposal for grouping was agreed on. Three researchers from the project group then individually investigated and sorted the pain patterns into the different groups. Then, all the 120 different graphs were assessed by the three examiners together, resulting in a revised set of subgroups. Box 1 describes the different subgroups before and after delivery. A new assessment was done individually, blinded to the initial decisions. Thereafter, in a final meeting, a consensus for all 120 graphs was reached. The outcome in paper IV was substantial recovery first 6 six weeks after delivery as defined in Box 1.

Box 1 – Subroups before and after delivery.

Before delivery (10 weeks)	After delivery (6 weeks)
Severe PGP Persistent 6 or 7 days with bothersome PGP per week. Included in this group was also women with increasing number of days the last 3 weeks before delivery (average ≥5 days), and women with decreasing number of days the last 3 weeks before delivery. **Moderate PGP** Intermittent or moderate number of days with bothersome PGP per week, average ≥3 days. **No or mild PGP** Average <3 days of bothersome PGP per week before delivery. **Missing data** Not possible to classify due to completely or partially missing data.	**Substantial recovery** 0, 1 or 2 days with bothersome PGP per week within the first 6 weeks after delivery. If 0 was never reported, 1 or 2 days with bothersome PGP had to be registered twice within 6 weeks. **Poor recovery** *No or transitory recovery* No reduction or initial decrease in number of days, but before week 6 increasing number of days with bothersome PGP per week. *Incomplete recovery* Reduction in number of days with bothersome PGP per week, but not full recovery. **Missing data** Not possible to classify due to completely or partially missing data.

4.4 Statistical analysis

For all papers descriptive statistics were presented as means and standard deviations for continuous data, and as counts and percentages for categorical variables. A *p*-value of <0.05 was considered statistically significant. Unless otherwise stated, all statistical analyses were performed in the most recent IBM SPSS Statistics version available.

For Paper I, confidence intervals (CIs) for proportions were calculated by the Wilson procedure with continuity correction (127). Cut-offs for continuous variables were decided by clinical reasoning and consideration of group sizes, and cut-offs for ODI were set to be low (0–20), moderate (21–40), or high (>40) (120). Baseline data of women with and without persistent PGP were compared, using independent samples *t* tests (applying the Welch correction in situations with evident heteroscedasticity) for continuous data, and chi-squared tests for proportions. Variables with *p* values ≤ 0.25 were entered into a multiple logistic regression analysis with persistence of PGP (yes/no) as dependent variable. The best model was decided by a manual stepwise process using likelihood ratio test and finally, also the variables with higher *p* values in the univariable analyses were considered.

In Paper II, clinical outcomes were presented as mean change and confidence intervals. Due to the low number of participants, additional statistical analyses were not performed.

In Paper III, because of dropout and contamination of treatment, we conducted two types of analyses, an intention-to-treat analysis and a per-protocol analysis. The proportion of women reporting new occurrence of sick leave in the treatment and the control group were compared using chi square-tests. Relative risks with 95% CIs were estimated using the online statistical calculator at http://vassarstats.net/odds2x2.html. For the secondary outcomes, treatment effects were estimated using linear regression analysis, including the respective baseline measurements as

covariates. In the next instance, possible confounders that were not satisfactorily balanced at baseline, i.e., exercise before and during pregnancy and PP one year before pregnancy, were included in the models.

In Paper IV, proportions of women with substantial recovery and women with either no, transitory or incomplete recovery were presented as percentages and 95% CIs, estimated using the online statistical calculator at http:vassarstats.net. Women with substantial recovery were compared with women with either no, transitory or incomplete recovery, using independent samples *t* test for continuous data, and chi-square test for proportions. A generalized estimating equations (GEE) analysis was used for an overall comparison of pain trajectory (NRS) during pregnancy between women with substantial recovery and women with a poor recovery after delivery.

4.5 Ethics

The study that collected data for Paper I and II was carried out in accordance with the Helsinki Declaration II and was approved by the Regional Committee for Medical and Health Research Ethics of Western Norway (Rek.nr. 2009/798). All subjects consented to participate in the study, and a written informed consent was obtained. The pilot study (Paper II) was also registered in ClinicalTrials.gov (NCT00974103). The additional recruitment attempt in 2014 was approved by the Regional Ethics Committee of Western Norway (Rek.nr. 2013/2322).

The study for Papers III and IV was conducted in accordance with the Helsinki Declaration II and was approved by the Regional Ethics Committee of Northern Norway (Rek.nr. 2010/174). All subjects consented to participate in the study and a written informed consent was obtained. The RCT study (Paper III) was registered in ClinicalTrials.gov (NCT01098136).

Several ethical aspects have been taken into consideration in planning and conducting this research. All women included in the project signed a written consent form. This form contained information about the study and what research questions the project group wanted to investigate. In addition, information on how the data would be stored and anonymized were given. Also, the women were informed that they could withdraw their consent from the study at any time without giving any reason.

Overall, clinical researchers need to be aware of the number of questionnaires, clinical examinations and SMS questions used in data collection. Although it is tempting to include a number of various questionnaires and examinations, it is important to reduce the load on participants to those methods which reflect and answer the specific research questions that is asked.

The phrase "first, do no harm" is essential in treatment and research. The treatment and rehabilitation offered in the intervention studies were considered safe, and any type of adverse event were to be registered.

In Paper III, the women in the control group were asked to return to conventional health care without any restrictions and recommendations. The study design would have been more optimal if these women did not receive any treatment at all in the study period; however, asking women diagnosed with persistent PGP to refrain from any type of treatment would have been unethical.

5 Results

The results are described and discussed in detail in the papers, and only a summary of the main results is presented here.

5.1 Paper I

This study found 16% of women reporting PP during pregnancy to have persistent PGP verified by clinical examination 3–6 months after delivery. The women reported mild and moderate pain and a reduced quality of life, but seemed to cope fairly well with their daily activities. Risk factors for persistent pain were 30 years of age or above, a moderate or high ODI in pregnancy, and combined PP and LBP during pregnancy. If all three risk factors were present, there was a 35% absolute risk of developing persistent PGP. The odds of developing persistent PGP for a woman with neither of these risk factors were 0.013. Women reporting PP and/or LBP the year before pregnancy were also at risk of having persistent PGP; however, this was not retained in the best model of risk factors using multiple logistic regression analysis.

5.2 Paper II

In all, 11 women with verified persistent dominating one-sided PGP 3–6 months after delivery were included in the pilot study. They were randomized into receiving individualized rehabilitation and chiropractic treatment versus individualized rehabilitation alone. After 20 weeks of intervention, both groups reported improvement in disability and pain, but not in general health status. Because of the low number of women with persistent PGP and a high drop-out rate, statistical analyses were not conducted. Three women in the treatment group reported temporary tenderness as a result of the last treatment; however, no serious or long-lasting adverse events were registered after treatment or rehabilitation.

5.3 Paper III

In Paper III we conducted both intention-to-treat and per-protocol analyses, but because we found no substantial differences between the two methods, we chose only to present the intention-to-treat analyses in the paper. Tables 3 and 4 present the results for the primary and secondary outcome measures following both intention-to-treat and per-protocol analyses.

Table 3 – New occurrence of sick leave due to PGP and/or LBP disregarding sick leave at baseline, and estimated effect of treatment.

	Treatment group	**Control group**	**RR**	**95% CI**	***p***
Intention-to-treat					
Week 19–30, n (%)	7/21 (33)	8/21 (38)	0.88	0.39–1.98	0.75
Week 31–36, n (%)	8/21 (38)	10/19 (53)	0.72	0.36–1.45	0.36
Per-protocol					
Week 19–30, n (%)	7/19 (37)	6/14 (43)	0.86	0.37–2.00	0.73
Week 31–36, n (%)	8/20 (40)	7/14 (50)	0.80	0.38–1.69	0.57

RR relative risk, CI confidence interval

We found no statistically significant differences in sick leave, pain intensity of PGP, disability or health-related quality of life between the treatment group and the control group during pregnancy or after delivery. The confidence intervals were wide, containing both positive and negative clinically relevant effects. No severe or long-lasting adverse events were registered.

Table 4 – Estimated means of secondary outcome measure and estimated effect of treatment.

	Treatment group Mean (95% CI)	Control group Mean (95% CI)	Mean difference[a] β (95% CI)	*p*
Intention-to-treat				
Pain load[1], week 1—18	17.4 [n=26] (10.1–24.7)	20.0 [n=28] (13.6–26.4)		
Pain load[1], week 21—30	42.7 [n=25] (33.5–51.8)	46.4 [n=21] (37.3–55.6)	-3.3 (-15.1–8.5)	0.58
Pain load[1], week 33—40	40.3 [n=24] (27.9–52.8)	44.2 [n=21] (29.8–58.5)	-1.6 (-19.4–16.3)	0.86
Pain load, week 1-6 after delivery	19.1 [n=24] (10.0–28.2)	12.8 [n=21] (3.8–21.8)	7.8 (-4.9–20.4)	0.22
ODI[2], week 18	22.8 [n=26] (17.6–28.1)	21.5 [n=26] (17.0–26.0)		
ODI[2], week 30	29.7 [n=25] (22.1–37.2)	27.1 [n=21] (21.0–33.2)	-0.9 (-8.3–6.4)	0.80
ODI[2], 6 weeks after delivery	9.7 [n=25] (4.3–15.1)	7.1 [n=20] (3.2–10.9)	0.3 (-4.9–5.4)	0.92
EQ-5D[3], week 18	64.9 [n=28] (59.2–70.7)	62.0 [n=26] (55.3–68.6)		
EQ-5D[3], week 30	58.3 [n=26] (48.9–67.7)	62.0 [n=21] (54.6–69.5)	-3.3 (-14.5–7.9)	0.56
EQ-5D[3], 6 weeks after delivery	84.7 [n=25] (77.8–91.6)	86.8 [n=20] (78.6–95.1)	-0.8 (-11.1–9.4)	0.87
Per-protocol				
Pain load[1], week 1—18	15.5[n=24] (8.1–22.8)	23.2[n=31] (15.5–31.0)		
Pain load[1], week 21—30	42.3[n=24] (32.7–51.8)	51.2[n=14] (40.2–62.2)	-6.8 (-21.0–7.3)	0.33
Pain load[1], week 33—40	40.3[n=24] (27.9–52.8)	50.2[n=15] (32.0–68.3)	-6.1 (-26.8–14.6)	0.55
Pain load, week 1-6 after delivery	19.1[n=24] (10.0–28.2)	12.0[n=15] (0.3–23.7)	9.4 (-5.2–24.0)	0.20
ODI[2], week 18	23.3[n=23] (17.4–29.2)	20.6[n=21] (15.4–26.3)		
ODI[2], week 30	31.0[n=23] (23.1–39.0)	28.9[n=14] (22.1–35.6)	-2.9 (-10.9–5.1)	0.46
ODI[2], 6 weeks after delivery	10.1[n=24] (4.5–15.6)	8.6[n=14] (3.4–13.7)	-1.0 (-6.6–4.6)	0.72
EQ-5D[3], week 18	65.0[n=25] (58.6–71.3)	60.2[n=21] (52.1–68.1)		
EQ-5D[3], week 30	57.9[n=24] (47.7–68.1)	59.6[n=14] (52.2–67.1)	2.4 (-7.5–12.3)	0.62
EQ-5D[3], 6 weeks after delivery	84.1[n=24] (77.0–91.1)	82.8[n=14] (71.7–93.8)	1.4 (-9.3–12.0)	0.80

[a]Results from linear regression, adjusting for the relevant outcome measured at baseline
[b]Pain intensity (numerical rating scale) with possible values 0 to 100, where 0 represents no pain and 100 represents most pain imaginable
[c]Oswestry disability index with possible values 0 to 100, where 0 represents no disability and 100 represents maximum disability possible
[d]Eurocol-5D with possible values −7 to 100, where −7 represents poorest health and 100 represents full health
CI confidence interval, ODI Oswestry disability index, EQ-5D Eurocol-5D

5.4 Paper IV

In this study, the majority (83%) of the women that reported severe or moderate PGP during the final 10 weeks of pregnancy experienced a substantial recovery within six weeks after delivery. For almost half of them (44%), the recovery occurred within two weeks after delivery. Multiparity, PGP the year before pregnancy, and a high pain intensity of PGP during pregnancy were found to be risk factors for persistent PGP six weeks after delivery.

6 Discussion

6.1 Methodological considerations

6.1.1 Study population and study design

This thesis is based on two cohort studies of women recruited at the Department of Obstetrics and Gynecology at Stavanger University Hospital. In general, a cohort study enables us to study multiple outcome and calculate incidence and relative risk (128, 129).

The number of births at the hospital was 4788 in 2009 and 4958 in 2010 (130), which is why a relatively high number of eligible women could be included in a short period of time. The mean ages of women included in the retrospective and prospective studies were 30.0 and 29.9 respectively, comparable to the average age of women giving birth in Norway in 2009 and 2010 (30.3 both years) (131).

A retrospective cohort study can be completed quickly and is relatively inexpensive compared with a prospective cohort study (132). However, for the retrospective study, one of the major limitations is the recall bias. In addition, we may speculate that the women in our study (Papers I and II) were in an especially vulnerable situation when answering the questionnaire within 24 hours after giving birth. Giving birth is undeniably a stressful and life-changing experience. However, it is uncertain how this affected our data.

We did not include any qualitative research methodologies in our project. Despite a growing awareness of the relevance of qualitative research in recent years, a systematic review investigating women's experience of pregnancy-related PGP found only eight papers meeting the inclusion criteria for review (133). Quantitative researchers seek to test hypotheses to identify cause and effect, whereas the aim of qualitative researchers is to answer questions, such as "How do first-time mothers experience

persistent PGP after childbirth?" (134, 135). More focus on qualitative research will contribute to a better in depth understanding of the experiences and consequences of struggling with pregnancy-related PGP.

The follow-up in Paper I was 3–6 months after delivery, and this is clearly a weakness to our study. It is possible that the number of women with persistent PGP changes between the time points three and six months after delivery. However, Albert et al. found that improvement levels off around three months after delivery (12), and this is also reported in the European guidelines for the diagnosis and treatment of PGP (1). Findings in our Paper IV indicates that most of the improvement occurs within six weeks after delivery.

Because the number of women with persistent PGP is generally small, and women in a subgroup of persistent PGP (dominating one-sided PGP) is even smaller, Paper II was planned as a pilot RCT. However, it is debatable whether the design fulfills the requirements for a pilot study or whether it is merely an inadequately populated study. A pilot study is a small study conducted in order to have various purposes such as testing study procedures, estimation of the recruitment rate, and estimation of parameters such as the variance of the outcome to calculate for example sample size (136). In the peer-review process of Paper II, we encountered differing opinions on how to define the study. Some reviewers may regard a pilot study more favorably than a small clinical trial (136). In retrospect, when the study was designed previous research had already shown women with one-sided PGP to have a faster recovery compared with women with PGP syndrome (pain in all three pelvic joints) (12). With this knowledge, the study could have been designed to include women from several subgroups of PGP in order to achieve a bigger sample size. Nevertheless, we believe it is important that Paper II was published. It can help researchers in the same area of study when planning new research, and hence avoid wasting valuable time and resources.

Women who participated in the RCT study during pregnancy (Paper III) were not excluded from the SMS-Track study (Paper IV). In total, 42 of 120 women (35%) included in the SMS study had participated in the RCT during pregnancy (22 women in the treatment group and 20 women in the control group). It is a weakness of Paper IV that we did not investigate whether women who were not included in the RCT underwent chiropractic treatment to the same extent as the control group. We might suspect that women who were randomized to the control group were disappointed not to receive any intervention, and therefore sought chiropractic treatment inspired by the study. In addition, we did not perform any analyses to investigate whether the women who participated in the RCT had a faster recovery from PGP after delivery, and this is also a weakness in our study. In order to investigate this, we could have estimated the effect treatment had on recovery after delivery and thereafter predicted a recovery rate for a population with a normal frequency of treatment. We do believe however, that because the RCT did not show any substantial effect of treatment, including those women in the SMS-Track study would not influence the results (Paper IV).

6.1.2 Questionnaires and clinical examination

Although the ODI questionnaire was originally recommended for patients with moderate and severe and/or persistent disability due to spinal disorders, it is commonly used in PGP research (1, 17, 51, 71). A more specific questionnaire for PGP is the PGQ. The PGQ is a condition-specific questionnaire for PGP and is reliable, valid, and feasible for use in research and clinical practice (49, 137). It is regrettable that the PGQ was not included in the prospective longitudinal study. Both the ODI and PGQ should be included in future PGP research in order to compare results with previous research.

We did not use the Roland-Morris Disability Questionnaire (RMDQ), which has been used in several research studies on PGP (138-141). A systematic review and meta-analysis investigated which of the ODI and

RMDQ questionnaires has better properties for measuring physical functioning in patients with nonspecific LBP and found them equally good (142).

Traditionally, pain has been the main focus in PGP research, followed by function and disability (141). Although psychosocial factors have been a part of musculoskeletal research the past few decades, it has not had a strong position in PGP research. This might be because PGP is perceived as a transient condition and factors associated with persistent PGP and chronicity have not been targeted (141). Our study would have been strengthened if we had included questionnaires on psychosocial aspects such as fear avoidance and pain catastrophizing (143, 144). Psychosocial factors are especially important when it comes to the transition from acute and subacute pain to chronicity (145). Some researchers argue that the Fear Avoidance Beliefs Questionnaire is more predictive in relation to expectations rather than to fear (146). In addition, both resilience and self-efficacy have been investigated in relation to musculoskeletal pain (147). These aspects need to be investigated further, and which specific questionnaires are most optimal to assess psychosocial factors for pregnancy-related PGP are yet to be decided.

It is a weakness in our studies (Papers I and II) that the women were asked to report pain (NRS) up to nine months in retrospect. However, it is unclear whether the women reported less or more pain due to recall bias and memory decay.

In the follow-up examination 3–6 months after delivery (retrospective study), and in the clinical examinations at 18 and 30 weeks of pregnancy and six weeks after delivery (prospective study), we performed several clinical tests. These tests have been found to have a high specificity but a lower sensitivity (1). A test with a high specificity (true negative rate) relates to the test's ability to correctly reject healthy women without PGP, whereas a test with a high sensitivity relates to the test's ability to

correctly detect PGP in women who have PGP (148). It is therefore recommended to perform several tests, even if one test might be negative. We did however, diagnose women with dominating one-sided PGP (Papers II and III) even if they only had one positive specific provocation test (clinical tests described in 4.2.2.). More recent research includes provocation tests in the diagnosis of PGP, compared with earlier studies which focused more on the inspection and palpatory findings (1). A wide consensus on the diagnosis and diagnostic tests of PGP does not exist.

6.1.3 SMS-tracking

The response rate to the SMS question was close to 90% before delivery, indicating that SMS surveys can be efficient for data collection in a pregnant population. After delivery, the response rate dropped gradually. One reason for the falling response rate is because the SMS-tracking was set to last until six weeks after the EDD. This resulted in that women who gave birth 1–2 weeks after the EDD did not receive the SMS question five and six weeks after delivery. This is a weakness of the study. However, this is not the only reason for the drop in response rate, as many women had already stopped answering the SMS the same week as giving birth. A reason for this might be the stressful situation of having a newborn baby, in which case our results may still be representative and would not bias our results. However, if they stop answering the SMS because of a loss of interest/or motivation due to resolution of pain, our recovery rate may be underestimated. In other words, the prognosis could be better than our findings indicate.

Text messages have been found to be inexpensive, and compared to paper-based surveys, a better and more reliable method to collect data in LBP studies (149, 150). Data collection with weekly text messages has shown a high response rate, and some authors recommend using the method to investigate different conditions and populations (150). This is somewhat in line with our experience; however, actions to prevent the

falling response rate after delivery must be adressed in future studies on persistent pregnancy-related PGP. In addition, we could have included one or two additional SMS questions for the women to answer, which would have provided us with more information on for example, pain and disability. It is, however, difficult to assess if an increased number of SMSs sent every week would cause some women to drop out of the study.

We have not validated the SMS question, and this is a weakness in our study. The term "bothersomeness" has been used in several studies in musculoskeletal research (151-153). Dunn and Croft were probably the first to use and to some degree validate the term "bothersome" (154). They found associations between a single question of "bothersomeness" and measures of pain, disability, psychologic health, and work absence (154). A Swedish research group used the term as a proxy for the global effects of pain, both physical and physiological, on the subjects´ everyday life (150). In addition, the term was also central in other Scandinavian studies on LBP (153, 155). We argue that the question captures what is important to the individual and that it is a valid term to be used when investigating the impact of PGP in pregnant and postpartum women.

6.1.4 Randomization

Randomization is the process of assigning participants to treatment and control groups, giving each participant an equal chance of being assigned to any group (156). The process aims to balance and as such remove confounding effects of other variables. If the groups in a clinical trial are systematically different, the results will be biased if not adjusted for. Hence, randomization is thought to strengthen the results and data interpretation (156).

In the clinical trials (Papers II and III), women with a randomly assigned number that ended with an even digit were asked to join the intervention

group, whereas women with an odd digit were allocated to the control group. Four envelopes were prepared at a time, two envelopes with even digits and two envelopes with odd digits. This type of randomization is called block randomization and will secure equally sized groups, also in small studies (156).

6.1.5 Intervention

In the pilot study and the RCT (Papers II and III), the women in the treatment group received chiropractic treatment. It may be considered a weakness that the treatment was not specific or standardized. However, the studies were aimed at investigating the treatment women would receive when contacting a random chiropractor in primary health care. As previously described, Norwegian chiropractors include soft tissue techniques (mainly trigger points and stretching), instruction and advice on exercises, in addition to SMT (116). Therefore, the pragmatic nature of the study can also be considered a strength because the women received treatment according to their individual needs, and thus reflected clinical practice.

The individualized rehabilitation in Paper II consisted of standardized exercises but also allowed for additional exercises if the women improved quickly. The standardized exercises focused on posture and stretching, in addition to five general strengthening exercises. In a previous study, the efficacy of specific stabilizing exercises for patients with PGP after pregnancy was investigated, and an individualized treatment approach with specific stabilizing exercises appeared to be more effective than physical therapy without such (18). In this study, the exercises included in our pilot study resembles the exercise used in the control group (18). A possible weakness in our study could be that we did not limit the individual rehabilitation to the standardized program, and that the standardized program did not include specific stabilizing exercises that had been shown to be effective.

In the intervention studies, the examiner performing the clinical examinations was blinded for group allocation. Additional blinding was not implemented. In general, it appears impossible for a chiropractor or a physical therapist to be blinded for the treatment they are conducting. This is a weakness in intervention studies investigating possible effects of manual treatment. Recently, sham manipulation (placebo treatment) has been applied when investigating the effect of chiropractic treatment for headache and migraine (157-159) and this method was also successfully validated (160). On the other hand, a systematic review of the quality of placebo SMT in RCTs of lumbar and pelvic joints found that the majority of trials did not report on blinding success, or subject expectation regarding treatment success (161). Implementation of sham treatment in RCTs investigating the effect of manual therapy/SMT will increase the value of these studies and reduce bias.

6.1.6 Adverse events

As previously described, information on adverse events was collected at the follow-up sessions of chiropractic treatment or individualized rehabilitation. The women were asked if they had experienced any negative reactions after the intervention, and this was to be registered in the treatment journal.

When someone is offered any type of intervention, the main focus should be to avoid serious and long-lasting adverse events. However, only 13% of the studies included in a systematic review of outcomes, and core outcomes measurements in intervention studies of PGP and lumbopelvic pain examined potential adverse events (141). It is a strength in our project that we registered potential adverse events. The advantage of questioning each woman at each session is that the clinician can interpret the information given in regard to type, severity, and duration. Any symptoms that might be unrelated to the intervention can be excluded. However, some women might abstain from reporting negative reactions directly to the clinician and the clinician might interpret the information

incorrectly. Perhaps a different way of reporting adverse events would have been more favorable, for example, in an SMS message or online survey. This would also include any possible adverse events following the last session.

In Paper III, the majority of the women received spinal manipulation as part of the chiropractic treatment. Very few adverse events have been reported after spinal manipulation for pregnancy-related PGP (117). It is, however, less studies on the possible adverse events following physical exercising during pregnancy and after delivery. A systematic review investigating whether spinal exercises were associated with adverse maternal and fetal outcomes was inconclusive (162). Another study, including a 12-week standardized exercise program, that included both aerobic and strength training, did not reveal any serious adverse events (163, 164). Clearly, more focus on reporting adverse events in exercise studies is needed.

Nevertheless, our papers will, together with additional intervention studies, contribute to meta-analyses on the incidence of adverse events following chiropractic treatment during pregnancy and after delivery, and rehabilitation exercises after delivery.

6.1.7 Primary and secondary outcome measures

Simple and standardized outcome measures are not established when investigating musculoskeletal disorders (165), and this is also the case for PGP.

In Paper III, the primary outcome measure was sick leave. Unfortunately, we experienced sick leave to be a sub-optimal outcome measure during pregnancy. Many women are unable to work in the beginning of their pregnancies due to fatigue and nausea (6). For most women, these symptoms improve at the beginning of second trimester, usually when women start to have PGP symptoms. However, because the women

reported several reasons for sick leave, it was difficult to assess what was the main reason for the absence from work. In addition, we speculate that many women never return to work after sick leave during the first trimester, due to the sum of all symptoms and not due to PGP alone, even though this is the given reason for sick leave. Therefore, we chose to include only new occurrences of sick leave after week 18 of pregnancy, avoiding the bias of sick leave from the first trimester. Unfortunately, this resulted in 9 women (6 women in treatment group and 3 women in control group) being excluded from the study.

Regrettably, some confusion regarding the primary outcome measure in Paper III led us to not present the same outcome measure as registered in ClinicalTrials.gov (NCT01098136). In ClinicalTrials.gov, it is stated that the primary outcome measure was P4; however, the clinical tests are not included in the summary of outcome measures in the description of the study in the same study record. It is unclear, and maybe a mistake, that the clinical tests were registered in ClinicalTrials.gov as a primary outcome. We acknowledge the importance of presenting the outcome measures registered in ClinicalTrials.gov and that it is unfortunate to report other outcome measures than the ones already registered.

Paper III was recently included in a systematic review investigating the outcomes and outcome measurements in intervention studies of PGP and lumbopelvic pain (141). The authors discovered a wide variety of outcomes, and discussed difficulties in pooling data in meta-analyses in a meaningful and interpretable way to increase the certainty of effect measures. An ongoing Delphi survey will hopefully reach a consensus on a PGP core outcome set (166). Together with the inconsistent use of terminology of PGP, this has complicated the comparison of our findings with previously conducted research. It is imperative that future research adheres to the upcoming consensus on outcome measurements in PGP studies.

6.1.8 Statistical analyses

The difference between two groups in an intervention study will usually be explored in terms of an estimate of effect, appropriate confidence intervals, and *p*-values (167). However, the testing of null hypothesis at a *p*-value of 0.05 has been claimed to have no basis in medicine and that it should be discouraged (128). It is emphasized that the use of confidence intervals reveals the strength, direction, and a plausible range of an effect, as well as the likelihood of chance occurrence (128). In our papers, we have presented the *p*-values following statistical analyses but have also focused on the extended information obtained from the confidence intervals.

Ideally, power analyses should be done a priori before the data are collected. A study with sufficient power will likely detect a difference between groups if it exists, and if no difference is found, one can be reasonably confident in concluding that none exists in reality (167). In general, higher power is achieved by increasing sample size (167). An underpowered study is susceptible to the possibility of the results being misinterpreted (Type I error), for example, when a large *p*-value is interpreted as a negative conclusion (168).

Although studies with a low statistical power have been criticized for undermining the purpose of scientific research unethical , it has also been discussed that it is important not to include too many participants (168). Underpowered studies may have value, specifically in producing useful estimates and confidence intervals or by contributing to meta-analyses (169-171). Post hoc power analyses using the observed estimates are not recommended (172, 173).

The retrospective cohort and the prospective longitudinal cohort included 569 and 506 women respectively. However, the number of women with persistent PGP is generally small, and a subgroup of women with persistent dominating one-sided PGP even smaller. In addition to drop-outs, this resulted in an overall low sample size. A larger study

sample could have answered the research questions more exactly and reduced the variance of the results.

6.2 Discussion of results

6.2.1 Paper I

In this paper, 16% of women with self-reported PP during pregnancy had persistent PGP 3–6 months after delivery (174). Another paper, based on the same study population, investigating the prevalence of LBP and PP during pregnancy found that almost 50% of the women experienced moderate and severe LBP and PP during pregnancy, and half of them (26%), reported only PP symptoms (175). The European guidelines for the diagnosis and treatment of PGP calculated the point prevalence of women suffering from PGP to be close to 20% (1). However, their inclusion criteria were strict and demanded a clinical examination for a diagnosis of PGP. Hence, our original study population appears to be representative for the general population of pregnant women. The number of women with persistent PGP 3–6 months after delivery appears to be in line with other prospective studies with verified symptoms where the prevalence of pregnancy-related PGP has been found to be between 16% and 25% (1, 2, 33, 43, 44).

The women who reported persistent PGP had overall mild and moderate pain and seemed to cope fairly well with their daily activities. Nevertheless, affected women reported having reduced health-related quality of life. The personal consequences of having persistent PGP have only been explored to a limited extent; however, in the last few years the interest has been growing. Two studies have investigated how persistent PGP impacts the lives of primiparous women and their health-seeking behavior (135, 176). They found that women with persistent PGP experienced conflicting advice given by health-care professionals. The affected women also felt that the postnatal follow-up was inadequate,

and that the PGP complaint was ignored (176). A Swedish study focused on women's adaptation to pain and were able to identify two ways of coping (177). One group of women struggled with the pain in an effort to live normal lives, whereas the other group changed their lifestyles and habits to adapt to the situation. (177). In a recent Norwegian study, nine women with persistent PGP 3– 26 years after giving birth were interviewed (178). Overall, the women had significant challenges. The pain required careful planning and time for rest, influenced the women's ability to work and created a feeling of isolation and shame (178). These studies investigated the consequences of severe persistent PGP, whereas our study population consisted of women with only mild and moderate symptoms. This is perhaps one of the reasons why the women in our paper had only minor disabilities. Overall, it is evident that women with persistent PGP are struggling with daily life activities, being a mother and a partner, and returning to normal work life.

Paper I revealed that age (30 years or above), a moderate or high ODI during pregnancy, and combined PP and LBP in pregnancy were risk factors for persistent PGP 3–6 months after delivery. In addition, women reporting PP and/or LBP the year before pregnancy were also at risk of persistent PGP. A recently published literature review investigating factors associated with PGP persisting for over three months after delivery included our Paper I (179). Maternal age was found to be an inconsistent risk factor for persistent PGP (179). One study discusses whether age might have an interaction effect with trunk flexor endurance (10). In addition, age has been discussed to be a risk factor both when the mother is younger and older (2). The pattern of the effect of age has been speculated to present as a U-form with a higher risk for very young women as well as an increased risk for "older" women (2).

Both pain intensity of PGP and disability during pregnancy are recognized risk factors for persistent PGP (54, 106, 179-181). We found a moderate or high ODI in pregnancy to be a risk factor; however, we

did not analyze pain intensity in our study. It is likely that these two factors are somewhat related.

Because of the inconsistent use of terminology and several studies not including a clinical examination, it is difficult to compare PGP studies. We found that having LBP in addition to PGP during pregnancy was a risk factor for persistent pain, and another study revealed that the number of pain sites were significantly associated with pain intensity (54). Altogether, women reporting a high pain intensity, moderate or high disability, and more widespread pain in the pelvic area, appear to be at greater risk for persistent PGP after delivery (54, 106, 179-181). This was also the finding of a recent study investigating prevalence and severity of upper back, lower back, and PGP in primiparous women during pregnancy and 6–10 weeks after delivery (182). Women with pain in all three sites during pregnancy were least likely to experience pain resolution (182).

Again, because of the varying terminology and outcome measures used in PGP research, not many studies have investigated PP before pregnancy as a risk factor for persistent PGP. Several studies have, however, found a history of LBP to be a predictor of persistent PGP after delivery (10, 183-185).

6.2.2 Paper II

In the pilot study, all included women experienced improvement in disability and pain, but not in general health status. In addition, no severe or serious adverse events after treatment or training were reported.

A protocol of a Cochrane Systematic Review investigating physical therapy interventions for PGP after pregnancy has been published, but the results are yet to be presented (186). Overall, research on treatment for persistent PGP has been less investigated than treatment options for PGP during pregnancy. The results from our pilot study show that this

type of study is feasible; however, in order for the study to have a bigger sample size, all subgroups of women with persistent PGP need to be included.

6.2.3 Paper III

The RCT did not reveal any statistically significant differences between the treatment group and the control group in any of the outcome measures. The estimates had confidence intervals with both positive and negative clinically relevant effects.

A systematic review from 2009 investigating manipulative treatment for pregnancy-related LBP and other conditions characterized the evidence as emerging, and recommended clinicians to use SMT as a treatment option if no contraindications are present (20). A more recent systematic review with meta-analysis from 2016 found limited evidence to support the use of complementary manual therapies as an option for managing lumbopelvic pain during pregnancy (187). The authors were, however, only able to include one study on chiropractic and four studies on osteopathic manipulative treatment (187).

Based on the data from our prospective longitudinal cohort we investigated the course of bothersome symptoms through the second half of pregnancy after subgrouping women with PGP using the results from the ASLR and P4 tests (188). Women who tested positive on both ASLR and P4 tests at mid pregnancy had a course of persistent bothersome PP for more than five days per week throughout the pregnancy (188). We may hypothesize that the women diagnosed with PGP following a clinical examination, including positive clinical tests, are poor responders to manual treatment. These women will perhaps not experience a resolution of pain until after delivery. More research is needed to investigate which subgroups of women will potentially respond to manual treatment and which will not.

In 2015, a Cochrane Systematic Review investigating the interventions for preventing and treating LBP and PP during pregnancy was published; however, most of the included studies were of low quality and were unable to support different interventions (189). A more recent systematic review and meta-analysis investigating exercises for prevention and treatment of LBP, PGP, and lumbopelvic pain during pregnancy found that exercises initiated during pregnancy were not effective in decreasing the prevalence (190). Nevertheless, the researchers conclude that prenatal exercise decreased the severity of pain during pregnancy (190).

6.2.4 Paper IV

In Paper IV, we found that 83% of women with severe and moderate PGP during pregnancy reported a substantial recovery within six weeks after delivery. Of these, 44% experienced a substantial recovery within two weeks after delivery (191).

To our knowledge, this is the first study to investigate the recovery from pregnancy-related PGP in the very first weeks after delivery. A previous study from 2001 had follow-up conducted at one, three, six, 12, 18, and 24 months after delivery (12), and a study from 2019 had follow-ups at one, three and six months after delivery (192). Both studies showed that the majority of women experienced disappearance of PP within one month after delivery (12, 192). However, the numbers are difficult to compare due to different methodology.

Our results indicate that improvement from PGP occurs earlier than what has been previously reported. Papers I and IV are from two different cohorts and have different methodologies, yet the results are very similar. In Paper I, 16% of women with PP during pregnancy had persistent PGP 3–6 months after delivery, whereas Paper IV revealed that 83% of women with moderate or severe PGP the last 10 weeks of pregnancy had

a substantial recovery within six weeks after delivery —but 17% had not. Consequently, it seems that most women recover already within six weeks after delivery, but very few experience significant recovery between six weeks and 3–6 months after delivery. Additional studies and larger study samples are needed to confirm this finding. Nevertheless, this study should have implications for women who present with persistent PGP at six weeks follow-up after delivery. They may be at risk of chronicity (12, 84).

Multiparity, PGP the year before pregnancy, and a high pain intensity for PGP during pregnancy were found to be risk factors for persistent PGP six weeks after delivery. Multiparity was not a risk factor for persistent PGP 3–6 months after delivery in Paper I, and was not recognized as a risk factor in the review from 2019 (179). In Paper IV we did not find older age to be a risk factor and consider these results conflicting, as we might argue that older age is confounded with multiparity.

The risk factors pain intensity during pregnancy and a history of PGP were discussed in relation to the findings in Paper I.

7 Conclusions

One out of six women reporting PP during pregnancy had persistent PGP 3-6 months after delivery. The affected women reported mild and moderate pain but coped fairly well. Women with persistent PGP reported a reduced health-related quality of life. Risk factors for persistent pain were 30 years of age or above, a moderate or high ODI in pregnancy, and combined PP and LBP during pregnancy.

Both groups in the pilot randomized trial reported improvement in disability and pain, but not in general health status. The number of women with persistent dominating one-sided PGP was low. Future studies should include all subgroups of women with persistent PGP.

When investigating chiropractic treatment versus conventional care during pregnancy, we found no statistically significant differences in sick leave, pain, disability, or general health status between the treatment group and the control group during pregnancy or after delivery. However, the confidence intervals were wide, and we were not able to draw any conclusions.

The majority of women who reported severe or moderate PGP during the final 10 weeks of pregnancy experienced a substantial recovery within six weeks after delivery. For almost half of these, the recovery occurred within two weeks after delivery. Risk factors for a poor recovery were multiparity, PGP the year before pregnancy, and a high pain intensity of PGP during pregnancy.

8 Future perspectives

One of the biggest challenges in PGP research has been the vast variation in terminology and methodology. Although several studies find the prevalence of PGP during pregnancy to be an average of 20%, there is still a need for high quality studies to assess the prevalence of PGP during pregnancy and persistent PGP after delivery. It is especially important to include a clinical examination for a precise diagnosis. In addition, the use of subgrouping is useful. Some researchers have found different subgroups of PGP to have different prognoses, but subgroups of PGP have been less investigated during pregnancy. In addition, qualitative research will contribute to a better understanding of the emotional burdens of PGP.

Although the evidence for prevention and treatment of PGP during pregnancy and after delivery is appearing, there is a lack of high quality studies. It is especially important to include standardized reporting of adverse events to make sure that the intervention offered is safe. It would also be interesting to conduct an RCT investigating the effect of chiropractic treatment for women with only LBP symptoms during pregnancy. Perhaps these women respond better to treatment than women with positive clinical provocation tests for PGP? The ongoing Delphi study developing a core outcome set for PGP will contribute to a more consistent research, making it easier to compare research studies (166).

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10 Erratum

Paper I, conclusion: 35% relative risk should be replaced with 35% absolute risk.

11 Ethical approvals

UNIVERSITETET I BERGEN
Regional komité for medisinsk og helsefaglig forskningsetikk, Vest-Norge (REK Vest)

Stefan Malmquist
Samfunnsvitenskaplig fakultet
Universitetet i Stavanger
4036 Stavanger

Deres ref	Vår ref	Dato
	2009/356-CAG	02.02.2009

Ad. prosjekt: En retrospektiv, longitudinell kohortstudie av forekomst og risiko for utvikling av korsrygg- og bekkensmerter hos gravide i stavangerregionen (020.09).

Det vises til din søknad om godkjenning av forskningsprosjekt, datert 03.01.09.

Komiteen behandlet søknaden i møtet den 22.01.09.

Sissel Moe Lichtenberg deltok ikke i behandling av søknaden på grunn av inhabilitet.

Komiteen har ingen merknader til forskningsprotokollen. En har imidlertid en merknad til informasjonsskrivet. I forespørselen til deltakerne er kontaktperson nevnt to steder. En finner det mer hensiktsmessig å slå sammen informasjonen til en kort presentasjon av kontaktperson/ forsker.

Vedtak:
Prosjektet godkjennes på vilkår av at ovennevnte merknader tas til følge.

Komiteen ber om å få tilsendt sluttrapport evt. trykt publikasjon for studien når dette foreligger.

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Besøksadresse
Haukeland Universitetssykehus

Vennlig hilsen

Jon Lekven
leder

Camilla Gjerstad
førstekonsulent

De regionale komiteene for medisinsk og helsefaglig forskningsetikk foretar sin forskningsetiske vurdering med hjemmel i Forskningsetikklovens § 4. Saker vedrørende forskningsbiobanker behandles i samsvar med Biobankloven. Saksbehandlingen følger Forvaltningsloven.

Komiteenes vedtak etter Forskningsetikklovens § 4 kan påklages (jfr. forvaltningsloven § 28) til Den nasjonale forskningsetiske komité for medisin og helsefag. Klagen skal sendes REK-Vest (jfr. forvaltningsloven § 32). Klagefristen er tre uker fra den dagen du mottar dette brevet (jfr. forvaltningsloven § 29).

UNIVERSITETET I BERGEN
Regional komité for medisinsk og helsefaglig forskningsetikk, Vest-Norge (REK Vest)

Inger Kjærmann
ingerkjaer@yahoo.co.uk
Nasjonalt kompetansesenter for bevegelsesforstyrrelser
Stavanger universitetssykehus

Deres ref	Vår ref	Dato
	2009/798	02.02.09

Ad. prosjekt: Vedvarende smerter i korsrygg og bekken 3-6 måneder etter fødsel

Det vises til prosjektsøknad, datert 03.08.09.

Komiteen behandlet søknaden i møtet 20.08.09.

Komiteen mener at dette er en veldesignet og viktig studie. Prosjektbeskrivelsen er godt gjennomarbeidet.

I forbindelse med telefonintervjuene må det imidlertid foretas én endring: Det fremgår av helseforskningsloven § 13 annet ledd at samtykke til deltakelse i medisinske og helsefaglige forskningsprosjekt skal være dokumenterbart. Dette innebærer at man må utarbeide et eget informasjons- samtykkeskriv også for denne delen av studien. Samtykket må innhentes før telefonintervjuene foretas. Informasjonsskrivet kan godt ta utgangspunkt i innledningen til appendiks 3.

Noen mindre feil/unøyaktigheter i informasjonsskrivet bør korrigeres. Se vedlegg.

Vedtak: *Prosjektet godkjennes på vilkår av ovennevnte merknad.*

Komiteen ber om å få tilsendt sluttrapport evt. trykt publikasjon for studien.

Vennlig hilsen

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2. etasje, sentralblokken,
Haukeland universitetssykehus

Ny ordning fra 01.07.09:
En gjør oppmerksom på at denne søknaden er vurdert i henhold til helseforskningsloven, som ble satt i kraft 01.07.09. Dette innebærer at REK fra og med denne dato har kompetanse til å godkjenne opprettelse og endring av forskningsbiobank, å innvilge dispensasjon fra taushetsplikt og å gi tillatelse til bruk av personopplysninger til forskning. Saker som er søkt Helsedirektoratet, NSD eller Datatilsynet vedrørende ovennevnte, vil utelukkende bli behandlet av REK. Dette for å unngå parallellbehandling av saker nå i overgangsfasen.

REK Vest forutsetter at dette vedtaket blir forelagt den forskningsansvarlige til orientering. Se helseforskningsloven § 6, jfr. § 4 bokstav e.

De regionale komiteene for medisinsk og helsefaglig forskningsetikk foretar sin forskningsetiske vurdering med hjemmel i helseforskningsloven § 10, jfr. forskningsetikkloven § 4.
Saksbehandlingen følger forvaltningsloven. Komiteenes vedtak etter forskningsetikklovens § 4 kan påklages (jfr. forvaltningsloven § 28) til Den nasjonale forskningsetiske komité for medisin og helsefag. Klagen skal sendes REK Vest (jfr. forvaltningsloven § 32). Klagefristen er tre uker fra den dagen du mottar dette brevet (jfr. forvaltningsloven § 29).

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK vest	Camilla Gjerstad	55978499	30.01.2014	2013/2322/REK vest
			Deres dato:	
			10.12.2013	

Vår referanse må oppgis ved alle henvendelser

Anne Marie Gausel
Stavanger universitetssjukehus

2013/2322 Vedvarende smerter i korsrygg og bekken 3-6 måneder etter fødsel

Forskningsansvarlig: Helse Stavanger HF
Prosjektleder: Anne Marie Gausel

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK vest) i møtet 16.01.2014. Vurderingen er gjort med hjemmel i helseforskningsloven (hfl.) § 10, jf. forskningsetikklovens § 4.

Prosjektomtale
Dette er en søknad om forlengelse av et pilotprosjekt beskrevet i prosjektet 2009/798 «Vedvarende smerter i korsrygg og bekken 3-6 måneder etter fødsel.» Prosjektet ble godkjent av REK Vest i 2009. Målet med studien var å finne ut hvor vanlig det er med vedvarende smerter i bekken og korsrygg 3-6 måneder etter fødsel og hvem som har økt risiko for vedvarende plager. Videre ønsket man å undersøke hvilken effekt kiropraktorbehandling og individuelt tilrettelagt trening har på vedvarende bekkensmerter. Prosjektet 2009/798 har blitt forsinket og skulle vært avsluttet i 2011, men har likevel tillatelse til å oppbevare data til 2015. Pilotstudien inkluderer kvinner med ensidige bekkenplager. Søker ønsker å fortsette rekrutteringen til piloten samt endre prosjektleder. I hovedsak er pilotprosjektet (protokoll, spørreskjema) fra 2009 uforandret. Det er 11 deltakere inkludert i pilotstudien så langt. Man ønsker nå å inkludere 19 nye deltakere, slik at det totalt blir 30 deltakere i pilotstudien. Det er utarbeidet nytt informasjonsskriv til de kvinnene som rekrutteres fremover. Det fremgår av søknaden at deltakerne får undersøkelse og eventuell behandling kostnadsfritt.

Vurdering
Hva søkes det forlengelse om?
I søknaden fremgår det at prosjektleder ønsker å forlenge prosjektet 2009/798. REK Vest forstår søknaden imidlertid slik at det kun er snakk om forlengelse av pilotstudien, ikke den samlete studien som ble søkt i 2009. Kvinner med ensidige bekkenplager som ønsker å delta i pilotstudien vil bli randomisert til to grupper. Den ene gruppen vil få kiropraktorbehandling og trening som er individuelt tilrettelagt, mens den andre gruppen kun vil gjennomføre individuelt tilrettelagt trening.

Pilotundersøkelsen og informasjonsskriv

- Studien er designet som en pilotundersøkelse som skal inkludere 30 kvinner. Komiteen minner om at hensikten med en pilotstudie er å undersøke gjennomføringsgrad og om designet er egnet for en større vitenskapelig studie. Gjennom en slik pilot kan forskerne avdekke eventuelle mangler og svakheter med studieoppsettet, jf. artikkel fra Leon et al: *«The role and interpretation of pilot studies in clinical research.»* Pilotstudien har ikke statistisk styrke til å kunne gi vitenskapelige og

allmenngyldige svar på hvilke effekter behandlingen har. Informasjonsskrivet kan likevel gi inntrykk av at studien tar sikte på å gi slike svar: *«Dette er et spørsmål til deg om å delta i en forskningsstudie for å undersøke hvilken effekt kiropraktorbehandling og individuelt tilrettelagt trening har på vedvarende bekkensmerter 3-6 måneder etter fødsel».* Forskingsformålet i pilotstudien må derfor presenteres på en slik måte at de som skal rekrutteres ikke forledes til tro at pilotstudien kan fastslå behandlingseffekter. Komiteen forutsetter at informasjonsskrivet ikke lover mer enn det pilotstudien faktisk kan gi svar på. Videre må resultatene av studien presenteres på en nøytral måte.

- Komiteen ber også om at skrivet inkluderer informasjon om at koblingsnøkkelen slettes og opplysningene anonymiseres innen prosjektslutt 31.12.20.

Prosjektslutt
Prosjektslutt i den nye søknaden oppgis å være 31.12.20. REK Vest legger til grunn at koblingsnøkkelen slettes og opplysninger anonymiseres ved prosjektslutt. En forutsetter videre at opplysninger slettes innen utgangen av 2015 for de kvinnene som har samtykket i prosjekt 2009/798 til at *«opplysningene blir senest slettet 2015».*

Vilkår
Informasjonsskrivet til kvinnene som skal rekrutteres må revideres i henhold til merknadene over.

Vedtak
REK Vest godkjenner prosjektet på betingelse av at ovennevnte vilkår tas til følge.

Sluttmelding og søknad om prosjektendring
Prosjektleder skal sende sluttmelding til REK vest på eget skjema senest 30.06.2021, jf. hfl.
12. Prosjektleder skal sende søknad om prosjektendring til REK vest dersom det skal gjøres vesentlige endringer i forhold til de opplysninger som er gitt i søknaden, jf. hfl. § 11.

Klageadgang
Du kan klage på komiteens vedtak, jf. forvaltningslovens § 28 flg. Klagen sendes til REK vest. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK vest, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Ansgar Berg
Prof. Dr.med
Komitéleder

Camilla Gjerstad
rådgiver

Kopi til: forskning@sus.no

Fra: Regional komite for medisinsk og helsefaglig forskningsetikk REK nord

Til:
Stefan Malmqvist
stefan.malmqvist@uis.no

Dokumentreferanse: 2010/174-4
Dokumentdato: 09.02.2010

BEKKENLØSNINGSSMERTER I SISTE HALVDEL AV SVANGERSKAPET FOREKOMST, FORLØP OG MULIG EFFEKT AV BEHANDLING - INFORMASJON OM VEDTAK
Prosjektleders prosjektomtale:
Årsakene til bekkenløsning (Pelvic Girdle Pain, PGP) er ikke kjent. I tillegg er det uklare kriterier for klassifisering og varierende terminologi innen temaet. Dette hindrer en fornuftig tilnærming til forebygging og behandling av problemstillingen PGP. Målet med denne prospektive studien er å kartlegge forekomst og nye tilfeller av PGP i siste halvdel av svangerskapet, og å klassifisere mulige PGP-subgrupper. Videre skal kvinner med hovedsaklig ensidige bekkensmerter få tilbud om å gå videre i en pilotstudie – en randomisert, blindet, klinisk studie – der kiropraktorbehandling sammenlignes med det tradisjonelle behandlingstilbudet. Primært effektmål som skal brukes i studien er smerte (VAS), funksjonskår (ODI) og sykmeldingsfrekvens. Vi planlegger også å se om det er mulig å forutsi effekt av kiropraktorbehandling hos kvinner med ensidige bekkensmerter.

Komiteens merknader:

Forskningsansvarlig
Komiteen anser Helse Stavanger HF som forskningsansvarlig institusjon for prosjektet.

Prosjektmedarbeidere
I protokollen oppgis også Jan Petter Larsen MD Phd. Han er ikke nevnt i søknadsskjemaet. Komiteen legger protokollen til grunn, og at Larsen også skal delta i prosjektet.

Forespørsel/informasjonsskriv
Ordet "samtykkeerklæring" må fjernes fra overskriften. Omfanget av, og type spørsmål bør utdypes.

Forespørselen om deltakelse i forskningsprosjektet må utformes i samsvar med retningslinjene til de forskningsetiske komiteene. Mal finnes bla på http://helseforskning.etikkom.no/xnet/public.

Som det fremgår av malen, vil informasjonen som presenteres differensieres og lagdeles i en hoveddel og kapitler (A og B). Informasjonen som er gitt i hoveddelen skal ikke repeteres i kapitlene, men utfylle hoveddelen, dersom det er nødvendig.

Vi gjør oppmerksom på at hvert enkelt av de oppgitte punktene under kapittel A og B bare skal spesifiseres dersom dette er nødvendig. De benyttes kun i den grad de er relevante og nødvendige å detaljere, for eksempel dersom ikke tilstrekkelige opplysninger allerede finnes under hoveddelen av pasientinformasjonen. Det er også gitt rom for at egne og mer hensiktsmessige overskrifter kan benyttes under kapittel. A (jf malen).

Vedtak :
Prosjektet godkjennes under forutsetning av at komiteens merknader tas til følge. Reviderte forespørselsskriv merket med dato eller versjon nummer bes sendt inn til vårt arkiv.

Godkjenningen er gitt under forutsetning av at prosjektet ellers gjennomføres slik det er beskrevet i søknaden og protokollen, og de bestemmelser som følger av helseforskningsloven med forskrifter.

Dersom det skal gjøres endringer i prosjektet i forhold til de opplysninger som er gitt i søknaden, må prosjektleder sende endringsmelding til REK. Vi gjør oppmerksom på at hvis endringene er "vesentlige", må prosjektleder sende ny søknad, eller REK kan pålegge at det sendes ny søknad.

Det forutsettes at forskningsdata oppbevares forskriftsmessig.

Godkjennelsen gjelder til 30.11.2010

Prosjektleder skal sende sluttmelding i henhold til helseforskningsloven § 12.

Komiteens vedtak kan påklages til Den nasjonale forskningsetiske komité for medisin og helsefag, jf. forvaltningsloven § 28 flg. Eventuell klage sendes til REK Nord. Klagefristen er tre uker fra mottak av dette brevet.

Vennlig hilsen

May Britt Rossvoll
Sekretariatsleder

Monika Rydland Gaare
Førstekonsulent

Regional komité for medisinsk og helsefaglig forskningsetikk, Nord-NorgeREK NORD Besøksadresse: TANN-bygget, Universitetet i Tromsø, N-9037 Tromsøtelefon sentralbord 77 64 40 00 telefon ekspedisjon 77620758 e-post: post@helseforsking.etikkom.no

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Stefan Malmqvist
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Universitetet i Stavanger
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4036 STAVANGER

Vår dato: 05.03.2009 Vår ref: 20912 / 2 / PB Deres dato: Deres ref:

TILRÅDING AV BEHANDLING AV PERSONOPPLYSNINGER

Vi viser til melding om behandling av personopplysninger, mottatt 07.01.2009. All nødvendig informasjon om prosjektet forelå i sin helhet 27.02.2009. Meldingen gjelder prosjektet:

20912	*En retrospektiv, longitudinell kohortstudie av forekomst og risiko for utvikling av korsrygg- og bekkensmerter hos gravide i Stavangerregionen*
Behandlingsansvarlig	*Universitetet i Stavanger, ved institusjonens øverste leder*
Daglig ansvarlig	*Stefan Malmqvist*

Personvernombudet har vurdert prosjektet, og finner at behandlingen av personopplysninger vil være regulert av § 7-27 i personopplysningsforskriften. Personvernombudet tilrår at prosjektet gjennomføres.

Personvernombudets tilråding forutsetter at prosjektet gjennomføres i tråd med opplysningene gitt i meldeskjemaet, korrespondanse med ombudet, eventuelle kommentarer samt personopplysningsloven/-helseregisterloven med forskrifter. Behandlingen av personopplysninger kan settes i gang.

Det gjøres oppmerksom på at det skal gis ny melding dersom behandlingen endres i forhold til de opplysninger som ligger til grunn for personvernombudets vurdering. Endringsmeldinger gis via et eget skjema, http://www.nsd.uib.no/personvern/forsk_stud/skjema.html. Det skal også gis melding etter tre år dersom prosjektet fortsatt pågår. Meldinger skal skje skriftlig til ombudet.

Personvernombudet har lagt ut opplysninger om prosjektet i en offentlig database, http://www.nsd.uib.no/personvern/prosjektoversikt.jsp.

Personvernombudet vil ved prosjektets avslutning, 30.06.2009, rette en henvendelse angående status for behandlingen av personopplysninger.

Vennlig hilsen

Bjørn Henrichsen

Pernilla Bollman

Kontaktperson:Pernilla Bollman tlf: 55 58 24 10
Vedlegg: Prosjektvurdering

Personvernombudet for forskning

Prosjektvurdering - Kommentar

20912

I forbindelse med studien vil det bli registrert sensitive personopplysninger om helseforhold og om seksuelle forhold, jf. personopplysningsloven (pol) § 2 pkt. 8 c, 8 d. Personopplysninger kan behandles med hjemmel i pol §§ 8 første ledd (samtykke), 9 a.

Senest ved prosjektslutt 30.06.2009 skal datamaterialet anonymiseres ved at kodenøkkel/navneliste slettes og eventuelle indirekte personidentifiserbare bakgrunnsopplysninger slettes eller endres (grovkategoriseres). Dersom det blir aktuelt med en oppfølgingsstudie som inkluderer de samme kvinnene skal et nytt samtykke innhentes til deltakelse og fortsatt oppbevaring av allerede innsamlede data. Oppfølgingsstudien skal meldes til ombudet som nytt prosjekt eller som endring/utvidelse av dette prosjektet.

Personvernombudet mottok 27.02.2009 revidert informasjonsskriv til utvalget og finner skrivet tilfredsstillende. Prosjektet er tilrådd av REK Vest i følge brev datert 02.02.2009.

Paper I

Gausel, A.M., Kjærmann, I., Malmqvist, S. et al. (2016)
Pelvic girdle pain 3–6 months after delivery in an unselected cohort of Norwegian women.
European Spine Journal, 25, pp. 1953–1959.
DOI 10.1007/s00586-015-3959-1

Paper II

Adding Chiropractic Treatment to Individual Rehabilitation for Persistent Pelvic Girdle Pain 3 to 6 Months After Delivery: A Pilot Randomized Trial

Anne M. Gausel, Cand.manu,[a] Ingvild Dalen, PhD,[b] Inger Kjærmann, MSc,[c] Stefan Malmqvist, MSc,[d] Knut Andersen, PhD,[c] Jan Petter Larsen, PhD,[e] and Inger Okland, PhD[a]

ABSTRACT

Objective: The purpose of this study was to investigate the feasibility of conducting a study examining the influence of individualized rehabilitation and chiropractic treatment, compared with individualized rehabilitation alone, in women with persistent dominating 1-sided pelvic girdle pain (PGP) 3 to 6 months after delivery.

Methods: Women were recruited from an outpatient clinic at Stavanger University Hospital, Norway and in a private chiropractic clinic in Stavanger. Those with persistent, dominating 1-sided PGP were included in this pilot study. Those who met inclusion criteria were randomized into 2 groups, one group received individualized rehabilitation and chiropractic treatment and the other group women received individualized rehabilitation alone. Treatment was measured for 20 weeks.

Results: Of 330 consenting women who were recruited who reported pelvic pain during pregnancy, 68 reported PGP or low back pain, and 63 consented to fill in a questionnaire. Forty-seven women underwent a clinical examination 3 to 6 months after delivery. During the examination, the women were diagnosed into subgroups for PGP. After exclusion of the women with low back pain only, a total of 13 women were diagnosed with dominating 1-sided PGP and thus included in this study. Six were randomized to the individualized rehabilitation and chiropractic treatment group and 5 to the individualized rehabilitation alone group. After 20 weeks of intervention, both groups reported improvement in disability and pain, but not in general health status. No serious or long-lasting adverse events were registered after treatment or training.

Conclusion: We found that a study of this nature is feasible. However, the conditions of patient recruitment need to be considered carefully. We learned that a trial to investigate the effect of chiropractic treatment for PGP pain should include all subgroups of PGP to reach an acceptable sample size. (J Manipulative Physiol Ther 2019;42:601-607)

Key Indexing Terms: *Pelvic Girdle Pain; Chiropractic; Exercise Therapy; Postpartum Period*

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0161-4754

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INTRODUCTION

Pelvic pain (PP) is a common complaint during pregnancy, and the women experience moderate to severe pain affecting their daily life activities and their possibility of working.[1-4] Most often, the pain resolves and the women recover completely within 3 to 6 months after delivery.[5-7] However, it has been shown that 6% to 8% of women experiencing pelvic girdle pain (PGP) confirmed by clinical examination during pregnancy have not yet recovered 2 to 3 years later.[5,8] The women, who still have PGP 12 weeks after delivery, are suggested to be in transition to a more chronic PGP status.[7]

The etiology of PGP is multifactorial, and there is no obvious explanation for the onset of most cases of PGP. Some risk factors have been discussed, but recent studies are conflicting, and, obviously, several risk factors are at play.[1]

The effect of training and spinal manipulative therapy (SMT) on PGP during pregnancy has been investigated to some degree.[9-12] However, fewer studies on interventions for women with persistent pain have been performed.[13-15] It is necessary to identify possible effective treatment options for affected women. They experience varying degrees of disability and are prone to sick leave and to be excluded from normal work life on a permanent basis.[16,17] Also, the women being affected in their everyday life report that they feel discouraged, isolated, and lonely.[18]

In our study, we define PP as the subjective pain women report during pregnancy, whereas PGP is a diagnosis that can be reached only after a clinical examination according to the European guidelines for the diagnosis and treatment of PGP.[1]

The aim of this study was to investigate the feasibility of conducting a randomized clinical trial on the impact of adding chiropractic treatment to individual rehabilitation for women with persistent 1-sided PGP 3 to 6 months after delivery.

Design

This was a pilot randomized trial conducted in an outpatient clinic at Stavanger University Hospital, Norway and in a private chiropractic clinic in Stavanger. Women diagnosed with persistent dominating 1-sided PGP 3 to 6 months after delivery were randomized into 2 groups. Both groups received intervention: a group of women to receive individualized rehabilitation and additional chiropractic treatment, and another group of women to receive individualized rehabilitation alone. The intervention was measured for 20 weeks, and the women filled in questionnaires and underwent clinical examination at baseline and at the end of the study period.

The data from the intervention study were collected from October 2009 until May 2010. The study was in accordance with the Declaration of Helsinki, approved by the Regional Ethics Committee of Western Norway (2009/798), and registered in ClinicalTrials.gov (NCT00974103).

Study Population

The women were recruited from a previous, retrospective study of PP and low back pain (LBP) during pregnancy in an unselected sample of women who gave birth at Stavanger University Hospital, Norway from March 2009 until June 2009.[2] The day after delivery, 569 women gave their informed consent to participate in a retrospective and a prospective study. A total of 550 of these women were reached by telephone 3 to 6 months later, and then 9 women declined participating in the prospective study. Out of 330 women reporting PP during pregnancy, 68 of them reported having persistent PGP or LBP, and 63 consented to fill in a questionnaire. Forty-seven women underwent a clinical examination 3 to 6 months after delivery. During the examination, the women were diagnosed according to Albert et al's subgroups for PGP.[5] After exclusion of the women with LBP only, a total of 13 women were diagnosed with dominating 1-sided PGP. Albert et al define 1-sided sacroiliac syndrome as "daily pain from one sacroiliac joint alone, confirmed by objective findings."[5] We also included women with secondary lumbar pain because the affected women often have problems differentiating between lumbar pain and PP.

Two women then declined to participate in the intervention study, whereas 11 women were randomized into the 2 different intervention groups. A flowchart of the inclusion process is shown in Figure 1, and further details are also given in Malmqvist et al's study.[2]

Questionnaires and Clinical Examination

The day after delivery, the women completed a general questionnaire on demographic and clinical features during pregnancy, including the Norwegian versions of Oswestry Disability Index (ODI) and EuroQol-5D (EQ-5D)[19] and the numeric rating scale (NRS) for retrospective information on monthly pain intensity. At 3 to 6 months after delivery, and again after the intervention, the women completed a questionnaire on demographic features, ongoing pain, current disability, and function including the ODI, EQ-5D and Pelvic Girdle Questionnaire (PGQ).[20]

The clinical examinations at 3 to 6 months after delivery, and after intervention, were performed by a chiropractor (S.M.) at the hospital. The examinations consisted of a neurologic and orthopedic examination to rule out LBP only, disc herniation, or other related diagnoses. To evaluate sacroiliac joint pain and symphysis pain, we conducted a number of specific clinical tests recommended in the European guidelines for diagnosis and treatment of PGP, including the posterior pelvic pain provocation test (P4), Patrick's Faber test, palpation of the long dorsal sacroiliac joint ligament, Gaenslen's test, palpation of the symphysis, modified Trendelenburg test, and active straight leg raise (ASLR).[1] Subgrouping was performed according to Albert et al,[5] and women with dominating 1-sided PGP were invited to participate in the intervention study.

Intervention

The treatment group received chiropractic treatment in a private clinic in addition to individualized rehabilitation. The treatment consisted of manipulation, mobilization, soft tissue treatment, and advice chosen by the chiropractor (K.A.) to fit each woman individually. The number of consultations was decided by the chiropractor and limited to a maximum of 12 treatments during the 20 weeks of intervention.

The women in both groups were offered a maximum of 10 consultations with another chiropractor (I.K.) for

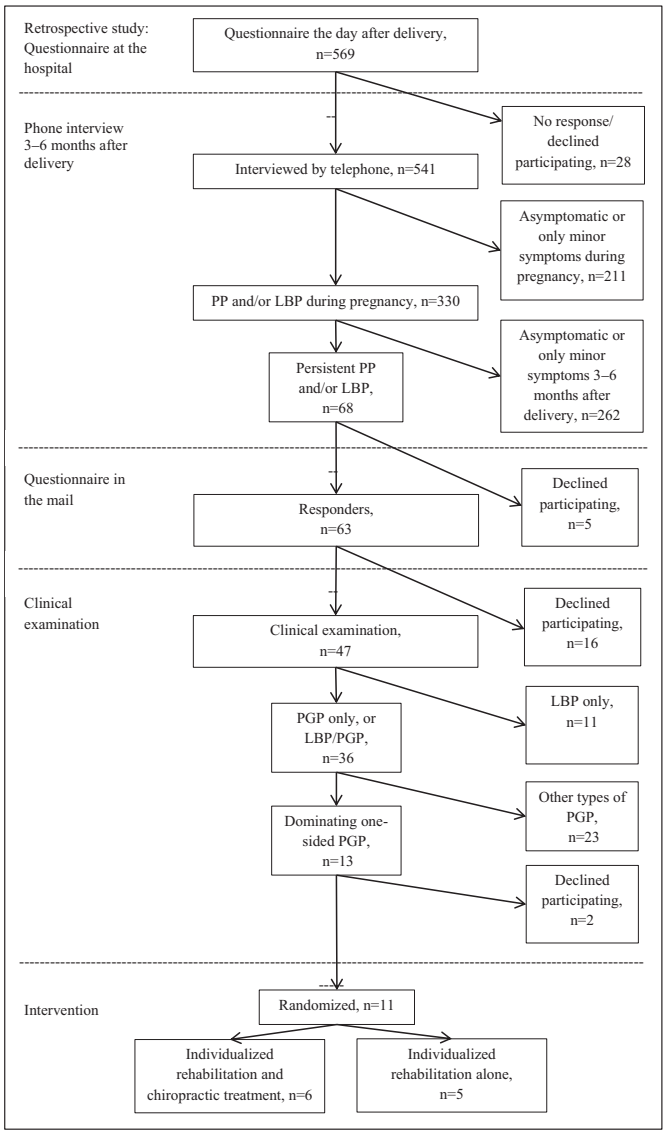

Fig 1. *Flowchart of the inclusion process into the pilot study.* LBP*, low back pain;* PGP*, pelvic girdle pain;* PP*, pelvic pain.*

rehabilitative training sessions. In addition, the women were given a program with exercises to perform at home at least 3 times per week, and they were asked to keep a training diary. All exercises were to be performed without pain. The training program was standardized and consisted of postural awareness exercises, core stability exercises, and stretching and strengthening exercises for the lower extremities. Which exercises to do and the number of

Table 1. *Demographic and Clinical Features for the 2 Groups Before and During Pregnancy*

Variables	Chiropractic and Rehabilitation Group (n = 6)	Rehabilitation Alone Group (n = 5)	Both Groups (n = 11)
Age at delivery (y), mean (SD)	31.8 (2.9)[n = 5]	31.8 (3.8)	31.8 (3.1)
Education length (y), mean (SD)	15.2 (2.3)	15.4 (1.5)	15.3 (1.9)
Workload, [a] mean (SD)	3.0 (0.6)	2.0 (1.2)	2.6 (1.0)
BMI before pregnancy, mean (SD)	23.5 (3.1)	24.6 (2.6)	24.0 (2.8)
Primiparous, n (%)	2 (33)	2 (40)	4 (36)
Depressed during pregnancy, [b] n (%)	2 (33)	2 (40)	4 (36)
Physical activity before pregnancy, [c] n (%)	5 (83)	0 (0)	5 (45)
Physical activity during pregnancy, [c] n (%)	2 (33)	0 (0)	2 (18)
LBP or PP 1 year before, n (%)	3 (50)	2 (40)	5 (45)
PP and LBP during pregnancy, n (%)	4 (67)	3 (60)	7 (64)

Treatment group received individualized rehabilitation and chiropractic treatment. Control group received individualized rehabilitation alone.
BMI, body mass index; *LBP*, low back pain; *PP*, pelvic pain; *SD*, standard deviation.
[a] Workload from (1) very light to (5) very heavy.
[b] Sometimes/often/always.
[c] At least 2 to 3 times per week.

repetitions were decided by the chiropractor to fit each woman individually. If the women improved quickly, they were given additional exercises in addition to those in the standardized diary.

Blinding

The women were randomized using closed envelopes. The envelope was handed out by the examining chiropractor (S.M.) after the first clinical examination 3 to 6 months after delivery and contained information about the allocation. Inside the envelope was a complete identification (ID) code. Women with an ID code that ended with an even number joined the treatment group, whereas women with an ID code that ended with an uneven number were enrolled in the group that received individualized rehabilitation alone. Hence, the examiner (S.M.) was blinded to which group the women belonged to at the clinical examination before and after the intervention. Additional blinding or placebo treatment was not implemented.

Outcome Measures

The primary outcome measure was disability measured by the ODI. In addition, we investigated the specific orthopedic tests ASLR and P4, pain (NRS), pelvic pain (PGQ), and quality of life (EQ-5D) as secondary outcome measures. The ASLR and P4 have been found to have high specificity and sensitivity for PGP.[1,21]

Statistics

All statistical analyses were performed in SPSS (IBM SPSS Statistics version 24) (IBM Corp, Armonk, New York). Descriptive statistics are given as means and standard deviations (SDs) and as counts and percentages. The clinical outcomes before and after the intervention are presented as means and range, mean change, and CIs.

Results

Eleven women with persistent dominating 1-sided PGP were included in the pilot study and randomized into two groups. Six women underwent individualized rehabilitation and chiropractic treatment, and five women were offered individualized rehabilitation alone. Figure 1 shows a flowchart of the inclusion process.

The women were on average 31.8 years of age, and 36% of them were primiparous. The demographic features, presented in Table 1, did not differ substantially between the 2 groups; however, more women in the chiropractic treatment group reported being physically active before and during pregnancy, compared with the group that received individualized rehabilitation alone.

Except for the results of the orthopedic tests P4 and ASLR, the clinical features differed somewhat between the 2 groups before the intervention. The chiropractic treatment group reported a higher degree of disability (ODI), more pain (NRS), more pelvic pain symptoms (PGQ), and a lower general health status (EQ-5D). Twenty weeks later,

Table 2. *Clinical Outcomes for the 2 Groups at Baseline and After Intervention*

	Chiropractic and Rehabilitation Group		Rehabilitation Alone Group	
Variables	Mean (Range)	Mean Change (95% CI)	Mean (Range)	Mean Change (95% CI)
ODI, [a] baseline	22.7 (12-36)		14.8 (4-28)	
ODI, [a] after	15.3 (0-30)	-7.3 (-21.0 to 6.3)	11.6 (4-26)	-3.2 (-16.9 to 10.5)
P4 and ASLR, [b] baseline	2 (1-3)		2 (1-3)	
P4 and ASLR, [b] after	0.5 (0-2)	-1.5 (-2.4 to -0.6)	1.4 (0-3)	-0.6 (-2.2 to 1.1)
NRS average, [c] baseline	4.5 (2-9)		2.1(0.5-4)	
NRS average, [c] after	2.3 (0-5.5)	-2.3 (-4.9 to 0.4)	1.8 (0-4)	-0.3 (-3.2 to 2.6)
PGQ, [d] baseline	35.8 (16-58.7)		22.9 (2.7-42.7)	
PGQ, [d] after	25.8 (2.7-54.7)	-10.2 (-31.1 to 11.1)	22.1 (4-58.7)	-0.8 (-27.5 to 25.9)
EQ-5D, [e] baseline	63.9 (33.7-78.3)		80.2 (76-84.1)	
EQ-5D, [e] after	61.5 (27-77.9)	-2.4 (-4.7 to -0.1)	80.1 (75.3-84.6)	-0.1 (-0.8 to 0.5)

Note. Treatment group received individualized rehabilitation and chiropractic treatment. Control group received individualized rehabilitation alone. *ASLR*, active straight leg raise; *EQ-5D*, EuroQol-5D; *NRS*, numeric rating scale; *ODI*, Oswestry Disability Index; *P4*, posterior pelvic pain provocation test; *PGQ*, Pelvic Girdle Questionnaire.

[a] ODI ranging from 0 (no disability) to 100 (maximum disability possible).

[b] Number of positive tests with possible values 0 to 4 (P4-right, P4-left, ASLR-right, ASLR-left).

[c] NRS ranging from 0 (no pain) to 100 (most pain imaginable).

[d] PGQ ranging from 0 (no disability) to 100 (maximum disability possible).

[e] EQ-5D ranging from 7 (poorest health) to 100 (full health).

both groups reported improvement in disability and pain, but not in general health status. However, the differences between the 2 groups were almost eliminated. The clinical outcomes before and after the intervention are presented in Table 2.

The women in the chiropractic treatment group received between 4 and 12 treatments, with a mean of 8 (SD 3.7), and altogether for both groups the women had between 2 and 9 consultations for individualized rehabilitation with a mean of 6 (SD 1.6).

Adverse Events

When asked at the next treatment, 3 women in the treatment group reported temporary tenderness as a result of the last treatment. No severe or serious adverse events after treatment or training were reported in the study.

Discussion

This study investigated the feasibility of conducting a randomized clinical trial on the treatment effect of individualized rehabilitation and chiropractic treatment compared with individualized rehabilitation alone, for women with persistent dominating 1-sided PGP 3 to 6 months after delivery. Both the originally low number of women with persistent dominating 1-sided PGP and the additional dropouts resulted in only 11 women participating in the intervention study. One reason for this is that persistent PGP after pregnancy is infrequent. In the original cohort study, from which we recruited patients to this intervention study, we found only 16% to have persistent PGP 3 to 6 months after delivery.[6] Moreover, dominating 1-sided PGP is a small subgroup out of 5 PGP subgroups.[5]

We believe it is important to subgroup women with PGP during and after pregnancy when investigating possible effective treatments. Women with pain in the symphysis recover faster than women with pain in all 3 pelvic joints.[5] However, because the number of women with persistent PGP is relatively low compared with the frequent experiencing of PGP during pregnancy, future studies should include all women diagnosed with persistent PGP after clinical examination. Statistical analyses should then be according to the subgroups.

Limitations

A limitation to our study is that both groups underwent interventions, and moreover, the same type of intervention: individualized rehabilitation. Randomized clinical trials are regarded the golden standard in clinical research, and additional placebo treatment could help minimize bias and maximize the validity of the results. Although an established method to perform placebo treatment in SMT

studies does not exist, Chaibi et al managed to conduct a study where they successfully included a valid placebo group in a study investigating the effect of SMT.[22] It is strongly recommended that future research establishes placebo treatment groups when planning manual therapy research projects.

No serious or long-lasting adverse events were registered after treatment or rehabilitation. A systematic review investigating adverse events from spinal manipulation in pregnancy and the postpartum period found only a few reported cases of adverse events following spinal manipulation.[23] Our study does not adhere to the Guideline for Reporting Interventions on Spinal Manipulative Therapy: Consensus on Interventions Reporting Criteria List for Spinal Manipulative Therapy.[24] These guidelines did not exist when we planned and carried out this study. Since the introduction of the 2010 Consolidated Standards of Reporting Trials guidelines, reporting of adverse events have increased. However, improved reporting is still required for all kinds and severities of adverse events.[23-25]

Conclusion

A low number of women with persistent PGP and a high dropout rate resulted in an insufficient number of women participating in the study. Future studies should include all subgroups of women with persistent PGP and should adhere to Guideline for Reporting Interventions on Spinal Manipulative Therapy: Consensus on Interventions Reporting Criteria List for Spinal Manipulative Therapy and the Consolidated Standards of Reporting Trials 2010 Statement.

Funding Sources and Conflicts of Interest

No funding sources or conflicts of interest were reported for this study.

Contributorship Information

Concept development (provided idea for the research): I.K., S.M., K.A., J.P.L., I.Ø.
Design (planned the methods to generate the results): I.K., S.M., K.A., J.P.L., I.Ø.
Supervision (provided oversight, responsible for organization and implementation, writing of the manuscript): J.P.L., I.Ø.
Data collection/processing (responsible for experiments, patient management, organization, or reporting data): I.K., S.M., K.A.
Analysis/interpretation (responsible for statistical analysis, evaluation, and presentation of the results): A.M.G., I.D.
Literature search (performed the literature search): A.M.G.
Writing (responsible for writing a substantive part of the manuscript): A.M.G., I.Ø.
Critical review (revised manuscript for intellectual content, this does not relate to spelling and grammar checking): I.D., I.K., S.M., K.A., J.P.L., I.Ø.

Practical Applications

- This study included only a limited number of women with persistent 1-sided pelvic girdle pain.
- The study did not include an adjusted statistical analysis owing to insufficient sample size.
- There were no adverse events registered in the study.

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Paper III

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RESEARCH ARTICLE Open Access

Chiropractic management of dominating one-sided pelvic girdle pain in pregnant women; a randomized controlled trial

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Abstract

Background: The aim of this study was to investigate the outcome of chiropractic management for a subgroup of pregnant women with dominating one-sided pelvic girdle pain (PGP).

Methods: The study population was recruited from a prospective longitudinal cohort study of pregnant women. Women reporting pelvic pain (PP), and who were diagnosed with dominating one-sided PGP after a clinical examination, were invited to participate in the intervention study. Recruitment took place either at 18 weeks, or after an SMS-tracking up to week 29. The women were randomized into a treatment group or a control group. The treatment group received chiropractic treatment individualized to each woman with regards to treatment modality and number of treatments. The control group was asked to return to conventional primary health care. The primary outcome measure was new occurrence of full time and/or graded sick leave due to PP and/or low back pain. Secondary outcome measures were self-reported PP, physical disability and general health status. Proportion of women reporting new occurrence of sick leave were compared using Chi squared tests. Differences in secondary outcome measures were estimated using linear regression analyses.

Results: Fifty-Six women were recruited, and 28 of them were randomized into the treatment group, and 28 into the control group. There was no statistically significant difference in sick leave, PP, disability or general health status between the two groups during pregnancy or after delivery.

Conclusion: The study did not demonstrate superiority of chiropractic management over conventional care for dominating one-sided PGP during pregnancy. However, the analyses revealed wide confidence intervals containing both positive and negative clinically relevant effects.

Trial registration: The study was registered in ClinicalTrials.gov (NCT01098136; 22/03/2010).

Keywords: Pregnancy, Manual therapy, Sick leave, Subgroups, SMS track

Background

Pelvic pain (PP) is a common complaint during pregnancy, and about 50% of pregnant women are troubled with pain in the pelvic region during pregnancy [1–3]. The pain varies in intensity and duration, and the women experience different degrees of disability [4, 5]. These complaints are a frequent cause of sick leave during pregnancy [6, 7]. Also, we found in a previous study that 16% of women with PP during pregnancy reported persistent pain that affected their daily life activities 3–6 months after delivery [8].

A large number of different terms have been used to describe PP during pregnancy, such as lumbopelvic pain, sacroiliac pain and pelvic instability [4, 5], but there are little consensus on definition and classification. Therefore, it is difficult to compare therapies, and to assess their effect on PP in pregnancy.

In Norway, most clinics in the primary health care system offer treatment for women with PP during pregnancy. Manual therapy is a common treatment modality, yet its

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evidence is limited, and the studies showing that chiropractic care during pregnancy is safe and might relieve symptoms are of low and medium quality [4, 9–11]. Moreover, a recent Cochrane review, investigating interventions for preventing and treating PP and back pain in pregnancy, found no studies of high quality to prove that spinal manipulation has a positive effect on PP [12]. The European guidelines for the diagnosis and treatment of pelvic girdle pain (PGP) also conclude that there is a need for more studies on the effect of manipulative treatment of PP during pregnancy [4].

To our knowledge, none has so far investigated the effect of chiropractic treatment on specific subgroups of PP. This is relevant because the diagnostic picture of PP is complex. By isolating subgroups of pregnancy-related PP it might be possible to differentiate the women who could favor from chiropractic treatment from those who will not.

The aim of this study was to investigate the effect of chiropractic management for a subgroup of pregnant women with dominating one-sided PGP in a randomized controlled trial (RCT).

Methods

Study design

This is a randomized controlled intervention study of pregnant women, conducted in an obstetric and chiropractic outpatient clinic at Stavanger University Hospital, Norway.

The participants were recruited from a prospective longitudinal cohort study, which investigated the incidence and the course of PGP during pregnancy, using questionnaires, clinical examination and SMS-tracking. All women admitted for the routine second-trimester ultrasound examination at Stavanger University Hospital were asked to participate in the cohort study.

Inclusion criteria for participation in the prospective cohort study were a low risk, singleton pregnancy and comprehension of the Norwegian language. At the routine ultrasound examination at 18 weeks of pregnancy, all women willing to participate in the prospective cohort study were asked to sign an informed consent, to fill in questionnaires containing demographic and clinical information. Furthermore, women reporting PP verified by pain drawings were invited to meet for a clinical examination performed by a chiropractor.

As part of the prospective cohort study, all women were followed by means of an SMS track survey [13–15]. This consisted of a question that every Sunday was sent to the participant's mobile phone, asking about the number of days with bothersome PP experienced during the last week. Those without PP at baseline were asked to meet for clinical examination if they, according to the SMS track survey, reported more than four days with PP and were still less than 29 weeks pregnant. Only women diagnosed with dominating one-sided PGP after the clinical examination were invited to participate in this RCT.

For all symptomatic women in the cohort, the examination procedure at baseline, including the questionnaire package, was repeated at 30 weeks of pregnancy and six weeks after delivery. The information collected around week 18 will be referred to as baseline data.

In this sub-study, we included the women that were diagnosed with dominating one-sided PGP after a clinical examination. The women were randomized into a treatment group or a control group.

The data were collected in the period March 2010 – December 2010, and the women were followed from inclusion around pregnancy week 18 until six weeks after delivery. The study was approved by the Regional Ethics Committee of Western Norway (no. 2010/174), adheres to the CONSORT guidelines regarding RCTs and is registered in ClinicalTrials.gov (NCT01098136; 22/03/2010).

Study population

In total, 506 women were recruited for the prospective cohort study. Out of these, 196 (39%) participants reported pain in the pelvic region at inclusion. After the clinical examination, 48 women were diagnosed with dominating one-sided PGP, and included in the intervention study. Additionally, eight women recruited from the SMS-tracking before 29 weeks´ pregnancy were diagnosed with dominating one-sided PGP and included in the study, i.e. in total 56 women were randomized into the treatment group (n = 28) or the control group (n = 28). Figure 1 shows the inclusion process into the RCT.

Questionnaires and clinical examination

At baseline, all the women answered questions regarding demographic information, sick leave, previous illnesses and treatments, current symptoms, pain location and duration, workload, possible co-morbidities, and filled in the Norwegian version of Oswestry Disability Index questionnaire (ODI), and the EQ-5D health questionnaire (EQ-5D) [8]. Intensity of PP was examined using a numeric rating scale (NRS). The women were asked to retrospectively report average PP. The characteristics of the different questionnaires are described in detail elsewhere [8].

The physical examination included a functional analysis of the lumbar spine and pelvis, and a neurological examination of the lower extremities. In addition, several specific orthopedic tests were performed. These tests are considered to have a high specificity for PGP and are recommended in the European guidelines [4]. We included posterior pelvic pain provocation test, Patrick's Faber test, palpation of the long dorsal sacroiliac ligament and Gaenslen's test. In addition, symphysis

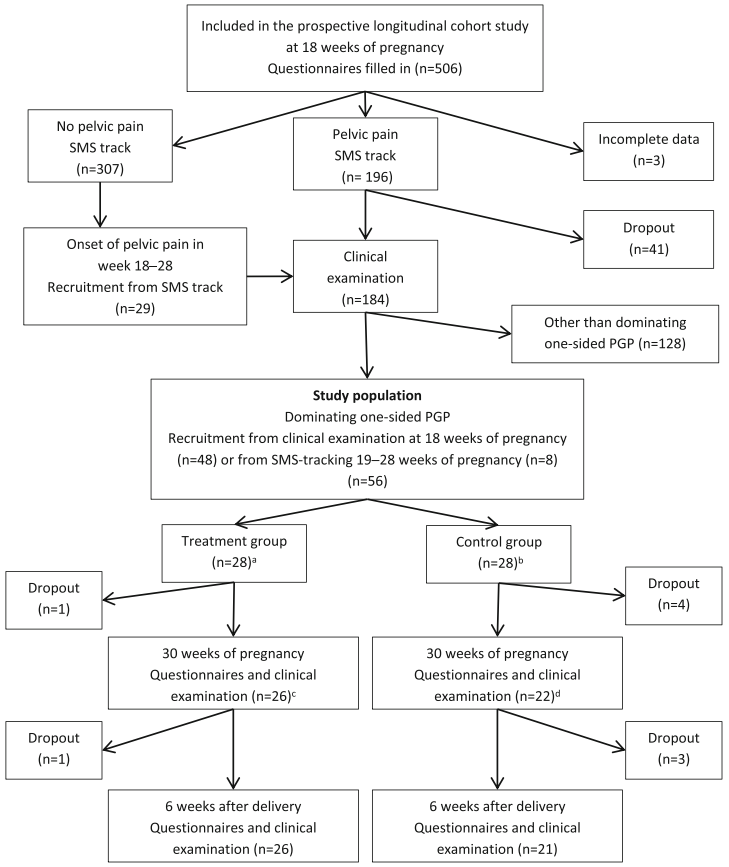

Fig. 1 Flow chart of the inclusion process into the randomized controlled trial. **a** 3 women did not meet for scheduled appointment for treatment and did not respond to several attempts of contact. They were included in the intention-to- treat analyses, but excluded from per-protocol subanalyses. **b** 7 women underwent chiropractic treatment as conventional care. They were included in the control group in the intention-to-treat analyses but excluded in the per protocol subanalyses. **c** 1 missing observation. The woman did not fill in questionnaires nor meet for clinical examination at 30 weeks of pregnancy, but returned to the study six weeks after delivery. **d** 2 missing observations. The women woman did not fill in questionnaires nor meet for clinical examination at 30 weeks of pregnancy, but returned to the study six weeks after delivery

pain was assessed using palpation of the symphysis and modified Trendelenburg test of the pelvic girdle. Active straight leg raise was also performed as a functional pelvic test. A PGP diagnosis was achieved if the women reported pain in the vicinity of the pelvic joints, and had reproducible pain after one of the specific pain provocation tests listed above, and if a lumbar cause of pain were excluded. Women with a one-sided positive posterior pelvic pain provocation test, a bilateral negative Lasègue test, and a pain drawing indicating one-sided pelvic symptoms were considered to have dominating one-sided PGP.

Intervention

The women were randomized into a treatment group or a control group, using a closed envelope. The envelope contained a complete ID-code, and was handed out after the first clinical examination. Women with an ID-code that ended with an even number were asked to join the intervention group, whereas women with and ID-code that ended with an uneven number were asked to return to conventional health care. The examiner was blinded for which group the women belonged to at the clinical examinations. Additional blinding or sham treatment (placebo) was not implemented.

For the treatment group, the intervention consisted of manipulation, mobilization, soft tissue treatment, exercises, and advices chosen by the chiropractor to fit each participant individually. The frequency and number of visits were also determined by the chiropractor. The chiropractic treatment was conducted in two different private clinics, by five different chiropractors. The chiropractors were randomly chosen, and willing to contribute to the study. They were experienced generalists, not specialized in treatment of pregnant women and were given information about the study in order to keep to the protocol.

The women in the control group were asked to return to conventional primary health care without any restrictions or recommendations.

Outcome measures

The primary outcome measure was new occurrence of full time and/or graded sick leave due to PP and/or low back pain (LBP), in the periods 19 – 30 weeks and 31 – 36 weeks of pregnancy, among the women who did not report sick leave for any reason in week 1 – 18. In Norway, working women are offered maternity leave paid by the Norwegian Labour and Welfare Service (NAV), starting at 37 completed pregnancy weeks.

Secondary outcome measures were self-reported pain intensity, as an average of the periodical NRS scores, physical disability as measured by the ODI questionnaire and general health as measured by the EQ-5D questionnaire.

Statistical analysis

Three of the 28 women (11%) that were randomized into the treatment group did not meet for treatment. In the control group, seven women (25%) reported having chiropractic treatment as part of conventional care. Because of this, we conducted two types of analyses, an intention-to-treat analysis and a per-protocol analysis. Overall, results from the per-protocol analysis did not differ substantially from those from the intention-to-treat analysis, and therefore only the intention-to-treat results are presented.

All statistical analyses were performed in SPSS (PASW Statistics 21). Descriptive statistics are given as means and standard deviations (SDs), and as counts and percentages. Proportion of women reporting new occurrence of sick leave in the treatment and the control group were compared using Chi squared tests. Relative risks with 95% CIs were estimated using the online statistical calculator at http://vassarstats.net/odds2x2.html. For the secondary outcomes, treatment effects were estimated using linear regression analysis, including the respective baseline measurements as covariates. In the next instance, possible confounders that were not satisfactorily balanced at baseline, i.e., exercise before and during pregnancy and PP one year before pregnancy (Table 1), were included in the models.

Results

Out of the 28 women in the treatment group, 25 received chiropractic treatment. On average, they started treatment at week 23.1 (SD 2.1) and completed treatment at week 36.6 (SD 5.0). In total, they received

Table 1 Demographic and clinical features for the treatment and control group at baseline. Given as counts (%) unless otherwise stated

	Treatment group $n = 28$	Control group $n = 28$
Age at inclusion (years), mean (SD)	28.9 (4.5)	29.9 (4.8)
Age ≥ 30	13 of 28 (46)	14 of 28 (50)
Primiparous	16 of 26 (62)	15 of 27 (56)
Education length (years)[a], mean (SD)	14.7 (4.0)	14.8 (3.1)
More than 12 y education baseline	21 of 27 (78)	21 of 25 (84)
Heavy workload baseline	6 of 28 (21)	6 of 28 (21)
BMI before pregnancy, mean (SD)	23.4 (3.1)	24.2 (4.0)
Depressed in pregnancy	1 of 27 (4)	1 of 28 (4)
Exercise before pregnancy	5 of 26 (19)	12 of 27 (44)
Exercise in early pregnancy (week 1 to18)	2 of 27 (7)	5 of 27 (19)
PP one year before pregnancy	9 of 27 (33)	4 of 27 (15)
PP and LBP in early pregnancy (week 1 to 18)	22 of 26 (85)	22 of 27 (82)
Sick leave in early pregnancy[b] (week 1 to 18)	6 of 28 (21)	3 of 28 (11)

SD standard deviation BMI body mass index PP pelvic pain LBP low back pain
[a]n for education length is 27 and 25 for treatment and control group, respectively
[b]Only sick leave due to PGP and/or LBP

between three and 15 treatments, with a mean of 10.3 (SD 3.6). The women received high-velocity, low-amplitude manipulative therapy to the lumbar spine and the sacroiliac joints, except for one, who underwent mobilization therapy that included low-velocity, passive movement within or at the limit of joint range. All participants had soft-tissue therapy, and 17 women also received information and a program on how to perform exercises at home.

Demographic information and clinical features for the treatment group and the control group are presented in Table 1. There were some baseline imbalances: the treatment group exercised less before and during pregnancy, and reported more PP one year before pregnancy, compared with the control group.

Table 2 shows the primary outcome measure, reported as new occurrence of sick leave in the periods 19 – 30 and 31 – 36 weeks. There was no statistically significant difference between the two groups. The treatment group reported 33% and 38% new occurrence of sick leave in the two periods, compared with 38% and 53% in the control group. The relative risk for new sick leave was 0.88 (95% CI, 0.39– 1.98) at 19 – 30 weeks, and 0.72 (95% CI, 0.36 – 1.45) at 31 – 36 weeks.

Secondary outcome measures and estimated effect of treatment are presented in Table 3. Both groups reported increased pain intensity at the follow-up visit during pregnancy, compared with PP at baseline. Adjusting for baseline pain, the treatment group reported somewhat lower PP in week 21 – 30 and week 33 – 40, compared with the control group. Oppositely, 0 – 6 weeks after delivery, the treatment group reported more pain than the control group. However, none of these differences were statistically significant.

The reported disability was comparable for the two groups. Both groups reported a high degree of disability at 30 weeks and only minor disability at six weeks after delivery. The treatment group reported a worsened health status at 30 weeks, whereas the control group did not. Six weeks after delivery both groups reported an improved general health status.

Linear regression analysis with adjustment for the respective baseline measures showed no statistically significant difference between the two groups in any of the outcome measures, as shown in Table 3. Also, adjusting for the baseline imbalances in PP one year before pregnancy, and exercise before pregnancy and in early pregnancy (1 – 18 weeks), did not affect the conclusions. See Table 4.

Another observation from these regression analyses was that pain score reported at baseline was a predictor for pain in later pregnancy (week 21 – 30: $R^2 = 0.14$, $p = 0.009$; week 33 – 40: $R^2 = 0.12$, $p = 0.020$), but not for pain reported six weeks after delivery ($R^2 = 0.03$, $p = 0.30$). The strongest associations were seen for disability, for which the baseline ODI score explained half of the variance in ODI, both at pregnancy week 30 ($R^2 = 0.50$, $p < 0.001$), and at six weeks after delivery ($R^2 = 0.50$, $p < 0.001$). Also for general health, the baseline measure was associated the same measure at 30 weeks of pregnancy ($R^2 = 0.24$, $p = 0.001$), and at six weeks after delivery ($R^2 = 0.12$, $p = 0.022$).

At the next follow-up consultation, the women were asked to recall any negative reactions, however, no serious or long-lasting adverse events was registered.

Discussion

The aim of this study was to investigate the effect of chiropractic treatment for a subgroup of pregnant women with dominating one-sided PGP. We found no statistically significant difference in sick leave, pain, disability or general health status between the treatment group and the control group during pregnancy or after delivery.

There is limited research on the natural course of PGP during pregnancy. Typically, PGP begins by the end of the first trimester and reaches peak intensity between pregnancy week 24 and 36 [1, 2, 5, 16]. After delivery, the PGP resolves within three months in most cases [2, 4, 8, 16, 17]. This is in line with our findings, as both the treatment and the control group had worsening of symptoms from week 18 and onwards, and they reported less pain and disability and a better general health status six weeks after delivery.

Previous studies [4, 9, 11], including the latest Cochrane review on interventions for preventing and treating low-back and pelvic pain during pregnancy [12], have shown limited evidence for the effect of manipulative therapy for PP during pregnancy. There is some evidence that spinal manipulation improves pain and functioning in patients with chronic LBP [18], however, these results cannot be immediately transferred to apply for pregnant women, due to inherent biomechanical, physiological and hormonal changes.

Table 2 New occurrence of sick leave due to PGP and/or LBP disregarded sick leave at baseline, and estimated effect of treatment

	Treatment group	Control group	RR	95%CI	*p*
Week 19 – 30, n (%)	7/21 (33)	8/21 (38)	0.88	0.39 – 1.98	0.75
Week 31 – 36, n (%)	8/21 (38)	10/19 (53)	0.72	0.36 – 1.45	0.36

RR relative risk, *CI* confidence interval

Table 3 Estimated means of secondary outcome measures and estimated effect of treatment

	Treatment group Mean	95% CI	Control group Mean	95%CI	Mean difference[a] β	95% CI	*p*
Pain intensity[b], week 1 – 18	17.4 $^{n=26}$	10.1 – 24.7	20.0 $^{n=28}$	13.6 – 26.4			
Pain intensity[b], week 21 – 30	42.7 $^{n=25}$	33.5 – 51.8	46.4 $^{n=21}$	37.3 – 55.6	−3.3	−15.1 – 8.5	0.58
Pain intensity[b], week 33 – 40	40.3 $^{n=24}$	27.9 – 52.8	44.2 $^{n=21}$	29.8 – 58.5	−1.6	−19.4 – 16.3	0.86
Pain intensity[b], week 1 – 6 after delivery	19.1 $^{n=24}$	10.0 – 28.2	12.8 $^{n=21}$	3.8 – 21.8	7.8	−4.9 – 20.4	0.22
ODI[c], week 18	22.8 $^{n=26}$	17.6 – 28.1	21.5 $^{n=26}$	17.0 – 26.0			
ODI[c], week 30	29.7 $^{n=25}$	22.1 – 37.2	27.1 $^{n=21}$	21.0 – 33.2	−0.9	−8.3 – 6.4	0.80
ODI[c], 6 weeks after delivery	9.7 $^{n=25}$	4.3 – 15.1	7.1 $^{n=20}$	3.2 – 10.9	0.3	−4.9 – 5.4	0.92
EQ-5D[d], week 18	64.9 $^{n=28}$	59.2 – 70.7	62.0 $^{n=26}$	55.3 – 68.6			
EQ-5D[d], week 30	58.3 $^{n=26}$	48.9 – 67.7	62.0 $^{n=21}$	54.6 – 69.5	−3.3	−14.5 – 7.9	0.56
EQ-5D[d], 6 weeks after delivery	84.7 $^{n=25}$	77.8 – 91.6	86.8 $^{n=20}$	78.6 – 95.1	−0.8	−11.1 – 9.4	0.87

[a]Results from linear regression, adjusting for the relevant outcome measured at baseline
[b]Pain intensity (numerical rating scale) with possible values 0 to 100, where 0 represents no pain and 100 represents most pain imaginable
[c]Oswestry disability index with possible values 0 to 100, where 0 represents no disability and 100 represents maximum disability possible
[d]Eurocol-5D with possible values −7 to 100, where −7 represents poorest health and 100 represents full health
CI confidence interval, *ODI* Oswestry disability index, *EQ-5D* Eurocol-5D

Chiropractic treatment aims at manipulation and joint mobilization; however, the uncertain etiology is reflected in the variety of offered treatments. Adverse events following spinal manipulation during pregnancy are found to be relatively rare [10]. Nevertheless, treatment should not be performed over a longer period of time unless there is a positive response. This is in compliance with the recommendation that manipulation and joint mobilization may be used for symptomatic relief, but should only be applied for a few treatments [4].

This study represents a new approach to investigate the effect of chiropractic treatment, by including only a specific subgroup of PGP. Albert et al. have proposed that PGP could be divided into five subgroups, and they found that women with pain in all three pelvic joints had the worst prognosis regarding development of long term pain, whereas women with isolated symphysiolysis recovered shortly after delivery [17]. To our knowledge, no previous intervention study has been carried out on pregnant women with dominating one-sided PGP.

Pain in the pelvic region is affecting around 50% of all pregnant women, resulting in various degrees of disability and frequent sick leave [2, 4–7]. In a qualitative study from Sweden, it is emphasized that improved treatment of PGP is of importance to increase the quality of life of pregnant women [19]. In our study, 25% of the women in the control group underwent chiropractic treatment as part of conventional care, indicating a wish for some kind of therapy. It is possible that the women in the control group had been biased by the information about the study and therefore wanted to try chiropractic treatment for their PP.

There are several limitations in this study. Unfortunately, we managed to include a relative low number of women into the clinical trial, despite a substantial number of women were recruited to participate in the

Table 4 Estimated effect of treatment adjusted for baseline imbalances[a]

	Mean Difference[b] β	95%CI	*p*
Pain intensity[c], week 21 – 30	−0.4	−13.1 – 12.4	0.95
Pain intensity[c], week 33 – 40	−2.7	−23.0 – 17.6	0.79
Pain intensity[c], week 1 – 6 after delivery	5.4	−8.5 – 19.2	0.44
ODI[d], week 30	−1.2	−9.2 – 6.8	0.76
ODI[d], 6 weeks after delivery	−0.1	−5.3 – 5.2	0.97
EQ-5D[e], week 30	−2.7	−16.3 – 10.9	0.69
EQ-5D[e], 6 weeks after delivery	−1.3	−12.8 – 10.1	0.81

CI confidence interval ODI Oswestry disability index EQ-5D Eurocol-5D
[a]PP one year before pregnancy and exercise before and in early pregnancy
[b]Results from linear regression, adjusting for the relevant outcome measured at baseline
[c]Pain intensity (numerical rating scale) with possible values 0 to 100, where 0 represents no pain and 100 represents unbearable
[d]Oswestry disability index with possible values 0 to 100, where 0 represents no disability and 100 represents maximum disability possible
[e]Eurocol-5D with possible values −7 to 100, where −7 represents poorest health and 100 represents full health

prospective cohort study. As a result, the confidence intervals are wide, containing both positive and negative clinically relevant effects. With a larger cohort we would probably get a clearer result. There were a relative high number of dropouts in the control group and seven women in the control group underwent chiropractic treatment as part of conventional care. Also, three women randomized to the treatment group did not meet for treatment. Additional analyses to correct for non-compliance did not substantially change the results.

Blinding or sham treatment was not performed. So far, an established method for blinding in studies where spinal manipulation is used does not, to our knowledge, exist [20]. A placebo or a specific alternative treatment for the control group might have prevented women in the control group from dropping out or seeking chiropractic care.

The chiropractors were told to perform necessary treatment to fit each patient individually. This can be considered to be a limitation to our study, and is diverging from the Guideline for Reporting Interventions on Spinal Manipulative Therapy [21]. However, the design of our intervention is equivalent to the treatment a woman would receive, consulting a random chiropractor for PGP during pregnancy.

Registration of adverse events following treatments were of poor quality in our study. The women were asked if they had experienced any side-effects or negative reactions at the next consultation. This retrospective reporting could lead to missed incidents. In general, the quality of evidence of adverse events following manipulative treatment is poor, and future studies should track possible adverse events throughout the study.

The information on sick leave was self-reported and retrospective, and this could result in a bias with respect to the reasons for, and duration of sick leave. Sick leave due to PGP and/or LBP was chosen to be our primary outcome measure because it represents a rather robust and easily measurable endpoint. Also, sick leave may indicate the level of pain experienced by these women, as well as the expense for the society. We intended to address sick leave caused by PGP and/or LBP only, but in many cases several different reasons for sick leave were reported. Nausea and fatigue are prominent disorders in the first trimester, and it seems that many women never return to work after having been on sick leave for some weeks. Because of this, we chose to exclude women on sick leave in week 1 – 18 when analyzing our primary outcome.

It is a strength to our study that we conducted a randomization process, enabling us to evaluate treatment results, as randomized studies have been particularly asked for in review articles when different PGP-treatments have been assessed [9, 11]. We believe that focusing on a specific subgroup of PGP is a strength to this study. Also, the RCT originates from a large prospective longitudinal study with follow-up during pregnancy and after delivery.

Conclusions

In conclusion, we found no find statistically significant difference between the treatment and the control group in any of the outcome measures. The confidence intervals are wide, containing both positive and negative clinically relevant effects. Further studies on the effect of chiropractic management for specific subgroups of PGP are needed.

Abbreviations

EQ-5 D: Eurocol-5D; LBP: low back pain; NRS: numeric rating scale; ODI : Oswestry Disability Index; PGP: pelvic girdle pain; PP: pelvic pain; RCT: randomized controlled trial; SD: standard deviation

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Availability of data and materials

The datasets supporting the conclusions of this article are available in the The Norwegian Centre for Movement Disorders repository, www.sus.no, email: nkb@sus.no.

Authors' contributions

SM, IK, JPL, KA and IØ planned and designed the study. SM and IK performed all the physical examinations. KA participated in the treatment of the women. AMG conducted the statistical analyses with help from ID, and AMG drafted the manuscript together with ID, JPL and IØ. All authors have read and approved the final manuscript.

Ethics approval and consent to participate

The women signed an informed consent prior to participation in the study. The study was approved by the Regional Ethics Committee of Northern Norway (no. 2010/174).

Competing interests

The authors declare that they have no competing interests.

Publisher's Note

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Paper IV

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ORIGINAL ARTICLE

Subjective recovery from pregnancy-related pelvic girdle pain the first 6 weeks after delivery: a prospective longitudinal cohort study

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Abstract

Purpose The purpose of this study was to investigate the subjective recovery from pregnancy-related pelvic girdle pain (PGP) during the first 6 weeks after delivery and to detect possible risk factors for a poor recovery.

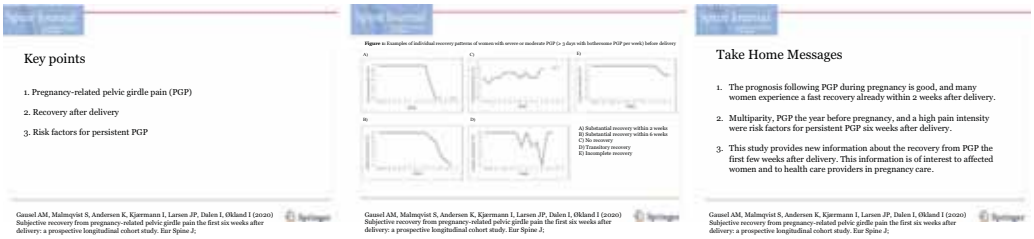
Methods The participants were included in this study at the routine ultrasound examination at 18 weeks of pregnancy. The women received a weekly SMS with the question "How many days during the last week has your PGP been bothersome?" The SMS-track from the final 10 weeks of pregnancy and first 6 weeks after delivery were assessed and sorted, based on individual graphs. A total of 130 women who reported PGP during pregnancy and met for clinical examination 6 weeks after delivery were included in the study.

Results In all, 83% of the women experienced substantial recovery from severe or moderate PGP within 6 weeks after delivery. Of these, 44% reported a substantial recovery already within 2 weeks after delivery. More multiparous women, women reporting PGP the year before pregnancy, and women with high pain intensity during pregnancy had a poor recovery.

Conclusions The prognosis following PGP in pregnancy is good and the majority of women recovered substantially from severe and moderate pregnancy-related PGP within 6 weeks after delivery. For many women, a subjective substantial recovery occurred within 2 weeks after delivery. Predictors for a poor recovery were multiparity, PGP the year before pregnancy and a high pain intensity during pregnancy.

Graphic abstract

These slides can be retrieved under Electronic Supplementary Material.



Keywords Pelvic girdle pain · Pregnancy · Persistent · Recovery · Risk factors

Introduction

Musculoskeletal pelvic girdle pain (PGP) during pregnancy is a common condition [1–3]. The exact prevalence is difficult to assess due to inconsistent definitions of PGP and the lack of clinical testing. Depending on the

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definition, the prevalence of pain in the lumbopelvic area during pregnancy ranges from 4−90% in various studies. This indicates many different ways to measure and define this condition [4–6].

The European guidelines for the diagnosis and treatment of PGP from 2008 define PGP as "pain experienced between the posterior iliac crest and the gluteal fold, particularly in the vicinity of the sacroiliac joints. The pain may radiate in the posterior thigh and can also occur in conjunction with/or separately in the symphysis. The endurance for standing, walking, and sitting is diminished" [5]. Although the guidelines exclude lumbar causes of pain for the PGP diagnosis, many pregnant women experience low back pain (LBP), exclusively or in addition to pain in the pelvic area. The consequences of PGP vary, from only minor pain and disability to severe pain, disability, reduced quality of life and absence from work. Overall, the etiology of PGP is poorly understood, and so are the reasons why some women recover and some women do not.

Although most women recover from PGP within 6 months after delivery [7–9], some women experience years of intermittent or persistent PGP affecting their daily life activities, ability to work and quality of life [10–15]. We have previously shown that 16% of women reporting musculoskeletal pelvic pain (PP) during pregnancy were found to have persistent PGP 3−6 months after delivery, and that the risk factors for persistent pain were age 30 years and above, both PP and LBP during pregnancy, and moderate or high disability measured by Oswestry Disability Index (ODI) during pregnancy [16].

Researchers have investigated the recovery from PGP one or several months after delivery, but to our knowledge, there are no studies investigating the subjective recovery from PGP the very first weeks after delivery. Moreover, women with persistent PGP after birth want more information about the course of PGP and the factors influencing recovery [11]. Women with recurrent or continuous PGP after delivery have increased risk of future sick leave and disability [10, 14].

The use of automated text messaging and mobile phones has previously been used to describe recovery patterns [17], and short message service (SMS) is a low-key method that requires little effort from the participants. Also, most people check their mobile phones regularly, which limits memory decay. Women who have just given birth are in a stressful situation, and to answer an SMS may be more feasible than to fill in a traditional questionnaire, answer a phone call, or to meet for an interview or a clinical examination.

The aim of this study was, by means of a weekly SMS question, to investigate the subjective recovery from pregnancy-related PGP the first 6 weeks after delivery and to detect possible risk factors for a poor recovery.

Methods

Study design and study population

This is an SMS-based, prospective, longitudinal cohort study of women during the final 10 weeks of pregnancy and the first 6 weeks after delivery. The women were included in the study at the routine ultrasound examination at 18 weeks of pregnancy at Stavanger University Hospital, Norway, from March to June 2010 [18].

Inclusion criteria were a low-risk singleton pregnancy and comprehension of the Norwegian language. All women, both symptomatic and asymptomatic, were asked to sign an informed consent. They were followed from pregnancy week 18 until 6 weeks after delivery with weekly, automated text messages (SMS-track). Women that reported pain in the pelvic area at or beyond 18 weeks were invited to undergo a clinical examination and fill in questionnaires at 18 and 30 weeks of pregnancy, and 6 weeks after the ultrasound estimated date of delivery (EDD).

The prospective longitudinal cohort study recruited 506 symptomatic and asymptomatic women at 18 weeks of pregnancy. In this substudy, we included the symptomatic women who reported PGP and who met for the clinical examination 6 weeks ($n = 130$) after delivery. To be able to sort the SMS data into pre- and post-delivery, the actual date of delivery was registered at the clinical examination 6 weeks after EDD.

Questionnaires

At 18 weeks of pregnancy, all women filled in a questionnaire on demographic information. In addition, the women reporting pain in the pelvic area answered questionnaires on previous illnesses and treatments, workload, possible comorbidities, current symptoms, pain location, duration of pain and sick leave. The intensity of PGP was retrospectively reported using a numeric rating scale (NRS) where the women were asked to report the average level of PGP in the previous trimester. In this study, the scale ranged from 0 to 100, and score 0 was described as "No pain" and 100 as "Unbearable pain." The questionnaires with information on current symptoms, pain location, duration of pain and sick leave were repeated at 30 weeks of pregnancy and 6 weeks after delivery.

SMS-track

Every Sunday, the women were asked in an SMS: "How many days during the last week has your pelvic pain been bothersome?" If there was no reply, the question was

repeated 24 h later. The question should be answered with one single number between 0 and 7, and the response was automatically entered into a database, where continuous information from each woman was saved.

Analyses of data

The SMS-track from 10 randomly selected women was assessed by two of the authors. The individual pain patterns were visualized in graphs, including the final 10 weeks of pregnancy and the first 6 weeks after delivery. From a clinical perspective, a first proposal for grouping was agreed on. Then, three authors individually investigated and sorted the pain patterns into the different groups. The 120 different graphs were assessed by these authors together, resulting in a revised set of subgroups. A new assessment was then done individually, blinded to the initial decisions. Thereafter, in a final meeting, a consensus for all 120 graphs was reached. The subgroups are defined and presented in Box 1, and examples of individual pain patterns are given in Fig. 1.

Proportions of women with substantial recovery and women with either no, transitory, or incomplete recovery are presented as percentages and 95% confidence intervals (CI), estimated using the online statistical calculator at http:vassarstats.net. Demographic and clinical features are given as means and standard deviations (SDs), and as counts and percentages. Women with substantial recovery were compared with women with either no, transitory, or incomplete recovery, using independent samples *t* test for continuous data, and Chi-squared test for proportions. A generalized estimating equations (GEE) analysis was used for an overall comparison of pain intensity (NRS) between women with substantial recovery and women with a poor recovery throughout the whole pregnancy. A p value ≤ 0.05 was considered statistically significant, and statistical analyses were performed in IBM SPSS Statistics Version 24.

Results

In all, 130 women met for the clinical examination 6 weeks after EDD. However, 10 women lacked information on when the SMS-track started, resulting in 120 women eligible for further assessment. Seventy-six women reported a high number of days (≥ 5) with bothersome PGP per week before delivery and were categorized as having severe PGP; see Table 1. Another 18 women reported on average ≥ 3 days per week of bothersome PGP, and were categorized with moderate PGP.

In all, 21 women had on average less than 3 days of bothersome PGP per week the final 10 weeks before delivery. Another five women did not respond, or responded irregularly, to the weekly SMS before delivery, and were categorized as missing. These 26 women are not included in the statistical analyses.

The response rate to the SMS question was on average 89% the final 10 weeks before delivery. After delivery, the response rate dropped week by week from 71% (week 1) to 43% (week 6) (Fig. 2).

Of the 94 women with severe or moderate PGP before delivery, we had valid information after delivery on 76 women. 83% (63 of 76) (95% CI 73–90%) reported a substantial recovery from PGP after delivery. Of these, 44% (28 of 63) (95% CI 33–57%) responded with 0 days of bothersome PGP per week within 2 weeks after delivery. The remaining had a slower or more intermittent recovery pattern, but reached our definition of substantial recovery from PGP within 6 weeks after delivery.

Demographic and clinical features for the women with substantial recovery ($n = 63$) and women with either no, transitory, or incomplete recovery ($n = 13$) are shown in Table 2. For most variables, there was no statistically significant difference between the two groups. More than

Box 1 Subgrouping before and after delivery

Before delivery (10 weeks)	After delivery (6 weeks)
Severe PGP	Substantial recovery
Persistent 6 or 7 days with bothersome PGP per week. Included in this group was also women with increasing number of days the last 3 weeks before delivery (average ≥ 5 days), and women with decreasing number of days the last 3 weeks before delivery	0, 1, or 2 days with bothersome PGP per week within the first 6 weeks after delivery. If 0 was never reported, 1 or 2 days with bothersome PGP had to be registered twice within 6 weeks
Moderate PGP	Poor recovery
Intermittent or moderate number of days with bothersome PGP per week, average ≥ 3 days	*No or transitory recovery* No reduction or initial decrease in number of days, but before week 6 increasing number of days with bothersome PGP per week
No or mild PGP	*Incomplete recovery*
Average < 3 days of bothersome PGP per week before delivery	Reduction in number of days with bothersome PGP per week, but not full recovery
Missing data	Missing data
Not possible to classify due to completely or partially missing data	Not possible to classify due to completely or partially missing data

PGP pelvic girdle pain

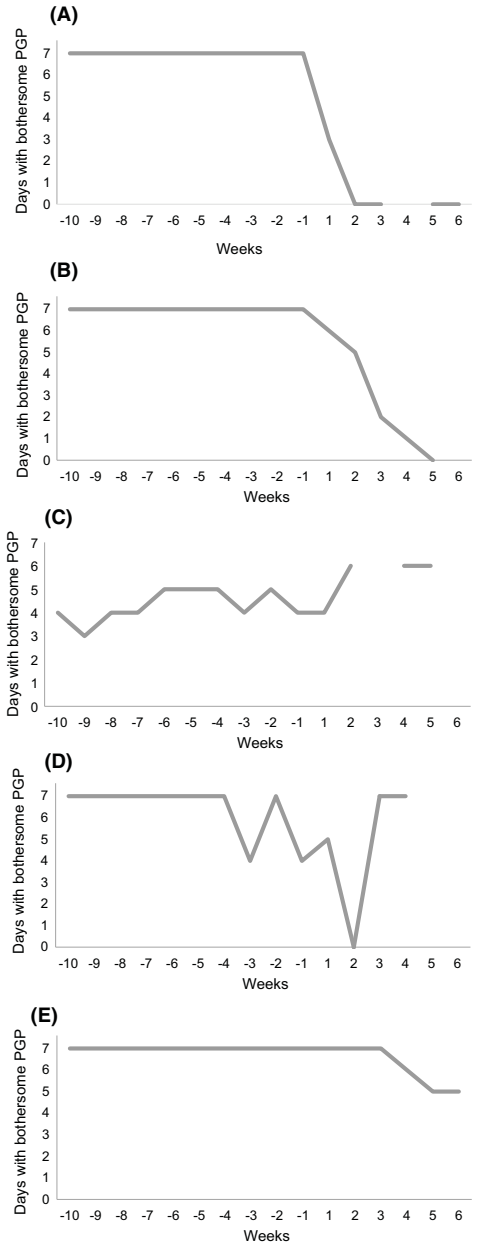

Fig. 1 Examples of individual recovery patterns of women with severe or moderate PGP (≥3 days with bothersome PGP per week) before delivery. **a** Substantial recovery within 2 weeks. **b** Substantial recovery within 6 weeks. **c** Norecovery. **d** Transitory recovery. **E** Incomplete recovery

Table 1 Overview of women in categories after delivery by categories before delivery, excluding women with inadequate SMS-track and women with mild or no PGP before delivery

	Severe PGP before delivery	Moderate PGP before delivery
Total, *n*	76	18
Substantial improvement, *n* (%)	49 (65)	14 (78)
No or transitory recovery, *n* (%)	4 (5)	1 (6)
Incomplete recovery, *n* (%)	6 (8)	2 (11)
Missing, *n* (%)	17 (22)	1 (6)

PGP pelvic girdle pain

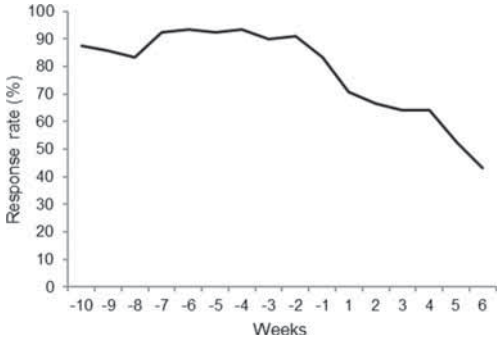

Fig. 2 Response rate to the weekly SMS question

50% of the women were 30 years or older at inclusion in the study, and the majority of women had more than 12 years of education. More women in the substantial recovery group were primiparous, 37% versus 8% in the poor recovery group, and 1 out of 4 women had experienced depression in the beginning of pregnancy or before 30 weeks of pregnancy. Before pregnancy, 1 out of 4 women exercised regularly, but once pregnant, the number of women dropped to 0−10%. Many women had experienced PGP in previous pregnancies and the majority of women (85%) reported having LBP in addition to PGP.

Two variables were statistically significantly different between the two groups. First, more multiparous women experienced no, transitory, or incomplete recovery compared with primiparous women ($p = 0.042$). Second, women who reported PGP the year before pregnancy were found to have insufficient recovery compared with women who reported no PGP the year before ($p = 0.047$).

Figure 3 shows the retrospectively reported pain intensity due to PGP, as reported in questionnaires at 18 and 30 weeks of pregnancy and 6 weeks after delivery. Women with either no, transitory, or incomplete recovery reported

Table 2 Demographic and clinical features among women with substantial recovery ($n=63$), and women with no, transitory, or incomplete recovery ($n=13$)

Variables	Substantial recovery ($n=63$)	Poor recovery ($n=13$)	p
Age at 18 weeks of pregnancy, years	30.4 (4.7)	32.1 (4.6)	0.24
Age ≥ 30 years, *n* (%)	35 (56)	8 (62)	0.69
Education length, years	14.9 (2.7)$^{n=61}$	15.4 (1.9)	0.48
More than 12 years education, *n* (%)	53 (84)	13 (100)	0.17
Heavy workload[a], *n* (%)	16 (25)	2 (15)	0.44
BMI before pregnancy	24.9 (5.4)	22.9 (3.8)	0.22
BMI at 18 weeks of pregnancy	26.4 (4.6)$^{n=61}$	24.9 (4.1)	0.28
Primiparous, *n* (%)	23 (37)	1 (8)	0.042
Depressed during pregnancy up to 18 weeks[b], *n* (%)	14 (23)$^{n=61}$	3 (23)	0.99
Depressed during pregnancy up to 30 weeks[b], *n* (%)	14 (26)$^{n=53}$	3 (23)	0.81
Exercise before pregnancy[c], *n* (%)	15 (25)$^{n=60}$	2 (23)	0.88
Exercise in pregnancy up to 18 weeks[c], *n* (%)	6 (10)$^{n=61}$	0 (0)	0.24
Exercise in pregnancy up to 30 weeks[c], *n* (%)	5 (10)$^{n=51}$	1 (8)	0.82
PGP in previous pregnancies, *n* (%)	29 (58)$^{n=50}$	9 (75)$^{n=12}$	0.28
PGP in the year before pregnancy, *n* (%)	12 (20)	6 (46)	0.047
PGP and LBP in pregnancy up to 18 weeks, *n* (%)	52 (84)$^{n=62}$	11 (85)	0.95
Pregnancy length at delivery, weeks			
Mode of delivery			0.26
Spontaneous vaginal delivery	41 (68)$^{n=60}$	9 (75)$^{n=12}$	
Operative vaginal delivery (forceps or vacuum)	9 (15)$^{n=60}$	3 (25)$^{n=12}$	
Cesarean section	10 (17)$^{n=60}$	0 (0)$^{n=12}$	

The number of available women is indicated for the variables where data is missing. The results are given as means (SD) and counts (percentages)

SD standard deviation, *BMI* body mass index, *LBP* low back pain

[a]Quite/very heavy work

[b]Depressed: sometimes, often, always

[c]At least 2–3 times per week

overall statistically significant higher pain intensity throughout the whole pregnancy ($p=0.026$).

Discussion

In this study, 83% of the women that reported severe or moderate PGP during the final 10 weeks before delivery experienced a substantial recovery within 6 weeks after delivery. Of these, 44% reported 0 days of bothersome PGP per week already within 2 weeks after delivery. Risk factors for a poor recovery were found to be multiparity and PGP the year before pregnancy. Also, women reporting a high pain intensity for PGP on the NRS scale during pregnancy experienced a poor recovery.

To our knowledge, this is the first study to investigate pregnancy-related PGP week by week before and after delivery. Other studies investigating persistent PGP have collected data several weeks, months, or years after delivery. Our data support the findings of Albert et al. [7], where the majority of women experienced recovery from PGP within 1 month after delivery. In addition, we find that for many women a full recovery occurs within 2 weeks after giving birth.

The SMS question investigates number of bothersome days with PGP. Dunn et al. [19] studied the concept bothersome, and they found that a single bothersomeness question was a valid measure of LBP severity, as it correlates with pain, disability, and psychological health. The SMS question including bothersome days the last week was also used by Axén et al. [17] in a LBP study, and they discussed the use of 2 days or less with bothersome LBP per week as a clinically sensible option for recovery.

The weekly SMS data collection is a strength of this study, and the response rate to the SMS question before delivery was close to 90%. However, after delivery, the response rate gradually dropped. We speculate that a reason for this is the exposed situation the women are in, with a newborn infant and life-changing situation. Another reason might be that the women who experienced a fast recovery abstained from answering the SMS question because they

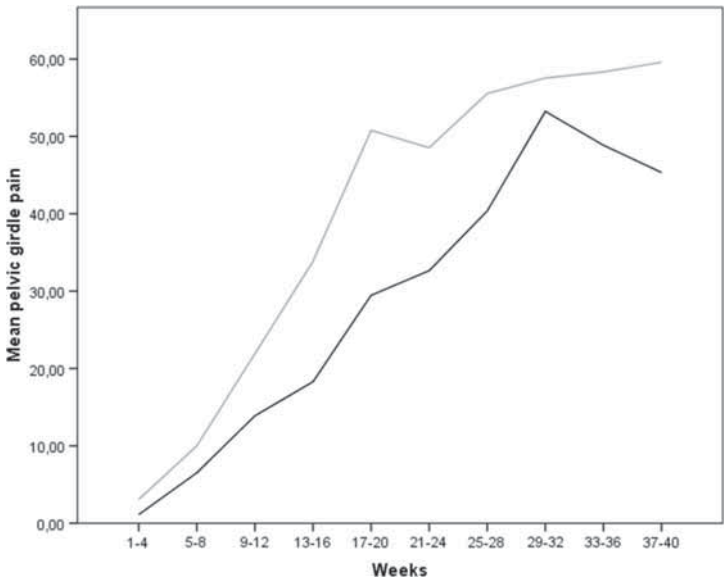

Fig. 3 Pain intensity (NRS) during pregnancy for women with substantial recovery (dark gray) and women with poor recovery (light gray)

had no pain to report. Hence, the falling response rate is a weakness in our study.

A sensitivity analysis including all women with missing data in the substantial recovery group resulted in an estimate of 86% (95% CI, 78–92) experiencing a substantial recovery within 6 weeks. Oppositely, if all the women with missing data were in the no, transitory, or incomplete recovery group, and the percentage of women with substantial recovery within 6 weeks after delivery was 67% (95% CI, 57–76).

To describe musculoskeletal pain in the pelvic area during pregnancy the term "pelvic girdle pain" is generally preferred to "pelvic pain". This is to emphasize that the pain is not derived from the pelvic viscera, but more likely from muscles, ligaments, and joint capsules in the pelvic area [8]. We have chosen to use the term PGP in this study. However, because our data are self-reported and obtained from an SMS question, this is in conflict with the European guidelines, which specify that the PGP diagnosis needs to be verified by specific clinical tests [5]. Nevertheless, we believe that by using the term PGP we minimize confusion regarding terminology.

The SMS question was sent every Sunday, and for the SMS-track in week 1, the answer reflected the last days of pregnancy for some women, while for others it reflected giving birth and the very first days after delivery. Because of this, the SMS-track for week 1 has not been emphasized. Also, women who delivered 1–2 weeks past the EDD, did not receive an SMS at 5–6 weeks after delivery, as the SMS-track was set to last until 6 weeks after the EDD. It is a weakness to this study that we do not have any follow-up data beyond 6 weeks after delivery.

The etiology for PGP is currently unknown, and the large variation in recovery patterns contributes to the belief that PGP is multifactorial. Pregnancy induces extensive biomechanical and hormonal changes to the female body, and a suggested theory is that PGP arises from the large, stabilizing muscles surrounding the pelvis [20]. After delivery, there is a sudden change in biomechanics and hormones, and for women with a quick recovery, this theory is therefore plausible.

We found that 17% of women reporting severe or moderate PGP the final 10 weeks of pregnancy had persistent PGP 6 weeks after delivery. In a previous study, we investigated persistent PGP in another study population, and found 16% of women reporting PP during pregnancy to have persistent PGP 3−6 months after delivery [16]. Although there are some differences between the two studies regarding study design, these findings indicate that PGP that last for more than 6 weeks may tend to become persistent. This information is important for pregnant women and pregnancy healthcare providers, and attention should be given to women with persistent PGP symptoms 6 weeks after delivery.

We found multiparity to be a risk factor for either no, transitory, or incomplete recovery from PGP 6 weeks after delivery, and although this is in line with findings from other studies investigating risk factors for PGP during pregnancy [6, 21], it is not an established risk factor for persistent PGP after delivery [22].

In a systematic review, Wuytack et al. [23] found previous LBP, overweight and obesity, a high comorbidity index, and severity of pain during pregnancy to be risk factors for persistent PGP. We found that having PGP the year before pregnancy is a risk factor for persistent PGP. In addition, our study also shows that a high pain intensity during pregnancy is a risk factor for persistent PGP 6 weeks after delivery. All the women reported increasing PGP during pregnancy, but for the women with a poor recovery, the pain intensity was higher throughout the entire pregnancy.

Conclusion

In conclusion, 83% of women with severe or moderate PGP the final 10 weeks of pregnancy experienced a subjective substantial recovery within 6 weeks after delivery. For almost half of them, the recovery occurred already within 2 weeks. This information is of interest to affected women and to pregnancy health care providers.

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Data availability The datasets generated during and analyzed during the current study are available from the corresponding author on reasonable request.

Compliance with ethical standard

Conflicts of interest None of the authors has any potential conflict of interest.

Ethical approval The project was registered and approved at The Norwegian National Research Ethics Committee: REK Nord 28.01.2010 with ref.nr:20107174.

Informed consent Informed consent was obtained from all individual participants included in the study.

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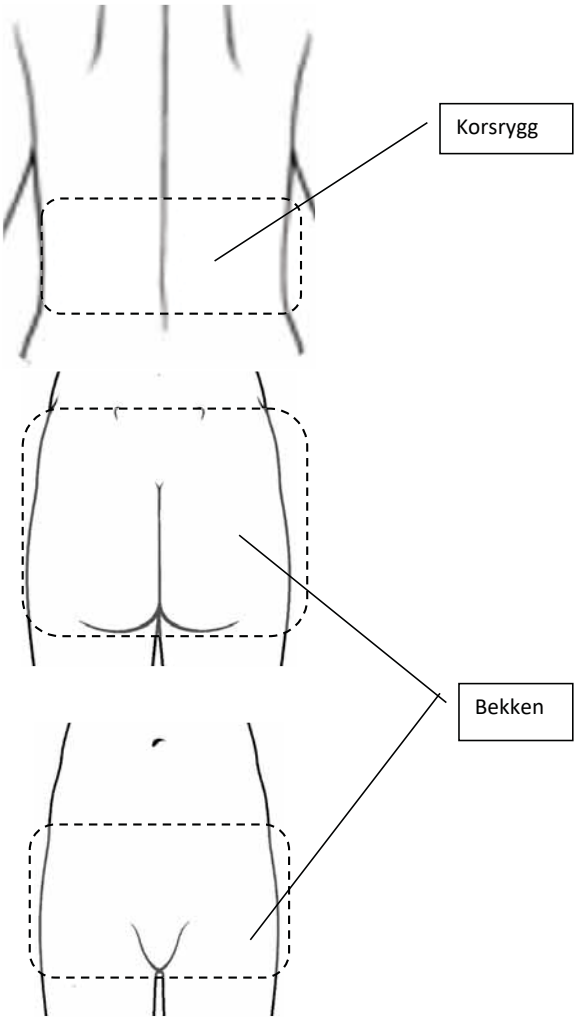
Appendix I – Questionnaires from the retrospective cohort study with follow-up 3–6 months after delivery

Initialer:_____ Fødselsdato: _____ Dagens dato:_____

Dette er en spørreundersøkelse om forekomsten av korsrygg- og bekkensmerter i svangerskapet. For å gjøre dette må vi gi en definisjon på hvor korsryggen og bekken er lokalisert. Nedenfor finner du illustrasjoner på hvor vi definerer de to ulike områdene.



ID-kode:

Rygg- og bekkensmerter i svangerskapet - en spørreundersøkelse

Universitetet i Stavanger

Stavanger Universitetssjukehus
Helse Stavanger HF

Initialer:_____ Fødselsdato: _____ Dagens dato:_____

1. Hvor mange års utdanning har du (inkludert folkeskole/grunnskole)?_____år

2. Hvor fysisk tungt jobber du?
Sett ett kryss.

Veldig lett Arbeid	Ganske lett arbeid	Verken lett eller tungt arbeid	Ganske tungt arbeid	Veldig tungt arbeid

3. Yrket ditt:_____

4. Hvor bra trives du på din jobb eller der du jobbet sist?
Sett ett kryss.

Veldig dårlig	Ikke så bra	Verken bra eller dårlig	Ganske bra	Veldig bra

5. Hvor mange uker i svangerskapet har du vært sykmeldt?
100%: _____ antall uker.
Delvis_____ %:_____ antall uker.

6. Oppgi den/de viktigste årsakene til sykmeldingen(e): _____

_____

7. Din høyde:_____cm

8. Din vekt før svangerskapet:_____kg

9. Din vekt like før fødselen:_____kg

10. Har du vært deprimert i løpet av svangerskapet?
Sett ett kryss.

Aldri	Av og til	Ofte	Nesten hele tiden

11. Dersom du har vært deprimert, i hvilken måned/er var du det?
Sett ett eller flere kryss.

1	2	3	4	5	6	7	8	9

12. Har du en kronisk sykdom: _____Ja _____Nei

13. Hvis ja; hvilken sykdom:_____

_____

14. Antall tidligere fødsler: _____

15. I tidligere svangerskap har du hatt
    a) Korsryggsmerter? __Ja __Nei
    b) Bekkensmerter? __Ja __Nei

16. Fikk du hormonbehandling for å bli gravid før dette svangerskapet? __Ja __Nei

17. Trente du regelmessig (minst 2-3 ganger i uka) før svangerskapet? __Ja __Nei

18. Har du trent regelmessig (minst 2-3 ganger i uka) i svangerskapet? __Ja __Nei

19. Har du hatt vondt i korsryggen siste år før svangerskapet? __Ja __Nei

20. Har du hatt vondt i bekkenet siste år før svangerskapet? __Ja __Nei

21. Har du noen gang skadet korsryggen eller bekkenet slik at du måtte oppsøke lege/sykehus?
    __Ja __Nei

22. Hvis ja, hva slags type skade hadde du?
    _____

23. Har du hatt vondt i korsryggen eller bekkenet i løpet av dette svangerskapet?
    ___Ja ____Nei

Hvis svaret ditt var Nei på spørsmål 23 kan du stoppe her. Var svaret ditt Ja på spørsmål 23 trenger vi litt mer informasjon. Vennligst fortsett med å svare på spørsmålene under.

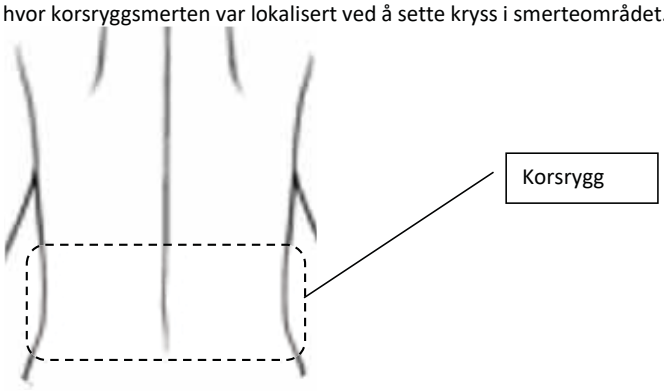
Dersom du har hatt KORSRYGGSMERTER

(har du ikke hatt korsryggsmerte gå til spørsmål 28)

24. I hvilken **måned** i svangerskapet begynte **korsryggsmerten**? Markér med kryss i riktig rute.

1	2	3	4	5	6	7	8	9

25. Vis på figuren nedenfor hvor korsryggsmerten var lokalisert ved å sette kryss i smerteområdet.



26. Markér i hver rute, som representerer hver måned i svangerskapet, i gjennomsnitt hvordan du har opplevd korsryggsmerten.
Bruk tall fra 0 – 100 (0 = ingen smerte; 100 = uutholdelig smerte).

1	2	3	4	5	6	7	8	9

27. Dersom du har vært sykmeldt pga. korsryggsmerte: Markér nedenfor i hvilke måneder i ditt svangerskap du har vært sykmeldt. (Markér med kryss i riktig rute eller ruter.)

1	2	3	4	5	6	7	8	9

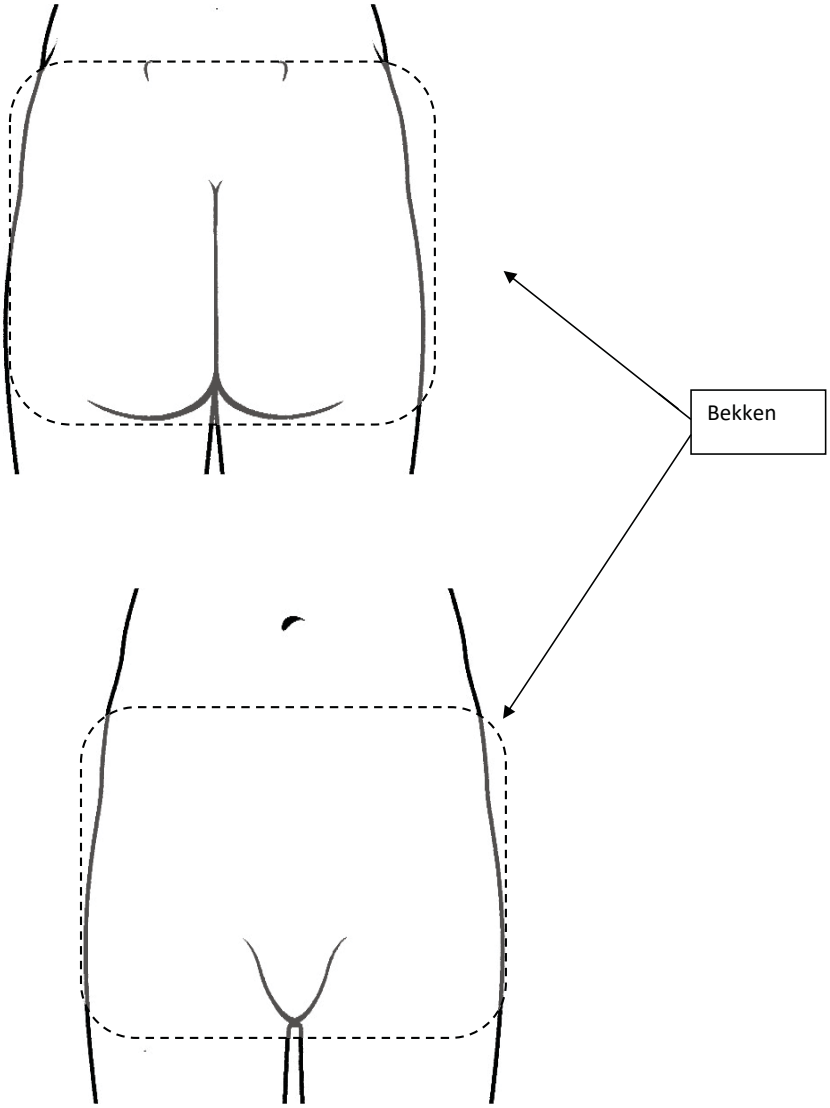
Dersom du har hatt BEKKENSMERTER

(Dersom du ikke har hatt bekkenplager kan du fortsette til spørsmål 32)

28. I hvilken måned i svangerskapet begynte **bekkenplagene**? Markér med kryss i riktig rute.

1	2	3	4	5	6	7	8	9

29. Vis på følgende figurer nedenfor hvor bekkensmerten din var lokalisert ved å skravere smerte området og sette kryss der smerten var mest intens.



30. Markér i hver rute, som representerer hver måned i svangerskapet, hvordan du i gjennomsnitt har opplevd bekkensmerten. Bruk tall fra 0 – 100 (0 = ingen smerte; 100 = uutholdelig smerte)

1	2	3	4	5	6	7	8	9

31. Dersom du har vært sykmeldt pga. bekkensmerte: Markér nedenfor i hvilke måneder i svangerskapet du har vært sykmeldt.

1	2	3	4	5	6	7	8	9

32. Markér måned for måned nedenfor hvor godt du fungerte i dagliglivet gjennom dette svangerskapet. Bruk tall fra 0 – 100 (0 = ingen problem, jeg klarte meg på egenhånd; 100 = veldig dårlig, jeg måtte ha hjelp til alt)

1	2	3	4	5	6	7	8	9

33. Har smerten vært så sterk i svangerskapet slik at du har trengt hjelpemidler?

Krykker __Ja __Nei

Rullestol __Ja __Nei

”Glidelaken” __Ja __Nei

Bekkenbelte/korsett __Ja __Nei

34. Har du fått behandling under svangerskapet pga korsrygg- eller bekkensmerter?
__Ja __Nei

(visst Nei så er du nå ferdig med dette spørreskjemaet).

35. Hvem oppsøkte du for behandling? (f.eks. Lege, Kiropraktor, Fysioterapeut , Akupunktør, Osteopat, Manuell Terapeut, Naprapat, annet)?
_____

Vi er interessert i å vite hva slags behandling du har gjennomgått. Nedenfor finner du spørsmål om eventuelle behandlingsmetoder som er blitt brukt. Hvis du har vært hos flere terapeuter sett gjerne i parentes hvem som gjorde hva.

36. Råd om å takle hverdagen med smerter? __Ja __Nei
Hvis ja, hva slags type råd?_____
_____

Hvor god effekt/utbytte hadde du av rådene?

Verre	Ingen effekt	Litt effekt	God effekt	Symptomfri

37. Ble det brukt varme? __Ja __Nei (Hvis ja, hvilkenterapeut?_____)

38. Ble det brukt akupunktur? __Ja __Nei (Hvis ja, hvilken terapeut?_____)

39. Var du med på bassengtrening? __Ja __Nei (Hvis ja, hvilken terapeut?_____)

40. Fikk du massasje? __Ja __Nei (Hvis ja, hvilken terapeut?_____)

41. Fikk du hjemmeøvelser? __Ja __Nei (Hvis ja, hvilken terapeut?_____)

42. Trening med veiledning ? __Ja __Nei (Hvis ja, hvilken terapeut?_____)

43. Fikk du medikamenter? __Ja Nei (Hvis ja, hvilken terapeut?_____)

44. Ble det brukt TENS maskin/strøm? __Ja __Nei (Hvis ja, hvilken terapeut?_____)

45. Fikk du manipulasjonsbehandling ? __Ja __Nei
Visst ja av hvem: Kiropraktor, Manuell Terapeut, Osteopat, Naprapat eller annet?

_____

46. Har du hatt noen annen form for behandling? __Ja __Nei
Hvis Ja, hva slags type behandling?
_____

47. Antall ganger du var til behandling? _____

48. I ca hvor mange uker fikk du behandling? _____

49. Har du en kommentar til behandlingen(e)?
_____

_____

50. Hvor godt fornøyd er du med behandlingen du fikk i svangerskapet? Fra null til ti (0=ikke fornøyd i det hele tatt, 10= veldig fornøyd). Sett ett kryss.

0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10

51. Generelt hvor godt fornøyd er du med behandlingstilbudet for korsrygg- og bekken smerter under svangerskapet? Fra null til ti (0=ikke fornøyd i det hele tatt, 10= veldig fornøyd). Sett ett kryss.

0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10

Takk for all informasjon!

Universitetet i Stavanger

Stavanger Universitetssjukehus
Helse Stavanger HF

ODI

Initialer:	ID:	Dato:

Dette spørreskjemaet er utformet for å gi opplysninger om hvordan rygg- og bekkensmertene dine i gjennom svangerskapet har påvirket din evne til å klare deg i dagliglivet. Vi vil gjerne vite ***hvordan det har vært på det verste****. Vennligst svar på hvert avsnitt, og markér bare* ***det ene feltet*** *i hvert avsnitt som gjelder for deg. Vi forstår at du kanskje synes at to av utsagnene i hvert avsnitt kan gjelde deg, men vennligst* ***markér bare feltet som best beskriver ditt daværende problem****.*

Smerteintensitet

- ☐ 1. Jeg hadde ingen smerter i svangerskapet
- ☐ 2. Smertene var veldig svake i svangerskapet
- ☐ 3. Smertene var moderate i svangerskapet
- ☐ 4. Smertene var temmelig sterke i svangerskapet
- ☐ 5. Smertene var veldig sterke i svangerskapet
- ☐ 6. Smertene var de verste jeg kan tenke meg i ett svangerskapet

Personlig stell (vaske seg, kle på seg, osv.)

- ☐ 1. Jeg kunne stelle meg selv på vanlig måte uten at det forårsaket ekstra smerter
- ☐ 2. Jeg kunne stelle meg selv på vanlig måte, men det var veldig smertefullt
- ☐ 3. Det var smertefullt å stelle meg selv, og jeg måtte gjøre det langsomt og forsiktig
- ☐ 4. Jeg trengte noe hjelp, men klarte det meste av mitt personlige stell
- ☐ 5. Jeg trengte hjelp hver dag til det meste av eget stell
- ☐ 6. Jeg kledde ikke på meg, hadde vanskeligheter med å vaske meg, og holdt sengen

Løfte

- ☐ 1. Jeg kunne løfte tunge ting uten å få mer smerter
- ☐ 2. Jeg kunne løfte tunge ting, men fikk mer smerter
- ☐ 3. Smertene hindret meg i å løfte tunge ting opp fra gulvet, men jeg greide det hvis det som skulle løftes var gunstig plassert, f.eks. på et bord
- ☐ 4. Smertene hindret meg i å løfte tunge ting, men jeg klarte å løfte lette eller middels tunge ting, hvis det var gunstig plassert
- ☐ 5. Jeg kunne bare løfte noe som var veldig lett
- ☐ 6. Jeg kunne ikke løfte eller bære noe i det hele tatt

Gå

- ☐ 1. Smertene hindret meg ikke i å gå i det hele tatt
- ☐ 2. Smertene hindret meg i å gå mer enn 1500 m
- ☐ 3. Smertene hindret meg i å gå mer enn 750 m
- ☐ 4. Smertene hindret meg i å gå mer enn 100 m
- ☐ 5. Jeg kunne bare gå med stokk eller krykker
- ☐ 6. Jeg lå for det meste i sengen og jeg måtte krabbe til toalettet

Sitte

- ☐ 1. Jeg kunne sitte så lenge jeg ville i en hvilken som helst stol
- ☐ 2. Jeg kunne sitte så lenge jeg ville i min favorittstol
- ☐ 3. Smertene hindret meg i å sitte i mer enn en time

- ☐ 4. Smertene hindret meg i å sitte i mer enn en halv time
- ☐ 5. Smertene hindret meg i å sitte i mer enn ti minutter
- ☐ 6. Smertene hindret meg i å sitte i det hele tatt

Stå

- ☐ 1. Jeg kunne stå så lenge jeg ville uten å få mer smerter
- ☐ 2. Jeg kunne stå så lenge jeg ville, men fikk mer smerter
- ☐ 3. Smertene hindret meg i å stå i mer enn en time
- ☐ 4. Smertene hindret meg i å stå i mer enn en halv time
- ☐ 5. Smertene hindret meg i å stå i mer enn ti minutter
- ☐ 6. Smertene hindret meg i å stå i det hele tatt

Sove

- ☐ 1. Søvnen min ble aldri forstyrret av smerter
- ☐ 2. Søvnen min ble forstyrret av og til av smerter
- ☐ 3. På grunn av smerter fikk jeg mindre enn seks timers søvn
- ☐ 4. På grunn av smerter fikk jeg mindre enn fire timers søvn
- ☐ 5. På grunn av smerter fikk jeg mindre enn to timers søvn
- ☐ 6. Smertene hindret all søvn

Seksualliv

- ☐ 1. Seksuallivet mitt var normalt og forårsaket ikke mer smerter
- ☐ 2. Seksuallivet mitt var normalt, men forårsaket noe smerter
- ☐ 3. Seksuallivet mitt var normalt, men svært smertefullt
- ☐ 4. Seksuallivet mitt var svært begrenset pga smerter
- ☐ 5. Seksuallivet mitt var nesten borte på grunn av smerter
- ☐ 6. Smertene forhindret alt seksualliv

Sosialt liv

- ☐ 1. Det sosiale livet mitt var normalt og forårsaket ikke mer smerter
- ☐ 2. Det sosiale livet mitt var normalt, men økte graden av smerter
- ☐ 3. Smertene hadde ingen betydelig innvirkning på mitt sosiale liv, bortsett fra at de begrenset mine mer fysisk aktive sider, som sport osv.
- ☐ 4. Smertene begrenset mitt sosiale liv og jeg gikk ikke så ofte ut
- ☐ 5. Smerte begrenset mitt sosiale liv til hjemmet
- ☐ 6. På grunn av smertene hadde jeg ikke noe sosialt liv

Reising

- ☐ 1. Jeg kunne reise hvor som helst uten smerter
- ☐ 2. Jeg kunne reise hvor som helst, men det gav mer smerter
- ☐ 3. Smertene var ille, men jeg klarte reiser på to timer
- ☐ 4. Smertene begrenset meg til korte reiser på under en time
- ☐ 5. Smertene begrenset meg til korte, nødvendige reiser på under 30 minutter
- ☐ 6. Smertene forhindret meg fra å reise, unntatt for å få behandling

The Modified Oswestry Disability Index (Baker et al 1990)
Oversatt av Margreth Grotle og Nina K:Vøllestad 2001,
Seksjon for Helsefag, Universitetet I Oslo

Initialer:	ID:	Dato:

Universitetet i Stavanger

EQ-5D

Stavanger Universitetssjukehus
Helse Stavanger HF

Spørreskjema om Helse

Vis hvilke utsagn som passer best på din helsetilstand **en uke før fødsel** ved å sette kryss i en av rutene utenfor hver av gruppene nedenfor.

Gange

Jeg hadde ingen problemer med å gå omkring. ☐
Jeg hadde litt problemer med å gå omkring. ☐
Jeg var sengeliggende. ☐

Personlig stell.

Jeg hadde ingen problemer med personlig stell. ☐
Jeg hadde litt problemer med å vaske meg eller å kle meg. ☐
Jeg var ute av stand til å vaske meg eller å kle på meg. ☐

Vanlige gjøremål (f.eks. arbeid, studier, husarbeid, familie- eller fritidsaktiviteter).

Jeg hadde ingen problemer med å utføre mine vanlige gjøremål. ☐
Jeg hadde litt problemer med å utføre mine vanlige gjøremål. ☐
Jeg var ute av stand til å utføre mine vanlige gjøremål. ☐

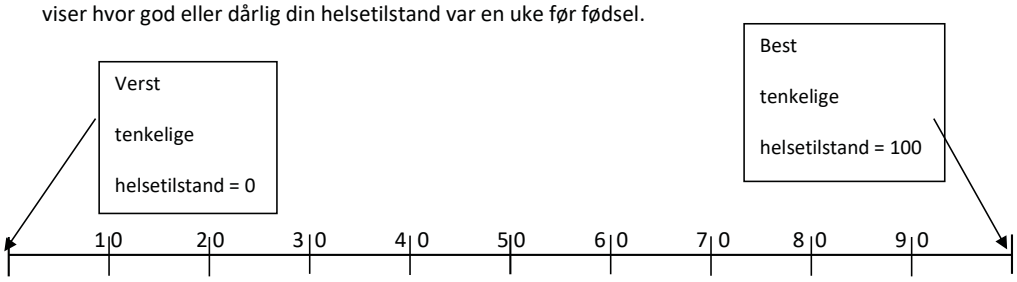
Smerte/ubehag

Jeg hadde verken smerte eller ubehag. ☐
Jeg hadde moderat smerter eller ubehag. ☐
Jeg hadde sterk smerte eller ubehag. ☐

Angst/depresjon

Jeg var verken engstelig eller deprimert. ☐
Jeg var noe engstelig eller deprimert. ☐
Jeg var svært engstelig eller deprimert. ☐

For å hjelpe folk til å si hvor god eller dårlig en helsetilstand er, har vi laget en skala (omtrent som et termometer) hvor den beste helsetilstanden du kan tenke deg er merket 100 og den verste tilstanden du kan tenke deg er merket 0.
Vi vil gjerne at du viser på denne skalaen hvor god eller dårlig din helsetilstand var en uke før fødsel, etter din oppfatning. Vær vennlig å gjøre dette ved å sette ett kryss på det punktet på skalaen som viser hvor god eller dårlig din helsetilstand var en uke før fødsel.



Spørreskjema for kvinner med bekkenplager

Universitetet i Stavanger

Stavanger Universitetssjukehus
Helse Stavanger HF

Pasientdata

Initialer

Kode

Høyde Vekt

Formålet med studien er å undersøke og klassifisere kvinner med vedvarende korsrygg og /eller bekkensmerter etter 3–6 måneder fødsel.

Spørreskjemaet består av fem deler. Første del omhandler ulike sider ved din utdanning og familie samt dine smerter og plager. De neste delene består av fire ulike sett spørsmål for måling av din nåværende helse. Den første av disse (kalt Oswestery-skåre) måler hvordan ryggplagene påvirker dine dagligdagse gjøremål. Det andre (kalt EQ-5D) måler din helse-relaterte livskvalitet. Den tredje delen er en skala der du merker hvor god eller dårlig din helsetilstand er. Den siste delen (kalt Funksjonskåre bekken) måler hvordan bekkenplagene påvirker dine dagligdagse gjøremål.

Dato for utfylling

Dag Måned År

Røyker du? Ja Nei

Utdanning og yrke

1. **Hva er din høyeste fullførte utdanning? (Sett *kun ett* kryss)**

- Grunnskole 7-10 år, framhaldsskole eller folkehøyskole
- Yrkesfaglig videregående skole, yrkesskole eller realskole
- Allmennfaglig videregående skole eller gymnas
- Høyskole eller universitet (mindre enn 4 år)
- Høyskole eller universitet (4 år eller mer)

Familie og barn

1. Sivilstatus (sett *kun ett* kryss)

- Gift
- Samboende
- Enslig

Hvor sterke smerter har du hatt siste uke?

Hvor sterk er din smerte på det verste om morgenen (etter du har stått opp) i korsrygg -og/eller bekken den siste uken?
Sett ring rundt ett tall

0 1 2 3 4 5 6 7 8 9 10

Ingen smerter — Så vondt som det går an å ha

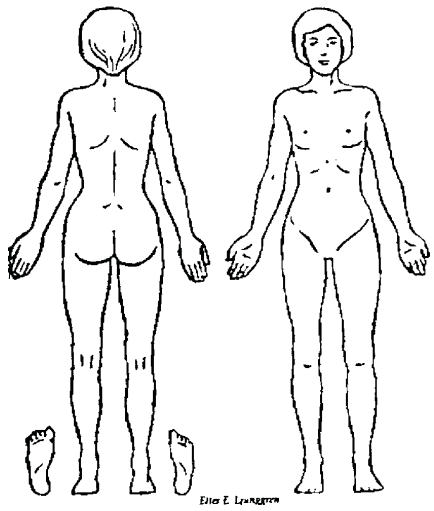
Hvor sterk er din smerte på det verste om kvelden (før du går og legger deg) i korsrygg -og/eller bekken den siste uken?
Sett ring rundt ett tall.

0 1 2 3 4 5 6 7 8 9 10

Ingen smerter — Så vondt som det går an å ha

Hvor har du vondt nå for tiden?

Sett et eller flere kryss på de områder du har vondt.



Funksjonsskår (Oswestry)

Disse spørsmålene er utarbeidet for å gi oss informasjon om hvordan dine smerter har påvirket dine muligheter til å klare dagliglivet ditt. Vær snill å besvare spørsmålene ved å sette kryss (*kun ett* kryss for hvert avsnitt) i de rutene som passer best for deg.

1. Smerte

- ☐ Jeg har ingen smerter for øyeblikket
- ☐ Smertene er veldig svake for øyeblikket
- ☐ Smertene er moderate for øyeblikket
- ☐ Smertene er temmelig sterke for øyeblikket
- ☐ Smertene er veldig sterke for øyeblikket
- ☐ Smertene er de verste jeg kan tenke meg for øyeblikket

2. Personlig stell

- ☐ Jeg kan stelle meg selv på vanlig måte uten at det forårsaker ekstra smerter
- ☐ Jeg kan stelle meg selv på vanlig måte, men det er veldig smertefullt
- ☐ Det er smertefullt å stelle seg selv, og jeg gjør det langsomt og forsiktig
- ☐ Jeg trenger noe hjelp, men klarer det meste av mitt personlige stell
- ☐ Jeg trenger hjelp hver dag til det meste av eget stell
- ☐ Jeg kler ikke på meg, har vanskeligheter med å vaske meg og holder sengen

3. Å løfte

- ☐ Jeg kan løfte tunge ting uten å få mer smerter
- ☐ Jeg kan løfte tunge ting, men får mer smerter
- ☐ Smertene hindrer meg i å løfte tunge ting opp fra gulvet, men jeg greier det hvis det som skal løftes er gunstig plassert, for eksempel på et bord
- ☐ Smertene hindrer meg i å løfte tunge ting, men jeg klarer lette og middels tunge ting, hvis det er gunstig plassert
- ☐ Jeg kan bare løfte noe som er veldig lett
- ☐ Jeg kan ikke løfte eller bære noe i det hele tatt

4. Å gå

- ☐ Smerter hindrer meg ikke i å gå i det hele tatt
- ☐ Smerter hindrer meg i å gå mer enn 1 ½ km
- ☐ Smerter hindrer meg i å gå mer enn ¾ km
- ☐ Smerter hindrer meg i å gå mer enn 100 m
- ☐ Jeg kan bare gå med stokk eller krykker
- ☐ Jeg ligger for det meste i sengen, og jeg må krabbe til toalettet

5. Å sitte

- ☐ Jeg kan sitte så lenge jeg vil i en hvilken som helst stol
- ☐ Jeg kan sitte så lenge jeg vil i min favorittstol
- ☐ Smerter hindrer meg i å sitte i mer enn en time
- ☐ Smerter hindrer meg i å sitte i mer enn en halv time
- ☐ Smerter hindrer meg i å sitte i mer enn ti minutter
- ☐ Smerter hindrer meg i å sitte i det hele tatt

6. Å stå

- ☐ Jeg kan stå så lenge jeg vil uten å få mer smerter
- ☐ Jeg kan stå så lenge jeg vil, men får mer smerter
- ☐ Smerter hindrer meg i å stå i mer enn en time
- ☐ Smerter hindrer meg i å stå i mer enn en halv time
- ☐ Smerter hindrer meg i å stå i mer enn ti minutter
- ☐ Smerter hindrer meg i å stå i det hele tatt

7. Å sove

- [ ] Søvnen min forstyrres aldri av smerter
- [ ] Søvnen min forstyrres av og til av smerter
- [ ] På grunn av smerter får jeg mindre enn seks timers søvn
- [ ] På grunn av smerter får jeg mindre enn fire timers søvn
- [ ] På grunn av smerter får jeg mindre enn to timers søvn
- [ ] Smerter hindrer all søvn

8. Seksualliv

- [ ] Seksuallivet mitt er normalt og forårsaker ikke mer smerter
- [ ] Seksuallivet mitt er normalt, men forårsaker noe mer smerter
- [ ] Seksuallivet mitt er normalt, men svært smertefullt
- [ ] Seksuallivet mitt er svært begrenset av smerter
- [ ] Seksuallivet mitt er nesten borte på grunn av smerter
- [ ] Smerter forhindrer alt seksualliv

9. Sosialt liv (omgang med venner og kjente)

- [ ] Det sosiale livet mitt er normalt og forårsaker ikke mer smerter
- [ ] Det sosiale livet mitt er normalt, men øker graden av smerter
- [ ] Smerter har ingen betydelig innvirkning på mitt sosiale liv, bortsett fra at de begrenser mine mer fysisk aktive sider, som sport osv.
- [ ] Smerter har begrenset mitt sosiale liv, og jeg går ikke så ofte ut
- [ ] Smerter har begrenset mitt sosiale liv til hjemmet
- [ ] På grunn av smerter har jeg ikke noe sosialt liv

10. Å reise

- [ ] Jeg kan reise hvor som helst uten smerter
- [ ] Jeg kan reise hvor som helst, men det gir mer smerter
- [ ] Smertene er ille, men jeg klarer reiser på to timer
- [ ] Smerter begrenser meg til korte reiser på under en time
- [ ] Smerter begrenser meg til korte, nødvendige reiser på under 30 minutter
- [ ] Smerter forhindrer meg fra å reise, unntatt for å få behandling

Beskrivelse av helsetilstand (EQ-5D)

Vis hvilke utsagn som passer best på din helsetilstand i dag ved å sette *kun ett* kryss i en av rutene for hvert punkt nedenfor.

1. Gange

- [ ] Jeg har ingen problemer med å gå omkring
- [ ] Jeg har litt problemer med å gå omkring
- [ ] Jeg er sengeliggende

2. Personlig stell

- [ ] Jeg har ingen problemer med personlig stell
- [ ] Jeg har litt problemer med å vaske meg eller kle meg
- [ ] Jeg er ute av stand til å vaske meg eller kle meg

3. Vanlige gjøremål (f.eks. arbeid, studier, husarbeid, famile- eller fritidsaktiviteter)

- [ ] Jeg har ingen problemer med å utføre mine vanlige gjøremål
- [ ] Jeg har litt problemer med å utføre mine vanlige gjøremål
- [ ] Jeg er ute av stand til å utføre mine vanlige gjøremål

4. Smerte og ubehag

- [ ] Jeg har hverken smerte eller ubehag
- [ ] Jeg har moderat smerte eller ubehag
- [ ] Jeg har sterk smerte eller ubehag

5. Angst og depresjon

- [ ] Jeg er hverken engstelig eller deprimert
- [ ] Jeg er noe engstelig eller deprimert
- [ ] Jeg er svært engstelig eller deprimert

Smertestillende medisiner

Bruker du smertestillende medisiner på grunn av dine korsrygg -og/eller bekkensmerter?

- [ ] Ja
- [ ] Nei

Hvis du har svart ja: Hvor ofte bruker du smertestillende medisiner? (Sett *kun ett* kryss)

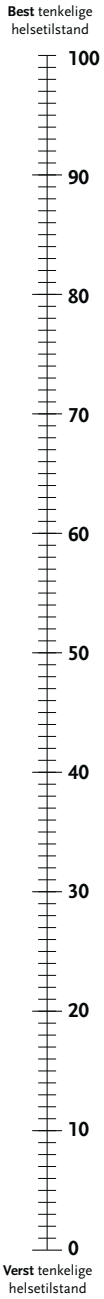
- [ ] Sjeldnere enn hver måned
- [ ] Hver måned
- [ ] Hver uke
- [ ] Daglig
- [ ] Flere ganger daglig

Helsetilstand

For at du skal kunne vise oss hvor god eller dårlig din helsetilstand er, har vi laget en skala (nesten som et termo-meter), hvor den beste helsetilstanden du kan tenke deg er markert med 100 og den dårligste med 0.

Vi ber om at du viser din helsetilstand ved å trekke ei linje fra boksen nedenfor til det punkt på skalaen som passer best med din helsetilstand.

Nåværende helsetilstand



Har du søkt om uføretrygd? (Sett kun ett kryss)

☐ Ja ☐ Nei

☐ Planlegger å søke ☐ Er allerede innvilget

Arbeidsstatus

Hva var din arbeidsstatus før svangerskapet startet

☐ Mammapermisjon ☐ Aktivt sykemeldt

☐ I arbeid ☐ Delvis sykemeldt

☐ Hjemmeværende, ulønnet _____ % sykemeldt

☐ Student/skoleelev ☐ Attføring/rehabilitering

☐ Arbeidsledig ☐ Uføretrygdet

☐ Sykemeldt evt _____ % uføretrygdet

Funksjonsskår bekken

Hvor problematisk er det på grunn av bekkenet å:	Ikke i det hele tatt	I liten grad	I noen grad	I stor grad
Kle på deg selv	☐	☐	☐	☐
Stå mindre enn 10 minutter	☐	☐	☐	☐
Stå mer enn 60 minutter	☐	☐	☐	☐
Bøye deg	☐	☐	☐	☐
Sitte mindre enn 10 minutter	☐	☐	☐	☐
Sitte mer enn 60 minutter	☐	☐	☐	☐
Gå mindre enn 10 minutter	☐	☐	☐	☐
Gå mer enn 60 minutter	☐	☐	☐	☐
Gå trapper	☐	☐	☐	☐
Husarbeid	☐	☐	☐	☐
Bære lett	☐	☐	☐	☐
Løfte tungt	☐	☐	☐	☐
Reise/sette seg	☐	☐	☐	☐
Skyve en vogn	☐	☐	☐	☐
Løpe	☐	☐	☐	☐
Utføre sportslige aktiviteter	☐	☐	☐	☐
Ligge	☐	☐	☐	☐
Snu deg i sengen	☐	☐	☐	☐
Ha et normalt seksualliv	☐	☐	☐	☐
Skyve noe med den ene foten	☐	☐	☐	☐

Hvor sterke smerter har du om:	Ingen	Noe	Mode-rate	Svært mye
Morgenen	☐	☐	☐	☐
Kvelden	☐	☐	☐	☐

I hvilken grad på grunn av plagene i bekkenet:	Ikke i det hele tatt	I liten grad	I noen grad	I stor grad
svikter benet/bena under deg?	☐	☐	☐	☐
gjør du ting langsommere?	☐	☐	☐	☐
forstyrres nattesøvnen din?	☐	☐	☐	☐

LUNDBLAD MEDIA AS – SVANEGODKJENT TRYKKSAK – 241 762 ONR:101560

Undersøkelsesskjema

Funksjons/bevelighet:

Gange (sett ring rundt riktig svar);

- Normal gange
- Rolig, korte steg men symmetrisk gange
- Halter usymmetrisk gange
- Bruker krykker
- Bruker rullestol

Nevrologisk Undersøkelse:

Reflekser (graderes fra 0 til 4+);	Hø	Ve
Patella (L4)		
Hamstring (L5)		
Akilles (S1)		

Myotomer (graderes fra 0 til 5);	Hø	Ve
Fleksjon hofte (L2/3)		
Ekstensjon hofte (L3/4)		
Fleksjon kne (L4/5)		
Ekstensjon kne (L5/S1)		
Ankel Dorsifleksjon (L5)		
Ankel Plantarfleksjon (S1)		
Store tå ekstensjon (L5)		
Storetå fleksjon (S1)		

Hel gange (L5);

Tå gange (S1);

Sensibilitet Hø hypoestesi/hyperestesi Ve hypoestesi/hyperestesi

L1- dermatom

L2-dermatom

L3-dermatom

L4dermatom

L5 dermatom

S1 dermatom

Ikke dermatomisk mønster

Ortopediske tester

(sett hake ved smerter og tall på ASLR) Hø Ve

- Lasegue
- P4
- ASLR (graderes fra 0-5)
- Palpation of the long dorsal SIJ ligament.
- Gaenslens test.
- Palpation of the symphysis
- Modified Trendelenburg test of the pelvic girdle..
- Patrick Fabere
- MDT tester

ASLR **Hø** **Ve**

Graderes fra 0-5.

0= Ikke vanskelig å gjøre i det hele tatt.

1= Litt vanskelig å gjøre

2= Vanskelig å gjøre

3= Ganske vanlig å gjøre

4= veldig vanskelig å gjøre

5= klarer ikke å gjennomføre testen

Indirekte tester;

Hø **Ve**

Passiv Hofte fleksjon

Passiv SLR

Passiv innad hofte rotasjon

Appendix 2 – Questionnaires from the prospective longitudinal cohort study

Universitetet i Stavanger

Stavanger Universitetssjukehus
Helse Stavanger HF

ID-kode:_____

Rygg- og bekkensmerter i svangerskapet

Spørreskjema for symptomfrie kvinner ved 18 -20 ukers svangerskap

Initialer:_____ Fødselsdato: _____ Dato i dag:_____

1. Hvor mange års utdanning har du (**inkludert folkeskole/grunnskole**)?_____år

2. Hvor fysisk tungt jobber du?
   Sett ett kryss.

Veldig lett arbeid	Ganske lett arbeid	Verken lett eller tungt arbeid	Ganske tungt arbeid	Veldig tungt arbeid

Jobber ikke ☐

3. Yrket ditt:_____

4. Hvor bra trives du på din jobb eller der du jobbet sist?
   Sett ett kryss.

Veldig dårlig	Ikke så bra	Verken bra eller dårlig	Ganske bra	Veldig bra

5. Hvor mange uker har du vært sykmeldt til nå i svangerskapet?

   Har ikke vært sykmeldt ☐
   100%: _____ antall uker.
   Delvis_____ %:_____ antall uker.

6. Oppgi den/de viktigste årsakene til sykmeldingen(e): _____
   _____

7. Din høyde:_____cm

8. Din vekt:_____kg

9. Din vekt før svangerskapet:_____kg

10. Har du vært deprimert til nå i svangerskapet?
Sett ett kryss.

Aldri	Av og til	Ofte	Nesten hele tiden

11. Dersom du har vært deprimert, i hvilke uker er/var du det?
Sett ett eller flere kryss.

1-4	5-8	9-12	13-16	17-20

12. Har du en kronisk sykdom: _____Ja _____Nei

13. Hvis ja; hvilken sykdom:_____

14. Antall tidligere fødsler: _____

15. Har du hatt bekkensmerter i tidligere svangerskap? __Ja __Nei

16. Fikk du hormonbehandling for å bli gravid før dette svangerskapet? __Ja __Nei

17. Trente du regelmessig (minst 2-3 ganger i uka) før svangerskapet? __Ja __Nei

18. Har du trent regelmessig (minst 2-3 ganger i uka) til nå i dette svangerskapet? __Ja __Nei

20. Har du hatt vondt i bekkenet siste år før svangerskapet? __Ja __Nei

21. Har du noen gang skadet bekkenet slik at du måtte oppsøke lege/sykehus?
__Ja __Nei

22. Hvis ja, hva slags type skade hadde du?

_____

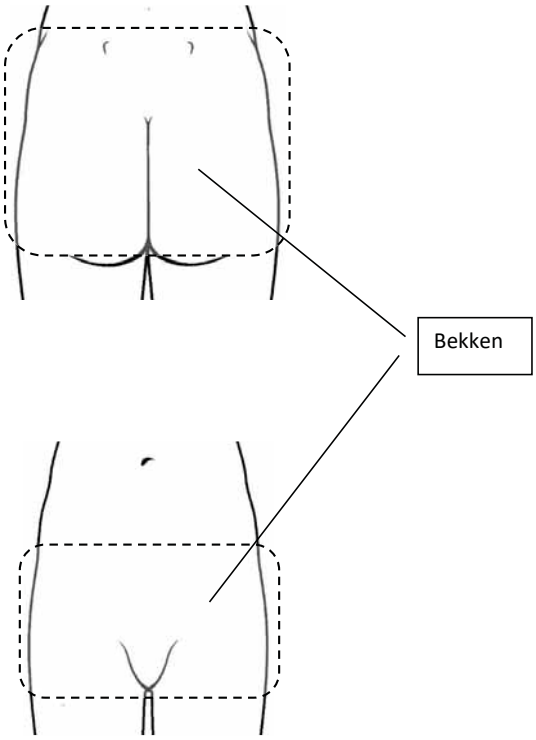
_____

Takk for all informasjon!

Rygg - og bekkensmerter i svangerskapet

Spørreskjema ved rutineundersøkelsen

Vi ønsker å kartlegge forekomsten av bekkensmerter i svangerskapet. For å kunne tolke resultatene må vi gi en definisjon av hvor bekkenet er lokalisert. Nedenfor finner du en illustrasjon av hvor vi definerer bekkenområdet.



ID-kode:_____

Rygg- og bekkensmerter i svangerskapet

Spørreskjema ved rutineundersøkelsen

Initialer:_____ Fødselsdato: _____ Dato i dag:_____

1. Hvor mange års utdanning har du (**inkludert folkeskole/grunnskole**)?_____år

2. Hvor fysisk tungt jobber du?
Sett ett kryss.

Veldig lett arbeid	Ganske lett arbeid	Verken lett eller tungt arbeid	Ganske tungt arbeid	Veldig tungt arbeid

Jobber ikke ☐

3. Yrket ditt:_____

4. Hvor bra trives du på din jobb eller der du jobbet sist?
Sett ett kryss.

Veldig dårlig	Ikke så bra	Verken bra eller dårlig	Ganske bra	Veldig bra

5. Hvor mange uker har du vært sykmeldt til nå i svangerskapet?

Har ikke vært sykmeldt ☐
100%: _____ antall uker.
Delvis_____ %:_____ antall uker.

6. Oppgi den/de viktigste årsakene til sykmeldingen(e): _____
_____

7. Din høyde:_____cm

8. Din vekt:_____kg

9. Din vekt før svangerskapet:_____kg

10. Har du vært deprimert til nå i svangerskapet?
Sett ett kryss.

Aldri	Av og til	Ofte	Nesten hele tiden

11. Dersom du har vært deprimert, i hvilke uker er/var du det?
Sett ett eller flere kryss.

1-4	5-8	9-12	13-16	17-20

12. Har du en kronisk sykdom: _____Ja _____Nei

13. Hvis ja; hvilken sykdom:_____

14. Antall tidligere fødsler: _____

15. Har du hatt bekkensmerter i tidligere svangerskap? __Ja __Nei

16. Fikk du hormonbehandling for å bli gravid før dette svangerskapet? __Ja __Nei

17. Trente du regelmessig (minst 2-3 ganger i uka) før svangerskapet? __Ja __Nei

18. Har du trent regelmessig (minst 2-3 ganger i uka) til nå i dette svangerskapet? __Ja __Nei

20. Har du hatt vondt i bekkenet siste år før svangerskapet? __Ja __Nei

21. Har du noen gang skadet bekkenet slik at du måtte oppsøke lege/sykehus?
__Ja __Nei

22. Hvis ja, hva slags type skade hadde du?
_____

23. Har du hatt vondt i korsryggen til nå i dette svangerskapet?
___Ja ____Nei

24. Har du hatt vondt i bekkenet til nå i dette svangerskapet?
___Ja ____Nei

(Hvis **Nei** på spørsmålene 23 og 24 er du nå ferdig med dette spørreskjemaet)

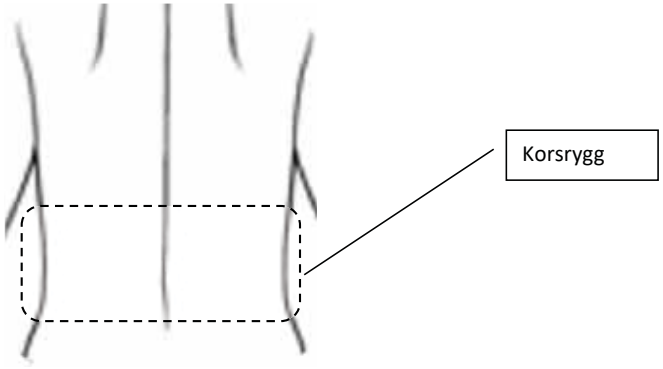
Dersom du har hatt KORSRYGGSMERTER

(har du ikke hatt korsryggsmerte, gå til spørsmål 29)

25. I hvilke **uker** i svangerskapet begynte **korsryggsmerten**? Markér med kryss i riktig rute.

1-4	5-8	9-12	13-16	17-20

26. Vis på figuren nedenfor hvor korsryggsmerten var lokalisert ved å sette kryss i smerteområdet.



27. Markér i hver rute i gjennomsnitt hvordan du har opplevd korsryggsmerten.
Bruk tall fra 0 – 100 (0 = ingen smerte; 100 = uutholdelig smerte).

1-4	5-8	9-12	13-16	17-20

28. Dersom du har vært sykmeldt pga. korsryggsmerte: Markér nedenfor i hvilke uker i ditt svangerskap du har vært sykmeldt. (Markér med kryss i riktig rute)

1-4	5-8	9-12	13-16	17-20

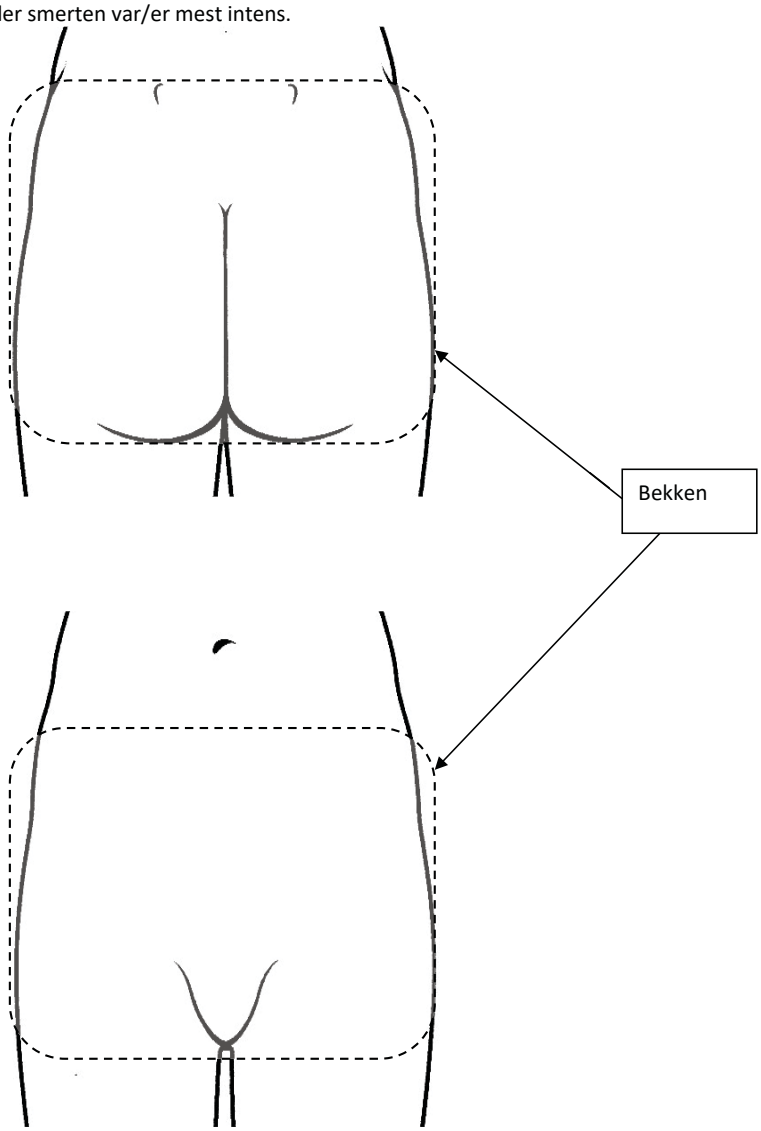
Dersom du har hatt BEKKENSMERTER

(Dersom du ikke har hatt bekkenplager, kan du gå til spørsmål 33)

29. I hvilke uker i svangerskapet begynte **bekkenplagene**? Markér med kryss i riktig rute.

1-4	5-8	9-12	13-16	17-20

30. Vis på følgende figurer nedenfor hvor bekkensmerten din var/er lokalisert ved å skravere smerte-området og sette kryss der smerten var/er mest intens.



31. Markér i hver rute, som representerer uker i svangerskapet, hvordan du i gjennomsnitt har opplevd bekkensmerten. Bruk tall fra 0 – 100 (0 = ingen smerte; 100 = uutholdelig smerte)

1-4	5-8	9-12	13-16	17-20

32. Dersom du har vært sykmeldt pga. bekkensmerte: Markér nedenfor i hvilke uker i svangerskapet du har vært sykmeldt.

1-4	5-8	9-12	13-16	17-20

33. Markér nedenfor hvor godt du har fungert i dagliglivet til nå i svangerskapet. Bruk tall fra 0 – 100 (0 = ingen problem, jeg klarte meg på egenhånd; 100 = veldig dårlig, jeg måtte ha hjelp til alt)

1-4	5-8	9-12	13-16	17-20

34. Har smerten vært så sterk at du har trengt hjelpemidler?

Krykker __Ja __Nei

Rullestol __Ja __Nei

"Glidelaken" __Ja __Nei

Bekkenbelte/korsett __Ja __Nei

35. Har du fått behandling pga bekkensmerter i dette svangerskapet?
__Ja __Nei

(Hvis **Nei** er du nå ferdig med dette spørreskjemaet)

36. Hvem oppsøkte du for behandling? (f.eks. Lege, Kiropraktor, Fysioterapeut , Akupunktør, Osteopat, Manuell Terapeut, Naprapat, annet)?
_____

Vi er interessert i å vite hva slags behandling du har gjennomgått. Nedenfor finner du spørsmål om eventuelle behandlingsmetoder som er blitt brukt. Hvis du har vært hos flere terapeuter sett gjerne i parentes hvem som gjorde hva.

37. Råd om å takle hverdagen med smerter? __Ja __Nei
Hvis ja, hva slags type råd?_____
_____

38. Hvor god effekt hadde du av rådene?

Verre	Ingen effekt	Litt effekt	God effekt	Symptomfri

39. Ble det brukt varme? __Ja __Nei (Hvis ja, hva slags terapeut?_____)

40. Ble det brukt akupunktur? __Ja __Nei (Hvis ja, hva slags terapeut?_____)

41. Var du med på bassengtrening? __Ja __Nei (Hvis ja, hva slags terapeut?_____)

42. Fikk du massasje? __Ja __Nei (Hvis ja, hva slags terapeut?_____)

43. Fikk du hjemmeøvelser? __Ja __Nei (Hvis ja, hva slags terapeut?_____)

44. Trening med veiledning ? __Ja __Nei (Hvis ja, hva slags terapeut?_____)

45. Fikk du medikamenter? __Ja Nei (Hvis ja, hva slags terapeut?_____)

46. Ble det brukt TENS-maskin/strøm? __Ja __Nei (Hvis ja, hva slags terapeut?_____)

47. Fikk du manipulasjonsbehandling ? __Ja __Nei
Hvis ja, av hvem: Kiropraktor, Manuell Terapeut, Osteopat, Naprapat eller annet?

_____

48. Har du hatt noen annen form for behandling? __Ja __Nei
Hvis Ja, hva slags type behandling?
_____

49. Hvor mange ganger har du har vært til behandling til nå i svangerskapet? _____

50. I ca hvor mange uker har du fått behandling? _____

51. Hvor godt fornøyd er du med behandlingene du har fått i svangerskapet?
Fra null til ti (0=ikke fornøyd i det hele tatt, 10= veldig fornøyd). Sett ett kryss.

0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10

52. Generelt hvor godt fornøyd er du med **behandlingstilbudet** for korsrygg- og bekkensmerter i svangerskapet?
Fra null til ti (0=ikke fornøyd i det hele tatt, 10= veldig fornøyd). Sett ett kryss.

0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10

ID-kode:

Bekkensmerter i svangerskapet

Spørreskjema ved ca 30 ukers svangerskap

Initialer:_____ Fødselsdato: _____ Dato i dag:_____

1. Hvor fysisk tungt jobber du?
Sett ett kryss.

Veldig lett Arbeid	Ganske lett arbeid	Verken lett eller tungt arbeid	Ganske tungt arbeid	Veldig tungt arbeid

Jobber ikke ☐

2. Hvor bra trives du på din jobb eller der du jobbet sist?
Sett ett kryss.

Veldig dårlig	Ikke så bra	Verken bra eller dårlig	Ganske bra	Veldig bra

3. Hvor mange uker har du vært sykmeldt til nå i svangerskapet?

Har ikke vært sykmeldt ☐
100%: _____ antall uker.
Delvis_____ %:_____ antall uker.

4. Oppgi den/de viktigste årsakene til sykmeldingen(e): _____

_____

5. Din vekt:_____kg

6. Har du vært deprimert til nå i svangerskapet?
Sett ett kryss.

Aldri	Av og til	Ofte	Nesten hele tiden

7. Dersom du har vært deprimert, i hvilke uker er/var du det?
Sett ett eller flere kryss.

17-20	**21-24**	**25-28**	**29-32**

8. Har du trent regelmessig (minst 2-3 ganger i uka) til nå i dette svangerskapet? __Ja __Nei

9.Har du hatt vondt i korsryggen til nå i dette svangerskapet?

___Ja ____Nei

10.Har du hatt vondt i bekkenet til nå i dette svangerskapet?
___Ja ____Nei

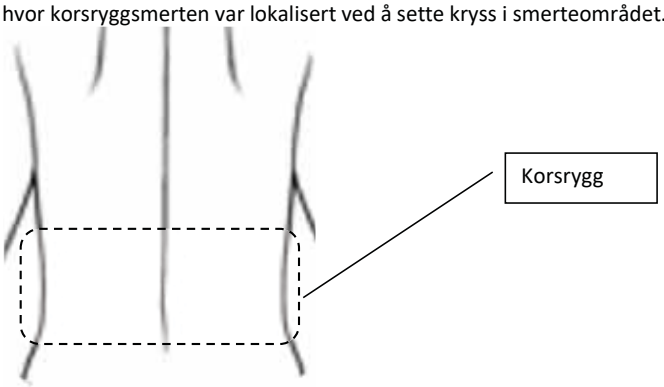
Dersom du har hatt KORSRYGGSMERTER

(har du ikke hatt korsryggsmerte, gå til spørsmål 15)

11. I hvilke **uker** i svangerskapet begynte **korsryggsmerten**? Markér med kryss i riktig rute.

17-20	**21-24**	**25-28**	**29-32**

12. Vis på figuren nedenfor hvor korsryggsmerten var lokalisert ved å sette kryss i smerteområdet.



13. Markér i hver rute, som representerer uker i svangerskapet, i gjennomsnitt hvordan du har opplevd korsryggsmerten.
Bruk tall fra 0 – 100 (0 = ingen smerte; 100 = uutholdelig smerte).

17-20	**21-24**	**25-28**	**29-32**

14. Dersom du har vært sykmeldt pga. korsryggsmerte: Markér nedenfor i hvilke uker i ditt svangerskap du har vært sykmeldt. (Markér med kryss i riktig rute.)

17-20	**21-24**	**25-28**	**29-32**

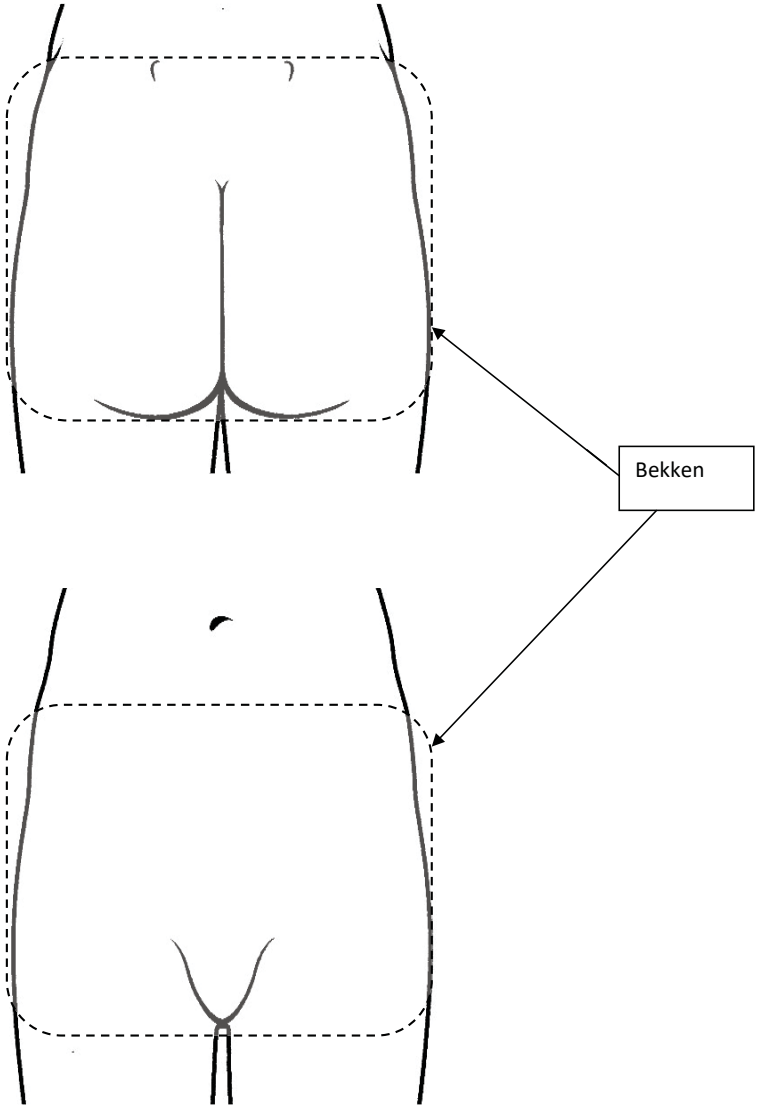
Dersom du har hatt BEKKENSMERTER

(Dersom du ikke har hatt bekkenplager, kan du gå til spørsmål 19)

15. I hvilke **uker** i svangerskapet begynte **bekkenplagene**? Markér med kryss i riktig rute.

17-20	**21-24**	**25-28**	**29-32**

16. Vis på følgende figurer nedenfor hvor bekkensmerten din er/var lokalisert ved å skravere smerteområdet og sette kryss der smerten er/var mest intens.



17. Markér i hver rute, som representerer uker i svangerskapet, hvordan du i gjennomsnitt har opplevd bekkensmerten. Bruk tall fra 0 – 100 (0 = ingen smerte; 100 = uutholdelig smerte)

17-20	**21-24**	**25-28**	**29-32**

18. Dersom du har vært sykmeldt pga. bekkensmerte: Markér nedenfor i hvilke uker i svangerskapet du har vært sykmeldt.

17-20	**21-24**	**25-28**	**29-32**

19. Markér nedenfor hvor godt du har fungert i dagliglivet i denne delen av svangerskapet. Bruk tall fra 0 – 100 (0 = ingen problem, jeg klarte meg på egenhånd; 100 = veldig dårlig, jeg måtte ha hjelp til alt)

17-20	**21-24**	**25-28**	**29-32**

20. Har smerten vært så sterk at du har trengt hjelpemidler?

Krykker __Ja __Nei

Rullestol __Ja __Nei

"Glidelaken" __Ja __Nei

Bekkenbelte/korsett __Ja __Nei

21. Har du fått noen annen form for behandling? __Ja __Nei
Hvis Ja, hva slags type behandling?
_____

22. Hvor mange ganger har du vært til behandling i denne delen av svangerskapet? _____

23. I ca hvor mange uker har du fått behandling? _____

24. Hvor godt fornøyd er du med behandlingene du fått i svangerskapet? Fra null til ti (0=ikke fornøyd i det hele tatt, 10= veldig fornøyd). Sett ett kryss.

0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10

Takk for all informasjon!

ID-kode:_____

Bekkensmerter i svangerskapet

Siste spørreskjema (ca 6 uker etter fødsel)

Initialer:_____ Barnets fødselsdato: _____ Dato i dag:_____

1. Hvor mange uker var du sykmeldt i svangerskapet?

Har ikke vært sykmeldt ☐

100%: _____ antall uker.
Delvis_____ %:_____ antall uker.

2. Oppgi den/de viktigste årsakene til sykmeldingen(e): _____
_____

3. Din vekt:_____kg

4. Din vekt like før fødselen:_____kg

5. Har du vært deprimert i løpet av svangerskapet eller etter fødselen?
Sett ett kryss.

Aldri	Av og til	Ofte	Nesten hele tiden

6. Dersom du har vært deprimert, i hvilke uker var du det?
Sett ett eller flere kryss.

29-32	33-35	36-40
Uker etter fødsel:		
1-2	3-4	5-6

7. Trente du regelmessig (minst 2-3 ganger i uka) i svangerskapet? __Ja __Nei

8. Har du hatt vondt i korsryggen i svangerskapet eller etter fødselen?
___Ja ____Nei

9. Har du hatt vondt i bekkenet i svangerskapet eller etter fødselen?
___Ja ____Nei

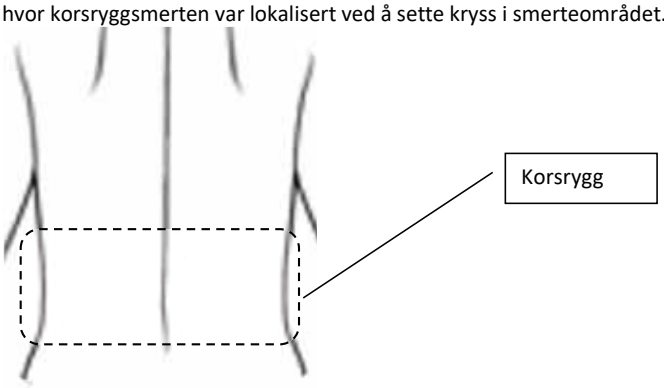
Dersom du har hatt KORSRYGGSMERTER

(har du ikke hatt korsryggsmerte, gå til spørsmål 14)

10. I hvilke **uker** i eller etter svangerskapet begynte **korsryggsmerten**? Markér med kryss i riktig rute.

29-32	33-35	36-40
Uker etter fødsel:		
1-2	3-4	5-6

11. Vis på figuren nedenfor hvor korsryggsmerten var lokalisert ved å sette kryss i smerteområdet.



12. Markér i hver rute, som representerer uker i og etter svangerskapet, i gjennomsnitt hvordan du har opplevd korsryggsmerten.

Bruk tall fra 0 – 100 (0 = ingen smerte; 100 = uutholdelig smerte).

29-32	33-35	36-40
Uker etter fødsel:		
1-2	3-4	5-6

13. Dersom du har vært sykmeldt pga. korsryggsmerte: Markér nedenfor i hvilke uker du var sykmeldt. (Markér med ett eller flere kryss.)

29-32	33-35	36-40
Uker etter fødsel:		
1-2	3-4	5-6

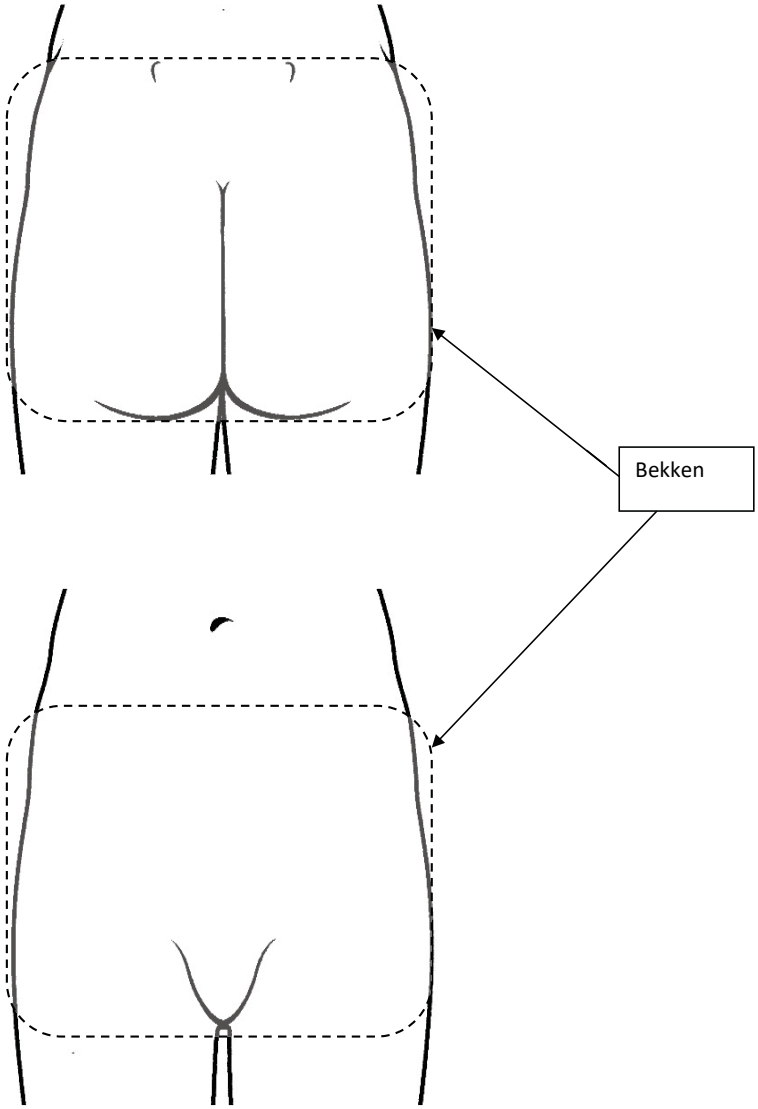
Dersom du har hatt BEKKENSMERTER

(Dersom du ikke har hatt bekkenplager, kan du gå til spørsmål 18)

14. I hvilke **uker** i eller etter svangerskapet begynte **bekkenplagene**? Markér med kryss i riktig rute.

29-32	33-35	36-40
Uker etter fødsel:		
1-2	3-4	5-6

15. Vis på følgende figurer hvor bekkensmerten din er/var lokalisert ved å skravere smerteområdet og sette kryss der smerten er/var mest intens.



16. Markér i hver rute, som representerer uker i og etter svangerskapet, hvordan du i gjennomsnitt har opplevd bekkensmerten. Bruk tall fra 0 – 100 (0 = ingen smerte; 100 = uutholdelig smerte)

29-32	33-35	36-40
Uker etter fødsel:		
1-2	3-4	5-6

17. Dersom du har vært sykmeldt pga. bekkensmerte: Markér nedenfor i hvilke uker du var sykmeldt.

29-32	33-35	36-40
Uker etter fødsel:		
1-2	3-4	5-6

18. Markér nedenfor hvor godt du har fungert i dagliglivet i den siste delen av svangerskapet og etter fødselen. Bruk tall fra 0 – 100 (0 = ingen problem, jeg klarte meg på egenhånd; 100 = veldig dårlig, jeg måtte ha hjelp til alt)

29-32	33-35	36-40
Uker etter fødsel:		
1-2	3-4	5-6

19. Har smerten vært så sterk at du har trengt hjelpemidler i eller etter svangerskapet ?

Krykker __Ja __Nei

Rullestol __Ja __Nei

"Glidelaken" __Ja __Nei

Bekkenbelte/korsett __Ja __Nei

20. Har du fått behandling pga bekkensmerter i eller etter dette svangerskapet?
__Ja __Nei

(Hvis **Nei** er du nå ferdig med dette spørreskjemaet).

21. Hvem oppsøkte du for behandling? (f.eks. Lege, Kiropraktor, Fysioterapeut , Akupunktør, Osteopat, Manuell Terapeut, Naprapat, annet)?
_____

Vi er interessert i å vite hva slags behandling du har gjennomgått. Nedenfor finner du spørsmål om eventuelle behandlingsmetoder som er blitt brukt. Hvis du har vært hos flere terapeuter sett gjerne i parentes hvem som gjorde hva.

22. Råd om å takle hverdagen med smerter? __Ja __Nei
Hvis ja, hva slags type råd?_____
_____

23. Hvor god effekt hadde du av rådene?

Verre	Ingen effekt	Litt effekt	God effekt	Symptomfri

24. Ble det brukt varme? __Ja __Nei (Hvis ja, hva slags terapeut?_____)

25. Ble det brukt akupunktur? __Ja __Nei (Hvis ja, hva slags terapeut?_____)

26. Var du med på bassengtrening? __Ja __Nei (Hvis ja, hva slags terapeut?_____)

27. Fikk du massasje? __Ja __Nei (Hvis ja, hva slags terapeut?_____)

28. Fikk du hjemmeøvelser? __Ja __Nei (Hvis ja, hva slags terapeut?_____)

29. Trening med veiledning ? __Ja __Nei (Hvis ja, hva slags terapeut?_____)

30. Fikk du medikamenter? __Ja Nei (Hvis ja, hva slags terapeut?_____)

31. Ble det brukt TENS-maskin/strøm? __Ja __Nei (Hvis ja, hva slags terapeut?_____)

32. Fikk du manipulasjonsbehandling ? __Ja __Nei
Hvis ja, av hvem: Kiropraktor, Manuell Terapeut, Osteopat, Naprapat eller annet?

_____

33. Har du hatt noen annen form for behandling? __Ja __Nei
Hvis Ja, hva slags type behandling?

_____

34. Hvor mange ganger har du vært til behandling i og etter svangerskapet? _____

35. I ca hvor mange uker har du fått behandling? _____

36. Hvor godt fornøyd er du med behandlingene du har fått i svangerskapet?
Fra null til ti (0=ikke fornøyd i det hele tatt, 10= veldig fornøyd). Sett ett kryss.

0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10

37. Generelt hvor godt fornøyd er du med **behandlingstilbudet** for korsrygg- og bekkensmerter i svangerskapet?
Fra null til ti (0=ikke fornøyd i det hele tatt, 10= veldig fornøyd). Sett ett kryss.

0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10

Universitetet i Stavanger

Stavanger Universitetssjukehus
Helse Stavanger HF

ODI

Initialer:	ID:	Dato:

Dette spørreskjemaet er utformet for å gi opplysninger om hvordan rygg- og bekkensmertene dine i gjennom svangerskapet har påvirket din evne til å klare deg i dagliglivet. Vi vil gjerne vite ***hvordan du har det nå****. Vennligst svar på hvert avsnitt, og markér bare* ***det ene feltet*** *i hvert avsnitt som gjelder for deg. Vi forstår at du kanskje synes at to av utsagnene i hvert avsnitt kan gjelde deg, men vennligst* ***markér bare feltet som best beskriver ditt problem****.*

Smerteintensitet

- ☐ 1. Jeg hadde ingen smerter i svangerskapet
- ☐ 2. Smertene var veldig svake i svangerskapet
- ☐ 3. Smertene var moderate i svangerskapet
- ☐ 4. Smertene var temmelig sterke i svangerskapet
- ☐ 5. Smertene var veldig sterke i svangerskapet
- ☐ 6. Smertene var de verste jeg kan tenke meg i ett svangerskapet

Personlig stell (vaske seg, kle på seg, osv.)

- ☐ 1. Jeg kunne stelle meg selv på vanlig måte uten at det forårsaket ekstra smerter
- ☐ 2. Jeg kunne stelle meg selv på vanlig måte, men det var veldig smertefullt
- ☐ 3. Det var smertefullt å stelle meg selv, og jeg måtte gjøre det langsomt og forsiktig
- ☐ 4. Jeg trengte noe hjelp, men klarte det meste av mitt personlige stell
- ☐ 5. Jeg trengte hjelp hver dag til det meste av eget stell
- ☐ 6. Jeg kledde ikke på meg, hadde vanskeligheter med å vaske meg, og holdt sengen

Løfte

- ☐ 1. Jeg kunne løfte tunge ting uten å få mer smerter
- ☐ 2. Jeg kunne løfte tunge ting, men fikk mer smerter
- ☐ 3. Smertene hindret meg i å løfte tunge ting opp fra gulvet, men jeg greide det hvis det som skulle løftes var gunstig plassert, f.eks. på et bord
- ☐ 4. Smertene hindret meg i å løfte tunge ting, men jeg klarte å løfte lette eller middels tunge ting, hvis det var gunstig plassert
- ☐ 5. Jeg kunne bare løfte noe som var veldig lett
- ☐ 6. Jeg kunne ikke løfte eller bære noe i det hele tatt

Gå

- ☐ 1. Smertene hindret meg ikke i å gå i det hele tatt
- ☐ 2. Smertene hindret meg i å gå mer enn 1500 m
- ☐ 3. Smertene hindret meg i å gå mer enn 750 m
- ☐ 4. Smertene hindret meg i å gå mer enn 100 m
- ☐ 5. Jeg kunne bare gå med stokk eller krykker
- ☐ 6. Jeg lå for det meste i sengen og jeg måtte krabbe til toalettet

Sitte

- ☐ 1. Jeg kunne sitte så lenge jeg ville i en hvilken som helst stol
- ☐ 2. Jeg kunne sitte så lenge jeg ville i min favorittstol
- ☐ 3. Smertene hindret meg i å sitte i mer enn en time
- ☐ 4. Smertene hindret meg i å sitte i mer enn en halv time
- ☐ 5. Smertene hindret meg i å sitte i mer enn ti minutter
- ☐ 6. Smertene hindret meg i å sitte i det hele tatt

Stå

- ☐ 1. Jeg kunne stå så lenge jeg ville uten å få mer smerter
- ☐ 2. Jeg kunne stå så lenge jeg ville, men fikk mer smerter
- ☐ 3. Smertene hindret meg i å stå i mer enn en time
- ☐ 4. Smertene hindret meg i å stå i mer enn en halv time
- ☐ 5. Smertene hindret meg i å stå i mer enn ti minutter
- ☐ 6. Smertene hindret meg i å stå i det hele tatt

Sove

- ☐ 1. Søvnen min ble aldri forstyrret av smerter
- ☐ 2. Søvnen min ble forstyrret av og til av smerter
- ☐ 3. På grunn av smerter fikk jeg mindre enn seks timers søvn
- ☐ 4. På grunn av smerter fikk jeg mindre enn fire timers søvn
- ☐ 5. På grunn av smerter fikk jeg mindre enn to timers søvn
- ☐ 6. Smertene hindret all søvn

Seksualliv

- ☐ 1. Seksuallivet mitt var normalt og forårsaket ikke mer smerter
- ☐ 2. Seksuallivet mitt var normalt, men forårsaket noe smerter
- ☐ 3. Seksuallivet mitt var normalt, men svært smertefullt
- ☐ 4. Seksuallivet mitt var svært begrenset pga smerter
- ☐ 5. Seksuallivet mitt var nesten borte på grunn av smerter
- ☐ 6. Smertene forhindret alt seksualliv

Sosialt liv

- ☐ 1. Det sosiale livet mitt var normalt og forårsaket ikke mer smerter
- ☐ 2. Det sosiale livet mitt var normalt, men økte graden av smerter
- ☐ 3. Smertene hadde ingen betydelig innvirkning på mitt sosiale liv, bortsett fra at de begrenset mine mer fysisk aktive sider, som sport osv.
- ☐ 4. Smertene begrenset mitt sosiale liv og jeg gikk ikke så ofte ut
- ☐ 5. Smerte begrenset mitt sosiale liv til hjemmet
- ☐ 6. På grunn av smertene hadde jeg ikke noe sosialt liv

Reising

- ☐ 1. Jeg kunne reise hvor som helst uten smerter
- ☐ 2. Jeg kunne reise hvor som helst, men det gav mer smerter
- ☐ 3. Smertene var ille, men jeg klarte reiser på to timer
- ☐ 4. Smertene begrenset meg til korte reiser på under en time
- ☐ 5. Smertene begrenset meg til korte, nødvendige reiser på under 30 minutter
- ☐ 6. Smertene forhindret meg fra å reise, unntatt for å få behandling

The Modified Oswestry Disability Index (Baker et al 1990)
Oversatt av Margreth Grotle og Nina K:Vøllestad 2001,
Seksjon for Helsefag, Universitetet I Oslo

Initialer:	ID:	Dato:

Universitetet i Stavanger

EQ-5D

Stavanger Universitetssjukehus
Helse Stavanger HF

Spørreskjema om Helse

Vis hvilke utsagn som passer best på din helsetilstand ved å sette kryss i en av rutene utenfor hver av gruppene nedenfor.

Gange

Jeg hadde ingen problemer med å gå omkring. ☐
Jeg hadde litt problemer med å gå omkring. ☐
Jeg var sengeliggende. ☐

Personlig stell.

Jeg hadde ingen problemer med personlig stell. ☐
Jeg hadde litt problemer med å vaske meg eller å kle meg. ☐
Jeg var ute av stand til å vaske meg eller å kle på meg. ☐

Vanlige gjøremål (f.eks. arbeid, studier, husarbeid, familie- eller fritidsaktiviteter).

Jeg hadde ingen problemer med å utføre mine vanlige gjøremål. ☐
Jeg hadde litt problemer med å utføre mine vanlige gjøremål. ☐
Jeg var ute av stand til å utføre mine vanlige gjøremål. ☐

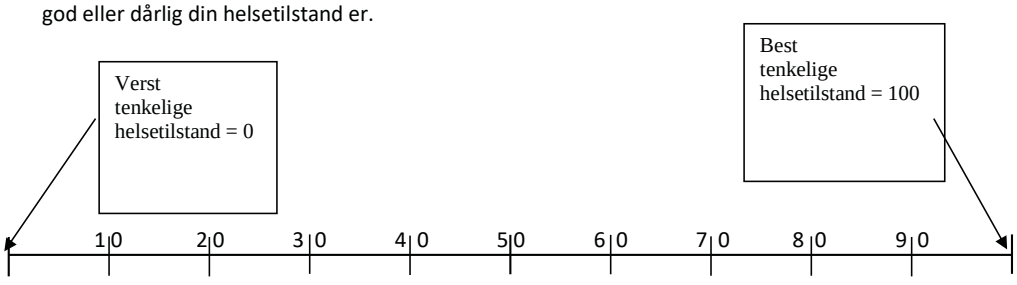
Smerte/ubehag

Jeg hadde verken smerte eller ubehag. ☐
Jeg hadde moderat smerter eller ubehag. ☐
Jeg hadde sterk smerte eller ubehag. ☐

Angst/depresjon

Jeg var verken engstelig eller deprimert. ☐
Jeg var noe engstelig eller deprimert. ☐
Jeg var svært engstelig eller deprimert. ☐

For å hjelpe folk til å si hvor god eller dårlig en helsetilstand er, har vi laget en skala (omtrent som et termometer) hvor den beste helsetilstanden du kan tenke deg er merket 100 og den verste tilstanden du kan tenke deg er merket 0.
Vi vil gjerne at du viser på denne skalaen hvor god eller dårlig din helsetilstand er, etter din oppfatning. Vær vennlig å gjøre dette ved å sette ett kryss på det punktet på skalaen som viser hvor god eller dårlig din helsetilstand er.



Undersøkelsesskjema

Funksjons/bevelighet:

Gange (sett ring rundt riktig svar);
Normal gange
Rolig, korte steg men symmetrisk gange
Halter usymmetrisk gange
Bruker krykker
Bruker rullestol

Nevrologisk Undersøkelse:

Reflekser (graderes fra 0 til 4+); Hø Ve

Patella (L4)
Hamstring (L5)
Akilles (S1)

Myotomer (graderes fra 0 til 5); Hø Ve

Fleksjon hofte (L2/3)
Ekstensjon hofte (L3/4)
Fleksjon kne (L4/5)
Ekstensjon kne (L5/S1)
Ankel Dorsifleksjon (L5)
Ankel Plantarfleksjon (S1)
Store tå ekstensjon (L5)
Storetå fleksjon (S1)
Hel gange (L5);
Tå gange (S1);

Sensibilitet Hø hypoestesi/hyperestesi Ve hypoestesi/hyperestesi

L1- dermatom
L2-dermatom
L3-dermatom
L4dermatom
L5 dermatom
S1 dermatom
Ikke dermatomisk mønster

Kliniske tester

(sett hake ved smerter og tall på ASLR)	Hø	Ve
Lasegue		
P4		
ASLR (graderes fra 0-5)		
Palpation of the long dorsal SIJ ligament.		
Gaenslens test.		
Palpation of the symphysis		
Modified Trendelenburg test of the pelvic girdle..		
Patrick Fabere		

ASLR	Hø	Ve

Graderes fra 0-5.
0= Ikke vanskelig å gjøre i det hele tatt.
1= Litt vanskelig å gjøre
2= Vanskelig å gjøre
3= Ganske vanlig å gjøre
4= veldig vanskelig å gjøre
5= klarer ikke å gjennomføre testen

Indirekte tester;	Hø	Ve
Passiv Hofte fleksjon		
Passiv SLR		
Passiv innad hofte rotasjon		

KONKLUSJON

Unspecific Low back pain/Uspesifikke ryggsmerter	□
Skivepatologi med isjalgi	□
Hanne Alberts Subgrupper;	
Gruppe 1 (Pelvic Girdle syndrome-3 ledd smerter)	□
Gruppe 2 (Symphysiolysis)	□
Gruppe 4 (Dobbelsidig Ileosacralledd)	□
Gruppe 5 (Diverse)	□

Gruppe 3 Validert smertetegning (ensidig smerter) □

Negativ Lasegue □

Positiv P4 test □

NB!
Kombinert Gruppe 3 pluss positiv symphyse test går inn i gruppe
Kombinert med lette korsryggsmerter går inn i gruppe 3.

Kommentarer:

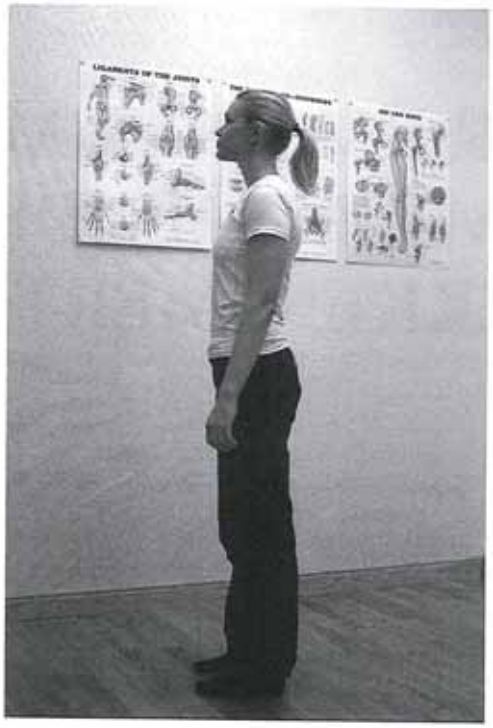
Appendix – Training diary

ØVELSE DAGBOK

FOR KVINNER MED VEDVARENDE BEKKENSMERTER

1. HOLDNING.

-Kjenn hvordan du står?
-Har du tyngden foran eller bak på foten?
-Hvordan kjennes det i rygg/bekken?
-Hev helene fra gulvet (gå nesten opp på tå), senk rolig ned, løsne i knærene og kjenn at du står midt over foten-Hvordan kjennes det i rygg/bekken? Noen forskjell?
-Kjenn at du slapper av i brystrygg og skuldre.



2. SITTENDE BEKKEN VIPP

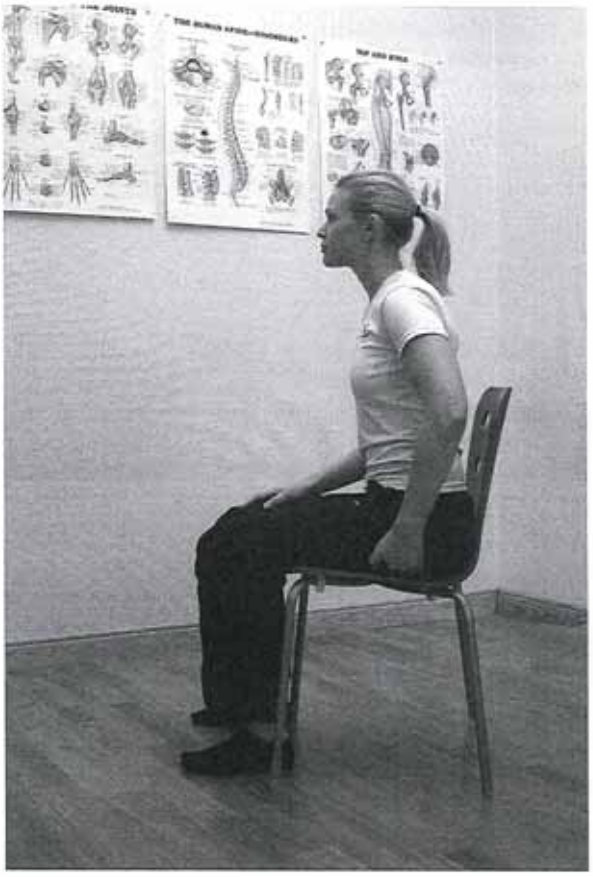
- Sitt godt inn på stolen, sitt bredt (trekk sitteknutene litt fra hverandre), beina litt fra hverandre og slapp av i brystryggen.
- Legg en finger i hofte leddet på hver side.
- Len fremover og beveg hofteleddet (kjenn at fingeren "blir borte" inn mot hofteleddet)
- Gå rolig tilbake.
- Gjenta noen ganger og kjenn at bevegelsen bare skjer i hofteleddet.
- Dett skal ikke provosere smerter i bekken/rygg.

3. REISE/SETTE SEG.

- Sett ett ben litt bak det andre, støtt gjerne hendene på lårene, bøy i hofteleddet og len deg framover mens du reiser deg opp. Se gjerne på et punkt foran deg mens du utfører øvelsen.
-Hold hele tiden ryggen i midtstilling (ikke svai eller krum nedre del av ryggen).
-Øvelsen skal ikke gjøre vondt.
- Når du setter deg, setter du ett ben bak det andre, støtter hendene på lårene, bøyer i hofteleddet (setter baken litt ut) og setter deg ned.
-Hold ryggen i midtstilling (ikke svai eller krum nedre del av ryggen)
- Det skal ikke gjøre vondt.

4. SITTE BREDT.

- Sitt på en stol og føl at du har lik tyngde på begge sitteknutene.
- Ta tak under høyre sitteknute og dra utover til siden.
- Ta tak under venstre sitteknute og dra utover til siden.
- Føl at du sitter bredt, stødig og med lik tyngde på begge sider. Ikke snurp den ene siden sammen!
-Kjenn at du slapper av i korsryggen (midtstilling) og i brystrygg og skuldre.
- Bruk øvelsen i dagliglivet (dvs. når du sitter passer du på at du sitter stødig og bredt).
-Varier stilling ofte og etter behov.



5. ENSIDIG SKREDDERSTILLING MED STREKK AV SETEMUSKULATUR.

Alternativ sittestilling.

-Legg det ene benet over det andre slik at du sitter med det ene benet i skredderstilling.
- Slapp av og la kneet senke seg.
- Kjenn at ryggen er i midtstilling og at du slapper av i brystrygg og skuldre.

Tøyning.

- Sitt skrått inn i en sofa (eller bord) med det ene benet i skredderstilling.
- Bygg opp med puter hvis det strekker mye (og du er stram og kort i setemuskulaturen).
-Len deg forsiktig fremover ved å bøye i hofteleddene og svaie lett i ryggen, kjenn at strekket i muskulaturen øker, hold i 35-40 sekunder mens du puster rolig. Len deg ytterligere litt fremover når strekket avtar. Det skal være litt "godt-vondt"
- Gjenta 2 ganger om dagen

6. MOTSITTENDE STOL.

- Når du er sliten og ønsker å slappe litt av i ryggen kan du bruke denne hvilestillingen.
- Snu en stol (helst uten armlener) slik at stolryggen er mot deg.
- Sett deg overskrevs på stolen og len deg lett framover og slapp av i ryggen, eventuelt krum korsryggen som variasjon. Slapp av i denne stillingen en stund før du setter deg tilbake i en annen stilling.
- Innta denne stillingen gjerne før du blir sliten også.

7. TØYE FRAMSIDE LÅR OG HOFTE

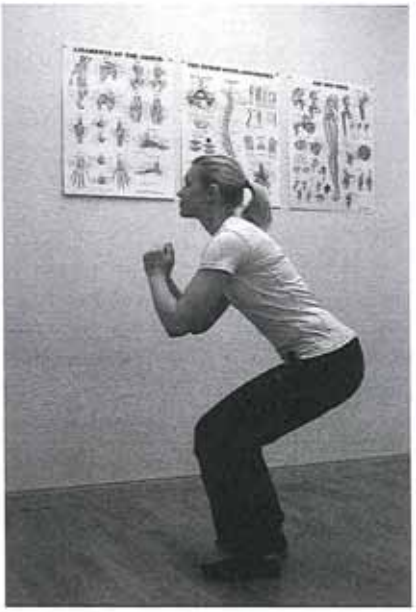
- Stå og grip tak i ankelen på det ene benet, trekk setet under deg, skyv hoftekammen frem, UTEN og svaie i ryggen, kjenn at det strekker, press så forsiktig benet bakover.
- Hold i 30-45 sekunder, mens du puster. Trekk ytterligere litt bakover når strekken avtar.
- Det skal være "godt-vondt"

Alternativt;

Stå på ett kne med det andre benet støttet ved siden av deg, trekk setet under deg, skyv hoftekammen frem- Uten å svaie i ryggen, kjenn at det strekker, skyv deg så forsiktig litt fremover.

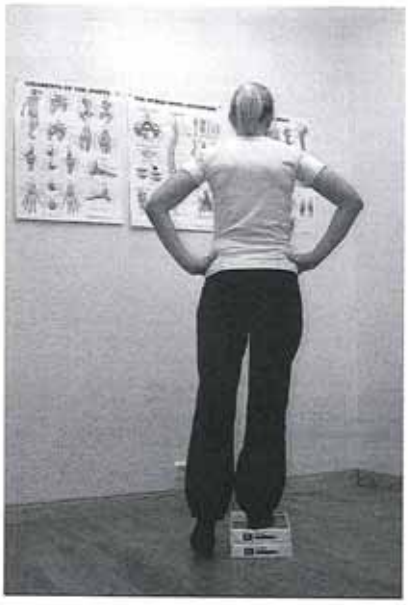
8. KNEBØY.

- Stå med beina lett fra hverandre (skulderbreddes avstand). Eventuelt litt under helene.
- Tyngden midt over foten, slapp av i rygg og skuldre. Bøy i hofteleddet og la hendene gli nedover lårene til knærne.
- Strekk lårene mens du reiser deg opp igjen.
- Gjenta, etter hvert kan du øke tempo og vekt.
- For å gjøre øvelsen tyngre hold barnet ditt inntil deg mens du utfører øvelsen. God trening for lårene og gøy for barnet.



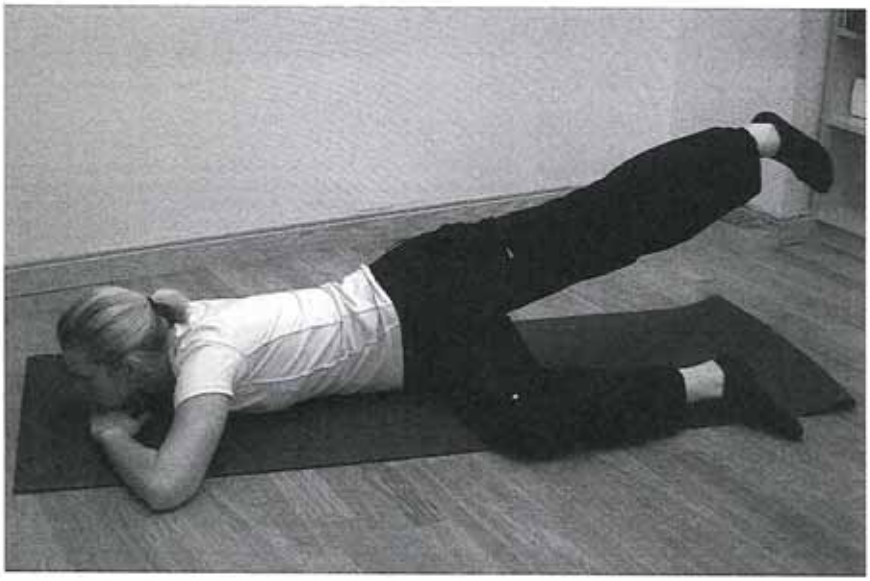
9. GÅ OPP TRAPPETRINN

- Stå ved en trapp.
- Sett ett ben i første trinn, senk hoften, legg vekt på benet (kne over tå) og strekk opp.
- Kjenn at du bruker muskulatur i lår og hoftens sidemuskulatur.
- Senk rolig ned og gjenta.



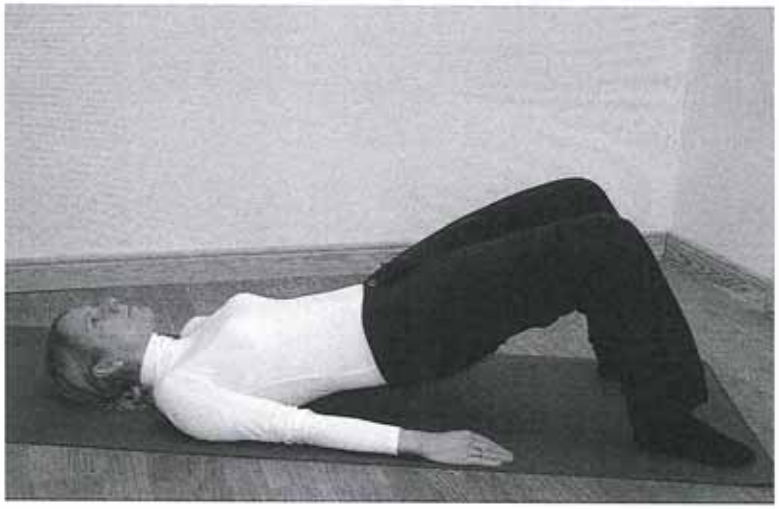
10. ENSIDIG LØFT AV BEN.

- Ligg stødig på siden med nederste ben bøyd under deg.
- Strekk det øverste benet BAKOVER (bak midtlinjen og hoftekammen) og løft strak opp.
- Kjenn at du jobber med setemuskulaturen, senk rolig ned og gjenta.

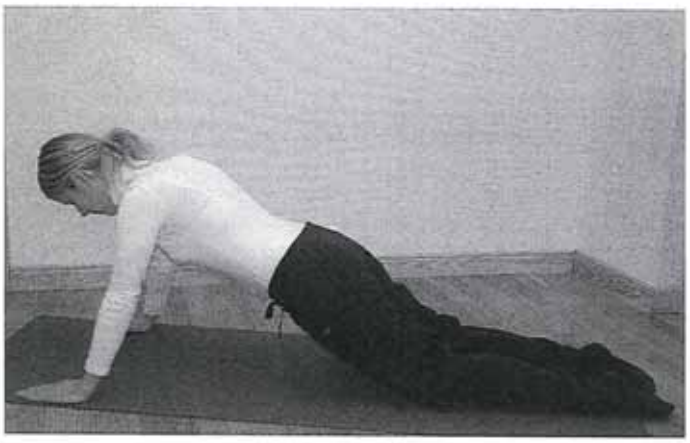


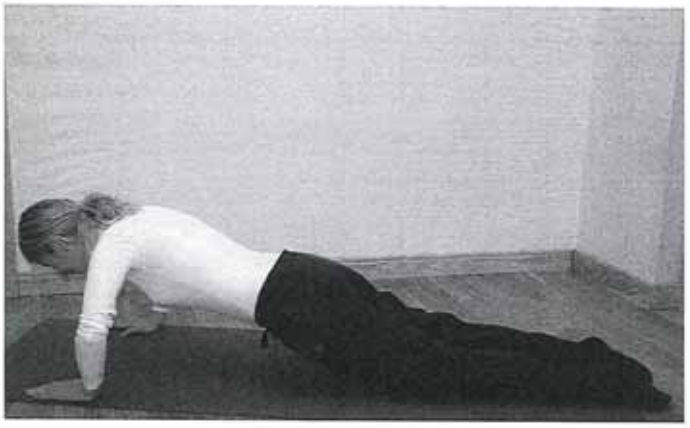
11. RYGGLIGGENDE SETELØFT.

- Ligg på rygg med bøyde ben (eventuelt med bena over noe).
- Trekk forsiktig nedre del av magen inn mot ryggen, trekk setemuskulaturen (rompehalvdelene) mot hverandre og løft setet opp.
- Hold ryggen i midtstilling (ikke svai eller krum rygg).



12. ARMHEVINGER PÅ KNE.





ØVELSER	MAN	TIRS	ONS	TOR	FRE	LØR	SØN
1. HOLDNING							
2. SITTENDE BEKKEN VIPP							
3. REISE/SETTE SEG							
4. SITTE BREDT.							
5. ENSIDIG SKREDDERSTILLING MED STREKK							
6. MOTSITTENDE STOL.							
7. TØYE FRAMSIDE LÅR							
8. KNEBØY.							
9. GÅ OPP TRAPPETRINN.							
10. ENSIDIG LØFT AV BEN							
11. RYGGLIGGENDE SETELØFT							
12. ARMHEVNINGER PÅ KNE							

Id Kode; **Intialer;**

Kommentarer:

Øvelser gitt:

	dato	dato	dato	dato	dato	dato	dato	dato	dato	dato	dato
Hold											
Sitt vipp											
Reise seg											
Sitte Bredt											
Ensidigskredd											
Motsi stol											
Tøye lår											
Knebøy											
Trappe Trinn											
Ensidig løft											
Seteløft											
Armhevinger											
Skrå mage											