UNIVERSITY OF PRIMORSKA
FACULTY OF MATHEMATICS, NATURAL SCIENCES
AND INFORMATION TECHNOLOGIES

Iva Šklempe Kokić

# EFFECTS OF THERAPEUTIC EXERCISES ON PREGNANCY-RELATED LOW BACK PAIN AND PELVIC GIRDLE PAIN

# UČINKI TERAPEVTSKE VADBE NOSEČNIC NA BOLEČINO V KRIŽU IN MEDENICI

Master's thesis

Koper, June 2016

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APPLIED KINESIOLOGY

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Master's thesis

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Povzetek: Nosečniška bolečina v ledvenem predelu hrbta (BLP) in medeničnem obroču (BMO) je opredeljena kot ponavljajoča se ali stalna bolečina v spodnjem delu hrbta in medenici, ki traja več kot teden dni. Termin ledveno-medenična bolečina se uporablja, kadar se BLP in BMO ne ločujeta. Cilj magistrske naloge je bil raziskati učinke nadzorovanega individualizirano strukturiranega terapevtskega programa vadbe, ki se sestoji iz aerobnih vaj in vaj proti uporu, na pojavnost in resnost nosečniške ledveno-medenične bolečine. Opazovali smo stopnjo samoocenjene ledveno-medenične bolečine, rezultate Numeric Rating Scale (NRS), Roland-Morris Disability Questionnaire (RMDQ), Pelvic Girdle Questionnaire (PGQ) in pogostost koriščenja bolniškega dopusta. Petinštirideset nosečnic je bilo naključno razvrščenih v dve skupini: eksperimentalno, ki je izvajala terapevtsko vadbo (ES; N = 20) in kontrolno (KS; N = 22), z običajno predporodno nego. Strukturiran vadbeni program je bil izvajan dvakrat tedensko, od začetka vključitve v študijo do zaključka nosečnosti. Poleg tega, so nosečnice v ES dnevno izvajale najmanj 30 minut hitre hoje. Skupno je bilo v času študije izvedenih 419 individualnih vadbenih ur, v povprečju 21 ± 7.6 vadbenih ur na nosečnico in povprečno realizacijo 83.7%. Rezultati so pokazali statistično značilno razliko v PGQ rezultatih v 30. tednu nosečnosti ($P = 0.05$, $d = -0.64$, $r = -0.31$) in v NRS, PGQ in RMDQ rezultatih v 36. tednu nosečnosti ($P = 0.017$, $d = -0.80$, $r = -0.37$; $P = 0.005$, $d = -0.85$, $r = -0.39$; $P < 0.001$, $d = -0.90$, $r = -0.41$). Pri nosečnicah v ES je prej prišlo do pojava ledveno-medenične bolečine ($P = 0.013$). V stopnji samoocenjene ledveno-medenične bolečine, NRS in RMDQ rezultatih v 30. tednu nosečnosti in deležu bolniškega dopusta, med skupinama ni bilo statistično pomembnih razlik. Prav tako smo ugotovili, da se število vadbenih ur in trajanje

intervencije negativno povezujeta z intenzivnostjo bolečine v ledveno-medeničnem predelu. Rezultati naše študije jasno potrjujejo pozitivne učinke vadbenega programa na intenzivnost bolečine v ledveno-medeničnem predelu v nosečnosti. Vadba ni imela vpliva na razširjenost bolečine v ledveno-medeničnem predelu, ampak je zmanjšala intenzivnost bolečine in nesposobnosti.

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Key words: pregnancy, low back pain, pelvic girdle pain, therapeutic exercise, training, physical activity

Abstract: Pregnancy related low back pain (LBP) and pelvic girdle pain (PGP) are defined as lower back and pelvis recurrent or continuous pain which lasts for more than one week. The term lumbopelvic pain is used where there is no distinction between LBP and PGP. The aim of this thesis was to investigate effects of supervised individualized structured therapeutic exercise programme consisting of aerobic and resistance exercises on the prevalence and severity of pregnancy-related lumbopelvic pain. Main outcomes were rate of self-reported lumbopelvic pain, results of Numeric Rating Scale (NRS), Roland-Morris Disability Questionnaire (RMDQ), Pelvic Girdle Questionnaire (PGQ) and frequency of sick leave. Forty-five pregnant women were randomly assigned into two groups: experimental group who performed therapeutic exercise (EG; N = 20) and control group (CG; N = 22) with standard antenatal care alone. Structured exercise programme was performed from the inclusion in the study till the end of pregnancy biweekly. Furthermore, pregnant women in EG performed at least 30 minutes of vigorous walk once per day. A total of 419 exercise sessions were performed during the trial, with 20.95 ± 7.56 sessions on average per subject and adherence to protocol was 83.70%. Results showed significant difference in PGQ scores in 30$^{th}$ week of pregnancy (P = 0.05, *d* = -0.64, *r* = -0.31) and NRS, PGQ and RMDQ scores in 36$^{th}$ week of pregnancy (P = 0.017, *d* = -0.80, *r* = -0.37; P = 0.005, d = -0.85, *r* = -0.39; P < 0.001, *d* = -0.90, *r* = -0.41). EG had earlier onset of lumbopelvic pain (P = 0.013). There were no significant differences between groups in the rate of self-reported lumbopelvic pain, NRS and RMDQ score in 30$^{th}$ week of pregnancy and rate of sick leave. We also found positive dose-response relationship because number of sessions and duration of the intervention were negatively correlated with the severy of lumbopelvic pain. Our results clearly confirm positive effects of exercise programme on severity of

lumbopelvic pain in pregnancy. Exercise did not have influence on prevalence of lumbopelvic pain but it reduced intensity of pain and disability.

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# IZJAVA O AVTORSTVU MAGISTRSKEGA DELA

Podpisana Iva Šklempe Kokić študentka magistrskega študijskega programa 2. stopnje Aplikativna kineziologija,

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- rezultat lastnega raziskovalnega dela,
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# LIST OF ABBREVIATIONS

| Abbreviation | Description |
|---|---|
| ASLR | active straight leg raise |
| ACOG | American College of Obstetricians and Gynecologists |
| BMI | body mass index |
| bpm | beats per minute |
| *d* | Cohen's d |
| DRI | Disability Rating Index |
| CG | control group |
| EG | experimental group |
| FHR | fetal heart rate |
| HR | heart rate |
| LBP | low pack pain |
| max | maximum |
| maxHR | maximal heart rate |
| MET | metabolic equivalent |
| min | minimum |
| N | sample size |
| NRS | Numeric Rating Scale |
| PGQ | Pelvic Girdle Questionnaire |
| PGP | pelvic girdle pain |
| PPAQ | Pregnancy Physical Activity Questionnaire |
| PRLP | pregnancy-related lumbopelvic pain |

| | |
|---|---|
| QDQ | Quebec Disability Questionnaire |
| $r$ | Pearson's correlation coefficent |
| $r_s$ | Spearman's rank correlation coefficient |
| $r_{pbi}$ | point-biserial correlation coefficient |
| RMDQ | Rolland Morris Disability Questionnaire |
| SD | standard deviation |
| SF-8 MCS | Short-form Health Survey Mental Component Summary |
| SF-8 PCS | Short-form Health Survey Physical Component Summary |
| THR | target heart rate |
| VAS | visual analogue scale |

# LIST OF APPENDICES

# 1 INTRODUCTION

Pregnant women without contraindications should engage in regular, moderate-intensity physical activity during pregnancy for at least 20-30 minutes per day on most or all days of the week (American College of Obstetricians and Gynecologists (ACOG), 2015). Women with uncomplicated pregnancies should be encouraged to engage in aerobic and strength-conditioning exercise before, during and after pregnancy (ACOG, 2015). On the other hand, pregnant women tend to reduce their physical activity levels and those with lumbopelvic pain are less likely to exercise regularly (Owe, Nystad & Bø, 2009). Observational studies have demonstrated protective effects of physical activity before pregnancy on development of lumbopelvic pain (Mogren & Pohjanen, 2005; Östgaard, Zetherstrom, Roos-Hansson & Svanberg, 1994). However, sedentary coping strategies are more frequent than exercising in women with lumbopelvic pain (Chang, Yang, Jensen, Lee & Lai, 2011). Inactivity leads to deconditioning and there is association between reduced muscle function and lumbopelvic pain in pregnancy (Gutke, Östgaard & Öberg, 2008).

Moreover, lack of physical activity is associated with a large number of possible complications during pregnancy and childbirth. Regular physical activity during pregnancy improves or maintains physical fitness, helps with weight management, reduces the risk of gestational diabetes mellitus in obese women and enhances psychologic well-being (ACOG, 2015). No study has reported adverse effects of stabilizing exercises on pregnancy and fetal outcomes (Elden, Östgaard, Fagevik-Olsen, Ladfors & Hagberg, 2008). Prospective epidemiology study of 92 671 pregnant women has reported no association between exercise performed after 18 weeks of pregnancy and risk of miscarriage (Madsen et al, 2007).

## 1.1 Pregnancy-related lumbopelvic pain

Pregnancy-related lumbopelvic pain includes low back pain (LBP) and pelvic girdle pain (PGP). It is a common musculoskeletal dysfunction during pregnancy affecting quality of life and causing work absenteeism and disability. Pregnancy related LBP

and PGP is defined as lower back and pelvis recurrent or continuous pain which lasts for more than one week (Mogren & Pohjanen, 2005). LBP is defined by pain between the 12$^{th}$ rib and the gluteal fold and it may radiate down the leg (Vleeming, Albert, Östgaard, Sturesson & Stuge, 2008). PGP is defined by pain between the posterior iliac crest and the gluteal fold, particularly in the vicinity of the sacroiliac joints (Vleeming et al, 2008). It can also radiate in the posterior thigh. Likewise, it can occur in conjuction with, or exclusive, pain in the symphysis pubis (Vleeming et al, 2008). The term lumbopelvic pain is used when there is no distinction between LBP and PGP (Wu et al, 2004).

PGP can be diagnosed after exclusion of lumbar pathology (Vleeming et al, 2008). There is no international agreement on differentiation between LPB and PGP, however, classification of PGP exists (Vleeming et al, 2008). Correct treatment is difficult due to several factors with lack of clear definition and unclear pathogenesis being the most important.

Despite extensive clinical interest and increasing number of trials and publications. there is still no consensus regarding the incidence, symptoms, treatment strategies and final outcome of pregnancy-related PGP and LBP wich is the result of the multiplicity and overlapping of the terminology and definitions (Kanakaris, Roberts & Giannoudis, 2011).

### 1.1.1 Prevalence end etiology of pregnancy-related lumbopelvic pain

Imprecise definition and heterogeneity of study designs caused incosistent reporting of the prevalence of lumbopelvic pain in pregnancy. Prevalence of lumbopelvic pain vary between 4% to 90% (Albert, Godskesen & Westergaard, 2002; Mazicioglu et al, 2006; Östgaard, Andersson & Karlsson, 1991; Pennick & Young, 2007; Vleeming et al, 2008; Vermani, Mittal & Weeks, 2010; Pennick & Liddle, 2013). Prevalence of PGP is 20.1% (Albert et al, 2002). PGP is classified into 5 subgroups with different prevalence: pelvic girdle syndrome (6%), symphysiolysis (2.3%), one-sided sacroiliac syndrome (5.5%), double-sided sacroiliac syndrome (6.3%) and miscellaneous pain (1.6%) (Albert et al, 2002). There are no

geographical differences between PGP prevalence among pregnant women in the world (Björklund & Bergström, 2000).

The reported risk of PGP relapse in subsequent pregnancies is 85% (Mens, Vleeming, Stoeckart, Stam & Snijders, 1996). Considering the low back pain prevalence of around 6% in general population of non pregnant 30 year old women (Bierring-Sørenson, 1984) it is evident that pregnancy-related lumbopelvic pain represents serious health and socioeconomic problem.

Pathogenesis and etiology of pregnancy-related lumbopelvic pain is unclear and probably multifactorial. High incidence is probably caused by several factors such as altered posture during pregnancy with increased lumbar lordosis, ligamentous laxity caused by hormones relaxin and progesterone, and fluid retention within connective tissues (MacEvilly & Buggy, 1996). Anterior shift in the center of gravity causes an increased anterior pelvic tilt and places more stress on sacroiliac joints and ligaments, as well as paraspinal musculature (Ritchie, 2003). Also, stretch in abdominal diameter causes insufficiency of the abdominal muscles (Fast, Weiss, Docummun, Medina & Butler, 1990). It is not known if the shift in the center of gravity, or insufficient abdominal muscles, or both, lead to pregnancy-related LBP (Noon & Hoch, 2012). Weight gain in pregnancy increases the force on joints, which in combination with increased joint laxity and muscle weakness or poor endurance may lead to LBP and PGP (Noon & Hoch, 2012). Reduced EMG activity in L4 and L5 paraspinal musculature of women in their first trimester of pregnancy is associated with more pain and disability throughout the pregnancy (Sihvonen, Huttunen, Makkonen & Airaksinen, 1998). Furthermore, muscular endurance of the back extensors and back flexors along with decreased hip extensor strength is reduced in women with pregnancy-related LBP and PGP (Gutke et al, 2008). Norén, Östgaard, Johansson & Östgaard (2002) also reported lower endurance of the back extensors and hip abductors in women with pregnancy-related LBP and PGP. Weakness in m. gluteus medius is associated with pregnancy-related LBP (Bewyer, Bewyer, Messenger & Kennedy, 2009). Pregnancy-related weight gain places increased stress upon the m. gluteus medius during stance and gait (Foti, Davids & Bagley, 2000). If m. gluteus medius endurance and/or strength is reduced, lateral trunk stabilizers are at increased activation with a possibility for developing Trendelenburg gait pattern. This increased activation along increased pelvic tilt can

lead to posterior pelvic pain (Foti et al, 2000). Furthermore, Trendelenburg gait pattern can itself contribute to LBP (Bewyer & Bewyer, 2003).

Possible mechanism for pain and disability in pregnant women with PGP could be also abnormal motor control patterns since positive changes in motor control are associated with reduction in pain and disability (O'Sullivan & Beales, 2007; Stuge, Veierød, Laerum & Vøllestad, 2004; Stuge, Laerum, Kirkesola & Vøllestad, 2004). During the last months of pregnancy and the first 3 weeks after delivery, motion of the pelvic girdle joints is 32-68% higher in patients with lumbopelvic pain in comparison to healthy controls (Mens, Pool-Goudzwaard & Stam, 2009). This finding supports the idea that hypermobility is one of the factors that cause pain and justifies treatment strategies aimed to reduce that motion (Mens et al, 2009). There is also theory that pain which worsens at night could be the result of venous engorgement in the pelvis. Uterus presses on the vena cava, especially in supine position which in combination with fluid retention leads to venous congestion and hypoxia in the pelvic and lumbar spine (Sabino & Grauer, 2008). Disc herniation or bulging of an intervertebral disc and subsequent nerve compression only presents in about 1% of pregnant women (Sabino & Grauer, 2008).

Physically and psychosocially demanding working conditions like physically strenuous work, rotating shifts, night shifts and high job strain are associated with an increased incidence of pelvic pain in pregnancy (Juhl, Andersen, Olsen & Andersen, 2005). Likewise, parity, previous trauma to the pelvis, previous LBP and PGP, abnormal BMI, history of hypermobility and amenorrhea are also risk factors for developing lumbopelvic pain (Mogren & Pohjanen, 2005; Vleeming et al, 2008).

### 1.1.2 Symptoms and course of pregnancy-related lumbopelvic pain

The main symptome is pain which usually increases as pregnancy advances. This can have negative effect on daily activities, such as: walking, lifting, climbing stairs, lying in prone position, housework and employment, hobbies and leisure (Wormslev et al, 1994). Symptoms are usually worse during the night, especially in the last trimester of pregnancy. Common tasks, like walking or standing, further increase the pain in 80% of pregnant women (Röst, Jacqueline, Kaiser, Verhagen & Koes,

2004). Among women with lumbopelvic pain, 45% women reported the pain-related problems as „mild", 30% as „moderate", and 25% as „severe" (Wu et al, 2004).

Diagnosis of lumbopelvic pain during pregnancy is based on symptoms and provocation tests. Pain intensity is usually measured by Visual Analogue Scale or Numeric Rating Scale, and disability with questionnaires. The onset of pain is usually by weeks 17-19 and incidence peaks by weeks 24-36 (Östgaard et al, 1991). Twenty to thirty percent of pregnant women describe their symptoms as severe and disabling (Björklund, Nordström & Bergström, 1999; Hansen et al, 1999; Östgaard et al, 1991). PGP in pregnancy is more disabling than LBP. Pregnant women affected by PGP have higher pain scores and they are perceived as more difficult to treat (Berg, Hammar, Möller-Nielsen, Lindén, Thorblad, 1998; Gutke, Östgaard & Öberg, 2006; Östgaard et al, 1994; Robinson, Mengshoel, Bjelland & Vøllestad, 2010). Main characteristics of pregnancy-related LBP and PGP can be found in Table 1.

*Table 1: Characteristics of LBP and PGP*

| LBP | PGP |
|---|---|
| Pain may be present earlier in life | New type of pain, debut during pregnancy |
| Pain located in the lumbar region | Pain located between the posterior iliac crest and the gluteal folds, predominantly around sacroiliac joints |
| Decreased lumbar spine range of movement | Normal lumbar spine range of movement |
| Tenderness to palpation over lumbar paraspinal musculature | Tenderness to palpation over sacroiliac joints and gluteal musculature |
| Problems with walking and standing to a lesser degree | Pain with walking and/or standing |
| Constant pain | Pain-free intervals |
| Negative provocation test for pelvic pain | Positive provocation test for pelvic pain |

*Source: Norén et al, 2000; Noon & Hoch, 2012.*

Pregnant women diagnosed with both LBP and PGP have much stronger odds ratio for persistent pain (Gutke et al, 2008). Postpartum depressive symptoms are 3 times more prevalent in women who had lumbopelvic pain in comparison to those without (Gutke, Josefsson & Öberg, 2007). Combined PGP and LBP and women with pain in all three pelvic joints reported the greatest negative impact on health and function (Gutke et al, 2006; Albert, Godskesen & Westergaard, 2001).

Pain is usually resolved after delivery. However, persistant pain is present in 5-27% women 1-3 months and in 7% women six months after delivery (Östgaard et al, 1997). Furthermore, 51% of women report LBP 1 year postpartum (Padua et al, 2005), and 20% of women 3 years postpartum (Norén et al, 2002). High pain intensity indicates bad prognosis after delivery (Östgaard, Roos-Hansson & Zetherstrom, 1996). Pain location is possibly the most important predictor of recovery. Less than 10% of pregnant women affected by PGP with pain in two or less joint regions had symptoms 2 years after delivery compared to 21% of pregnant women with pain in all three joints (Grotle, Brox, Veierød, Glomsrød, Lønn & Vøllestad, 2005). Two years postpartum prevalence of lumbopelvic pain equals that of the general population (Östgaard et al, 1997). Ten percent of women with chronic LBP report that their pain started during pregnancy (Svensson, Andersson, Hagstad & Jansson, 1990). Up to 85% of women with pregnancy-related LBP will have LBP in subsequent pregnancies (Brynhildsen, Hansson, Persson & Hammar, 1998).

Active straight leg raise (ASLR) test and belief in improvement are strong predictors of clinical significance in women with PGP postpartum (Vøllestad & Stuge, 2009). Predictors of persistent PGP or combined PGP and LBP postpartum are low endurance of back flexors, older age, combined pain in early pregnancy and work dissatisfaction (Gutke et al, 2008). For every 10 seconds lost in endurance, which was assessed by isometric contraction of back flexors in supine position where participants had to lift their inferior angle of scapula from surface and keep it that way as long as they could, the risk of PGP or combined PGP and LBP was increased by 18% (Gutke et al, 2008). Likewise, for being older by every year, the risk increases by 20% (Gutke et al, 2008). Epidural or spinal anaesthesia during labour is not associated with long term risk of persistent LBP, however, elective Caesarean section is significantly associated with an increased risk of persistent LBP postpartum compared to emergency Caesarean section (Mogren, 2007).

### 1.1.3 Treatment of pregnancy-related lumbopelvic pain

Pregnancy-related lumbopelvic pain is traditionally accepted as a common and normal condition. However, given the negative impact on the quality of life, and

activities of daily life, it should not be accepted as a normal condition and treatment should be offered to all pregnant women with symptoms.

First line of treatment is conservative, non-pharmacological treatment, both for LBP and PGP in pregnancy. Physiotherapy is the main treatment, including passive therapies like manual therapy, and active treatment like therapeutic exercise (Vleeming et al, 2008). Further treatment modalities include aquatic therapy, acupuncture, ergonomic advice, use of pelvic belt and other physiotherapy modalities. Surgical treatment is not an option. Pharmacological treatment options are very limited.

Acupuncture and use of pelvic belt are supported by a strong level of evidence (Gutke, Betten, Degerskär, Pousette & Olsén, 2015). Different types of pelvic belts reduced the intensity of pain for pregnant women with lumbopelvic pain (Kalus, Kornman & Quinlivan, 2008). For women with PGP, a non rigid belt was useful only over short term (Kordi et al, 2013), and only rigid belt reduced the pain for women with pain in symphysis pubis (Depledge, McNair, Keal-Smith & Williams, 2005). Exercise can reduce intensity of pain, improve function and reduce disability (Pennick & Liddle, 2013; Gutke et al, 2015). However, there are no specific guidelines regarding the type, duration and frequency of exercise for lumbopelvic pain in pregnancy.

Supervised exercise programme is recommended as a first line treatment for patients with non-specific chronic low back pain in non pregnant population (Airaksinen et al, 2006). Manual therapy, specific training of the local muscles and education are also effective in increasing functional capacity and reducing the symptoms. Also, there is evidence that therapeutic aquatic exercise is beneficial for non-specific low back pain (Waller, Lambeck & Daly, 2009). Specific stabilisation exercise programme is an effective treatment option for many forms of spinal pain and related disability (Ferreira, Ferreira, Maher, Herbert, Refshauge, 2006). Therapeutic exercises recommended for pregnancy-related LBP are similar to those for non-specific LBP, with minor modifications, and it is assumed that they have similar mechanism of action (Vermani et al, 2010).

Group exercise might not be optimal treatment for the treatment of lumbopelvic pain. The European guidelines for PGP (Vleeming et al, 2008) recommend

individualized exercises in pregnancy. Supervision of exercises is very important for maintaining quality of exercise performance and there is a strong correlation between quality of exercise performance and decrease of pain (Friedrich, Cermak & Maderbacher, 1996). Individualized treatment programmes are more effective at reducing the intensity of pain and sick leave in comparison to group programmes (Östgaard et al, 1994; Norén, Östgaard, Nielsen & Östgaard, 1997).

Over 50% of women receive little or no treatment from healthcare providers for lumbopelvic pain in pregnancy (Greenwood & Stainton, 2001; Skaggs et al, 2007). Likewise, pregnant women constitute one third of all sick leave for women between 20 and 39 years, and by 32$^{nd}$ week of pregnancy, 63% of Norwegian women are on sick leave, most of them because of PGP (Dörheim, Bjorvatn & Eberhard-Gran, 2013). In the United States, 11% of pregnant women take sick leave because of LBP (Wang et al, 2004). Also, there are increasing numbers of pregnant women requesting Caesarean sections and labour inductions prior the 39$^{th}$ week of pregnancy with the purpose to alleviate the symptoms (Vermani et al, 2010). Nineteen percent of women with pregnancy-related LBP chose not to have subsequent pregnancy because of fear of recurrent LBP (Brynhildsen et al 1998). All these suggest that there is a great need to investigate etiology, pathogenesis and treatment strategies for LBP and PGP in pregnancy.

## 1.2 Therapeutic exercise and pregnancy-related lumbopelvic pain

Therapeutic exercise is one of the commonest interventions for pregnancy-related lumbopelvic pain. Twenty studies have been conducted untill now regarding the effects of exercise therapy and its efficiency in treating and prevention of lumbopelvic pain in pregnant women (Table 2). These studies included 4173 subjects. The number of studies is relatively small and overall methodological quality moderate. Moreover, results are inconsistent. Most commonly assessed outcomes were pain and disability. However, methods of outcome measurement, time and number of measurements varied through studies. Also, definition of LBP and PGP varied through studies, and some studies did not differentiate between PGP and LBP.

Most of the studies compared some type of exercise therapy as unique intervention or combination of exercise therapy and some other physiotherapy modality to standard antenatal care (Kihlstrand, Stenman, Nilsson & Axelsson, 1999; Suputtitada, Wacharapreechanont & Chaisayan, 2002; Depledge et al, 2005; Garshasbi & Faghih Zadeh, 2005; Martins & Pinto e Silva, 2005; Nillson-Wikmar, Holm, Öijerstedt & Harms-Ringdahl, 2005; Haugland, Rasmussen & Daltveit, 2006; Mørkved, Salvesen, Schei, Lydersen & Bø, 2007; Sedaghati, Ziaee & Ardjmand, 2007; Beyaz, Özcan, Ketenci & Beyaz, 2011; Kluge, Hall, Louw, Theron & Grové, 2011; Eggen, Stuge, Mowinckel, Jensen & Hagen, 2012; Stafne, Salvesen, Romundstad, Stuge & Mørkved, 2012; George, Skaggs, Thompson, Nelson, Gavard & Gross, 2013; Miquelutti, Cecatti & Makuch, 2013; Haakstad & Bö, 2015).

One study compared exercise therapy to acupuncture (Wedenberg, Moen & Norling, 2000) and another one exercise with acupuncture and standard care (Elden, Ladfors, Olsen, Östgaard & Hagberg, 2005). Third study compared exercise therapy with chiropractic manual techniques (Peterson, Hass & Gregory, 2012). Granath, Hellgren & Gunnarsson (2006) compared land based and water exercises.

Duration of interventions was from 1 week to 20 weeks, but majority was conducted between 8-12 weeks. Sample size varied from 36 to 761 pregnant women. Gestational age also varied, but most of the interventions were during the second half of the pregnancy. Types of intervention included stabilization exercises (Depledge et al, 2005; Elden et al, 2005; Nillson-Wikmar et al, 2005; Kluge et al, 2011; Haugland et al, 2006; Eggen et al, 2012), water gymnastics (Kihlstrand et al, 1999), combination or comparison of land and/or water exercises and other physiotherapy modalities (Wedenberg et al, 2000; Granath et al, 2006, Peterson et al, 2012; George et al, 2013), exercises for global muscle activity and stretching (Martins & Pinto e Silva, 2005), combination of pelvic floor, aerobic and additional strength exercises (Garshasbi & Faghih Zadeh, 2005; Mørkved et al, 2007; Sedaghati et al, 2007; Stuge et al, 2012; Beyaz et al, 2011; Miquelutti et al, 2013; Haakstad & Bö, 2015) and pelvic tilt exercise (Suputtitada et al, 2002). Three studies included aquatic exercise, as part of the multimodal physiotherapy programme (Wedenberg et al, 2000), as the main intervention (Kihlstrand et al, 1999) and in comparison to land based exercises (Granath et al, 2006).

Most studies (12) found positive effects of exercise therapy on pain and disability (Kihlstrand et al, 1999; Suputtitada et al, 2002; Depledge et al, 2005; Elden et al, 2005; Garshasbi & Faghih Zadeh, 2005; Martins & Pinto e Silva, 2005; Granath et al, 2006; Mørkved et al, 2007; Sedaghati et al, 2007; Beyaz et al, 2011; Kluge et al, 2011; George et al, 2013). Some of the studies (8) did not find significant difference between exercise and control group (Wedenberg et al, 2000; Nilsson-Wikmar et al, 2005; Haugland et al, 2006; Eggen et al, 2012; Stafne et al, 2012; Peterson et al, 2012; Miquelutti et al, 2013; Haakstad & Bö, 2015).

Acupuncture, compared to multimodal physiotherapy programme (Wedenberg et al, 2000) and stabilizing exercises (Elden et al, 2005) showed superior results. Wedenberg et al (2000) conducted a study to compare 10 sessions of acupuncture and 10 sessions of multimodal physiotherapy programme which included education, correction of the posture, use of pelvic belt, soft tissue mobilisation and land and aquatic exercises. Interventions were conducted 1 to 2 times per week during 6-8 weeks. Sixty pregnant women before their $32^{nd}$ week of gestation were included in the study. Outcomes were disability, measured by Disability Rating Index (DRI), and pain, measured by Visual Analogue Scale (VAS). Mean VAS values were significantly lower in acupuncture group, both in the morning (3.4 to 0.9, 3.7 to 2.3, respectively, $p = 0.02$), as well as in the evening (7.4 to 1.7, 6.6 to 4.5, respectively, $p < 0.01$). Mean DRI values decreased significantly only in acupuncture group. However, 12 pregnant women from the exercise group dropped out of the trial making it difficult to determine general clinical significance of the trial.

Elden et al (2005) had similar results on larger sample size. They included 386 pregnant women between $12^{th}$ and $31^{st}$ week of pregnancy. There were two experimental groups and one control group receiving standard care. First experimental group received acupucture, advice, home exercise programme and pelvic belt for 6 weeks. Second experimental group received 6 hours of instruction of specific individual stabilization exercises, advice, home exercise programme and pelvic belt for 6 weeks. Control group received standard care plus advice, pelvic belt and home exercise programme. Stabilization exercises emphasized activation and control of local deep lumbopelvic muscles. Also, dynamic exercises of more superficial muscles to improve mobility, strength and endurance capacity were gradually introduced. After the intervention stabilizing exercise group had less pain in the morning ($p = 0.03$) and in the evening ($p = 0.02$) than control group.

Acupuncture group had less pain in the evening than the stabilizing exercise group ($p = 0.01$). No significant differences in positive pain drawings were reported between the groups; 93% from control group, 85% from acupuncture group and 87% from stabilizing exercise group reported pain.

Sixty minutes of group exercise, once per week during 12 weeks including pelvic floor muscle contractions twice per day and education is effective in reducing the prevalence of lumbopelvic pain in pregnancy ($p = 0.01$) in comparison to control group who received only information (Mørkved et al, 2007). Research indluded 301 pregnant women in their $20^{th}$ week of pregnancy. Group exercises consisted of aerobic exercises, pelvic floor muscles contractions and additional strength exercises. Exercise programme prevented lumbopelvic pain in 1 in 8 women. However, intensity of pain was not measured. Also, there was no difference in sick leave during the pregnancy, but exercise group had significantly higher scores on functional status ($p = 0.01$). Measured outcome was disability (DRI), but reported clinical relevance was less than 10%.

Martins & Pinto e Silva (2005) found similar results in their study on much smaller sample which included 69 women after their $12^{th}$ week of pregnancy. Intervention consisted of group exercises for global muscle activity and stretching. Control group received only standard care. At the end of the study, 61% of women from the experimental group reported no lumbar or posterior pelvic pain ($p = 0.01$). On the other hand, only 11% of participants from control group had no pain.

Sedaghati et al (2007) studied effects of exercise programme on 90 women which were included in the study between $20^{th}$ and $22^{nd}$ week of pregnancy. Intervention included three exercise sessions per week for 8 weeks in duration. Measured outcome was lower back pain (Quebec Disability Questionnaire). Control group had significant increase in the intensity of low back pain at the end of the trial ($p < 0.0001$).

Garshasbi & Faghih Zadeh (2005) also investigated the effect of the exercise during pregnancy on the intensity of low back pain and spine kinematics. They included 212 women during their second half of the pregnancy. Exercise programme was performed three times per week for 60 minutes during 12 weeks and included 15 exercises for abdominal and hamstring muscles and for increasing flexibility of

iliopsoas and paravertebral muscles. Control group received only standard antenatal care. At the end of the trial low back pain was increased in the control group and exercise group showed significant reduction in the intensity of low back pain after exercise ($p < 0.0001$).

One small study (Beyaz et al, 2011) also confirmed positive effects of exercise programme consisting of aerobic exercises, strength exercises and stretching performed 3 times per week from second trimester of pregnancy till the 37 weeks of pregnancy on frequency and intensity of low back pain. However, this trial was not randomized.

South African study performed by Kluge et al (2011) confirmed beneficial effect of exercise which consisted of stretches, exercises for m. transversus abdominis and pelvic floor muscles along with co-contraction of various other muscle groups. There were significant differences in pain intensity and functional ability scores between the groups at the end of the study ($p < 0.01$ and $p = 0.03$, respectively).

Nilsson-Wikmar et al (2005) had different results. Their trial included 118 pregnant women with PGP before their $35^{th}$ week of gestation. One experimental group received advice, pelvic belt and participated in exercise programme which consisted of 4 different strengthening and stabilization exercises twice per week. Exercises were performed until $39^{th}$ week of pregnancy. Average time between inclusion and week 38 was 16 weeks (4-27). Second experimental group received advice, pelvic belt and home exercise programme consisting of 3 exercises for pelvic stabilization. Compliance was not recorded. Control group received only advice and pelvic belt. There were no significant differences in pain and activity between 3 groups during pregnancy or at follow ups postpartum.

Haugland et al (2006) reported similar results. They investigated effects of group intervention for pregnant women with PGP in their second half of pregnancy. Intervention group consisted of 275 women who participated in education program which involved advice, ergonomics and exercises once per week for 4 weeks. Control group consisted of 285 women which were not offered any treatment. However, 60% of them searched for an alternative treatment. No significant differences between groups were reported regarding pain, however self-evaluated utility of the intervention group was high in the intervention group.

Two recent studies from 2012 were also unable to confirm positive effects of group exercise in pregnancy (Eggen et al, 2012; Stafne et al, 2012). Eggen et al (2012) investigated effects of exercise on prevalence of LBP and PGP in pregnancy. Authors included 257 healthy pregnant women. Experimental group received supervised exercise programme, ergonomic and home exercise advice. Exercise session were conducted once a week for 60 minutes, from gestational week 16 to week 36. Aim of the exercise programme was to achieve efficient motor control and ability to dynamically control and stabilize lumbopelvic region during activities of daily life. Exercises focused on pelvic floor muscles and trasversely oriented abdominal muscles with coordinated activity of global muscles. There was no effect on prevalence of LBP or PGP. Likewise, there were no significant differences in pain intensity and disability between groups.

Stafne et al (2012) came to similar results. They studied lumbopelvic pain in 765 women randomised to a regular exercise programme group and control group receiving only standard care. Their intervention included aerobic and strengthening exercises between $20^{th}$ and $36^{th}$ week of pregnancy, once per week under supervision, and twice per week at home. There were no significant differences between groups regarding pain levels in $36^{th}$ week. however, proportion of sick leave was lower in the intervention group ($p = 0.01$). Most recent study performed on sedentary pregnant women by Haakstad & Bö (2015) also did not find significant differences between exercising and control group in number of women reporting low back pain and pelvic girdle pain at the end of their intervention and postpartum. Likewise, there were no differences regarding disability and severity of complaints. Their intervention consisted of 60 minutes of general fitness class, with 40 minutes of endurance training and 20 minutes of strength training performed at least twice per week for a minimum of 12 weeks.

Home exercise programme performed three times a day for one week improved functional outcome measured by Roland-Morris Questionnaire and Patient Specific Functional Scale (Depledge et al, 2005). Trial included 90 pregnant women with lumbopelvic pain in three groups. First group only exercised, second group exercised and used rigid pelvic belt and third group exercised and used non rigid pelvic belt. There was no control group. There was significant reduction in the Roland-Morris Questionnaire score, Patient Specific Functional Score and pain scores in all groups. However, there were no differences between groups, with the

exception of average pain score. The worst pain scores decreased by 22.6 in exercise only group, by 12.7% in group which used non rigid pelvic belt and exercised and by 10.8% in group which used rigid belt and exercised.

Likewise, home exercise programme performed 2 times a day in combination with education and manual therapy in total duration of 5-9 weeks significantly reduces Numerical Rating Scale and Quebec Disability Questionnaire scores in pregnant women with LBP and PGP (George, Skaggs, Thompson, Nelson, Gavard & Gross, 2013). On the other hand, intervention consisting of education and non aerobic exercises during monthly prenatal visits and home exercise programme consisting of pelvic muscles exercises, activation of m. transversus abdominis, stretching and 30 minutes of aerobic exercises performed daily does not impact prevalence nor intensity of lumbopelvic pain in healthy pregnant women (Miquelutti, Cecatti & Makuch, 2013). However, this intervention encouraged women to exercise more during pregnancy as shown on Pregnancy Physical Activity Questionnaire (PPAQ) scores ($p = 0.009$). Furthermore, home exercise programme consisting of strengthening exercises and stretching performed 5 times per week does not offer any advantages in comparison to manual chiropractic treatment for LBP in pregnancy (Peterson et al, 2012).

Kihlstrand et al (1999) compared aquatic exercise performed once per week for 1 hour during 20 weeks of pregnancy with standard care. Study sample consisted of 258 pregnant women included before $19^{th}$ week of gestation. Measured outcomes were pain, sick leave and adverse effects. Intensity of pain and sick leave significantly reduced in the experimental group, with no adverse effects. Pelvic tilt exercise performed 5 times per week for 8 weeks in third trimester also reduced intensity of pain without any adverse effects (Suputtitada et al, 2002). The mean VAS score of back pain in the experimental group was significantly lower at day 56 of the trial in comparison to day 0, and also lower than the control group at day 56 ($p < 0.05$). Water aerobics focused on strength, flexibility and fitness, in comparison to similar land exercise programme offers significant benefits (Granath et al, 2006). Pregnant women enrolled in water aerobics had significantly lower prevalence of LBP ($p = 0.04$) and less sick leave ($p < 0.0001$) in comparison to women enrolled in land exercises. However, there were no differences regarding the occurence of PGP.

Generally, pregnant women who participated in exercise programmes reported less pain and disability. However, not all studies reported this positive effect. Methodological quality of studies was moderate with high potential for bias. Some authors did not use adequate methods of allocation of participants. Likewise, some authors did not report if the main assessor was blinded. Heterogeneity of participants and interventions does not allow precise comparison of performed trials. There were large differences among gestational age, sample size, type of intervention, mode of intervention, duration, timing and frequency of intervention as well as measured outcomes. There were also several variables which could possibly affect pregnancy-related back pain including time of day, trimester of pregnancy, mental health status, work place factors, previous experience of back pain, hypermobility and maternal age (Albert, Godskesen, Korsholm, Westergaard, 2006; Gutke et al, 2007; Juhl et al, 2005; Kristiansson, Svaredsudd & von Schoultz, 1996; Mogren & Pohjanen, 2005; Östgaard et al, 1991; Östgaard, Andersson, Shultz & Miller, 1993; Orvieto, Achiron, Ben-Rafael & Achiron, 1994). Also, there is no consensus in literature regarding most valid and reliable outcome measures for pregnancy-related LBP and PGP. Different methods for outcome measurement affect the possibility to interpret effects of different intervention for the same pathology and it is impossible to distinguish whether the difference is the result of a different outcome measurement or the intervention.

Regardless, overall results are promising in reduction of pain intensity, increase in fuctional status and decrease in sick leave. There were no reported adverse effects on pregnancy and fetus. Specific stabilization exercises for trasversely oriented abdominal muscles which also include both local and global muscles showed most benefit for LBP and PGP. Different training parameters like duration, intensity, timing and frequency are not investigated enough and evidence is very limited. There is a great need for more research in that area.

*Table 2: Characteristics of prospective trials on the role of exercise in the treatment and prevention of lumbopelvic pain*

| Authors | Sample | R | Intervention | Outcome measures and results |
|---|---|---|---|---|
| Kihlstrand et al, 1999 | 258; ≤ 19 week of gestation | yes | EG (n=129): 1-hour weekly water gymnastics, 20x<br>CG (n=129): no treatment<br>Duration in weeks: 20<br>Type of intervention: group exercise | VAS: p = 0.034 (in first postpartum week)<br>Sick leave: p = 0.031 |
| Wedenberg et al, 2000 | 60 ; ≤ 32. week of gestation, with LBP | yes | EG1 (n=30): acupuncture, 10x<br>EG2 (n=30, 12 dropped out): multimodal physiotherapy (including exercises), 1-2 weekly, 10x<br>CG: none<br>Duration in weeks: 6-8<br>Type of intervention: home exercise | DRI: significant only in acupuncture group<br>VAS: lower in acupuncture group (p = 0.02 in the morning and in the evening p < 0.01) |
| Suputtitada et al, 2002 | 67; 3rd trimester, with LBP | yes | EG (n=32): sitting pelvic tilt exercise, twice a day, 5 days/week<br>CG (n=35): standard care<br>Duration in weeks: 8<br>Type of intervention: N/A | VAS at day 56: p < 0.05 |
| Martins & Pinto e Silva, 2005 | 69; > 12 weeks of gestation, with LBP or PGP | yes | EG (n=33): exercises in groups for «global active stretching»<br>CG (n=36): routine medical recommendations<br>Duration in weeks: up to 8 | VAS and provocation tests: reduced intensity of pain in exercise group (p < 0.01) |

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| | | | Type of intervention: group exercise | |
| Depledge et al, 2005 | 90; with PGP | yes | EG1 (n=30): exercises, advice, rigid pelvic belt<br>EG2 (n=30): exercises, advice, non rigid pelvic belt<br>CG (n=30): exercises, advice<br>Duration in weeks: 1<br>Type of intervention: group exercise | RMDQ: no difference between groups<br>Patient-Specific Functional Scale: no difference between groups<br>NRS-101: pain reduction in exercise-only group and the group receiving exercise plus a rigid belt but not for non rigid pelvic belt group ($p = 0.04$) |
| Elden et al, 2005 | 386 ; within 12-31 week, with PGP | yes | EG1 (n=125): acupuncture, advice, home exercise, pelvic belt<br>EG2 (n=131): specific individual stabilization exercise, advice, home exercise, pelvic belt<br>CG (n=130): standard care, advice, home exercise, pelvic belt<br>Duration in weeks: 6<br>Type of intervention: home exercise | VAS: reduced intensity of pain compared to CG ($p = 0.03$), but acuncture group had lower intensity of pain than exercise group ($p < 0.0001$) |
| Garshasbi & Faghih Zadeh, 2005 | 212; 2nd half of pregnancy | yes | EG (n=107): 15 exercises , 60 min, 3x weekly<br>CG (n=105): standard care<br>Duration in weeks: 12<br>Type of intervention: N/A | KEBK questionnaire: $p < 0.0001$<br>Flexibility of the spine: $p < 0.0001$ |
| Nilsson-Wikmar et al, 2005 | 118; before week 35, with PGP | yes | EG1 (n=37): information, nonelastic sacroiliac belt, in clinic exercise<br>EG2 (n=41): information, nonelastic sacroiliac belt and | VAS: no significant difference<br>DRI : no significant difference |

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| | | | home exercise program<br>CG (n=40): information, nonelastic sacroiliac belt<br>Duration in weeks: 16<br>Type of intervention: home and in clinic exercise | |
| Haugland et al, 2006 | 560; 18-32 weeks of gestation, PGP | yes | EG (n=275): information, ergonomics/body posture, stretching and stabilizing exercises<br>CG (n=285): no treatment<br>Duration in weeks: 4<br>Type of intervention: group exercise | VAS: no significant differences 6 months postpartum |
| Granath et al, 2006 | 330, after gestational week 11-12 | yes | EG1 (n= 198): land based aerobic and strengthening exercises 1x weekly<br>EG2 (n=132): water aerobic and strengthening exercises, 1x weekly<br>CG: none<br>Duration in weeks: on average 13 for land based exercises; on average 16 for water aerobic exercises<br>Type of intervention: N/A | Frequency of LBP: $p = 0.04$ (in favour of water aerobic group)<br>Frequency of PGP: no significant difference<br>Sick leave: $p < 0.001$ (in favour of water aerobic group) |
| Mørkved et al, 2007 | 301; from week 20 | yes | EG (n=148): daily pelvic floor muscle training at home and weekly group training for pelvic muscles and additional muscles for 60 minuts<br>CG (n=153): standard care<br>Duration in weeks: 12 | Self-reported symptoms at 36 weeks: $p= 0.033$<br>Sick leave: no significant difference<br>DRI: $p = 0.011$ |

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| | | | Type of intervention: group exercise | |
| Sedaghati et al, 2007 | 90; 20-22 weeks of gestation | yes | EG (n=40): aerobic exercise program, 3 x per week<br>CG (n=50): standard care<br>Duration in weeks: 8<br>Type of intervention: supervised exercise | Quebec Low Back Pain Questionnaire: increase in control group ($p < 0.001$), but not in experimental group; no comparison between groups |
| Beyaz et al, 2011 | 36; in second trimester | no | EG (n=15): exercise program 3 x per week consisting of aerobic and strenghtening exercises and stretching<br>CG (n=21): standard care<br>Duration in weeks: n/a<br>Type of intervention: group exercise | Frequency of LBP: $p < 0.001$<br>VAS: $p = 0.0001$ |
| Kluge et al, 2011 | 50; 16-24 weeks of gestation, with LBP | yes | EG (n=26): group exercise and home exercise for m. transversus abdominis, pelvic floor, other muscles and stretching<br>CG (n=24): standard care<br>Duration in weeks: 10<br>Type of intervention: group exercise | NRS: $p < 0.01$<br>Likert-modified RMDQ: $p = 0.03$ |
| Eggen et al, 2012 | 257; before 20 weeks of gestation | yes | EG (n=129): supervised weekly exercises consisting of aerobic and strenghtening exercises for 60 min, local + global muscles, advice, home exercise with 3 exercises daily<br>CG (n=128): standard care<br>Duration in weeks: 16-20 | Self-reported LPB and PGP: no significant difference<br>NRS: no significant difference<br>RMDQ: no significant difference<br>SF-8 PCS: no significant difference<br>SF-8 MCS: no significant difference |

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| | | | Type of intervention: group exercise | |
| Stafne et al, 2012 | 761; between weeks 20-36 | yes | EG (n=396): exercise program 1x weekly consisting of aerobic and strenghtening exercises for 60 min, 2x weekly home exercises<br>CG (n=365): standard care<br>Duration in weeks: 12<br>Type of intervention: group exercise | Self reports of pain: no significant difference<br>Self reports of sick leave: less sick leave (p=0.04)<br>DRI: no significant difference<br>VAS: no significant difference |
| Peterson et al, 2012 | 57; at any point during pregnancy, with LBP | yes | EG1 (n=22): home programme of strengthening and streching exercises, 5x per week<br>EG2 (n=15): spinal manipulation<br>EG3 (n=20): neuro emotional technique<br>CG: none<br>Duration in weeks: n/a<br>Type of intervention: home exercise | RMDQ: no significant difference<br>NRS: no significant difference |
| George et al, 2013 | 169; between weeks 24-28, with LBP/PGP | yes | EG(n=87): education, manual therapy, home exercise 2x per day<br>CG(n=82): standard care<br>Duration in weeks: 5-9<br>Type of intervention: home exercise | NRS: $p < 0.001$<br>QDQ: $p < 0.001$<br>Clinical tests: $p < 0.001$<br>Patient global impression of change: $p < 0.001$ |
| Miquelutti et al, 2013 | 197; between weeks 18- | yes | EG(n=97): education and non aerobic exercises on the same days of prenatal visits, home exercise consisting of pelvic floor exercises, m. transversus abdominis activation, | PPAQ: significant difference regarding energy expenditure on physical exercise (p=0.009) |

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|---|---|---|---|---|
| | 24 | | stretching and aerobic exercise 1x per day<br>CG(n=100): standard care<br>Duration in weeks: n/a<br>Type of intervention: home exercise and supervised exercise | Self-report on lumbopelvic pain: no significant difference<br>VAS: no significant difference |
| Haakstad & Bö, 2015 | 105; sedentary women within first 24 weeks of pregnancy | yes | EG (n=52): 60 min of general fitness class, with 40 min of endurance training and 20 min of strength training 2x per week<br>CG (n=53): standard care<br>Duration: minimum of 12 weeks<br>Type of intervention: group exercise | Number of women reporting pain after the intervention (mean week of pregnancy 36.6) and postpartum: no significant differences<br>Disability and severity of pain: no significant differences |

EG – experimental group; CG – control group; NRS – numeric rating scale; QDQ – Quebec task force disability questionnaire; PPAQ – Pregnancy Physical Activity Questionnaire; VAS – visual analogue scale; RMDQ – Roland-Morris Disability Questionnaire; SF-8 PCS – Short-form Health Survey Physical Component Summary; SF-8 MCS – Short-form Health Survey Mental Component Summary; DRI - Disability Rating Index

## 1.3 Aim of the thesis

The aim of this master thesis was to examine and add new scientific evidence on health-related effects of supervised individualized structured therapeutic exercise programme consisting of aerobic and resistance exercises on the prevalence and severity of pregnancy-related lumbopelvic pain. The primary goal of research was to examine how this exercise programme influences pregnancy-related lumbopelvic pain, specifically:

- pain intensity level
- self-reported symptoms, activity limitations and disability
- sick leave
- onset of pain during pregnancy

### 1.3.1 Hypotheses

The main hypotesis of this master thesis is that the participation in a structured supervised individualized programme of exercise significantly impacts intensity of pregnancy-related lumbopelvic pain, scores of self-reported questionnaires regarding symptoms, activity limitations and disability, rate of sick leave and the onset of lumbopelvic pain during pregnancy, i.e. there are significant differences between the experimental group of pregnant women who exercised and those in the control group who received only standard antenatal care. The following specific hypotheses were developed based on the objective of the trial:

H1: There will be a significant statistical differences regarding prevalence and severity of pregnancy-related lumbopelvic pain between women who participated in a structured exercise programme and those who received only standard antenatal care.

$H1_1$: There will be a significant statistical difference in the scores of Numeric Rating Scale for pain between women who participated in a structured exercise programme and those who received only standard antenatal care.

$H1_2$: There will be a significant statistical difference in the scores of Roland-Morris Disability Questionnaire between women who participated in a structured exercise programme and those who received only standard antenatal care.

$H1_3$: There will be a significant statistical difference in the scores of Pelvic Girdle Questionnaire between women who participated in a structured exercise programme and those who received only standard antenatal care.

$H1_4$: There will be a significant statistical difference in the rates of sick leave and work absenteeism due to pregnancy-related lumbopelvic pain between women who participated in a structured exercise programme and those who received only standard antenatal care.

$H1_5$: There will be a significant statistical difference in the onset of pregnancy-related lumbopelvic pain between women who participated in a structured exercise programme and those who received only standard antenatal care.

# 2 METHODS AND MATERIALS

## 2.1 Study design and ethics

The study was designed as randomized controlled trial (pretest-posttest randomized-groups design). The trial was conducted in conjunction with the research for doctoral dissertation of the same author where the primary aim was to investigate effects of structured exercise programme on the course and outcome of gestational diabetes mellitus. Among secondary outcomes of that study were prevalence and severity of pregnancy-related lumbopelvic pain which are primary outcomes for this master thesis.

Participants were randomized by block randomization using Internet based computerized service in two groups, experimental and control (Sealed Envelope Ltd., 2013). Physiotherapists involved with exercise sessions and assessment had no influence on the randomization procedure. The study was not blinded because of its nature.

Ethical approvals were obtained from University Hospital Centre Zagreb, Department of Gynaecology and Obstetrics of the University Hospital Centre Zagreb and University Hospital Merkur (Appendices 1-3). Written informed consent was obtained from every participant. Trial was conducted according to Good Clinical Practice, Declaration of Helsinki and positive legislature on patient's rights. Patient confidentiality was protected.

## 2.2 Participants

Pregnant women from Zagreb, the capital of Croatia, and its surroundings were potential participants in this study. They were healthy pregnant women or women diagnosed with gestational diabetes mellitus, but otherwise in good health. Participants were recruited by direct contact at two large hospitals, University Hospital Zagreb and University Hospital Merkur. The goal and implications of the study were briefly explained at the first contact and an information leaflet was

given to women who expressed interest in the study. Interested women contacted the author of this thesis if they decided to participate in the study and a formal interview was scheduled to give them detailed information, check eligibility criteria and obtain the consent form.

Inclusion criteria were pregnancy, age between 20 and 40, and the ability to read, understand and speak the Croatian language. The upper limit for inclusion was set at 30 weeks of gestation to allow the minimum of exercise period of 6 weeks, until at least the 36$^{th}$ week of pregnancy. Exclusion criteria were medical history of miscarriages, pharmacological treatment during pregnancy, contraindications for exercise according to ACOG (2002) criteria, smoking, previous trauma to lumbopelvic region or severe lumbopelvic pain history prior to the pregnancy. Furthermore, women unable to attend exercise sessions were ineligible.

## 2.3 Assessments and measurements

Baseline information, taken at the initial interview, included demographic and occupational data, medical and obstetric history, data regarding current pregnancy, lifestyle habits and physical activity levels, existence of contraindications for exercise, height, body mass at the start of the pregnancy, sick leave, and existence and onset of pregnancy-related LBP and PGP. Pregnant women randomized in the experimental group were scheduled for their first exercise session. Women randomized in the control group were not seen until the 30$^{th}$ week of pregnancy where the next assessment and measurements were performed for the both groups.

In the 30$^{th}$ and 36$^{th}$ week we recorded their body mass and calculated BMI, levels of physical activity using specific questionnaire, levels of pain intensity using Numeric Rating Scale (NRS), and scores of Roland-Morris Disability Questionnaire (RMDQ) and Pelvic Girdle Questionnaire (PGQ), along with sick leave and onset of pain. A review of medical chart was done to assess the course of pregnancy.

### 2.3.1 Measurement of body mass

Body mass was taken in pregnancy weeks 30 and 36 by the independent, blinded physiotherapist using medical grade digital scale measuring to the nearest 0.1 kg (Body Composition Monitor BF511, Omron Healtcare, Kyoto, Japan). Body mass index was calculated according to the standard equation [1].

$$BMI = \frac{mass\ (kg)}{height^2 (m^2)} \qquad [1]$$

### 2.3.2 Assessment of physical activity

Assessment of Physical Activity was performed in the 30$^{th}$ and 36$^{th}$ week of the pregnancy with Pregnancy Physical Activity Questionnaire (PPAQ) (Chasan-Taber et al, 2004). This is a reliable and valid questionnaire which provides measure of physical activity of pregnant women. It is self-administered and measures type, duration and frequency of activities performed by pregnant women. It reports the time spent in 32 activities including household/caregiving activities, occupational activities, sports/exercise, transportation activities and inactivity. The recall period we used was 6 weeks. Pregnant women were asked to report estimated frequency and duration spent in specific activities (i.e. "none", "less than 1/2 hour per day", "1/2 to 1 hour per day", "1 to 2 hours per day", "2 to 3 hours per day", "3 or more hours per day") during the last 6 weeks. Scoring and permission was provided by the author of the questionnaire. An estimated average metabolic equivalent (MET-hour/week) value was calculated by multiplying the duration of the time spent in each activity and established categorical intensity associated with the question. Activities were categorized by type and intensity, and values calculated for every category.

### 2.3.3 Measurement of pain intensity

For the measurement of pain intensity we used Numeric Rating Scale (NRS) which is a unidimensional measure of pain intensity in adults (Jensen & McFarland, 1993; Childs, Piva & Fritz, 2005). NRS is reliable and valid method of measuring pain

intensity (Downie et al, 1978; Ferraz et al, 1990). We used the most common 11-item NRS which is a segmented numeric version of the Visual Analogue Scale (VAS) were the respondent selects a whole number between 0 (no pain) and 10 (worst pain imaginable) that best reflects the intensity of their pain. Recall period was one week (Bolton, Humphreys & van Hedel, 2010).

### 2.3.4 Roland-Morris Disability Questionnaire

The Roland-Morris Disability Questionnaire (RMDQ) is a condition specific, patient-reported, reliable and valid health status measure for assessment of physical disability due to LBP (Roland & Morris, 1983; Roland & Fairbank, 2000). It is used both in research and clinical practice. RMDQ is the most sensitive for patients with mild to moderate disability due to acute, sub-acute or chronic LBP (Davies & Nitz, 2009). There are 24-, 18- and 11-item RMDQ versions. We used 24-item version of the RMDQ. Each item consists of a statement related specifically to a physical function that is likely to be affected by the LBP and combined with the phrase „because of my back pain". Patients are asked to place a check mark beside a statement if it applies to them. The score is calculated by adding up the number of items checked. It ranges from 0 (no disability) to 24 (maximum disability).

### 2.3.5 Pelvic Girdle Questionnaire

The Pelvic Girdle Questionnaire (PGQ) is the first condition-specific, patient-reported outcome measure developed for people with PGP (Stuge, Garratt, Krogstad Jenssen & Grotle, 2011). It has high reliability and validity in people with PGP during pregnancy and it is very feasible for use in clinical practice and research. It consists of 25 items in the activity and symptom subscales. It assesses aspects of quality of life, i.e. the extent of problems during carrying out several activities of daily life, intensity of pain in the morning and in the evening and sleep disturbance because of the PGP. The scores are summarized and recalculated to percentage scores from 0 (no problem at all) to 100 (to a large extent).

## 2.4 Intervention

Women from the experimental group participated in an individualized, supervised structured exercise progamme twice per week, along with their standard antenatal care. Duration of the exercise session was 50-55 minutes. Also, they were instructed to perform at least 30 minutes of vigorous walking once per day. They started with the exercise within a week after the inclusion into the trial and they exercised throught the whole duration of the pregnancy. Attendance was recorded at every exercise session and they were also asked to keep a diary of daily walks. The minimum duration of the intervention was 6 weeks. The attendance was set at 70% of calculated expected exercise sessions between the time of inclusion in the trial and the 38$^{th}$ week of the pregnancy. Participants in the control group received only standard antenatal care. However, they were not discouraged from exercising on their own because this would be unethical.

### 2.4.1 Exercise programme

The exercise programme was developed in accordance with official guidelines for exercise in pregnancy (ACOG, 2002; Royal College of Obstetricians and Gynaecologists, 2006). Absolute and relative contraindications for exercise, along with warning signs for termination of exercise were strictly respected. We avoided jumps, sudden changes of movement directions and body positions, deep lunges, trunk rotations and supine position.

With the goal to achieve good adherence to the protocol, women were able to chose the days of the week and the time of the day when they were able to exercise. All exercise sessions were performed in the private physiotherapy practice, with room air conditioned to 20-22$^{\circ}$C, and humidity between 40% and 60%. Participants wore standard comfortable sports clothing and footwear. They were advised to drink plenty of water during and after exercise sessions and to have a meal consisting of complex carbohydrates, fat, and proteins two hours prior to exercise.

The exercise programme consisted of aerobic exercise (20 minutes), resistance exercises (20-25 minutes), pelvic floor, stretching and relaxation at the end of the

session (10 minutes). The treadmill (Axos Runner, Heinz Kettler GmbH, Ense-Parsit, Germany) was used for the aerobic part of the training. The aimed exercise intensity was within aerobic zone (65-75% of maximal heart rate), i.e. 13-14 on The Borg Rating of Perceived Exertion scale (Borg, 1982). Aerobic part of the exercise started with warm-up for the first 5 minutes which included walking on treadmill at normal pace and gradually adjusting velocity and incline. After that, pregnant women were free to adjust the velocity and incline of the treadmill required to achieve desired intensity.

Resistance exercises included all major muscle groups at each session. They included stabilisation exercises for lumbopelvic area, exercises for upper and lower limb muscles, back extensors and deep abdominal muscles. Exercises were performed using body weight, elastic bands (TheraBand, The Hygenic Corporation, Akron, OH, USA) and hand held weights of 0.5 and 1 kg (Aerobic Dumbbels, Heinz Kettler GmbH, Ense-Parsit, Germany). Intensity target values were the same as in the aerobic part of the session. Six different exercises were performed in three sets of 10-15 repetitions in each set. There were three standardized resistance exercise protocols developed and interchanged throughout time (Appendix 4).

Stretching and pelvic floor exercises were performed at the end of every exercise session. Every stretching position was held for 10-15 seconds, but only once. Stretching included all major muscle groups. Our goal was not to increase flexibility and to avoid over-stretching because pregnant women are at increased risk to injury secondary to hypermobility caused by hormonal factors. At the end of the training session a short relaxation was performed for proper cool-down.

### 2.4.2 Measurements during exercise sessions

We monitored several physiological parameters before, during and after the exercise session for safety of pregnant women and their fetuses. We monitored maternal heart rate (HR) continuously (Mio Alpha, Mio Global, Vancouver, BC, Canada). Baseline values of HR were recorded before the session, after aerobic part of the session, after resistance part of the session, and after 5 minutes of relaxation. Also, we monitored HR during the exercise and our target heart rate

(THR) was calculated according to Karvonen's formula [2]. Maximum HR was calculated according the traditional formula 220 – age.

$$THR = ((\max HR - resting\ HR)\ x\ \%Intensity) + resting\ HR \quad [2]$$

Also, we recorded arterial blood pressure before, during and after the exercise session using mercury sphygmomanometer (Erkameter 300, ERKA, Kallmeyer Medizintechnik, Bad Tölz, Germany) using the first and fifth Korotkoff sound to identify systolic and diastolic arterial blood pressure, respectively. Furthermore, we recorded tympanic membrane temperature before, during and after the exercise session using an infrared ear thermometer (ThermoScan 6023, Braun GmbH, Kronberg, Germany) (Purssell, While & Coomber, 2009). Finally, we also recorded fetal heart rate (FHR) before the exercise, periodically during the exercise and at the end of each session. We used an ultrasound device (MAS Baby Watcher, MAS Future Medical GmbH, Leibnitz, Austria) with doppler effect with the accuracy of ± (2% +1 digit).

## 2.5 Statistical analyses

Statistical analyses were performed with SPSS 19.0 (IBM, Armonk, NY, USA). Descriptive statistics were performed for all variables of interest. It included mean, standard deviation and minimal and maximal value where appropriate. Normality of data was checked with Shapiro-Wilk test. Homogeneity of variances was checked with Levene's test. Non normally distributed variables and categorical data were analysed with the Mann-Whitney U test.

Specifically, we used the Mann Whitney U test for comparison of baseline participants' characteristics, results of PPAQ, NRS, RMDQ, PGQ, onset of lumbopelvic pain and rate of sick leave. Two-tailed Mann Whitney U test without Bonferroni correction was used. The level of significance was set at $P < 0.05$. Cohen's d (*d*) and effect size (*r*) were calculated for all outcome variables with the level of significance ≤ 0.05.

Baseline participants' characteristics are shown in Table 3. All data are presented as means ± standard deviation.

*Table 3: Baseline characteristics for the experimental and control groups.*

| Variable | EG (N = 20) | CG (N = 22) | P |
|---|---|---|---|
| Maternal age (years) | 32.8 ± 3.6 | 32.2 ± 4.9 | 0.536 |
| Body height (m) | 1.67 ± 0.07 | 1.68 ± 0.06 | 0.528 |
| Pre-pregnancy body mass (kg) | 66.6 ± 13.7 | 70.6 ± 15.1 | 0.391 |
| Pre-pregnancy BMI in ($kg/m^2$) | 23.9 ± 4.8 | 24.9 ± 4.6 | 0.450 |
| Gestational age at the inclusion in the trial (week) | 22.29 ± 6.3 | 21.6 ± 6.3 | 0.801 |
| Parity | 0.65 ± 0.81 | 0.59 ± 0.80 | 0.822 |
| Education | | | |
| Secondary level (N; (%)) | 7 (35) | 7 (31.8) | |
| Tertiary level (N; (%)) | 13 (65) | 15 (68.2) | |
| Pre-pregnancy regular physical activity (N; (%)) | 9 (45) | 6 (27.3) | 0.237 |
| Strenuous work conditions (N; (%)) | 5 (25) | 8 (36.4) | 0.432 |
| Work in shifts (N; (%)) | 6 (30) | 10 (45.5) | 0.309 |
| Work during night (N; (%)) | 3 (15) | 3 (13.6) | 0.901 |
| Work satisfaction (scale 1-5) | 3 ± 1.5 | 3.6 ± 1.2 | 0.160 |
| Psychological stress at work (scale 1-5) | 3.1 ± 1.8 | 3.5 ± 1.3 | 0.577 |
| Pre-pregnancy lumbopelvic pain (N; (%)) | 9 (45) | 12 (54.5) | 0.542 |
| Total activity (MET-h*$week^{-1}$) | 154.4 ± 72.4 | 124.7 ± 43.8 | 0.107 |
| Total activity of light intensity and above (≥ 1.5 METs) (MET-h*$week^{-1}$) | 130.4 ± 71.8 | 98.9 ± 42.3 | 0.074 |
| By intensity of activity | | | |
| Sedentary (< 1.5 METs) (MET-h*$week^{-1}$) | 24 ± 13.7 | 25.8 ± 19.7 | 0.909 |
| Light (1.5 – 2.9 METs) (MET-h*week$^{-}$ | 97.8 ± 45.5 | 75.9 ± 30.2 | 0.124 |

| | | | |
|---|---|---|---|
| $^{1}$) | | | |
| Moderate (3.0 – 5.9 METs) (MET-h*week$^{-1}$) | 32.5 ± 41.3 | 22.7 ± 21.8 | 0.496 |
| Vigorous (≥ 6.0 METs) (MET-h*week$^{-1}$) | 0.2 ± 0.3 | 0.4 ± 0.7 | 0.356 |
| By type of activity | | | |
| Household/caregiving (MET-h*week$^{-1}$) | 85.7 ± 68.2 | 60.4 ± 39.6 | 0.107 |
| Occupational (MET-h*week$^{-1}$) | 17.5 ± 29.6 | 8.3 ± 21.9 | 0.188 |
| Sport/exercise (MET-h*week$^{-1}$) | 3 ± 2 | 2 ± 2.1 | 0.058 |
| Transportation activity (MET-h*week$^{-1}$) | 15 ± 6.5 | 17.4 ± 11.5 | 0.870 |
| Inactivity (MET-h*week$^{-1}$) | 33.3 ± 17 | 36.6 ± 24.8 | 0.950 |

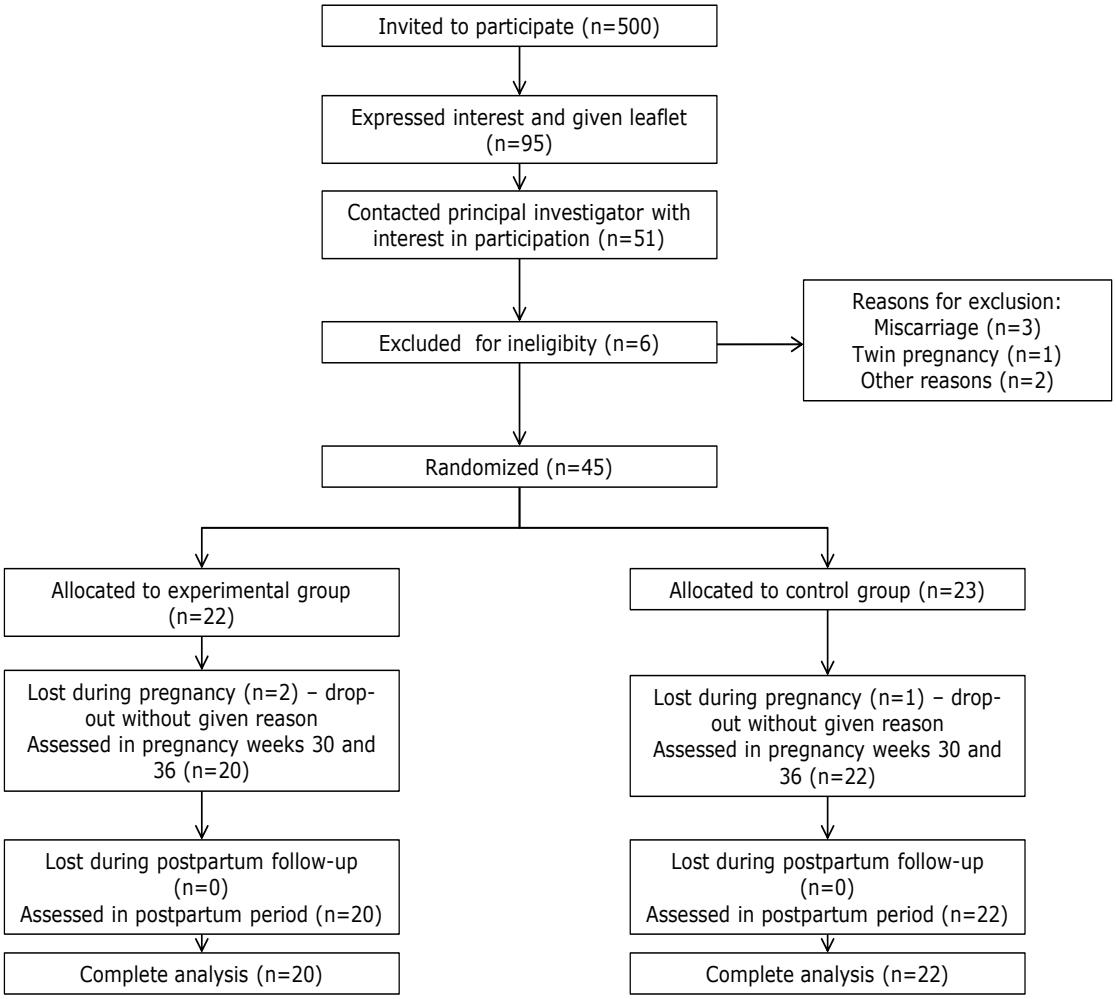
*EG – experimental group; CG – control group; N – sample size; BMI – body mass index; MET – metabolic equivalent.*

The degree of relationship between variables was calculated with Spearman's rank correlation coefficient ($r_s$) and the point-biserial correlation coefficient ($r_{pbi}$). Specifically, number of exercise sessions, duration of the intervention in weeks and number of daily walks were correlated with NRS, PGQ and RMDQ scores in 30$^{th}$ and 36$^{th}$ week, and also with the week of onset of lumbopelvic pain using Spearman's rank correlation coefficient ($r_s$). Point-biserial correlation coefficeint was calculated to determine relationship between number of exercise sessions, number of daily walks, duration of interventin in weeks and onset of lumbopelvic pain.

# 3 RESULTS

A total of 45 pregnant women were finally enrolled and randomized in the trial. We assigned 22 women in the experimental group and 23 in the control group. Three participants (6.7%) dropped out of the trial, 2 from the experimental group (9.1%) and one from the control group (4.4%). The final sample taken into account for the analysis was 42 pregnant women with 20 in the experimental group and 22 in the control group. Figure 1 represents the flow chart of the study participants.

*Figure 1: Flow chart of study participants.*



## 3.1 Participants characteristics

The Mann-Whitney U test was used to compare baseline participants' characteristics. Both groups, the experimental and the control were well matched. There were no significant statistical differences in baseline variables (Table 3) ($P > 0.05$).

## 3.2 Characteristics of exercise sessions

A total of 419 exercise sessions were performed during the trial. Average number of exercise sessions per subject was 21 ± 7.6. The minimum number of exercise sessions per subject was 12, and the maximum 34 exercise sessions. General characteristics of exercise sessions are in the Table 4. Average adherence to protocol was 83.7% (minimum 70% and maximum 96%), well above the treshold which was 70%. That made intervention 100% successful for all participants in the experimental group.

*Table 4: General characteristics of exercise sessions.*

| Variable | Mean ± SD | Minimum | Maximum |
|---|---|---|---|
| Start of the intervention (week of pregnancy) | 25 ± 5.2 | 13 | 30 |
| End of the intervention (week of pregnancy) | 37.2 ± 0.8 | 36 | 39 |
| Week of birth | 39 ± 1 | 38 | 40 |
| Period between last exercise session and birth (weeks) | 1.8 ± 0.9 | 0 | 3 |
| Exact duration of the intervention (weeks) | 12.7 ± 5 | 7 | 23 |
| Expected number of exercise sessions | 25.4 ± 1 | 14 | 46 |
| Exact number of exercise sessions | 21 ± 7.6 | 12 | 34 |
| Percentage of the exact number of exercise sessions versus expected number of sessions (%) | 83.7 ± 8.3 | 70 | 96 |
| Number of missed execrise sessions | 4.4 ± 3.4 | 1 | 12 |

We monitored some acute physiological responses to exercise sessions. We recorded maternal heart rate, systolic and diastolic blood pressure, tympanic temperature and fetal heart rate before the exercise session, after aerobic part of the session, after resistance part of the session and at the end of the exercise session, after relaxation. Acute physiological responses to exercise sessions are shown in Table 5.

*Table 5: Acute effects of exercise sessions.*

| **Variable** | **Mean ± SD** | **Min** | **Max** |
|---|---|---|---|
| **Heart rate (bpm)** | | | |
| Maximum heart rate (bpm; 220-age) | 187.3 ± 3.6 | 181 | 196 |
| Heart rate before the exercise session | 90.6 ± 7.8 | 76.2 | 106.6 |
| Average heart rate during aerobic exercise | 126.9 ± 9.1 | 113.9 | 143.1 |
| Percentage of maximal heart rate during aerobic exercise (%) | 67.8 ±5.1 | 60 | 7 |
| Heart rate after the aerobic part of the exercise session | 101 ± 8.6 | 87 | 116.9 |
| Average heart rate during resistance exercises | 95.5 ± 7.7 | 85.3 | 109.7 |
| Percentage of maximal heart rate during resistance exercises (%) | 115.4 ± 9.1 | 52 | 71 |
| Heart rate after resistance exercises | 95.5 ± 7.7 | 80.3 | 109.7 |
| Heart rate at the end of the exercise session | 90.9 ± 6.9 | 74.7 | 101.9 |
| Average heart rate during whole exercise session | 120.8 ± 8.6 | 105.5 | 137 |
| Percentage of max heart rate during whole exerise session | 64.5 ± 4.7 | 56 | 74 |
| **Systolic blood pressure (mmHg)** | | | |
| Before the exercise session | 111.5 ± 7 | 101.9 | 128.7 |
| After the aerobic part of the exercise session | 111.8 ± 7.4 | 101.2 | 129.6 |
| After resistance exercises | 110.7 ± 6.9 | 97.3 | 124.3 |
| At the end of the exercise session | 111.5 ± 6.2 | 99.8 | 124.5 |

| | | | |
|---|---|---|---|
| **Diastolic blood pressure (mmHg)** | | | |
| Before the exercise session | 70.1 ± 6.7 | 56.7 | 81.4 |
| After the aerobic part of the exercise session | 69.8 ± 6.3 | 61.1 | 81.5 |
| After resistance exercises | 69.8 ± 6.1 | 60.5 | 80.8 |
| At the end of the exercise session | 70.8 ± 5.4 | 60.7 | 78.6 |
| **Tympanic temperature (°C)** | | | |
| Before the exercise session | 36.5 ± 0.3 | 36.1 | 36.9 |
| After the aerobic part of the exercise session | 36.8 ± 0.3 | 36.3 | 37.6 |
| After resistance exercises | 36.7 ± 0.4 | 35.7 | 37.4 |
| At the end of the exercise session | 36.6 ± 0.2 | 36.2 | 36.9 |
| **Fetal heart rate (bpm)** | | | |
| Before the exercise session | 141.3 ± 5.7 | 129.3 | 153 |
| After the aerobic part of the exercise session | 149.8 ± 5.6 | 140.1 | 163.3 |
| After resistance exercises | 145.3 ± 6.2 | 135.4 | 157 |
| At the end of the exercise session | 141.8 ± 4.5 | 134.5 | 151 |
| Treadmill velocity (km/h) | 3.9 ± 0.4 | 3.1 | 4.9 |
| Treadmill incline (°) | 3 ± 1.2 | 0.2 | 4 |

*min – minimum; max – maximum; bpm – beats per minute.*

There were no warning signs which would require termination of the exercise nor adverse effects caused by exercise. None of participants developed contraindications for exercise. We did not detect dangerous increase in core body temperature or drop in FHR. Our primary determinant of exercise intensity was to achieve values 13-14 of the Borg Rating of Perceived Exertion scale, which corresponded with the average of 64.5% ± 4.7 of the maximal heart rate.

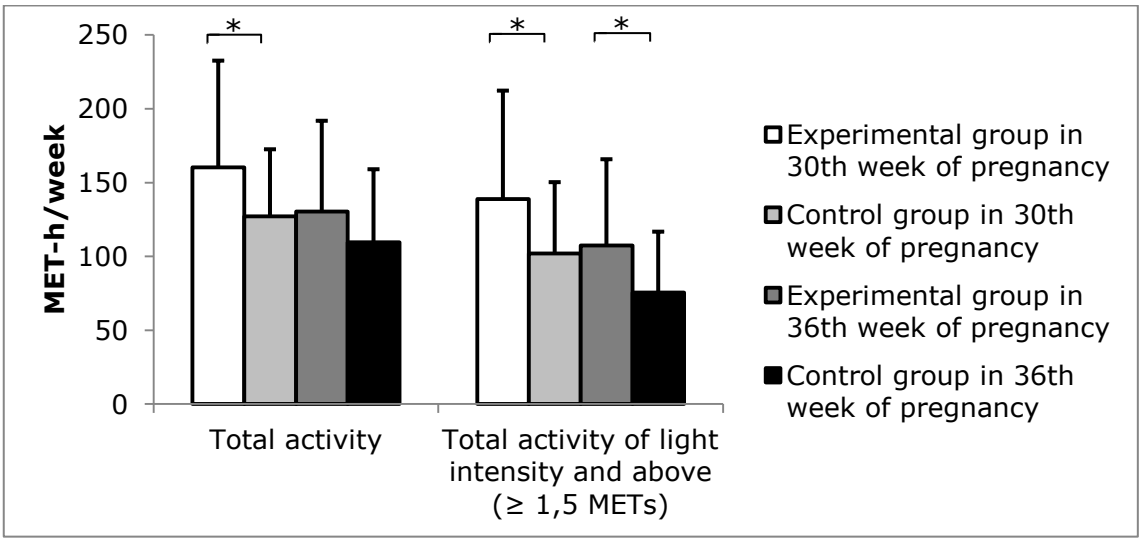
Aside from regular exercise sessions, we also asked all pregnant women in the experimental group to vigorously walk every day for at least 30 minutes and

keeping their walking diaries. They performed 84.7 ± 34.5 (minimum 43; maximum 161) walks vs. planned 87.9 ± 33.6. Adherence to protocol was 95.8% ± 4.4, well above the treshold of 70% adherence.

## 3.3 Physical Activity in Pregnancy Questionnaire

Almost all variables were not normally distributed so we used Mann-Whitney U test to compare the experimental and the control group regarding their total activity, intensity of activity and the type of activity in their 30$^{th}$ and 36$^{th}$ week of the pregnancy (Table 6). While there were no differences in baseline levels of physical activity (Table 3) we found differences in the 30$^{th}$ and the 36$^{th}$ week of pregnancy. Pregnant women from the experimental group had higher levels of total physical activity in 30$^{th}$ week of pregnancy (P = 0.047, *d* = 0.55, *r* = 0.26) (Figure 2). Furthermore, pregnant women from the experimental group had significantly higher levels of total activity of light intensity and above (≥ 1.5 METs) both in 30$^{th}$ week (P = 0.034, *d* = 0.59, *r* = 0.28) and 36$^{th}$ week of pregnancy (P = 0.027, *d* = 0.63, *r* = 0.30) (Figure 2).

*Figure 2: Total activity levels and total activity of light intensity and above in 30$^{th}$ and 36$^{th}$ week of pregnancy.*




** - P < 0.05*

Also, pregnant women from the experimental group had significantly higher levels of sport/exercise activities with very large effect sizes both in 30$^{th}$ week (P < 0.001,

*d* = 2.37, *r* = 0.76) and in 36$^{th}$ week of pregnancy (P < 0.001, *d* = 2.26, *r* = 0.75) (Figure 3). Levels of moderate physical activity (3.0 – 5.9 METs) were higher in the experimental group in 36$^{th}$ week of pregnancy (P = 0.014, *d* = 0.63, *r* = 0.30) (Figure 4). Also, women from the experimental group had higher levels on transportational activities (P = 0.027, *d* = 0.77, *r* = 0.36) in 36$^{th}$ week of pregnancy. While the experimental group had higher levels of transportational activities in 36$^{th}$ week in comparison to 30$^{th}$ week of pregnancy, the control group had much lower levels of these activities in 36$^{th}$ week in comparison to 30$^{th}$ week of pregnancy and the difference between groups was significant (P = 0.040, *d* = 0.64, *r* = 0.30).

Table 6: Results of PPAQ.

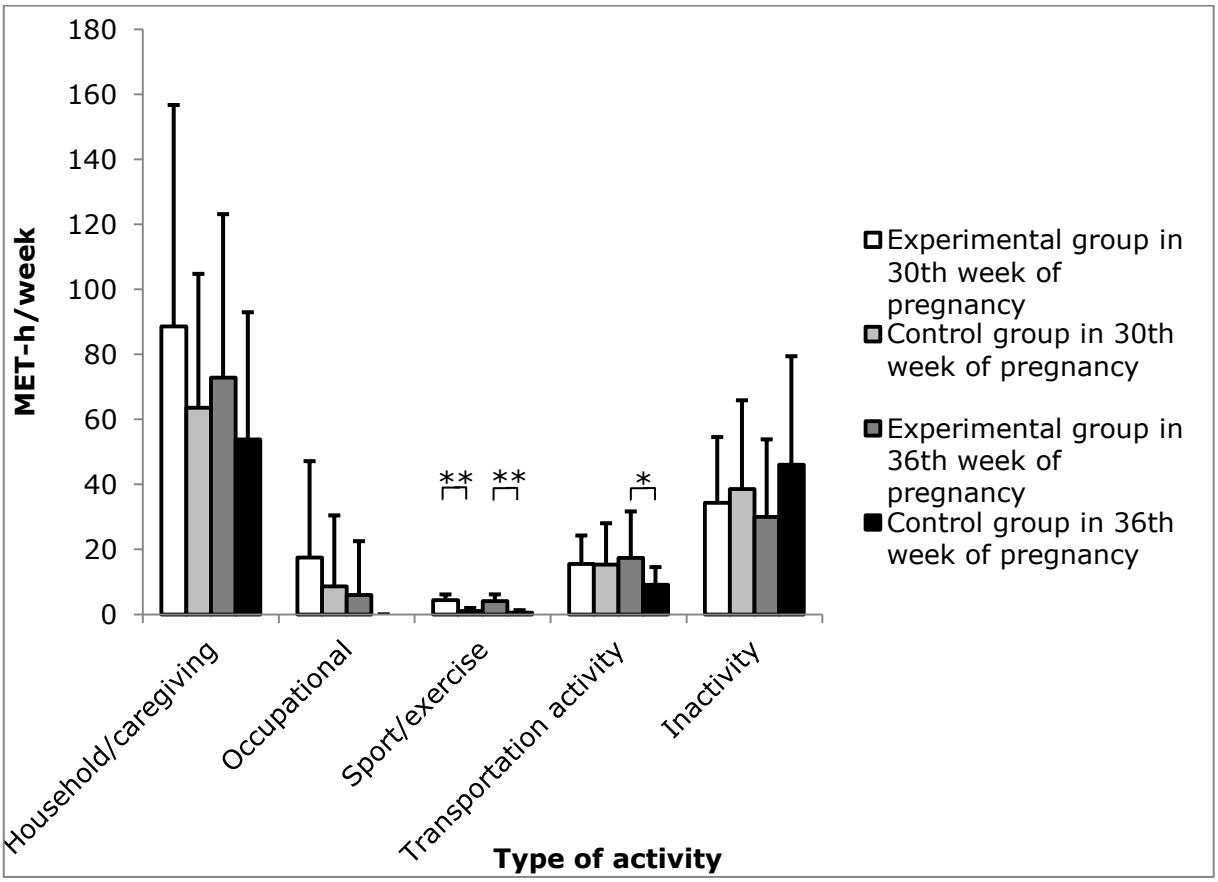
| Variable | EG (N = 18; MET-h*week$^{-1}$) Mean ± SD | CG (N = 20; MET-h*week$^{-1}$) Mean ± SD | P |
|---|---|---|---|
| 30 $^{th}$ week of pregnancy | | | |
| Total activity | 160.2 ± 72.4 | 127.2 ± 45.4 | 0.047 |
| Total activity of light intensity and above (≥ 1.5 METs) | 138.9 ± 73.4 | 102 ± 48.4 | 0.034 |
| By intensity of activity | | | |
| Sedentary (< 1.5 METs) | 25 ± 16.8 | 27.9 ± 21.2 | 0.791 |
| Light (1.5 – 2.9 METs) | 100.2 ± 43.7 | 77.5 ± 30.4 | 0.087 |
| Moderate (3.0 – 5.9 METs) | 63.6 ± 40.6 | 50.3 ± 27.4 | 0.113 |
| Vigorous (≥ 6.0 METs) | 0.2 ± 0.4 | 0.1 ± 0.3 | 0.548 |
| By type of activity | | | |
| Household/caregiving | 88.6 ± 68.1 | 63.6 ± 41.1 | 0.137 |
| Occupational | 17.5 ± 29.6 | 8.7 ± 21.8 | 0.304 |
| Sport/exercise | 4.4 ± 1.8 | 1 ± 0.9 | < 0.001 |
| Transportation activity | 15.5 ± 8.6 | 15.3 ± 12.7 | 0.604 |

| | | | |
|---|---|---|---|
| Inactivity | 34.4 ± 20.2 | 38.6 ± 27.2 | 0.811 |
| 36 $^{th}$ week of pregnancy | | | |
| Total activity | 130.3 ± 61.6 | 109.5 ± 49.6 | 0.351 |
| Total activity of light intensity and above (≥ 1.5 METs) | 107.4 ± 58.4 | 75.5 ± 41.3 | 0.027 |
| By intensity of activity | | | |
| Sedentary (< 1.5 METs) | 22.9 ± 18.1 | 37 ± 24.7 | 0.071 |
| Light (1.5 – 2.9 METs) | 77.8 ± 44.1 | 61.3 ± 30 | 0.365 |
| Moderate (3.0 – 5.9 METs) | 29.6 ± 38.1 | 11.3 ± 15.1 | 0.014 |
| Vigorous (≥ 6.0 METs) | 0.1 ± 0.2 | 0 ± 0 | 0.133 |
| By type of activity | | | |
| Household/caregiving | 72.9 ± 50.2 | 53.8 ± 39.1 | 0.162 |
| Occupational | 6 ± 16.5 | 0 ± 0 | 0.063 |
| Sport/exercise | 4.1 ± 2.1 | 0.6 ± 0.7 | < 0.001 |
| Transportation activity | 17.4 ± 14.2 | 9.2 ± 5.4 | 0.027 |
| Inactivity | 30 ± 23.8 | 46 ± 33.4 | 0.118 |
| Difference between 36$^{th}$ and 30$^{th}$ week of pregnancy (36$^{th}$ – 30$^{th}$) | | | |
| Total activity | -29.9 ± 55.7 | -17.7 ± 45.4 | 0.614 |
| Total activity of light intensity and above (≥ 1.5 METs) | -31.5 ± 51.7 | -29.5 ± 41.6 | 0.669 |
| By intensity of activity | | | |
| Sedentary (< 1.5 METs) | -2.1 ± 17 | 9.1 ± 19.5 | 0.091 |
| Light (1.5 – 2.9 METs) | -22.4 ± 48 | -16.2 ± 32.8 | 0.782 |
| Moderate (3.0 – 5.9 METs) | -34.1 ± 15.8 | -39.1 ± 19.9 | 0.650 |

| | | | |
|---|---|---|---|
| Vigorous (≥ 6.0 METs) | -0.1 ± 0.4 | -0.1 ± 0.3 | 0.916 |
| By type of activity | | | |
| Household/caregiving | -15.7 ± 35.8 | -9.8 ± 28.7 | 0.481 |
| Occupational | -11.5 ± 28.8 | -8.7 ± 21.8 | 1.000 |
| Sport/exercise | -0.3 ± 2.2 | -0.4 ± 0.9 | 0.790 |
| Transportation activity | 1.9 ± 14.3 | -6.2 ± 11 | 0.040 |
| Inactivity | -4.4 ± 25.1 | 7.4 ± 23 | 0.158 |

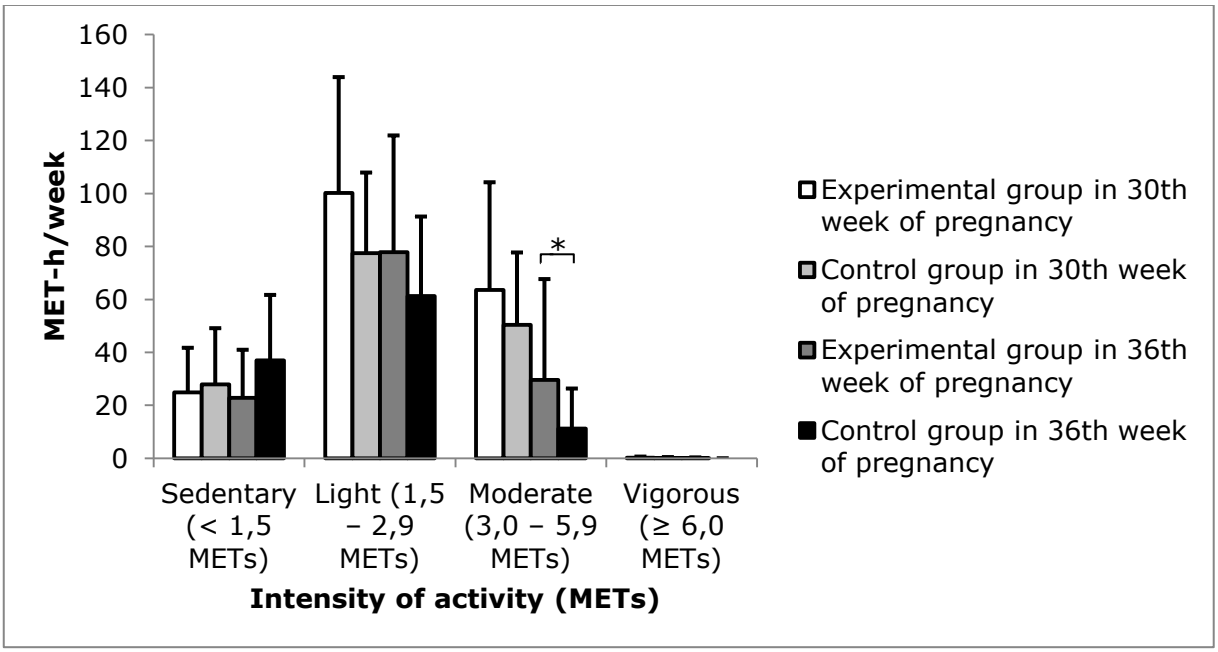
*EG – experimental group; CG – control group; N – sample size; MET – metabolic equivalent.*

*Figure 3: Time spent in activities by type in 30 th and 36 th week of pregnancy.*




** - P < 0.001; * - P = 0.040

*Figure 4: Time spent in activities by intensity in 30 th and 36 th week of pregnancy.*




*MET – metabolic equivalent; * - P =0.014*

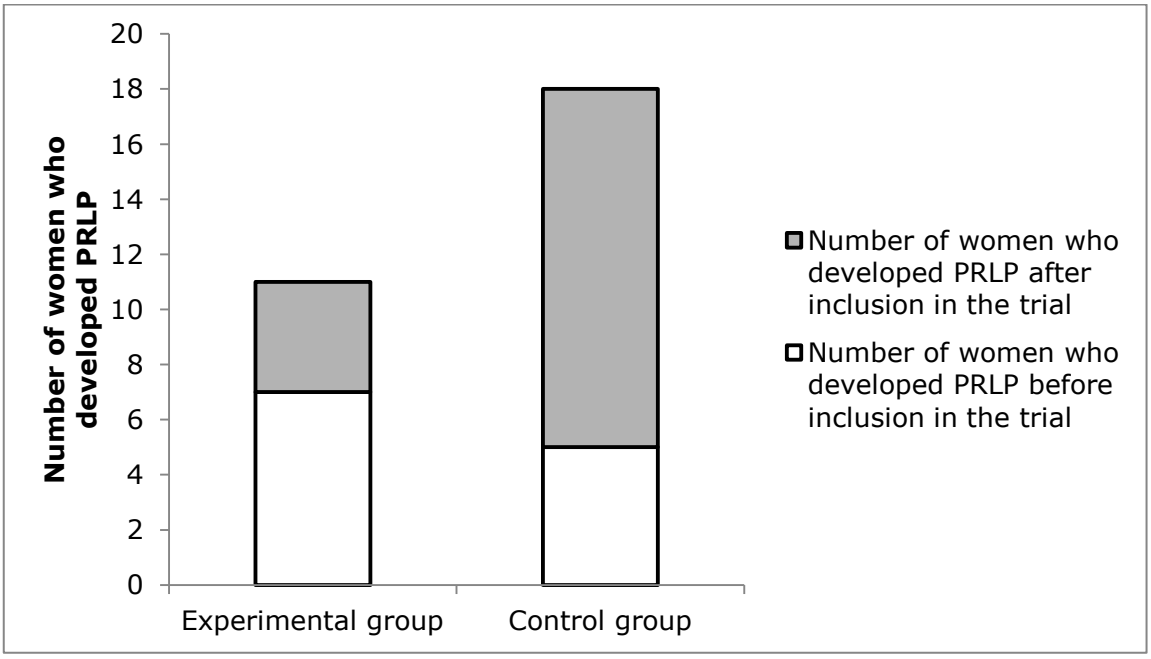
## 3.4 Prevalence and onset of pregnancy-related lumbopelvic pain

Data were analyzed by Mann Whitney U test. There were no significant differences regarding the number of women who developed pregnancy-related lumbopelvic pain, however, less percentage of women (55%) from the experimental group developed pain in comparison to the control group (81.8%) (Figure 5). Furthermore, there were no differences between groups regarding existing pregnancy-related lumbopelvic pain prior to the inclusion in the trial (35% vs. 22.7%). However, pregnant women from the experimental group had earlier onset of lumbopelvic pain (P = 0.013, $d$ = -0.77, $r$ = -0.36) (Figure 6). These results are shown in Table 7.

On the other hand, onset of lumbopelvic pain in EG was negatively correlated with both number of performed exercise sessions ($r_{pbi}$ = -0.470, P = 0.036), and duration of intervention in weeks ($r_{pbi}$ = -0.445, P = 0.049). It was also negatively correlated with the number of performed vigorous walks ($r_{pbi}$ = -0.470, P = 0.036). However, week of the onset of lumbopelvic pain was also negatively correlated with

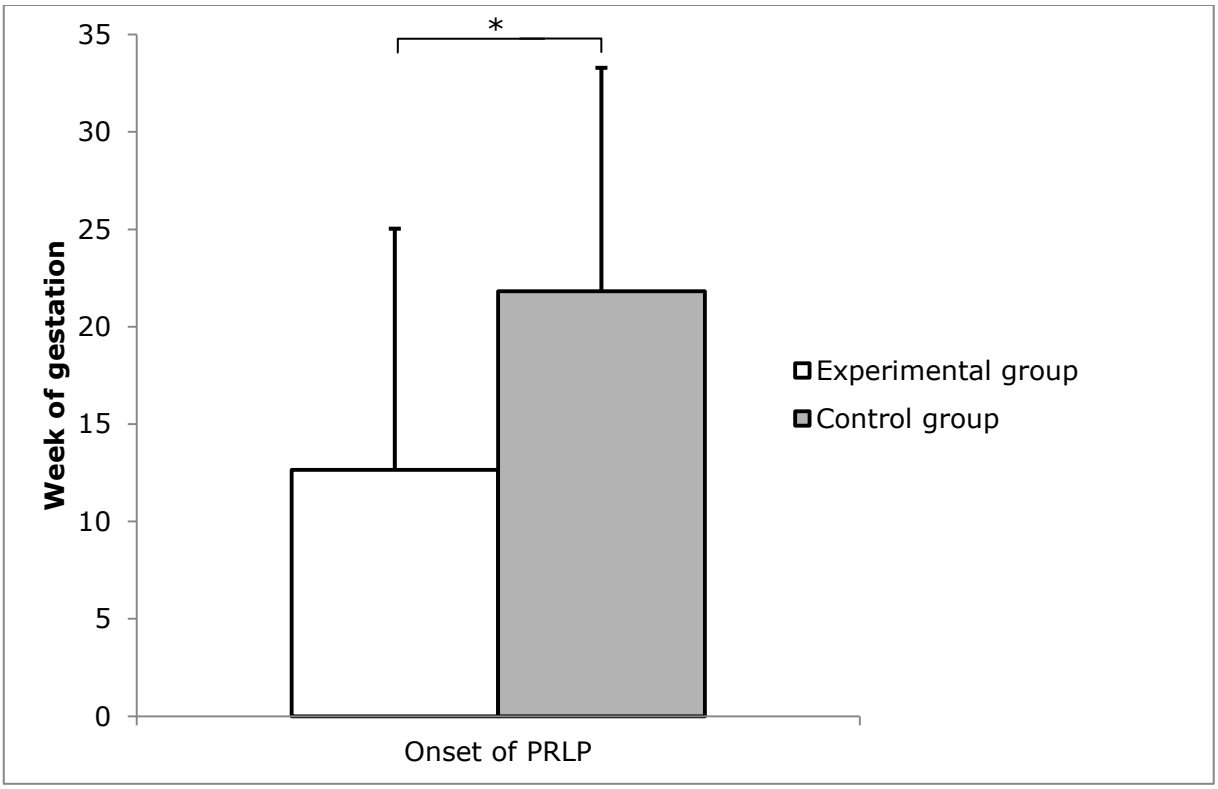
number of performed exercise sessions ($r_s$ = -0.559, P = 0.005), duration of intervention ($r_s$ = -0.532, P = 0.008, and number of performed walks ($r_s$ = -0.466, P = 0.019).

*Figure 5: Prevalence of pregnancy-related lumbopelvic pain.*




*PRLP – pregnancy-related lumbopelvic pain*

*Figure 6: Onset of pregnancy-related lumbopelvic pain*




*PRLP – pregnancy-related lumbopelvic pain; * - P = 0.013*

Table 7: Prevalence and onset of pregnancy-related lumbopelvic pain.

| Variable | EG (N = 20) | | | CG (N = 22) | | | P |
|---|---|---|---|---|---|---|---|
| | | Min | Max | | Min | Max | |
| Number of women who developed PRLP (N;(%)) | 11 (55) | | | 18 (81.8) | | | 0.064 |
| Number of women who developed PRLP before inclusion in the trial (N; (%)) | 7 (35) | | | 5 (22.7) | | | 0.385 |
| Onset of PRLP (week of gestation) | 12.7 ± 12.4 | 0 | 28 | 21.8 ± 11.5 | 0 | 35 | 0.013 |

*EG – experimental group; CG – control group; N – sample size; min – minimum; max – maximum; PRLP – pregnancy-related lumbopelvic pain*

## 3.5 Pain intensity of pregnancy-related lumbopelvic pain

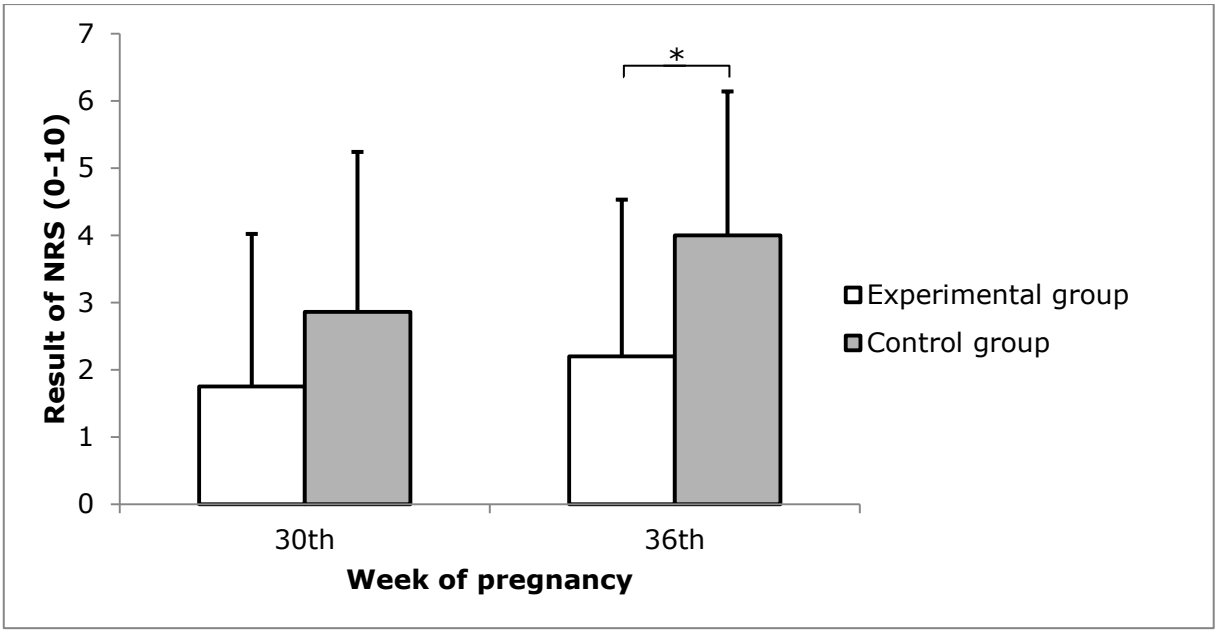
Data were not normally distributed and because of that we used Mann Whitney U test. While the result of Numeric Rating Scale for the pain intensity was lower in the experimental group in the 30$^{th}$ week of pregnancy, this was not significant (Table 8). However, it was significantly lower in the experimental group in the 36$^{th}$ week of pregnancy (P = 0.017, *d* = -0.80, *r* = -0.37) (Figure 7). There were no significant difference between groups in NRS score change between 36$^{th}$ and 30$^{th}$ week of pregnancy.

Table 8: Results of NRS.

| Variable | EG (N = 20) | | | CG (N = 22) | | | P |
|---|---|---|---|---|---|---|---|
| | Mean ± SD | Min | Max | Mean ± SD | Min | Max | |
| Result of NRS in 30 $^{th}$ week (0-10) | 1.8 ± 2.3 | 0 | 7 | 2.9 ± 2.4 | 0 | 8 | 0.103 |
| Result of NRS in 36 $^{th}$ week (0-10) | 2.2 ± 2.3 | 0 | 7 | 4 ± 2.1 | 0 | 8 | 0.017 |
| Difference in NRS between 36$^{th}$ and 30$^{th}$ week (0-10) | 0.5 ± 2.6 | -6 | 5 | 1.1 ± 2.6 | -6 | 6 | 0.187 |

*EG – experimental group; CG – control group; N – sample size; min – minimum; max – maximum; NRS – Numeric Rating Scale*

*Figure 7: Results of NRS*




*NRS – Numeric Rating Scale; * - P = 0.017*

Duration of intervention negatively correlated with NRS scores both in 30$^{th}$ ($r_s$ = -0.684, P < 0.001), and in 36$^{th}$ week of the pregnancy ($r_s$ = -0.380, P = 0.049). Number of performed exercise sessions negatively correlated with NRS score in 30$^{th}$ week of the pregnancy ($r_s$ = -0.690, P < 0.001) but not in 36$^{th}$ week. Number of performed walks also negatively correlated with NRS score in both 30$^{th}$ ($r_s$ = -0.642, P = 0.001) and 36$^{th}$ week of the pregnancy ($r_s$ = -0.415, P = 0.031).

## 3.6 Pelvic girdle pain and disability

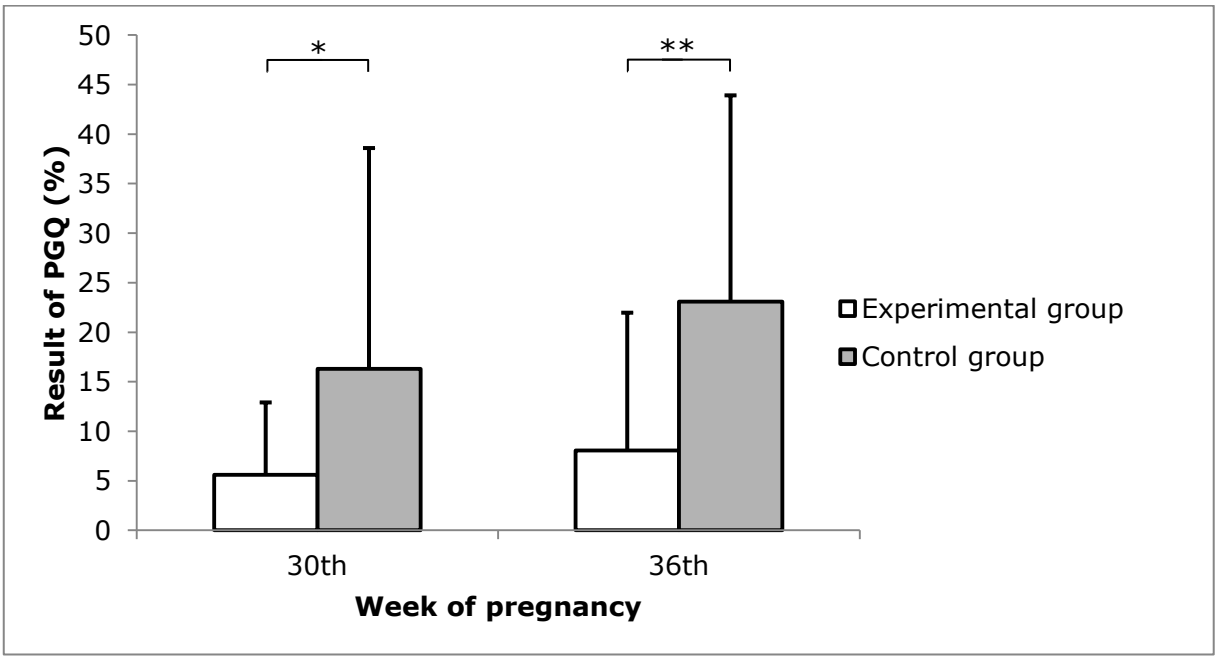
The distribution of data was not normal and Mann Whitney test was used for analysis. There were significant differences both in 30$^{th}$ (P = 0.05, *d* = -0.64, *r* = -0.31) and 36$^{th}$ (P = 0.005, d = -0.85, *r* = -0.39) week of pregnancy in scores of PGQ (Figure 8). Experimental group had lower scores on Pelvic Girdle Questionnaire, i.e. less disability and symptoms (Table 9).

Table 9: Results of PGQ.

| Variable | EG (N = 20) | | | CG (N = 22) | | | P |
|---|---|---|---|---|---|---|---|
| | Mean ± SD | Min | Max | Mean ± SD | Min | Max | |
| Result of PGQ in 30 $^{th}$ week (%) | 5.6 ± 7.3 | 0 | 22.6 | 16.3 ± 22.3 | 0 | 77.3 | 0.050 |
| Result of PGQ in 36 $^{th}$ week (%) | 8.1 ± 13.9 | 0 | 46.7 | 23.1 ± 20.8 | 0 | 62.7 | 0.005 |
| Difference in PGQ between 36$^{th}$ and 30$^{th}$ week (%) | 2.47 ± 13.87 | -12 | 45.3 | 6.8 ± 22.3 | -56 | 62.7 | 0.098 |

*EG – experimental group; CG – control group; N – sample size; min – minimum; max – maximum; PGQ – Pelvic Girdle Questionnaire*

*Figure 8: Results of PGQ*




*PGQ – Pelvic Girdle Questionnaire; * - P = 0.05; ** - P = 0.005*

There were negative correlations between duration of the intervention and PGQ scores in 30$^{th}$ ($r_s$ = -0.574, P = 0.004) and 36$^{th}$ week of the pregnancy ($r_s$ = -0.380, P = 0.049). Also, number of exercise sessions and daily walks were also negatively correlated with PGQ scores in 30$^{th}$ ($r_s$ = -0.617, P = 0.002; $r_s$ = -0.512, P = 0.011) and 36$^{th}$ week of the pregnancy ($r_s$ = -0.419, P = 0.033; $r_s$ = -0.528, P = 0.008) respectively.

## 3.7 Disability caused by low back pain

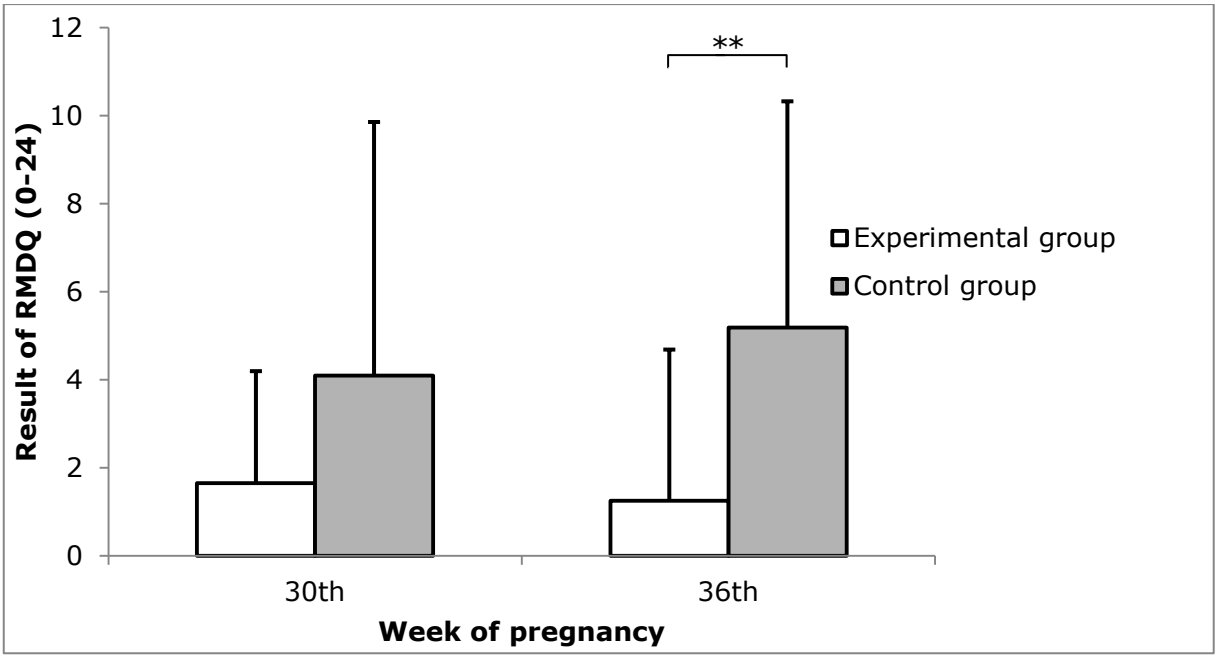
Because of non normal distribution of data, analysis was performed using Mann Whitney U test. While there was no difference between groups in the score of RMDQ in 30$^{th}$ week of pregnancy, we found significant difference in the 36$^{th}$ week ($P < 0.001$, $d = -0.90$, $r = -0.41$) (Figure 9). Pregnant women from the experimental group had lower scores on RMDQ and less disability (Table 10).

Table 10: Results of RMDQ.

| Variable | EG (N = 20) | | | CG (N = 22) | | | P |
|---|---|---|---|---|---|---|---|
| | Mean ± SD | Min | Max | Mean ± SD | Min | Max | |
| Result of RMDQ in 30 $^{th}$ week (0-24) | 1.7 ± 2.5 | 0 | 8 | 4.1 ± 5.8 | 0 | 17 | 0.187 |
| Result of RMDQ in 36 $^{th}$ week (0-24) | 1.3 ± 3.4 | 0 | 13 | 5.2 ± 5.1 | 0 | 18 | <0.001 |
| Difference in RMDQ between 36$^{th}$ and 30$^{th}$ week (%) | -0.4 ± 2.4 | -6 | 5 | 1.1 ± 5.2 | -15 | 10 | 0.006 |

*EG – experimental group; CG – control group; N – sample size; min – minimum; max – maximum;*
*RMDQ – Roland-Morris Disability Questionnaire*

*Figure 9: Results of RMDQ*




*RMDQ – Roland-Morris Disability Questionnaire; ** - P < 0.001*

RMDQ scores in 30th week of pregnancy were negatively correlated with the duration of the intervention ($r_s$ = -0.416, P = 0.034), and with number of performed exercise sessions ($r_s$ = -0.451, P = 0.023), but not in 36th week. Number of performed daily walks was not correlated to RMDQ scores neither in 30th week, nor in 36th week of the pregnancy.

## 3.8 Sick leave

There was only one case of sick leave caused by pregnancy-related lumbopelvic pain, in the control group. Data were analysed with Mann Whitney U test. The difference between groups was not significant (Table 11).

Table 11: Sick leave rate.

| Variable | EG (N = 20) | CG (N = 22) | P |
|---|---|---|---|
| Number of women on sick leave due to PRLP (N; (%)) | 0 (0) | 1 (4.5) | 0.340 |

*EG – experimental group; CG – control group; N – sample size; PRLP – pregnancy-related lumbopelvic pain*

# 4 DISCUSSION

The aim of the present thesis was to investigate the effects of structured, therapeutic exercise programme which combines aerobic and resistance exercises with daily vigorous walks on pregnancy-related lumbopelvic pain. The thesis covers two main aspects of pregnancy-related lumbopelvic pain. Firstly, it investigates incidence of the pain. Secondly, it investigates its severity and impact on the quality of life. Main investigated outcomes were self-reported rate of lumbopelvic pain, onset of pain, intensity of pain and disability caused by pain.

The motivation for this study was significant percentage of pregnant women affected by lumbopelvic pain and lack of existing scientific evidence regarding the optimal treatment strategies. Exercise in pregnancy is recommended, but there are still not enough scientific evidences regarding the effects of exercise on some conditions, and lumbopelvic pain is one of them.

Pregnancy-related pain can have very negative effect on the quality of life, especially in the last trimester of pregnancy. It has tremendous effect on physical and psychological wellbeing of pregnant women, and it can persist postpartum. On the other hand, health care providers usually take it lightly, normal for pregnancy. This leads to suboptimal treatment and support for this population where over 50% of pregnant women with LBP and PGP receive little or no treatment (Greenwood & Stainton, 2001; Skaggs et al, 2007). It is also a major cause of work absenteeism in pregnancy (Dörheim, Bjorvatn & Eberhard-Gran, 2013; Wang et al, 2004) and it can negatively influence the decision for subsequent pregnancy (Brynhildsen et al, 1998).

To the best of our knowledge, this is the first study to evaluate effects of an individualized, supervised exercise programme for pregnancy-related lumbopelvic pain. Also, this study is one of the few (Granath et al, 2005; Mørkved et al, 2007; Beyaz et al, 2011; Stafne et al, 2012; Haakstad & Bö, 2015) which investigated the effects of the combination of aerobic and resistance exercise. However, all previous trials with that type of intervention were performed in group setting, not individually (except Granath et al (2005) did not specify if their intervention was performed in a group setting). Furthermore, this is the second trial (Beyaz et al, 2011) which adds daily walking intervention to biweekly exercise sessions.

Physical activity has many beneficial effects for non-pregnant population. Some of the benefits include lower rates of coronary heart disease, hypertension, cerebrovascular insult, type 2 diabetes mellitus, metabolic syndrome, colon and breast cancer, and depression (Physical Activity Guidelines Advisory Committee, 2008). It also improves functional abilities of muscles and cardiorespiratory system, it prevents obesity and improves lean body mass, as well as bone density.

In the past, pregnant women have been advised to limit their physical activity because there was certain fear of spontaneus abortion and preterm birth (ACOG, 1985). This is not the case in the last 15 years. Physical activity is not only recommended for non-pregnant population, it is now recommended by all the major antenatal obstetrical guidelines for all women without contraindications (ACOG, 2015; RCOG, 2006; Davies, Wolfe, Mottola, MacKinnon & Society of Obstetricians and Gynecologists of Canada, SOCG Clinical Practice Obstetrics Committee, 2003). While the beneficial effects and safety of exercise in pregnancy are well known today, there is still not enough evidence regarding some specific effects of exercise in some pathological conditions, such as lumbopelvic pain. However, recently, exercise in pregnancy started to be investigated as a treatment and/or prevention strategy for a broad range of conditions like hypertension and pre-eclampsia, gestational diabetes, musculoskeletal disorders and mental health problems.

Pregnant women are not engaged in physical activity well enough. Only 15.8% of pregnant women exercise according to recommendations (Evenson, Savitz & Huston, 2004). Two out of three pregnant women reported reduced levels of physical activity at 18 weeks of gestation (Liu, Blair, Teng, Ness, Lawlor & Riddoch, 2011). In general, pregnant women have lower participation in exercise than non-pregnant adult female population (Evenson et al, 2004; Domingues & Barros, 2007). Worldwide, 33.9% of adult female population are not physically active (Hallal et al, 2012). In Croatia this is not different, 31.9% of women are not physically active (Milošević et al, 2009).

LPB and PGP are very common among pregnant women (Pennick & Liddle, 2013). There is moderate-quality evidence that exercise reduces evening PGP or lumbopelvic pain in comparison to usual antenatal care, and low-quality evidence

that it reduces pain and disability from LBP (Pennick & Liddle, 2013). However, performed trials have different, and sometimes contradictory results.

Furthermore, supervised exercise programme is recommended in the treatment of the patients with non-specific chronic low back pain in non pregnant population (Airaksinen et al, 2006; Ferreira, Ferreira, Maher, Herbert, Refshauge, 2006). It is assumed that exercise could have similar mechanism of action for lumbopelvic pain in pregnancy (Vermani et al, 2010). The European guidelines for PGP (Vleeming et al, 2008) recommend individual exercise in pregnancy because supervision leads to the better quality of exercise performance. Individual treatment is more effective at reducing the intensity of pain and sick leave in comparison to group programmes (Östgaard et al, 1994; Norén, Östgaard, Nielsen & Östgaard, 1997).

Our groups were well-matched at the start of the trial. Also, there were no differences between groups regarding existing pregnancy-related lumbopelvic pain prior to the inclusion in the trial (35% vs. 22.7%). There were no differences in baseline levels of physical activity between groups at the start of the trial. However, we recorded higher levels of total physical activity in $30^{th}$ week of pregnancy in the experimental group ($P = 0.047$, $d = 0.55$, $r = 0.26$). They also had higher levels of total activity of light intensity and above (≥ 1.5 METs) in $30^{th}$ and $36^{th}$ week of pregnancy ($P = 0.034$, $d = 0.59$, $r = 0.28$; $P = 0.027$, $d = 0.63$, $r = 0.30$). Furthermore, they had higher levels of sports/exercise activities with a very large effect sizes in $30^{th}$ and $36^{th}$ week of pregnancy ($P < 0.001$, $d = 2.37$, $r = 0.76$; $P < 0.001$, $d = 2.26$, $r = 0.75$). We believe that our intervention directly contributed to these differences beause they were not present before the inclusion in the study.

## 4.1 Impact of exercise programme on prevalence and onset of pregnancy-related lumbopelvic pain

We were unable to confirm our initial hypothesis regarding the prevalence and onset of pregnancy-related lumbopelvic pain. There were no significant differences in the rate of self-reported pregnancy-related lumbopelvic pain between two groups. However, less percentage of experimental group developed lumbopelvic pain in comparison to control group (55% vs. 81.8%). Larger sample could possibly

reveal statistical significance. In general, 69% of all participants developed lumbopelvic pain.

Mørkved et al (2007) investigated effects of supervised exercise programme which combined aerobic and resistance exercises. Their intervention lasted 12 weeks and is similar to our intervention. At the end of their intervention (36$^{th}$ week of pregnancy) 43.9% women from the exercising group vs. 56.2% women from the control group reported lumbopelvic pain (P = 0.03). However, their sample was much larger (N = 301). Beyaz et al (2011) also confirmed lower frequency of LBP in their exercising group compared to the control group after their intervention (P < 0.001).

Prevalence of lumbopelvic pain in our study was comparable with the results from one Swedish study (Kihlstrand et al, 1999) where 70.5% pregnant women from water gymnastics group and 74% of women from the control group developed some kind of LBP at some period during pregnancy. Also, there were no significant differences between groups. Eggen et al (2012) also did not find significant difference on frequency of self-reported LBP and PGP after their exercise intervention. In their study, 50.2% women from the training group and 51.4% from the control group developed PGP. Also, 42.7% women from the training group and 45.8% from the control group developed LBP. Neither Stafne et al (2012) found significant difference in self-reporting lumbopelvic pain at 36$^{th}$ week of pregnancy, after 12 weeks of exercise programme which combined aerobic and resistance exercises. Seventy-four percent of women from the experimental group versus 75% from the control group developed lumbopelvic pain. Miquelutti et al (2013) and Haakstad et al (2015) also did not find any difference between groups. Percentage of women self-reporting LBP in the study conducted by Miquelutti et al (2013), between weeks 36 and 38 of pregnancy, in the exercising group was 63.5% versus 63.2% in the control group. PGP developed 28.2% women in the exercising group and 27.6 women in the control group.

On the other hand, study performed by Martins & Pinto e Silva (2005) found significant difference. After their intervention, which was „global active stretching" method, 61% of women (P < 0.01) from the experimental group reported no pain at the lumbar/or posterior pelvic area compared with 11% (P = 0.50) from the group who followed routine medical recommendations. Another study (Granath et al,

2006) investigated frequency of pregnancy-related LBP and PGP. Forty-two percent of pregnant women reported LBP and/or PGP. Authors compared water aerobic exercise programme and land based aerobic and strengthening exercises. Women in the water aerobics group had less LBP compared to women in land based exercise group (25.4% vs. 14.4%) (P = 0.04). There was no significant difference regarding frequency of PGP (25.4% vs. 24.2%).

Also, opposite to our expectations pregnant women from the experimental group had earlier onset of lumbopelvic pain (12.7 ± 12.4 week of gestation vs. 21.8 ± 11.5) (P = 0.013, *d* = -0.77, *r* = -0.36). We are unable to explain this difference. The mean time of the onset of lumbopelvic pain in another study (Depledge at al, 2005) was 25.9 ± 6.7 week of pregnancy, and almost half of the women experienced the onset of pain beetween 27 and 32 weeks of pregnancy.

## 4.2 Impact of exercise programme on the scores of NRS

We were able to partially confirm our initial hypothesis regarding the impact of exercises on the intensity of pain. While the NRS score was not significantly different in the $30^{th}$ week of pregnancy, in $36^{th}$ week of pregnancy it was significantly lower with large effect size in the experimental group (2.2 ± 2.3 vs. 4 ± 2.1) (P = 0.017, *d* = -0.80, *r* = -0.37).

This result is in accordance with the result from another study (Kihlstrand et al, 1999) where women who performed water gymnastics had significantly lower pain levels within the first postpartum week (P = 0.034). Also, Suputtitada et al (2002) had significantly lower VAS score in their experimental group which performed pelvic tilt exercise programme in comparison to control group at day 56 of intervention ($p < 0.05$). Depledge at al (2005) also had significant reduction of pain intensity measured by NRS-101 in all three groups with already developed PGP where they compared exercise only intervention with exercise with the use of pelvic belts (P < 0.001), but the duration of their intervention was only one week. However, their results are not comparable to our results due to different nature, type and duration of interventions. Haugland et al (2006), on the other hand, did not find any difference in VAS scores. However, their intervention consisted of 2

hour sessions once a week for 4 consecutive weeks, and ther outcome measures were recorded not at the end of the intervention, but 6 and 12 months postpartum which also makes comparison to our results impossible.

Elden et al (2005) compared effects of additional stabilization exercises and acupuncture with standard care only (which included advice, home exercise and pelvic belt) for six weeks in pregnant women with PGP. Both, stabilization exercises and acupuncture group, had significantly reduced intensity of pain measured by VAS compared to control group ($P = 0.03$; $P < 0.001$), but acupuncture showed more benefit than stabilization exercises in the evening pain scores ($P = 0.01$). Garshasbi & Faghih Zadeh (2005) also reported significantly reduced pain intensity after their 12-week exercise programme intervention ($P = 0.006$). Exercise programme, performed from $2^{nd}$ trimester of pregnancy until $37^{th}$ week of pregnancy for three times per week with addition of daily walks also significantly reduced VAS scores in the exercise group ($P < 0.001$) and increased them in the control group ($P = 0.0001$) (Beyaz et al, 2011). Kluge et al (2011) also found reduction in NRS scores following 10 week exercise intervention ($P < 0.01$), as well as George et al (2013) after 5-9 weeks of home exercise ($p < 0.001$).

Opposite to that, Nilsson-Wikmar et al (2006) did not find any difference among the three groups (information group, home exercise group and in clinic group) in VAS scores at the end of the intervention. Pregnant women who exercised under supervision in clinic performed 16 exercise session on average during 16 weeks (median) which means relatively poor adherence to protocol. Furthermore, Eggen et al (2012) also did not find significant difference in NRS scores after exercise intervention which consisted of supervised weekly exercise with combination of aerobic and strenghtening exercises for local and global muscles and lasted between 16 and 20 weeks. Likewise, Peterson et al (2012) also did not find difference in NRS scores, as well as Miquelutti et al (2013) in VAS scores between groups after exercise intervention.

## 4.3 Impact of exercise programme on the results of PGQ

We were able to fully confirm our initial hypothesis regarding the impact of exercises on the results of PGQ. There were significant differences in 30$^{th}$ week of pregnancy with medium effect size (P = 0.05, *d* = -0.64, *r* = -0.31). Experimental group had much lower score on PGQ (5.6 ± 7.3 vs. 16.3 ± 22.3), i.e. their quality of life was better and they had less problems during several activities of daily life associated with PGP. This was recorded again in the 36$^{th}$ week of pregnancy. Again, experimental group had lower scores on PGQ (8.1 ± 13.9 vs. 23.1 ± 20.8), with large effect size (P = 0.005, d = -0.85, *r* = -0.39). Unfortunately, other authors did not use PGQ and we are unable to compare are results.

Depledge at al (2005) used Patient Specific Functional Scale for women with PGP, specifically pubic symphysis dysfunction. They compared exercise only and exercise with pelvic belts and found significant decrease in scores in all three groups (P < 0.001), but no difference between groups. However, duration of their intervention was much shorter than ours. Another study (Elden et al, 2005) examined severity of pelvic girdle pain by an independant examiner before and after the intervention which compared stabilization exercises and acupuncture with standard care. Acupuncture showed significantly superior effects to stabilization exercises, but both interventions were superior to standard care only.

## 4.4 Impact of exercise programme on the results of RMDQ

Our hypothesis has been partially confirmed regarding the impact of exercises on the results of RMDQ. There was no difference between groups in 30$^{th}$ week of pregnancy. However, we found significant difference in the 36$^{th}$ week with large effect size (P < 0.001, *d* = -0.90, *r* = -0.41). Experimental group had lower scores (1.3 ± 3.4 vs. 5.2 ± 5.1) on RMDQ, hence less disability caused by LBP.

Kluge et al (2011) also found significant improvement in Likert-modified RMDQ scores after 10 weeks of exercise intervention (P = 0.03). Another study (Depledge

et al, 2005) also recorded significant reduction in RMDQ scores post-intervention in all three groups with developed PGP ($P < 0.001$). However their intervention lasted only for one week. Opposite to that, Eggen et al (2012) and Peterson et al (2012) did not find improvement in RMDQ scores after their exercise intervention.

Nilsson-Wikmar et al (2006) used Disability Rating Index (DRI) for the assessment of functional abilities and found no significant differences between exercising and non exercising women with PGP at the end of their intervention. However, adherence to protocol in supervised exercising group was not high. DRI was also used in the study performed by Mørkved et al (2007), and it was significantly improved in the exercising group after the intervention ($P = 0.011$). Opposite to that, Stafne at al (2012) did not found any difference between groups after exercise intervention in DRI scores.

Sedaghati et al (2007) used Quebec Disability Questionnaire for the assessment of low back pain. Scores did not significantly increase in the exercising group in comparison to baseline values. However, they were increased in the control group ($P < 0.001$). Unfortunately, they did not compare between groups. George et al (2013) used the same questionnaire and found significant difference between groups after exercise intervention ($P < 0.001$).

## 4.5 Impact of exercise programme on the rate of sick leave

We were not able to confirm our hypothesis regarding the difference in the rate of sick leave caused by lumbopelvic pain. Only one women from the control group (4.5% within control group) had to take sick leave because of the pregnancy-related lumbopelvic pain, but this was not statistically significant.

Our rate of sick leave was much lower than that recorded by Kihlstrand et al (1999) where 12.9% of women from the water gymnastics group and 21.7% of women from the control group were on sick leave because of LBP ($P = 0.09$). Higher rates of sick leave, however without significant differences between groups, were also reported by Mørkved et al (2007) where 20.9% of women from the exercising

group versus 24.8% of women from the control group were on sick leave related to lumbopelvic pain. Stafne et al (2012) also found lower rates of sick leave among women who performed exercise in pregnancy (P = 0.04). They had 22% of exercising women on sick leave due to lumbopelvic pain in comparison to 31% in the control group.

Low rate of sick leave was also reported by Granath et al (2006). In their land based exercise group only 4.5% of women with LBP and 8.2% of women with PGP had to use sick leave. Water aerobics group had 0% of women with LBP and 8.3% of women with PGP on sick leave. While there was no significant difference between women with PGP in these two groups, they found significant difference between groups for women with LBP (P = 0.03).

## 4.6 Limitations and future research

The main limitation of this study was a small sample size. On the other hand, nature of intervention, which included individually supervised exercise sessions, would be very difficult to perform on a larger sample of participants. Also, there are no data for Croatian pregnant population on exact prevalence of lumbopelvic pain which makes very difficult to calculate an ideal sample size. Worldwide percentage ranges from 4% to 90% of the whole pregnant population. It is possible that the studied population is not a representative sample of the general population affected by pregnancy-related lumbopelvic pain. Since these women volunteered to participate in this study they might have been more interested in active and healthy lifestyle.

Another limitation of this study is not distinguishing between LBP and PGP. There are two reasons for that. First is relatively small sample. Second reason is the fact that there is currently no single gold standard test for diagnosis of PGP and it is not always easy to distinguish LBP and PGP because symptoms often overlap or two conditions exist at the same time.

Future research should aim to compare levels of supervision required to achieve optimal adherence to protocol and best outcomes. Also, same exercise protocol should be tested and compared between group setting, individual supervised

session and as a home exercise programme to determine if there are differences in adherence to protocol and outcomes. Higher level of supervision and individualised approach probably improves participation and outcomes. However, at the same time it represents higher cost to the healthcare system. Furthermore, future research should investigate different protocols of exercise and different combinations of aerobic and resistance exercise on short- and long-term outcomes. Finally, there is a great need to develop valid and reliable instrument for distinguishing LBP and PGP and to test different exercise protocols in these two conditions to determine optimal treatment strategy and expected outcomes for specific condition.

# 5 CONCLUSION

In conclusion, we successfuly proved that exerecise offers significant benefits for pregnant women regarding lumbopelvic pain. While we were unable to prove that exercise influences incidence of pain, we were able to prove beneficial effects on its severity, functional abilities and quality of life.

We had lower percentage of women with lumbopelvic pain in the experimental group, however that was not statistically significant. Still, even with unsignificant difference in the percentage of women who developed pregnancy-related lumbopelvic pain, those in the experimental group were less affected and better coped with it. They had significantly lower levels of pain, higher quality of life and lower disability levels. There was a positive dose-response relationship because number of sessions and duration of the intervention were negatively correlated with the severity of lumbopelvic pain.

Our adherence to protocol was very high. Probable cause for that was individualized approach to each participant. Also, they were able to chose the time and days of the week to attend exercise sessions. In that way, some of the barriers to exercising in pregnancy were removed. Furthermore, there were no development of warning signs which would require termination of exercise or adverse side effects. None of participants developed contraindications for exercise. There was no dangerous increase in core body temperature or drop in FHR.

Our exercise programme completely complied with the recommendation that pregnant women without contraindications should engage in aerobic and strength-conditioning exercises for at least 20-30 minutes per day on most or all days of the week. Considering the other benefits of exercise in pregnancy, which include improvement and maintainance of physical fitness, prevention of excessive weight gain, prevention of gestational diabetes mellitus and enhancement of psychologic well-being, our exercise programme probably had multiple health benefits.

Still, there is the need for development of specific guidelines for the optimal type, frequency, duration and intensity of exercise for prevention and treatment of LBP and PGP. These guidelines should be incorporated into general guidelines for exercise in pregnancy.

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# POVZETEK V SLOVENSKEM JEZIKU

# 1 UVOD

Nosečnice brez zdravstvenih zapletov naj bi bile redno zmerno intenzivno gibalno aktivne vsaj 20-30 minut dnevno večino ali vse dni v tednu (Ameriško združenje porodničarjev in ginekologov (ACOG), 2015). Po drugi strani pa je znano, da nosečnice zmanjšujejo količino gibalne aktivnosti, in tiste, ki imajo bolečine v križu in bolečine v medenici, so še veliko manj gibalno aktivne (Owe, Nystad & Bo, 2009).

Nosečniška bolečina spodnjega dela hrbta in bolečina medeničnega obroča, se definira kot periodična ali neprekinjena bolečina spodnjega dela hrbta in medenice, ki traja več kot en teden (Mogren & Pohjanen, 2005). Bolečina v križu je definirana kot bolečina med 12. rebrom in glutealno gubo, in se lahko širi v noge (Vleeming, Albert, Östgaard, Sturesson & Stuge, 2008). Bolečina v medenici je definirana kot bolečina med posteriornim črevničnim grebenom in glutealno gubo, predvsem v bližini sakroiliakalnih sklepov (Vleeming idr., 2008). Lumbopelvična bolečina je izraz ki se uporablja, če ni moč ugotoviti razlike med bolečino v hrbtu in bolečino v medenici (Wu idr., 2004).

Patogeneza in etiologija nosečniške bolečine v hrbtu in bolečine v medenici ni znana popolno in verjetno ima več dejavnikov. Visoka pojavnost najverjetnejših vzrokov ima več dejavnikov, kot so spremenjena drža med nosečnostjo s povečano ledveno lordozo, laksoznost ligamenotv, ki je posledica hormona relaksina in progesterona in zastajanja tekočine v vezivnem tkivu (MacEvilly & Buggy, 1996). Glavni simptom je bolečina, ki se običajno poveča z napredovanjem nosečnosti. Fizioterapija je glavna oblika zdravljenja in lahko vsebuje pasivne tretmaje kot manualno terapijo in aktivno zdravljenje, kot terapevtsko vadbo (Vleeming idr., 2008). Telovadba lahko zmanjša intenzivnost bolečine in izboljša funkcijo (Pennick & Liddle, 2013; Gutke idr., 2015). Evropske smernice za bolečine v medeničnem obroču (Vleeming idr., 2008) priporočajo individualno vadbo v času nosečnosti.

Terapevtska vadba je eden od najpogostejših načinov za zmanjševanje bolečine v lumbopelvičnem področju med nosečnostjo. Do 2016. je bilo poročanih 20 študij o

učinku vadbe in o učinkovitosti zdravljenja na preprečevanje bolečine v lumbopelvičnem področju nosečnic. Največkrat so primerjali eno obliko vadbe, kot eno intervencijo, ali kombinacijo terapevtske vadbe in nekaterih drugih načinov fizioterapije s standardno prenatalno nego.

Večina študij (12) je potrdila pozitivne učinke vadbe na bolečino in invalidnostjo. (Kihlstrand idr., 1999; Suputtitada idr., 2002; Depledge idr., 2005; Elden idr., 2005; Garshasbi & Faghih Zadeh, 2005; Martins & Pinto e Silva, 2005; Granath idr., 2006; Mørkved idr., 2007; Sedaghati idr., 2007; Beyaz idr., 2011; Kluge idr., 2011; George idr., 2013 ). Nekatere študije (8) niso ugotovile bistveno razliko med vadbeno skupino in kontrolno skupino. (Wedenbert idr., 2000; Nilsson-Wikmar idr., 2005; Haugland idr., 2006; Eggen idr., 2012; Stafne idr., 2012; Peterson idr., 2012; Miquelutti idr., 2013; Haakstad & Bø, 2015).

Namen magistrske naloge je preučiti in dodati nove znanstvene dokaze o učinkih na zdravje nadziranega individualiziranega strukturiranega programa vadbe, ki ga sestavljajo aerobne dejavnosti in vadbe proti uporu. Glavna hipoteza je, da sodelovanje v programu vadbe direktno vpliva na zmanjšenje bolečine, rezultate vprašalnika, ki merijo simptome, omejitve dejavnosti in invalidnosti, pogostost bolniškega dopusta in začetek nosečniške bolečine v ledvenem delu hrbtenice in medeničnem obroču.

# 2 METODE IN MATERIALI

Eksperimentalna raziskava je bila zasnovana kot naključna kontrolirana raziskava. Zaradi same narave študije, le-ta ni bila slepa. Etična odobritev je bila pridobljena s strani vseh ustreznih organih in pisno dovoljenje prav tako s strani vseh udeželencev raziskave.

Preiskovanke so bile zdrave nosečnice. Vključitveni kriteriji so bili: nosečnost, starost med 20 in 40 let in sposobnost branja, razumevanja in govora hrvaškega jezika. Izključitveni kriteriji so bili: anamneza spontanih splavov, farmakološko zdravljenje, kontraindikacije za vadbo po ACOG (2002) merilih, kajenje, prejšnja poškodba ledvene hrbtenice in/ali medenice ali huda bolečina ledvene hrbtenice in medenice pred nosečnostjo. Izhodiščni podatki so bili zabeleženi ob prvem

intervjuju. V 30. in 36. tednu smo beležili telesno maso in izračunali indeks telesne mase (ITM), s specifičnim vprašalnikom smo beležili tudi stopnjo gibalne/športne aktivnosti, z uporabo Numerične ocenjevalne lestvice (Numeric Rating Scale (NRS)) stopnjo intenzivnosti bolečine ter sm o beležili rezultate Roland-Morrisovega vprašalnika nesposobnosti (Roland-Morris Disability Questionnaire (RMDQ)) in Vprašalnika o medeničnem obroču (Pelvic Girdle Questionnaire (PGQ)), skupaj z bolniškim dopustom in začetkom bolečine.

Nosečnice v eksperimentalni skupini so bile vključene v individualiziran, strukturiran program vadbe dvakrat tedensko, poleg že obstoječih postopkov obravnave. Trajanje programov vadbe je bilo 50-55 minut. Nosečnice su tudi izvajale minimalno 30 min visoko intenzivne hoje dnevno. Nosečnice v kontrolni skupini so prejele edino standardno predporodno nego. Program vadbe je bil sestavljen iz aerobne vadbe (20 minut), vadbe proti uporu (20-25 minut), vaje za krepitev medeničnega dna, raztezne vaje in vaje za sprostitev (10 minut). Ciljna intenzivnost vadbe je bila v aerobni coni (65-75% maksimalnega srčnega utripa), t.j. 13-14 na Borgovi ocenjevalni lestvici zaznavanja napora (The Borg Rating of Perceived Exertion scale) (Borg, 1982). Vadba proti uporu je vključevala vaje za stabilizacijo ledvenega predela in medeničnega dna (ledveno-medeničnega predela), vaje za mišice zgornjih in spodnjih udov, vaje za mišice iztegovalke na hrbtu in globoke trebušne mišice. Šest različnih vaj je bilo izvedenih v treh serijah z 10-15 ponovitvami na serijo.

Statistične analize so bile izvedene s pomočjo programa SPSS 19.0 (IBM, Armonk, NY, USA). Opisna statistika je bila opravljena za vse spremenljivke. Vključevala je povprečje, standardno deviacijo, in minimalne ter maksimalne vrednosti kjer je to bilo primerno. Normalnost podatkov je bila preverena s Shapiro-Wilkovim testom. Homogenost varianc je bila preverena s Levenovim testom. Uporabili smo Mann Whitney U test za primerjavo izhodiščnih vrednosti, rezultate PPAQ, RMDQ in PGQ vprašalnika, nastop bolečine v ledveni hrbtenici in medenici ter pogostnost bolniškeg dopusta. Stopnja, pri kateri smo sprejemalii hipoteze je bila določena pri $P < 0.05$ in v primeru statističnih raztlik smo izračunali Cohen d (*d*) in velikost učinka (*r*).

# 3 REZULTATI

V študijo je bilo vključenih 45 nosečnic in sicer 22 merjenk v eksperimentalno ter 23 merjenk v kontrolno skupino. Tri merjenke (6.7%) so predčasno zapustile študijo, dve iz eksperimentalne (9.1%) in ena iz kontrolne skupine (4.4%). Končni vzorec, ki je uporabljen v analizi je štel 42 merjenk, 20 v eksperimentalni in 22 v kontrolni skupini. Obe skupini sta bili uravnoteženi, ni bilo statistično značilnih razlik glede izhodiščnih značilnosti ($P > 0.05$).

V času študije smo izvedli 419 vadbenih enot. Povprečno število vadbenih enot na merjenko je bilo 21 ± 7.6. Minimalno število vadbenih enot po merjenki je bilo 12, maksimalno 34. Povprečna realizacija vadbe je bila v 83.7% (minimum 70% in maksimum 96%), kar je nad zastavljeno mejo 70%.

Nosečnice eksperimentalne skupine so imele višjo raven skupne gibalne aktivnosti v 30. tednu nosečnosti ($P = 0.047$, $d = 0.55$, $r = 0.26$). Imele so tudi značilno višjo raven skupne gibalne aktivnosti nižjih in višjih intenzivnosti (≥ 1,5 MET) v 30. tednu ($P = 0.034$, $d = 0.59$, $r = 0.28$), kot tudi v 36. tednu nosečnosti ($P = 0.027$, $d = 0.63$, $r = 0.30$). Nosečnice eksperimentalne skupine su imele tudi višjo raven gibalne aktivnosti v 30. tednu nosečnosti ($P < 0.001$, $d = 2.37$, $r = 0.76$) in v 36. tednu nosečnosti ($P < 0.001$, $d = 2.26$, $r = 0.75$).

Nismo ugotovili značilnih razlik v številu nosečnic, pri katerih se je razvila bolečina v spodnjem delu hrbta in medenici, kljub temu smo ugotovili, da so v ekperimentalni skupini nosečnice razvile bolečni v manjšem deležu (55%) kot v kontrolni skupini (81.8%). Razlika pri pojavnosti bolečine, pred vključitvijo v študijo med skupinama ni bilo (35% proti 22.7%). No, kljub temu smo pri nosečnicah iz eksperimentalne skupine ugotovili zgodnejši pojav bolečin ($P = 0.013$, $d = -0.77$, $r = -0.36$).

Rezultat NRS glede intenzivnosti bolečine je bil nižji v eskperimentalni skupini v 30. tednu nosečnosti, vendar razlika ni bila značilna. Značilna razlika se pojavi v 36. tednu nosečnosti ($P = 0.017$, $d = -0.80$, $r = -0.37$). Značilne razlike smo ugotovili tudi v 30. tednu ($P = 0.05$, $d = -0.64$, $r = -0.31$), kot tudi v 36. tednu nosečnosti ($P = 0.005$, $d = -0.85$, $r = -0.39$) pri rezultatih PDQ. Manjše število simptomov in večjo opravilnost smo zasledili pri eksperimentalni skupini skozi nižje rezultate PGQ-ja. V 30. tednu nosečnosti nismo ugotovili značilnih razlik med skupinama pri

RMDQ-ju, dobili pa smo značilne razlike v 36. tednu nosečnosti ($P < 0.001$, $d = -0.90$, $r = -0.41$). Višjo raven zdravja in nižje rezultate na RMDQ-ju so imele nosečnice eksperimentalne skupine. Tekom študije je samo ena preiskovanka kontrolne skupine morala na bolniško zaradi bolečine v spodnjem delu hrbta ali medenice. Razlika med skupinama ni bila značilna.

# 4 RAZPRAVA

Cilj magistrske naloge je raziskati vplive strukturiranega programa terapevtskih vaj, ki se kombinirajo z aerobno vadbo in vajami z obremenitvijo ob vsakodnevni hitri hoji na nosečniške bolečine v ledvenem delu hrbtenice in medenice. Ključne opazovane spremenljivke so bile: samoocenjena pojavnost bolečine v ledvenem delu hrbtenice in medenice, intenzivnost bolečine in zaradi omenjenih bolečin povzročena onesposobljenost. Po naših ugotovitvah, je to prva študija, ki ocenjuje učinke individualnega, nadziranega programa vadbe na bolečine v ledvenem delu hrbtenice in medenice med nosečnostjo. Je pa to druga študija (Beyaz idr., 2011), ki dodaja vsakodnevno hitro hojo programu vadbe, ki se odvija dvakrat tedensko.

Svojo začetno hipotezo o razširjenosti in pojavu bolečin nismo imeli možnosti potrditi. Med obema skupinama ni bilo pomembnih razlik v pogostosti samoocenjene bolečine v ledvenem delu hrbtenice in medenice. Mørkved idr. (2007) so prav tako raziskovali učinke nadzorovane vadbe, ki je kombinirala aerobno vadbo z vadbo z obremenitvijo. Ob zaključku vadbe (36. teden nosečnosti), je 43,9% žensk iz skupine, ki so telovadile v primerjavi z 56,2% ženskami iz kontrolne skupine, poročalo o bolečini v ledvenem delu hrbtenice in medenice ($P = 0.03$). Beyaz idr. (2011) so prav tako potrdili manjšo pogostost bolečine v vadeči skupini ($P < 0.001$). Eggen idr. (2012) ter Kihlstrand idr. (1999) tudi niso niso ugotovili pomembnih razlik, po zaključku vadbe, v pogostosti samoocenjene bolečine v ledvenem delu hrbtenice in medenice .

Delno smo potrdili hipotezo o vplivu vadbe na intenzivnost bolečine. Medtem ko rezultati NRS niso bistveno drugačni v 30. tednu nosečnosti, so pa bili v 36. tednu občutno nižji in to z velikim učinkom (2.2. ± 2.3 v primerjavi z 4 ± 2.1) ($P = 0.017$, $d = -0.80$, $r = -0.37$). Garshasbi in Faghih Zadeh (2005) ter Beyaz idr. (2011) prav tako poročajo o znatno zmanjšani intenzivnosti bolečine po zaključku njihove

vadbe. Eggen idr. (2012) ter Peterson idr. (2012) niso potrdili razlike v rezultatih NRS po izvajanju telovadbe, ki je z kombinacijo aerobne vadbe in vajami za krepitev lokalnih in globalnih mišic obsegala nadzorovano vadbo enkrat tedensko v obdobju med 16. in 20. tednom.

V celoti smo potrdili našo hipotezo o vplivu vadbe na rezultate PGQ. V 30. tednu nosečnosti so bile pomembne razlike z zmernim učinkom (P = 0.05, *d* = -0.64, *r* = -0.31). Eksperimentalna skupina je imela znatno nižje rezultate na PGQ-ju (5.6 ± 7.3 v primerjavi 16.3 ± 22.3). To se je prav tako potrdilo v 36. tednu nosečnosti, ko je poskusna skupina ponovno z velikim učinkom (P = 0.005, d = -0.85, *r* = -0.39) imela nižje rezultate na PGQ-ju (13.9 ± 8.1 v primerjavi 23.1 ± 20.8). Žal drugi avtorji niso uporabili PGQ, in naših rezultatov nismo imeli možnosti primerjati.

Delno smo potrdili hipotezo glede učinka vadbe na rezultate RMDQ. Po 30. tednu nosečnosti med skupinami ni bilo razlike. Vendar pa smo ugotovili pomembne razlike z velikim učinkom v 36. tednu nosečnosti (P < 0.001, *d* = -0.90, *r* = -0.41). Poskusna skupina je imela nižje ocene (1.3 ± 3.4 v primerjavi z 5.2 ± 5.1) v RMDQ-ju in posledično manjšo onesposobljenost povzročeno zaradi bolečin v ledvenem delu hrbtenice. Kluge idr. (2011) so prav tako potrdili znatno izboljšanje rezultatov Likertovega modificiranega RMDQ-ja po 10-ih tednih vadbe (P = 0.03). Nasprotno, Eggen idr. (2012) ter Peterson idr. (2012) niso ugotovili izboljšanja rezultatov RMDQ-ja po izvedbi vadbe. Ni nam uspelo potrditi hipoteze o razliki v pogostosti bolniškega dopusta zaradi bolečin nastalih v ledvenem delu hrbtenice in medenice. Samo ena oseba v kontrolni skupini (4.5% vseh vprašanih v kontrolni skupini), je morala vzeti bolniški dopust zaradi bolečine, vendar ta razlika ni bila statistično pomembna.

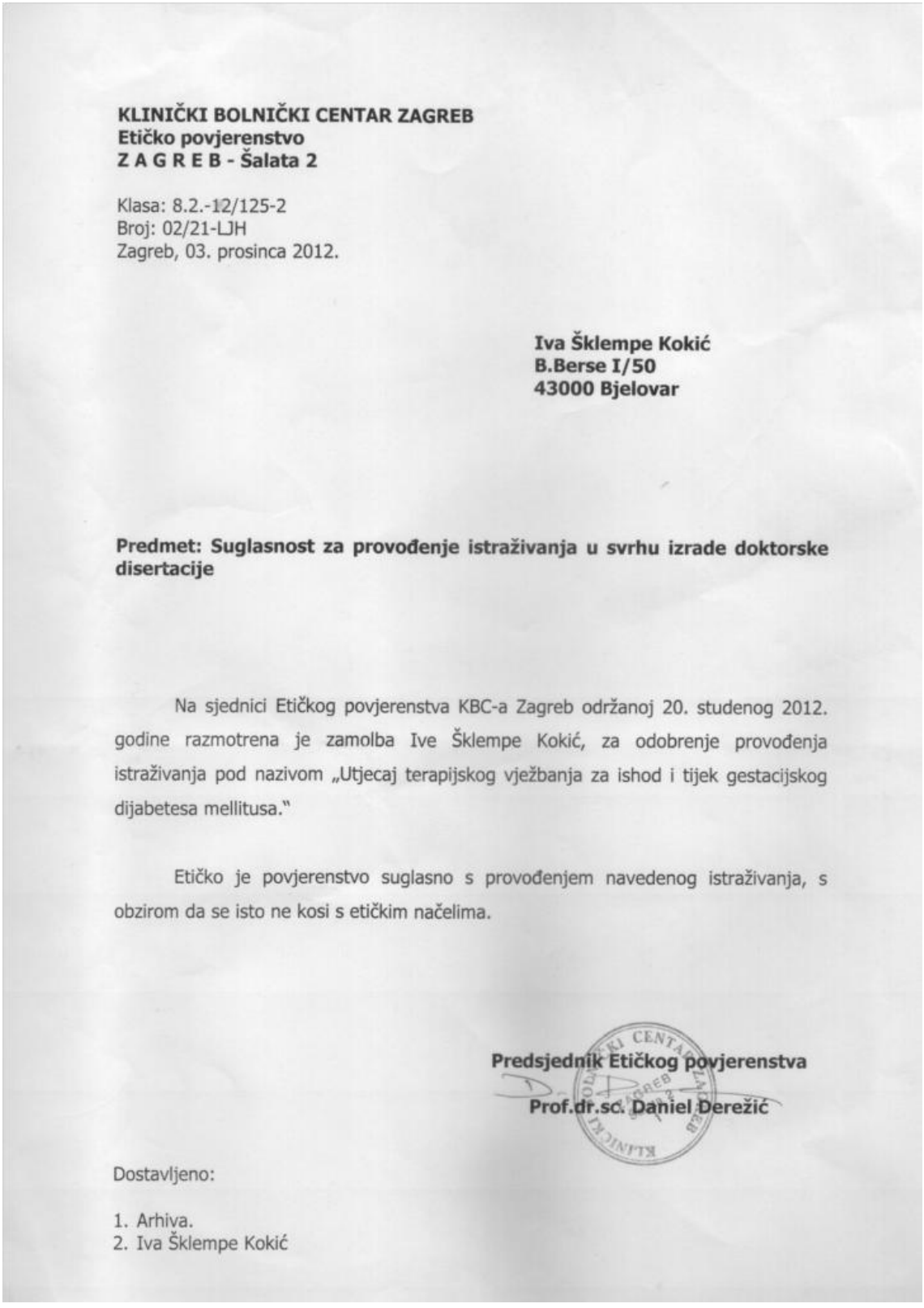
Glavna omejitev te študije je bil premajhen vzorec. Po drugi strani pa je bila narava izvedbe, ki vključuje posamično nadzorovano vadbo taka, da bi izvedba raziskovanja na večjem vzorcu izprašanih bila bistveno težja. Možno je, da zajeti vzorec ni reprezentativen za celotno populacijo nosečnic. Druga omejitev te študije je, da nismo posebej ločili bolečine v ledvenem delu hrbtenice in bolečine v medenici.

# 5 ZAKLJUČEK

Na koncu smo uspešno potrdili, da vadba ponuja pomembne prednosti za nosečnice v zvezi z bolečino v ledvenem delu hrbtenice in medenice. Medtem, ko nismo mogli dokazati, da vadba vpliva na pojavnost bolečine, smo bili uspešni pri potrjevanju pozitivnih učinkov na intenzivnost bolečine, funkcionalno sposobnost in kakovost življenja. Imeli smo nižji odstotek žensk z bolečino v eksperimentalni skupini, vendar to ni bilo statistično pomembno. Vendarle pa so pomembne razlike v deležu žensk, ki se jim je razvila bolečina, tiste v eksperimantalni skupini so bile manj prizadete in so se z bolečino lažje spopadale. Imele so precej nižjo intenzivnost bolečine, višjo kakovost življenja in nižjo stopnjo onesposobljenosti.

# APPENDICES

**Appendix 1:** Study approval by the Ethics Committee, University Hospital Centre Zagreb.



**KLINIČKI BOLNIČKI CENTAR ZAGREB**
**Etičko povjerenstvo**
**Z A G R E B - Šalata 2**

Klasa: 8.2.-12/125-2
Broj: 02/21-LJH
Zagreb, 03. prosinca 2012.

**Iva Šklempe Kokić**
**B.Berse I/50**
**43000 Bjelovar**

**Predmet: Suglasnost za provođenje istraživanja u svrhu izrade doktorske disertacije**

Na sjednici Etičkog povjerenstva KBC-a Zagreb održanoj 20. studenog 2012. godine razmotrena je zamolba Ive Šklempe Kokić, za odobrenje provođenja istraživanja pod nazivom „Utjecaj terapijskog vježbanja za ishod i tijek gestacijskog dijabetesa mellitusa."

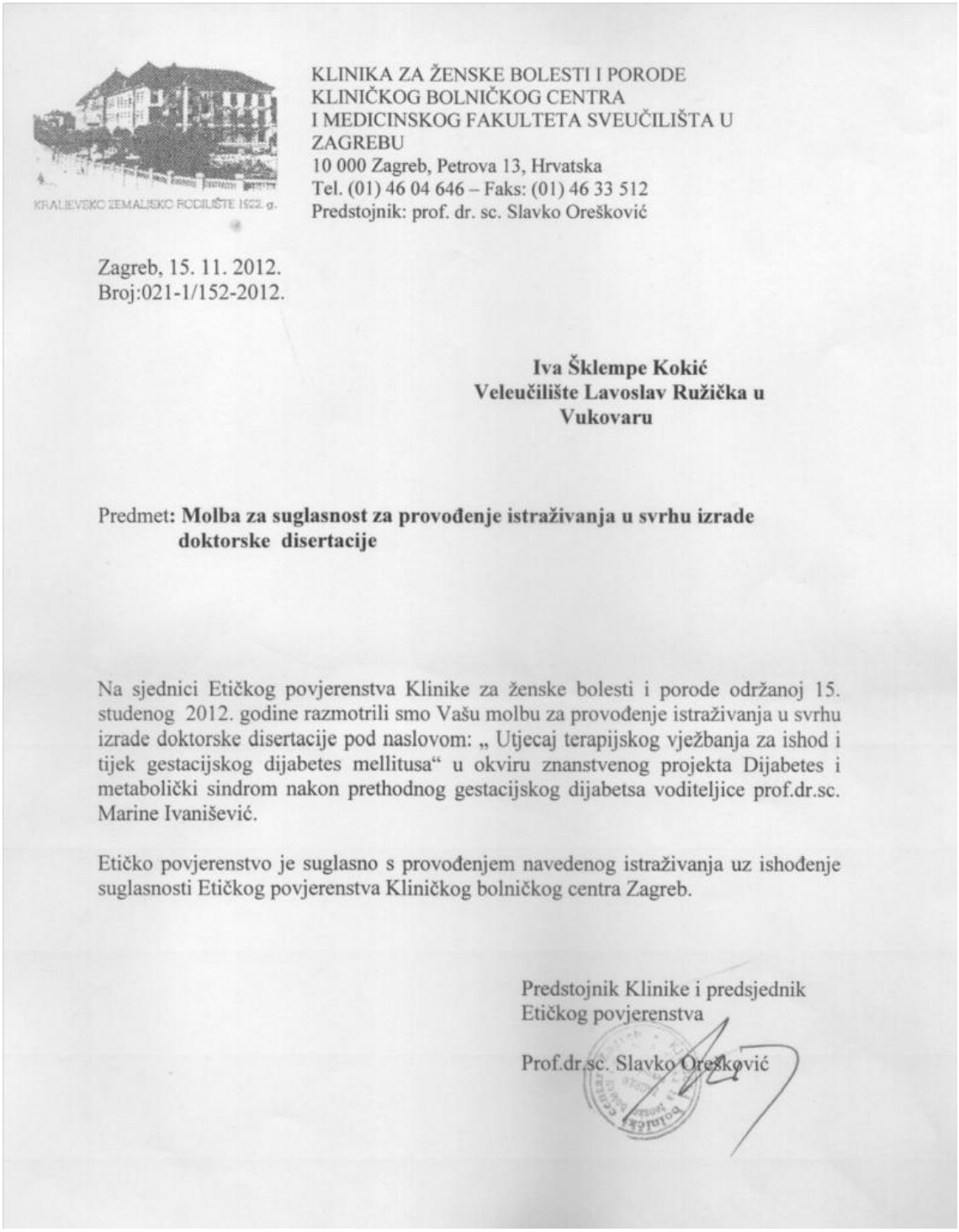
Etičko je povjerenstvo suglasno s provođenjem navedenog istraživanja, s obzirom da se isto ne kosi s etičkim načelima.

**Predsjednik Etičkog povjerenstva**
**Prof.dr.sc. Daniel Derežić**

Dostavljeno:

1. Arhiva.
2. Iva Šklempe Kokić

**Appendix 2:** Study approval by the Ethics Committee, Department of Gynaecology and Obstetrics, University Hospital Centre Zagreb.



KRALJEVSKO ZEMALJSKO PODILIŠTE 1922. g.

KLINIKA ZA ŽENSKE BOLESTI I PORODE
KLINIČKOG BOLNIČKOG CENTRA
I MEDICINSKOG FAKULTETA SVEUČILIŠTA U ZAGREBU
10 000 Zagreb, Petrova 13, Hrvatska
Tel. (01) 46 04 646 – Faks: (01) 46 33 512
Predstojnik: prof. dr. sc. Slavko Orešković

Zagreb, 15. 11. 2012.
Broj:021-1/152-2012.

**Iva Šklempe Kokić**
**Veleučilište Lavoslav Ružička u Vukovaru**

Predmet: **Molba za suglasnost za provođenje istraživanja u svrhu izrade doktorske disertacije**

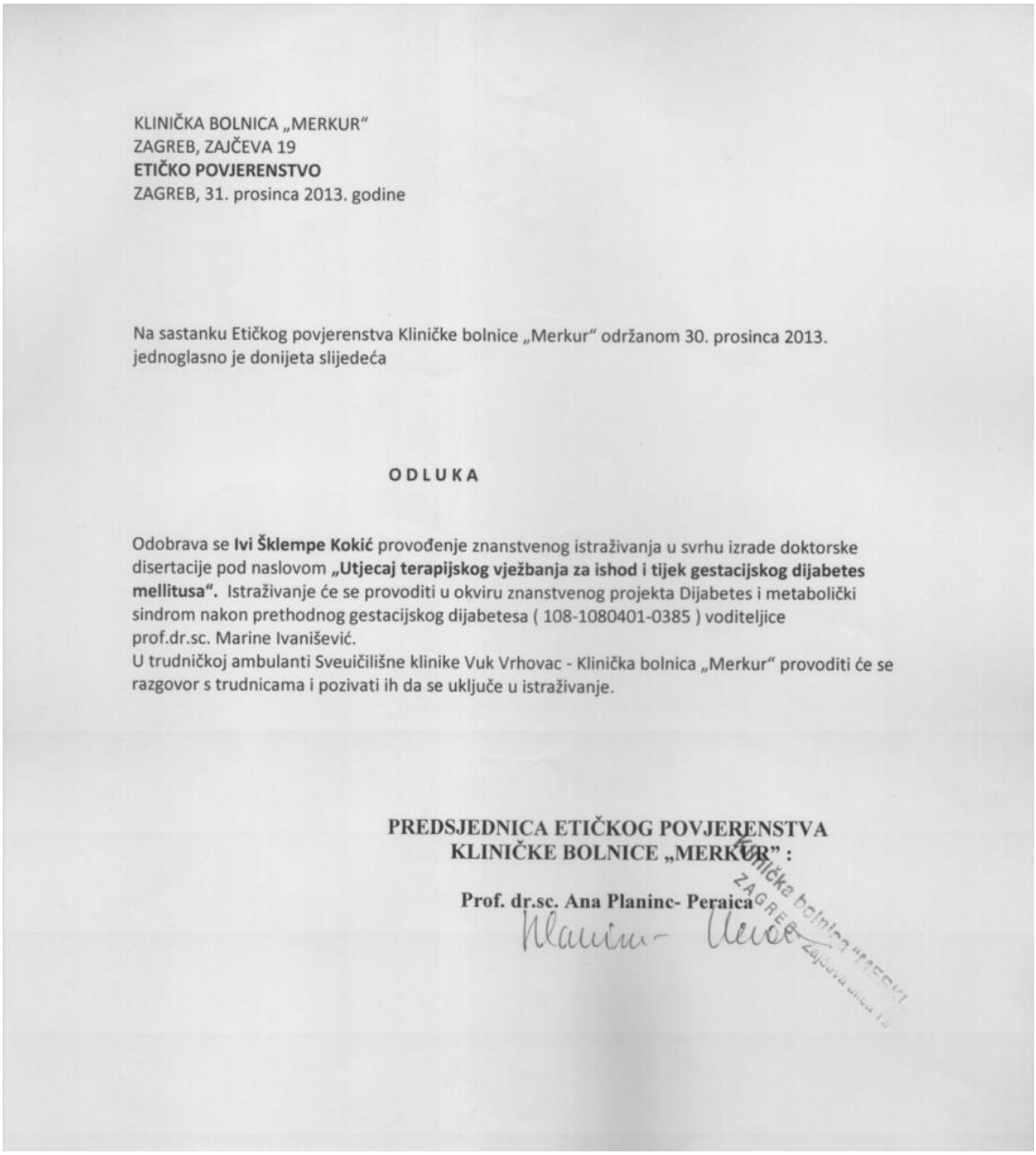
Na sjednici Etičkog povjerenstva Klinike za ženske bolesti i porode održanoj 15. studenog 2012. godine razmotrili smo Vašu molbu za provođenje istraživanja u svrhu izrade doktorske disertacije pod naslovom: „ Utjecaj terapijskog vježbanja za ishod i tijek gestacijskog dijabetes mellitusa“ u okviru znanstvenog projekta Dijabetes i metabolički sindrom nakon prethodnog gestacijskog dijabetsa voditeljice prof.dr.sc. Marine Ivanišević.

Etičko povjerenstvo je suglasno s provođenjem navedenog istraživanja uz ishođenje suglasnosti Etičkog povjerenstva Kliničkog bolničkog centra Zagreb.

Predstojnik Klinike i predsjednik
Etičkog povjerenstva

Prof.dr.sc. Slavko Orešković

**Appendix 3:** Study approval by the Ethics Committee, University Hospital Merkur



KLINIČKA BOLNICA „MERKUR"
ZAGREB, ZAJČEVA 19
**ETIČKO POVJERENSTVO**
ZAGREB, 31. prosinca 2013. godine

Na sastanku Etičkog povjerenstva Kliničke bolnice „Merkur" održanom 30. prosinca 2013. jednoglasno je donijeta slijedeća

**ODLUKA**

Odobrava se **Ivi Šklempe Kokić** provođenje znanstvenog istraživanja u svrhu izrade doktorske disertacije pod naslovom **„Utjecaj terapijskog vježbanja za ishod i tijek gestacijskog dijabetes mellitusa".** Istraživanje će se provoditi u okviru znanstvenog projekta Dijabetes i metabolički sindrom nakon prethodnog gestacijskog dijabetesa ( 108-1080401-0385 ) voditeljice prof.dr.sc. Marine Ivanišević.
U trudničkoj ambulanti Sveučilišne klinike Vuk Vrhovac - Klinička bolnica „Merkur" provoditi će se razgovor s trudnicama i pozivati ih da se uključe u istraživanje.

**PREDSJEDNICA ETIČKOG POVJERENSTVA**
**KLINIČKE BOLNICE „MERKUR" :**

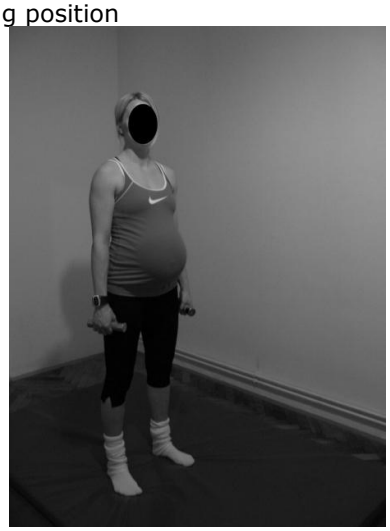
**Prof. dr.sc. Ana Planinc- Peraica**

**Appendix 4:** Resistance exercise protocols.

Protocol 1

Exercise 1

Starting position



Semi-squat with free weights
*Photo: Iva Šklempe Kokić*

Final position

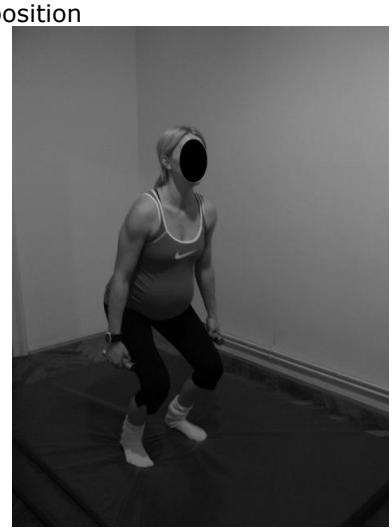
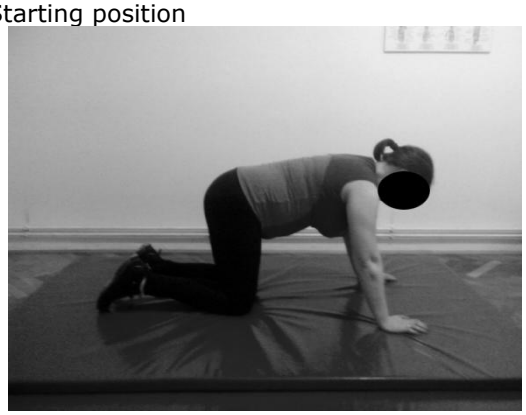


*Photo: Iva Šklempe Kokić*

Exercise 2

Starting position



Alternating reciprocal leg extension and arm flexion from quadruped position
*Photo: Iva Šklempe Kokić*

Final position

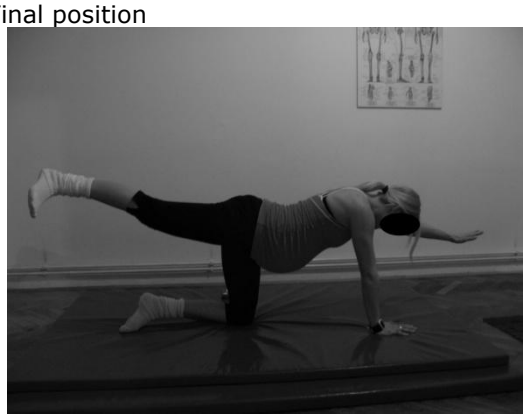


*Photo: Iva Šklempe Kokić*

Exercise 3

Starting position

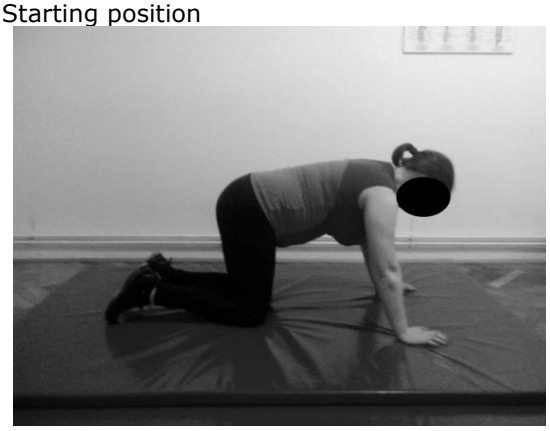
Bilateral arm abduction with theraband
*Photo: Iva Šklempe Kokić*

Final position

*Photo: Iva Šklempe Kokić*

Exercise 4

Starting position



Leg abduction from quadruped position
*Photo: Iva Šklempe Kokić*

Final position

*Photo: Iva Šklempe Kokić*

Exercise 5

Starting position

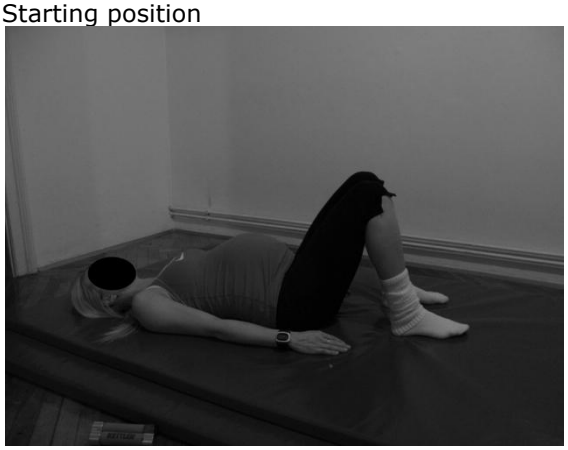
Leg abduction from side-lying position
*Photo: Iva Šklempe Kokić*

Final position

*Photo: Iva Šklempe Kokić*

Exercise 6

Starting position



„Bridge" (pelvis elevation from supine position)
*Photo: Iva Šklempe Kokić*

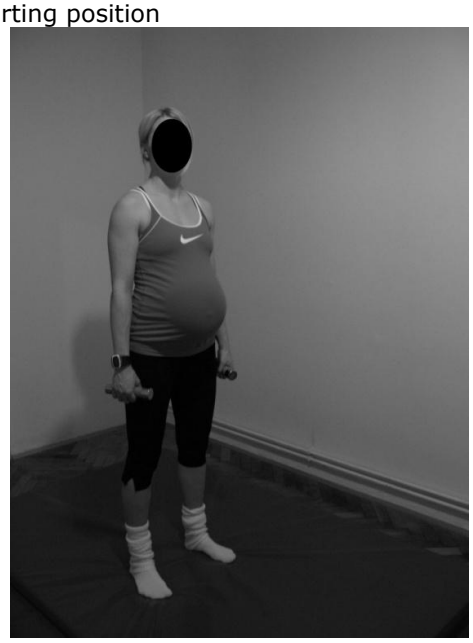
Final position

*Photo: Iva Šklempe Kokić*

Protocol 2

Exercise 1

Starting position



„Lunge" with free weights
*Photo: Iva Šklempe Kokić*

Final position

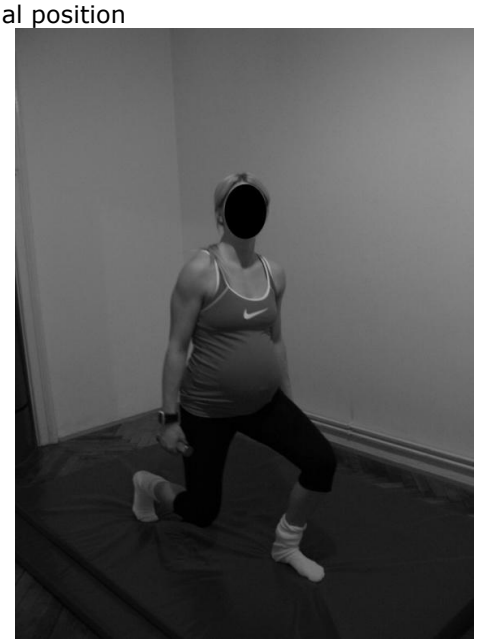


*Photo: Iva Šklempe Kokić*

Exercise 2

Starting position

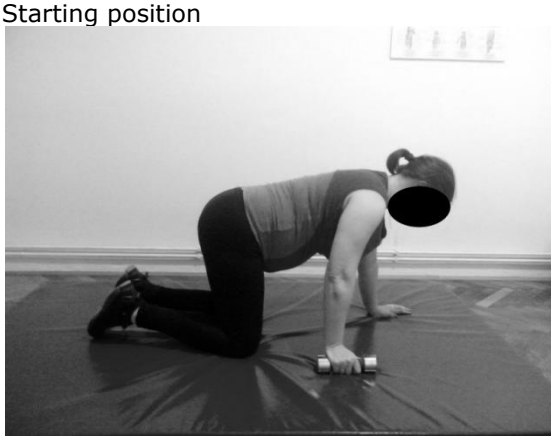


*Photo: Iva Šklempe Kokić*

Final position

*Photo: Iva Šklempe Kokić*

Arm extension with elbow flexion from quadruped position with free weight

Exercise 3

Starting position

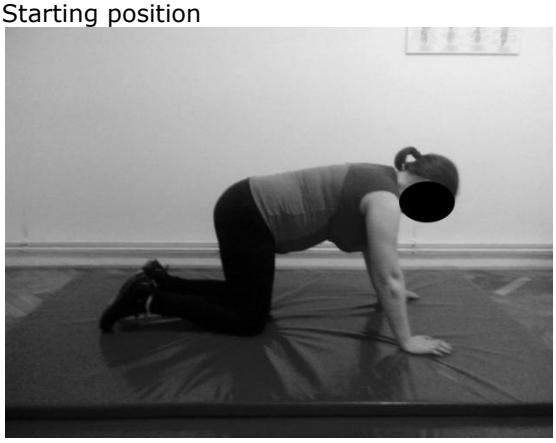


*Photo: Iva Šklempe Kokić*

Final position

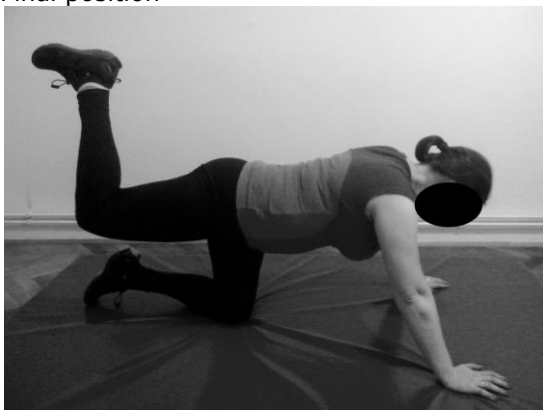


*Photo: Iva Šklempe Kokić*

Leg extension with knees in flexion from quadruped position

Exercise 4

Starting position

*Photo: Iva Šklempe Kokić*

Final position

*Photo: Iva Šklempe Kokić*

Leg abduction from side-lying position

Exercise 5

Starting position

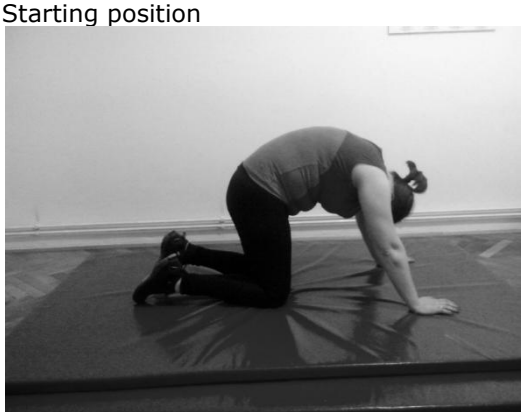
Bilateral arm external rotation with theraband
*Photo: Iva Šklempe Kokić*

Final position

*Photo: Iva Šklempe Kokić*

Exercise 6

Starting position



Back arch exercise („cat and camel")
*Photo: Iva Šklempe Kokić*

Final position

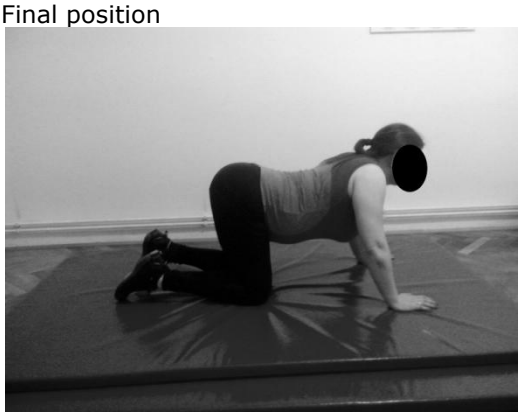


*Photo: Iva Šklempe Kokić*

Protocol 3

Exercise 1

Starting position

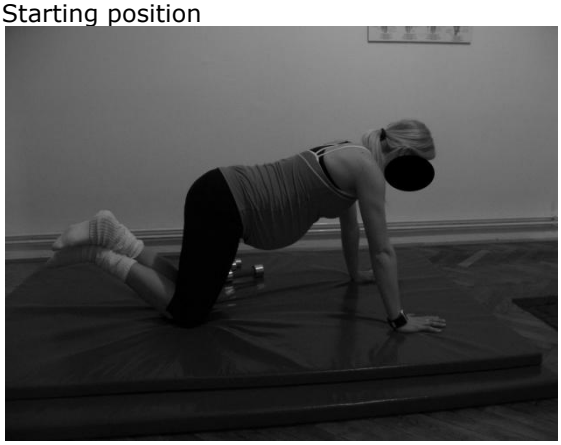
*Photo: Iva Šklempe Kokić*

Final position

Alternating leg extension with flexed knee from quadruped position
*Photo: Iva Šklempe Kokić*

Exercise 2

Starting position



Push-up from quadruped position
*Photo: Iva Šklempe Kokić*

Final position

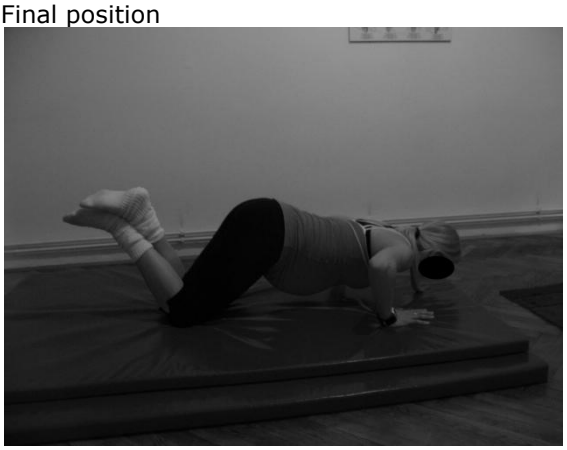


*Photo: Iva Šklempe Kokić*

Exercise 3

Starting position

„Side-lunge" with free weights

*Photo: Iva Šklempe Kokić*

Final position

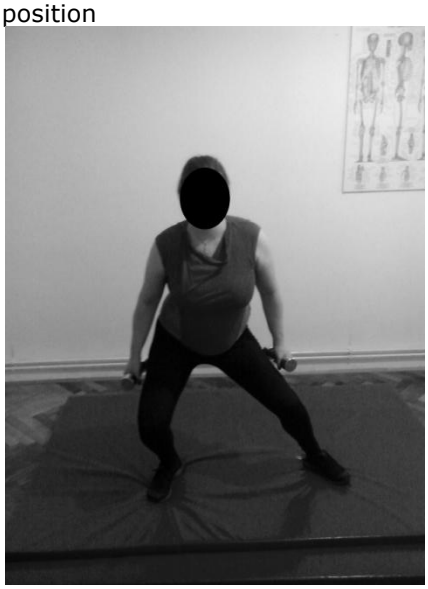


*Photo: Iva Šklempe Kokić*

Exercise 4

Starting position

Leg adduction from side-lying position

*Photo: Iva Šklempe Kokić*

Final position

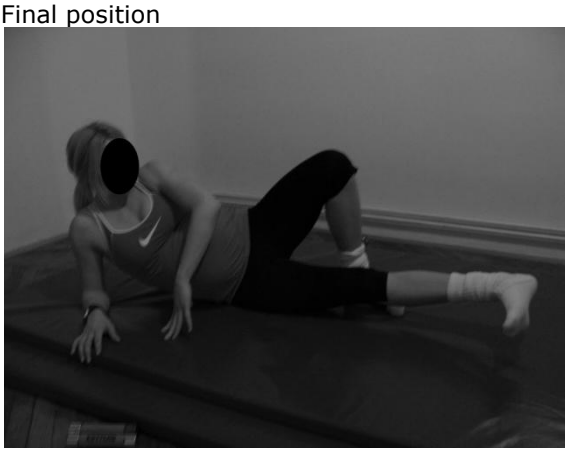


*Photo: Iva Šklempe Kokić*

Exercise 5

Starting position

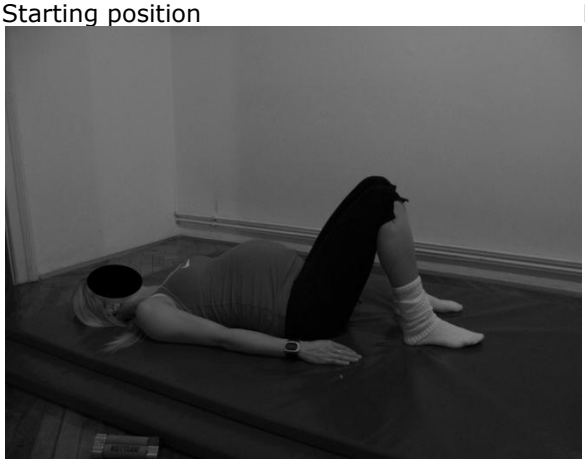


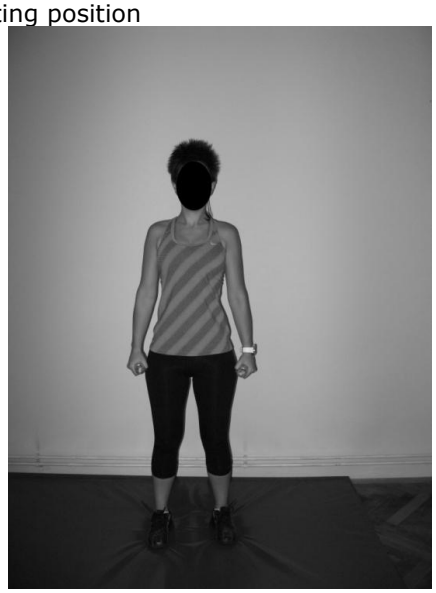
*Photo: Iva Šklempe Kokić*

Final position

„Bridge" (pelvis elevation from supine position)
*Photo: Iva Šklempe Kokić*

Exercise 6

Starting position



Bilateral arm abduction
*Photo: Iva Šklempe Kokić*

Final position

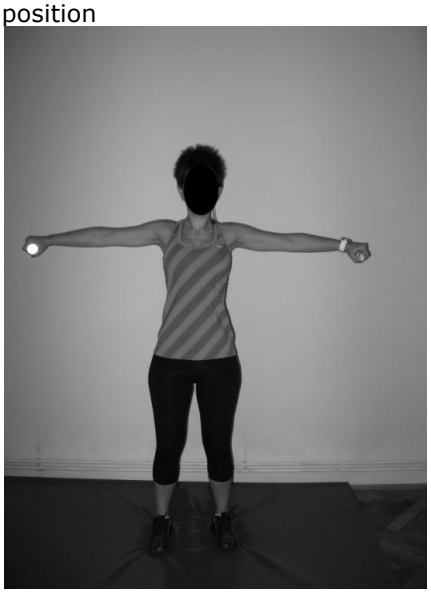


*Photo: Iva Šklempe Kokić*