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

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## ABSTRACT

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

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

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

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

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

## INTRODUCTION

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

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

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

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

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

## Design

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

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

## Study Population

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

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

## Questionnaires and Clinical Examination

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

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

## Intervention

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

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

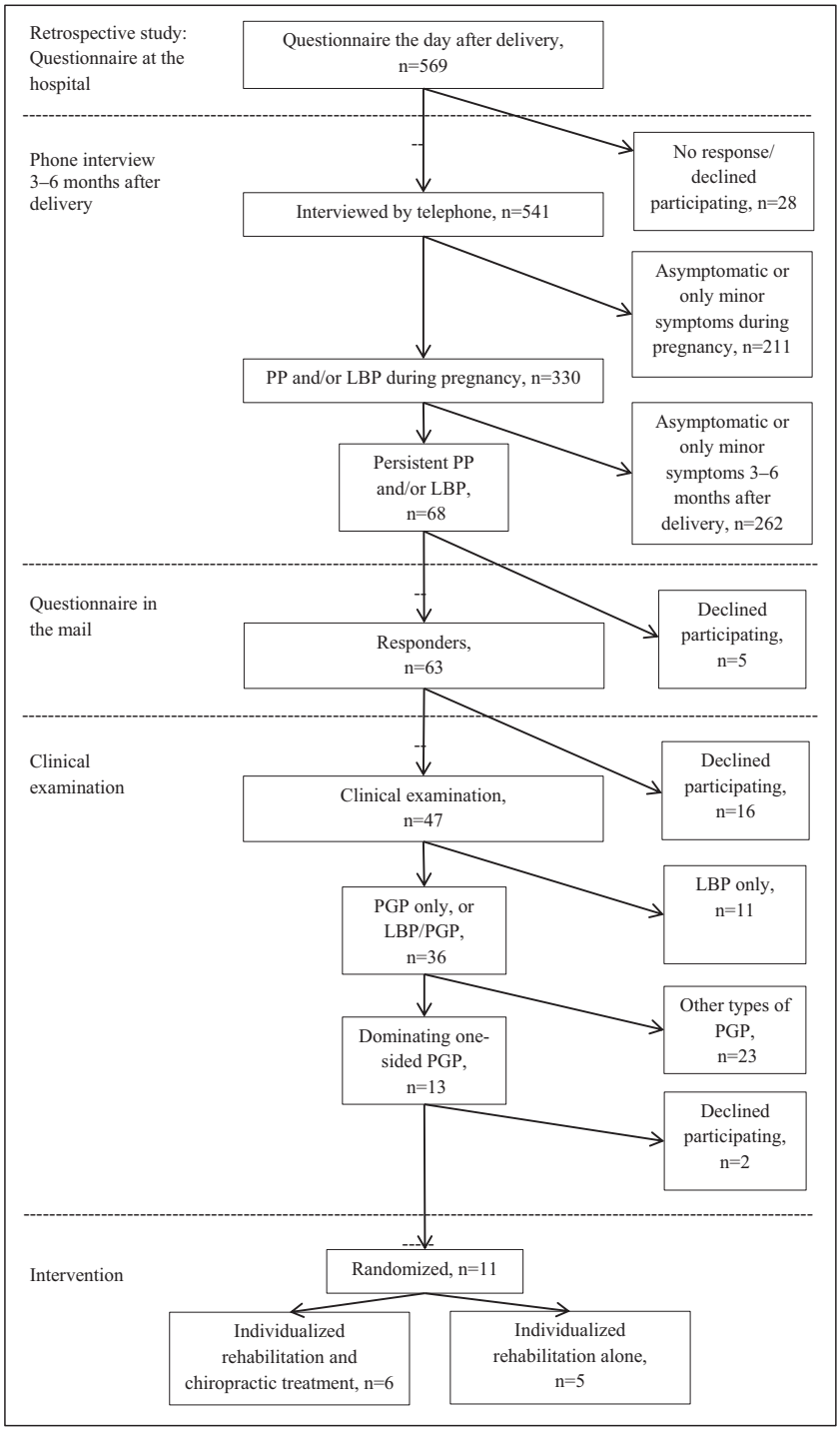


**Fig 1.** *Flowchart of the inclusion process into the pilot study.* LBP*, low back pain;* PGP*, pelvic girdle pain;* PP*, pelvic pain.*

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

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

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

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

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

### Blinding

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

### Outcome Measures

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

### Statistics

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

## Results

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

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

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

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

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

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

[a] ODI ranging from 0 (no disability) to 100 (maximum disability possible).
[b] Number of positive tests with possible values 0 to 4 (P4-right, P4-left, ASLR-right, ASLR-left).
[c] NRS ranging from 0 (no pain) to 100 (most pain imaginable).
[d] PGQ ranging from 0 (no disability) to 100 (maximum disability possible).
[e] EQ-5D ranging from 7 (poorest health) to 100 (full health).

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

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

### Adverse Events

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

## Discussion

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

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

### Limitations

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

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

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

## Conclusion

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

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

## Contributorship Information

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

**Practical Applications**

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

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