

CLINICAL PAPER

Pelvic girdle pain – part 1: quantitative results from a mixed-methods service evaluation introducing a manual therapy treatment approach to usual care

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Abstract

Pelvic girdle pain (PGP) is a musculoskeletal condition that affects 20% of pregnant women. Physiotherapists in the UK routinely treat PGP using a variety of approaches, including advice, stability exercises, pelvic belts, stretches and manual therapy. At Sheffield Teaching Hospitals National Health Service (NHS) Foundation Trust, Sheffield, UK, manual therapy techniques were not routinely used as part of usual care for antenatal women with PGP, despite a body of literature to support the efficacy of these methods. The aim of this service evaluation was to establish whether a newly introduced manual therapy treatment approach added to usual care improved patient-reported outcome measures in women with PGP, as compared to usual care alone. Forty-six patients completed the Pelvic Girdle Questionnaire (PGQ) at baseline and 6 weeks after assessment: 24 women received usual care alone; and 22 received a manual therapy treatment approach as an adjunct to usual care. Data were analysed using descriptive and inferential statistics. Although no significant differences were observed between the usual care and manual therapy groups, a significant difference was observed between the PGQ scores at baseline and 6 weeks in the manual therapy group. Clinically, these results may indicate that treatment with manual therapy will improve women's outcomes. Overall, the participants reported reduced pain and improved function after receiving a manual therapy treatment approach alongside usual care.

Keywords: manual therapy, pelvic girdle pain, physical therapy, service evaluation, treatment.

Introduction

Pelvic girdle pain (PGP) is a musculoskeletal condition that affects 20% of pregnant women (Vleeming *et al.* 2008), and while most women spontaneously recover soon after delivery, pain can persist for more than 2 years postpartum in 7% of cases (Wu *et al.* 2004). The disorder can have a marked impact on a woman's quality of life (Mogren 2007), affecting sleep (Olsson *et al.* 2004), and functional activities such as climbing stairs, walking and turning over in bed (Röst *et al.* 2006; Wellock & Crichton 2007;

Vermani *et al.* 2010). It can also result in absenteeism from work (Norén *et al.* 1997).

The aetiology of PGP is still unclear, but it is likely to be multifactorial since research indicates that altered biomechanics and neuromuscular control, hormonal changes, and the weight of the foetus all contribute to its onset (Mens *et al.* 1996; Vleeming *et al.* 2008). The risk factors that are known to be associated with the development of the condition include trauma to the pelvis and a previous history of low back pain (LBP; Vleeming *et al.* 2008). Risk factors associated with PGP continuing in the postpartum period include: a prolonged labour (Röst *et al.* 2006); a high proportion of pain provocation tests being positive (Albert *et al.* 2001); and very

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severe PGP during pregnancy (Östgaard *et al.* 1997).

There are approximately 8000 births a year in Sheffield, UK. During 2012–2013, approximately 1000 referrals for PGP were made to Women's Health Physiotherapy Outpatients at Sheffield Teaching Hospitals NHS Foundation Trust (STHNHSFT). In 2013, physiotherapists at STHNHSFT treated antenatal women who presented with PGP with advice, education, exercises, stretches, pelvic belts and elbow crutches. This existing approach is referred to in the present study as "usual care". Clinical practice guidelines recommend that appropriate manual therapy should be used in conjunction with existing management and treatment methods, where appropriate (ACPWH 2011; CPWHC & DSCPHSE 2012; RCOG 2015).

A recent national cross-sectional survey of UK physiotherapists (Bishop *et al.* 2016) showed that 48% of respondents used manual therapy as an intervention for pregnancy-related LBP. Advice on work (88%) and posture (98%), and the use of postural exercises (93%), home exercise programmes (94%) and support belts (48%) were also frequently reported. Postgraduate courses are also available that specifically teach different manual therapy techniques for the management of PGP (PGPW 2015; POGP 2015).

Despite this, in 2013, the women's health physiotherapy service in Sheffield did not routinely assess and treat patients with PGP using a manual therapy treatment approach involving specific joint mobilization techniques. There is anecdotal and research evidence within the physiotherapy profession that manual therapy can address joint dysfunction and alleviate pain, and therefore, improve women's functional ability (Daly *et al.* 1991; McIntyre & Broadhurst 1996; Stuge *et al.* 2003; ACPWH 2011). Daly *et al.* (1991) and McIntyre & Broadhurst (1996) treated pregnant women with pain arising from sacroiliac joint (SIJ) dysfunction with spinal and SIJ manipulation, respectively. Both interventions demonstrated pain relief after one or two treatments, although the sample sizes were small in both studies, and no control groups were used.

However, George *et al.* (2013) published a randomized controlled trial (RCT) comparing the provision of manual therapy, stabilization exercises and patient education by chiropractic specialists with standard obstetric care. Their findings showed that the multimodal treatment approach resulted in a significant reduction in

pain, and an improvement in the quality of activities of daily living. Although this study did not involve a placebo control group, and treatment effects could not be attributed to each of the specific approaches, it does reflect the pragmatic, real-life situation clinicians find themselves in when treating pregnant women with PGP. In clinical practice, women would rarely be treated with only one approach (Di Fabio 1992; Bishop *et al.* 2016), and therefore, George *et al.*'s (2013) results are encouraging for physiotherapists who use manual therapy as an adjunct to usual care.

Recent research has concluded that women who report high levels of pain during their third trimester of pregnancy are at an increased risk of requiring an assisted delivery and/or Caesarean section, and experiencing a longer and more painful labour (Brown & Johnston 2013). This association between increased pain and complications during labour make it even more pertinent to identify and actively treat women with PGP in a timely manner in order to reduce their antenatal pain. Research has also linked high pain scores during pregnancy with pain persisting postpartum (Albert *et al.* 2001), and therefore, effective antenatal treatment could reduce the risk of these women developing a chronic condition. In turn, this would reduce the impact on physiotherapy referrals postnatally and in the years that follow.

Currently, there is much debate within the physiotherapy profession about what a "hands-on" approach achieves when treating musculoskeletal conditions (CSP 2013). Some researchers believe that the biomechanical model for treating musculoskeletal conditions is outdated (Lederman 2011), and does not reflect the advances made by the pain sciences. It is argued that mechanistic treatments based on correcting movement dysfunction are too simplistic. Nevertheless, there is a significant body of evidence to support the hypoalgesic effect of manual therapy. This is achieved by activating descending pain inhibitory systems (Wright 1995), and pain-gate mechanisms, as described by Ronald Melzack and Patrick Wall (Melzack 1999).

O'Sullivan & Beales (2007) suggested that a "mechanism-based" classification system for PGP can be embedded within a biopsychosocial framework, which would satisfy both the manual therapy and biopsychosocial treatment approaches. These authors devised a classification framework based on the potential mechanisms that can drive PGP, one aimed at guiding

the clinician through appropriate management options. These mechanisms include: neurophysiological factors (e.g. hormonal changes, and peripheral and central sensitization); social factors (e.g. work and relationships); physical factors involving structural pathology and ligamentous laxity; genetic factors; and psychological factors (e.g. hypervigilance, and beliefs and attitudes). Peripherally mediated (i.e. mechanically induced) PGP disorders can arise from reduced force closure, and may benefit in the short term from mobilization, manipulation and muscle energy techniques, alongside functional motor control retraining to improve load transfer through the pelvis (O'Sullivan & Beales 2007).

Damen (2001) identified a clear relationship between asymmetrical laxity of the SIJs and pregnancy-related PGP, and more recently, Adhia *et al.* (2016) found that individuals with SIJ pain demonstrated a unilateral pattern of innominate movement. It is postulated that the unilateral movement pattern is indicative of joint restriction as a result of an asymmetrical stiffness of the pelvic joints. Further studies are now exploring the clinical measurement, relevance and management of the movement variations seen in patients with SIJ pain (Adhia *et al.* 2016). This latest evidence may further support the movement tests that are used as part of physiotherapy assessment of SIJ dysfunction. While waiting for higher standards of clinical research to emerge, physiotherapists rely on thorough examination, sound clinical reasoning, theoretical knowledge and the patient's history to treat PGP in pregnancy. This is supported by the European guidelines for the diagnosis and treatment of PGP (Vleeming *et al.* 2008), which recommend the use of personalized physical therapy for PGP based on findings of an individual assessment.

Service development question

Can a manual therapy treatment approach used as an adjunct to usual care improve the Pelvic Girdle Questionnaire (PGQ; Stuge *et al.* 2011, p. 1107; Stuge 2012, p. 9) outcome score, when compared with usual care alone, in the treatment of PGP?

Objective

The aim of the present study was to assess the effectiveness of using a manual therapy approach as an adjunct to usual care by applying appropriate descriptive and statistical analyses to the quantitative data.

Staff training

Two training sessions were delivered to the four members of the women's health team. The content of these sessions was intended to teach or update physiotherapists from the team about the assessment and treatment of PGP using a manual therapy approach. A range of band 5–7 physiotherapists attended the training. The teaching sessions were based on the content of a PGP workshop run by the Pelvic Partnership in 2012, and the assessment and treatment techniques acquired formed the basis of the manual therapy approach (PGPW 2015). The assessment involved using movement tests to determine symmetry; for example, a stork test (single-leg standing), gliding of the SIJ, a seated flexion test and symmetry (not pain) at the symphysis pubis joint (Fishburn & Cooper 2015). Treatment involved manual therapy modalities (e.g. muscle energy techniques, myofascial trigger points and joint mobilizations) that reflected the findings of the examination. The manual therapy approach was integrated with usual care for the treatment of women with PGP with the overall aim of restoring balanced movement around the pelvic joints.

Participants and methods

Participants

The study population was made up of antenatal women with PGP who were referred to Women's Health Physiotherapy Outpatients at the Royal Hallamshire Hospital, Sheffield. The patients were recruited using a purposive sampling strategy (Bryman 2008). Patients were selected for usual care alone (group 1) if they had been assessed and completed the PGQ before the introduction of the manual therapy approach. Those receiving manual therapy plus usual care (group 2) were selected from the physiotherapists' current caseload on a non-random basis. This pragmatically reflected the availability of the patients. The inclusion and exclusion criteria are shown in Table 1.

Methods

The data were collected over a 3-month period.

Usual care data were collected retrospectively by the first author (C.M.). The information was extrapolated from the PGQs, which had already been completed by the participants between November 2012 and February 2013. The PGQ was completed when a new participant was

Table 1. Inclusion and exclusion criteria for the quantitative recruitment of the participants

Variable	Inclusion criteria	Exclusion criteria
Age (years)	≥ 16	< 16
Fluency in English	Yes	No
Reason for referral	Pelvic girdle pain	Another musculoskeletal condition
Pelvic Girdle Questionnaire	Completed at assessment and 6 weeks	Not completed at assessment and/or 6 weeks

assessed, and then 6 weeks later. These data reflected current practice or usual care. The first author collected the usual care data at the 6-week follow-up point by telephoning participants. This approach eased the time and caseload pressures of the women's health physiotherapy team.

The data for the manual therapy treatment plus usual care approach were collected by the first author and members of the women's health physiotherapy team. This occurred between May 2013 and July 2013. Baseline data were collected at the participant's first assessment. If patients were not seeing their physiotherapist, the first author was involved in telephoning them to collect their follow-up PGQ results 6 weeks after assessment. These data reflected the new manual therapy approach, which was being offered as an adjunct to usual care. As demonstrated by Stuge *et al.* (2011), the PGQ has acceptably high validity and reliability in people with PGP both antenatally and postpartum. A further research paper concluded that the PGQ had good test-retest reliability, internal consistency and construct validity for women with PGP (Grotle *et al.* 2012).

Patient information was anonymized. Data were also recorded for the participants' stage of gestation at assessment, date of birth, gravidity, parity and number of treatment sessions. Both groups had a 60-min appointment with a women's health physiotherapist, and if required, additional follow-up appointments lasted 30 min. The first author was not blinded to the data or groups at the analysis stage because the service evaluation was part of her Master of Clinical Research degree, and she had to work independently. The study was granted approval by the Clinical Effectiveness Unit at STHNHSFT, and ethical approval was gained from the University of Sheffield's School of Health and Related Research (SchARR).

Results

A non-random, purposive sample of data was collected in the form of PGQs from two groups of patients: 24 women received usual care alone; and 22 received a manual therapy treatment approach as an adjunct to usual care. This

was lower than the number of participants recommended by the Clinical Effectiveness Unit as a result of time constraints. The PGQ was completed for each patient at the initial assessment, which gave a baseline percentage score, and after 6 weeks, generating a total of 96 data sets. Four PGQ results from two women were excluded from the usual care group. This was because one woman contracted a urinary tract infection, which was treated with antibiotics that cleared the pain, and another's baby "changed position", which relieved her pain.

Both descriptive and inferential statistical analyses were applied to the data. There were no missing data to report. The IBM SPSS Statistics 20.0 software package (IBM Corporation, Armonk, NY, USA) was used to facilitate data management and analysis.

Descriptive statistics

There were 24 and 22 women in groups 1 and 2, respectively. The mean ages of the participants in the two groups were 30 and 31 years, and the mean lengths of gestation at the initial assessment were 28 and 25 weeks, respectively. Data relating to trimesters were collected (Fig. 1): 16 women (72.5%) from group 2 were in their second trimester, as were 11 women (45.8%) from

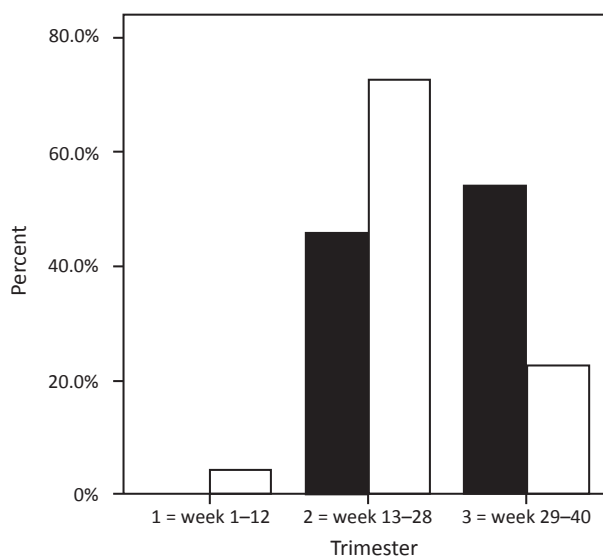


Figure 1. Variation in trimesters (in weeks) between the two groups at assessment: (■) usual care alone; and (□) manual therapy in addition to usual care.

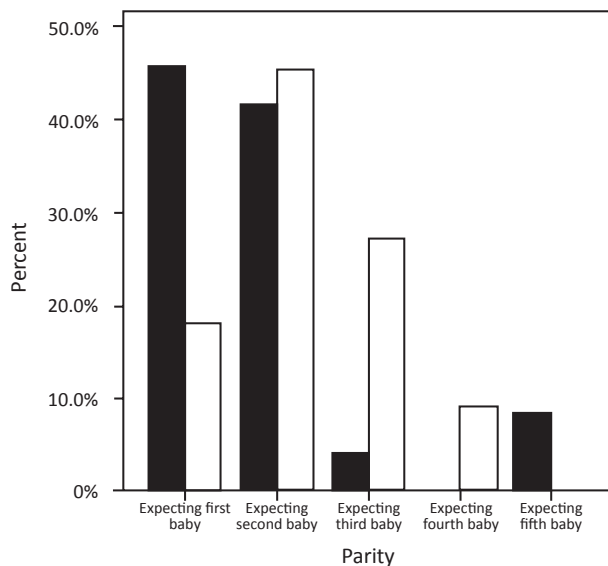


Figure 2. Variation in parity between the two groups at assessment: (■) usual care alone; and (□) manual therapy in addition to usual care.

group 1; and the latter group had more than double the women in their third trimester (13 of 24, 54.2%) than the former (five of 22, 22.7%). The differences and similarities in parity in the two groups are shown in Fig. 2.

Measures of central tendency were calculated to summarize the data for the PGQ at baseline and 6 weeks in the two groups. Measures of dispersion were used to understand the variability of the PGQ scores. The summary statistics are presented in Fig. 3.

The mean PGQ scores for both groups were similar at baseline. The box and whisker plot (Fig. 3) shows that women in group 2 started with higher minimum and maximum PGQ scores compared with those in group 1, indicating an increased level of pain and functional restrictions. However, at 6 weeks, the lowest minimum and maximum PGQ scores were found for participants in group 2, when compared to the results for those in group 1. After the initial assessment, participants in group 1 did not book for any follow-up appointments, whereas those in group 2 attended an average of 1.82 treatment sessions.

Inferential statistics

A paired-samples *t*-test conducted to compare the PGQ scores at baseline [mean = 52.96, standard deviation (SD) = 18.22] and 6 weeks (mean = 52.63, SD = 23.47) in group 1 revealed no significant difference [$t_{(23)} = 0.097$, $P = 0.923$, 95% confidence interval (CI) = -7.94, 8.72]. These results suggest that usual care does not have an effect on PGQ scores between baseline and 6 weeks. Clinically, this may indicate

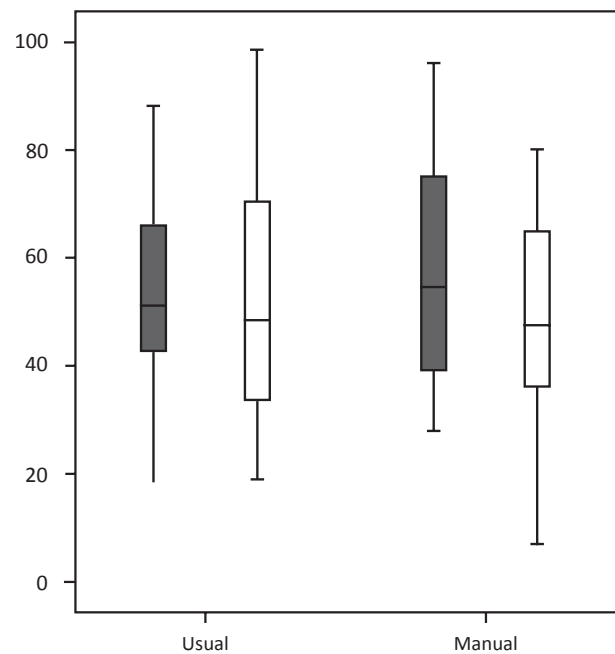


Figure 3. Box-and-whisker plot for the summary statistics for the Pelvic Girdle Questionnaire for the two groups: (■) baseline; (□) 6 weeks; (usual) usual care alone; and (manual) manual therapy in addition to usual care.

that treatment with usual care will not improve women's outcomes.

Another paired-samples *t*-test was then conducted to compare the PGQ scores at baseline (mean = 56.91, SD = 20.09) and 6 weeks (mean = 47.27, SD = 22.44) in group 2, and a significant difference was found [$t_{(21)} = 2.18$, $P = 0.041$, 95% CI = 0.43, 18.85]. These results suggest that manual therapy does have a positive effect on PGQ scores between baseline and 6 weeks. The estimated effect size is 9.64 (mean difference), but that is an imprecise estimate because of the wide confidence interval. Clinically, this may indicate that treatment with manual therapy will improve women's outcomes.

An independent-samples *t*-test was conducted to compare the PGQ scores at baseline for group 1 (mean = 52.96, SD = 18.22) and group 2 (mean = 56.91, SD = 20.09). Although the box and whisker plot (Fig. 3) showed a difference at baseline, this was not statistically significant [$t_{(44)} = -0.699$, $P = 0.49$, 95% CI = -7.43, 15.34]. These results suggest that the PGQ scores for both groups were similar at baseline, and therefore, in clinical terms, the women began physiotherapy with similar levels of pain and functional problems. Both groups had an initial assessment for 60 min, and if required, a 30-min follow-up session.

The research question sought to investigate whether PGQ scores could be improved using

a manual therapy treatment approach in conjunction with usual care, as compared with usual care alone. An independent samples *t*-test was conducted to compare the changes in PGQ scores between baseline and 6 weeks for group 1 (mean=0.33, SD=19.88) and group 2 (mean=9.22, SD=20.56). No significant difference was found [$t_{(44)} = 1.49, P=0.143, 95\% CI=-3.15, 20.91$]. Using the 95% CI, the present authors are 95% confident that the true population mean difference in PGQ score between the two groups lies somewhere between -3.15 and 20.91, but their best estimate of the mean difference is 8.89. However, the CI of the difference is unbalanced around zero, with only 3.15 below and 20.91 above. This could indicate that, although there is not enough evidence of a change in PGQ scores between the two groups, there is a trend towards showing that manual therapy could improve PGQ scores more than usual care alone. The minimum clinically important difference for the PGQ is currently unknown because it is a new outcome measure; once published, this will assist in making a judgement about the clinical relevance of the present results.

Discussion

The descriptive and inferential analyses revealed a number of unexpected findings. Descriptive analysis of the baseline results confirmed that there was very little variation between the two groups of women in terms of their age, length of gestation, trimester and initial PGQ scores. Initially, the women's health physiotherapy team had concerns regarding the effect that a manual therapy treatment approach would have on their caseloads because they assumed that more appointments would be needed. In fact, the data show that, on average, women in group 2 had only 1.82 appointments, as compared to the single appointment made for those in group 1. Forty-one per cent of participants in group 2 attended once, 36% attended twice and 23% attended for three treatment sessions, which made a smaller demand on follow-up appointments than was originally anticipated by the women's health team. Therefore, using a manual therapy approach alongside usual care should not have a negative impact on a physiotherapist's caseload.

The design of the present study did not include a scientific sample size calculation, and the first author did not expect to obtain statistical significance for any of the comparative tests. The most significant result was found for group 2 when

PGQ scores at baseline and the 6-week follow-up were compared. This suggests that using manual therapy as an adjunct to usual care lowers PGQ scores after 6 weeks, which reflects a reduction in pain and an improvement in function. The PGQ scores of participants in group 1, who did not receive any manual therapy treatment, did not change between baseline and 6 weeks. This study found that the estimated effect size was 9.64%, which suggests that a change of 9.64% or more in PGQ scores could be clinically significant. Further studies would need to be undertaken that included a sample size calculation and controlled for potential confounders.

An independent *t*-test was used to compare the differences in the means (i.e. changes in PGQ scores) at baseline and 6 weeks between the two groups, but this did not produce a significant result. Therefore, there is insufficient evidence to demonstrate that a manual therapy treatment approach used as an adjunct to usual care improved the PGQ scores in comparison to usual care alone. One possible reason for the results achieving non-significance was the small sample size, but it should be noted that a power calculation was not performed because of time constraints. However, the 95% CI suggests that the change in the means between the two groups was heading in a favourable direction, and further research with a larger sample size might detect a significant alteration. Another factor to consider was that all the participants were 6 weeks more advanced in their pregnancy, and the physical implications of the size of their pregnant abdomen could have had an impact on the outcomes.

Previous clinical trials, which excluded the pregnant population, have shown that manual therapy (i.e. mobilization and manipulation) can be an effective treatment for chronic, subacute and acute LBP in adults (Brontfort *et al.* 2010). However, RCTs can be too protocol driven and not reproducible in the clinical setting. Results from RCTs do not always support those seen in clinical practice (Brontfort *et al.* 2010). This may be explained by evidence that supports non-specific or therapeutic treatment effects that can occur as a result of clinician-patient interactions (Brontfort *et al.* 2010), which are not readily measurable, but can contribute to the effectiveness of a treatment. One advantage of the present study was that a pragmatic design was used so that outcomes could be evaluated in normal clinical conditions. The quantitative results indicate that a manual therapy treatment approach used in

conjunction with usual care has a positive effect on women's PGP and function.

This multimodal treatment approach in clinical practice is supported by the largest survey of UK physiotherapists' management of pregnancy-related LBP (Bishop *et al.* 2016). However, the latest systematic review of recommendations for the management of lumbopelvic pain in pregnancy (van Bentem *et al.* 2014) concluded that strong evidence is lacking in the current literature for the use of combined interventions and manual therapy. This was because of the methodological limitations of the research reviewed and the small number of available studies.

Limitations

The sample size of the present study was restricted by time and staffing limitations. Because of the small number of participants in the trial, there is insufficient statistical evidence of a change in PGQ scores between the two groups to assert that an effect has been observed.

Summary of key points

The present service evaluation used PGQ results and data gleaned from semi-structured interviews, which will be reported in the second part of this paper (Monaghan & Haywood 2017), to ascertain whether a manual therapy treatment approach used as an adjunct to usual care could improve patients' PGQ scores when compared to usual care alone. There is evidence to support the assertion that a manual therapy treatment approach, when used in conjunction with usual care, has a positive effect on women's pain and function between baseline and 6-week follow-up. There seems to be an indication that manual therapy could improve PGQ scores more than usual care alone.

Recommendations for future research and practice

The present results indicate that women with PGP can benefit from a multifactorial treatment approach in which manual therapy is used as an adjunct to usual care, when clinically appropriate. Using manual therapy may lead to improvements in the outcome and experience of physiotherapy for women who have to cope with PGP during and after their pregnancies.

A larger, funded, pragmatic mixed-methods trial could evaluate the effectiveness of this treatment approach while taking the following factors taken into consideration: the use of a sample size calculation; controlling for potential confounders;

and a longer-term follow-up of patients including the postpartum period. Appropriate outcome measures to assess quality of life could be added to the PGQ outcome measure. Treatment guidelines could be developed in order for treatments to be more reproducible within the trial. Other UK NHS trusts could be included in a multicentre trial. Identification of possible subgroups of women with PGP who are likely to benefit from manual therapy would guide future clinicians in their management approach. This may be linked to pain intensity, initial scores on the PGQ or a number of SIJ diagnostic tests (as outlined in the European guidelines for the diagnosis and treatment of PGP; Vleeming *et al.* 2008) that are found to be positive. It would be beneficial to complete an economic evaluation in order to establish the cost of PGP to the local and national economies. Further research could investigate the effect that manual therapy as an adjunct to usual care has on work attendance and/or sick leave compared to usual care alone.

At STHNHSFT, the women's health physiotherapy team have continued to use a manual therapy as an adjunct to usual care treatment approach when managing PGP. Changes to the antenatal class have been made in order to ensure that all women have the opportunity to have a brief "mechanical" assessment to ascertain whether manual therapy is required at an individual follow-up appointment.

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