The Effectiveness of Massage in Managing Pregnant Women with Pelvic Girdle Pain: a Randomised Controlled Crossover Feasibility Study

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Introduction: Pelvic girdle pain is a common problem experienced during pregnancy, with high incidence rates and significant impacts on quality of life. Remedial massage might be able to provide some reduction in pain.

Aim: This study aimed to investigate the feasibility of conducting a randomised controlled trial on the effectiveness of massage in treating pregnant women with pelvic girdle pain to determine its merits and viability for use in a large-scale study.

Methods: A two-arm pilot randomised feasibility crossover-controlled trial. The two treatment phases were a) remedial pregnancy massage, and b) exercise.

Results: Twenty-four women started the study and 19 women completed the study. Data were collected on recruitment and retention rates, crossover study design methodology, participant sub-characteristics, and acceptability of the outcome measures (pain, quality of life, and disability).

Conclusion: Recruiting participants for a pregnancy-related pelvic girdle pain study is indeed feasible; however, a crossover study design is not appropriate and future studies should consider a mixed methods study design.

KEYWORDS: Pregnancy-related pelvic girdle pain; massage; exercise; feasibility study

INTRODUCTION

Pelvic girdle pain is a common problem experienced during pregnancy. Pelvic girdle pain in pregnancy, also known as PPGP, is defined as "pain between the posterior iliac crest and the gluteal fold, particularly in the vicinity of the sacroiliac joint, which may radiate to the thighs and hips" that develops in pregnancy.[1,2] Pain can be experienced in conjunction with, or separate to, pain in the pubic symphysis.[1-3] The prevalence of PPGP is not clear, with incidences ranging from 20% to 75% worldwide;[2-7] however, an Australian study reported a prevalence rate of 55%.[8]

PPGP significantly impacts women's lives, with literature demonstrating it limits daily activities, decreases quality of life, alters sleep patterns, impairs mobility, decreases independence, and decreases women's ability to care for their other children.[1,2,9,10] Further, women with PPGP are more likely to have depression, report social isolation, and take more sick leave from work than women without PPGP.[8,10-12] In some cases, women with PPGP are so severely impacted that they are housebound and have reported taking more than the recommended doses of analgesia in attempts to reduce pain.[10]

Risk factors for the development of PPGP include previous low back or pelvic pain before pregnancy and/or during pregnancy,[1,3] pain in multiple pelvic locations or sites which also increases pain severity,[3,13] multiparity,[1] increased body mass,[1] history of trauma to the back or pelvis and emotional distress.[1,3] The exact aetiology of PPGP is not known, but it is believed to be multifactorial and related to 'hormonal, biomechanical, traumatic, metabolic, genetic, and degenerative factors' (p.439).[1,13] Research has postulated that individual

tissue sensitivity to relaxin, pelvic ligament and muscle microtrauma, impaired load transfer, altered pelvic mechanism and/or motor control are involved in the pathogenesis of pelvic girdle pain.[7,13] There is no consensus about how to best manage PPGP; however, it is generally managed conservatively with a multidisciplinary approach that addresses pain, psychological impacts, and activity modification.[1,4]

Remedial massage is defined as a complementary therapy which aims to systematically asses and treat muscles, tendons, ligaments and connective tissue of the body that are damaged, knotted, tense or immobile, and assist in rehabilitation, pain and injury management.[14] Massage is a popular, non-pharmacological treatment option to reduce or manage PPGP; however, there is a scarcity of information on the effectiveness of massage as a treatment for PPGP.[5,6,15] A 2016 systematic review and meta-analysis investigating pregnancy-related back and pelvic pain only included one massage study which investigated massage's effect on pregnancy-related low back pain, not pelvic pain.[16,17] Women seeking massage for PPGP present differently than women without PPGP.[18] Women with PPGP have significantly higher levels of pain at presentation and, after treatment, they have significantly less range of movement than women without PPGP.[18] Preliminary data suggested that massage may be effective in helping to manage PPGP.[18] Women with PPGP, in a single arm observational study receiving massage, experienced a reduction in pain, decreased stress, and increased range of motion post-massage treatment, with large effect sizes noted.[18]

Massage is a sought after and potentially effective management option for women with PPGP; however, to date, no studies have investigated the direct effects of massage on pain and dysfunction in women with PPGP. Given the complexity of PPGP, its multifactorial aetiology, and its impact on multiple body systems,[7,8] this study aimed to investigate the feasibility of conducting a randomised controlled trial on the effectiveness of massage in treating pregnant women with pelvic girdle pain to determine its merits and viability for use in a large-scale study.

METHODS

Study Design

A 2-arm pilot randomised feasibility crossover-controlled trial was run to investigate the management of massage on pain and disability in women with self-identified PPGP. The two treatment phases were a) remedial pregnancy massage and b) exercise. Feasibility measures included recruitment and retention rates, crossover study design methodology, participant sub-characteristics and acceptability of the outcome measures (pain, quality of life and disability) (see Table 1).

TABLE 1. Feasibility Outcome Measures

Outcome	*How Measured*
Recruitment	Information about where participants were recruited from to determine future advertising strategies. Information on the reason and number of people excluded from the study to determine inclusion/exclusion criteria for future studies.
Retention	Information on the reasons for participant drop out to determine any potential issues with participant retention.
Crossover study design methodology	Statistical analysis to determine any period or carry over effects to guide future washout periods and study design.
Participants sub characteristics	The presentation of PPGP can differ between participants and this was investigated via the following participant sub characteristics: Number of sites of pelvic girdle (1-2 sites of pain versus three or more sites)[3] Positive pain reproduction testing versus negative pain reproduction testing Those with PPGP and lumbar pain versus PPGP and no lumbar pain
The acceptability of the outcome measures used	The acceptability of the outcome measures used (pain, quality of life and disability) was measured using a post intervention questionnaire asking questions such as 'did the study questionnaires capture the symptoms and impact the PPGP had on you physically, emotionally, and psychologically'?

Inclusion Criteria

Women 18 years of age or greater, between 13 and 30 weeks of pregnancy who were able to get on and off the floor/massage table. Participants were eligible if they had sought treatment for their PPGP prior to enrolling in the study. Women self-identified as having PPGP, but to be eligible to participate they had to describe the location of their pain as being "between the posterior iliac crest and the gluteal fold".[1,2]

Exclusion Criteria

Women with a diagnosis of Cauda Equina Syndrome, rheumatic disease of the spine, osteomyelitis, neoplastic disease, and osteoporosis were excluded. Pre-existing conditions that were well-managed under the care of a GP or obstetrician did not lead to exclusion. Multiparity was not an exclusion criterion unless there was compromised health.

Interventions

All study interventions were provided by the first author, who is a trained remedial and pregnancy massage therapist, at her clinic in Melbourne, Australia. Participants received two 60-minute massage treatments and two 60-minute exercise treatments. Analysis shows that women with PPGP have similar levels of stress and pain and range of motion a week post-massage to their pre-massage levels,[18] thus treatments were aimed to be spaced between seven and 11 days apart. The washout period was 11–14 days. Two active interventions were chosen to determine if the differing treatments were impacting different aetiological causes of PPGP such as massage disrupts nociception from microtrauma, and exercise improves pain due to load transfer dysfunction.

Remedial Pregnancy Massage Arm

Treatment consisted of remedial massage techniques specifically for pregnant women, and each treatment was tailored for participants depending on the presentation of their PPGP (see Appendix 1). Treatment consisted of a warm-up, the treatment, and finishing strokes. Participants all received similar techniques to any areas of gluteal muscle thickening and or tightness. Additional techniques were added based on the results of the provocation tests (see Appendix 1). The sequence and intensity of the massage techniques were at the discretion of the massage therapist.

Exercise Arm

Treatment consisted of exercises designed by a physiotherapist with expertise in treating women with PPGP. Exercises were targeted to the deep and superficial lumbopelvic muscles, pelvic floor, and transverse abdominis to help manage and reduce PPGP.[19-21] The exercise regime was administered and supervised by the first author (see Appendix 1).

Trial Allocation

An independent researcher based at Western Sydney University prepared the randomisation schedule, which was computer generated using an online service (www.sealedenvelope.com; Sealed Envelope ltd., London, UK). The allocation was made and advised directly to the therapist after consent was obtained. Randomisation was to either a) massage treatment followed by exercise treatment, or b) exercise treatment followed by massage treatment. A washout period was applied between treatment arms. Participant and therapist blinding was not possible for the manual treatments in this study as the two interventions were distinctive; thus participants and the therapist knew which intervention they were receiving/providing.

Informed Consent and Ethics

All participants provided written informed consent to participant in the study and verbal informed consent for each study treatment. The study was approved by the Human Research Ethics Committee at Western Sydney University (Reference number H13613).

Outcome Measures

Feasibility

Feasibility was determined by the following: recruitment and retention rates, crossover study design methodology, participant sub-characteristics, and acceptability of the outcome measures (pain, quality of life, and disability) (see Table 1).

Pain, Quality of Life and Disability Measures

The study used the following self-reported outcome measures:

- Pain perception via a pain intensity-numeric rating scale (PINR)[22] (pre- and post-treatment and one week post final treatment). The scale scores from 0 (no pain) to 10 (worst possible pain).[22]
- Function via The Pelvic Girdle Questionnaire (PGQ)[23] (pre-treatment and one week post final treatment). The PGQ is a condition-specific instrument that assesses activity limitations and symptoms in women with PGP during pregnancy. Scores are presented as a percentage ranging from 0 (no disability) to 100 (severe disability).[23]
- Quality of life via The Short Form Health Survey (SF-36)[24] (pre-treatment and one week post final treatment). The SF-36 has "eight health concepts: physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue, and general health perceptions, and one single item of perceived change in health".[24] Domains are scored from 0 (worst quality of life) to 100 (best quality of life).
- Patient satisfaction via the Patient Satisfaction Questionnaire Short-Form (PSQ-18)[25] (one week post final treatment). The PSQ-18 has seven domains: general satisfaction, technical quality, interpersonal manner, communication, financial aspects, time, and accessibility and convenience.[25] Scores range from 0 to 5 with a higher score reflecting greater satisfaction.[25]

Sample Size and Statistical Power Issues

Sample size for a feasibility studies is determined by ensuring enough study participants to adequately test the feasibility and by budgetary costs.[26] Based on recommendations for sample size calculations in pilot trials,[27] the required sample size was n=10 per group. As it was unknown if a period effect would occur, leading to an inability to combine treatment groups received in different periods, we planned to recruit 24 people (10 per group plus four extra to account for a potential dropout rate of 20%).

Data Analysis

Data analysis was undertaken by the first author using a modified intention to treat analysis where all participants who completed one arm of the study were included in the analysis of that arm. Data from both periods were used in the analysis. Participants who dropped out and did not complete the end-point data were excluded from analysis in that arm.

Demographic data were summarised using summary statistics (for continuous variables (e.g., mean ± SD for age] and categorical variables [e.g., count/percentage for previous pregnancy massage experience]). A *t* test was used to determine period effects, and to compare baseline and post-treatment scores for patient sub-characteristics.

Data Interpretation

Feasibility studies involve limited data interpretation; however, to limit assumptions about correlation, causation, and coincidences, all members of the team were involved in the interpretation of the data. The team consisted of skilled and experienced researchers and clinicians who provided a balance of perspectives to enhance the utility of the research results.

RESULTS

Demographics of the Participants

Participants had mean age of 32 years (SD 3.77 years). Every (100%) participant had had a massage prior to this study and 20 (83.3%) had had a previous pregnancy massage. The mean gestation was 24 weeks and 3 days (range 14 +4 to 30 +4). The mean number of pregnancies (gravida) was 2 (range 1–5), and the mean number of times they had given birth (parity) was 1 (range 0–2). All participants (100%) were having a singleton. Only 4 (16.7%) listed PPGP as a problem in previous pregnancies.

Presentation of the Participants

Ten participants presented with 1 or 2 sites of PPGP and 14 presented with 3 or more sites of PPGP (see Table 2). Participants described their pain most commonly as sharp (n=13), followed by diffuse and catching (both n=7), see Table 2. One-third of participants had radiation of pain (n=8; 33.3%),

TABLE 2. Presentation and Testing

Presentation and Testing n=24							
Number of Sites of Pain (n, %)	1 (n=5; 20.8%)	2 (n=5; 20.8%)	3 (n=6; 25%)	4 (n=6; 25%)		5 (n=2; 8.3%)	
Type of pain[a](n)	Sharp (n=13)	Diffuse (n=7)	Catching (n=7)	Dull (n=3)	Bruised (n=2)	Tightness (n=1)	Vague (n=1)
Radiation of pain (n, %)	Yes (n=8; 22.2%)		5 radiating down their leg 1 radiating into their groin 1 radiating across the front of pelvic region 1 did not state where pain radiated				
Pain Worse:				n (%)			
Prolonged standing				19 (79.2%)			
Prolonged sitting				20 (83.3%			
Turning over in bed				20 (83.3%)			
Got worse as the day progressed				20 (83.3%)			
Provocation Testing (for Pain):				Yes n (%)			
P4 Left				8 (33.3%)			
P4 Right				7 (29.2%)			
Pubic symphysis palpation				12 (50%)			
Modified Trendelenburg Left				11 (45.8%)			
Modified Trendelenburg Right				12 (50%)			
				Positive n (%)	No pain but struggled to do the movement n (%)		Negative n (%)
Active Straight Leg Raise Left				9 (37.5%)	2 (8.3%)		13 (54.2%)
Active Straight Leg Raise Right				6 (25%)	3 (12.5%)		15 (62.5%)

[a]Participants could pick more than one type of pain.
SD = standard deviation.

with five (62.5%) experiencing pain that radiated down their leg.

The provocation testing presented no singular pattern of provocation. Two participants did not have their pain replicated with any of the provocation tests (8.3%). Four participants (16.7%) had their pain provoked by one test only (one with The Posterior Pelvic Pain Provocation test (P4), one with palpation of the pubic symphysis, and two with the Modified Trendelenburg test). The rest of the participants' pain was provoked in more than one test (n=18; 75%). There was no pattern of grouping of provocation tests for those who had pain provoked in multiple tests.

Recruitment and Retention

Recruitment

Participants were recruited from a Mum's social media group, from a private midwife, and by word-of-mouth from study participants. The recruitment rate was 78.1% (see Figure 1).

Retention Rates

Prior to receiving treatment, there was a 4% loss between signing up and receiving treatment (see Figure 1). During the study, the dropout rate for those receiving treatment was 20.8% (see Figure 1).

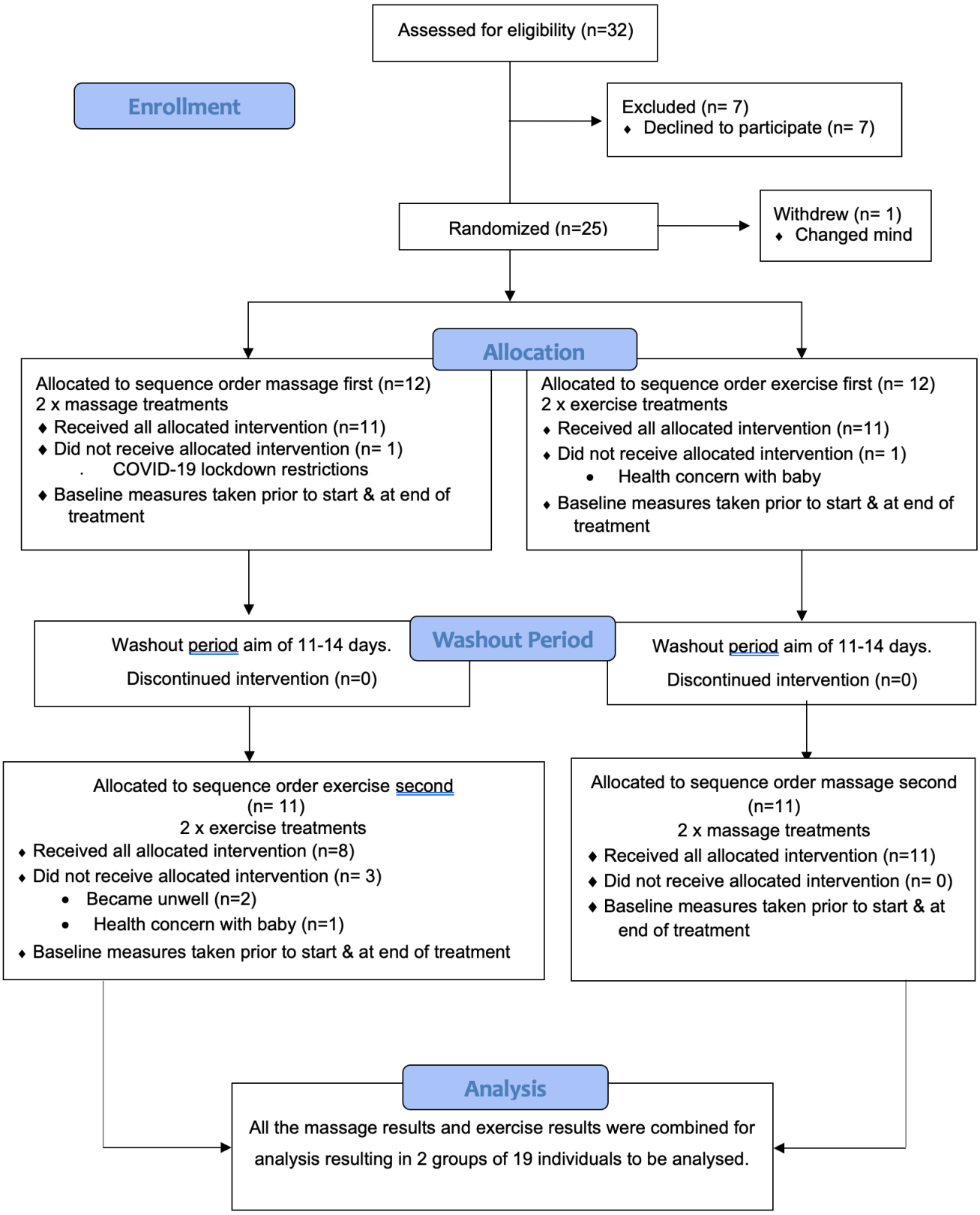

Figure 1. CONSORT flow diagram.

Study Design

Study Treatment Times

The initial plan was for treatments to be 7 to 11 days apart, with a washout period of 11 to 14 days. This did not occur consistently due to several factors including illness of participant or their family members (COVID-19, "gastro", flu and other respiratory infections including the common cold), isolation requirements, coordinating appointments with other appointments, work, and childcare.

The mean number of days between the first and second appointment was 11.9 days (SD 7.5), the mean washout period between treatment interventions was 12.3 days (SD 5.9), and the mean number of days between the third and the fourth treatment was 10.6 days (SD 6.7). The massage appointments were a mean of 12.8 days apart (SD 8.2) and the exercise sessions were a mean of 10.2 days apart (SD 6.1). There was no statistically significant difference between the number of days between treatments for the massage and exercise treatments (p=.14)

Crossover Study Design Methodology

There were no period effects (where participants do better in one period due to circumstances independent of treatment) for any of the validated questionnaire measures.

An analysis for carryover effects (where participants do better in a latter period because their state has changed due to the first treatment) was not undertaken due to the heterogeneity of the washout period (range of 4 days to 28 days) which could lead to misleading and inaccurate results for future research studies. However, carryover did occur for one study participant who experienced a total reduction in pain after the first intervention (massage).

Validated Questionnaires

Pain—Pre and Post Each Treatment

Exercise participants had a statistically significant mean reduction in pain of 1.0 in their first exercise session (p< .001) and 0.8 in their second session (p=.011) (see Table 3). Massage participants had a statistically significant mean reduction in pain of 2.2 in their first massage session (p< .001) and 2.1 in their second session (p< .001). The exercise group experienced a large and medium effect size and the massage group large effect sizes (see Table 3).

Pain—Baseline to Post-Intervention Scores

Both interventions had a small reduction in pain from baseline to post intervention (-.65 exercise and -.9 massage). The massage group's reduction in pain was statistically significant (p=.012), but the reduction of pain in the exercise group failed to reach significance (p=.153) (see Table 4).

TABLE 3. Pain Intensity Changes Within Individual Treatments

	Pain Perception Via a Pain Intensity-Numeric Rating Scale (PINR)[a] *Within Treatment*					
	mean (SD)			*t value*	*p*	*Effect Size (Cohen's d)*[b]
	Pre-treatment	*Post- treatment*	*Pre- to post-treatment change*			
Exercise Treatment 1 n=22	3.9 (2.2)	2.8 (1.5)	-1.0 (1.1)	4.563	<.001[c]	Large (0.996)
Exercise Treatment 2 n=19	4.4 (2.3)	3.6 (2.1)	-0.8 (1.2)	2.878	.011[c]	Medium (0.698)
Massage Treatment 1 n=23	4.9 (2.1)	2.7 (1.9)	-2.2 (1.1)	9.274	< .001[c]	Large (1.934)
Massage Treatment 2 n=22	4.5 (2.7)	2.4 (1.9)	-2.1 (1.4)	7.105	< .001c	Large (1.515)

[a]Values from 0-10. A higher score equates to greater pain.
[b]Cohen's effect size: small (d = 0.2), medium (d = 0.5), large (d = 0.8).
[c]Statistically significant at p < .05.

TABLE 4. Pre- to Post-Study Intervention Outcomes

Pre- and Post-Intervention Outcomes					
	mean (SD)			*t value*	*p*
	Baseline	*Post Final Intervention*	*Pre-Post Intervention Change*		
Pain perception via a Pain Intensity-Numeric Rating Scale (PINR)[a] Massage n=20 Exercise n=20					
Exercise	4.6 (2.4)	3.9 (2.2)	-0.65 (2.0)	1.488	.153
Massage	4.7 (1.8)	3.8 (2.1)	-0.9 (1.5)	2.871	.012[b] (effect size medium (.622))
Pelvic Girdle Questionnaire–Activity Subscale[c] Massage n=21, exercise n=20					
Exercise	43.4 (17.9)	44.7 (22.0)	1.2 (11.8)	-.467	.646
Massage	49.5 (20.4)	47.3 (24.6)	-2.1 (14.2)	.682	.503
Pelvic Girdle Questionnaire–Symptoms Subscale[c]					
Exercise	49.1 (14.9)	47.4 (22.0)	-1.6 (11.8)	.709	.488
Massage	51.7 (19.7)	50.2 (18.6)	-1.6 (17.9)	.408	688
Pelvic Girdle Questionnaire–Total[c]					
Exercise	44.8 (16.9)	45.7 (21.2)	0.8 (10.6)	-.337	.740
Massage	50.3 (19.8)	48.2 (23.0)	-2.1 (14.3)	.660	.517
Quality of life via The Short Form Health Survey (SF-36)[d] Massage n=20, exercise n=20					
SF-36 Physical functioning subscale[d]					
Exercise	51.1 (25.5)	49.2 (27.2)	-2.9 (9.9)	1.000	.330
Massage	45.7 (27.5)	46.8 (27.4)	1.4 (16.5)	-.266	793
SF-36 Role limitations due to physical health subscale[d]					
Exercise	76.3 (32.9)	77.5 (37.1)	1.2 (26.4)	-.213	.834
Massage	76.2 (33.9)	77.5 (31.9)	1.3 (33.5)	-.165	.871
SF-36 Role limitations due to emotional problems subscale[d]					
Exercise	76.7 (36.0)	71.7 (44.9)	-5.0 (33.8)	.679	.505
Massage	70.0 (41.7)	73.3 (37.4)	3.3 (27.7)	-.525	.606
SF-36 Pain subscale[d]					
Exercise	49.2 (18.7)	50.1 (22.7)	0.9 (17.5)	-.220	.828
Massage	41.5 (19.2)	49.8 (19.1)	8.9 (17.1)	-2.139	.046[b]
SF-36 Energy/fatigue subscale[d]					
Exercise	37.8 (18.0)	40.3 (21.1)	2.5 (9.5)	-1.209	.242
Massage	36.3 (19.7)	38.8 (17.1)	2.5 (11.7)	-.934	.362
SF- Emotional well-being subscale[d]					
Exercise	73.6 (11.7)	74.0 (12.0)	0.4 (9.1)	-.197	.846
Massage	71.0 (18.9)	75.4 (10.4)	4.4 (11.5)	-1.718	.102
SF-36 Social functioning subscale[d]					
Exercise	74.4 (20.9)	73.7 (22.9)	-0.7 (14.1)	.175	.863
Massage	69.4 (26.1)	71.9 (21.4)	2.5 (25.3)	-.535	.599
SF-36 General Health subscale[d]					
Exercise	63.0 (15.6)	63.7 (18.9)	0.7 (9.8)	.348	.732
Massage	62.8 (21.5)	62.3 (20.9)	-0.5 (6.6)	.335	.741
SF-36 Health change subscale[d]					
Exercise	43.8 (19.7)	40.3 (26.5)	-3.5 (15.1)	1.028	.317
Massage	37.5 (27.4)	40.0 (27.4)	2.5 (12.8)	-.623	.541

[a]Values from 0–10; a higher score equates to greater pain.
[b]Statistically significant at $p < .05$.
[c]A higher score indicates greater disability
[d]A high score defines a more favourable health state.

Pelvic Girdle Questionnaire (PGQ)

The massage group had reductions across all areas of the PGQ with a 2.1% reduction in the activity subscale, 1.6% in the symptom subscale, and 2.1% reduction in the total score, but these failed to reach significance (see Table 4).

The exercise group had a reduction in the symptoms subscale (1.6% reduction), and increases in the activity subscale (1.2% increase) and the total score (0.8% increase), but these failed to reach significance (see Table 4).

Health-Related Quality Of Life (SF-36)

There were no statistically significant differences for any quality-of-life domains of the SF-36 from baseline to post-intervention for the exercise intervention (see Table 4). The massage intervention group experienced an average statistically significant increase in quality of life for the pain domain (8.9 increase; p=.046). No other changes for the quality-of-life domain of the SF-36 were statistically significant for the massage group.

Patient Satisfaction Questionnaire Short-Form (PSQ-18)

Patient satisfaction scored above 4 (out of 5) for five of the seven domains (not financial aspect nor accessibility and convenience) for both interventions (see Table 5). General satisfaction was the only domain that differed significantly between the exercise and massage intervention (p=.007).

Participant Subgroup Analysis

Number of Sites of Pain

There was no statically significant difference in changes in PINR pain pre- and post-treatment for either intervention comparing participants who had 1–2 sites of pain to those who had three or more sites of pain (p>.05).

Lumbar Pain

Eleven participants self-reported lumbar pain as well as PPGP (55%). There was no statically significant difference in changes in PINR pain pre- and post-treatment for either intervention comparing participants who had lumbar pain and PPGP to those with PPGP and no lumbar pain (p>.05).

Positive Pain Reproduction Testing

The heterogeneity of positive pain reproduction testing did not allow for sub-group analysis.

Acceptability of the Outcome Measures

The majority of participants felt the study questionnaires captured the symptoms and impact that PPGP had on them physically (n=16; 88.9%), emotionally (both n=16; 88.9%), and psychologically (n=15; 83.3%). Those who didn't feel the study questionnaire captured the symptoms and impact of their PPGP felt that the questionnaires weren't specific enough to pregnancy, and that they did not differentiate the impact of pregnancy and PPGP on health;

TABLE 5. Patient Satisfaction Outcomes Between Group Analysis

Patient Satisfaction Questionnaire Short-Form (PSQ-18)[a]				
	Exercise n=20	*Massage n=21*	*t value*	*Between Groups Analysis*
	mean (SD)			p
General satisfaction	4.3 (0.4)	4.7 (0.4)	-2.66	.012[b]
Technical quality	4.5 (0.3)	4.4 (0.4)	.327	.746
Interpersonal manner	4.8 (0.3)	4.6 (0.6)	1.63	.113
Communication	4.6 (0.3)	4.6 (0.4)	.375	.710
Financial aspects	3.6 (0.6)	3.5 (0.7)	.585	.562
Time spent with therapist	4.6 (0.6)	4.4 (0.6)	.697	.490
Accessibility and convenience	3.9 (0.5)	4.0 (0.6)	-.884	.382

[a]A higher score reflects greater satisfaction with a score from 0 to 5.
[b]Statistically significant at $p < .05$

in particular, that the questions did not "take into consideration other factors that may influence this such as having been diagnosed with depression or anxiety" (PPGP13). They also didn't feel the study questionnaire captured what support/s they were accessing or seeking.

Benefits and Likes/Dislikes

Participants felt that both treatments targeted the areas they felt were important in their PPGP (n=18; 100%). The perceived benefits and aspects of the study that participants liked was the sense of agency developed during the study, with participants valuing learning a resource they could use "during the week to lessen pain" (PPGP01). The exercise intervention specifically provided participants with "a baseline to discover what I could and couldn't do at that stage of pregnancy" (PPGP10). The educative and informative aspect of the study allowed participants to be more aware of how to manage PPGP including understanding and "learning more about pelvis pain and how things in that area are connected" (PPGP21), as well as understanding "different potential treatment options available" (PPGP6). Some participants felt the study exceed their expectations as they were not "expecting to learn as much as I did and also skills I can use at home" (PPGP21).

A reduction in pain and management of symptoms was valued with respondents perceiving that both interventions lessened their pain; however, massage was often singled out when discussing pain such as participant 10 who felt "the massage treatment helped manage my symptoms and pain".

Study participants reflected that the study reinforced or engendered the premise that PPGP is a condition worthy of care and treatment, and participants felt the study "provided care for my pelvic girdle pain, … and provided options that were good to investigate for my pain" (PPGP06).

The aspect of the study that the participants disliked was the paperwork, some post-exercise and massage soreness, the length of time between the treatments, and not being able to complete the study (COVID-19 related).

The Study Experience and the Therapist

Participants felt that the therapist provided them with reassurance, was sensitive, and made them feel secure (n=18; 100%). Respondents also indicated the things they liked about the study process was that it was "very easy to participate and attend and questionnaires weren't too long" (PPGP04), and the study was "informative and well researched" (PPGP05).

DISCUSSION

Our study found that the study design was feasible in many areas including capacity to recruit, and satisfaction with the interventions and retention rates, especially given the COVID-19 environment. Outcomes measures generally captured the important aspects of PPGP on individuals physically, but some participants felt that their mental health and capacity to cope with PPGP were not covered in the outcome measures. Research shows that a belief in improvement is a strong predictor for improvement in PPGP[28] and personality traits predict persistent PPGP.[29] Outcome measures that capture self-agency and or beliefs would be useful in future studies.

A crossover study design is not recommended for future studies. This is due to a number of factors including that the crossover study design is not suitable for conditions where a remission of all PPGP symptoms can occur, and when the time between treatments and the washout periods varies considerably. A mixed methods study might better capture the impact of massage and or exercise treatment on PPGP, and allow for a deeper qualitative insight into the impact of the interventions. Mixed methods studies combine qualitative and quantitative methods and this study design is 'becoming recognized for the potential to investigate complex questions".[30] "This type of design combines the best parts of a RCT along with qualitative design, … to enhance the data collected and, subsequently, the results".[30]

Our study found that both massage and exercise were significantly helpful in reducing pain after each treatment. Participants receiving the massage had significantly improved pain in the health-related quality of life measure and reduced pain intensity as per the pain intensity numerical rating scale. Minimum important change (MIC) for pain scores are important and research on pregnancy-related low back and pelvic girdle pain assessed during an

eight-week time period during pregnancy was 1.3; however, this population all had pregnancy-related lower back pain and some individuals did not have PPGP.[31] The authors could find no research indicating the MIC for PPGP during pregnancy with which to compare our study findings. Pain reduction was higher pre- to post-treatment and was not maintained from intervention beginning to end. Pain may be influenced by an inability for participants to avoid movements or actions that potentially aggravated their PPGP, such as picking up infant children, and this may be a factor in why pain reduction was not maintained post-intervention. Fear avoidance measures and previous experiences of PPGP may impact participants' levels of pain and capacity to tolerate pain, which may lead to differences in perception of pain for participants who were multiparous.[32]

There were no significant changes in the PGQ scales. Despite the lack of significance in PGQ scores, participants were satisfied with the treatments and felt that the treatments were beneficial. It may be that the massage and exercise interventions provide benefit in only a small section of the areas covered by the PGQ, such as pain, which do not translate into changes in function.

Both the massage and the exercise groups scored high in terms of satisfaction. The two areas that participants were less satisfied with were accessibility and financial aspects, which may reflect the research nature of the study with participants not paying for their study treatments and the set number of treatments in the study. There was a significant difference in the general satisfaction domain for the massage and exercise interventions, and participants expressed that they viewed massage as more of a 'treatment' and that exercise was a 'skill' that was acquired. The massage treatment was more passive (participants did not have to do anything) compared to the exercise treatment which required the participants to actively participate (they had to 'do' the intervention to obtain the treatment effects). Additionally, the massage may have been perceived to specifically address the areas where they experienced pain compared to the exercise treatment which may have influenced satisfaction. While all participants were able to receive all interventions, no participants received a skill (exercise) and a 'treatment' (massage) at the same time. Having an intervention in future studies where participants received both massage and exercises within the same treatment may be warranted.

Recommendations for Future Research

The willingness of health-care professionals to refer clients to the study and of participants to contribute towards generating an evidence base for PPGP and massage therapy indicates that future studies would be well-supported by health-care providers and individuals with PPGP. Future research should not use a crossover study design and, instead, could incorporate a mixed methods study design to measure the effect of massage on PPGP. The addition of a massage and exercise arm should be considered. The addition of self-agency and coping outcome measures should be considered in future studies. It is not within the scope of massage therapists to provide the physiotherapist designed exercise treatments in this study to pregnant women. Future studies could choose interventions that massage therapists can provide and thus only include exercises or suggestions within the scope of the massage therapists' practice.

Limitations

The health-related quality of life (SF-36) is not specific to pregnancy and this limits the questionnaire's capacity to capture specific pregnancy-related quality of life concerns. Participants enrolled in the study during the uncertainly of the COVID-19 pandemic and in between the numerous lockdown measures that took place; therefore, their experience of PPGP and pregnancy may have been influenced by this unusual time. A well-recognised limitation for massage therapy RCT research study designs is the inability to blind participants and therapists;[30] thus the research results reflect any biases participants had about the interventions.

CONCLUSION

This study shows that recruiting participants for a PPGP study involving massage and exercise is indeed feasible. The crossover study design is not appropriate for conditions that have the capacity to resolve fully, and a different study methodology

should be considered, such as a mixed methods study design. The results from this study support the call for larger randomised clinical trials to measure the effects of massage therapy on PPGP.

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CONFLICT OF INTEREST NOTIFICATION

SF is a practicing massage therapist and business owner. KV is a practising physiotherapist and a business owner. CM is the owner of Pregnancy Massage Australia who funded the study. CM was not involved in the study design, implementation of the study nor the data analysis. The other authors declare no conflict of interest.

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APPENDIX 1.

Treatment intervention protocols (Consultation includes documenting site of pain, type of pain, radiation of pain, aggravating activities (5 min approximately). A: Massage pelvic girdle pain remedial massage routine (approx. 53 minutes); B: Physiotherapist designed exercise routine (approx. 50-53 minutes).

A.

Treatment (repeat on each side)

Core Treatment (everyone will get these areas treated)

Time Total: 19 minutes

Gluteals/Buttocks/Hips

Position	*Sidelying*
Warm up: (approx. 2 min)	Gluteal area approx. 2 minutes. The techniques used will include petrissage, effleurage and longitudinal gliding.
Main work: (15 min)	Involving treating muscle thickening around the gluteal region including taut fibrous bands within muscles and general muscle tightness, deactivating active trigger points with myofascial release [33]. Including piriformis, gluteus maximus, medius and minimus, quadratus femoris, superior and inferior gemellus, obturator internus. All have: • Release of sacrotuberous and sacropsinous ligament • Cluneal nerve release • Release of the muscles at the Greater Trochanter Techniques: Transverse gliding, kneading, friction, sustained longitudinal pressure on taut bands and myofascial release. Cross friction strokes from PSIS to ischial tuberosity and then fanning out up the gluts towards the ASIS.

Treatment Depending on Results of Testing
(If more than one area then pick one or two from each section for a maximum of four)

Lumbar pain as well as PPGP	*P4 and or ASLR test positive*	*Modified Trendelenburg positive*	*Pubic symphysis test positive*	*Piriformis palpation positive*
Massage to Lx/Tx (see below) • Sacral lumbar stretch • Myofascial stretch of Quadratus Lumborum • Release of LX Fascia/ Release Gluteus Max	• Sacral lumbar stretch • Myofascial sacroiliac joint stretch	• Contract-Relax and reciprocal inhibition piriformis • Obturator Internus Release	• Adductor massage • Release Round Ligament • Contract Relax Reciprocal Inhibition Piriformis	• Piriformis release • Piriformis release using a myofascial stretch • Sciatic nerve release

Finishing strokes: (approx. 2 min)	Gluteal area approx. 2 minutes. The techniques used will include petrissage, effleurage and longitudinal gliding.

Only if Lumbar Pain as Well as PPGP

Low Back (Lx and Tx)	Warm up: Lx/Tx area approx. 2 minutes. The techniques used will include petrissage, vibration and effleurage. Main work: Involving treating muscle thickening around the lumbar region including taut fibrous bands within muscles and general muscle tightness, deactivating active trigger points with myofascial release. Involving lumbar multifius and longissimus muscles, intertransverserii and quadratus lumborum. Time on thoracolumbar fascia. Techniques: Transverse gliding, kneading, friction, sustained longitudinal pressure on taut bands and myofascial release.

B.

	Exercises
Exercise 1	Transverse abdominus activation. Hold for 10 seconds, whilst breathing. Release and rest for 5 seconds Repeat 10 times.
Position	Standing
Exercise 2	Swiss Ball Wall Squats 10 reps x 3 sets
Position	Standing leaning against Swiss ball.
Exercise 3	Static gluteal activation. Squeeze buttocks together and hold for 3 seconds. Release fully and rest for 3 seconds. Repeat 10 times.
Position	Seated on chair
Exercise 4	Pelvic Circles/Rotations Perform 10 circles in each direction.
Position	Four Point Kneeling. Begin in neutral spine.
Exercise 5	The Cat Repeat slowly 10 times.
Position	Four Point Kneeling
Exercise 6	Childs Pose Hold for 30 seconds. Rest by rising back up into 4 point kneeling. Repeat 3 times.
Position	Four Point Kneeling
Exercise 7	Adductor stretch Hold for 30 seconds. Release and rest for 10 seconds. Repeat 3 times.
Position	Seated on floor with both legs outstretched and abducted as far as is comfortable.
Exercise 8	Piriformis stretch Hold for 30 seconds, then perform on opposite side. Repeat 3 times on each leg
Position	Reclined/supported supine or seated depending on provocation results
Exercise 9	Belly breathing 1-2 minutes
Position	Either supported/reclined supine or side/lying at patient's preference for comfort.