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Evaluation of an Orthotic Intervention for the Management of Pregnancy Related Pelvic Girdle Pain (PGP)

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Evaluation of an Orthotic Intervention for the Management of Pregnancy Related Pelvic Girdle Pain (PGP)

by

LEE CAMERON

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Author's Signed Declaration

At no time during the registration for the degree of Doctor of Philosophy has the author been registered for any other University award without prior agreement of the Doctoral College Quality Sub-Committee. Work submitted for this research degree at the University of Plymouth has not formed part of any other degree either at the University of Plymouth or at another establishment. This trial was financed with the aid of a grant from the European Social Fund in collaboration with the Cornwall Combined Colleges and a grant from the Chartered Society of Physiotherapy Charitable Trust, and supported by the School of Health Professions, University of Plymouth. A programme of advanced study was undertaken, which included methodological and speciality specific training.

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Date…….

Abstract

Name: Lee Cameron

Title: Evaluation of an orthotic intervention for the management of pregnancy related pelvic girdle pain (PGP)

The overall aim of the thesis was to evaluate the effectiveness of a novel orthotic intervention, a customised Dynamic Elastomeric Fabric Orthosis (DEFO), in the management of both antenatal and post-partum pelvic girdle pain (PGP). In the first instance the fabric, from which the DEFO was constructed, underwent testing to determine if the different colour fabrics available possessed the same underlying fabric stiffness and elastic hysteresis to ensure that each orthotic was standardised. Laboratory testing identified significant differences in both fabric stiffness and elastic hysteresis, between colours. The findings of this study enabled standardisation of the intervention by using a single coloured customised DEFO (Black), ensuring rigor of the planned evaluation studies.

A randomised controlled trial, with participants experiencing antenatal PGP, was then completed assessing the effectiveness of the novel customised DEFO in comparison to a standard issue pelvic belt (Serola Belt). It found that there was both a statistically ($p<.05$) and clinically significant (one point minimal clinically important difference (MCID)) change in favour of the DEFO in reducing both day and night pain as measured by the numerical pain rating scale (NPRS).

Following impromptu discussions with participants experiencing long-standing PGP, and a further review of the literature, it was evident that this was an under-researched area. A single case study series was therefore undertaken to explore the potential effectiveness of the customised DEFO in reducing pain and improving function and quality of life in women with chronic (> 3months) PGP. The single case study series also afforded an opportunity to identify potential outcome measures that could be used if a larger trial was considered in the future. This single case study series suggests that a customized DEFO could potentially reduce pain, increase health related quality of life, improve mood and increase activity levels for persons suffering from chronic post-partum PGP, thereby hopefully identifying a possible new treatment option for managing this condition. The results of this single case study series provides the basis for a larger clinical trial.

Conclusion

This thesis has provided an evaluation of orthotic intervention for pregnancy related PGP. The results have shown that orthotic intervention in antenatal PGP can provide an improvement in PGP related symptoms such as pain and function. This research has helped to fill a knowledge gap and provided current evidence to move towards improved clinical care. Furthermore, this thesis has provided a more in-depth awareness into chronic post-partum PGP and the magnitude of improvement that may be associated with the customized DEFO. The results of this single case study series provides the basis for a larger clinical trial.

List of Peer Reviewed Publications

Cameron, L., Marsden, J., Watkins, K. and Freeman, J. (2018). 'Management of Antenatal Pelvic Girdle Pain Study (MAPS): A Double Blinded, Randomised Trial Evaluating the Effectiveness of Two Pelvic Orthoses.' *International Journal of Women's Health Care,* 3(2), pp. 1–9.

List of Conferences and Presentations

Chartered Society of Physiotherapists (CSP) national conference, Liverpool. (2014). *Management of Antenatal pelvic girdle pain Study: A Double Blinded, Randomised Trial Evaluating the Effectiveness of Two Pelvic Orthoses.* Platform Presentation and Poster Presentation.

International Society or Prosthetics & Orthotics (ISPO) international conference, Lyon. (2015). *Management of Antenatal pelvic girdle pain Study: A Double Blinded, Randomised Trial Evaluating the Effectiveness of Two Pelvic Orthoses.* Platform Presentation.

European Social Fund (ESF) local conference, Falmouth, UK. (2015). *Management of Antenatal pelvic girdle pain Study: A Double Blinded, Randomised Trial Evaluating the Effectiveness of Two Pelvic Orthoses*. Platform Presentation.

Institute of Health and Community local Conference, Plymouth, UK. (2015). *Management of Antenatal pelvic girdle pain Study: A Double Blinded, Randomised Trial Evaluating the Effectiveness of Two Pelvic Orthoses.* Platform Presentation. (Presentation Prize Winner)

Chartered Society of Physiotherapy (CSP), Birmingham, UK. (2017). *Management of post-partum pelvic girdle pain: A Replicated Case Series of Single Case Studies Evaluating the Effectiveness of a Customised Dynamic elastomeric Fabric Orthoses (DEFO)*. Poster Presentation.

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Abbreviations

ASIS	Anterior Superior Iliac Spine
ASLR	Active SLR
CASP	Critical Appraisal Skills Programme
CEA	Cost Effectiveness Analysis
CI	Confidence Interval
CSP	Chartered Society of Physiotherapy
DEFO	Dynamic Elastomeric Fabric Orthosis
EMG	Electromyography
ESF	European Social Fund
EQ5D	European Quality of Life 5 Dimension
FABERs	Flexion Abduction External Rotation Test
HADS	Hospital Anxiety and Depression Scale (HADS)
ICIQ	International Consultation on Incontinence Questionnaire
ISPO	International Society of Prosthetics and Orthotics
LBP	Low Back Pain
MCD	Minimum Amount of Change
MCID	Minimal Clinically Important Difference
N	Newtons
NICE	National Institute for Health Excellence
NPRS	Numerical Pain Rating Scale
P4	Posterior Pelvic Provocation Test
PEDro	Physiotherapy Evidence Database
PGP	Pelvic Girdle Pain
PGQ	Pelvic Girdle Questionnaire

PSIS	Posterior Superior Iliac Spine
RCT	Randomised Control trial
SD	Standard Deviation
SF36	Short Form 36 Item Questionnaire (Version 2)
SIJ	Sacro-iliac Joint
SP	Symphysis Pubis
TrA	Transverse Abdominus
UI	Urinary Incontinence
UK	United Kingdom

Chapter One:

Literature Review

1.1 Introduction

The purpose of this chapter is to provide a rationale for the work undertaken in this thesis. This chapter will introduce and critically appraise the current literature on pelvic girdle pain, discussing a range of issues pertaining to definitions, prevalence, aetiology, mechanical stresses, risk factors and orthotic strategies. More specifically, the aim of the literature review is to describe and critically appraise published research undertaken to investigate the effectiveness of pelvic orthotic interventions in women suffering from PGP.

Pelvic Girdle Pain (PGP) is commonly experienced by women during pregnancy (Ho et al., 2009). It is, however, difficult to manage (Vleeming et al., 2008). It has a significant impact on the ability of individuals to undertake everyday activities such as turning in bed, prolonged walking, or carrying items; impacting negatively on quality of life and emotional status (Wang et al., 2004). In economic terms, societal costs are significant mainly as a consequence of work absenteeism (Vermani et al., 2010); with 20% of women with PGP requiring an average of seven weeks sick leave (Bergstrom et al., 2015; Malmqvist et al., 2018; Norén et al., 1997). There are high direct health costs as well as increased health risks associated with care as women with PGP have a higher request for induction of labour and elective caesarean section to achieve symptomatic relief (Gholitabar et al., 2011; Norén et al., 1997; Vermani et al., 2010). The magnitude of this problem is substantial with 679,106 deliveries occurring throughout the United Kingdom (UK) in 2017/18, of which 5162 were in Cornwall and the Isles of Scilly (www.ons.org.uk), which is the geographical region in which the studies were undertaken for this dissertation.

1.2 Defining Pelvic Girdle Pain (PGP)

PGP has been defined by the European Guidelines for the diagnosis and treatment of PGP as: *"Pain experienced between the posterior iliac crest and the gluteal fold, particularly in the vicinity of the sacroiliac joints (SIJ). The pain may radiate in the posterior thigh and can also occur in conjunction with/or separately in the symphysis"* (Vleeming et al., 2008). This now appears to be the most widely accepted terminology to describe PGP both within the clinical and research arena. This attempt by the European Guidelines (2008) to standardise terminology and to make a clear distinction between PGP and low back pain has, however, not always been recognised. For instance, in 2016 the World Health Organisation released information called 'Antenatal care for a positive pregnancy' (WHO, 2016), which did not consider the classification of PGP as a separate condition to low back pain (LBP). It is perhaps unsurprising therefore, that PGP remains under classified, and that it has proven challenging to accurately understand the scale of this condition during pregnancy.

1.3 Prevalence

There is a large disparity in the quoted prevalence of pregnancy related PGP, with ranges from 4% to 76.4% (Albert et al., 2001; Gutke et al., 2015; Ho et al., 2009; Kanakaris et al., 2011; Mogren et al., 2005; Ostgaard et al., 1991; Vleeming et al., 2008; Wang et al., 2004; Wu et al., 2004). Within this large variation, it is reported that of all women with pregnancy related PGP, 45% present with mild PGP symptoms, 30% moderate PGP symptoms and 25% with severe PGP symptoms (Ho et al., 2009). Symptoms can range from difficulties with activities such as walking or stair climbing, to use of walking aids, use of a wheelchair or confinement to bed (Wu et al., 2004).

The large disparity in prevalence of PGP is believed to be a result of the variable definitions used to encompass PGP, such as symphysis pubis dysfunction, sacroiliac joint dysfunction, and other non-pregnancy related pelvic pain (Kanakaris et al., 2011). PGP has historically also been classified under the umbrella term lumbopelvic pain (lumbar spine pain and pelvic pain). The interchangeable terminology and lack of uniformity has led to research being undertaken using these umbrella terms as opposed to PGP as a separate condition, with different classifications and diagnostic criteria although they are being considered as the same condition (Bertuit et al., 2018a). This has led to challenges in accurately understanding the scale of pregnancy related PGP as a separate condition, in comparison to LBP. The European Guidelines (2008) emphasised that it was imperative to accurately classify PGP to aid future research and improve diagnosis, management and treatment (Vleeming et al., 2008).

1.4 Anatomy and Physiology of PGP

The pelvis is made up of the ilium and sacrum. It has three joints, the symphysis pubis (SP) at the anterior section of the pelvis where the ilium meets and bilateral sacroiliac joints (SIJ), which are located at the posterior section of the pelvis where the ilium meets the sacrum (Figure 1.1). Pain from a musculoskeletal origin is commonly experienced in either the symphysis pubis and/or sacroiliac joints.

The congruent state of the articular surface and cartilage of the SIJ increases friction through the joint, which in turn offers high friction coefficient that contributes to the stability of the SIJ. This is referred to as 'form closure' (Vleeming and Scheunke., 2019). During load, daily activities or ambulation the pelvis is under vertical load that cause the sacrum to nutate (tip forward) and counter-nutate (tip backwards). This can

lead to a reduction of stiffness of the pelvic joints, and rely on lateral forces of the ligamentous, muscular and fascial structures to give adequate friction causing compression to the pelvic joints, leading to increase stability (Vleeming et al., 2008). This is referred to as 'force closure' (Vleeming and Scheunke., 2019). The implications of suboptimal form and force closure is described in more detail in section 1.6. In brief, it is postulated that pregnancy related PGP is musculoskeletal in its origin (Vleeming et al., 2008), arising as a result of pelvic instability, with a subsequent increase in shear forces through both the symphysis pubis and the sacroiliac joints. These shearing forces can apply excessive loading to tendons, ligament and the synovial membrane of the articular surface. It is suggested that this can lead to an inflammatory process leading to a nociceptive meditated response, which may be described as a stabbing, dull, shooting, or burning sensation (Aldabe et al., 2012).

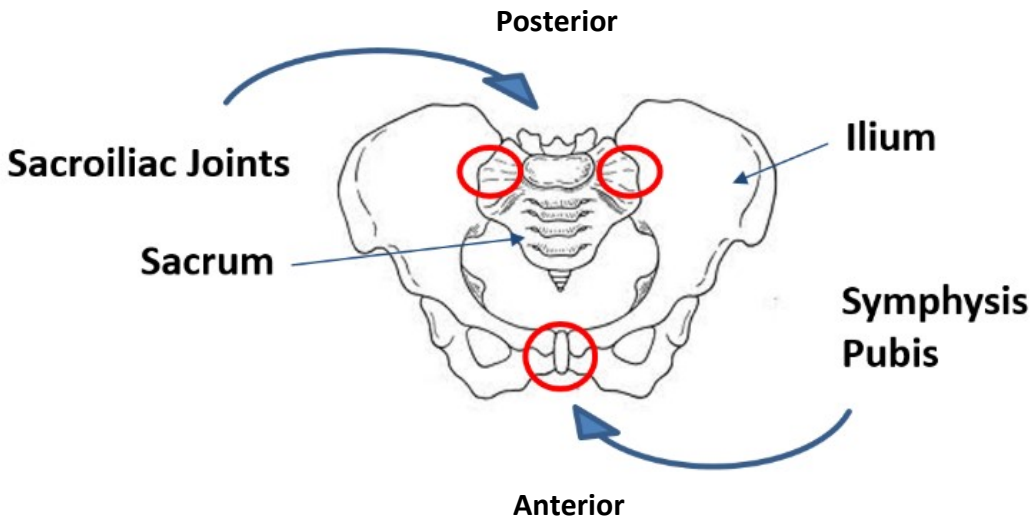


Figure 1.1 The pelvic anatomy, along with location of the symphysis pubis (Anterior red ring) and sacroiliac joints (Posterior two red rings).

1.5 Potential causes of pregnancy related PGP

The patho-physiological mechanisms which lead to PGP in pregnant women are still unclear (Vermani et al., 2010; Versraete et al., 2013; Vleeming et al., 2008). It was previously thought that hormonal changes and metabolic changes can lead to musculoskeletal dysfunctions for women during pregnancy (Blackburn et al., 2007; Descherney et al., 2007). The hormone relaxin has historically been considered the potential cause of increased laxity in pelvic ligaments, leading to an increase in shear forces in both the anterior and posterior pelvis (Aldabe et al., 2012). More recently, however, this view has been questioned, with many highlighting the anomaly which exists with this argument given that PGP presents more frequently in the 2nd and third trimester, whereas relaxin is at its highest level in the first trimester (Aldabe et al., 2012). Furthermore, studies demonstrate that an increase in relaxin does not significantly correlate with PGP during pregnancy (Bjorklund et al., 2000; Peterson et al., 1994). It is believed that pregnancy hormones can indirectly lead to pain and discomfort, but it has been postulated that this is due to their interaction with biomechanical stresses, which may be treatable with musculoskeletal physiotherapy (Aldabe et al., 2012).

1.6 Mechanical Causes of Pregnancy related PGP

Both Lee and Vleeming (1998) propose that the anatomical structures of the SIJ (form closure) are required to optimise stability through the pelvis. The anatomical position of the joint along with the ligamentous structures are said to increase the friction coefficient through the SIJ (Pel et al., 2008). The surrounding musculature and fascia (force closure) surrounding the joints increase friction and lead to an increase in tension across the joints. The two further components for creating optimal stability are

neuromuscular control, and emotional/awareness (Lee and Vleeming, 1998). There are variable factors which may lead to sub-optimal pelvic joint stability.

It has been suggested that pelvic instability is the primary cause of PGP during pregnancy (Depledge et al., 2005). During pregnancy the related changes in posture and biomechanics can lead to altered pelvic stability (Branco et al., 2014; Foti et al., 2000; Liddle and Pennick, 2015). Biomechanical changes occur in the lumbar spine and pelvis during pregnancy, due to the need to adapt to a change in the centre of gravity as a result of the increasing weight of the uterus, resulting from the growth of the foetus (Liddle and Pennick, 2015). The increase in maternal weight is believed to play a role in the requirement for changing lumbar biomechanics, with increased lordotic adjustment in the lumbar spine required to maintain the centre of gravity (Branco et al., 2014; Foti et al., 2000). The reduced ability to undertake the natural 'self-locking' mechanism of the SIJ can lead to abnormal forces through the pelvis (Arumugum et al., 2012; Bertuit et al., 2018b). This reduced ability to transfer load through the pelvis (Mens et al., 2000) can lead to undue stress throughout the pelvic joints, leading to an increase in shear forces and subsequently pain (Damen et al., 2001). Research has shown that during pregnancy women can have altered symmetry in the SIJ (Damen et al., 2001). This could potentially prevent optimal joint stability leading to adverse stresses and load throughout the pelvis, due to reduced 'form closure'. This leads to impaired motor control believed to be, in part, a result of pain inhibition (Mens et al., 2017) or reduced ability to perform, due to posture and change in biomechanics (Aldabe et al., 2012; Mens et al., 2017). A study by Kalus (2008) identified a moderate correlation between poor muscle function at the beginning of pregnancy in women with severe PGP symptoms. Reduced force closure due to lack of transverse and

oblique activation has also been believed to lead to PGP (Hu et al., 2010), although studies undertaking training programmes specifically targeting these muscle groups did not find any significant improvement in symptoms (Mens et al., 2000). A study by Mens et al, (2017) went on to find that there is actually an excessive contraction in the transverse abdominus (TrA) of women suffering with PGP, when they undertook ultrasound imaging (using a RUSI, 2D mode) during an active straight leg raise (ASLR) test in comparison to healthy controls.

Many studies have observed the self-locking nature of the SIJs and the underlying joint surface 'roughness', which can aid an increase in friction alongside the self-locking ability (Pel et al., 2008; Soisson et al., 2015). It was believed that the release of reproductive and maternal hormones, in particular relaxin, could lead to connective tissue laxity but this hypothesis has now been rejected with recent research showing that there is a weak correlation between this hormone and the onset of PGP (Aldabe et al., 2012; Clinton et al., 2017).

1.7 Risk factors

A recent review concluded that there is moderate to strong evidence for a range of risk factors for pregnancy related PGP (Clinton et al., 2017). The risk factors identified were previous history of pregnancy (multiparity) alongside previous PGP/LBP, orthopaedic dysfunctions, increased body mass index (BMI), smoking, as well as work dissatisfaction and a lack of belief of improvement (Gutke et al., 2008; Kanakaris et al., 2013; Vermani et al., 2010; Vleeming et al., 2008). Other risk factors for pregnancy related PGP have also been suggested in the literature, which include: a maternal age of ≥30 years (Gutke et al., 2017) and mode of delivery such as

instrumental or caesarean section (Albert et al., 2001; Gutke et al., 2017; Vleeming et al., 2008; Vollestad et al., 2009; Wuytack et al., 2018).

1.8 Orthotic management

Pregnancy support devices have been used throughout many cultures, and since the 12th century in Asia (Carr et al., 2003). Within the context of this thesis, the term orthotics has been used to describe these "support devices", however it is acknowledged that this terminology is not commonly used within the research associated with pregnancy related PGP. Instead such devices have been variously described as 'maternity support binder', 'pelvic belt', 'pregnancy support', 'rigid or non-rigid belt', 'elastic or non-elastic support belt' (Ho et al., 2008). As a consequence, it was challenging to ensure that all pregnancy orthotics were included within this literature review. Terminology is also broad because of the large variation in design such as belts, brief, cradle and torso support (Ho et al., 2008), which can be rigid, non-rigid, elastic, non-elastic, and wide or narrow (Elden et al., 2005).

Maternity orthotics capture a considerable proportion of this discipline as reflected by the large number of recorded patents of belt designs in this area (Ho et al., 2008). Notably, they have also been used to treat a host of conditions other than pregnancy related PGP, including LBP, athletic groin pain, pelvic instability and chronic pelvic pain. Despite their growing presence within the market, current international guidelines do not recommend their use due to the lack of high-level evidence to support their use (Vleeming et al., 2008). However, guidance by the World Health Organisation (WHO, 2016) recommends pelvic belts for use in pregnancy related PGP, although it is notable that this was made on the basis of the results of a single research

study and so should be considered with some caution. The research evidence on which these recommendations were drawn was by Kalus et al. (2008), who undertook a RCT (n=115) consisting of two groups, one wearing a BellyBra support and one wearing tubigrip support which was identified as being an underpowered study. Although both groups reported a decrease in pain and increase in function, and there was a greater improvement seen in the BellyBra group, the difference between the two groups was not statistically significant (Kalus et al., 2008).

1.9 Critical Appraisal Tools

In line with good practice, a critical appraisal tool was used to evaluate the retrieved articles. Katrak et al's systematic review (2004), identified a wide range of critical appraisal tools that can be used to achieve this, with no single tool considered best able to inform allied health professionals. They recommended that, given the lack of such a 'gold standard', it was a requirement of the appraiser to choose the tool which they felt offered the best outcome for their review (Katrak et al., 2004).

1.9.1 *Physiotherapy Evidence Database (PEDro) Scale*

The Physiotherapy Evidence Database (PEDro) scale was developed in 1998 and was based on The Delphi List (Verhagen et al., 1998). It is an 11-item list to aid quick, critical appraisal of randomised control trials. To establish the generic core items of the PEDro scale, a group of experts in the field of quality assessment of RCTs participated in a Delphi study. Expert consensus was gained on nine of the 11 items listed.

The PEDro scale was developed to aid the quick assessment of internal validity (questions 2-9) and assist in gaining sufficient statistical information to make results

interpretable (questions 10-11). Question one, which is aimed at evaluating the external validity of an RCT, does not count towards the total PEDro scale score, which has a total score range of 0-10 points. One point is scored, when the criteria is met, for each of the remaining 10 questions. Studies that score ≥6 points are considered "moderate" to "high" quality. This cut off score of six points has therefore been used in this literature review. The PEDro scale has demonstrated to be a valid measure for assessing methodological quality of RCTs (Morton, 2009). It has also been shown to possess acceptable reliability, based on consensus judgements, of RCTs (Maher et al., 2003). The PEDro scale was also shown to be preferred over other critical appraisal tools for RCTs such as the Jarrad (Boghal et al., 2005).

1.9.2 *Critical Appraisal Skills Programme (CASP) Tool*

Studies which were not RCTs but were pertinent to include within this literature review were assessed using the Critical Appraisal Skills Programme checklist (CASP, (https://casp-uk.net/casp-tools-checklists/), thus allowing for studies such as cohort, case-control, and diagnostic studies to also be assessed in terms of their methodological quality.

1.10 Database search strategy

The literature review undertaken for this chapter employed a systematic approach to searching the following databases: CINHAHL (EBSCO), MEDLINE (OVID), Joanna Briggs Institute Library, PubMed, Web of Science, EMBASE (OVID), Cochrane Library, The Cochrane Central Register of Controlled Trials (CENTRAL), AMED (EBSCO), and PROSPERO.

The search was limited to articles from 1999- 2019, thereby covering a 20-year duration. This limit was made to ensure that the orthotic interventions evaluated were relevant to current practice as orthotic design has significantly evolved over the last 15-20 years. It was considered that a 20-year search criteria would be wide enough to include all available relevant studies. The literature search was further refined to only include quantitative research designs and English language papers.

To keep abreast of the most recent material available, a search of clinical trials registers via www.controlled-trials.com and http://clinicaltrials.gov was also undertaken to identify any current registered studies.

Search terms:

(“Pelvic pain” OR “pelvic girdle pain” OR “PGP” OR “lumbopelvic pain” OR “sacroiliac joint dysfunction” OR “symphysis pubis dysfunction” OR “anterior pelvic pain” OR “posterior pelvic pain”) AND (“pregnan*” OR “antenatal”) AND (“pelvic orth*” OR “pelvic support garment” OR “pelvic belt” OR “pelvic short*” OR “maternity support” OR “maternity belt” OR “Corset” OR pelvic corset” OR “lumbopelvic corset” OR “Maternity corset” OR “Dynamic Elastomeric fabric Orth*” OR “DEFO” OR “Serola”).

The results of the database searches are shown in Table 1.1, while the PRISMA diagram of the literature review process is summarised below in Figure 1.2.

DATABASE	SEARCH RESULTS
CINHAL VIA EBSCOHOST	27
AMED	12
MEDLINE VIA EBSCOHOST	33
PUBMED	272
MEDLINE VIA OVID	269
COCHRANE LIBRARY	3
TOTAL	**616**

Table 1.1 Shows the database search results.

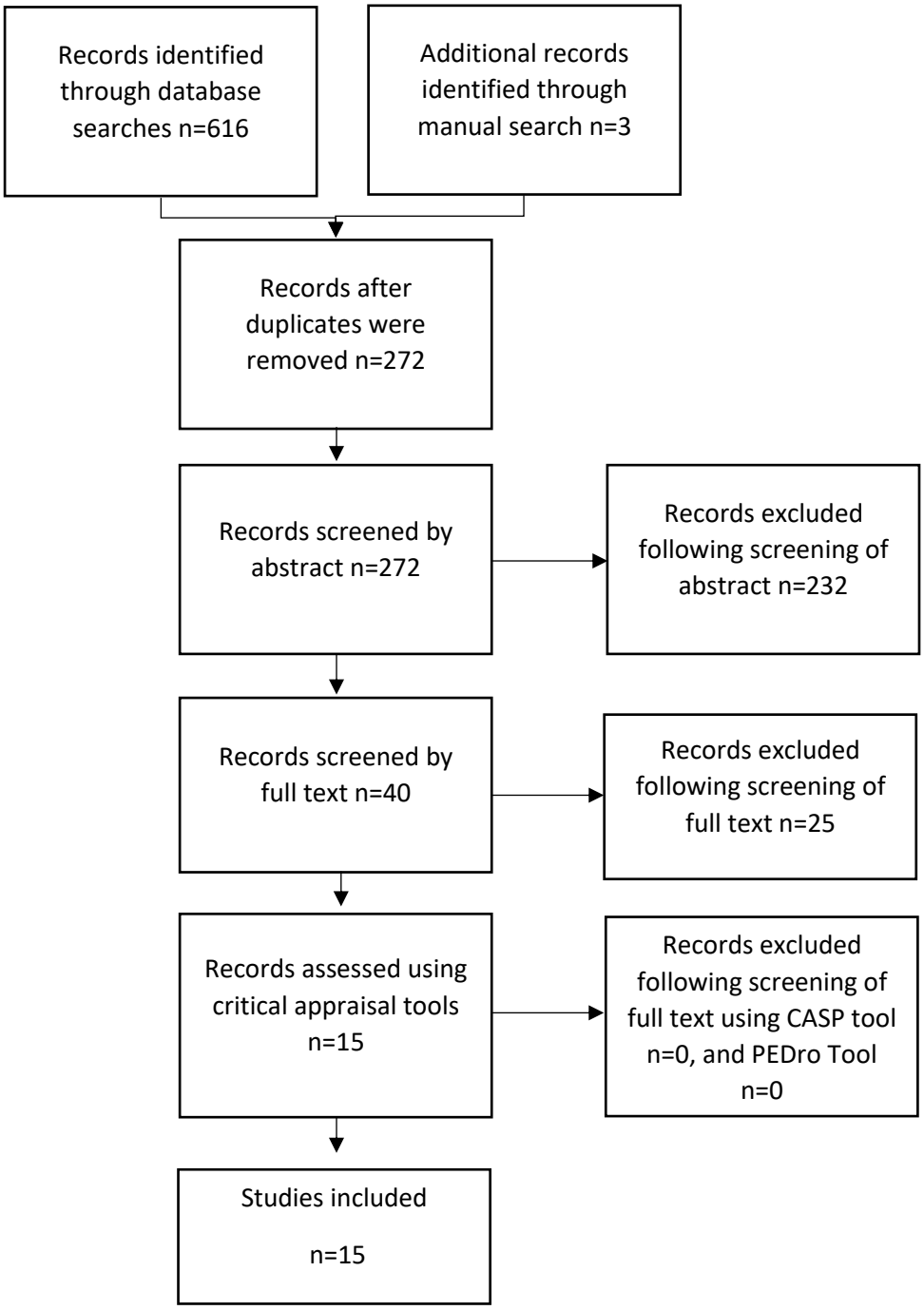


Figure 1.2 *PRISMA diagram of the literature review search process.*

Study	Design	Sample	Sample Characteristics (All units of measurement figure use mean +/- SD)	What did they do?	Outcome Measures	Findings
Bertuit et al., (2018a)	RCT	n=46 Divided into two groups A + B (Group A was divided into subgroups of A1 and A2 depending on which belt was used. Group B was no belt). Both groups were pregnant women with PGP.	Group A Age 30 (±5); Parity NR; Timing of intervention: Gestation 27 (±5); Baseline pain VAS 60 (±20). Group B Age 29 (±5); Parity NR; Timing of intervention: Gestation 27 (±6); Baseline VAS 50 (±30).	Two different types of belt Wide and rigid, narrow and flexible	VAS (pain) QBPDS (function)	Pelvic belt reduced pain and increased function in both groups
Bertuit et al., (2018b)	RCT	n=127 Divided into Three Groups: Pregnant women with PGP (n=46) (Group A), Healthy Pregnant women (n=58)(Group B) and non- pregnant women (n=23) control group (Group C) Group A was divided into A1 and A2: Group A1 (Belt 1) and group A2 (Belt 2) and Group B (No belt) Healthy pregnant women group B Non-pregnant women control group C	Group A, Pregnant women with PGP group Age 30 (±5). Group B, Healthy pregnant women group Age 29 (±5). Group C, Non-pregnant women control group Age 27 (±5). For all groups: Parity NR; Timing of intervention: NR; Baseline pain not measured.	Undertook gait trials at different velocities on a treadmill. Determining the effects of being pregnant or not; having pain or not; stage of pregnancy; and gait speed on Centre of pressure (COP) parameters (displacement and velocity) while walking	COP displacement / velocity to identify any differences between groups	PGP resulted in lower COP displacement and velocity. Wearing a belt during pregnancy decreased walking velocity and increased COP velocity. There were no differences between belts in walking velocity or COP parameters

Carr et al., (2003)	Controlled trial	Pregnant females with low back pain at minimum 20 weeks gestation. Group A no back support (n=10); Group B "Loving comfort" back support (n=30)	Authors reported that groups did not differ from each other in ethnicity, age, and years of education or gestation; Parity NR; Baseline Pain: Group A 3.85 (±2.36), Group B 4.13 (±2.01); Intervention timing NR.	Participants completed a pain assessment at pre-test. Intervention participants received a maternity support binder to wear while awake for 2 weeks. At an appointment 2 weeks later, a post-test questionnaire and a taped interview were administered. The comparison group participants received the support binder after the second appointment.	Back pain intensity, duration, and effect on daily activities were assessed using a pain in pregnancy questionnaire.	Group B had a significant reduction in mean pain scores and effect of pain on daily activities
Depledge et al., (2005)	RCT	n=87 Rigid support belt (n=28) Non-rigid support belt (n=29) Specific strengthening exercise programme and advice (n=30)	Rigid support belt group Age 29.8 (±4.6); Parity 0.83 (±0.9); Timing of Intervention: Gestation 30.5 (±5.2); Baseline pain VAS 43.0 (±21.9). Non-rigid support group Age 28.7 (±6.3); Parity 0.83 (±0.8); Timing of intervention:	Specific muscle strengthening exercises and advice concerning appropriate methods for performing activities of daily living were given to the 3 groups, and	RMQ PSFS VAS	Use of a rigid or non-rigid belt did not add to the benefits of exercise and advice group

			Gestation 31.1 (±5.4); Baseline pain VAS 50.5 (±18.5). Exercise only group Age 30.7 (±4); Parity 0.93 (±0.8); Timing of intervention: Gestation 32.2 (±5.2); Baseline pain VAS 47.8 (±14.2).	2 of the groups were given either a rigid pelvic support belt or a Non-rigid pelvic support belt.		
Elden et al., (2005)	RCT	n=386 standard treatment (n=130), standard treatment plus acupuncture (n=125), standard treatment plus stabilising exercises (n=151)	Standard group Age 30.8 (±4.8); Parity NR; Timing of intervention: Gestation 24 (±3); Baseline pain VAS 23 (13-41). Acupuncture group Age 30.6 (±4); Parity NR; Timing of intervention: Gestation 24 (±3); Baseline pain VAS 23 (15-44). Stabilising exercise group Age 30.0 (±4); Parity NR; Timing of intervention: Gestation 24 (±3); Baseline pain VAS 22 (13-43).	Standard treatment consisted of a pelvic belt, home exercise programme, patient education, with either additional acupuncture or stabilising exercises	VAS assessment of severity of PGP by independent examiner before and after treatment, although no further information given	Acupuncture was superior to stabilising exercises for reducing pain. Both used interventions alongside standard treatment, which included a pelvic belt.

Flack et al., (2015)	RCT (Pilot)	n=20 Two groups Flexible Pelvic Belt n=10 Rigid Pelvic Belt n=10	Flexible pelvic belt group Age 28.6 (±5.6); Parity NR; Timing of intervention: Gestation 32.0 (±4.8); Baseline pain VAS 55.5 (±24.0). Rigid pelvic belt group Age 30.2 (±7.6); Parity NR; Timing of intervention: Gestation 29.6 (±5.5); Baseline pain VAS 58.2 (±24.4).	Two separate groups but comparatively looking at adherence, tolerance and effectiveness of a flexible and rigid belt.	PSFS VAS Modified ODQ	Preliminary results suggest the flexible pelvic support belt may be more effective in reducing pain and is potentially better tolerated than a rigid belt, although both groups showed good improvements in pain levels. Concluded that a larger trial is required.
Haugaland et al., (2006)	RCT	n=560 Intervention group (n=275) Control group (n=285)	Intervention group Age 28.9 (±4.49); Parity NR; Timing of intervention: Gestation 24.0 (±4.79); Baseline pain VAS 6. Control group Age 28.9 (±4.41); Parity NR; Timing of intervention: Gestation 23.8 (±4.51); Baseline pain VAS 6.	Looked at the difference in intervention group who had pelvic belt/crutches, education programme, and information about delivery Control, were not offered any treatment but were free to seek advice and treatment	VAS	Identified no statistical difference between groups post-partum.

Hu et al., (2010)	Observational Study	n=17	Age 28.7 (±2.8); No other data reported.	Healthy individuals Assessed muscle function whilst participants walked on a treadmill and during an ASLR with and without a pelvic belt	Fine-wire EMG and Surface EMG	Confirmed Snijders 'force closure' theory, by identifying that the transverse and oblique abdominal muscles were less active in conditions with a pelvic belt, suggesting that the belt provides the forces required for 'force closure'.
Kalus et al., (2008)	RCT	n=115 BellyBra Group (n=55) Tubi Grip Group (n=60)	The authors reported no significant differences between the study device and control groups in baseline data: age, height, weight, parity or gestational age. Bellybra group Timing of intervention: Gestation 28.2; Baseline pain VAS 6.1 (±2.2). Tubi Grip group Timing of intervention: Gestation 29.2; Baseline pain VAS 6.0 (±2.0).	Two groups one group trialled the "BellyBra" orthotic and group two trialled the Tubigrip orthotic	VAS SWLS (life satisfaction)	Reduced pain in both groups and increased function was seen more in the "Belly Bra" group opposed to the Tubigrip group
Kordi et al., (2013)	RCT	n= 105 Exercise and belt group (n= 31) Information and belt group (n=31) Information alone (n=34) Lost to follow up (n=9)	Exercise and belt group Age 26.45 (±5.37); Parity NR; Timing of intervention: Gestation 24.7 (±3.9); Baseline pain VAS 58.2 (±13.93). Information and belt group	Trialled non-rigid pelvic belt plus information, belt plus stabilising exercises, or just information alone	VAS ODI WHOQOL-BREF	Lumbopelvic belt plus information was more effective than exercises plus information or information alone on pain, and improved function disability.

			Age 28.26 (±4.82); Parity NR; Timing of intervention: Gestation 26.5 (±3.7); Baseline pain VAS 64.4 (±13.96). Information alone group Age 25.45 (±5.59); Parity NR; Timing of intervention: Gestation 25.3 (±3.8); Baseline pain VAS 51.0 (±13.79).			
Mens et al., (2000)	RCT	N=44 Group A control (n=14) Group B Placebo (n=14) Group C: Training of diagonal trunk muscle exercise (n=16)	Age 31.7 (±3.2); No other data reported.	Group A: refrain from exercises Group B: training of longitudinal trunk muscle exercises Group C: Training of diagonal trunk muscle exercise 30 minute videotape with information, ergonomic advice and how to use a pelvic belt given to all three groups	VAS	No significant difference in the mean change pain score (VAS) from baseline No significant difference in the mean change in global improvement and physical mobility
Mens et al., (2006)	Observational study	n=25	Age 33.0 (±4.0); Parity 1.8 (±1.0); No other data reported.	Influence of pelvic belt on SIJ laxity, during an ASLR. With pelvic belt and without. Two different locations ASIS (high position) and pubic symphysis (low position)	Doppler imaging of vibrations	Application of a pelvic belt significantly reduces SIJ laxity. Better reduction in SIJ mobility at level of ASIS than pubic symphysis.

Mens et al., (2017)	Observational study	n=82 PGP (n=43) Controls (n=39)	Age 36.7 (±6.8); No other data reported.	They assessed the pelvic belts' effect during an ASLR and at rest on TrA activation/thickness	Ultrasound imaging of TrA thickness at rest and during an ASLR (percentage change of thickness)	Significant excessive contraction of TrA during ASLR with patients with longstanding posterior PGP, not supporting clinical understanding that TrA is underworking.
Nilson-Wilkmar et al., (2005)	RCT	n=118 Information group Non-elastic SIJ belt and advice (n=40) Home exercise group as above plus home exercise programme (n=41) In clinic exercise group same as information plus training programme (n=37)	Information group Age 28.4 (±3.9); Parity NR; Timing of intervention: Gestation 25 (±7); Baseline pain VAS 49 (8-77). Home exercise group Age 29.5 (±3.3); Parity NR; Timing of intervention: Gestation 22 (±7); Baseline pain VAS 46 (0-100). In clinic exercise group Age 29.7 (±5.4); Parity NR; Timing of intervention: Gestation 21 (±6); Baseline pain VAS 47 (5-95).	Used 3 different groups to test the effect of non-elastic SIJ belt and advice against all of the above plus home exercise programme and all of above plus training programme in clinic All pregnant females with PGP	VAS DRI	No significant difference between the three groups In all groups pain decreased and activity ability increased between gestational week 38 and at 12 months post-partum
Wedenburg et al., (2000)	RCT	n=60 acupuncture (n=30) Physiotherapy (n=30) Included individualised	Acupuncture group Age 28.4 (Range 21-39); Parity NR; Timing of intervention: Gestation 24.2 (Range 20-32);	Compared acupuncture to physiotherapy (individualised training	VAS DRI	Acupuncture relieved pain and diminished disability in low back pain during pregnancy better than

		training programme and a trochanteric pelvic belt	Baseline pain NR. Physiotherapy group Age 29.4 (Range 22-36); Parity NR; Timing of intervention: Gestation 24.2 (Range 20-29); Baseline pain NR.	programme/trochanteric belt) for the management low back and pelvic pain in pregnancy		physiotherapy group consisting of bot an individualised training programme and trochanteric belt

Table 1.2 *Summarises the studies included in this literature review*

ASIS – Anterior Superior Iliac Spine
ASLR – Active Straight Leg Raise
COP – Centre of Pressure
DRI – Disability Rating Index
EMG – Electromyography
NR – Not Reported
ODQ – Oswestry Disability Questionnaire
PGP – Pelvic Girdle Pain
Preg – Pregnancy/pregnant
PSFS – Patient Specific Functional Scale
QBPDS – Quebec Back Pain Disability Scale
RCT – Randomised Control Trial
RMQ – Roland Morris Questionnaire
SIJ – Sacroiliac Joint
SWLS – Satisfaction with Life Scale
TrA – Transverse Abdominus
VAS – Visual analogue Scale
WHOQOL-BREF – World Health Organisation's Quality of Life Questionnaire

1.11 Study Design

There were 11 RCTs and one controlled trial. Three observational trials assessed the effects of pelvic belts on either transversus abdominus (TrA) thickness or SIJ laxity (as measured via the transmission of ultrasound vibrations across the joint) in people with and without PGP (Table 1.2). The remaining observational study assessed healthy participants. It examined how abdominal muscle activation varied (as measured via surface and fine wire EMG) with and without a pelvic belt while walking.

Most RCTs examined the long-term effects of an intervention against a control group although some (e.g. Bertuit et al., 2018b) examined the immediate effects of a belt on gait speed and measures of dynamic balance (centre of pressure). Only six of the RCTs were adequately powered; a further five did not report any power calculation nor state as being a pilot study. In the one pilot study, inferential statistical analysis was performed despite being inappropriate for a design of this nature.

It is clear from figure 1.2 that many of the studies had methodological limitations with regards both allocation concealment and blinding of the subject, assessor and therapist, leading to potential risk of bias.

1.12 Interventions

Varied orthotics were used in the studies. These included pelvic belts, whose position could vary from high (ASIS level) to low (pubic symphysis level); Tubigrip and Bellybra. Orthotics could be used in combination with stabilising/ strengthening exercises or acupuncture. Exercises were used in isolation in one study. The length of the intervention period varied from short term (on the day measurement) and when worn over time from two to six weeks.

1.13 Outcome Measures

Pain, function, activity levels, and health related quality of life were all outcomes that were assessed in the studies. There were many variations of outcome measures used making it difficult to compare and contrast results. The trials used recognised outcome measures whose psychometric properties (reliability and validity) have been defined in people with PGP. No disease specific questionnaires were used in the studies. It has been reported that commonly used outcome measures in PGP have good internal consistency along with test re-test reliability and construct validity (Grotle et al., 2012). The observational studies used novel (e.g. assessment of vibration across the SIJ) or established methods (e.g. electromyography) but their psychometric properties were not reported as having been defined/established previously.

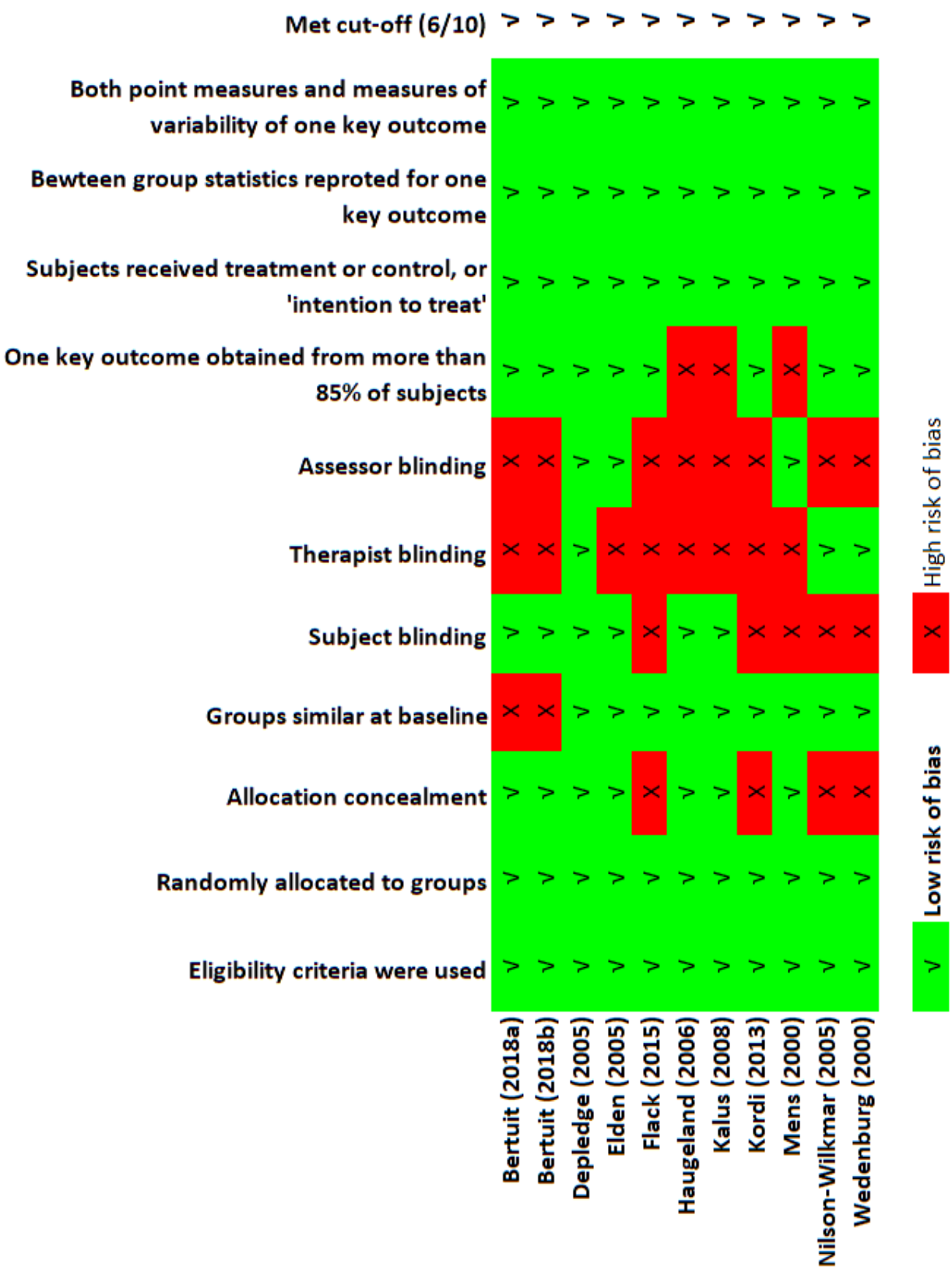


Figure 1.3 *High and low risk of bias based on PEDro scale assessment*

Table 1.3 shows the CASP results

		Carr et al (2003)			Hu et al (2010)			Mens et al (2006)			Mens et al (2017)		
Question No.	**Question**	**Yes**	**Can't Tell**	**No**	**Yes**	**Can't Tell**	**No**	**Yes**	**Can't Tell**	**No**	**Yes**	**Can't Tell**	**No**
1	Did the study address a clearly focused issue?	√			√			√			√		
2	Was the cohort recruited in an acceptable way?	√			√			√			√		
3	Was the exposure accurately measured to minimise bias?	√			√			√			√		
4	Was the outcome clearly measured to minimise bias?	√			√			√			√		
5(a)	Have the authors identified all confounding factors?	√			√			√			√		
5(b)	Have they taken account of the confounding factors in the design and/or analysis?		√		√			√			√		
6 (a)	Was the follow-up of subjects complete enough?	√			√			√			√		
6 (b)	Was the follow-up of subjects long enough?	√			√			√			√		
7	How precise are the results?		√		√			√			√		
8	Do you believe the results?	√			√			√			√		
9	Can the result be applied to the local population?		√			√			√			√	
10	Do the results of the study fit with other available evidence?	√			√			√	X		√		
11	What are the implications of this study for future practice?		√			√			√			√	

1.14 Study findings

1.14.1 Studies investigating the effects of orthoses on pain and function

In a three arm study (n=105), Kordi et al. (2013) evaluated the use of a non-rigid belt plus standardised advice in comparison to an exercise group (specific stabilising exercises) and advice only group, reporting a significant decrease in pain intensity, along with decrease in disability in the orthotic group. It was a 6-week trial, with analysis of >85% of participants completing the study. A sample size calculation was not documented, and elements of methodology such as the allocation concealment procedure and lack of blinding of both the subject and assessor could have put the outcome at risk of bias. Nevertheless, it met the PEDro cut-off score, and was graded as moderate methodological quality.

Along similar lines, Bertuit et al. (2018a) (*n* = 46) utilised two belts, one wide and rigid, and one narrow and flexible. They demonstrated that both pelvic belts reduced pain and increased function, although there was no statistically significant difference between groups (Bertuit et al., 2018a). Unfortunately, this study had poorly balanced groups with a significant drop out rate, particularly in the control group (*n* = 12 dropouts), making it difficult to be confident of the results generated and to generalise the results to the pregnancy population.

Depledge et al. (2005) also compared the effects of a rigid (n=28) and non-rigid belt (n=29), along with a control group who undertook a specific strengthening exercise programme (n=30). Participants, all of whom suffered from anterior pelvic girdle pain, were randomised into the groups. The addition of either a rigid or non-rigid belt did not show any significant difference to the specific strengthening exercise

programme group, although all groups did show an improvement in function with intervention.

Nilson-Wilkmar et al. (2005) undertook a three-armed RCT (n=118) to investigate the difference between the use of: a non-elastic SIJ belt; a non-elastic SIJ belt plus home exercise programme; and a non-elastic SIJ belt and a clinic training programme. All groups had a reduction in pain levels and increase in activity levels but there were no significant differences between groups. Whilst it seems that the pelvic orthotic may have played an active role in reducing pain levels in this study, a lack of a control group means it is not possible to ascertain the true benefit of the pelvic orthotic. It can be argued that it is unethical to recommend the use of a pelvic orthotic without considering standard treatment alongside as females may suffer the effect of increased pain, reduced function, and quality of life as a result; this poses challenges to researchers in this area. One way in which this conundrum can be managed is exemplified by a small study by Mens et al. (2000). In their study, participants were allocated to one of three groups. All participants were provided with "standard treatment" which comprised a pelvic belt, information and ergonomic advice. The groups were differentiated as follows: Group A refrained from exercises, Group B were given a placebo (training of longitudinal trunk muscles), and Group C were given diagonal trunk muscle exercises. No significant difference was demonstrated in the mean change for pain, global improvement, or physical mobility from baseline. It was disclosed that the study was powered for n=30 participants per group but ceased recruitment following 44 participants being enrolled into the study and did not disclose why. The conclusions drawn should be interpreted with caution as the study was significantly underpowered.

A similar study by Elden et al. (2005) also employed this methodology in a large three-armed RCT (n=386), wherein all groups engaged in standard treatment (which comprised of advice, exercises and pelvic belt), but with one group receiving acupuncture alongside standard treatment and another group engaging in specific stabilising exercises plus standard treatment. They concluded that both the acupuncture and stabilising exercises alongside standardised treatment had a more favourable outcome in the primary outcome, pain reduction. Their secondary outcome measure was an independent health professional assessment of improvement of the patients. Although they do not document how they went about this, it would be reasonable to assume that they repeated the pain provocation tests to identify if there was any improvement in these factors, although this cannot be confirmed. The results showed that patients had a reduction in pain as determined by the VAS. The independent examiners' assessment also highlighted improvement in the groups that included an additional acupuncture or stabilising exercise modality (Elden et al., 2005).

Flack et al. (2015) investigated the comparative effectiveness of two different pelvic orthotics, although this was in a small (n=20) randomised pilot study and so their results should be considered with some caution. Their study involved the comparison of a flexible (n=10) and rigid (n=10) pelvic orthotic, showing positive preliminary results for improved pain levels. In this study the flexible belt was evaluated as being marginally better at reducing pain levels than the rigid belt, and the flexible belt group also tolerated the orthoses better in terms of wearing comfort (Flack et al., 2015).

Haugaland et al. (2006) also undertook an RCT with a large sample of 526 pregnant women. They aimed to identify if there was any difference between standard interventions (an education programme that consisted of information, ergonomics,

exercises, pain management, advice for daily life movement, pelvic belt/crutches) and the control group (no formal treatment but the women were able to seek advice and treatment if required). Using the VAS as their primary outcome measure to evaluate pain, they introduced the intervention between the 18th and 32nd week of gestation and undertook two follow-up assessments at six and 12 months postpartum. This study found that there was no statistically significant difference between groups, with both groups demonstrating a gradual improvement in symptoms (Haugaland et al., 2006). Within the control group, 60% of participants had sought intervention for their symptoms. As a result, it is difficult to clearly interpret and apply the results of this study to the pregnant population. The lack of standardisation of the control, meant that it was unclear what interventions were provided to the 60% of the control group who sought treatment for their symptoms. Furthermore, there was no follow-up prior to birth to ascertain whether there was any improvement pre-partum, which is a meaningful outcome for the antenatal PGP population. Finally, the post-partum effects are also difficult to attribute to the intervention as compliance was not monitored during this phase making it impossible to determine whether improvement was due to the intervention or to the natural course of pain postpartum.

1.14.2 *Studies investigating potential mechanisms of effect*

When considering the effects a belt may have on the pelvis, Mens et al. (2017) looked at Doppler imaging of vibrations of the SIJ. They aimed to identify whether: (1) the application of a pelvic belt impacted on SIJ laxity; (2) there was a difference in relative effectiveness for different levels of belt application (high position, just caudal to the level of ASIS; or low position, at the level of the symphysis pubis). This small study sample (n=25), comprised of pregnant individuals suffering PGP. Results showed

that application of a pelvic belt significantly reduced SIJ laxity, and this was greater if the pelvic belt was applied to the high position. The application of a pelvic belt, either in a high or low position, also had a significant improvement in the ASLR (perceived effort scores) compared to without the pelvic belt (Mens et al., 2006). The limitation to this study was that although the Doppler was able to identify changes in perceived laxity, Doppler imaging has not been validated for this function.

A potential symptom of pregnancy related PGP is a decreased activation of underlying musculature such as the transverse abdominal muscle (TrA). Treatments frequently aim at increasing the ability of this muscle to function in order to improve neuromuscular control of the pelvic girdle musculature via force closure (Gutke et al., 2017; Vleeming et al., 2008). Ultrasound imaging is undertaken to identify changes in TrA muscular thickness (considered to reflect contraction of the muscle) during a functional activity such as an ASLR. Of interest, a study by Mens et al. (2017) this highlighted that, in people with PGP, TrA was activated more than controls. This finding challenges the current rationale for providing specific stabilising exercises to help reduce PGP. It suggests that stabilising muscles responsible for force closure are already active in people with PGP. This could reflect a compensatory strategy to aid stability and reduce pain or it could reflect pathological over activity that could contribute to the pain syndrome. The study included participants who suffered from PGP during their pregnancy but were now in their post-partum period, although were still suffering from persistent PGP, along with a group of a non-pregnant healthy women. As there were no pregnant women with PGP the results should be viewed with caution when generalising these findings to this patient group.

An investigation into whether the pelvic belt had any changes to the centre of plantar pressure motion while walking (a measure of dynamic balance) in pregnant women was undertaken by Bertuit et al. (2018b). They found that the pelvic belt increased the centre of plantar pressure velocity. This was hypothesised to reflect alterations in trunk/lower limb function as a result of wearing a pelvic orthotic. However, there could be multiple causes of alterations in plantar pressure motion that may / may not reflect enhanced stability in the pelvic region (Bertuit et al., 2018b).

1.15 Critical Appraisal Tools

Two critical appraisal tools were used to assess the quality of studies within this literature review; the PEDro and CASP tools. This decision reflected the varying designs of the studies that were reviewed: 11 of which were RCTs (assessed using PEDro) and four studies (assessed using CASP – see Table 1.3). Figure 1.3 provides a schematic representation of the bias that studies present and highlights that blinding of either the subject, assessor or therapist was one common weakness with methodology in the studies, and along with this 36% of studies did not complete or document their allocation concealment procedure.

1.16 Limitations

This literature review highlighted methodological limitations in the design and conduct of studies undertaken to date, which included variability in the timing of intervention and selection of functional outcome measures across the studies. Sample sizes also varied considerably with many studies failing to report whether or not they had undertaken a sample size calculation. There was also a significant variation in the timing and duration of intervention. These are common methodological problems

faced in many RCTS evaluating health care interventions. More unique to the pregnancy PGP population is that the women experience the onset of symptoms at differing times within their gestation and that the gestation period varies with individuals. This means that some women may give birth prior to completion of the intervention; these factors add further challenges which need to be carefully considered when designing studies and interpreting the results. Variability in symptom onset also means that pregnant women's gestational age varies across the three trimesters, which complicates the analysis and reporting of findings.

Of note, the literature highlighted that there was a lack of consistency in the definition of PGP across studies; some included participants with lumbopelvic pain, and others included those with low back pain. A further potential limitation was the variety of treatments that were undertaken, often as a "package", such as the provision of advice, exercises, pelvic belt, crutches, acupuncture, and specific stabilising exercises. This, in particular, makes it highly challenging to identify the true effect of pelvic orthotics in isolation as additional adjuncts / treatments were not matched between groups. One final limitation which was detected in all of the RCTs reviewed was that none documented that they had conformed to the Consolidated Standards of Reporting Trials (CONSORT) statement. The CONSORT statement was developed to improve the reporting of RCTs, which shows transparency from the researcher but also assists readers in critiquing the validity and reliability of the studies (Pandis et al., 2017).

1.17 Adverse Effects

It has been identified that pelvic support belts can lead to increased pain in some patients, resulting in a discontinuation of their use (Mens et al., 1996). Assessing whether the orthotics are associated with any changes in maternal and foetal haemodynamics is a crucial safety aspect. Beaty et al. (1999) assessed this in 25 pregnant women who were wearing pelvic support for a 20-minute time period (Beaty et al., 1999). No significant changes were detected in maternal blood pressure, cardiac outputs, or foetal heart rate (baseline and variability; Beaty et al., 1999), with the conclusion that these products were safe for both the mother and baby. A potential limitation was that common adherence patterns were not replicated and future studies could aim to provide further information.

1.18 Discussion

Pregnancy related PGP affects a significant proportion of women. Early identification of the condition, alongside consideration of risk factors aims to enhance its prevention (wherever possible) and early management, in order to minimise pain and maximise function throughout the pregnancy.

In the case where pregnancy related PGP exists, with concomitant impaired function, the results of this literature review shows that there is some evidence to support the use of a pelvic orthotic alongside standardised treatments in its management. However, there are many variations of pelvic orthoses that are commercially available, and no 'gold standard' orthotic appears to exist which complicates decision making in terms of the evidence-based selection of an orthosis for use in clinical practice. The varying designs, which include TubiGrip, BellyBra,

LovingComfort, Maternity Binders, all positively impact to some degree on pain and function although not always at a statistically significant level. Given this large range of products, their categorisation as either rigid, non-rigid, elastic, non-elastic, wide or narrow appears to be an appropriate way to classify pelvic orthotics when attempting to combine outcomes of the current literature. This approach may also allow for clearer guidance for clinicians on what type of orthotic to recommend.

Although the European Guidelines (2008) have advocated an updated definition of pelvic girdle pain and made recommendations regarding diagnosis of the condition, there are a number of studies which have not appeared to adhere to this guidance, complicating both the interpretation and translation of results into clinical practice.

1.19 Conclusion and recommendations

The use of clear and standardised terminology, together with an agreed classification system for categorising pelvic orthoses would help to facilitate a more consistent approach to both the design and reporting of future research studies, and better identification of the potential benefits of different orthoses. Alongside this, further comparative trials would help to form a better understanding of their relative benefits for reducing pregnancy related PGP. New research should aim to conform to the European Guidelines (2018) for both the definition and diagnosis of PGP. Alongside this, where available, future studies should consider incorporating disease specific questionnaires and should aim to conform to CONSORT guidelines.

Chapter Two:

Fabric Testing

2.1 Introduction

This chapter describes an experiment undertaken to investigate the fabrics that are used to construct the customised Dynamic Elastomeric Fabric Orthoses (DEFO) which was the intervention evaluated in the studies undertaken for this dissertation. The customised DEFO, which is produced by DM Orthotic Ltd (https://www.dmorthotics.com), can be made in a range of nine colours. Following discussions with the DM Orthotic Ltd production team, it was felt that on 'touch' and 'feel', the different fabric colours appeared to have different properties with some having greater tension when stretched compared to others. This is an important consideration since the mechanism of effect of the orthoses is hypothesised to be, at least in part, due to increased stability of the pelvis as a direct consequence of the external pressure provided by the stiffness of the DEFO.

The overall aim of the dissertation was to evaluate the effectiveness of the customised DEFO in the management of pregnancy related PGP; it was therefore essential to have a standardised intervention offering the same support to each participant. Therefore, the experiment described in this chapter aimed to objectively investigate the underlying properties of the fabrics used to make the customised DEFO to determine whether participants engaged in the interventional studies could be offered a choice in the colour of their orthoses, or not.

2.2 Background

The customised DEFO is constructed with two fabrics, Lycra and Powernet. Both fabrics are made of a combination of Nylon and Elastane. Nylon and Elastane have shown to be the most popular choice of fabric in the construction of pressure

orthoses in the UK (Macintyre and Baird, 2005). The relative composition of Nylon and Elastane determines the fabric's ability to maintain tension, also referred to as stiffness (Macintyre and Baird, 2006) and its' elastic properties (Anbumani and Hayavadana, 2011). From a clinical perspective this is essential because an orthosis is used to brace or support a weak or injured body part. Nylon and Elastane can be described as synthetic linear macromolecules. Nylon is a thermoplastic with strands made up of repeating units joined by amide links. Adjacent strands can align up and form hydrogen bonds creating a strong supermolecule structure. Elastane (also known as spandex) consists of a long chain of at least 85% segmented polyurethane bonds, which is broken into hard and soft segments. It is the soft segments of the chain that give the Elastane its exceptional elastic properties and its recoverable stretch ability, otherwise referred to as elastic hysteresis (Anbumani and Hayavadana, 2011). The fabric also possesses durable qualities, which the hard chain segments supply. The selection for the use of this fabric in the construction of a support orthosis is based upon the need for a combination of properties such as elasticity, its ability to support, durability and breathability whilst allowing the participant to maintain freedom of movement (Uttam et al., 2013).

2.3 Research Question and Aims

2.3.1 *Research Question*

In this fabric testing study, we asked the question: "Are there underlying differences in fabric stiffness and elastic hysteresis in the Lycra and Powernet materials which are used to produce the customised DEFO?"

2.3.2 Research Aims

- To investigate if there were any differences in stiffness between fabric colours in both the Lycra and Powernet fabrics, used as the basis for the customised DEFO.
- To investigate if there was any difference in elastic hysteresis between fabric colours in both the Lycra and Powernet fabrics, used as the basis for the customised DEFO.

2.4 Methodology

2.4.1 *Study Design*

This study used a repeated measures design

2.4.2 *Measurement of Fabric Stiffness*

Fabric stiffness was measured by applying different weights and measuring the subsequent elongation of the fabric. Each fabric was tested by attaching the fabric to a constructed overhang using clamps, and then a bucket attached to the bottom of the fabric to which weights were added in a systematic manner (Figure 2.1). The weights used for the fabric testing ranged from 0.2kg to 1.2kg. The weights were added to the bucket in weight order as follows: 0.2kg (1.96 N), 0.4kg (3.92 N), 0.6kg (5.88 N), 0.8kg (7.84 N), 1kg (9.8 N), 1.2kg (11.76 N), and 1.4kg (13.72 N).

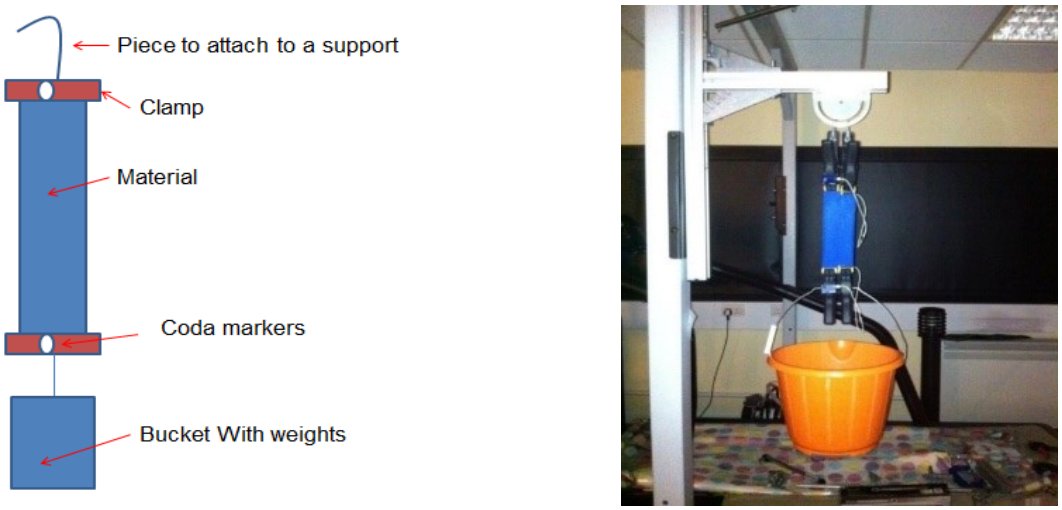


Figure 2.1 *Apparatus laboratory set up for fabric stiffness testing*

The change in position when a weight was added was measured using a Codamotion system (Codamotion, Lancashire, UK). Codamotion is a 3D movement analysis and motion capturing device (Figure 2.2). The technology uses miniature infra-red markers (each with a unique identity) to track the key position on any subject. Signals from the infra-red markers are beamed to 'CODA' sensor units. The 'CODA' sensor units, consisting of three masked linear arrays (MLAs) in each CODA unit, combine to measure X, Y and Z coordinates of each marker, providing an immediate and precise 3D measurement of movement.

Figure 2.2 *Codamotion 3D movement analysis and motion capturing device (above left) and a sensor (above right)*

The Codamotion system measured the positional change that occurred to the fabric following the application of each weight change. Markers were placed at the highest and lowest point of the fabric (Figure 2.1). After each weight was added and the system was stationary a 10 second recording was made. Signals were sampled at 100 Hz. The mean position of the lower marker in the vertical (y) direction was determined. Data was subsequently exported into excel for analysis.

2.4.3 *Measurement of Fabric Elastic Hysteresis*

A Biodex computerised robotic dynamometer (System 3, UK) was used to test material stretch-recovery. Metal accessory bars were added to the Biodex and clamps were used to attach the fabrics to the Biodex machine in a standardised manner. The system was then set-up to repeatedly stretch the fabric by 15 degrees with a peak velocity of degrees (deg/s) for a duration of 120 seconds. The analogue torque and position signals (*Figure 2.3*) were obtained via the EMG-analog interface. They were

sampled at 1Kz via an analog-digital converter (1401, CED Cambridge UK) and stored using the spike 2 program (CED Cambridge UK).

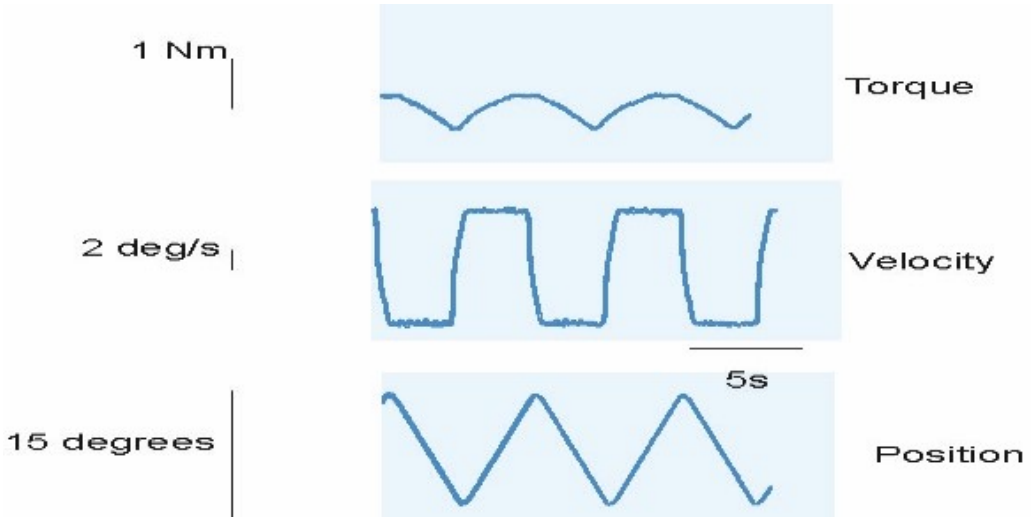


Figure 2.3 *Biodex wave forms showing torque, velocity and position*

2.5 Analysis

2.5.1 *Analysis of Fabric Stiffness*

For each fabric a plot of the position of the lower marker (mm) versus applied weight (N) was made and a best-fit line was determined using a least squares error method in excel (*Figure 2.4*). The slope of the line gives a measure of the stiffness of the fabric (N/mm) and the upper and lower 95% confidence intervals.

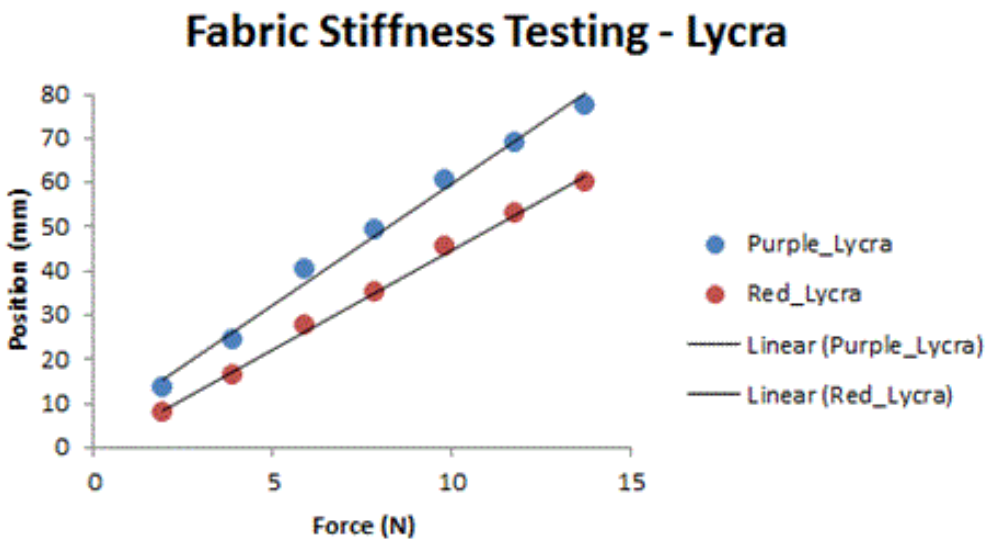


Figure 2.4 *Fabric stiffness testing (Lycra)*

2.5.2 *Analysis of Fabric Elastic Hysteresis*

Text files were then exported to Matlab for secondary analysis using a program written in house. To eradicate high frequency noise a Butterworth low pass filter was applied. The Butterworth low pass filter has been designed to only allow certain frequencies to pass through the filter and to eliminate any undesired frequencies (high frequency noise) (Manal and Rose, 2007). The allowances and elimination of certain frequencies is dependent upon the limits set up within the filter. A Butterworth low pass filter set to 30Hz was applied to the wave form data, effectively 'smoothing' the wave form data. The onset / offset of each stretch cycle were determined by differentiating the position trace to detect the acceleration maxima and minima. The first five cycles were then aligned and a plot of torque versus position made (*Figure 2.5*). An upslope identifies the change the fabric undergoes whilst it is being stretched, and the downslope identifies the change the fabric undergoes when the fabric is returning to the start position (Liang et al., 2019). The area between the curves

provides a measure of hysteresis. The higher the value the more viscous the material. Viscocity transforms kinetic energy into heat; thus the area between the curves is an indication of the energy lost (to heat) with repeated stretching.

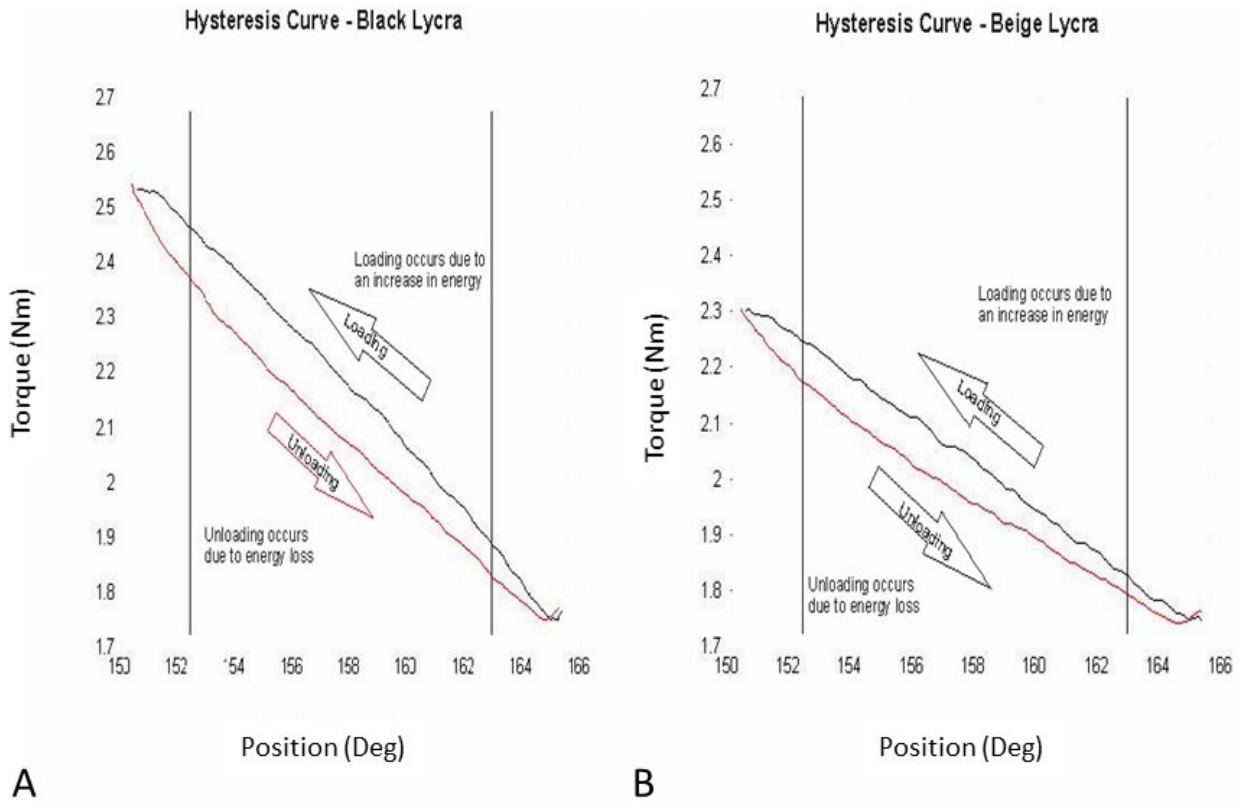
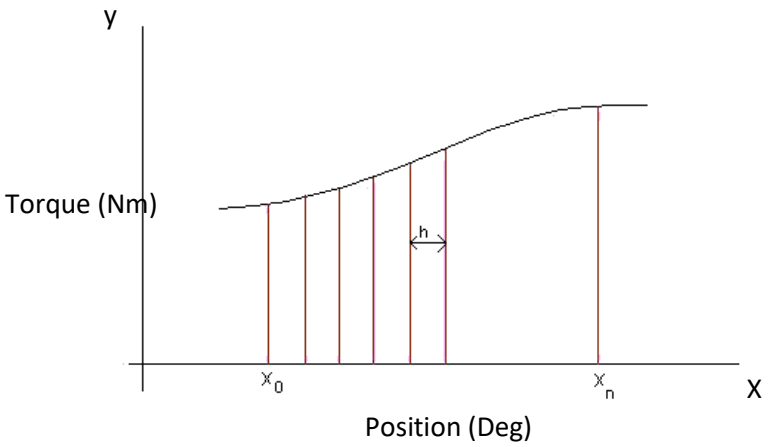


Figure 2.5 *Elastic hysteresis curves for A black Lycra and b Beige Lycra (above right), with arrows identifying upslope or downslope.*

The area under the stretch and release curve (Nm/deg) was determined using a trapezium rule. This divides the area concerned into smaller trapezium shapes (h). A formula is then applied to the total area of each trapezium used (Figure 2.6). The difference gives the area between the curves (Xo – Xn). The area under the curve was measured over the same angular change for each fabric as indicated by the lines in figure 2.6. For each fabric the mean area +/- standard deviation for the five stretch-recovery cycles was determined (Li et al., 2010).



$$\int_{x_0}^{x_n} f(x)\,dx = \frac{1}{2}h[(y_0 + y_n) + 2(y_1 + y_2 + \ldots + y_{n-1})]$$

Figure 2.6 *Trapezium rule equation (top): $y_0, y_1..y_n$ indicate the y (torque) values when the position (x)=xo,x1..xn. h indicates the sampling interval between (x_1-x_o) and diagram of implemented formula (above).*

2.6 Results

2.6.1 Fabric Stiffness Results

Fabric stiffness and elastic hysteresis were analysed using a 95% confidence interval to identify statistical differences between fabrics. The change in position for each applied load is given in appendix 1. The mean stiffness (+/- 95% confidence interval) is indicated in Table 2.1 (Lycra and Powernet). The data demonstrate that there are differences between each of the colours in both the Lycra and Powernet fabrics.

Fabric Colour/Type	Compliance (N/mm)	95% Lower CI	95% Upper CI
Beige Powernet	10.2	9.7	10.7
Blue Powernet	**9.0**	**8.8**	**9.3**
Red Powernet	**8.3**	**7.5**	**9.0**
Black Powernet	**7.3**	**7.0**	**7.6**
Purple Powernet	**6.8**	**6.6**	**7.0**
White Powernet	**6.5**	**6.1**	**6.9**
Purple Lycra	**6.1**	**5.6**	**6.5**
White Lycra	**5.2**	**5.0**	**5.4**
Blue Lycra	**5.1**	**5.0**	**5.3**
Beige Lycra	**4.7**	**4.7**	**4.9**
Black Lycra	**4.5**	**4.4**	**4.6**
Red Lycra	**4.5**	**4.3**	**4.6**

Table 2.1 *Stiffness (K) coefficients and 95% confidence intervals for each fabric colour/ type*

The beige Powernet had the highest recorded stiffness of 10.2 N/mm, a difference of 3.7 N/mm from the white Powernet, which recorded the lowest stiffness (6.5 N/mm) (Figure 2.7). This trend is also seen in the findings from the Lycra stiffness testing; with purple Lycra having the highest recorded stiffness at 6.1 N/mm, compared to red Lycra recording the lowest stiffness at 4.5 N/mm (Figure 2.7), a difference of 1.6 N/mm. There were larger differences in stiffness between the Powernet coloured fabrics compared to the Lycra coloured fabrics.

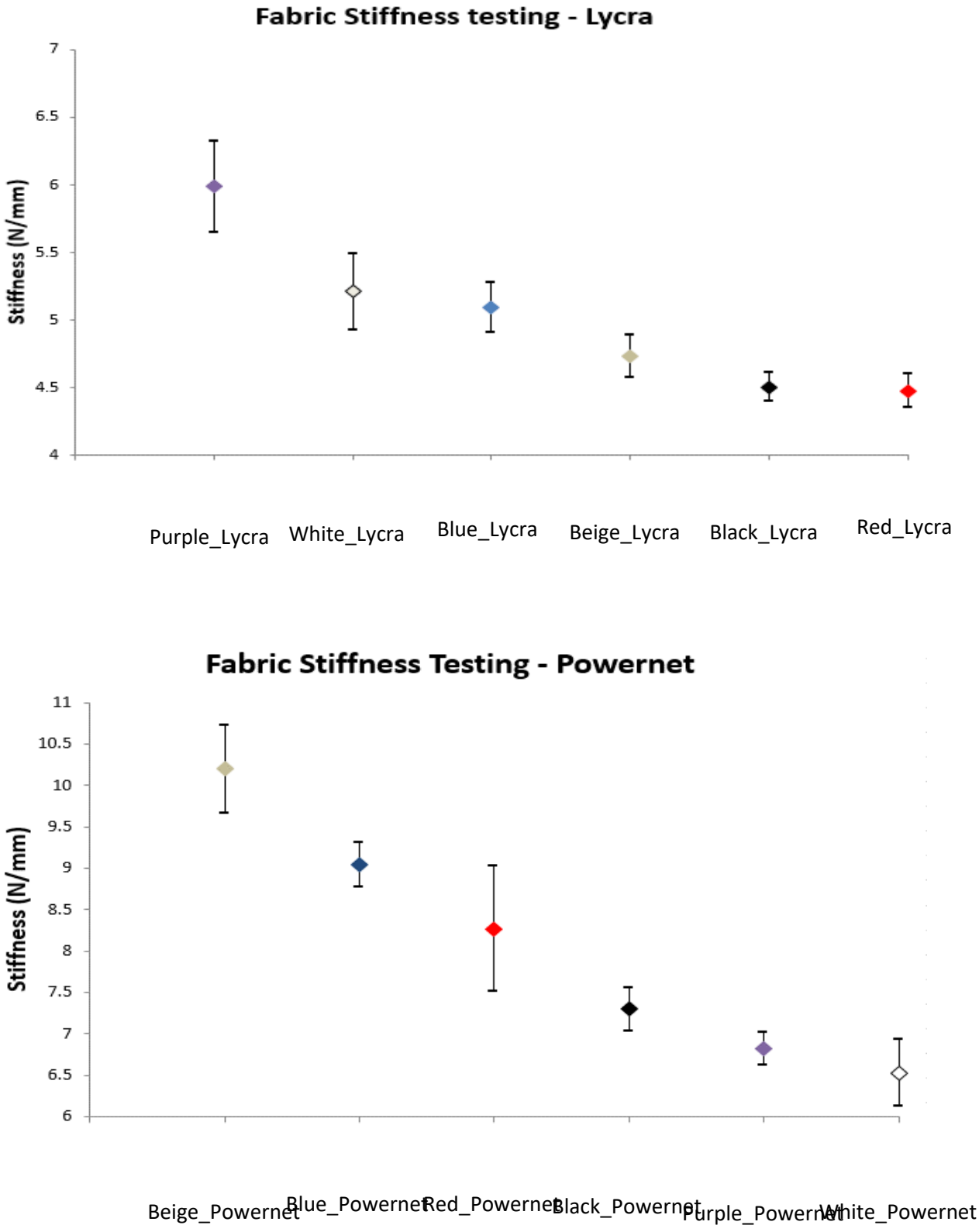


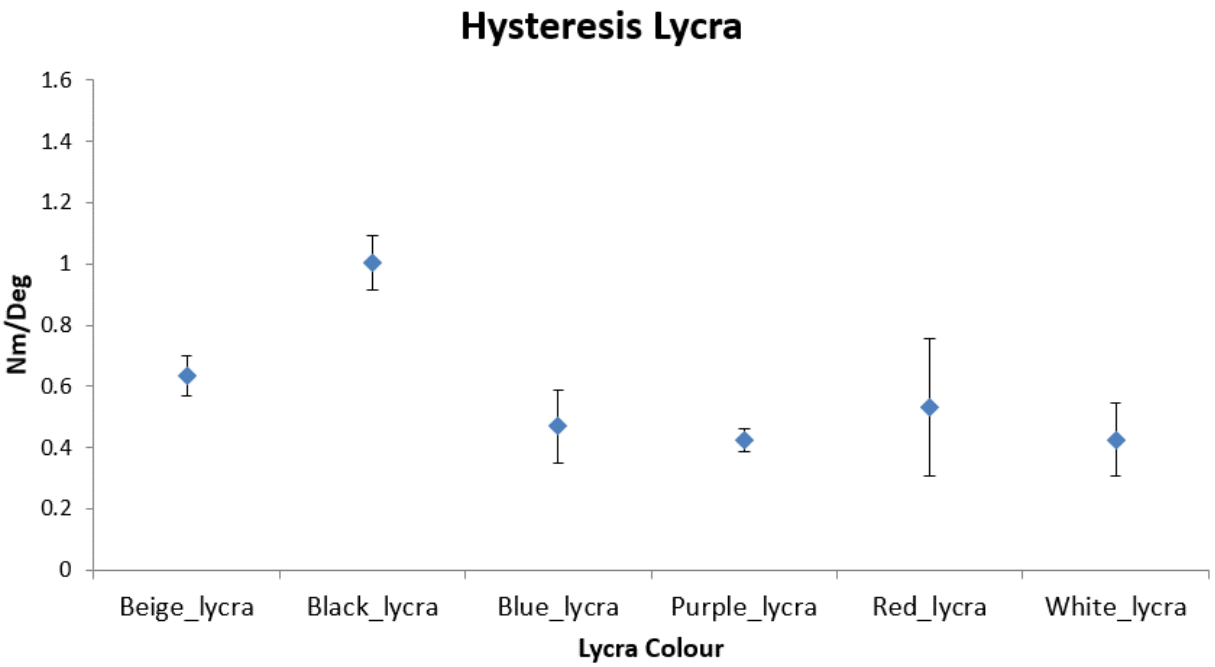
Figure 2.7 *Fabric stiffness Mean and upper and lower 95% confidence intervals values for both Lycra (top) and Powernet (bottom)*

2.6.2 Fabric Elastic Hysteresis Results

The area under the curve varied with the colour of the lycra and powernet (Table 2.2 and Figure 2.8). Higher values indicate that the fabric was more viscous; offering greater resistance to movement with faster stretches. For lycra the most viscous material was the black colour whilst for Powernet the most viscous material was the blue colour.

Fabric Colour/Type	Mean (Nm/deg)	95% Lower CI	95% Upper CI
Beige Powernet	0.98	0.91	1.04
Black Powernet	1.17	1.06	1.27
Blue Powernet	1.37	1.31	1.45
Purple Powernet	1.20	1.08	1.31
Red Powernet	1.25	1.09	1.38
White Powernet	0.85	0.81	0.89
Beige Lycra	0.63	0.57	0.70
Black Lycra	1.00	0.91	1.09
Blue Lycra	0.47	0.35	0.59
Purple Lycra	0.42	0.39	0.46
Red Lycra	0.53	0.31	0.75
White Lycra	0.43	0.31	0.55

Table 2.2 *Hysteresis mean data and 95% confidence intervals (CI); Lycra (top) and Powernet (bottom)*



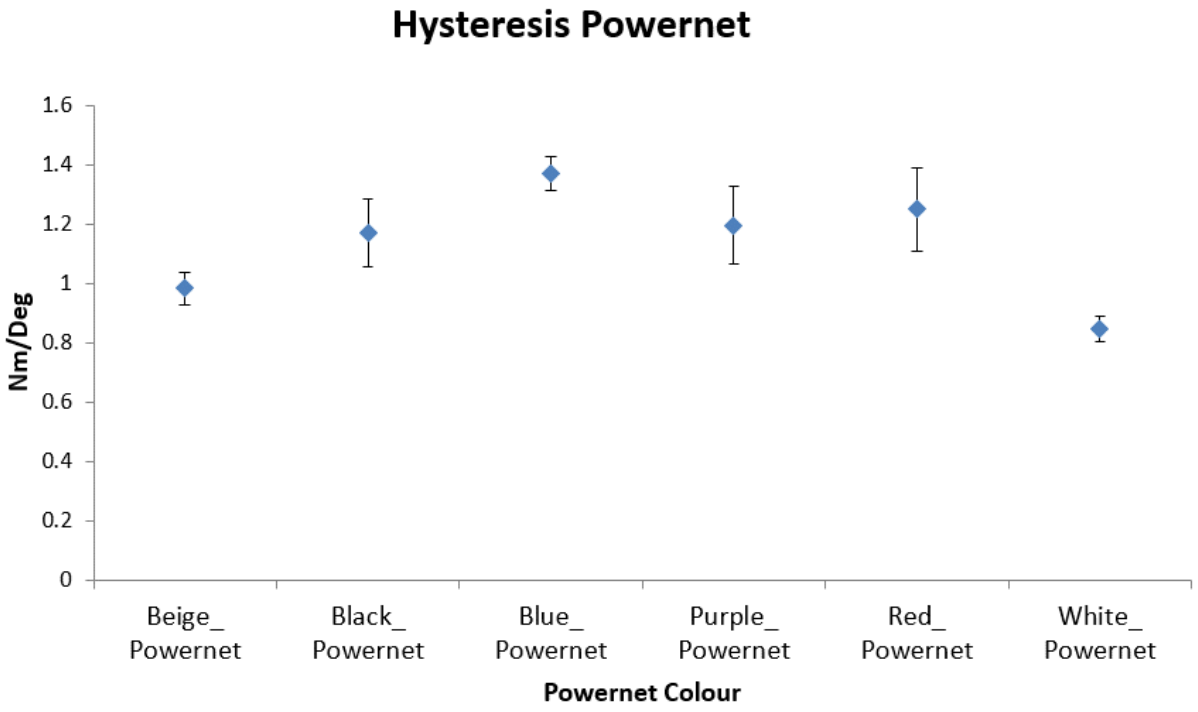


Figure 2.8 *Fabric stretch-recovery hysteresis data, including mean and upper and lower 95% confidence intervals for Lycra (A) and Powernet (B)*

2.7 Discussion

There is little current guidance about standardised testing for pressure garment fabrics. The decision to use the current methods were based partly upon burn management and scar management literature which use similar fabrics (Macintyre and Baird, 2005; Macintyre and Baird, 2006; Macintyre, 2007). There are many factors that could potentially affect the findings. Factors such as fabric slippage, changes in tension around clamp sites, the edge effect (changes in tension around the lateral edges of the fabric) and a wide range of machinery developed to test very similar properties may all have a potential impact on the results(Anbumani and Hayavadana, 2011).

The fabrics that have undergone investigation in this study were those that were available to be selected for use by DM Orthotics Ltd in the construction of the customised DEFO orthoses used for pregnancy related PGP. As described previously, this DEFO aims to add support, and thereby stability, to the participant's pelvic girdle. To have more ecological validity this study would have tested the multi-directional nature of the fabrics since these are the forces that the customised DEFO supplies to the pelvic girdle. However limitations with the laboratory equipment available precluded the testing of such multi-directional, real-time performance. Therefore, a unidirectional test had to be applied to the fabric. Nevertheless, the results were able to provide an estimation of the fabrics' capabilities and properties, and to highlight differences between fabric colours and types. It is not unreasonable to assume that these differences would remain, at least to some extent, with multi-directional testing.

The construction of a pressure garment normally requires a reduction factor to be added, which is a reduction to the initial fabric measurements to allow the fabric to increase pressure to the area it needs to support. This reduction factor is normally

around 20% (Macintyre, 2007). Previous studies testing stretch-recovery have applied a reduction factor to the fabric and this was considered during this study. However, it was decided that the test would be adequate to identify any differences in the fabric properties, and that a reduction factor would be more appropriately required if the research aim was to test pressures supplied by the fabric. The differences in fabric stiffness and elastic hysteresis would have directly affected the level of reduction factor given to each of the participant's pelvic orthoses and therefore we could not standardise our intervention. In the interventional studies undertaken for this dissertation (described in future chapters) it was essential to have a standardised intervention offering the same support and therefore, based on the results of this fabric testing study, a decision was made for the DEFO's to be produced in the same colour for every participant.

The hysteresis values clearly demonstrated the black Lycra material to have the greatest viscosity, with values that were in the mid-range for the Powernet compared to the other colours. Overall, therefore, the black materials offered greater resistance to movement. In addition, informal discussions with women (who are the audience for wearing the orthosis), highlighted a strong preference for black over the other colours. Black was therefore chosen based on the rationale that the aim of the DEFO is to increase pelvic girdle stability as a direct consequence of the external pressure provided by the stiffness of the DEFO, and that acceptability of the DEFO from an aesthetic perspective is important to enhance adherence to wear-time.

There is a potential for each batch of fabric to potentially have slight differences in fabric specification, even within the same colour spectrum. To investigate this we could have repeatedly tested each colour before comparing to

other colours. It is acknowledged that this is a limitation of this study; however, the time constraints imposed by the PhD time schedule meant that this was not feasible to implement. It is proposed that future studies should test individual fabrics more extensively before testing as a group. A further limitation is that the elastic hysteresis was tested in a unilateral direction. To my knowledge there are currently no devices to test such multi-directional, real-time stresses. Should technological advances be made within this area then future studies should incorporate a multi-directional approach to enhance ecological validity.

2.8 Conclusion

The aims of this fabric testing study were to investigate if there were any differences in stiffness and elastic hysteresis between different fabric colours, in both Lycra and Powernet. The results showed a significant difference in fabric stiffness and elastic hysteresis between fabric colours in each type of fabric (Lycra and Powernet). They demonstrated that it would be inappropriate to offer the participants of the interventional pelvic-girdle pain studies a choice in coloured fabric for their customised DEFO orthosis. An evidence-based decision was therefore made to choose a single coloured fabric (black) in production of the customised DEFO used in these studies.

Chapter Three:

Management of Antenatal Pelvic Girdle Pain study (MAPS): A Single Centred, Blinded, Randomised Comparative Trial Evaluating the Effectiveness of Two Pelvic Orthoses

3.1 Introduction

This chapter will detail the RCT, which was undertaken to fill the knowledge gap identified within the literature (Chapter 1). It will include a description and critical appraisal of the research methods used to evaluate the effectiveness of two pelvic orthoses in the management of antenatal PGP. An explanation of the study research question, aims and objectives will be followed by a discussion of the approach used to address the research question. The format of this methods chapter is based around the framework provided by the CONSORT (Consolidation Standards of Reporting Trials) Guidelines for the Reporting of Randomised Controlled Trials (Schulz et al., 2010), the CONSORT Extension for Randomized Trials of Non-pharmacologic Treatment (Boutron et al., 2017), and TiDieR Guidance (Hoffman et al., 2014).

3.2 Background

The background context of this study was introduced in Chapter 1, Section 1.2. There is a need for clinical trials to undertake comparative evaluations to facilitate the knowledge gap that exists for this intervention (Vleeming et al., 2008). This is the first randomised comparative trial undertaken to evaluate the use of a rigid pelvic belt orthosis with a customised dynamic elastomeric fabric orthosis (DEFO) for pregnancy related PGP.

3.2.1 Research Question and Aims

3.2.1.1 *Research Question*

This single-centre, blinded, randomised comparative trial asked the question "In women with pregnancy related PGP, what is the relative clinical and cost-effectiveness of wearing a rigid pelvic orthotic (Serola belt) compared to a customised DEFO, in terms of pain, activity, and health related quality of life?"

3.2.1.2 *Primary Aim:*

To determine the relative effectiveness of a rigid pelvic belt (plus standardised advice) compared to a customised DEFO (plus standardised advice) in affecting the level of pain in pregnant women with PGP.

3.2.1.3 *Secondary Aims:*

- To determine the relative effectiveness of a rigid pelvic belt (plus standardised advice) compared to a customised DEFO (plus standardised advice) in affecting activity levels and health-related quality of life in pregnant women with PGP.

- To determine the cost effectiveness of a rigid pelvic belt (plus standardised advice) compared to a customised DEFO (plus standardised advice) in pregnant women with PGP.

3.3 Methods

3.3.1 Trial Design

A single centred, double blinded, randomised comparative trial (RCT) was used to evaluate the effectiveness of two pelvic orthoses. RCT's are considered the gold standard for evaluating interventions because of their ability to minimise or avoid bias (McPherson et al., 2012). CONSORT guidelines were adhered to in order to maintain a quality and transparent approach to this RCT (Schulz et al., 2010). Ethical approval was gained from the National Research Ethics Service, South West 3 Regional Ethics Committee (REC reference number: 12/SW/0014), and from the Faculty of Health Ethics Committee at The University of Plymouth. National Health Service (NHS) Research and Development approval was gained from the participating NHS centre. The trial was registered with ClinicalTrials.gov, registration number NCT01820013.

3.3.2 Participants

3.3.2.1 Inclusion Criteria

Participants were required to have intermittent PGP (commenced or aggravated by pregnancy), which caused walking and/or stairs to be bothersome and were between 20 and 36 weeks pregnant. The participant also had to test positive on at least three out of seven pain provocation tests (see section 3.3.5).

3.3.2.2 Exclusion Criteria

Potential participants were excluded if they reported any history or signs and symptoms indicative of a serious cause of pain that might be inflammatory, infective, traumatic, neoplastic, degenerative or metabolic, i.e. trauma, unexplained weight loss, history of cancer, steroid use, drug abuse, HIV infection, immunosuppressed state, neurological symptoms such as bowel or bladder, sensory, motor, reflex involvement (cauda equina, lumbar disc lesion, spinal stenosis), fever, systemically unwell, obstetric complications, pain that did not improve with rest/severe disabling pain, history of chronic back or pelvic pain requiring surgery, focal inflammatory signs/tenderness of the spine (spondylolisthesis). Also excluded were any participants who had a known allergy to Lycra, or were <20 or > 36 weeks pregnant. The decision was taken to not enrol any participants before 20 weeks due to the potential for increased complication rates within the 1st Trimester. Along the same lines, they were not enrolled into the trial if they were > 36 weeks pregnant due to the time it would take to issue the participant with a customised pelvic orthosis; the participant would already be 37 weeks pregnant and very close to their delivery date, which would effectively make the orthosis redundant.

3.3.2.3 Recruitment Process, Setting and Location

The trial, and associated recruitment processes were carried out within the Princess Alexandra Wing (maternity department) at The Royal Cornwall Hospital (Treliske, Truro, Cornwall, TR1 3LJ), between January 2013 and July 2014. The Consultant Obstetricians and Midwifery staff were the main recruiters for the study, due to their first contact with participants with pregnancy related musculoskeletal

problems. These staff members raised awareness about the study with their clients and, with the clients consent, subsequently informed the researcher (LC) of potential participants via a generic email account pelvicpainstudy@plymouth.ac.uk or contact telephone number. This ethically approved process had been successfully utilised by other studies previously undertaken within this Department at this Trust. The researcher attempted to contact the participant by telephone within 24 hours to identify if they met the inclusion criteria and, with the verbal consent of the potential participant, booked an initial appointment to undergo further screening for the study. Individuals were invited consecutively until the target sample size had been achieved (see section 3.3.7, page 109).

3.3.3 Screening Procedure

Screening (visit 1) was carried out at The Royal Cornwall Hospital (Treliske), Truro, Cornwall within the outpatient clinic rooms in the maternity department (Princess Alexandra Wing). A second person (female chaperone) was present at this session. Having verbally confirmed the participant wished to take part in the study, their written informed consent was obtained (Appendix 2) prior to enrolment. Following this, the screening procedure was commenced. Data gathered at the screening session occurred in a standardised order:

- Demographic baseline information (age, gestation, parity and body mass index (BMI) (Appendix 3). This information was gathered by self-report, and confirmed by the lead researcher by cross checking details with the participant's medical records.

- Identification of pain sites using a Pain Referral Map (Appendix 4)
- Pain provocation test battery (section 3.3.5).

If the participant met the inclusion criteria they were then enrolled in the study.

3.3.4 Study Procedures

Following enrolment into the study, the participant was immediately measured for a pelvic orthosis (measurements detailed in section 3.3.9). They were then requested to return to the clinic for a pre-scheduled appointment with the researcher one week later.

After the participant left the room, they were immediately randomly allocated by the method of minimisation (see section 3.3.8) to either group A or B. Depending on group allocation, the researcher then either conveyed these measurements to DM Orthotics Ltd to enable manufacturing of the customised DEFO, or to collect a correctly sized Serola Belt.

The participant returned to the outpatient clinic rooms in the maternity department at The Royal Cornwall Hospital in seven days. At this appointment the female chaperone provided the participant with their first questionnaire to independently complete in the waiting room before contact with the researcher (to maintain researcher blinding). When they had completed their first baseline self-report questionnaire booklet (Appendix 5) the participant placed the questionnaire booklet into a sealed, opaque, freepost envelope and was asked by the chaperone to then post the envelope.

Following completion of the questionnaire booklet, the participant was seen by the researcher who fitted them with either a customised DEFO or Serola Belt, depending on their randomised group allocation. They were provided with a standard advice sheet regarding the washing of their orthosis (Appendix 6) and the standard advice booklet from the Association of Pelvic, Obstetric and Gynaecological Physiotherapy (see section 3.3.9.3). They were also given two folders containing their self-report, postal questionnaire booklets:-

- Folder One: this pink folder (Appendix 7) contained the self-report, postal questionnaire booklets and freepost envelopes for the participant to complete during their pregnancy. This folder contained between three and 10 self-report questionnaire booklets depending upon their current gestation time.
- Folder Two: this blue folder (Appendix 7) contained the self-report, postal questionnaire booklets and freepost envelopes for them to complete during their first six weeks post-partum. This folder contained three self-report questionnaire booklets.

The only time the participant was contacted was if they did not return a self-report questionnaire booklet or if there was missing information on their returned self-report questionnaires, as identified by the independent (blinded) assistant.

The participants were requested to return their self-report postal questionnaire booklets every two weeks from the date they received their orthosis. The associated freepost envelopes were addressed to 'PELVIC PAIN STUDY, Faculty of Health, Education & Society, Peninsula Allied Health Centre (Derriford Road), University of Plymouth, FREEPOST PHY271, Drake Circus, PL4 8ZZ'. Each envelope was uniquely identifiable by the independent blinded assistant by a unique code containing

‘Participant number, questionnaire number, and pre or post pregnancy e.g. P01-WK01-PREPREG or P01-WK01-POSTPREG and once checked the questionnaire booklet was locked into a steel cabinet, within a locked office, which only the external assistant had access to.

The independent blinded assistant was responsible for checking every questionnaire booklet that was received to ensure that every question within the questionnaire booklet was completed correctly (for example a number outside of the possible available range). If there was any missing or incorrect data or a questionnaire booklet had not been received, the independent assistant immediately issued the researcher with the participant ID and the item on the questionnaire that was missing or completed incorrectly. This ensured that the information was gained in a timely manner so that it was relevant to the same questionnaire week. The researcher then telephoned the participant, to obtain any missing data. This was the only time that the participant could have potentially been influenced, or the researcher could have biased the proceedings. To prevent this happening at the beginning of the telephone conversation the researcher informed the participant that they were being contacted as the questionnaire had some missing information and the researcher would like to gather this information. The researcher then read the question out, asked the participant for a response, and repeated that the researcher could only read the question and not explain or alter it. The use of a script allowed all telephone conversations with participants to be standardised.

3.3.5 Pain Provocation Tests

A wide range of pain provocation tests are currently used for the diagnosis of pregnancy related PGP (Vleeming et al., 2008). They are divided between sacro-iliac joint (SIJ) and symphysis pubis (SP) pain provocation tests, to identify between posterior and anterior PGP respectively. Common tests which have been identified in the literature for SIJ symptoms are the Posterior Pelvic Pain Provocation (PPPP or P4), Long Dorsal Sacroiliac Ligament (LDL), Patrick's/Flexion-Abduction-External Rotation (FABER), Compression, Separation, Distraction, Sacral Thrust, Gaenslen's test and Menell's Test (Albert et al., 2000; Arab et al., 2009; Gutke et al., 2010; Laslett et al., 2005; Robinson et al., 2007;). Tests identified for the SP symptoms are the Modified Trendelenburg test and Palpation of SP (Albert et al., 2000; Hansen et al., 1999; Kristiansson et al., 1996;). The following section will detail the reasoning behind why specific pain provocation tests were chosen for this study. These decisions were informed by the literature, which included the most recent European Guidelines (Vleeming et al., 2008) for the diagnosis and treatment of PGP. Key to selection of the screening measures were that they demonstrated good levels of sensitivity and specificity as diagnostic screening tests, and that they generated reliable results.

3.3.5.1 *Pain in the Sacroiliac Joint (SIJ)*

The European Guidelines (Vleeming et al., 2008) supported the use of four pain provocation tests from the above list for the diagnosis of posterior PGP, of which three were considered for this study; the posterior pelvic pain provocation test (P4/Thigh thrust), Patrick's FABER test, and Gaenslan's test. Within the literature there is a wide variability in results for the sensitivity, specificity and validity of these tests (Albert et

al., 2000; Arab et al., 2009; Gutke et al., 2010; Hansen et al., 1999; Laslett et al., 2005; Robinson et al., 2007; Vleeming et al., 2008;), which is thought to be due to differing sample sizes, different sample populations, experience of examiners and stages of pregnancy (antenatal or post-partum). Table 3.1 shows the inter-rater reliability (kappa coefficient level) of these tests and Table 3.2 shows the sensitivity and specificity for the chosen SIJ pain provocation tests. To optimise sensitivity and specificity it has been suggested that a cluster of techniques are performed for the diagnosis of SIJ symptoms, therefore the participant was considered positive for posterior PGP and eligible for the study if they were found to be positive in two out of five SIJ tests (Arab et al., 2009; Laslett et al., 2005; Robinson et al., 2007).

3.3.5.1.1 *Posterior Pelvic Pain Provocation Test (P4,PPPP test)*

To perform the P4 test the patient lies supine with the hip flexed to 90°. The examiner applies pressure on the flexed knee in the longitudinal axis of the femur while stabilizing the pelvis, with the other hand resting on the opposite anterior superior iliac spine. The test is considered positive if this maneuver produces a familiar pain in the gluteal region of the provoked side. It is recorded as either yes or no and both left and right sides are tested and scored separately, therefore this test can potentially be counted as two positive tests per participant.

The P4 test has demonstrated a kappa coefficient level of 0.70 when tested within a pregnant population (Albert et al., 2000). This study by Albert et al. (2000) completed a battery of 15 pain provocation tests on a large sample of 535 pregnant women, who met inclusion criteria from a possible 2269 women. Other studies report variable reliability (0.50-0.80) within a non-pregnant population (Gutke et al., 2010); Robinson

et al., 2007). Even though this level of reliability is rated as good to moderate, it is unclear as to why there is such a wide spectrum of values. It is hypothesised that this is related to the limitations previously discussed within this section, namely the differing sample sizes, populations, experience of examiners and stages of pregnancy.

Test	Kappa Coefficient	Population	Author
P4	0.70	Women peri-partum	Albert et al. (2000)
	0.50-0.80	Non pregnant	Gutke et al. (2010)
	0.74-0.76	Non pregnant	Robinson et al. (2007)
FABERS	0.54	Women peri-partum	Albert et al. (2000)
	0.48-0.60	Non pregnant	Robinson et al. (2007)
	0.44-0.49	Non pregnant	Arab et al. (2009)
Gaenslan's	0.41-0.50	Women peri-partum	Gutke et al. (2010)
	0.72	Non pregnant	Laslett et al. (2005)
	0.61	Non pregnant	Dreyfuss et al. (1996)

Table 3.1 *Inter-rater reliability scores for the sacro-iliac joint provocation tests, detailing kappa coefficient levels*

The P4 test has been specifically evaluated for use in antenatal women and has demonstrated to have a sensitivity and specificity of 0.69-0.93 and 0.80-0.98 respectively (Albert et al., 2000; Kristiansson et al., 1996; Mens et al., 2001; Ostgaard et al., 1994). Studies by Dreyfuss et al., (1994, 1996) reported much lower sensitivity and specificity levels (0.36 and 0.50 respectively). However, systematic reviews have questioned the validity of the results of the studies by Dreyfuss (Van der Wurff et al., 2000) because of their poor methodological quality as reflected by their lack of documentation about blinding, examiner experience, inclusion/exclusion criteria, and no standardization in the description of the performed pain provocation test.

3.3.5.1.2 *Patrick's or FABER (Flexion, Abduction, External Rotation) Test*

To perform the FABER test the patient lies supine; the examiner flexes the hip, and abducts and externally rotates one leg to bring the ipsilateral heel to rest on the opposite knee. The patient is asked to relax the limb to allow the weight of the leg to draw the knee toward the floor. The test is considered positive if pain is felt in the ipsilateral SIJ or in the symphysis pubis.

The FABER test has shown to have some of the highest reliability and specificity scores, and is one of the most commonly used tests along with the P4 test (Albert et al., 2000; Arab et al., 2009; Hansen et al., 1999; Van der Wurff and Meyne, 2000; Vleeming et al., 2008). Albert et al. (2000) reported it to have a moderate kappa coefficient level (kappa = 0.54), which is consistent with other authors findings showing a kappa level of 0.48-0.62 amongst a post-partum PGP population (Robinson et al. 2007). The FABER test was deemed to have a superior sensitivity of 0.70

compared to the other 15 pain provocation tests that were studied, and was reported to have a very high specificity of 0.99.

The sensitivity of the FABER test has been reported to be 0.41-0.70 (peri-partum) and 0.57-0.77 (non-pregnant) and with a specificity of 0.99 (peri-partum) and 0.49-1.00 (non-pregnant) (Albert et al., 2000; Arab et al., 2009; Hansen et al., 1999; Van der Wurff and Meyne, 2000; Vleeming et al., 2008), showing the test to have moderate (although variable) sensitivity but very high specificity.

3.3.5.1.3 *Gaenslan's test*

To perform Gaenslan's test, the patient lies supine near the edge of the table. One leg hangs over the edge of the table and the other hip and knee is flexed towards the patient's chest. The examiner applies firm pressure to the knee being flexed to the patient's chest and a counter pressure is applied to the knee of the hanging leg, towards the floor. The procedure is carried out on both sides (thus it can be counted as two tests). The test is positive if the patient experiences pain in the SIJ or gluteal area.

Inter rater reliability has been evaluated for women peri-partum producing kappa levels of 0.41-0.50 (Gutke et al., 2010) and for non-pregnant populations kappa levels of 0.61-0.72 (Dreyfuss et al., 1994; Dreyfuss et al., 1996; Laslett et al., 2005). The sensitivity and specificity have shown to be moderate to good (0.50-0.63 and 0.71-0.79 respectively) (Gutke et al., 2010; Laslett et al., 2005; Van der Wurff and Meyne, 2000). Studies by Dreyfuss et al., (1994, 1996) were excluded by Van der Wruff and Meyne (2000) when completing a systematic methodological review. The Dreyfuss studies presented a sensitivity of 0.71 but specificity of 0.26 that was unusual as it differed markedly from many other studies; it was excluded due to a low methodological score.

Test	Sensitivity	Specificity	Population	Author
P4	0.81	0.80	Women Peri-partum	Ostgaard et al. (1994)
	0.84-0.93	0.98	Women peri-partum	Albert et al. (2000)
	0.69	0.90	Women peri-partum	Kristiansson et al. (1996)
	0.69		Women peri partum	Mens et al. (2001)
	0.88	0.69	Non pregnant	Laslett et al. (2005)
	0.80	1.00	No pregnant	Van de Wurff et al. (2000)
	0.93	0.64	Non pregnant	Van de Wurff et al. (2000)
FABERS	0.70	0.99	Women Peri-partum	Albert et al. (2000)
	0.77	1.00	Non pregnant	Van der Wruff et al. (2000)
	0.44	0.49	Non pregnant	Arab et al. (2009)
	0.41-0.44	No data	Women peri-partum	Hansen et al. (1996)

Gaenslan's test	0.50-0.53	0.71-0.77	Non pregnant population	Laslett et al. (2005)
	0.63	0.79	Non pregnant population	Van der Wruff et al. (2000)
	0.71	0.26	Non pregnant population	Dreyfuss et al. (1996)

Table 3.2 *Sensitivity and specificity scores for the sacroiliac joint provocation tests*

3.3.5.2 *Pain in the Symphysis Pubis (SP)*

The European guidelines have supported both the Modified Trendelenburg test and the palpation of the SP and both tests have been used within a pregnancy related PGP population (Albert et al., 2000; Hansen et al., 1999; Kristiansson et al., 1996; Vleeming et al., 2008). Table 3.3 shows the inter-rater reliability (kappa coefficient level) for each for the tests and Table 3.4 shows the sensitivity and specificity for the chosen SP pain provocation tests. As previously stated, to optimise sensitivity and specificity, it has been suggested to perform a cluster of techniques for the diagnosis of PGP, therefore the participant was considered positive for posterior PGP and eligible for the study if they were found to be positive in one out of the two SP tests (Arab et al., 2009; Robinson et al., 2007).

3.3.5.2.1 *Direct Palpation of the Symphysis Pubis*

To perform this test the examiner palpates the participants symphysis pubis and if the woman experiences symphyseal pain, then the test is considered positive (Vleeming et al., 2008). The palpation of the SP has shown to have acceptable reliability with kappa levels of 0.55-0.89 (Albert et al., 2000). Sensitivity and specificity has been reported as 0.60-0.87 and 0.85-0.99 respectively (Albert et al., 2000; Hansen et al., 1999; Kristiansson et al., 1996).

Test	Kappa Coefficient	Population	Author
Palpation of the SP	0.89	Women peri-partum	Albert et al. (2000)
	0.55	Women Peri-partum	Wormslev et al. (1994)
Modified Trendelenburg test	0.63	Women peri-partum	Albert et al. (2000)
	0.52	Women peri-partum	Wormslev et al. (1994)

Table 3.3 *Inter-rater reliability scores for the symphysis pubis provocation tests, detailing kappa coefficient levels.*

Test	Sensitivity	Specificity	Population	Author
Palpation of the SP	0.60-0.81	0.99	Women Peri-partum	Albert et al. (2000)
	0.87	0.85	Women peri-partum	Kristiansson et al. (1996)
	0.80	No Data	Women peri-partum	Hansen et al. (1996)
Modified Trendelenburg Test	0.60-0.62	0.99	Women Peri-partum	Albert et al. (2000)
	0.40	No Data	Women Peri-partum	Hansen et al. (1996)

Table 3.4 *Sensitivity and specificity scores for the symphysis pubis provocation tests*

3.3.5.2.2 *Modified Trendelenburg tests*

To perform the Modified Trendelenburg test the patient stands on one leg and flexes the ipsilateral hip and knee to 90 degrees. If pain is experienced in the symphyseal area then the test is considered positive (Vleeming et al., 2008). Reliability scores for the Modified Trendelenburg test show acceptable kappa levels of 0.52-0.63 (Albert et al., 2000; Hansen et al., 1999). It has been shown to have reduced sensitivity compared to palpation of the SP (0.40-0.62) (Albert et al., 2000; Hansen et al., 1999; Kristiansson et al., 1996). The sensitivity and specificity of this test has been reported to be 0.40-0.62 and 0.99, respectively (Albert et al., 2000; Hansen et al., 1999; Kristiansson et al., 1996), which is considered acceptable.

3.3.5.3 *Feasibility*

The feasibility of implementing a battery of outcome measures is an important consideration, for instance in minimizing patient burden, participant drop-out, and missing data. Therefore, in the design stage of the study, a discussion was undertaken with an experienced midwife regarding the feasibility of implementing the pain provocation tests in women suffering with severe PGP who would be participating in this study. There was concern that the tests would potentially exacerbate the participants' symptoms, with subsequent impact on both the participants' well-being, and methodological issues such as a reluctance for potential participants to engage in the study having completed the screening phase. The outcome of this clinically focused discussion was that a hierarchy of tests would be performed, aimed at limiting irritation of the women's current symptoms whilst remaining sensitive to identifying the presence of PGP (figure 3.1). For the SIJ pain provocation tests the P4 test would be performed first (bilaterally), followed by FABERS test (bilaterally), followed by Gaenslan's test. As soon as the participant had met the inclusion criteria for the study the testing would cease to avoid further potential exacerbation. If inclusion was not met then the screening tests would continue.

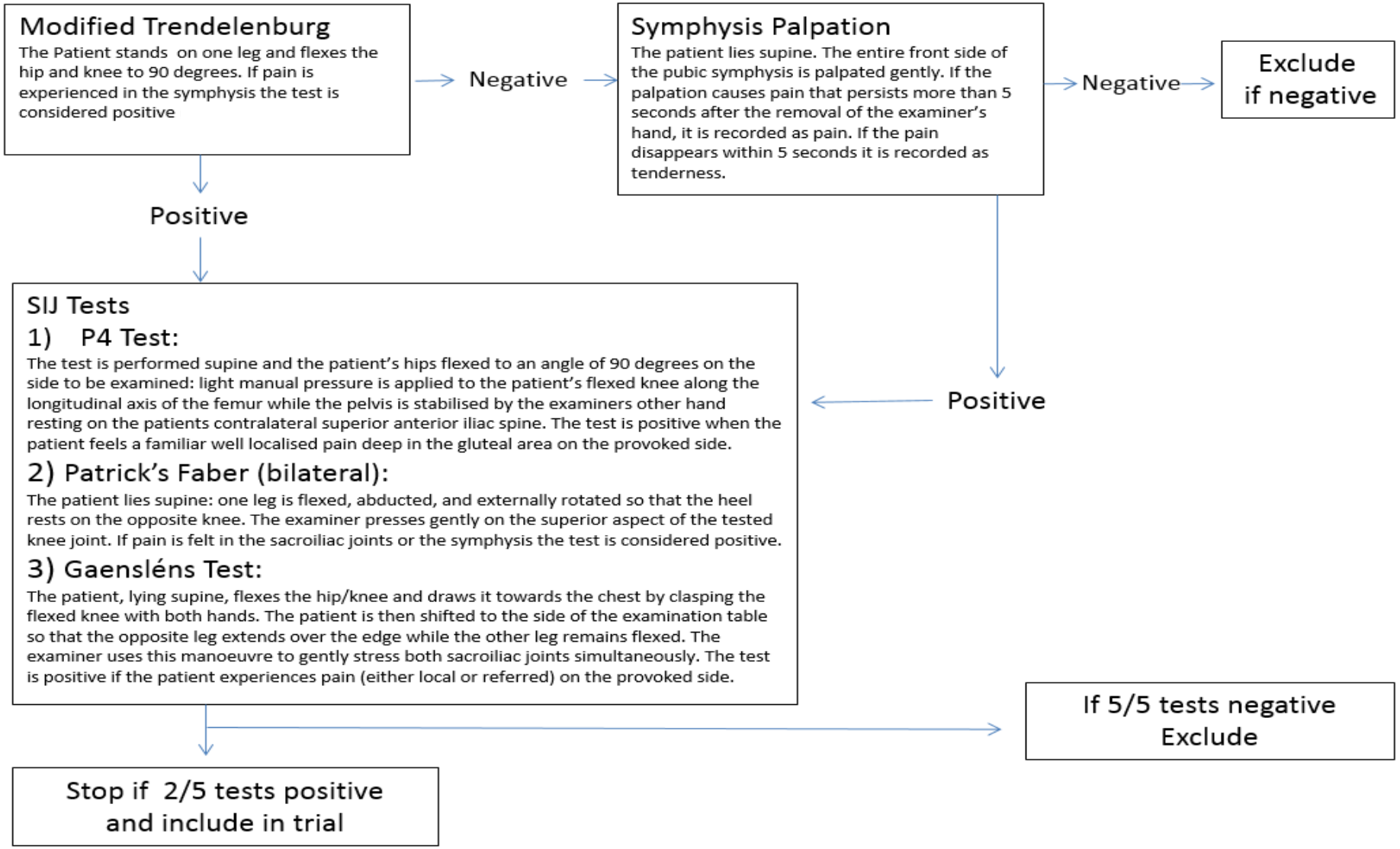
The order of the tests was organized in the light of both clinical experience and the literature (previously discussed). It was felt that Gaenslan's test would be more difficult to perform on someone with severe PGP and therefore would be the last provocation test implemented. A decision was also made to perform the Modified Trendelenburg test prior to the direct palpation of the SP, as if found to be positive it would prevent the participant from undergoing direct palpation. This was for two reasons; the test can be very unpleasant when implemented, and there are delicate

issues associated with this area of palpation, particularly when the palpation is undertaken by a man, even though a female chaperone was going to be present at all times.

3.3.5.4 *Summary*

All pain provocation tests selected for the study were based on the best available evidence alongside the information provided from the European Guidelines (Vleeming et al., 2008). There are limitations with the pain provocation tests chosen, especially with regard to the validity of the SIJ pain provocation tests, however, given the lack of a 'gold standard' test for PGP, assessing the validity of these tests is challenging. Of importance, the pain provocation tests used in this study have been widely used with the pregnant PGP population, enabling familiarity for the relevant readership in terms of interpreting the results, and the ability to compare the results with other studies in this area.

Figure 3.1 *The pain provocation pathway required for inclusion or exclusion of participants to the study*



3.3.6 Outcome Measures

This section describes the standardised outcome measures that were used to determine the effectiveness of the pelvic orthoses evaluated within this study. These measures were chosen on the basis of their proven psychometric abilities (reliability, validity, responsiveness) to measure the most common symptoms reported in pregnancy related PGP. All outcome measures used within this study are self-report questionnaires. This was due to their feasibility and low cost of implementation; clinician rated measures would have required participants to attend a potential 15 clinic appointments. This was considered prohibitive for a number of reasons. Most importantly it would have been overly burdensome to participants, many of whom would be experiencing considerable PGP when travelling. This inevitably would have impacted on both recruitment and drop-out rate, and hence the generalizability of study results. Furthermore, it would have incurred extensive researcher time, chaperone costs and expenses for all parties, which was cost-prohibitive within the scope of this PhD dissertation.

The individual self-report questionnaires are described in turn below. For the purposes of this study they were all compiled into a single stapled booklet, to minimise the potential for loss of questionnaires and to optimise the likelihood of the questionnaires being completed by the participants in the same order. These questionnaire booklets were provided to the participants at the beginning of the study in two folders (see appendix 7). A total of between 79 and 88 questions could be answered within the booklet. Some answers required extra information if answered 'yes' or 'no' and that could lead to an extra nine questions from the core 79.

The primary outcome measure used was the Numerical Pain Rating Scale (NPRS); to evaluate changes in pain levels. For the secondary outcome measures a disease specific questionnaire, the Pelvic Girdle Questionnaire (PGQ) was used to identify activity/disability levels. Non-disease specific questionnaires - the European quality of life - 5 Dimensions (EQ5D – 5L) and the Short-Form 36 Item Health Survey version 2 (SF36-V2) - were used to identify changes in health related quality of life. All selected questionnaires were chosen for their proven psychometric properties. The intention of the following sections is to review the reliability, validity and responsiveness of each measure.

3.3.6.1 *Primary Outcome*

3.3.6.1.1 *Numerical Pain Rating Scale (NPRS)*

The NPRS is widely used within healthcare and has been considered appropriate for research and clinical practice due to good validity and reliability and self-report being the gold standard for reporting pain (Ferreira-Valente et al., 2011; Jensen et al., 1999; Williamson and Hoggart et al., 2005). The NPRS aims to measure the participant's perceived pain intensity using an 11-point self-report scale consisting of integers from 0 (no pain) to 10 (unbearable pain). The participant is required to select one number that best represents their pain intensity. In this study pain intensity was measured using the NPRS, by asking participants two questions: "Over the last week, how would you rate your average level of pelvic pain *during the day*?" and "Over the last week, how would you rate your average level of pelvic pain *during the night*

(after going to bed)?" Pain classifications were divided between mild pain, (0-4) moderate pain, (5-7) and severe pain (8-10).

Many studies have shown the NPRS to have good validity in a wide range of disease populations (Childs et al., 2005; Farrar et al., 2008; Ferreira-Valente et al., 2011; Jensen et al., 1999; Hjermstad et al., 2011). Acceptable to good levels of test re-test reliability have also been demonstrated by a number of studies including that of Childs et al. (2005)(ICC 0.61) and Farrar et al (2008) (ICC = 0.83) (Farrar et al., 2008).

When using an outcome measure it is important to consider the measure's ability to detect change over time. The minimal detectable change (MDC) can be considered, as the smallest change, which is not likely to be due to measurement error (Wright et al., 2012). Childs et al. (2005) determined that the MDC of the NPRS required a two-point change to be statistically significant and thus avoid any change being attributable to random error (MDC= 1.99 points). It is important to consider that the MDC is calculated on a statistical threshold, meaning that the MDC alone does not provide information on clinical significance (Wright et al., 2012). Also important to consider is the score change that is meaningful to the patient. This is termed the minimal clinically important difference (MCID) (Ferreira et al., 2012). It is the smallest difference in score reported by patients that correlates with the patient stating they are 'slightly better' in comparison to early scores (Salaffi et al., 2004). As the MCID is based upon patient response-anchor method, it is more appropriate for assessing clinical significance (Wright et al., 2012).

However, this can be complicated to interpret, since the importance of a change in pain intensity can differ depending upon issues such as where the score is on the pain scale, or the health condition (Dworkin et al., 2008). A number of studies have

attempted to define what score change reflects this clinically significant change for the NPRS in musculoskeletal conditions. The range of values across these studies, however, do differ. For example, Salaffi et al. (2004) reported that a 15.0% (1 point) change on the NPRS represented the MCID for the patient signifying a 'slightly better' change. Others have determined that a two-point change is required to be deemed clinically significant (Farrar et al., 2001; Jensen et al., 1999), with a 1.7 point change required for those with chronic musculoskeletal pain (Farrar et al., 2001). Whilst recognising these differences exist, recommendations have been made for interpreting the clinical importance of treatment outcomes in chronic pain clinical trials (The IMMPACT Recommendations, Dworkin et al., 2008). These recommendations suggest that, on the basis of the available body of research, score changes of approximately 1 point represent minimally important (but perhaps not very important) decreases in pain when using the NPRS. This provides the rationale for defining what constituted a clinically important change in our study. It is acknowledged that this needs to be confirmed in future studies that directly assess patient evaluations of what is noticeable, important, and major improvement in the pregnancy-related pelvic girdle pain population.

The NPRS is more responsive than other commonly used pain rating scales (such as the Visual Analogue Scale, Verbal Rating Scale and Faces Pain Scale-Revised) (Ferreira-Valente et al., 2011). Furthermore, in a study using temperature change to differentiate pain levels (1 °C - 7 °C), the NPRS, when compared to the VAS, was found to have a marginal increase in effect size (0.25- 0.59 NPRS compared to 0.22- 0.58 VAS) and higher f values (93.49 - NRS and 85.74 - VAS).

Jensen et al., (1999) concluded that pain scale ratings consisting of 0-10 are psychometrically robust in terms of reliability, validity and responsiveness in a wide range of disease populations. It was suggested that a 0-10 point scale provides maximal reliability when using smaller sample sizes or following pain intensity in an individual. To further support its use within this study, it has been recommended for group level analysis as it allows for statistical testing (Jensen et al., 1999). Additional qualities that influenced the choice of the NPRS related to its ease of use, simplicity and time effectiveness (it takes less than three minutes to complete). In line with this, it has been reported to have higher compliance rates and less error rates when compared to the VAS which was deemed to be potentially more complicated (Hjermstad et al., 2011).

3.3.6.2 *Secondary Outcomes*

3.3.6.2.1 *Pelvic Girdle Questionnaire (PGQ)*

The Pelvic Girdle Questionnaire (PGQ) is a condition-specific, self-report questionnaire. It was initially developed because of the lack of distinction between low back pain and PGP outcome measures, and evaluates treatment outcomes relating to activity/participation and body functions/symptoms specifically for the pregnant PGP population (Stuge et al., 2011). The PGQ consists of 25 questions, using a 4-point Likert scale (0, not at all; 1, to a small extent; 2, to some extent and 3, to a large extent). The 25 questions are related to activity (20 questions) and symptoms (5 questions). It is easy to use and takes approximately three minutes to complete. It is the first, and to my knowledge the only, condition-specific questionnaire designed for PGP; with

limited studies to date that have evaluated its psychometric qualities. The initial study by the developer of this outcome measure, Stuge et al. (2011) reported acceptability, high validity and reliability, however more research is required to further support this claim.

In the development of this questionnaire, focus groups were undertaken of patients experiencing PGP (both antenatal and post-partum), during which time they were asked to detail the activities they considered most important to them. This was undertaken to optimise its content validity (Grotle et al., 2012; Stuge et al., 2011). Alongside this, literature searches were completed to identify all other outcome measures that had been used to evaluate PGP; and a Rasch analysis undertaken to enable item reduction (Stuge et al., 2011).

Grotle et al. (2012) provides evidence to support the discriminative validity of the PGQ, demonstrating that the questionnaire discriminated females who were pregnant from females who were not, and also females who were peri-partum from those who were post-partum. The PGQ included pain location as it was specifically designed for patients suffering with PGP.

The PGQ has also been shown to have high reliability (Cronbach's alpha=0.86) and test re-test reliability (ICC=0.93) within the pregnant PGP population (Grotle et al., 2012; Stuge et al., 2011).

There is limited published evidence to support the responsiveness of the PGQ. The MDC, i.e. the smallest amount of change which is considered real change and not due to measurement error, and is commonly used to determine the responsiveness of a measure. For the PGQ it has been calculated at between 7-14% in the pregnant PGP population (Grotle et al., 2012).

In conclusion, there is a small body of evidence to suggest the PGQ has good internal consistency, test re-test reliability and validity (content, face and discriminative). It has been recommended for the evaluation of treatments aimed at pregnancy related PGP participants by identifying symptoms and disability in both clinical and research environments; however, more research is needed to further explore the psychometric properties of the PGQ.

3.3.6.2.2 *Short Form 36 – Version 2*

The Short-Form 36 – item health survey version 2 (SF-36v2) is a self-report questionnaire developed from the Medical Outcomes Study (MOS), and is described as the gold standard self-report questionnaire for generic health related quality of life (HRQoL) (Ware, 1992; Ware and Gandek, 1998). The SF-36v2 asks participants to rate their quality of life over the past week. Given that assessments were undertaken on a two weekly basis in our study, this version was selected over the standard SF-36 which uses a four-week timeframe for the participants to consider when rating their quality of life, and which therefore was inappropriate. It contains 36 questions, assessing eight of the following dimensions: physical functioning, social functioning, function limitations secondary to physical problems, function limitations secondary to emotional problems, mental health, vitality, pain and general health. Participants are required to answer the questions using a three, five and six-point Likert scale (one answer per question). To analyse the data 'raw scores' are converted to a 100 point scale in which a higher number reflects a better health related functional status (Forger et al., 2005; Ware et al., 2000).

The SF36 has been shown to have good internal consistency (Cronbach's alpha level a=0.85) and test re-test reliability (intra-class correlation coefficient [ICC] =0.75) (Brazier et al., 1992), for all dimensions except social functioning where internal consistency has shown to be lower (Cronbach's a=0.64) (Picavet and Hoeymans, 2004); potentially because of the low number of items (two) in that dimension (Brazier et al., 1992). The test re-test reliability has also been confirmed by Grotle et al. (2012), with an acceptable to good level of test re-test reliability (ICC = 0.78-0.89).

Evidence from a range of studies in varied populations demonstrates that the SF36 has good validity (for example, Brazier et al., 1992; Grotle et al., 2012). More specifically in relation to PGP the study by Grotle et al., (2012) assessed the SF36's construct and discriminative validity along with other commonly used outcome measures with females suffering with PGP. It was shown that the SF36 had good construct validity when used within this population, however, the measure did not satisfactorily discriminate for patients suffering with pregnancy related PGP, and this could be because it is not a disease specific questionnaire. The PGQ which is a disease specific questionnaire (previously discussed in section 3.3.6.2.1) was deemed to have the best discriminatory validity in this population.

To evaluate the effect that an intervention has had on a participant's HRQoL the MDC has been considered within previous studies (Escobar et al., 2007; Grotle et al., 2012; Quintana et al., 2005). The study by Grotle et al. (2012) assessed the SF-36 responsiveness within the pregnancy PGP population. They identified an MDC (individual) of 7.3 and 12.8 and MDC (Group) of 1.1 to 2.0. Measurement errors were reported to be low at 7% to 14% for the MDC (individual), and for MDC (group) was

18% to 22% which was similar to previous studies reported for self-report measurements (10% to 35%) (Grotle et al., 2012 Wolfe et al., 2007).

Other advantages of the SF36v2.0 are the practicality of the measure and its broader coverage (Picavet and Hoeymans, 2004). It requires low contact time with patients which reduces patient burden, and which can be cost effective when undertaking research and also within a clinical setting when patient time is limited, it is easy to use and it is self-administered. It has also been shown to have no floor or ceiling effects, giving confidence that the measure will detect both improvement and decline in a patient's outcome or health.

3.3.6.2.3 *European Quality of Life - 5 dimensions – 5 Level (EQ5D – 5L)*

The European Quality of Life - 5 Dimensions Questionnaire (EQ-5D) is a short, generic, self-report questionnaire for subjectively describing and valuing HRQoL. It is one of the most common, nationally used outcome measurement tools (Johnsen et al., 2013) and has been clinically and scientifically approved (Rabin and de Charro, 2001). It was developed to be a non-disease specific measure that could be used alongside other HRQoL measurement tools. It can be used to measure health and to gain a standardised health index to complete a cost utility or cost-effectiveness analysis (Badia et al., 2001).

The instrument is comprised of five questions divided into mobility, self-care, usual activities, pain/discomfort, anxiety and depression. The participants answer the questions using a five-point Likert scale. When the questionnaire is complete it is scored to give a health index. The values allocated range from one to five (no problem =1, slight problem = 2, moderate problem = 3, severe problem = 4 and unable = 5),

therefore an answer of 'no problem' for each question gives a health index of '11111', indicating "full health". This health index is then used to calculate an index value (using EQ5D software) which is compared to a value set which provides an overall health profile.

Some authors have expressed concerns that pre-set values can lead to wrongly expected views due to population norms variation which may occur with different cultures, experiences and language differences (Badia et al., 2001). The European Quality of Life group have completed value sets for the UK, France, Denmark, Germany, Netherlands, Japan, Spain, Zimbabwe and the United States to allow for more accurate profiles to be gained (Grenier et al., 2003). There are a total of 243 potential health states that have been validated by the Measurement and Valuation of Health Group, who undertook a large-scale survey within the UK to validate the EQ-5D time trade off health states using 2997 interviews of the general population (Rabin and de Charro, 2001). There is also a VAS ranging from 0 (worst health you can imagine) to 100 (best health you can imagine) which is 20 centimetres long to score how good or bad your health is today.

A significant benefit of the EQ5D is that Quality Adjusted Life Years (QALYs) can be calculated from the index score which enables a cost utility or cost-effectiveness analysis to be completed to test the effectiveness of the intervention. QALYs are the number of life years that would be added following an intervention (Rabin and de Charro, 2001); they are calculated using a time trade off technique.

Despite the EQ5D being a non-disease specific outcome measure there is a direct relevance to both the primary and secondary aims of the RCT study undertaken for this dissertation; its dimensions are relevant to the symptoms experienced by

females with pregnancy related PGP showing good face, content and construct validity. Further, it has been found to have good test re-test reliability (Keller et al., 1998).

To test the responsiveness of the EQ5D, Orbradovic (2013), compared the questionnaire to the SF-6D and a disease specific questionnaire, in this case, chronic pain (Obradovic et al. 2013). The standard response mean (SRM)*)* is one of several available effect size indices used to gauge the responsiveness of scales to clinical change along with mean (*M)*. The SRM is computed by dividing the mean score change by the standard deviation of the change. It was shown the EQ-5D had a greater SRM than the SF-6D, with participants within the mild to moderate criteria reporting SRM=0.65 (*M*=0.142), moderate to severe SRM = 1.33 (*M*=0.418) and severe to extreme 2.02 (*M*=0.608). The EQ-5D has been used amongst the PGP population to identify changes in HRQoL. The study by Gutke et al. (2011) identified one in three participants reported moderate to severe disability (Gutke et al., 2011). It was also shown by Picavet (2001) who used both the EQ-5D and SF-36 to identify HRQoL changes associated with musculoskeletal disorders. The EQ5D was able to discriminate in detecting participants with a musculoskeletal disorder compared to the general population and this was represented with a worsening quality of life. The studies above identify the EQ-5D's ability to detect worsening health, however, Harrison et al. (2009) reported that it was also responsive in detecting improvement in a participant's health.

Some disadvantages of the EQ-5D have been reported by Brazier et al. (1999), who highlighted potential ceiling effects when compared to the SF-6D. He identified that participants who reported full health in the EQ-5D were still identified as having some difficulties with physical functioning, mental health and vitality. These are

sections which are included within the EQ-5D, but it was suggested by Brazier et al. (1999) that the addition of more intermediate levels within each section may reduce any ceiling effect.

The EQ-5D was chosen for use within this study for its robust psychometric properties in evaluating HRQoL. It has been previously used within a pregnancy related PGP population and all of the dimensions within the measure relate directly to our study aims.

3.3.6.2.4 *Resource Use Questionnaire*

The resource use questionnaire was developed in association with a health economist and a consultant obstetrician. It was a customised questionnaire, and covered key items of direct and indirect resource use such as medication, walking aids, health care use, sick leave and partner sick leave (to assist with care).

3.3.6.2.5 *Cost Effectiveness*

To allow for a cost effectiveness analysis to be undertaken the resource use questionnaire was developed, as previously discussed. The direct and indirect costs, along with the mode of delivery costs of participants were required to calculate associated costs. The EQ5D allowed a health index to be calculated for each participant and the SF36-V2, was translated (Quality Metric Outcomes TM Scoring Software 4.5) to the SF6D which allowed for a Quality Adjusted Life year (QALY) to be calculated for each participant.

3.3.7 Sample Size Calculation

A RCT assessing the effectiveness of two different forms of pelvic belts (rigid and non-rigid) plus exercise on PGP in pregnant women (Depledge et al., 2005) provided the data upon which the sample size was calculated for this study. Depledge et al. (2005) measured average pain (VAS scale) before and after a one-week intervention. The non-rigid pelvic belt plus exercise group experienced a decrease in pain from 42.5% to 38.5% with a mean SD of 11 whilst a rigid pelvic belt plus exercise decreased pain from 52% to 38.5% also with a mean SD of 11. The resultant effect size was 0.86 ((42.5-38.5)-(52-38.5)/11). For a two-tailed unpaired t-test at 85% power and significance level of 0.05 an estimated 25 people are required in each group. Depledge et al's. (2005) attrition rate was 6.6% for two outcome measures spaced one week apart; attrition rates of 0-20% have been reported in other studies. With an estimated 10% attrition rate for each measure (n=4) the intention was to recruit 36 participants in each group, therefore having a total of 72 participants.

3.3.8 Randomisation

Many methods of randomisation were considered for the random allocation of participants in this study, such as simple randomisation, restricted randomisation, and covariate-balancing randomisation (stratification and minimisation).

Allocation by simple randomisation allocates participants to either an intervention or control group. It maintains an unbiased approach due to the unpredictability of which group a participant will be allocated (Herbert et al., 2005). Simple randomisation does not consider the effect of baseline prognostic factors, as in large studies where large sample sizes are present, a balance of prognostic factors will

be ensured (McPherson et al., 2012). However, it is common practice for simple randomisation to cause an unbalance in groups (Scott et al., 2002), and while this is an acceptable risk with larger sample sizes, in smaller studies it is important to reduce the risk of this occurring. Since our study sample size was relatively small, and the literature demonstrated essential prognostic factors that needed to be identified at baseline, simple randomisation was ruled out.

Restricted randomisation allocates participants into permuted blocks. This allows for a balance in participants into either an intervention or control group, which cannot be guaranteed with simple randomisation (McPherson et al., 2012). While this method can also allow for certain baseline characteristics, it still fails to take into consideration baseline prognostic factors and therefore was also ruled out. When compared to minimisation through a computer simulation, minimisation has shown to outperform restricted random allocation and result in fewer imbalances (Scott et al., 2002).

Stratified random allocation maintains balance between groups and takes into consideration a limited number (1-2) of baseline prognostic factors. This involves allocating participants into permuted blocks using either simple randomisation or permuted blocks (McPherson et al., 2012). A disadvantage of stratified random allocation is the potential for some participant groups to fill up more quickly than others, leading to potential imbalances if the study prematurely ceases and also leads to prediction of the last participant to be known (Herbert et al., 2005). When compared to minimisation, stratified random allocation performs similarly when using a limited number of prognostic factors, however, when there are more than three prognostic factors, Scott et al. (2002) have shown that minimisation begins to

outperform stratified random allocation when sample sizes exceed 50. Thus, since the intended study sample size was 72, and there were seven prognostic factors; minimisation was determined as the most viable and effective method for random allocation of the participants.

Treatment allocation by minimisation is a widely accepted alternative to stratification. It is increasingly used in clinical trials (Taves, 2010) and has been described by CONSORT as the platinum standard for clinical trials (Schulz et al., 2011). This method ensures that there is a balance between treatment groups with respect to predefined participant factors (Scott et al., 2002) and was the chosen method of randomisation for this study. When using minimisation, the user has to consider important prognostic factors before the trial has started, increasing adherence to the studies protocol (Taves, 2010).

Some authors (Scott et al., 2002) have questioned the credibility of studies using minimisation, due to the to the persuasive nature of allocation ensuring precise balance between groups and prognostic factors. However, it is argued that there is sufficient evidence in the literature to support the need for the groups to be balanced with regard to these factors to enable an unbiased comparison of the interventions. One potential disadvantage of minimisation is the element of predictability, and some authors have therefore described it as a non-random method. To reduce this risk the first 10 participants were randomly allocated to this study using an external randomisation computer programme (described below). This procedure was undertaken to avoid potential criticism regarding this approach being non-random in nature.

With the added complexity required to structure the allocation of participants by minimisation it has been suggested that this can add time, cost and potentially harm recruitment (Peto et al., 1976). The use of free software, as used in this study, helps to limit the time and cost required to organise manually and also helps with record keeping as this is automatically completed.

3.3.8.1 *Sequence Generation (Minimisation)*

An external randomisation computer programme (http http://www.random.org/) was used to randomise the initial 10 participants into the study as suggested by Scott et al. (2002). The remaining participants were allocated using 'Minim' software (www.sghms.ac.uk/depts/phs/guide/randser.htm). This computer software allows the researcher to set up the number of groups required and the number of prognostic factors considered. This study required two groups (Group A and Group B), with prognostic factors of age, gestation, parity, BMI, pre pregnancy, low back pain or pelvic pain and PGP. After the initial 10 participants were allocated using the external randomisation computer programme, the participant's information was entered into the Minim software that made a decision on group allocation, as determined by the characteristics of participants already in the study.

3.3.8.2 *Allocation Concealment Mechanism*

Allocation concealment is considered an essential component to maintain an unbiased randomisation process and limit exaggerated treatment effect size (Schulz and Grimes, 2002). The first step in ensuring appropriate randomisation is the sequence generation. As above (see section 3.3.8.1), this can be undertaken using random number generators or software. The second crucial process is ensuring that

the sequence used for randomisation cannot be deciphered and is concealed from the person who is undertaking the random group generation (allocation concealment); if this is not in place then the randomisation process fails (Schulz and Grimes, 2002).

In this study the random allocation to intervention groups was undertaken by the researcher using either a random number generator (for the first 10 participants), or minim software (for the remaining participants). This was necessary for the study to maintain a balance between groups when using a relatively small sample size. Once the participant had been screened for their enrolment into the study and their baseline data taken (see section 3.3.3), they would leave the clinic room, and then the randomisation by minimisation would take place having first entered the prognostic variables into the computer software to allow for the balance between groups. This also identifies a clear procedure of enrolment.

As described previously, many forms of randomisation were considered, however, minimisation was the only available method of randomisation that was able to incorporate the increased number of prognostic factors. The use of computer software meant that the minimisation software was able to determine the group allocation and removed this responsibility from the researcher, limiting the potential to allocate participants to favoured intervention groups. All that was required was the baseline data to be inputted by the researcher.

As previously discussed, there are possible ways of deciphering minimisation, as the next allocation is based on the previous characteristics of participants already enrolled. However, when inputting the participant characteristics into the minimisation software, it calculates the group allocation internally, meaning the researcher does not have access to the database of previous participant

characteristics. The only potential for the researcher to decipher the minimisation process was therefore the access they had to participants' baseline data during their enrolment. Theoretically, this could have been manually written down and deciphered to attempt to interpret the next group allocation, however, would be labour-some to complete.

While researchers are required to always remain unbiased, there is evidence to show that this doesn't always happen (Schulz et al., 1995); when asked via an anonymous survey it was found that many researchers were able to decipher the randomisation due to inadequate methods. Ultimately, it resides with the integrity of the researcher to be responsible for the allocation concealment and the adequacy of their method, to prevent such activity.

3.3.8.3 *Implementation of Randomisation Sequence*

The researcher generated the random allocation using the external randomisation computer programme and the minim software. The researcher was also responsible for enrolling participants into the study and the minim software would assign each participant to either group A or B to prevent any bias towards allocation or implementation of interventions.

3.3.9 Interventions

Eligible participants were randomised to receive one of two pelvic orthoses plus standardised advice (Serola Belt, Group A; Customised DEFO, Group B) using allocation by minimisation (See section 3.3.8.1). The researcher, who is a Chartered Society of Physiotherapy registered musculoskeletal physiotherapist (Band 7), provided the intervention for all participants in both groups. As he is male, in line with professional practice, all of the assessments were completed with the assistance of a female chaperone, within the hospital setting. The two pelvic orthoses were:

3.3.9.1 *Serola Belt (Group A)*

This is an 'off the shelf' rigid pelvic belt (supplied by Serola Biomechanics Inc., https://www.serola.net/) which consists of an open cell urethane inner layer (3" in width), wrapping the circumference of the pelvic girdle and fastening with Velcro tape (Figure 3.2). It has added extra-strong, double-pull elastic straps, which can be applied, also with Velcro tape, for further tension and support. To prescribe the appropriate size of the Serola Belt, a single waist measurement is required, which takes approximately one minute to complete (see Appendix 11a). This was undertaken by the researcher.

3.3.9.2 *Customised Dynamic Elastomeric Fabric Orthoses (DEFO, Group B)*

This customised Dynamic Elastomeric Fabric Orthoses (DEFO) (supplied by DM Orthotics' Ltd, https://www.dmorthotics.com/) is individually tailored to the participant based on 12 measurements for the 2nd trimester participants (20-27 weeks pregnant) and 13 measurements for 3rd trimester participants (28-36 weeks pregnant).

This required a combination of circumferential measurements of the torso, pelvis and thighs, along with linear measurements of the torso, pelvis and thighs to establish length. The extra measurement in the third trimester required an additional circumferential measurement at the level of the sternum to cater for growth during the third trimester (see Appendix 11b). The measurement process is undertaken by a trained assessor, in this case the researcher with the assistance of a female chaperone. It takes approximately five to seven minutes to complete.

Designed in the form of a pair of shorts as opposed to the standard belt, the customised DEFO is made of a flexible compression fabric (Lycra) to aid pelvic stability, with the intention of providing comfort and movement (Figure 3.2). It has reinforced panelling for strength and stability with an option for open crotch available (a closed crotch was used for this study).

Figure 3.2 The *orthotic interventions Serola belt (left) and customised Dynamic Elastomeric Fabric Orthosis (DEFO) (right).*

3.3.9.3 *Standardised Advice*

During a physiotherapy appointment, it is typical for any patient experiencing pregnancy related PGP to be routinely given standardised advice alongside their intervention. For this reason the researcher provided each participant in both Group A and Group B a standardised advice sheet 'Guidance for mothers to be and new mothers: Pregnancy-related pelvic girdle pain' supplied by the Association of Pelvic, Obstetric and Gynaecological Physiotherapy (POGP) website (https://pogp.csp.org.uk/system/files/pogp-pgppat_3.pdf). There were a number of advantages of providing this publicly available, approved, standardised leaflet: it enabled the information given to each participant to be the same; ensured the information provided was reflective of current best practice, and was more efficient than memorising a script to ensure all advice was given to all participants equally. The participant could also use this as an on-going resource throughout their pregnancy.

3.3.9.4 *Blinding*

The researcher was blinded to the participant's treatment effects (self-report questionnaire results). As previously described in section 3.2.9.4, an independent blinded assistant had the remit of checking returned self-report questionnaire booklets and supplying the researcher with any missing information or incorrectly answered questions, to maintain the blinding of the researcher. To maintain blinding of the independent assistant, they were only privy to the participants ID and questionnaire booklet responses and did not know which participants were allocated to which group (customised DEFO or Serola Belt) as no information regarding groups were placed on

the returned envelopes or questionnaire booklets. All questionnaire booklets were locked into a steel cabinet and the key was held by the independent assistant only.

All attempts were also made to blind the participant as to which group they were allocated. The Participant Information Sheet (and associated verbal discussion) stated that "the study was evaluating the effectiveness of two different pelvic support orthoses aimed at reducing pelvic girdle pain during pregnancy"; neither of the orthoses were specifically named or described. In addition, to minimise the effects of attention in relation to the time spent with each participant, and to further avoid potential un-blinding, every participant, whether allocated to the Serola or DEFO group underwent either 12 or 13 measurements (dependent on their gestation), at the initial assessment (see section 3.3.9).

3.3.9.5 *Statistical Methods*

Ongoing statistical advice and support from the University of Plymouth Statistics Department was undertaken over the course of the study.

3.3.10 Data Analysis

Descriptive statistics were used to describe the sample in terms of demographic and diagnostic issues. Due to a variable baseline length, as a result of participants entering the trial at different time points relative to their delivery date, the analyses of outcome measures were calculated using the final three time points pre partum (antenatal -6 /-4 /-2 weeks) and the first three time points post-partum (postnatal +2/+4/+6 weeks). Separate analyses were performed for each of the

outcome measures using SPSS Software (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY) and Quality Metric Outcomes TM Scoring Software 4.5 to score the SF36 - V2. Separate 2x3 (Group x Time) repeated measures analysis of variance (RM-ANOVA), were used to analyse the NPRS and the EQ - 5D dimensions and EQ-5D- VAS pre and postpartum. A Mann- Whitney U test was used for analysis of the SF36v2 to compare group differences at each time point and Freidman's test to compare differences between time intervals within each group. A Mann-Whitney U test was used for analysis of the PGQ and the EQ- 5D subscales. For all tests, the alpha level was set at .05 and Bonferroni corrections were used when post hoc pair wise comparisons were calculated.

The primary outcome measure, NPRS, was assessed for clinical significance using a Minimal Clinically Important Difference (MCID) of one point (Salaffi et al., 2004). The mean difference from the final pre-pregnancy data point (-2 weeks) was compared against baseline in both the groups to identify any reduction in pain score.

3.3.10.1 *Cost Effectiveness Analysis (CEA)*

With regard to the cost effectiveness analysis, ongoing advice and support was available from a Health Economist. The data were presented descriptively. Analyses were undertaken over the same time frame as the clinical outcomes, and no discounting of future costs was required. Unit costs were obtained from the personal social services research unit (PSSRU), office of national statistics (ONS), NICE guidelines, and NHS supply chains for walking aids (source references detailed in Table 3.7). To complete the cost effectiveness analysis resource use, direct and indirect costs, mode of delivery costs and quality of life years (see Table 3.7) had to be

calculated. Means and standard deviations were calculated for direct and indirect costs along with the mode of delivery costs, which were included within the cost effectiveness analysis (Table 3.8).

The EQ5D and the SF6D were used to gain QALYs and both means and standard deviations were calculated. QALYs were obtained at baseline, final pre-pregnancy data point (final data point prior to delivery) and final post-partum data point (6 weeks post-delivery). There was no requirement to adjust for baseline as minimisation was used to equally balance participants in both groups.

For the cost effectiveness analysis the total DEFO (novel intervention) costs were subtracted from the Serola Belt (usual care) costs to calculate incremental cost (Table 3.9). This included cost of intervention, direct and indirect costs. The total effectiveness was calculated using both the EQ5D and SF6D to calculate the incremental effectiveness. To complete the cost effectiveness analysis the incremental costs were divided by the incremental effectiveness.

3.4 Results

Figure 3.3 shows the flow of participants to the study and table 3.5 shows the sample characteristics. Table 3.6 shows the descriptive statistics for all outcome measures across time and allocated groups (Serola and DEFO).

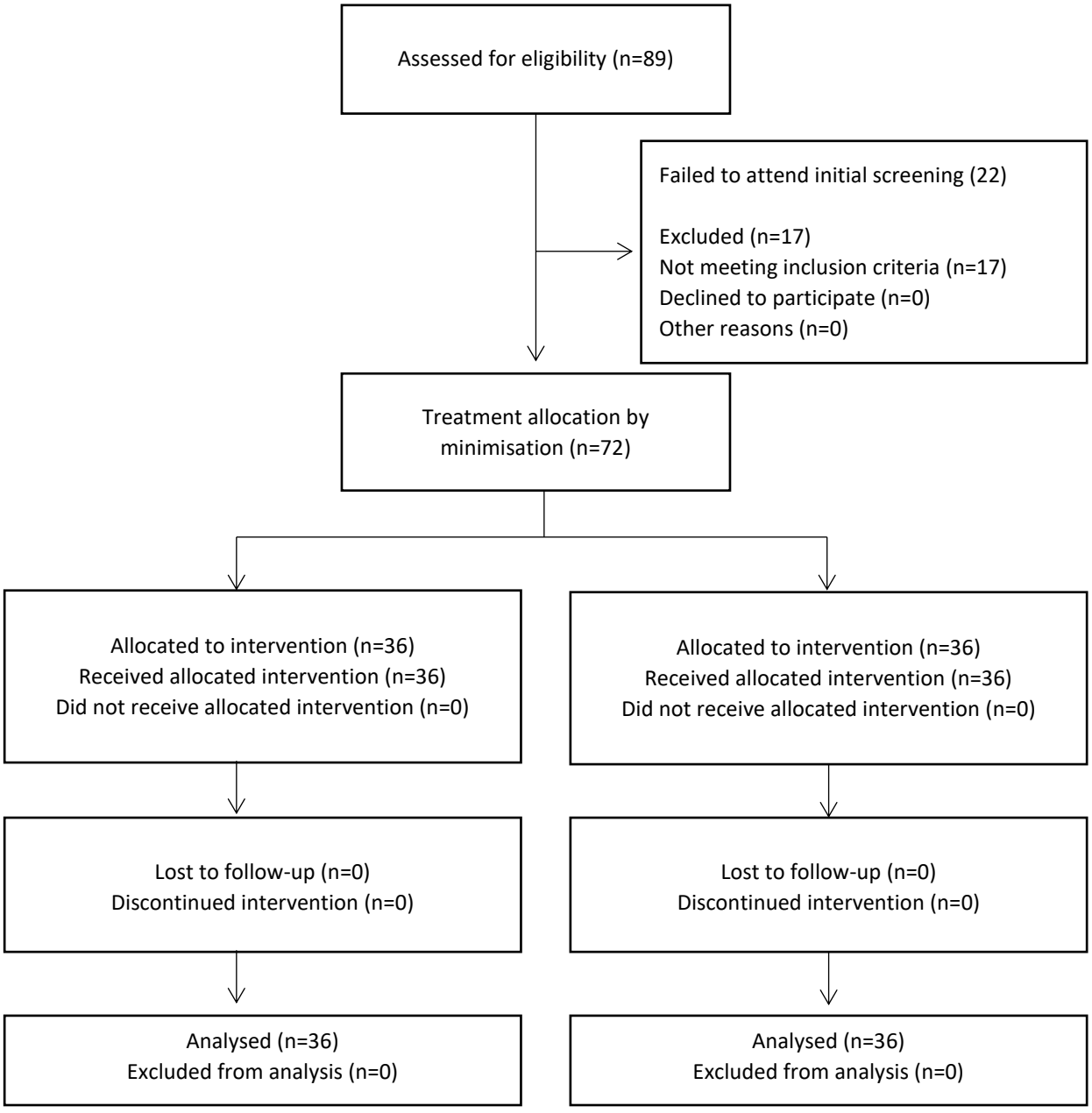


Figure 3.3 *Flow of the participants recruited to the study*

Participant Characteristics		
(n=72)	**Serola (n=36)**	**DEFO (n=36)**
Age (mean (range))	29 (18-39)	30 (20-40)
Gestation (mean (range))	29 (20-35)	28 (20-35)
Parity (mean (range))	1.3 (0-3)	1.4 (0-3)

Table 3.5 *Sample Characteristics*

There was complete data for all participants for all time points; Serola = off-the-shelf rigid orthosis; DEFO = customised Dynamic Elastomeric Fabric Orthosis. All participants were female with an average age 29 years old (±4.97) in the Serola group and 30 years old (±5.91) in the DEFO group. Average gestation week was 29 (±4.98) in the Serola group and 28 (±4.06) in the DEFO group. Average parity of participants in the Serola group was 1.3 (±1.17) and 1.4 (±1.29) in the DEFO group. Overall, this recognises the randomisation process was effective in producing the baseline group's equivalent demographic variable outcomes.

3.4.1 *Primary Outcome Measure*

3.4.1.1 *Numerical Pain Rating Scale – Day (NPRS-Day):*

NPRS Day -6 to -2

With baseline score as a covariate there was no significant main effect of time $F(2, 138) = .000$, $p = 1.000$, or interaction between time and group $F(2, 138) = .705$, $p = .496$. However, there was a significant difference between groups $F(1, 69) = 4.491$ $p = .038$, with lower NPRS scores being seen in the DEFO group (see figure 3.4 and 3.5)

NPRS Day +2 to +6

With baseline score as a covariate there was no significant main effect of time $F(2, 138) = .000$, $p = 1.000$, or interaction between time and group $F(2, 138) = .705$, $p = .496$. No significant differences were found between groups $F(1, 69) = .002$ $p = .966$ (see figure 3.4 and 3.5).

The MCID was found in the DEFO group with a one point reduction in the NPRS (baseline = 5.917; final pre-pregnancy data point = 4.917 (-2)). The MCID was not found for the Serola group.

3.4.1.2 *Numerical Pain Rating Scale – Night (NPRS-Night)*

NPRS Night -6 to -2

With baseline score as a covariate there was no significant main effect of time $F(2, 138) = .391$, $p = .677$, or interaction between time and group $F(2, 138) = 1.286$, $p = .280$. No significant differences were found between groups $F(1, 69) = 1.531$, $p = .220$) (see figure 3.6 and 3.7).

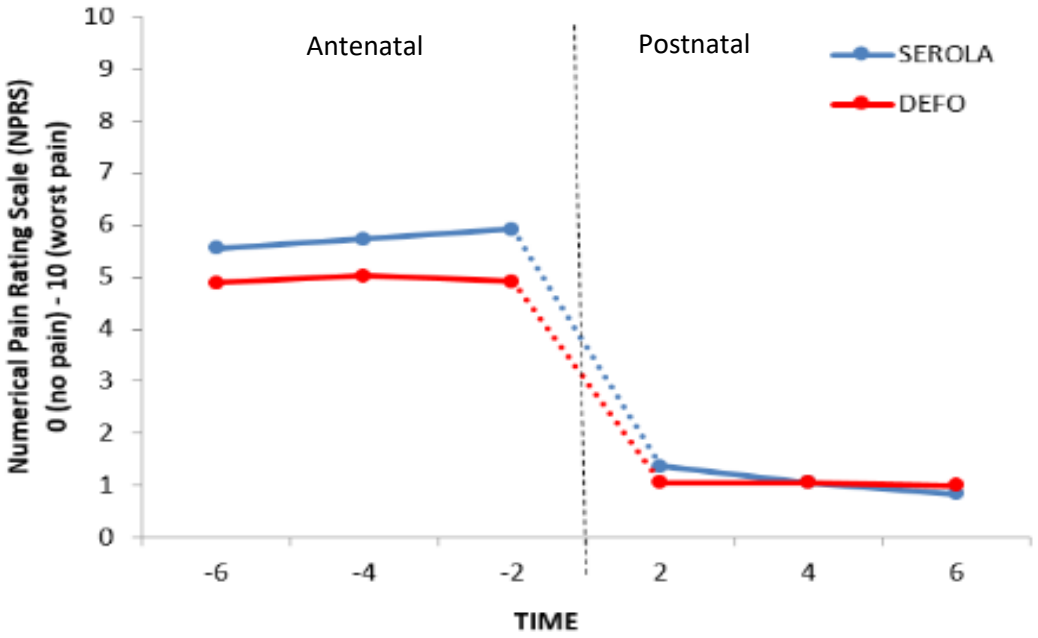


Figure 3.4 Day-time Numerical Pain Rating Scale (NPRS) Scores, shows mean day NPRS for Serola and DEFO groups at pre-birth time points (-6, -4, -2 weeks) and post-birth time points (+2, +4, +6 weeks). Vertical dotted line symbolises birth of child.

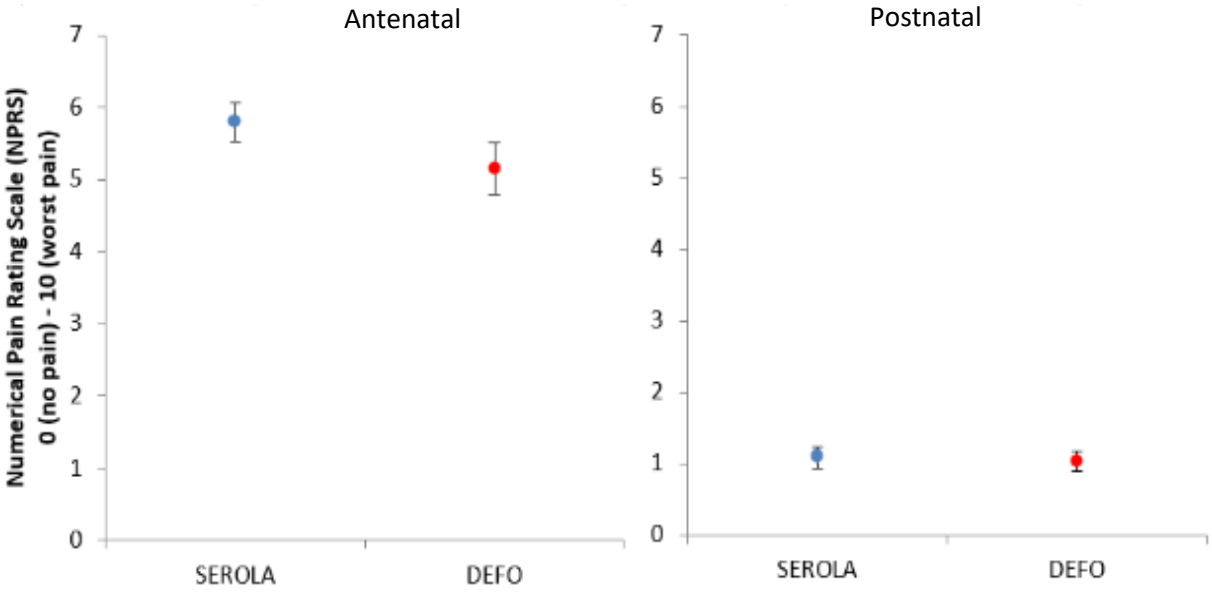


Figure 3.5 Day-time Numerical Pain Rating Scale (NPRS) Scores, shows grand average day NPRS for Serola and DEFO groups over the pre and post birth periods, along with 95% confidence intervals.

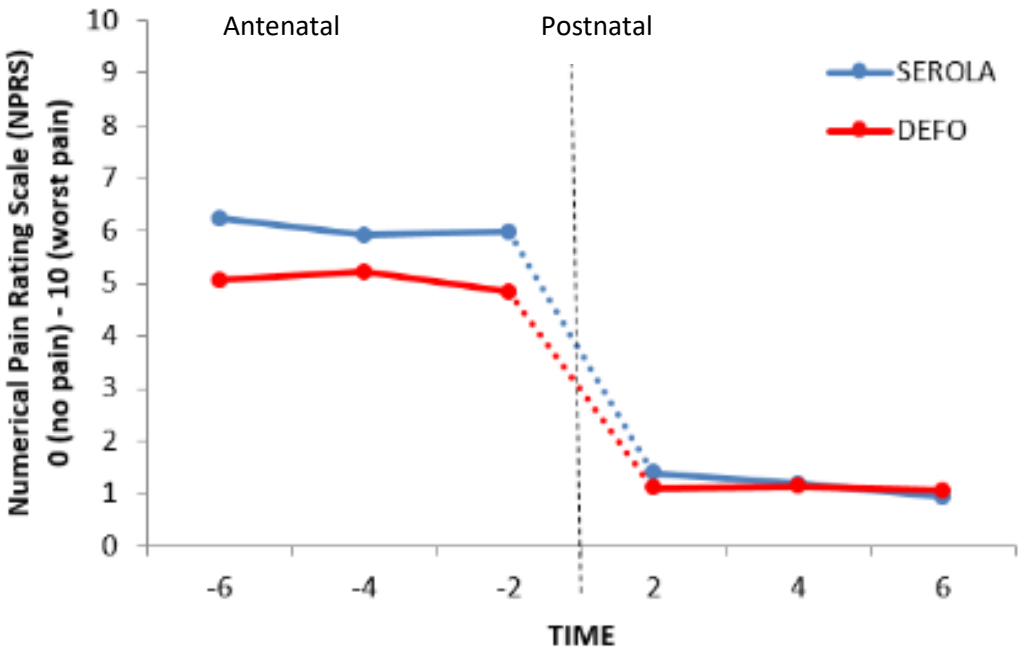


Figure 3.6 Night-time Numerical Pain Rating Scale (NPRS) Scores, shows mean night NPRS data for both Serola and DEFO, at pre-birth time points (-6, -4, -2) and post-birth time points (+2, +4, +6); dotted line symbolises birth of child.

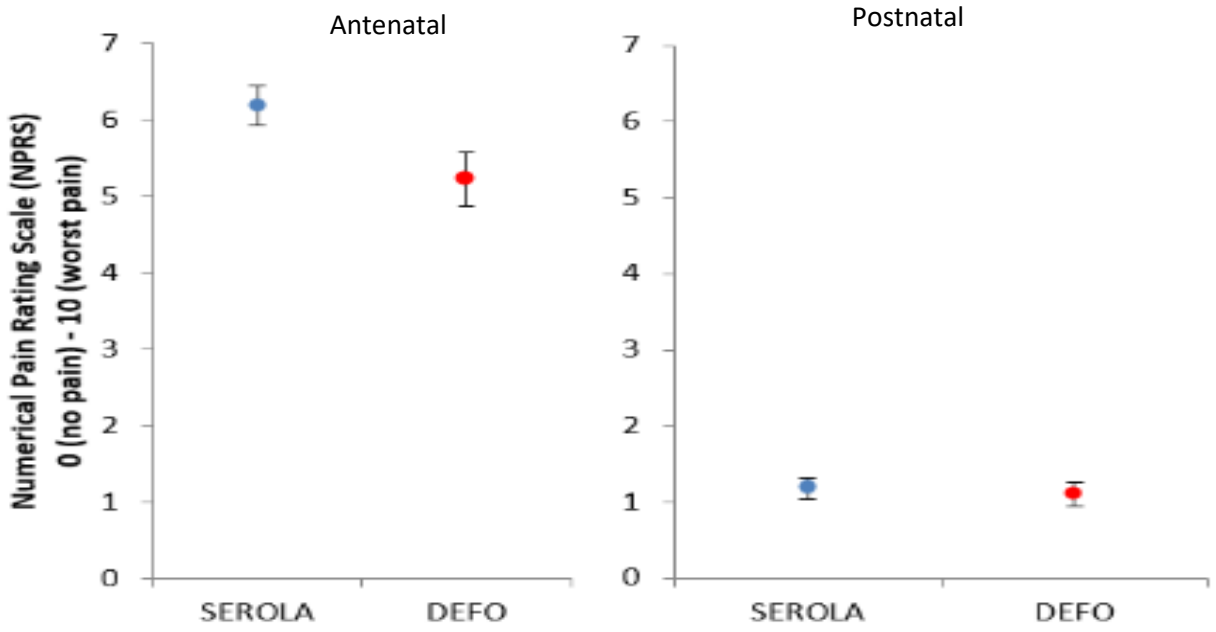


Figure 3.7 Night-time Numerical Pain Rating Scale (NPRS) Scores, shows total mean data for both Serola and DEFO, at pre and post birth, along with upper and lower 95% confidence intervals.

NPRS Night +2 to +6

With the baseline score as a covariate there was no significant main effect of time $F(2, 138) = .260$, $p = .772$, or interaction between time and group $F(2, 138) = 1.097$, $p = .337$. There was no significant difference groups $F(1, 69) = .332$ $p = .566$ when baseline scores were included as a covariate (see Fig 3.6 and 3.7).

There was no MCID found for either the Serola or DEFO, although both groups reported a reduction in pain. However, the mean difference between baseline and final antenatal (-2 weeks) NPRS score for the DEFO approached clinical significance (0.94), but not for the Serola group (0.64).

Table 3.6 Descriptive statistics for all outcome measures across time and allocated groups (Serola and DEFO)

	Serola (Antenatal)					Serola (Postnatal)			DEFO (Antenatal)					DEFO (Postnatal)		
	Time in weeks relative to birth *Antenatal = -6/-4/-2 & Postnatal = +2/+4/+6*															
Outcome Measures (Mean(+/- SD))	**Baseline scores**	**-6**	**-4**	**-2**	**This line signifies birth of child**	**+2**	**+4**	**+6**	**Baseline scores**	**-6**	**-4**	**-2**	**This line signifies birth of child**	**+2**	**+4**	**+6**
NPRS DAY *	6.00	5.56	5.72	5.92		1.36	1.06	0.83	5.92	4.89	5.03	4.92		1.06	1.06	1.00
Available range 0-10	(1.20)	(1.59)	(1.65)	(1.65)		(1.07)	(0.92)	(0.91)	(1.42)	(1.83)	(1.76)	(1.86)		(1.51)	(1.96)	(2.00)
NPRS NIGHT *	6.61	6.22	5.92	5.97		1.39	1.19	0.94	5.78	5.06	5.22	4.83		1.11	1.14	1.06
Available range 0-10	(1.75)	(1.94)	(1.79)	(2.04)		(1.27)	(1.06)	(1.07)	(2.17)	(2.33)	(2.19)	(2.30)		(1.19)	(2.02)	(2.10)
PGQ †	64.78	61.9	62.3	64.8		16.9	12.2	10.1	64.19	62.2	61.4	62.0		14.1	14.8	12.1
Available range 0-100	(12.64)	(16.61)	(17.42)	(19.12)		(13.41)	(10.95)	(10.31)	(11.91)	(18.80)	(20.28)	(20.98)		(13.08)	(19.62)	(19.60)
EQ5D‡	0.52	0.51	0.51	0.47		0.74	0.78	0.81	0.49	0.48	0.52	0.47		0.77	0.78	0.81
Available range 0-10	(0.17)	(0.22)	(0.17)	(0.17)		(0.11)	(0.12)	(0.12)	(0.20)	(0.19	(0.17)	(0.20)		(0.13)	(0.23)	(0.23)
EQ5D VAS §	55.69	54.89	52.22	50.56		74.36	74.39	77.50	60.89	58.33	57.61	55.64		70.50	74.86	77.44
Available range 0-100	(17.33)	(16.68)	(17.09)	(16.36)		(13.13)	(13.83)	(14.16)	(17.17)	(20.24)	(18.39)	(18.47)		(18.57)	(20.18)	(19.37)
SF36 (PC) ‖	35.51	34.91	34.91	33.12		45.37	48.27	50.60	35.62	34.26	34.78	35.09		46.16	47.82	51.86
Available range 0-100	(7.30)	(7.46)	(7.64)	(7.98)		(7.94)	(7.78)	(7.90)	(5.95)	(5.72)	(6.37)	(6.61)		(7.00)	(9.24)	(9.06)
SF36 (MC) ¶	43.61	43.75	42.84	41.98		49.34	51.27	50.86	46.77	47.85	48.16	48.52		55.08	56.65	56.03
Available range 0-100	(9.46)	(11.02)	(11.45)	(10.41)		(9.07)	(8.97)	(9.13)	(9.90)	(11.29)	(10.62)	(10.54)		(9.77)	(10.64)	(9.44)

*Numerical Patient Reported Scale Score (NPRS) primary outcome measure - higher scores = worse pain; negative change score = improvement

† Pelvic Girdle Questionnaire (PGQ) Secondary outcome measure – higher scores = more pain during tasks; positive change score = improvement

‡EuroQol 5 dimension (EQ5D) secondary outcome measure higher scores = worse quality life; positive change score = improvement

§EuroQol 5 dimension Visual Analogues Scale (EQ5D – VAS) secondary outcome measure lower scores = worse quality of life; negative change score = improvement

|| Short Form 36 item questionnaire – physical component (SF36 (PC)) secondary outcome measure Low scores = worse quality of life; positive change score = improvement

¶ Short Form 36 item questionnaire – mental health component (SF36 (MC)) secondary outcome measure. Low scores = worse quality of life; † change score = improvement

3.4.2 *Secondary Outcome Measures*

3.4.2.1 *EuroQOL- 5 DimensionS, 5 Level: (EQ5D-5L)*

EQ5D-5L -6 to -2

Analysis of the EQ5D antenatal data with baseline score as a covariate revealed no significant main effect of time $F(2, 138) = 2.394$, $p = .095$, or interaction between time and group $F(2, 138) = .559$, $p = .545$. No significant differences were found between groups $F(1, 69) = .001$ $p = .972$.

EQ5D-5L +2 to +6

Postpartum data revealed no significant main effect of time $F(2, 138) = 2.363$, $p = .098$, or interaction between time and group $F(2, 138) = .439$, $p = .646$. No significant differences were found between groups $F(1, 69) = .168$ $p = .683$.

3.3.2.2 *EuroQOL - 5 Dimensions – Visual Analogue Scale (EQ- 5D-VAS)*

EQ5D VAS -6 to -2

Analysis of the antenatal (-6 to -2) data with baseline scores as a covariate revealed no significant main effect of time $F(2, 138) = .714$, $p = .492$, or interactions between time and group $F(2, 138) = .888$, $p = .414$. No significant differences were found between groups $F(1, 69) = .008$, $p = .931$.

EQ5D VAS +2 to +6

Postnatal results revealed no significant main effect of time $F(2, 138) = 2.438$, $p = .091$, or interaction between time and group $F(2, 138) = 1.130$, $p = .273$. There were no significant differences between groups $F(1, 69) = 2.873$, $p = .095$.

3.4.2.3 *Pelvic Girdle Questionnaire (PGQ)*

PGQ -6 to -2

No significant effect of time was found $F(2, 138) = .241$, $p = .786$, or interactions between time and group $F(2, 138) = .894$, $p = .411$. There was no significant differences between groups $F(1, 69) = .033$, $p = .857$, indicating that both groups reported similar levels of activity and pain over time.

PGQ +2 to +6

No significant effect of time was found $F(2, 138) = 1.330$, $p = .270$, or interactions between time and group $F(2, 138) = .734$, $p = .483$. No significant differences were found between groups $F(1, 69) = .985$, $p = .327$.

3.4.2.4 *Short Form-36, Version 2 (SF-36v2)*

SF36 MCS -6 to -2

Analysis of antenatal data with baseline scores as a covariate revealed a significant decrease in health related quality of life over time $F(2, 138) = 5.761$, $p = .004$, and no significant interaction between time and group $F(2, 138) = 2.423$, $p = .092$. No significant differences were found between groups $F(1, 69) = .140$, $p = .709$.

SF36 MCS +2 to +6

No significant main effect of time was found during analysis of the postnatal scores $F(2, 138) = .344$, $p = .709$, or interactions between time and group $F(2, 138) = .944$, $p = .392$. No significant differences were found between groups $F(1, 69) = .052$, $p = .821$.

SF36 PCS -6 to -2

Analysis of antenatal data with baseline scores as a covariate revealed a significant decrease in health related quality of life over time $F(2, 138) = 8.248$, $p = .001$, and no significant interaction between time and group $F(2, 138) = 2.771$, $p = .066$. However,there was a group effect with significantly lower scores for the Serola group compared to the DEFO $F(1, 69) = 4.623$, $p = .035$.

SF36 PCS +2 to +6

No significant main effect of time was found during analysis of the postnatal scores $F(2, 138) = .612$, $p = .544$, or interactions between time and group $F(2, 138) = .365$, $p = .631$. Consistent with antenatal scores, significantly lower scores were found for the Serola group compared to the DEFO $F(1, 69) = 4.265$, $p = .043$ when baseline scores were included as a covariate.

3.4.3 *Cost Effectiveness Analysis*

The product cost of the usual care orthotic (Serola Belt) was £35.99 compared to the customised DEFO, which was £260.00. Direct costs for the Serola belt were £196.04 in comparison to £163.26 for the DEFO. Indirect costs were higher in the DEFO group with a mean difference of £92.76 (Serola £548.17 and DEFO £640.93). The DEFO has higher combined direct and indirect costs of £1064.19 in comparison to the Serola belt at £780.20. The DEFO also had higher mode of delivery costs at £65,572.00 compared to the Serola belt £63,460.00 (see Table 3.8). With the total effectiveness obtained from the SF6D of 0.176 QALYs gained in the Serola group and 0.166 gained in the DEFO group, there was a mean difference of 0.01 incremental effectiveness (see Table 3.9). There was no requirement to

adjust for baseline as all participants were randomised into the study using minimisation (see chapter 3.2.8). The total cost effectiveness for the DEFO in comparison to the usual care Serola belt was -£28399.00 (see Table 3.10).

Resource Item	Unit Costs	Source of Cost Data	Basis of Estimate
Health Services			
GP	£44.46	PSSRU 2017	GP/Appt at surgery, based on 11.7 mins (£3.8 per minute)
Midwife	£44 p/h	PSSRU 2017	Based on hospital cost per hour
Physiotherapist	£34 p/h	PSSRU 2017	Based on hospital cost per hour
Walking Aids			
Walking stick/cane	£6.45	nhs supplies	https://www.supplychain.nhs.uk/
Elbow Crutches	£19.95	nhs supplies	https://www.supplychain.nhs.uk/
Walking frame	£29.95	nhs supplies	https://www.supplychain.nhs.uk/
Mode of delivery			
Spontaneous Vaginal Delivery	£1,665	NICE Guidelines	https://www.nice.org.uk/guidnace/cq123/resources/costing-report-184766797
Instrumental Delivery	£1,877	NICE Guidelines	https://www.nice.org.uk/guidance/cq123/resources/costing-report-184766797
Emergency Lower Segment Caesarean Section	£2,369	NICE Guidelines	https://www.nice.org.uk/guidance/cq123/resources/costing-report-184766797
Elective Lower Segment Caesarean Section	£2,668	NICE Guidelines	https://www.nice.org.uk/guidance/cq123/resources/costing-report-184766797
Other costs			
Participant Sick Leave (Days)	£101.20	ONS 2017-2018	Based on average weekly gross salary £506
Partner Sick Leave (Days)	£101.20	ONS 2017-2018	Based on average weekly gross salary £506

Table 3.7 *Unit costs for direct/indirect and mode of delivery costs*

		Serola		DEFO				Serola		DEFO	
NHS Costs	**n=**	**mean resource use (SD)**	**n=**	**mean resource use (SD)**	**mean difference (no adjustment)**		**n=**	**£ Mean Cost (SD)**	**n=**	**£ Mean Cost (SD)**	**mean difference (no adjustment)**
GP	36	4 (1.74)	36	3.3 (1.55)	**0.7**		36	91.39 (77.33)	36	69.16 (65.03)	**22.23**
Midwife	36	2.16 (1.19)	36	2.49 (0.97)	**0.33**		36	48.89 (52.36)	36	56.22 (42.87)	**-7.33**
Physio	36	2.81 (1.5)	36	2.11 (1.36)	**0.7**		36	49.11 (51.04)	36	34.00 (43.01)	**15.11**
Walking Stick	36	0	36	0	**0**		36	0.00	36	0.00	**0.00**
Elbow crutches	36	0.33 (0.47)	36	0.19 (0.40)	**0.14**		36	6.65 (9.54)	36	3.88 (8.01)	**2.77**
Walking Frame	36	0	36	0	**0**		36	0.00	36	0.00	**0.00**
SOCIETAL Costs											
Patient sick leave	36	4.25 (6.59)	36	5.5 (8.00)	**1.25**		36	430.10 (667.08)	36	556.60 (809.78)	**126.50**
Partner/relative Sick leave	36	1.17 (1.76)	36	0.83 (1.40)	**0.287**		36	118.07 (178.59)	36	84.33 (142.09)	**33.74**
MODE OF DELIVERY Costs	**n=**		**n=**				**n=36**		**n=36**		
Spontaneous	23	23	16	16	**7**			38,295.00		26,640.00	**11,655.00**
Instrumental	8	8	12	12	**4**			13,320.00		19,980.00	**6,660.00**
Elective Caesarean	3	3	5	5	**2**			7,107.00		11,845.00	**4,738.00**
Emergency Caesarean	2	2	3	3	**1**			4,738.00		7,107.00	**2,369.00**

Table 3.8 *Mean costs for direct/indirect and mode of delivery*

Measure (Time-point)	Serola		DEFO		Difference (No Adjustment)	Difference Adjusted for baseline
	n=36	Mean (SD)	n=36	Mean (SD)		Mean (95% CI)*
EQ-5D: (Baseline)	36	0.127	36	0.122	0.005	
EQ-5D: (Final Pre-Preg)	36	0.075	36	0.074	0.001	**0.001 (-0.009 - 0.011)**
EQ-5D: (12/52 Follow-up)	36	0.117	36	0.116	0.001	**0.001 (-0.010 - 0.011)**
SF-6D: (Baseline)	36	0.143	36	0.143	0	
SF-6D: (Final Pre-Preg)	36	0.145	36	0.140	0.005	**0.005 (0.00 - 0.009)**
SF-6D: (12/52 Follow-up)	36	0.176	36	0.166	0.01	**0.010 (0.001 - 0.019)**

Table 3.9 *Mean and Standard deviation QALYs using both EQ5D and SF6D*

	A	B	C	D	E
Intervention	**Total Cost**	**Total Effectiveness**	**Incremental Cost**	**Incremental Effectiveness**	**Cost Effectiveness**
Serola Belt (Usual Care)	£780.20	0.176	-	-	-
DEFO (Novel intervention)	£1,064.19	0.166	-£283.99	0.01	-£28,399

Table 3.10 The cost effectiveness analysis

3.5 Adverse Effects

There were no adverse effects related to the intervention reported during the undertaking of this RCT.

3.6 Discussion

This is the first double blinded, randomised comparative trial evaluating the effectiveness of a rigid belt orthosis with a DEFO during pregnancy. Further, it includes the evaluation of a novel intervention, the customised DEFO. It shows that, in comparison to the 'off the shelf' rigid pelvic belt (Serola Belt), antenatal day time pain levels for those wearing the customised DEFO were, on average, significantly less during the day time. These changes in antenatal day time pain were clinically significant, as determined by a one point reduction in the NPRS, which equates to a 'slightly better' improvement in pain. Whilst no significant difference was detected between the two groups with regard to the secondary outcomes of activity levels and quality of life, it is highlighted that the study was not powered to detect changes in these outcomes. Further studies could address this issue.

Lee and Vleeming (1998) report the need for force-form closure, neuromuscular control and emotion/awareness for optimum joint function and a balance between movement and control for optimal stability (Lee and Vleeming, 1998) During pregnancy, multiple factors have been shown to affect these aspects and potentially contribute to PGP. This reduction in stability can lead to increased shear forces through the SP and SIJ potentially causing pain (Mens et al., 2009). The European Guidelines for Management and Diagnosis of PGP, along with a systematic review completed by Aldabe et al. (2012), reported that there was a low association between relaxin levels and pregnancy related PGP, therefore no conclusion could be

drawn (Aldabe et al., 2012; Vleeming et al., 2008). Biomechanical changes occur in the lumbar spine and pelvis during pregnancy due to the need to adapt the centre of gravity as a result of the increasing weight of the womb (Liddle and Pennick, 2015). The increase in maternal weight is believed to play a role in the requirement for changing lumbar biomechanics, with increased lordotic adjustment in the lumbar spine required to maintain the centre of gravity (Branco et al., 2014; Foti et al., 2000). Other changes such as reduced muscular activity and compensatory muscle patterns can also be a potential cause of pain through reduction of joint proprioception and neuromuscular control (Oh et al., 2014).

Pelvic belts are hypothesised to enhance 'force closure', thereby aiding stability of the pelvic ring and reducing shearing forces through the SP and SIJ (Arumugum et al., 2012; Bertuit et al., 2018a; Mens et al., 2006; Mens et al., 2017). Applying external pelvic compression can: be a substitute for normal isometric abdominal activity; increase hip adduction strength; and reduce SIJ laxity (Arumugum et al., 2012; Mens et al., 2006; Mens et al., 2017). This can also lead to a decrease in compensatory mechanisms through the pelvis and lumbar spine and facilitate load transfer more appropriately (Oh et al., 2014). A pelvic belt has been observed to influence proprioception and neuro-motor control, which can also contribute with the reduction of compensatory patterns, further improving force closure (Arumugum et al., 2012; Bertuit et al., 2018a; Shaffer and Harrison, 2007; Sicthing et al., 2014; Soisson et al., 2015; Takasaki et al., 2009). With changing pelvic biomechanics, it has been observed that a pelvic orthosis can release strain on sacroiliac ligaments which can reduce potential tensile stress thus reducing the pain (Liddle and Pennick, 2015; Takasaki et al., 2009; Sichting et al., 2014). As passive force-closure using a pelvic belt reduces

abdominal muscle activation and there are concerns this could lead to muscle weakness (Hu et al., 2010). The European Guideline advocates that pelvic belts should be considered alongside other treatment modalities (Vleeming et al., 2008); our study supplemented its use with standardised advice.

Following the undertaking of the cost effectiveness analysis (see section 3.4.3) it was deemed that the customised DEFO was not deemed to be cost effective.

3.7 Strengths and limitations of the study

This study is the first to compare the relative clinical and cost effectiveness of a rigid pelvic orthosis with a DEFO (plus standardised advice) on pain, activity levels and quality of life, providing clinicians, patients and commissioners with evidence on which to guide treatment selection. Self-report questionnaires were used in this study, primarily to reduce participant burden and missing data in a sample who may find it difficult to attend follow-up assessments due to work and family commitments and in whom travelling can irritate their pain. This approach, alongside our data checking and management systems, are strengths of this study since there was no missing data. This is important since missing data can compromise inferences made from clinical trials (Little et al., 2012). The minimisation procedure utilised to reduce the likelihood of disparity between the groups, was successful in ensuring there were no significant difference between the two groups in their baseline level of pain and the time they entered the study.

A particular challenge in this trial was that a pre-defined threshold of pain needed to be reached before participants were eligible for entry, resulting in participants entering the study at different time points during their pregnancy (relative to delivery date). This was successfully dealt with by the analytical approach used

which focused on the final three data points in the antenatal phase and the first three data points in the post-partum phase – a total of 12 weeks. Future studies could explore whether a DEFO could be used at an earlier stage in those individuals at high risk of developing PGP since with many musculoskeletal conditions prevention/early intervention is favoured.

In this study fitting and provision of the two orthotic devices was undertaken by a single band 7 physiotherapist, specialised in musculoskeletal physiotherapy. Further, the orthoses were only evaluated for pregnant women that met specific entry criteria, which included a pre-defined threshold of pain. It is possible therefore that the results may not generalise to all pregnant women who experience PGP, or when the intervention is implemented by differing grades of physiotherapist. The highly protocolised nature of the assessment process, and the standardised format of the information sheet provided, means that the skill level of staff is unlikely to significantly influence the outcome. Nevertheless these factors should be taken into account when considering generalisability of the study results.

3.8 Conclusion

The novel, customised dynamic elastomeric fabric orthosis was more effective than the off-the-shelf rigid Serola pelvic belt at reducing antenatal day time pain in pregnant women with pelvic girdle pain, although was not deemed to be cost effective.

Chapter Four:

Management of Post-Partum Pelvic Girdle Pain: A Replicated Case Series of Single Case Studies Evaluating the Effectiveness of a Customized Dynamic Elastomeric Fabric Orthosis (DEFO)

4.1 Introduction

This chapter describes the evaluation of the customised DEFO in females suffering from chronic post-partum PGP in a single case study series (n=8). An explanation of the study research question, aims and objectives will be followed by a discussion of the approach used to address the research question. The chapter will include an evaluation of the research methods.

4.1.1 Research Question

This single case study series asked the question "In women with chronic post-partum PGP, does wearing a dynamic elastomeric orthosis affect pain, activity, health related quality of life, incontinence, anxiety and depression?"

4.2 Background

This chapter continues the journey for females suffering from PGP following the birth of their child. During the RCT in Chapter 3, information was gathered for 12 weeks following the delivery of their child, as the literature suggests that symptoms resolve during this time span (Albert et al., 2001). During an incidental discussion whilst undertaking the RCT a midwife asked if she could trial one of the orthotics being used for the RCT as she had suffered with persistent PGP for more than six years following the delivery of her second child. This lead to discussions with the research team, a review of the literature and the development of a replicated case series of single case studies to better understand the pelvic girdle pain journey that females may undertake following delivery and to explore whether the customized DEFO might be effective in managing post-partum PGP. There is a scarcity of studies, which have evaluated the management of chronic PGP post-partum, which is problematic since it

has been reported in the literature that this condition does not appear to be self-limiting and can continue for many years following childbirth (Sjodhal et al., 2013). Therefore, preliminary research to identify the effectiveness of the DEFO within this population was felt to be indicated and justified.

As previously stated, PGP occurs in 70% of pregnant women, of whom an estimated 25% have severe pain and 8% severe disability requiring the use of crutches, wheelchair or confinement to bed (Wu et al., 2004). PGP is difficult to manage; activities such as turning in bed, prolonged walking, or carrying items may cause pain; impacting negatively on quality of life (Wang et al., 2004). This PGP during pregnancy is thought to occur due to increased pelvic joint motion as a consequence of hormonal and biomechanical factors (Mens et al., 2009). Whilst PGP symptoms are considered by some authors to be self-limiting and that they should resolve within three months of delivery for the majority of women (Albert et al., 2001) this is not always the case. For instance, the prevalence of postpartum PGP is reported by some authors to be between 33% to 38% of females beyond three months following delivery (Gutke et al., 2010; Van de Pol et al., 2006). Others estimate that up to 80% of females who suffer from pregnancy related PGP continue to have persistent post-partum symptoms following delivery; varying from recurrent to constant pain (Bergstrom et al., 2014). It is evident therefore that there is a large variation in the reported prevalence of chronic PGP (Bergstrom et al., 2014). One reason for this variation in reported prevalence could be related to the lack of research into this condition. Geographical variation could also account for this, since factors such as sick leave (which can differ markedly in different countries) could affect reporting of the condition (Bergstrom et al., 2014; Bergstrom et al., 2016).

It is unknown why chronic symptoms develop, but high maternal age, parity, pre-pregnancy-BMI and previous PGP have been identified as risk factors associated with chronic PGP, along with emotional and psychosocial factors (Robinson et al., 2010). Another factor that is believed to increase the risk of chronic PGP symptoms is the preferred mode of delivery. Due to increasing PGP throughout the pregnancy, an increasing number of women are electing for caesarean section for early symptomatic relief, which is supported by guidelines produced by the National Institute for Healthcare and Care Excellence (NICE) on caesarean sections in 2011 (NICE, 2011). However, this is believed to be a risk factor for the chronicity of PGP (Bjelland et al., 2013).

Orthoses such as rigid pelvic belts (Wang et al., 2004) are commonly prescribed with the aim of improving pelvic joint stability and reducing pain (Damen et al., 2002; Hu et al., 2010; Ostgaard et al., 1994). More recently dynamic elastomeric fabric orthoses (DEFO) have been developed to address this problem. In my previous study (Chapter 3), I evaluated the comparative effectiveness of these two orthotic interventions in women during pregnancy (Cameron et al., 2018) (Clinical Trials.gov ID - PGP-LC12; NRES Ethics Ref - 12/SW/0014). The single-case study series described here complements this by broadening the investigation to women postpartum with chronic PGP. The intention was to undertake a preliminary evaluation of the potential benefits of the customised DEFO on chronic post-partum PGP symptoms in terms of how it might impact on pain, health related quality of life, activity levels, urinary incontinence, anxiety and depression.

4.3 Research Aims

4.3.1 *Primary Aim:*

To investigate the effectiveness of a customised DEFO (plus standardised advice) in reducing pain in women with post-partum chronic PGP.

4.3.2 *Secondary Aims:*

To investigate the effectiveness of a customised DEFO (plus standardised advice) for women with post-partum chronic PGP in:-

- optimising activity levels
- optimising health-related quality of life
- reducing anxiety and depression
- reducing urinary incontinence

4.4 Methods

4.4.1 *Trial design*

A series of replicated single case studies was undertaken. Single case research design has been acknowledged as a scientifically robust and clinically useful method of exploring the effectiveness of an intervention when there is little existing evidence (Graham et al., 2012). An AB design was chosen for its applicability to this specific clinical setting (Zhan and Ottenbacher, 2001). The A-B design is the basic single-subject design. It includes a set baseline phase with repeated measurements (phase A) followed by a set intervention phase continuing the same measures (phase B). The initial baseline serves as a control to enable comparison against the intervention phase.

Each single case study incorporated an AB multiple baseline randomisation test that allows the results of single case studies to be combined to assess for group effects (Todman and Dugard, 2001). In total, there were 18 data points that were taken at weekly intervals. The baseline measurement phase (A) consisted of at least eight consecutive weekly data points where no intervention was in place. The intervention phase (B) consisted of at least eight consecutive weekly data points where the orthotic intervention (customised DEFO) was in place (Nourbakhsh and Ottenbacher, 1994). The onset of intervention phase was randomised and could occur at weeks 9, 10 or 11. Therefore, the baseline phase or intervention phase could consist of between 9-11 data points. The point of randomisation was determined for each participant using a computer programme (randperm function in MATLAB®, Mathworks UK).

4.4.2 *Participants*

4.4.2.1 *Inclusion Criteria*

Women were included in the study if they fulfilled the following criteria:

- Experiencing PGP, commenced or aggravated during pregnancy, where symptoms have continued for > 3 months post-partum,
- PGP which causes walking and/or stair climbing to be bothersome
- Positive on at least three out of seven pain provocation tests (detailed below).

4.4.2.2 *Exclusion Criteria*

Women were excluded from the study if they had:

- A recent history/signs or symptoms indicative of serious causes of pain that might be inflammatory, infective, traumatic, neoplastic, degenerative or metabolic, i.e.
    - trauma
    - unexplained weight loss
    - history of cancer
    - steroid use
    - drug abuse
    - HIV infection
    - immunosuppressed state
    - neurological symptoms/signs (such as bowel, bladder, sensory, motor, reflex involvement)
    - cauda equina, lumbar disk lesion or spinal stenosis
    - history of chronic back or pelvic pain requiring surgery, focal inflammatory signs/tenderness of spine (spondylolisthesis),
    - fever, systemically unwell
    - obstetric complications
    - pain that does not improve with rest/severe disabling pain,
- Known skin allergy to Lycra.

4.4.2.3 *Setting and Location*

Recruitment was conducted through local children's centres within the Plymouth area using a poster advertisement. This had ethical approval from the National Research Ethics Service Committee South West (Cornwall and Plymouth) (IRAS Project ID 177493, REC Reference 15/SW/0160); University of Plymouth ethics committee; and Plymouth City Council. We aimed to recruit a convenience sample of a maximum of eight participants from three different centres (Plymstock Children's Centre, Plum Tree Children's Centre and Plym Bridge Nursery School and Children's Centre). The poster (Appendix 8) included details of the trial, contact telephone numbers for the research physiotherapist and an email address for a generic email account (pelvicgirdlepain@plymouth.ac.uk).

4.4.3 *Intervention*

As the researcher was male, in line with professional practice the assessments were completed with the assistance of a female chaperone. TIDieR Guidelines were adhered to for the reporting of the intervention (Hoffman et al., 2014) utilised during the intervention period (phase B).

4.4.3.1 *Customised Dynamic Elastomeric Fabric Orthoses (DEFO)*

In this single case study, 12 measurements were undertaken for each participant to inform the production of the customised DEFO (see Appendix 11b). These were the same measures taken at the second trimester for participants recruited to the RCT described in Chapter 3, section 3.3.9.2.

4.4.4 *Data Collection Procedure*

4.4.4.1 *Screening Procedure*

All the screening and testing was completed by a single tester (LC, Chartered Physiotherapist) in order to optimise the reliability of the measures taken. Screening (visit 1) was carried out at The Peninsula Allied Health Centre (PAHC), School of Health Professions, Derriford Road, Derriford, PL6 8BH.

When a potential participant had responded to the poster advertisement, via the phone or e-mail contact numbers provided, they were contacted within 24 hours and an appointment arranged with them (visit 1) wherein the project was discussed and their written informed consent obtained (Appendix 8). After written consent had been gained, the participant was screened to determine their suitability for inclusion to the study. Demographic and diagnostic descriptive data and a pain referral map (Appendix 4) were completed at baseline. The participant also completed a self-report questionnaire booklet at baseline (Appendix 10). Pain provocation tests (described in section 3.3.5) were completed where a female chaperone was present during assessments. Participants found to be eligible were measured for the fitting of a customized DEFO (Chapter 3, Section 3.3.9.2), which was the intervention used during phase B.

The self-report questionnaire booklets were then completed by the participants at weekly intervals, and returned in stamped and self-addressed envelopes provided, for the 8 (to 11) week control period (Phase A). Following the completion of the initial 8 (to 11) week control period (Phase A) the participant was then supplied and fitted with a customised DEFO and commenced an 8 (to 11) week

intervention period (Phase B), during which time the same self-report data was be gathered in the same way.

In the unlikely event that the participant demonstrated a full recovery on all outcome measures by the end of the baseline, it was protocolised that this would be noted, and the participant would be withdrawn from the study.

4.4.4.2 *Pain Provocation tests*

The same provocation tests were chosen for the single case study case series as were used within the RCT for both SIJ and SP Symptoms (see Chapter 3, Section 3.3.5 for details). The same criteria was also used with positive outcomes on three out of the seven provocation tests required for inclusion in the study.

4.4.4.3 *Outcome Measures*

The same outcome measures were chosen for the single case study case series as were used within the main study (see Chapter 3, section 3.3.6 for further details). The tests were:

- Numeric Pain Rating Scale (NPRS) - day and night
- Pelvic Girdle Questionnaire (PGQ)
- European Quality of Life – 5 Dimension – 5 Level (EQ5D – 5L)
- European Quality of Life – 5 Dimension – Visual Analogue Scale (EQ5D – VAS)
- Short form 36 item Questionnaire - Version 2 – Physical Component Score (SF36 – V2 PCS)
- Short form 36 item Questionnaire - Version 2 – Mental Component Score (SF36 – V2 MCS)

Two new outcome measures were undertaken in addition to those used in the RCT during this single case study series, to identify other issues within PGP, which have been identified in the literature (Gutke et al., 2017). As previously discussed there is an emotional impact of PGP and hence the Hospital Anxiety and depression Scale (HADS) was incorporated within the battery of outcome measures to identify if there were any changes in anxiety and depression. Further, the International Consultation on Incontinence Questionnaire – Short Form (ICIQ) was used to identify if incontinence was experienced alongside the chronic PGP, and whether this was impacted upon by the DEFO.

4.4.4.4.1 *Hospital Anxiety and Depression Scale (HADS)*

The Hospital Anxiety and Depression Scale is a 14-item self-report questionnaire designed to detect anxiety and depression in people with physical health problems. Seven items relate to anxiety (HADS-A) and seven items to depression (HADS-D). Each item on the questionnaire is scored from 0-3, with a possible total score range of 0 - 21 for either anxiety or depression. A cut-off point of 8/21 for anxiety or depression has been identified (Bjelland et al., 2002). For anxiety, this gave a specificity of 0.78, and a sensitivity of 0.9. For depression, this gave a specificity of 0.79 and a sensitivity of 0.83 (Bjelland et al., 2002). The HADS has also shown good internal consistency, test-retest reliability and construct validity when used in the pregnancy PGP population (Gutke et al., 2011; Elden et al., 2017).

4.4.4.4.2 *International Consultation on Incontinence Questionnaire (ICIQ)*

The International Consultation on Incontinence Questionnaire Short Form (ICIQ-UI- SF), comprised three scored questions regarding how often the participant

leaked urine, what amount, and how much it interfered with their everyday life, in addition to an unscored question about type of urinary incontinence (UI). UI was defined as either absent (0) or present (≥1). In a study of pregnant Taiwanese women, the ICIQ-UI SF was reported as being a suitable instrument for evaluating UI (Chang et al., 2001). It has also been reported that the ICIQ has good internal consistency and test re-test reliability, with no floor or ceiling effects, suggesting that it can be effectively and efficiently used for patients suffering from varying severities of UI (Hajebrahimi et al., 2012). Finally, it has shown to have good discriminate validity within the pregnancy related PGP population (Fitzgerald et al., 2012). This combined evidence supporting its psychometric properties provided the justification for its use in this single study case series.

4.5 Data Analysis

Data from each outcome measure at each time-point was plotted on a separate graph for each single case study participant, with the baseline and intervention phases differentiated. Visual inspection initially looked for changes in trend, level, slope and variability (Parker et al., 2011). The celeration line method, also known as the split-middle technique (Kazdin, 1982) was used as a straightforward method of identifying if any of the plotted intervention data differed from the plotted baseline data. The celeration line was obtained by dividing the plotted baseline data in half. Then the median is taken from each half of the baseline data. The two calculated median points are then joined together. The celeration line is then extended into the intervention line using the equation from the trend line to predict the continuation of this data. This provided some evidence to help identify any treatment effect. If, for example, the

celeration line divided the baseline data into four data points above and below the celeration line, if this trend is not continued into the intervention phase (e.g. there are now more values above the celebration line) then it is deemed that there has been a change (Nourbakhsh and Ottenbacher, 1994).

The two standard deviation band method (+/- 2SD) was also applied to strengthen these initial visual findings (Nourkbakhsh and Ottenbacher, 1994). The mean and standard deviation (SD) was calculated from the baseline scores. The SD was multiplied by two, then added to the mean to give the +2 SD band and subtracted from the mean to give the -2 SD band. A significant change in performance occurs when at least two consecutive data points fall outside the 2SD range within the intervention phase (Nourkbakhsh and Ottenbacher 1994).

The Point of Non-overlapping Data (PND) statistic was also applied to the data to further strengthen visual findings (Scruggs and Mastropieri, 2001). Here, the most extreme data point within the baseline is identified (this can be either the highest or lowest data point depending on the expected direction of improvement on the scale used). The intervention data points are then counted to determine how many data points fall above or below (again depending on the direction of improvement on the scale) the extreme data point identified during the baseline phase. A percentage is then calculated (e.g. if six out of eight intervention data points fall outside the extreme data point then the PND percentage is 75%). For a very effective treatment a PND score of ≥ 90% is required, 70% - 90% = effective treatment, 50% - 70% = questionable effectiveness and <50% = ineffective treatment (Scruggs et al., 1986). The use of these statistical tests in addition to the visual analysis enables consistent interpretation of

results and reduces the requirement for stable baselines (Nourbakhsh and Ottenbacher, 1994).

4.6 Randomisation Testing

AB multiple baseline randomisation tests (Todman and Dugard, 2001) were undertaken using MatLab (MathWorks, UK) for each of the outcome measures (with and without the DEFO). This enabled the data from all the single case studies to be combined and examined to see whether any improvement was due to the intervention or chance. This method works on the principle of comparing the change in an outcome measure between the baseline and intervention period across all participants. As the onset of the intervention phase was randomised between the eight participants, it is possible to compare the actual change in the score with the change in the score if the onset had occurred at one of the other possible intervention points. In this case, intervention could occur at three possible points (week 9, 10 or 11). Six single case studies were able to be analysed in this way. The first single case study (participant 1) did not undergo the randomisation procedure. Participant 6 had missing data in week 18 that precluded the inclusion in the analysis. With six participants, this resulted in a potential 729 potential intervention-start combinations or 3^6. The MatLab program randomly generated 500 combinations that could start on day 9-11 for subjects 2-5 and 7-8. In each case the difference between the mean of the baseline and intervention, periods were calculated. The percentage of randomly generated change scores that were lower than that actually recorded provides a probability that the actual change did not occur by chance. If their actual change was higher than all the randomly generated change scores this resulted in a probability of 0.002 (i.e. 1 in 500

comparisons). Significance level was set at 0.05. Therefore, if more than 50 randomly generated change scores were higher than that actually achieved then the probability that this occurred by chance is >0.05 and considered to be non-significant.

4.7 Results

Adherence was extremely high with 70% applying their orthotic for the recommended 12 hours. A further 10% were wearing the orthotic for longer than the recommended 12 hours and 20% wearing below the recommended 12 hours. Table 4.1 details participant characteristics and Table 4.2 shows results of the celeration line, 2+/- standard deviation band method and PND statistic for all outcome measures for all participants. The numerical Pain Rating Scale (NPRS day and night) are plotted for each participant.

Participant	Age	Parity	Mode of Delivery	Duration of Symptoms (in months)	Body Mass Index
1	40	2	Caesarean	74	23.2
2	39	1	Normal delivery	6	25.1
3	31	1	Ventouse	18	21.8
4	28	2	Normal delivery	12	24.3
5	26	2	Normal delivery	30	25.6
6	31	3	Normal delivery	48	26.1
7	28	1	Forceps	24	26.8
8	33	2	Ventouse	36	25.9

Table 4.1 *Participant characteristics*

Outcome Measure	1	2	3	4	5	6	7	8
NPRS (day)								
Celeration Line	↓	↓	↓	↓	↑	↑	↓	↓
2SD +/- Band Method	X	√	X	X	X	√	X	√
PND Statistic	75%	62.50%	<50%	<50%	<50%	<50%	<50%	67%
NPRS (Night)								
Celeration Line	↓	↓	↓	↓	–	↑	↓	–
2SD +/- Band Method	X	√	√	X	√	X	√	√
PND Statistic	<50%	87.50%	75%	67%	<50%	<50%	78%	89%
Pelvic Girdle Questionnaire								
Celeration Line	↓	↓	↓	↓	–	↑	↓	↓
2SD +/- Band Method	√	√	X	√	X	X	√	√
PND Statistic	>90%	70-90%	50-70%	<50%	70-90%	50-70%	50-70%	<50%
EQ5D - 5L								
Celeration Line	↑	–	↑	↑	↑	↑	↑	↑
2SD +/- Band Method	X	X	X	X	X	X	X	X
PND Statistic	70-90%	70-90%	<50%	<50%	<50%	<50%	<50%	<50%
EQ5D - VAS								
Celeration Line	↓	↑	↑	↑	↓	↓	↑	↑
2SD +/- Band Method	√	√	√	X	√	√	√	X
PND Statistic	70-90%	70-90%	70-90%	<50%	50-70%	<50%	<50%	<50%
SF36 - V2 (PCS)								
Celeration Line	↑	↑	↑	↑	↓	↓	↑	–
2SD +/- Band Method	√	√	X	X	X	X	X	√
PND Statistic	>90%	70-90%	<50%	<50%	<50%	<50%	<50%	67%
SF36 - V2 (MCS)								
Celeration Line	↑	↑	↓ (neg)	↑	↓	↓ (neg)	–	↓
2SD +/- Band Method	√	X	X	X	X	X	X	X
PND Statistic	>90%	<50%	<50%	<50%	<50%	<50%	<50%	<50%
HADS								
Celeration Line	N/A	–	↓	↓	–	↓	↑	–
2SD +/- Band Method	N/A	X	X	X	X	X	X	X
PND Statistic	N/A	<50%	<50%	<50%	<50%	<50%	<50%	<50%
ICIQ								
Celeration Line	N/A	–	–	–	–	–	–	–
2SD +/- Band Method	N/A	X	X	X	X	X	X	X
PND Statistic	N/A	<50%	<50%	<50%	<50%	<50%	<50%	<50%

Celeration Line - ↑indicates intervention above celeration line, ↓ indicates intervention below celeration line, – indicates flat intervention celeration line

2SD+/- Band Method - √ indicates a signifcant change with 2 consecutive datapoints falling outside the 2SD band in the intervention phase, X indicates non-significant change

PND Statistic - >90% = Very Effective change, 70%-90% = Effective change, 50%-70% = Questionable change, <50% = Ineffective change

Table 4.2 *Shows participant outcome measure results for each analysis used; celeration line, 2SD+/- band method and PND statistic. Legend reflects an overview of results from all analyses with an indication of direction of change.*

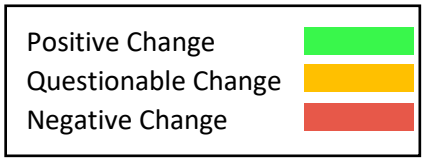


Table 4.2 provides an overview of the outcome measure results for each of the eight subjects across the three separate analysis methods used; celeration line, 2SD+/- band method and PND statistic. Each of these analyses provides their own measure of change (see section 4.5). However, for ease of reference a colour-coded overview has been provided indicating where either a positive, questionable or a negative change had occurred based on the individual measure of change.

NPRS Day

Visual analysis of the celeration line indicated that there was a positive and significant change in the intervention phase for 6/8 participants. The PND statistic demonstrated an effective change for one of the participants (75%) and a questionable change for two participants. The 2SD band method revealed a significant treatment effect for 3/8 participants with the observation of two or more consecutive data points occurring out with 2SDs within the intervention phase.

NPRS Night

Visual analysis of the celeration line indicated that there was a positive and significant change in the intervention phase for 6/8 participants. The PND statistic demonstrated a significant change for four of the participants (70%-90%). The 2SD band method revealed a significant treatment effect for 5/8 participants with the observation of two or more consecutive data points occurring outwith 2SDs within the intervention phase.

PGQ

Visual analysis of the celeration line indicated that there was a positive and significant change in the intervention phase for 6/8 participants. The PND statistic demonstrated a questionable change for three participants (50%-70%), an effective change for two participants (705-90%) and a very effective change for one participant (>90%). The

2SD band method revealed a significant treatment effect for 5/8 participants with the observation of two or more consecutive data points occurring outwith 2SDs within the intervention phase.

EQ5D – 5L

Visual analysis of the celeration line indicated that there was no change in the intervention phase for all participants. The PND statistic demonstrated a significant change (70%-90%) for 2/8 participants. The 2SD band method revealed a non-significant treatment effect for all participants as no observations of two or more consecutive data points outwith 2SDs were seen within the intervention phase.

EQ5D – VAS

Visual analysis of the celeration line indicated that there was a positive and significant change in the intervention phase for 3/8 participants. The PND statistic demonstrated an effective change for 3/8 participants. The 2SD band method revealed a significant treatment effect for 6/8 participants with the observation of two or more consecutive data points occurring outwith 2SDs within the intervention phase.

SF36 - V2 PCS

Visual analysis of the celeration line indicated that there was a positive and significant change in the intervention phase for 2/8 participants. The PND statistic demonstrated a questionable change for one participant (50%-70%), an effective change for one participant (70%-90%), and a very effective change for one participant (>90%). The 2SD band method revealed a significant treatment effect for 3/8 participants with the observation of two or more consecutive data points occurring outwith 2SDs within the intervention phase.

SF36 - V2 MCS

Visual analysis of the celeration line indicated that there was a positive and significant change in the intervention phase for one participant. The PND statistic demonstrated a very effective change for one participant (>90%), but a non-significant change for the remaining 7/8 participants. The 2SD band method revealed a significant treatment effect for one participant with the observation of two or more consecutive data points occurring outwith 2SDs within the intervention phase.

HADS

Participant one was the only participant not to undertake the HADS outcome measure. Visual analysis of the celeration line indicated that there was a positive and significant change in the intervention phase for 3/7 participant (see Table 4.2). The PND statistic and 2SD band method identified no change in the intervention phase for all participants.

ICIQ

Participant one was the only participant not to undertake the ICIQ outcome measure. Visual analysis of the celeration line indicated that there was no change in the intervention phase for all participants. The PND statistic and 2SD band method identified no significant change in the intervention phase for all participants.

4.7.1 *Participant 1*

Participant one was a 40 year old female who worked as a midwife. She had suffered from her PGP symptoms for approximately seven years. Her symptoms commenced during her first pregnancy, which involved both a ventouse and caesarean section. Following the delivery her symptoms persisted, significantly impacting upon her quality of life, with pain

and reduced function. The participant believed that her "traumatic pregnancy" was the reason why her symptoms were continuing. Her symptoms continued into her second pregnancy, where she opted for a caesarean section to prevent the trauma that had occurred in the first pregnancy. Following the delivery of her second child her symptoms persisted. She had seen a wide variety of NHS and private health care professionals to assist with her symptoms but had no significant improvement (see Figure 4.1 and 4.2 for results).

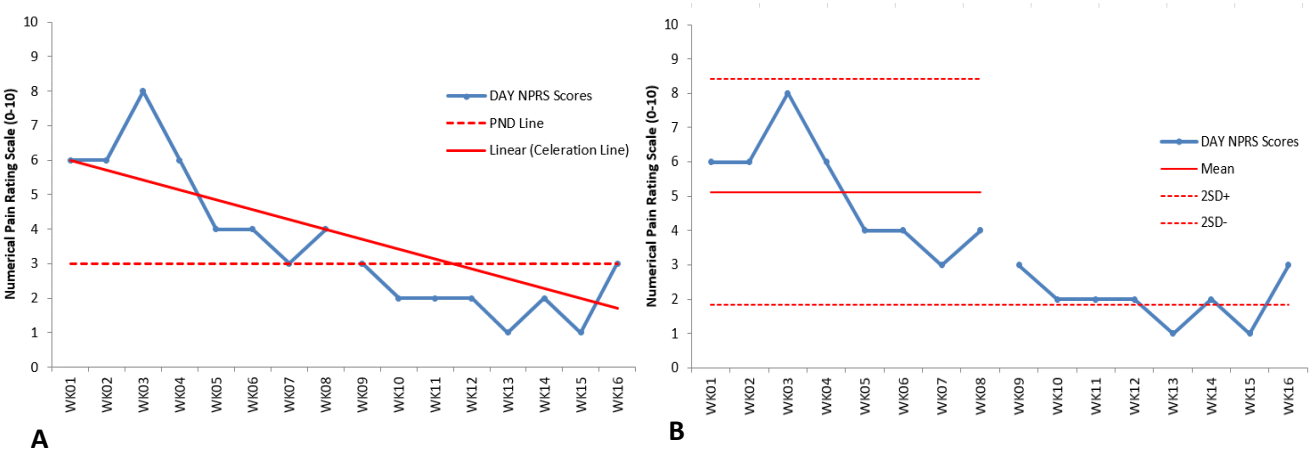


Figure 4.1 Participant 1 Numerical pain rating scale (Day) results, **A** = Celeration line and Position of Non-overlapping Data statistic (PND), **B** = +/- 2 standard deviation Band Method

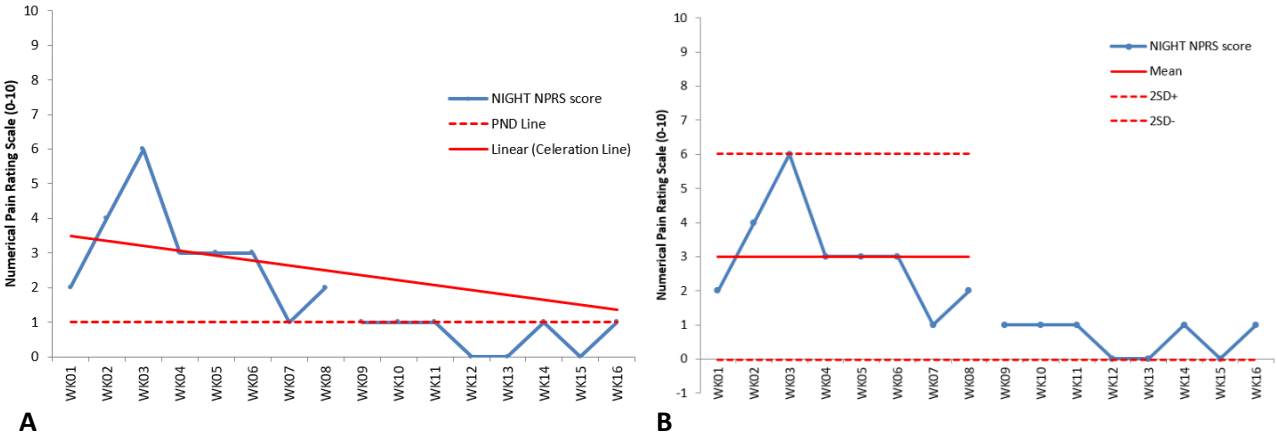


Figure 4.2 Participant 1 Numerical pain rating scale (Night) results, **A** = Celeration line and Position of Non-overlapping Data statistic (PND), **B** = +/- 2 standard deviation Band Method.

4.7.2 *Participant 2*

Participant Two was a 39 year old female who was a lecturer at a university. She had reported symptoms for approximately six months following the delivery of her child. She reported generalised pain into her posterior pelvis during pregnancy that did not resolve in the post-partum period. This led to general pain and discomfort, causing reduced activity and function (see Figure 4.3 and 4.4 for results).

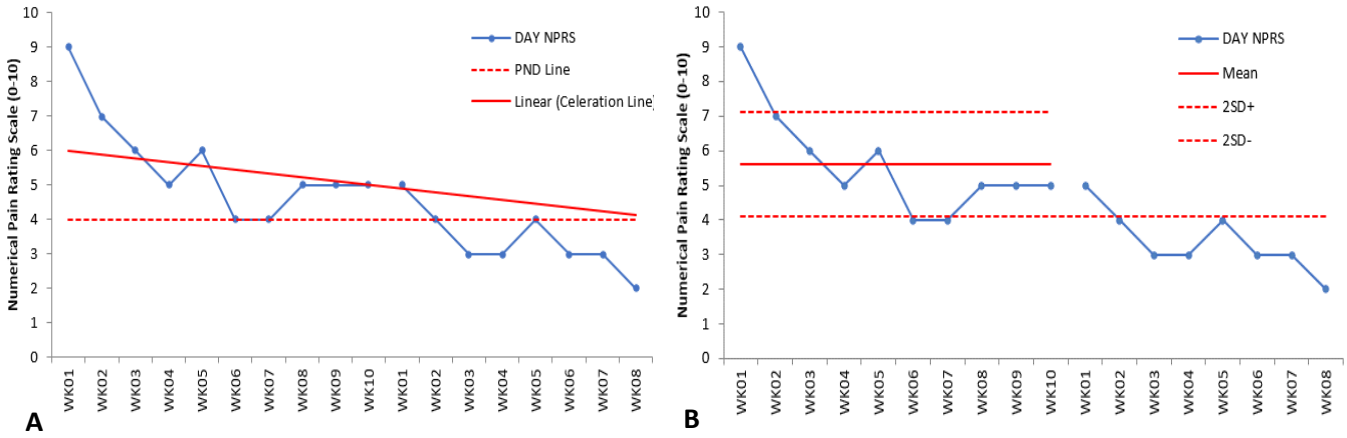


Figure 4.3 Participant 2 Numerical pain rating scale (Day) results, **A** = celeration line and position of Non-overlapping Data statistic (PND), **B** = +/- 2 standard deviation Band Method

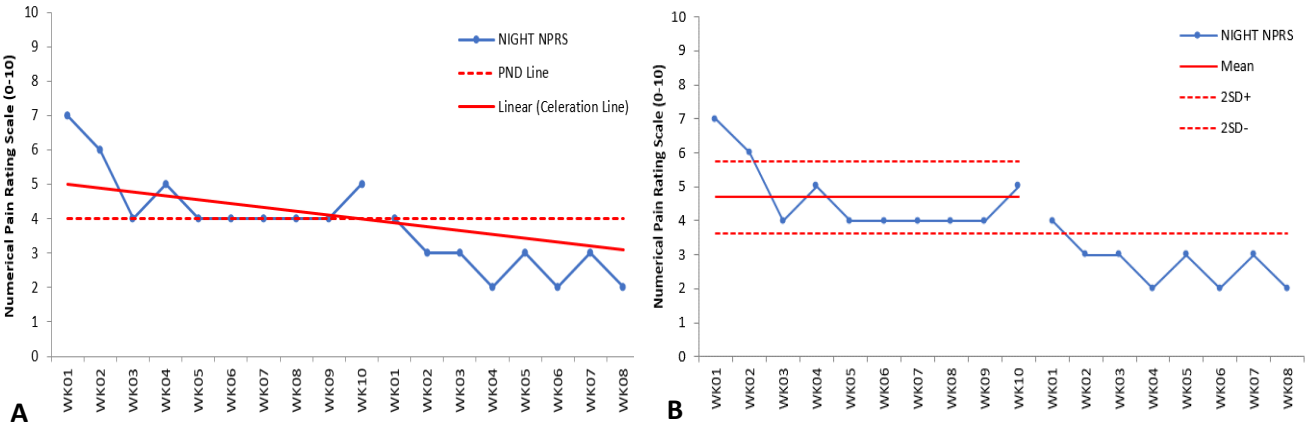


Figure 4.4 Participant 2 Numerical pain rating scale (NIGHT) results, **A** = celeration line and position of Non-overlapping data statistic (PND), **B** = +/- 2 standard deviation Band Method

4.7.3 *Participant 3*

Participant Three was a 31 year old female who was a nurse. She had suffered with persistent PGP symptoms following her pregnancy with symptoms continuing at 18 months following the natural delivery of her child. She had previously attempted to seek help but reported being dismissed by her General Practitioner (GP) and subsequently continued to attempt to manage her symptoms independently with modification of her activities (see Figure 4.5 and 4.6 for results).

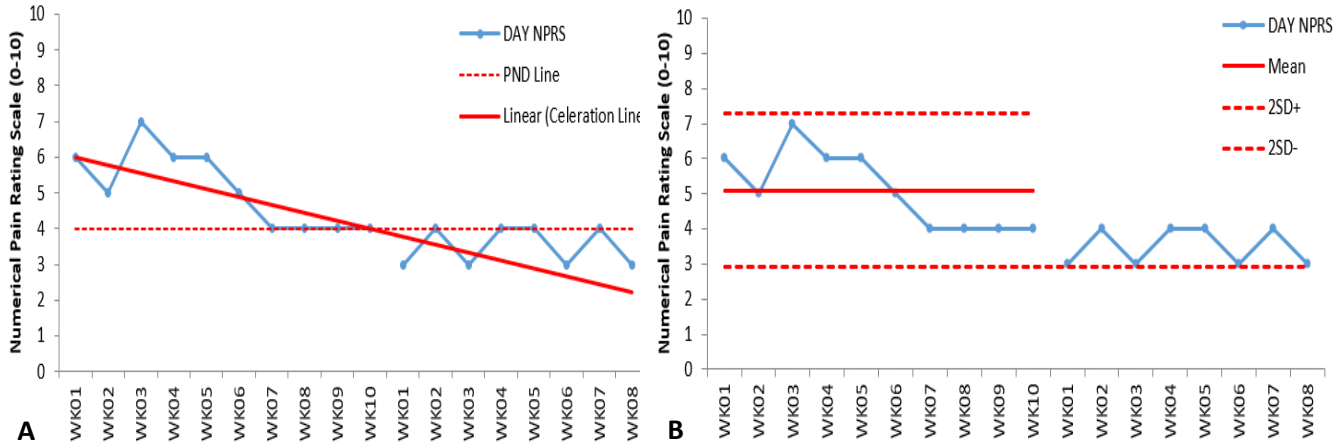


Figure 4.5 Participant 3 Numerical pain rating scale (Day) results. **A** = celebration line and Position of Non-overlapping Data statistic (PND), **B** = +/- 2 standard deviation Band Method

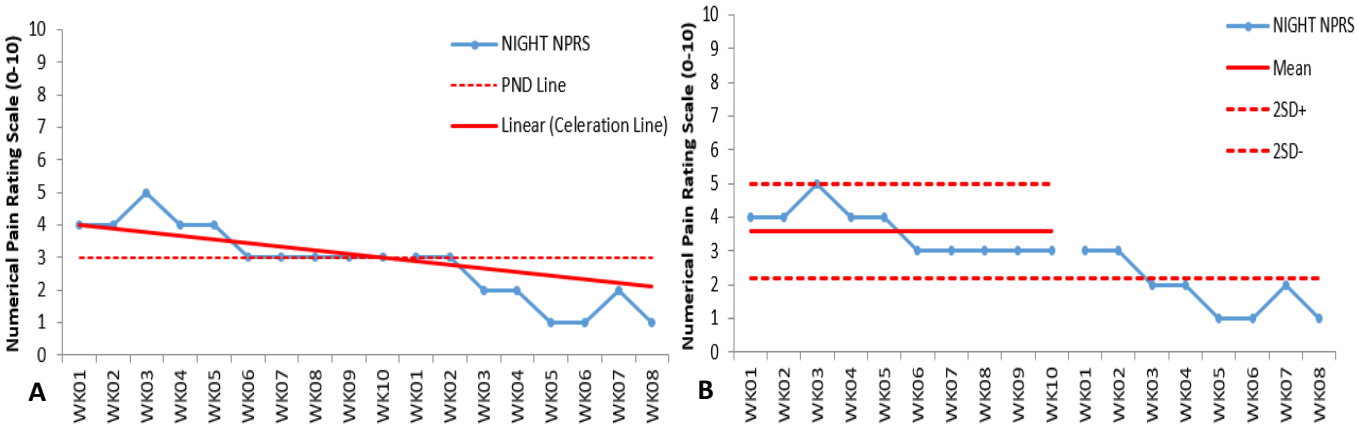


Figure 4.6 Participant 3 Numerical pain rating scale (Night) results, **A** = celebration line and Position of Non-overlapping data statistic (PND), **B** = +/- 2 standard deviation Band Method

4.7.4 *Participant 4*

Participant Four was a 28 year old female who worked as a bank administrator. She had two children and her last delivery was a natural birth. She had experienced pregnancy related PGP symptoms during her second pregnancy and had not experienced symptoms in her first pregnancy. Her PGP had persisted for approximately 12 months. She had reported not seeking any help to manage her current symptoms (see Figure 4.7 and 4.8 for results).

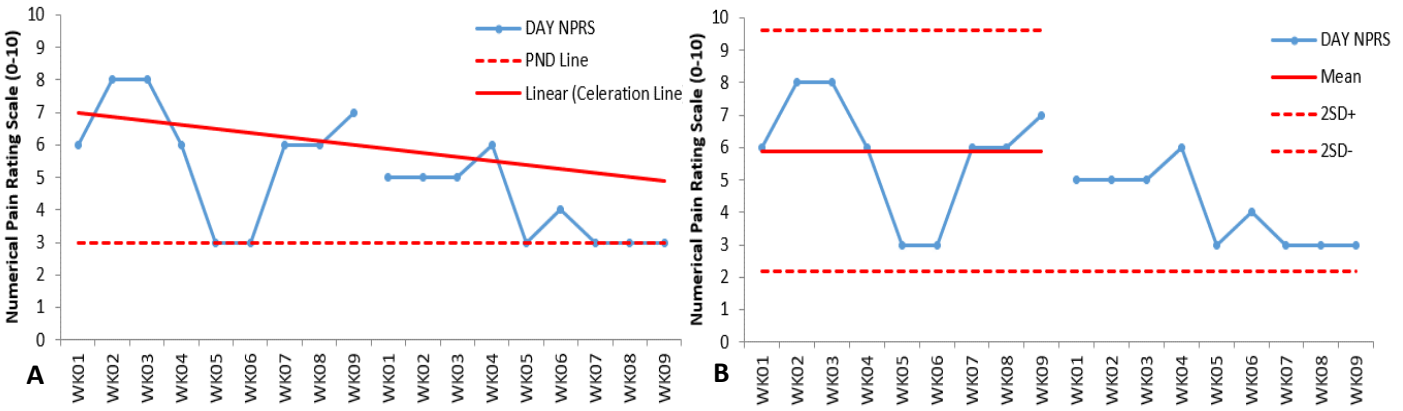


Figure 4.7 Participant 4 Numerical pain rating scale (Day) results, **A** = celeration line and Position of Non-overlapping Data statistic (PND), **B** = +/- 2 standard deviation Band Method

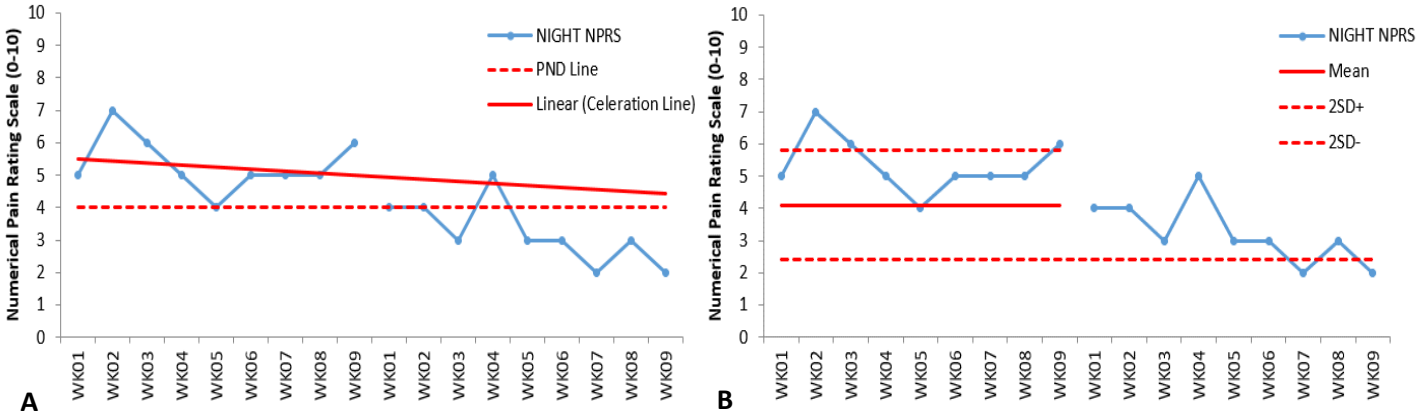


Figure 4.8 Participant 4 Numerical pain rating scale (Night) results, **A** = celeration line and Position of Non-overlapping Data statistic (PND), **B** = +/- 2 standard deviation Band Method

4.7.5 *Participant 5*

Participant Five was a 26 year old female who worked as an administrator for an insurance company. She had two children and reported that her pregnancy related PGP commenced during the end of her first pregnancy and persisted into her second pregnancy, which commenced less than 12 months following the delivery of her first child. In total, her pregnancy related PGP had persisted for approximately 30 months (see Figure 4.9 and 4.10 for results).

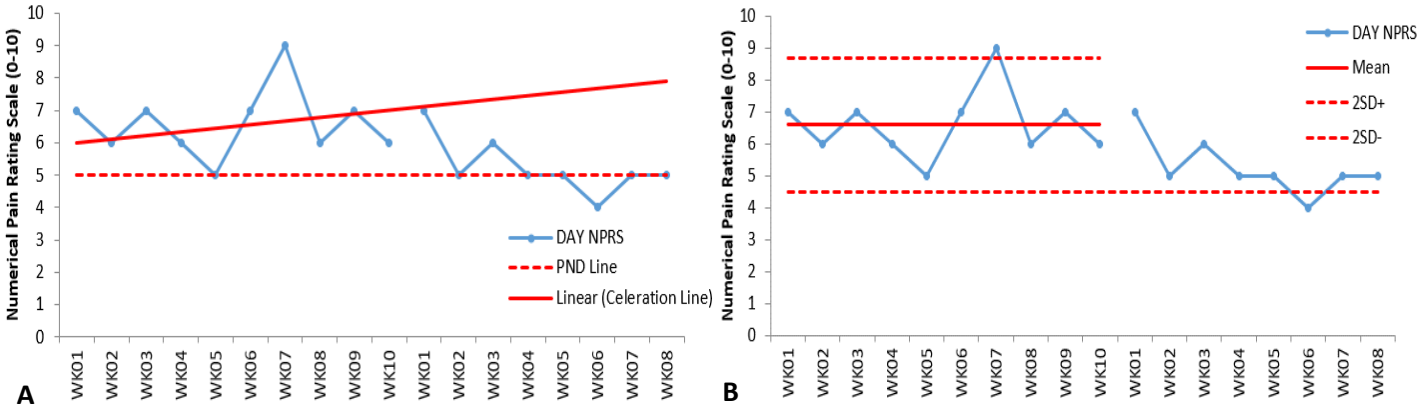


Figure 4.9 Participant 5 Numerical pain rating scale (Day) results, **A** = celeration line and Position of Non-overlapping Data statistic (PND), **B** = +/- 2 standard deviation Band Method

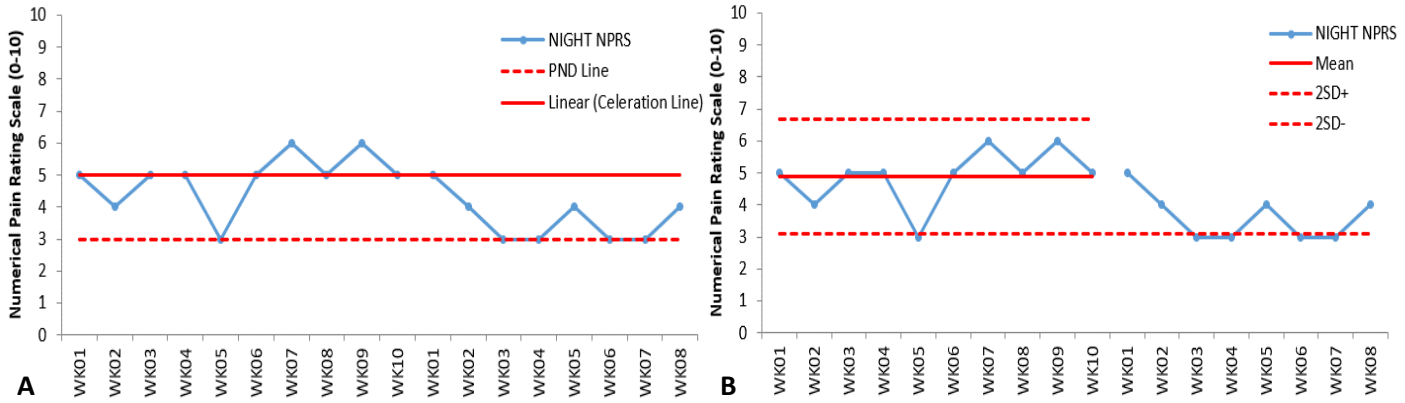


Figure 4.10 Participant 5 Numerical pain rating scale (Night) results, **A** = celebration line and Position of Non-overlapping Data statistic (PND), **B** = +/- 2 standard deviation Band Method

4.7.6 *Participant 6*

Participant six was a 31 year old full time mother. She had experienced PGP symptoms for approximately 48 months following the delivery of her third child. She reported requiring instrumented delivery during the delivery of her first child, however, the delivery for her third child was a natural delivery (see Figure 4.11 and 4.12 for results).

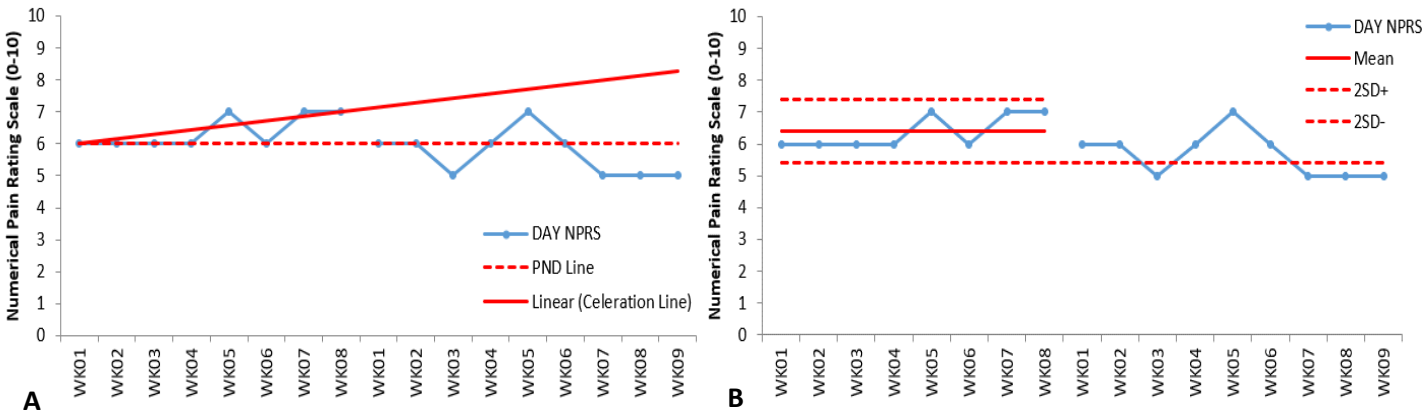


Figure 4.11 Participant 6 Numerical pain rating scale (Day) results, **A** = celeration line and Position of Non-overlapping Data statistic (PND), **B** = +/- 2 standard deviation Band Method

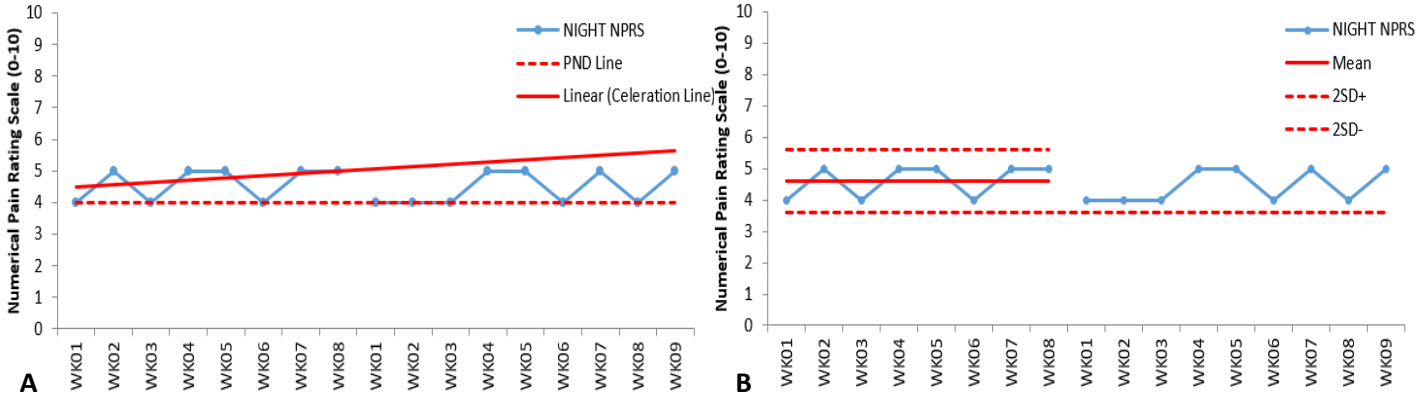


Figure 4.12 Participant 6 Numerical pain rating scale (Night) results, **A** = celebration line and Position of Non-overlapping Data statistic (PND), **B** = +/- 2 standard deviation Band Method

4.7.7 *Participant 7*

Participant seven was a 28 year old female, healthcare assistant. She reported suffering with PGP that commenced during her pregnancy and had persisted for approximately 24 months. She required a forceps delivery during her delivery (see Figure 4.13 and 4.14 for results).

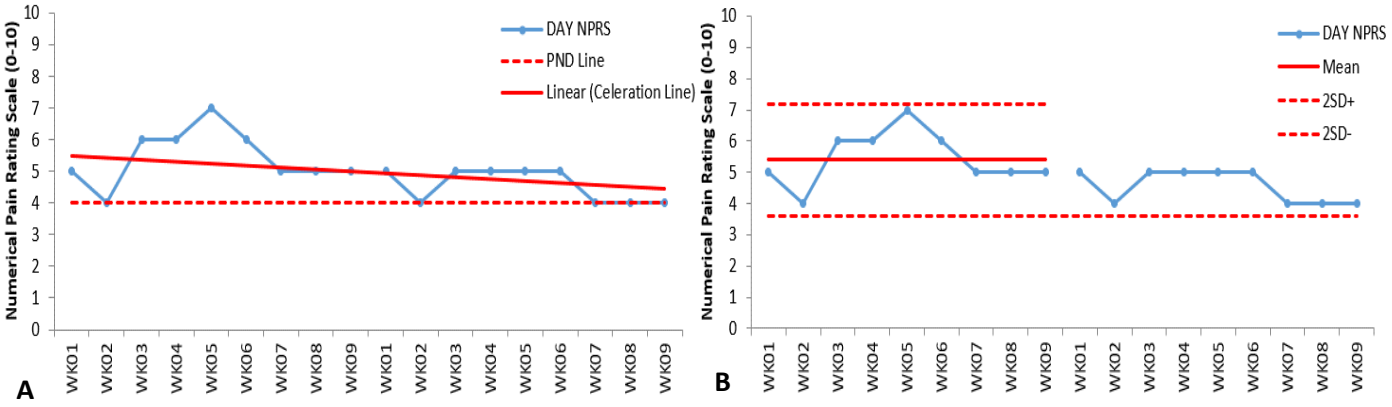


Figure 4.13 Participant 7 Numerical pain rating scale (Day) results, **A** = celeration line and Position of Non-overlapping Data statistic (PND), **B** = +/- 2 standard deviation Band Method

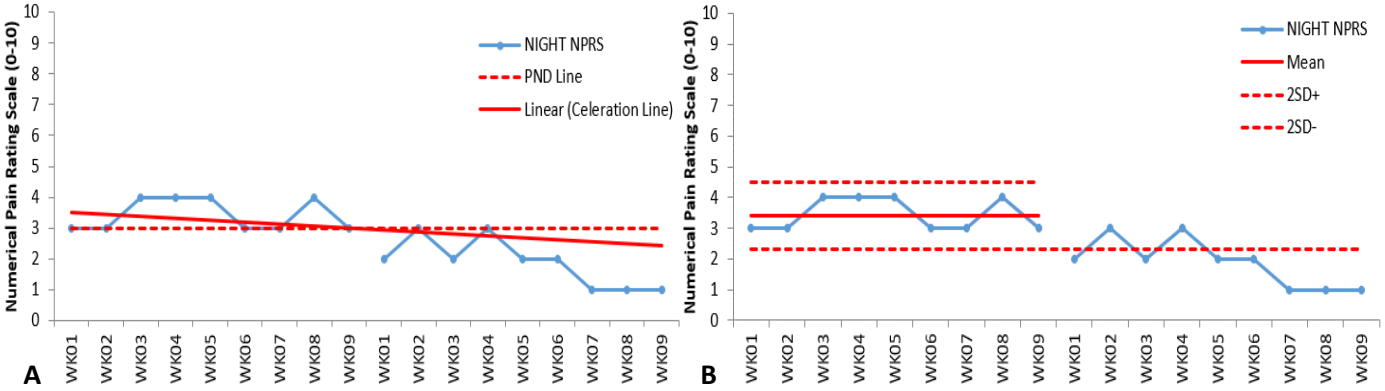


Figure 4.14 Participant 7 Numerical pain rating scale (Night) results, **A** = celeration line and Position of Non-overlapping Data statistic (PND), **B** = +/- 2 standard deviation Band Method

4.7.8 *Participant 8*

Participant eight was a 33 year old full time mother. She reported having two children, requiring instrumented deliveries for both deliveries. Her most recent delivery required ventouse instrumented assistance. She reported a 36 month history of PGP symptoms. She reported initial symptoms commenced during her first pregnancy however these were mild and resolved following her delivery. During her second pregnancy her symptoms of PGP returned and she reported symptoms of 36 months from this onset (see Figure 4.15 and 4.16 for results).

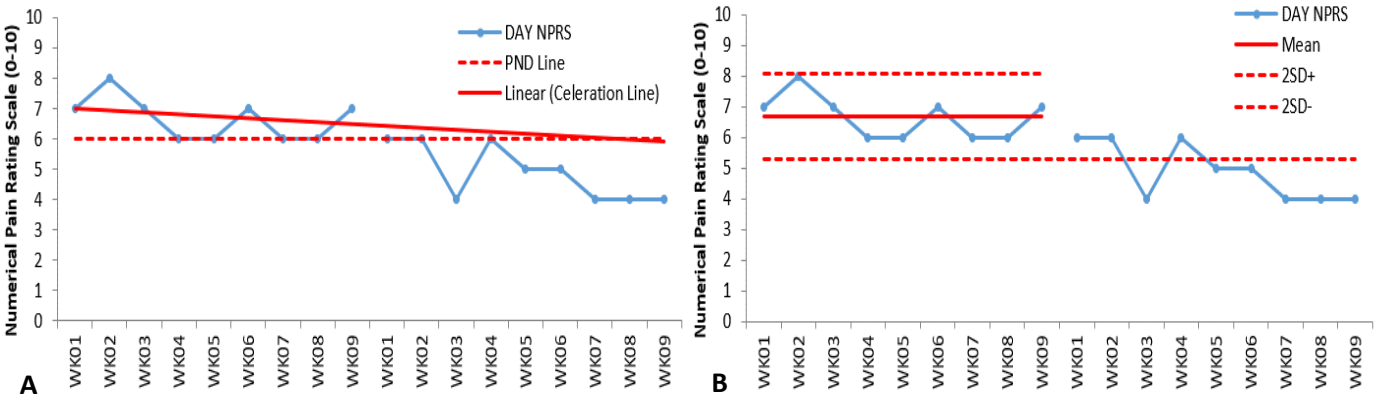


Figure 4.15 Participant 8 Numerical pain rating scale (Day) results, **A** = celeration line and Position of Non-overlapping Data statistic (PND), **B** = **+**/- 2 standard deviation Band Method

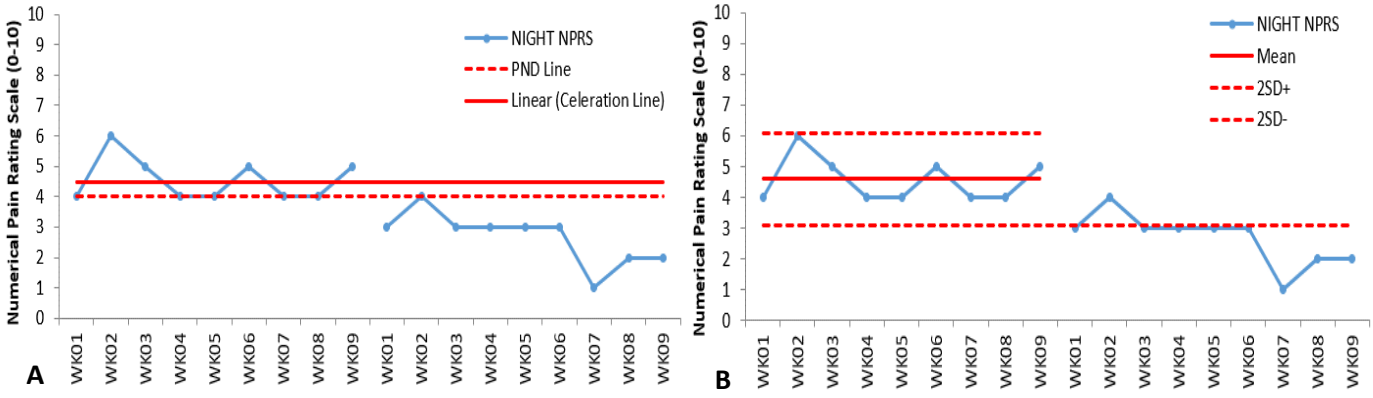


Figure 4.16 Participant 8 Numerical pain rating scale (Night) results, **A** = celeration line and Position of Non-overlapping Data statistic (PND), **B** = +/- 2 standard deviation Band Method

4.7.9 *Group Randomisation Testing Results*

The results of group analysis, combining six participants using a randomisation test are shown in Table 4.3 below. Participant 1 was excluded as they were the original case study and only 16 data points were used; eight pre and eight post, with baseline and intervention period not randomised. Participant 6 was excluded due to a missing data point.

Outcome Measures	Customised DEFO
NPRS (DAY)	0.002*
NPRS (NIGHT)	0.002*
EQ5D-5D-5L	0.218
EQ5D-VAS	0.707
PGQ	0.002*
SF36-V2 - PCS	0.661
SF36 - V2 - MCS	0.749
HADS	0.002*
ICIQ-SF	1.000

Table 4.3 *Randomisation test p values for all outcome measures (* significant values)*

These values indicate if there is a statistically significant difference between the actual changes at baseline to intervention scores compared with the randomly generated change when all participant scores are grouped together. The values compare the baseline

scores to the scores obtained during the intervention period whilst wearing the customised DEFO. This highlights that there was a significant effect with the use of the DEFO for both day and night pain (NPRS day and night).

4.8 Discussion

The results of this replicated single case study case series provides evidence to suggest that a customized DEFO can potentially help to reduce day and night time pain and reduce anxiety and depression in persons experiencing chronic, post-partum PGP. These findings are supported on a case-by-case basis as well as the group analysis. When visually analysing the data, many participants presented with variable baselines throughout all outcome measures, with data points at both high and low extremes (e.g. for Participant 1 there was a five point difference between the highest and lowest data point on the NPRS – lowest being 1 and highest being 6) . This reflects the natural variability of symptoms that can occur with this chronic condition, a situation that clinicians are regularly faced with in practice. Nevertheless the visual analysis of data for most participants did indicate an improvement during the intervention phase compared to baseline; alongside this it was apparent that the scores were more consistent (aka “stable”) during the intervention phase. Although not assessed, it could be that the increased stability of symptoms during the intervention phase could be important in allowing participants to plan activities more confidently with the knowledge that pain levels would not vary before, during or afterwards.

It was observed that Participant 4 had a significant reduction in pain over two data points during the baseline phase of the primary outcome measure; which coincided with her holiday/annual leave. This impacted upon the overall results of participant 4, with tests such as PND and 2+/- SD band method having less positive results. Participant 6, on visual analysis did not appear to have any significant improvement in the intervention, however,

demonstrated a significant change in the standard deviation band method for the NPRS and EQ5D-VAS indicating improvement in pain and health. Participant 3 appeared to show improvement in her baseline phase which continued into the intervention phase. It would be difficult to postulate the cause for this as her work patterns were consistent (working as a nurse and continuing with 12 hour working shifts) but it is possible that this could have been related to the standardised physiotherapy intervention (see section 3.3.9.3) which was provided to all participants. In summary, most participants appeared to present with improvement in the intervention phase.

When considering the disease specific questionnaire, the PGQ showed a significant improvement for five out of eight females who reported improvement in pain and activity levels. Participant 4 was again affected by the two weeks of improvement, which coincided with her annual leave during the baseline data collection phase. An improvement in the PGQ was observed for participant 6 who did not visually, or on analysis, appear to have a marked improvement during the intervention phase on pain with no effect of night pain and an effect on day pain only suggested by one method. From observations and analyses participant 1 also had a significant response for most outcome measures (except HAD and ICIQ as they didn't undertake them) but did not gain as positive a result on the NPRS night unlike the others. This suggests that improvements in quality of life and activity may not always be strongly associated with a reduction in pain.

The unstable baseline in some of the case studies complicated the interpretation of the NPRS pain data. In addition to this there were limitations to some of the analyses methods. For example, when using the 2+/- SD band method, the extreme scores resulted in large SD's which prevented the possibility for findings to be significant, since the minus 2+/- SD band fell below a score of zero. Of interest the NPRS 'night' had a lower pain score at baseline, compared to the daytime scores, indicating that pain levels at night were generally

less; this is opposite to PGP during pregnancy. Whether there are differences in sleep patterns and sleep quality between the two groups and with the intervention is a potential area of future study. In a similar fashion, the relatively wide-ranging scores during baseline also impacted on the interpretation of the PND statistic (PND = <50% ineffective).

Pelvic orthotics have been reported to influence pelvic joint stability and this could have been one potential mechanism for the improvement of the participants' symptoms (Damen et al., 2001; Mens et al., 2017). By improving their force/form closure throughout the pelvis and enabling optimisation of muscle function as a result of compression and joint stability, this could have led to reduced pain and improved function (Mens et al., 2017). It has been previously stated that enhanced joint shear forces could be a mechanism for pain to commence in PGP and subsequently any improvement in pelvic stability could have reduced this symptoms. The effects of pelvic orthotics have been previously reported to improve SIJ stability when undertaking an ASLR (Damen et al., 2001; Beales et al., 2010).

Alongside the potential for enhanced pelvic stability to improve symptoms, pelvic orthotics are also speculated to improve proprioceptive deficit (Bertuit et al., 2018a). The compression gained to both joint and soft tissue is believed to influence subcutaneous receptors further improving joint positional awareness and potentially improving impaired muscle function (Shaffer and Harrison et al, 2007). All of these components could lead to reduced joint and soft tissue irritation. Direct evidence for this mechanism of action however is limited. Future work could assess joint movement thresholds and joint position sense at the hip with and without the DEFO. This could look at the minimal velocity of hip movement that could be subjectively detected using motorised devices such as a dynamometer to slowly move a joint at different speeds (for the same amplitude of movement) whilst other sensory cues (e.g. the sound of the motor) are nulled. Joint position matching could also be assessed although this may be difficult as the test is usually assessed

by moving one joint to a position passively by an examiner/motor and then asking the participant to match the position with the contralateral limb. For this test, the contralateral limb should not be affected whilst in PGP the pain is often felt bilaterally. Finally it may be possible to assess sensori-motor control by assessing whether the response to short, fast motor-driven stretches to the hip adductors result in larger stretch reflex responses in the hip adductors when wearing the DEFO. This would imply that for the same stimulus (stretch amplitude and speed) the motor output is larger when wearing the DEFO implying that the stretch caused a larger afferent volley into the spinal cord (reflecting the hypothesised increased in afferent stimulation with the DEFO).

All the females within this study reported symptoms of PGP for longer than three months. With this chronicity in mind, it is important to be aware that many factors may contribute to post-partum PGP. Although the true nature is still not well understood, it could be hypothesised that a combination of factors leads to the continuing symptoms. Factors such as reduced pelvic stability, suboptimal muscle functioning, poor motor control, and reduced proprioception could be important alongside factors such as low mood, reduced confidence along with biopsychosocial issues (Vleeming et al., 2008; Shaffer and Harrison, 2007; Mens et al., 2017; Bergstrom et al., 2014). Not all of these factors could be immediately modifiable with a DEFO. However, although the DEFO may act through mechanical stabilisation and sensory stimulation its impact on activity may have longer consequences. The immediate improvements in pain could allow people to increase activity levels, which in turn could impact positively on other causative factors such as muscle strength and motor control. Greater ability to move pain free could also impact on factors such as occupation, participation and mood. These in turn could further help to reduce the symptoms and impact of PGP.

Females suffering from chronic PGP have been shown to present with higher rates of depression than healthy individuals (Elden et al., 2016). It is for this reason that the HADS was included in the battery of outcome measures. On group analysis, a significant improvement in the HADS was observed. Future work could explore in more detail the association between pain reduction and improvement in mood with DEFOs and to ascertain whether changes occur in parallel or whether changes in one variable precedes the other to get an indication of cause-and-effect relationships.

Interestingly, studies identify maternal age as a risk factor for suffering from chronic PGP and the average age for females in this single case study series was 32 years old (Bergstrom et al., 2014). It was identified by Bergstrom 2014, that females aged 30 and above are at higher risk (Bergstrom et al., 2014). Although this factor is not modifiable it could be used clinically to identify at risk individuals as part of a future PGP care pathway.

Although enhanced activity levels could positively affect muscle strength, it is important to be mindful that research undertaken by Hu et al. (2010) identified that pelvic belts cause a decrease in both the transverse and oblique abdominal musculature (Hu et al, 2010). This is supported by Beales et al. (2010) who showed a continued abnormal muscular response despite improvement in joint stability (Beales et al., 2010). This could result from disuse muscle atrophy as the belt / orthotic assumes responsibility for the stabilisation role of the muscles. As undertaken in this study, the provision of standardised physiotherapy advice and a holistic approach to rehabilitation would hopefully prevent this. Future work could therefore look at whether the observed improvements with the DEFO can be further enhanced with more intensive, personalised rehabilitation package. It is also important to look at the longer term (>2 months) effect of a DEFO to see whether people still require the orthosis long term or whether they develop (e.g. through improvements in stability, strength and motor control) the ability to be pain free without the orthosis. It may be that

long term use, although potentially affecting local muscle strength (e.g. causing abdominal weakness), may allow other factors underlying force closure (e.g. ligament support) to improve. For example, repeated positioning of a joint in shortened position (as facilitated with the DEFO) might lead to increased stiffness. The short and long term stability of the SIJ, for example, could be assessed using the ultrasound transmission of vibratory stimuli across the joint as has been performed previously (Vlaanderen et al., 2005).

4.9 Strengths and Limitations

The ability to undertake group testing was a strength to this study. Single case studies can give valuable insight into conditions and research issues, such as the suitability of outcome measures. However, single case studies can be limited in their generalizability. The ability to undertake randomisation tests in this case study series, provides preliminary evidence that improvements in pain, quality of life, activity levels and mood could be occurring at a group level.

Unfortunately, there was missing data for participant 6. This precluded them from group testing which may have affected the overall randomisation results. Participant 1 was also precluded from group testing as they were the original case study, which prompted the development of a case study series. Participant 1 was therefore not randomly allocated to their baseline or intervention period and only undertook 16 data points opposed to the suggested 18. The results of these single case studies suggest that future work, such as a powered randomised controlled trial, is indicated within the chronic post-partum PGP population.

4.10 Conclusion

This replicated single case study series was undertaken in eight females who all suffered from chronic post-partum PGP where the pain was not self-limiting, as previous evidence suggests. This preliminary work identified some promising results for the benefit of using the customised DEFO in the management of this condition.

It has been shown that evidence for treatment modalities for females suffering from chronic PGP is lacking. This single case study series suggests that a customized DEFO could potentially reduce pain, increase health related quality of life, improve mood and increase activity levels for persons suffering from chronic, post-partum, pelvic girdle pain thereby hopefully identifying a possible new treatment option for managing this condition. This single case study series has also given a more in-depth awareness into the magnitude of improvement that may be associated with the customized DEFO. The results of this single case study series provides the basis for a larger clinical trial.

In summary, information gleaned from this case study series has highlighted that chronic post-partum PGP is not necessarily self-limiting and proposes a novel intervention, which may potentially improve participant symptoms.

Chapter Five:

Discussion

5.1 Introduction

In this discussion chapter the intention is to provide a brief critical reflection of key methodological challenges, followed by a summary of the findings from the three studies which contribute to this dissertation: (1) the fabric testing; (2) randomised controlled trial; (3) case series studies. This is followed by a deeper contextualisation of key future research directions and understandings from the knowledge gained from undertaking this novel work within pregnancy related PGP. The chapter will finish with the conclusions drawn from the research presented.

5.2 Summary of findings

The impetus for the development of research studies for this thesis originated from the recommendations from the European Guidelines for the management and treatment of PGP (Vleeming et al., 2008). It stated that there was a lack of high quality research evidence to support the use of a pelvic orthotic to treat PGP, no evidence to recommend the use of a pelvic orthotic as a single treatment, only recommended to be used to test for symptomatic relief, and only applied for short periods of time. My clinical experience, however, suggested that orthoses often appeared effective in managing PGP, and the lack of specific guidance in this area was frustrating. The need for further research was clearly evident. At around this time, the use of DEFOs was being investigated as an innovative orthotic approach in the management of PGP in athletes; and it was apparent that there were many parallels between the orthotic management of these two conditions. The amalgamation of these issues was the starting point for developing the research questions which are addressed in this dissertation.

Each chapter, summarised below, provides a brief account and discussion of the research underpinning the studies undertaken for this dissertation.

5.2.1 Chapter 1: Literature Review

This chapter, provides an updated critical review of the studies undertaken that have investigated the orthotic management of pregnancy related PGP. It clearly identifies the considerable growth in research since the advent of the 2008 Guidelines (Vleeming et al, 2008). Since the publication of these Guidelines, the landscape of orthotic management in this area has significantly changed in line with the considerable growth of research in this area. Eleven studies (nine of which are RCTs) have been published since the 2008 international Guidelines. Although the research undertaken suffers from a range of methodological flaws, the general trend in the findings from these studies contradict those of the Guidelines, suggesting that pelvic orthotics are potentially beneficial for reducing pain and function in pregnancy related PGP. Two of the studies undertaken as part of this dissertation, the RCT (Chapter 3) and series of replicated single case studies (chapter 4) both support this conclusion with regard to improved day time pain and contribute to this body of evidence

One could argue therefore that the recommendations from Vleeming's et al. (2008) guidelines may be outdated. Conventionally, the median lifespan of a clinical guideline is 60 months (Alderson et al., 2014), with updating of guidelines in the US being typically every 3.5 years, and in the UK (NICE guidelines) every 5 years; thereby ensuring guidance and practice is relevant (Alderson et al., 2014). Eleven studies (nine of which are RCTs), together with the two studies undertaken as part of this dissertation, have been published since the 2008 international Guidelines.

The literature review highlighted a number of methodological flaws that persist in the design and implementation of many of these published studies. These include, for example, the lack of stratification within the randomisation process, which has resulted in either (1) an imbalance in group characteristics (e.g. timing of the intervention) or (2) a lack

of certainty as to whether baseline characteristics are well matched because these data are not reported (e.g. parity). The latter, for instance, are potential risk factors for suffering from PGP (Kanakaris et al., 2013; Gutke et al., 2008; Vleeming et al., 2008; Vermani et al., 2010), and hence it is argued that there are benefits to implementing more refined methods of randomisation such as minimisation. A lack of blinding, both from the perspective of the assessor and the participant, was also noted in the literature review as an ongoing problem which has not, as yet, been resolved in many of the studies. Whilst recognising that reporting guidelines for research studies have escalated in recent years, a key finding, even with regard to the newer studies, was that they did not report adhering to CONSORT guidelines. None of the RCTs reviewed reported their trial in line with CONSORT guidelines, despite the original CONSORT guidelines being published in 1996. Furthermore, six of the RCTs were published after the publication of the revised 2010 CONSORT guidelines (Maher et al., 2010; Pandis et al., 2017).

5.2.2 Chapter 2: Fabric Testing

This repeated measures design study was undertaken to determine the fabric stiffness and elastic hysteresis of different fabric colours. This was a crucial question to address because the DEFO that was tested in the planned RCT, could be made from a range of colours. It was therefore critical to know whether it would be possible for the participants to be offered a choice of colours for their customised DEFO (which we anticipated might impact on adherence to wearing the orthoses). The findings of the study demonstrated that there were significant differences in the stiffness and elastic hysteresis between the fabrics of different colours. The decision was therefore made to standardise the colour of fabric for all participants within the customised DEFO group. The findings of this study, enabled standardisation of fundamental characteristics of the customised orthotic, a necessary requirement to ensure rigor of the planned evaluation studies. Black

was chosen based on user preference. However, one potential issue to consider with the black Lycra is its relatively low stiffness and high viscosity. This means that a greater stretch would be required to achieve a given tension compared to other colours and hence with repeated stretch-release cycles there would be greater energy dissipation as heat. Thus, future work could assess whether different fabric properties (stiffness and viscosity) are associated with differences in subjective reports of comfort and coolness. Differences in DEFO design (e.g. lines of pull and position of tensioned fabric) on applied pelvic pressure could also be assessed in future studies. This may require the production of an instrumented manikin capable of measuring applied forces in three dimensions.

5.2.3 Chapter 3: Management of Antenatal Pelvic Girdle Pain Study (MAPS): A single centre, double blinded, randomised comparative trial evaluating the effectiveness of two pelvic orthotics

This chapter describes the RCT undertaken to investigate the comparative effectiveness of the off the shelf rigid Serola pelvic belt and the customised DEFO. The initial scoping review of the literature had highlighted the rigid belt as being commonly provided within NHS practice, hence being defined in this RCT as 'standard care'. To complement this, as is often the case in usual care (based on the authors anecdotal experience, since there is a lack of published data describing "usual care"), standardised advice and education was provided and the participants were able to access other treatments as they saw fit. This comparative trial enabled an important clinical question to be addressed as to whether one type of orthotic was more effective than another. The RCT was designed to address some of the methodological flaws that had been identified in the literature review (Chapter 1). For instance, the RCT was double blinded to reduce risk of bias. Further, the minimisation procedure ensured an equal balance of key characteristics (age, trimester, BMI, parity) between the two groups. The findings from the RCT showed

that the novel, customised DEFO was more effective (both with respect to statistical and clinical significance) than the off-the-shelf rigid Serola pelvic belt at reducing day time pain (the primary outcome measure) in pregnant women with PGP. It is notable, however, that the changes in day time pain are defined as minimally important (but perhaps not very important) in terms of clinical significance and hence some caution is advised when translating these results to clinical practice.

5.2.4 Chapter 4: Management of post-partum pelvic girdle pain Study: A replicated case series of single case studies evaluating the effectiveness of a customized Dynamic Elastomeric Fabric Orthoses (DEFO)

As the work for this dissertation evolved over time, the significance of chronic PGP became increasingly self-evident. Whilst undertaking the RCT, the midwife that was working in the department where the RCT was being conducted, posed the question, would the customised DEFO be effective in managing chronic PGP symptoms. In response, an informal review of the literature was undertaken which identified a clear knowledge gap, which prompted me to further investigate this aspect. A subsequent comprehensive literature research highlighted that no previous studies had explored this question in relation to the use of customised DEFOs in the management of chronic PGP; the use of a replicated single case study design was therefore chosen as an appropriate method for investigating this. A key benefit of undertaking a case study series (n=8) was that it enabled investigation of the impact of the DEFO on a wide range of outcomes, to more fully understand the potential effectiveness of the DEFO. By using group randomisation and analysis, clearer conclusions could also be drawn about the potential value of this intervention at both the level of the individual and the group. An incidental, and somewhat alarming finding, from this study was the apparent lack of awareness of the prevalence or impact of this problem, both within the research and clinical context.

5.3 Future work within the context of these studies

This section aims to consider the future direction of research and clinical management of antenatal and post-partum pelvic girdle pain. An important clinical question is, “Does better management in the acute phase of pregnancy related PGP, ultimately impact on the likelihood of reduction of chronicity in the post-partum stage?” Although this question was not addressed in this thesis, it was highlighted as an important issue by one of the participants who complained of persistent PGP symptoms (6-7 years) following the delivery of her second child. This participant’s experience echoes the findings of a recent qualitative systematic review investigating the psychological and emotional effect of pregnancy (and post-partum) related PGP (MacKenzie et al., 2018). This identified that sufferers of PGP commonly report negative emotions such as anger and frustration due to typical effects of PGP, pain and reduced function. The authors showed that this, in turn, was associated with women abusing analgesics to manage symptoms, especially if they lacked the social support to manage activities of daily living. There was also a safety issue raised related to the expectations placed on them to care for a baby/toddler/ young child (especially when the child becomes more mobile), despite their chronic pain and restricted function (MacKenzie et al., 2018). It is apparent that there is a general expectation that PGP is a normal process of pregnancy and post-partum stages which women need to deal with (Albert et al, 2001); however, this is not the case (Fishburn and Cooper, 2015).

A more accurate understanding of the prevalence of PGP is important to know whether “this is a normal process of pregnancy”. The UK currently lacks updated prevalence information, with a heavy reliance on data from other regions, such as Scandinavia, in relation to this. The context for countries such as Sweden, however, is significantly different for the diagnosis and management of pregnancy related PGP. For example, the Swedish perspective of pregnancy, including parental leave and parental leave pay is markedly

different than that of the UK. Furthermore, the financial support given to women and partners in Sweden during parental leave is substantially higher, receiving full pay for up to 16 months, in conjunction with parental leave being compulsory, with an allocation of 480 days to be taken between parents (https://ec.europa.eu/social/main.jsp?catId=1130&langId=en&intPageId=4808). When considering parents returning to work, there is further support given to parents, as figures suggest the average cost of nursery fees are significantly lower in comparison to the UK with an average of £196 fees per month in Sweden compared to £700 in the UK (www.forsakringskassan.se). These, and other factors, provide some indication as to why there is a higher interest in pregnancy related issues; as reflected by Sweden appearing to be leading the way with pregnancy related research. With this in mind, discussions have been held with an obstetrics and gynaecology consultant at Treliske hospital, Cornwall as to the potential for undertaking research to better understand the prevalence of women suffering from chronic PGP within the UK, and to gain further insight into the current problem at hand.

Determining whether early effective management of antenatal pain may reduce the likelihood of symptoms persisting in the longer-term post-partum, is important. It is acknowledged, however, that this is a complex research question, and one which would require the design of a RCT with long-term follow-up for an estimated two years. This would require considerable resource, both in terms of finance, time and participant engagement. This study design would allow the participant's symptoms to be mapped from early onset of the condition, through the post-partum stages. Had resources (finance and time) been available, it would have been ideal if the participants from the RCT undertaken for this dissertation had been followed up for longer than the 12 weeks, however, this was not practically possible within the constraints of a PhD. This design would provide some insight

into whether early intervention would be beneficial both in the short and longer term (Fishburn and Cooper, 2015). The questionnaire-based outcome measures used in the current study could facilitate long-term follow up by reducing the burden on the participants compared to having to attend outcome measurement sessions away from the home.

Undertaking research in the area of chronic PGP is important, both in identifying potential effective treatment options, and in raising awareness of this condition. Clinical experience suggests that women with chronic PGP are frequently slow in being identified and are often not referred for intervention (Bishop et al., 2016); this has been recognised as an area that needs further exploration (Close et al., 2016). One participant in the chronic case studies reported attending her GP, only to be told "I don't deal with women's problems"; future qualitative research could provide a method for determining whether this is a common experience for women with pregnancy related PGP. Research which explores the perspectives of people with a condition, has the potential to increase insight into the way this condition is experienced (Osborn et al., 2010), as well as enhance understanding about how the condition is identified and managed by healthcare services (Al Busaidi et al., 2008; Barry et al., 2000; Crawford et al., 2002) .

It is recognised that, just as listening to people with a condition will help to increase knowledge about the conditions and its management, so too can their involvement enhance the effectiveness of the research process itself. An essential aspect of future research would be the utilisation of patient and public involvement (PPI). In the design of the RCT for this dissertation this was incorporated to some extent by the use of an initial single case study to consider issues such as patient burden, patient preference, and to guide the selection of outcome measures. On reflection, however, greater use of PPI would have been beneficial. For example, recruitment within the chronic PGP study was slow, and utilisation of PPI

would have been a mechanism for considering different strategies to improve this such as the best methods of raising study awareness, appropriate wording in adverts, and alternative recruitment strategies. Future research in this area should ensure that PPI is incorporated more comprehensively to help with issues such as these.

A systematic review could be considered as a starting point (key to strong evidence is the methodological rigour of this method). The review of literature undertaken for this thesis found that many of the published RCTs had methodological flaws. In response, the aim was to design a methodologically robust comparative study which had been highlighted as lacking in the current literature, and as recommended by the European guidelines.

5.4 Guidelines

It was considered a high priority to utilise current reporting guidelines to enhance the transparency and robustness of the reporting of the RCT study undertaken for this dissertation. Since 2014, TIDier guidelines have been produced to ensure interventional studies provide a clear description of the intervention in order to facilitate replication of studies, and CONSORT guidelines which provide a framework for optimising the transparency and robustness of the reporting of randomised controlled trials (Hoffman et al., 2014; Maher et al., 2010). In 2017, further guidelines such as GRIPP2 were developed with the aim to further improve the quality, transparency and consistency of PPI in studies. Future RCTs investigating the effects of DEFOs on chronic post-partum PGP should endeavour to adhere to such guidelines (Staniszewska et al., 2017).

5.5 NHS Implementation

Following the dissemination of the research to the wider research team, a consultant Obstetrician and Gynaecologist highlighted the need to raise awareness about the potential use of the customised DEFO with patients in the NHS, given that it had demonstrated to be effective within the RCT, although we have to take into account the lack of control group within the study. In line with this, there are currently ongoing discussions within one NHS hospital as to whether information about this product might be offered to patients during their consultation. This has the advantage of providing patient choice and engaging the individual in the shared decision making process.

Other implementation considerations are the need to raise awareness of the potential benefit of using orthotics in the management of both antenatal and post-natal PGP. As a result of the studies undertaken for this dissertation, patient care clinical pathways have been implemented within my NHS Trust, to facilitate earlier interventions to aid the management of PGP. Alongside this, the results have also informed the development of tailored training in an intermediate skills programme for senior musculoskeletal staff. Future work will involve the development of services for the chronic PGP population.

5.6 Priorities for Future Research

Areas for future research have been highlighted in the discussion sections of each chapter. Of particular importance is the under-researched area of chronic PGP, which appears to be a particularly neglected issue. Prevalence data in the UK is outdated and future research is urgently needed to fill this knowledge gap. Following discussion with an NHS consultant within obstetrics and gynaecology, who feels that this could be a multi-centre study, there is potential for my work in this field to continue to develop and provide further, much needed research.

5.7 Conclusion

The thesis was developed on the basis of undertaking research to fill a knowledge gap and the call for future research in orthotic management of pregnancy related PGP. During the undertaking of this thesis, a literature review has provided information to suggest that current guidelines (Vleeming et al., 2008) may be outdated in their recommendations, and that orthotic management in pregnancy related PGP appears effective in reducing antenatal daytime pain. Prior to undertaking the RCT, laboratory testing of orthotic fabric was undertaken to inform decisions about the selection of fabric and to ensure standardisation of intervention. The RCT results concluded that the customised DEFO was effective in reducing day antenatal day time pain in comparison to the rigid Serola belt; the difference between the two groups was statistically significant. When considering the DEFO's clinical application, it bordered clinical significance when using the lower threshold of the MCID (1 point) indicating some caution when considering clinical application. This research has been published in a peer review journal (Cameron et al., 2018). The thesis also explored pregnancy related PGP that persisted into the post-partum period. Although not planned for at the start of the PhD, the single case study series provided a natural progression to cover orthotic management in both the antenatal and post-partum period. Future work should consider identifying the true prevalence of chronic PGP within the UK, and the single case study series provides the foundation for a pilot RCT.

Appendices

Appendix 1: Fabric Testing Chapter Spreadsheet of each fabric colour and mean collected from weight application during stiffness testing.

Force (n)	Purple_ Powernet	White_ Powernet	Black_ Powernet	Beige_ Powernet	Blue_ Powernet	Red_ Powernet
1.96	14.07	13.65	11.61	29.68	13.55	10.79
3.92	23.61	28.99	27.95	42.51	32.71	23.33
5.88	38.8	44.5	45.61	63.53	53.41	41.65
7.84	51.22	54.61	59.12	81.42	69.74	57.16
9.8	66.98	64.94	74.15	102.59	91.34	79.68
11.76	80.89	73.61	85.39	118.77	107.95	100.76
13.72	95.65	85.96	96.98	134.67	122.88	122.17

Force (n)	Purple_ Lycra	White_ Lycra	Black_ Lycra	Beige_ Lycra	Blue_ Lycra	Red_ Lycra
1.96	13.42	5.35	7.47	8.49	10.18	7.85
3.92	24.45	16.62	16.2	17.85	19.75	16.37
5.88	40.26	31.22	26.47	29.21	32.23	27.43
7.84	49.39	41	35.34	38.01	40.93	35.23
9.8	60.68	52.81	45.54	48.47	52.06	45.46
11.76	69.15	61.88	53.28	55.82	59.66	52.82
13.72	77.65	71.28	61.18	62.64	67.07	59.97

Appendix 2. RCT Written Informed Consent Form

Royal Cornwall Hospitals NHS Trust

Princess Alexandra Wing

Royal Cornwall Hospital

Truro, TR1 3LJ

CONSENT FORM

PELVIC GIRDLE PAIN IN PREGNANCY: A BLINDED RANDOMIZED TRIAL EVALUATING THE EFFECTIVENESS OF TWO PELVIC SUPPORT BELTS.

Researcher taking Consent: Lee Cameron

If you have any unanswered questions about this study then do NOT complete this form.

PLEASE INITIAL ALL BOXES

1	I confirm that I have read and understood the information sheet (Version 1, December 13th 2011) for the above study and have had the opportunity to ask questions.	
2	I confirm that I have had the opportunity to discuss the study with the researcher. I do not have any further questions about this study.	
3	I understand that the information collected during this study will remain strictly confidential and accessible only to appropriate members of the research team.	

4	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without affecting my medical or physiotherapy care or legal rights.	
5	I agree that auditors, monitors, regulatory authorities and ethics committees may have restricted access to my research records.	
6	I agree to my GP being notified of my participation	
7	I agree to take part in the above study	

Name of Patient _____

Date _____ Signature _____

Name of Person taking consent _____

Date _____ Signature _____

Copies (1 for patient; 1 for researcher; 1 to be kept patient notes)

Appendix 3. Demographic baseline information

RESEARCH WITH PLYMOUTH UNIVERSITY

BASELINE DESCRIPTIVE DATA

Project Title: PELVIC GIRDLE PAIN IN PREGNANCY: A BLINDED RANDOMIZED TRIAL EVALUATING THE EFFECTIVENESS OF TWO PELVIC SUPPORT BELTS

1) Age……..

2) Parity.....

3) Mode of Delivery……

4) Occupational status (tick the correct answer)

Full-time paid or self-employment	☐	Part-time paid or self-employment	☐
Voluntary employment	☐	Sheltered employment	☐
Unemployed	☐	Student	☐
Housewife/husband	☐		
Retired	☐	Other (specify)	☐

5) Occupation (if employed)

Professional (e.g. health, teaching, legal)	☐
Associate professional (e.g. technical, nursing)	☐
Clerical worker/secretary	☐
Services/sales (e.g. retail)	☐
Skilled agricultural/fishery worker	☐

Skilled labourer/craftsman (e.g. building, electrical etc.) ☐

Elementary occupation (e.g. domestic, caretaker, labourer) ☐

Armed Forces ☐

Other (Please specify) ☐

6) Body-mass Index (BMI)

…….....

7) History of low-back pain?

Before current pregnancy YES ☐ NO ☐

During current pregnancy YES ☐ NO ☐

8) History of pelvic pain?

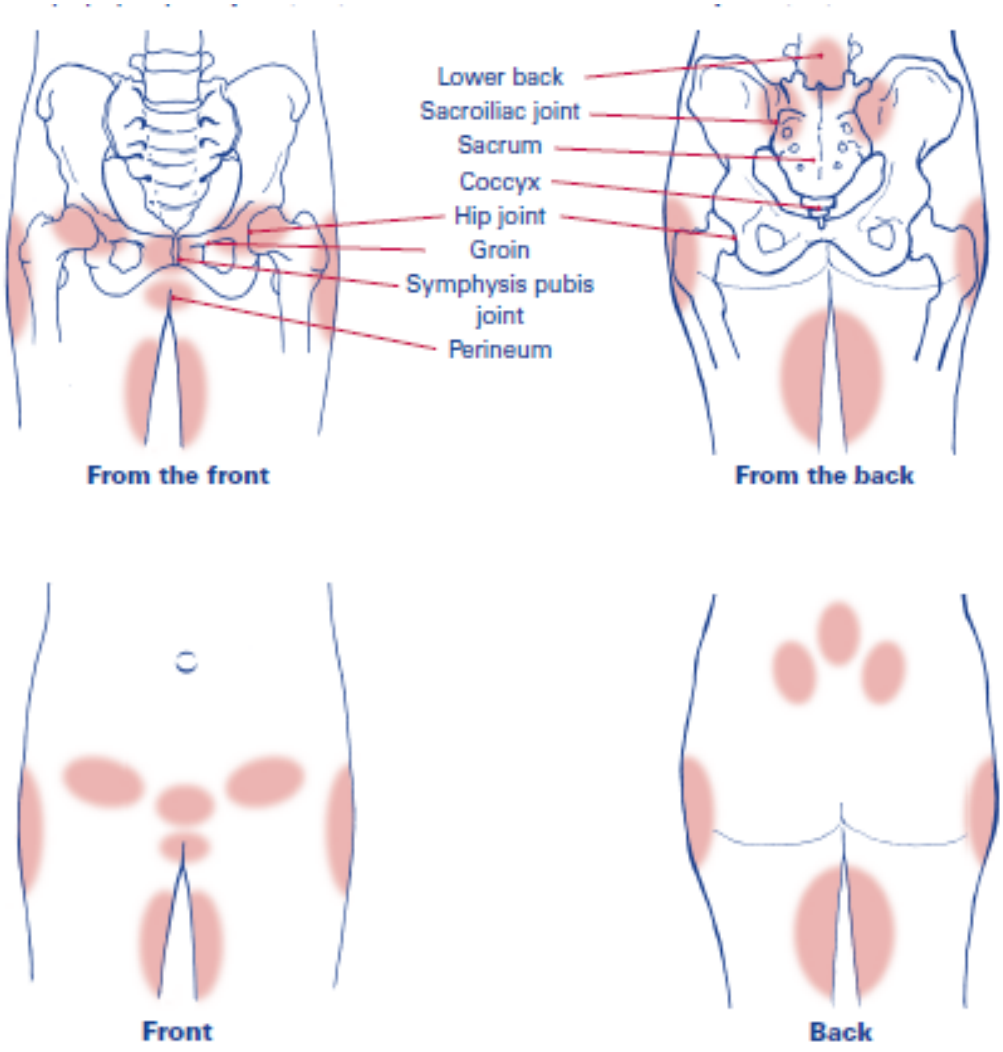
Before current pregnancy YES ☐ NO ☐

During current pregnancy YES ☐ NO ☐

Appendix 4. Pain Referral Map

1) Pelvic Girdle Pain Referral Map:

Please look carefuly at the pictures and indicate the site of your pain:



Appendix 5. RCT Self-Report Questionnaire Booklet

RESEARCH WITH PLYMOUTH UNIVERSITY

The University of Plymouth
Faculty of Health, Education and Society
Peninsula Allied Health Centre
Derriford Road
Plymouth
PL6 8BH

NHS
Royal Cornwall Hospitals
NHS Trust

Princess Alexandra Wing
Royal Cornwall Hospital
Truro, TR1 3LJ

Pelvic girdle pain during pregnancy: a blinded randomized trial evaluating the effectiveness of two pelvic support garments.

Pelvic Girdle Pain Questionnaire Booklet

Participant Number: | | |

Questionnaire Number: | | |

Date sent: | | | | | | |

Date completed: | | | | | | |

(please fill this in)

- The aim of this project is to compare the effectiveness of two different types of pelvic support garments with regard to management of pregnancy-related pelvic girdle pain (PGP), daily function and quality of life.

- We hope that you will complete this questionnaire booklet since the information you provide is very important for the success of the project. If you have trouble reading or writing you can ask someone to help you.

- You may find some of the questions a bit repetitive, or possibly not very relevant to you, however please answer **all** the questions in this booklet.

- If you have any questions about completing the questionnaire booklet please call the researching physiotherapist Mr. Lee Cameron at: **01752-587541**, or the research supervisor Dr. Jenny Freeman at: **01752-588835, or email us @ pelvicpainstudy@plymouth.ac.uk** and they will be glad to help you.

- Please note that your full name **does not** appear anywhere in this booklet and all the information that you provide will be treated with complete confidentiality.

- It is important that you complete this questionnaire **on the last day** of the two-week interval, or as close to it as possible.

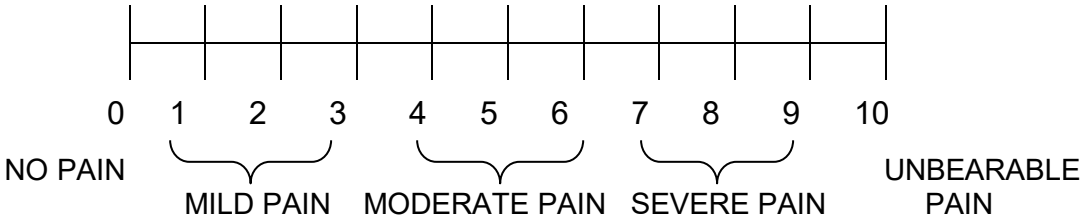
- Please return the completed questionnaire booklet to Plymouth University in the stamped addressed envelope provided.

NUMERIC RATING SCALE FOR PAIN INTENSITY

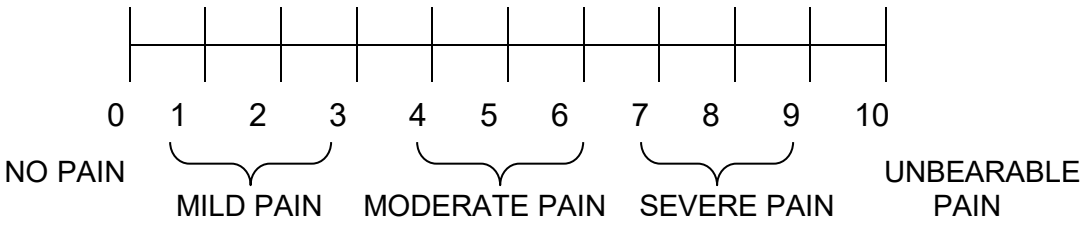
Instructions:
On a scale from 0 to 10 please circle the number that best describes

the level of your pelvic pain:

1) Over the last 2 weeks, how would you rate your average level of pelvic pain during the day?



2) Over the last 2 weeks, how would you rate your average level of pelvic pain during the night (after going to bed)?



PELVIC GIRDLE QUESTIONNAIRE

To what extent do you find it problematic to carry out the activities listed below because of pelvic girdle pain? For each activity tick the box that best describes how you are today.

How problematic is it for you because of your pelvic girdle pain to:	Not at all (0)	To a small extent (1)	To some Extent (2)	To a large extent (3)
1) Dress yourself				
2) Stand for less than 10 minutes				
3) Stand for more than 60 minutes				
4) Bend down				
5) Sit for less than 10 minutes				
6) Sit for more than 60 minutes				
7) Walk for less than 10 minutes				
8) Walk for more than 60 minutes				
9) Climb stairs				
10) Do housework				
11) Carry light objects				
12) Carry heavy objects				
13) Get up/sit down				
14) Push a shopping cart				
15) Run				
16) Carry out sporting activities*				
17) Lie down				
18) Roll over in bed				
19) Have a normal sex life*				
20) Push something with one foot				

If not applicable, mark box to the right

How much pain do you experience	None (0)	Some (1)	Moderate (2)	Considerable (3)
21) In the morning				
22) In the evening				

To what extent because of pelvic girdle pain:	Not at all (0)	To a small extent (1)	To some Extent (2)	To a large extent (3)
23) Has your leg/have your legs given away?				
24) Do you do things more slowly?				
25) Is your sleep interrupted?				

SHORT FORM 36-ITEM HEALTH SURVEY (SF-36v2)

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicated.

If you are unsure about how to answer a question, please give the best answer you can.

1) In general, would you say your health is:

Circle one number

Excellent……. 1
Very Good……....2
Good…….....3
Fair…….....4
Poor……..5

2) <u>Compared to one year ago</u>, how would you rate your health in general <u>now</u>?

Circle one number

Much better now than one year ago……. 1
Somewhat better now than one year ago…….2
About the same as one year ago……...3
Somewhat worse now than one year ago…….4
Much worse now than one year ago……..5

SHORT FORM 36-ITEM HEALTH SURVEY (SF-36v2) continued

3) The following questions are about activities you might do during a typical day.

Does <u>your health now limit you</u> in these activities? If so, how much?

	Circle one number on each line		
ACTIVITIES	**Yes, limited a lot**	**Yes, limited a little**	**No, not limited at all**
a) **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b) **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
c) Lifting or carrying groceries	1	2	3
d) Climbing **several** flights of stairs	1	2	3
e) Climbing **one** flight of stairs	1	2	3
f) Bending, kneeling, or stooping	1	2	3
g) Walking **more than a mile**	1	2	3
h) Walking **half a mile**	1	2	3
i) Walking **one hundred yards**	1	2	3
j) Bathing or dressing yourself	1	2	3

4) During the <u>past week</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health?</u>

Circle one number on each line	**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a) Cut down the **amount of time** you spent on work or other activities	1	2	3	4	5
b) **Accomplished less** than you would like	1	2	3	4	5
c) Were limited in the **kind** of work or other activities	1	2	3	4	5
d) Had **difficulty** performing the work or other activities (e.g. it took extra effort)	1	2	3	4	5

SHORT FORM 36-ITEM HEALTH SURVEY (SF-36v2) continued

5) During the <u>past week</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

Circle one number on each line	**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a) Cut down the **amount of time** you spent on work or other activities	1	2	3	4	5
b) **Accomplished less** than you would like	1	2	3	4	5
c) Didn't do work or other activities as **carefully** as usual	1	2	3	4	5

6) During the <u>past week</u>, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

Circle one number

Not at all……...1

Slightly…….....2

Moderately……...3

Quite a bit…….4

Extremely……5

7) How much bodily pain have you had during the <u>past week</u>?

Circle one number

None…….....1

Very mild…….....2

Mild…….....3

Moderate……...4

Severe…….....5

Very severe.....6

8) During the <u>past week</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?

Circle one number

Not at all……1

A little bit…..2

Moderately.....3

Quite a bit……..4

Extremely……..5

9) These questions are about how you feel and how things have been with you <u>during the past week.</u> For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time <u>during</u> the <u>past week…</u>

	Circle one number on each line				
	All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a) Did you feel full of life?	1	2	3	4	5
b) Have you been a very nervous person?	1	2	3	4	5
c) Have you felt so down in the dumps than nothing could cheer you up?	1	2	3	4	5
d) Have you felt calm and peaceful?	1	2	3	4	5
e) Did you have a lot of energy?	1	2	3	4	5
f) Have you felt downhearted and low?	1	2	3	4	5
g) Did you feel worn out?	1	2	3	4	5
h) Have you been a happy person?	1	2	3	4	5
i) Did you feel tired?	1	2	3	4	5

SHORT FORM 36-ITEM HEALTH SURVEY (SF-36v2) continued

10) During the <u>past week</u>, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

Circle one number

All of the time……1

Most of the time…….....2

Some of the time……....3

A little of the time….....4

None of the time.....5

11) How TRUE or FALSE is each of the following statements for you?

	Circle one number on each line				
	Definitely true	**Mostly true**	**Don't know**	**Mostly false**	**Definitely false**
a) I seem to get ill a little easier than other people	1	2	3	4	5
b) I am as healthy as anybody I know	1	2	3	4	5
c) I expect my health to get worse	1	2	3	4	5
d) My health is excellent	1	2	3	4	5

EQ-5D HEALTH QUESTIONNAIRE

Under each heading, please tick the ONE box that best describes your health TODAY

MOBILITY

- I have no problems in walking about ☐
- I have slight problems in walking about ☐
- I have moderate problems in walking about ☐
- I have severe problems in walking about ☐
- I am unable to walk about ☐

SELF-CARE

- I have no problems washing or dressing myself ☐
- I have slight problems washing or dressing myself ☐
- I have moderate problems washing or dressing myself ☐
- I have severe problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐

USUAL ACTIVITIES ***(e.g. work, study, housework, family or leisure activities)***

- I have no problems doing my usual activities ☐
- I have slight problems doing my usual activities ☐
- I have moderate problems doing my usual activities ☐
- I have severe problems doing my usual activities ☐
- I am unable to do my usual activities ☐

PAIN/DISCOMFORT

- I have no pain or discomfort ☐
- I have slight pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have severe pain or discomfort ☐
- I have extreme pain or discomfort ☐

ANXIETY/DEPRESSION

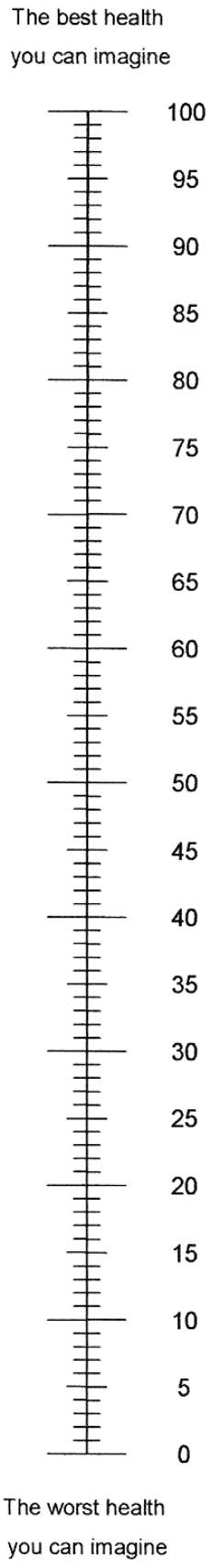
- I am not anxious or depressed ☐
- I am slightly anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am severely anxious or depressed ☐
- I am extremely anxious or depressed ☐

EQ-5D HEALTH QUESTIONNAIRE continued

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the <u>best</u> health you can imagine.
  0 means the <u>worst</u> health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you scaled in the box below.

YOUR HEALTH TODAY = ☐

.



RESOURCE USE FOR PELVIC GIRDLE PAIN (PGP)

1) MEDICATION USE

1a) During the last 2 weeks, did you use any kind of pain-relieving or other type of medication to treat your PGP?

YES ☐ **NO** ☐

1b) If **YES**, please specify:

Name of medicine	How many tablets did you take and how often?	How did you obtain this medicine?	If the medicine was bought by yourself, how much did you pay for it?
E.g. Paracetamol	*2 × 500 mg. tablets, 4 times/day*	Prescribed ☐ Free prescription ☐ Bought by yourself over the counter ☐	*£2.50*
		Prescribed ☐ Free prescription ☐ Bought by yourself over the counter ☐	
		Prescribed ☐ Free prescription ☐ Bought by yourself over the counter ☐	
		Prescribed ☐ Free prescription ☐ Bought by yourself over the counter ☐	
		Prescribed ☐ Free prescription ☐ Bought by yourself over the counter ☐	

2) USE OF WALKING AIDS

2a) During the last 2 weeks, did you use any walking-aids (crutches, walking-frame, wheelchairs etc.) because you had difficulty walking as a result of your pelvic girdle pain?

YES ☐ **NO** ☐

2b) If **YES**, please specify:

What type of walking aid did you use?	How did you obtain this walking aid?	If bought/rented by yourself, how much did you pay?
Walking stick/cane ☐	Provided by NHS ☐ Bought/rented yourself ☐	
Crutches ☐	Provided by NHS ☐ Bought/rented yourself ☐	
Walking Frame ☐	Provided by NHS ☐ Bought/rented yourself ☐	
Wheelchair ☐	Provided by NHS ☐ Bought/rented yourself ☐	
Other (please specify) ☐	Provided by NHS ☐ Bought/rented yourself ☐	

3) USE OF HEALTH SERVICES

3a) During the last 2 weeks, did you use the services of a health-practitioner to treat your pelvic girdle pain?

YES ☐ **NO** ☐

3b) If **YES**, please specify:

Profession	Service	If treatment was obtained privately, how much did you pay per visit?	How many times did you see the health-practitioner during the last 2 weeks? (put number in box)
Family Doctor (GP) ☐	NHS ☐	(leave blank)	NHS ☐☐
Midwife ☐	NHS ☐	(leave blank)	NHS ☐☐
Obstetrician ☐	NHS ☐	(leave blank)	NHS ☐☐
Physiotherapist (PT) ☐	NHS ☐ Private Practice ☐	Less than £30 ☐ £30- £50 ☐ More than £50 ☐	NHS ☐☐ Private Practice ☐☐
Occupational Therapist (OT) ☐	NHS ☐ Private Practice ☐	Less than £30 ☐ £30- £50 ☐ More than £50 ☐	NHS ☐☐ Private Practice ☐☐
Chiropractor ☐	Private Practice ☐	Less than £30 ☐ £30- £50 ☐ More than £50 ☐	Private Practice ☐☐
Acupuncturist ☐	NHS/community-based ☐ Private Practice ☐	Less than £30 ☐ £30- £50 ☐ More than £50 ☐	NHS ☐☐ Private Practice ☐☐

4) TRAVEL COSTS

4a) How much did you spend on travel costs (e.g. bus/taxi/train fares) to attend these appointments over the last 2 weeks?

£ ☐☐☐ ☐☐

4b) If you used your own car to attend health-care appointments, please tell us the approximate number of miles travelled.

Miles: ☐☐☐

5) EMPLOYMENT

5a) How many hours do you work (on average) per week? **(If employed)**

Hours: ☐☐

5b) During the last 2 weeks, did you have to take any days off from work because of your pelvic girdle pain?

YES ☐ **NO** ☐

5c) If **YES**, how many days have you been absent from work because of your pelvic girdle pain over the last 2 weeks?

Days: ☐☐

5d) Have you lost any earnings over the last 2 weeks, as a result of your pelvic girdle pain?

YES ☐ **NO** ☐

5e) Have you given up any leisure time in the last 2 weeks, as a result of your pelvic girdle pain?

YES ☐ **NO** ☐

6) SUPPORT FROM OTHERS

6a) During the last 2 weeks, have friends and/or relatives stayed off work to help you?

YES ☐ **NO** ☐

6b) If **YES**, how many days did they take off from work during the last 2 weeks?

Days: ☐☐

7) COMPLIANCE WITH TREATMENT

7a) During the last 2 weeks, for how many days did you wear your pelvic garment?

- Every day ☐
- If **not** every day, please specify for how many days you **didn't** wear it:

  Days: ☐☐

7b) During the last 2 weeks, approximately how many hours per day did you wear your pelvic garment?

- 12 hours (recommended) ☐
- More than 12 hours ☐
- Less than 12 hours ☐

7c) If you didn't wear your pelvic garment every day, or wore it for less than 12 hours per day, can you please specify the reason(s) you took it off? (You can tick more than one answer)

- General discomfort ☐
- Irritation ☐
- Rash ☐
- Restriction of movement ☐

- Aesthetic reasons ☐
- Other (please specify).....

Appendix 6. Washing advice

WEARING AND CARING FOR YOUR GARMENT

Wearing your garment

For best results, you should wear the shorts during the day (recommended: 12 hours) including (if desired) for activities such as swimming. Do not wear the shorts at night **as they may cause circulation problems. If irritation or rash is encountered, discontinue use and see a doctor.**

Care of your garment:

The shorts are extremely easy to care for. They can be washed either by hand, or in a washing machine at 30°C. Their lightweight composition enables them to dry overnight, ready for next day use. Do not tumble dry or place over heat source (e.g. radiators).

If you have any questions please contact:

Mr Lee Cameron **TEL: (01752) 587541**

Dr Jenny Freeman **TEL: (01752) 588835**

EMAIL: pelvicpainstudy@plymouth.ac.uk

Appendix 7. Pink and Blue RCT Folders

Appendix 8. Recruitment poster

Appendix 9. Written informed consent Chronic PGP

CONSENT FORM

MANAGEMENT OF POST-PARTUM PELVIC GIRDLE PAIN: EVALUATING THE EFFECTIVENESS OF A CUSTOMISED PELVIC SUPPORT GARMENT

If you have any unanswered questions about this study then do NOT complete this form.

PLEASE INITIAL ALL BOXES

1	I confirm that I have read and understood the information sheet (Version 1, September 3rd 2013) for the above study and have had the opportunity to ask questions.	
2	I confirm that I have had the opportunity to discuss the study with the researcher. I do not have any further questions about this study.	
3	I understand that the information collected during this study will remain strictly confidential and accessible only to appropriate members of the research team.	
4	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without affecting my medical or physiotherapy care or legal rights.	
5	I agree that auditors, monitors, regulatory authorities and ethics committees may have restricted access to my research records.	
6	I agree to my GP being notified of my participation	
7	I agree to take part in the above study	

Name of Participant _____

Date _____ Signature _____

Name of Person taking consent _____

Date _____ Signature _____

Copies (1 for participant; 1 for researcher)

Appendix 10. Chronic PGP Questionnaire

RESEARCH WITH PLYMOUTH UNIVERSITY

Management of postpartum pelvic girdle pain: replicated single case series study evaluating the effectiveness of a customised elastomeric fabric orthoses (DEFO)

Pelvic Girdle Pain Questionnaire Booklet

Participant Number: | | |

Questionnaire Week No: | | |

Date Sent: | | | | | | |

Date Completed: | | | | | | |

(please fill this in)

- We hope that you will complete this questionnaire booklet since the information you provide is very important for the success of the project. If you have trouble reading or writing you can ask someone to help you.

- You may find some of the questions a bit repetitive, or possibly not very relevant to you, however please answer **all** the questions in this booklet.

- If you have any questions about completing the questionnaire booklet please call the researching physiotherapist Mr. Lee Cameron at: **01752-587541**, or the research supervisor Dr. Jenny Freeman at: **01752-588835, or email us @ pelvicpainstudy@plymouth.ac.uk** and they will be glad to help you.

- Please note that your full name **does not** appear anywhere in this booklet and all the information that you provide will be treated with complete confidentiality.

- It is important that you complete this questionnaire **on the last day** of the one-week interval, or as close to it as possible.

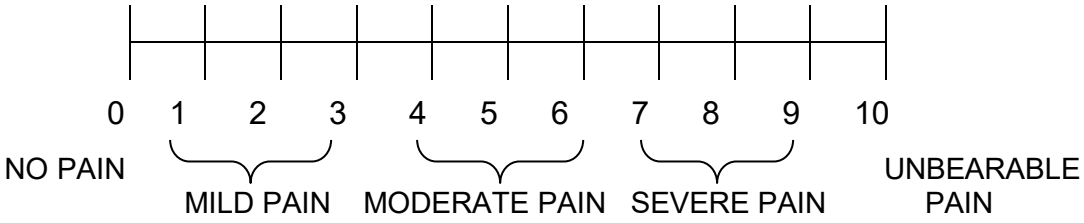
- Please return the completed questionnaire booklet to Plymouth University in the stamped addressed envelope provided.

NUMERIC RATING SCALE FOR PAIN INTENSITY

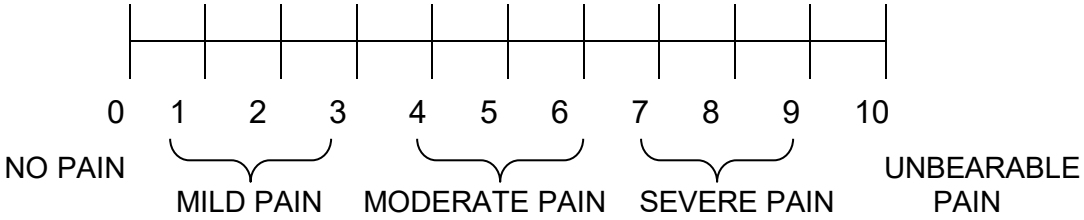
Instructions:
On a scale from 0 to 10 please circle the number that best describes

the level of your pelvic pain:

4) Over the last week, how would you rate your average level of pelvic pain during the day?



5) Over the last week, how would you rate your average level of pelvic pain during the night (after going to bed)?



PELVIC GIRDLE QUESTIONNAIRE

To what extent do you find it problematic to carry out the activities listed below because of pelvic girdle pain? For each activity tick the box that best describes how you are today.

How problematic is it for you because of your pelvic girdle pain to:	Not at all (0)	To a small extent (1)	To some Extent (2)	To a large extent (3)
26) Dress yourself				
27) Stand for less than 10 minutes				
28) Stand for more than 60 minute				
29) Bend down				
30) Sit for less than 10 minutes				
31) Sit for more than 60 minutes				
32) Walk for less than 10 minutes				
33) Walk for more than 60 minutes				
34) Climb stairs				
35) Do housework				
36) Carry light objects				
37) Carry heavy objects				
38) Get up/sit down				
39) Push a shopping cart				
40) Run				
41) Carry out sporting activities*					☐
42) Lie down				
43) Roll over in bed				
44) Have a normal sex life*					☐
45) Push something with one foot				

If not applicable, mark box to the right

How much pain do you experience	None (0)	Some (1)	Moderate (2)	Considerable (3)
46) In the morning				
47) In the evening				

To what extent because of pelvic girdle pain:	Not at all (0)	To a small extent (1)	To some Extent (2)	To a large extent (3)
48) Has your leg/have your legs given away?				
49) Do you do things more slowly?				
50) Is your sleep interrupted?				

SHORT FORM 36-ITEM HEALTH SURVEY (SF-36v2)

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicated.

If you are unsure about how to answer a question, please give the best answer you can.

12) In general, would you say your health is:

Circle one number

Excellent……. 1
Very Good……....2
Good……....3
Fair……....4
Poor……..5

13) <u>Compared to one year ago</u>, how would you rate your health in general <u>now</u>?

Circle one number

Much better now than one year ago……. 1
Somewhat better now than one year ago…….2
About the same as one year ago……...3
Somewhat worse now than one year ago…….4
Much worse now than one year ago……..5

SHORT FORM 36-ITEM HEALTH SURVEY (SF-36v2) continued

14) The following questions are about activities you might do during a typical day.

Does <u>your health now limit you</u> in these activities? If so, how much?

	Circle one number on each line		
ACTIVITIES	**Yes, limited a lot**	**Yes, limited a little**	**No, not limited at all**
k) **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
l) **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
m)Lifting or carrying groceries	1	2	3
n) Climbing **several** flights of stairs	1	2	3
o) Climbing **one** flight of stairs	1	2	3
p) Bending, kneeling, or stooping	1	2	3
q) Walking **more than a mile**	1	2	3
r) Walking **half a mile**	1	2	3
s) Walking **one hundred yards**	1	2	3
t) Bathing or dressing yourself	1	2	3

15) During the <u>past week</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health?</u>

Circle one number on each line	**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
b) Cut down the **amount of time** you spent on work or other activities	1	2	3	4	5
b) **Accomplished less** than you would like	1	2	3	4	5
e) Were limited in the **kind** of work or other activities	1	2	3	4	5
f) Had **difficulty** performing the work or other activities (e.g. it took extra effort)	1	2	3	4	5

SHORT FORM 36-ITEM HEALTH SURVEY (SF-36v2) continued

16) During the <u>past week</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

Circle one number on each line	**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
d) Cut down the **amount of time** you spent on work or other activities	1	2	3	4	5
e) **Accomplished less** than you would like	1	2	3	4	5
f) Didn't do work or other activities as **carefully** as usual	1	2	3	4	5

17) During the <u>past week</u>, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

Circle one number

Not at all……...1

Slightly…….....2

Moderately……...3

Quite a bit…….4

Extremely…….5

18) How much bodily pain have you had during the <u>past week</u>?

Circle one number

None…….....1

Very mild…….....2

Mild…….....3

Moderate……...4

Severe…….....5

Very severe.....6

SHORT FORM 36-ITEM HEALTH SURVEY (SF-36v2) continued

19) During the <u>past week</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?

Circle one number

Not at all……1

A little bit…....2

Moderately.....3

Quite a bit……..4

Extremely……..5

20) These questions are about how you feel and how things have been with you <u>during the past week.</u> For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time <u>during</u> the <u>past week…</u>

	Circle one number on each line				
	All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
j) Did you feel full of life?	1	2	3	4	5
k) Have you been a very nervous person?	1	2	3	4	5
l) Have you felt so down in the dumps than nothing could cheer you up?	1	2	3	4	5
m)Have you felt calm and peaceful?	1	2	3	4	5
n) Did you have a lot of energy?	1	2	3	4	5
o) Have you felt downhearted and low?	1	2	3	4	5
p) Did you feel worn out?	1	2	3	4	5
q) Have you been a happy person?	1	2	3	4	5
r) Did you feel tired?	1	2	3	4	5

SHORT FORM 36-ITEM HEALTH SURVEY (SF-36v2) continued

21) During the <u>past week</u>, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

Circle one number

All of the time……1

Most of the time…….....2

Some of the time……....3

A little of the time….....4

None of the time.....5

22) How TRUE or FALSE is each of the following statements for you?

	Circle one number on each line				
	Definitely true	**Mostly true**	**Don't know**	**Mostly false**	**Definitely false**
e) I seem to get ill a little easier than other people	1	2	3	4	5
f) I am as healthy as anybody I know	1	2	3	4	5
g) I expect my health to get worse	1	2	3	4	5
h) My health is excellent	1	2	3	4	5

EQ-5D HEALTH QUESTIONNAIRE

Under each heading, please tick the ONE box that best describes your health TODAY

MOBILITY

- I have no problems in walking about ☐
- I have slight problems in walking about ☐
- I have moderate problems in walking about ☐
- I have severe problems in walking about ☐
- I am unable to walk about ☐

SELF-CARE

- I have no problems washing or dressing myself ☐
- I have slight problems washing or dressing myself ☐
- I have moderate problems washing or dressing myself ☐
- I have severe problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐

USUAL ACTIVITIES ***(e.g. work, study, housework, family or leisure activities)***

- I have no problems doing my usual activities ☐
- I have slight problems doing my usual activities ☐
- I have moderate problems doing my usual activities ☐
- I have severe problems doing my usual activities ☐
- I am unable to do my usual activities ☐

PAIN/DISCOMFORT

- I have no pain or discomfort ☐
- I have slight pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have severe pain or discomfort ☐
- I have extreme pain or discomfort ☐

ANXIETY/DEPRESSION

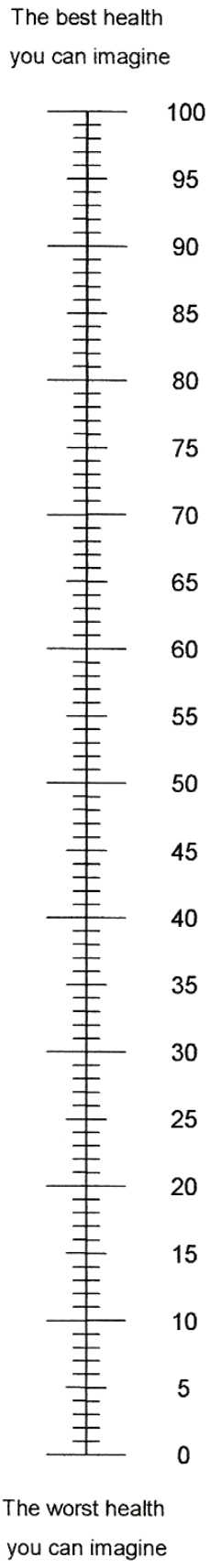
- I am not anxious or depressed ☐
- I am slightly anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am severely anxious or depressed ☐

EQ-5D HEALTH QUESTIONNAIRE continued

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the <u>best</u> health you can imagine.
  0 means the <u>worst</u> health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you scaled in the box below.

YOUR HEALTH TODAY = ☐

.



RESOURCE USE FOR PELVIC GIRDLE PAIN (PGP)

1) MEDICATION USE

1a) During the last week, did you use any kind of pain-relieving or other type of medication to treat your PGP?

YES ☐ **NO** ☐

1b) If **YES**, please specify:

Name of medicine	How many tablets did you take and how often?	How did you obtain this medicine?	If the medicine was bought by yourself, how much did you pay for it?
E.g. Paracetamol	*2 × 500 mg. tablets, 4 times/day*	Prescribed ☐ Free prescription ☐ Bought by yourself over the counter ☐	*£2.50*
		Prescribed ☐ Free prescription ☐ Bought by yourself over the counter ☐	
		Prescribed ☐ Free prescription ☐ Bought by yourself over the counter ☐	
		Prescribed ☐ Free prescription ☐ Bought by yourself over the counter ☐	
		Prescribed ☐ Free prescription ☐ Bought by yourself over the counter ☐	

USE OF WALKING AIDS

2a) During the last week, did you use any walking-aids (crutches, walking-frame, wheelchairs etc.) because you had difficulty walking as a result of your pelvic girdle pain?

YES ☐ **NO** ☐

2b) If **YES**, please specify:

What type of walking aid did you use?	How did you obtain this walking aid?	If bought/rented by yourself, how much did you pay?
Walking stick/cane ☐	Provided by NHS ☐ Bought/rented yourself ☐	
Crutches ☐	Provided by NHS ☐ Bought/rented yourself ☐	
Walking Frame ☐	Provided by NHS ☐ Bought/rented yourself ☐	
Wheelchair ☐	Provided by NHS ☐ Bought/rented yourself ☐	
Other (please specify) ☐	Provided by NHS ☐ Bought/rented yourself ☐	

6) USE OF HEALTH SERVICES

3a) During the last week, did you use the services of a health-practitioner to treat your pelvic girdle pain?

YES ☐ **NO** ☐

3b) If **YES**, please specify:

Profession	Service	If treatment was obtained privately, how much did you pay per visit?	How many times did you see the health-practitioner during the last 2 weeks? (put number in box)
Family Doctor (GP) ☐	NHS ☐	(leave blank)	NHS ☐☐
Midwife ☐	NHS ☐	(leave blank)	NHS ☐☐
Obstetrician ☐	NHS ☐	(leave blank)	NHS ☐☐
Physiotherapist (PT) ☐	NHS ☐ Private Practice ☐	Less than £30 ☐ £30- £50 ☐ More than £50 ☐	NHS ☐☐ Private Practice ☐☐
Occupational Therapist (OT) ☐	NHS ☐ Private Practice ☐	Less than £30 ☐ £30- £50 ☐ More than £50 ☐	NHS ☐☐ Private Practice ☐☐
Chiropractor ☐	Private Practice ☐	Less than £30 ☐ £30- £50 ☐ More than £50 ☐	Private Practice ☐☐
Acupuncturist ☐	NHS/community-based ☐ Private Practice ☐	Less than £30 ☐ £30- £50 ☐ More than £50 ☐	NHS ☐☐ Private Practice ☐☐

3) TRAVEL COSTS

4a) How much did you spend on travel costs (e.g. bus/taxi/train fares) to attend these appointments over the last 2 weeks?

£ ☐☐☐ ☐☐

4b) If you used your own car to attend health-care appointments, please tell us the approximate number of miles travelled.

Miles: ☐☐☐

4) EMPLOYMENT

5a) How many hours do you work (on average) per week? **(If employed)**

Hours: ☐☐

5b) During the last 2 weeks, did you have to take any days off from work because of your pelvic girdle pain?

YES ☐ **NO** ☐

5c) If **YES**, how many days have you been absent from work because of your pelvic girdle pain over the last 2 weeks?

Days: ☐☐

5d) Have you lost any earnings over the last 2 weeks, as a result of your pelvic girdle pain?

YES ☐ **NO** ☐

5e) Have you given up any leisure time in the last 2 weeks, as a result of your pelvic girdle pain?

YES ☐ **NO** ☐

5) SUPPORT FROM OTHERS

6a) During the last week, have friends and/or relatives stayed off work to help you?

YES ☐ **NO** ☐

6b) If **YES**, how many days did they take off from work during the last 2 weeks?

Days: ☐☐

6) COMPLIANCE WITH TREATMENT

7a) During the last week, for how many days did you wear your pelvic garment?

- Every day ☐
- If **not** every day, please specify for how many days you **didn't** wear it:

  Days: ☐☐

7b) During the last week, approximately how many hours per day did you wear your
pelvic garment?

- 12 hours (recommended) ☐
- More than 12 hours ☐
- Less than 12 hours ☐

7c) If you didn't wear your pelvic garment every day, or wore it for less than 12 hours per day,
can you please specify the reason(s) you took it off? (You can tick more than one answer)

- General discomfort ☐
- Irritation ☐
- Rash ☐
- Restriction of movement ☐
- Aesthetic reasons ☐
- Other (please specify).....

Appendix 11a – Serola Belt

TIDieR (Template for Intervention Description and Replication) Checklist:

Item Number	Item	Details
1	**Brief name**	Serola belt, (Serola biomechanics, Inc, https://www.serola.net/)
2	**Why**	The pelvic orthotic is an external compression device aimed at increasing stiffness and stability through the pelvis. It is designed to improve pain by providing targeted stability, support and re-alignment of the pelvis, whilst optimising movement and function. It is postulated that a reduction in shear forces through the symphysis pubis and sacroiliac joints leads to a reduction in pain irritation.
3	**What materials**	The Serola Belt consists of an open cell urethane inner layer (3" in width), wrapping the circumference of the pelvic girdle and fastening with Velcro tape. It has added extra-strong, double-pull elastic straps, which can be applied, also with Velcro tape, for further tension and support
4	**What: Procedures**	When the participant was fitted with the Serola belt they were also provided with a standard advice sheet regarding the washing of their orthotic and a standard advice booklet from the association of Pelvic, Obstetric and Gynaecological Physiotherapy (POGP), https://pogp.csp.org.uk/system/files/pogp-pgppat_3.pdf.
5	**Provider**	A senior musculoskeletal physiotherapist (Band 7) who was experienced in assessing and treating females with pregnancy related pelvic girdle pain (PGP) by following manufacturer advice and information on measuring for the Serola belt.

6	**How**	If randomised to the Serola belt group, each participant received their own Serola belt.
7	**Where**	The participant would wear these during their normal daily activities.
8	**When and how much**	
a)	**Intensity**	Participants were advised not to wear their Serola belt for longer than 12 hours each day and not to be wear them at night.
b)	**Frequency**	Participants would wear their Serola belt daily. There was potential for some participants to wear their Serola belt for longer periods depending on which trimester they entered the trial on. However, minimisation was used to balance groups for gestation.
c)	**Session time**	One face-to-face physiotherapy session to fit the orthotic and provide advice. Orthotic wear time: Advised not to wear for longer than 12 hours per day.
d)	**Overall duration**	Orthotic worn for the duration of the participant's engagement in the study, with advice to continue to wear the orthotic following cessation of the trial if they wished. Advised not to wear orthotic for longer than 12 hours per day.
9	**Tailoring**	Individual measurements were undertaken for each participant who was allocated to the Serola group. The Serola belt group only required one measurement around their waist; however, to maintain consistency and ensure equal time spent on the measurement process, every participant underwent customised DEFO measurements (see Appendix 11b).
10	**Modification**	There were no modifications to the intervention during the course of the study.
11	**How well: Planned**	
a)	**Fidelity strategies**	No other strategies were used to maintain or improve fidelity
b)	**Fidelity assessment**	Not assessed
12	**How well: Actual**	Not assessed

Appendix 11b – Customised Dynamic Elastomeric Fabric Orthosis (DEFO)

TIDieR (Template for Intervention Description and Replication) Checklist:

Item Number	Item	Details
1	**Brief name**	Customised Dynamic Elastomeric Fabric Orthoses (DEFO), (DM Orthotics' Ltd, https://www.dmorthotics.com)
2	**Why**	The pelvic orthotic is an external compression device aimed at increasing stiffness and stability through the pelvis. It is designed to improve pain by providing targeted stability, support and re-alignment of the pelvis, whilst optimising movement and function. It is postulated that a reduction in shear forces through the symphysis pubis and sacroiliac joints leads to a reduction in pain irritation.
3	**What materials**	The customised DEFO is a Lycra based orthotic, designed in the form of customised pelvic support shorts, with biomechanically positioned lycra and powernet reinforcement panels.
4	**What: Procedures**	When the participant was fitted with the DEFO they were also provided with a standard advice sheet regarding the washing of their orthotic and a standard advice booklet from the association of Pelvic, Obstetric and Gynaecological Physiotherapy (POGP), https://pogp.csp.org.uk/system/files/pogp-pgppat_3.pdf.
5	**Provider**	A senior musculoskeletal physiotherapist (Band 7) who was experienced in assessing and treating females with pregnancy related pelvic girdle pain (PGP) was trained by DM Orthotics to undertake the measurements required for the DEFO.
6	**How**	If randomised to the DEFO group, each participant received their own customised DEFO.

7	**Where**	The participant would wear these during their normal daily activities.
8	**When and how much**	
a)	**Intensity**	Participants were advised not to wear their DEFO for longer than 12 hours each day and not to be wear them at night.
b)	**Frequency**	Participants would wear their DEFO daily. There was potential for some participants to wear their DEFO for longer periods depending on which trimester they entered the trial on. However, minimisation was used to balance groups for gestation.
c)	**Session time**	One face-to-face physiotherapy session to fit the orthotic and provide advice. Orthotic wear time: Advised not to wear for longer than 12 hours per day.
d)	**Overall duration**	Orthotic worn for the duration of the participant's engagement in the study, with advice to continue to wear the orthotic following cessation of the trial if they wished. Advised not to wear orthotic for longer than 12 hours per day.
9	**Tailoring**	Individual measurements were undertaken for each participant who was allocated to the DEFO group. Depending on which trimester they entered the trial, they would undergo wither 12 measurements (2^{nd} Trimester) or 13 measurements (3^{rd} trimester). This required a combination of circumferential measurements of the torso, pelvis and thighs, along with linear measurements of the torso, pelvis and thighs to establish length. The extra measurement in the third trimester required an additional circumferential measurement at the level of the sternum to cater for growth during the third trimester.
10	**Modification**	There were no modifications to the intervention during the course of the study.
11	**How well: Planned**	
a)	**Fidelity strategies**	No other strategies were used to maintain or improve fidelity
b)	**Fidelity assessment**	Not assessed
12	**How well: Actual**	Not assessed

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