**FULL/LONG TITLE OF THE TRIAL**

**Evaluating the Management of Chronic Pelvic Girdle Pain following pregnancy (EMaPP): A randomised controlled Feasibility trial**

**SHORT TRIAL TITLE / ACRONYM**

**Evaluating the Management of Chronic Pelvic Girdle Pain** **(EMaPP)**

|  |  |
| --- | --- |
| **IRAS Number: 297938** |  |
| **ISRCTN Number:** |  |
| **SPONSORS Number:** |  |
| **FUNDERS Number: NIHR201930**  |  |

**This protocol has regard for the HRA guidance and order of content**

# SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and in accordance with the UK Policy Framework for Health and Social Care Research (Data Protection Act 2018), the principles of Good Clinical Practice (GCP) and the Sponsor’s (and any other relevant) SOPs.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest, accurate and transparent account of the trial will be given; and that any discrepancies and serious breaches of GCP from the trial as planned in this protocol will be explained.

|  |
| --- |
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#

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## LIST OF ABBREVIATIONS

Define all unusual or ‘technical’ terms related to the trial. Add or delete as appropriate to your trial. Maintain alphabetical order for ease of reference.

AE Adverse Event

AR Adverse Reaction

CI Chief Investigator

CRF Case Report Form

CTU Clinical Trials Unit

DEFO Dynamic Elastomeric Fabric Orthoses

DMC Data Monitoring Committee

EC European Commission

EQ-5D European Quality of Life – 5 Domains

FreBAQ Freemantle Back Awareness Questionnaire

ICF Informed Consent Form

ICIQUI SF International Consultation on Incontinence Questionnaire

 Short Form

ISF Investigator Site File (This forms part of the TMF)

ISRCTN International Standard Randomised Controlled Trials Number

NHS R&D National Health Service Research & Development

NICE National Institute for Health and Care Excellence

NIHR National Institute for Health Research

NPRS Numerical rating of pain scale

PenCTU Peninsula Clinical trials Unit

PGP Pelvic Girdle Pain

PI Principal Investigator

PIC Participant Identification Centre

PIS Participant Information Sheet

QA Quality Assurance

QC Quality Control

RCHT Royal Cornwall Hospital NHS trust

RCT Randomised Controlled Trial

REC Research Ethics Committee

SAE Serious Adverse Event

SAR Serious Adverse Reaction

SDV Source Data Verification

SOP Standard Operating Procedure

SSI Site Specific Information

SUSAR Suspected Unexpected Serious Adverse Reaction

TMF Trial Master File

TSK Tampa Scale of Kinesiophobia

TMG Trial Management Group

TSC Trial Steering Committee

UKCRC UK Clinical Research Collaboration

## TRIAL SUMMARY

|  |  |
| --- | --- |
| Full Title | Evaluating the Management of Chronic Pelvic Girdle Pain following pregnancy (EMaPP): A randomised controlled Feasibility trial  |
| Short Title | Evaluating the Management of Chronic Pelvic Girdle Pain (EMaPP) |
| Trial Acronym | EMaPP |
| Trial Design | Randomised controlled feasibility trial |
| Trial Participants | Women, aged 18 and over, experiencing chronic and severe Pelvic Girdle Pain (PGP) following childbirth. |
| Planned Sample Size | 60  |
| Treatment duration | Two physiotherapy sessions, spaced approximately one week apart. All women will undertake a standardised home exercise programme for the 24 week duration of the study. Those allocated to the pelvic support shorts group will wear the shorts for the 24 week duration of the study. |
| Follow up duration | 24 weeks  |
| Planned Trial Period | 24 months duration Trial set up: Months 1-6Participant recruitment: Months 7-13Outcome data collection: Months 6-19Data analysis and reporting: Months 20-22Feedback to sites, participants /PPI: Months 22-24 |
| Trial Aim  | This feasibility trial aimsto obtain the data and operational experience necessary to inform the conduct and finalise the design of the definitive trial. |
| Trial objectives  | To estimate rates of screening, recruitment, randomisation, retention and adherence to the pelvic support shortsTo evaluate acceptability of outcome measures and data collection methodsTo allow a preliminary assessment of the support shorts intervention in women experiencing severe post-partum PGP |
| Intervention | Pelvic support shorts + standardised physiotherapy advice and exercise (x2 sessions) |
| Control | Standardised physiotherapy advice and exercise (x2 sessions) |

## FUNDING AND SUPPORT IN KIND

|  |  |
| --- | --- |
| **FUNDER(S)** | **FINANCIAL SUPPORT GIVEN** |
|  NIHR  | £250,432.00 |

## ROLE OF TRIAL SPONSOR AND FUNDER

The sponsor for this study, Royal Cornwall Hospital NHS Trust (RCHT), assumes overall responsibility for the initiation and management of the trial.

The sponsor and funder will not have direct involvement in trial design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

## ROLE OF THE COORDINATING CLINICAL TRIALS UNIT (CTU)

The sponsor of the study has allocated tasks associated with data management to the Peninsula Clinical Trials Unit (PenCTU) by way of formal written agreement.

## ROLES OF TRIAL MANAGEMENT COMMITTEES AND GROUPS

The Trial Steering Committee (TSC) has an independent chair, (Professor Shea Palmer, Coventry University / University Hospitals Coventry & Warwickshire NHS Trust). It has an independent clinician and statistician and one patient representative. The TSC will meet at least every 6 months to review the progress of the trial and any serious adverse events and will report to the sponsor. Detailed role and remit of the TSC is described in a separate TSC Charter.

The Trial Management Group (TMG) is chaired by the Chief Investigator and includes a representative from the sponsor and CTU as well as the trial statistician and patient representative. It also has representation from co-investigators and leads for the qualitative and health economic components. The TMG will meet monthly to review trial progress and to ensure appropriate management of the trial.

A Data Monitoring and Ethics Committee will not be convened for this trial which is considered low risk of harm to participants.

## KEY WORDS:

Pelvic Girdle Pain (PGP), Post-Partum, Orthoses, Physiotherapy

## TRIAL FLOW CHART

Recruitment Pathway



**Participant pathway:**



### BACKGROUND AND RATIONALE

#### Background

In the United Kingdom, an estimated 49,000 women every year suffer from severe, long-lasting pelvic girdle pain following pregnancy (Bergstrom et al 2017, Wuytack & O’Donavon 2019), with an estimated 10% experiencing this for longer than three months post-partum with some experiencing pain for more than a decade (Wuytack et al 2015, Stuge et al 2017, Wuytack et al 2018). This has significant physical, psychological and socio-economic consequences. Everyday activities are affected, such as moving in bed, walking, driving, breast-feeding (due to discomfort and analgesics), continence (due to associated pelvic floor dysfunction), and safely caring for the baby/toddler/young child and siblings, especially as the child becomes more mobile (Mackenzie et al 2018) . The emotional impacts of “living with enduring pain”, include anger and frustration and feelings of “being a burden” (Persson et al 2013) with related abuse of analgesics highlighted (Bergstrom et al 2016, Malmqvist et al 2018). Work absenteeism contributes significantly to the economic consequences.

Despite such wide ranging impacts, symptoms can be overlooked or dismissed by health professionals who focus on what they consider to be more serious conditions, believing the pain will naturally resolve soon after delivery (Wuytack et al 2015, Close et al 2016) . In reality, severe long-lasting pain is typically recalcitrant to usual management (Albert et al 2000, Szkwara et al 2019) and can ultimately require invasive and expensive pelvic joint injections and surgical procedures. There is an urgent need for effective preventative and management strategies to address this personal and societal burden. Pelvic Orthoses are one option available to manage PGP. They are supported by European guidelines (Vleeming et al 2008), Royal College of Obstetricians and Gynaecologists (RCOG, 2015) and NHS advice websites (NHS, 2019). However, all current guidance relates to pain during pregnancy with NICE guidance only covering the first 8 weeks post-partum (NICE 2006). Research is urgently required to inform evidence based decision making.

#### Rationale

In light of this, NHS England has committed to improving access to postnatal physiotherapy (HEE, 2019). However, evidence-based physiotherapy treatment options for severe chronic pelvic girdle pain, such as exercise, hydrotherapy and acupuncture are limited in their success (Richards et al 2012). Another intervention used to manage this pain are pelvic orthoses. These are externally worn devices designed to increase pelvic joint stability, alignment and sensory input to optimise muscle control, pain and function (Mens & Pool-Goudzwaard 2017). A wide range of ‘off-the-shelf’ pelvic orthoses are available (e.g. maternity support belts, briefs, cradle and torso supports), however they have been shown to be of mixed benefit, and often ineffective when pain is severe. Furthermore, women report wear-time issues due to discomfort, lack of ease of use, reduced aesthetics, and impact on movement (Skwara et al, 2019).

In response to these issues, a novel customised pelvic orthosis for people with *severe* pelvic girdle pain has been designed. This bespoke Dynamic Elastomeric Fabric Orthosis (hereon referred to as “pelvic support shorts”) (DM Orthotics’ Ltd, https://www.dmorthotics.com) differs markedly in design, material and compression grades to ‘off-the-shelf’ rigid support belts. These pelvic support shorts are designed to improve pain by providing targeted support and realignment, whilst optimising movement and function. Wear-time is crucial for orthotics, as benefits gained are dependent upon this, hence these customised pelvic support shorts are designed to be practical, comfortable and aesthetically acceptable. Members of our research team undertook a RCT to investigate their use *during* pregnancy, finding these pelvic support shorts significantly improved pain, over and above the traditional rigid belt (Cameron et al 2018). This team also undertook an exploratory case study series (n=8) of women experiencing severe persistent PGP following pregnancy, identifying that the pelvic support shorts improved pain, function and quality of life (Cameron, 2017). Furthermore, both studies indicated the support shorts were acceptable to women (wear-time, comfort, and aesthetics). Together, these results indicate they offer a potentially effective new treatment option for managing this difficult-to-treat condition in women following pregnancy. However, there are no current studies examining the clinical or cost effectiveness, feasibility or acceptability of these customised pelvic support shorts in women experiencing persistent PGP *following* pregnancy.

#### Justification

Before considering a definitive trial to assess the clinical and cost-effectiveness of customised pelvic support shorts alongside current standard management in women with chronic severe pregnancy-related pelvic girdlepain, the research team first need to test the feasibility of running such a trial. This study aims to collect the information necessary for the planning of a future trial including the willingness of patients to take part, the willingness of clinicians to recruit to the study, the likely rate of participant recruitment and retention and the acceptability of outcome data collection methods. A qualitative sub study will explore participant experiences of wearing (participant) and providing (clinicians) the shorts and of engaging in the study itself.

### OBJECTIVES AND OUTCOME MEASURES / ENDPOINTS

The eventual aim is to undertake a definitive, multi-centre, assessor blinded RCT asking the research question“What is the clinical and cost-effectiveness of pelvic support shorts plus standardised information and exercisesversus standardised information and exercises alone in women with chronic, severe pregnancy-related pelvic girdlepain?” Before moving to a definitive trial there are a number of uncertainties that need addressing in this study, by meeting the following objectives.

#### Study aim and objectives

Our **aim is** to conduct a randomised feasibility trial of a customised pelvic support shorts and standard physiotherapy (advice and exercise) versus standard physiotherapy alone (advice and exercise). We aim to provide high quality data to facilitate the design and planning of a future definitive trial.

Our study **objectives** are to estimate:

1. Feasibility and acceptability of trial procedures
2. Suitability of eligibility criteria
3. Numbers of eligible and interested participants from the target population: specifically conversion rates by recruitment method (invitation letter, personal contact with clinician, social media)
4. Willingness of clinicians to recruit participants, and understand any differences between this for different referral pathways (for example GP vs Women’s Health vs Musculoskeletal vs Self-referral)
5. Willingness of patients to be randomised
6. Retention rates as participants move through the trial
7. Intervention fidelity between sites (including timely delivery of shorts)
8. Feasibility and acceptability of wearing the support shorts (adherence)
9. Completion and performance of self-report outcome measures, including; completion rates, baseline scores, distributional properties and standard deviations, responsiveness to inform selection of the primary outcome measure (and refine see the secondary outcomes) for the definitive trial
10. Baseline factors associated with outcomes, as potential stratification factors in the definitive trial
11. Estimates of the correlation between baseline and follow up outcome measures to inform future sample size calculation
12. Feasibility of collecting data to estimate intervention resource requirements and costs and health, social care and broader societal resource use and costs
13. Total resource required for the full trial

To meet these aims and objectives, this trial will use the same general research approach, design and methods as intended in the anticipated definitive RCT. In brief, a pragmatic multi-centre feasibility RCT with assessor blinded outcome assessment will be undertaken. Participants will be randomised to receive the pelvic support shorts plus advice / exercises or advice and exercises alone.

#### Study Outcomes Measures

##### Feasibility trial operational outcome measures (objectives i – vi)

We will gather the following data pertaining to operational activities:

* Recruitment rate (overall and by centre)
* Retention rate at 12 weeks and 24 weeks (overall and by centre)
* Completeness of data collection
* Identification of how participants are ‘lost to follow-up’: The research team will identify participants lost to follow-up and investigate the reasons as to why they have been lost to follow-up.

##### Participant reported and other clinical outcomes (objectives vii – xi)

###### Demographic and diagnostic Information

Following informed consent, the following self-report data will be collected:

* Screening: age, parity, severity, duration and site of pain
* Baseline:

*Demographics:* ethnicity, employment status (as an indicator of socio-economic status), medication, co-morbid status,

*Birth details (*relating to birth of last child): gestational week of delivery, length of labour, induction required, mode of delivery, episiotomy/perineal tear, neonatal gender and weight

*Pain history:* presence/absence of lumbo-pelvic pain prior to pregnancy,

*Other:* participant height and weight (to determine BMI), Beighton scale (Self-reported line drawing) (see 2.2.2.3)

###### Patient Reported Outcome measures

All participants will be requested to complete standardised, validated patient self-reported questionnaires via a web-based App. For those whose preference is to complete paper versions of the questionnaires, a FREEPOST envelope will be provided to return these by post. All measures will be undertaken at baseline, 12 weeks and 24 weeks after the first scheduled intervention session. In addition, at fortnightly intervals throughout the trial, participants will record NPRS (detailed below) and current pain medication usage. The fortnightly serial collection of data enables the trajectory of pain to be captured over the timeline of the trial, which is important given the potentially cyclical nature of pain. The 12 and 24 week follow-ups are important to comprehensively assess potential benefits and the maintenance of any observed effect. All patient reported outcome measures included within this study align with the pelvic girdle pain core outcome set for evaluating the effectiveness of interventions in post-partum PGP (Remus et al 2021).

1. *Numerical Pain Rating Scale (NPRS)*

To evaluate pelvic girdle pain intensity (probable primary outcome for the definitive trial). This 0-10 point scale is widely used (Dworkin et al 2008) quick to complete, with a format suitable for completion through a mobile/app. There is evidence in chronic pain patients to suggest a 1-point change is clinically significant (Childs et al 2005), and hence evidence of a difference between groups of >1.0 being plausible at 24 week follow up will be used to indicate a signal of efficacy.

Women will be asked to rate their pain experience over the past fortnight, using the NPRS, in four categories:

- Worst level of pelvic pain during the day

- Average level of pelvic pain during the day

- Worst level of pelvic pain during the night

- Average level of pelvic pain during the night

1. *Pelvic Girdle Questionnaire (PGQ)*

This condition-specific questionnaire has been psychometrically evaluated in this population. It comprises 25 questions related to activities [20 questions] and symptoms [5 questions]. It takes ~ three minutes to complete. Minimally important changes are available [>25-point change total score, > 20-point change symptom subscale (Stuge et al 2011). Improving function is important, being a primary complaint of women who report interference with daily activities such as: moving in bed, walking, cooking and driving.

1. *European Quality of Life-5 dimensions (EQ-5D-5L) & Short form 36 item health survey V2 (SF-36-V2)*

Evaluation of health related QOL. Both have been widely used within clinical trials, and psychometrically validated for use with pregnant women (Wuytack & O’Donavon 2019). Both can be used to calculate quality adjusted life-years (QALYs), enabling cost-utility analyses.

1. *Edinburgh Postnatal Depression Scale (EPDS)*

This is the most commonly used, validated self-report screening tool for post-natal depression. Comprising 10 questions rating feelings over the past 7-days, it is easy to complete, with good diagnostic accuracy at a cut-off of ≥11 points (Cox et al 1987, Smith-Nielsen et al 2018)

1. *International Consultation on Incontinence Questionnaire Short Form (ICIQ-UI SF)*

This validated self-report questionnaire (Avery et al, 2004) has been used in pregnancy-related PGP studies (Fitzgerald et al 2012), demonstrating good psychometric qualities. It comprises questions regarding frequency/amount of urine leakage, and interference with everyday life. It obtains a brief yet comprehensive summary of the level, impact and perceived cause of the symptoms of incontinence.

1. *Tampa Scale of Kinesiophobia (TSK)*

This 17-item questionnaire is used to assess the subjective rating of kinesiophobia or fear of movement (Miller et al 1991). It has been shown to be a valid and reliable psychometric measure (Hudes, 2011). This outcome measure has been used within the PGP population in a range of previous trials (Wand et al 2017, Beales et al 2016).

1. *Fremantle Back Awareness Questionnaire (FreBAQ)*

This quick and simple tool assesses a person’s perceptual awareness of their lumbo-pelvic region (explicit somatoperception), which has been demonstrated to be associated with pain experience. This measure has been used within the PGP population, demonstrating good psychometric properties (Wand et al 2017, Wand et al 2016, Yamashita et al 2019).

1. *Health and social care Resource Use Questionnaire*

Data on health, social and wider care resource use will be collected using a self-report resource use questionnaire, developed for the ante-natal RCT which evaluated the effectiveness and cost effectiveness of these support shorts (Cameron et al 2018).

###### Clinical Measures (gathered via video conference)

1. *2PET (two point estimation task)*

 This measure of implicit somatoperception involves a 2 point estimation task. It is a

 quick and simple measure of tactile size estimation providing a measure of implicit

 somatoperception. The participant’s spouse/trusted other will be instructed to apply two points

 of contact on the participants skin over their pelvic girdle and the participant then uses a digital

 calliper to estimate the distance between these two points (Adamczyk et al 2018, Adamczyk et

 al 2019).

1. *Beighton score (Self report line drawings)*

This self-reported measure has been developed as proxy to the in person Beighton score (Beighton et al 1973). The standard Beighton score is 9 point clinician rated measure undertaken in person and therefore with the use of a goniometer. This measure developed by (Cooper et al 2018) provides a valid and reliable assessment of the presence of generalised joint hypermobility via self-report.

1. *Pelvic girdle pain referral Map*

This image provides both an anterior and posterior view of the pelvic girdle low back and lower limbs. Women will be able to identify to the researcher the location of the Pain and assist in the confirmation of the diagnosis of PGP*.*

###### Intervention Fidelity

To assess the intervention fidelity all clinicians will be required to complete the electronic therapist reported fidelity checklist. This will be recorded for the initial appointment and the follow up appointment.

Attendance at the two physiotherapy sessions (via video-conference) will be monitored and recorded by the NHS physiotherapist on a pre-formatted electronic form.

Participants allocated to the intervention group are also advised to wear the pelvic support shorts daily, for a maximum of 12 hours/day. Adherence to wearing the support shorts, will be assessed via a temperature sensor integrated into the seam of the customised support shorts. The Orthotimer sensor (Rollerwerk Medical Engineering, Balingen, Germany) is embedded in a small (13mm × 9mm × 5 mm), dust-tight and watertight unit. It is powered with a lithium dry cell battery (3.0 V/5.5 mAh) with a lifespan of at least 18 months. It records time, date, and temperature every 15 min and has 400 days of storage capacity. The sensor has a temperature precision of ± 0.1°C.

As part of the pelvic support shorts production process, DM Orthotics will initialise the orthotimer sensor using the orthotimer reader (Rollerwerk Medical Engineering, Balingen, Germany) prior to integrating it into the pelvic support shorts. This will be achieved by sewing the sensor into a small fabric pouch compartment next to the leg seam. This fabric pouch will be designed to enable it to be cut off by the participant, at the completion of the trial period (24weeks), and returned to the research team within a reply paid padded envelope.

To assess the timely delivery of the pelvic support shorts:

* The research team will keep a record of the “date measurements provided”
* DM orthotics will record the date pelvic support shorts are sent to participants, and email the EMaPP team this information.
* EMaPP administrator will text/phone the participants to record the “date of delivery” on the trial database.

###### Intervention costing (objectives xii,)

Resource use and costs associated with delivery of both intervention arms will be estimated.

Data on resource use associated with the measurement, ordering and delivery of the support shorts intervention (exclusive of time spent on research elements, e.g. reading the protocol and SOPS) will be collected via within trial reporting, including participant level contact and non-contact time for staffing input on delivery, equipment and consumable costs, training and supervision for delivery staff.

* NHS treating physiotherapists will complete contact sheets to capture time spent on each participant contact (including any follow up additional to the scheduled two sessions).

#### Table 1 summarising the objectives and outcomes

|  |  |  |
| --- | --- | --- |
| **Objectives** | **Outcome Measures**  | **Objectives met** |
| **Operational:**Rates of recruitmentRates of retentionData completeness | Number of patients screened and recruitedNumber of recruited patients attending follow-up visitsCompleteness of data capture and outcome measures (to include number of completed questionnaires, number of missing items within a questionnaire by time point) | iii, iv, viviix |
| **Patient reported/Clinical** PainFunction Health-related quality of lifePost-natal depressionIncontinence Kinesiophobia Body perception (explicit)Body perception (implicit)Hypermobility | Numerical rating of pain scale (NRPS) Pelvic Girdle Questionnaire (PGQ)EQ-5D-5L & Short Form 36 version 2 (SF 36)Edinburgh Post Natal Depression Scale (EPDS)International Consultation on Incontinence Questionnaire Short Form (ICIQ UI SF)Tampa Scale Kinesiophobia (TSK)Freemantle back awareness Questionnaire (FreBAQ)2 point estimation task (2PET)Self-reported Beighton score (line drawings) | ix, x, xi |
| **Adherence** Support shorts wear time adherence | Orthotimer data  | viii |
| **Resource Use**  | Therapist completed time sheets Patient reported Resource Use Questionnaire  | xii |

### Table of objectives and outcome measures. Refer to tabulated schedule of events (Table 2) for timings of outcome measures.

### THE INTERVENTIONS

All treatment will be provided by NHS physiotherapists (Musculoskeletal, Women’s health, or First Contact Practitioners dependent upon referral mechanism) at two video-based consultation sessions. At the patient’s preference, face to face sessions can be undertaken in place of these video–based consultations. The booking of both treatment sessions will be the responsibility of the NHS therapy department local to the participant (section 10.2.3).

#### Control Group

At the initial session (60 minutes) women will receive advice about pelvic girdle pain management and will be instructed in a home exercise programme, as follows:

1. *Advice:* standardised advice on management of PGP, through a discussion centred around the ‘Guidance for Mothers-to-be and New Mothers: Pregnancy-related Pelvic Girdle Pain’ booklet (https://pogp.csp.org.uk/system/files/pogp-pgppat\_3.pdf). This publicly available, specialist physiotherapy approved, standardised booklet, provides information reflective of current best practice. The booklet can either be provided in a paper format and posted to the participant or provided as an online resource. The participant will be able to choose which method is most suitable for them. The participant can use this booklet as an on-going resource.
2. *Exercise:* The physiotherapist will teach participants a standardised programme of lumbo-pelvic exercises, typical of those provided within usual physiotherapy practice. Written explanation/illustrations of these exercises will be provided (printed and posted copy/emailed according to their preference) and the women will be asked to undertake these at home, three times/week. See (Appendix 1) for the standardised exercise regime.

A second, follow-up session (30 minutes), will be scheduled approximately 10 days after their initial session. This session will allow for problem solving specific to the individual’s needs, further advice centred on the provided booklet, and review of the exercises to ensure they are being performed correctly.

#### Intervention group

In addition to the advice and exercise programme described above, at the initial session (60 minutes) the NHS physiotherapist will check the comfort and fitting of the bespoke pelvic support shorts (DM Orthotics Ltd, <https://www.dmorthotics.com>), which will have been posted to them (2 pairs) prior to this appointment. They will be provided with standardised written information on wear time/washing. Women will not have started wearing the support shorts until this appointment.

At session two (30 minutes), approximately 10 days later, the physiotherapist will review the fit and wearing of the shorts, problem solve any issues that have arisen, and review the exercises to ensure they are being performed correctly.

***The pelvic support shorts:***

The support shorts apply targeted compressive forces to the pelvic girdle through selective, precisely positioned reinforced elastomeric lycra panels that aim to stabilize and align body segments to improve function and reduce unwanted movements. The construction material (Nylon and Elastane) is durable and breathable, and its mechanical properties enable it to provide “dynamic” stability and support (rather than the rigid support provided by “off-the-shelf” belts) during movement/functional activities (Swale et al 2016).

Women will be advised to wear the support shorts daily, as tolerated, during their usual activities. They will be advised to wear the orthotic for a maximum of 12 hours per day, and not to wear them at night when they are sleeping.

All participants in the intervention group will be able to keep the customised pelvic support shorts on cessation of the trial.

### TRIAL DESIGN

This is a pragmatic multi-centre randomised controlled feasibility trial, with assessor blinded outcome assessment, randomising participants to receive either the customised pelvic support shorts in addition to exercise and advice (intervention) or exercise and advice alone (control).

### TRIAL SETTINGS

The sites involved are:

* Secondary Care: two NHS care trusts (University Hospitals Plymouth NHS Trust, Royal Cornwall Hospital NHS trust)
* Primary Care: approved GP practices from across Devon and Cornwall.

A Principal Investigator will be based at each recruitment site.

This trial will undertake a remote, distance-based approach. This will replicate current practice, account for a possible shift towards virtual appointments in the future, and mitigate the risks and challenges associated with face-to-face methods stemming from the Covid-19 pandemic. The remote assessment of PGP using a testing battery has previously been investigated during pregnancy (Fagevik et al 2014), and this is likely to translate to post-partum group.

All sites will implement the trial protocol in the same manner. Physiotherapists from each of these sites will perform the interventions as part of their NHS role, and the EMaPP Researcher (employed specifically for the trial) will undertake the research telephone and video-based screening assessments.

If women are eligible to participate but unable to access technology to undertake the interventions a face to face to face appointment will be arranged with a local healthcare establishment to provide these two appointments.

### PARTICIPANT ELIGIBILITY CRITERIA

#### Inclusion criteria

Patients must satisfy all of the following criteria to be enrolled in the study:

* Women ≥18 years
* Able and willing to provide informed consent
* Self-reported persistent PGP (for a minimum of three months post-partum)
* Self-reported severe PGP (causing walking or stair climbing to be bothersome)
* Diagnosed with PGP in line with European guidelines; pain between the posterior iliac crest and inferior gluteal fold, particularly in the sacroiliac joint vicinity, that may radiate to the posterior thigh and occur in conjunction with or separately in the symphysis pubis (Vleeming et al 2008), captured using the pain referral map, and scoring positively with one anterior PGP test and or 2 tests for posterior PGP (Fagevik et al 2021). This will be determined by the clinician rated video-based screening assessment (refer to section 8, Figure 2 for details).
* The PGP must have started or been aggravated during pregnancy, as determined by self-report.

#### Exclusion criteria

Patients who meet any of the following criteria, as determined by self-report, will be excluded from study participation:

* Known allergy to Lycra
* Age < 18
* Currently pregnant
* Currently wearing a catheter
* PGP for > than 2 years post-partum
* Self-reported history of pathologies causative of lumbo-pelvic pain (e.g. infection, trauma, cancer)
* Participating in concurrent interventional research which may over-burden the patient or confound data collection
* There are no special arrangements made for participants who are unable to adequately understand verbal and/or written English. There is no intention to exclude patients, therefore, if they have regular access to a friend or family member who is able to translate for them they would be able to participate.
* Participants who lack capacity to provide informed consent.

### RECRUITMENT STRATEGY

A multi-faceted recruitment approach will be undertaken using both national and local routes.

This feasibility trial will only recruit from the South West Region (to sites which have received ethical approval), but the possibility of a future national trial will be made clear.

*Nationally,* recruitment will be promoted via a number of sources:

i) Mums net – UK’s biggest internet based forum/network for parents with around 7 million unique visitors per month

ii) Facebook/twitter pages of:

* Pelvic partnership pelvic girdle pain support group The pelvic partnership provides women with information about best practice for the treatment and management of pregnancy related PGP and to enable and empower women to access the right treatment
* National maternity voices – In the national group of maternity voices partnership in England. **A Maternity Voices Partnership (MVP) is a NHS working group: a team of women and their families, commissioners and providers (midwives and doctors) working together to review and contribute to the development of local maternity care.**
* National Childbirth Trusts – supports thousands of women across the UK both ante-natally and post-natally.

All promotional materials will include information inviting people to make contact via the trial’s generic email address. Emails to this address will be monitored by the EMaPP research team, who will send interested potential participants a trial information pack. The pack will consist of a letter of invitation; the participant information sheet’s (PIS); a list of ethically approved participating study sites who will provide the intervention; an editable reply form (or Freepost envelope if the person requests information to be sent via the post); a pain referral map, self-report Beighton score images, testing battery images and consent forms.

*Locally*, recruitment will also be via a number of routes, which include:

1. This trial will be adopted onto the UK Clinical Research Network (CRN) Portfolio; the local Clinical Research Speciality Lead will also promote the trial through existing clinical networks. CRN staff will undertake a database search of GP practice lists of each study site, eligibility check and mail out a trial information pack to potential participants (described above).
2. Through the caseloads of physiotherapists working within Musculoskeletal (MSK) outpatients and Women’s Health (WH) services, who could discuss the trial with interested patients, or write to potential participants from their caseload with a letter of invitation and a trial information pack (described above).
3. Through the caseloads of First Contact Practitioners/Advanced Practice Physiotherapists (FCP’s/APP’s) who work within/with local GP practices and are often a patient’s first contact with health services for MSK related complaints. These practitioners could discuss the trial with interested patients, or contact potential participants from their caseload with a letter of invitation and a trial information pack. With client consent, the FCP’s/APP’s will be able to inform the research team of potential participants.
4. Leaflets and posters will be placed in relevant outpatient clinics/waiting areas of the participating health establishments. Details of the generic email account will be provided on all study raising awareness material, so that potential participants can contact the research team directly to receive further information about the study.
5. Promotion through local initiatives where they exist, for example the local PPI group in Cornwall or hospital twitter accounts (e,g, @RCHTWeCare, UHP\_NHS); with generic email details provided to enable contact with the research team for further information.

Women who are identified through the healthcare practitioners or CRN research staff will be sent (either via email or post) an EMaPP trial information pack which will consist of a letter of invitation; the participant information sheet (PIS); a list of the participating study sites; and an editable reply form (or Freepost envelope if the person requests information to be sent via the post). Where packs are distributed through direct contact (either face-to-face or by telephone), potential participants will be given the option to be contacted by the EMaPP research team to verbally discuss the project and answer any questions. If the potential participant opts in to this option, the healthcare practitioner will pass the patient’s name and contact details (email address or telephone number). Patients will be asked to read the PIS and return the reply form to indicate their interest, to confirm they feel they are eligible, and to give consent for the research team screeners to contact the relevant NHS treating team to confirm their capacity to implement the trial interventions.

### SCREENING AND CONSENT

#### Eligibility screening process

##### Initial telephone screen

On receipt of the completed reply form the EMaPP research team will telephone the potential participant to answer any questions and, following consent, to undertake an initial phone screen for eligibility using a pre-formatted screening checklist based on the eligibility criteria. During this initial screening telephone call, should the participant be deemed eligible to continue to the next stage of screening, their preferred contact details will be confirmed and the planned date of the second stage of screening (via video conference) will be scheduled. All screen failures will also be recorded and inputted into the database as required for the purpose of monitoring recruitment.

##### Stage 2 Screening (via video consultation) - confirmation of PGP diagnosis

At this second stage of screening (following video recorded consent) the EMaPP researcher will assess the eligibility of the potential participant (pelvic girdle pain referral map and testing battery for PGP (figure 2)) via an online video consultation. A requirement for this screening session is agreement by the participant for their spouse/ preferred other to be present to assist with the physical assessment (under the supervision of the distance based researcher). This assistance is required from a practical perspective, to enable sensory testing with the digitial calliper (2PET), which cannot be carried out by the women themselves. All of the screening tests for PGP can be undertaken by women themselves but under guidance from the EMaPP researcher.

If potentially eligible participants are identified at the screening stage but do not have access to suitable IT or stable broadband, then the local physiotherapist will be contacted to request that a face to face screening appointment could be offered by them at their local health care establishment.

**Figure 2 Physical screening test battery for PGP**



At this same session, measurements will be undertaken to enable production of the customised pelvic support shorts, should the participant be allocated to the intervention group. To ensure accuracy, the researcher will instruct the spouse/preferred other on using the linear or digital system, provided by DM Orthotics, to capture the patient measurement data. This approach has been successfully protocolled and trialled during the Covid pandemic by the Company.

Finally, a 2 point estimation task to determine sensory awareness, will be conducted with the assistance of the spouse/preferred other under the guidance of the EMaPP researcher.

Once eligibility is confirmed (telephone screen, pelvic girdle pain referral map and PGP testing battery), the researcher will input the participant details into the study database in order to trigger the randomisation process (see randomisation section 9.1). Screening Failures at this second phase (i.e. patients who do not meet eligibility criteria based on assessment at the video conference) will also be entered into the database as required for the purpose of monitoring recruitment.

#### Consent

The EMaPP researcher will be responsible for ensuring informed consent has been obtained prior to each stage of the screening process and the collection of any baseline data. They will be suitably trained in the relevant principles of Good Clinical Practice and the requirements of the trial protocol.

There will be three layers of consent to this trial, with an additional fourth layer for the sub-group of 10 women agreeing to be involved in the post-trial qualitative component (section :10.1.7)-

1. Permission to be telephone screened:

Women interested in participating will be invited to contact the research team as described in section 7. They will then be sent the EMaPP trial information pack and asked to return the form giving permission for the researcher to undertake the telephone screening process.

Prior to providing consent, women will have at least 24 hours to review the PIS and discuss with family and friends before responding to the research team. During this time, they will also have the opportunity to ask questions via the trial e-mail (details listed in the PIS), or via telephone.

1. Permission to be screened via video conference:

If they have met the eligibility criteria to move to the second phase of screening, an appointment will be made for the potential participant and their partner/trusted other to attend an online video–conference session at which time the physical assessment screening process will be undertaken. Video recorded consent will be undertaken at this session, prior to any assessments being completed. Participants will need to send back completed signed consent forms back to the Research team. If participants are not able to attend then an appointment at a local healthcare establishment will be arranged where they will provide consent to undertake the physical screening battery.

1. Consent to be recruited to the trial:

If the participant is deemed eligible for entry to the trial, video recorded informed consent will be obtained by the EMaPP researcher at the conclusion of the second screening session. Consent will also be sought to contact the woman’s GP to inform them of the woman’s participation in the trial.

1. Consent to participate in the post-trial qualitative interviews

All women participating in the study will be informed of the post-trial qualitative interviews within the PIS, and consent will be included within the pre-baseline informed consent processes. Prior to the final trial assessment at 24 weeks, consent to participate in the interviews will be reviewed and confirmed by the EMaPP researcher. Finally, verbal confirmation of ongoing consent will be obtained by the Researcher undertaking the interview prior to its commencement.

The process of obtaining informed consent will include:

* discussion with the potential participant about the nature and objectives of the study and possible risks associated with their participation
* the provision of the approved PIS and reply slip giving consent to be contacted
* the opportunity for potential participants to ask questions
* an assessment of capacity to consent (Appendix 2)
* advising the potential participant that they have the right to refuse participation without giving reasons and that they are free to withdraw at any time without giving reasons and without prejudicing his/her further treatment
* advising the potential participant on how their data will be used and signposting to further information about data used for research purposes

The PI takes responsibility for ensuring that all vulnerable participants are protected and participate voluntarily in an environment free from coercion or undue influence.

Original versions of completed ICFs will be stored in the Investigator Site File (ISF). One copy should be provided to the participant for him/her to retain, a copy should be filed in the hospital notes/electronic health record and a de-identified copy should be provided to the CTU for central monitoring purposes.

Consent to participate within the trial will occur in the form of a short online one-to- one recorded meeting within which participants show the researcher a completed Informed consent form on screen. These recordings are then stored separately from the data on a password protected secure server.

If the participant prefers to undertake written consent then they will be provided with three blank paper copies. Two signed consent forms will be posted back to the research team and the participant will be requested to keep one copy for themselves. One copy will be sent for filing in the hospital notes/electronic health record and a de-identified copy will be provided to the CTU for central monitoring purposes.

#### Recording screening and recruitment information

CRN staff and the EMaPP research team, will keep accurate records in provided screening logs regarding:

* The number of potential participants sent a trial information pack.
* The number of potential participants directly referred to the research team by the CRN staff / site investigators).
* The number of potential participants who made contact with the research team (from any source), and how they heard about the trial (e.g. specific social media source, CRN, therapist letter / personal contact)
* The number of patients screened for eligibility by the research team
* The number and *characteristics* of patients deemed ineligible (with reasons where available)

*Characteristics* to be recorded for potential participants who have engaged in the screening process but are not deemed to be eligible will include: age, pain duration, pain triggers (n/5 specific triggers), and physical assessment screening score.

Anonymised data from the screening log will be inputted into the PenCTU database for the purpose of monitoring recruitment. These data will be used to determine the proportion of people who expressed an interest in the trial, those who were ineligible (with reasons), and which recruitment methods might be the most effective for a future trial.

### RANDOMISATION AND CONCEALMENT

#### Randomisation

Once eligibility is confirmed by the second screening stage, the researcher will input participant details into the study database to trigger the stratified randomisation process. This will automatically generate a text/email (participant preference), sent to the participant, to provide them with a link to the baseline study questionnaires, with a request to complete all questionnaires within the following 24-48 hours. To optimise data collection a maximum of 5 text/email reminders (one per day) will be automatically sent to the participant. This will only occur if the measures have not yet been completed. Once participants complete the measures the text reminders will automatically stop.

After all baseline data collection is complete, the participant will be randomly allocated to either the intervention (support shorts + exercise / advice) or control group (exercise/advice). Treatment allocation will be achieved by a web-based system created by PenCTU in conjunction with a statistician independent of the trial team, and in accordance with the PenCTU’s standard operating procedure. Participants will be allocated to receive the intervention on a 1:1 ratio, using random permutated blocks, stratified (by region [Devon or Cornwall] and presence/ absence of lumbo-pelvic pain pre pregnancy). The randomisation list and the program that generated it will be stored in a secure network location within the PenCTU, accessible only to those responsible for provision of the randomisation system. Pen-CTU staff independent of the trial will verify the integrity of the randomisation system throughout the trial according to established written protocols.

After randomisation has taken place an automatic email will be generated by the randomisation system. This will be communicated in a blinded fashion (no details of group allocation will be included) to key members of the central research team. Further, automatically generated emails will be sent to the following people, advising them that a participant has been randomised and disclosing the treatment group to which the participant has been allocated to:

* the NHS treating physiotherapist at the relevant site,
* DM Orthotics Ltd to enable production and delivery of the pelvic support shorts by them
* The CI

Following receipt of the randomisation notification, the NHS physiotherapist will be responsible for booking the two physiotherapy treatment sessions (as described in section 3).

Access to the randomisation code/list will be confined to the PenCTU data programmer; no-one else in the trial team will be aware of allocated trial arms until formal randomisation is completed, hence maintaining effective concealment. Following randomisation, only the individuals described above will be aware of the allocations to intervention or control arm; the blinded EMaPP researcher will NOT have access to treatment allocation.

Following receipt of the notification email (which will include name and postal address of the participant), DM Orthotics Ltd will begin production of the customised pelvic support shorts. They will then send the shorts directly to the participant’s home within 10 days. In line with usual procurement practice, they will invoice Royal Cornwall Hospital Trust for one pair of shorts, the second pair being produced gratis.

#### Blinding

The trial participants are unable to be blinded in this trial due to the nature of the intervention they are receiving. Similarly, the NHS treating physiotherapists are unable to be blinded.

The EMaPP researcher conducting eligibility checks, screening assessments, and communicating with participant’s completion of the self-reported outcome assessments, will be blinded to participants’ allocated group.

The initial baseline assessment will be undertaken prior to randomisation.

All outcome measures, at each time-point, are patient reported assessments, using a web-based App, thereby minimising the opportunity for the researcher to influence the outcome assessment. Nevertheless, every effort will be made throughout the trial period to maintain blinding of the EMaPP researcher, for example by reminding participants not to discuss their support shorts /exercises /physiotherapy with them.

At the end of the trial, the blinded EMaPP researcher will be asked to record on an electronic CRF any cases of inadvertent unblinding to group allocation. If this occurred, they will be asked to provide details as to how this un-blinding happened. Regardless of whether or not they had been un-blinded, they will also be asked to make a judgement as to which group the participant had been allocated.

Final unblinding of the research team (including the trial statistician) will be after the creation of a locked analysis data set and analysis has been undertaken.

### TRIAL SCHEDULE

This section describes the conduct of the trial in chronological order, detailing procedures for data collection at each of the time points. A summary flow chart is provided in Figure 1. A tabulated summary of the trial schedule is given in Table 2.

#### Trial Assessments

The trial involves a 2 part screening process undertaken by the researcher: an initial phone based interview, followed by a remote assessment undertaken by video conferencing.

Following recruitment all participants will complete a comprehensive battery of PROMS at three time-points: baseline, 12 weeks and 24 weeks. In addition, all participants will be requested, on a fortnightly basis, to rate their pain intensity level and pain medication usage. All PROMS assessments will be reported via a web based report system (with reminders to optimise data completeness). If participants are not able to access the web based system, paper versions of outcome measures will be mailed out in advance to these participants at the set time frames. Any non-compliances will be noted.

Table 2: Tabulated summary of trial schedule

|  | **Pre-baseline** | **Baseline** | **Allocation** | **Post-initial appointment** |
| --- | --- | --- | --- | --- |
| **TIMEPOINT** |  | ***t0*** |  | ***Fortnightly*** ***t1*** | ***12 weeks******t2*** | ***24 weeks******t3*** |
| **ENROLMENT:** |  |  |  |  |  |  |
| **Eligibility screen (inclusion/exclusion criteria)** | X |  |  |  |  |  |
| **Informed consent for telephone screening**  | X |  |  |  |  |  |
| **Telephone screening** | X |  |  |  |  |  |
| **Informed consent for video-based screening**  | X require for |  |  |  |  |  |
| **Video-based screening (physical exam)** | X |  |  |  |  |  |
| **Informed consent to enter trial** | X |  |  |  |  |  |
| **Allocation** |  |  | x |  |  |  |
| **INTERVENTIONS:** |  |  |  | Initial session | Follow up session | 24 Weeks t3 |
| ***Intervention Group:***  | ***Pelvic support shorts,***  |  |  |  |  |  |  |
| ***\*Exercise*** ***Advice*** |  |  |  |  |  |  |
| ***Control Group:*** | ***\*Exercise***  |  |  |  |  |  |  |
|  | ***Advice*** |  |  |  |  |  |  |
| **ASSESSMENTS:** |  |  |  | ***Fortnightly*** ***t1*** | ***12 weeks******t2*** | ***24 weeks******t3*** |
| ***Demographics, birth details, pain history***  |  | X |  |  |  |  |
| ***Pain medication*** |  | X |  | X | x | x |
| ***Assessments (anchored to initial appointment)***  |  |  |  |  |  |  |
| ***NPRS***  |  | X |  | X | x | x |
| ***PGQ*** |  | X |  |  | X | X |
| ***SF36***  |  | X |  |  | X | X |
|  ***EQ-5D-5L Questionnaire***  |  | X |  |  | X | X |
| ***ICIQ-UI SF*** |  | X |  |  | X | X |
| ***FreBAQ*** |  | X |  |  | X | X |
| ***TSK*** |  | X |  |  | X | X |
| ***Two point estimation task***  |  | X |  |  |  | X |
| ***Beighton score*** |  | X |  |  |  |  |
| ***Resource use questionnaire***  |  | X |  |  | X | X |
| ***Wear time adherence***  |  |  |  |  |  | X |
| ***Qualitative Interviews*** |  |  |  |  |  | X |
| **SAFETY MONITORING:** |  |  |  |  |  |  |
| ***Adverse events*** |  |  |  |  |  |  |

* \*Exercise is delivered over the two consultations with the physiotherapists but is then self-directed for the remainder of the trial. Exercises will not be reviewed again during the course of the trial.

##### Collection of participant contact details

Included within the PIS is a reply slip on which participants will be asked to provide primary contact details (telephone number, email address, postal address) and the preferred method of contact to allow for the setup of the eligibility screen and physical screening. As all other outcome measures are recorded remotely via the PenCTU web based system it is anticipated that only the postal address of those recruited who wish to complete paper based records.

##### Baseline Data

After informed consent has been obtained, an email/text link will be sent to the participant to request them to complete the baseline questionnaire booklet battery of measures. The following information will be collected:

*Demographic data*: age, gender, ethnicity, employment status (as an indicator of socio-economic status), marital status, height and weight (to determine BMI)

*Pregnancy/birth related data*: parity (the number of pregnancies a woman has had that have each resulted in the birth of an infant capable of survival); and for the most recent birth - gestational week of delivery (recorded as week + days [i.e 40+5], length of labour (recorded as hours), Induction (Recorded as Yes or No), mode of delivery (Vaginal, Caesarean section, Assisted delivery), Episiotomy/ Perineal Tear (Perineal tear (1st, 2nd and 3rd - 4th [OASI]), Episiotomy (Yes or No), Neonatal gender (Male/Female), neonatal weight (KG +grams to 1 decimal place), Presence or absence of lumbo-pelvic pain prior to pregnancy (Present/absent)

*Medications*: all current prescribed medications and their dose will be listed.

*Co-morbid conditions*: will be recorded*,* including presence of hypermobility (as determined by the Beighton score)

*Patient reported clinical outcome measures:* Pain Levels (NPRS scale), Function (Pelvic Girdle Questionnaire), Quality of Life (EQ-ED-5L and SF 36), Incontinence (ICIQ-UI SF), Kinesiophobia (TSK), Explicit somatoperception (FreBAQ).

##### Follow-up assessments (fortnightly)

At fortnightly intervals anchored to the initial treatment session all participants will be sent an email/text link via the Web-based App requesting them to complete:

* a rating of their pelvic girdle pain levels (via the NPRS, see section 2.2.2.2)
* pain medication details

Text/email reminders will be sent once a day for a maximum of 5 days after the schedule date to optimise data completeness.

##### Follow-up assessments (12 weeks)

At 12 weeks, all participants will be sent an email/text link via the Web-based App requesting them to complete the same battery of patient reported clinical outcome measures that were completed at the baseline assessment. Participants will be able to record the self-report measures up to 2 weeks after the first text/email reminder (to allow for holidays, sickness etc).

##### Follow-up assessments (24 weeks)

At 24 weeks:

1. all participants will be sent an email/text link via the Web-based App requesting them to complete the same battery of patient reported clinical outcome measures that was completed at the baseline and 12 week assessment. Participants will be able to record the self-report measures up to 2 weeks after the first text reminder (to allow for holidays, sickness etc).
2. all participants will be sent a letter (together with are reply paid padded envelope and a set of callipers), requesting them to undertake the 2 Point Estimation Test, using the enclosed callipers).
3. those allocated to the intervention group, within the same letter, will also be requested to remove and return the orthotimer wear time adherence sensor (see section 2.2.2.4), together with the callipers in the reply paid envelope.

##### “Other” assessments

1. *Identification of how participants are ‘lost to follow-up’*

The blinded researcher will identify participants lost to follow up and the reasons as to why they have been lost to follow-up.

1. *Outcome data that will be recorded from protocol non-adherers*

As far as is possible, all outcome data will be collected for all participants, regardless as to whether or not they have adhered to the protocol.

At the final data collection point (24 weeks) those participants allocated to the interventions group will be asked (through the web based app) if they continued to wear the support shorts for the duration of the trial. If participants have not worn the shorts for the duration they will be offered a multiple choice answer with possible reasons for ceasing their use.

##### Qualitative assessments

The aim of the qualitative component is to explore participant experiences of wearing (participant) and providing (clinicians) the shorts and of engaging in the study itself. This will help to further elucidate the acceptability of the intervention and the trial procedures from the perspective of the participants and NHS physiotherapists. The qualitative component of this trial will aim to meet objectives (i, ii, v & vi).

The specific aims of this will be to investigate:

* acceptability of trial methods across both trial arms
* acceptability (comfort, wear-time) of the support shorts
* impact the intervention may/may not have on women’s lives.
* adherence to the exercise regime over the course of the trial

######  Participant interviews

Ten purposively sampled participants from the trial will include 5 trial participants randomised to the control group and 5 participants from the intervention group. These will include women receiving interventions from both the secondary care (RCHT & UHP) and primary care sites (GP practices). This will be run through individual one off semi-structured telephone interviews using a topic guide (Appendix 4). The interviews will be conducted at the end of the trial period.

##### Participating Clinicians

Five NHS physiotherapists (from secondary and primary care sites) involved within the trial will be purposively sampled to provide information on the acceptability of the trial methods across both trial arms.

##### Informal Exit Interviews:

Should any participant either withdraw from the trial or discontinue their involvement during the course of the trial, the EMaPP researcher will be informed. On receipt of this information the researcher will telephone the participant to ask them to share their reasons for stopping the trial. This telephone interview will be informal in nature and will take place within approximately one week of discontinuation. It will ask participants about their experience of participating in the trial. These interviews are informal and entirely optional. If the participant does not wish to pursue the interview, then there is no requirement of them to do so. The “interview” will not be recorded or transcribed; instead field notes will be taken of the participant’s responses.

#### THE INTERVENTIONS

The interventions will be provided by NHS physiotherapists (musculoskeletal, women’s health, or First Contact Practitioners dependent upon referral mechanism) at two video-based consultation sessions. At the patient’s preference, face to face sessions can be undertaken in place of these video–based consultations.

The NHS physiotherapist will be responsible for booking the two physiotherapy treatment sessions (as described in section 3), following receipt of the randomisation and group allocation notification. The first physiotherapy session should be scheduled approximately 10 days (but ideally no more than 14 days) following randomisation, with the second session scheduled approximately 7 days after that. The NHS physiotherapist must record the two scheduled sessions in the electronic CRF on completion of each session.

##### Control Group (advice and exercises)

At the initial session the NHS physiotherapist will provide the participant with standardised advice about pelvic girdle pain management and will be instructed in a home exercise programme. This session will last a maximum of 60 minutes (replicating a new patient appointment within the NHS), and the content of the session will comprise:

1. *Advice:* standardised advice on management of PGP, through a discussion centred around the ‘Guidance for Mothers-to-be and New Mothers: Pregnancy-related Pelvic Girdle Pain’ booklet (https://pogp.csp.org.uk/system/files/pogp-pgppat\_3.pdf). This publicly available, specialist physiotherapy approved, standardised booklet, provides information reflective of current best practice. The booklet can either be provided in a paper format (posted to the participant) or as an online resource, depending on participant preference. The participant can use this booklet as an on-going resource and will be able to keep this booklet after the trial has been completed. The participant will be able to ask specific questions to the physiotherapist at this consultation.
2. *Exercise:* The physiotherapist will teach participants a standardised programme of lumbo-pelvic exercises, typical of those provided within usual physiotherapy practice. Written explanation/illustrations of these exercises will be provided (printed and posted copy/emailed according to their preference) and the women will be asked to undertake these at home, three times/week. See Appendix 1 for the standardised exercise regime

A second follow-up session (30 minutes) will be scheduled approximately 10 days after the initial session. This session will allow for problem solving specific to the individual’s needs, further advice centred on the provided booklet, and for the physiotherapist to review the exercises to ensure they are being performed correctly and to problem solve issues around exercise adherence/ parameters of the exercises prescribed.

##### Intervention Group (pelvic support shorts, advice and exercises)

DM Orthotics Ltd will post 2 pairs of the customised pelvic support shorts (DM Orthotics Ltd, <https://www.dmorthotics.com>), to the participant, within 10 days of receipt of the required measurements. The pack will include a letter which asks the participant not to wear the shorts until the first physiotherapy appointment, and also wear time and washing instructions. The pack must have been received prior to their first physiotherapy appointment.

At the initial physiotherapy session (60 minutes), in addition to the advice and exercise programme described above, the NHS physiotherapist will check the comfort and fitting of the bespoke pelvic support shorts. Participants will be advised to wear the support shorts daily, as tolerated, during their usual activities. They will be advised to wear the orthotic for a maximum of 12 hours per day, and not to wear them at night when they are sleeping. To complement this, they will have received the standardised written information on wear time/washing.

At session two (30 minutes), approximately 10 days later, in addition to the advice and exercise elements described above the physiotherapist will review the fit and wearing of the shorts and problem solve any issues that have arisen in relation to the shorts.

All participants will be able to keep the customised pelvic support shorts on cessation of the trial.

##### Contacting participants for research assessments and physiotherapy intervention sessions

**For Eligibility and screening**: Following receipt of a reply slip from interested participants, the EMaPP researcher will contact the potential participant via telephone or email (dependent upon their stated preference) to arrange an initial telephone screening appointment. If the individual meets the criteria to move forwards to the second phase of screening, then an appointment will be scheduled by the researcher, for a video-conference assessment at a time that is convenient for both parties.

**For the physiotherapy intervention sessions:** Following receipt of the email notifying the NHS physiotherapist of the participant’s group allocation, the physiotherapist will make contact with the participant via that standard means of contact for the practice or NHS department. This may be through letter, email or via telephone.

### WITHDRAWALS

Each participant has the right to voluntarily withdraw from the trial at any time, without repercussions. This is distinct from participants terminating their involvement in the physiotherapy interventions.

#### Discontinuation of physiotherapy intervention

Participants in the intervention group may choose not to attend the physiotherapy sessions, wear the support shorts, engage in the home exercise programme, or implement the advice that is offered to them. Or, they may wish to discontinue intervention on the recommendation of a health professional, for example following an adverse event. Withdrawal from engagement in any element of the intervention does not preclude the participant from remaining in follow-up, and all participants will be encouraged to continue with study assessments as per protocol.

##### Withdrawal from the trial

All participants will be encouraged to complete study follow-up, however, any participant may at any time decide that they no longer wish to be part of the trial. This may be through personal choice (i.e. they withdraw their consent) or in consultation with a health professional, for example where it becomes impossible to provide outcome data or comply with any other trial procedures for whatever reason.

If participants choose to withdraw from follow-up they will be asked to provide a reason for withdrawal (see section 10.1.9, informal exit interviews). Participants will be made aware that they are not obliged to give a reason and that their decision to withdraw will not affect their ongoing involvement in trials or in accessing NHS treatment. In line with CONSORT Guidelines, if reasons for withdrawal are known then these will be recorded. Participants that withdraw will not be replaced.

Withdrawal from trial follow-up and the reason, if known, will be clearly documented in an electronic withdrawal form and inputted into the trial database. Data collected prior to withdrawal from follow-up will be included in the study analysis. Participants will be provided with a contact point where he/she may obtain further information about the study.

Withdrawn participants will not be replaced with new participants.

### END OF TRIAL DEFINITION

The end of trial is the date of the last assessment/ last data item collected of the last participant (including the qualitative interviews).

There are no formal stopping criteria. The trial will be prematurely stopped if a decision is made by the TSC and TMG on the grounds of safety issues, such as an unacceptable number of adverse events.

### SAFETY and management of risk

##### Participant safety

Whilst participants are highly unlikely to experience any harm as a direct result of participating in the trial, processes will be implemented to ensure such harms are detected and monitored appropriately.

Throughout the trial, all possible precautions will be taken to ensure participant safety and wellbeing, and protocol-defined adverse events (see section 14) reported to NHS physiotherapists, PI’s or the research team will be managed according to a SOP.

NHS employed physiotherapists will use a widely accepted intervention approach: a Specialist, standardised information booklet will form the basis of advice given, and the exercise regime will be comprised of a basket of commonly used exercises to prescribe the participant’s personalised exercise prescription. The customised pelvic support shorts that participants allocated to the intervention group will be asked to wear (DM Orthotics’ Ltd, https://www.dmorthotics.com), have been evaluated by our research team in a RCT of women during pregnancy, demonstrating to be effective in reducing pain, safe and comfortable (Cameron 2018). Our team also undertook an exploratory single case study series (n=8) of women experiencing severe persistent PGP following pregnancy, identifying that the support shorts were safe and comfortable to wear and improved pain, function and quality of life (Cameron, 2017). In line with these studies, our participants will be advised to wear the support shorts daily, as tolerated, during their usual activities, but for a maximum of 12 hours per day, and not to wear them at night when they are sleeping.

##### Allergy to Lycra

The pelvic supports shorts are made of lycra material. Women who report a known allergy to lycra will not be eligible to participate in this study. However, to minimise the risk of unknown allergy, potential skin irritation is included within the participant information sheet. All support shorts come with a written guide on wearing and cleaning. All women will receive 2 pairs of shorts to enable regular washing of the shorts.

##### Possible of worsening of symptoms associated with wearing the support shorts

Whilst these support shorts have demonstrated to be effective in improving pain and function in women during pregnancy, and a small single case series of women post-partum, nevertheless it is theoretically possible that participant’s symptoms may worsen when they wear the support shorts.

All women will receive an initial appointment where the shorts will be tried on and immediate comfort assessed. They will then receive a follow up review appointment (within 10 days) to further review comfort. In addition, the NHS physiotherapist will provide their contact details to provide ongoing advice where needed. Should worsening of symptoms occur the women will be advised that, if they feel this is related to support shorts wear, they should stop wearing them. Their right to withdraw from the trial will be fully respected, however, regardless or not as to whether they wear the shorts, they will be encouraged to continue completing the self-report trial assessments, to inform the trial results.

##### Long term dependence on the support shorts

All participants will be provided with two pairs of the support shorts. They will not be asked to return the shorts at the end of the trial. There are currently no long term studies into use of the shorts, and hence evidence based advice related to this is not available. It is anticipated that the participants will wear them during the trial period but that this might not be required in the long term. The shorts used within the trial are commercially available should participants wish to purchase a pair at a later point in time.

##### Potential burden for the participants

This trial has been designed to run entirely via distance based methods. The intention of this approach is to reduce the travel burden on participants, reduce the risk of potential COVID-19 exposure from face to face appointments, as well as the uncertainty of pandemic related disruption in face to face appointments.

Screening for eligibility will be undertaken, initially by telephone and then via a video based consultation, and all of the study measures are patient-reported outcome measures which are completed via a web-based app at a time that is convenient to them. For those allocated to the intervention group, the support shorts will be posted to them prior to the first physiotherapy session. Finally the physiotherapy sessions will typically be undertaken via video consultation, although face to face appointments will be an option if the participant prefers this.

This trial is categorised as: Type A = No higher than the risk of standard medical care.

##### Researcher safety

A distance based assessment to confirm participant eligibility for entry into the trial is required. This involves the implementation of up to 5 physical tests to identify the pelvic girdle pain. Further, measurements of the thigh circumference and pelvic girdle are required to ensure the support shorts are customised to the woman’s body. Some of these measurements and tests are of a more intimate nature, since they relate to the pelvic girdle region. For this reason, it is required that the participant’s spouse/preferred other is present at this second video-based screening to ensure there is always a second person present throughout the assessment. If the EMaPP researcher undertaking the assessments is male a female chaperone will be required. However, should a woman decline a male researcher then a female therapist will undertake the assessment in line with good clinical practice.

##### Participant safety

The EPDS is a screening tool for post-natal depression and not a diagnostic tool. A score of 12 or more indicates that the respondent may be suffering from depression and therefore may require an appointment with their GP. If women score this threshold the EMaPP research team will be alerted to make contact with the participant to seek consent to make contact with their GP.

### SAFETY REPORTING

The safety of participants will be monitored throughout the trial, from the time that consent is obtained until the end of trial visit, via collection of adverse events.

#### Definitions

An **Adverse Event (AE)** is any unfavourable sign, symptom, or disease in a participant, regardless of severity and regardless of cause.

An **Adverse Reaction (AR)** is an adverse event which is considered to have been definitely, probably or possibly caused by the pelvic support shorts intervention or any other aspect of trial participation or Exercise prescribed.

**An Adverse Device Effect (ADE)** is an adverse reaction **which is related** to the use of an investigational medical device (i.e. the pelvic support shorts), including any which result from insufficiencies or inadequacies in the instructions for use, the deployment, the implantation, the installation, the operation, or any malfunction of the investigational medical device.

A **Serious** Adverse Event (SAE) or **Serious** Adverse Reaction (SAR) or **Serious** Adverse Device Effect (SADE):

* results in death
* is life-threatening\*
* requires inpatient hospitalisation or prolongation of existing hospitalisation\*\*
* results in persistent or significant disability/incapacity
* is a significant or important medical event

\*The term "life-threatening" in this context refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

\*\*Hospital admissions for elective procedures **will not be reported as SAEs.** All unplanned hospital admissions will be reported as SAEs, regardless of duration of hospital stay. This includes visits to ED departments.

A **Suspected Unexpected Serious Adverse Reaction (SUSAR)** is an event which:

* is serious, as defined above, **and**
* is considered to have been definitely, probably or possibly caused by either the Orthoses intervention or the trial procedures, **and**
* is deemed ‘unexpected’ i.e. the reaction is one which has not been foreseen by the Chief Investigator.

Guidance on assessing events against these definitions is described later in this section.

#### Adverse Event reporting in the EMaPP trial

The likelihood of participants being harmed by either the support shorts, exercise programs or any of the trial procedures is very low. As such, the collection and reporting of adverse events in the EMaPP trial is restricted to only those events which are classified as ARs (including ADEs), or which are serious, as defined above (section 14.1). In the context of clinical care and in accordance with local practice, AEs should be recorded by investigator site staff in the participants’ medical records. For the purposes of the trial, only ARs (including ADEs) and SAEs (including SARs and SADEs) will be collected and entered into the eCRF.

#### Detecting and recording serious adverse events

Detailed instructions for the recording and reporting of adverse events will be provided to Investigator Sites by the trial manager.

Adverse events will be detected via two mechanisms:

(1) through the web based app at all self-report time points (fortnightly and at 12 and 24 weeks) where a single item will ask participants to report any adverse events; and

(2) via participants reporting this to the clinician who has provided them the intervention for the trial. In line with good clinical practice all participants will be provided with their clinician’s contact details to highlight any concerns. Clinicians will report back to the EMaPP research team regarding any adverse reactions or adverse device effects.

Any events meeting the criteria for seriousness (defined in section 14.1 [above]) must be recorded by the research team member in the eCRF. SAEs are subject to expedited reporting so must be processed in a timely manner (see section 14.5).

Serious events (as defined above) are subjected to expedited reporting as described in section 14.4.Adverse device effects (as defined above) will be promptly notified to the DM Orthotics Design department. Adverse device effect are recorded for review and audit by DM Orthotics ISO13485 (2016) Medical devices class 1 regulatory body. DM orthotics are responsible for reporting how the issues raised are solved.

#### Assessing causality of serious adverse events.

No assessment of causality will be made for non-serious events unless requested by the Chief Investigator or Trial Steering Committee. For serious events, the PI (or authorised delegate) will assess the causal relationship between the event and trial participation according to the guidance given in table 3 below.

For participants in the intervention group, the PI will record their opinion on whether or not the SAE was caused by the intervention, and whether or not the SAE was caused by any trial procedures. For participants in the control group, the PI will record their opinion on whether or not the SAE was caused by any trial procedures

Table 3: Guidelines for assessing causal relationship

|  |  |
| --- | --- |
| ***Relationship***  | ***Description*** |
|  |  |
| ***Definitely related***  | *There is clear evidence to suggest the event was caused by trial procedures and/or the trial intervention, and no other contributory factors are evident.* |
| ***Probably related*** | *There is evidence to suggest the event was caused by trial procedures and/or the trial intervention, and other contributory factors such as the participant’s underlying health condition or concomitant treatments do not reasonably explain the occurrence of the event by themselves.* |
| ***Possibly related*** | *There is some evidence to suggest the event was caused by trial procedures and/or the trial intervention, and factors such as the participant’s underlying health condition or concomitant treatments are less likely to be contributory factors.* |
| ***Unlikely to be related*** | *There is little evidence to suggest the event was caused by trial procedures and/or the trial intervention, and other contributory factors such as the participant’s underlying health condition or concomitant treatments are more likely to be the cause of the event.*  |
| ***Unrelated***  | *There is no evidence of any causal relationship (e.g. because the event did not occur within a reasonable time after administration of the trial treatment/procedure).* |

Causal relationship will be recorded in the participant’s eCRF.

#### Reporting Serious Adverse Events and Serious Adverse Reactions

All SAEs and SARs must be reported to PenCTU within 24 hours of the research staff becoming aware of the event, according to instructions provided by PenCTU.

For each SAE/SAR the following information will be collected:

* full details in medical terms and case description
* event duration (start and end dates, if applicable)
* action taken
* outcome
* seriousness criteria
* causal relationship

PenCTU will immediately notify the EMaPP researcher and CI of any reported SAEs / SARs and the CI will record a second assessment of causal relationship.

The CI may upgrade the causality assessment (e.g. from not related to related) but may not downgrade the assessment (e.g. related to not related).

Where a causal relationship is suggested, the CI will record an assessment of expectedness. Expectedness will be judged on a case-by-case basis. An event deemed to be unexpected will be regarded as a SUSAR and will be subject to expedited onward reporting as described in section 14.5.

Events will be followed up until the event has resolved or a final outcome has been reached.

#### Onward reporting of SAEs / SARs / SUSARs

Table 4

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Event**  | **Reported by** | **Reported to** | **Reported when** | **Reported how** |
|  |  |  |  |  |
| SUSARs | EMaPP researcher | Sponsor | Within 24 hours\*  | Email to Mike Visick, Sponsor representative |
|  |  |  |  |  |
| SUSARs | EMaPP researcher | REC† & TSC‡ | Within 7 or 15 days\*¶ | Using non-CTIMP safety report form (available on HRA website), by email to Mike Visick, Sponsor representative |
|  |  |  |  |  |
| All SAEs/SARs | EMaPP researcher | Sponsor & TSC | Quarterly | Line listing, by email to Mike Visick, Sponsor representative |
|  |  |  |  |  |
| All ARs (inc ADEs) SAEs/SARs/SADEs | EMaPP researcher | REC | Annually  | Using annual progress report form (available on HRA website), by email to Mike Visick, Sponsor representative |
|  |  |  |  |  |
| ADEs/SADEs | EMaPP researcher | DM Orthotics | Within 7 days\* | E-mail to DM Orthotics m.matthews@dmorthotics.com or Admin@dmorthotics.com  |

*\*of the CI becoming aware of the event;* †*REC - Research Ethics Committee;* ‡*TSC - Trial Steering Committee*

¶*7days for fatal or life-threatening events. 15 days for others*

#### Unblinding for SUSAR reporting purposes

SUSARs will be unblinded before onward reporting to the REC. Unblinding will be performed by designated member(s) of PenCTU.

#### Recording of adverse events

PenCTU will maintain a register of all recorded adverse events.

##### Safety oversight

The Trial Management Group (TMG) will discuss any SUSARs and any emerging safety concerns at monthly TMG meetings. Line listings of SAEs/SARs, produced by the EMaPP research team, will be reviewed periodically by the Trial Steering Committee (TSC) in accordance with the details set out in the agreed TSC Charter.

### STATISTICS AND DATA ANALYSIS:

#### QUANTITATIVE

##### Target sample size and justification

As this proposal is for a feasibility trial, the more usual sample size calculation, based on considerations of power for detecting a between-group clinically meaningful difference in a primary clinical outcome, is not appropriate. Instead, the aim is to provide robust estimates of the likely rates of recruitment and follow-up, as well as provide estimates of the variability of the proposed primary and secondary outcomes to inform sample size calculations for the planned definitive trial.

The trial will aim to recruit 60 participants over a 7-month period. It is estimated a need to approach 265 women assuming that 70% agree to participate (n=185), of which approximately 65% (n=120) will be eligible after screening. We anticipate 50% of those eligible will consent to participate, leaving 60 participants to be randomised. The target of 60 participants has been set to enable us to determine whether it would be practicable to recruit adequate number of participants in a manner that was conducive to implementing a reasonably costed future powered trial. We expect this target to be achieved within the recruitment period. A sample size of 60 will allow overall retention rate at six month follow-up to be estimated to within a 95% confidence interval of approximately ±13% (±10% if retention rate is 80%). Assuming a non-differential retention rate of 80%, this should provide follow-up outcome data on a minimum of 24 participants per group.

##### Progression criteria

Progression criteria for a definitive trial will be confirmed with the TSC. A red, amber, green system will be used to assist in the decision making progress, with Red indicating “Stop”, Amber indicating “Discuss and Modify” and Green indicating “Go”. The progression criteria is anticipated to include:

* 60 Participants recruited within a 7-month recruitment window (Red <60%, Amber 60-80%, Green 80+%)
* Percentage of participants randomised to intervention group non-compliant in wearing the shorts secondary to an adverse device effect (e.g. skin irritation, increased discomfort) (non-compliance – not meeting minimum wear time 6 hours/day or total of 42 hours/week) (Red 70+%, Amber 50-70%, Green <50%)
* Percentage of participants completing primary outcome measure (NRPS) at 24 week follow up (Red 60%, Amber 60-80%, Green 80+%)
* Percentage of participants completing secondary outcome measures at 24 week follow-up in (Red 60%, Amber 60-80%, Green 80+%) in the following order of priority (EQ-5D-5L, SF-36, PGQ, ICIQ). This progression criteria relates to the selection of outcome measures to be used in a definitive trial. It does not influence the decision as to whether or not there should be progression to a definitive trial
* Evidence to suggest efficacy, i.e. that the support shorts hold promise as an effective intervention, demonstrated by an 80% confidence interval that indicates plausibility of the between group difference in change in pelvic girdle day time pain at 24 weeks being ≥1 point, on the numerical rating pain scale
* Total resource estimated to conduct the definitive trial within levels likely to attract funding

Progression criteria will be discussed with the Trial Steering Committee.

##### Summary of baseline data and flow of patients

The analysis and reporting of this feasibility trial will follow the CONSORT guidance for feasibility trials (Eldridge et al 2016). The flow of participants throughout the trial will be presented in a CONSORT style diagram with reasons for discontinuation or withdrawal given where available. Descriptive statistics of participants demographic and baselines characteristics will be presented by allocated groups and overall.

##### Outline of statistical analyses

A detailed statistical analysis plan will be finalised ahead of trial database locking.

A CONSORT diagram will display data from screening, recruitment and follow-up logs and be used to generate estimates of eligibility, recruitment, consent and follow-up rates. Completion rates will be estimated for outcome measures at each time-point, including the health, social and wider care resource-use data. Recruitment and retention rates will be accompanied by 95% confidence intervals, to inform assumptions for planning the definitive trial. Adherence data (wear-time) will contribute to evaluation of intervention acceptability/feasibility.

All outcomes will be summarized by allocated group at each follow-up with appropriate descriptive statistics. Between-group differences will also be reported with 80% confidence intervals, with particular focus on change in pelvic girdle day-time pain at the proposed primary end point of six-months. According to the 2008 IMMPACT consensus statement (Dworkin et al, 2008), changes of approximately 1 point represent minimally important decreases in pain using the numerical rating scale of chronic pain intensity. We will therefore inspect the confidence interval of the between group difference to see if there is evidence that the difference is above zero and that a 1 point or more between-group difference in change in favour of the intervention, is plausible. Estimates of the correlation between baseline and follow-up outcome measures to inform a future sample size calculation for a definitive RCT.

Wear-time will be evaluated as total hours and as a percentage of total possible daytime wearing time (12 hours/day).

##### Procedure(s) to account for missing or spurious data

Reasons for being unable to collect data during an assessment will be recorded on the electronic case report form (eCRF) where appropriate. Case report forms will be assessed for missing data by the CTU. No imputation of missing data will be undertaken.

#### QUALITATIVE ANALYSIS

The qualitative analysis will be undertaken collaboratively by members of the EMaPP research team, and led by Prof Jill Shawe. See section 10.1.7 for details on content for the qualitative analysis.

The qualitative data for analysis will include verbatim transcripts from the one-to-one participant telephone/virtual interviews of participants and NHS physiotherapy staff. The anonymised transcribed data will be uploaded into NVivo 12 software for organisation and analysis (QSR International, Southport, UK). Data will be analysed using thematic analysis adopting Braun and Clarke’s six-phase process of (i) data familiarisation; (ii) coding; (iii) generation of initial themes; (iv) reviewing themes; (v) defining and naming themes and (vi) writing up to identify patterns of meaning within the data sources. Initial themes will be refined by two researchers to maximise credibility and dependability.

Interviewees will be invited to review a draft of the analysis to ensure accurate representation of their views/experiences.

### Economic evaluation

The resources required to provide the intervention will be assessed and a framework will be established for a future cost-effectiveness analysis alongside a full RCT. Methods for collection of resource use and outcome data will be developed and tested. Data on intervention resources will be collected via within-trial reporting, including participant-level contact and non-contact time, and training for delivery staff. Participants will self-report health, social and wider care resource use, using the Resource Use Questionnaire from our antenatal study (Cameron et al 2018) and adapted for this trial by our PPI Group. Participants will complete the EQ-5D-5L (the anticipated primary economic outcome measure in a full trial), and QALYs will be estimated over the follow-up period. The appropriateness of using the SF-6D (based on the SF-36) for estimating QALYs will be explored with this population. The economic evaluation methods will be developed to provide a future policy-relevant cost-effectiveness analysis of the intervention in the context of the UK NHS/Personal Social Services.

### DATA MANAGEMENT

Data management activities are summarised in this section. Detailed data management activities are described in a separate Data Management Plan (DMP).

#### Data collection tools and source document identification

A web based system developed by PenCTU will be used for the recording of all trial data as recorded in table 2 and in section 2.2.2. Each participant will be allocated a unique trial number when they are registered on the data collection website by the CRN staff/ EMaPP Research team.

##### Data handling and record keeping

Electronic data captured in PenCTU’s bespoke web-based system will be stored on Microsoft Azure servers located in the North Europe data centre (located in Dublin). The servers are certified to Cyber Essentials PLUS standards. PenCTU staff develop applications in the Azure environment according to the requirements of the UK NHS Health and Social Care Cloud Security - Good Practice Guide.

The eCRF is built in REDCap Cloud. eCRF data is stored in the REDCap Cloud production infrastructure, hosted in Amazon Web Server (AWS) datacentres located in the European Union. AWS datacentres are Service Organization Control (SOC) type 1 and type 2 compliant. Data will be stored on hardware dedicated to REDCap Cloud.

In both systems, all electronic data are backed up and stored with a full audit trail.

#### Data quality and completeness

PenCTU Data Management staff will monitor completeness and quality of data recorded in eCRFs and will correspond regularly with the EMaPP research team with the aim of capturing any missing data where possible, and ensuring continuous high quality of data. Data quality and completeness checks will be defined by the Data Manager through consultation with the CI, trial statistician, EMaPP researchers and other members of the Trial Management Group as required. Checks will be described in the Data Management Plan. Throughout the trial, the Data Manager will report on the quality and completeness of accumulating data to the Trial Management Group.

#### Access to Data

Direct access to investigator site records will be granted to authorised representatives from the Sponsor (including PenCTU staff) to permit trial-related monitoring, audits and inspections in line with participant consent.

#### Archiving

Following completion of trial data analysis, the Sponsor will be responsible for archiving the study data and Trial Master File in a secure location for at least five years after the end of the trial. The EMaPP research team will prepare the Trial Master File for archiving in accordance with the requirements of the Sponsor’s SOP. PenCTU will prepare a copy of the final dataset for archiving according to the requirements of the CTU’s SOP.

Principal Investigators at sites will be responsible for archiving Investigator Site Files and trial data generated at the site according to local policy. No trial-related records should be destroyed unless or until the Sponsor gives authorisation to do so.

### MONITORING, AUDIT & INSPECTION

A trial monitoring plan will be developed and agreed by the Trial Management Group (TMG) and Trial Steering Committee (TSC). The TMG will meet monthly. The TSC will meet three times over the 24 month period of the project, with the first meeting taking place prior to the start of study recruitment. The TSC will include member’s independent from the trial and include an independent chair and statistician (see below for details)

**Trial Management Group (TMG)**

*Make up:* Most members of the TMG were involved in the development of the grant application. It includes representation from the CTU (trial management), the sponsor and a person with experience of chronic PGP.

*Frequency of meetings:* The TMG will meet approximately monthly (via face-to-face, webinar or telephone conference) over the course of the trial.

*Responsibilities:* Development of the protocol and other essential documentation, monitor progress, troubleshoot problems, report to TSC, funder, REC. The responsibility of this group is to ensure all practical details of the trial are progressing well and working well, and everyone within the trial understands them. This will include, for instance, monitoring adverse events, recruitment and attrition rates, the project timeline and finances. It will also include responsibility for the release of the trial results and publications.

*Degree of independence from Sponsor and Investigators:* the sponsor is represented on this group

Minutes of meetings will be sent to all members and the sponsor, and retained in the trial master file.

**Trial Steering Committee (TSC)**

*Make up:* the TSC comprises a group of experienced trialists and clinicians with majority independent representation: chair (independent), external statistician (independent), midwife (independent), lay member (independent), physiotherapist (independent), CI, trial statistician, representative from the CTU (for observation), representative from the sponsor, PhD student (for observation).

*Frequency of meetings:* the TSC will meet before the start of the trial and subsequently at least annually during the course of the trial. In addition, the TSC will receive a quarterly report of adverse events, and a telephone conference/additional face-to-face meeting will be instigated by the chair or the CI should any issues need to be discussed.

*Responsibilities*: The responsibility for calling and organising the TSC meetings lies with the EMaPP research team in association with the independent chair.

*Degree of independence from Sponsor and Investigators:* Confirmation that independent members of the TSC are unconnected to either the trial sponsor or investigators will be made through the completion of Conflict of Interests documents by all TSC members.

Minutes of meetings will be sent to all members, the sponsor, and the funder and be retained in the trial master file.

### ETHICAL AND REGULATORY CONSIDERATIONS

#### Research Ethics Committee (REC) review & reports

The trial will not be initiated before the protocol, informed consent forms, participant information sheets and other relevant documents (e.g. advertisements and GP information letters) have received approval from the Research Ethics Committee (REC), and the respective NHS R&D department. The Investigator will ensure that this study is conducted in full conformity with relevant regulations and with the UK Policy Framework for Health and Social Care Research (2017), which have their basis in the Declaration of Helsinki

#### Peer review

This study was funded by the NIHR RfPB (research for Patient benefit) Scheme through submission and review of the proposed study undergoing 2 rounds of review prior to awarding of funding.

#### Public and Patient Involvement

PPI input has been provided by lay members with experience of severe persistent PGP. Our PPI has provided input into key aspects of study design. Discussion with our PPI have led the trial to; implement the recording of self-report measures via a web based app to minimise burden, choose telephone interviews over face to face for the qualitative strand of this study. They will be involved with topic guide development for the qualitative component of the trial.

#### Regulatory Compliance

Thetrial will not commence until a favourable REC opinion and HRA approval has been obtained.

Before any site can enrol patients into the study, the CI/PI or designee will ensure that appropriate approvals from participating organisations are in place.

For any amendment to the study, the CI or designee, in agreement with the sponsor, will submit information to the appropriate body in order for them to issue approval for the amendment. The CI or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

#### Protocol compliance

Any deviation from or non-compliance with the study protocol or GCP will be documented on the relevant study specific form and will be reported by the EMaPP research team to the TMG and TSC. Non-compliance with outcome measures or data capture will be identified by the CTU and reported to the EMaPP research team who will report to the wider TMG (including sponsor) and TSC.

Deviations from the protocol which are found to recur frequently are not acceptable, will require immediate action and could potentially be classified as a serious breach.

The EMaPP research team will review episodes of non-compliance with the CI/TMG (and Sponsor if appropriate) and every effort will be made to address any recurrent problems, including amendment of the study protocol if appropriate.

#### Notification of Serious Breaches to GCP and/or the protocol

A “serious breach” is a breach which is likely to effect to a significant degree –

* 1. the safety or physical or mental integrity of the participants of the trial; or
	2. the scientific value of the trial

The sponsor will be notified immediately of any case where the above definition applies during the trial conduct phase. The sponsor of a clinical trial will notify the ethics committee in writing of any serious breach of

* 1. the conditions and principles of GCP in connection with that trial; or
	2. the protocol relating to that trial, as amended from time to time, within 7 days of becoming aware of that breach

#### Data protection and patient confidentiality

All investigators and trial site staff will comply with the requirements of the Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act’s core principles.

Personal information will be collected, kept secure, and maintained so that:

* all CRF’s (source data) will be pseudo-anonymised by the use of unique participant identifying numbers
* the ID coded data and the linking code will be securely stored in separate locations using encrypted digital files within password protected folders and storage media
* only the research team will have access to the data

#### Financial and other competing interests for the chief investigator, PIs at each site and committee members for the overall trial management

No members of the research team or the PI’s or trial management committee members have any financial or other competing interests.

#### Indemnity

This is an NHS-sponsored research study. If an individual suffers negligent harm as a result of participating in the study, NHS indemnity covers NHS staff and those people responsible for conducting the trial who have honorary contracts with the relevant NHS Trust. In the case of non-negligent harm, the NHS is unable to agree in advance to pay compensation, but an *ex-gratia* payment may be considered in the event of a claim.

#### Amendments

The sponsor may make a non-substantial amendment at any time during a trial. If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor must submit a valid notice of amendment to the REC for consideration. It is the sponsor’s responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

Amended documents will be allocated a new sequential version number. Once approved by REC, this version will supersede any previous versions.

#### Post-trial care

The Declaration of Helsinki 2013 states that “In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial”. This information will be disclosed to participants during the trial. Participants in the intervention arm of the trial will have continued use of the shorts as they are not required to be returned. Inclusion within the trial will not affect the ability for participants to seek further care after the trial has concluded.

#### Access to the final trial dataset

Data generated as a result of this trial will be available for inspection on request by the EMaPP research team, University of Plymouth representatives, the REC, local R&D Departments and regulatory authorities.

### DISSEMINATION POLICY

#### Dissemination policy

Results of this feasibility trial will inform the design of the anticipated definitive trial, rather than directly inform clinical decision making since clinical and cost effectiveness cannot be determined at this level. Hence dissemination, regardless of outcome, will focus on publication of the trial protocol, and related methodological issues in a peer reviewed journal.

Other means of dissemination will include:

* Funding proposal for a full-scale effectiveness trial to be submitted to the NIHR ‘Health Technology Assessment’ programme or ‘Wellbeing of Women’ funding scheme if the trial meets our criteria for progression to a definitive trial.
* Two lay oriented research feedback events (Devon/Cornwall) at the end of the trial for participants, staff and the general public
* All participants who wish will receive a lay summary of the results. A clinically oriented trial summary will be posted on websites/newsletters of organisations involved in recruitment.
* Regular updates via our study web-site and social forums (e.g. twitter) regarding progress of the study (note - results will not be shared until study completion), and newsletters will be emailed to participating services to provide transparency, and raise study awareness.
* Conference presentations of results in grass root level physiotherapy meetings (eg Womens Health Special Interest Groups), and research conferences and to engender enthusiasm for the potential definitive trial.

#### Authorship eligibility guidelines and any intended use of professional writers

Professional writers will not be used in the preparation of any material for publication at the end of the trial.

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### APPENDICES

**Appendix 1 Standardised Exercise Regime**

Reference: Exercises adapted from “Exercise and Advice after pregnancy” PGOP booklet. https://pogp.csp.org.uk/system/files/publication\_files/POGP-E%26AA5%28UL%29.pdf

**Location**: completed at home independently.

**Frequency**: Aim x 3 per week

**Dosage**: Aim for up 20 - 30 min’s per session. Participants may need to break this into 2 parts.

**Repetitions**: Exercises described have suggested sets and repetitions. However, this should be guided by treating clinician and the women’s capacity to exercise.

**Quantity**: Choose a maximum of 4 exercises

**Advice to be provided to all women:** If any of the exercises cause pain then reduce the amount of repetitions that you are performing. If this continues on more than two occasions then cease the exercise and discuss with your clinician at your follow up appointment.

Permitted exercises are described below:

1. Pelvic floor exercises
* *Exercise description*: Imagine that you are trying to stop yourself passing urine or wind: ‘squeeze and lift’ your pelvic floor muscles, closing and drawing up the 3 passages. You may not feel that much is happening at first, but keep trying. Hold the squeeze for a few seconds, and then relax for a few seconds. Do not hold your breath. You may find that abdominal hollowing takes place at the same time.
* *Positions* – consider the use of different position to exercise in (e.g. standing, sitting and lying),
* *Speed of contraction/Dosage*:
	+ *For endurance:* Start gently and rhythmically. Gradually increase the hold time and the number that you do until you can hold the squeeze for up to 10 seconds and repeat up to 15 times in a set (up to 3 sets)
	+ *For speed*: It is also important that the pelvic floor muscles are able to react quickly to stop you leaking when you cough, sneeze, laugh or shout. Tighten them as quickly and strongly as you can, and then relax. Do this between 8-15 times a set with up to 3 sets.
* *Advice*: Always tighten your pelvic floor muscles before and during any activity requiring physical effort; for example, when lifting, coughing or sneezing
1. Abdominal hollowing exercise:
* *Exercise description*: Place one or both hands on your abdomen, below the level of your umbilicus (‘tummy button’). Breathe in through your nose, and as you breathe out, draw in your lower abdomen, pulling it gently away from your hands towards your back and then relax. You should be able to breathe and talk while you are doing this exercise and your lower back should stay still. You may feel the muscles working under your hand.
* *Positions*: Start doing this exercise in the most comfortable position for you; for example, lying on your back or side with your knees bent, or sitting with your back well supported. Once you have learnt this exercise, you should be able to practise it in standing.
* Suggested Dosage: Start at a level that your patient can tolerate. Aiming to reach a hold 10 seconds and can repeat for a maximum of 10 times up to 3 sets.
* *Advice*: You may also feel these muscles working as you do the pelvic floor muscle exercises. Use these deep muscles by doing the hollowing throughout the day - before and during any physical activity requiring effort; for example, when lifting. If you notice any bulging of your abdominal muscles while doing any of the following 4 exercises, stop the exercise, return to abdominal hollowing and seek advice from your physiotherapist.
1. Pelvic tilt**:**
* *Exercise description*: Hollow your abdomen as described above, tighten your pelvic floor muscles, and flatten your lower back into the bed as your pelvis tilts. Breathe normally. Hold the position for 3 seconds and release gently. Repeat this up to 8-12 reps for 3 sets.
* *Position*: Progress by doing this exercise when in sitting, standing, crook lying, kneeling or lying on your side.
* Suggested Dosage: Aim for between 8-15 reps for up to 3 sets.
1. Bridge:
* *Exercise description*: Place both feet flat on the bed/floor. Hollow your abdomen as described above, tighten your pelvic floor muscles. Slowly lift your bottom off the bed to a height you are comfortable with.
* *Position*: Crook lying
* Suggested Dosage: Hold for up to 3 seconds before slowly lowering. Aim to complete 8-15 for up to 3 sets.
1. Knee bends:
* *Exercise description*: Hollow your abdomen, keep you’re back flat on the bed, and bend one hip and knee up as far as is comfortable. Hold up to the count of 10, and then bring the leg down so that the foot is back on the bed. Repeat with the other side.
* *Position*: crook lying
* Suggested Dosage: Hold for 10 seconds. Aim for 8-15 reps for up to 3 sets.
1. Knee rolls:
* *Exercise description*: Hollow your abdomen, and gently lower both knees to the right as far as is comfortable. Bring them back to the middle and rest for a few seconds. Hollow your abdomen again and repeat to the left.
* *Position*: crook lying
* Suggested Dosage: Aim for between 8-15 reps for up to 3 sets.
1. Head lift:
* *Exercise description*: Lie on your back with your head resting on two pillows. Hollow your abdomen, and tighten the pelvic floor muscles as you gently lift your head and shoulders a little way off the pillows.
* Position : crook lying
* Advice: If you have neck pain, DO NOT do this exercise.
* Suggested Dosage: Hold for 3 seconds, lower and relax. Repeat between 8-15 reps for up to 3 sets.
* Progression advice: Progress by removing one pillow, and ensure that you do not strain your neck muscles as you do this exercise.
1. Hip extension:
* *Exercise description*: Participant lies prone on a flat surface with both hips in neutral and knees in full extension. Action: Hip extension against gravity
* *Positions*: in standing with a flexed knee or in prone lying
* *Suggested Dosage*: Aim for between 8-15 reps for a maximum of 3 sets with guidance on adding a weight or theraband as able.
1. Hip Abduction:
* *Exercise description*: Side lying hip abduction: In a side lying position the participant abducts superficial limb to their maximum height, slowly lowers the limb back to its resting position.
* Positions: Side lying
* *Suggested Dosage*: Aim up to 3 sets of 8-15 reps. Position of knee bend is at therapist discretion. Perform either at 900 knee flexion or 00 extension
1. Knee Drop outs:
* Exercise description: Hollow your abdomen, keep you’re back flat on the bed and feet in contact with the bed. Allow one leg at a time to drop away from your midline down towards the surface you are lying on as far as you feel able before returning back to the starting position
* Positions: Crook lying
* Suggested Dosage: Aim for between 8-15 reps over 3 sets.

**Appendix 2 – Assessment of capacity to provide informed consent**

For consent to be ethical and valid in law, participants must be capable of giving consent for themselves. A capable person will:

* understand the purpose and nature of the research
* understand what the research involves, its benefits (or lack of benefits), risks and burdens
* understand the alternatives to taking part
* be able to retain the information long enough to make an effective decision
* be able to make a free choice
* be capable of making this particular decision at the time it needs to be made (though their capacity may fluctuate, and they may be capable of making some decisions but not others depending on their complexity)

Where participants are capable of consenting for themselves but are particularly susceptible to coercion, it is important to explain how their interests will be protected.

**Appendix 3 Gantt chart**



**Appendix 4: Qualitative interview topic guide**

Introduction

* Thank you for taking part in this interview (Post EMaPP trial Qualitative interview or exit interview)–
* We would like to check that you have had the opportunity to read the participant information sheet provided for this part of the study
* Check that consent form is signed
* I have some questions that we would like to ask you but feel free to ask any questions at any stage.
* Recording – This meeting will be recorded if you have consented and agreement to making notes (for informal exit interview)

**Women (intervention arm)**:

* Please can you tell me about your experience of being involved in the trial?
* How was your experience of wearing the shorts and advice/exercise?

**Women (Control arm):**

* Did the treatments meet your expectations?
* How was the experience of being randomised to the control arm?

**Women both arms**

* How did you find the data collection methods of the trial?

Self-report measures,

Twice weekly pain report measures,

Text reminders,

Virtual nature of the trial

* Did you feel able to adhere to the exercise prescription from the physiotherapist?

Would there be anything that would facilitate you adherence?

Were there any barriers to exercise adherence?

If so what were these?

* Did the treatments have any impact on you?

Behaviour: activity level, function, posture, sleep

Health: pain levels

Psychological: mood, energy

* Final thoughts: Do you have any final points that you would like to discuss or that you feel you didn’t have the opportunity to say?

**Clinicians**

* How did you find the process of being involved in the trial?
* How did you find process of delivering the intervention (both pelvic support shorts & exercise/advice)?
* Did the trial interventions (advice/exercise) resemble usual clinical practice?
* Is there anything else that you feel would have improved the trial?
* Final thoughts: Do you have any final points that you would like to discuss or that you feel you didn’t have the opportunity to say?

**Exit interviews:**

What were the reason/s why you could not continue to participate with the trial?

How did you find participating in the trial?

Was there any part of the trial that if altered or improved would have led you to remain in the trial?

**Appendix 5: Amendment History**

Amendments to be made using the IRAS template:

[IRAS Help - Maintaining your approvals - Amendments (myresearchproject.org.uk)](https://www.myresearchproject.org.uk/help/hlpamendments.aspx#Amendment-Tool)