ISRCTN67232113 https://doi.org/10.1186/ISRCTN67232113

Evaluating the use of support shorts to manage chronic pelvic girdle pain in women following pregnancy

Submission date
02/08/2021

Recruitment status
No longer recruiting

Registration date
05/08/2021

Overall study status
Completed

Last Edited
28/04/2025

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Pelvic girdle pain is common during pregnancy. This pain will often reduce following childbirth, but almost 20% of women continue to suffer significant pain for at least 3 months afterwards. When pain is severe it will affect everyday activities and quality of life. The usual treatment typically involves physiotherapy (advice and exercise) and the provision of an “off the shelf” rigid pelvic support belt. Women often find these uncomfortable and difficult to use. A customised pelvic orthotic (referred to as pelvic support shorts) is an alternative that on initial testing has shown promising results in women with chronic pelvic girdle pain. This study aims to obtain the data and experience necessary to inform a future larger trial. The researchers will also gather women's views about the support shorts and the trial. It is vital to understand what treatments are beneficial to this group of women and this is the main driver for this trial.

Who can participate?
Women aged 18 years and over experiencing pelvic girdle pain that has been present for longer than 3 months but less than 2 years causing walking or stair climbing to be bothersome

What does the study involve?
Participants are randomly allocated to receive either usual care (advice and exercise) or usual care and customised pelvic support shorts. All participants will receive two web-based sessions with a physiotherapist who will provide this intervention. All will complete web-based questionnaires (pain, function, quality of life, continence, depression) at the start of the study and after 3 and 6 months. Pain and medication usage are recorded fortnightly. Fifteen women and five clinicians will be interviewed at the end of the trial to explore their experiences of wearing/providing the support shorts and participating in the trial.

What are the possible benefits and risks of participating?
Participants will receive evidence-based advice from a chartered physiotherapist along with an exercise programme with or without the pelvic support shorts. It is not yet known if the support shorts are beneficial in managing persistent pelvic girdle pain. It is possible that involvement in the study will not lead to any improvement in pelvic girdle pain. Participants will need to

undertake some physical tests to ensure their pain is caused by the structures around the pelvic girdle. These tests, which are undertaken routinely within NHS practice, may temporarily worsen pelvic pain (for up to 24 hours). The researchers will undertake the tests in an order designed to progressively test the pelvic girdle. This means that they will stop testing as soon as they reach the set level for entry into the study. The physiotherapy advice and exercise reflects standard NHS care for women experiencing pelvic girdle pain. Therefore this part of the study does not pose any greater risk. The support shorts contain Lycra so women with a known allergy to Lycra will not be eligible to participate in the study. There is a possibility that the shorts will worsen their pain. Previous studies have shown that this is not expected. Participants' comfort will be carefully assessed by a physiotherapist at the two intervention appointments. If they feel that the support shorts are worsening their symptoms they will be advised to stop wearing them. Participants will also be provided with the contact name and telephone number of the NHS physiotherapist so that they can report any issues that may arise, and so that they are supported with regard to the shorts wear.

Where is the study run from?
University of Plymouth (UK)

When is the study starting and how long is it expected to run for?
March 2020 to February 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
emapp@plymouth.ac.uk
Nishita Nair, nishita.nair@nihr.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mr Bradley Halliday

ORCID ID
https://orcid.org/0000-0003-1296-108X

Contact details
University of Plymouth
Intercity Place
Plymouth Railway Station
North Road East
Plymouth
United Kingdom
PL4 6AB
+44 (0)1752 588873
emapp@plymouth.ac.uk

Type(s)

Scientific

Contact name
Prof Jenny Freeman

Contact details
University of Plymouth
Faculty of Health
Peninsula Allied Health Centre
Derriford Road
Plymouth
United Kingdom
PL6 8BH
+44 (0)1752 588835
jenny.freeman@plymouth.ac.uk

Additional identifiers

ClinicalTrials.gov (NCT)
NCT04981418

Integrated Research Application System (IRAS)
297938

Central Portfolio Management System (CPMS)
49691

Study information

Scientific Title
Evaluating the Management of chronic Pelvic girdle Pain following pregnancy (EMaPP): a randomised controlled feasibility trial

Acronym
EMaPP

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/07/2021, West Midlands - Edgbaston Research Ethics Committee (3rd Floor, Barlow House, Minshull Street, Manchester, M1 3DZ, UK; +44 (0)20 7104 8112, +44 (0)207 104 8019, +44 (0)2071048089; edgbaston.rec@hra.nhs.uk), REC ref: 21/WM/0155

Study design
Randomized; Interventional; Design type: Treatment, Education or Self-Management, Device, Rehabilitation

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic pelvic girdle pain following pregnancy

Interventions
The eventual aim is to undertake a large, multi-centre, assessor-blinded randomised controlled trial (RCT) asking the research question “What is the clinical and cost-effectiveness of pelvic support shorts plus standardised information and exercises versus standardised information and exercises alone in women with chronic, severe pregnancy-related pelvic girdle pain?” Before moving to a definitive trial there are a number of uncertainties that need addressing.

This randomised controlled feasibility trial aims to clarify these uncertainties by obtaining the data and operational experience necessary to inform the conduct and finalise the design of the definitive trial. Its design and methodology therefore purposefully reflects that which we anticipate would be the future definitive trial. This is summarised in detail below.

OVERVIEW
The researchers will undertake a multi-centre feasibility RCT, randomising participants to receive either the “pelvic support shorts” plus standardised information and exercises (intervention) or standardised information and exercises alone (control). They will recruit 60 women from the South West of England who are experiencing chronic (≥3 months) and severe pelvic girdle pain following pregnancy.

Following screening and consent, baseline assessment will be undertaken using a range of patient-reported measures: pain, depression, continence, function, quality of life, health/social care and patient resource use. Women will be randomly allocated to intervention or control. Two weeks following randomisation, all participants will attend a physiotherapy session via web conference to receive standardised information and suggested exercises. In addition, intervention group participants will receive two pairs of pelvic support shorts. In line with usual physiotherapy practice, all participants will receive a follow-up review session via web conference, approximately 10 days later. Throughout the study timeframe, medication usage and pain rating scale scores will be completed by the women, on a fortnightly basis, via web-based self-report questionnaires. Additionally, at 12 and 24 weeks all baseline patient-reported measures will again be collected. A qualitative sub-study, involving interviews (telephone or web-based) will explore participant experiences of wearing (patient) and providing (physiotherapists) the support shorts, and of the study itself.

The Population
The researchers shall recruit women, 18 and over, experiencing chronic and severe pelvic girdle pain. This pain must have started or been aggravated during pregnancy and have continued for at least 3 months following childbirth. The pain is ‘severe’ if it causes walking or stairclimbing to be bothersome and scores positively on a range of pain provocation tests. Potential participants

will be excluded if they have pathologies that cause pelvic girdle pain (e.g. infection, trauma), are currently pregnant, report an allergy to Lycra, or where pain has persisted for >2 years following pregnancy to limit the risk of other pathologies being the origin of pain.

Intervention and Control
All treatment will be provided by NHS physiotherapists at two web-based sessions.

Control Group
Both groups will receive standardised advice on the management of pelvic girdle pain, through a discussion centred around '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 leaflet, provides information reflective of current best practice. The participant can use this as an ongoing resource. The physiotherapist will teach participants a standardised programme of exercises, typical of those provided within usual physiotherapy practice. Written explanation/illustrations of these exercises will be provided and the women asked to undertake these at home, three times/week. Intervention Group.

In addition to the above, women in the intervention group will be fitted with customised pelvic support shorts (DM Orthotics Ltd, https://www.dmorthotics.com). These apply targeted compressive forces to the pelvic girdle through selective precisely positioned reinforced 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. This aims to optimise comfort and movement to increase wear compliance, which is crucial as any benefits gained rely upon this.

Prior to the first physiotherapy session, those women allocated to the intervention group will have received the support shorts in the post together with standardised written information on wear time/washing. At the first physiotherapy session (one hour), the woman will be asked to try them on so that the physiotherapist can review the fit and comfort of the shorts. The physiotherapist will reinforce the written advice about wear time and care of the shorts, and answer any queries/brainstorm any issues. At session two (30 minutes), ~10 days later, the physiotherapist will review the fit and wearing of the shorts, problem solve any issues that have arisen, and review exercises to ensure they are being performed correctly.

After these two appointments all participants will continue to self-manage the condition for the remainder of the trial. Participants are not prevented from accessing further healthcare. The trial is capturing this information through a resource use questionnaire which is collected at baseline, 12 and 24 weeks.

Outcomes and their measurement
In our feasibility trial, participants will be requested to complete a range of self-report outcome measures via a mobile/web app. Our PPI discussions led us to choose self-report questionnaires, completed via a web-based application, to minimise burden (time and travel) on our participants who are experiencing significant pain. This is particularly important since driving and travelling frequently exacerbated this pain. Some women may prefer paper versions, returned by post.

In line with the remit of a feasibility trial, the researchers include a variety of measures to determine their performance in the context of this trial and, along with trial participants and our PPI group, to identify those that may be most appropriate for the definitive trial. All are

standardised patient-report measures that have been previously used in studies investigating pelvic girdle pain.

Demographic data will be collected at screening (age, weight, number of pregnancies, severity /duration/site of pain). Additional clinical data will be collected at baseline: medication, week of delivery, length of labour, induction required, mode of delivery, episiotomy/perineal tear, baby's gender and weight, presence/absence of back pain prior to pregnancy.

All outcome measures will be completed at baseline and 12 and 24 weeks following the first intervention session, apart from the Pain Rating Scale and medication usage which will be completed fortnightly.

Self-report measures:
1. Numerical Pain Rating Scale, evaluating pelvic girdle pain intensity.
This 0-10 point scale is widely used and quick to complete. There is evidence in chronic pain patients to suggest a 1-point change is clinically significant.

2. Pelvic Girdle Questionnaire, evaluating function.
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. This 25-item questionnaire has been evaluated in this population. It takes about three minutes to complete.

3. European Quality of Life-5 Dimensions [EQ-5D–5L] and Short-Form 36 Item Health Survey version 2 [SF-36- V2], evaluating health-related quality of life.
These two measures are quick and straightforward to complete. Both have been widely used within clinical trials and evaluated for use with pregnant women.

4. Edinburgh Postnatal Depression Scale, evaluating depression.
This is the most commonly used, self-report screening tool for postnatal depression. It comprises 10 questions rating feelings over the past 7-days, it is easy to complete, with a score of > 12 points indicating depression.

5. International Consultation on Incontinence Questionnaire Short Form, evaluating continence
This self-report questionnaire has been used in pregnancy-related pelvic girdle pain studies, demonstrating measurement qualities. It comprises questions regarding frequency/amount of urine leakage, and interference with everyday life.

6. Wear-time of the support shorts.
For the intervention group wear-time will be determined by a sensor sewn into the seam of the support shorts (able to distinguish wear-time from washing/drying cycles, Orthotimer Ltd, www. orthotimer.com). After the 6-month trial, women will be asked to remove the sensor and post it back to the research team (FREEPOST envelope) for them to download the data and analyse it.

Recruitment Procedure
Women will be recruited from three NHS Trusts across the Southwest of England:

1. Royal Cornwall NHS Foundation Trust, Cornwall Partnership NHS Foundation Trust, and University Hospitals Plymouth NHS Trust. Physiotherapists in musculoskeletal outpatient and women's health services will be key recruiters due to their contact with women experiencing chronic pain following pregnancy. They will raise study awareness and provide patients with study information leaflets. The Clinical Research Network (CRN) staff will undertake a database search, eligibility check, and mail-out to potential participants. With the clients' consent, the CRN

nurse will inform the research team of potential participants via a study-specific email account. The research team will telephone/email the potential participant to undertake initial screening and, if still apparently eligible, book a web-based screening appointment.

2. Research active general practices with an on-site First Contact Physiotherapy Practitioner. CRN staff will undertake a database search and mail-out to potentially eligible patients, inviting them to express an interest in the trial. With the consent of those interested, names will be forwarded to the research team.

The study will be advertised in local children's centres and on social media [Mumsnet; Facebook pages of the Pelvic Partnership Pelvic Girdle Pain Support Group, National Maternity Voices, National Childbirth Trusts], and via relevant hospital website and Twitter accounts that advertise research trials.

A research physiotherapist will undertake the web-based screening/measurement for shorts and baseline assessments, in separate sessions independent of treatment. The nature of the self-report measures ensures the assessor will not influence participant responses. Participants will be asked not to discuss their treatment with the researcher.

Randomisation and blinding.
Following baseline assessment, the research physiotherapist will enter key participant details (number of pregnancies, pain onset/duration) into the Clinical Trial Unit's (CTU) web-based randomisation system and immediately receive that participant's group allocation.
Randomisation will be stratified by centre and presence/absence of back pain pre- pregnancy.

An automatic email will be sent by the CTU to the NHS-treating physiotherapist to inform them of the woman's group allocation and enable them to schedule an outpatient appointment approximately two weeks (+/-1 week) later. A second email with the patient's measurements will be sent to DM Orthotics Ltd to allow the manufacture of the customised shorts.

Sample size
The researchers aim to recruit 60 participants over 7 months. As this proposal is for a feasibility trial, a sample size calculation is not appropriate. Instead, the researchers aim to sample sufficient participants to provide the operational experience to conduct a larger trial and to provide data to inform future sample size calculation.

EMBEDDED QUALITATIVE COMPONENT.
Qualitative research to explore "real-life" experience is important in order to understand and learn from participants about whether trial processes, the intervention and outcome measures are acceptable. The researchers will therefore undertake interviews with a sub-sample of women to explore the:
1. Acceptability of trial methods across both trial arms
2. Acceptability (comfort, wear-time) of the support shorts
3. Impact the intervention may/may not have on women's lives.

Women consenting to participate in an interview will be purposely selected to ensure a range of diversity such as age, number of pregnancies, type of delivery and severity of pelvic pain. Ten women who were randomised to wear the support shorts and five from the control group will be invited to a telephone or web-based interview lasting approximately 45 minutes. Our PPI discussions confirmed that telephone interviews were acceptable and preferable because of convenience when having a young baby. Five health professionals connected with the study [two women's health physiotherapists, a consultant obstetrician, midwife, and GP], will also be invited

for interview in order to understand the impact of the research and the intervention from their perspective.

The interviews will be semi-structured using topic guides in order to provide a basic structure and sequence for the interview and to ensure all intended topics are covered. The topic guides have been developed by the research team in collaboration with PPI input and include the experience of being in the trial; acceptability of the support shorts intervention; interactions with health professionals; impact on daily life. Interviews for health professionals focus on the acceptability of study procedures and the provision/fitting of the orthosis.

ECONOMIC EVALUATION.
The researchers will estimate the resource requirements of the intervention, and establish the framework for a future cost-effectiveness analysis alongside a full RCT. Data on intervention resources will be collected about 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 and adapted for this trial by the PPI Group.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Customised pelvic support shorts, physiotherapy

Primary outcome(s)
Pain intensity 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) measured using the Numerical Rating of Pain Scale (NRPS) questionnaire at baseline then fortnightly for 24 weeks

Key secondary outcome(s))
1. Symptoms and function assessed using the pelvic girdle questionnaire (PGQ) at baseline, 12 and 24 weeks
2. Quality of life assessed using EQ5D5L at baseline, 12 and 24 weeks
3. Quality of life assessed using SF36v2 at baseline, 12 and 24 weeks
4. Incontinence assessed using the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) at baseline, 12 and 24 weeks
5. Depression assessed using the Edinburgh Postnatal Depression Scale (EPDS) at baseline, 12 and 24 weeks
6. Kinesiophobia/fear of movement assessed using Tamp Scale Kinesiophobia (TSK) at baseline, 12 and 24 weeks
7. Body perception assessed using Freemantle Back Awareness Questionnaire (FreBAQ) at baseline, 12 and 24 weeks
8. Resource use assessed using health resource use questionnaire at baseline, 12 and 24 weeks

Completion date
04/02/2023

Eligibility

Key inclusion criteria
1. Women aged greater than or equal to 18 years
2. Able and willing to provide informed consent
3. Self-reported persistent pelvic girdle pain (PGP) (≥3 months postpartum)
4. Self-reported severe PGP (causing walking or stair climbing to be bothersome)
5. Diagnosed with PGP in line with European guidelines
6. PGP must have started or been aggravated during pregnancy, as determined by self report

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
24

Key exclusion criteria
1. Known allergy to lycra
2. Age <18 years
3. Currently pregnant
4. PGP for >2 years post partum
5. Self reported history of pathologies causative of lumbopelvic pain (e.g. Infection, trauma, cancer)
6. Participating in concurrent interventional research which may over-burden the patient or confound data collection
7. 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
8. Participants who lack capacity to provide informed consent

Date of first enrolment
04/10/2021

Date of final enrolment
04/08/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Derriford Hospital
Derriford Rd
Plymouth
United Kingdom
PL6 8DH

Sponsor information

Organisation
Royal Cornwall Hospital Trust

ROR
https://ror.org/026xdcm93

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR201930

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository at https://pearl.plymouth.ac.uk/. Data are expected to be available 1 year after the trial end date and stored for 10 years. Participants were made aware of this in the participant information sheet.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/04/2025	28/04/2025	Yes	No
Basic results		14/05/2024	14/05/2024	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version 1.0		05/08/2021	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes