Pilot and Feasibility Studies

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

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Abstract

Background Postpartum pelvic girdle pain (PGP), experienced by approximately 10% of women, is typically refractory to conservative management. Customised dynamic elastomeric fabric orthoses (DEFOs) are one novel option to address this. We assessed the feasibility and acceptability of a randomised controlled trial comparing a DEFO plus standardised advice/exercises (intervention) versus standardised advice/exercise alone (control).

Methods A multicentre randomised controlled feasibility trial with embedded qualitative study and economic evaluation. Participants were randomised to either intervention or control group. All received two remote physiotherapy sessions via videoconferencing separated by 14 days. Primary feasibility outcomes were related to the feasibility and acceptability of methods and interventions, recruitment, intervention fidelity, outcome measure performance and completion. The proposed primary outcome measure for the definitive trial was the Numerical Pain Rating Scale (NPRS) which assessed pain intensity fortnightly over 24 weeks. Secondary outcome measures assessed kinesiophobia, continence, function, health-related quality of life, depression and health/care resource use at baseline, 12 and 24 weeks. Adverse events were recorded. Pre-defined progression criteria were set to decide whether, and how, to proceed with a future definitive trial: (1) Target sample size (60 from 3 centres over a 7-month recruitment period), (2) outcome measure completion (> 60% at 24 weeks), (3) orthosis wear-time compliance (> 70% for 6 h/day) as measured by the Orthotimer, and (4) evidence suggesting efficacy.

Results Of 180 participants sent information sheets, 40 were screened and 24 randomised. At 24 weeks, 95% completed NPRS and 89–95% the secondary outcome measures. Wear-time adherence appeared below the set target of 42 h per week. Outcomes were broadly comparable between groups. Recruitment was insufficient to estimate a signal of efficacy with confidence. Two intervention participants experienced Candida infections, considered possibly due to the DEFO.

Conclusions Trial procedures and interventions were acceptable to participants. Technical Orthotimer issues are resolvable through modification of recording parameters. Recruitment of participants was a major challenge. Work to understand how best to engage women in this research is needed before moving to a definitive trial.

Trial registration ISCRTN, ISRCTN67232113. Registered 08/05/2021, https://www.isrctn.com/ISRCTN67232113.

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Key messages

• What uncertainties existed regarding the feasibility?

➢ There is uncertainty regarding the feasibility of recruiting participants at a rate conducive to a definitive trial.

• What are the key feasibility findings?

➢ Twenty-four participants were recruited over 7 months. Retention and complete NPRS data were available for analysis at final follow-up for 18 participants (75%).

➢ Overall, the trial procedures and interventions were perceived as acceptable by participants and clinicians.

➢ Overall recruitment was insufficient to estimate a signal of efficacy with confidence.

➢ Technical issues with the Orthotimer significantly impacted on adherence data collection.

➢ Progression criteria indicate that progression to a definitive trial in its current format is not recommended.

• What are the implications of the feasibility findings for the design of the main study?

➢ Further research is required to best understand how to recruit women to a future study.

➢ A hybrid approach to intervention delivery may be preferable.

➢ Orthotimer reading intervals for capturing orthosis wear-time adherence require careful consideration.

➢ An internal pilot within a future definitive multicentre randomised controlled trial would add value.

Keywords Pelvic girdle pain, Rehabilitation, Feasibility trial, Orthosis, DEFO

Background

Pelvic girdle pain (PGP) is experienced by an estimated 70% of women during pregnancy [1] with 10% continuing to experience it for more than 3 months after birth [2–4]. PGP can have significant psychological (through the co-occurrence of depression [5], lack of sleep [2, 6, 7] and subsequent challenges with coping with a newborn [2]), socioeconomic (increased rates of sick leave and delayed return to work [8]) and physical consequences, impacting on everyday functional tasks, mobility and activity levels [9].

Despite the high prevalence, women with PGP are commonly dismissed by clinicians, in the belief the condition will spontaneously resolve [2, 10], despite evidence of its presence more than a decade postpartum [2, 3, 11]. Chronic PGP is often refractory to conservative management [12, 13], potentially requiring costly fluoroscopically guided injection and surgery involving ablation or fusion [14]. There is currently a lack of evidence to support the management of pain beyond 8 weeks postpartum [15], highlighting the need for efficacious interventions to address this condition.

Pelvic orthoses, supported by the Royal College of Obstetricians and Gynaecologists (RCOG) and European guidelines [16, 17], are one management option. These are hypothesised to improve joint stability and alignment and provide sensory input to optimise muscle control and function, reduce pain and improve function with daily tasks [18]. Orthoses may provide external support to weaker structures, may exert their effect by improving proprioception [19], and may impact on perception of the painful area. A range of "off-the-shelf" pelvic orthoses demonstrate equivocal outcomes and have several issues such as being uncomfortable [20], poor aesthetics and inhibiting movement [21]. This presents a challenge as the effect of orthoses is likely to be related to wear-time.

To address these issues, a customised pelvic dynamic elastomeric fabric orthosis (DEFO) has been designed (DM Orthotics Ltd [22]), different in material and design to "off-the-shelf" orthoses. Pelvic DEFOs have been shown to be acceptable to wear in postpartum women and improve pain and quality of life during pregnancy [23, 24]. These data combined suggest potential for this intervention in the postpartum period. However, there is a need to establish the clinical and cost-effectiveness in women with chronic postpartum PGP. Prior to addressing this in a definitive trial, the feasibility of undertaking such a trial needs to be tested.

Aims

To assess the feasibility and acceptability of trial procedures via a feasibility randomised controlled trial (RCT) comparing a DEFO with standardised advice and exercises versus standardised advice and exercises alone in postpartum women with chronic and severe PGP. The aim of the economic evaluation was to test the feasibility of methods and data collection for a subsequent, policy-relevant, cost-effectiveness analysis within a full-scale trial.

Primary study objectives

To assess the following:

- Feasibility and acceptability of trial procedures
- Suitability of eligibility criteria
- Most effective recruitment methods
- Numbers of eligible and interested participants from the target population: Specifically, conversion rates by recruitment method.
- Recruitment and retention rates as participants move through the trial
- Intervention fidelity between sites (including timely delivery of the DEFO)
- Most appropriate primary and secondary outcome measures
- Feasibility of collecting data to estimate intervention resource requirements and costs and health, social care and broader societal resource use and costs.
- Feasibility and acceptability of the interventions (exercise, DEFO)

The objectives of the qualitative sub-study were to assess the following:

- Participant experiences of wearing the DEFO (comfort and wear-time)
- Adherence to the exercise regime
- Impact of the intervention
- Clinicians' experiences of providing the interventions and trial procedures

Methods

Trial design

A multicentre randomised controlled, assessor blinded, feasibility trial comparing standardised advice and exercises (control) to a DEFO with standardised advice and exercises (intervention). The design incorporated an embedded economic analysis and qualitative sub-study to further examine the acceptability of the intervention and study processes. Study methods are detailed in the published protocol [25] and are summarised below. During the trial, ethical approval was sought and approved to include a telephone call follow-up to women who had been sent a participant information sheet (PIS) but had not responded, to assess reasons for not engaging with the trial.

Participants and setting

Women ≥18 years old with severe PGP (> 3-month postpartum) were included. Three study sites were based in different geographical regions of England: West Yorkshire, Buckinghamshire and Devon. Interventions were delivered remotely, via web conferencing, as default, using locally approved software.

Recruitment and screening

A multifaceted recruitment approach was undertaken which included the following: physiotherapy caseloads and waiting lists (women's health and musculoskeletal); newsletters and posters in healthcare and university organisations, nurseries, children's centres, and primary schools; generic social media and targeted paid social media through Facebook and Twitter of several local and national organisations (including breastfeeding groups, pregnancy pain support groups, doctors surgeries, National Childbirth Trust, Mumsnet, Pelvic Obstetric and Gynaecological Physiotherapy [POGP] special interest group).

Eligibility screening adopted a two-stage process: initial eligibility check via telephone call followed by a virtual physical screening via videoconference. PGP was diagnosed in line with European guidelines [16] through a self-performed testing battery under the guidance of a researcher [25]. All eligible participants were measured for the DEFO. Participants verbally consented to the telephone screening and virtual physical assessment (consent video recorded). Written consent was provided for trial participation.

Interventions

Intervention sessions were delivered through two protocolised videoconference-based sessions, spaced 10–14 days apart where possible. The control group received standardised advice through a discussion based on the POGP booklet [26] and up to four exercises chosen from a protocolised exercise programme. The intervention group received the same standardised advice and exercise and, in addition, was provided with two DEFOs to wear as per manufacturer's guidelines (building wear-time up from 1 h on day 1 to a maximum of 12 h a day) for the duration of the trial. These were delivered directly to the women and worn for the first time at the first physiotherapy session, at which time correct fitting of the DEFOs was assessed and a discussion held about their use.

Potential full trial outcomes

Baseline characteristics

Demographics (age, gender, ethnicity, employment status, marital status, height, and weight); pregnancy and most recent birth-related details (parity, the most recent birth — gestational week of delivery, length of labour, induction, mode of delivery, episiotomy/perineal tear,

neonatal gender, and the presence or absence of lumbopelvic pain prior to pregnancy); pain history; current medication use; comorbid conditions; and the presence of hypermobility as determined by the Beighton score were collected. All in-trial reporting by participants was undertaken through a bespoke web-based app designed by the Peninsula Clinical Trials Unit (PenCTU).

Primary outcome measure

The self-report Numerical Pain Rating Scale (NPRS) [27] is the proposed primary outcome measure for a definitive RCT. Participants rated pain intensity over the past 2 weeks using a four category NPRS (worst and average of daytime and night-time pain), assessed at baseline and then at fortnightly intervals tied to their first intervention session.

Secondary outcomes measures

A range of validated outcome measures were collected remotely relating to function (Pelvic Girdle questionnaire — PGQ [28]), health-related quality of life (EQ-5D- 5L and Short Form- 36 [29]), postnatal depression (Edinburgh Postnatal Depression Scale — EPDS [30]), continence (International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form — ICIQ-UI-SF [31]), kinesiophobia (Tampa Scale Kinesiophobia — TSK [32]) and body perception (Fremantle Back Awareness Questionnaire — FreBAQ [33]), and 2-point estimation task—2PE [34]. All proposed secondary outcome measures were assessed at baseline and 12 and 24 weeks except for the 2PE (baseline and 24 weeks). If women scored ≥12 on the EPDS, a letter was sent to notify the participant's general practitioner (GP) of possible postnatal depression.

All outcome measures, apart from the 2PE, were self-report, completed by the participants via a REDCap survey. The 2PE was completed remotely via web conference. Fortnightly, 12- and 24-week data collection timepoints were linked to the timing of the participant's first intervention session.

Adherence

Adherence to DEFO wear-time was assessed via a temperature sensor — Orthotimer® (Rollerwerk Medical Engineering, Balingen, Germany), integrated into the seam of the DEFO, recording date, time, and temperature at 15-min intervals throughout the course of the trial, with a temperature precision of ±0.1 °C. DM orthotics activated the Orthotimers® at the point of postal delivery to the participants. Participants were asked to return the Orthotimers®, via a pre-paid postage envelope, at the final 24-week assessment. Wear-time data were downloaded to the Orthotimer cloud-based software package for analysis, in line with GDPR guidelines [35]. Data was downloaded to Microsoft Excel and stored in accordance with the data management plan and is detailed in the study protocol [36].

Progression criteria

Progression criteria were set, using a red, amber, and green (RAG) rating system to decide whether, and how, to proceed with a future definitive trial [37]. These are detailed in the published protocol, and related to recruitment, adherence to intervention (DEFO wear-time), outcome measure completion, and a signal of efficacy [25].

Sample size

In line with usual practice for feasibility studies, a sample size calculation was not undertaken but was based on the feasibility objectives [38]. The trial aimed to recruit 60 participants over a period of 7 months, allowing for an overall retention rate at 24-week follow-up to be estimated to within a 95% CI of approximately ± 13% (± 10% if retention rate was 80%). This sample size was pragmatic and set to determine the practicality of recruiting numbers in a manner conducive to implementing a reasonably costed definitive trial.

Randomisation and blinding

Randomisation was initiated once eligibility was confirmed and baseline data completed. Participants were randomised on a 1:1 basis using random permuted blocks to control or intervention, stratified by centre and the presence/absence of lumbopelvic pain pre-pregnancy. Randomisation was performed within the bespoke PenCTU web-based system. The participants were not blinded to group allocation, as we considered that an appropriate sham was not feasible. This is due to the unknown main therapeutic component of the orthosis, which may involve multiple mechanisms of action, including sensory input from the orthosis itself. Physiotherapists delivering the intervention were also not blinded to the group allocation as the intervention package required a check of DEFO fitting at the protocolised intervention sessions. However, physiotherapists were blind to all outcome measure reporting. The assessing researcher was blinded for the measure requiring researcher involvement (the 2PE); all other measures were based on self-report. Trial statisticians were blinded to group allocation until analyses that required unblinding were undertaken.

Qualitative sub-study

A qualitative sub-study, utilising semi-structured telephone interviews, was undertaken at the end of the trial, using teleconferencing software. Ten purposively

sampled participants ($n=5$ intervention group, $n=5$ control group) and five clinicians were approached to participate. A sampling matrix was used to select a range of participants in regard to study site, age, parity, and duration of PGP. For the clinicians, study site was the only sampling variable used. Interviews were digitally recorded and transcribed verbatim and stored securely in line with the study data management plan. Thematic analysis [39], using an inductive, semantic approach, was undertaken collaboratively with two researchers (independently coding) refining initial themes, facilitated using NVIVO 12 (QSR International, Southport, UK). A summary of the main themes was sent to participants for member checking.

Statistical methods

Analyses were undertaken according to a pre-defined statistical analysis plan (SAP https://www.plymouth.ac.uk/research/emapp-trial) [40]. Summary statistics were obtained using StataSE (V17.0) and supplemented where required by R (V4.0.3) [41]. Baseline data were summarised by group and overall.

Primary analysis (in the form of descriptive statistics) was undertaken on an intention-to-treat (ITT) basis. Participants were included in the ITT analysis providing they had data for the outcome/time-point under consideration. For example, if a participant was missing data for only one outcome, they were included in the analysis of all outcome measures except for the one outcome that had missing data (a modified intention-to-treat basis (mITT) as data was not imputed). Data for any participant who missed a follow-up visit or did not complete the whole outcome measure was not imputed. Any missing clinical measures, such as the 2PE and Beighton score, were not imputed.

Between-group differences for proposed full trial outcomes were summarised descriptively and presented with 80% as well as 95% confidence intervals (CIs). Estimates of the standard deviation of the proposed primary outcome and correlation between baseline and follow-up measure that may be used for future sample size calculations were calculated with 80% and 95% confidence intervals in line with current guidance [42, 43].

Wear-time was identified by Orthotimer® data showing an increase in temperature of more than 3°, with the temperature between 30 and 38 °C. The change from wearing to not wearing was identified by a decrease of > 1 °C and temperature below 30 °C or temperature above 38 °C. Manual inspection of the adherence files was also undertaken to assess for similarities in wear-time reports. If both Orthotimers® reported wear-time at the same period, both files were manually overwritten to detail no wear-time.

Economic evaluation

Intervention delivery resources were assessed, and health, social care, and wider societal resource use were captured via a self-report Resource Use Questionnaire (RUQ) at baseline and 12- and 24-week follow-up. Participants also completed the EQ- 5D- 5L and SF- 36 at each assessment point, from which EQ- 5D- 5L and SF- 6D health state utility values and quality-adjusted life years (QALYs) were estimated [44].

Results

The results are presented in accordance with CONSORT guidance for randomised pilot and feasibility trials [38].

Participant flow

A consort diagram [45] shows the flow of the participants through the trial (Fig. 1).

Recruitment

Recruitment of participants occurred over a 7-month window for each site between October 2021 and August 2022. Forty participants were screened for eligibility. Seven (17.5%) were ineligible for the virtual physical screening primarily because pain was not severe enough ($n=4$, 57% of ineligible participants). At video consultation, 7 of the 33 women screened were ineligible, primarily due to participants not reporting pain in a distribution consistent with PGP. Twenty-four women therefore met the trial inclusion criteria and were randomised. Additional file 1 details recruitment rate by site and method of invitation.

One site recruited 75% of participants included in the study. The two further sites each contributed 12.5% of the participants. Reasons for nonparticipation are detailed in the Supplementary files (see Additional file 2).

Telephone follow-up

From records of clinicians' waiting lists at 1 site, 45 women were contacted, who had been sent a PIS but had not responded to assess reasons for not engaging with the trial ($n=16$ an answerphone message was left with no reply, and 3 were unable to answer questions ($n=1$ unwell child, $n=1$ declined to answer, $n=1$ requested a call back). Eighteen women confirmed they received the PIS ($n=6$ reported not receiving it), of whom 13 had read it and 5 had not. Of the 13 that had received and read the PIS, 4 were too busy to complete the reply slip, 2 were too busy to read the PIS properly, 2 could not wear tight clothing, 2 pain had resolved, 2 did not feel they met the inclusion criteria, 2 the burden of assessment was too great, and 1 did not believe they had PGP (this participant was screened and recruited). Of the women that received the PIS but did not read it, two reported

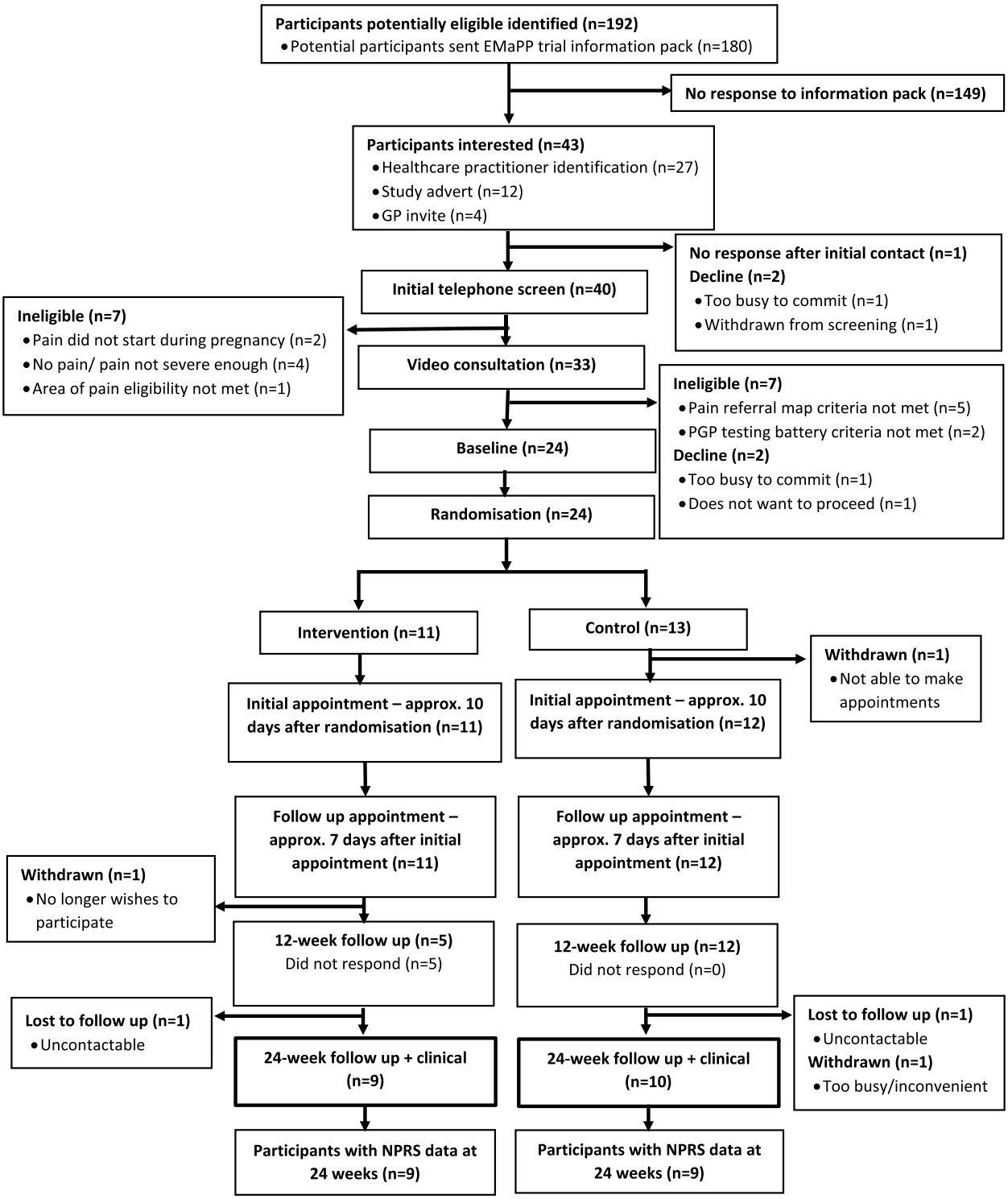

Fig. 1 CONSORT diagram. Legend: GP, general practitiioner; NPRS, Numerical Pain Rating Scale; PGP, pelvic girdle pain

they were too busy to read the PIS, two felt the burden of assessment was too great with children, one did not favour the virtual nature of the trial and one was on holiday. For the six women that reported not receiving the PIS, two felt they did not have PGP, two were interested and requested further information, one does not read any post, receiving all important documents via email, and for one, their pain had improved. Of note, this process of contacting women to explore their experience of nonparticipation resulted in the receipt of 10 reply slips expressing an interest to participate in the study. Of these, two were lost to further contact, three were excluded ($n = 2$ not PGP, $n = 1$ pain not severe enough to cause bothersome walking or stair climbing), and five women were recruited. This was the only month that exceeded the recruitment rate of four per month.

Screening

All screening was undertaken remotely. Nine assessments were undertaken outside of normal working hours (9 am to 5 pm), of which three required rearranging. The total time taken to complete assessments and administration outside of working hours was 12.5 h.

Baseline data

Baseline characteristics are shown in Table 1. The mean age of participants was 35.2 (standard deviation (SD) 7.5). There were more participants in part-time work (54%) in the control group compared to the intervention (27%). The intervention group had a higher rate of comorbidities (18% had none) compared to the control group (77% had none). Hypermobility as determined by the self-assessed Beighton score [46] and depression/anxiety was the most frequent comorbidities and demonstrated the largest between-group differences: hypermobility (9% intervention vs 31% control) and depression/anxiety (46% intervention vs 15% control). Other baseline characteristics were similar between the two groups. The impact and severity of the co-morbidities were not assessed. Further data on baseline characteristics are included in Additional file 3.

Withdrawals

$N = 3$ (13%) withdrawals. Two withdrew post-randomisation but before week 12. One participant was not able to make an appointment, and one no longer wished to participate; reasons were not provided. One participant withdrew between weeks 12 and 24, due to the inconvenience of the study.

Intervention fidelity

Two participants required the DEFOs to be remade due to poor fit. This required an additional appointment with the physiotherapist. All other participants received the two protocolised appointments.

Data collection completeness

Completeness of the self-report questionnaires was generally high (baseline intervention 90.9–100%, control 92.3–100% and at 24-week intervention 72.7–81.8%, control 53.8–69.2%) except for the intervention group at week 12, where it was markedly lower and varied across the two groups (27.3–45.5% intervention, 69.2–92.3% control). Technical issues with the REDCap survey tool were identified as the reason for this. In REDCap, all survey distributions expire by default at a 12-month timepoint; this coincided with the timing of the survey distribution. The unbalanced effect on those in the intervention group at week 12 appeared coincidental, as there were larger numbers of participants in the intervention group at this timepoint (based on the randomisation procedure). Completeness of the researcher-assessed 2PE was higher in the intervention group at 24 weeks (72%) compared to the control group (38%). Data completeness for the self-report measures at baseline and 12 and 24 weeks are detailed in Additional file 4 and for the fortnightly questions in Additional file 5.

Proposed primary outcome measure

The score for all four NPRS questions showed no trends over the course of the trial in either group. At 24 weeks, the largest change in the NPRS was demonstrated in the intervention group for the worst pain at night, mean −2.63 (*SD* 2.88) (Fig. 2). Further detail is provided in Additional file 6. Data is only presented for baseline and 24 weeks due to the technical issues with 12-week data collection. Summary statistics for the fortnightly NPRS questions are detailed in the supplementary files (see Additional file 7).

Overall, the participants' pain improved across all NPRS variables (Fig. 2) with only the control group including a range with a positive score, indicating a worsening of pain.

The between-group difference in the NPRS for daytime pain (worst and average) did not demonstrate a signal of efficacy with the between-group difference in worst pain in the day (− 0.68 80% *CI* [− 2.14, 0.78]) and average level in the day (0.13, 80% *CI* [− 1.07, 1.32]). This indicates that the control group had a greater reduction in worst daytime pain. In contrast, the between-group difference in the worst pain at night favoured the intervention group (1.63, 80% *CI* [− 0.07, 3.32]) (see Additional file 8).

Table 1 Baseline characteristics

Factors	Both	Group	
		Intervention	Control
Age *n*: mean (SD) [range]	24: 35.2 (7.5) [20.8, 48.6]	11: 33.3 (8.7) [20.8, 47.5]	13: 36.9 (6.2) [26.1, 48.6]
Ethnicity *N* (%)			
White	18 (75.0)	8 (72.7)	10 (76.9)
Mixed/multiple	3 (12.5)	1 (9.1)	2 (15.4)
Asian	2 (8.3)	1 (9.1)	1(7.7)
Missing	1 (4.2)	1 (9.1)	0 (0)
Employment status *N* (%)			
Unemployed	5 (20.8)	3 (27.3)	2 (15.4)
Part-time work	10 (41.7)	3 (27.3)	7 (53.8)
Full-time work	5 (20.8)	2 (18.2)	3 (23.1)
Student	1 (4.2)	1 (9.1)	0 (0.0)
Maternity leave	4 (16.7)	3 (27.3)	1 (7.7)
Other	1 (4.2)	1 (9.1)	0 (0.0)
Missing	1 (4.2)	1 (9.1)	0 (0.0)
Comorbid status *N* (%)			
None	12 (50.0)	2 (18.2)	10 (76.9)
CHD/hypertension	1 (4.2)	1 (9.1)	0 (0.0)
Diabetes	1 (4.2)	0 (0.0)	1 (9.1)
COPD/asthma	1 (4.2)	1 (9.1)	0 (0.0)
Migraine	1 (4.2)	1 (9.1)	0 (0.0)
Depression and/or anxiety	7 (29.2)	5 (45.5)	2 (15.4)
Hypermobility	5 (20.8)	1 (9.1)	4 (30.8)
Other	8 (33.3)	5 (45.5)	3 (23.1)
Missing	1 (4.2)	1 (9.1)	0 (0.0)
BMI (kg/m^2) n: mean (SD) [range]			
Pregnancy details n: mean (SD) [range]	23: 27.0 (4.9) [17.4, 34.9]	10: 26.8 (5.0) [17.4, 34.4]	13: 27.1 (5.0) [20.5, 34.8]
Number of children	23: 1.5 (0.7) [1.0, 3.0]	10: 1.5 (0.7) [1.0, 3.0]	13: 1.5 (0.7) [1.0, 3.0]
Number of pregnancies	23: 2.1 (1.3) [1.0, 5.0]	10: 2.3 (1.6) [1.0, 5.0]	13: 1.9 (1.0) [1.0, 4.0]

Legend: *CHD* coronary heart disease, *COPD* chronic obstructive pulmonary disease, *BMI* body mass index, *kg* kilograms

Proposed secondary outcome measures

Summary statistics of baseline outcome measures and change between baseline and 24 weeks for proposed secondary outcome measures are presented in Additional file 9. Secondary outcome measures were broadly similar between baseline and 24 weeks with an apparent decrease (indicating improvement) in the PGQ in both groups between baseline and 24 weeks.

Depression

Seven participants had a score of ≥12 on the EPDS at baseline ($n=4$ [13, 16, 16, 18] intervention, $n=3$ [13, 14, 21] control) and six ($n=4$ [12, 14, 15, 17] intervention, $n=2$ [16, 17] control) at week 24. In total, 17 ($n=9$ [range 12–18] intervention, $n=8$ [range 12–21] control) referrals (7 intervention and 4 control participants) were made to the participants' GP to highlight depression over the 24 weeks of the trial.

Economic evaluation

Data completeness for the Resource Use Questionnaire (RUQ) and the two measures used to estimate quality-adjusted life-years (QALYs) (SF6D and EQ- 5D- 5L) was $n=24$ (100%) at baseline. Completion for all outcome measures (RUQ, SF- 6D, EQ- 5D- 5L) was $n=9$ (82%) in the intervention group and $n=9$ (69%) in the control group. Health state utility values improved for participants in both groups from baseline to 24 weeks indicating better states of health, and QALYs over this period were no different whether the EQ- 5D- 5L or SF- 6D was used for their calculation (Additional file 10).

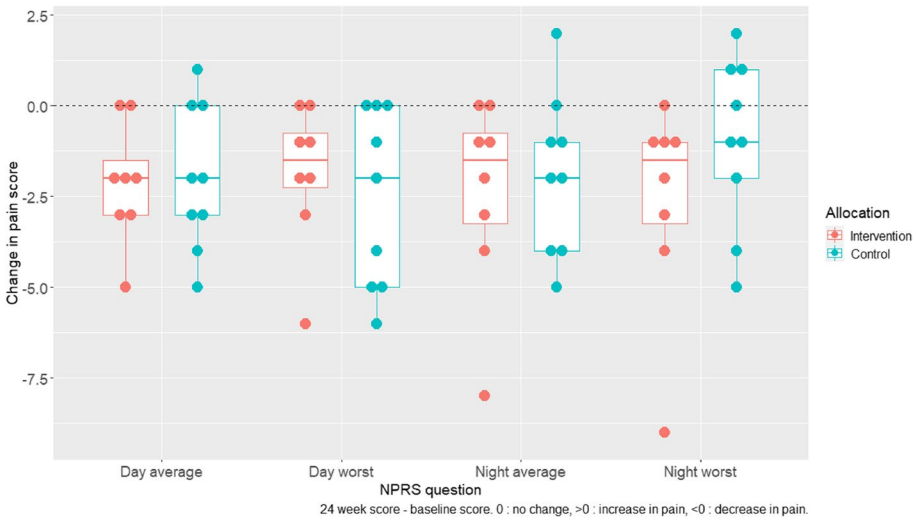

Fig. 2 Numerical pain rating scale change between baseline and 24 weeks

Adverse events

Four adverse events (three in the intervention group) occurred during the trial. Two participants reported *Candida* infections possibly related to the orthosis, and one reported pain with orthosis wear because of a vulval cyst which was present prior to the study. One participant (control) reported increased pain with the exercise programme. One serious adverse event (scarlet fever) occurred in a control group participant but was not related to the study.

Adherence to orthosis wear-time

Nine of the 11 intervention participants returned the Orthotimers®. One participant only returned one out of two Orthotimers®, having lost the second pair of shorts. All Orthotimers® (except one participant who had two new pairs of shorts) had a 12- to 14-week time frame of missing data (out of a possible 24 weeks). It was identified that this was due to technical issues, whereby the default setting on the Orthotimer® was to automatically overwrite data after 100 days. This was not stipulated in the Orthotimer® guidance and hence was unbeknown to the researchers.

From the limited Orthotimer® data registered, one participant had wear-time data for the duration of the trial, three had no wear-time data, and two had 2 days or less wear-time data. Four participants demonstrated more than 1 h of wear-time across the data collection period. One participant wore the DEFO for more than the 42 h per week target on two occasions.

Visual inspection of wear-time alongside the NPRS measures showed no pattern in terms of wear-time and pain levels (Fig. 3).

Due to the loss of Orthotimer data, women who had consented to be recontacted were asked for details on their perceived wear-time. This self-report data did not match the wear-time reported by the Orthotimer®, with women overestimating their wear-time.

Sample size for a definitive trial

A range of sample sizes were estimated with a minimal clinically important difference (MCID) of 1 on the NPRS, power of 90%, alpha of 0.05, and drop-out rate of 20% (see Additional file 11). A standard deviation (SD) of 1.5 provides a target sample of $n = 124$. A SD of 4.5 (upper limit of the CI for all four NPRS questions) provides a target sample size of $n = 1068$. Estimates of standard deviations for the proposed primary outcome NPRS and for a range of scenarios when the minimum clinically importance difference (MCID) between the control and intervention group in NPRS is 1 (± 0.5) and SDs ranging from 1.5 to 4.5 (see Additional file 12).

Progression criteria

Table 2 illustrates how only progression criteria relating to data completeness at the follow-up timepoints were met in this trial. All other progression criteria were not met.

Qualitative findings

Seven participants ($n = 5$ intervention, $n = 2$ control) and five clinicians (physiotherapists) who had provided the intervention (80% female) from across the three recruiting sites were interviewed at the end of the trial. To gain maximum variation, participants were purposively sampled from those who had provided consent.

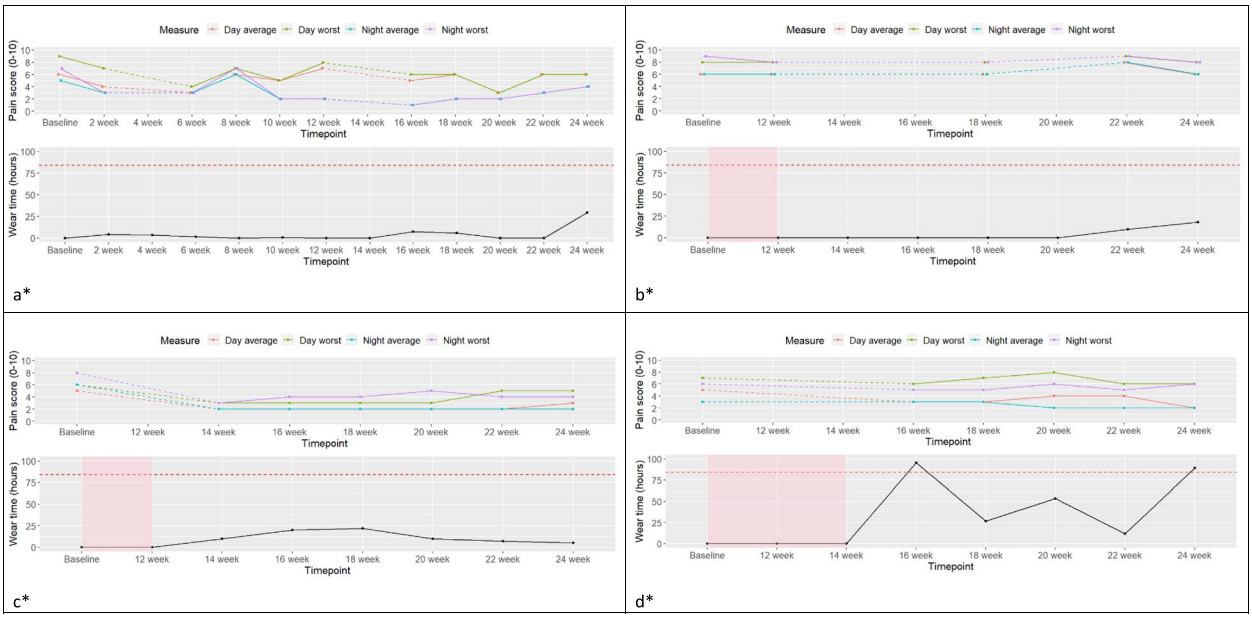

Fig. 3 Adherence to intervention (DEFO). Legend: Top graph demonstrates NPRS pain data (fortnightly intervals), and lower graph indicates wear-time. Dotted lines on top graph indicate data noncompletion. Red dotted line (lower graph) set at 84 h (wear-time compliance threshold over 2 weeks). Graphs **b***, **c***, and **d*** indicate the Orthotimer data loss period with a shaded red area. Participant **a*** had data for the whole trial period — the DEFOs were remade due to poor fit. Total wear-time over whole intervention (hours) for participants **a***, **b***, **c***, and **d*** was 51.5, 27.8, 72.5, and 276.5, respectively. Mean wear-time on days worn (hours) for participants **a***, **b***, **c***, and **d*** was 2.6, 5.6, 4.3, and 8.9, respectively

Four main themes with a range of subthemes were identified across the interviews:

1) Acceptability of trial methods

   a. Screening — Three clinicians expressed a lack of trust in the screening process (nature of diagnostic tests/virtual assessments) and eligibility criteria, with no cap on chronicity. One participant recalled the pain caused by the testing battery, which validated the pain they were experiencing.
   b. Data collection processes — The use of the web-based app for data collection was viewed positively by the participants, who were thankful of the reminders. Suggested improvements were to ensure that these reminders highlighted the time commitment at each timepoint (longer for the 12- and 24-week assessments) and were sent at an appropriate time of day (the database default setting was to send these late at night). Participants did not find the fortnightly pain intensity questions burdensome, with some suggesting it would be easier to estimate on a weekly basis.
   c. Virtual nature of intervention sessions — Clinicians reported a clear preference for in-person sessions, whilst participants reported a more mixed picture with some indicating that the first one should be in-person.

2) Intervention acceptability

   a. Advice — This component was generally acceptable, but clinicians identified a scope for improvement in the advice booklets. Two clinicians reported doubts over the applicability of the advice booklet as not everyone "presents the same". The booklet was viewed positively by the participants; however, they did not regularly refer to it during the trial.
   b. Exercise — The personalised nature of the exercise programme was welcomed by participants; however, clinicians commented that there was scope for a greater range of exercises to further challenge women.
   c. DEFO — The DEFO was acceptable to participants, apart from in hot weather for three participants. Clinicians were happy with the process of DEFO delivery. Clinicians did not review women after the second session and hence felt unable to comment on the acceptability of the DEFOs.

Table 2 Progression criteria

Criteria	RAG rating	Result	
Sixty participants recruited within a 7-month recruitment window	• Red: < 60% • Amber: 60–80% • Green: > 80%	24/60 (40%)	
Percentage of participants randomised to intervention group *noncompliant* in wearing the shorts (noncompliance — wearing the shorts for less than 6 h/day or total of 42 h/week)	• Red: > 70% • Amber: 50–70% • Green: < 50%	9/9 (100%)	
Percentage of participants completing primary outcome measure (NPRS) at 24-week follow-up	• Red: < 60% • Amber: 60–80% • Green: > 80%	18/24 (75%) of those randomised	18/19 (95%) of those followed up
*Percentage of participants completing secondary outcome measures at 24-week follow-up	• Red < 60% • Amber: 60–80% • Green > 80%	Of those randomised • EQ- 5D- 5L: 18/24 (75%) • SF- 36: 18/24 (75%) • PGQ: 18/24 (75%) • ICIQ: 17/24 (71%)	Of those followed up • EQ- 5D- 5L: 18/19 (95%) • SF- 36: 18/19 (95%) • PGQ: 18/19 (95%) • ICIQ: 17/19 (89%)
Evidence to suggest efficacy, i.e. that the DEFO holds promise as an effective intervention, demonstrated by an 80% CI that indicates plausibility of the between-group difference in the primary outcome measure being ≥ 1 point, on the NPRS	N/A	• **Worst level in day: −0.68 [− 2.14, 0.78] • Average level in day: 0.13 [− 1.07, 1.32]	

Total resource for a definitive trial was not able to be estimated due to the lack of certainty in the sample size required. *This criterion relates to the selection of outcome measures to be used in a definitive trial. It does not influence the decision about whether there should be progression to a definitive trial. **Negative indicates that control saw a greater reduction in pain. Positive indicates intervention saw a greater reduction in pain

CI confidence interval, *NPRS* Numerical Pain Rating Scale, *SF- 36* Short Form- 36, *PGQ* Pelvic Girdle Questionnaire, *ICIQ* International Consultation on Incontinence Questionnaire

3) Impact of the DEFO — Participants viewed that the DEFO had a positive impact, consistently commenting that they were supportive and helped to "hold them together", providing them with the confidence and support to be more physically active. Some also reported that the DEFO made them more aware of their movement abilities, ensuring they took more time to undertake activities and providing helpful feedback when undertaking the exercises. This reflects findings from the literature that DEFOs may provide proprioceptive feedback [47].
4) Adherence to exercise: Participants described how they struggled to continue to perform the exercises over the 24 weeks of the trial. They identified barriers (e.g. lack of contact with a clinician over the trial period) and facilitators (e.g. having supportive family members and involving their children in the exercise).

Discussion

To our knowledge, this is the first study assessing the feasibility and acceptability of a RCT comparing a novel pelvic DEFO plus standard care with standard care in women with severe and chronic postpartum PGP.

The primary challenge in this trial was recruitment, with only 40% of the target rate being met. This was despite significant and persistent effort by the research team and the regional Clinical Research Network.

During the trial, several interventions were made to boost recruitment. The 2-year cap on recruitment was lifted, paid for targeted social media advertising was undertaken, and women who had previously been sent a PIS were telephoned to understand why they had not made contact about the study. Re-contacting women was the most effective approach, resulting in a higher-than-target recruitment rate in the month undertaken.

The primary method for recruitment was via NHS waiting lists which were principally self-referral. It is reasonable to consider that women who had self-referred themselves for intervention may be interested in participating in a trial. However, there was a low conversion rate from the number of information packs sent to recruited participants. There are several reasons which may account for this:

1) PGP is often not seen as a distinct entity from low back pain by health care practitioners or women post-partum [48], and consistently not reported to health care professionals [49]; hence, women/health professionals did not view the study as being relevant to them. Whilst PPIE informed the language used to describe PGP and reviewed the public-facing study materials, this did not adequately resolve the issues we faced regarding nomenclature. A future study would need to consider in more depth the language used in advertisements to ensure that women with PGP were captured in the recruitment activity. Broader terminology, such as lumbopelvic pain, may be more inclusive, with the physical

screening enabling the detection of PGP. Further, PPIE involvement would be critical in this step. In addition, increasing the awareness of PGP in clinicians, such as GPs and musculoskeletal (MSK) outpatient physiotherapists who are not women's health specialists, would be of benefit, as approximately 20% of MSK physiotherapists see women with PGP [50].

2) The length of the PIS was cited by potential participants who had not contacted the team following receipt of the PIS, as a barrier to registering interest. A single-sided PIS, linked to a more detailed information pack, may enhance engagement [51], particularly in women with postpartum PGP, with competing demands on time. This would require consideration by ethics committees. A single-sided short trial summary was used on the trial web page, however was not sent out to potential participants.
3) Methods used for registering an interest were a barrier for some women. The study used two options for registering interest: either completing a paper reply slip with a pre-paid return envelope or registering interest through a study-specific email address. Ensuring that women can register interest with low investment via a form integrated into the trial web page may increase initial engagement and may better reflect how patients engage with their primary care provider, as 55.1% of the population use technology to contact the GP [52].
4) Women may not prioritise their own healthcare needs [53] and may benefit from support to engage with healthcare professionals in the postpartum period [54, 55], with evidence that messaging women enhances engagement with postpartum clinical services [56]. The ethical amendment made within the trial to recontact women (via a phone call, text, or email) who had previously received a PIS but had not made contact was a positive step that increased recruitment. The addition of this follow-up facility in any future study may assist women in engaging with a study at a time when there are competing demands on their time. This is of particular relevance in this population, where the prevalence of depression is 17–18% [57–61], requiring a further prompt for initiating engagement in healthcare activities [62]. In the UK, health visitors play a role in supporting women during the postpartum period and may be a useful avenue for enhancing recruitment. However, in the UK, the service is under pressure with the numbers of health visitors having fallen by 40% since 2015 [63]. In addition, health visitors may require upskilling to recognise pelvic health concerns and signpost women appropriately [64].

A significant challenge for recruitment was the difficulty in successfully engaging with primary care, despite CRN input during the study design, protocol, and operational phase of the trial, with only one GP site advertising the study. A specific issue highlighted was the lack of awareness by primary care practitioners of PGP as a distinct entity from low back pain [48] and the lack of an ICD- 11 code to identify the condition. This resulted in a reluctance of practices to run a database search of potential participants. This avenue therefore remains unexplored, but we believe it is essential to recruitment success in future studies within this area. The 6- to 8-week postpartum [15] check in primary care would be one timepoint to identify those women with ongoing pain and to raise study awareness. Critical to operationalising this is the acknowledgement by primary care practitioners of the importance of managing postpartum PGP [65], an issue which currently remains problematic [66].

Described above are several potential avenues to boost recruitment in future studies. Further PPIE and research however are needed to investigate how to best engage women with PGP and the primary care workforce prior to proceeding to a definitive trial.

Despite the low recruitment rate, it was encouraging that when participants were enrolled in the trial, retention rate and data completeness were high.

The COVID- 19 pandemic had an impact on study set-up with one initial site removing support and several others who had demonstrated interest, removing support. Despite this, there was extensive interest nationally with 12 sites indicating interest. COVID- 19 delayed the set-up of two of the sites; however, the 7-month recruitment window was adhered to.

The trial was remote by design which presented some challenges to researchers at screening in that a partner or trusted other was required to be present to assist with some of the measurements. This required flexibility in scheduling of the virtual screening sessions to enable them to be undertaken outside of a standard working day. This requirement would need to be considered in the design of a future trial.

Once participants were recruited, data completeness was high. The use of the web-based app with text reminders was highlighted by participants to have had a positive impact on the completion of outcome measure data. Some participants reported that the ability to request a time preference for reminders to be sent would further increase outcome measure data completion. This should be considered in a future trial design. In addition, the timing and content of reminders require consideration. Once participants had opened the questionnaire (rather than entered data), no further reminders were sent. The design of any bespoke system

used in a definitive trial would need to consider this to maximise data collection.

The sizeable proportion of women in this feasibility RCT (29.2%) scoring ≥ 12 on the EPDS outcome measure at baseline (indicating postpartum depression) suggests an unmet need in this population regarding emotional support. This is broadly line with reported estimates which indicate that one in four women will experience a mental health problem in the perinatal period [67]. Determining, more specifically, the prevalence of depression in women with pregnancy-related PGP requires further investigation [68].

Although interventions were perceived as generally acceptable to participants, the qualitative interview data highlights the need to consider an alternative approach to delivery in future. The trial was designed to run during the COVID- 19 pandemic using a remote approach to screening and intervention delivery. The perspectives from the qualitative interviews suggest that a hybrid delivery may be preferrable with at least one appointment, probably the initial appointment, being delivered in-person. Overall, our data supports that a remote approach to the delivery of care for women in the postpartum period [69–71] appears to be feasible [72–74]. Within practice, the chosen method of service delivery should be clinically reasoned, taking into consideration patient need, preference, and service infrastructure.

The orthoses were broadly acceptable to participants; however, issues were raised about wearing them in warmer conditions. During 2022, the United Kingdom (UK) had a heatwave at three different timepoints which coincided with the trial intervention period [75]. This is an important practical consideration, which may have affected adherence to wear-time.

Two participants in the intervention group reported experiencing *Candida* infections, which may have been related to wearing the DEFO. This should be highlighted as a potential adverse event to women in future study PISs and in clinical practice.

The limited available adherence data (Orthotimer® data) indicated that no participants met the pre-set adherence threshold (42 h per week) for orthosis wear-time for the whole intervention period. However, certainty over true orthosis wear-time and over the trial is weak due to the significant data loss. Orthotimers® overwrite data after 100 days, when recording at 15-min intervals if data is not downloaded. This was unknown to the research team during trial set-up. In collaboration with the manufacturer, the user guidebook has been updated because of this study. To overcome this logistical challenge, in future studies, Orthotimers® could be set to record at 30-min intervals, increasing the storage to 200 days. In addition, a weaning-in period of approximately 2 weeks could be factored in to extend the available data. Furthermore, due to the inaccurate nature of subjective reports of orthosis use, the continued use of an objective means of assessment would be favourable in any future trial.

Although it might seem logical to anticipate that a linear dose–response relationship is expected with orthoses, there may be reason to reconsider this [76]. Qualitative interviews and Orthotimer® data suggested a more nuanced pattern of wear. In line with other studies in this arena [76], participants in this feasibility RCT reported wearing the orthoses for particular reasons, e.g. exercise and certain activities (longer walks), rather than wearing them all day. If traditional patterns of wear are expected and wear-time targets set accordingly, progression criteria may not be met, despite the orthosis having a positive effect. Patterns of wear, and thresholds for required wear-time, require further investigation to better understand this factor before any future definitive trial.

Women consistently felt the shorts "held them together" indicating they viewed their pelvis as being unstable. Mechanistic work however indicates that this is not the case [77]. Terminology used in advice components of future intervention packages should therefore be carefully considered [78]. Language has the potential to harm [79], and health professionals may impart unhelpful beliefs surrounding their condition to the patient [80].

Several women highlighted one of the barriers to exercising was a lack of support (limited interaction with the physiotherapist), a view consistent with the literature concerning remote delivery [81]. The design of the trial was based on detailed discussions with women's physiotherapy health specialists about what constituted standard care for PGP. In future, based on our qualitative findings, the consideration of a least one further point of contact during the 24-week period, as would be expected when managing a complex chronic pain condition [82], could be a valuable addition. However, uptake of such additional sessions would need to be carefully considered, as there is evidence to highlight a lack of engagement in sessions with a peri-partum population [83].

The trial has demonstrated that it is feasible to collect the data required for a policy relevant cost-effectiveness analysis in a full trial. There was minimal difference between QALYs measured by the SF- 6D and EQ- 5D-5L (Additional file 10), and therefore, a future definitive trial should use the EQ- 5D- 5L for assessment of QALYs as it is the preferred measure of the National Institute for Health and Care Excellence (NICE). Of interest, the health state utility values of women with PGP in our sample were equivalent to a population of people with multiple sclerosis, assessed as being moderately disabled such

that full daily activities are impaired and with inability to work a full day without special provisions [84]. This further contextualises the disabling nature of PGP.

Conclusions

The findings from this feasibility trial indicate that despite study processes being acceptable to participants and clinicians and data completeness being high, progression to a future definitive trial in its current design is not supported. Recruitment is the primary barrier. All other challenges faced in the trial have immediate solutions. Further research is required to ascertain how best to engage women with postpartum pelvic girdle pain in research and involve primary care as a recruitment avenue for studies within this arena. Sample size estimates for a future trial are uncertain due to low recruitment. Further work is required to provide a robust estimate.

Abbreviations

CI	Confidence interval
DEFO	Dynamic elastomeric fabric orthosis
EPDS	Edinburgh Postnatal Depression Scale
FreBAQ	Fremantle Back Awareness Questionnaire
GP	General practitioner
ICIQ-UI-SF	International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form
ISRCTN	International Standard Randomised Controlled Trial Number
ITT	Intention to treat
MCID	Minimal clinically important difference
mITT	Modified intention to treat
NHS	National Health Service
NPRS	Numerical Pain Rating Scale
NIHR	National Institute for Health Research
NRES	National Research Ethics Service
PenCTU	Peninsula Clinical Trials Unit
PGP	Pelvic girdle pain
PGQ	Pelvic Girdle Questionnaire
PIS	Participant information sheet
POGP	Pelvic Obstetric and Gynaecological Physiotherapy
QALYs	Quality adjusted life years
RfPB	Research for Patient Benefit
RCT	Randomised controlled trial
RCOG	Royal College of Obstetricians and Gynaecologists
RUQ	Resource Use Questionnaire
SAP	Statistical analysis plan
SD	Standard deviation
TSK	Tampa Scale Kinesiophobia
UK	United Kingdom
2PE	Two-point estimation task

Supplementary Information

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Additional file 1. Recruitment rate by site and method of invitation

Additional file 2. Reasons for non-participation

Additional file 3. Additional baseline characteristics

Additional file 4. Completeness of primary and secondary outcome measures

Additional file 5. Completeness of fortnightly follow-up questionnaires

Additional file 6. Change between baseline and 24 weeks on Numerical Pain Rating Scale

Additional file 7. Summary statistics of Numerical Pain Rating Scale

Additional file 8. Between group differences and CIs of change between baseline and 24 weeks for the NPRS

Additional file 9. Secondary outcome measures. Summary statistics at baseline, 24 weeks and change at 24 weeks

Additional file 10. Health economics data

Additional file 11. Estimates of standard deviations for the proposed primary outcome Numerical Pain Rating Scale

Additional file 12. Sample size scenarios for a definitive trial

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Protocol

Protocol V4, accessible via trial web page: https://www.plymouth.ac.uk/research/emapp-trial.

Authors' contributions

JF is the principal investigator and together with LC and JS conceived the study. BH, JF, JS, LC, AH and CH contributed to the study design. BH, SC, LC, JH, JS, AH, MB, KC, CH and JF were involved with the conduct of the study. JH, JC and LS contributed to the statistical analysis and interpretation of results. MB created and managed the bespoke web-based app for data collection. BH drafted the first manuscript with all others reviewing and editing subsequent versions and the final version. JF is responsible for the overall content as guarantor.

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Data availability

Individual participant data that underlie the results will be made available (after deidentification) on a controlled access basis, subject to suitable data-sharing agreements. Requests for data sharing should be made to the chief investigator (CI: J. Freeman) in the first instance. Requesters will be asked to complete an application form detailing specific requirements, rationale and proposed usage. Requests will be reviewed by the CI and study sponsor, who will consider the viability and suitability of the request and the credentials of the requester. Where access to requested data is granted, requesters will be asked to sign a data-sharing agreement. Requested data will be made available, along with supporting documentation (e.g. data dictionary) on a secure server or through other secure data transfer method.

Declarations

Ethics approval and consent to participate

This study was approved by the National Research Ethics Scheme (NRES Committee Health and Care Research Wales Research Ethics Committee (21/WM/0155) and University of Plymouth Faculty of Health Research Ethics and Integrity Committee (ref.: 2966). Written consent was gained from all participants.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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