

**University of Plymouth**

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Faculty of Health: Medicine, Dentistry and Human Sciences

School of Health Professions

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## Background

Post-partum pelvic girdle pain (PPGP), experienced by approximately 10% of women, is typically refractory to conservative management. Customised dynamic elastomeric fabric orthoses (DEFO's) are one novel option to address this.

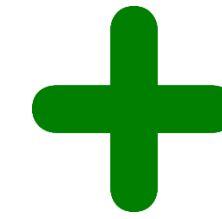
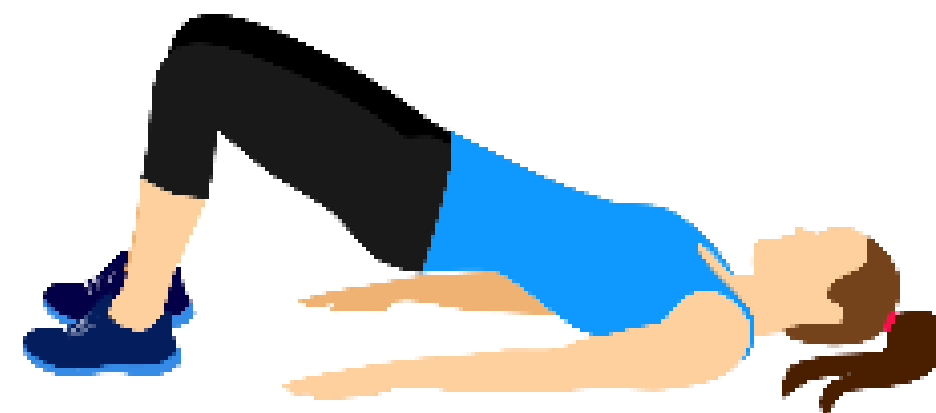
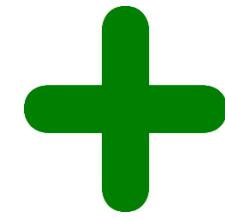
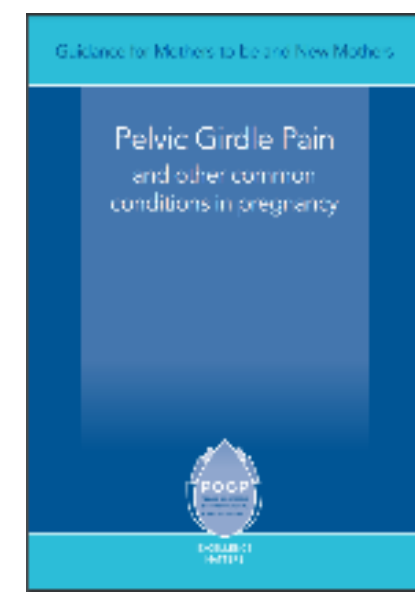
## Aims

Assess the feasibility and acceptability of an anticipated randomised controlled trial (RCT) study comparing a DEFO plus standardised advice/exercises (Intervention) versus standardised advice/exercise alone (Control).

## Methods

- Design:** Multicentre feasibility RCT with embedded qualitative study and economic evaluation.
- Procedures:** Participants randomised to receive two physiotherapy sessions [Intervention/Control] remotely, separated by 14 days.
- Outcome measures:** Remotely completed via a web-based app. All measures self-report.
- Proposed primary outcome measure for definitive trial:** Numerical Pain Rating Scale (NPRS) assessed pain intensity fortnightly over 24 weeks.
- Secondary outcomes:** Secondary measures assessed kinesiophobia, continence, function, quality of life and depression at baseline, 12 and 24 weeks. Wear time adherence measured by an Orthotimer. Adverse events recorded.

**Control:**  
Standardised advice  
Protocolised exercises



**Intervention:**  
Standardised Advice  
Protocolised Exercises  
DEFO

## Results: Quantitative

### 1) Recruitment

- Target for recruitment = 60 within 7-month window
- Actual recruitment = 24 (40% of target)

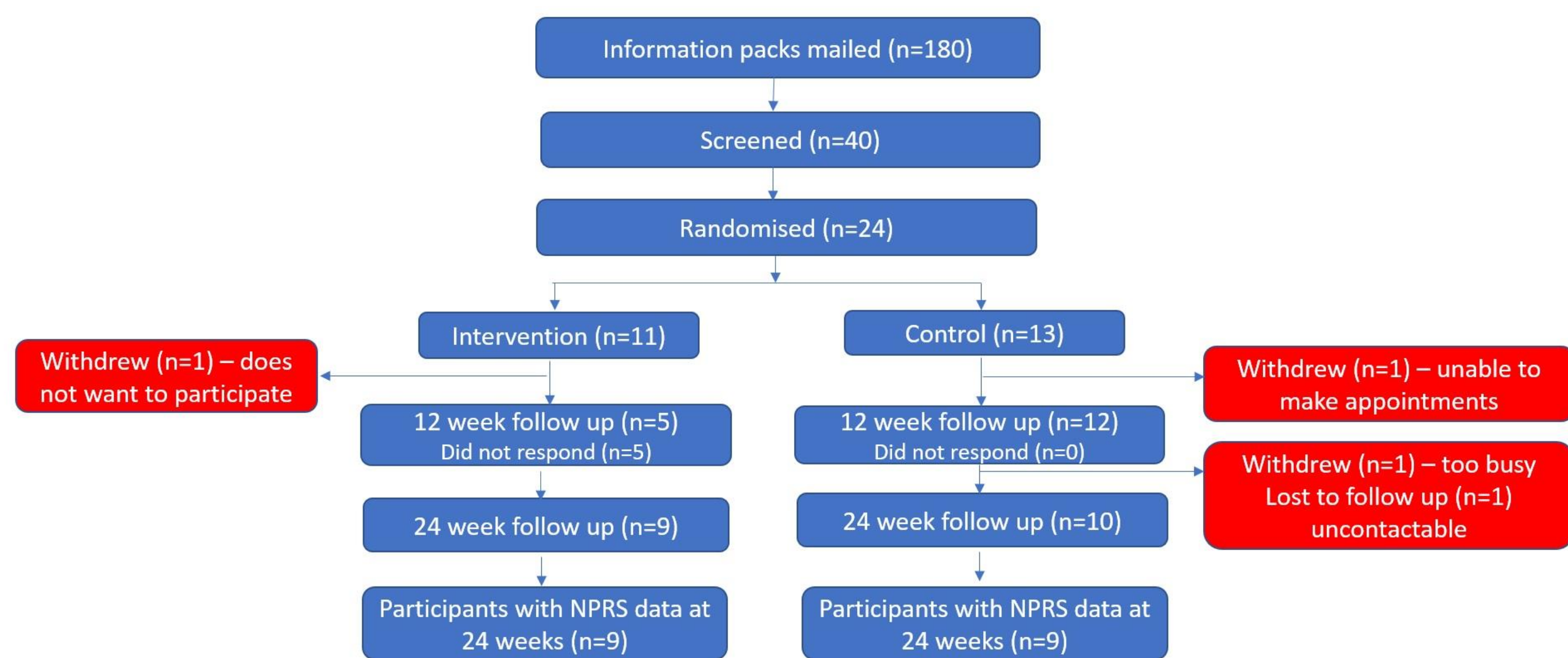


Fig. 1 Flow of participants through the study

### 2) Adherence to the intervention

- Criteria set for minimum wear time indicating adherence: 42 hours/week
- No participants met the wear time adherence criteria
- No pattern was evident in terms of wear time and pain levels
- Fig 2 shows the wear-time and pain profile for an individual participant as an example of available data. Shaded red area indicates period of data loss.

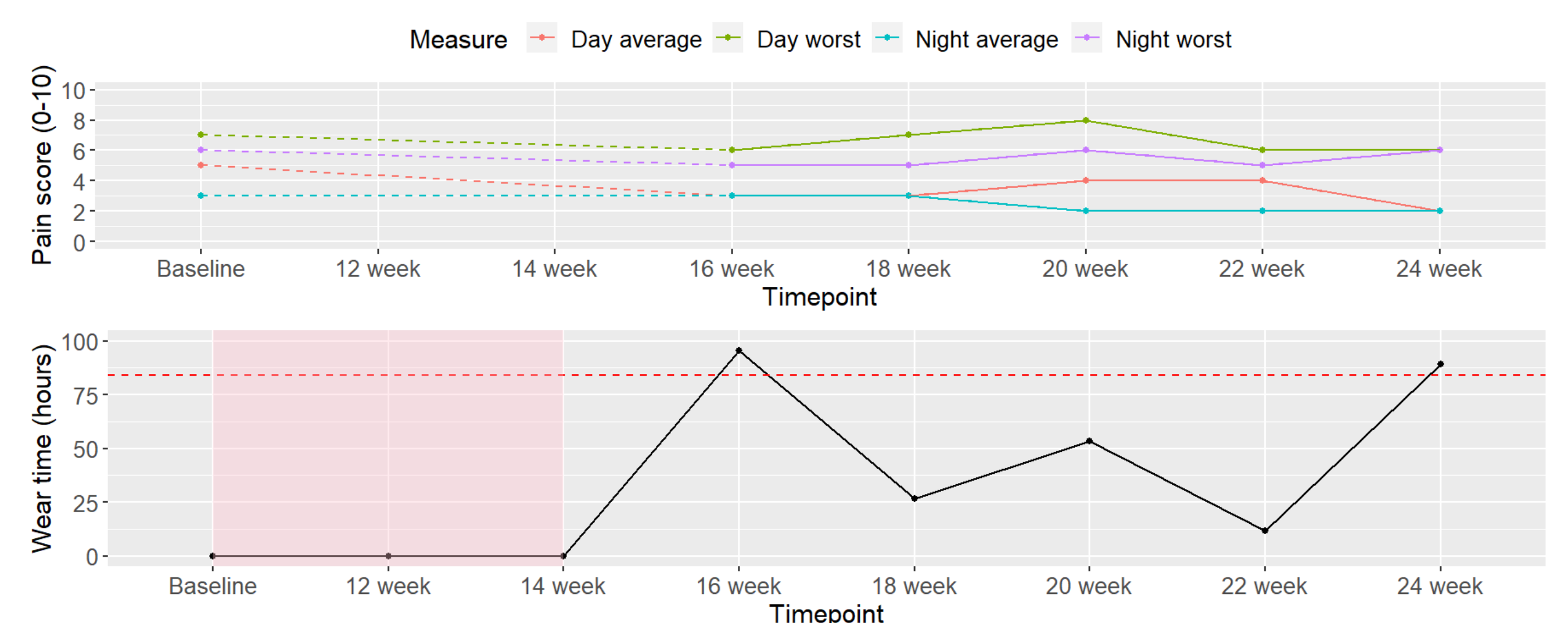


Fig. 2 Orthotimer and NPRS data

### 3) Outcome measure completion at 24 weeks

Variable	Outcome (% of those randomised)
Primary outcome measure completion (NRPS)	95%
% completing secondary outcome measures	89-95%

### 4) Signal of efficacy at 24 weeks

Numerical Pain Rating Scale change (primary outcome measure)	Between group difference	80% CI
Worst level in the day (0 - 10)	-0.68	[-2.14, 0.78]
Average level in the day (0 - 10)	0.13	[-1.07, 1.32]

### 5) Health Economics

- Data completeness of Resource Use Questionnaire and EQ-5D-5L at 24 weeks was 75%

Health State Utility Values (summary statistics)		
	Intervention	Control
	n / Mean (SD) [range]	n / Mean (SD) [range]
EQ-5D-5L	Baseline n=11 / 0.627 (0.124) [0.496, 0.871]	n=13 / 0.590 (0.183) [0.025, 0.733]
	24 weeks n=9 / 0.744 (0.135) [0.460, 0.871]	n=9 / 0.678 (0.218) [0.138, 0.868]

Quality adjusted life years (QALYS) – Baseline to 24 weeks		
	Intervention	Control
	n / Mean (SD) [range]	n / Mean (SD) [range]
EQ-5D-5L	n= 9 / 0.322 (0.049) [0.225, 0.402]	n= 9 / 0.284 (0.098) [0.038, 0.370]

### 6) Adverse Events

Five adverse events

#### Intervention group

- 3 - (x2 thrush, x1 vulval cyst – present prior to intervention)

#### Control

- 1 Serious Adverse Event (SAE)- Scarlet Fever

## Results: Qualitative

### 1) Acceptability of trial methods

- Positive views on web-based app for data collection.
- Participants would like a hybrid approach to intervention delivery, with one session in-person (probably the first). Clinicians expressed a clear preference for all in-person sessions.

### 2) Intervention acceptability

- Shorts were acceptable but not in hot weather.

### 3) Impact of DEFO

- “Held me together”
- Confidence and support to be more physically active.
- Increased awareness of movement ability.

### 4) Adherence to exercise

- Struggled to maintain adherence.
- Identified barriers (lack of therapist contact) and facilitators (family support).

## Conclusion

Feasibility of a future RCT was not demonstrated in its current format; low recruitment rate was the key barrier despite varied and intensive efforts to recruit participants. Technical issues that caused significant Orthotimer missing data are resolvable. Trial procedures/interventions were acceptable. Understanding how best to engage women in this research is needed before a definitive trial is undertaken.