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Evaluating the Management of chronic Pelvic girdle pain following Pregnancy (EMaPP): A randomised controlled feasibility trial

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EMaPP Evaluating the Management of chronic Pelvic girdle Pain following pregnancy

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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.

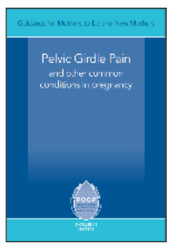
Aims

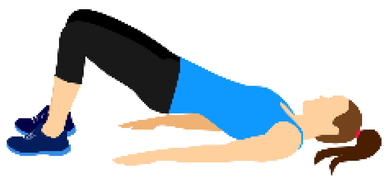
Assess the feasibility and acceptability of an anticipated randomised controlled trial (RCT) study comparing a DEFO plus standardised advice/exercises (Intervention) versus standardised advice/exercise alone (Control).

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)

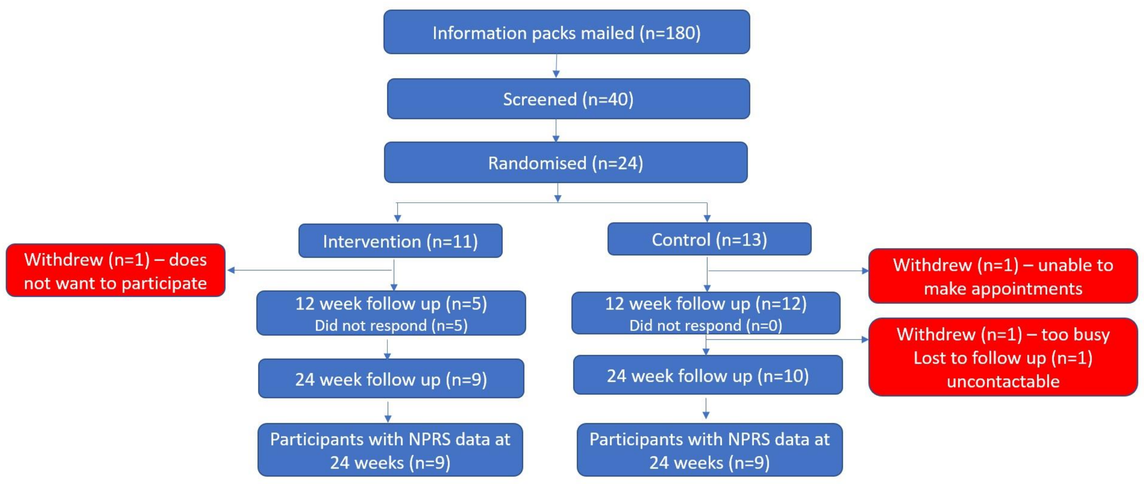


Fig. 1 Flow of participants through the study

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.

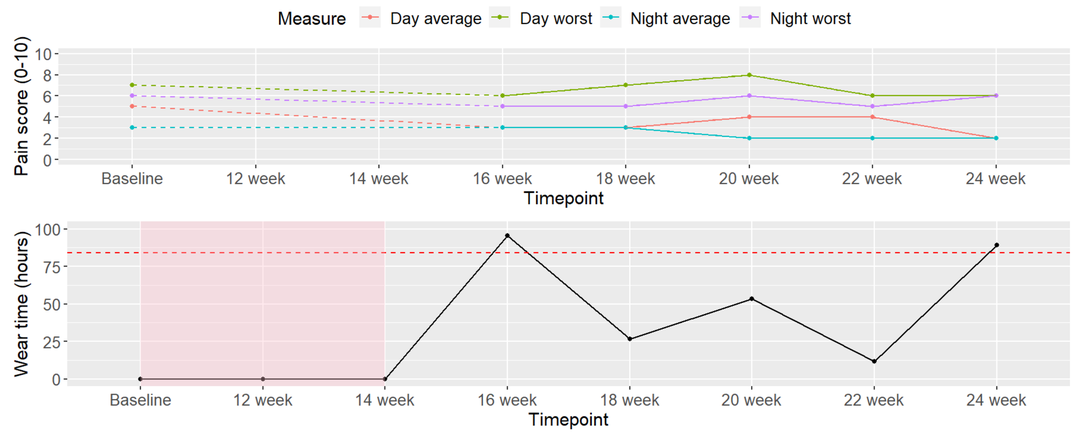


Fig. 2 Orthotimer and NPRS data

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.

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