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EVALUATING THE MANAGEMENT OF CHRONIC PELVIC GIRDLE PAIN FOLLOWING PREGNANCY (EMAPP): A RANDOMISED CONTROLLED FEASIBILITY TRIAL

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Main Topic: Physical/occupational therapies

Background and aims: 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. 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: Design: Multicentre randomised controlled feasibility trial with embedded qualitative study and economic evaluation.

Procedures: Participants with PPGP were randomised to receive two physiotherapy sessions [Intervention/Control], separated by 14 days. Wear time adherence was measured by an Orthotimer. Numerical Pain Rating Scale (NPRS) assessed pain intensity fortnightly, over 24 weeks. Secondary outcome measures assessed kinesiophobia, continence, function, quality of life, and depression at baseline, 12 and 24 weeks. Adverse events were recorded.

Progression criteria: (1) Target sample size (60 from three centres over a 7-month recruitment period); (2) Outcome measure completion (>60% at 24 weeks); (3) Orthotic wear-time compliance (>70% for 6 hours/day); (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. Technical issues caused significant orthotimer missing data, although wear-time adherence appeared below the set target. Outcomes were broadly comparable between groups. Two Intervention participants experienced thrush.

Conclusions: Trial procedures/interventions were acceptable to participants. Technical orthotimer issues are resolvable. 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.