A prospective quasi-experimental controlled study evaluating the use of dynamic elastomeric fabric orthoses to manage common postpartum ailments during postnatal care

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Abstract

Objective: To evaluate the effectiveness of a postnatal dynamic elastomeric fabric orthoses to manage postpartum pain, improve functional capacity and enhance the quality of life arising from postnatal ailments immediately to an 8-week postpartum, compared with patients who did not wear dynamic elastomeric fabric orthoses.

Method: A total of 51 postpartum women were recruited (day 0 to 10 days post-delivery) from hospitals and community-based health clinics to participate in a prospective quasi-experimental controlled study using parallel groups without random allocation. The subgroup of the compression shorts group wore SRC recovery shorts and received standard postnatal care. The comparison group received standard postnatal care alone. Wear compliance was monitored throughout the study. Primary outcome measure, Numeric Pain Rating Scale, and secondary outcome measures, Roland Morris Disability Questionnaire, Pelvic Floor Impact Questionnaire–7, and Short Form (SF-36) were assessed fortnightly over 8 weeks for both groups.

Results: The compression shorts group reported a larger reduction in mean (SD) Numeric Pain Rating Scale score (−3.09 (2.20)) from baseline to 8 weeks, compared to the comparison group (−2.00 (1.41)). However, there was insufficient evidence of a statistical difference in Numeric Pain Rating Scale score at 8 weeks when comparing the compression shorts group and comparison group (−1.17; 95%CI: (−2.35, −0.01), $R^2 = .19$, $p = .050$). The compression shorts group met the wear compliance of the dynamic elastomeric fabric orthoses and reported an average wear of the dynamic elastomeric fabric orthoses as 9 out of 14 days for 11 h per day (SD 4.8 h) between the fortnightly timepoints.

Conclusion: The use of dynamic elastomeric fabric orthoses may be considered during postnatal care as a non-pharmacological therapeutic intervention to manage pain resulting from common postpartum ailments. While the dynamic elastomeric fabric orthoses was clinically well accepted by participants with high wearing compliance, future research with larger population samples are needed to enable statistical conclusions on the effectiveness of a dynamic elastomeric fabric orthoses in postnatal care to be made.

Registration: Trial registration was not required as per the Australian Government Department of Health, Therapeutic Goods Administration.

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Introduction

Common prenatal ailments such as low back pain (LBP) and pelvic girdle pain (PGP) have the potential to carry through into the postpartum period in addition to the common ailments experienced in post vaginal or cesarean section deliveries.[1–3] Published research demonstrates that high levels of self-reported pain intensity during pregnancy have a strong correlation to an earlier onset of postpartum pelvic pain with rates of re-occurrence ranging from 44% to 47%.[4] Common postpartum ailments reported in the empirical literature include LBP, PGP, vaginal, incisional or perineal pain,[1,5,6] sexual problems, urinary incontinence,[5] and diastasis of the rectus abdominis muscle (DRAM).[7–9]

Common complications following vaginal deliveries such as genital tract trauma, perineal pain, sexual problems, and urinary incontinence are known to affect women and their activities of daily living.[5,6] Women who have experienced a cesarean section may also report incisional pain and persistent LBP that is not correlated with epidural anesthesia, and they may also experience PGP up to 6 months following cesarean section.[1–3] Research shows a rising rate of cesarean section with suggested reasons being older in age when delivering,[2] increased maternal requests without obstetric indication[3] and larger rates of repeated cesarean section.[2] As cesarean section is classed as major abdominal surgery, standard surgical complications may occur (i.e. deep vein thrombosis, infection, wound management, decreased muscle strength and activation, and effects of immobilization),[1,2,10] and each of these complications requires regular monitoring and or intervention. Irrespective of the mode of delivery, common general complaints during hospital stay immediately following delivery include pain (perineal and back), functional problems (e.g. breast problems) and decreased quality of life (extreme tiredness and exhaustion), and these complaints can remain for up to 18 months.[2]

Effective prevention and intervention strategies to address postpartum complications that women experience are essential for postnatal care. This is especially important in the immediate postpartum period because these ailments can affect women physically and can decrease their functional capacity and ability to perform activities of daily living, which can negatively impact women's quality of life.[11] Various potentially beneficial non-pharmacological therapies have been suggested in previous research as treatment options for postpartum ailments including physiotherapy, specific exercise programs, and acupuncture.[12] In addition, a systematic review, published in 2013 reported on a range of non-pharmacological treatment options available for women in the postnatal phase for PGP and LBP.[13] Definitive conclusions regarding the efficacy of the above-mentioned treatment options were difficult to draw due to the heterogeneity across study designs,

interventions and outcome measures.[13] Furthermore, limited high-quality clinical trials have been undertaken to evaluate the effectiveness of these treatments.[11] Stuge et al.[11] demonstrated a reduction in postnatal LBP and PGP, and an increase in the activities of daily living with a combination of non-pharmacological therapies, such as physical therapy and stabilizing exercises, ergonomic advice, massage, mobilization, and stretching. Similarly, interventions that prescribe a combination of specific transverse abdominis strengthening exercises, and the use of abdominal muscle and pelvic support belts have been effective for treating DRAM.[9,14]

In recent years, the term dynamic elastomeric fabric orthoses (DEFO) has been used in published research literature to describe compression garments, which are designed to apply consistent compression through tailored elastomeric panels.[15] Limited evidence is available to determine the effectiveness of DEFO postpartum; however, there is some evidence supporting the use of DEFO to positively impact ailments experienced in the postnatal period, such as varicose veins, leg edema,[16] deep vein thrombosis,[17] and pain following cesarean delivery.[18,19] DEFO may also have a role in postpartum management and care, post-cesarean section. While not exploring the use of a DEFO specifically, previous research has shown that wearing an elasticized abdominal binder supporting the incision improved early mobilization and provided ideal pain control after cesarean section.[18,19] Furthermore, Sawle et al.[15] suggest that DEFO may be used to address common musculoskeletal conditions that are prevalent in the postnatal phase such as LBP and ailments in the pelvic region and refer to DEFO having the potential to stabilize the joints surrounding the pelvic girdle. Such stabilization may facilitate a possible improvement in pain enabling women to have better functional capacity while wearing the DEFO.[15,20–22]

Commercial manufacturers have considered previously published research regarding compression garments in postnatal care and DEFO in other populations. That has resulted in the development and design of specific compression garments to address the associated common ailments and/or conditions that women suffer in the postnatal period. However, definitive empirical evidence is lacking to determine the effectiveness, feasibility, and acceptability of DEFO as an appropriate intervention strategy for women in the postnatal periods to reduce pain and maintain daily activity.[9,14,20–22]

The objective of this study was to explore the effects of a specific DEFO ((SRC recovery shorts (ARTG188014), manufactured by SRC Health Pty Ltd, Port Melbourne, Australia)), as a non-pharmacological postpartum therapeutic intervention. Specifically, we aimed to evaluate the impact of women in the postnatal period wearing SRC recovery shorts on (1) pain, (2) functional capacity, and (3) quality of life during the first 8 weeks post-delivery.

Method

Study design

This prospective quasi-experimental controlled study involved two nonrandomized parallel groups—(1) compression shorts group (SSG) and (2) comparison group (CG)—and was conducted on the Gold Coast, Australia. Ethical approval was granted by the Queensland Health Office of Human Research Ethics Committee (HREC/14/QGC/180) and Bond University Human Research Ethics Committee (BUHREC: RO1800b).

It is important to note that a randomized control trial was initially presented for ethical approval; however, it was suggested by the ethics committee that a quasi-experimental controlled study was more favorable as it allowed postnatal women the opportunity to select their preferred group upon participation. Consequently, a prospective quasi-experimental study was designed with the use of a parallel comparison group to compare outcomes. The shorts group (SG) received standard physiotherapy care, broader health care as required, and wore SRC recovery shorts,[23] whereas the CG received standard physiotherapy and broader health care.

As per the criteria set out by the Australian Government Department of Health Therapeutic Goods Administration,[24] this study was not subject to registration under the clinical trial notification scheme or the clinical trial exemption as the DEFO used in this study did not involve "unapproved" therapeutic goods.

Participants and recruitment

Recruitment was conducted at a local university, a metropolitan hospital, and local maternity care providers on the Gold Coast, Australia, by means of advertising in maternity care providers' offices, social media portals, online and newspaper articles, and referrals from other participants. Participants were recruited from March 2015 to April 2018. Women fulfilled the inclusion criteria to participate if they were aged 18–50 years, had recently undergone a cesarean section or a vaginal delivery within the last ten days, had no or less than 6 cm DRAM (measured by their postnatal care provider), and were complaining of LBP, PGP, pelvic swelling and/or edema, pelvic floor dysfunction, or urinary and/or fecal incontinence. Women were excluded if they presented with a ≥ 6 cm DRAM, a known venous thrombus or deep vein thrombosis, thrombophlebitis, bleeding of the varicose vein, pulmonary embolism, wound infection, severe hemorrhaging, infection vaginal or rectal prolapse, an intellectual or mental impairment, or pregnancy. Figure 1 provides the participant flow diagram. The authors acknowledged the considerable additional requirements of caring for a newborn infant and felt that the dropout rate would be substantial.[25–29]

A sample size of 100 was deemed to give a statistical power of 80%, which was necessary to conduct a multivariable linear regression with four predictors (treatment group, baseline score, age, and delivery type) to detect a medium effect size (Cohen's $f^2 = 0.15$) and significance level of 0.05 for the outcomes. We aimed to recruit 180 patients to allow for at least 40% dropouts or losses to follow up. A subgroup of the SSG was formed after matching the participants' characteristics with the CG and used in the primary analysis.

To ensure consistency in the recruitment process, all physiotherapists and postnatal care providers at the recruitment facilities attended four information sessions lead by the chief investigator (J.S.)) to provide the recruitment team with an explanation of the study, procedures for recruitment, the consent and enrollment processes, the DEFO and how to fit correctly, and the opportunity to address any questions and/or concerns.

Intervention

After the women had provided informed written consent and were enrolled in the study, they were given the choice to join whichever group they wished to participate in. Each participant was allocated a participation code to access the online survey (discussed below). The SG was provided with a DEFO, specifically the SRC recovery shorts[23] combined with standard postnatal physiotherapy and broader health care. The SRC recovery shorts (SRC Health Pty Ltd, Melbourne, Australia; AUD$189.00, www.srchealth.com) are made from a breathable warp knit fabric that has a top panel covering the torso that provides support to the abdominal area and lower back as well as a lower front panel (gusset) to provide gentle and constant compression to the pelvic floor area.[23] These shorts are available in nine sizes, ranging from triple extra-small to triple extra-large.

Physiotherapists measured and fitted the DEFO, explained to the participants in the SSG how to wear the garment, alter its size as required using the adjustable tabs on each side, and advised participants to wear the DEFO daily for a minimum of 8 h per day during the awake period from the date of recruitment for a total of 8 weeks. The participants were expected to wash the SRC recovery shorts (SRC Health Pty Ltd.,[23] Port Melbourne, Australia) as needed (every three days at minimum) to enable the participant to wear them daily over usual underwear. Participant DEFO education was provided by the physiotherapist to ensure correct fitting. The DEFO shorts were to be firm around the pelvis, but not tight or restrictive, and needed to be comfortable.

The CG participants did not receive a DEFO at any time during the 8-week study. The CG received standard physiotherapy care and broader health care as needed.

Outcome measurements

Participants in the SG and CG completed a baseline questionnaire online which included general demographic
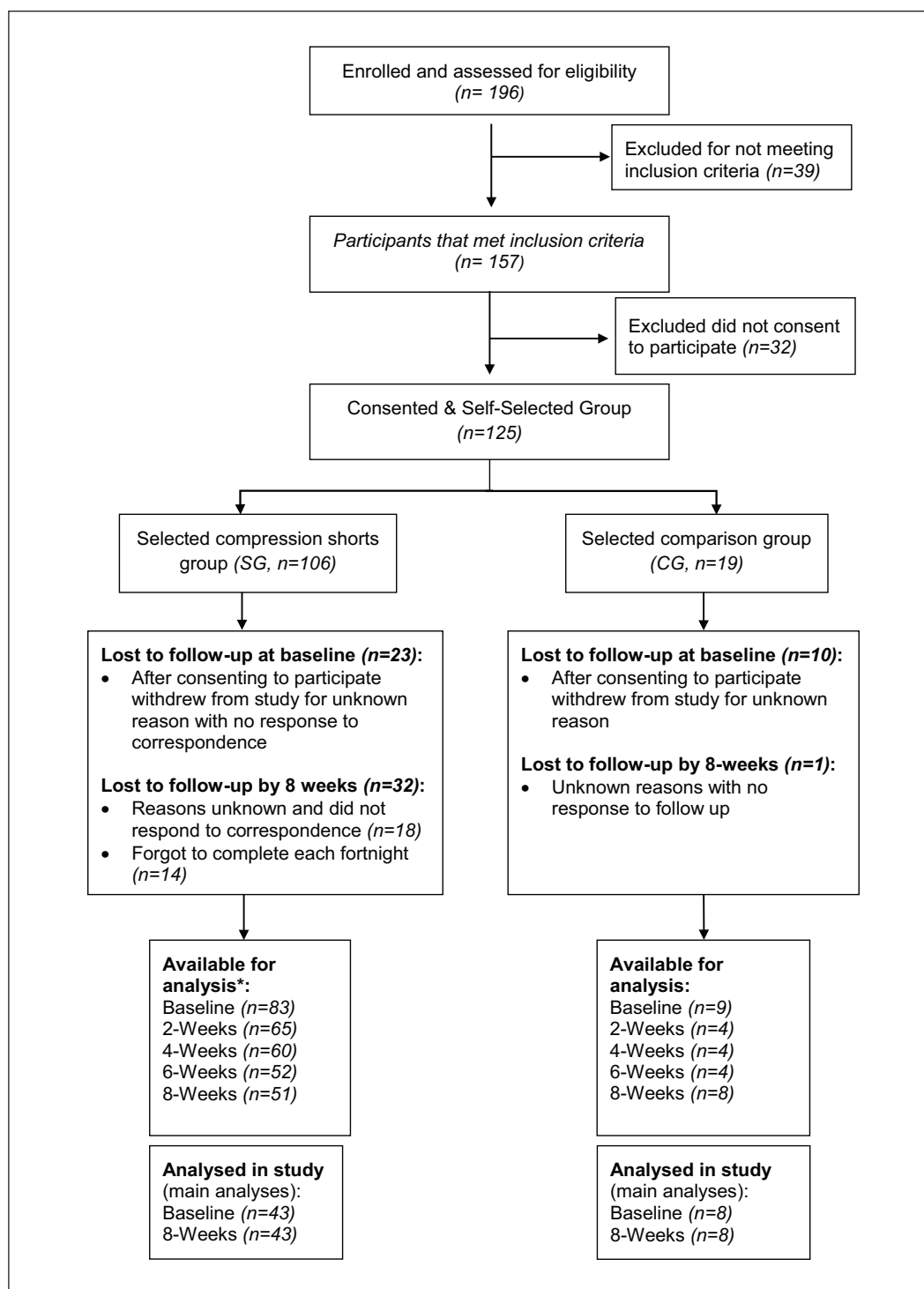
Figure 1. Participant recruitment flow diagram.
*All available data for the SG (*n* = 83) were used in the main and supplementary analyses. A subgroup SSG (*n* = 43) was determined by matching characteristics to the CG for the main analyses (matched by the potential confounding factors such as age and delivery type).

questions (i.e. identifying their group, age, delivery type (vaginal delivery—no tear, vaginal delivery—perineal tear, vaginal delivery—episiotomy, cesarean section—elective, cesarean section—emergency), number of days post-delivery, gravida/parity, DRAM (previous, prenatal,

or current), postpartum ailments and treatment received for ailments). The data were collected fortnightly and included general demographic questions and ailments experienced in the last fortnight and treatment received for ailments during that period. The SG group also recorded

the levels of compliance in wearing the DEFO commenting on hours worn per day, number of days worn per fortnight, and reasons for noncompliance, if any.

Primary outcome. The primary outcome measure for the online survey was the Numeric Pain Rating Scale (NPRS),[30] an 11-item scale, to quantify pain (0 was defined as "no pain" and 10 as "the worst pain").[30] A 2-point difference in scores is considered the minimal clinically important difference (MCID).[31]

Secondary outcomes. Secondary outcome measures were the Roland Morris Disability Questionnaire (RMDQ),[32] Pelvic Floor Impact Questionnaire–7 (PFIQ-7),[33] and short form health survey (SF36).[34,35] To determine the impact LBP has on the functional activities of daily living and mobility, the RMDQ, a 24-item self-report questionnaire, was implemented where 0 was defined as "no disability" and 24 as "severe disability."[32] A 3-point change in scores if the participant scores are ≥ 7 or a change of 30% if the participant scores < 7 is considered an MCID on the RMDQ.[36]

To determine the influence of the pelvic floor function or dysfunction on the participants' daily activities, emotional health, and quality of life, the PFIQ-7 was utilized which rates a perceived impact on a scale of 0 (lowest) and 300 (highest).[33] The MCID was defined as a 36 point or a 12% difference in scores as per the previously published thresholds.[33]

To determine the effect on the quality of life, the SF36[34,35] was used. It is a 36-item questionnaire that measures across eight domains that are physically and emotionally based.[34,35,37] Each domain is scored independently where 0 is defined as "a very low-level quality of life/worst possible level of functioning" and 100 as "the highest or best possible level of functioning/high-level quality of life."[34,35] A 4-point difference is needed to show an MCID.[38]

Data analysis

A statistical analysis was conducted using IBM SPSS software (Version 25) and R version 3.4.2. Descriptive statistics were reported as mean (SD) for normally distributed continuous variables, and median (IQR) for skewed variables. Categorical variables were summarized using counts (%). The assumption of normality for outcome measures was assessed with normal Q–Q plots, histograms, and the Shapiro–Wilk test. The baseline characteristics for the outcomes for the treatment groups were compared using independent *t*-tests or Mann–Whitney U tests. Unadjusted analyses were carried out to assess paired differences between baseline and week 8 within the treatment groups for the NPRS and RMDQ outcomes, using the paired *t*-test and the Wilcoxon signed-rank test,

respectively. Between-group differences at week 8 and in the change from baseline were tested with independent *t* or Mann–Whitney U tests. Multivariable linear regression was used to examine the effect of treatment group on the outcome, after adjusting for baseline score, age, and delivery mode. The percentage of women who achieved the minimal clinically important difference (MCID) within each treatment group was computed.

Supplementary analyses included linear mixed models on all women in the SG who were measured at 4 timepoints at follow-up, to model the change in NPRS and to assess the effect of potential confounders, age, and delivery mode, after controlling for baseline score. Polynomial models up to the cubic term were investigated but linear models were deemed sufficient. Random effects included random intercepts for the women for changeover time, which was treated as a factor. Interaction terms were not assessed. The final models were fitted using the maximum likelihood estimation method. Residual diagnostics were used to check distributional assumptions.

The criterion for statistical significance was set at the 0.05 level for all outcome measures and supplementary analyses.

Results

Primary analysis

Participant recruitment and characteristics. Among the 125 participants who consented to participate, 106 chose to participate in the SSG and 19 in the CG. Twenty-three women in the SG and 10 in the CG were lost to follow up at baseline, after consenting to participate. These women withdrew from the study for unknown reasons with no response to correspondence. The data for four women in the CG were incomplete with all women reporting outcomes at initial and 8 weeks, and four women providing data at all timepoints. By the final timepoint, a further 32 participants were lost to follow-up in the SG groups and one in the CG (unknown reasons, did not respond to correspondence or forgot to complete each fortnight). All available data for the SG (*N*=83) were used in the primary and supplementary analyses. A subgroup of the SSG (*n*=43) with characteristics matching the CG (matched on age and delivery type) were used in the main analyses (see Figure 1). No adverse events were reported during this study.

Demographic characteristics were comparable between the two groups as described in Table 1. Following delivery, DRAM was reported in similar proportions (about 37%) in the SSG and the CG, and thus it was excluded as a confounding factor for analysis. The mean (SD) size of DRAM following delivery in those that reported current DRAM identified at baseline in the SSG was 2.50 cm (0.71) and 4.50 cm (2.12) in the CG. Common postpartum complaints reported at baseline are shown in Table 2.

Table 1. Baseline demographic and clinical characteristics for the postnatal participants' data are counts (*n* (%)) unless otherwise specified.

Characteristics	Compression SSG[a] (*n*=43)	CG[b] (*n*=8)	Compression SG[a] (*N*=83)
Age Category			(*n*=78)
21–29	11 (25.6)	4 (50.0)	20 (25.6)
30–33	16 (37.2)	3 (37.5)	27 (34.6)
34–37	16 (37.2)	1 (12.5)	24 (30.8)
38–45	0 (0.0)	0 (0.0)	7 (8.8)
			(*N*=83)
Days post-delivery mean(SD)	7.1 (3.2)	8.5 (3.1)	6.9 (3.3)
Delivery type			(*n*=79)
vaginal delivery- no tear	5 (11.6)	2 (25.0)	12 (15.2)
vaginal delivery- perineal tear	11 (25.6)	2 (25.0)	24 (30.4)
vaginal delivery- episiotomy	8 (18.6)	2 (25.0)	13 (16.5)
cesarean section- emergency	6 (13.9)	2 (25.0)	8 (10.1)
cesarean section- elective	13 (30.2)	0 (0.0)	22 (27.8)
			(*n*=79)
First pregnancy, Yes	26 (60.5)	5 (62.5)	41 (51.9)
Gravida			
0	26 (60.5)	5 (62.5)	41 (49.4)
1	10 (23.3)	1 (12.5)	19 (22.9)
2	4 (9.3)	1 (12.5)	8 (9.6)
3	2 (4.6)	1 (12.5)	6 (7.2)
4	1 (2.3)	0 (0.0)	3 (3.6)
5	0 (0.0)	0 (0.0)	1 (1.2)
8	0 (0.0)	0 (0.0)	1 (1.2)
Parity			
0	26 (60.5)	5 (62.5)	42 (50.6)
1	4 (9.3)	1 (12.5)	10 (12.0)
2	8 (18.6)	1 (12.5)	15 (18.1)
3	4 (9.3)	0 (0.0)	10 (12.0)
4	1 (2.3)	1 (12.5)	1 (1.2)
7	0 (0.0)	0 (0.0)	1 (1.2)
Current DRAM, Yes	16 (37.2)	3 (37.5)	11 (13.9)
Prenatal DRAM, Yes	29 (67.4)	4 (50.0)	48 (61.5)
			(*n*=78)
NPRS, mean (SD)	4.5 (1.9)	4.6 (2.7)	4.6 (2.0)

SSG, Shorts Group Subgroup; CG, Comparison Group; SG, Shorts Group; DRAM, Diastasis of the rectus abdominis muscle; NPRS, Numeric Pain Rating Scale.
[a]SSG (SSG- subgroup of the SG, which was matched to the CG by age and delivery type) and SG wore SRC Recovery Shorts (SRC Health Pty Ltd., Port Melbourne, Australia) and received usual care.
[b]CG received usual care only.

Acceptability of DEFO. On average, the SSG wore the DEFO 9 out of 14 days and reported reasons for non-compliance such as "forgot," "garment needed to be washed," and "pressure on incision." The SSG wore the DEFO on average 11 h per day (SD of 4.8 h) between the fortnightly timepoints (baseline to 2 weeks, 2 to 4 weeks, 4 to 6 weeks, and 6 to 8 weeks) meeting the compliance goal of a minimum of 8 h per day. Similarly, participants in the SSG reported the same reasons for not wearing the shorts for additional hours. In the final fortnight time frame (6 to 8 weeks), SSG participants wore the compression shorts for a mean (SD) of 6.8 (4.7) days per fortnight, for an average of 9.6 (4.4) h per day.

Effectiveness of DEFO. Table 3 shows the summary statistics for the raw data and change scores for outcome measures; there were no significant differences between the treatment groups at baseline for NPRS, RMDQ, PFIQ-7, SF-36 PCS, and SF-36 MCS. Table 4 presents the estimated regression coefficients from the multivariable linear regression to evaluate the effects of the DEFO at 8 weeks after adjusting for baseline, age and delivery type covariates for all outcome measures. Normality of residuals was met for the NPRS, the UIQ-7 (subscale of the PFIQ-7 questionnaire), the SF-36 PCS and MCS. PFIQ-7 and two out of the three subscales (CRAIG-7 and POPIQ-7) were transformed using natural logarithm to improve residual

Table 2. Frequencies (n (%)) of participants with specific postpartum ailments at baseline.

Postpartum ailment	Primary analysis		Supplementary analysis
	Compression shorts subgroup (*n* = 43)	Comparison group (*n* = 8)	Compression shorts group (*n* = 78)
Low back pain	19 (44.2)	2 (25.0)	37 (47.4)
Pelvic girdle pain	11 (25.6)	1 (12.5)	19 (24.4)
DRAM	16 (37.2)	3 (37.5)	11 (14.1)
Incisional/Wound pain	25 (58.1)	4 (50.0)	35 (44.9)
Swelling of perineum	16 (37.2)	3 (37.5)	23 (29.5)
Swelling of vagina	12 (27.9)	4 (50.0)	21 (26.9)
Perineal pain	14 (32.6)	1 (12.5)	24 (30.8)
Vaginal pain	6 (13.9)	2 (25.0)	13 (16.7)
Vulval varicosities	1 (2.3)	0 (0.0)	3 (3.8)
Genital tract problems	1 (2.3)	0 (0.0)	1 (1.3)
Sexual problems	1 (2.3)	0 (0.0)	1 (1.3)
Urinary incontinence	7 (16.3)	2 (25.0)	13 (16.7)
None	2 (4.6)	0 (0.0)	7 (9.0)
Other[a]	2 (4.6)	6 (75.0)	10 (12.8)

SSG, Shorts Group Subgroup; DRAM, Diastasis of the rectus abdominis muscle.
[a]Other included self-reported heaviness in pelvis, excessive fluid retention, hematoma around perineal area, hemorrhoids, sore coccyx, stitches and numbness in buttocks.

Table 3. Raw data and change scores for NPRS, RMDQ, PFIQ-7, SF-36 PCS, and SF-36 MCS.

	Compression Shorts Subgroup SSG (*n* = 43)	Comparison Group CG (*n* = 8)	*p*-values
NPRS mean (SD)			
Baseline	4.51 (1.93)	4.63 (2.67)	.89
8 weeks	1.42 (1.56)	2.63 (1.85)	
Change score[a]	−3.09 (2.20)	−2.00 (1.41)	
RMDQ median (IQR)			
Baseline	1.00 (1.00, 23.00)	1.00 (1.00, 4.00)	.55
8 weeks	1.00 (1.00, 5.00)	1.00 (1.00, 1.00)	
Change score[a]	0.00 (−22.00, 1.00)	0.00 (−3.00, 0.00)	
PFIQ-7 median (IQR)			
Baseline	24.00 (0.00, 238.00)	12.50 (0.00, 125.00)	.64
8 weeks	0.00 (0.00, 86.00)	0.00 (0.00, 50.00)	
Change score[a]	−19.00 (−228.00, 14.00)	−12.50 (−75.00, 67.75)	
SF-36 PCS mean (SD)			
Baseline	48.79 (20.38)	47.50 (26.78)	.88
8 weeks	78.70 (17.59)	75.63 (18.94)	
Change score[a]	29.91 (18.80)	28.12 (20.12)	
SF-36 MCS mean (SD)			
Baseline	58.56 (19.12)	50.88 (26.99)	.33
8 weeks	72.21 (21.26)	76.25 (12.61)	
Change score[a]	13.65 (23.06)	25.37 (22.21)	

NPRS: Numeric Pain Rating Scale; RMDQ: Roland Morris Disability Questionnaire; PFIQ-7: Pelvic Floor Impact Questionnaire short form-7; SF-36 PCS: SF-36 Physical Component Summary; SF-36 MCS: SF-36 Mental Component Summary; SSG: Shorts Group Subgroup; CG: Comparison Group; IQR: Interquartile Range.
[a]Negative change score indicates a reduction in pain or disability or a reduction in the perceived effect of pelvic dysfunction on the quality of life or an increase in the level of functioning from baseline.

normality. Figure 2 shows paired data plots showing change patterns from baseline to 8 weeks in NPRS and RMDQ. Figure 3 demonstrates a comparison of the percentage of women within each group (SSG and CG) for each outcome measurement at 8 weeks from baseline that achieved MCID. Women in both groups achieved MCID

Table 4. Estimated regression coefficients from the multivariable linear regression to show the effect at week 8 of wearing compression shorts (SSG, $n = 43$) when compared to the comparison group (CG, $n = 8$) for all outcome measures, after adjusting for baseline covariates.

Variable	Regression coefficient	95% Confidence interval	R^2	p-value
NPRS				
Constant	1.33	−.12, 2.79	.19	.072
Group[a]	−1.17	−2.35, −.001		.050
Baseline	0.28	.07, .49		.011
PFIQ-7[b]				
Constant	.72	−.26, 1.70	.36	.145
Group[a]	−.57	−1.60, .452		.266
Baseline	.02	.01, .02		.000
UIQ-7				
Constant	5.63	.50, 10.75	.38	.032
Group[a]	−5.49	−10.76, −.23		.041[c]
Baseline	.18	.10, .26		.000
CRAIG-7[b]				
Constant	1.21	.19, 2.23	.22	.020
Group[a]	−.13	−.89, .62		.728
Baseline	.02	.002, .03		.021
Type of delivery[d]	−.60	−1.17, −.03		.038[c]
POPIQ-7[b]				
Constant	1.02	.28, 1.76	.54	.008
Group[a]	−1.27	−2.04, −.49		.002[c]
Baseline	.03	.02, .04		.000
SF-36 PCS				
Constant	54.17	39.77, 68.58	.30	.000
Group[a]	2.49	−9.19, 14.17		.670
Baseline	.45	.25, .65		.000
SF–36 MCS				
Constant	57.90	38.68, 77.12	.14	.000
Group[a]	−6.81	−21.71, 8.09		.363
Baseline	.37	.09, .63		.009

All outcome measures were adjusted for baseline, age category, and type of delivery. Baseline was significant for all outcome measures.
SSG: Shorts Group Subgroup; CG: Comparison Group; NPRS: Numeric Pain Rating Scale; PFIQ-7: Pelvic Floor Impact Questionnaire short form-7; UIQ-7: Urinary Impact Questionnaire- 7; CRAIG-7: Colorectal-Anal Impact Questionnaire; POPIQ-7: Pelvic Organ Prolapse Impact Questionnaire; SF-36 PCS: SF-36 Physical Component Summary; SF-36 MCS: SF-36 Mental Component Summary.
[a]Group was coded as 0 = CG and 1 = SSG. A negative regression coefficient indicates a lower change score for the SSG, which indicates a more favorable result for the SSG when compared to the CG.
[b]Outcome was transformed using $Ln(x + 1)$.
[c]Statistically significant at the 0.05 level.
[d]Type of delivery was coded as 0 = vaginal delivery and 1 = cesarean section.

for all outcome measures, however in each instance, with the exception of the SF-36 MCS, women in the SSG demonstrated a greater change.

Pain. Unadjusted analyses showed that the SSG reported a larger reduction in mean (SD) NPRS pain score (−3.09 (2.20)) from baseline, compared to the CG (−2.00 (1.41)) at 8 weeks from baseline. The SSG achieved MCID, with both clinically and statistically significant differences achieved for NPRS (Mean difference: −3.09; 95%CI: −3.77, −2.42, $p < 0.001$) (Figure 2). Adjusted analyses using multivariable linear regression showed that there was insufficient evidence of a between group difference in NPRS change score at 8 weeks when comparing the SSG and the CG (−1.17; 95%CI: (−2.35, −0.01), $R^2 = .19$, $p = .050$).

Functional capacity. Multivariable linear regression RMDQ results are not reported as normality of the residuals were skewed and did not improve when transformations were applied. Unadjusted analyses of the week 8 scores and change from baseline to 8 weeks showed that there was no significant difference between the groups ($p = 0.77$ and $p = 0.67$, respectively). The SSG had a larger clinical improvement (59.7%) than the CG (33.3 %). A significant difference was observed within
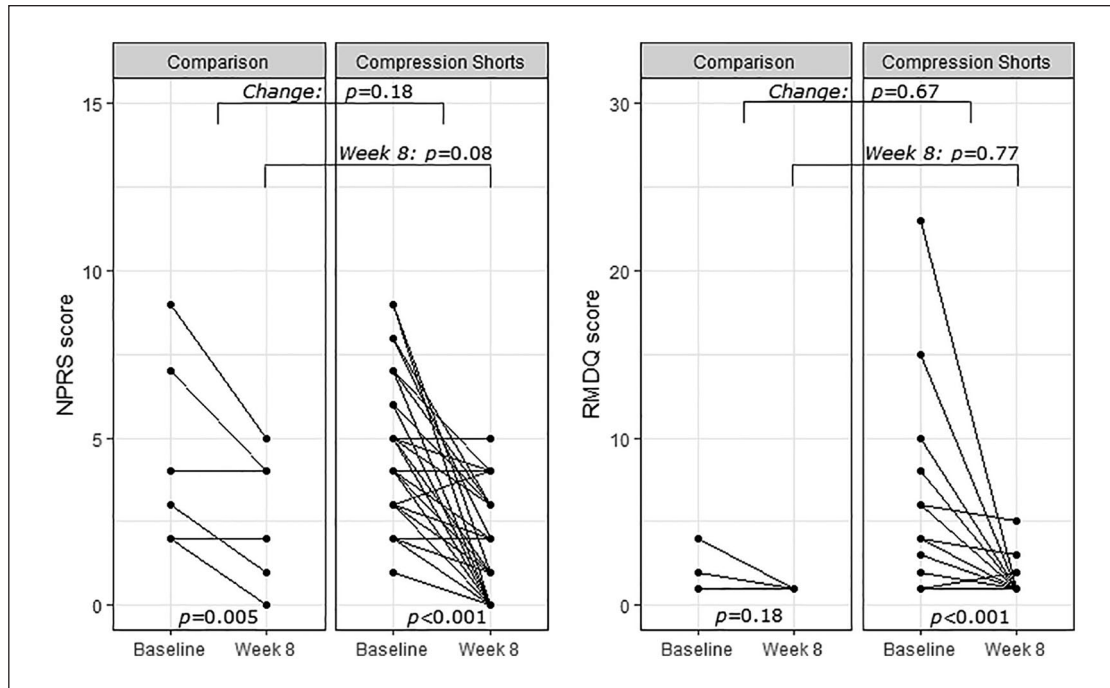
Figure 2. Paired data plots showing change patterns from baseline to week 8 in NPRS and RMDQ in the Comparison Group and Compression Shorts (Subgroup of Compression Shorts Group (SSG)). Clinically and statistically significant differences were achieved within the compression shorts group for NPRS (mean difference: −3.09; 95%CI: −3.77, −2.42, $p < 0.001$).
NPRS: Numeric Pain Rating Scale; RMDQ: Roland Morris Disability Questionnaire.

the SSG for RMDQ ($p < 0.001$), while there was none in the CG (see Figure 2).

Table 4 shows the effects of wearing compression shorts at week 8 of the intervention study. Adjusted analyses with multivariable linear regression at 8 weeks showed that UIQ-7 and POPIQ-7 (subscales of PFIQ-7) were significantly different between SSG and CG suggesting that women in the SSG experienced less impact of urinary incontinence and bladder function (i.e. pelvic organ prolapse) on quality of life ($p = .041$ and $p = .002$, respectively), the SSG scoring 72.8% lower than the CG on the POPIQ-7. The difference between the groups in CRAIG-7 (subscale of PFIQ-7) and PFIQ-7 at 8 weeks was not statistically significant using multivariable linear regression after transformation. The CRAIG-7 subscale did show delivery type was statistically significant ($p = .038$), indicating that vaginal deliveries had a worse outcome as those participants that experienced a vaginal delivery scored 46.2% higher on the CRAIG-7 questionnaire compared to cesarean section delivery. Neither group demonstrated a MCID for the subscales of the PFIQ-7 (UIQ-7, CRAIGQ-7 and POPIQ-7). The SSG attained a MCID for the PFIQ-7 (reduction of 43.0 points), whereas the CG (reduction of 27.6 points) did not.

Quality of life. SF-36 PCS and SF-36 MCS were not significantly different between SSG and CG at 8 weeks when adjusted for baseline, age and delivery type covariates. Both SSG and CG groups achieved MCID on the SF-36 PCS, with an improvement of 29.9 and 28.1 points, respectively. Likewise, the improvement scores were above the MCID on the SF-36 MCS for SSG and CG with 13.7 and 25.3 points being recorded, respectively.

Supplementary analyses of participants within the SG only

Participant characteristics. The data from all 83 participants available for analysis were included in the supplementary analyses (please see the demographic characteristics in Table 1). The participants clinically presented at baseline with common postpartum ailments (see Table 2). On average, the SG wore the DEFO 9 days out of 14 days, 11.56 h per day (SD 0.77 h) between the fortnightly timepoints and reported similar reasons for non-compliance as in the main analysis, such as "forgot," "garment needed to be washed," and "pressure on incision."

Longitudinal analyses of NPRS were conducted using linear mixed models for all 83 women in the SG to determine if time, age, and delivery type were contributors to the effectiveness of SRC recovery shorts on the participants' perceived levels of pain, after adjusting for baseline score. A total of 34% of the variance in any individual NPRS score can be explained by the properties of
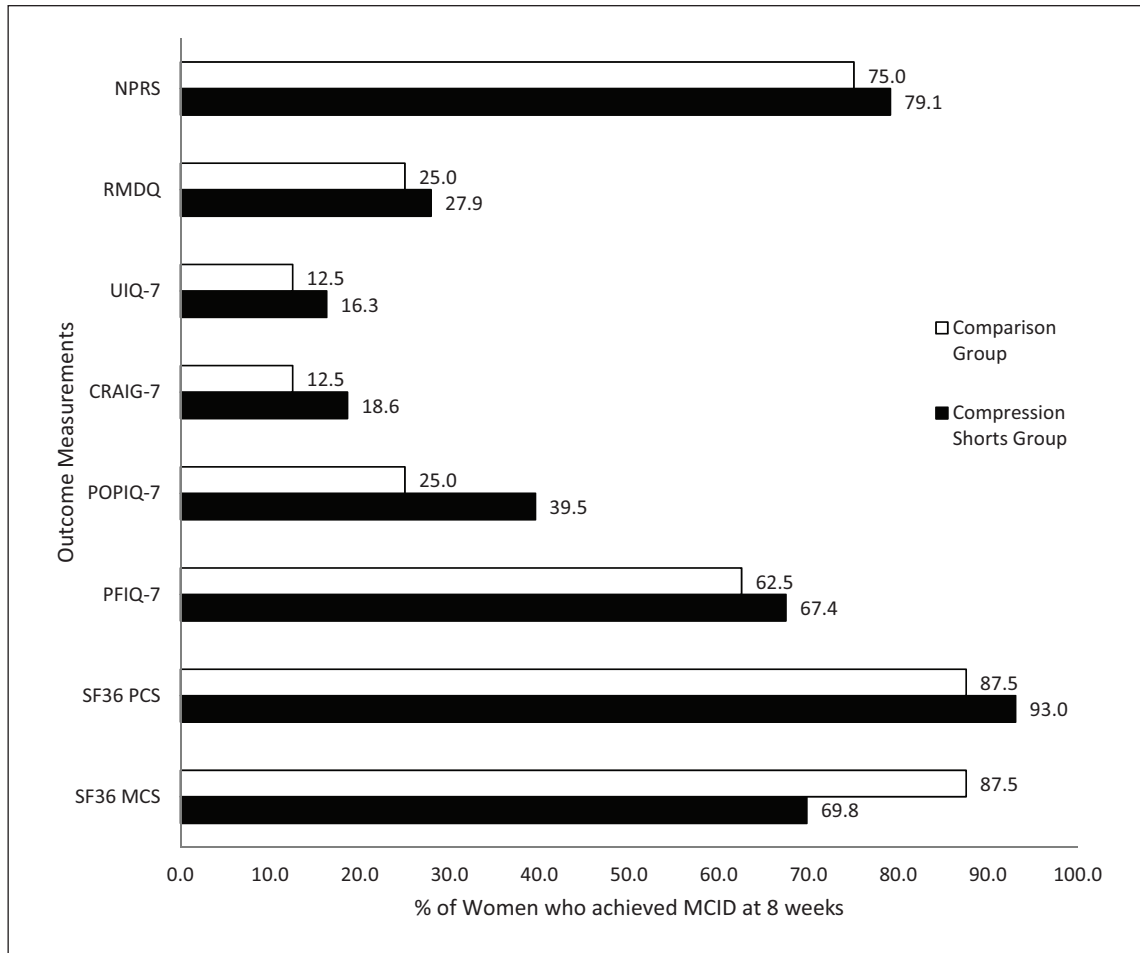
Figure 3. Percentage (%) of women within each group, compression shorts subgroup (SSG) and comparison group (CG), who achieved MCID for each outcome measure at 8 weeks.
NPRS: Numeric Pain Rating Scale; RMDQ: Roland Morris Disability Questionnaire; PFIQ-7: Pelvic Floor Impact Questionnaire short form-7; UIQ-7: Urinary Impact Questionnaire- 7; CRAIG-7: Colorectal-Anal Impact Questionnaire; POPIQ-7: Pelvic Organ Prolapse Impact Questionnaire; SF-36 PCS: SF-36 Physical Component Summary; SF-36 MCS: SF-36 Mental Component Summary.

the individual who provided the rating. The linear mixed models showed that time was a statistically significant predictor for the NPRS score, while age and delivery type were not, after adjusting for baseline. For example, the mean NPRS score at 2 weeks follow-up for women aged 21–29 who had a cesarean section and reported a baseline score of 5 was 3.26. The score was significantly lower at four weeks (mean difference: -1.28, 95% CI: -1.72, -0.84, $p < 0.001$), 6 weeks (mean difference: -1.97, 95% CI: -2.43, -1.51, $p < 0.001$), and 8 weeks (mean difference: -2.12, 95% CI: -2.58, -1.66, $p < 0.001$) when compared to follow-up at 2 weeks. Figure 4 visually displays a decrease in pain over time at follow up by showing the distributions of NPRS scores over time for the SG.

Discussion

This study aimed to determine the effects of a specific DEFO as an immediate non-pharmacological postpartum
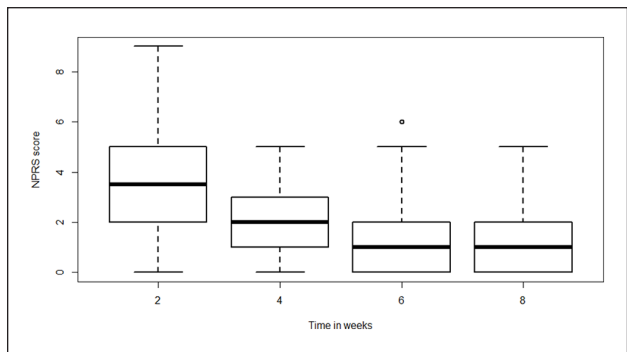
Figure 4. Boxplots showing the distributions of actual NPRS scores over time for 83 women who wore compression shorts postnatally (SG). Results of the linear mixed model applied to the dataset showed that all NPRS scores at follow-up were significantly different ($p < 0.001$) when compared with scores at 2 weeks, after adjusting for baseline, age, and delivery type.
NPRS: Numeric Pain Rating Scale.

therapeutic intervention by evaluating the effectiveness of a DEFO to improve pain, functional capacity, and quality of life from common postnatal ailments compared to not wearing a DEFO. Overall, this study demonstrated a larger reduction in mean (SD) pain scores in those participants that wore the DEFO and statistically significant differences between groups in some areas of functional capacity (UIQ-7 and POPIQ-7). However, insufficient evidence of a statistical difference was revealed in the secondary outcome measures that evaluated functional capacity (RMDQ, PFIQ-7 (CRAIG-7)) and quality of life (SF-36 PCS and SF-36 MCS). Primary (NPRS) and secondary measures (RMDQ, PFIQ-7 and SF-36 PCS) revealed clinical significance with the SSG achieving MCID.

Pain

Pain from common postpartum ailments following delivery is a well-established problem in research literature and in the clinical setting; yet, investigations examining effective non-pharmacological postpartum therapeutic interventions have not received much attention in the literature.[13]

Unadjusted analyses demonstrated an improvement in NPRS scores for the SSG and larger improvement compared to the CG. There was insufficient evidence of a statistically significant difference between groups. However, a larger sample size in the CG would have raised the power of the study and potentially provided sufficient evidence of a difference. These results suggested that although statistical significance was not found, clinical importance for the SSG was demonstrated which suggests that clinically the use of commercially designed DEFO for postpartum pain may be of benefit. Our results align with previous research[18,19,39–41] that discuss how a larger reduction of pain can be observed for women following delivery by using DEFO during postnatal care compared to medication, exercise, and patient education.

Functional capacity

No statistical differences were seen between the groups with most scores equaling 1 at baseline and 8 weeks in the SSG and the CG regarding functional capacity scores on the RMDQ. This leads to questions regarding the validity of the RMDQ in the immediate post-delivery period. RMDQ is designed to assess the impact LBP has on the functional capacity of an individual; therefore, if the area of impact causing greater pain has shifted to other areas based on delivery, this tool will not accurately describe such impact. The larger clinical improvements observed in the SSG may be because the mechanism of action of the DEFO (i.e. location of compression) could possibly simulate the co-contraction of the transversus abdominus and the multifidus which may have a beneficial effect on

reducing LBP as suggested in the previously published research.[11,15,18,19,41]

The use of the PFIQ-7 (questions 1–4) is perhaps a better choice to evaluate the impact of common postnatal ailments on females' functional capacity following delivery because in previous research it was demonstrated that PFIQ-7 showed a significant association between women's symptoms and their pelvic floor condition.[33] From a clinical viewpoint we can understand how providing women with constant and gentle compression in the area of common postpartum pain or ailments can have a positive effect on their functional capacity as it can result in a feeling of support and security.

Quality of life

Quality of life, reflected in the PFIQ-7 (questions 5–7) and the SF-36 assessments, were both found to improve from baseline to 8 weeks. The CG did not achieve the MCID on the PFIQ-7 in comparison to the SSG that achieved a MCID. When considering these results, it would be beneficial to consider the findings of the PFIQ-7 more informative of the emotional well-being and mental health status of the participants because the PFIQ-7 questionnaire is a specific outcome measure that focuses on the pelvic region dysfunctions and the effects it has on an individual's emotional and psychological well-being. In contrast, the SF-36 is a generic or global outcome measure designed to examine a person's perceived health status.

Although statistically significant differences are important when comparing groups to determine the effectiveness of a specific intervention, clinically important differences are also necessary to consider as they are perhaps more directly reflective of individuals' perception. Woolhouse et al.[2] discussed the idea that pregnancy, delivery, and the postnatal phase should be regarded as a major life transition for women and a range of emotional, physical, and interpersonal challenges are associated with these experiences. Therefore, as women's perceptions of these experiences vary, postnatal care interventions should be adaptive, flexible, and individualized in order to maximize the postnatal health of the female to ensure that the choice of interventions considers equally the physical and emotional changes of the mother.[29,42]

Limitations

Given that this study was a prospective quasi-experimental controlled study, a more rigorous study design such as a prospective randomized controlled trial would enable stronger conclusions to be drawn. Small comparison group size reduced the power for analyses. The relatively high loss to follow-up limited the extent to which DEFO effectiveness could be determined. Future studies could consider identifying methodologies to evaluate the effects on

scar tissue healing at the incision site with compression applied via a DEFO. Although the results of this study should be considered with caution, the limitations of this study do not affect the clinical relevance. Further research is required using robust methodology to explore the effectiveness of DEFO in postnatal populations.

Conclusion

The main findings of this study indicate that the use of DEFO may assist to decrease pain scores and in turn limit the impact that postnatal complications have on women's functional capacity and quality of life. As the DEFO is a moderate expense and devoid of adverse events or side effects, this non-pharmacological therapeutic intervention may be a useful option for health care providers to suggest and educate women on postnatal care. This study was the first of its kind to explore the acceptability and impact of using DEFO as a therapeutic intervention in the postnatal period. Therefore, since the main findings in this study were clinically relevant and demonstrated good wear compliance, they may be used to inform current decision-making regarding the use of a DEFO in the postnatal period. The findings from this study can be used to support a larger-scale study that is more rigorous in design to statistically conclude the effectiveness of DEFO in postpartum care.

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