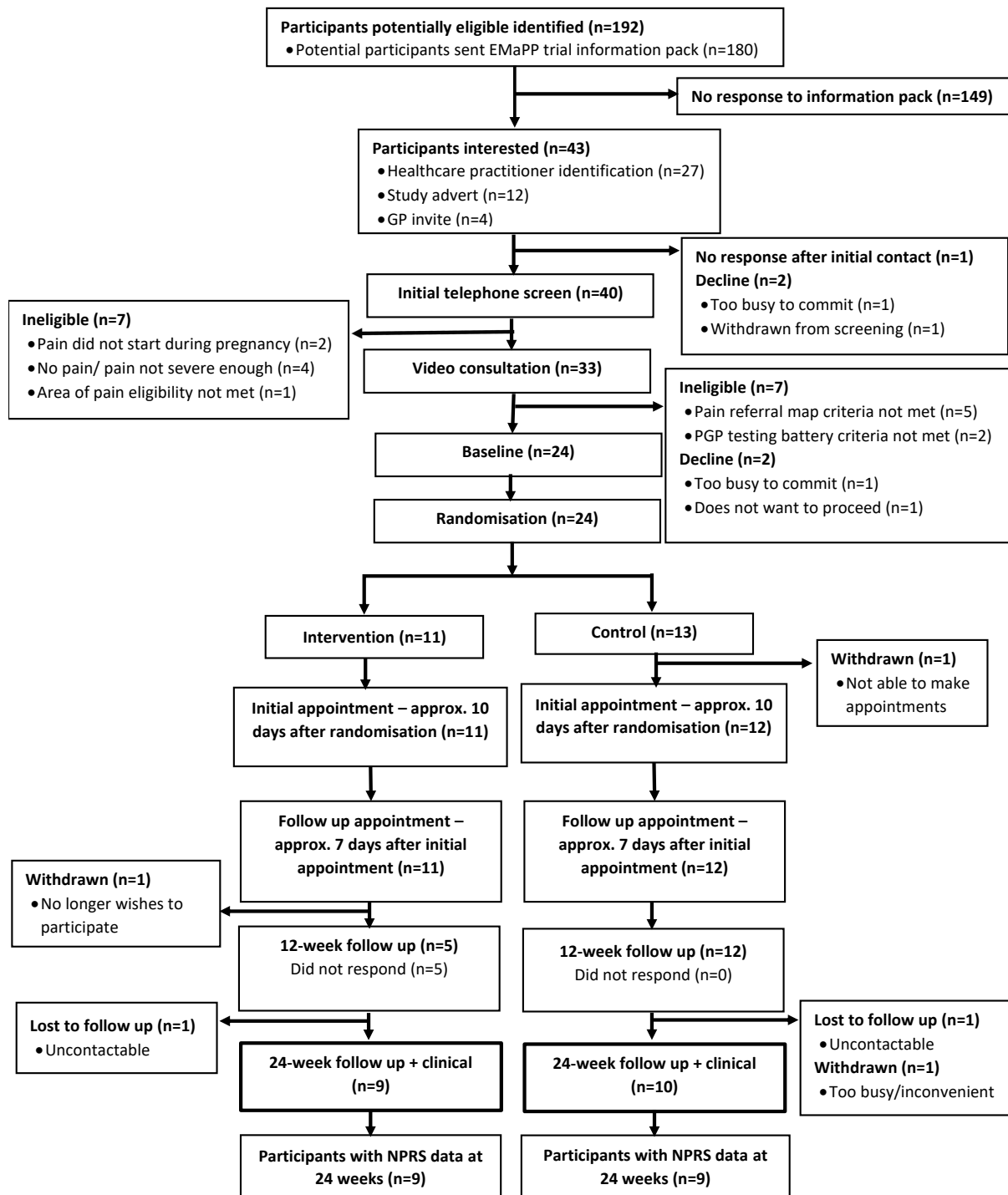


Basic results summary

Participant flow



Baseline characteristics

Table 2. Baseline characteristics			
		Group	
Factors	Overall	Intervention (n=11)	Control (n=13)
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)
Co morbid 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/m²) n: mean (SD) [range]	23: 27.0 (4.9) [17.4, 34.9]	10: 75.5 (16.5) [46.0, 98.0]	13: 73.4 (14.5) [52.6, 98.0]
Pregnancy details n: mean (SD) [range]			
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.

Adverse events

Description	Number of participants affected
Candida infections	2
Vulval cyst	1
Increased pain with exercise	1
Scarlet fever	1

Primary outcome measure: Change between baseline and 24 weeks on Numerical Pain Rating Scale (NPRS)

Variable	Question	Intervention	Control
NPRS	Worst level in the day (0 - 10)	8: -1.88 (1.96) -1.50 [-6.00, 0.00]	9: -2.56 (2.46) -2.00 [-6.00, 0.00]
	Average level in the day (0 - 10)	8: -2.13 (1.64) -2.00 [-5.00, 0.00]	9: -2.00 (2.00) -2.00 [-5.00, 1.00]
	Worst level in the night (0 - 10)	8: -2.63 (2.88) -1.50 [-9.00, 0.00]	9: -1.00 (2.35) -1.00 [-5.00, 2.00]
	Average level in the night (0 - 10)	8: -2.38 (2.67) -1.50 [-8.00, 0.00]	9: -1.89 (2.20) -2.00 [-5.00, 2.00]

Legend – NPRS Numerical Rating of Pain Scale

Secondary outcome measures

Table 5. Secondary outcome measures. Summary statistics at baseline, 24 weeks and change at 24 weeks					
Variable	Question	Timepoint	Both	Intervention	Control
PGQ - n: mean [SD] median [range]	(0 - 75)	Summary statistics at Baseline	24: 56.9 (16.6) 57.5 [27.8, 88.0]	11: 56.6 (18.0) 55.1 [27.8, 88.0]	13: 57.1 (16.0) 60.0 [29.3, 86.7]
		Summary statistics at 24 weeks	18: 37.0 (19.6) 35.3 [4.0, 70.8]	9: 33.2 (17.3) 30.7 [4.0, 59.7]	9: 40.8 (22.0) 40.0 [10.7, 70.8]
		Change at 24 weeks	18: -21.5 (17.1) -24.0 [-51.1, 6.7]	9: -23.5 (17.1) -24.0 [-51.1, 0.1]	9: -19.6 (17.9) -24.0 [-41.9, 6.7]
EPDS - n: mean [SD] median [range]	(0 - 30)	Summary statistics at Baseline	23: 9.7 (5.2) 10.0 [0.0, 21.0]	11: 10.6 (5.0) 10.0 [1.0, 18.0]	12: 8.8 (5.5) 7.5 [0.0, 21.0]
		Summary statistics at 24 weeks	16: 8.5 (5.8) 7.0 [0.0, 17.0]	8: 10.1 (4.9) 9.5 [5.0, 17.0]	8: 6.9 (6.6) 5.5 [0.0, 17.0]
		Change at 24 weeks	16: -1.0 (4.7) -3.0 [-7.0, 9.0]	8: 0.1 (5.8) -2.0 [-7.0, 9.0]	8: -2.1 (3.4) -3.0 [-7.0, 4.0]
ICIQ-UI SF - n: median (IQR) [min, max]	(0 - 21)	Summary statistics at Baseline	24: 4.0 (0.0, 7.0) [0.0, 11.0]	11: 4.0 (0.0, 6.0) [0.0, 10.0]	13: 4.0 (2.0, 8.0) [0.0, 11.0]
		Summary statistics at 24 weeks	15: 3.0 (0.0, 4.0) [0.0, 13.0]	8: 3.0 (0.0, 3.5) [0.0, 11.0]	7: 0.0 (0.0, 9.0) [0.0, 13.0]
		Change at 24 weeks	15: 0.0 (-3.0,2.0) [-6.0, 3.0]	8: 0.5 (-1.0,2.5) [-5.0, 3.0]	7: -3.0 (-5.0, 1.0) [-6.0, 2.0]
TSK - n: median (IQR) [min, max]	(17 - 68)	Summary statistics at Baseline	24: 41.0 (37.0, 44.0) [27.0, 48.0]	11: 41.0 (39.0, 46.0) [35.0, 47.0]	13: 40.0 (34.0, 42.0) [27.0, 48.0]
		Summary statistics at 24 weeks	15: 39.0 (32.0, 46.0) [25.0, 52.0]	8: 37.0 (32.5, 45.0) [28.0, 49.0]	7: 40.0 (30.0, 46.0) [25.0, 52.0]

		Change at 24 weeks	15: -1.0 (-6.0, 4.0) [-9.0, 4.0]	8: -2.0 (-7.5, -0.5) [-9.0, 4.0]	7: 1.0 (-3.0, 4.0) [-6.0, 4.0]
FREBAQ - n: mean [SD] median [range]	(0 - 36)	Summary statistics at Baseline	24: 12.8 (6.7) 13.5 [0.0, 29.0]	11: 14.3 (5.4) 15.0 [4.0, 24.0]	13: 11.6 (7.7) 12.0 [0.0, 29.0]
		Summary statistics at 24 weeks	15: 8.9 (6.1) 8.0 [0.0, 23.0]	8: 8.1 (5.3) 8.5 [0.0, 17.0]	7: 9.7 (7.2) 8.0 [3.0, 23.0]
		Change 24 weeks	15: -5.1 (4.5) -5.0 [-11.0, 7.0]	8: -6.8 (3.7) 8.0 [-11.0, -1.0]	7: -3.3 (5.0) -4.0 [-9.0, 7.0]
2PE - n: mean [SD] median [range]	Mean Painful area	Screening	20: 89.6 (33.8) 94.9 [10.2, 134.5]	9: 90.8 (35.0) 93.6 [40.2, 134.5]	11: 88.7 (34.4) 96.2 [10.2, 121.3]
		24 weeks	13: 85.7 (33.4) 90.2 [17.6, 135.7]	8: 75.2 (36.2) 72.7 [17.6, 121.3]	5: 102.5 (22.0) 97.4 [78.2, 135.7]
		Change at 24 weeks	10: -8.8 (29.2) -15.6 [-50.2, 44.3]	6: -14.2 (25.2) -15.6 [-50.2, 22.3]	4: -0.6 (36.7) -7.1 [-32.4, 44.3]
	Mean unpainful area	Screening	20: 87.9 (36.6) 96.8 [8.0, 149.5]	9: 92.2 (41.4) 95.7 [28.2, 149.5]	11: 84.4 (33.8) 97.9 [8.0, 131.6]
		24 weeks	13: 90.3 (36.8) 93.4 [4.4, 134.5]	8: 77.6 (40.7) 82.8 [4.4, 131.8]	5: 110.7 (17.7) 100.9 [93.4, 134.5]
		Change at 24 weeks	10: -0.3 (31.7) -9.9 [-34.7, 67.1]	6: -10.1 (22.9) -14.8 [-34.7, 32.7]	4: 14.3 (40.8) 10.6 [-31.1, 67.1]
	Normalised score painful	Screening	20: 25.3 (28.1) 20.9 [-12.1, 91.5]	9: 24.3 (29.2) 22.0 [-12.1, 66.5]	11: 26.1 (28.7) 19.9 [-1.0, 91.5]
		24 weeks	13: 28.6 (27.9) 24.9 [-13.1, 85.3]	8: 37.3 (30.2) 39.4 [-1.1, 85.3]	5: 14.6 (18.4) 18.9 [-13.1, 34.9]
		Change at 24 weeks	10: 7.3 (24.3) 13.0 [-36.9, 41.8]	6: 11.8 (21.0) 13.0 [-18.6, 41.8]	4: 0.5 (30.6) 5.9 [-36.9, 27.0]
	Normalised score unpainful	Screening	20: 26.7 (30.5) 19.3 [-24.6, 93.3]	9: 23.2 (34.5) 20.3 [-24.6, 76.5]	11: 29.7 (28.2) 18.4 [-9.7, 93.3]
		24 weeks	13: 24.7 (30.6) 22.1 [-12.1, 96.3]	8: 35.4 (33.9) 31.0 [-9.8, 96.3]	5: 7.7 (14.7) 15.9 [-12.1, 22.1]

Change at 24 weeks	10: 0.3 (26.4) 8.3 [-55.9, 28.9]	6: 8.4 (19.1) 12.3 [-27.3, 28.9]	4: -11.9 (34.0) -8.8 [-55.9, 25.9]
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