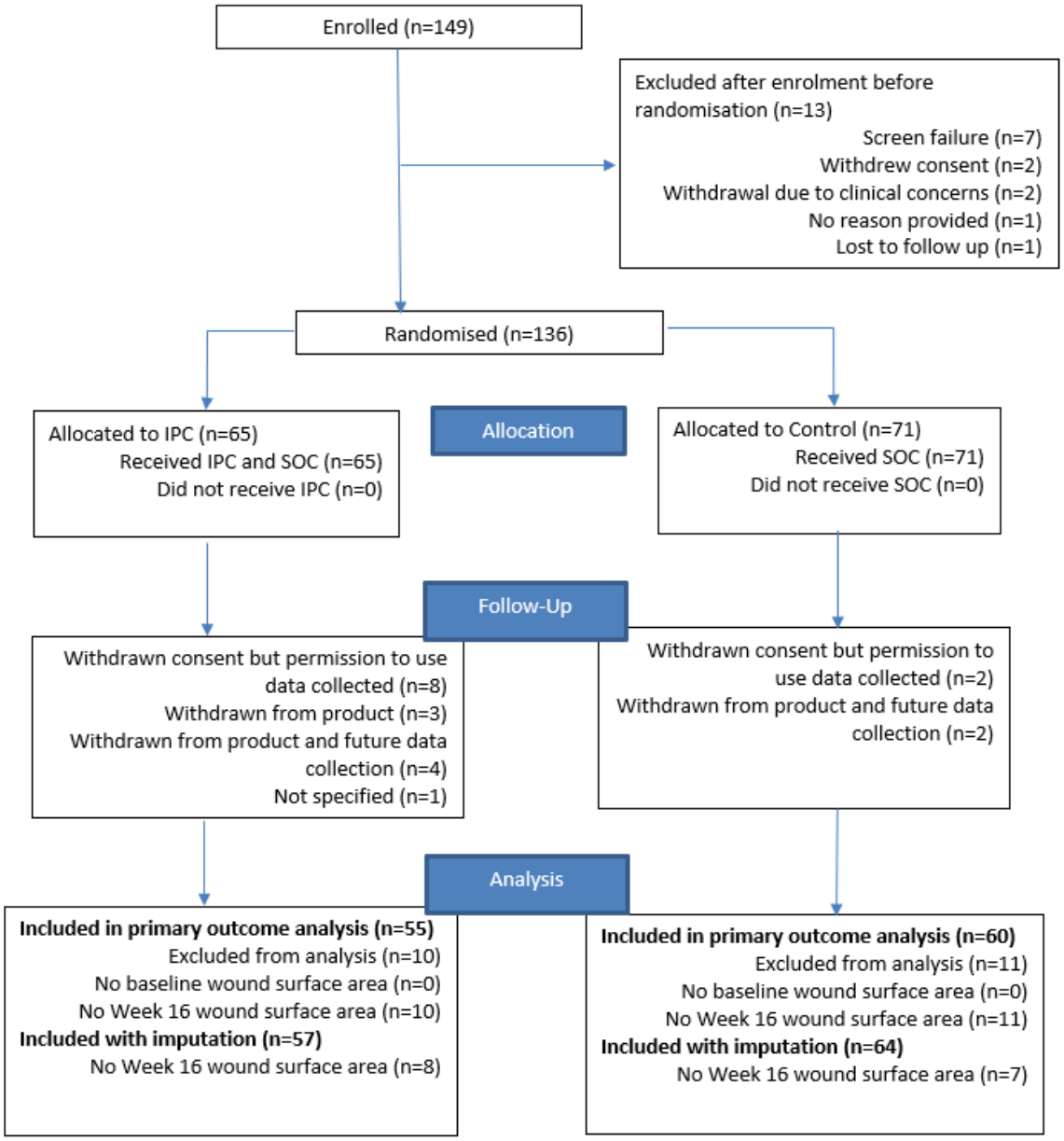
Basic results summary

Participant flow



Baseline characteristics			
	Randomised Treatment Group		
	Group A - IPC (N=65)	Group B - Control (N=71)	Total (N=136)
Age (years)			
Mean (SD)	66.8 (13.96)	65.2 (15.03)	66.0 (14.49)
Median	69.0	65.5	67.0
Range	30.0, 91.0	28.0, 93.0	28.0, 93.0
N	64	70	134
Missing	1	1	2
Weight (kg)			
Mean (SD)	91.5 (27.43)	95.7 (24.43)	93.7 (25.91)
Median	88.0	95.0	94.0
Range	41.3, 175.0	55.0, 167.8	41.3, 175.0
N	65	70	135
Missing	0	1	1
Height (cm)			
Mean (SD)	168.2 (21.52)	174.4 (12.00)	171.4 (17.43)
Median	170.6	174.0	172.5
Range	69.6, 205.0	152.0, 198.0	69.6, 205.0
N	65	71	136
Missing	0	0	0
Gender, n (%)			
Female	28 (43.1%)	30 (42.3%)	58 (42.6%)
Male	37 (56.9%)	41 (57.7%)	78 (57.4%)
Ethnic origin, n (%)			
Asian	3 (4.6%)	1 (1.4%)	4 (2.9%)
Black, African or Caribbean	6 (9.2%)	9 (12.7%)	15 (11.0%)
White	50 (76.9%)	56 (78.9%)	106 (77.9%)
Mixed or multi-racial	1 (1.5%)	0 (0.0%)	1 (0.7%)
Other	5 (7.7%)	5 (7.0%)	10 (7.4%)

Summary of outcome measures over 16-week study period by treatment group

Outcome measure	Characteristic	Parameter	Treatment Group		Difference between groups least square mean scores at Week 16 (95% CI)	P-value (Difference between groups at Week 16)
			Control	IPC		
Wound surface area (cm2)	Baseline	Mean (SD)	11.9 (13.1)	14.9 (19.7)	-	-
	Change from baseline at Week 16	Mean (SD)	4.4 (8.1)	6.7 (12.8)	1.3 (-1.5 to 4.1)	0.35
	Change from baseline at Week 16 - imputed data	Mean (SD)	3.5 (9.2)	5.8 (13.5)	1.3 (-1.5 to 4.2)	0.35
	Percent change from baseline at Week 16 (%)*	Mean (SD)	-13.7 (448.3)	48.7 (78.4)	-	-
	Percent change from baseline at Week 16 (%) - imputed data*	Mean (SD)	-17.9 (434.4)	42.6 (84.7)	-	-
Wound healing	Proportion of wounds healed	N (%)	13 (18.3%)	11 (16.9%)	-	-
Pain VAS	Baseline	Mean (SD)	3.1 (2.9)	3.7 (3.0)	-	-
	Change from baseline at Week 16	Mean (SD)	-1.4 (2.7)	-1.3 (2.8)	0.1 (-0.7 to 0.9)	0.80
CWIS: Well-being	Baseline	Mean (SD)	46.6 (19.6)	41.8 (22.3)	-	-
	Change from baseline at Week 16	Mean (SD)	5.9 (19.0)	11.8 (21.4)	3.7 (-3.5 to 10.9)	0.31
CWIS: Physical Symptoms and Daily Living	Baseline	Mean (SD)	65.1 (23.0)	61.9 (23.8)	-	-
	Change from baseline at Week 16	Mean (SD)	1.8 (16.8)	7.1 (17.6)	4.5 (-1.9 to 10.8)	0.17
CWIS: Social life	Baseline	Mean (SD)	70.2 (26.9)	68.1 (28.7)	-	-
	Change from baseline at Week 16	Mean (SD)	2.9 (13.6)	4.5 (22.1)	2.2 (-4.4 to 8.8)	0.51
CWIS: Global HRQoL	Baseline	Mean (SD)	6.6 (2.1)	6.1 (2.1)	-	-
	Change from baseline at Week 16	Mean (SD)	0.6 (1.8)	0.6 (1.7)	-0.1 (-0.7 to 0.5)	0.77
CWIS: Satisfaction with HRQoL	Baseline	Mean (SD)	6.4 (2.8)	6.1 (2.4)	-	-
	Change from baseline at Week 16	Mean (SD)	0.4 (2.9)	0.5 (2.2)	0.1 (-0.8 to 0.9)	0.85

*Percent change from baseline did not undergo statistical testing due to skewed data. Calculated percentage change using change from baseline model was 36.3% in the Control group versus 37.9% in the IPC group (32.3% versus 24.8% for the imputed data set).

Analyses reported using all available data unless stated otherwise.

Safety

There were five serious adverse event (SAEs) in the IPC group and nine SAEs in the control group. The five SAEs in the IPC group included one infection (resolved), one suspected deep vein thrombosis (DVT; resolved), one non-small cell bronchial carcinoma (resolved), one hospitalization due to a fall with fracture of the left ischiopubic ramus (ongoing) and one jaundiced patient with concern of decompensated heart failure with possible recurrent pericardial effusion (ongoing). Additionally, one withdrawn patient came to the hospital because of general feeling of weakness. The patient was withdrawn from the study due to clinical concerns.

Serious adverse events

	Randomised group		**Total (N=14)**
	IPC (N=5)	**Control (N=9)**	
Serious Adverse event, n (%)			
Cellulitis		3 (33.3%)	3 (21.4%)
Infection	1 (20%)	1 (11.1%)	2 (14.3%)
Infection and cellulitis		1 (11.1%)	1 (7.1%)
Deep vein thrombosis (DVT)	1 (20%)		1 (7.1%)
DVT and infection		1 (11.1%)	1 (7.1%)
Non-small cell bronchial carcinoma	1 (20%)		1 (7.1%)
Hospitalisation due to fall with fracture	1 (20%)		1 (7.1%)
Hospitalisation for vascular assessment		1 (11.1%)	1 (7.1%)
Hospitalisation for asthenia		1 (11.1%)	1 (7.1%)
Hospitalisation (unspecified)		1 (11.1%)	1 (7.1%)
Jaundice	1 (20%)		1 (7.1%)

IPC - Intermittent Pneumatic Compression