CONFETTI – ISRCTN

- **Participant Flow**

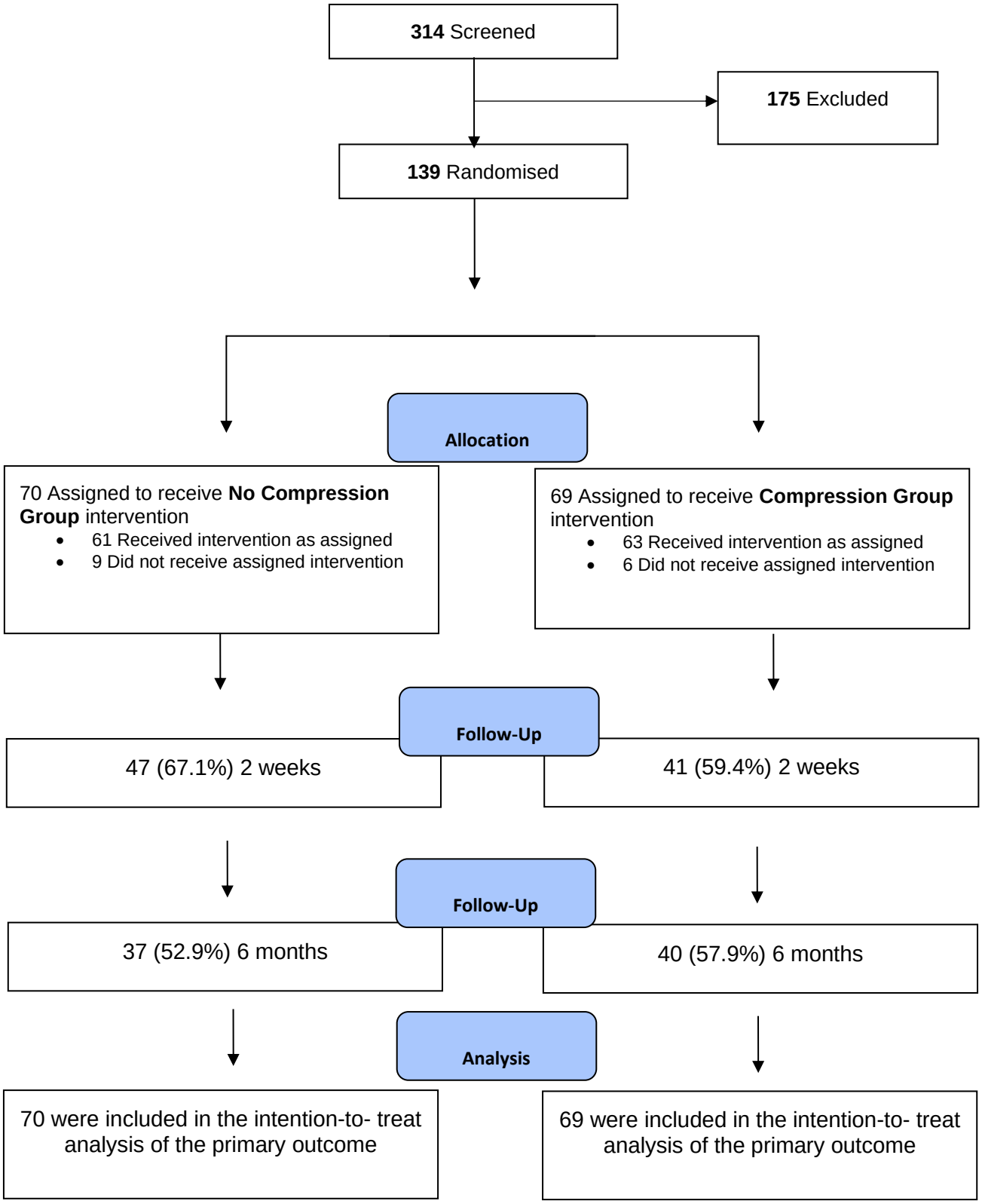

Figure 1. Study Consort Diagram

Baseline Characteristics

Table 1. Baseline patient characteristics

Characteristics	**Overall (n=139)**	**NCG (n=70)**	**CG (n=69)**	**P-value**
Age — yr. (mean (± SD))	57.7 (± 14)	57.0 (± 14)	58 (± 14)	.897[a]
Sex — no. (%)				
Female	101 (72.7)	54 (53.5)	47 (46.5)	.233[b]
Height in metres (mean (± SD))	1.67 (± 0.92)	1.67 (± 0.95)	1.68 (± 0.90)	.949[a]
Weight in Kg (mean (± SD))	77.7 (± .20.3)	79.8 (± .20)	75.7 (± 20)	.602[a]
BMI (mean (± SD)) (kg/m2)	27.1 (± 7.2)	28.5 (± 7.5)	26.9 (± 6.8)	.855[a]
BMI>30 — no. (%)	37 (35.9)	18 (35.3)	19 (36.5)	.895[b]
Smoker — no. (%)	23 (18.1)	9 (14.5)	14 (21.5)	.304[b]
Hypertension — no. (%)	22(17.1)	12(19)	10 (15.2)	.556[b]
Previous treatment of VVs	82(59)	43 (61.4)	39 (56.5)	.549[b]
Clinical CEAP Class–no. (%) *				
C2	56 (42.7)	28 (43.1)	28 (42.4)	.868[b]
C3	39 (29.8)	21(32.3)	18 (27.3)	
C4	32 (24.4)	14 (21.5)	18 (27.3)	
C5	4 (3.1)	2(3.1)	2 (3)	
Clinical severity scoring– (median (IQR))				
VCSS	4 (3–6)	4 (3–6)	4 (3–5)	.951[c]
VDS	1 (1–2)	1 (1–2)	1 (1–2)	414[c]
Generic QOL– (median (IQR))				
EQ-VAS	80 (70–90)	80 (70–92)	80 (70–90)	.388[c]
EQ-5D	.73 (.66–.76)	.76 (.65–.76)	.71 (.67–.76)	.468[c]

Disease-Specific QOL– (median (IQR))				
AVVQ	17.95 (11–25.3)	17.7 (9.9–26.6)	18.2 (11.2–24.1)	.968[c]
CIVIQ-14	25 (12.5–44.6)	23.2 (10.7–40.6)	28.5 (14.2–53.5)	.220[c]

BMI: body mass index; CEAP: clinical etiology anatomy pathology; VCSS: venous clinical severity score; VDS: venous disability score; EQ-5D: Euroqol 5 Domain 3 Level; EQ-VAS:EuroQol's visual analog scale; AVVQ: Aberdeen varicose vein questionnaire; CIVIQ-14: chronic venous insufficiency quality of life questionnaire. NCG: No Compression group; CG: Compression group; IQR: interquartile range; SD: standard deviation; a: Student t-test; b: X2 test; c: Mann-Whitney U test; * Not all randomly assigned patients received the intervention.

Primary Outcome Measure

The VAS pain scores in both groups were low in the first ten days. However, patients in the CG reported significantly less pain scores than those in the NCG, with a median of 7 mm (IQR: 1–9) after CG compared to 19 mm (IQR: 15–28) after NCG, (Mann-Whitney U-test, $P < 0.001$).

Table 2. Pain score over the first 10 days (median)

	Compression Group	No Compression Group
VAS pain score (mm) (median)	7	19
Inter-quartile range	1-9	15-28
Mann-Whitney U-Test	p<0.001	

(VAS: visual analogue scale)

Secondary Outcome Measures

Table 3. Secondary Outcome Measures

Secondary outcomes	Overall	NCG (n=70)	CG (n=69)	P-value
Clinical severity scoring– no. (median (IQR))				
VCSS				
Baseline 133*	4 (3–6)	4 (3–6)	4 (3–5)	.951[c]
2 weeks 88*	3 (2–5)	3 (2–4)	4 (2–6)	.103[c]
6 months 75*	3 (2–6)	3 (2–5)	4 (2.7–6)	.185[c]
VDS				
Baseline 132*	1 (1–2)	1 (1–2)	1 (1–2)	414[c]
2 weeks 87*	1 (0–1)	1 (0–1)	1 (0–1)	.330[c]
6 months 74*	1 (0–1)	0 (0–1)	1 (0–1)	.373[c]
Generic QOL– (median (IQR))				
EQ-VAS				
Baseline 123*	80 (70–90)	80 (70–92)	80 (70–90)	.388[c]

2 weeks 82*	85(70–94)	83.5 (70–93)	89 (74.7–95)	.373[c]
6 months 77*	80 (63–90)	85 (70–95)	79.5(60–90)	.036[c]
EQ-5D				
Baseline 133*	.73 (.66–.76)	.76 (.65–.76)	.71 (.67–.76)	.468[c]
2 weeks 84*	.76 (.66–.80)	.76 (.68–.81)	.76(.65-0.83)	.971[c]
6 months 75*	.76(.65–.96)	.76(.69–1)	.69 (.65–76)	.013[c]
Disease-Specific QOL– (median (IQR))				
AVVQ				
Baseline 130*	17.95 (11–25.3)	17.7 (9.9–26.6)	18.2 (11.2–24.1)	.968[c]
2 weeks 86*	17.6 (10–25.4)	13.5 (8.1–24)	19.5 (13.1–26.4)	.103[c]
6 months 74*	15.8(6.9–23.6)	11.47(6.1–23.8)	17 (9.3–23)	.290[c]
CIVIQ-14				
Baseline 127*	25 (12.5–44.6)	23.2 (10.7–40.6)	28.5 (14.2–53.5)	.220[c]
2 weeks	17.5 (8.9–39.2)	16 (8.9–33.9)	19.6 (12.5-44.6)	.374[c]

86*				
6 months 69*	19.6 (8–39.2)	16.9 (3.57–30.8)	19.6(12.5–44.6)	.233[c]
Compliance with wearing compression– (median (IQR))	_	_	8 (5–10)	
Return to normal activities– (median (IQR))	2(0-3)	2(1–3)	1 (0–3)	.479[c]
Return to work– (median (IQR))	2 (1-5)	2 (1–4)	2(1–6)	.331[c]
Complete occlusion rates at 6 months— no. (%)				
56 (40.2%)				
Complete Occluded	32	13 (40.6)	19 (59.4)	.315[b]
Partially Occluded	24	13 (54.2)	11 (45.8)	
Ecchymosis– no. (%)				
<25%	67 (94.4)	22 (97.4)	13 (90.6)	0.266[b]
25%)	4 (5.6)	1(2.6)	3(9.4)	

VCSS: venous clinical severity score; EQ-5D: Euroqol 5 Domain 3 Level; EQ-VAS:EuroQol's visual analog scale; AVVQ: Aberdeen varicose vein questionnaire; CIVIQ-14: chronic venous insufficiency quality of life questionnaire; NCG: No Compression group; CG: Compression group; IQR: interquartile range; SD: standard deviation; b: X2 test; c: Mann-Whitney U test; *Number of questionnaires completed by patients.

Adverse Events

GROUP	COMPLICATION	Number of patients affected
Compression Group	SVT	2
	DVT	0
No Compression Group	SVT	1
	DVT	1

Table 4. Complications following procedures (SVT: superficial vein thrombosis; DVT: deep vein thrombosis)