

CONSORT

Figure 1: CONSORT diagram of participant flow through the RESOLVE feasibility study (part 1)

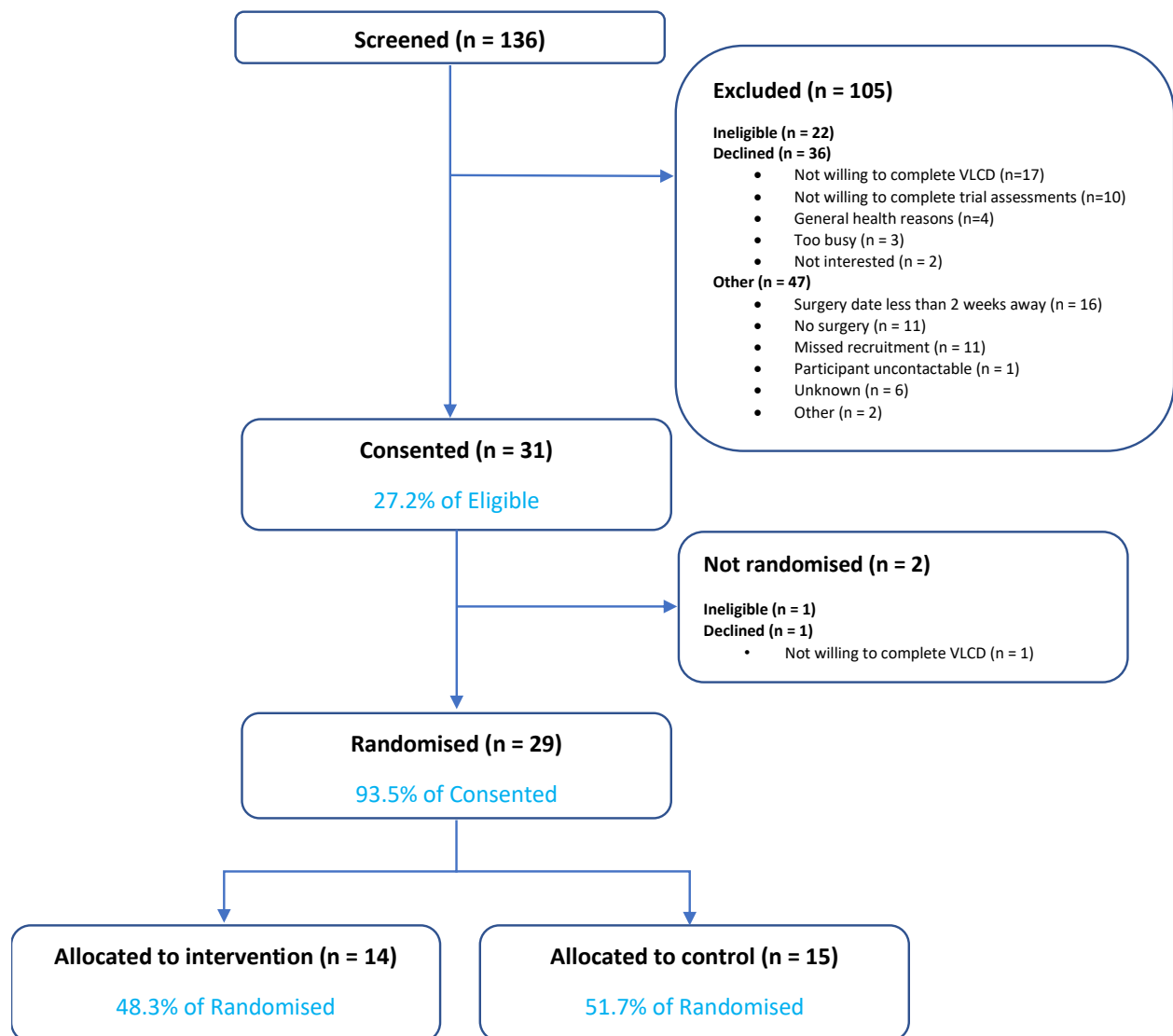


Figure 2: CONSORT diagram of participant flow through the RESOLVE feasibility study (part 2)

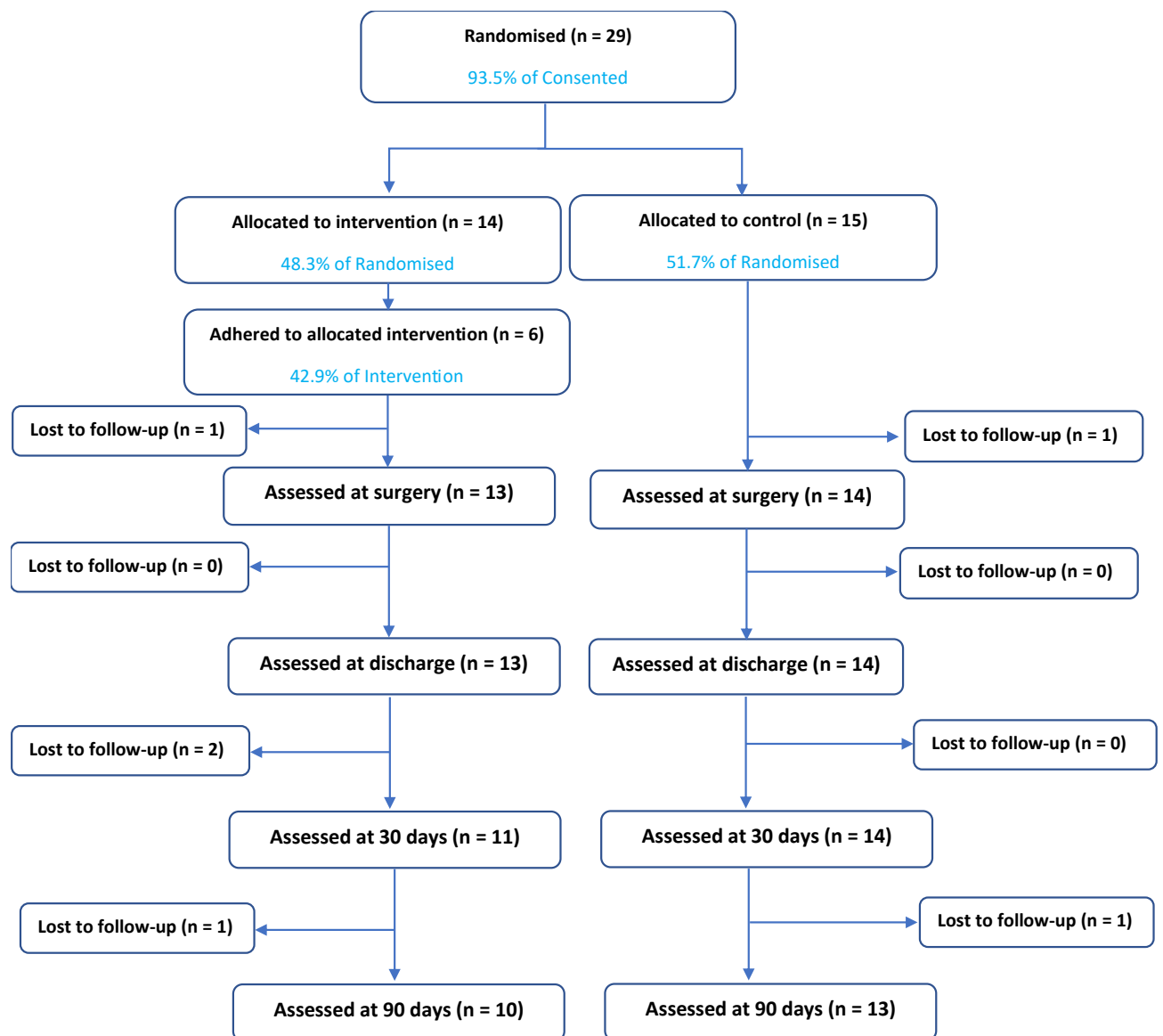


Table 1: Participant characteristics at baseline [n (%) unless otherwise stated]

Characteristic	Both (n=29)	Control (n=15)	Intervention (n=14)
Age (years)			
n: mean (SD)	29: 60.5 (11.2)	15: 63.6 (9.5)	14: 57.2 (12.2)
median (Q1, Q3)	61.5 (56.4, 68.7)	63.1 (58.5, 73.0)	59.8 (44.9, 68.5)
[min, max]	[33.1, 78.0]	[45.2, 78.0]	[33.1, 71.1]
Assigned sex at birth			
Female	8 (27.6)	5 (33.3)	3 (21.4)
Male	21 (72.4)	10 (66.7)	11 (78.6)
Self-identified gender equal to sex at birth – yes	29 (100.0)	15 (100.0)	14 (100.0)
Ethnic group			
White	27 (93.1)	14 (93.3)	13 (92.9)
Mixed/multiple	1 (3.4)	0 (0.0)	1 (7.1)
Prefer not to say	1 (3.4)	1 (6.7)	0 (0.0)
Religion			
No religion	12 (41.4)	5 (33.3)	7 (50.0)
Christian	15 (51.7)	9 (60.0)	6 (42.9)
Prefer not to say	2 (6.9)	1 (6.7)	1 (7.1)
Highest education level			
Apprenticeship	4 (13.8)	3 (20.0)	1 (7.1)
Degree-level or higher	9 (31.0)	5 (33.3)	4 (28.6)
NVQ or equivalent	2 (6.9)	1 (6.7)	1 (7.1)
A and AS level or equivalent	5 (17.2)	2 (13.3)	3 (21.4)
GCSE or equivalent	5 (17.2)	3 (20.0)	2 (14.3)
CSE	1 (3.4)	0 (0.0)	1 (7.1)
Left school at 15	1 (3.4)	0 (0.0)	1 (7.1)
Unknown	1 (3.4)	1 (6.7)	0 (0.0)
Prefer not to say	1 (3.4)	0 (0.0)	1 (7.1)
Employment status			
Working as an employee	10 (34.5)	5 (33.3)	5 (35.7)
Self-employed or freelance	4 (13.8)	4 (26.7)	0 (0.0)
Away from work ill	3 (10.3)	1 (6.7)	2 (14.3)
Other paid work	1 (3.4)	1 (6.7)	0 (0.0)
Unemployed	1 (3.4)	1 (6.7)	0 (0.0)
Semi-retired	1 (3.4)	0 (0.0)	1 (7.1)
Retired	9 (31.0)	3 (20.0)	6 (42.9)
Marital status			
Single	2 (6.9)	2 (13.3)	0 (0.0)
Co-habiting	3 (10.3)	0 (0.0)	3 (21.4)
Married	21 (72.4)	12 (80.0)	9 (64.3)
Separated	2 (6.9)	1 (6.7)	1 (7.1)
Divorced	1 (3.4)	0 (0.0)	1 (7.1)
Smoking status			
Smoker (regular)	1 (3.4)	1 (6.7)	0 (0.0)
Ex-smoker	7 (24.1)	4 (26.7)	3 (21.4)

Characteristic	Both (n=29)	Control (n=15)	Intervention (n=14)
Non-smoker	21 (72.4)	10 (66.7)	11 (78.6)
Performance status			
0	20 (69.0)	12 (80.0)	8 (57.1)
1	8 (27.6)	3 (20.0)	5 (35.7)
2	1 (3.4)	0 (0.0)	1 (7.1)

Summary statistics of feasibility outcomes

Table 2: Reasons for non-participation

		n (%)
Eligibility (1)		136 (100.0)
Declined	Not willing to complete trial assessments	5 (3.7)
	General health reasons	3 (2.2)
	Not willing to complete VLCD	13 (9.6)
	Total	22 (16.2)
Excluded	Ineligible	20 (14.7)
	Surgery date less than 2 weeks away	16 (11.8)
	No surgery	10 (7.4)
	Missed recruitment window	7 (5.1)
	Unable to recruit due to recruitment pause	2 (1.5)
	Surgery date not confirmed before recruitment end	2 (1.5)
	Health reasons (determined by clinical team)	1 (0.7)
	Surgery in private sector	1 (0.7)
	Unknown	5 (3.7)
	Total	64 (47.1)
Eligibility (2)		51 (37.5)
Declined	Not willing to complete trial assessments	1 (0.7)
	General health reasons	1 (0.7)
	Total	2 (1.5)
Excluded	Unknown	1 (0.7)
	Total	1 (0.7)
Pre-consent		48 (35.3)
Declined	Too busy	3 (2.2)
	Not willing to complete trial assessments	4 (3.7)
	Not interested	2 (1.5)
	Not willing to complete VLCD	4 (2.9)
	Total	13 (9.6)
Excluded	Ineligible	2 (1.5)
	Participant uncontactable	1 (0.7)
	Surgery cancelled	1 (0.7)
	Total	4 (3.7)

Pre-randomisation		31 (22.8)
Declined	Not willing to complete VLCD	1 (0.7)
	Total	1 (0.7)
Excluded	Ineligible	1 (0.7)
	Total	1 (0.7)

Table 3: Withdrawal in the RESOLVE trial

		n (%)
Post randomisation		
Withdrawal from trial	Surgery cancelled	2 (33.3)
30 day follow up		
Withdrawal from trial	Loss to follow up	2 (33.3)
90 day follow up		
Withdrawal from trial	Loss to follow up	2 (33.3)
Total		6 (100.0)

Table 4: Recruitment by site [n (%) unless otherwise stated]

Plymouth	Screened	34
	Recruited	15 (44.1)
	Randomised	13 (38.2)
	Proportion randomised [95% CI]	38.2 [22.2, 56.4]
	Retained at 30-day follow-up	10 (76.9)
	Retained at 90-day follow-up	10 (76.9)
Southampton	Screened	23
	Recruited	6 (26.1)
	Randomised	6 (26.1)
	Proportion randomised [95% CI]	26.1 [10.2, 48.4]
	Retained at 30-day follow-up	6 (100.0)
	Retained at 90-day follow-up	5 (83.3)
Surrey	Screened	45
	Recruited	4 (8.9)
	Randomised	4 (8.9)
	Proportion randomised [95% CI]	8.9 [2.5, 21.2]
	Retained at 30-day follow-up	3 (75.0)
	Retained at 90-day follow-up	3 (75.0)
Liverpool	Screened	23
	Recruited	5 (21.7)
	Randomised	5 (21.7)
	Proportion randomised [95% CI]	21.7 [7.5, 43.7]
	Retained at 30-day follow-up	4 (80.0)
	Retained at 90-day follow-up	4 (80.0)

Leeds	Screened	11
	Recruited	1 (9.1)
	Randomised	1 (9.1)
	Proportion randomised [95% CI]	9.1 [0.2, 41.3]
	Retained at 30-day follow-up	1 (100.0)
	Retained at 90-day follow-up	1 (100.0)
Overall	Screened	136
	Recruited	31 (22.8)
	Randomised	29 (21.3)
	Proportion randomised [95% CI]	21.3 [14.8, 29.2]
	Retained at 30-day follow-up	24 (82.8)
	Retained at 90-day follow-up	23 (79.3)

Table 5: Completeness of proposed primary outcome measures of those randomised [n (%) unless otherwise stated]

Outcome	Time point	Both (n=29)	Control (n=15)	Intervention (n=14)
Duration of surgery (mins)	Intra-operative	27 (93.1)	14 (93.3)	13 (92.9)
Ease of surgery		27 (93.1)	14 (93.3)	13 (92.9)
Surgeon estimated intra-operative blood loss (ml)		27 (93.1)	14 (93.3)	13 (92.9)
Blood transfusion requirement (number of transfusions)	Discharge	27 (93.1)	14 (93.3)	13 (92.9)
Time to return to function (days)		27 (93.1)	14 (93.3)	13 (92.9)
Length of hospital stay (days)		27 (93.1)	14 (93.3)	13 (92.9)
CCI	30 days	25 (86.2)	14 (93.3)	11 (78.6)
	90 days	23 (79.3)	13 (86.7)	10 (71.4)
Readmission	30 days	25 (86.2)	14 (93.3)	11 (78.6)
	90 days	24 (82.8)	13 (86.7)	11 (78.6)
Mortality	30 days	25 (86.2)	14 (93.3)	11 (78.6)
	90 days	23 (79.3)	13 (86.7)	10 (71.4)
EQ-5D-5L	Baseline	29 (100.0)	15 (100.0)	14 (100.0)
	Pre-op	25 (86.2)	13 (86.7)	12 (85.7)
	30 days	24 (82.8)	13 (86.7)	11 (78.6)
	90 days	23 (79.3)	13 (86.7)	10 (71.4)
Health resource use questionnaire	30 days	24 (82.8)	13 (86.7)	11 (78.6)
	90 days	23 (79.3)	13 (86.7)	10 (71.4)

Table 6: Summary statistics for clinical and patient-reported outcomes (as-treated) [n (%) unless otherwise stated]

Outcome	Both (n=29)	Control (n=15)	Intervention (n=14)
Duration of surgery (minutes)			
n: mean (SD)	27: 287.0 (127.1)	22: 266.8 (117.1)	5: 375.8 (144.5)
median (Q1, Q3)	270.0 (209.0, 405.0)	257.0 (209.0, 304.0)	420.0 (305.0, 480.0)
[min, max]	[78.0, 529.0]	[78.0, 529.0]	[160.0, 514.0]
Missing	2 (6.9)	1 (4.3)	1 (16.7)
Ease of surgery			
1	0 (0.0)	0 (0.0)	0 (0.0)
2	6 (20.7)	6 (26.1)	0 (0.0)
3	13 (44.8)	10 (43.5)	3 (50.0)
4	7 (24.1)	5 (21.7)	2 (33.3)
5	1 (3.4)	1 (4.3)	0 (0.0)
Missing	2 (6.9)	1 (4.3)	1 (16.7)
Surgeon estimated intra-operative blood loss (ml)			
n	27	22	5
median (Q1, Q3)	500.0 (200.0, 999.0)	500.0 (200.0, 999.0)	750.0 (700.0, 800.0)
[min, max]	[31.0, 2982.0]	[31.0, 2982.0]	[300.0, 1050.0]
Missing	2 (6.9)	1 (4.3)	1 (16.7)
Blood transfusion requirements up to discharge (number of transfusions)			
Values	1, 2	1, 2	-
Missing	2 (6.9)	1 (4.3)	1 (16.7)
Length of hospital stay (days)			
n	27	22	5
median (Q1, Q3)	6.0 (5.0, 8.0)	6.0 (5.0, 7.0)	8.0 (6.0, 8.0)
[min, max]	[2.0, 30.0]	[2.0, 30.0]	[5.0, 18.0]
Missing	2 (6.9)	1 (4.3)	1 (16.7)
Time to return to function (days)			
n	27	22	5
median (Q1, Q3)	4.0 (3.0, 7.0)	4.0 (3.0, 6.0)	7.0 (3.0, 7.0)
[min, max]	[1.0, 29.0]	[1.0, 29.0]	[3.0, 17.0]
Missing	2 (6.9)	1 (4.3)	1 (16.7)
CCI at 90 days			
n	23	18	5
median (Q1, Q3)	0.0 (0.0, 8.7)	0.0 (0.0, 8.7)	0.0 (0.0, 0.0)
[min, max]	[0.0, 55.7]	[0.0, 18.4]	[0.0, 55.7]
Missing	6 (20.7)	5 (21.7)	1 (16.7)
Mortality at 90 days - yes	0 (0.0)	0 (0.0)	0 (0.0)
Readmission at 90 days - yes	9 (31.0)	6 (26.1)	3 (50.0)

Table 7: Summary statistics of VLCD outcomes [n, median (Q1, Q3), min, max unless otherwise stated]

Importance of success, confidence in ability [1 to 10].

Outcome	n	median (Q1, Q3)	min, max
Important of success	14	8.0 (8.0, 10.0)	[5.0, 10.0]
Confidence in ability	14	9.0 (8.0, 10.0)	[5.0, 10.0]
Number of days on VLCD – n, mean (SD)	14, 13.4 (5.9)	14.0 (14.0, 14.0)	[0.0, 28.0]
Surgery delayed – yes n (%)	4 (28.6)		
Number of empty sachets	14	46.0 (2.0, 54.0)	[0.0, 107.0]
Percentage of empty sachets	14	90.2 (3.6, 95.8)	[0.0, 100.0]
Number of days diary marked as complete (persist) – n, mean (SD)	14, 11.0 (7.6)	14.0 (6.0, 14.0)	[0.0, 28.0]
Initiate – yes n (%)	11 (78.6)		
Discontinue – yes n (%)	1 (9.1)		
Implement – yes n (%)	6 (42.9)		

Table 8. Adherence to the VLCD

VLCD	Adherence (n=14)	At least 75% of all sachets over the intervention period (n=14)	Participants who adhered to the VLCD on at least 10 days (n=14)	Days participants adhered to the VLCD	Number of sachets per day	Mean number of sachets per day by participant	At least 50% of protein requirement (if applicable, n=8)
n (%)	6 (42.9)	4 (28.6)	6 (42.9)				4 (50.0)
n mean [95% CI]				14 7.5 [3.7, 11.3]	202 3.2 [3.0, 3.4]	14 3.2 [2.4, 4.0]	
median (Q1, Q3)				7.0 (2.0, 12.0)	4.0 (3.0, 4.0)	3.8 (3.1, 4.0)	
min, max				0.0, 23.0	0.0, 4.0	0.0, 4.0	

Table 9: Summary statistics of the EQ-5D-5L at baseline

Outcome	Both (n=29)	Control (n=15)	Intervention (n=14)
Mobility			
n: mean (SD)	29: 1.3 (0.6)	15: 1.3 (0.6)	14: 1.2 (0.6)
median (Q1, Q3)	1.0 (1.0, 1.0)	1.0 (1.0, 2.0)	1.0 (1.0, 1.0)
[min, max]	[1.0, 3.0]	[1.0, 3.0]	[1.0, 3.0]
Missing	0 (0.0)	0 (0.0)	0 (0.0)
Self-care			
n: mean (SD)	29: 1.1 (0.4)	15: 1.2 (0.6)	14: 1.1 (0.3)
median (Q1, Q3)	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)
[min, max]	[1.0, 3.0]	[1.0, 3.0]	[1.0, 2.0]
Missing	0 (0.0)	0 (0.0)	0 (0.0)
Active			
n: mean (SD)	29: 1.3 (0.8)	15: 1.5 (0.9)	14: 1.2 (0.6)
median (Q1, Q3)	1.0 (1.0, 1.0)	1.0 (1.0, 2.0)	1.0 (1.0, 1.0)
[min, max]	[1.0, 4.0]	[1.0, 4.0]	[1.0, 3.0]
Missing	0 (0.0)	0 (0.0)	0 (0.0)
Pain			
n: mean (SD)	29: 1.6 (0.9)	15: 1.8 (1.1)	14: 1.4 (0.6)
median (Q1, Q3)	1.0 (1.0, 2.0)	1.0 (1.0, 2.0)	1.0 (1.0, 2.0)
[min, max]	[1.0, 5.0]	[1.0, 5.0]	[1.0, 3.0]
Missing	0 (0.0)	0 (0.0)	0 (0.0)
Anxiety			
n: mean (SD)	29: 1.5 (0.7)	15: 1.6 (0.8)	14: 1.4 (0.6)
median (Q1, Q3)	1.0 (1.0, 2.0)	1.0 (1.0, 2.0)	1.0 (1.0, 2.0)
[min, max]	[1.0, 3.0]	[1.0, 3.0]	[1.0, 3.0]
Missing	0 (0.0)	0 (0.0)	0 (0.0)
Health			
n: mean (SD)	29: 74.8 (16.3)	15: 73.3 (18.3)	14: 76.4 (14.2)
median (Q1, Q3)	75.0 (70.0, 90.0)	75.0 (60.0, 88.0)	75.0 (70.0, 90.0)
[min, max]	[30.0, 97.0]	[30.0, 97.0]	[50.0, 95.0]
Missing	0 (0.0)	0 (0.0)	0 (0.0)

Table 10: Summary statistics of the EQ-5D-5L at pre-op

Outcome	Both (n=29)	Control (n=15)	Intervention (n=14)
Mobility			
n: mean (SD)	25: 1.3 (0.7)	13: 1.5 (0.8)	12: 1.2 (0.6)
median (Q1, Q3)	1.0 (1.0, 1.0)	1.0 (1.0, 2.0)	1.0 (1.0, 1.0)
[min, max]	[1.0, 3.0]	[1.0, 3.0]	[1.0, 3.0]
Missing	4 (13.8)	2 (13.3)	2 (14.3)
Self-care			
n: mean (SD)	25: 1.2 (0.6)	13: 1.3 (0.8)	12: 1.0 (0.0)
median (Q1, Q3)	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)
[min, max]	[1.0, 3.0]	[1.0, 3.0]	[1.0, 1.0]
Missing	4 (13.8)	2 (13.3)	2 (14.3)
Active			
n: mean (SD)	25: 1.2 (0.7)	13: 1.4 (1.0)	12: 1.0 (0.0)
median (Q1, Q3)	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)
[min, max]	[1.0, 4.0]	[1.0, 4.0]	[1.0, 1.0]
Missing	4 (13.8)	2 (13.3)	2 (14.3)
Pain			
n: mean (SD)	25: 1.5 (1.0)	13: 1.7 (1.2)	12: 1.3 (0.6)
median (Q1, Q3)	1.0 (1.0, 2.0)	1.0 (1.0, 2.0)	1.0 (1.0, 1.0)
[min, max]	[1.0, 5.0]	[1.0, 5.0]	[1.0, 3.0]
Missing	4 (13.8)	2 (13.3)	2 (14.3)
Anxiety			
n: mean (SD)	25: 1.5 (0.6)	13: 1.5 (0.7)	12: 1.4 (0.5)
median (Q1, Q3)	1.0 (1.0, 2.0)	1.0 (1.0, 2.0)	1.0 (1.0, 2.0)
[min, max]	[1.0, 3.0]	[1.0, 3.0]	[1.0, 2.0]
Missing	4 (13.8)	2 (13.3)	2 (14.3)
Health			
n: mean (SD)	25: 80.5 (13.4)	13: 77.5 (16.5)	12: 83.8 (8.4)
median (Q1, Q3)	80.0 (75.0, 90.0)	80.0 (65.0, 90.0)	82.5 (80.0, 87.5)
[min, max]	[50.0, 100.0]	[50.0, 97.0]	[70.0, 100.0]
Missing	4 (13.8)	2 (13.3)	2 (14.3)

Table 11: Summary statistics of the EQ-5D-5L at 30 day follow up

Outcome	Both (n=29)	Control (n=15)	Intervention (n=14)
Mobility			
n: mean (SD)	24: 1.6 (1.1)	13: 1.4 (0.7)	11: 1.9 (1.4)
median (Q1, Q3)	1.0 (1.0, 2.0)	1.0 (1.0, 2.0)	1.0 (1.0, 3.0)
[min, max]	[1.0, 5.0]	[1.0, 3.0]	[1.0, 5.0]
Missing	5 (17.2)	2 (13.3)	3 (21.4)
Self-care			
n: mean (SD)	24: 1.4 (1.1)	13: 1.1 (0.3)	11: 1.7 (1.6)
median (Q1, Q3)	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)
[min, max]	[1.0, 5.0]	[1.0, 2.0]	[1.0, 5.0]
Missing	5 (17.2)	2 (13.3)	3 (21.4)
Active			
n: mean (SD)	24: 1.8 (1.2)	13: 1.6 (0.8)	11: 2.1 (1.5)
median (Q1, Q3)	1.5 (1.0, 2.0)	1.0 (1.0, 2.0)	2.0 (1.0, 2.0)
[min, max]	[1.0, 5.0]	[1.0, 3.0]	[1.0, 5.0]
Missing	5 (17.2)	2 (13.3)	3 (21.4)
Pain			
n: mean (SD)	24: 2.1 (1.1)	13: 1.8 (0.7)	11: 2.5 (1.3)
median (Q1, Q3)	2.0 (1.5, 2.0)	2.0 (1.0, 2.0)	2.0 (2.0, 3.0)
[min, max]	[1.0, 5.0]	[1.0, 3.0]	[1.0, 5.0]
Missing	5 (17.2)	2 (13.3)	3 (21.4)
Anxiety			
n: mean (SD)	24: 1.5 (0.8)	13: 1.3 (0.5)	11: 1.6 (1.0)
median (Q1, Q3)	1.0 (1.0, 2.0)	1.0 (1.0, 2.0)	1.0 (1.0, 2.0)
[min, max]	[1.0, 4.0]	[1.0, 2.0]	[1.0, 4.0]
Missing	5 (17.2)	2 (13.3)	3 (21.4)
Health			
n: mean (SD)	24: 72.8 (23.5)	13: 76.5 (20.6)	11: 68.5 (26.8)
median (Q1, Q3)	78.5 (70.0, 87.5)	80.0 (75.0, 90.0)	76.0 (70.0, 85.0)
[min, max]	[0.0, 100.0]	[30.0, 100.0]	[0.0, 95.0]
Missing	5 (17.2)	2 (13.3)	3 (21.4)

Table 12: Summary statistics of the EQ-5D-5L at 90 day follow up

Outcome	Both (n=29)	Control (n=15)	Intervention (n=14)
Mobility			
n: mean (SD)	23: 1.5 (0.9)	13: 1.4 (0.8)	10: 1.6 (1.1)
median (Q1, Q3)	1.0 (1.0, 2.0)	1.0 (1.0, 1.0)	1.0 (1.0, 2.0)
[min, max]	[1.0, 4.0]	[1.0, 3.0]	[1.0, 4.0]
Missing	6 (20.7)	2 (13.3)	4 (28.6)
Self-care			
n: mean (SD)	23: 1.1 (0.4)	13: 1.2 (0.6)	10: 1.0 (0.0)
median (Q1, Q3)	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)
[min, max]	[1.0, 3.0]	[1.0, 3.0]	[1.0, 1.0]
Missing	6 (20.7)	2 (13.3)	4 (28.6)
Active			
n: mean (SD)	23: 1.6 (1.1)	13: 1.4 (0.9)	10: 1.8 (1.3)
median (Q1, Q3)	1.0 (1.0, 2.0)	1.0 (1.0, 1.0)	1.0 (1.0, 3.0)
[min, max]	[1.0, 4.0]	[1.0, 4.0]	[1.0, 4.0]
Missing	6 (20.7)	2 (13.3)	4 (28.6)
Pain			
n: mean (SD)	23: 1.7 (1.0)	13: 1.7 (0.9)	10: 1.8 (1.1)
median (Q1, Q3)	1.0 (1.0, 2.0)	1.0 (1.0, 2.0)	1.0 (1.0, 3.0)
[min, max]	[1.0, 4.0]	[1.0, 4.0]	[1.0, 4.0]
Missing	6 (20.7)	2 (13.3)	4 (28.6)
Anxiety			
n: mean (SD)	23: 1.4 (0.9)	13: 1.4 (0.9)	10: 1.5 (1.1)
median (Q1, Q3)	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)
[min, max]	[1.0, 4.0]	[1.0, 4.0]	[1.0, 4.0]
Missing	6 (20.7)	2 (13.3)	4 (28.6)
Health			
n: mean (SD)	23: 78.3 (18.7)	13: 80.6 (16.6)	10: 75.2 (21.5)
median (Q1, Q3)	85.0 (75.0, 90.0)	85.0 (80.0, 90.0)	81.0 (75.0, 85.0)
[min, max]	[20.0, 98.0]	[50.0, 98.0]	[20.0, 95.0]
Missing	6 (20.7)	2 (13.3)	4 (28.6)

Table 13: Summary statistics of health resource use questionnaire at 30 days and 90 days follow up – n (%) unless otherwise stated

Outcome	Both (n=29)	Control (n=15)	Intervention (n=14)
30 day follow up			
Outpatient appointments kept since discharge			
n: mean (SD)	24: 1.2 (1.1)	13: 1.2 (1.1)	11: 1.1 (1.1)
median (Q1, Q3)	1.0 (0.0, 2.0)	1.0 (0.0, 2.0)	1.0 (0.0, 1.0)
[min, max]	[0.0, 4.0]	[0.0, 3.0]	[0.0, 4.0]
Missing	5 (17.2)	2 (13.3)	3 (21.4)
Outpatient appointments missed since discharge			
0	23 (79.3)	12 (92.3)	11 (78.6)
1	1 (3.5)	1 (7.7)	0 (0.0)
Missing	5 (17.2)	2 (13.3)	3 (21.4)
Accident & Emergency visits since discharge			
0	18 (62.1)	9 (60.0)	9 (64.3)
1	5 (17.2)	4 (26.7)	1 (7.1)
2	1 (3.5)	0 (0.0)	1 (7.1)
Missing	5 (17.2)	2 (13.3)	3 (21.4)
90 day follow up			
Outpatient appointments kept since discharge			
n: mean (SD)	23: 3.5 (4.8)	13: 4.2 (6.1)	10: 2.6 (2.1)
median (Q1, Q3)	3.0 (1.0, 3.0)	3.0 (1.0, 3.0)	2.5 (1.0, 3.0)
[min, max]	[0.0, 24.0]	[1.0, 24.0]	[0.0, 6.0]
Missing	6 (20.7)	2 (13.3)	4 (28.6)
Outpatient appointments missed since discharge			
0	23 (79.3)	13 (86.7)	10 (71.4)
Missing	6 (20.7)	2 (13.3)	4 (28.6)
Accident & Emergency visits since discharge			
0	17 (58.6)	10 (66.7)	7 (50.0)
1	4 (13.8)	3 (20.0)	1 (7.1)
2	1 (3.5)	0 (0.0)	1 (7.1)
15	1 (3.5)	0 (0.0)	1 (7.1)
Missing	6 (20.7)	2 (13.3)	4 (28.6)

Table 14: MedDRA System Organ Class and Preferred Term by group for each SAE

MedDRA System Organ Class	MedDRA Preferred Term	Control (n=4)	Intervention (n=5)	Total (n=9)
Cardiac disorders	Myocardial infarction	0	1	1
Gastrointestinal disorders	Colitis	1	0	1
Infections and infestations	Sepsis	0	2	2
	Campylobacter infection	0	1	1
	Total	0	3	3
Neoplasms benign, malignant and unspecified	Glioblastoma multiforme	1	0	1
Nervous system disorders	Central nervous system disorder	1	0	1
Respiratory, thoracic and mediastinal disorders	Pleural effusion	0	1	1
	Epistaxis	1	0	1
	Total	1	1	2