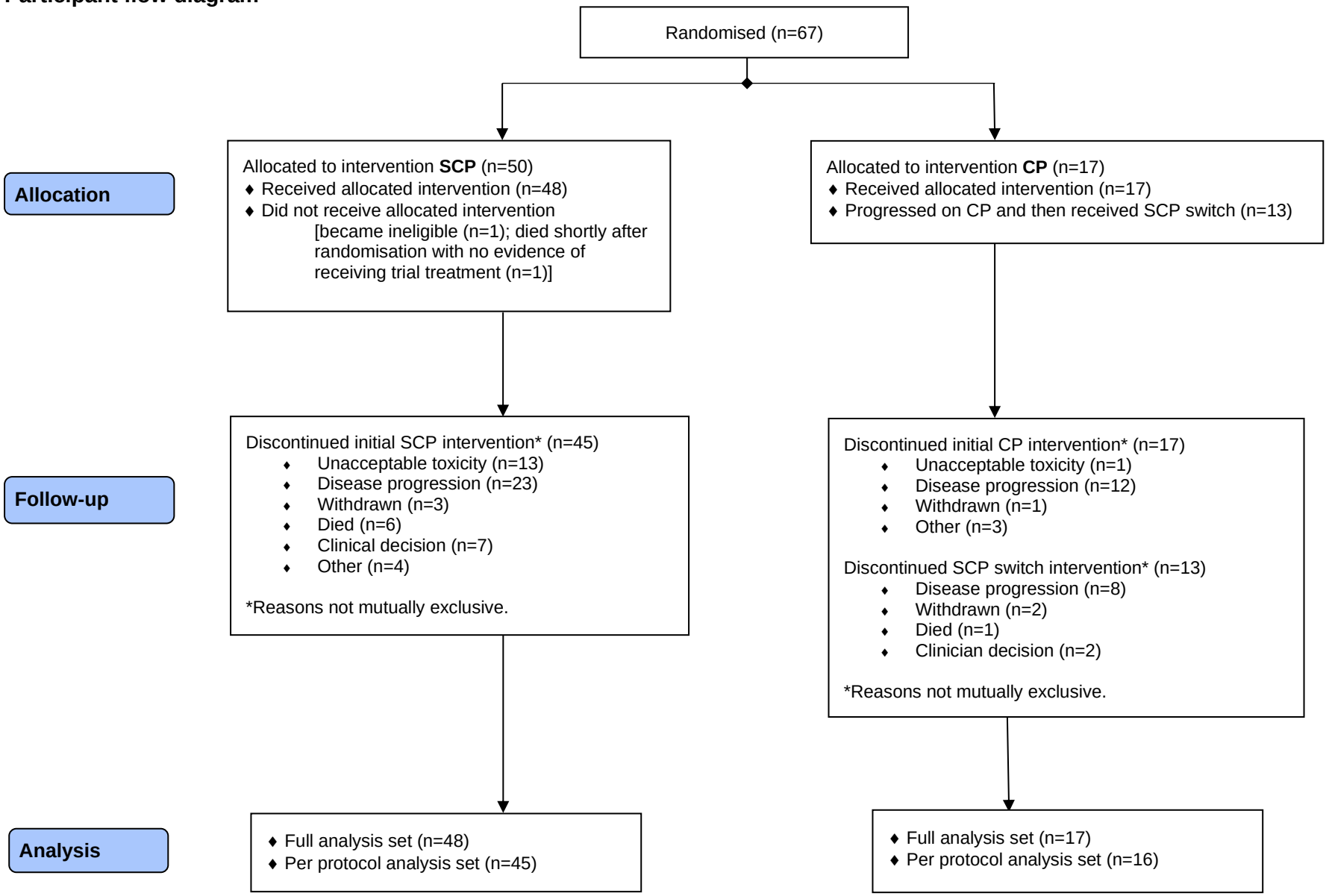
Participant flow diagram



Baseline Characteristics

	SCP (n=48)	CP (n=17)
Age at randomisation (years)		
Median (range)	71.0 (44.0, 81.0)	69.0 (57.0, 84.0)
Sex		
Male	26 (54.2%)	8 (47.1%)
Female	22 (45.8%)	9 (52.9%)
Time from diagnosis (years)		
Median (range)	8.3 (2.4, 22.9)	10.4 (3.2, 21.7)
ECOG performance status		
0	9 (18.8%)	7 (41.2%)
1	29 (60.4%)	7 (41.2%)
2	10 (20.8%)	3 (17.6%)
Number of prior lines of therapy		
3	1 (2.1%)	0
4	12 (25.0%)	3 (17.6%)
5 or more	35 (72.9%)	14 (82.4%)

Outcome Measures

Primary outcome=The number and proportion of participants alive and progression free at six months post randomisation. Analysis population, n=61.

Alive and progression-free at 6 months?	SCP (n=45)	80% CI for SCP	CP (n=16)	80% CI for CP
Yes	11 (24.4%)	16.2-34.6%	4 (25.0%)	11.4-43.9%
No	34 (75.6%)		12 (75.0%)	

Secondary outcome=Maximum response. Analysis population, n=65.

Maximum response	SCP (n=48)	CP (n=17)
Very Good Partial Response (VGPR)	1 (2.1%)	0

Maximum response	SCP (n=48)	CP (n=17)
Partial Response (PR)	13 (27.1%)	4 (23.5%)
Minimal Response (MR)	4 (8.3%)	1 (5.9%)
Stable Disease or No Change (SD or NC)	18 (37.5%)	6 (35.3%)
No maximum response – Progressive Disease (PD)	8 (16.7%)	6 (35.3%)
No post-baseline response assessment	4 (8.3%)	0

Secondary outcome=Time to maximum response calculated from date of randomisation. Analysis population, n=65.

	Median time to maximum response (months)	Lower 95% Confidence Limit (months)	Upper 95% Confidence Limit (months)
SCP	2.1	2.0	2.4
CP	3.0	2.0	4.6

Secondary outcome=Duration of response calculated from first occurrence of a participant's response of ≥PR until disease progression. Analysis population, n=18.

	Median duration of response (months)	Lower 95% Confidence Limit (months)	Upper 95% Confidence Limit (months)
SCP	3.1	1.1	10.5
CP	2.3	1.9	.

Secondary outcome=Compliance to therapy (dose delays, omissions, and reductions). Analysis population, n=65.

Has the participant…	SCP (n=48)	CP (n=17)
Had a cycle delayed?		
Yes	32 (66.7%)	8 (47.1%)
No	16 (33.3%)	9 (52.9%)
Had a dose reduction?		
Yes	19 (39.6%)	2 (11.8%)

Has the participant…	SCP (n=48)	CP (n=17)
No	29 (60.4%)	15 (88.2%)
Had a dose omitted?		
Yes	38 (79.2%)	11 (64.7%)
No	10 (20.8%)	6 (35.3%)

Adverse Events Analysis population, n=65

Serious adverse events (SAEs) – summary statistics

	SCP	CP
Number of participants with one or more SAE	27	6
Number of SAEs reported	45	19
Number of SAEs per participant		
Mean (Standard Deviation)	1.7 (0.96)	3.2 (1.47)
Median (Interquartile Range)	1.0 (1, 2)	2.5 (2, 5)
Range	(1, 5)	(2, 5)

SAEs – number of events by MedDRA code (not mutually exclusive)

MedDRA System Organ Class	SCP N (%)	CP N (%)
Blood and lymphatic system disorders	4 (8.9)	0 (0.0)
Cardiac disorders	3 (6.7)	1 (5.3)
Gastrointestinal disorders	5 (11.1)	0 (0.0)
General disorders and administration site conditions	1 (2.2)	0 (0.0)
Infections and infestations	23 (51.1)	5 (26.3)
Injury, poisoning and procedural complications	0 (0.0)	1 (5.3)
Metabolism and nutrition disorders	2 (4.4)	2 (10.5)
Musculoskeletal and connective tissue disorders	2 (4.4)	3 (15.8)
Neoplasms benign, malignant and unspecified (including cysts and polyps)	1 (2.2)	1 (5.3)
Nervous system disorders	0 (0.0)	0 (0.0)
Renal and urinary disorders	4 (8.9)	5 (26.3)

MedDRA System Organ Class	**SCP N (%)**	**CP N (%)**
Endocrine disorders	0 (0.0)	1 (5.3)
Total	**45 (100.0)**	**19 (100.0)**

Adverse events – most common adverse events reported.

	SCP N (%)		**CP N (%)**	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Anaemia	31 (64.6%)	18 (37.5%)	7 (41.2%)	1 (5.9%)
Diarrhoea	15 (31.3%)	1 (2.1%)	5 (29.4%)	0
Fatigue	22 (45.8%)	2 (4.2%)	5 (29.4%)	0
Nausea	26 (54.2%)	6 (12.5%)	1 (5.9%)	0
Neutrophil count decreased	21 (43.8%)	13 (27.1%)	3 (17.6%)	1 (5.9%)
Platelet count decreased	29 (39.6%)	20 (41.7%)	5 (29.4%)	0