Figure 1. Participant flow

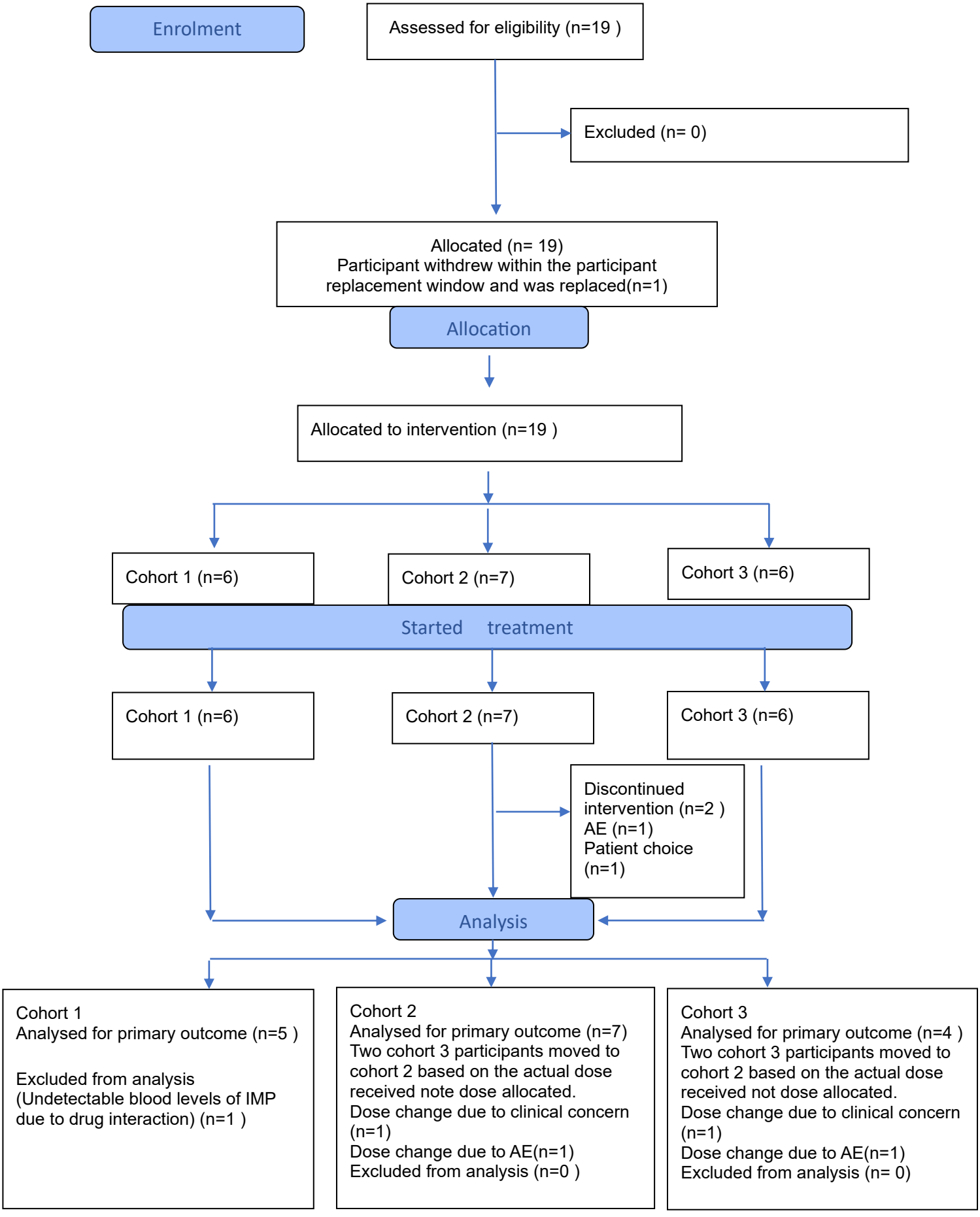

Table 1. Baseline characteristics

Variable	1	2	3	Total
Observation	5	7	4	16
Were participant details obtained				
Yes	5/5 (100%)	7/7 (100%)	4/4 (100%)	16/16 (100%)
Is the participant re-screening?				
No	5/5 (100%)	7/7 (100%)	4/4 (100%)	16/16 (100%)
Demographic				
Age at consent				
Valid Obs.	5	7	4	16
Mean (SD)	52.4 (12.1)	55.1 (7.58)	54.5 (12.8)	54.1 (9.82)
Median [Min, Max]	55.0 [40.0, 69.0]	57.0 [42.0, 64.0]	59.0 [36.0, 64.0]	56.5 [36.0, 69.0]
Gender				
Female	2/5 (40.0%)	4/7 (57.1%)	1/4 (25.0%)	7/16 (43.8%)
Male	3/5 (60.0%)	3/7 (42.9%)	3/4 (75.0%)	9/16 (56.3%)
Ethnicity				
Mixed			1/4 (25.0%)	1/16 (6.3%)
White	5/5 (100%)	7/7 (100%)	3/4 (75.0%)	15/16 (93.8%)
Smoking status				
Smoking status				
Smoker		1/7 (14.3%)		1/16 (6.3%)
Ex-smoker	3/5 (60.0%)	2/7 (28.6%)	3/4 (75.0%)	8/16 (50.0%)
Non-smoker	2/5 (40.0%)	4/7 (57.1%)	1/4 (25.0%)	7/16 (43.8%)
Number of cigarettes smoked per day				
Valid Obs.	3	3	3	9
Mean (SD)	16.7 (5.77)	9.00 (9.85)	15.0 (5.00)	13.6 (7.14)
Median [Min, Max]	20.0 [10.0, 20.0]	6.00 [1.00, 20.0]	15.0 [10.0, 20.0]	15.0 [1.00, 20.0]
Number of years smoked (round to nearest year)				
Valid Obs.	3	3	3	9
Mean (SD)	17.0 (12.0)	31.0 (15.7)	25.3 (5.03)	24.4 (11.9)
Median [Min, Max]	17.0 [5.00, 29.0]	34.0 [14.0, 45.0]	26.0 [20.0, 30.0]	26.0 [5.00, 45.0]
Alcohol intake				
Does the participant currently drink alcohol?				
No	3/5 (60.0%)	2/7 (28.6%)	2/4 (50.0%)	7/16 (43.8%)
Yes	2/5 (40.0%)	5/7 (71.4%)	2/4 (50.0%)	9/16 (56.3%)
If yes, alcohol consumed, units/week				
Valid Obs.	2	5	2	9
Mean (SD)	4.00 (1.41)	15.0 (13.7)	2.50 (0.707)	9.78 (11.5)
Median [Min, Max]	4.00 [3.00, 5.00]	5.00 [5.00, 30.0]	2.50 [2.00, 3.00]	5.00 [2.00, 30.0]
If no, history of heavy alcohol consumption in the last 6 months				
No	3/3 (100%)	2/2 (100%)	2/2 (100%)	7/7 (100%)
If heavy drinker, heavy consumption, units/week				
Valid Obs.	0	0	0	0

Variable	1	2	3	Total
Recreational drug				
Used recreational drugs within the last 6 months?				
No	5/5 (100%)	7/7 (100%)	4/4 (100%)	16/16 (100%)
If yes, what recreational drug(s) have they taken				
Valid Obs.	0	0	0	0

Table 2. Outcome measure
Number of participants who had an SAE or AE attributable to felodipine

Population: mITT (n = 16)

Cohort	1	2	3	Total
n=	5	7	4	16
SAEs attributable to felodipine				
Yes	0/5	0/7	0/4	0/16
No	5/5 (100%)	7/7 (100%)	4/4 (100%)	16/16 (100%)

Cohort	1	2	3	Total
n=	5	7	4	16
AEs attributable to felodipine				
Yes	0/5 (0%)	1/7 (14.29%)	2/4 (50%)	3/16
No	5/5 (100%)	6/7 (85.71%)	2/4 (50%)	13/16

Table 3. Adverse Events

MedDRA (v25.0) Preferred Term	Cohort 1	Cohort 2	Cohort 3
Headache			
Mild	3 (50.0%)	6 (66.7%)	2 (50.0%)
Moderate		1 (11.1%)	
Back pain			
Mild	1 (16.7%)	6 (66.7%)	
Nasopharyngitis			
Mild	1 (16.7%)	4 (44.4%)	
COVID-19			
Mild	1 (16.7%)		
Moderate	1 (16.7%)	2 (22.2%)	
Fall			
Mild		2 (22.2%)	1 (25.0%)
Lower respiratory tract infection			
Mild	1 (16.7%)		
Oedema peripheral			
Mild		2 (22.2%)	
Lower respiratory tract infection			
Moderate		2 (22.2%)	
Oedema peripheral			
Moderate		1 (11.1%)	
Diarrhoea			
Mild		2 (22.2%)	
Dyspepsia			
Mild		1 (11.1%)	1 (25.0%)
Musculoskeletal pain			
Mild	1 (16.7%)	1 (11.1%)	
Vomiting			
Mild		2 (22.2%)	
Abdominal discomfort			
Mild		1 (11.1%)	
Cholelithiasis			
Mild	1 (16.7%)		
Contusion			
Mild			1 (25.0%)
Hypokalaemia			
Mild		1 (11.1%)	
Ligament strain			
Mild		1 (11.1%)	
Malaise			
Mild			1 (25.0%)
Mouth ulceration			
Mild		1 (11.1%)	
Nausea			
Mild			1 (25.0%)

MedDRA (v25.0) Preferred Term	Cohort 1	Cohort 2	Cohort 3
Panic attack			
Mild	1 (16.7%)		
Periodontitis			
Mild			1 (25.0%)
Pruritus			
Mild		1 (11.1%)	
Rash			
Mild		1 (11.1%)	
Rhinitis allergic			
Mild		1 (11.1%)	
Tinnitus			
Mild		1 (11.1%)	
Tonsillitis			
Mild		1 (11.1%)	
Tooth extraction			
Mild		1 (11.1%)	
Trigger finger			
Mild		1 (11.1%)	
Urinary tract infection			
Mild		1 (11.1%)	
Accidental overdose			
Moderate			1 (25.0%)
Arthralgia			
Moderate			1 (25.0%)
Epilepsy			
Moderate			1 (25.0%)
Macular oedema			
Moderate		1 (11.1%)	
Palpitations			
Moderate		1 (11.1%)	
Respiratory distress			
Moderate			1 (25.0%)

Multiple AEs in of the same severity are counted only once for each participant.

Table 4. Serious Adverse Events

MedDRA preferred term (v25.0)	Signs and symptoms	Outcome	Resulted in death	Life-threatening	Required inpatient or prolonged hospitalisation	Resulted in persis or sig disability/incapacity	Resulted in congenital anomaly/birth defect	Event description	Action taken	Causality
Epilepsy	Focal onset seizure	Recovered / Resolved WITHOUT Sequelae	No	No	No	No	No	Seizures	None	Not related
Respiratory distress	Excessive mucus on lung	Recovered / Resolved WITHOUT Sequelae	No	No	Yes	No	No	Elective admission for removal of left lower scapular lipoma. Respiratory distress during extubation requiring ITU	Treatment Delayed	Not related