

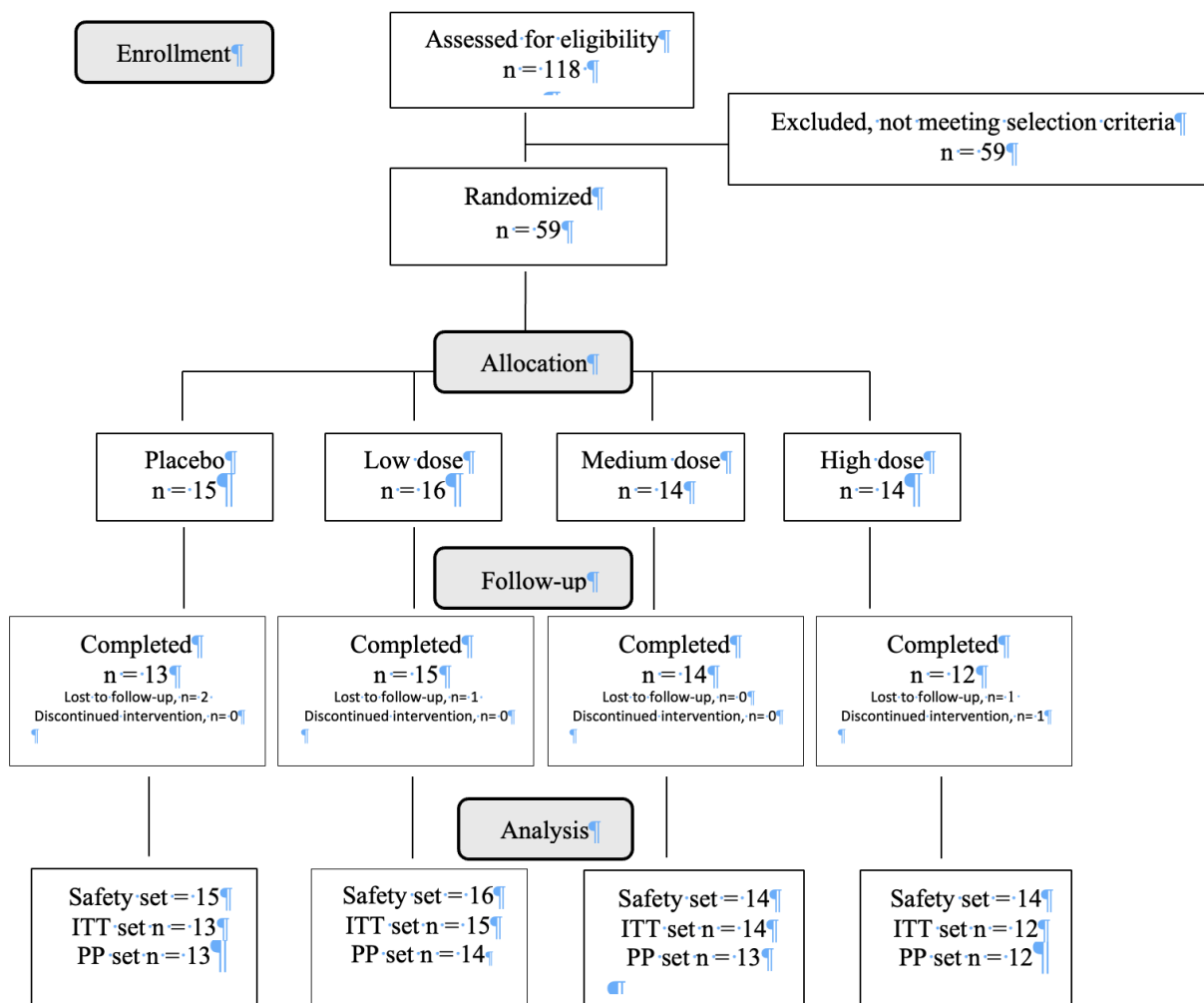


Figure 1. Consort flow diagram. ITT: intention to treat, PP: Per Protocol

Table 1. Demographic data shown as mean (SD).

Parameter		Placebo (N = 15) n (%)	Low dose (N = 16) n (%)	Medium dose (N = 14) n (%)	High dose (N = 14) n (%)	Total (N = 59) n (%)
Age		39.5 (9.38)	41.3 (11.36)	41.4 (10.61)	38.1 (11.34)	40.1 (10.52)
Sex	Female	10 (66.7)	9 (56.3)	7 (50.0)	7 (50.0)	33 (55.9)
	Male	5 (33.3)	7 (43.8)	7 (50.0)	7 (50.0)	26 (44.1)
Ethnicity	Asian	2 (13.3)	2 (12.5)	3 (21.4)	3 (21.4)	10 (16.9)
	Black	0 (0)	0 (0)	1 (7.1)	1 (7.1)	2 (3.4)
	White	13 (86.7)	14 (87.5)	10 (71.4)	10 (71.4)	47 (79.7)
Tobacco and Nicotine Product Use	Never smoker	9 (60.0)	10 (62.5)	8 (57.1)	10 (71.4)	37 (62.7)
	Former smoker	3 (20.0)	6 (37.5)	4 (28.6)	1 (7.1)	14 (23.7)
	Someday smoker	1 (6.7)	0 (0)	0 (0)	1 (7.1)	2 (3.4)
	Everyday smoker	2 (13.3)	0 (0)	2 (14.3)	2 (14.3)	6 (10.2)
Height (cm)		169.6 (9.91)	172.0 (9.53)	170.8 (8.50)	168.2 (8.44)	170.2 (9.02)
Weight (kg) (screening)		66.2 (8.01)	71.5 (10.29)	69.5 (8.74)	66.8 (10.87)	68.6 (9.55)
BMI (kg/m2) (screening)		23.0 (2.10)	24.1 (1.63)	23.8 (2.19)	23.5 (2.43)	23.6 (2.07)

Table 2. Reported AEs for the trial. Only two TEAEs were assessed by the investigator as “possibly related” to the trial product. Both events were diarrhoea (mild), once occurring in the low dose and once in the medium dose group.

	Placebo (N = 15)		Low dose (N = 16)		Medium dose (N = 14)		High dose (N = 14)	
	f	n (%)	f	n (%)	f	n (%)	f	n (%)
All AEs	15	8 (53.5)	20	7 (43.8)	20	8 (57.1)	21	7 (50.0)
All PTAEs	-	-	-	-	1	1 (7.1)	1	1 (7.1)
All TEAEs	15	8 (53.5)	20	7 (43.8)	19	8 (57.1)	20	7 (50.0)
All related ^a TEAEs	-	-	1	1 (6.3)	1	1 (7.1)	-	-
All severe TEAEs	-	-	-	-	-	-	-	-
All serious TEAEs	-	-	-	-	-	-	-	-
All TEAEs leading to disc.	-	-	-	-	-	-	-	-

^a “Possibly related”, “probably related”, and “definitely related” adverse events are all classified as related. AE = adverse event, disc. = discontinuation, f = number of events, N = number of participants in intervention group, n = number of participants with events, PTAE = pre-treatment emergent adverse event, TEAE = treatment emergent adverse event.

Table 3. Gastrointestinal Symptoms (GSRS) dimensions summarized as mean (SD) at Weeks 1, 4 and 8.

Parameter	Visit Name	Placebo (N = 15)	Low dose) (N = 16)	Medium dose (N = 14)	High dose (N = 14)	Total (N = 59)
Abdominal pain	Week 1	1.26 (0.396)	1.27 (0.443)	1.26 (0.557)	1.18 (0.220)	1.25 (0.416)
	Week 4	1.21 (0.320)	1.20 (0.303)	1.15 (0.292)	1.08 (0.151)	1.16 (0.274)
	Week 8	1.17 (0.314)	1.07 (0.142)	1.05 (0.125)	1.15 (0.220)	1.11 (0.215)
Constipation	Week 1	1.43 (0.619)	1.06 (0.181)	1.26 (0.396)	1.31 (0.552)	1.26 (0.467)
	Week 4	1.33 (0.527)	1.09 (0.153)	1.10 (0.210)	1.22 (0.328)	1.18 (0.337)
	Week 8	1.48 (0.759)	1.38 (0.504)	1.23 (0.658)	1.23 (0.394)	1.33 (0.590)
Diarrhoea	Week 1	1.48 (0.770)	1.19 (0.321)	1.19 (0.535)	1.23 (0.316)	1.27 (0.517)
	Week 4	1.46 (0.928)	1.33 (0.701)	1.05 (0.125)	1.08 (0.151)	1.24 (0.608)
	Week 8	1.07 (0.142)	1.07 (0.267)	1.05 (0.185)	1.18 (0.259)	1.09 (0.219)
Indigestion	Week 1	1.84 (0.677)	1.47 (0.455)	1.41 (0.476)	1.50 (0.586)	1.55 (0.562)
	Week 4	1.48 (0.515)	1.40 (0.480)	1.19 (0.341)	1.27 (0.291)	1.34 (0.425)
	Week 8	1.43 (0.523)	1.20 (0.356)	1.33 (0.563)	1.40 (0.331)	1.34 (0.451)
Reflux	Week 1	1.18 (0.372)	1.03 (0.125)	1.11 (0.289)	1.08 (0.188)	1.10 (0.258)
	Week 4	1.04 (0.139)	1.07 (0.258)	1.08 (0.277)	1.08 (0.195)	1.07 (0.220)
	Week 8	1.18 (0.668)	1.07 (0.182)	1.31 (1.109)	1.00 (0.000)	1.14 (0.640)

Table 4. Descriptive summary of bowel movement frequency

Visit Name	Statistics	Placebo (N = 15)	Low dose (N = 16)	Medium dose (N = 14)	High dose (N = 14)	Total (N = 59)
Week 1	Mean (SD)	1.1 (0.52)	1.3 (0.48)	1.3 (1.03)	1.4 (0.76)	1.3 (0.70)
Week 4	Mean (SD)	1.0 (0.55)	1.2 (0.41)	1.4 (1.08)	1.8 (0.73)	1.3 (0.77)
Week 8	Mean (SD)	1.0 (0.50)	1.3 (0.46)	1.2 (0.70)	1.5 (0.66)	1.2 (0.60)

Table 5. Descriptive summary of stool consistency

Visit Name	Statistics	Placebo (N = 15)	Low dose (N = 16)	Medium dose (N = 14)	High dose (N = 14)	Total (N = 59)
Week 1	Mean (SD)	3.74 (0.916)	3.70 (0.676)	3.85 (0.953)	3.66 (0.803)	3.74 (0.818)
Week 4	Mean (SD)	3.94 (0.902)	3.30 (0.685)	3.69 (0.403)	3.35 (0.633)	3.57 (0.717)
Week 8	Mean (SD)	3.39 (0.650)	3.45 (0.976)	3.27 (0.820)	3.49 (0.688)	3.40 (0.782)