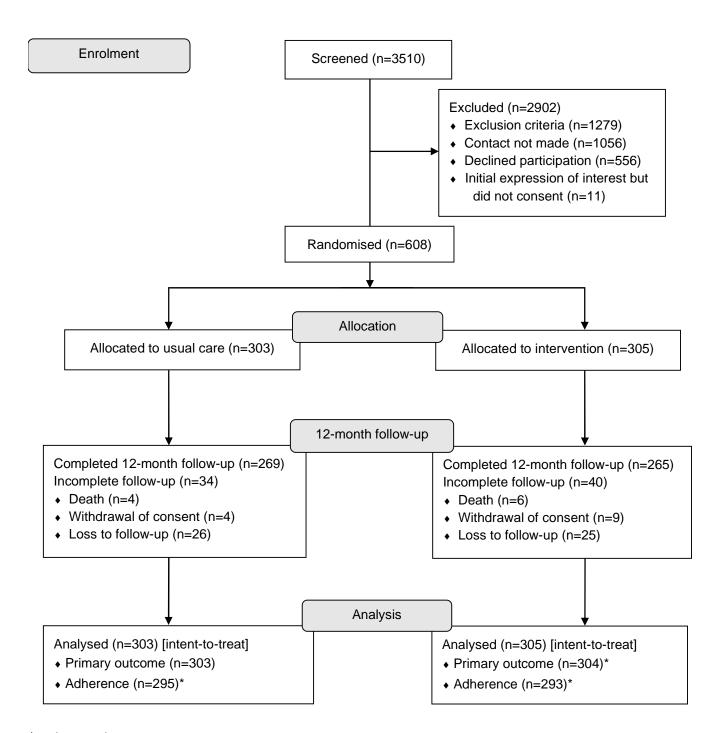
ISRCTN55504164

Self-management intervention to support adherence in adults with cystic fibrosis: a randomised trial

PARTICIPANT FLOW



^{*}Exclusions due to missing covariates.

Baseline Characteristics: A tabular summary showing baseline demographic (age and gender) and clinical characteristics of the participants.

BASELINE CHARACTERISTICS

	Usual Care		I	Intervention	
	N*	$Mean \pm SD^{\dagger}$	N*	Mean±SD [†]	
Female – n (%)	303	n=154 (50.8%)	304	n=156 (51.3%)	
Age – years	303	30.3±10.8	304	31.1±10.6	
Socioeconomic deprivation quintiles – n (%)					
1 (least deprived)	302	n=51 (16.9%)	302	n=50 (16.6%)	
2	302	n=71 (23.5%)	302	n=59 (19.5%)	
3	302	n=66 (21.9%)	302	n=63 (20.9%)	
4	302	n=67 (22.2%)	302	n=63 (20.9%)	
5 (most deprived)	302	n=47 (15.6%)	302	n=67 (22.2%)	
Pseudomonas status – n (%) [‡]					
Chronic	299	n=175 (58.5%)	304	n=174 (57.2%)	
Non-chronic	299	n=124 (41.5%)	304	n=130 (42.8%)	
Previous year's IV treatment – days	303	27.7±33.0	304	24.2±27.9	
Secondary outcomes: baseline values					
Normative adherence (weekly, numerator-adjusted) – %	295	45.5±34.1	293	54.1±33.0	
FEV ₁ % predicted – %	302	58.3±22.6	304	60.7±23.5	
Body mass index – kg/m ²	303	22.5±4.2	304	22.7±4.2	
Patient-reported outcomes: baseline values [§]					
Beliefs about medication (BMQ-Specific):					
Concerns	301	2.1±0.5	304	2.1±0.6	
Necessities	301	3.6±0.8	304	3.6±0.7	
SRBAI (habit strength for using nebuliser)	300	12.0±4.7	303	12.1±5.0	
CFQ-R (cystic fibrosis burden):					
Physical	302	53.0±30.2	304	54.3±30.6	
Emotional	302	66.2±24.1	304	66.5±21.6	
Social	302	60.9±20.9	304	61.9±20.0	
Eating	302	80.5±24.3	304	82.1±22.5	
Body image	302	66.1±29.3	304	65.6±28.0	
Treatment burden	302	51.8±20.2	304	54.4±19.8	
Respiratory	302	56.6±21.9	304	58.2±22.1	
Digestion	302	81.1±19.4	304	79.9±21.5	
Perceptions of treatment adherence (3-item scale)	274	9.9±3.4	280	10.2±3.4	
Effort of nebuliser treatments	300	3.1±1.2	302	3.1±1.3	
Subjective adherence question – % (self-report estimate of adherence)	298	69.0±30.8	300	69.9±31.0	
CHAOS-6 (life chaos or routine)	300	9.5±2.9	303	9.5±2.9	
PAM-13 (health style assessment)	302	65.3±13.3	304	65.8±14.5	
PHQ-8 (depression)	301	6.4±5.1	304	6.4±5.2	
GAD-7 (anxiety)	302	4.7±4.7	302	4.6±4.9	
EQ-5D-5L (generic health status)	300	0.84±0.16	303	0.85±0.15	

IV=intravenous; $FEV_1=forced$ expiratory volume in one second; SD=standard deviation.

Full details and references for all patient-reported outcomes are available in the statistical analysis plan (see supplementary material).

^{*}There were 608 participants randomised but one participant randomised to the intervention arm withdrew on the day of consent prior to baseline data collection, giving a maximum N=607 for baseline summaries.

[†]Unless otherwise stated.

[‡]Consensus definition.

[§]All patient-reported outcomes based on points, unless otherwise stated. For direction of positive effect and possible range, see table 2.

OUTCOME MEASURES

Primary outcome, pulmonary exacerbation incidence rate over the 12 months post consent by randomised treatment group

Usual care			Inter	vention			
N	Exacerbations	Person- years	Exacerbation rate	N	Exacerbations	Person- years	Exacerbation rate
303	526	297.2	1.77	304	482	294.9	1.63

Secondary outcomes at 12 months, by randomised treatment group

Normative adherence (weekly, numerator-adjusted) − % FEV₁ % predicted − % 282 56.9±23.0 274 60.6±24.2 282 22.6±4.1 273 23.1±4.4 282 282 22.6±4.1 273 23.1±4.4 283 282 282 283 2	Secondary outcomes at 12 mol		•		
Normative adherence (weekly, numerator-adjusted) – % FEV ₁ % predicted – % 282 56.9±23.0 274 60.6±24.2 Body mass index – kg/m² 282 22.6±4.1 273 23.1±4.4 Patient-reported outcomes† Beliefs about medication (BMQ-Specific): Concerns 271 2.1±0.5 271 2.0±0.5 Necessities 271 3.5±0.7 271 3.7±0.8 SRBAI (habit strength for 271 11.7±4.9 261 12.9±4.9 using nebuliser) CFQ-R (cystic fibrosis burden): Physical 274 52.6±30.6 264 55.8±30.2 Emotional 274 66.5±24.7 264 66.6±22.9 Social 274 59.6±20.0 264 60.5±20.0 Eating 274 81.0±23.2 264 84.0±21.5 Body image 274 51.5±19.7 265 56.6±19.5 Respiratory 271 56.6±21.9 263 58.0±22.5 Digestion 272 80.2±21.6 263 80.4±19.4 Perceptions of treatment adherence (3-item scale) Effort of nebuliser treatments 270 3.0±1.2 260 3.3±1.3 Subjective adherence question – % (self-report estimate of adherence) CHAOS-6 (life chaos or routine) 272 80.8±0.0 265 68.1±15.6 EQ-5D-5L (generic health status) 272 0.81±0.18 264 0.84±0.15 Patient-reported outcomes – safety measures† PHQ-8 (depression) 272 6.4±5.0 262 6.3±5.6		Usual care Intervention			
numerator-adjusted) − % FEV₁ % predicted − % EV1 % predicted − % Body mass index − kg/m² Patient-reported outcomes¹ Beliefs about medication (BMQ-Specific): Concerns Perceptions of treatments burden Empiratory Digestion Respiratory Digestion Perceptions of treatment adherence (Self-report estimate of adherence) CHAOS-6 (life chaos or routine) EV2 6.9±23.0 274 66.9±23.0 274 2.0±0.5 271 2.0±0.5 271 2.0±0.5 271 3.7±0.8 271 3.5±0.7 271 3.7±0.8 272 52.6±30.6 264 55.8±30.2 273 52.6±30.6 264 55.8±30.2 264 66.6±22.9 274 52.6±30.6 264 66.6±22.9 274 66.5±24.7 264 66.6±22.9 274 81.0±23.2 264 84.0±21.5 275 66.6±21.9 276 66.6±21.9 277 56.6±21.9 278 263 58.0±22.5 279 263 58.0±22.5 270 3.0±1.2 280 3.3±1.3 280 3.4±1.3 280 3.4±1.3 280 3.4±1.3 280 3.4±0.4 282 22.6±4.1 273 23.1±4.4 274 2.1±0.5 271 2.0±0.5 271 3.7±0.8 272 280.2±21.6 283 2.1±0.8 283 2.2±21.6 283 2.2±21.6 283 2.2±21.6 283 2.2±21.6 283 2.2±21.6 284 2.2±21.6 285 2.2±21.6 285 2.2±21.6 286 2.2±21.6		N	Mean±SD	N	Mean±SD
Body mass index – kg/m² 282 22.6±4.1 273 23.1±4.4 Patient-reported outcomes¹ Beliefs about medication (BMQ-Specific): 271 2.1±0.5 271 2.0±0.5 Concerns 271 3.5±0.7 271 3.7±0.8 SRBAI (habit strength for using nebuliser) 271 11.7±4.9 261 12.9±4.9 Using nebuliser) 272 52.6±30.6 264 55.8±30.2 26.8±20.0 264 66.6±22.9 25.8±30.2 26.8±20.0 264 66.6±22.9 25.8±30.2 26.8±20.0 264 66.5±24.9 26.8±20.0 264 67.2±27.3 26.8±20.0 264 67.2±27.3 27.8±27.3 265 56.6±19.5 26.6±21.9 265 56.6±19.5 <td></td> <td>295</td> <td>34.9±31.7</td> <td>293</td> <td>52.9±31.4</td>		295	34.9±31.7	293	52.9±31.4
Patient-reported outcomes¹ Beliefs about medication (BMQ-Specific): 271 2.1±0.5 271 2.0±0.5 Concerns 271 3.5±0.7 271 3.7±0.8 Necessities 271 11.7±4.9 261 12.9±4.9 SRBAI (habit strength for using nebuliser) 271 11.7±4.9 261 12.9±4.9 Using nebuliser) 274 52.6±30.6 264 55.8±30.2 Emotional 274 52.6±30.6 264 55.8±30.2 Emotional 274 66.5±24.7 264 66.6±22.9 Social 274 59.6±20.0 264 60.5±20.0 Eating 274 81.0±23.2 264 84.0±21.5 Body image 274 65.1±29.3 264 67.2±27.3 Treatment burden 274 51.5±19.7 265 56.6±19.5 Respiratory 271 56.6±21.9 263 58.0±22.5 Digestion 272 80.2±21.6 263 80.4±19.4 Perceptions of treatment adherence 245 9.9±3.6 237 10.8±3.3 (3-item	FEV₁ % predicted – %	282	56.9±23.0	274	60.6±24.2
Beliefs about medication (BMQ-Specific): Concerns 271 2.1±0.5 271 2.0±0.5 Necessities 271 3.5±0.7 271 3.7±0.8 SRBAI (habit strength for 271 11.7±4.9 261 12.9±4.9 using nebuliser) CFQ-R (cystic fibrosis burden): Physical 274 52.6±30.6 264 55.8±30.2 Emotional 274 66.5±24.7 264 66.6±22.9 Social 274 59.6±20.0 264 60.5±20.0 Eating 274 81.0±23.2 264 84.0±21.5 Body image 274 65.1±29.3 264 67.2±27.3 Treatment burden 274 51.5±19.7 265 56.6±19.5 Respiratory 271 56.6±21.9 263 58.0±22.5 Digestion 272 80.2±21.6 263 80.4±19.4 Perceptions of treatment adherence 245 9.9±3.6 237 10.8±3.3 (3-item scale) Effort of nebuliser treatments 270 3.0±1.2 260 3.3±1.3 Subjective adherence question - % 267 65.6±32.8 258 68.6±31.3 (self-report estimate of adherence) CHAOS-6 (life chaos or routine) 272 9.6±3.2 263 9.4±3.4 PAM-13 (health style assessment) 274 64.9±13.0 265 68.1±15.6 EQ-5D-5L (generic health status) 272 0.81±0.18 264 0.84±0.15 Patient-reported outcomes - safety measures PHQ-8 (depression) 272 6.4±5.0 262 6.3±5.6	Body mass index – kg/m ²	282	22.6±4.1	273	23.1±4.4
Concerns 271 2.1±0.5 271 2.0±0.5 Necessities 271 3.5±0.7 271 3.7±0.8 SRBAI (habit strength for using nebuliser) 271 11.7±4.9 261 12.9±4.9 using nebuliser) 274 52.6±30.6 264 55.8±30.2 Emotional 274 66.5±24.7 264 66.6±22.9 Social 274 59.6±20.0 264 60.5±20.0 Eating 274 81.0±23.2 264 84.0±21.5 Body image 274 65.1±29.3 264 67.2±27.3 Treatment burden 274 51.5±19.7 265 56.6±19.5 Respiratory 271 56.6±21.9 263 58.0±22.5 Digestion 272 80.2±21.6 263 80.4±19.4 Perceptions of treatment adherence 245 9.9±3.6 237 10.8±3.3 (3-item scale) Effort of nebuliser treatments 270 3.0±1.2 260 3.3±1.3 Subjective adherence question - % 267 65.6±32.8 258 68.6±31.3 (self-report estimate of adherence) 272 9.6±3.2 263 9.4±3.4 PAM-13 (health style assessment) 274 64.9±13.0 265 68.1±15.6 EQ-5D-5L (generic health status) 272 0.81±0.18 264 0.84±0.15 Patient-reported outcomes - safety measures PHQ-8 (depression) 272 6.4±5.0 262 6.3±5.6	Patient-reported outcomes [†]				
Necessities 271 3.5±0.7 271 3.7±0.8 SRBAI (habit strength for using nebuliser) 271 11.7±4.9 261 12.9±4.9 CFQ-R (cystic fibrosis burden): 274 52.6±30.6 264 55.8±30.2 Emotional 274 66.5±24.7 264 66.6±22.9 Social 274 59.6±20.0 264 60.5±20.0 Eating 274 81.0±23.2 264 84.0±21.5 Body image 274 65.1±29.3 264 67.2±27.3 Treatment burden 274 51.5±19.7 265 56.6±19.5 Respiratory 271 56.6±21.9 263 58.0±22.5 Digestion 272 80.2±21.6 263 80.4±19.4 Perceptions of treatment adherence 245 9.9±3.6 237 10.8±3.3 (3-item scale) 256 65.6±32.8 258 68.6±31.3 Subjective adherence question – % 267 65.6±32.8 258 68.6±31.3 (self-report estimate of adherence) 272 9.6±3.2 263 9.4±3.4 PAM-13 (health style assessment)					
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using nebuliser) CFQ-R (cystic fibrosis burden): Physical 274 52.6 ±30.6 264 55.8±30.2 Emotional 274 66.5±24.7 264 66.6±22.9 Social 274 59.6±20.0 264 60.5±20.0 Eating 274 81.0±23.2 264 84.0±21.5 Body image 274 65.1±29.3 264 67.2±27.3 Treatment burden 274 51.5±19.7 265 56.6±19.5 Respiratory 271 56.6±21.9 263 58.0±22.5 Digestion 272 80.2±21.6 263 80.4±19.4 Perceptions of treatment adherence 245 9.9±3.6 237 10.8±3.3 (3-item scale) Effort of nebuliser treatments 270 3.0±1.2 260 3.3±1.3 Subjective adherence question – % (self-report estimate of adherence) 267 65.6±32.8 258 68.6±31.3 (Self-report estimate of adherence) 272 9.6±3.2 263 9.4±3.4 PAM-13 (health style assessment) 274 64.9±13.0 265 68.1±15.6 EQ-5D-5L (generic healt	Necessities	271	3.5 ± 0.7	271	3.7±0.8
Physical 274 52.6 ±30.6 264 55.8±30.2 Emotional 274 66.5±24.7 264 66.6±22.9 Social 274 59.6±20.0 264 60.5±20.0 Eating 274 81.0±23.2 264 84.0±21.5 Body image 274 65.1±29.3 264 67.2±27.3 Treatment burden 274 51.5±19.7 265 56.6±19.5 Respiratory 271 56.6±21.9 263 58.0±22.5 Digestion 272 80.2±21.6 263 80.4±19.4 Perceptions of treatment adherence 245 9.9±3.6 237 10.8±3.3 (3-item scale) 250 3.0±1.2 260 3.3±1.3 Subjective adherence question – % (self-report estimate of adherence) 267 65.6±32.8 258 68.6±31.3 (self-report estimate of adherence) 272 9.6±3.2 263 9.4±3.4 PAM-13 (health style assessment) 274 64.9±13.0 265 68.1±15.6 EQ-5D-5L (generic health status) 272 0.81±0.18 264 0.84±0.15	using nebuliser)	271	11.7±4.9	261	12.9±4.9
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Eating 274 81.0±23.2 264 84.0±21.5 Body image 274 65.1±29.3 264 67.2±27.3 Treatment burden 274 51.5±19.7 265 56.6±19.5 Respiratory 271 56.6±21.9 263 58.0±22.5 Digestion 272 80.2±21.6 263 80.4±19.4 Perceptions of treatment adherence 245 9.9±3.6 237 10.8±3.3 (3-item scale) Effort of nebuliser treatments 270 3.0±1.2 260 3.3±1.3 Subjective adherence question – % 267 65.6±32.8 258 68.6±31.3 (self-report estimate of adherence) CHAOS-6 (life chaos or routine) 272 9.6±3.2 263 9.4±3.4 PAM-13 (health style assessment) 274 64.9±13.0 265 68.1±15.6 EQ-5D-5L (generic health status) 272 0.81±0.18 264 0.84±0.15 Patient-reported outcomes – safety measures † PHQ-8 (depression) 272 6.4±5.0 262 6.3±5.6					
Body image 274 65.1±29.3 264 67.2±27.3 Treatment burden 274 51.5±19.7 265 56.6±19.5 Respiratory 271 56.6±21.9 263 58.0±22.5 Digestion 272 80.2±21.6 263 80.4±19.4 Perceptions of treatment adherence 245 9.9±3.6 237 10.8±3.3 (3-item scale) 270 3.0±1.2 260 3.3±1.3 Subjective adherence question – % (self-report estimate of adherence) 267 65.6±32.8 258 68.6±31.3 (self-report estimate of adherence) 272 9.6±3.2 263 9.4±3.4 PAM-13 (health style assessment) 274 64.9±13.0 265 68.1±15.6 EQ-5D-5L (generic health status) 272 0.81±0.18 264 0.84±0.15 Patient-reported outcomes – safety measures [†] PHQ-8 (depression) 272 6.4±5.0 262 6.3±5.6					
Treatment burden 274 51.5±19.7 265 56.6±19.5 Respiratory 271 56.6±21.9 263 58.0±22.5 Digestion 272 80.2±21.6 263 80.4±19.4 Perceptions of treatment adherence 245 9.9±3.6 237 10.8±3.3 (3-item scale) Effort of nebuliser treatments 270 3.0±1.2 260 3.3±1.3 Subjective adherence question – % 267 65.6±32.8 258 68.6±31.3 (self-report estimate of adherence) CHAOS-6 (life chaos or routine) 272 9.6±3.2 263 9.4±3.4 PAM-13 (health style assessment) 274 64.9±13.0 265 68.1±15.6 EQ-5D-5L (generic health status) 272 0.81±0.18 264 0.84±0.15 Patient-reported outcomes – safety measures¹ PHQ-8 (depression) 272 6.4±5.0 262 6.3±5.6	•				
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Digestion 272 80.2±21.6 263 80.4±19.4 Perceptions of treatment adherence (3-item scale) 245 9.9±3.6 237 10.8±3.3 Effort of nebuliser treatments 270 3.0±1.2 260 3.3±1.3 Subjective adherence question – % (self-report estimate of adherence) 267 65.6±32.8 258 68.6±31.3 (Self-report estimate of adherence) 272 9.6±3.2 263 9.4±3.4 PAM-13 (health style assessment) 274 64.9±13.0 265 68.1±15.6 EQ-5D-5L (generic health status) 272 0.81±0.18 264 0.84±0.15 Patient-reported outcomes – safety measures † PHQ-8 (depression) 272 6.4±5.0 262 6.3±5.6		274	51.5±19.7	265	56.6±19.5
Perceptions of treatment adherence (3-item scale) 245 9.9±3.6 237 10.8±3.3 Effort of nebuliser treatments 270 3.0±1.2 260 3.3±1.3 Subjective adherence question – % (self-report estimate of adherence) 267 65.6±32.8 258 68.6±31.3 CHAOS-6 (life chaos or routine) 272 9.6±3.2 263 9.4±3.4 PAM-13 (health style assessment) 274 64.9±13.0 265 68.1±15.6 EQ-5D-5L (generic health status) 272 0.81±0.18 264 0.84±0.15 Patient-reported outcomes – safety measures¹ PHQ-8 (depression) 272 6.4±5.0 262 6.3±5.6	Respiratory	271	56.6±21.9	263	58.0±22.5
(3-item scale) Effort of nebuliser treatments 270 3.0±1.2 260 3.3±1.3 Subjective adherence question – % 267 65.6±32.8 258 68.6±31.3 (self-report estimate of adherence) CHAOS-6 (life chaos or routine) 272 9.6±3.2 263 9.4±3.4 PAM-13 (health style assessment) 274 64.9±13.0 265 68.1±15.6 EQ-5D-5L (generic health status) 272 0.81±0.18 264 0.84±0.15 Patient-reported outcomes – safety measures † PHQ-8 (depression) 272 6.4±5.0 262 6.3±5.6	Digestion	272	80.2±21.6	263	80.4±19.4
Subjective adherence question – % (self-report estimate of adherence) 267 65.6±32.8 258 68.6±31.3 CHAOS-6 (life chaos or routine) 272 9.6±3.2 263 9.4±3.4 PAM-13 (health style assessment) 274 64.9±13.0 265 68.1±15.6 EQ-5D-5L (generic health status) 272 0.81±0.18 264 0.84±0.15 Patient-reported outcomes – safety measures [†] PHQ-8 (depression) 272 6.4±5.0 262 6.3±5.6		245	9.9±3.6	237	10.8±3.3
(self-report estimate of adherence) 272 9.6±3.2 263 9.4±3.4 PAM-13 (health style assessment) 274 64.9±13.0 265 68.1±15.6 EQ-5D-5L (generic health status) 272 0.81±0.18 264 0.84±0.15 Patient-reported outcomes – safety measures [†] PHQ-8 (depression) 272 6.4±5.0 262 6.3±5.6	Effort of nebuliser treatments	270	3.0±1.2	260	3.3±1.3
PAM-13 (health style assessment) 274 64.9±13.0 265 68.1±15.6 EQ-5D-5L (generic health status) 272 0.81±0.18 264 0.84±0.15 Patient-reported outcomes – safety measures† PHQ-8 (depression) 272 6.4±5.0 262 6.3±5.6	(self-report estimate of adherence)				
EQ-5D-5L (generic health status) 272 0.81±0.18 264 0.84±0.15 Patient-reported outcomes – safety measures [†] PHQ-8 (depression) 272 6.4±5.0 262 6.3±5.6	CHAOS-6 (life chaos or routine)	272	9.6±3.2	263	9.4±3.4
Patient-reported outcomes – safety measures [†] PHQ-8 (depression) 272 6.4±5.0 262 6.3±5.6	PAM-13 (health style assessment)	274	64.9±13.0	265	68.1±15.6
safety measures [†] PHQ-8 (depression) 272 6.4±5.0 262 6.3±5.6	EQ-5D-5L (generic health status)	272	0.81±0.18	264	0.84±0.15
	Patient-reported outcomes – safety measures [†]				
GAD-7 (anxiety) 273 4.5±4.8 262 4.9±5.3		272	6.4±5.0	262	6.3±5.6
	GAD-7 (anxiety)	273	4.5±4.8	262	4.9±5.3

FEV₁=forced expiratory volume in one second; IV=intravenous.

ADVERSE EVENTS

	Usual Care (N=303)	Intervention (N=305)
All AE		
Number of AE, overall – n (% of all AE)	301 (46.9)	341 (53.1)
Number of participants experiencing ≥1 AE – n (% of participants in treatment arm)	125 (41.3)	139 (45.6)
Number of AE, by category – n (% of AE in treatment arm)		
Expected	242 (80.4)	263 (77.1)
Other	58 (19.3)	73 (21.4)
Serious AE*		
Number of serious AE, overall - n (% of all serious AE)	64 (47.4)	71 (52.6)
Number of participants experiencing ≥1 serious AE – n (% of participants in treatment arm)	43 (14.2)	56 (18.4)
Number of serious AE, by category – n (% of serious AE in treatment arm)		
Expected	21 (32.8)	28 (39.4)
Other	41 (64.1)	42 (59.2)
Unknown	2 (3.1)	1 (1.4)

AE=adverse event.

^{*}There were no serious AEs deemed related to the intervention (non-serious AEs were not assessed for relatedness).