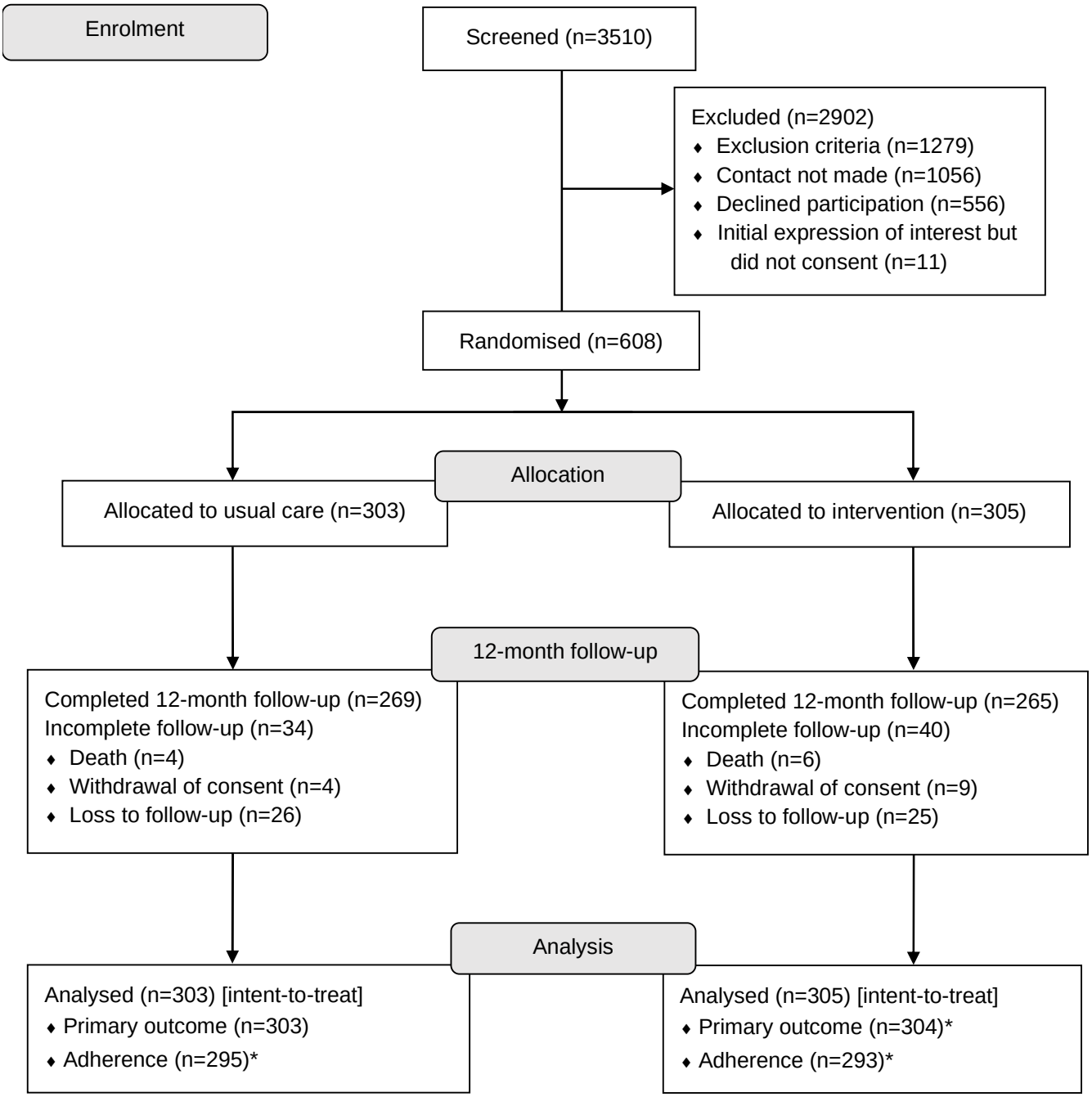
ISRCTN55504164

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		Intervention	
	N*	Mean±SD[†]	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.
*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.
Full details and references for all patient-reported outcomes are available in the statistical analysis plan (see supplementary material).

OUTCOME MEASURES

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

Usual care				Intervention			
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

	Usual care		Intervention	
	N	**Mean±SD**	**N**	**Mean±SD**
Normative adherence (weekly, numerator-adjusted) – %	295	34.9±31.7	293	52.9±31.4
FEV_1 % predicted – %	282	56.9±23.0	274	60.6±24.2
Body mass index – kg/m^2	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 using nebuliser)	271	11.7±4.9	261	12.9±4.9
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 (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 measures[†]				
PHQ-8 (depression)	272	6.4±5.0	262	6.3±5.6
GAD-7 (anxiety)	273	4.5±4.8	262	4.9±5.3

FEV_1=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).