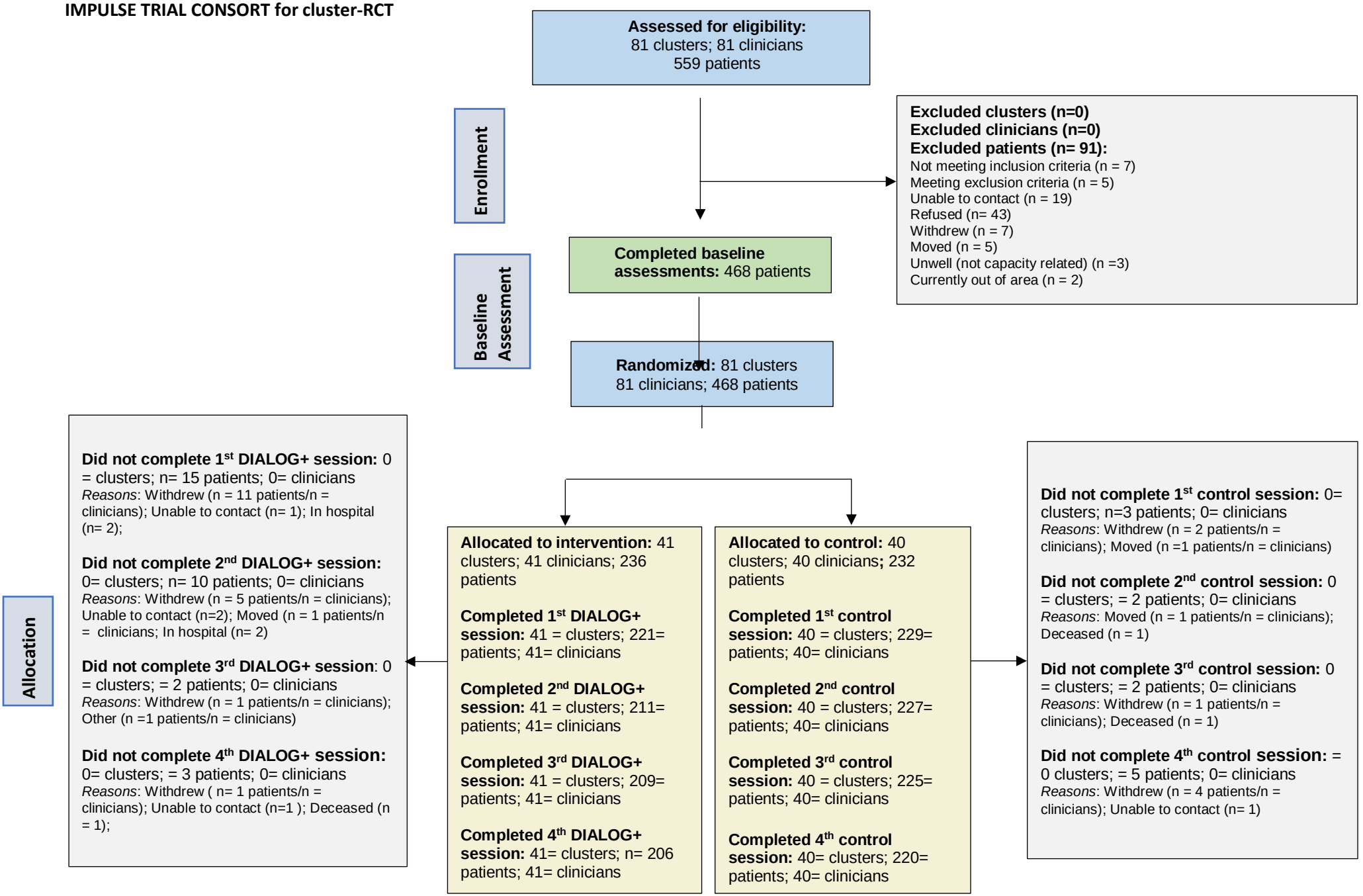
IMPULSE TRIAL CONSORT for cluster-RCT



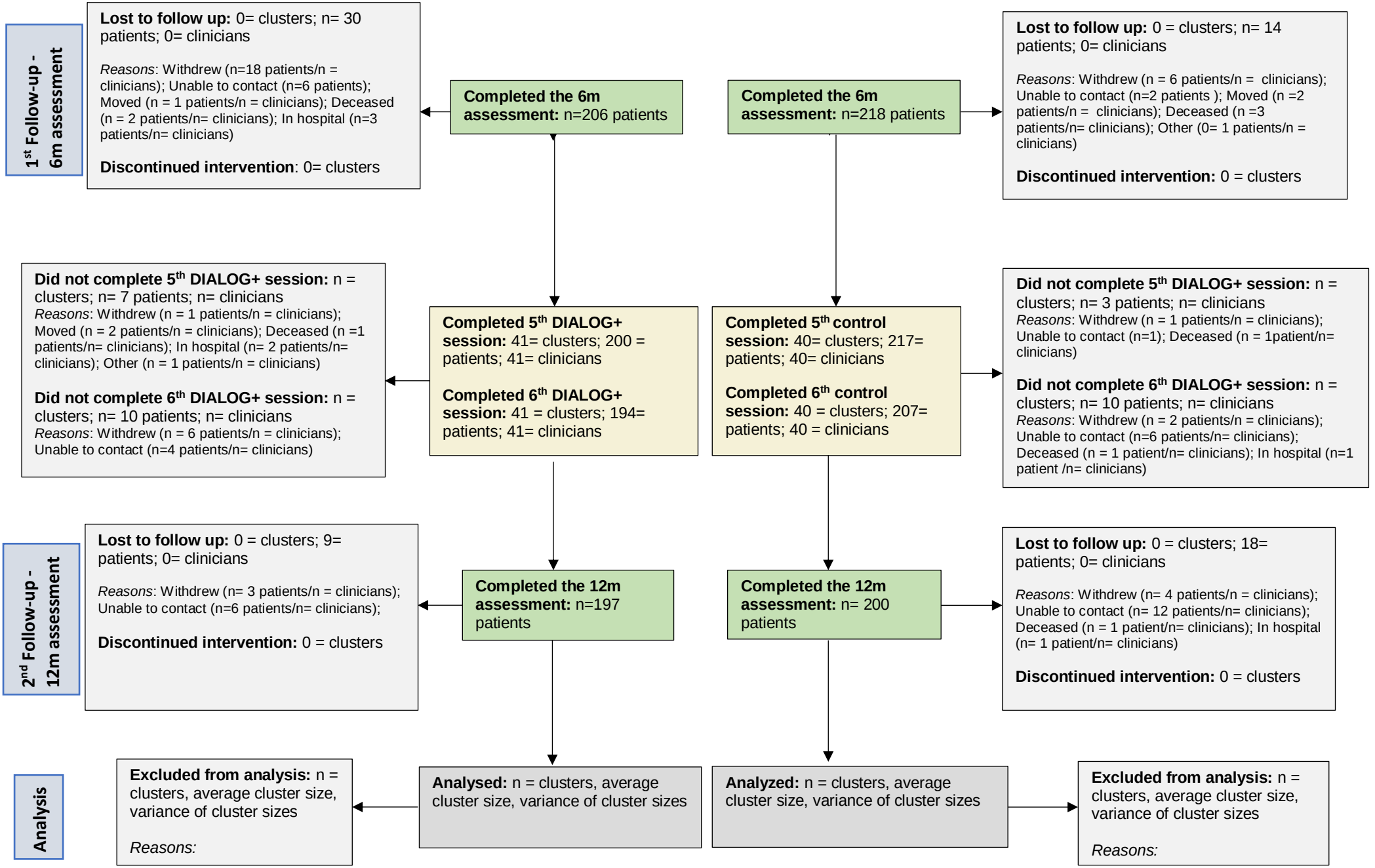

1st Follow-up - 6m assessment
Lost to follow up: 0= clusters; n= 30 patients; 0= clinicians
Reasons: Withdrew (n=18 patients/n = clinicians); Unable to contact (n=6 patients); Moved (n = 1 patients/n = clinicians); Deceased (n = 2 patients/n= clinicians); In hospital (n=3 patients/n= clinicians)
Discontinued intervention: 0= clusters
Completed the 6m assessment: n=206 patients
Completed the 6m assessment: n=218 patients
Lost to follow up: 0 = clusters; n= 14 patients; 0= clinicians
Reasons: Withdrew (n = 6 patients/n = clinicians); Unable to contact (n=2 patients); Moved (n =2 patients/n = clinicians); Deceased (n =3 patients/n= clinicians); Other (0= 1 patients/n = clinicians)
Discontinued intervention: 0 = clusters
Did not complete 5th DIALOG+ session: n = clusters; n= 7 patients; n= clinicians
Reasons: Withdrew (n = 1 patients/n = clinicians); Moved (n = 2 patients/n = clinicians); Deceased (n =1 patients/n= clinicians); In hospital (n= 2 patients/n= clinicians); Other (n = 1 patients/n = clinicians)
Did not complete 6th DIALOG+ session: n = clusters; n= 10 patients; n= clinicians
Reasons: Withdrew (n = 6 patients/n = clinicians); Unable to contact (n=4 patients/n= clinicians)
Completed 5th DIALOG+ session: 41= clusters; 200 = patients; 41= clinicians
Completed 6th DIALOG+ session: 41 = clusters; 194= patients; 41= clinicians
Completed 5th control session: 40= clusters; 217= patients; 40= clinicians
Completed 6th control session: 40 = clusters; 207= patients; 40 = clinicians
Did not complete 5th DIALOG+ session: n = clusters; n= 3 patients; n= clinicians
Reasons: Withdrew (n = 1 patients/n = clinicians); Unable to contact (n=1); Deceased (n = 1patient/n= clinicians)
Did not complete 6th DIALOG+ session: n = clusters; n= 10 patients; n= clinicians
Reasons: Withdrew (n = 2 patients/n = clinicians); Unable to contact (n=6 patients/n= clinicians); Deceased (n = 1 patient/n= clinicians); In hospital (n=1 patient /n= clinicians)
2nd Follow-up - 12m assessment
Lost to follow up: 0 = clusters; 9= patients; 0= clinicians
Reasons: Withdrew (n= 3 patients/n = clinicians); Unable to contact (n=6 patients/n= clinicians);
Discontinued intervention: 0 = clusters
Completed the 12m assessment: n=197 patients
Completed the 12m assessment: n= 200 patients
Lost to follow up: 0 = clusters; 18= patients; 0= clinicians
Reasons: Withdrew (n= 4 patients/n = clinicians); Unable to contact (n= 12 patients/n= clinicians); Deceased (n = 1 patient/n= clinicians); In hospital (n= 1 patient/n= clinicians)
Discontinued intervention: 0 = clusters
Analysis
Excluded from analysis: n = clusters, average cluster size, variance of cluster sizes
Reasons:
Analysed: n = clusters, average cluster size, variance of cluster sizes
Analyzed: n = clusters, average cluster size, variance of cluster sizes
Excluded from analysis: n = clusters, average cluster size, variance of cluster sizes
Reasons:

Table 1 Sample (patients and clinicians) characteristics

		Standard care (control arm)		DIALOG+ (intervention arm)	
		N	Summary	N	Summary
PATIENTS					
Country (all patients)	Total	232		236	
	Bosnia & Herzegovina		41 (17.7%)		40 (17.0%)
	Macedonia		41 (17.7%)		41 (17.4%)
	Kosovo*		51 (22.0%)		52 (21.0%)
	Montenegro		60 (25.9%)		62 (26.3%)
	Serbia		39 (16.8%)		41 (17.4%)
Age	-	232	40.8 ± 11.3	236	44.3 ± 11.1
Sex	Female	232	111 (47.8%)	236	103 (43.6%)
	Male		121 (52.2%)		133 (56.4%)
Marital status	Single	232	133 (57.3%)	236	121 (51.3%)
	Married / co-habit.		59 (25.4%)		66 (28.0%)
	Separated / divorced		37 (16.0%)		38 (16.1%)
	Widow / widower		3 (1.3%)		11 (4.7%)
Level of education	Less elementary	232	7 (3.0%)	236	2 (0.9%)
	Elementary		30 (12.9%)		49 (20.8%)
	High school		144 (62.1%)		139 (58.9%)
	University		45 (19.4%)		40 (17.0%)
	Postgraduate		4 (1.7%)		4 (1.7%)
	Other		2 (0.9%)		2 (0.9%)
Living situation	Living alone	232	29 (12.5%)	236	30 (12.7%)
	With others		207 (89.2%)		202 (85.6%)
ICD-10 diagnosis	Schizophrenia	232	129 (55.6%)	236	155 (65.7%)
	Bipolar		43 (18.5%)		24 (10.2%)
	Other diagnosis		60 (25.9%)		57 (24.2%)
Antipsychotic medication (Olanzapine Equivalents in mg/daily)	-	202	9.9 (6.6)	213	11.9 (6.8)
Hospitalisations	No	232	34 (14.7%)	235	33 (14.0%)
	Yes		198 (85.3%)		202 (86.0%)

Number of hospitalisations	-	228	1 [1, 4]	231	2 [1, 4]
History of receiving psychological treatment	No	231	112 (48.5%)	232	141 (60.8%)
	Yes		119 (51.5%)		91 (39.2%)
Clinician's gender	Female	232	175 (75.4%)	236	189 (80.1%)
	Male		57 (24.6%)		47 (19.9%)
Clinician's profession	Psychiatrists	232	174 (75.0%)	236	145 (61.4%)
	Other profession		58 (25.0%)		91 (38.6%)
CLINICIANS					
Country (all clinicians)	Total	40		41	
	Bosnia & Herzegovina		8 (20%)		8 (19.5%)
	Macedonia		8 (20%)		8 (19.5%)
	Kosovo*		8 (20%)		8 (19.5%)
	Montenegro		8 (20%)		8 (19.5%)
	Serbia		8 (20%)		9 (22%)
Clinician's gender	Female	61	28 (45.9%)		33 (54.1%)
	Male	20	12 (60%)		8 (40%)
Clinician's profession	Psychiatrists	55	28 (50.9%)		27 (49.1%)
	Other profession	26	12 (46.7%)		14 (53.8%)

Table 2 - Primary outcome at baseline, 6 and 12 months

Outcome	Whole sample N
Quality of Life (MANSA)	
Baseline	468
6 months	424
12 months	397

Note: Results on differences between intervention and control arms on primary outcome will reported upon submission/publication of the final manuscript

Table 3 Secondary outcomes at baseline, 6 and 12 months

Outcome	Whole sample N
Observed clinical symptoms (BPRS)	
Baseline	465
6 months	417
12 months	216
Self-reported mental health problems (BSI)	
Baseline	468
6 months	424
12 months	396
Treatment satisfaction (CSQ-8)	
Baseline	468
6 months	224
12 months	396
Negative symptoms (CAINS-MAP)	
Baseline	453
6 months*	
12 months	375
Negative symptoms (CAINS-EXP)	
Baseline	468
6 months*	
12 months	383

Note: Results on differences between intervention and control arms on secondary outcomes will reported upon submission/publication of the final manuscript

**CAINS was assessed only at baseline and 12-months*

Table 4 List of (Serious) Adverse Events

Type of SAE/AE	**Standard Care**	**Intervention Arm**
Hospitalisation (SAE)	4 (SAE)	4 (SAE)
Sudden death (SAE)		1 (SAE)
Death (SAE)	2 (SAE)	
Medication intoxication		1 (SAE)
Involuntary medication intoxication		1 (SAE)
Feeling unwell		1 (AE)
TOTAL	6 (SAE)	8 (7 SAE, 1 AE)

Note: None of the SAEs/AEs were found to be related to the intervention