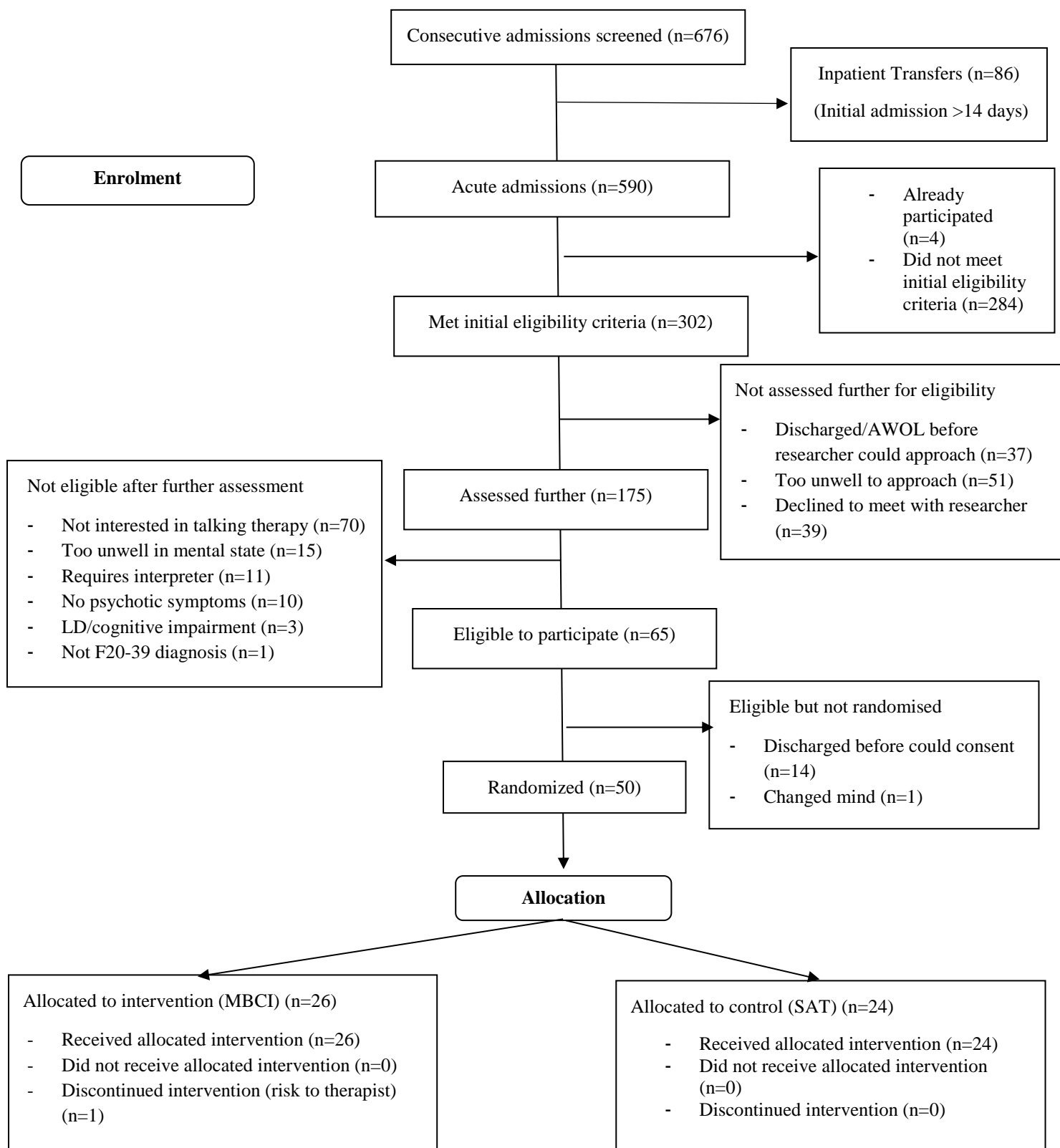
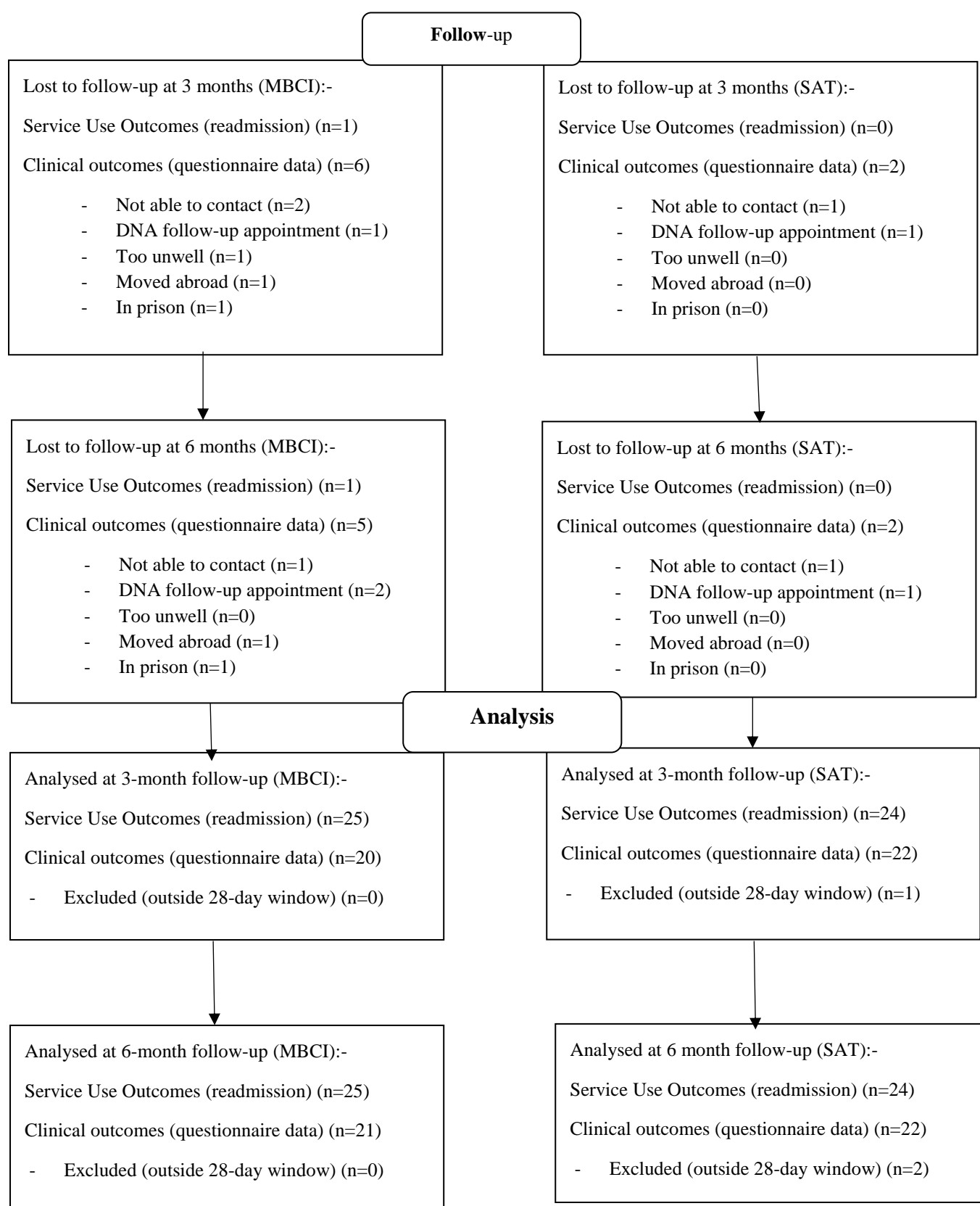


## Participant Flow





## Baseline Characteristics

	SAT (N=24)	MBCI (N=26)	OVERALL (N=50)
<b>DEMOGRAPHIC CHARACTERISTICS</b>			
<b>Age</b>			
- Mean (range)	33 years (19-65)	35 years (18-52)	34 years (18-65)
<b>Gender</b>			
- Male	17 (71%)	17 (65%)	34 (68%)
- Female	7 (29%)	9 (35%)	16 (32%)
<b>Ethnicity</b>			
- White	8 (33%)	8 (30%)	16 (32%)
- Asian	3 (13%)	3 (12%)	6 (12%)
- Black	9 (37%)	12 (46%)	21 (42%)
- Mixed Race	3 (13%)	3 (12%)	6 (12%)
- Other	1 (4%)	0 (0%)	1 (2%)
<b>Highest educational qualification</b>			
- No formal qualifications	3 (13%)	5 (18%)	8 (16%)
- GCSE (or equivalent)	6 (25%)	8 (31%)	14 (28%)
- A-Levels (or equivalent)	7 (29%)	8 (31%)	15 (30%)
- Graduate	6 (25%)	2 (8%)	8 (16%)
- Post-Graduate	1 (4%)	1 (4%)	2 (4%)
- Vocational Qualification	1 (4%)	1 (4%)	2 (4%)
- Not known	0 (0%)	1 (4%)	1 (2%)
<b>Employment status</b>			
- Working (full/part-time)	7 (29%)	2 (8%)	9 (18%)
- Studying	3 (13%)	4 (15%)	7 (14%)
- Retired	1 (4%)	0 (0%)	1 (2%)
- Looking after family	1 (4%)	0 (0%)	1 (2%)
- Unemployed	2 (8%)	6 (23%)	8 (16%)
- Disability benefits	10 (42%)	14 (54%)	24 (48%)
<b>Currently in a relationship</b>			
- Yes	5 (21%)	1 (4%)	6 (12%)
- No	19 (79%)	25 (96%)	44 (88%)
<b>Accommodation status</b>			

- Council tenant	10 (41%)	11 (42%)	21 (42%)
- Private tenant	3 (13%)	0 (0%)	3 (6%)
- Own property	2 (8%)	0 (0%)	2 (4%)
- Living in family home	5 (21%)	11 (42%)	16 (32%)
- Supported accommodation	3 (13%)	2 (8%)	5 (10%)
- Temporary accommodation/homeless	1 (4%)	2 (8%)	3 (6%)
<b>Live alone</b>			
- Yes	11 (46%)	15 (58%)	26 (52%)
- No	13 (54%)	12 (42%)	24 (48%)

	<b>SAT (N=24)</b>	<b>MBCI (N=26)</b>	<b>ALL PARTICIPANTS (N=50)</b>
<b>CLINICAL CHARACTERISTICS</b>			
<b>Diagnosis</b>			
- F20-29 (Schizophrenia-spectrum)	17 (71%)	20 (77%)	37 (74%)
- F30-39 (Mood disorder)	7 (29%)	6 (23%)	13 (26%)
<b>Psychotic symptoms (self-report)</b>			
- Delusions only	12 (50%)	14 (54%)	26 (52%)
- Voices only	1 (4%)	0 (0%)	1 (2%)
- Delusions + voices	11 (46%)	12 (46%)	23 (46%)
<b>Legal status on admission</b>			
- Informal	6 (25%)	8 (31%)	14 (28%)
- MHA Sec 2	13 (54%)	14 (54%)	27 (54%)
- MHA Sec 3	5 (21%)	3 (11%)	8 (16%)
- MHA Sec 37	0 (0%)	1 (4%)	1 (2%)
<b>Open to CMHT on admission</b>			
- Yes	12 (50%)	10 (38%)	22 (44%)
- No	12 (50%)	16 (62%)	28 (56%)

<b>Psychiatric medication on admission</b>			
- Prescribed at least one medication	20 (83%)	19 (73%)	39 (78%)
- Prescribed anti-psychotic	18 (75%)	18 (69%)	36 (72%)
- Prescribed an anti-depressant	3 (13%)	4 (15%)	7 (27%)
- Prescribed a mood-stabilizer	5 (21%)	1 (4%)	6 (12%)
<b>Years known to services</b>			
- <1 year	5 (21%)	4 (15%)	9 (18%)
- 1-5 years	4 (17%)	6 (23%)	10 (20%)
- 6-10 years	6 (25%)	8 (31%)	14 (28%)
- 11-15 years	2 (8%)	2 (8%)	4 (8%)
- >15 years	7 (29%)	6 (23%)	13 (26%)
<b>Previous admissions</b>			
- Yes	14 (58%) (mean = 5.64, range 1-14)	21 (81%) (mean= 4.00, range 1-10)	35 (70%) (mean = 4.66, range 1-14)
- No	10 (42%)	5 (19%)	15 (30%)
<b>Admission in previous 12 months</b>			
- Yes	7 (29%)	8 (31%)	15 (30%)
- No	17 (71%)	18 (69%)	35 (70%)
<b>Psychological therapy in past 5 years</b>			
- None	11 (46%)	12 (46%)	23 (46%)
- Offered	3 (12%)	4 (15%)	7 (14%)
- Received	10 (42%)	10 (39%)	20 (40%)

## Outcome measures

*Primary (Feasibility/Acceptability)*

Feasibility Outcome				
1. Number of eligible participants identified over study period	65			
2. Total numbers recruited into trial and recruitment rate (benchmark of 80% of target)	50 (83% of target)			
3. Proportion of participants who dropped out during the intervention stage	No drop out during interventions stage. All participant randomised into trial received at least 1 therapy session.			
4. Range and average number of sessions completed (including number of sessions attended as a proportion of those offered)	Range 1-5 sessions, mean number of sessions completed= 3.04 in SAT group, and 2.81 MBCI group. Total number of sessions attended/offered= 146/191 (76%).			
5. Number lost to follow-up and reasons (benchmark of less than 20%)	At 6-month trial end-point: - 1 (2%) participant lost to follow-up for service use outcomes (readmission), 7 (14%) participants lost to follow-up for clinical measure outcomes (self-report questionnaires).			
6. Satisfaction with therapy at 6-month follow-up	SAT (N=24)	MBCI (N=26)	Overall (N=50)	
Mean (SD)	8.27 (1.91)	9.11 (1.1)	8.66 (1.62)	
Range	2-10	7-10	2-10	
0=Not satisfied at all 10=Completely satisfied				

*Secondary Outcomes (Pilot outcome data on readmission rates)*

	<b>Up to F2 (0-6mths)</b>	
<b>Outcome</b>	<b>MBCI (N=25<sup>1</sup>)</b>	<b>SAT (N=24)</b>
<b>1) Re-hospitalisation (≥1 OBD<sup>2</sup>)</b>  - Yes - No	6 (24%) 19 (76%)	5 (21%) 19 (79%)
<b>2) Time to first re-admission (days)</b>  - Mean (SD) - Range - 95% CI	80 (29) 41-122 49-111	101 (56) 58-176 32-171
<b>3) Total number of OBDs</b>  - Mean (SD) - Range - 95% CI	45 (38) 2-83 4-85	51 (44) 4-117 0-105
<b>4) Episodes of care with crisis/home treatment team (HTT)<sup>3</sup></b>  - Yes - No	0 (0%) 25 (100%)	2 (8%) 22 (92%)

<sup>1</sup> Re-admission data not available for 1 participant (moved abroad)

<sup>2</sup> OBD=occupied bed day

<sup>3</sup> Stand-alone episodes of care only (i.e. not overlapping with inpatient admissions)

Secondary outcome measures – Clinical measure outcomes

	<b>T1 (Baseline)</b>		<b>T2 (End of therapy)</b>		<b>F1 (3-month follow-up)</b>		<b>F2 (6-month follow-up)</b>	
	<b>MBCI</b>	<b>SAT</b>	<b>MBCI</b>	<b>SAT</b>	<b>MBCI</b>	<b>SAT</b>	<b>MBCI</b>	<b>SAT</b>
	N=26	N=23	N=23	N=23	N=20	N=20	N=21	N=19
<b>Self-rating of psychotic symptoms (Beliefs)</b>								
<b>Frequency (1-7)</b>								
Mean	5.58	5.65	3.17	3.61	3.25	3.00	2.57	2.63
S.D	1.65	1.34	2.15	2.08	2.33	2.36	1.89	2.03
(95% CI)	(4.91-6.24)	(5.07-6.23)	(2.25-4.1)	(2.71-4.51)	(2.16-4.34)	(1.89-4.11)	(1.71-3.43)	(1.65-3.61)
<b>Distress (0-10)</b>								
Mean	6.69	7.70	2.83	5.26	3.70	2.90	2.24	2.16
S.D	3.42	3.42	2.82	3.40	3.94	3.43	3.21	2.97
(95% CI)	(5.31-8.07)	(6.22-9.17)	(1.61-4.05)	(3.79-6.73)	(1.86-5.54)	(1.29-4.51)	(0.78-3.70)	(0.73-3.59)
<b>Believability (0-10)</b>								
Mean	8.15	7.48	4.70	6.00	3.95	3.90	4.38	3.74
S.D	3.08	3.38	3.61	3.45	4.12	4.41	4.41	4.01
(95% CI)	(6.91-9.40)	(6.02-8.94)	(3.13-6.26)	(4.51-7.49)	(2.02-5.88)	(1.84-5.96)	(2.37-6.39)	(1.80-5.67)
	<b>T1</b>		<b>T2</b>		<b>F1</b>		<b>F2</b>	
	<b>MBCI</b>	<b>SAT</b>	<b>MBCI</b>	<b>SAT</b>	<b>MBCI</b>	<b>SAT</b>	<b>MBCI</b>	<b>SAT</b>
	N=12	N=12	N=11	N=12	N=9	N=11	N=9	N=10
<b>Self-rating of</b>								

<b>psychotic symptoms (Voices)</b>								
<b>Frequency (1-7)</b>								
Mean	5.08	5.58	4.09	3.42	3.00	2.73	4.22	2.30
S.D	1.62	1.5	2.07	2.11	2.18	2.15	2.33	1.95
(95% CI)	(4.06-6.11)	(4.63-6.54)	(2.70-5.48)	(2.08-4.76)	(1.32-4.68)	(1.28-4.17)	(2.43-6.02)	(0.91-3.69)
<b>Distress (0-10)</b>								
Mean	6.50	8.42	3.27	3.75	2.22	1.18	3.00	1.80
S.D	3.03	2.50	3.10	3.82	3.15	2.44	4.03	2.62
(95% CI)	(4.57-8.43)	(6.83-10.01)	(1.19-5.36)	(1.32-6.18)	(0.00 <sup>4</sup> -4.65)	(0.00-2.82)	(0.00-6.10)	(0.00-3.67)
<b>Believability (0-10)</b>								
Mean	6.83	6.17	4.00	5.17	3.11	2.45	4.78	2.90
S.D	3.24	3.22	3.58	4.26	3.98	3.75	4.60	4.01
(95% CI)	(4.77-8.89)	(4.12-8.21)	(1.6-6.40)	(2.46-7.87)	(0.05-6.17)	(0.00-4.97)	(1.24-8.32)	(0.03-5.77)
<b>HPSVQ (0-36)</b>								
(Hamilton Program for Schizophrenia Voices Questionnaire)								
Mean	20.67	25.5	16.45	13.00	9.44	8.55	13.63 <sup>5</sup>	5.70
S.D	8.49	4.78	8.10	10.87	8.99	9.13	10.66	7.60
(95% CI)	(15.27-25.06)	(22.46-28.54)	(11.01-21.90)	(6.09-19.91)	(2.54-16.4)	(2.41-14.7)	(4.71-22.5)	(0.26-11.14)
	<b>T1</b>		<b>T2</b>		<b>F1</b>		<b>F2</b>	
	<b>MBCI</b>	<b>SAT</b>	<b>MBCI</b>	<b>SAT</b>	<b>MBCI</b>	<b>SAT</b>	<b>MBCI</b>	<b>SAT</b>
	N=24	N=26	N=23	N=24	N=20	N=21	N=20 <sup>6</sup>	N=20

<sup>4</sup> Lower Bound Confidence Interval truncated to 0 where calculated value is negative to indicate floor effect

<sup>5</sup> N=8 in MBCI group for HPSVQ as 1 participant failed to complete all measures in the F2 assessment

<sup>6</sup> 1 MBCI participant failed to complete all questionnaire measures in the F2 assessment

<b>Mood</b> (DASS-21; Depression, anxiety & stress)								
<b>Depression</b> (0-42)								
Mean	15.77	20.75	9.04	15.42	13.7	11.81	12.60	13.80
S.D	12.44	14.62	10.48	12.28	10.53	12.18	11.86	12.66
(95% CI)	(10.75- 20.79)	(14.58- 26.92)	(4.51- 13.57)	(10.23- 20.60)	(8.77- 18.63)	(6.27- 17.35)	(7.05- 18.15)	(7.87- 19.73)
<b>Anxiety</b> (0-42)								
Mean	15.85	19.75	10.00	15.17	8.5	9.52	7.70	10.40
S.D	13.25	11.67	8.66	12.17	8.15	10.52	10.61	10.21
(95% CI)	(10.49- 21.20)	(14.82- 24.68)	(6.26- 13.74)	(10.03- 20.31)	(4.68- 12.32)	(4.73- 14.31)	(2.74- 12.66)	(5.62- 15.18)
<b>Stress</b> (0-42)								
Mean	19.31	25.58	15.04	17.58	13.50	9.62	11.40	12.40
S.D	11.76	11.57	9.36	10.23	11.20	11.57	11.75	9.37
(95% CI)	(14.56- 24.06)	(20.7- 30.47)	(11.00- 19.09)	(13.26- 21.90)	(8.26- 18.74)	(4.35- 14.89)	(5.90- 16.90)	(8.01- 16.79)

	<b>T1</b>		<b>T2</b>		<b>F1</b>		<b>F2</b>	
	<b>MBCI</b>	<b>SAT</b>	<b>MBCI</b>	<b>SAT</b>	<b>MBCI</b>	<b>SAT</b>	<b>MBCI</b>	<b>SAT</b>
	N=24	N=26	N=23	N=24	N=20	N=21	N=20	N=20
<b>Recovery (0-88)</b>								
(QPR; Questionnaire about the Process of Recovery)								
Mean	65.31	60.58	67.09	61.00	63.40	63.52	62.20	61.00
S.D	13.25	18.75	13.94	13.20	15.04	15.26	20.45	16.06
(95% CI)	(69.96- 70.66)	(52.67- 68.5)	(61.06- 73.11)	(55.42- 66.58)	(56.36- 70.44)	(56.58- 70.47)	(53.49- 68.51)	(53.49- 68.51)
	<b>MBCI</b>	<b>SAT</b>	<b>MBCI</b>	<b>SAT</b>	<b>MBCI</b>	<b>SAT</b>	<b>MBCI</b>	<b>SAT</b>
	N=24	N=26	N=23	N=23	N=20	N=21	N=20	N=19 <sup>7</sup>
<b>Mindfulness (0-96)</b>								
(SMQ; Southampton Mindfulness Questionnaire)								
Mean	56.27	47.25	58.13	53.26	57.50	57.57	55.00	57.05
S.D	14.96	14.67	12.28	14.08	11.88	16.52	11.81	12.84
(95% CI)	(50.23- 62.31)	(41.05- 53.45)	(52.82- 63.44)	(47.17- 59.35)	(51.94- 63.06)	(50.05- 65.09)	(49.47- 60.53)	(50.86- 63.24)

<sup>7</sup> 1 participant in the SAT group did not complete the SMQ at F2

### **Adverse events**

Three participants (2 SAT; 1 MBCI) experienced a total of 5 adverse events over the course of the trial. These adverse events were all reported to the chair of the Trial Steering Committee who was in agreement that they were highly unlikely to be related to trial participation.

	<b>Number of events</b>	<b>Number of participants</b>
Minor assault by another patient during inpatient admission (not requiring medical treatment)	1	1
Medication overdose (overnight medical admission for observation – no further treatment required)	3	2
Fractured shoulder in a fall (brief hospital admission for treatment)	1	1