

CaFI Trial Basic Result Summary

Final Trial Result

Project Details

Project Title: The effect on relapse of Culturally-adapted Family Intervention (CaFI) compared to usual care among African & Caribbean people diagnosed with psychosis in the UK: a Randomised Controlled Trial

ISRCTN Registry: ISRCTN12622538

Participant Flow

Figure 1: CONSORT flow diagram for CaFI

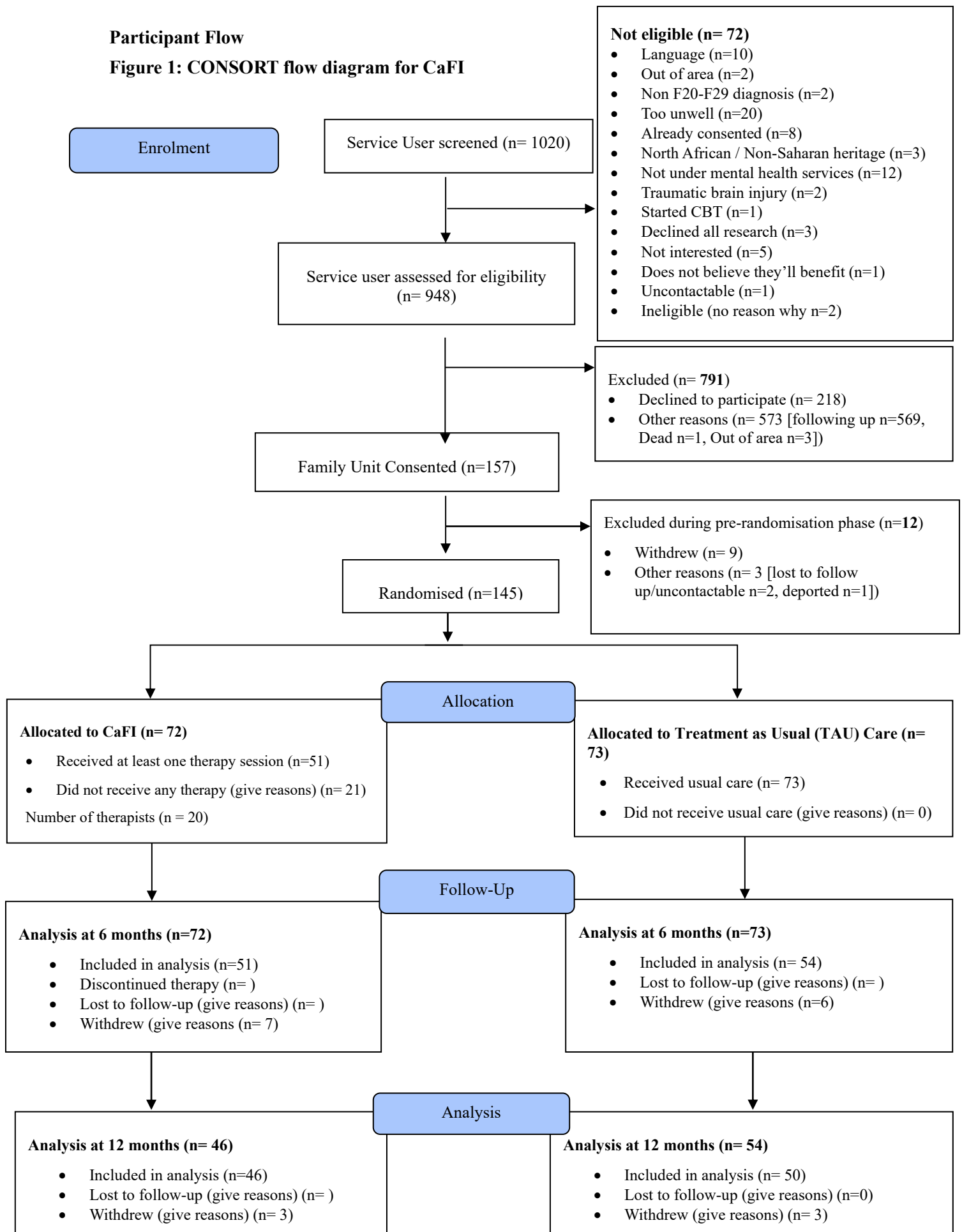
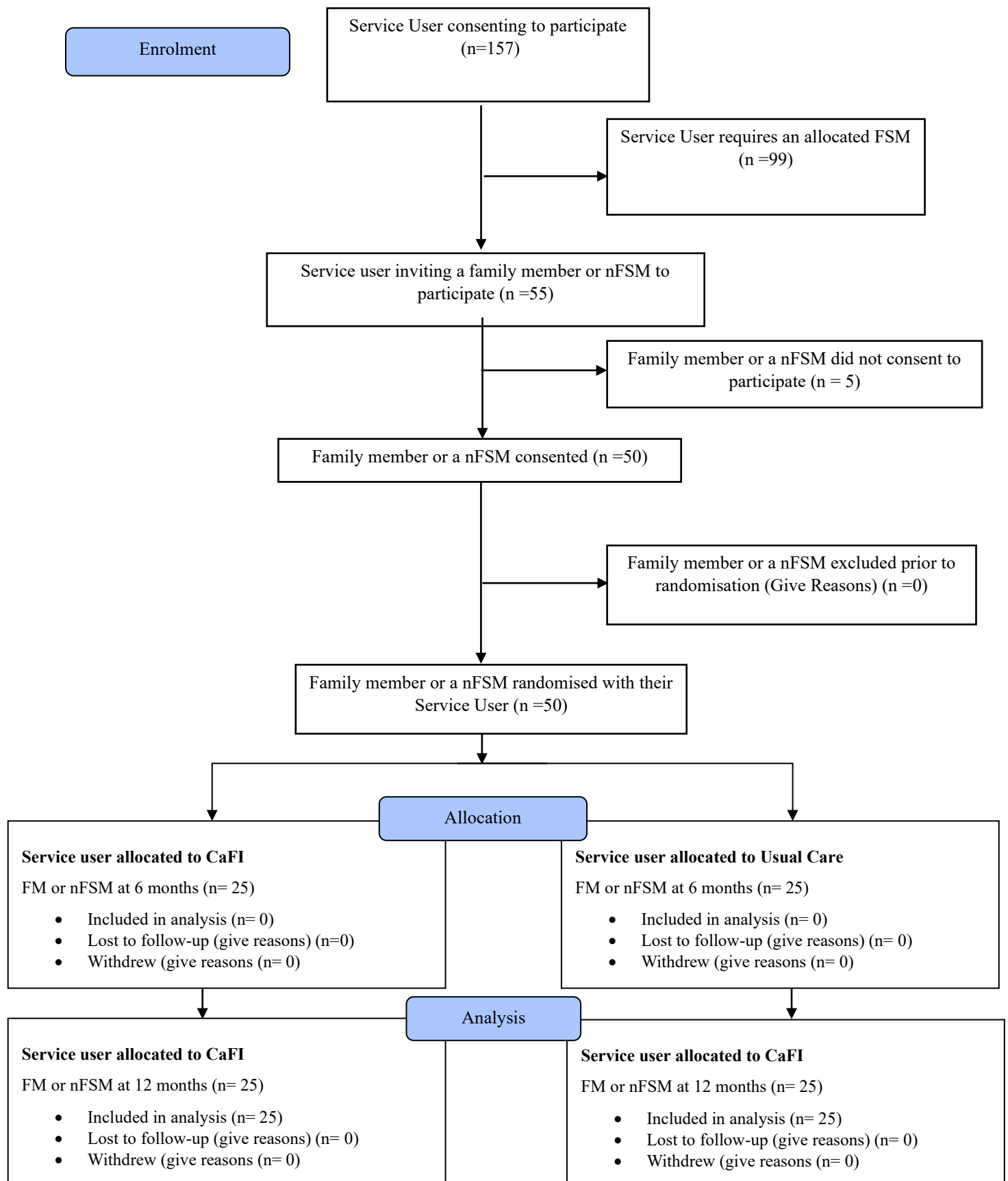


Figure 2: CONSORT flow diagram for Therapy Partners (Family members and nominated Family Support Members)



Baseline Characteristics

Table 1. Baseline characteristics for Service Users

	Trial Arm		
	TAU (N = 73)	CaFI (N = 72)	Total (N = 145)
Site Name			
Greater Manchester Mental Health	38.0 (52.1%)	38.0 (52.8%)	76.0 (52.4%)
South London and Maudsley	23.0 (31.5%)	23.0 (31.9%)	46.0 (31.7%)
Birmingham and Solihull	4.0 (5.5%)	3.0 (4.2%)	7.0 (4.8%)
Southern Healthcare	7.0 (9.6%)	6.0 (8.3%)	13.0 (9.0%)
Pennine Care	1.0 (1.4%)	2.0 (2.8%)	3.0 (2.1%)
Ethnic Background			
African Heritage	43.0 (58.9%)	42.0 (58.3%)	85.0 (58.6%)
Caribbean Heritage	26.0 (35.6%)	27.0 (37.5%)	53.0 (36.6%)
Mixed African/Caribbean Heritage	4.0 (5.5%)	3.0 (4.2%)	7.0 (4.8%)
Therapy Partner			
Family member or nominated FSM	25.0 (34.2%)	25.0 (34.7%)	50.0 (34.5%)
Allocated FSM	48.0 (65.8%)	47.0 (65.3%)	95.0 (65.5%)
Mean Age (SD)			
	39.3 (12.9)	41.7 (12.4)	40.5 (12.7)
Gender			
Male	46.0 (63.9%)	43.0 (59.2%)	89.0 (61.5%)
Female	27.0 (36.1%)	29.0 (40.8%)	56.0 (38.5%)
Ethnicity¹			
Black British	23.0 (32.4%)	17.0 (24.3%)	40.0 (28.4%)
Black Caribbean	8.0 (11.3%)	8.0 (11.4%)	16.0 (11.3%)
Black African	23.0 (32.4%)	27.0 (38.6%)	50.0 (35.5%)
Any other Black / African / Caribbean background	6.0 (8.5%)	7.0 (10.0%)	13.0 (9.2%)
White and Black Caribbean	3.0 (4.2%)	6.0 (8.6%)	9.0 (6.4%)
White and Black African	3.0 (4.2%)	0.0 (0.0%)	3.0 (2.1%)
Any other mixed / multiple ethnic background	5.0 (7.0%)	5.0 (7.1%)	10.0 (7.1%)
Religious beliefs¹			
No religion	8.0 (11.3%)	16.0 (22.9%)	24.0 (17.0%)
Christian	49.0 (69.0%)	44.0 (62.9%)	93.0 (66.0%)
Muslim	8.0 (11.3%)	7.0 (10.0%)	15.0 (10.6%)
Buddhist	1.0 (1.4%)	1.0 (1.4%)	2.0 (1.4%)
Other	5.0 (7.0%)	2.0 (2.9%)	7.0 (5.0%)
Marital Status²			
Married or in Civil Partnership	7.0 (10.0%)	3.0 (4.3%)	10.0 (7.1%)
Separated/divorced	4.0 (5.7%)	6.0 (8.6%)	10.0 (7.1%)
Cohabiting	0.0 (0.0%)	3.0 (4.3%)	3.0 (2.1%)
Single	59.0 (84.3%)	58.0 (82.9%)	117.0 (83.6%)
Employment Status¹			
Full-time work	5.0 (7.0%)	8.0 (11.4%)	13.0 (9.2%)
Volunteer	4.0 (5.6%)	6.0 (8.6%)	10.0 (7.1%)
Unemployed	29.0 (40.8%)	23.0 (32.9%)	52.0 (36.9%)
Looking after family or home	1.0 (1.4%)	1.0 (1.4%)	2.0 (1.4%)
Part-time work	8.0 (11.3%)	7.0 (10.0%)	15.0 (10.6%)
Student	10.0 (14.1%)	6.0 (8.6%)	16.0 (11.3%)
Not working due to sickness or disability	13.0 (18.3%)	17.0 (24.3%)	30.0 (21.3%)
Retired	1.0 (1.4%)	2.0 (2.9%)	3.0 (2.1%)
Housing Status			
Owner occupier	3.0 (4.2%)	4.0 (5.8%)	7.0 (5.0%)
House or flat rented from a housing association or local council	31.0 (43.7%)	31.0 (44.9%)	62.0 (44.3%)

House, flat or room rented from a private landlord	4.0 (5.6%)	3.0 (4.3%)	7.0 (5.0%)
Residential home or supported housing	15.0 (21.1%)	12.0 (17.4%)	27.0 (19.3%)
Hostel	2.0 (2.8%)	1.0 (1.4%)	3.0 (2.1%)
Staying with a friend or family but have own bed	5.0 (7.0%)	4.0 (5.8%)	9.0 (6.4%)
Other	11.0 (15.5%)	14.0 (20.3%)	25.0 (17.9%)
Service user lives alone³			
No	28.0 (41.2%)	27.0 (42.2%)	55.0 (41.7%)
Yes	40.0 (58.8%)	37.0 (57.8%)	77.0 (58.3%)
<i>Service user lives with parent/parents</i>			
No	21.0 (75.0%)	14.0 (51.9%)	35.0 (63.6%)
Yes	7.0 (25.0%)	13.0 (48.1%)	20.0 (36.4%)
<i>Service user lives with friends</i>			
No	24.0 (85.7%)	26.0 (96.3%)	50.0 (90.9%)
Yes	4.0 (14.3%)	1.0 (3.7%)	5.0 (9.1%)
<i>Service user lives with partner/spouse</i>			
No	25.0 (89.3%)	24.0 (88.9%)	49.0 (89.1%)
Yes	3.0 (10.7%)	3.0 (11.1%)	6.0 (10.9%)
<i>Service user lives with other family members</i>			
No	23.0 (82.1%)	22.0 (81.5%)	45.0 (81.8%)
Yes	5.0 (17.9%)	5.0 (18.5%)	10.0 (18.2%)
<i>Service user lives with children under 18</i>			
No	23.0 (82.1%)	23.0 (85.2%)	46.0 (83.6%)
Yes	5.0 (17.9%)	4.0 (14.8%)	9.0 (16.4%)
<i>Service user lives with children over 18</i>			
No	25.0 (89.3%)	23.0 (85.2%)	48.0 (87.3%)
Yes	3.0 (10.7%)	4.0 (14.8%)	7.0 (12.7%)
<i>Service user lives with other people</i>			
No	22.0 (78.6%)	21.0 (80.8%)	43.0 (79.6%)
Yes	6.0 (21.4%)	5.0 (19.2%)	11.0 (20.4%)
Service that provides most of their current mental health care²			
Community mental health team	52.0 (73.2%)	54.0 (78.3%)	106.0 (75.7%)
Community (other)	5.0 (7.0%)	1.0 (1.4%)	6.0 (4.3%)
Inpatient ward	5.0 (7.0%)	9.0 (13.0%)	14.0 (10.0%)
Rehabilitation ward	0.0 (0.0%)	1.0 (1.4%)	1.0 (0.7%)
Forensic inpatient	7.0 (9.9%)	4.0 (5.8%)	11.0 (7.9%)
Other	2.0 (2.8%)	0.0 (0.0%)	2.0 (1.4%)
Mean number of years known to care coordinator (SD)			
	2.5 (4.7)	2.8 (3.7)	2.7 (4.2)
Service user knows their mental health diagnosis²			
No	3.0 (4.3%)	3.0 (4.3%)	6.0 (4.3%)
Yes	67.0 (95.7%)	67.0 (95.7%)	134.0 (95.7%)
Service user agrees with their mental health diagnosis³			
No	14.0 (21.5%)	21.0 (31.3%)	35.0 (26.5%)
Yes	51.0 (78.5%)	46.0 (68.7%)	97.0 (73.5%)
Mean age (years) at which service user first got professional help for their mental health problem (SD)			
	25.5 (9.3)	25.1 (8.7)	25.3 (9.0)
Mean number of times service user has been admitted as a psychiatric inpatient UNDER SECTION (SD)			
	2.8 (3.9)	3.3 (4.6)	3.1 (4.2)
Mean number of times service user has been admitted as a psychiatric inpatient NOT under section (SD)			
	0.7 (1.2)	1.5 (2.6)	1.1 (2.1)

Regular substance use⁴				
	No	60.0 (89.6%)	55.0 (78.6%)	115.0 (83.9%)
	Yes	7.0 (10.4%)	15.0 (21.4%)	22.0 (16.1%)
<i>Regular alcohol use</i>				
	No	4.0 (57.1%)	6.0 (40.0%)	10.0 (45.5%)
	Yes	3.0 (42.9%)	9.0 (60.0%)	12.0 (54.5%)
<i>Regular cannabis use</i>				
	No	4.0 (57.1%)	8.0 (53.3%)	12.0 (54.5%)
	Yes	3.0 (42.9%)	7.0 (46.7%)	10.0 (45.5%)
<i>Regular use of other illicit substance(s)</i>				
	No	5.0 (71.4%)	11.0 (73.3%)	16.0 (72.7%)
	Yes	2.0 (28.6%)	4.0 (26.7%)	6.0 (27.3%)
Mean Baseline PANSS Total Score²		54.9 (17.3)	55.5 (18.1)	55.2 (17.7)
Mean Baseline PSP Score⁵		60.7 (13.4)	59.3 (12.5)	60.0 (12.9)
Mean Baseline Brief IPQ Score⁶		49.2 (18.0)	51.5 (19.6)	50.3 (18.8)
Mean Baseline WAI (Service User rating Care Coordinator)				
	Goal ⁷	21.2 (5.6)	21.1 (5.5)	21.2 (5.5)
	Bond ⁸	22.9 (5.5)	23.2 (5.6)	23.0 (5.5)
	Task ⁹	20.8 (4.8)	20.9 (5.4)	20.9 (5.1)
Mean Baseline WAI (Care Coordinator rating Service User)				
	Goal ¹⁰	22.1 (5.1)	22.4 (3.9)	22.2 (4.5)
	Bond ¹¹	24.0 (3.4)	24.1 (2.8)	24.1 (3.1)
	Task ¹¹	20.4 (5.7)	21.1 (4.3)	20.8 (5.0)
Mean Baseline EQ-5D-5L Utility (SD)¹²		0.6 (0.3)	0.6 (0.3)	0.6 (0.3)

¹Missing for 4 SUs. ²Missing data for 5 SUs. ³Missing data from 13 SUs ⁴Missing data from 8 SUs ⁵Missing data from 30 SUs ⁶Missing data from 7 SUs. ⁷Missing data from 20 SUs. ⁸Missing data from 21 SUs. ⁹Missing data from 19 SUs. ¹⁰Missing data from 93 SUs. ¹¹Missing data from 92 SUs. ¹²Missing data for 6 SUs.

Table 2. Baseline characteristics for FSMs/nFSMs

		Trial Arm		
		TAU (N = 25)	CaFI (N = 25)	Total (N = 50)*
Mean Age (SD)		50.3 (25.2)	42.4 (12.5)	46.3 (19.7)
Gender				
	Female	13.0 (92.9%)	13.0 (86.7%)	26.0 (89.7%)
	Male	1.0 (7.1%)	2.0 (13.3%)	3.0 (10.3%)
Ethnicity				
	Black British	5.0 (35.7%)	3.0 (20.0%)	8.0 (27.6%)
	Black Caribbean	2.0 (14.3%)	2.0 (13.3%)	4.0 (13.8%)
	Black African	4.0 (28.6%)	3.0 (20.0%)	7.0 (24.1%)
	Any other Black / African / Caribbean background	0.0 (0.0%)	1.0 (6.7%)	1.0 (3.4%)
	White and Black Caribbean	0.0 (0.0%)	1.0 (6.7%)	1.0 (3.4%)
	White and Black African	1.0 (7.1%)	0.0 (0.0%)	1.0 (3.4%)
	Any other mixed / multiple ethnic background	0.0 (0.0%)	1.0 (6.7%)	1.0 (3.4%)
	White	2.0 (14.3%)	3.0 (20.0%)	5.0 (17.2%)
	Other	0.0 (0.0%)	1.0 (6.7%)	1.0 (3.4%)
Religious Beliefs				
	No religion	2.0 (14.3%)	7.0 (46.7%)	9.0 (31.0%)
	Christian	8.0 (57.1%)	6.0 (40.0%)	14.0 (48.3%)
	Muslim	4.0 (28.6%)	1.0 (6.7%)	5.0 (17.2%)
	Other	0.0 (0.0%)	1.0 (6.7%)	1.0 (3.4%)
Marital Status ¹				
	Married or in Civil Partnership	2.0 (15.4%)	2.0 (13.3%)	4.0 (14.3%)
	Separated/divorced	1.0 (7.7%)	0.0 (0.0%)	1.0 (3.6%)
	Widowed	1.0 (7.7%)	1.0 (6.7%)	2.0 (7.1%)
	Single	9.0 (69.2%)	12.0 (80.0%)	21.0 (75.0%)
Employment Status				
	Full-time work	8.0 (57.1%)	8.0 (53.3%)	16.0 (55.2%)
	Unemployed	0.0 (0.0%)	1.0 (6.7%)	1.0 (3.4%)
	Looking after family or home	0.0 (0.0%)	1.0 (6.7%)	1.0 (3.4%)
	Part-time work	4.0 (28.6%)	2.0 (13.3%)	6.0 (20.7%)
	Student	0.0 (0.0%)	2.0 (13.3%)	2.0 (6.9%)
	Not working due to sickness or disability	0.0 (0.0%)	1.0 (6.7%)	1.0 (3.4%)
	Retired	2.0 (14.3%)	0.0 (0.0%)	2.0 (6.9%)
Housing Status				
	Owner occupier	3.0 (21.4%)	4.0 (26.7%)	7.0 (24.1%)
	House or flat rented from a housing association or local council	5.0 (35.7%)	8.0 (53.3%)	13.0 (44.8%)
	House, flat or room rented from a private landlord	3.0 (21.4%)	1.0 (6.7%)	4.0 (13.8%)
	Residential home or supported housing	2.0 (14.3%)	0.0 (0.0%)	2.0 (6.9%)
	Staying with a friend or family but have own bed	0.0 (0.0%)	1.0 (6.7%)	1.0 (3.4%)
	Other	1.0 (7.1%)	1.0 (6.7%)	2.0 (6.9%)
FM/nFSM lives alone				
	No	9.0 (64.3%)	10.0 (66.7%)	19.0 (65.5%)
	Yes	5.0 (35.7%)	5.0 (33.3%)	10.0 (34.5%)
<i>FM/nFSM lives with parent/parents</i>				
	No	8.0 (88.9%)	8.0 (80.0%)	16.0 (84.2%)

	Yes	1.0 (11.1%)	2.0 (20.0%)	3.0 (15.8%)
<i>FM/nFSM lives with friends</i>				
	No	9.0 (100.0%)	9.0 (90.0%)	18.0 (94.7%)
	Yes	0.0 (0.0%)	1.0 (10.0%)	1.0 (5.3%)
<i>FM/nFSM lives with partner/spouse</i>				
	No	7.0 (77.8%)	8.0 (80.0%)	15.0 (78.9%)
	Yes	2.0 (22.2%)	2.0 (20.0%)	4.0 (21.1%)
<i>FM/nFSM lives with other family members</i>				
	No	6.0 (66.7%)	5.0 (50.0%)	11.0 (57.9%)
	Yes	3.0 (33.3%)	5.0 (50.0%)	8.0 (42.1%)
<i>FM/nFSM lives with children under 18</i>				
	No	6.0 (66.7%)	6.0 (60.0%)	12.0 (63.2%)
	Yes	3.0 (33.3%)	4.0 (40.0%)	7.0 (36.8%)
<i>FM/nFSM lives with children over 18</i>				
	No	4.0 (50.0%)	5.0 (50.0%)	9.0 (50.0%)
	Yes	4.0 (50.0%)	5.0 (50.0%)	9.0 (50.0%)
<i>FM/nFSM lives with other people</i>				
	No	7.0 (77.8%)	9.0 (90.0%)	16.0 (84.2%)
	Yes	2.0 (22.2%)	1.0 (10.0%)	3.0 (15.8%)
The FM/nFSM identifies as the service user's carer				
	No	5.0 (35.7%)	6.0 (40.0%)	11.0 (37.9%)
	Yes	9.0 (64.3%)	9.0 (60.0%)	18.0 (62.1%)
Service user diagnosis ²				
	Schizophrenia	7.0 (53.8%)	7.0 (53.8%)	14.0 (53.8%)
	Schizotypal disorder	1.0 (7.7%)	0.0 (0.0%)	1.0 (3.8%)
	Brief psychotic disorder	1.0 (7.7%)	0.0 (0.0%)	1.0 (3.8%)
	Shared psychotic disorder	1.0 (7.7%)	0.0 (0.0%)	1.0 (3.8%)
	Schizoaffective disorder	1.0 (7.7%)	0.0 (0.0%)	1.0 (3.8%)
	Other psychotic disorder not due to a substance or known psychological condition	2.0 (15.4%)	0.0 (0.0%)	2.0 (7.7%)
	Unspecified psychosis not due to a substance or known psychological condition	0.0 (0.0%)	3.0 (23.1%)	3.0 (11.5%)
	Other	0.0 (0.0%)	3.0 (23.1%)	3.0 (11.5%)
Agreement about the service user's mental health diagnosis ²				
	No	1.0 (7.1%)	0.0 (0.0%)	1.0 (3.8%)
	Yes	13.0 (92.9%)	12.0 (100.0%)	25.0 (96.2%)
	Mean Total KAP Score (SD) ³	104.4 (39.5)	116.5 (8.2)	111.3 (26.4)
	Mean Total GHQ-12 Score (SD) ¹	2.8 (3.8)	1.7 (2.8)	2.2 (3.3)
	Mean Brief-IPQ Score (SD) ³	72.7 (15.3)	73.2 (10.1)	73.0 (12.6)

*Data only available for 29 out of 50 FSMs/nFSMs unless mentioned otherwise. ¹Based on 28 FSMs/nFSMs.

²Based on 26 FSMs/nFSMs ³Based on 27 FSMs/nFSMs.

Outcome Measures

Figure 1: Kaplan-Meier plot for survival probability

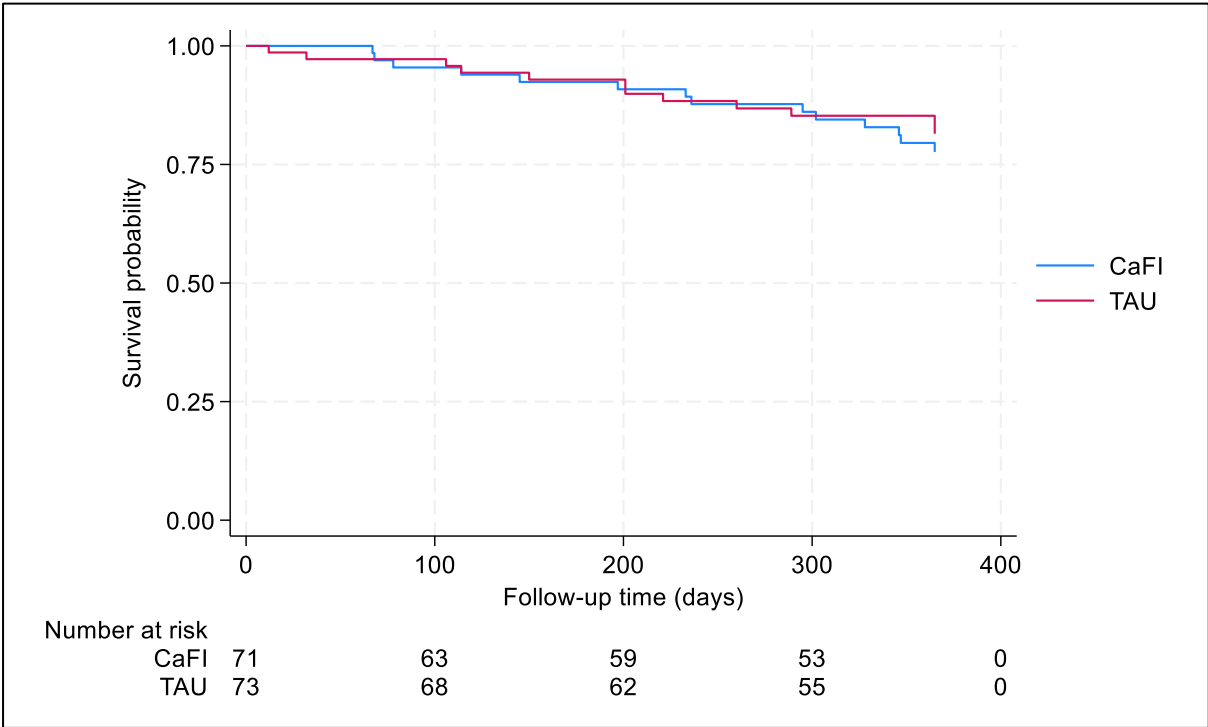


Table 3. Primary outcome results

Primary Outcome: Time to first relapse within 12 months	Hazard Ratio	95% CI	P-value
	0.73	0.28 to 1.87	0.509

Secondary Outcomes

Table 4. Secondary Outcome results

Secondary Outcome	N	Adjusted Mean Difference	95% CI
Total PANSS at 6 months ¹	95	1.62	-2.67 to 5.91
Total PANSS at 12 months	89	2.64	-0.93 to 6.22
PSP at 6 months	82	-3.33	-6.86 to 0.19
PSP at 12 months	78	-0.68	-5.55 to 4.20
KAP at 6 months ²	15	3.26	-9.82 to 16.35
KAP at 12 months ²	13	16.55	0.64 to 32.47
GHQ-12 at 6 months ²	16	-0.24	-2.04 to 1.57
GHQ-12 at 12 months ²	13	-0.33	-4.73 to 4.08
Brief-IPQ for service users at 6 months	87	-1.48	-9.08 to 6.12
Brief-IPQ for service users at 12 months	86	1.10	-6.26 to 8.46
Brief-IPQ for family members at 6 months ²	15	-0.29	-10.97 to 10.40
Brief-IPQ for family members at 12 months ²	13	-1.21	-13.55 to 11.14
WAI (Service User rating Care Coordinator)			
Goal at 6 months	72	-0.86	-3.07 to 1.36
Bond at 6 months	69	-0.86	-2.92 to 1.21
Task at 6 months	73	-0.48	-2.50 to 1.55
Goal at 12 months	66	-0.51	-2.96 to 1.94
Bond at 12 months	65	-0.81	-2.95 to 1.34
Task at 12 months	68	-0.33	-2.50 to 1.84
WAI (Care Coordinator rating Service User)			
Goal at 6 months	24	0.12	-3.49 to 3.73
Bond at 6 months	26	0.16	-2.06 to 2.39
Task at 6 months	26	-1.24	-4.32 to 1.83
Goal at 12 months²	19	-0.44	-4.14 to 3.26
Bond at 12 months²	20	-0.74	-3.84 to 2.36
Task at 12 months²	19	-2.26	-5.75 to 1.24
Service Engagement Scale at 6 months	26	2.30	-2.05 to 6.64
Service Engagement Scale at 12 months	21	-0.63	-5.33 to 4.06

Analyses adjusted for baseline outcome and minimization covariates.

¹Bootstrapping was used as residuals were skewed. ²No random effects included as number of FSMs/Care Coordinators included is low. Residuals are skewed but due to low numbers no bootstrapping done.

Table 5. WAI results for service user rating therapist (vice versa) at therapy session 3 and 8

Outcome	Hazard Ratio	95% CI
WAI (Service User rating Therapist) at therapy session 3 (N = 32)		
Goal	0.53	0.33 to 0.87
Bond	1.56	1.01 to 2.42
Task	1.74	1.11 to 2.75
WAI (Service User rating Therapist) at therapy session 8 (N = 30)		
Goal	0.87	0.41 to 1.84
Bond	0.99	0.43 to 2.29
Task	1.98	0.64 to 6.13
WAI (Therapist rating Service User) at therapy session 3 (N = 40)		
Goal	0.81	0.63 to 1.05
Bond	1.06	0.77 to 1.47
Task	1.21	0.87 to 1.68
WAI (Therapist rating Service User) at therapy session 8 (N = 33)		
Goal	1.54	0.92 to 2.59
Bond	1.02	0.51 to 2.05
Task	0.85	0.49 to 1.47

Table 6. WAI results for FM/nFSMs rating therapist (vice versa) at therapy session 3 and 8

Outcome	N	Mean (SD)
WAI (FM/nFSM rating Therapist) at therapy session 3		
Goal	12	23.8 (3.9)
Bond	12	25.1 (3.3)
Task	12	21.5 (2.9)
WAI (FM/nFSM rating Therapist) at therapy session 8		
Goal	10	21.5 (2.2)
Bond	10	24.9 (3.7)
Task	10	20.5 (2.4)
WAI (Therapist rating FM/nFSM) at therapy session 3		
Goal	13	15.0 (4.1)
Bond	14	21.5 (3.9)
Task	13	15.8 (3.3)
WAI (Therapist rating FM/nFSM) at therapy session 8		
Goal	10	18.9 (4.9)
Bond	10	23.2 (4.4)
Task	10	20.2 (4.7)

Adverse Events

Table 7. Adverse events (AE) type by Treatment arm

AE Type	Trial Arm	
	CaFI (N = 24)	TAU (N = 15)
Suicide Attempt	1 (4%)	1 (7%)
Self Harm	1 (4%)	0 (0%)
Serious violent incident	0 (0%)	1 (7%)
Loss of a family member	0 (0%)	0 (0%)
Change of family circumstances	1 (4%)	0 (0%)
Victimisation	1 (4%)	0 (0%)
Self-neglect	0 (0%)	0 (0%)
Other incident involving the police	5 (21%)	4 (27%)
Other	15 (63%)	9 (60%)

Table 8. Adverse events (AE) by Site

Site	Total Number of AE/SAEs (N=39)	% of site Recruitment
	N (%)	
Greater Manchester Mental Health	22 (56%)	29%
South London and Maudsley	7 (18%)	15%
Birmingham and Solihull	1 (3%)	14%
Southern Healthcare	8 (20%)	62%
Pennine Care	1 (3%)	33%

Table 9. Serious Adverse Events (SAE) details including severity and relatedness to the trial

SAE Details	Trial Arm		
	CaFI (N = 17)	TAU (N = 10)	Total (N = 27)
SAE Type			
Suicide Attempt	1 (6%)	1 (10%)	2 (7%)
Self-Harm	1 (6%)	0 (0%)	1 (4%)
Serious violent incident	0 (0%)	1 (10%)	1 (4%)
Loss of a family member	0 (0%)	0 (0%)	0 (0%)
Change of family circumstances	0 (0%)	0 (0%)	0 (0%)
Victimisation	0 (0%)	0 (0%)	0 (0%)
Self-neglect	0 (0%)	0 (0%)	0 (0%)
Other incident involving the police	4 (24%)	2 (20%)	6 (22%)
Other	11 (65%)	6 (60%)	17 (63%)
SAE Relatedness to the trial			
Definitely	0 (0%)	0 (0%)	0 (0%)
Probably	0 (0%)	0 (0%)	0 (0%)
Possibly	2 (12%)	1 (10%)	3 (11%)
Remote	3 (18%)	0 (0%)	3 (11%)
Not related	12 (70%)	9 (90%)	21 (78%)
SAE Severity			
Yes, results in death	1 (6%)	0 (0%)	1 (4%)
Yes, is life-threatening	0 (0%)	1 (10%)	1 (4%)
Yes, requires hospitalization or prolongation of existing physical and mental health hospitalization, including COVID-19	9 (53%)	7 (70%)	16 (59%)
Yes, persistent or significant disability or incapacity	0 (0%)	0 (0%)	0 (0%)
Yes, other	6 (35%)	2 (20%)	8 (29%)
Missing	1 (6%)	0 (0%)	1 (4%)