A feasibility trial of the partners at care transitions (PACT) intervention (ISRCTN51154948)
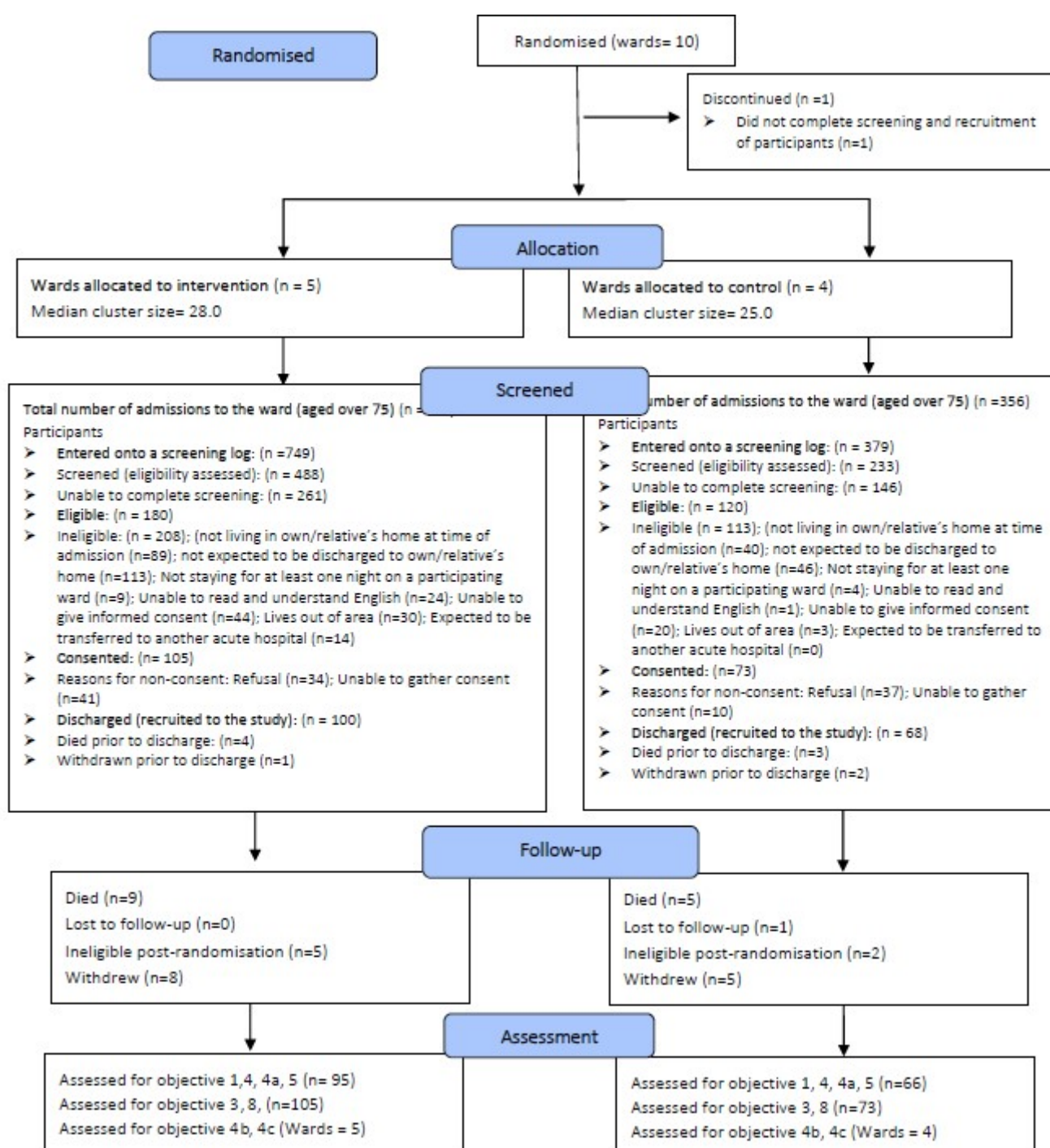
Basic Results Summary

Participant Flow:

Randomised

Randomised (wards= 10)

Discontinued (n =1)
➤ Did not complete screening and recruitment of participants (n=1)

Allocation

Wards allocated to intervention (n = 5)
Median cluster size= 28.0

Wards allocated to control (n = 4)
Median cluster size= 25.0

Screened

Total number of admissions to the ward (aged over 75) (n = [...])
Participants
➤ Entered onto a screening log: (n =749)
➤ Screened (eligibility assessed): (n = 488)
➤ Unable to complete screening: (n = 261)
➤ Eligible: (n = 180)
➤ Ineligible: (n = 208); (not living in own/relative's home at time of admission (n=89); not expected to be discharged to own/relative's home (n=113); Not staying for at least one night on a participating ward (n=9); Unable to read and understand English (n=24); Unable to give informed consent (n=44); Lives out of area (n=30); Expected to be transferred to another acute hospital (n=14)
➤ Consented: (n= 105)
➤ Reasons for non-consent: Refusal (n=34); Unable to gather consent (n=41)
➤ Discharged (recruited to the study): (n = 100)
➤ Died prior to discharge: (n=4)
➤ Withdrawn prior to discharge (n=1)

[N]umber of admissions to the ward (aged over 75) (n =356)
Participants
➤ Entered onto a screening log: (n = 379)
➤ Screened (eligibility assessed): (n = 233)
➤ Unable to complete screening: (n = 146)
➤ Eligible: (n = 120)
➤ Ineligible (n = 113); (not living in own/relative's home at time of admission (n=40); not expected to be discharged to own/relative's home (n=46); Not staying for at least one night on a participating ward (n=4); Unable to read and understand English (n=1); Unable to give informed consent (n=20); Lives out of area (n=3); Expected to be transferred to another acute hospital (n=0)
➤ Consented: (n=73)
➤ Reasons for non-consent: Refusal (n=37); Unable to gather consent (n=10)
➤ Discharged (recruited to the study): (n = 68)
➤ Died prior to discharge: (n=3)
➤ Withdrawn prior to discharge (n=2)

Follow-up

Died (n=9)
Lost to follow-up (n=0)
Ineligible post-randomisation (n=5)
Withdrew (n=8)

Died (n=5)
Lost to follow-up (n=1)
Ineligible post-randomisation (n=2)
Withdrew (n=5)

Assessment

Assessed for objective 1,4, 4a, 5 (n= 95)
Assessed for objective 3, 8, (n=105)
Assessed for objective 4b, 4c (Wards = 5)

Assessed for objective 1, 4, 4a, 5 (n=66)
Assessed for objective 3, 8 (n=73)
Assessed for objective 4b, 4c (Wards = 4)

Baseline characteristics of participants:

Variable		Intervention (n=95)	Control (n=66)	All (n=161)
Participant Status	Patient	85 (89.5%)	56 (84.8%)	141 (87.6%)
	Informal carer	10 (10.5%)	10 (15.2%)	20 (12.4%)
Gender	Male	48 (50.5%)	18 (27.3%)	66 (41.0%)
	Female	47 (49.5%)	48 (72.7%)	95 (59.0%)
Age (years)	N	95 (100.0%)	66 (100.0%)	161 (100.0%)
	Mean (SD)	83.3 (5.2)	83.7 (4.8)	83.4 (5.0)
	Median (IQR)	83.0 (79, 87)	83.5 (81, 86)	83.0 (79, 87)
	Min, Max	75.0, 95.0	75.0, 95.0	75.0, 95.0
Ethnicity	White British	91 (95.8%)	66 (100.0%)	157 (97.5%)
	White Irish	2 (2.1%)	0 (0.0%)	2 (1.2%)
	White other	1 (1.1%)	0 (0.0%)	1 (0.6%)
	Pakistani	1 (1.1%)	0 (0.0%)	1 (0.6%)
First Language	English	88 (92.6%)	61 (92.4%)	149 (92.5%)
	Other	2 (2.1%)	0 (0.0%)	2 (1.2%)
	Not reported	5 (5.3%)	5 (7.6%)	10 (6.2%)
Live in status	Alone	31 (32.6%)	27 (40.9%)	58 (36.0%)
	Alone with regular support from family	16 (16.8%)	16 (24.2%)	32 (19.9%)
	With spouse/partner	44 (46.3%)	17 (25.8%)	61 (37.9%)
	With son/daughter (in-law)	3 (3.2%)	4 (6.1%)	7 (4.3%)
	With brother/sister	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Other	1 (1.1%)	2 (3.0%)	3 (1.9%)
Has daily carers	Yes	10 (10.5%)	10 (15.2%)	20 (12.4%)
	No	83 (87.4%)	56 (84.8%)	139 (86.3%)
	Not reported	2 (2.1%)	0 (0.0%)	2 (1.2%)
Number of previous hospital admissions in the previous 12 months	N	90 (94.7%)	65 (98.5%)	155 (96.3%)
	Mean (SD)	0.8 (1.2)	1.0 (1.3)	0.9 (1.3)
	Median (IQR)	0.0 (0, 1)	1.0 (0, 2)	0.0 (0, 2)
	Min, Max	0.0, 5.0	0.0, 7.0	0.0, 7.0
	Not reported	5 (5.3%)	1 (1.5%)	6 (3.7%)
Number of previous hospital admissions in the previous 12 months	0	52 (54.7%)	30 (45.5%)	82 (50.9%)
	1	16 (16.8%)	18 (27.3%)	34 (21.1%)
	2	13 (13.7%)	12 (18.2%)	25 (15.5%)
	3	4 (4.2%)	0 (0.0%)	4 (2.5%)
	4+	5 (5.3%)	5 (7.6%)	10 (6.2%)
	Not reported	5 (5.3%)	1 (1.5%)	6 (3.7%)
Method of index admission	Emergency	88 (92.6%)	64 (97.0%)	152 (94.4%)
	Elective	2 (2.1%)	0 (0.0%)	2 (1.2%)
	Other	5 (5.3%)	2 (3.0%)	7 (4.3%)
EQ5D-5L score	N	95 (100.0%)	66 (100.0%)	161 (100.0%)
	Mean (SD)	0.512 (0.3)	0.441 (0.3)	0.483 (0.3)
	Median (IQR)	0.567 (0.3, 0.7)	0.514 (0.2, 0.7)	0.553 (0.3, 0.7)
	Min, Max	-0.043, 1	-0.51, 1	-0.51, 1
EQ5D VAS	N	95 (100.0%)	66 (100.0%)	161 (100.0%)
	Mean (SD)	50.1 (21.1)	56.2 (20.0)	52.6 (20.8%)
	Median (IQR)	50.0 (35, 65)	55.0 (40, 75)	50.0 (40, 70)
	Min, Max	5, 99	10, 100	5, 100
Barthel Index	N	95 (100.0%)	66 (100.0%)	161 (100.0%)
	Mean (SD)	14.3 (4.3)	13.0 (4.5)	13.8 (4.4)

	Median (IQR)	15.0 (10, 18)	14.0 (10, 17)	15.0 (10, 17)
	Min, Max	4, 20	1, 20	1, 20
Functional Co-Morbidity Index	N	95 (100.0%)	66 (100.0%)	161 (100.0%)
	Mean (SD)	3.7 (2.1)	3.5 (2.0)	3.6 (2.0)
	Median (IQR)	3.0 (2, 5)	3.0 (2, 4)	3.0 (2, 5)
	Min, Max	0, 10	0, 9	0, 10
Number of Comorbidities	0	2 (2.1%)	4 (6.1%)	6 (3.7%)
	1	9 (9.5%)	3 (4.5%)	12 (7.5%)
	2	17 (17.9%)	15 (22.7%)	32 (19.9%)
	3	22 (23.2%)	19 (28.8%)	41 (24.5%)
	4	19 (20.0%)	9 (13.6%)	28 (17.4%)
	5	13 (13.7%)	4 (6.1%)	17 (10.6%)
	6+	13 (13.7%)	12 (18.2%)	25 (15.5%)
Comorbidity[†]	Arthritis	48 (50.5%)	34 (51.5%)	82 (50.9%)
	Osteoporosis	14 (14.7%)	17 (25.8%)	31 (19.3%)
	Asthma	14 (14.7%)	9 (13.6%)	23 (14.3%)
	COPD, ARDS or emphysema	19 (20.0%)	8 (12.1%)	27 (16.8%)
	Angina	11 (11.6%)	5 (7.6%)	16 (9.9%)
	Congestive Heart Failure	30 (31.6%)	16 (24.2%)	46 (28.6%)
	Heart Attack	21 (22.1%)	5 (7.6%)	26 (16.2%)
	Neurological Disease	0 (0.0%)	5 (7.6%)	5 (3.1%)
	Stroke/TIA	26 (27.4%)	16 (24.2%)	42 (26.1%)
	Peripheral Vascular Disease	8 (8.4%)	3 (4.6%)	11 (6.8%)
	Diabetes	28 (29.5%)	16 (24.2%)	44 (27.3%)
	Upper gastrointestinal disease	14 (14.7%)	9 (13.6%)	23 (14.3%)
	Depression	7 (7.4%)	8 (12.1%)	15 (9.3%)
	Anxiety/ Panic Disorders	7 (7.4%)	12 (18.2%)	19 (11.8%)
	Visual impairment	42 (44.2%)	38 (57.6%)	80 (49.7%)
	Hearing impairment	27 (28.4%)	16 (24.2%)	43 (26.7%)
	Degenerative disk disease	20 (21.1%)	7 (10.6%)	27 (16.8%)
	Obesity/ BMI >30	13 (13.7%)	4 (6.1%)	17 (10.6%)

†*Categories are not mutually exclusive*

Outcome Measures:

Outcome Measure	Intervention (n=95)		Control (n=66)		Overall (n=161)	
	n(%)	Score*	*n(%)*	Score*	*n(%)*	Score*
Emergency Readmissions						
30-days post-discharge	87 (91.6%)	0.2 (0.4)	61 (92.4%)	0.2 (0.6)	148 (91.9%)	0.2 (0.5)
60-days post-discharge	87 (91.6%)	0.3 (0.6)	61 (92.4%)	0.4 (0.7)	148 (91.9%)	0.3 (0.6)
90-days post-discharge	87 (91.6%)	0.4 (0.6)	61 (92.4%)	0.5 (0.7)	148 (91.9%)	0.4 (0.7)
EQ5D-5L						
T1	68 (71.6%)	0.495 (0.3)	48 (72.7%)	0.506 (0.3)	116 (72.0%)	0.499 (0.3)
T2	51 (53.7%)	0.512 (0.3)	40 (60.6%)	0.484 (0.3)	91 (56.5%)	0.500 (0.3)
T3	11 (11.6%)	0.416 (0.4)	16 (24.2%)	0.587 (0.3)	27 (16.8%)	0.517 (0.3)
EQ5D VAS						
T1	69 (72.6%)	58.2 (18.0)	47 (71.2%)	53.7 (23.3)	116 (72.0%)	56.4 (20.3)
T2	53 (55.8%)	60.5 (20.6)	39 (59.1%)	60.2 (20.0)	92 (57.1%)	60.4 (20.2)
T3	11 (11.6%)	58.2 (20.3)	16 (24.2%)	67.8 (17.9)	27 (16.8%)	63.9 (19.1)
PACT-M						
T1	62 (65.3%)	50.8 (9.2)	38 (57.6%)	49.5 (9.6)	100 (62.1%)	50.3 (9.3)
T2	45 (47.4%)	54.4 (8.3)	34 (51.6%)	53.1 (9.0)	79 (49.1%)	53.8 (8.6)
T3	9 (9.5%)	51.3 (8.3)	11 (16.7%)	57.5 (6.6)	20 (12.4%)	54.7 (7.9)
CTM-3						
T1	63 (66.3%)	68.2 (18.6)	43 (65.2%)	64.0 (17.5)	106 (65.8%)	66.5 (18.2)
T2	45 (47.4%)	67.5 (18.5)	33 (50%)	63.1 (17.0)	78 (48.4%)	65.7 (17.9)
T3	11 (11.6%)	68.7 (19.8)	13 (19.7%)	63.2 (18.9)	24 (14.9%)	65.7 (19.1)

Adverse Events:

For the PACT feasibility study (WP5) safety was assessed by serious adverse events (SAEs) including deaths. The death of participants is expected within the study population. Non-serious adverse events (AEs) were not reportable as in this patient population, acute illness resulting in hospitalisation, new medical problems and deterioration or existing medical problems are not unlikely. Details of definitions of SAEs are outlined in the study protocol.

Relatedness of SAE	Death pre discharge			Death post discharge		
	Intervention	Control	Total	Intervention	Control	Total
	n= 4	n= 3	n= 7	n = 9	n = 5	14
Unlikely to be related	3 (75.0%)	1 (33.3%)	4 (57.1%)	5 (55.6%)	3 (60.0%)	8 (57.1%)
Not related	1 (25.0%)	2 (66.7%)	3 (42.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Not reported	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (44.4%)	2 (40.0%)	6 (42.9%)