ISSN 2044-4230

Medical Crises in Older People

The University of Nottingham

Medical Crises in Older People

Medical Crises in Older People. Discussion paper series.

ISSN 2044-4230

Issue 14 May 2014

Statistical report for the TEAM trial: Care in specialist medical and mental health unit compared with standard care for older people with cognitive impairment admitted to general hospital: randomised controlled trial

Bradshaw L E[1] Lewis SA[2,] Goldberg SE[1] Gladman JRF[1] & Harwood RH[3]

Medical Crises in Older People: a NIHR research programme 2008-2013
And
Better Mental Health: a SDO research study 2008-2011

Undertaken by the University of Nottingham and the Nottingham University Hospital NHS Trust, UK

Workstream 1: towards improving the care of people with mental health problems in general hospitals. Development and evaluation of a medical and mental health unit.

Workstream 2: Development and evaluation of interface geriatrics for older people attending an AMU

Workstream 3: Development and evaluation of improvements to health care in care homes

URL:www.nottingham.ac.uk/mcop

(1) Division of Rehabilitation and Ageing, University of Nottingham, Nottingham NG7 2UH; UK (2) Division of Epidemiology and Public Health, University of Nottingham, Nottingham NG7 1RD, UK (3) Health Care of Older People, Nottingham University Hospitals NHS Trust, Queens Medical Centre, Nottingham NG7 2UH, UK.

ISSN 2044-4230

Address for correspondence: Lucy E Bradshaw, Statistician, Division of Rehabilitation and Ageing, University of Nottingham, Nottingham NG7 2UH; UK. Email: lucy.bradshaw@nottingham.ac.uk

ISSN 2044-4230

Medical Crises in Older People

The University of Nottingham

Contents

ISSN 2044-4230

ISSN 2044-4230

Abstract

The TEAM study evaluated a medical and mental health unit compared to standard care for older people with delirium and dementia admitted to hospital, the methods [1] and clinical outcomes [2] of which have been published elsewhere. This paper provides the full statistical report of this trial, describing the statistical methods and results. This paper therefore provides a level of detail that is not available in other publications. It is published partly to ensure transparency in the reporting of trials, partly to assist others dealing with the necessary minutiae of statistical aspects of trials, and partly to give access to a wealth of fine grained baseline and outcome results, as well as pre-planned secondary analyses for researchers and service developers to base their plans upon. Being a statistical report there are no "Introduction" or "Discussion" sections in the report, and the "Methods" section refers only to the statistical methods: this paper is best understood having thoroughly read the published paper on the full methods for the TEAM trial.

ISSN 2044-4230

Statistical methods

Baseline characteristics were summarised in the two groups and Mann-Whitney U tests or Chi-squared tests, as appropriate, were used to test for any differences between the two groups due to the randomisation and recruitment process.

The difference in the primary days at home outcome measure in the two groups was summarised using the difference in means and medians and 95% confidence intervals for these differences were calculated using bootstrap methods with 10,000 samples. Similarly, the difference in median days at home in the two groups for the participants returning home was calculated using bootstrap methods. A Mann-Whitney U test was used to test for a difference in days at home between the two groups, consistent with the sample size calculation.

The distribution of days at home was similar to the distribution observed in the Better Mental Health cohort study: more than a quarter of participants spent no days at home after randomisation and the distribution was left skewed for the participants that did return home after randomisation. A two part model was therefore used to estimate the effect of the allocated group on returning home after the initial admission using logistic regression and the amount of time spent at home for those participants returning home. Linear regression on a logit transformation (log[days at home/(90 – days at home)]) was attempted for amount of time spent at home however the assumptions of normally distributed residuals and constant variance were not satisfied. A Beta regression model was therefore used for this, using a logit link for the mean parameter. The coefficient for the effect of the allocated group was exponeniated to show the relative change on the ratio of the number of days spent at home to not at home on the MMHU compared to standard care.

Three sets of estimates for the effect of the allocated group are presented: the unadjusted estimate, the estimate adjusted for the prognostically important variables: age, gender, residence type at admission, MMSE score, ADL score prior to the acute illness and at recruitment, number of medical diagnoses and length of hospital stay in the year prior to the study, as identified from analyses in the BMH cohort study and specified in the statistical analysis plan, and the estimate from models also including variables with apparent baseline differences between the two groups which were not already included in the pre-specified set of prognostically important variables.

ISSN 2044-4230

Continuous variables were checked for linearity and fitted in quartiles if there was evidence against the linearity assumption. Simple imputation methods based on residence type at admission (in the community or care home) were used for missing data at baseline to ensure that all recruited participants were included in these analyses. This was done for 22 participants where the Mini-Mental State Examination was not attempted at baseline, 2 participants where the Delirium Rating Scale was not completed at baseline and 6 participants where ability in activities in daily living prior to the acute illness was unknown.

Diagnostics using the residuals from these regression models were used to explore the adequacy of the fit of these models and to identify any unusual observations or outliers. In addition the above analyses were repeated removing each participant in turn to identify individual observations, if any, with a large influence on the estimate of the effect for the allocated group.

These analyses were repeated for the different components in the days at home definition that were considered as being away from home: mortality, length of hospital stay (total during study and initial length of stay), readmission and move from the community to a permanent care home. Cox regression was used for mortality, negative binomial regression for the length of hospital stay and logistic regression for readmission and care home placement.

Subgroup analyses for residence type at admission (community or care home), delirium at admission (DRS score </> 17.75) and length of the initial admission (5 days or less or greater than 5 days) were conducted by testing for a difference in the effect of allocated goup between the subgroups (test for interaction) in the chosen regression analysis.

The secondary health status outcomes were analysed for the participants completing each of these assessments and also for all participants surviving until the end of the study using multiple imputation for missing outcomes. As above for the days at home outcomes, three sets of estimates are presented for the effect of allocated group: the unadjusted estimate, the estimate adjusted for prognostically important variables as specified in the statistical analysis plan (and shown in the table 1) and an estimate from a sensitivity analysis with variables with an imbalance between the two groups at recruitment also included in models. The characteristics at recruitment of the participants completing each of these health status outcomes in the two groups were

ISSN 2044-4230

compared and any imbalances noted to inform the sensitivity analysis for the complete case analysis and the characteristics at recruitment of the participants surviving until the end of the study were also compared to inform the sensitivity analysis for the analysis using the imputed data.

Table 1: Variables used in adjusted analyses for health status outcomes

Health status outcome	Variables measured at recruitment pre-specified in statistical analysis plan to be used in adjusted analyses
Activities of daily living	Age, gender, residence at admission, ADL prior to acute illness and at recruitment
Cognitive impairment	Age, gender, residence at admission, cognitive impairment at recruitment
Behavioural and psychological symptoms	Age, gender, residence at admission, behavioural and psychological symptoms at admission, cognitive impairment at admission
Quality of life variables –	
participant completed EQ-5D patient DEMQoL (where MMSE > 10)	Age, gender, residence at admission
proxy completed EQ-5D (from POQ), proxy DEMQoL and London Handicap Scale (from COQ)	Age, gender, residence at admission, NPI depression and anxiety variables patient age, gender, residence at admission, total NPI score, ADL prior to acute illness and cognitive impairment at recruitment (+ baseline score for EQ-5D analysis)

Linear regression was used to analyse the Barthel Activity of Daily Living scores and the following quality of life scores: participant DEMQoL, proxy completed EQ-5D, carer proxy DEMQoL and London Handicap Scale scores at follow-up. The assumptions for linear regression were not met for the Mini-Mental State examination scores at follow-up due to a large density of zero scores. The change in MMSE score between recruitment and follow-up was therefore dichotomised and analysed using logistic regression to compare the proportion of participants in each group with an improvement of 3 or more points

ISSN 2044-4230

(reversible cognitive impairment). The assumptions for linear regression were also not met for the total score on the Neuropsychiatric Inventory at follow-up due to these scores being right skewed. Linear regression was therefore used to analyse a log transformation of these total scores. Similarly the assumptions for linear regression were not met for the participant completed EQ-5D score: the score at follow-up was dichotomised at the median to be able to use logistic regression to adjust for baseline differences between the groups. Logistic regression was also used to analyse the proportion of participants in each group at follow-up with each of the individual symptoms assessed on the Neuropsychiatric Inventory. The same procedures as in the analysis of days at home were used to check the functional form of the continuous variables to include in these regression models. The assumptions for these regression models were checked using the residuals and the fitted values.

Multiple imputation using chained equations was used to impute missing health status outcomes for participants alive at the end of the follow-up period using the Stata command `ice`. This was done under a missing at random assumption so that the probability a participant has missing data depends on the observed data (at both recruitment and any observed outcomes) but not on the unobserved outcomes. Sixty imputed datasets were created as 62% of participants had at least one health status outcome missing at follow-up (of activities of daily living, Mini-Mental State examination, participant or carer proxy DEMQoL, Neuropsychiatric Inventory and the London Handicap Scale). Predictive mean matching was used to impute the health status outcomes scores to ensure that no imputed values were outside the possible range for each scale. The total NPI score at baseline and follow-up was log transformed before inclusion in the imputation model. The imputation model included the health status variables measured at baseline, demographic characteristics, the number of medications, the number of medical diagnoses, the length of stay in the year prior to the study, the diagnosis variables with a imbalance between the two groups and a variable to indicate whether the Neuropsychiatric Inventory was completed at baseline. Missing baseline variables were imputed using simple methods (not based on allocated group) so that only missing information at follow-up was imputed using this model. Outcome information on the total length of the hospital stay during the study, readmissions and moves to care homes were also included in the imputation model. Imputations were done separately for each allocated group to be able to explore the pre-specified interactions. The distributions of the imputed values were compared visually to the observed data. The analyses specified

ISSN 2044-4230

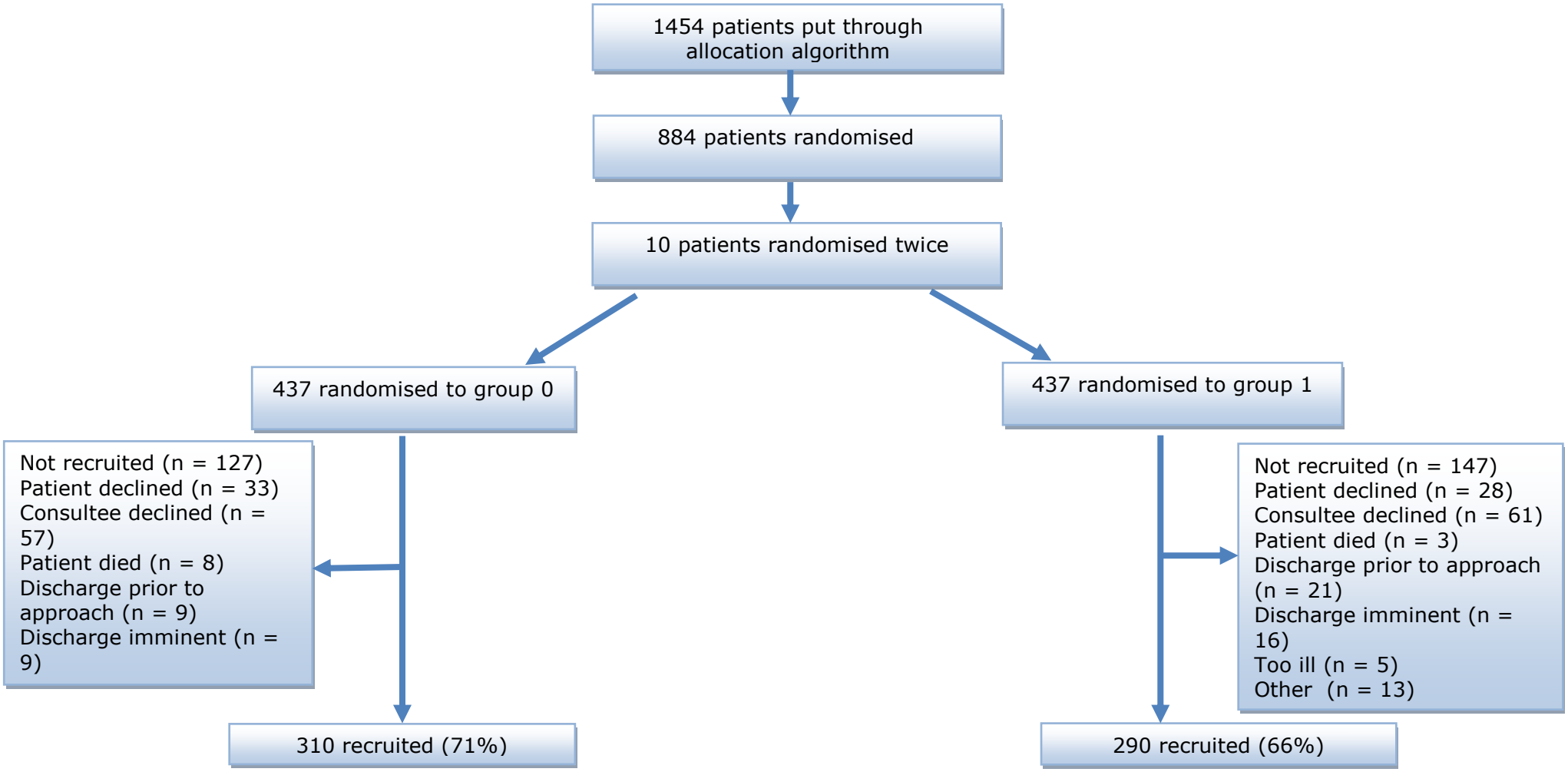
above for the complete cases were repeated using the imputed data and Rubin's rules were used to combine the estimates of the intervention effect across the imputed datasets. The Monte Carlo error for the estimate of the intervention effect was calculated to check the reproducibility of the result. The diagnostics used for the complete cases were repeated for a selection of the imputed datasets to check the fit of the models in the multiply imputed data.

Participant allocation

Patient flow through the ward allocation algorithm from allocation to recruitment is shown in Figure 1. In total 310 participants were recruited in the group randomised to MMHU and 290 participants were recruited in group randomised to standard care. The recruitment rate was slightly higher for MMHU: 71% of randomised participants were recruited on the MMHU compared to 66% on standard care.

ISSN 2044-4230

Figure 1: Patient flow through the ward allocation algorithm



ISSN 2044-4230

Recruitment

Table 2 compares the characteristics of patients randomised according to recruitment status by allocated group. The data used for this comes directly from the information entered at the time of randomisation so there may be some data entry errors. The permanent residence type entered at the time of randomisation, and used as a randomisation stratifier, does not always match the residence type subsequently recorded by the research team for recruited participants.

There is some suggestion from this table of a difference between the groups in recruitment success for patients randomised as care home residents and according to gender.

ISSN 2044-4230

Table 2: Basic characteristics of patients randomised recorded at the time of randomisation by recruitment status and ward allocation

	MMHU		Standard care	
	Not recruited (n = 127)	Recruited (n = 310)	Not recruited (n = 147)	Recruited (n = 290)
Age at randomisation				
Mean (SD)	82.7 (6.8)	84.1 (6.2)	84.1 (6.4)	84.3 (6.8)
Median (IQR)	84 (79 – 87)	85 (80 – 88)	84 (80 – 88)	85 (80 – 89)
Min – Max	65 - 97	65 - 98	66 – 101	65 - 102
Female – n (%)	62 (48.8%)	171 (55.2%)	79 (53.7%)	144 (49.7%)
Randomised as care home resident – n (%)	34 (26.8%)	90 (29.0%)	54 (36.7%)	70 (24.1%)
Post code at admission[1]				
NG8	17 (13.4%)	45 (14.5%)	19 (12.9%)	53 (18.3%)
NG5	20 (15.8%)	44 (14.2%)	28 (19.1%)	35 (12.1%)
NG9	17 (13.4%)	43 (13.9%)	10 (6.8%)	41 (14.1%)
NG11	19 (15.0%)	29 (9.4%)	14 (9.5%)	21 (7.3%)
NG2	9 (7.0%)	25 (8.1%)	17 (11.6%)	26 (9.0%)
NG3	9 (7.1%)	23 (7.4%)	13 (8.8%)	25 (8.6%)
NG4	9 (7.1%)	26 (8.4%)	13 (8.8%)	19 (6.6%)
NG6	11 (8.7%)	23 (7.4%)	10 (6.8%)	17 (5.9%)

1 – For post codes with total frequency greater than 50

ISSN 2044-4230

Baseline characteristics

Table 3 presents the baseline characteristics of the recruited participants from the initial questionnaire by allocated group.

The groups are well balanced with respect to age, ethnicity, marital status, proportion of participants living in the community at baseline admitted from respite care homes and abilities in activities of daily living prior to the acute illness and at admission.

There is a slight difference in the proportion of females recruited from each ward, as noted above in Table 2, and a difference in the permanent place of residence at admission between the two groups. On standard care, there were a smaller proportion of care home residents and a greater proportion of participants living alone compared to MMHU.

There is also a difference between the groups on variables measuring the severity of confusion: scores on both the Mini-Mental State examination and the Delirium Rating Scale indicate that problems were more severe for those recruited from standard care.

The EQ-5D quality of life scale was included in the initial questionnaire and items could be answered by the participant, a proxy informant or both the participant and a proxy informant. For cases where complete information for the 5 items was ascertained from both a participant and a proxy informant, participant rated health status scores were higher (median difference between health status scores for participants and proxies 0.20, IQR 0 to 0.5) with increasing variability in the proxy score as the participant score increased. Agreement was poorest on the mobility, usual activities and self care domains. Participant scores were most strongly correlated with abilities in daily living prior to the acute illness and at admission. The proxy scores were also strongly associated with these characteristics but were also much more strongly correlated with the participant's level of cognitive impairment and delirium rating scale score. Therefore due to these differences, summary statistics are presented separately for the health status score in Table 3 according to who provided this information. Overall, participant completed EQ-5D scores were slightly higher on MMHU compared to standard care ($p = 0.17$) and proxy completed EQ-5D scores were very similar in the two groups.

ISSN 2044-4230

Table 4 presents the baseline characteristics of the recruited participants from the medical data questionnaire by allocated group. The groups are balanced with respect to number of medications, presenting conditions, early warning score and the number of medical diagnoses. There were a similar proportion of participants in each group who had or who had ever had most of the medical diagnoses apart from hemiplegia, arthritis, eyesight problems and hip fracture. Two-thirds of the participants had had an inpatient stay or a visit to accident and emergency in the year before randomisation, however there was no difference between the groups for this or the length of hospital stay in the year prior to recruitment. There was also no difference between the groups in the number of nights between admission and randomisation: 173 participants (28.8%) were randomised on day of admission and 353 (58.8%) were randomised on the day after admission.

Information on the Neuropsychiatric Inventory (NPI) to assess behavioural and psychological symptoms was completed where a carer informant was available to provide this information and was completed for around 80% of participants in each group. Participants with this information were slightly older (mean 84.5 v 82.6 years, SD 6, for participants with/without this information), had slightly more cognitive impairment (median 13 v median 16, IQR 6 to 20), had more symptoms of delirium (median 20, IQR 13 to 27 v median 16, IQR 11 to 23) and were more dependent in Barthel ADL prior to the acute illness (median 14, IQR 9 to 18 v median 16, IQR 11 to 18) and at study recruitment (median 8, IQR 4 to 12 v median 9, IQR 6 to 15). Participants with mental capacity to consent to recruitment were less likely to have information on NPI (67%/85% of participants with/without mental capacity had NPI information), as well as participants who were divorced or separated (60-70%/80-90% of divorced or separated/married or widowed participants had NPI information). The differences between the groups noted from Table 3 for all participants persisted in the subset of participants with baseline NPI information.

Table 5 presents information on behavioural and psychiatric symptoms from the NPI at baseline in the two groups. The two groups are balanced, where this information was completed, with respect to both the proportion of participants with each of these symptoms, the total score for participants with the symptom present, the total NPI score and the number of symptoms present.

ISSN 2044-4230

Table 3: TEAM study baseline characteristics from the patient participant initial interview form

	MMHU (n = 310)	Standard care (n = 290)	p-value
Participant initial interview			
Age			
Mean (SD)	84.1 (6.2)	84.2 (6.8)	0.80
Med (IQR)	85 (80 – 88)	85 (80 – 89)	
Min - Max	65 – 98	65 – 102	
Sex (female)	170 (54.8%)	142 (49.0%)	0.15
Ethnicity (white)	305 (98.4%)	280 (96.6%)	0.24
Mental capacity	83 (26.8%)	55 (19.0%)	0.02
Consent type			0.05
Patient	80 (25.8%)	51 (17.6%)	
Consultee	200 (64.5%)	208 (71.7%)	
Professional	30 (9.7%)	31 (10.7%)	
Questionnaire completed by			0.22
Participant	95 (30.7%)	71 (24.5%)	
Jointly	165 (53.2%)	164 (56.6%)	
Informant	50 (16.1%)	55 (19.0%)	
Residence at admission			
Alone	119 (38.4%)	133 (45.9%)	0.13
With spouse, relative, friend	103 (33.2%)	96 (33.1%)	
Residential home	56 (18.1%)	38 (13.1%)	
Nursing home	32 (10.3%)	22 (7.6%)	
Unknown*	0	1 (0.3%)	

ISSN 2044-4230

	MMHU (n = 310)	Standard care (n = 290)	p-value
Admitted from respite care (for participants not living in permanent care homes at admission)	13/221 (5.9%)	15/227 (7.5%)	0.75
Unknown	1	3	
Marital status			
Married/partner	92 (29.7%)	87 (30.0%)	0.83
Divorced/separated	15 (4.8%)	19 (6.6%)	
Widowed	175 (56.5%)	158 (54.5%)	
Never married	25 (8.1%)	24 (8.3%)	
Unknown	3 (1.0%)	2 (0.7%)	
Cognition (MMSE)			
n	300	278	0.10
Median (IQR)	14 (6 – 20.5)	13 (6 – 19)	
MMSE > 24	25 (8.3%)	19 (6.8%)	
Delirium Rating Scale total score[1]			
n	308	290	0.03
Median (IQR)	19 (11 – 27)	20 (14 – 27)	
Delirium (DRS > 17.75)	164 (53.2%)	181 (62.4%)	0.02
Barthel ADL score prior to current illness[2]			0.76
N	308	286	
Mean (SD)	13.1 (5.6)	13.3 (5.4)	
Median (IQR)	14 (9 – 18)	14 (10 – 18)	
Barthel ADL score at admission[3]			0.30
Mean (SD)	9.1 (5.5)	8.6 (5.4)	
Median (IQR)	9 (5 – 13)	8 (4 – 13)	

ISSN 2044-4230

	MMHU (n = 310)	Standard care (n = 290)	p-value
NPI information completed	246 (79.4%)	237 (81.7%)	0.46
EQ-5D			
Source of information			
Participant only	102 (32.9%)	77 (26.6%)	
Informant only	80 (25.8%)	93 (32.1%)	
Participant and informant	116 (37.4%)	110 (37.9%)	
Incomplete information	12 (3.9%)	10 (3.3%)	
Health status scores according to who completed			
Participant only			
Mean (SD)	0.53 (0.37)	0.44 (0.34)	
Median (IQR)	0.67 (0.22 – 0.81)	0.52 (0.19 – 0.74)	
Informant only			
Mean (SD)	0.13 (0.29)	0.08 (0.26)	
Median (IQR)	0.08 (-0.09 – 0.27)	0.03 (-0.10 – 0.22)	
Participant where both completed			
Mean (SD)	0.51 (0.37)	0.51 (0.36)	
Median (IQR)	0.63 (0.25 – 0.81)	0.57 (0.26 – 0.81)	
Proxy where both completed			
Mean (SD)	0.26 (0.30)	0.27 (0.34)	
Median (IQR)	0.20 (0.03 – 0.53)	0.27 (0.04 – 0.52)	

ISSN 2044-4230

	MMHU (n = 310)	Standard care (n = 290)	p-value
Participant completed			
EQ-5D			0.17
n	218 (70.3%)	187 (64.5%)	
Mean (SD)	0.52 (0.37)	0.48 (0.36)	
Median (IQR)	0.64 (0.25 – 0.81)	0.52 (0.20 – 0.78)	
Proxy completed			
EQ-5D			0.77
n	196 (63.2%)	203 (70.0%)	
Mean (SD)	0.20 (0.31)	0.19 (0.32)	
Median (IQR)	0.19 (-0.03 – 0.35)	0.15 (-0.02 – 0.37)	

Median (IQR) presented for ordered/continuous variables and frequency/percentage (in each study group) for categorical variables, unless otherwise stated. Mann-Whitney test used to test for differences in continuous/ordered variables and chi-squared test for categorical variables.

* - strong evidence that participant admitted from community.

1 – DRS: 1 missing item (of 16) imputed for 43 participants, 2 missing items for 2 participants, 3 missing items for 3 participants and 4 missing items for 1 participant.

2 – ADL prior: 1 to 4 items imputed for 5 participants.

3 – ADL at admission: 1 missing item imputed for 5 participants.

ISSN 2044-4230

Table 4: TEAM study baseline characteristics from the patient participant medical data form

	MMHU (n = 310)	Standard care (n = 290)	p-value
Medical data information			
Number of medications			0.14
n	301	277	
Median (IQR)	7 (4 – 9)	6 (4 – 9)	
Early warning score	1 (1 – 2)	1 (1 – 2)	0.88
Presenting conditions			
Fall	129 (41.6%)	128 (44.1%)	0.53
Reduced mobility	140 (45.2%)	135 (46.6%)	0.73
New or increased continence disorder	48 (15.5%)	50 (17.2%)	0.56
Deteriorated cognitive skills in the past three months	207 (66.8%)	198 (68.3%)	0.70
Medical diagnoses (has or ever had)			
Myocardial infarction	71 (22.9%)	69 (23.8%)	0.80
Heart failure, LVF, CCF	43 (13.9%)	49 (16.9%)	0.30
Other heart disease (AF, valve disease)	101 (32.6%)	87 (30.0%)	0.50
Stroke or cerebrovascular disease	94 (30.3%)	101 (34.8%)	0.24
Dementia	206 (66.5%)	182 (62.8%)	0.34
COPD or asthma	56 (18.1%)	59 (20.3%)	0.48
Breathlessness or shortness of breath	72 (23.2%)	76 (26.2%)	0.40
Diabetes	63 (20.3%)	53 (18.3%)	0.53
Paralysis, weakness loss of arm or leg, hemiplegia, paraplegia	13 (4.2%)	28 (9.7%)	0.008
Kidney disease	63 (20.3%)	56 (19.3%)	0.76

ISSN 2044-4230

	MMHU (n = 310)	Standard care (n = 290)	p-value
Cancer	56 (18.1%)	61 (21.0%)	0.36
Osteoarthritis	98 (31.6%)	89 (30.7%)	0.81
Arthritis or rheumatism	87 (28.1%)	100 (34.5%)	0.09
Hip fracture	42 (13.6%)	21 (7.3%)	0.01
Depression	56 (18.1%)	45 (15.5%)	0.41
Eyesight problems (not corrected with glasses)	83 (26.8%)	97 (33.5%)	0.08
Deafness/hearing Difficulties	56 (18.1%)	54 (18.6%)	0.88
Peripheral vascular Diseases	15 (4.8%)	15 (5.2%)	0.85
Total number of above Diagnoses	4 (3 – 5)	4 (3 – 6)	0.44
Hospital activity in year prior to admission			
Any inpatient stay or visit to A & E	203 (65.5%)	195 (67.2%)	0.65
Length of stay in year prior to recruitment[1]	1 (0 – 16)	1.5 (0 – 17)	0.93
Length of stay between admission and randomisation	1 (0 – 1)	1 (0 – 1)	0.80

Median (IQR) presented for ordered/continuous variables and frequency/percentage (in each study group) for categorical variables, unless otherwise stated. Mann-Whitney test used to test for differences in continuous/ordered variables and chi-squared test for categorical variables.

1 – Length of stay in year prior to admission: not including the admission that the patient was randomised and recruited from.

ISSN 2044-4230

Table 5: Behavioural and psychological symptoms at baseline for 483 participants where this information was completed

	MMHU (n = 246)	Standard care (n = 237)	p-value
NPI information provided by			
Spouse/partner	42 (17.1%)	54 (22.8%)	0.39
Son/daughter	144 (58.5%)	132 (55.7%)	
Other relative	41 (16.7%)	32 (13.5%)	
Other (non-relative)	18 (7.3%)	19 (8.0%)	
Unknown	1 (0.4%)	0	
Delusions			0.75
Present	144 (58.5%)	134 (56.5%)	
Score where present	4 (2 – 8)	4 (3 – 8)	
Hallucinations			0.50
Present	91 (37.0%)	94 (39.7%)	
Score where present	3 (2 – 8)	3.5 (2 – 8)	
Agitation			0.34
Present	169 (68.7%)	151 (63.7%)	
Score where present	3 (1 – 6)	3 (2 – 6)	
Depression			0.18
Present	147 (59.8%)	130 (54.9%)	
Score where present	3 (2 – 8)	3 (2 – 6)	
Anxiety			0.25
Present	156 (63.4%)	136 (57.4%)	
Score where present	4 (2 – 8)	4 (2 – 8)	
Elation			0.33
Present	27 (11.0%)	33 (13.9%)	

ISSN 2044-4230

Score where present	2.5 (1 – 4)	2 (1 – 4)	
Apathy			0.58
Present	162 (65.9%)	160 (67.5%)	
Score where present	6 (3 – 8)	7 (3 – 9)	
Disinhibition			0.43
Present	76 (30.9%)	86 (36.3%)	
Score where present	3 (1.5 – 6)	3 (1 – 5)	
Irritability			0.79
Present	151 (61.4%)	143 (60.3%)	
Score where present	3 (1 – 6)	3 (2 – 6)	
Motor behaviour			0.59
Present	87 (35.4%)	89 (37.6%)	
Score where present	4 (3 – 8)	6 (3 – 8)	
Difficulty sleeping			0.39
Present	124 (50.4%)	136 (57.4%)	
Score where present	6 (3 – 8)	5 (3 – 8)	
Appetite problems			0.44
Present	141 (57.3%)	128 (54.0%)	
Score where present	8 (4 – 12)	8 (4 – 12)	
Number of conditions present at recruitment (out of 12)[1]			0.81
N	239	231	
Median (IQR)	6 (4 – 8)	6 (4 – 8)	
NPI total score[2]			0.99
N	245	236	
Median (IQR)	26 (13 – 42)	25 (14 – 39.5)	

Symptom present defined by NPI score on each domain (given by frequency x severity score) of more than 0.

Score where present shows median (IQR) where NPI domain score > 0

P-value from Mann-Whitney U test comparing the domain score in the two groups.

1 – For participants with information on all 12 symptoms completed.

2 – Calculated as the frequency x severity score for the 12 symptoms, range 0 to 144, higher scores indicating increased presence of behavioural and psychological symptoms. Information for one or two missing symptoms imputed for 29 participants.

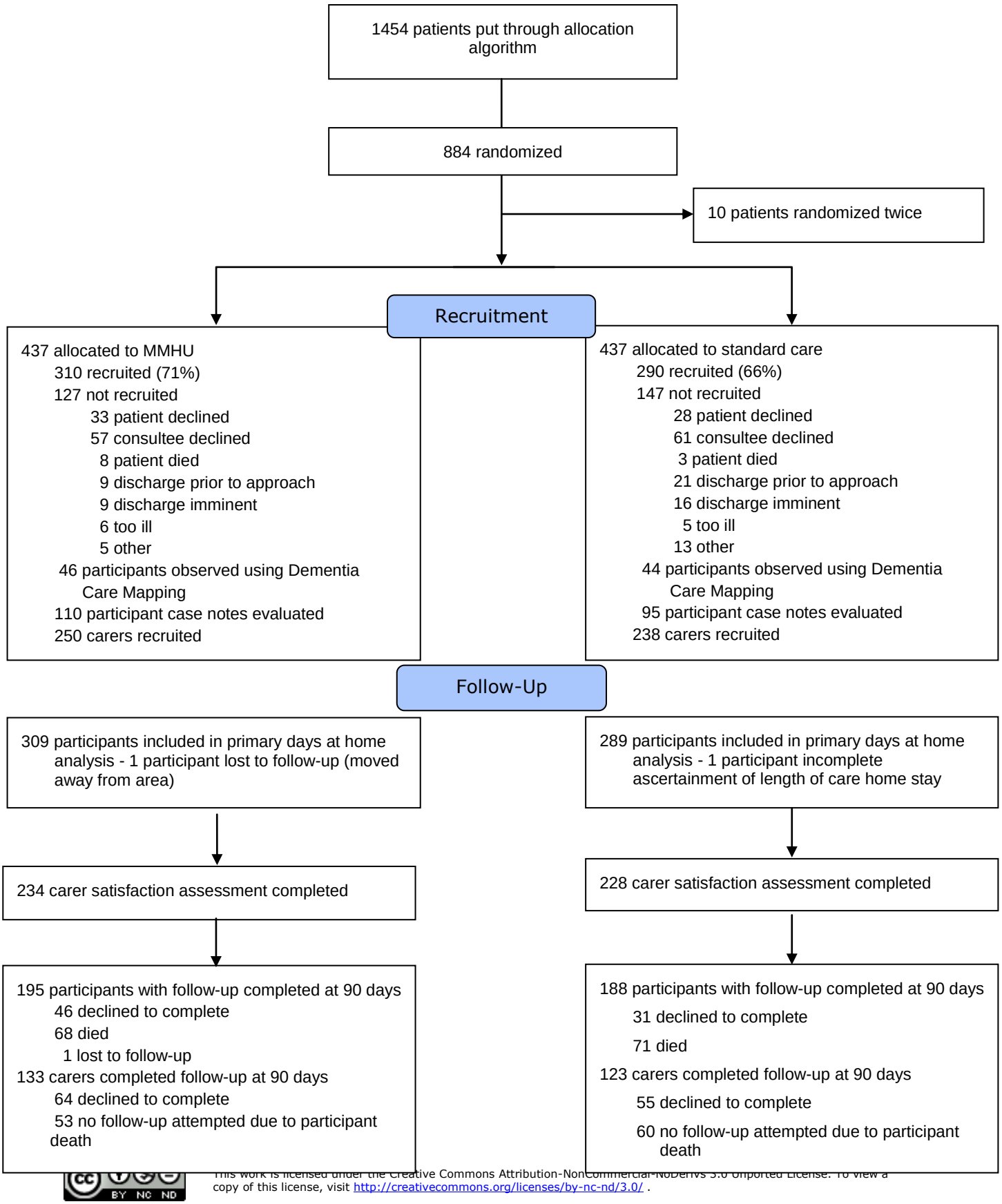
Participant flow through study

The flow of recruited participants from baseline data collection to 90 day follow-up is shown in Figure 2. This shows the number of participants with outcome information collected for the primary days at home outcome and the components of this outcome and the number of participants with health status outcome information collected through participant and carer interviews.

One participant who was living in a care home at admission was lost to follow-up during the study. This participant moved to a new care home during the study period but no further information could be obtained and so is not included in the analysis of the primary outcome or any of the secondary outcomes associated with this. Another participant was discharged to intermediate care after the initial hospital admission, however no details could be obtained on the length of this stay therefore this participant is not included in the analysis of the primary days at home outcome but is included in the analysis of mortality, hospital length of stay and permanent care home placement.

ISSN 2044-4230

Figure 2: TEAM study flow diagram



ISSN 2044-4230

Primary outcome: Days spent at home

Table 6 shows the number of days at home, numbers of participants returning home after the initial admission and the number of days these participants spent at home, mortality at 90 days, length of stay during the study, readmissions and care home placement for participants living in the community at admission in the two groups. The distribution of days at home in the two groups is shown in Figure 3 and the Kaplan Meier survival curves in the two groups are shown in Figure 4.

The adjusted estimates of the intervention effect for all of the outcomes presented in the table are adjusted for age, gender, residence at admission (community or care home), MMSE score at admission, ADL score prior to the acute illness and at recruitment, number of medical diagnoses and length of stay in hospital in the year prior to recruitment.

In addition differences were noted between the two groups at recruitment in delirium rating scale (DRS) score, type of residence in the community (alone or living with someone) and ever having a diagnosis of hemiplegia or hip fracture. These variables were therefore also included in the models to allow for these baseline differences between the groups (replacing the MMSE score used in the adjusted models above with the DRS score due to the collinearity between these variables).

Adjusted estimates for the intervention effect show odds ratios for returning home after the initial admission, care home placement and readmission, proportional change in the ratio of the number of days spent at home to not at home, hazard ratios for mortality and relative change for length of stay.

There is no evidence of a difference in the number of days at home overall, the proportion of participants returning home after the initial admission or the number of days spent at home if participants returned home between the two groups in the unadjusted, adjusted or sensitivity analyses. Similarly, there is no evidence of a difference between the two groups in survival, total length of hospital stay during the study or the proportion of participants readmitted between the two groups in any of the

ISSN 2044-4230

analyses. A greater proportion of participants living in the community at admission moved to care homes from standard care compared to MMHU, however the magnitude of this effect reduces in the adjusted analyses due to the poorer cognition and delirium rating scale scores for the participants on standard care compared to MMHU, meaning that there is insufficient evidence to conclude that there is a difference between the two groups in care home placement when these baseline variables are taken into account. Conversely for the length of the initial stay, there is little difference between the two groups in the unadjusted analyses, however the magnitude of the intervention effect increases (towards shorter initial length of stays on standard care, although this does not reach statistical significance) in the adjusted analyses due to the poorer delirium rating scale scores and the smaller proportion of participants recruited from care homes in this group.

ISSN 2044-4230

Table 6: Days at home outcomes at 90 days

				Adjusted intervention effect	
	MMHU (n = 310)	Standard care (n = 290)	Unadjusted intervention effect (95% CI)	With pre-specified prognostically important variables[1] (95% CI)	Also including baseline variables with imbalance[2] (95% CI)
Days at home			p = 0.31		
Median (IQR)	51 (0 – 79)	45 (0 – 78)	*Difference in medians*		
			6 (-12, 24)		
Mean (SD)	44.3 (35.3)	41.5 (36.0)	*Difference in means*		
	(n = 309)	(n = 289)	2.8 (-3.1, 8.5)		
			Odds ratio		
Days spent at			p = 0.29	p = 0.87	p = 0.54
home > 0 – n/N (%)	228/309 (73.8%)	202/289 (69.9%)	1.21 (0.85, 1.73)	0.97 (0.66, 1.43)	0.88 (0.59, 1.32)
			Proportional change in ratio		
Days spent at home if > 0			p = 0.64	p = 0.72	p = 0.51

ISSN 2044-4230

	MMHU (n = 310)	Standard care (n = 290)	Unadjusted intervention effect (95% CI)	Adjusted intervention effect: With pre-specified prognostically important variables[1] (95% CI)	Adjusted intervention effect: Also including baseline variables with imbalance[2] (95% CI)
Median (IQR)	70.5 (40 – 82.5)	71 (40 – 82)	1.05 (0.85, 1.31)	0.96 (0.78, 1.19)	0.93 (0.75, 1.15)
Mean (SD)	60.1 (27.3)	59.4 (28.2)	*Difference in medians (unadjusted)*		
	(n = 228)	(n = 202)	-0.5 (-6, 6.5)		
Components of days at home					
			Hazard Ratio		
			p = 0.50	p = 0.88	p = 0.89
Mortality – n/N (%)	68/309 (22.0%)	71/290 (24.5%)	0.89 (0.64, 1.24)	1.03 (0.73, 1.45)	1.03 (0.72, 1.45)
			Odds Ratio		
			p = 0.05	p = 0.10	p = 0.30
Move to permanent care home during study from community – n/N (%)	45/222 (20.3%)	65/230 (28.3%)	0.65 (0.42, 1.00)	0.68 (0.44, 1.07)	0.78 (0.49, 1.24)
			Relative change		
Initial length of stay –	11 (5 – 22)	11 (5 – 20)	p = 0.71	p = 0.11	p = 0.08

ISSN 2044-4230

	MMHU (n = 310)	Standard care (n = 290)	Unadjusted intervention effect (95% CI)	Adjusted intervention effect: With pre-specified prognostically important variables[1] (95% CI)	Adjusted intervention effect: Also including baseline variables with imbalance[2] (95% CI)
median (IQR)	(n = 310)	(n = 290)	1.03 (0.88, 1.20)	1.13 (0.98, 1.30)	1.14 (0.99, 1.32)
			Relative change		
Total length of stay during study	16 (8 – 30)	16 (7 – 30)	p = 0.96	p = 0.39	p = 0.32
median (IQR)	(n = 309)	(n = 290)	1.00 (0.87, 1.16)	1.06 (0.93, 1.22)	1.07 (0.93, 1.23)
			Unadjusted difference in medians (days)		
			0 (-3, 2)		
			Odds ratio		
Readmission – n/N (%)			p = 0.47	p = 0.26	p = 0.31
	99/309 (32.0%)	101/290 (34.8%)	0.88 (0.63, 1.24)	0.82 (0.57, 1.16)	0.83 (0.58, 1.19)

Intervention effect: MMHU compared to standard care

95% confidence intervals for the difference in median/mean days at home (MMHU – standard care) for all participants and for those returning home calculated using bootstrapping.

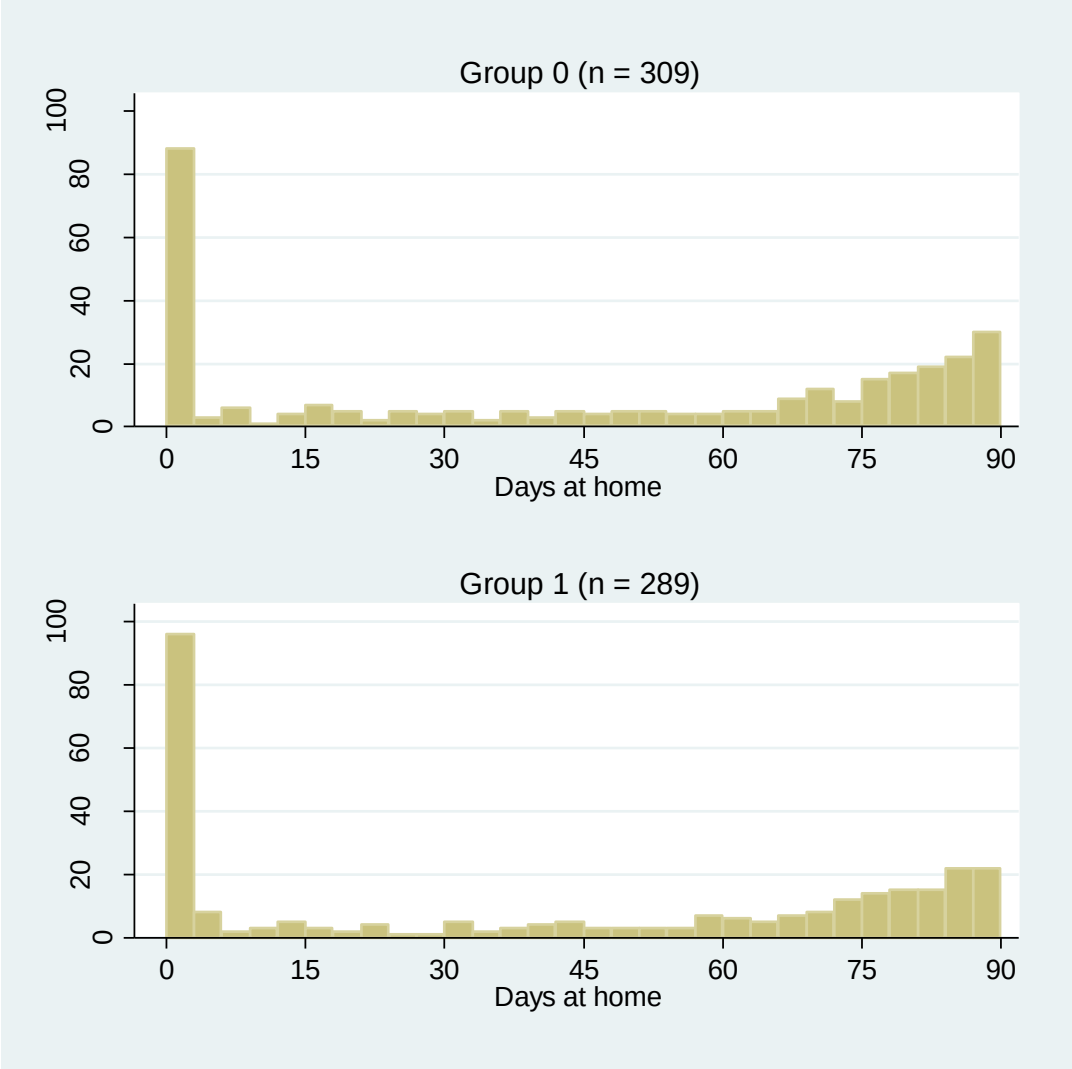
Initial length of stay is LoS from randomisation date to first discharge from hospital (i.e. including transfers to other wards or hospitals)

ISSN 2044-4230

1 – Adjusted for age, gender, residence at admission (community/care home), MMSE score (cognitive impairment), Barthel ADL score prior to acute illness and at admission, number of medical diagnoses and length of stay in year before admission

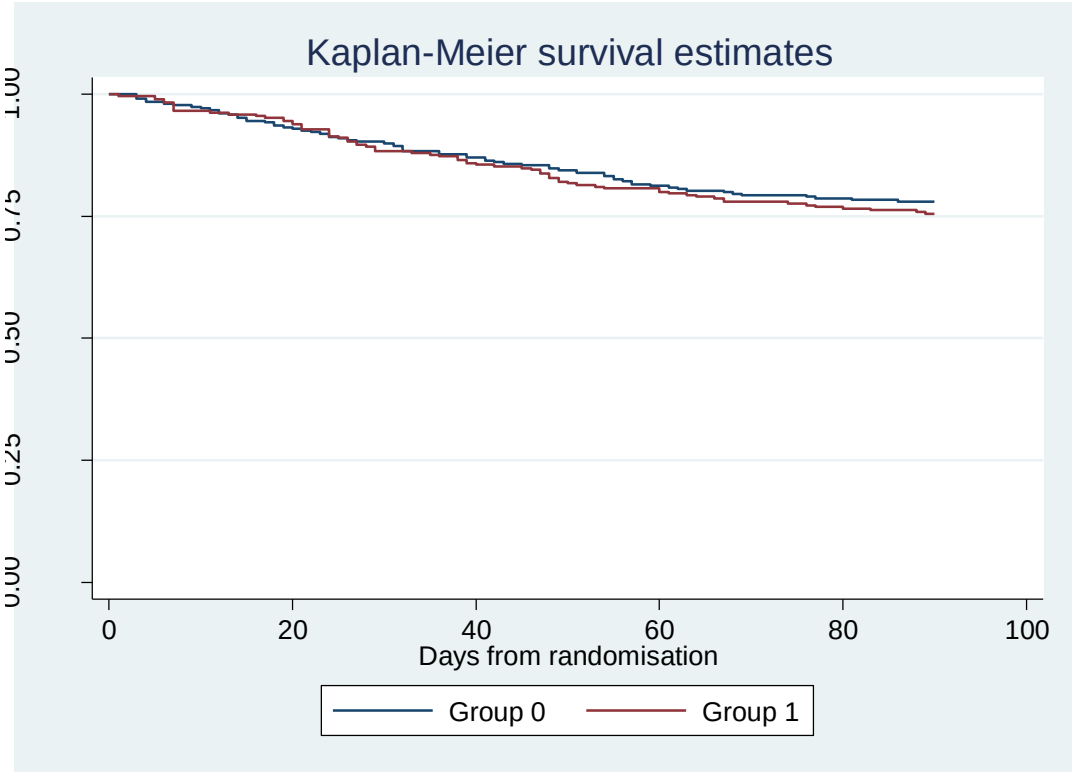
2 – Also adjusted according to whether living alone or with someone for participants living in the community at admission, for diagnosis of paralysis or hip fracture as imbalance between groups at baseline and MMSE score replaced with delirium rating scale score (not both included in model due to collinearity between these variables)

Figure 3: Histogram of days spent at home by group



Group 0 – MMHU Group 1 – Standard care

Figure 4: Kaplan Meier survival curves, by group



Group 0 – MMHU Group 1 – Standard care

Subgroup analysis for the primary outcome

The tables for each subgroup analysis show the outcomes in the two groups according to subgroup. In addition, interaction effects are presented (with 95% confidence intervals) which compare the intervention effect between the two subgroups. The interaction effects show the relative change in odds ratios for the intervention effect for returning home from the initial admission, care home placement and readmissions, the relative change in the proportional change in the ratio of days spent at home to not at home for the number of days spent at home for participants returning there, the relative change in hazards ratio for the intervention effect for mortality and the relative change in the factor change for the intervention effect for length of stay.

Table 7 shows the outcomes in the two groups according to residence at admission. There is no evidence of a difference in the intervention effect for any of these outcomes according to whether participants were living in the community or in a care home at admission.

ISSN 2044-4230

Table 7: 90 day outcomes by group according to residence at admission – community or care home

	MMHU (n = 310)	Standard care (n = 290)	Unadjusted interaction effect (95% CI)	Adjusted interaction effect: With pre-specified prognostically important variables[1] (95% CI)	Adjusted interaction effect: Also including baseline variables with imbalance[2] (95% CI)
Days at home					
Community					
Median (IQR)	49.5 (0 – 78)	39 (0 – 75)			
Mean (SD)	42.8 (35.3)	38.4 (35.6)			
	(n = 222)	(n = 229)			
Care home					
Median (IQR)	57 (7 – 83)	73.5 (11 – 82)			
Mean (SD)	48.1 (35.2)	53.2 (35.5)			
	(n = 87)	(n = 60)			
Days spent at home > 0					
Community	155/222 (69.8%)	150/229 (65.5%)	*Odds Ratio*		

ISSN 2044-4230

				Adjusted interaction effect	
	MMHU (n = 310)	Standard care (n = 290)	Unadjusted interaction effect (95% CI)	With pre-specified prognostically important variables[1] (95% CI)	Also including baseline variables with imbalance[2] (95% CI)
			p = 0.42	p = 0.45	p = 0.60
			1.52 (0.55, 4.21)	1.50 (0.52, 4.29)	1.33 (0.46, 3.87)
Care home	73/87 (83.9%)	52/60 (86.7%)			
Days spent at home if > 0					
Community					
Median (IQR)	70 (45 – 81)	68 (40 – 81)			
Mean (SD)	61.4 (25.5)	58.7 (27.3)			
	(n = 155)	(n = 150)	*Proportional change in ratio*		
			p = 0.48	p = 0.61	p = 0.75
			1.19 (0.74, 1.91)	1.13 (0.71, 1.80)	1.08 (0.68, 1.72)
Care home					
Median (IQR)	73 (27 – 84)	76 (41 – 83.5)			

ISSN 2044-4230

				Adjusted interaction effect	
	MMHU (n = 310)	Standard care (n = 290)	Unadjusted interaction effect (95% CI)	With pre-specified prognostically important variables[1] (95% CI)	Also including baseline variables with imbalance[2] (95% CI)
Mean (SD)	57.3 (30.8) (n = 73)	61.4 (30.7) (n = 52)			
Components of days at home					
Mortality – n/N (%)					
Community	36/222 (16.2%)	51/230 (22.2%)	*Hazard Ratio*		
			p = 0.28	p = 0.34	p = 0.41
			0.68 (0.33, 1.37)	0.70 (0.34, 1.44)	0.74 (0.36, 1.52)
Care homes	32/87 (36.8%)	20/60 (33.3%)			
Initial length of stay – median (IQR)					
Community	13 (6 – 26) (n = 222)	14 (6 – 25) (n = 230)	*Interaction effect*		

ISSN 2044-4230

				Adjusted interaction effect	
	MMHU (n = 310)	Standard care (n = 290)	Unadjusted interaction effect (95% CI)	With pre-specified prognostically important variables[1] (95% CI)	Also including baseline variables with imbalance[2] (95% CI)
			p = 0.16	p = 0.29	p = 0.20
			0.77 (0.55, 1.10)	0.83 (0.59, 1.17)	0.80 (0.57, 1.13)
Care homes	7.5 (3.5 – 14.5) (n = 88)	7 (4 – 11) (n = 60)			
Total length of stay – median (IQR)					
Community	18 (9 – 34) (n = 222)	18 (9 – 32) (n = 230)	*Relative change*		
			p = 0.08	p = 0.17	p = 0.17
			0.74 (0.54, 1.03)	0.80 (0.58, 1.10)	0.80 (0.58, 1.10)
Care homes	13 (5 – 20) (n = 87)	8 (6 – 16) (n = 60)			

ISSN 2044-4230

				Adjusted interaction effect	
	MMHU (n = 310)	Standard care (n = 290)	Unadjusted interaction effect (95% CI)	With pre-specified prognostically important variables[1] (95% CI)	Also including baseline variables with imbalance[2] (95% CI)
Readmission – n/N (%)					
Community	70/222 (31.5%)	79/230 (34.4%)	*Odds ratio*		
			p = 0.96	p = 0.69	p = 0.79
			1.02 (0.46, 2.25)	1.18 (0.52, 2.67)	1.12 (0.49, 2.57)
Care homes	29/87 (33.3%)	22/60 (36.7%)			

Interaction effect: comparison of intervention effect (standard care v MMHU) in care home residents compared to intervention effect in community residents.

1 – Adjusted for age, gender, residence at admission (community/care home), MMSE score (cognitive impairment), Barthel ADL score prior to acute illness and at admission, number of medical diagnoses and length of stay in year before admission

2 – Also adjusted according to whether living alone or with someone for participants living in the community at admission, for diagnosis of paralysis or hip fracture as imbalance between groups at baseline and MMSE score replaced with delirium rating scale score (not both included in model due to collinearity between these variables)

ISSN 2044-4230

Table 8 shows the outcomes in the two groups according to delirium rating scale score at recruitment (less than or greater than 17.75). Note that there were two participants with unknown DRS scores (0/5 items completed respectively, one participant living in the community at admission and one participant living in a care home at admission). These participants were categorised according to the median DRS score for their initial residence type for this analysis.

There is no evidence of a difference in the intervention effect for any of these outcomes according to DRS score at recruitment.

ISSN 2044-4230

Table 8: 90 day outcomes by group according to delirium rating scale score at recruitment – greater than or less than 17.75

			Adjusted interaction effect		
Outcome DRS > 17.75	MMHU (n = 310)	Standard care (n = 290)	Unadjusted interaction effect (95% CI)	With pre-specified prognostically important variables[1] (95% CI)	Also including baseline variables with imbalance[2] (95% CI)
Mortality – n/N (%)					
No	21/145 (14.5%)	15/109 (13.8%)	*Hazard Ratio*		
			p = 0.71	p = 0.46	p = 0.44
			1.15 (0.54, 2.50)	1.34 (0.61, 2.91)	1.36 (0.62, 2.95)
Yes	47/164 (28.7%)	56/181 (30.9%)			
Move to permanent care home from the community – n/N (%)					
No	16/125 (12.8%)	18/98 (17.4%)	*Odds Ratio*		
			p = 0.72	p = 0.76	p = 0.79
			0.85 (0.34, 2.13)	0.86 (0.34, 2.20)	0.88 (0.35, 2.27)

ISSN 2044-4230

				Adjusted interaction effect	
Outcome	MMHU	Standard care	Unadjusted interaction effect (95% CI)	With pre-specified prognostically important variables[1] (95% CI)	Also including baseline variables with imbalance[2] (95% CI)
DRS > 17.75	(n = 310)	(n = 290)			
Yes	29/97 (29.9%)	47/132 (35.6%)			
Initial length of stay – median (IQR)					
No	8 (4 – 20)	8 (3 – 17)			
	(n = 145)	(n = 109)	*Interaction effect*		
			p = 0.59	p = 0.38	p = 0.39
			0.92 (0.68, 1.25)	0.88 (0.66, 1.17)	0.88 (0.66, 1.17)
Yes	13 (6 – 25)	13 (7 – 24)			
	(n = 165)	(n = 181)			

ISSN 2044-4230

Outcome DRS > 17.75	MMHU (n = 310)	Standard care (n = 290)	Unadjusted interaction effect (95% CI)	Adjusted interaction effect With pre-specified prognostically important variables[1] (95% CI)	Adjusted interaction effect Also including baseline variables with imbalance[2] (95% CI)
Total length of stay – median (IQR)					
No	14 (6 – 29) (n = 145)	14 (6 – 26) (n = 109)	*Relative change* p = 0.32 0.86 (0.65, 1.15)	p = 0.14 0.82 (0.62, 1.07)	p = 0.15 0.82 (0.62, 1.07)
Yes	16 (9 – 34.5) (n = 164)	17 (8 – 31) (n = 181)			

ISSN 2044-4230

Outcome DRS > 17.75	MMHU (n = 310)	Standard care (n = 290)	Unadjusted interaction effect (95% CI)	Adjusted interaction effect With pre-specified prognostically important variables[1] (95% CI)	Adjusted interaction effect Also including baseline variables with imbalance[2] (95% CI)
Readmission – n/N (%)					
No	53/145 (36.6%)	43/109 (39.5%)	*Odds ratio*		
			p = 0.85	p = 0.79	p = 0.79
			1.07 (0.54, 2.13)	1.10 (0.54, 2.23)	1.10 (0.54, 2.24)
Yes	46/164 (28.1%)	58/181 (32.0%)			

Interaction effect: comparison of intervention effect (standard care v MMHU) for participants with DRS score > 17.75 compared to intervention effect for participants with DRS score < 17.75.

DRS categorical variable imputed for two participants using median score according to residence at admission. MMSE score not included in the adjusted model due to collinearity with the DRS score.

1 – Adjusted for age, gender, residence at admission (community/care home), Barthel ADL score prior to acute illness and at admission, number of medical diagnoses and length of stay in year before admission

2 – Also adjusted according to whether living alone or with someone for participants living in the community at admission and for diagnosis of paralysis or hip fracture as imbalance between groups at baseline.

The initial hospital stay was defined as the length of stay from randomisation to initial discharge from hospital. For most participants this consisted of one inpatient stay within the QMC. Ten participants spent less than 6 nights at the QMC but were transferred to other wards and so eventually had an initial length of hospital stay of greater than 5 nights (these participants were transferred to healthcare trust destinations or City hospital, 6 participants in one group and 4 participants in the other group). These participants were classified into the group spending more than 5 nights in hospital for the initial stay.

Table 9 shows the outcomes in the two groups according to the length of the initial hospital stay (5 days or less or greater than 5 days). There were 161 participants with an initial length of stay of 5 nights or less (26.8%) and 439 participants with an initial length of stay of more than 5 nights (73.2%), with a similar proportion of participants with an initial length of stay of more than 5 nights in the two groups (72.3% on MMHU and 74.1% on standard care).

There is no evidence of a difference in the intervention effect for any of these outcomes according to the length of the initial hospital stay.

ISSN 2044-4230

Table 9: 90 day outcomes by group according to length of initial hospital stay – 5 nights or less or more than 5 nights

Outcome Initial LoS > 5	MMHU (n = 310)	Standard care (n = 290)	Unadjusted interaction effect (95% CI)	Adjusted interaction effect With pre-specified prognostically important variables[1] (95% CI)	Adjusted interaction effect Also including baseline variables with imbalance[2] (95% CI)
Move to permanent care home from the community – n/N (%)					
No	3/51 (5.9%)	5/52 (9.6%)	*Odds Ratio*		
			p = 0.91	p = 0.74	p = 0.96
			0.92 (0.19, 4.36)	1.31 (0.27, 6.47)	1.05 (0.21, 5.22)
Yes	42/171 (24.6%)	60/178 (33.7%)			
Total length of stay – median (IQR)					
No	4 (2 – 13)	4 (3 – 10)			

ISSN 2044-4230

	(n = 85)	(n = 75)	*Relative change*		
			p = 0.56	p = 0.47	p = 0.59
			1.09 (0.81, 1.46)	1.11 (0.83, 1.50)	1.08 (0.81, 1.46)
Yes	20.5 (12 – 35.5)	19 (12 – 33)			
	(n = 224)	(n = 215)			
Readmission – n/N (%)					
No	34/85 (40.0%)	31/75 (41.3%)	*Odds Ratio*		
			p = 0.77	p = 0.75	p = 0.86
			1.12 (0.53, 2.37)	1.13 (0.52, 2.46)	1.07 (0.49, 2.35)
Yes	65/224 (29.0%)	70/215 (32.6%)			

Interaction effect: comparison of intervention effect (standard care v MMHU) for participants with initial length of stay of 5 nights or less compared to intervention effect for participants with an initial length of stay of more than 5 nights.

1 – Adjusted for age, gender, residence at admission (community/care home), MMSE score (cognitive impairment), Barthel ADL score prior to acute illness and at admission, number of medical diagnoses and length of stay in year before admission

2 – Also adjusted according to whether living alone or with someone for participants living in the community at admission, for diagnosis of paralysis or hip fracture as imbalance between groups at baseline and MMSE score replaced with delirium rating scale score (not both included in model due to collinearity between these variables).

ISSN 2044-4230

Of the 290 participants randomised and recruited from standard care, 204 were treated on acute geriatric wards (70%) and 86 were treated on other general medical wards. The characteristics of the participants treated on acute geriatric wards compared to the participants on other general medical wards were mostly similar in terms of age, residence at recruitment, MMSE score, delirium rating scale score, number of medications, number of medical conditions and numbers presenting with different geriatric conditions. Some differences were observed for activities of daily living score prior to admission (median 14 IQR 9 to 16 on acute geriatric wards and median 16 IQR 10 to 17 on other wards), although activities of daily living score at baseline were similar, and the number of participants with congestive heart failure (14% on the acute geriatric wards and 24% on the other wards).

Table 10 shows the 90 day outcomes split by type of standard care ward. To evaluate if there was an interaction effect between the intervention and the type of standard care ward, a likelihood ratio test was conducted to compare the model using the three level variable for ward type (MMHU, acute geriatric, other standard) to the model with the two level variable for ward type (MMHU, standard) in the regression analyses. These tests were not significant for any of the outcomes in Table 10 for either the unadjusted models or the models including the prognostically important covariates and variables with an imbalance between groups at baseline.

ISSN 2044-4230

Table 10: 90 day outcomes by type of standard care – acute geriatric or other

		Standard care (n = 290)	
	MMHU (n = 310)	Acute geriatric (n = 204)	Other wards (n = 86)
Days at home			
Median (IQR)	51 (0 – 79)	42 (0 – 76)	58 (0 – 82)
Mean (SD)	44.3 (35.3) (n = 309)	39.4 (35.6) (n = 203)	46.4 (36.9) (n = 86)
Days spent at home > 0 – n/N (%)	228/309 (73.8%)	138/203 (68.0%)	64/86 (74.4%)
Days spent at home if > 0			
Median IQR)	70.5 (40-82.5)	70 (39 – 80)	75.5 (42 – 85)
Mean (SD)	60.1 (27.3) (n = 228)	58.0 (28.0) (n = 138)	62.4 (28.7) (n=64)
Components of days at home			
Mortality – n/N (%)	68/309 (22.0%)	50/204 (24.5%)	21/86 (24.4%)
Move to permanent care home during study from community – n/N (%)	45/222 (20.3%)	50/161 (31.1%)	15/69 (21.7%)
Initial length of stay – median (IQR)	11 (5 – 22) (n = 310)	13 (6 – 19.5) (n = 204)	7.5 (2 – 21) (n = 86)
Total length of stay during study – median (IQR)	16 (8 – 30) (n = 309)	17 (8 – 29) (n = 204)	12.5 (6 – 31) (n = 86)
Readmission – n/N (%)	99/309 (32.0%)	71/204 (34.8%)	30/86 (34.9%)

ISSN 2044-4230

Secondary health status outcomes

At 90 days after randomisation, surviving participants were followed up to re-assess cognitive function, abilities in activities of daily living, behavioural and psychological symptoms and quality of life. This usually consisted of a interview in the participant's home. Of the 460 participants alive at the end of the study, 383 had follow-up for at least one of these health status assessments: 195 from the MMHU and 188 from standard care (83% of participants alive at the end of the follow-up period: 81% from the MMHU and 86% from standard care, Figure 2).

Characteristics at recruitment of surviving participants in the two groups

The characteristics of the surviving participants were similar in the two groups for age, gender, activities of daily living prior to the acute illness, number of medications taken at admission, early warning score at admission, presenting conditions, most of the medical diagnoses, behavioural and psychological symptoms where this information was completed at recruitment and hospital activity in the year prior to the study. Differences between groups remained for the characteristics where there was a difference at recruitment for all participants recruited, in particular:

- Scores on the MMSE were lower for participants from standard care (MMHU median 15 IQR 9 to 21, standard care median 14 IQR 6 to 20)
- Scores on the delirium rating scale were higher for participants from standard care (MMHU median 17, IQR 11 to 26, standard care median 19 IQR 13 to 26)
- A smaller proportion of participants from standard care had mental capacity at recruitment (MMHU 30.3%, standard care 21.9%).
- A greater proportion of participants from standard care lived alone at admission (MMHU 42%, standard care 53%)

Note these variables were also associated with survival during the follow-up period so these scores for participants surviving the follow-up period in the two groups are different to the scores for all participants recruited into the two groups.

ISSN 2044-4230

There was also some indication that surviving participants from standard care had poorer activity of daily living scores at recruitment than participants on the MMHU (MMHU median 10 IQR 7 to 14, standard care median 9 IQR 6 to 13) and some differences in the proportion of participants with the medical diagnoses assessed at recruitment:

- Hemiplegia – MMHU 3.3%, standard care 10%
- Hip fracture – MMHU 13.7%, standard care 6.4%
- Arthritis or rheumatism – MMHU 27.0%, standard care 35.6%
- Eyesight problems – MMHU 27.0%, standard care 35.6%

Characteristics at recruitment of participants with health status follow-up

Overall and within the two study groups, the 77 participants not followed up were slightly younger than the 383 participants followed up (mean 81.5 SD 5.7 compared to mean 84.1 SD 6.6), slightly less likely to live in care homes at admission (n = 10, 13% of participants not followed up and n = 86, 22% of those with some health status follow-up), more likely to never have been married (n = 16, 21% of participants not followed up and n = 25, 6.5% of those with some health status follow-up) and slightly less likely to have information on the Neuropsychiatric Inventory completed at baseline (n = 57, 74% of participants not followed up and n = 315, 82% of those with some health status follow-up).

Participants with health status follow-up from the MMHU had slightly lower scores on the MMSE (median 15, IQR 8.5 to 21) than the participants with no health status follow-up (median 18, IQR 12 to 22) whereas the scores were similar for participants from standard care. Also a smaller proportion of participants from the MMHU living in the community at admission moved to care homes for those with no health status follow-up (n = 5, 12%) compared to those with health status follow-up (n = 34, 24%) whereas the proportions were similar for standard care.

Participants with no health status follow-up from standard care were more likely to have been readmitted during the study period (n = 16, 52%) than those with health status

ISSN 2044-4230

follow-up (n = 61, 32%) whereas the proportions were more similar for participants from the MMHU.

Completion of health status outcomes for the participants with follow-up

Due to cognitive impairment and the requirement for a carer informant to provide information for some of the health status assessments, 208 participants with follow-up had incomplete information for at least one health status assessment. Table 11 shows the completion of health assessments grouped according to the assessments completed on the participant and carer outcome questionnaires in the two groups.

Table 11. Completion of health assessments

	MMHU (n = 195)	Standard care (n = 188)
All assessments from POQ and COQ completed	85	90
No assessments from COQ, assessments on POQ completed	28	27
No MMSE or DEMQoL assessment from POQ, assessments on COQ completed	21	14
No DEMQoL assessment from POQ, assessments on COQ completed	33	29
No assessments from COQ, ADL & MMSE only completed on POQ (no DEMQoL)	7	16
Other pattern of incomplete assessments	21	12

ISSN 2044-4230

Note: POQ = participant outcome questionnaire, COQ = carer outcome questionnaire

POQ assessed MMSE, ADL, EQ-5D and patient DEMQoL.

COQ assessed Neuropsychiatric Inventory, carer proxy DEMQoL and London Handicap Scale.

These groups of participants (specified in table 11) differed at baseline and outcome: the observed baseline and outcomes scores for ADL and cognition were highest in the participants with only assessments from the COQ not completed, participants with no DEMQoL assessment and no MMSE or DEMQoL assessments were similar in that at recruitment their cognition, delirium and ADL scores were poorer than for the participants with all health status outcomes completed and care home placement during the study was more likely for these participants. The participants with only an

ADL and MMSE assessment at follow-up almost all lived in care homes at follow up and had the worse cognition and delirium rating scale scores at baseline of all the participants completing at least some health status follow-up.

The number of completed assessments for each health status outcome by allocated group is shown in table 12. The highest follow-up rates were achieved for Barthel ADL and the MMSE scores and the follow-up rate was higher for participants from standard care than MMHU for these assessments. Follow-up for the assessments from the COQ was between 60 and 65% and similar in the two groups.

ISSN 2044-4230

Table 12. Completion of health status outcomes

	MMHU (n = 241)	Standard care (n = 219)
Barthel ADL	187 (77.6%)	184 (84.0%)
MMSE	163 (67.6%)	167 (76.3%)
Participant DEMQoL[1]	123 (51.0%)	117 (53.4%)
Neuropsychiatric inventory	154 (63.9%)	142 (64.8%)
Carer proxy DEMQoL	150 (62.2%)	138 (63.0%)
London Handicap Scale	152 (63.1%)	140 (63.9%)

1 – Completed by 16 participants with MMSE score at follow-up of less than 10 where use of DEMQoL is not recommended & 2 participants where the MMSE was not completed at follow-up

Percentages calculated using the number of participants alive at follow-up in the each group as the denominator.

ISSN 2044-4230

Follow-up for Barthel ADL

Barthel activities of daily living information at follow-up was completed for 187 participants from the MMHU and 184 participants from standard care. The MMSE scores and DRS scores were slightly worse for participants from standard care compared to MMHU for this subset of participants (MMSE median 15, IQR 8 to 21 for MMHU and median 14, IQR 6 to 20 for standard care) and more participants lived alone and less in care homes from standard care compared to MMHU (40% and 52% lived alone from the MMHU and standard care respectively and 26% and 18% lived in care homes). The differences between the two groups in the medical diagnoses of hemiplegia and hip fracture persisted for the participants with ADL information at follow-up, although the numbers were small (23 participants in total with hemiplegia and 40 in total with hip fracture). Otherwise the characteristics in the two groups for these participants were similar.

Complete case analysis

Table 13 shows summary statistics for abilities in activities of daily living throughout the study for participants with an ADL assessment at follow-up in the two groups. The ADL scores at all timepoints were similar in the two groups and the ADL scores at follow-up were well spread across the range of possible values. The mean change in ADL at follow-up from recruitment was a 1.9 point improvement (SD 5.3) and the mean change in ADL at follow-up from prior to the acute illness was a 2.4 point decline (SD 5.0) and these were similar between groups. The ADL score at follow-up improved by 2 or more points from recruitment for 52% of participants and was within 2 points or more of the score prior to the acute illness for 57% of participants.

Table 16 shows that there is no evidence of a difference in the ADL scores at follow-up in the two groups for the participants completing the ADL assessment in any of the analyses conducted and very little change in the estimate of the intervention effect between these analyses.

ISSN 2044-4230

Table 13: Summary statistics for activities of daily living for participants completing the ADL assessment at follow-up

	MMHU (n = 241)	Standard care (n = 219)
Follow-up for Barthel ADL	187 (77.6%)	184 (84.0%)
Barthel ADL score prior to current illness		
Mean (SD)	13.8 (4.9)	14.2 (4.8)
Median (IQR)	15 (10 – 18)	15 (10.5 – 18)
Barthel ADL score at recruitment		
Mean (SD)	10.0 (5.1)	9.3 (5.3)
Median (IQR)	10 (7 – 14)	9 (5.5 – 13.5)
Barthel ADL score at follow-up		
Mean (SD)	11.6 (5.6)	11.6 (5.7)
Median (IQR)	12 (7 – 16)	13 (7 – 16)
Change in ADL from recruitment		
Mean (SD)	1.5 (4.9)	2.2 (5.7)
Median (IQR)	1 (-2 - 5)	2 (-1 - 6)
Range	-11 – 13	-17 - 18
Change in ADL from prior to acute illness		
Mean (SD)	-2.3 (4.8)	-2.6 (5.2)
Median (IQR)	-2 (-5 – 0)	-2 (-5 – 1)
Range	-16 - 11	-18 - 12

Change calculated as (ADL score at follow-up – ADL score prior to acute illness/at recruitment). Positive values indicate an improvement, negative values indicate a deterioration.

Simple imputation used to impute: 1 to 4 missing items (of 10) for 4 participants for ADL score prior to acute illness, 1 item for 5 participants at recruitment and 1 item for 3 participants at follow-up.

ISSN 2044-4230

Analysis using imputed data

The ADL scores at follow-up for the participants from the MMHU were slightly higher overall in the imputed data compared to the participants followed up for ADL. On standard care, the ADL scores in the imputed data were similar to the observed data for the participants followed up for ADL. The estimated difference in mean follow-up scores between the two groups were however small in the analyses using the multiply imputed data, with no evidence of a difference between the two groups (Table 16).

There was no change in interpretation if the unobserved outcomes were assumed to be 1 point higher or lower in one group compared to under a missing at random (MAR) assumption and unobserved outcomes were assumed to be MAR in the other group. This also held if unobserved outcomes were assumed to be one point higher in one group and one point lower in the other group than if unobserved outcomes were MAR.

Follow-up for MMSE

The Mini-Mental State Examination was completed by 163 participants from the MMHU and 167 participants from standard care at follow-up. There were 53 participants with some health status follow-up but no follow-up for MMSE (32 from the MMHU and 21 from standard care). These participants tended to have slightly lower MMSE scores at recruitment than the participants with MMSE information at follow-up in both groups and slightly higher delirium rating scale scores for participants from standard care. The activities of daily living scores prior to the acute illness and at recruitment were slightly lower than for those where MMSE scores were completed at follow-up and the ADL scores at follow-up were smaller with bigger deteriorations compared to prior to the acute illness for these participants in both groups compared to participants with MMSE information completed at follow-up.

The baseline characteristics for the participants completing the MMSE at follow-up were quite similar in the two groups, including delirium rating scale scores, apart from residence type at admission (more participants living alone and less in care homes from standard care) and the proportion of participants with diagnoses of the hip fracture and hemiplegia.

ISSN 2044-4230

Complete case analysis

Table 14 shows the summary statistics for the MMSE scores throughout the study in the two groups for the participants completing the MMSE at follow-up. The MMSE scores were slightly smaller on standard care for these participants at recruitment and similar in the two groups at follow-up (difference in median score 0, 95% confidence interval -4 to 2). The MMSE scores were well spread across the range of possible values at both timepoints, however there was also a large proportion of participants with a score of zero (13% at recruitment and 16% at follow-up).

The mean change in score from recruitment to follow-up was a 1.2 point improvement (SD 6.8) and 35% of participants had an improvement of 3 or more points from recruitment. A slightly greater proportion of participants had an improvement of 3 or more points from recruitment on standard care, however Table 16 shows that there is no evidence of a difference in the proportion of participants with such an improvement in the two groups for the participants completing the MMSE assessment in any of the analyses conducted. There was also no change in estimate of the intervention effect when the diagnosis variables with an imbalance between the two groups were included in the analysis (not reported in Table).

ISSN 2044-4230

Table 14: Summary statistics for MMSE scores for participants completing the MMSE assessment at follow-up

	MMHU (n = 241)	Standard care (n = 219)
Follow-up for MMSE	163 (67.6%)	167 (76.3%)
MMSE score at recruitment		
n	162	166
Mean (SD)	14.3 (8.1)	13.3 (8.5)
Median (IQR)	15 (9 – 21)	14 (7 – 20)
MMSE score at follow-up		
Mean (SD)	15.2 (8.5)	14.8 (9.5)
Median (IQR)	16 (9 – 22)	16 (8 – 23)
Change in MMSE from recruitment		
Mean (SD)	0.9 (6.3)	1.5 (7.4)
Median (IQR)	0 (-2 – 4)	1 (-1 – 5)
Range	-23 – 22	-22 - 26
Improvement of 3 or more points from recruitment	52 (31.9%)	63 (37.7%)

Change calculated as (MMSE score at follow-up – MMSE score at recruitment). Positive values indicate an improvement, negative values indicate a deterioration.

ISSN 2044-4230

Analysis using imputed data

The imputed MMSE scores for participants from the MMHU with no health status follow-up were higher overall than for participants with observed MMSE scores at follow-up and slightly lower for participants with some health status follow-up but no MMSE. On standard care, the imputed MMSE scores for participants with no health status follow-up were much more similar to those with observed MMSE scores and slightly lower for participants with some health status follow-up but no MMSE. A slightly higher proportion of participants were imputed to have an improvement in MMSE score of 3 or more on MMHU for participants with no health status follow-up, otherwise the proportion of participants with an improvement in MMSE score were similar in the imputed data to the observed data in the two groups. From the analysis using the imputed data, the odds ratios for an improvement in MMSE score of 3 or more were slightly smaller compared to the complete case analysis in all of the analyses conducted with no evidence of a difference between the groups (Table 16).

There was no change in interpretation of no evidence of a significant difference between the two groups in the proportion with an improvement in MMSE score of 3 or more if the unobserved outcomes were assumed to be 1 point higher or lower in one group than if outcomes were MAR and unobserved outcomes were MAR in the other group. This also held if unobserved outcomes were assumed to be one point lower than under MAR for MMHU and 1 point higher than under MAR for standard care.

Follow-up for NPI

Information on behavioural and psychological symptoms using the Neuropsychiatric Inventory was completed for 154 participants from the MMHU and 142 participants from standard care at follow-up. This information was given by the children of the participants for 55%, partners of the participants for 21%, other relatives for 13% and other non-relatives for 11% (mostly paid carers) and the proportions were similar in the two groups. Information at recruitment on the NPI was completed for 276 of these participants and was given by a different informant at recruitment and follow-up for 13 participants. There were 71 participants alive at the end of the study where information

on the NPI was not completed at baseline or follow-up (38 from the MMHU and 33 from standard care).

There were 87 participants with no follow-up information on the NPI with follow-up for other health status outcomes (41 from the MMHU and 46 from standard care), of these 39 had information on the NPI completed at baseline. These participants from the MMHU tended to have higher MMSE scores at recruitment and smaller DRS scores than for participants where NPI information was completed at follow-up and a greater proportion lived alone at recruitment and a smaller proportion moved from the community to care homes during the study. The MMSE and DRS scores were similar for these participants from standard care compared to those where the NPI was completed however a greater proportion of these participants lived in care homes at recruitment and a greater proportion moved to care homes from the community compared to those where the NPI was completed in this group.

The baseline characteristics for the participants with NPI information at follow-up were quite similar in the two groups, including baseline MMSE scores and delirium rating scale scores, apart from residence type at admission (more participants living alone and less in care homes from standard care) and the diagnosis of the hip fracture (MMHU 15%, standard care 6%), arthritis (MMHU 31%, standard care 41%) and eyesight problems (MMHU 23%, standard care 35%). Where information on the NPI was completed at recruitment, there was a difference in the proportion of participants with symptoms of hallucinations (MMHU 34%, standard care 44%) and agitation (MMHU 71%, standard care 61%).

Complete case analysis of the total NPI score

Table 15 shows the summary statistics for the total NPI scores throughout the study in the two groups for the participants where information on the NPI was completed at follow-up. The total NPI scores were right skewed at both recruitment and follow-up and were similar in the two groups at both of these timepoints (difference in median total NPI score at follow-up 1.5, 95% confidence interval -5 to 7.5). There was an overall mean improvement in the total NPI score of 7.7 points (SD 22.4) at follow-up compared to recruitment and this was similar in the two groups.

ISSN 2044-4230

For the analysis, the total NPI score was transformed (using log[total NPI score + 12]) as the assumptions for linear regression were not satisfied using the untransformed score. Table 16 shows that there was no evidence of a difference between the two groups in any of the analyses conducted for the total NPI score at follow-up for the participants where the NPI was completed at follow-up. There was also no change in the estimate for the intervention effect when the diagnosis variables with an imbalance between the two groups for these participants, noted above, were included in the analysis (not reported in Table).

Analysis of the total NPI score using imputed data

The total NPI scores at follow-up were lower than the observed NPI scores at follow-up in both groups in the imputed data for participants with no NPI information at baseline. The total NPI scores at follow-up were also lower for participants from the MMHU in the imputed data for participants with no health status follow-up otherwise the total NPI scores in the two groups were quite similar in the imputed data compared to the observed data. The estimates for the effect of the intervention using the imputed data are presented in Table 16 for the 369 participants alive at follow-up with NPI information completed at recruitment (192/241 from the MMHU and 177/219 from standard care). These are similar to the estimates from the complete case analysis with no evidence of a difference between the two groups. Estimates of the intervention effect from analyses with the imputed data also including participants alive at the end of the study with no NPI information at recruitment were very similar with increased standard errors.

There was no change in interpretation of there being no difference in the total NPI score at follow-up in the two groups if the unobserved outcomes were assumed to be more similar to observed than under MAR in one group (i.e higher) and unobserved outcomes were MAR in the other group. The magnitude of the intervention effect increased (however with no change in interpretation) if there was assumed to be little change in NPI outcomes compared to at recruitment for participants with no health status follow-up from the MMHU and unobserved outcomes were MAR for other participants with no NPI information at follow-up (from the MMHU with some health status follow-up and not NPI and from standard care).

ISSN 2044-4230

Table 15: Summary statistics for total Neuropsychiatric Inventory score for participants where this information was completed at follow-up

	MMHU (n = 241)	Standard care (n = 219)
Follow-up for NPI	154 (63.9%)	142 (64.8%)
Total NPI score at recruitment		
n	143	133
Mean (SD)	29.8 (24.5)	31.6 (25.9)
Median (IQR)	24 (13 – 40)	26 (13 – 39)
Range	0 – 132	0 – 144
Total NPI score at follow-up		
Mean (SD)	22.5 (20.6)	22.2 (21.5)
Median (IQR)	18.5 (8 – 31)	17 (7 – 34)
Range	0 – 108	0 - 144
Change in total NPI score from recruitment[1]		
n	143	133
Mean (SD)	-6.9 (21.2)	-8.6 (23.6)
Median (IQR)	-7 (-19 – 6)	-6 (-21 – 4)
Range	-65 - 58	-107 - 73
Transformed total NPI score at follow-up[2]		
Mean (SD)	3.39 (0.54)	3.37 (0.56)
Median (IQR)	3.42 (3.00 – 3.76)	3.37 (2.94 – 3.83)
Range	2.48 – 4.79	2.48 – 5.05

The neuropsychiatric inventory total score is calculated as the sum of the frequency x severity score for the 12 symptoms assessed. Range 0 to 144. Higher scores indicating greater presence of neuropsychiatric conditions. At baseline simple imputation was used for 23 participants to impute missing information for one or two symptoms to calculate the total score and for 14 participants at follow-up with missing information for one, two or three missing symptoms.

ISSN 2044-4230

1 - Change calculated as (total NPI score at follow-up – total NPI at baseline). Negative values indicate an improvement.

2 - Total NPI score at follow-up transformed using log(total NPI score + 12). Range 2.48 to 5.05.

Complete case analysis of the individual symptoms assessed

For the participants where information on the NPI was completed the proportion of participants with each of the behavioural symptoms assessed remained high at follow-up despite the proportions falling in both groups between recruitment and follow-up for all symptoms, apart from elation, disinhibition and irritability (Table 17).

Where NPI information was completed at follow-up, symptoms of elation were more likely from standard care compared to MMHU and there was some evidence that disinhibition and irritability were less likely from standard care compared to MMHU at follow-up in both the unadjusted analysis and the analysis adjusting for the symptom at recruitment. For the other symptoms assessed there was no evidence of a difference in the proportion of participants with the symptom at follow up in these analyses (Table 17).

ISSN 2044-4230

Table 16: Analysis of activities of daily living, MMSE score and NPI score, by group, using complete cases and multiply imputed data for participants surviving to the 90 day follow-up

			Adjusted intervention effect		
	MMHU (n = 241)	Standard care (n = 219)	Unadjusted intervention effect (95% CI)	With pre-specified prognostically important variables (95% CI)	Also including baseline variables with imbalance (95% CI)
Follow-up for Barthel ADL	187 (77.6%)	184 (84.0%)			
Barthel ADL score at follow-up[1]			*Complete case analysis (n = 371)*		
			p = 0.73	p = 0.91	p = 0.44
Mean (SD)	11.6 (5.6)	11.6 (5.7)	-0.16 (-1.10, 0.77)	-0.05 (-0.98, 0.88)	-0.36 (-1.30, 0.57)
			Using multiple imputation for missing outcomes (n = 460)		
			p = 0.62	p = 0.59	p = 0.78
			0.24 (-0.70, 1.18)	0.26 (-0.68, 1.20)	-0.14 (-1.10, 0.82)
Follow-up for MMSE	163 (67.6%)	167 (76.3%)			
Improvement of 3 or			*Complete case analysis (n = 330)*		

more points on MMSE			p = 0.27	p = 0.40	p = 0.43
from recruitment[2]	52 (31.9%)	63 (37.7%)	0.77 (0.49, 1.22)	0.82 (0.51, 1.31)	0.83 (0.52, 1.32)
			Using multiple imputation for missing outcomes (n = 460)		
			p = 0.38	p = 0.64	p = 0.57
			0.82 (0.53, 1.27)	0.90 (0.57, 1.41)	0.88 (0.56, 1.37)
Follow-up for NPI	154 (63.9%)	142 (64.8%)			
Transformed total NPI			*Complete case analysis (n = 296)*		
score at follow-up[3]			p = 0.75	p = 0.47	p = 0.46
Mean (SD)	3.39 (0.54)	3.37 (0.56)	0.02 (-0.09, 0.13)	0.04 (-0.07, 0.16)	0.04 (-0.07, 0.16)
			Using multiple imputation for missing outcomes (n = 369)[4]		
			p = 0.93	p = 0.67	p = 0.51
			0.01 (-0.12, 0.13)	0.03 (-0.10, 0.15)	0.04 (-0.08, 0.17)

1 – the estimate for the unadjusted intervention effect for Barthel ADL at follow-up shows the difference in mean follow-up scores on MMHU compared to standard care adjusting for ADL score prior to the current illness and ADL score at recruitment. The models for the adjusted intervention effect for both the complete case analysis and the analysis with the multiply imputed data also include age, sex and residence type at admission (community or care home) and in the analysis including baseline variables with an imbalance between the two groups type of residence in the community (alone or with someone), MMSE score at recruitment and diagnosis of hemiplegia or hip fracture were also included.

2 – the intervention effect for MMSE shows the odds ratio for improvement of 3 or more points on MMSE at follow-up compared to recruitment for MMHU compared to standard care. The estimate from the adjusted model shows this odds ratio adjusted for age, sex, residence type at admission (alone, with someone or in a care home) and MMSE score at baseline. The MMSE score is replaced with the DRS score at baseline in the analysis including baseline variables with an imbalance between the two groups.

3 – the estimate for the unadjusted intervention effect for transformed total NPI score at follow-up shows the difference in mean follow-up scores for MMHU compared to standard care adjusting for the NPI score at recruitment. The models for the adjusted effect also include age, sex and residence type at admission (alone, with someone or in a care home) and MMSE score at recruitment and in the analyses including baseline variables with an imbalance between the two groups also include symptoms of hallucinations and agitation at recruitment in the complete case analysis and diagnosis of hemiplegia in the analysis using the multiply imputed datasets. For the complete case analysis, simple imputation was used based on the median NPI score at recruitment according to residence type to include the 20 participants with follow-up NPI information with no NPI information at recruitment in the adjusted analysis. Estimates were also checked including only the 276 participants with NPI information at baseline and follow-up and there was no change in interpretation.

4 – Estimates given for 369 participants with NPI information completed at baseline, estimates very similar (with bigger standard errors) if all participants alive at the end of the follow-up period are included in the analyses with the multiply imputed data.

Table 17: Presence of individual symptoms assessed on the Neuropsychiatric inventory, by group

	MMHU (n = 241)	Standard care (n = 219)	Unadjusted intervention effect (95% CI)	Adjusted intervention effect (95% CI)
Follow-up for NPI	154 (63.9%)	142 (64.8%)		
NPI completion at recruitment	143	133		
Delusions[1]				
Recruitment	89 (62.2%)	79 (59.4%)	p = 0.33	p = 0.16
Follow-up	71 (46.1%)	74 (52.1%)	0.80 (0.50, 1.26)	0.70 (0.42, 1.16)
Hallucinations				
Recruitment	49 (34.3%)	59 (44.4%)	p = 0.23	p = 0.56
Follow-up	40 (26.0%)	46 (32.4%)	0.73 (0.44, 1.21)	0.84 (0.47, 1.50)
Agitation				
Recruitment	101 (70.6%)	81 (60.9%)	p = 0.16	p = 0.63

ISSN 2044-4230

	MMHU (n = 241)	Standard care (n = 219)	Unadjusted intervention effect (95% CI)	Adjusted intervention effect (95% CI)
Follow-up	95 (61.7%)	76 (53.5%)	1.40 (0.88, 2.22)	1.14 (0.67, 1.92)
Depression				
Recruitment	84 (58.7%)	81 (60.9%)	p = 0.77	p = 0.46
Follow-up	84 (54.6%)	75 (52.8%)	1.07 (0.68, 1.69)	1.21 (0.73, 2.01)
Anxiety				
Recruitment	89 (62.2%)	86 (64.7%)	p = 0.96	p = 0.72
Follow-up	85 (55.2%)	78 (54.9%)	1.01 (0.64, 1.60)	1.10 (0.66, 1.84)
Elation				
Recruitment	16 (11.2%)	20 (15.0%)	p = 0.04	p = 0.03
Follow-up	16 (10.4%)	27 (19.0%)	0.49 (0.25, 0.96)	0.43 (0.21, 0.90)
Apathy				
Recruitment	95 (66.4%)	94 (70.7%)	p = 0.91	p = 0.55
Follow-up	90 (58.4%)	85 (59.9%)	0.97 (0.61, 1.55)	1.17 (0.69, 1.99)

ISSN 2044-4230

	MMHU (n = 241)	Standard care (n = 219)	Unadjusted intervention effect (95% CI)	Adjusted intervention effect (95% CI)
Disinhibition				
Recruitment	42 (29.4%)	45 (33.8%)	p = 0.07	p = 0.06
Follow-up	57 (37.0%)	38 (26.8%)	1.59 (0.97, 2.61)	1.68 (0.99, 2.88)
Irritability				
Recruitment	88 (61.5%)	81 (60.9%)	p = 0.06	p = 0.06
Follow-up	96 (62.3%)	73 (51.4%)	1.56 (0.98, 2.49)	1.73 (0.98, 3.06)
Motor behaviour				
Recruitment	53 (37.1%)	52 (39.1%)	p = 0.97	p = 0.97
Follow-up	51 (33.1%)	47 (33.1%)	1.00 (0.62, 1.62)	0.99 (0.58, 1.69)
Difficulty sleeping				
Recruitment	76 (53.2%)	74 (55.6%)	p = 0.31	p = 0.18
Follow-up	68 (44.2%)	54 (38.0%)	1.27 (0.80, 2.03)	1.42 (0.85, 2.37)
Appetite problems				
Recruitment	73 (51.1%)	70 (52.6%)	p = 0.78	p = 0.78

ISSN 2044-4230

	MMHU (n = 241)	Standard care (n = 219)	Unadjusted intervention effect (95% CI)	Adjusted intervention effect (95% CI)
Follow-up	65 (42.2%)	63 (44.4%)	0.94 (0.59, 1.49)	0.93 (0.57, 1.52)

Presence of each symptom defined by NPI score on each domain (given by frequency x severity score) of more than 0.

1 - Percentages for the individual symptoms are given for the number of participants where this information was completed at each time point (e.g. 143 from MMHU and 133 from standard care at recruitment and 154 from MMHU and 142 from standard care at follow-up). Intervention effect shows the odds ratio for the symptom at follow-up on MMHU compared to standard care. The adjusted intervention effect shows this odds ratio after adjusting for the symptom being present at recruitment.

ISSN 2044-4230

Follow-up for participant DEMQoL

Of the 330 participants completing the MMSE at follow-up, 118 (72%) from the MMHU and 122 (73%) from standard care had a score of ten or more and the DEMQoL questionnaire was completed by 110 of these participants from the MMHU and 112 of these participants from standard care. The participants completing this information from standard care had worse scores overall on the variables measuring the severity of the confusion at recruitment:

- MMSE – MMHU median 18 IQR 14 to 23, standard care median 16 IQR 12.5 to 22
- DRS – MMHU median 13 IQR 8 to 21, standard care median 16 IQR 11 to 21.5

and a greater proportion of participants lived alone from standard care (45% MMHU, 56% standard care) and were widowed (51% MMHU, 60% standard care). There were also some imbalances between the groups in the proportion of these participants with a diagnosis of hemiplegia, cancer, hip fracture, arthritis and peripheral vascular disease.

Complete case analysis

The majority of the density for the DEMQoL scores was towards the higher end of the scale (indicating a better quality of life), there were very few scores at the bottom end of the scale (indicating a worse quality of life). Table 20 shows summary statistics for the participants completing the DEMQoL at follow-up. There was no evidence of a difference between the two groups in the DEMQoL scores for these participants in any of the analyses conducted. In the adjusted analyses, this was checked using both information from participants about depression and anxiety at recruitment (using the EQ-5D item, reported in Table 20) and from carer informants (using information from the NPI). There was also no evidence of a difference between the two groups in DEMQoL scores when the diagnosis variables with an imbalance between the two groups, noted above, were included in the analysis (not reported).

ISSN 2044-4230

Analysis using imputed data

The analysis in each imputed dataset was restricted to those participants with an observed or imputed MMSE score at follow-up of 10 or more. Across the 60 imputed datasets, this meant the number of participants included varied between 320 and 346 (70% - 75% of participants surviving to the end of the study), consistent with the observed proportion of participants with an MMSE score greater than 10 at follow-up. The imputed and observed participant DEMQoL scores were similar in the two groups and the estimates of the intervention effect were similar in the analyses using the imputed data to the analyses using the observed data with no evidence of a difference between the two groups (Table 16). There was no change in interpretation of no evidence of a difference in DEMQoL scores if the unobserved outcomes were assumed to be 4 points lower or higher than compared to if these outcomes were missing at random in one group and unobserved outcomes were missing at random in the other group and if unobserved outcomes were assumed to be 8 points higher on standard care than under MAR and MAR on MMHU. If the unobserved outcomes were 8 points higher on MMHU than under MAR and MAR on standard care, the intervention effect was 3.5 (95% CI 0 to 7). The intervention effect was similar to this if unobserved outcomes were 4 points higher on MMHU than under MAR and 4 points lower on standard care than under MAR. This shows that there would have to be a big difference between the DEMQoL scores between the observed and unobserved outcomes for there to be any indication of an intervention effect.

Follow-up for carer proxy DEMQoL

The carer proxy DEMQoL was completed for 150 participants from the MMHU and 138 participants from standard care by either one of the participant's sons or daughters (56%), the participant's partner (21%), another relative (13%) or a non-relative (10%, usually a paid carer) and these proportions were similar in the two groups. There were 95 participants with no follow-up for carer proxy DEMQoL with follow-up for other health status outcomes (45 on MMHU and 50 on standard care). The characteristics of these

participants compared to the participants where the carer proxy DEMQoL was completed within the two groups is as described for the completion of the Neuropsychiatric Inventory above.

The baseline characteristics of the participants where the carer proxy DEMQoL was completed in the two groups were similar, including cognitive impairment and delirium rating scale scores, apart from residence type at admission where more participants from standard care were living alone (MMHU 37%, standard care 51%) and less in care homes (MMHU 27%, standard care 14%) and the proportion of these participants with a diagnosis of dementia, hip fracture, arthritis and eyesight problems. There was also a difference in the proportion of participants with symptoms of hallucinations (MMHU 35%, standard care 45%) and agitation (MMHU 71%, standard care 61%) in the two groups for the 270 of these 288 participants with information completed on the Neuropsychiatric Inventory at recruitment.

Complete case analysis

The density for the carer proxy DEMQoL, as for the participant DEMQoL scores, was located more towards scores at the top end of the scale (indicating a better quality of life) . Table 20 shows summary statistics for the participants where the carer proxy DEMQoL was completed at follow-up. The scores were similar in the two groups and there was no evidence of a difference between the groups in any of the analyses conducted for these participants. This also held when the diagnosis variables, noted above, with an imbalance between the two groups for these participants were included in the analysis.

Analysis using imputed data

The imputed and observed carer proxy DEMQoL scores were similar in the two groups. The estimates of the intervention effect from the analyses using the imputed data were very small, giving no evidence of a difference between the carer proxy DEMQoL scores in the two groups (Table 20).

There was no change in interpretation of no evidence of an intervention effect if the unobserved outcomes were 4 points higher or lower than under MAR in one group and

ISSN 2044-4230

MAR in the other group or if unobserved outcomes were 8 points lower than if outcomes were MAR on standard care and MAR for MMHU. If unobserved outcomes were 8 points higher on standard care than under MAR and MAR for MMHU, the intervention effect was -3.1 (95% CI -7.5 to 1.2). The intervention effect was similar to this if the unobserved outcomes were 4 points higher on standard care than under MAR and 4 points lower on MMHU than under MAR. This shows that there would have to be a big difference in the proxy DEMQoL scores between the observed and unobserved outcomes before there was any indication of an intervention effect.

Follow-up for LHS

The London Handicap Scale was completed for 152 participants from the MMHU and 140 participants from standard care. The relationship of the person completing the scale and the participant is as described for the carer proxy DEMQoL. There were 91 participants with no follow-up for the London Handicap Scale with follow-up for other health status outcomes (43 from the MMHU and 48 from standard care). The characteristics of these participants compared to the participants where the London Handicap Scale was completed within the two groups is as described for the completion of the Neuropsychiatric Inventory above.

The comparability of the baseline characteristics in the two groups where the London Handicap Scale was completed was the same as above for where the carer proxy DEMQoL was completed. In particular, there was some imbalance between the two groups for these participants in residence type at admission where more participants from standard care were living alone (MMHU 38%, standard care 50%) and less in care homes (MMHU 27%, standard care 15%) as well as the proportion of participants with a diagnosis of dementia, hemiplegia, hip fracture, arthritis and eyesight problems and symptoms of hallucinations and agitation where the Neuropsychiatric Inventory was completed at baseline.

Complete case analysis

The London Handicap Scale scores were well spread across the range of possible values with a slight right skew. Table 20 shows summary statistics for the participants where the London Handicap Scale was completed at follow-up. The scores were similar in the

ISSN 2044-4230

two groups and there was no evidence of a difference between the groups in any of the analyses conducted for these participants. This also held when the diagnosis variables with an imbalance between the two groups for these participants, noted above, were included in the analysis (not reported) even though there was evidence of lower LHS scores from these models for participants with hemiplegia and eyesight problems and higher scores for participants with arthritis.

Analysis using imputed data

The LHS scores at follow-up for the participants on MMHU were slightly higher overall in the imputed data compared to the participants followed up for LHS for both participants with no health status follow-up and participants with some health status follow-up and not LHS. For standard care, the imputed LHS scores were similar to the observed LHS scores. The estimates of the intervention effect using the imputed data were however small with no evidence of a difference between the two groups (Table 20).

There was no change in interpretation of no evidence of a difference between groups in London Handicap scores if the unobserved outcomes were assumed to be 8 points higher or lower in one group compared to under MAR and MAR in the other group. If the unobserved outcomes were 8 points higher on MMHU than under MAR and 8 points lower on standard care than under MAR, the estimate of the intervention effect would be 6.1 (95% CI 1.2, 11.0). This shows unobserved outcomes would have to be quite different to the observed outcomes in the two groups before the estimates of the intervention effect would indicate a difference equivalent to one point on the scale.

Follow-up for EQ-5D

EQ-5D information was completed on the patient outcome questionnaire and could be completed by the participant and/or a proxy informant. Table 18 shows the number of participants with responses from these two sources in the two groups and whether the corresponding baseline EQ-5D information was completed. The proportion of participants with a participant response to the EQ-5D was similar in the two groups but a greater proportion of participants from standard care had a proxy response to the EQ-5D at follow-up.

ISSN 2044-4230

Table 18. Completion of EQ-5D

Response from:	MMHU (n = 241)	Standard care (n = 219)
Participant	128 (53.1%)	123 (56.2%)
Baseline participant response	109	101
Proxy	129 (53.5%)	134 (61.2%)
Baseline proxy response	85	106

There were 67 participants from the MMHU and 65 participants from standard care with some health status follow-up but not participant EQ-5D. In both groups these participants had smaller MMSE scores at recruitment and follow-up, smaller ADL scores throughout the study, greater delirium rating scale scores at recruitment and were more likely to be living in care homes or move to a care home during the study compared to the participants where the participant EQ-5D was completed. The two groups where participant EQ-5D information was completed at follow-up were similar with respect to MMSE scores and DRS scores at recruitment, however a greater proportion of participants from the MMHU were living in care homes at admission (21% v 13%) and a smaller proportion were living alone (45% v 56%). There were also some imbalances between the groups, as observed for the other outcomes, for the proportions with diagnoses of congestive heart failure, hemiplegia, hip fracture, arthritis, eyesight problems and peripheral vascular disease.

There were 66 participants from the MMHU and 54 participants from standard care with some health status follow-up but no proxy response to the EQ-5D. In both groups these participants had greater MMSE scores at recruitment and follow-up, greater ADL scores throughout the study, smaller delirium rating scale scores at recruitment, were less likely to have had an inpatient stay in the year prior to the study and were more likely to be living alone at recruitment and less likely to move to a care home during the study

compared to participants where there was a proxy response to the EQ-5D. The two groups where there was a proxy response to the EQ-5D at follow-up were similar with respect to most of the characteristics assessed at recruitment, there were however some imbalances on:

- MMSE scores at recruitment, with slightly smaller scores for standard care: MMHU median 12.5 (IQR 6 to 19) and standard care median 12 (IQR 2 to 16) and
- Residence at recruitment: greater proportion of participant living in care homes from the MMHU (29% v 19%) and a smaller proportion living alone (48% v 36%) compared to standard care.

Complete case analysis

The participant EQ-5D scores were left skewed in both groups with more density towards higher scores whereas the proxy scores were less skewed and centred around much smaller values than the participant scores in both groups (Table 19). For the 151 participants with a completed response to the EQ-5D from both the participant and a proxy informant, there was a positive association between the responses (Spearman's correlation coefficient 0.46) with higher scores given by the participants (mean 0.2 points higher, SD 0.3, median 0.1, IQR 0 to 0.5) (correlation coefficient and differences between participant and proxy responses similar to as observed at recruitment).

For the participants completing the EQ-5D at follow-up, the EQ-5D scores were slightly greater for the MMHU at recruitment and similar in the two groups at follow-up (Table 19). The proportion of participants with an EQ-5D score greater than the overall observed median was similar in the two groups (Table 20) and there was no evidence of a difference between the two groups in this proportion in any of the analyses. This also held when participants with an MMSE score of less than 10 were not included in the analysis for consistency with the analysis of the participant DEMQoL scores. There was also no evidence of a difference in the mean participant score in the two groups (Table 20), although the assumption for normally distributed residuals was not satisfied in this analysis.

ISSN 2044-4230

For the participants with a proxy response to the EQ-5D at follow-up, the scores were similar in the two groups at recruitment and slightly higher for standard care compared to MMHU at follow-up (Table 19). This difference was not statistically significant in any of the analyses conducted (Table 20), however the lower bound of the confidence interval, although positive, was close to 0 consistent with there being some evidence of slightly greater scores on standard care. The change in scores were very similar in each group for the participant and the proxy responses with very small improvements at follow-up on average.

ISSN 2044-4230

Table 19: Summary statistics for EQ-5D quality of life scores from participant and proxy respondents at follow-up

	Participant responses		Proxy responses	
	MMHU (n = 241)	Standard care (n = 219)	MMHU (n = 241)	Standard care (n = 219)
Follow-up for EQ-5D	128 (53.1%)	123 (56.2%)	129 (53.5%)	134 (61.2%)
EQ-5D score at recruitment				
n	109	101	85	106
Mean (SD)	0.55 (0.38)	0.50 (0.36)	0.26 (0.28)	0.24 (0.32)
Median	0.71	0.59	0.20	0.20
IQR	0.27 – 0.85	0.21 – 0.80	0.04 – 0.38	0.03 – 0.38
EQ-5D score at follow-up				
Mean (SD)	0.59 (0.31)	0.57 (0.31)	0.26 (0.31)	0.31 (0.33)
Median	0.64	0.62	0.20	0.27
IQR	0.30 – 0.81	0.31 – 0.81	0.08 – 0.52	0.08 – 0.59
Change in EQ-5D from recruitment				
n	109	101	85	106
Mean (SD)	0.03 (0.43)	0.08 (0.38)	-0.03 (0.34)	0.04 (0.41)
Median	0	0.06	0	0.06
IQR	-0.23 – 0.26	-0.16 – 0.31	-0.25 – 0.17	-0.19 – 0.33
Range	-1.07 – 1.06	-0.76 – 0.81	-0.89 – 0.80	-1.28 – 0.91

Change calculated as (EQ-5D score at follow-up – EQ-5D score at recruitment). Positive values indicate an improvement, negative values indicate a deterioration.

ISSN 2044-4230

Analysis using multiply imputed data

The imputed participant responses to the EQ-5D were very similar to the observed participant responses to the EQ-5D in each group. The odds ratio for the intervention effect for a EQ-5D score greater than the overall median from the analysis using the imputed datasets remained close to 1 and similar to the estimates from the complete case analysis with no evidence of a difference between the groups. Similarly, the estimate for the difference in mean participant EQ-5D score was 0 using the multiply imputed data with no evidence of a difference between the groups (although again the normality assumption for the residuals was not satisfied in this analysis).

There was no change in the interpretation of no evidence of a difference in the proportion of participants with an EQ-5D score greater than the median value if the unobserved EQ-5D scores were 0.04 or 0.08 points higher in one group than under MAR and MAR in the other group and if EQ-5D scores were 0.08 points higher on the MMHU than under MAR and 0.04 points lower on standard care than under MAR.

The imputed proxy responses to the EQ-5D were greater than the observed responses in each group. The estimates of the intervention effect were very similar to those observed in the complete case analysis with slightly smaller p-values giving some evidence of higher scores at follow-up on standard care: in the analysis adjusting for prognostically important covariates and baseline imbalances between the two groups this became borderline significant at the 5% level ($p = 0.06$). The estimate of the intervention effect varied between -0.04 and -0.11 when the unobserved scores were assumed to be more similar to the observed proxy EQ-5D scores in one group and MAR in the other group. The lower bounds of the confidence intervals for the intervention effect varied under these different assumptions between -0.03 and 0.03 so in all of these analyses the support remained for greater proxy EQ-5D scores on standard care, however the relevance of such a difference for participants given the low scores on average given by all proxy respondents is much harder to interpret.

ISSN 2044-4230

Table 20: Quality of life outcomes at follow-up, by group

				Adjusted intervention effect	
	MMHU (n = 241)	Standard care (n = 219)	Unadjusted intervention effect (95% CI)	With pre-specified prognostically important variables(95% CI)	Also including baseline variables with imbalance (95% CI)
Participant DEMQoL[1]					
MMSE ≥ 10 where assessed at follow-up	118/163	122/167			
DEMQoL completed where MMSE ≥ 10 at follow-up	110	112			
			Complete case analysis (n = 222)		
			p = 0.92	p = 0.91	p = 0.90
Mean (SD)	83.5 (11.9)	83.3 (13.4)	0.2 (-3.2, 3.5)	0.2 (-3.1, 3.5)	0.2 (-3.1, 3.5)
Median (IQR)	84 (76 – 93)	84 (75.5 – 94)			
Range	56 – 107	42 - 105	*Using multiple imputation for missing outcomes (n 320 – 346)*		
			p = 0.71	p = 0.67	p = 0.70
			0.7 (-2.8, 4.1)	0.7 (-2.7, 4.1)	0.7 (-2.8, 4.1)
Carer proxy DEMQoL[2]					
Completed	150 (62.2%)	138 (63.0%)	*Complete case analysis (n = 288)*		

ISSN 2044-4230

			Adjusted intervention effect		
	MMHU (n = 241)	Standard care (n = 219)	Unadjusted intervention effect (95% CI)	With pre-specified prognostically important variables(95% CI)	Also including baseline variables with imbalance (95% CI)
			p = 0.65	p = 0.53	p = 0.40
Mean (SD)	91.0 (16.0)	91.9 (15.0)	-0.8 (-4.4, 2.8)	-1.1 (-4.7, 2.5)	-1.5 (-5.2, 2.1)
Median (IQR)	93 (81 – 104)	93 (83 – 103)			
Range	35 – 118	47 - 119	*Using multiple imputation for missing outcomes (n = 460)*		
			p = 1.00	p = 0.99	p = 0.84
			0.0 (-4.2, 4.2)	0.0 (-4.2, 4.1)	-0.4 (-4.6, 3.8)
London Handicap Scale[3]					
Completed	152 (63.1%)	140 (63.9%)	*Complete case analysis (n = 292)*		
			p = 0.31	p = 0.19	p = 0.33
Mean (SD)	39.1 (19.5)	41.4 (19.1)	-2.3 (-6.8, 2.2)	-2.7 (-6.9, 1.4)	-2.0 (-6.2, 2.2)
Median (IQR)	33.3 (25 – 50)	41.7 (25 – 50)			
Range	0 – 100	0 - 100	*Using multiple imputation for missing outcomes (n = 460)*		
			p = 0.56	p = 0.76	p = 0.87
			1.7 (-4.1, 7.5)	0.9 (-4.8, 6.6)	0.5 (-5.2, 6.2)

	MMHU (n = 241)	Standard care (n = 219)	Unadjusted intervention effect (95% CI)	Adjusted intervention effect: With pre-specified prognostically important variables(95% CI)	Adjusted intervention effect: Also including baseline variables with imbalance (95% CI)
EQ-5D scores[4]					
Completed by participant	128 (53.1%)	123 (56.2%)			
Median participant score	0.64	0.62			
(IQR)	(0.30 – 0.81)	(0.31 – 0.81)	*Complete case analysis (n = 251) – odds ratio.*		
Participant score > overall			p = 0.95	p = 0.97	p = 0.83
Median	65 (50.8%)	60 (48.8%)	0.98 (0.59, 1.65)	0.99 (0.59, 1.67)	0.94 (0.55, 1.61)
			Using multiple imputation for missing outcomes (n = 460)		
			p = 0.81	p = 0.80	p = 0.86
			0.94 (0.57, 1.57)	0.93 (0.56, 1.57)	0.95 (0.54, 1.67)
			Complete case analysis (n = 251)		
			p = 0.70	p = 0.67	p = 0.79
Mean participant score	0.59 (0.31)	0.57 (0.31)	0.01 (-0.06, 0.09)	0.02 (-0.06, 0.09)	0.01 (-0.07, 0.09)
			Using multiple imputation for missing outcomes (n = 460)		
			p = 0.98	p = 0.98	p = 0.96

ISSN 2044-4230

	MMHU (n = 241)	Standard care (n = 219)	Adjusted intervention effect: Unadjusted intervention effect (95% CI)	Adjusted intervention effect: With pre-specified prognostically important variables (95% CI)	Adjusted intervention effect: Also including baseline variables with imbalance (95% CI)
			0.00 (-0.08, 0.08)	0.00 (-0.08, 0.09)	0.00 (-0.09, 0.09)
Completed by proxy	129 (53.5%)	134 (61.2%)	*Complete case analysis (n = 263)*		
			p = 0.15	p = 0.18	p = 0.13
Mean proxy score (SD)	0.26 (0.31)	0.31 (0.33)	-0.06 (-0.13, 0.02)	-0.05 (-0.13,0.02)	-0.06 (-0.14, 0.02)
			Using multiple imputation for missing outcomes (n = 460)		
			p = 0.13	p = 0.11	p = 0.06
			-0.06 (-0.14, 0.02)	-0.06 (-0.14,0.01)	-0.07 (-0.15, 0.00)

Intervention effect shows the difference in mean quality of life scores for MMHU compared to standard care for participant and carer proxy DEMQoL, London Handicap Scores and the proxy completed EQ-5D score and the odds ratio for an EQ-5D score at follow-up greater than the overall median score for MMHU compared to standard care for the participant completed EQ-5D.

1 - Participant DEMQoL scores range between 27 and 108 with higher scores indicating a better quality of life. Note question on having enough money was asked instead of having enough company and so is not included in the total score. Participant specific mean of the completed items for 22 participants used to impute between 1 and 5 missing items (15 participants with 1 item not completed, 27 items in scale). Adjusted intervention effect adjusted for participant age, gender, residence type at admission (alone, with someone, in a care home) and participant response to EQ-5D question on anxiety/depression at baseline. The proxy response to the anxiety/depression question on the EQ-5d was used for 23 participants where the participant response was not completed at baseline for the complete case analysis and for between 11% and 16% of participants in the analysis using the imputed datasets. The delirium rating scale score at recruitment was also added to the model for the adjusted analyses including variables with an imbalance at baseline between the two groups.

2 - Carer proxy DEMQoL scores range between 31 and 124 with higher scores indicating a better quality of life. Participant specific mean of the completed items used to impute between 1 and 6 missing items for 14 participants (10 participants with 1 item not completed, 31 items in scale).

3 - London Handicap Scale scores range between 0 and 100 with higher scores indicating a smaller impact of health problems on everyday life, scores increase in steps of 8.3. The participant specific mean of the completed items was used to impute 1 missing item for 7 participants.

4 – EQ-5D scores range between –0.59 and 1, with higher scores indicating a better quality of life. The overall median EQ-5D score from the participant responses was 0.623 for the complete cases, in the analysis using the multiply imputed data, the overall median was calculated in each of the imputed datasets. Unadjusted analyses show the intervention effect adjusted for the participant/proxy score, as appropriate, at recruitment. Adjusted analysis for the participant EQ-5D include age, sex and residence type at admission and for analyses also with baseline variables with an imbalance between the two groups also include diagnosis of congestive heart failure, arthritis and eyesight problems for the complete cases and MMSE score at recruitment and diagnosis of hemiplegia, hip fracture, arthritis and eyesight problems for the analysis using the multiply imputed data. Adjusted analyses for the proxy EQ-5D score adjusted for age, gender, residence type at admission, cognitive impairment at recruitment, ADL scores prior to the acute illness and NPI scores at recruitment and for analyses with baseline variables with an imbalance between the two groups, models also include diagnosis of hemiplegia, hip fracture, arthritis and eyesight problems. Simple imputation based on residence type at recruitment was used to impute missing participant/proxy responses to the EQ-5D score at recruitment to be able to include these participants in the adjusted analyses (41 for complete cases and 118 for analysis using multiply imputed data for participant scores and 72 for complete cases and 169 for analysis using multiply imputed data for the proxy scores).

For the carer proxy DEMQoL & the London Handicap Scale, the adjusted intervention effect is adjusted for participant age, gender, residence type at admission, cognitive impairment at recruitment, ADL scores prior to the acute illness and NPI scores at recruitment. Symptoms of hallucinations and agitation were also added to the models for the complete cases for analysis including baseline variables with an imbalance between the two groups. For the analysis including baseline variables with an imbalance between the two groups using the imputed data, diagnoses of hemiplegia, arthritis and eyesight problems were added to the model for the London Handicap Score and the delirium rating scale score at recruitment for carer proxy DEMQoL. Simple imputation using the median score according to residence at recruitment was used to include 18 participants with no NPI information at baseline in the analysis of carer proxy DEMQoL and 17 participants in the analysis of London Handicap Scale for the complete case analysis. This was also done for the analysis using the imputed data for 91 participants in total (20%) with no NPI information at baseline for both outcomes. Estimates of the intervention effect were also checked including only participants with information on the NPI completed at baseline and there was no change in interpretation in either the complete case analysis or the analysis using the multiply imputed data.

ISSN 2044-4230

Carer satisfaction

Information on the carer satisfaction questionnaire was completed 1 to 3 weeks after discharge for 462 participants in total (77%), 234 participants from the MMHU (75.5%) and 228 participants from standard care (78.6%). In both groups, these participants were more likely to:

- be married or widowed rather than divorced or never married (carer satisfaction completed for 80% of participants divorced or married compared to 56% divorced or never married),
- not have mental capacity at recruitment (carer satisfaction completed for 80% with no mental capacity at recruitment and 67% with mental capacity) and
- have information on the NPI completed at baseline (carer satisfaction completed for 89% of participants with NPI information at baseline and 27% of those with no NPI information).

Participants with carer satisfaction information completed were also:

- slightly older (median 85, IQR 81 to 89 years compared to median 83, IQR 77 to 88 years where not completed),
- more dependent in ADL prior to the acute illness (median 14, IQR 9 to 18 compared to median 16, IQR 11 to 18 where not completed) and at study recruitment (median 8, IQR 5 to 12 compared to median 10, IQR 5 to 15 where not completed) and
- had slightly more symptoms of delirium at recruitment (median delirium rating scale score 20, IQR 13 to 27.5 compared to 18, IQR 11 to 25 where not completed).

The differences between the two groups noted from Table 3 for all participants in living arrangements, MMSE scores and delirium rating scale scores at recruitment persisted for the subset of participants with carer satisfaction information. For the 462 participants with carer satisfaction information, the initial length of stay was similar in the two groups (median 12 days, IQR 5 to 22 days) and 29% spent no days at home after the initial admission including 38 participants who died during the initial admission (20 from the MMHU and 18 from standard care).

ISSN 2044-4230

Table 21 below shows the responses to the carer satisfaction questionnaire in the two groups. Overall the proportion of carers responding as mostly satisfied or very satisfied were high: more than 75% of respondents gave these answers for 6 of the 9 questions. There was however some evidence of differences between the responses given in the two groups for the questions on overall care, feeding and nutrition, meeting the needs for patients with confusion, discharge arrangements and feeling adequately prepared for discharge with a smaller proportion of carers responding as being mostly unsatisfied or very unsatisfied for these questions from the MMHU compared to standard care. A slightly greater proportion of carers responded as feeling adequately prepared for discharge from the MMHU compared to standard care.

Table 21: Carer satisfaction information, by group

	MMHU (n = 234)	Standard care (n = 228)	p-value
Satisfaction with overall care			0.004
Very satisfied	113 (48.3%)	86 (37.7%)	
Mostly satisfied	101 (43.2%)	103 (45.2%)	
Mostly unsatisfied	9 (3.9%)	17 (7.5%)	
Very unsatisfied	11 (4.7%)	22 (9.7%)	
Satisfaction with admission arrangements			0.73
Very satisfied	80 (34.2%)	76 (33.3%)	
Mostly satisfied	104 (44.4%)	100 (43.9%)	
Mostly unsatisfied	24 (10.3%)	23 (10.1%)	
Very unsatisfied	14 (6.0%)	17 (7.5%)	
Not answered	12 (5.1%)	12 (5.3%)	
Satisfaction with car parking arrangements			0.43
Very satisfied	14 (6.0%)	14 (6.1%)	
Mostly satisfied	48 (20.5%)	49 (21.5%)	

ISSN 2044-4230

	MMHU (n = 234)	Standard care (n = 228)	p-value
Mostly unsatisfied	28 (12.0%)	32 (14.0%)	
Very unsatisfied	47 (20.0%)	59 (25.9%)	
Not applicable	96 (41.0%)	73 (32.0%)	
Not answered	1 (0.4%)	1 (0.4%)	
Satisfaction with help given feeding/ensuring nutrition adequate			0.02
Very satisfied	81 (34.6%)	64 (28.1%)	
Mostly satisfied	116 (49.6%)	105 (46.1%)	
Mostly unsatisfied	19 (8.1%)	24 (10.5%)	
Very unsatisfied	13 (5.6%)	27 (11.8%)	
Not answered	5 (2.1%)	8 (3.5%)	
Satisfaction with management of medical issues			0.11
Very satisfied	87 (37.2%)	76 (33.3%)	
Mostly satisfied	99 (42.3%)	87 (38.2%)	
Mostly unsatisfied	30 (12.8%)	35 (15.4%)	
Very unsatisfied	18 (7.7%)	29 (12.7%)	
Not answered	0	1 (0.4%)	
Satisfaction with how well kept informed			0.23
Very satisfied	76 (32.5%)	66 (29.0%)	
Mostly satisfied	80 (34.2%)	79 (34.7%)	
Mostly unsatisfied	50 (21.4%)	44 (19.3%)	
Very unsatisfied	26 (11.1%)	38 (16.7%)	
Not answered	2 (0.9%)	1 (0.4%)	
Satisfaction that participant treated with dignity and			0.05

ISSN 2044-4230

	MMHU (n = 234)	Standard care (n = 228)	p-value
respect			
Very satisfied	136 (58.1%)	117 (51.3%)	
Mostly satisfied	83 (35.5%)	80 (35.1%)	
Mostly unsatisfied	7 (3.0%)	12 (5.3%)	
Very unsatisfied	7 (3.0%)	18 (7.9%)	
Not answered	1 (0.4%)	1 (0.4%)	
Satisfaction that ward met needs of patients with confusion			< 0.001
Very satisfied	97 (41.5%)	64 (28.1%)	
Mostly satisfied	98 (41.9%)	97 (42.5%)	
Mostly unsatisfied	25 (10.7%)	35 (15.4%)	
Very unsatisfied	11 (4.7%)	30 (13.2%)	
Not answered	3 (1.3%)	2 (0.9%)	
Satisfaction with discharge arrangements			0.005
Very satisfied	78 (33.3%)	62 (27.2%)	
Mostly satisfied	86 (36.8%)	66 (29.0%)	
Mostly unsatisfied	20 (8.6%)	38 (16.7%)	
Very unsatisfied	25 (10.7%)	39 (17.1%)	
Not answered	25 (10.7%)	23 (10.0%)	
Carer felt adequately prepared for discharge			0.04
No	43 (18.4%)	60 (26.3%)	

ISSN 2044-4230

	MMHU (n = 234)	Standard care (n = 228)	p-value
Yes	164 (70.1%)	141 (61.8%)	
Not answered	27 (11.5%)	27 (11.8%)	
Carer opinion on timing of discharge			0.42
Too soon	35 (15.0%)	45 (19.7%)	
About right	151 (64.5%)	139 (61.0%)	
Delayed	22 (9.4%)	22 (9.7%)	
Not answered	26 (11.1%)	22 (9.7%)	

P-values for satisfaction questions calculated using Mann-Whitney tests for carers with a response to the question (not including not applicable for car parking) and chi-squared tests for the questions on timing and preparations for discharge.

ISSN 2044-4230

Funding acknowledgment and disclaimer

This paper presents independent research funded by the National Institute for Health Research (NIHR) under its Programme Grants for Applied Research funding scheme (RP-PG-0407-10147). The views expressed in this paper are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

ISSN 2044-4230

References

1 Harwood RH, Goldberg SE, Whittamore KH, Russell C, Gladman JRF, Jones RG, Porock D, Lewis SA, Bradshaw LE, Elliott RA and Medical Crises in Older People Study Group (mcop). Evaluation of a Medical and Mental Health Unit compared with standard care for older people whose emergency admission to an acute general hospital is complicated by concurrent 'confusion': a controlled clinical trial. Trials 2011, 12:123doi:10.1186/1745-6215-12-123.

2 Goldberg SE, Bradshaw SE, Kearney F, Russell C, Whittamore K, Foster PER, Mamza J, Gladman JRF, Jones RG, Lewis SA, Porock, D, Harwood RH on behalf of the Medical Crises in Older People study group. Care in specialist medical and mental health unit compared with standard care for older people with cognitive impairment admitted to general hospital: randomised controlled trial (NIHR TEAM trial). BMJ 2013;347:f4132 doi: 10.1136/bmj.f4132.