


## CLINICAL TRIAL

# Improving the safety and experience of transitions from hospital to home: a cluster randomised controlled trial of an intervention to involve older people in their care (Your Care Needs You)

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## Abstract

**Background:** Transitions from hospital to home are risky for older people. The role of patient involvement in supporting safe transitions is unclear.

**Objective:** To assess the clinical effectiveness of an intervention to improve the safety and experience of care transitions for older people.

**Trial design:** Cluster randomised controlled trial.

**Participants:** Eleven National Health Service acute hospital trusts and 42 wards (clusters) routinely providing care for older people (aged 75 years and older) planning to transition back home.

**Intervention:** Patient involvement ward-level intervention—Your Care Needs You (YCNy).

**Outcomes** Unplanned hospital readmission rates within 30 days of discharge (primary outcome). Secondary outcomes included readmissions at 60 and 90 days post-discharge, experience of transitions and safety events.

**Randomisation:** Ward as the unit of randomisation from varying medical specialities randomised to YCNy or care-as-usual on a 1:1 basis.

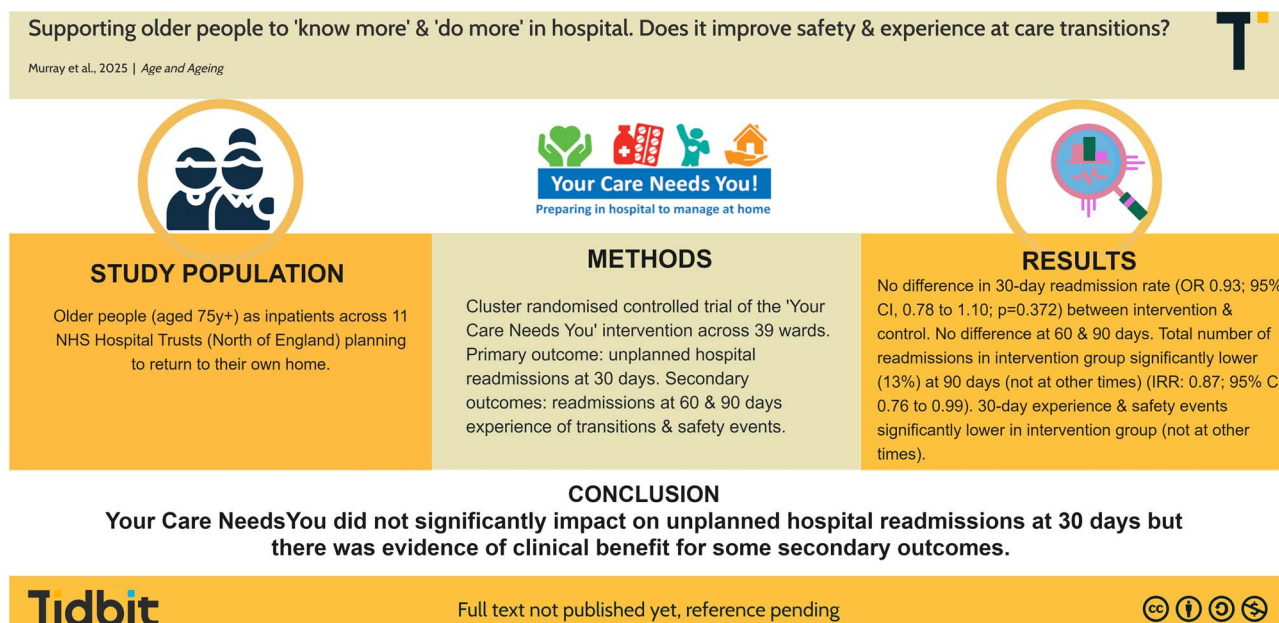
**Blinding:** Ward staff, research nurses and researchers were unblinded. Patients were unaware of treatment allocation. Statisticians were blinded to the primary outcome data until statistical analysis plan sign-off.

**Results:** Using a mixed effects logistic regression we saw no significant difference in unplanned 30-day readmission rates (OR 0.93; 95% CI, 0.78 to 1.10;  $P = .372$ ) between intervention (17%) and control (19%). At all timepoints, rates were lower in the intervention group. The total number of readmissions was lower in the intervention group (all timepoints) reaching

statistical significance across 90-days with 13% fewer readmissions (IRR: 0.87; 95% CI 0.76 to 0.99) than the control. At 30-days only, intervention group patients reported better experiences of transitions and significantly fewer safety events. Serious adverse events were similarly observed in both groups [YCN: 26 (52.0%), Care-as-usual: 24 (48.0%)]. None related to treatment.

**Conclusions:** YCN did not significantly impact on unplanned hospital readmissions at 30 days but in some secondary outcomes we did find evidence of clinical benefit.

## Graphical Abstract



Keywords: transitions; involvement; safety; older people

## Key Points

- Patient education or self-management within care transitions interventions is thought (but not proven) to contribute to positive patient outcomes.
- The Your Care Needs You is an evidence based co-designed intervention that facilitates patient involvement during their hospital stay to prepare them for managing at home.
- The cluster randomised controlled trial did not demonstrate a significant impact on the primary outcome of unplanned hospital readmission rates at 30 days post-discharge.
- The trial did demonstrate significantly fewer unplanned hospital readmissions 3 months after discharge and significantly fewer adverse events at 30 days post-discharge.

## Introduction

For older people and those with complex needs, the transitional period of moving from hospital to home poses many risks [1, 2]. Up to one in five patients experience an adverse event during this time; an estimated 62% of which could be prevented or ameliorated [3]. Over the last decade, unplanned readmission rates have been increasing with around 30% of all readmissions estimated to be avoidable [4–6]. In the UK, routinely recorded readmission data for 2022–23, shows that older people had the highest rates of

readmissions (average of 17.7%) [7]. This compares with the rate of emergency readmissions of 13.3% for those within the 16–74 age range. Thus, older people have the greatest need for support in improving transitions of care and reducing emergency readmissions [7].

A meta-analysis of 92 randomised controlled trials (RCTs) found that interventions to improve transitional care for older people with chronic illness reduced hospital readmissions at 3 and 12 months [8]. Included interventions were often costly and highly complex, comprising many of the Ideal Care Transitions model [9] and National Transitions

of Care Coalitions [10] including discharge planning, structured follow-up, coordination of care, patient education and self-management. They were generally initiated shortly after discharge, included follow-up calls and visits, and lasted around 6 months. The application of high intensity, multidomain and multidisciplinary transitions interventions for older people [10, 11] has been widely advocated, however, also acknowledged is the cost of these [8, 12]. There is some suggestion that interventions, which seek to enhance patient capacity to 'reliably access and enact' post-discharge care [13, 14] or which emphasise patient education and promote self-management [11], are most likely to be effective.

Qualitative evidence increasingly shows that patients and their carers have a central role in supporting safe care throughout the care pathway [15–17]. Patient involvement in care during the hospital stay (through retaining knowledge and capability to undertake usual care activities) may be a key mechanism for enhancing patients' capacity to support the system to deliver safe care [18]. A meta-synthesis of 20 studies investigating the experiences of older people as they transitioned from hospital to home [19] argued that those providing healthcare should seek to encourage cultures that supported questioning and discussion and older people's and carer's needs for independence in care transitions. Previously we too identified the importance of supporting the greater involvement of patients in their care, particularly during the hospital stay to help prepare patients for being at home [20, 21]. However, participants were not always willing or able to be actively engaged in their care and this desire was highly variable [20]. In fact, patient involvement in hospital care is not considered intuitive [20, 21] and is unlikely to be enacted without intervention or support. The mechanism for doing this has not been fully explored.

Using a theoretical approach that aims to build resilience in patients [22], we developed an intervention to support greater involvement of patients and their families. The 'Your Care Needs You' (YCNy) intervention was codesigned with patients and healthcare staff and aims to facilitate older people (and their family/carers) to 'know more' and 'do more' whilst in hospital [23, 24].

By involving people during their hospital stay, we hypothesise that they will be better prepared to manage their health and wellbeing on returning home [25] thus avoiding unplanned readmissions, enhancing their experience of the transitions process and reducing adverse events.

## Methods

### Study design and setting

A cluster RCT of the YCNy intervention vs care-as-usual for people aged 75 years and older, during the transition from hospital to home was conducted. For a full description see the published protocol [26]. We randomised at ward level to minimise the risk of contamination. Wards were eligible if they routinely provided care for people aged

75 years and older, from National Health Service hospital trusts in the north of England. Wards were ineligible if they: were non-NHS funded/private inpatient wards; did not routinely provide care for patients aged 75 years and over; did not have regular medical input (e.g. discharge wards); were acute medical admission wards; were participating in another trial, which included similar follow-up time points to this trial.

Full methods and findings from cost-effectiveness and fidelity analyses will be reported elsewhere. Findings from a parallel process are published elsewhere [27].

### The intervention

The intervention focuses on four key activities that were identified by modelling the transitional period using interview and observation data collected earlier in the programme of research [25]. The activities are managing their: health and wellbeing; medications; daily activities; and escalating care needs. These were incorporated into patient- and staff-facing intervention elements through codesign [23].

Wards were free to decide upon how and when the fixed and flexible elements were delivered, however, they were asked to deliver these at ward level and ensure that all elements (except the advice sheet for managing at home) were delivered early in the patient's ward stay.

### Outcomes

The primary outcome was unplanned hospital readmission (readmitted vs not) at 30 days post-discharge. Secondary outcomes comprised: unplanned readmission at 60 and 90 days; time to, number and duration of unplanned readmissions; patient experience and safety event rate measured using the Partners At Care Transition Measure (PACT-M) [28] and 3-item Care Transition Measure (CTM) [29] around 7, 30 and 90 days (see [Appendix 1](#) in the Supplementary Data section for full details of the measures); quality of life (Eq5D) [30] and resource use measures. The latter two outcomes were used for the health economics analysis that will be reported elsewhere.

Data relating to hospital readmissions were assessed using routinely collected hospital episode data from participating Trusts. All other data were collected through a nested cohort study requiring individual patient consent and completion of questionnaires.

### Sample size

Based on similar interventions targeting readmission [13] and an 18% baseline risk of readmission for older patients, we anticipated a 4%–6% absolute difference in readmission rates at 30 days between control and intervention wards. Using a 4.5% reduction in readmissions, with 80% power, alpha of 0.05, intracluster correlation coefficient (ICC) of 0.01, and an average cluster size of 140, accounting for a

10% attrition rate, we determined 5440 participants were required for the primary outcome.

A nested cohort for individual data was powered based on the secondary outcome of transition quality using the PACT-M [28]. With a mean difference of 2.7 points, which equates to a reduction of around half an adverse event and an Standard Deviation (SD) of 9, and 80% power, alpha 0.05, we required 170 patients per group. Adjusting for clustering and a 25% attrition rate, we aimed to recruit 500 patients per group (1000 total) across 40 clusters, assuming an ICC of 0.05.

### **Inclusion and exclusion criteria**

Eligible patients were aged 75 years and older expecting to be discharged back to their own homes; an inpatient on a participating ward for at least one night; were able to give informed consent (or personal consultee if lacking in mental capacity). Patients were excluded if they: had previously been recruited to the study; required an interpreter; lived out of area; expected to be transferred to another acute hospital/trust prior to discharge or a community rehabilitation unit; admitted for psychiatric reasons (other than dementia/delirium); nursing/residential home resident or planning to be discharged to a nursing/residential home on a permanent basis; at the end of their life/subject to fast-track discharge to palliative care or; unable to give informed consent (with no suitable personal consultee).

### **Randomisation**

Wards were randomly allocated following recruitment to the study in an equal allocation ratio (1:1) independently by statisticians at the York Trials Unit using minimisation software minimPy [31] and stratified by ward type (speciality), the percentage of patients over 75 years (split by  $\leq 66\%$  and  $> 66\%$ , based on the feasibility cRCT) [24] and NHS trust. Allocations were concealed until researchers notified wards about their allocation.

### **Masking**

Due to the study design, it was not feasible to mask participants, ward staff, research nurses or members of the study team. The intervention was delivered as treatment as usual on wards and patients were recruited (by local research team) to follow-up only and were unaware of ward treatment allocation. Statisticians did not see primary outcome data until after the statistical analysis plan was signed off.

### **Analysis**

All analyses were conducted in R v4.3.1 [32] and Stata v18 [33] and followed the principle of intention-to-treat. Results are reported using the CONSORT 2004 checklist [34] (See [Appendix 2](#) in the Supplementary Data section for the details of the CONSORT checklist).

### **Participant flow**

Ward and participant flow through the study are presented in CONSORT flow diagrams for the primary and nested cohorts.

### **Primary analysis**

The number of readmissions and deaths at 30 days are reported by treatment group.

The primary estimand was the difference in the proportion of patients with an unplanned hospital readmission (readmitted vs not) at 30 days post-discharge between patients on YCNY and care-as-usual wards, regardless of treatment crossovers but excluding those who died within 30 days and had no readmission recorded before death. A mixed effects logistic regression including treatment allocation, ward type, baseline ward readmission rate, percentage of patients 75 and over and gender as fixed effects and trust and ward as random effects was used. The prespecified model (including hospital and ward as random effects) did not fit the structure of the data so were excluded. Two wards had missing baseline readmission rates and were imputed using a simple linear regression model with ward type, percentage of patients 75 and over and average age as predictors. Robustness of the model to multicollinearity and the method for categorising ward type were evaluated. ICCs for wards have been presented.

A complier average causal effect (CACE) analysis was carried out using ward level scores for the fidelity to the intervention categorised as either 'low' (minimal evidence intervention delivery), 'medium' (evidence of delivery but with 'scope for improvement') or 'high' (competent delivery as intended) [35]. A two-stage instrumental variable approach was used with treatment allocation as the instrumental variable [36]. No missing data analysis was planned due to the method of data collection.

A subgroup analysis ( $< 85$  and  $\geq 85$  years of age) was conducted by including the interaction between age category and allocation in the primary analysis.

### **Secondary analyses**

Secondary data were analysed using the same fixed and random effects as specified in the primary analysis model unless otherwise stated. Readmissions at 60 and 90 days were analysed using the same model specification as the primary analysis. Time to first readmission was analysed using a Cox's proportional hazards model and deaths were accounted for using right censoring. Number of readmissions over 90 days was analysed using a negative binomial, zero inflated model due to overdispersion. Total duration of readmissions within 90 days was analysed using a mixed effects linear regression model and included an average length of stay at ward level as an additional fixed effect.

A mixed-effects linear regression was used to analyse CTM-3 and PACT-M experience. The primary time point of interest for the nested cohort was prespecified as 30 days. A mixed-effects Poisson regression model was used to analyse



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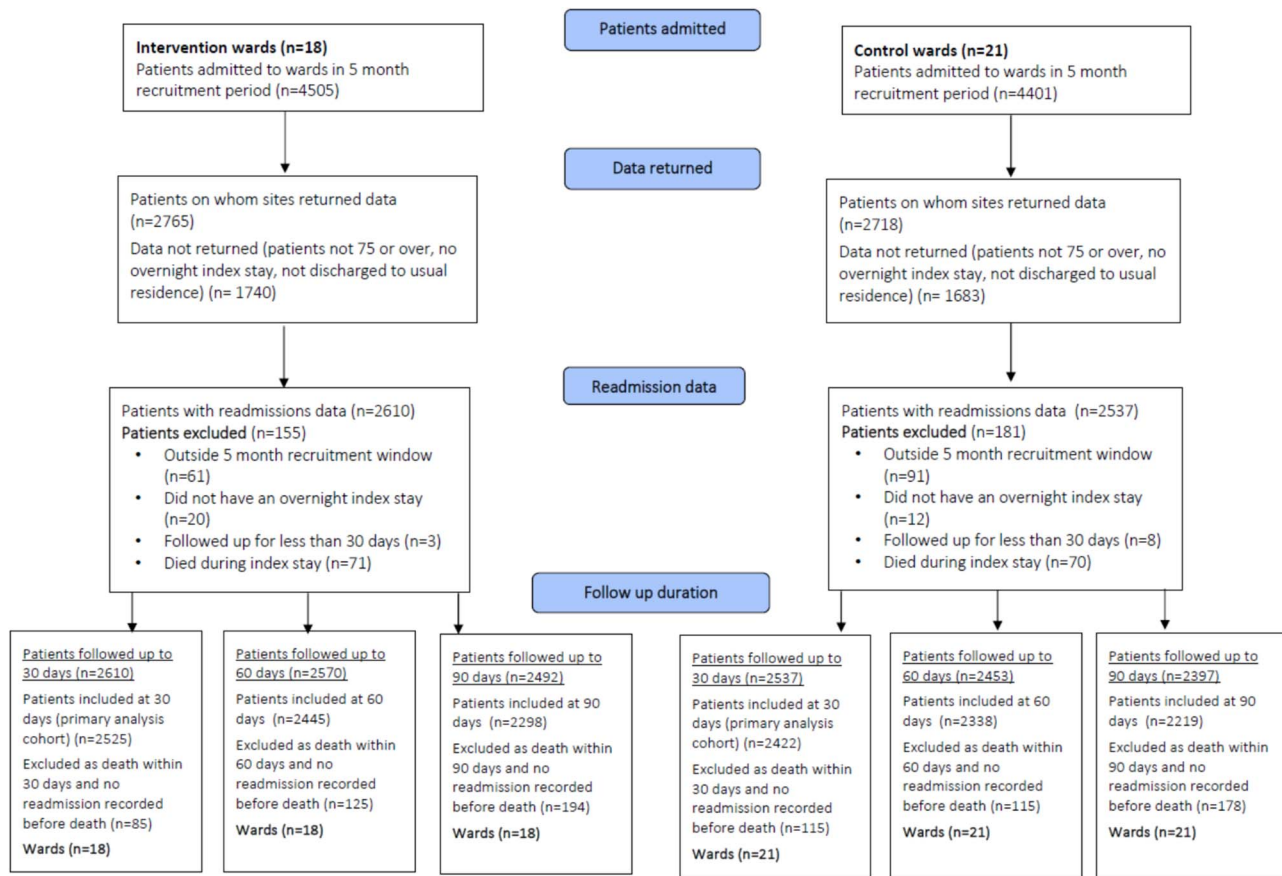


Figure 1. CONSORT flow diagram showing flow of patients in the primary cohort study.

the PACT-M Safety (number of adverse events experienced) due to severe deviations from the normality assumption. Sensitivity analyses were undertaken using the same models described above but restricted to participants recruited during the first 5 months to reflect the same recruitment period as in the nested cohort. No adjustments for multiple testing were applied.

## Results

### Participant flow

In total 42 wards were randomised (YCNV = 21 and Care-as-usual = 21). Three wards withdrew from the study: two from YCNV and one from Care-as-Usual. Reasons for withdrawal included one ward undergoing a change in function and two citing concerns over staffing and recruitment. Additionally, four wards (three from YCNV and one from Care-as-Usual) withdrew from the nested cohort but provided routine data. Participant screening for the nested cohort occurred from November 2021 to March 2023. However, data on readmissions were restricted to the initial 5 months of recruitment spanning November 2021 to November 2022.

### Primary cohort

Eleven Trusts returned routinely collected data from 39 wards (18 intervention, 21 control) (Fig. 1). During the first 5 months of recruitment a total of 8906 patients

were admitted to participating wards and readmission data was returned for 5483 patients (YCNV = 2765, Care-as-usual = 2718). Three hundred thirty-six (YCNV = 155, Care-as-usual = 181) patients were excluded for the reasons provided.

Routine data for 5147 patients (YCNV = 2610, Care-as-usual = 2537) were available for up to 30 days post-discharge and 4947 of these patients (YCNV = 2525, Care-as-usual = 2422) were included in the primary analysis, which exceeded the target of 4896.

### Nested cohort

Eight thousand, three hundred nineteen patients across 35 recruiting wards (Fig. 2) were screened for eligibility; an average of 237 patients per ward (mean = 237.7, minimum = 58, maximum = 600). Of those screened, 2542 (30.6%) were eligible, 625 (24.6% of those eligible) consented and 613 (98.2% of those consented) were discharged and subsequently sent follow-up questionnaires [331 (54%) care-as-usual and 282 (46%)] to YCNV. Complete summaries of reasons for ineligibility and refusal (where available) are provided in Appendix 3 (see Supplementary Data files).

### Baseline characteristics

Wards and patients showed similar characteristics across treatment groups in the primary cohort. For the nested

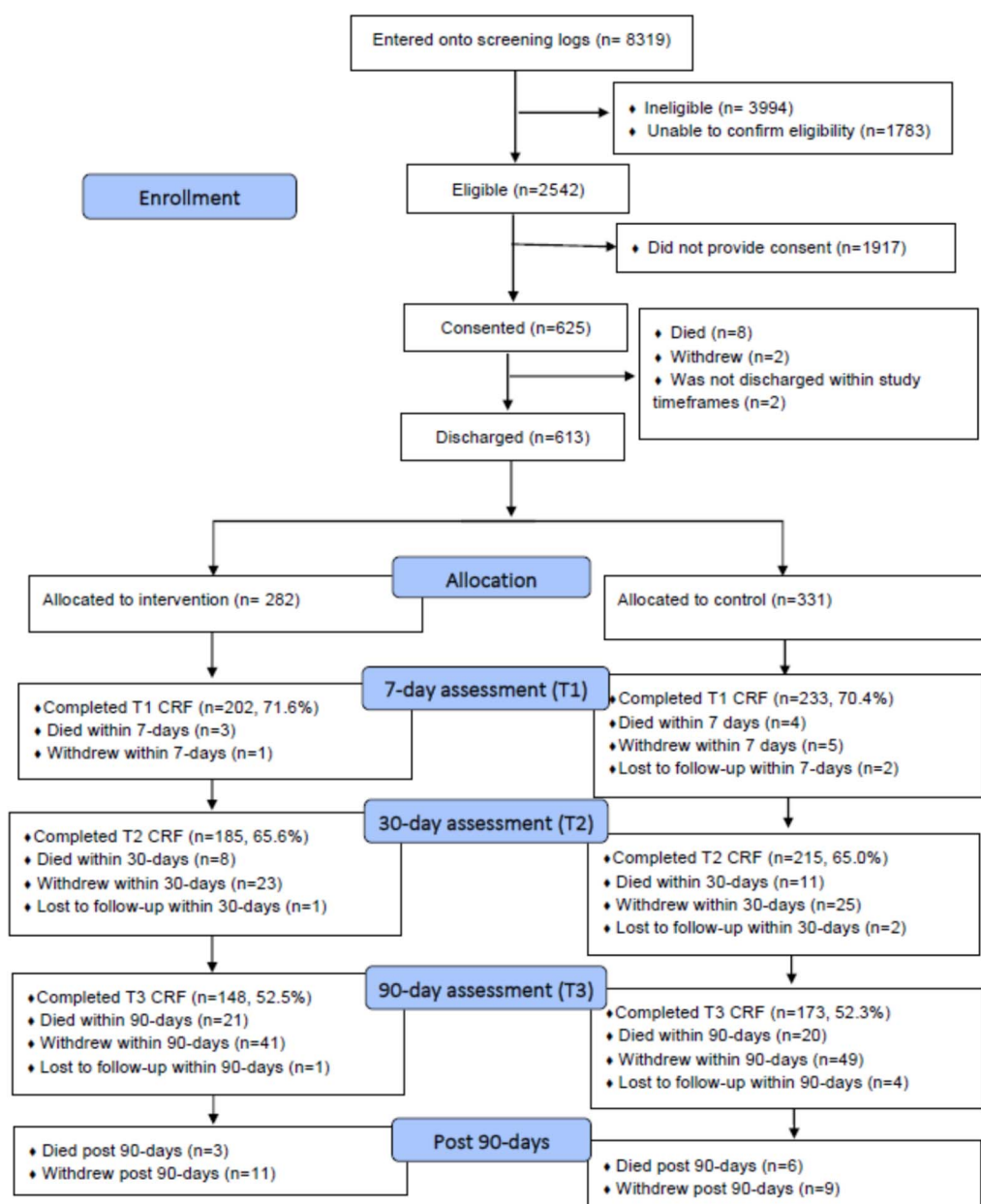


Figure 2. CONSORT flow diagram showing flow of participants in the nested cohort study.

Table 1. Primary outcome

			Readmissions at 30 days		Odds ratio (95% confidence interval)	<i>P</i> -value
	<i>n</i> in model	ICC (ward)	YCNy n (%)	Care-as-usual <i>n</i> (%)		
<hr/>						
		<i>Unplanned hospital readmission at 30 days post-discharge</i>				
Primary analysis model	4947	0.02	436 (17%)	459 (19%)	0.93 (0.78–1.10)	.372
		<i>Sensitivity analysis models to assess</i>				
CACE analysis (based on fidelity scores low, medium and high)	4947				0.98 (0.94–1.03)	.435

Table 2. Secondary analyses including both the primary and nested cohorts

	<i>n</i> in model	ICC (ward)	YCNV	Care-as-usual	Estimate (95% confidence interval)	<i>P</i> -value
<b>Primary analysis cohort</b>						
<b>Readmission at 60 and 90 days</b>			<b>N (%)</b>	<b>N (%)</b>	<b>Odds Ratio (95% CI)</b>	
60 days	4783	0.02	612 (25%)	677 (29%)	0.85 (0.70–1.03)	.100
90 days	4517	0.02	692 (30%)	779 (35%)	0.82 (0.67–1.01)	.061
			<b>25th percentile* readmission time in days (95% CI)</b>	<b>25th percentile* readmission time in days (95% CI)</b>	<b>Cox's proportional Hazard ratio (95% CI)</b>	
<b>Time to first readmission (days)</b>	5158	0.02	67 (58 to 77)	50 (46 to 57)	0.87 (0.75–1.01)	.076
			<b>Total number of readmissions</b>	<b>Total number of readmissions</b>	<b>Incidence rate ratio (95% CI)</b>	
<b>Total readmissions</b>	4517	0.03	898	1027	0.87 (0.76–0.99)	.039
			<b>Median duration of all readmissions (IQR)</b>	<b>Median duration of all readmissions (IQR)</b>	<b>Adjusted difference in means (95% CI)</b>	
<b>Total duration of readmissions (days)</b>	1179	0.02	9 (3 to 21)	10 (4 to 25)	−2.26 (−4.65–0.12)	.063
<b>Nested cohort</b>						
<b>CTM-3</b>					<b>Adjusted difference in means (95% CI)</b>	
T1	392	0.01	67.0	63.8	3.21 (−0.91, 7.33)	.127
T2	356	0.01	68.4	63.4	4.93 (0.46, 9.40)	.031
T3	297	0.01	68.5	65.9	2.59 (−2.08, 7.27)	.277
<b>PACT-M (8-experience items)</b>					<b>Adjusted difference in means (95% CI)</b>	
T1	407	0.01	20.2	19.6	0.68 (−0.50, 1.87)	.260
T2	372	0.02	23.7	23.2	0.57 (−0.41, 1.56)	.255
T3	309	0.01	24.2	23.8	0.47 (−0.66, 1.61)	.409
<b>PACT-M (7-safety items)</b>					<b>IRR (95% CI)</b>	
T1	420	0.02			0.86 (0.66, 1.10)	.231
T2	385	0.01			0.75 (0.57, 0.99)	.039
T3	318	0.01			0.85 (0.69, 1.04)	.120

cohort, participants were admitted into hospital between 26th October 2021 and 27th March 2023. The nested cohort had more females (58%) and more White British (94%) compared to the primary cohort (41%) and (89%), respectively (see [Appendices 4](#) and [5](#) in the Supplementary Data files for details of the baseline characteristics for the primary and nested cohorts).

### Primary outcome

A total of 895/4947 (18%) patients had at least one unplanned hospital readmission within 30 days post-discharge, 436 (17%) in the YCNV and 459 (19%) in the care-as-usual group. There were 289 (6%) deaths within 30 days post-discharge (YCNV: 130; 5% and Care-as-usual: 159; 6%).

There was no difference in 30-day readmission rates between the two groups (OR 0.93; 95% CI, 0.78 to 1.10;  $P = .372$ ) ([Table 1](#)). Results were robust to sensitivity analyses and did not change findings when assessing multi-collinearity, inclusion of index length of stay as a fixed effect and impact of fidelity to YCNV. There was no interaction between age and treatment (OR 0.89; 95% CI, 0.66–1.20;  $P = .447$ ) (See Supplementary Data files, [Appendix 6](#)).

### Secondary outcomes

At 60 and 90 days, readmission rates across groups were similar (OR 0.85; 95% CI, 0.70 to 1.03;  $P = .100$ , and OR 0.82; 95% CI, 0.67 to 1.01;  $P = .061$ ) ([Table 2](#)).

There was no significant difference in time to first readmission across 90 days (HR 0.87; 95% CI, 0.75 to

1.01;  $P = .076$ ) and total duration of readmissions (adjusted mean difference:  $-2.26$ ; 95% CI,  $-4.65$  to  $0.12$ ;  $P = .063$ ). Patients in wards randomised to intervention experienced 0.87 times as many readmissions within 90 days of discharge compared with participants in control wards, a 13% reduction in readmissions. This difference was significant (IRR 0.87; 95% CI, 0.76 to 0.99;  $P = .039$ ).

### **Nested cohort**

#### *Participant follow up and retention*

Of those consented, 110 (17.6%) subsequently withdrew from the study, 50 (8.0%) died, five (0.8%) were lost to follow-up, eight (1.3%) died prior to discharge, two (0.3%) withdrew prior to discharge and two (0.3%) were eligible but were not discharged within study time frames.

Overall, 435 (71.0%) participants completed the 7-day post-discharge assessment, 400 (65.3%) completed the 30-day assessment and 321 (52.4%) completed the 90-day assessment.

### **Secondary outcomes**

There was evidence of a difference in CTM-3 score, favouring the YCNY group at 30 days (adjusted mean difference 4.93, 95% CI 0.46 to 9.40,  $P = .031$ ) but not at 7 (3.21, 95% CI  $-0.91$  to 7.33,  $P = .127$ ) or 90 days (2.59, 95% CI  $-2.08$  to 7.27,  $P = .277$ ) (Table 2).

There was a decrease in the adverse event rate in the YCNY group (IRR 0.75, 95% CI 0.57 to 0.99,  $P = .039$ ) (Table 2). Sensitivity analyses, which restricted the population to those recruited and discharged within the first 5-month recruitment period, reflected these results. Further detailed considerations in relation the statistical methods and results can be found in Appendix 7 in the Supplementary Data files.

### **Serious adverse events**

A total of 50 deaths were recorded, 26 (52.0%) were within care-as-usual and 24 (48.0%) within the YCNY group. No deaths were determined to be related to YCNY or participation in the trial.

### **Discussion**

There were no significant differences in the primary outcome (unplanned 30-day readmissions rate), 60-day or 90-day readmission rates, which were similar to the national average [7]. The rates however were consistently lower in the YCNY group. The 'total number' of readmissions, whilst lower in the intervention group at all timepoints did not reach statistical significance until 90-days post-discharge. There were no significant differences in PACT-M experience and CTM-3 across all timepoints, and PACT-M safety items at 7- and 90-days post-discharge. At 30-days, a significant difference was observed for the CTM-3 and PACT-M safety items in favour of the intervention.

Our study has a number of strengths and limitations in relation to the analytical methods and trial implementation. Cluster randomisation can be susceptible to selection bias; however, our primary cohort was based on routinely collected data comprising all patients who met our eligibility criteria. Some contamination between wards may still have occurred through staff movement between wards. We did not monitor this. We did monitor patient movement however and observed that 25% of patients in intervention wards had at least one ward move to a control ward and that just over 1% moved in the opposite direction. It is possible that a small proportion of patients could have been readmitted to other hospitals or settings however we did not monitor this and assume that this would have been similar across groups. Some participants in the nested study were not followed up for the full 90-day period however this only affected some of the secondary outcomes and we assume this to be consistent across groups. The nested cohort had a higher proportion of females and White British people than the primary cohort so assessment of some secondary outcomes may not be fully representative of the diversity of patients on wards. Similarly, the intervention was developed and tested in the English language and we did not assess its acceptability across different cultural groups. The impact of the intervention on safety inequities remains unknown. Whilst readmission rates could be influenced by variability in patients from different ward specialities, this was a stratification variable in the randomisation and a covariate in the analysis model. To capture accurate recollections of hospital-based transition's experiences we included a 7-day post-discharge follow-up. However, this time point saw our greatest loss to follow-up, and we do not know if including this time point jeopardised participation in subsequent follow-up timepoints. Recruitment to the nested study was impacted by the COVID-19 pandemic. Of those who were eligible, 25% provided consent. This echoes reports of challenges from other clinical trials conducted at the same time [37, 38]. In addition to staff shortages, our recruitment was hampered by communication difficulties (due to mask and visor wearing), patient lethargy and disinterest (due to patients being restricted to the bed area), and lack of patient support (family members had limited access to wards). We also had to deliver condensed training sessions and support online because of reduced access and workforce availability. This will have affected the potential impact of our intervention. Despite the enormous challenges imposed by COVID-19 we managed to over-recruit to our primary outcome. Further we adapted at short notice and worked with services to deliver the trial to a high quality.

Our findings align with evidence from a meta-analysis of 92 'multidomain' transitions interventions, which showed a significant reduction in readmissions in intervention groups from 3 months post-discharge onwards [8]. The delayed impact (not seen at 1 month) on outcomes has been referred to as an 'investment effect' [39]. Our theory of change proposed that by 'doing more' and 'knowing more' during a hospital stay, patients would have a safer transition home [25].



One mechanism could be through the triggering of patients to take on an active role in their care resulting in more timely engagement with community services to manage symptoms. We know that there were fewer reported safety events in the intervention group at 30 days indicating a potential mechanism by which the ‘investment effect’ occurs. Further insight into when the intervention may have been triggered is suggested by other trial-related data. Preparedness for transitioning home (measured by CTM-3 and experience items in PACT-M1) did not suggest that patients in the intervention group felt more prepared for going home. This fits with our process evaluation findings that staff did not always have time to explain or interact with the booklet and that patients were rarely seen interacting with it [27]. This indicates that during this trial, the intervention may have been assimilated into care after discharge, perhaps supported by family members who had limited access to wards.

Prior transitions interventions have taken a broad approach by including multiple domains such as medicines reconciliations, patient and family education and post-discharge support. Our approach took a deep dive into one domain, patient involvement, to fully explore its potential contribution. Whilst subgroup analysis of previous multidomain intervention trials suggested that interventions, which aimed to ‘increase capacity to “enact” post-discharge care’, are most likely to be effective [13], the included studies were not necessarily about patient involvement. For example, a primary aim of medicines reconciliation would be to avoid errors rather than necessarily support patients or carers to identify and prevent them. Our intention, from the outset, was to involve patients and carers ‘as partners’ in care to anticipate, respond, and adapt to evolving situations in line with resilient healthcare theoretical approaches [22] and thereby supporting system resilience. This was based on literature that indicated that greater patient involvement in care was desirable and potentially amenable to change [40, 41] depending on the role or ‘work’ required [42]. That intentionality steered us to thoroughly examine both the concept of older people’s involvement in care transitions and the way that it manifested within a complex healthcare system [20, 21]. This intentionality, to go beyond an assumed understanding of, and approaches to, patient involvement perhaps indicates why we have been able to demonstrate some evidence of benefit through a single domain transitions intervention.

Systematic reviews of transitions interventions in general tend to omit reporting safety events as an outcome [8, 13], despite these being both linked with poor discharges and contributing to hospital readmissions [3, 43]. We therefore recommend that future transitions trials capture early post-discharge safety events and explore in more depth their management to elucidate the mechanisms behind such interventions.

## Conclusion

The World Health Organisation states that patient engagement and empowerment through involvement across the

care trajectory saves lives and money, reducing the burden of harm by 15% (<https://www.who.int/campaigns/world-patient-safety-day/2023>). They call for systems to engage and empower patients and families across the care trajectory [World Health Assembly resolution (WHA72.6)]. Patient involvement, as it is conceptualised through YCNY offers a promising contribution to this and may therefore be of interest to service planners and clinicians.

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## References

1. Glans M, Kragh Ekstam A, Jakobsson U *et al*. Risk factors for hospital readmission in older adults within 30 days of discharge — a comparative retrospective study. *BMC Geriatr*. 2020;**20**:467. <https://doi.org/10.1186/s12877-020-01867-32>.
2. Pedersen MK, Meyer G, Uhrenfeldt L. Risk factors for acute care hospital readmission in older persons in western countries: a systematic review. *JBISRI Database System Rev Implement Rep*. 2017;**15**:454–85. <https://doi.org/10.11124/JBISRI R-2016-003267>.
3. Forster AJ, Murff HJ, Peterson JF *et al*. The incidence and severity of adverse events affecting patients after discharge from the hospital. *Ann Intern Med*. 2003;**138**:161–7.
4. Auerbach AD, Kripalani S, Vasilevskis EE *et al*. Preventability and causes of readmissions in a National Cohort of general

- medicine patients. *JAMA Intern Med.* 2016;**176**:484–93. <https://doi.org/10.1001/jamainternmed.2015.7863>.
5. Blunt I, Bardsley M, Grove A *et al.* Classifying emergency 30-day readmissions in England using routine hospital data 2004–2010: What is the scope for reduction? *Emerg Med J.* 2015;**32**:44–50. <https://doi.org/10.1136/emermed-2013-202531>.
6. Van Walraven C, Bennett C, Jennings A *et al.* Proportion of hospital readmissions deemed avoidable: a systematic review. *CMAJ.* 2011;**183**:E391–402. <https://doi.org/10.1503/cma.j.101860>.
7. NHS Digital. Emergency readmissions to hospital within 30 days of discharge: indirectly standardised percent trends broken down by age bands and sex (102040). Retrieved 30.7.23 from: <https://digital.nhs.uk/data-and-information/publications/statistical/compendium-emergency-readmissions/current/emergency-readmissions-to-hospital-within-30-days-of-discharge>.
8. Le Berre M, Maimon G, Sourial N *et al.* Impact of transitional care services for chronically ill older patients: a systematic evidence review. *J Am Geriatr Soc.* 2017;**65**:1597–608. <https://doi.org/10.1111/jgs.14828>.
9. Burke RE, Guo R, Prochazka AV *et al.* Identifying keys to success in reducing readmissions using the ideal transitions in care framework. *BMC Health Serv Res.* 2014;**14**:423. <https://doi.org/10.1186/1472-6963-14-423>.
10. National Transitions of Care Coalition Measures Work Group. NTOCC Transitions of Care Measures. *Care Transitions bundle seven essential intervention categories*, 2022. <http://www.ntocc.org>.
11. Morkisch N, Upegui-Arango LD, Cardona MI *et al.* Components of the transitional care model (TCM) to reduce readmission in geriatric patients: A systematic review. *BMC Geriatr.* 2020;**20**:1–18. <https://doi.org/10.1186/s12877-020-01747-w>.
12. Rochester-Eyeguokan CD, Pincus KJ, Patel RS *et al.* The current landscape of transitions of care practice models: a scoping review. *Pharmacotherapy.* 2016;**36**:117–33. <https://doi.org/10.1002/phar.1685>.
13. Leppin AL, Gionfriddo MR, Kessler M *et al.* Preventing 30-day hospital readmissions: a systematic review and meta-analysis of randomized trials. *JAMA Intern Med.* 2014;**174**:1095–107. <https://doi.org/10.1001/jamainternmed.2014.1608>.
14. Naylor MD, Shaid EC, Carpenter D *et al.* Components of comprehensive and effective transitional care. *J Am Geriatr Soc.* 2017;**65**:1119–25. <https://doi.org/10.1111/jgs.14782>.
15. Mitchell SE, Laurens V, Weigel GM *et al.* Care transitions from patient and caregiver perspectives. *Ann Fam Med.* 2018;**16**:225–31. <https://doi.org/10.1370/afm.2222>.
16. Aase K, Waring J. Crossing boundaries: establishing a framework for researching quality and safety in care transitions. *Appl Ergon.* 2020;**89**:103228. <https://doi.org/10.1016/j.apergo.2020.103228>.
17. Backman C, Johnston S, Oelke ND *et al.* Safe and effective person- and family-centered care practices during transitions from hospital to home—a web-based Delphi technique. *PLoS One.* 2019;**14**:e0211024. <https://doi.org/10.1371/journal.pone.0211024>.
18. O'Hara JK, Aase K, Waring J. Scaffolding our systems? Patients and families 'reaching in' as a source of healthcare resilience. *BMJ Qual Saf.* 2019;**28**:3–6. <https://doi.org/10.1136/bmjqs-2018-008216>.
19. Allen J, Hutchinson AM, Brown R *et al.* User experience and care integration in transitional care for older people from hospital to home: a meta-synthesis. *Qual Health Res.* 2017;**27**:24–36.
20. Hardacre N, Murray J, Shannon R *et al.* Doing involvement: a qualitative study exploring the 'work' of involvement enacted by older people and their carers during transition from hospital to home. *Health Expect.* 2021;**24**:1936–47. <https://doi.org/10.1111/hex.13327>.
21. Murray J, Hardacre N, Birks Y *et al.* How older people enact care involvement during transition from hospital to home: a systematic review and model. *Health Expect.* 2019;**22**:883–93. <https://doi.org/10.1111/hex.12930>.
22. Hollnagel E, Braithwaite J, Wears RL (eds). *Resilient Health Care*. Surrey, UK: Ashgate, 2014.
23. Murray J, Baxter R, Lawton R *et al.* Unpacking the Cinderella black box of complex intervention development through the Partners at Care Transitions (PACT) programme of research. *Health Expect.* 2023;**26**:1478–90. <https://doi.org/10.1111/hex.13682>.
24. Baxter R, Murray J, Cockayne S *et al.* Improving the safety and experience of transitions from hospital to home: a cluster randomised controlled feasibility trial of the 'your care needs you' intervention versus usual care. *Pilot Feasibility Stud.* 2022;**8**:222. <https://doi.org/10.1186/s40814-022-01180-3>.
25. O'Hara JK, Baxter R, Hardacre N. Handing over to the patient': a FRAM analysis of transitional care combining multiple stakeholder perspectives. *Appl Ergon.* 2020;**85**:103060. <https://doi.org/10.1016/j.apergo.2020.103060>.
26. Lawton R, Murray J, Baxter R *et al.* Evaluating an intervention to improve the safety and experience of transitions from hospital to home for older people (your care needs you): a protocol for a cluster randomised controlled trial and process evaluation. *Trials.* 2023;**24**:671. <https://doi.org/10.1186/s13063-023-07716-z>.
27. Hampton S, Murray J, Lawton R *et al.* Understanding the challenges and successes of implementing 'hybrid' interventions in healthcare settings: findings from a process evaluation of a patient involvement trial. *BMJ Qual Saf.* 2025;**34**:92–9. <https://doi.org/10.1136/bmjqs-2024-017268>.
28. Oikonomou E, Page B, Lawton R *et al.* Validation of the Partners at Care Transitions Measure (PACT-M): assessing the quality and safety of care transitions for older people in the UK. *BMC Health Serv Res.* 2020;**20**:608. <https://doi.org/10.1186/s12913-020-05369-1>.
29. Parry C, Mahoney E, Chalmers SA *et al.* Assessing the quality of transitional care: Further applications of the care transitions measure. *Med Care.* 2008;**46**:317–22. <https://doi.org/10.1097/MLR.0b013e3181589bdc>.
30. Janssen MF, Pickard AS, Golicki D *et al.* Measurement properties of the EQ-5D-5L compared to the EQ-5D-3L across eight patient groups: A multi-country study. *Qual Life Res.* 2013;**22**:1717–27. <https://doi.org/10.1007/s11136-012-0322-4>.
31. Saghaei M, Saghaei S. Implementation of an open-source customizable minimization program for allocation of patients to parallel groups in clinical trials. *J Biomed Sci Eng.* 2011;**4**:734–9. <https://doi.org/10.4236/jbise.2011.411090>.
32. The R Project for Statistical Computing. [cited 2024 Mar 19]. <https://www.r-project.org/>.
33. StataCorp. *Stata Statistical Software: Release 18*. College Station, TX: Stata Press, 2023.

34. Campbell MK, Elbourne DR, Altman DG *et al.* Education and debate CONSORT statement: extension to cluster randomised trials. *BMJ*. 2004;**328**:702–8. <https://doi.org/10.1136/bmj.328.7441.702>.
35. Cross R, Greaves CJ, Withall J *et al.* Delivery fidelity of the REACT (REirement in ACTion) physical activity and behaviour maintenance intervention for community dwelling older people with mobility limitations. *BMC Public Health*. 2022;**22**:1112. <https://doi.org/10.1186/s12889-022-13496-z>.
36. Dunn G, Maracy M, Tomenson B. Estimating treatment effects from randomized clinical trials with noncompliance and loss to follow-up: the role of instrumental variable methods. *Stat Methods Med Res*. 2005;**14**:369–95.
37. Lorenc A, Rooshenas L, Conefrey C *et al.* Non-COVID-19 UK clinical trials and the COVID-19 pandemic: impact, challenges and possible solutions. *Trials*. 2023;**24**:424. <https://doi.org/10.1186/s13063-023-07414-w>.
38. McDonald K, Seltzer E, Lu M *et al.* Quantifying the impact of the COVID-19 pandemic on clinical trial screening rates over time in 37 countries. *Trials*. 2023;**24**:254. <https://doi.org/10.1186/s13063-023-07277-1>.
39. Manderson B, McMurray J, Piraino E *et al.* Navigation roles support chronically ill older adults through healthcare transitions: a systematic review of the literature. *Health Soc Care Community*. 2012;**20**:113–27. <https://doi.org/10.1111/j.1365-2524.2011.01032.x>.
40. Schwappach D. Engaging patients as vigilant Partners in Safety: a systematic review. *Med Care Res Rev*. 2010;**67**:119–48. <https://doi.org/10.1177/1077558709342254>.
41. Burrows Walters C, Duthie E. Patient engagement as a patient safety strategy: Patients' perspectives. *Oncol Nurs Forum*. 2017;**44**:712–8. <https://doi.org/10.1188/17>.
42. Peat M, Entwistle V, Hall J *et al.* Scoping review and approach to appraisal of interventions intended to involve patients in patient safety. *J Health Serv Res Policy*. 2010; **15**:17–25. <https://doi.org/10.1258/jhsrp.2009.009040>.
43. Williams H, Edwards A, Hibbert P *et al.* Harms from discharge to primary care: Mixed methods analysis of incident reports. *Br J Gen Pract*. 2015;**65**:e829–37. <https://doi.org/10.3399/bjgp15X687877>.

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