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Volume 13 • Issue 4 • April 2025

ISSN 2050-4330

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DOI 10.3310/KMNG5684

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Extended Research Article

Improving older people's experiences and safety at transitions of care: the PACT mixed-methods study including RCT

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Published April 2025
DOI: 10.3310/KMNG5684

This report should be referenced as follows:

Murray J, Baxter R, O'Hara J, Sheard L, Hewitt C, Hardicre N, *et al.* Improving older people's experiences and safety at transitions of care: the PACT mixed-methods study including RCT. *Programme Grants Appl Res* 2025;**13**(4). https://doi.org/10.3310/KMNG5684

Programme Grants for Applied Research

ISSN 2050-4330 (Online)

A list of Journals Library editors can be found on the NIHR Journals Library website

Programme Grants for Applied Research (PGfAR) was launched in 2013 and is indexed by Europe PMC, NCBI Bookshelf, DOAJ, Ulrichsweb™ (ProQuest LLC, Ann Arbor, MI, USA) and Scopus® (Elsevier, Amsterdam, Netherlands).

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE)(www.publicationethics.org/).

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This article

The research reported in this issue of the journal was funded by PGfAR as award number RP-PG-1214-20017. The contractual start date was in January 2017. The draft manuscript began editorial review in February 2024 and was accepted for publication in July 2024. As the funder, the PGfAR programme agreed the research questions and study designs in advance with the investigators. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The PGfAR editors and production house have tried to ensure the accuracy of the authors' manuscript and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this article.

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Abstract

Background: Transitions from hospital to home are a risky time for older people (aged 75 years and older). Unplanned and often avoidable hospital re-admissions are therefore high in this group. This research aimed to understand if increased involvement of older people in their care in hospital would improve the safety and experience of care transitions.

Objectives: In six work packages we set out to:

1. understand patient and carer involvement in and experience of care transitions
2. explore staff experiences of delivering good transitional care
3. develop and validate a new measure (the Partners at Care Transitions Measure) to assess patient experience and safety during care transitions
4. create a theory and logic model to inform the co-designed transitions intervention followed by a formative evaluation
5. test the feasibility of delivering a trial to evaluate the intervention
6. evaluate the clinical- and cost-effectiveness of the transitions intervention with a parallel process evaluation.

Design: Qualitative methods (1 and 2), literature reviewing, Delphi techniques and validation testing (3), co-design (4), cluster feasibility trial (5) and cluster randomised controlled trial (6).

Settings: National Health Service acute hospital trusts, general practices, patients and carer homes across the north of England, United Kingdom.

Participants: Patients aged 75 years and older and their caregivers. National Health Service staff working in acute National Health Service trusts on wards delivering the intervention.

Intervention: 'Your Care Needs You' intervention to support patient and carer involvement in hospital care in preparation for returning home. This comprised fixed components: a booklet, an advice sheet for managing at home and a film; and flexible components: ongoing staff involvement of patients through multiple approaches. Implementation included a nominated lead, staff training and posters.

Main outcome measures: Primary outcome was unplanned 30-day hospital re-admissions. Secondary outcomes included: unplanned 60- and 90-day hospital re-admissions; quality of transition; health-related quality of life (EuroQol-5 Dimensions, five-level version); and self-reported healthcare resource use.

Data sources: National Health Service Secondary Use Services data and Hospital Episodes data for work package 2 and routinely recorded National Health Service acute trust hospital data on re-admissions for work packages 5 and 6.

Review methods: Systematic narrative review for preparatory work on patient involvement; narrative meta review of transitions interventions; scoping review of transitions measures.

Results: Work package 1: Six themes relating to patient experience of care transitions. Patient involvement in hospital care found to be challenging 'work' that was often invisible to staff.

Work package 2: National Health Service staff reported that high-quality care transitions were facilitated primarily through trust and strong relationships.

Work package 3: A measure of quality and safety of care transitions (Partners at Care Transitions Measure) developed and validated with good internal reliability and internal consistency.

Work package 4: An intervention called 'Your Care Needs You' that required revisions to support implementation.

Work package 5: Primary outcome data were collected for 90% of participants. Follow-up questionnaire response rates were lower than anticipated (75% vs. 85%). Information on the acceptability, usability and implementation of the intervention informed iterations to the intervention and implementation package.

Work package 6: 4947 participants from 39 hospital wards took part in the main trial. Six hundred and thirteen participants from 35 wards took part in the nested cohort. No differences were observed in the primary outcome of unplanned re-admission (Y/N) at 30 days post discharge [17% experienced re-admission within 30 days in the 'Your Care Needs You' group, 18% in care-as-usual, odds ratio: (0.93; 95% confidence interval, 0.78 to 1.10; $p = 0.372$)], and also at 60 and 90 days post discharge but all results were in favour of the intervention with a reduction in total re-admissions of 13% over 90 days [incidence rate ratio: 0.87 (0.76 to 0.99), $p = 0.039$]. There was a statistically significant reduction in Partners at Care Transitions Measure safety concerns at 30 days post discharge. The intervention is likely to be cost-effective.

Limitations: The main trial was conducted during the COVID-19 pandemic which exacerbated staffing challenges and limited opportunities to enhance and support implementation of the intervention. Participant recruitment to the nested study was challenging, resulting in fewer patients than planned and a less diverse sample than that included in the primary cohort. Therefore, while our primary cohort is representative of the patients in the hospital during the trial period, the nested cohort may suffer from some bias.

Conclusions: The 'Your Care Needs You' intervention offers a way to support staff and patients/families to facilitate greater involvement in care. This research demonstrates that increased involvement in hospital care has the potential to improve safety at transitions. Finding ways to support staff to encourage better patient involvement could lead to even more benefits being realised.

Future work: Hospitals could consider involving volunteers in supporting greater patient and family involvement. There was some indication that the component of the intervention most favoured was the patient advice for discharge.

Trial registration: This trial is registered as Current Controlled Trials ISRCTN51154948 (WP5) and ISRCTN17062524 (WP6).

Funding: This award was funded by the National Institute for Health and Care Research (NIHR) Programme Grants for Applied Research programme (NIHR award ref: RP-PG-1214-20017) and is published in full in *Programme Grants for Applied Research*; Vol. 13, No. 4. See the NIHR Funding and Awards website for further award information.

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Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/KMNG5684).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

List of abbreviations

A&E	accident and emergency
CACE	complier-average causal effect
CAG	Confidentiality Advisory Group
CFIF	conceptual framework for fidelity implementation
COM-B	capabilities, opportunities, motivation and behaviours
CONSORT	Consolidated Standards of Reporting Trials
cRCT	cluster randomised controlled trial
CRF	case report form
CTM-3	Coleman's Transition Measure-3
EQ-5D	EuroQol-5 Dimensions
EQ-5D-5L	EuroQol-5 Dimensions, five-level version
FCMI	Functional co-morbidity index
FRAM	functional resonance analysis method
GP	general practitioner
HEAP	health economics analysis plan
HRQoL	health-related quality of life
ICER	incremental cost-effectiveness ratio
ITT	intention to treat
MAR	missing at random
MME-GLM	multiple mixed-effects-generalised linear models
MNAR	missing not at random
NICE	National Institute for Health and Care Excellence
PACT	Partners at Care Transitions
PACT-M	Partners at Care Transitions Measure
PPIE	patient and public involvement and engagement
QALYs	quality-adjusted life-years
RCT	randomised controlled trial
SUR	seemingly unrelated regression
WP	work package
YCNY	'Your Care Needs You'

Plain language summary

Moving from hospital to home (the 'transition') is a risky time for older patients (75+ years). Around 18% of patients end up back in hospital as an emergency. Most of the time, these re-admissions cannot be avoided, but oftentimes they can. In this research, we wanted to understand and improve the experience and safety of care for older people as they move from hospital to home to reduce unnecessary hospital re-admissions. To do this, we conducted six pieces of research (called work packages). First, we tried to understand from patients, families and staff how they experienced care transitions. Next, we developed a tool to measure these experiences. We then worked with staff and patients and members of the public to develop an approach (called 'Your Care Needs You'), to help involve and prepare older people for going home after a hospital stay. 'Your Care Needs You' included a booklet, an advice sheet for managing at home, and a film, for patients. We then ran a trial to find out if people who received 'Your Care Needs You' were less likely to go back into hospital. For this, we put 'Your Care Needs You' into 18 wards and compared hospital re-admissions there with 21 wards which delivered care as usual. We found that the rate at which patients were re-admitted to hospital was better in the 'Your Care Needs You' wards but this was not *significantly* better. Three months after discharge, the number of people being re-admitted to the hospital was 13% less in the 'Your Care Needs You' wards. The approach also reduced the problems that people experienced (such as falls) around 1 month after discharge. We found that many of the wards did not deliver the approach as planned, so not all patients got 'Your Care Needs You'. This was mainly because of staffing pressures after the COVID-19 pandemic. While some patients found the approach useful, others thought it was not for them. The approach is cheap to deliver and, on balance, is worth the cost.

Scientific summary

Background

For older people and those with complex needs, the transition from hospital to home is risky. Approximately one in five patients experience an adverse event; two-thirds of which could be prevented or ameliorated. Rates of unplanned hospital re-admissions have increased over the last 10 years, particularly for older people. Systematic reviews of transition interventions reveal that most include multiple elements, with strategies prior to and following discharge and variable success. Knowing which of these elements represent the active ingredients is important for the management of scarce resources. There is some suggestion that interventions that seek to involve patients are most effective, but no definitive evidence.

Here we address this gap in understanding.

Aim

To investigate whether greater involvement of patients and their families can improve patient experience and safety at transitions.

Objectives

Work package 1

- To capture the experiences of older patients (75 years +) and their families during the transition from hospital to home.
- To identify opportunities for greater patient involvement in care.

Work package 2

- To explore how high-performing teams successfully deliver safe care to older people during transitions.

Work package 3

- To develop a measure of the quality-of-care transitions.

Work package 4

- To develop and test the acceptability of the transition intervention.

Work package 5

- To assess the feasibility of the 'Your Care Needs You' (YCNY) intervention and trial processes.

Work package 6

- To determine the clinical effectiveness of YCNY in a full cluster randomised controlled trial (cRCT).
- To determine the cost-effectiveness of YCNY compared to care as usual.

Methods

Work package 1: Qualitative study of patient and family experience of care transitions

A longitudinal ethnographic study in two NHS Trusts exploring the involvement and experience of 32 community-dwelling older patients (75 years +) and 18 family members during their transitions from hospital to home. Semistructured interviews at up to five points from hospital admission to 3 months post discharge, supplemented with non-participant observations and go-along interviews. Data were analysed using thematic analysis.

Work package 2: Qualitative study exploring how high-performing teams support care transitions

A positive deviance approach to identify four wards and six general practices showing exceptionally low or reducing rates of hospital re-admissions compared to similar services. Semistructured interviews and focus groups with 157 multidisciplinary staff and observation of 9 discharge meetings. Interviews and focus groups were recorded and transcribed verbatim and data analysed using a pen-portrait approach.

Work package 3: Development and testing of a care transitions measure

Measure development and pilot testing

A conceptual model of the transitional period developed based on findings from literature reviews and WP1 findings. A pool of items tapping into the constructs of this model was refined and simplified resulting in a two-part measure: Partners at Care Transitions Measure 1 (PACT-M1) and Partners at Care Transitions Measure 2 (PACT-M2). PACT-M1 underwent pilot testing with 15 older patients. Descriptive statistics and frequencies were calculated for each questionnaire item.

Measure validation

A validation study measuring internal reliability and internal consistency in the PACT-M1 and PACT-M2 within one NHS hospital trust. Eligible patients were administered the questionnaire by telephone and post. Reliability was assessed using Cronbach's alpha and exploratory factor analysis used to evaluate dimensionality. Response rates and missing data were scrutinised and subscales refined.

Work package 4: Development and refinement of a care transitions intervention

Intervention development

Functional resonance analysis method was used to model the transition process. This revealed the informal handover of four functional care activities to patients and families at discharge: management of medications; daily activities; health conditions; and escalation processes. The programme theory proposed that for patients to manage these activities they would need to practise them in hospital. A scoping review and stakeholder workshops supported the development of the Partners at Care Transitions (PACT) intervention.

Formative evaluation and intervention refinement

A formative evaluation to explore the acceptability and usability of the prototype intervention and identified implementation strategies. On 3 wards in 1 NHS trust, we recruited 25 older patients and interviewed 15 staff and 6 informal carers. Data collection using semistructured interviews and observations of intervention use. Analysis was iterative, using template analysis and group discussions leading to intervention refinement and the YCNY intervention.

Work package 5: Trial feasibility study of Your Care Needs You

A cRCT was conducted to test the feasibility of the YCNY intervention and trial methodology. Wards caring for older people were recruited and randomised on a 3 : 2 basis. The feasibility of accessing hospital re-admission data for our primary outcome together with other trial critical data capture was assessed. We also tested the process of data collection for our secondary outcomes, patient experience (measured by PACT-M) at 5, 30 and 90 days post discharge. We aimed to recruit 20 older patients per ward, over a 4- to 5-month period. The feasibility of conducting a full cost-effectiveness analysis was evaluated. Acceptability, usefulness and feasibility of the intervention and implementation package were assessed by observations and interviews.

Work package 6: Cluster randomised controlled trial assessing the clinical effectiveness, cost-effectiveness and fidelity of Your Care Needs You with parallel process evaluation

Clinical effectiveness trial data collection

A cRCT of YCNY. Forty wards, covering a range of specialties and routinely caring for older people, from 11 NHS Trusts were randomly allocated equally to 1 of 2 arms: intervention or care-as-usual (control). Wards were stratified by specialty, the percentage of patients over 75 years, and NHS trust. Our primary outcome measure of 30-day unplanned hospital re-admission rates (routine data) required a sample size of 5440 based on a 10% attrition rate to detect a 4.5% difference in re-admissions with 80% power. We used a nested cohort to assess the quality of transitions (PACT-M and the validated Care Transition Measure-3) as secondary outcomes. Allowing for clustering and attrition, this required a sample size of 1000 for 80% power.

Clinical effectiveness analysis

Analysis for the primary outcome (30-day unplanned hospital re-admissions) included treatment allocation, ward type, baseline ward re-admission rate, percentage of patients 75 + and gender as fixed effects and trust and ward as random effects to account for clustering. Two sensitivity analyses were conducted as well as a secondary complier-average causal effect analysis to assess the impact of fidelity on outcomes. The same model specifications were used for the 60- and 90-day re-admission data. A mixed-effects linear regression approach was used to analyse patient experience measures [PACT-M and Coleman's Transition Measure-3 (CTM-3)] data and similar sensitivity analysis to those for the primary outcome were applied. All other data were summarised descriptively.

Fidelity data collection and analysis

We used the modified Conceptual Framework for Implementation to underpin frame fidelity assessment. Data were gathered from all intervention wards using a 26-item measure covering intervention delivery, receipt, engagement with and usefulness. An overall score from 0 to 3 was calculated, with three representing high fidelity.

Health economics analysis

Short-term cost-effectiveness (during the first 90 days post discharge) was calculated from the mean costs of intervention delivery (intervention group) and service utilisation (both groups) and quality-adjusted life-years (QALYs) for each group generated within the trial. Long-term (over a lifetime) cost-effectiveness was calculated using a de novo hybrid model comprising a decision-tree model and a partitioned survival model.

Process evaluation data collection and analysis

A process evaluation on eight intervention wards (across four trusts) to understand how the intervention was delivered, received and used by staff and patients and how this was shaped by context. We interviewed 23 staff and 19 patients (pre and post discharge) and conducted 94 hours of ward observations. Interview data in the form of recordings and detailed notes were analysed using constant comparison to identify themes/subthemes.

Results

Work package 1: Qualitative study of patient and family involvement and experience of care transitions

We identified six themes relating to: a disappointing discharge; delivery and receipt of community care; involvement (in care), choice and decision-making; information provision; physical and social environment; and medicines. While people mostly felt safe and cared for in hospital, many 'handed over' their care and so were unprepared for picking this back up when they returned home.

Work package 2: Qualitative study exploring how teams support care transitions

Three themes were identified that demonstrate how high-performing teams support safe care transitions: building relationships with patients based on a holistic understanding of their needs; having relationships with other staff (within and across teams) based on valuing and trusting one another; and bridging gaps in care by enhanced communication, adjusting patient expectations and adapting to competing priorities. Despite being identified as high-performing, staff

in these teams described that delivering exceptionally safe care was very challenging and only possible for the most complex patients.

Work package 3: Development and testing of a measure of care transitions

Development and pilot testing

Through modelling of transitions and item generation and refinement a measure comprising two parts: PACT-M1 administered to patients shortly after discharge with eight items measuring experiences of preparedness for managing at home and seven safety items measuring post-discharge adverse events; and the PACT-M2, administered 1 month post discharge with eight items measuring the patient experience of managing care at home and the same adverse event items. Participants reported that items were easy to understand and complete.

Measure validation

One hundred and eighty-five patients were recruited. Response rates were 75% (n = 138) at time point 1, 59% (n = 110) at time point 2 and 50% (n = 92) at time point 3. Reliability analyses of the PACT-M1 and PACT-M2 were good (α = 0.84 and 0.92, respectively). The factor analysis revealed a single-factor solution explaining 44% of the variance for PACT-M1 and 60% for PACT-M2. All items were retained.

Work package 4: Development and refinement of a transitions intervention

Intervention development

Guided by stakeholder workshops with patients and staff we co-designed a prototype intervention to support management of the four key functions (see above): knowing more, moving more, managing medicines and escalation. A scoping review and activities to consolidate all available evidence-supported intervention development.

Formative evaluation and intervention refinement

Staff and patients saw the value in, and need for, the intervention, but several challenges with the acceptability and usability of the prototype were identified. Examples include the messages within the booklet not being strong enough and the lack of time to complete the discharge template (by staff). We identified implementation strategies and key changes to the intervention.

Work package 5: Trial feasibility study of the Partners at Care Transitions intervention

We randomised 10 wards (6 to intervention and 4 to control) across 3 NHS Trusts. Subsequently, due to extreme staff shortages, five wards could not participate but were retained and treated according to their randomised allocation. Of 721 patients screened, 161 were recruited (95 intervention, 66 control). Routine primary outcome data were gathered for 90% of participants. Item completion within questionnaires was high. The COVID-19 pandemic meant follow-up data collection ceased early. Patient attrition rate (17.4%; n = 28) was higher than expected (10%). Data on usability, acceptability and implementation were gathered from 10 patients and 17 staff alongside 91 ward-level observations. Staff reported the need for, and value of, the intervention and patients varied in their views about its value and manner in how they engaged with it. Full implementation of the intervention was challenging because of staff shortages, lack of information technology embedding/integration (film and discharge summary), lack of buy-in from the wider ward team and organisational impediments. We responded to these challenges by modifying the intervention and enhancing the implementation strategy.

Work package 6: Cluster randomised controlled trial of the Partners at Care Transitions intervention

A total of 4947 patients from 39 wards were included in the primary analysis cohort. For the nested cohort, 613 participants from 35 wards were recruited.

Clinical effectiveness

There was no significant difference in the primary outcome of unplanned 30-day re-admissions or 60 or 90 days (as odds ratios) between intervention and control. However, at all time points, the rate was lower in the intervention group. *Total number* of re-admissions was also lower in the intervention group at all time points and this reached statistical significance across 90 days post discharge with 13% fewer re-admissions.

At 30 days post discharge, significant differences were observed in PACT-M adverse event items and in the CTM-3 in favour of the intervention but not at other times.

Fidelity

Twenty-three per cent of patients reported receiving booklets and 77% found them useful or very useful. Further, 29% of patients reported receiving the advice sheet for managing at home and 86% found them useful or very useful. Overall fidelity to the intervention was moderate for majority of wards (n = 11, 68.75%) and low for the remaining five (31.25%). Fidelity to the intervention had no impact on re-admissions at 30 days.

Cost-effectiveness

In the short term, differences in costs and QALYs were in favour of the intervention, suggesting that the intervention could be cost-effective. Similarly in the longer term (over a lifetime), the intervention is likely to be cost-effective.

Process evaluation

While the core values of the intervention appeared to be understood and valued by the staff, translating this into practice was oftentimes challenging and the patients interviewed felt they already had the knowledge in the booklet.

Conclusion

- We developed a novel intervention called YCNY to support safety and experience for older people leaving hospital and going home.
- We also developed and validated (PACT-M) to measure patient experience and safety during care transitions.
- A randomised controlled trial of YCNY found some evidence of clinical benefit with the majority of results in favour of YCNY, although only secondary outcomes were statistically significant (total number of unplanned re-admissions after 3 months and the number of patient-reported adverse events after 30 days).
- YCNY is likely to be cost-effective in both the short term and long term.
- Staff valued YCNY intervention, but they struggled to fully implement it in the challenging post-COVID era.

Implications for health care

- There is some promise for promoting safety at transitions from hospital to home through greater involvement of patients and their relatives in their care.
- To optimise the potential gains, staff need to engage differently with patients, and this was not always possible in the current depleted healthcare system.
- The intervention is freely available to all NHS hospitals.

Recommendations for research

- Further research is needed to explore opportunities for developing and delivering an intervention to support patient involvement in care *before* hospital admission.
- Patients found the advice sheet for managing at home (a component of the YCNY intervention) to be the most useful. Further research is needed to develop a systems-integrated patient-friendly discharge summary.
- The methodology of fidelity assessments for complex healthcare interventions requires further development.

Trial registration

This trial is registered as Current Controlled Trials ISRCTN51154948 (WP5) and ISRCTN17062524 (WP6).

Funding

This award was funded by the National Institute for Health and Care Research (NIHR) Programme Grants for Applied Research programme (NIHR award ref: RP-PG-1214-20017) and is published in full in *Programme Grants for Applied Research*; Vol. 13, No. 4. See the NIHR Funding and Awards website for further award information.

Synopsis

Background

First, we outline the background rationale for this research programme based on our understanding at the time of writing the proposal, before going on to briefly describe the literature reviews (unpublished and published) that informed our later work. The transition from hospital to home was identified as high risk, particularly for older patients.[1] As many as one in five experience an adverse event (including, e.g. medication-related events, falls, pressure sores) during this transition, 62% of which could be prevented or dealt with.[2–4] Emergency re-admission rates within 30 days of hospital discharge, a key indicator of quality and safety of transitions in the UK, are higher for those aged 75 years than the general population and have been rising over the last 5 years (16.7% in 2013–4 to 18% in 2021–2).[5]

The safety of transitions from hospital to home for older patients is highly variable and complex depending on the needs of the patient, their support network, levels of frailty and comorbidities as well as access to health and social care resources. Most transitions involve many different people [the hospital team, the general practitioner (GP), community nurse, social worker, family and patient] and the transfer of knowledge between these people.[6] This complexity and variability present a problem for traditional safety management approaches, which are underpinned by 'outmoded theories of control and standardisation of work'.[7] Over recent years, alternative, more flexible and positive approaches to safety management, commonly referred to as Safety II, have emerged.[8,9] This approach aims to build resilience, rather than to prescribe specific actions. Hollnagel[8] outlines four abilities that build resilience: responding to threats and disturbances, monitoring performance as it unfolds in real time, learning from past successes and failures, and anticipating changes in the future.

Although widely perceived as a period of high risk, according to resilience thinking, transitions can also be viewed as an opportunity for both identifying and responding to threats[10] and for taking a fresh look at the care of a patient by a different health professional/s. For example, this might be a chance to check patient understanding or to pick up on and recover from a patient safety incident.

This theoretical shift in emphasis from an approach to risk management based on preventing harm to one that focuses on building resilience coincides with emerging research on the important role of patients and caregivers in promoting safety. We now understand that there is a willingness among patients to share their experiences of care as well as their safety concerns.[11–13] Patients also suggest they are willing to be more involved and more engaged partners in their care especially when they feel that their contribution is clearly valued and necessary[14] but that there may be limits to this.[15–17] Greater engagement of patients has also been shown to reduce the likelihood of adverse events[18] during episodes of care but, at the time of writing this programme grant, only one study in the USA,[19] had explored the involvement of patients and their families in transitions and the impact of involvement on both the safety and experience of care. Here, we argue that the changing status of patients in health care, together with their position as the common denominator in the care pathway, makes them the ideal partners for understanding transitions of care and targets for interventions to promote safety at transitions. Through a series of six work interlinked packages, underpinned by preparatory work, we demonstrate how we moved from exploring the problems of and opportunities for older people's involvement during care transitions through to the development and evaluation of an intervention to improve their safety and experiences (*Figure 1*).

What is the evidence for transitions interventions?

In our original proposal, we described our plans to conduct a review of reviews of transitions interventions. However, when we embarked on this as part of the programme of work, we identified that such a review was already planned.[20] After contacting the authors, we agreed that we would not proceed but instead use the findings from their review to inform our intervention development. Unfortunately, no review was subsequently published. To address this gap, we conducted a rapid review in 2017 of published systematic reviews evaluating transitions interventions for older people.

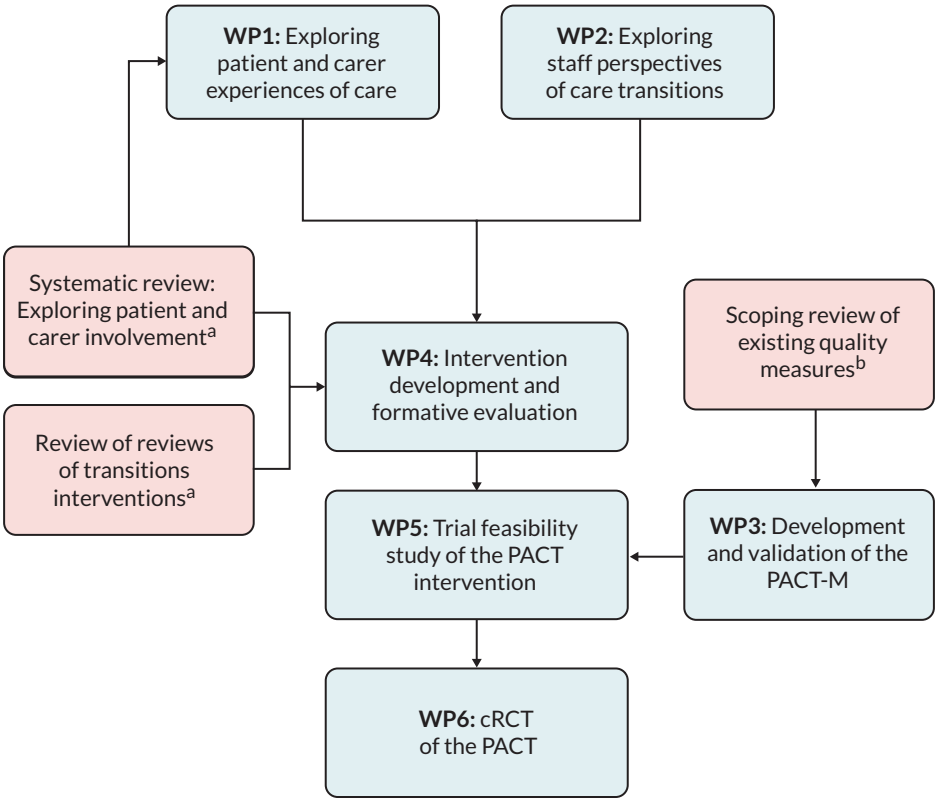

FIGURE 1 Research design pathway showing the relationship between WPs and other streams of work. a, This work is described in the background. b, This review is described in the WP3. Note: Blue boxes indicate planned WPs. Orange boxes show planned preparatory review work. PACT, Partners at Care Transitions; PACT-M, Partners at Care Transitions Measure.

Methods

The primary source of reviews was the meta-review protocol (described above) combined with an electronic search in MEDLINE. Reviews post-dating 2008 were included; this was felt sufficient to capture relevant intervention studies. We located 16 reviews, of which 6 were excluded because they were either (a) not about transitions, (b) focused on single conditions, for example, stroke or hip fractures or a single process, that is comprehensive geriatric assessment or (c) did not focus on older people. One review focused on caregivers of older people.[21] Six of the reviews were narrative[22–27] and four included a meta-analysis[21,28–30] (see *Appendix 1*, *Table 2*).

Key findings

- Most interventions have multiple elements which are provided across the whole transitional period, that is before, during and after hospital discharge.
- Common elements include patient education with or without self-management, medicines reconciliation, co-ordination, monitoring and managing, telephone support, communication, discharge planning, and enlisting the help of community and social services.
- Most trials include the same individual elements, so separating these out to identify the active ingredients is challenging.[21,24–26]
- Multiple element interventions are thought to provide an additive effect or additional value through a change in cultural or organisational factors.[24]
- Transitions interventions which commence well before discharge may offer the greatest opportunity for impact through creating the best preconditions for successful results;[26] however, this is unsubstantiated. Similarly, the number of domains targeted within the ideal transitions in care framework[23,31] is associated with significantly increased success in reducing re-admissions.

- Significant reductions in hospital re-admissions within one systematic review of 92 intervention studies were not found at 1 month[30] (but seen at later time points) and this lag is referred to as an 'investment effect'.[27]
- Subgroup analysis performed within one previous meta-analysis identified that interventions that 'support patient's capacity to reliably access and enact post-discharge care[29]' are 1.3 times more effective than other interventions.

Since this review of reviews, further reviews of transition interventions have been published.[32,33] Facchinetti and colleagues[32] conducted a meta-analysis of 30 randomised controlled trials (RCTs) of continuity of care interventions for older people. Intervention elements were ultimately the same as those reported in other reviews of transitions interventions with the only difference being how they categorised them for subgroup analysis. Their findings supported those of other meta-analyses,[29,30] that although re-admissions did decline 1 month post discharge, the greatest reductions were seen 3 months post discharge. They found that those interventions that encompassed three types of continuity of care (relational, informational and management) were most likely to be effective. This again supports other review findings which suggest that interventions with multiple elements and those that span multiple stages in the transition are more likely to be effective.[23,24,29] Rasmussen and colleagues[33] conducted a narrative systematic review of 11 studies (mixed design) of transitions interventions with multiple elements for older people that covered both pre- and post-discharge elements. Most studies reported lower re-admission rates in the intervention groups. The authors suggested that interventions which had the highest intensity and were delivered over 1 month or more had the greatest effects which again is suggestive of the advantage of interventions with multiple elements. As with other reviews,[21,25,26] deciphering the active ingredients in these transitions interventions remains challenging.

What does patient involvement in transitions look like?

As part of our preparatory work, we also intended to conduct a systematic review of patient and carer experiences of care transitions to help guide the intervention development. We identified a systematic review addressing this question.[34] On further exploration of the literature, we observed that although data on patient involvement in care were available, it had not yet been synthesised. We therefore agreed that rather than repeat an existing review, we would conduct a systematic review of patient involvement in care. Our now published, systematic review found that, for older people during transitions of care, being involved is a challenging nuanced, dynamic and interactional process mediated by many things, in particular, interactions with healthcare professionals (see page 8 within Murray *et al.*[35]). It highlighted the various states of involvement that patients can occupy in an attempt to 'reach in' to care including 'resigned non-involvement' (a consequence of failed attempts to try to be involved), passive involvement (receiving information) and active involvement (asking questions). These states indicated potential impacts on personal safety and resilience. The findings from the review informed our programme of research by informing the analysis of work package (WP) 1 interview data, informing content/wording of the intervention, contributing to the interpretation of findings from WP4 and by reinforcing the need that although the intervention would be primarily targeted at patients it needed to be bidirectional to ensure that involvement was recognised, encouraged and supported by staff.

Patient and public involvement and engagement and equality, diversity and inclusion

Aims of patient and public involvement and engagement

- To ensure our research was grounded in their experiences and ideas about what they would find helpful during transitions.
- To influence decision-making across every WP including the study approaches, materials and relatable outcomes.
- To act as our critical friends, providing feedback on documents and ideas.

Establishing the patient and public involvement and engagement group

We aimed to involve people aged 75+ years with experience of transitions and their caregivers. First, we held introductory workshops within diverse community organisations supporting older people. We recruited eight members, some of whom later left the group due to personal reasons or sadly, passing away. We recruited people who were older than 75 years, but we did not explicitly ask about protected characteristics. The groups were mixed in terms of age, seven were of White British ethnicity and two were known to have registered physical disabilities. There was a gender

balance. Members of the group attended our programme management group meetings (in rotation) and we also had an independent lay member on our Trial Steering Committee.

Co-ordination of the patient and public involvement and engagement group

The PACT patient and public involvement and engagement (PPIE) group was facilitated by the Programme Manager and PPIE Lead, who met face-to-face every month at the Bradford Institute for Health Research up until the COVID-19 pandemic. Communication methods between meetings and after the pandemic were tailored to member's preferences and needs and included telephone calls, postal activities and individual home visits. Agendas were developed by the PACT team and were sent out prior to meetings.

Equality, diversity and inclusion

Equality, diversity and inclusion was considered in two ways within our programme of research: within the PPIE group itself and in terms of the development and delivery of the intervention. As stated in *Establishing the patient and public involvement and engagement group*, we attempted to recruit a diverse membership (considering ethnicity, sociodemographics, gender and disabilities) and we consider that this was achieved. In the running of the PPIE group, we listened, learnt and adapted our interactions to ensure that everyone could take part and that all voices could be heard. Our PPIE group did advise us on ways to improve accessibility of the intervention through larger fonts, simple language and use of images, but our intervention was delivered in English and the video and written materials were not translated. Therefore, the intervention is likely to exclude those without the ability to understand English and who did not have family members who could support, and this is a limitation.

Results

The group contributed significantly to WPs 1–4. This encompassed an exploratory phase to understand their experiences, active participation in co-design workshops, and invaluable input into refining the intervention and informing processes for trial stages. In WP5 (pre-pandemic) and WP6 (post-pandemic), they received regular updates and contributed to dissemination plans.

The three examples given below display the range of activities undertaken.

Contributing to the development of a measure of patient safety in work package 3

The group reviewed an existing patient experience-reported questionnaire, which highlighted the need to develop a new measure. The group contributed to the identification and refinement of items and supported consultation into wider community groups to discuss and further improve the measure.

Co-design of intervention in work package 4

Four co-design workshops were held with multiple stakeholders (including patients, caregivers and healthcare staff). We used practical activities linking the concept of involvement to everyday life experiences and hospital transitions (see Murray *et al.*[36]). They provided suggestions for improvements to care (as possible intervention components), reviewed and refined all prototypes and later iterated intervention components. Two members took part in acting roles in the patient film component and some supported facilitation into wider community groups to support intervention refinement.

Comprehension of research materials

The panel contributed significantly to reviewing research materials, improving content, readability, recruitment documents for the feasibility and main trials, and dissemination outputs (e.g. lay summaries of publications).

Discussion and conclusions

Throughout the study, we reflected and adapted our approaches to PPIE based, in part, on member feedback. We built rapport and trust enabling members to express their needs and expectations, which were addressed. They taught us how to 'do' PPIE better within a culture of mutual respect.

They ensured we were inclusive in our approaches. The PPIE meetings developed to be structured with accessible materials such as large fonts, colourful and user-friendly activities to facilitate discussions. We purposefully strove for power sharing and 'critical friendship' through practical seating arrangements (mixing researchers and members

together), creative interactive methods, and creating a safe space between co-design workshops to ensure that they could contribute in a less time-pressured and familiar setting. Some panel members were able to act as critical friends more than others because they felt comfortable sharing 'negative' comments. Researchers explicitly invited other members to challenge and provide honest opinions.

Relational dynamics within the group were identified as a challenge. There were different communication needs and expectations between members which were to some extent labour-intensive and time-restricted, with occasional conflicts. For example, navigating situations with patient/carer dynamics brought unique challenges, such as caregivers advocating for decisions related to their loved ones, particularly among older stroke survivors who required adjustments to how activities are delivered. Individuals had different roles in their past work lives, which influenced the confidence of members with formalised institutional practices such as agendas, meeting formats, speaking up in groups, reviewing documents and ability to critique, that we often take for granted in research. Future grant proposals may seek to ensure adequate resources (e.g. time, facilitators and finance) are available to ensure that research involvement can undertake more inclusive practices.

Early in the process, we understood that members found aspects of the study difficult to follow due to the frequency of meetings and the complexity and speed of the programme. It was important to ensure their feelings and thoughts were heard, valued and considered, as their insights and reasoning were invaluable to our work. To remind PPIE members of their valuable contributions, our agendas included a summary of the previous discussion and suggestions indicating those that had been taken forward or not with a rationale. This afforded them valuable insight into the research process. They valued our openness and insights into the research process. We celebrated their contributions annually and included a certificate outlining their contributions and thanking them.

Researchers and PPIE members worked together to create meaningful and respectful involvement that contributed significantly to the research processes, outputs and shared learning.

Reflections: learning, challenges and limitations

Key critical moments of influence are integral to understanding the journey from PPIE plans to actual practice. One such 'moment' involved grasping the concept of involvement from a patient and caregiver perspective. We observed that this concept was sometimes understood by group members and at other times was lost. We attempted to stretch the lens of our PPIE group beyond their own experiences through our earlier PPIE meetings and specifically through a card-sorting activity based on our literature review about 'types' of patient involvement (see Murray *et al.* 2020[35]). Our aim was to enable them to contribute to intervention development in a more holistic way.

Linked with this, during our intervention refinement and iteration work, we observed that patients and the public (beyond the PPIE group) imagine their involvement differently to how they enact this in the moment. So, for example, saying that they *would* ask questions in the hospital but also demonstrating through conversation that they lacked knowledge about their medications. This imagined 'empowered sense of self' that is to some extent disconnected with practical realities has been particularly challenging in this programme of research and requires further exploration.

Our second critical moment related to the challenges of encouraging the role of a 'critical friend'. We committed ourselves to addressing and reducing these power imbalances; however, grasping knowledge of the NHS system, research processes and theories can be overwhelming, especially for older people with multiple comorbidities. Learning and resetting patient expectations, both regarding their role in PACT and reiterating the limitations of the research process, have been essential.

Being transparent about which of member suggestions were taken forward or not with reasons helped them to tangibly 'measure' their contributions. A source of tension for the panel was their early expectation of task-based work when the focus was on exploring patient involvement and ensuring they understood the programme of research and why it was needed. Researchers were able to reassure the panel about how these basics were worth spending time on and were foundational in their contribution to the research.

Concerning limitations, the COVID-19 pandemic significantly disrupted group dynamics, shifting the focus toward information sharing rather than gathering, as many feasibility trial decisions had already been made.

Work package 1: Patient and carer experiences of care transitions

Aims

- To capture the experiences of older patients (aged 75 years and older) and their families during the transition from hospital to home.
- To identify opportunities for greater patient involvement in care, particularly where this contributed to greater individual- and organisational-level resilience.

Data collection

We conducted a 'focused ethnography' comprising semistructured interviews supplemented with observations and 'Go-Along' interviews to capture patient and carer experiences across the care transition from admission to 90 days after discharge.[37] We planned to recruit 30 patients but recruited 32 (aged 75–99), and 18 family members, from various wards across 2 NHS Trusts in Yorkshire. Our purposive sampling strategy covered diverse ethnicities, people with or without caregivers, people aged from 75 years to the 'oldest old' (85+ years), those with or lacking in capacity (where suitable support was available), or with language or cognitive impairment. Data were collected at up to five time points throughout the patient's journey from admission to hospital to 3 months after discharge or on re-admission if sooner. Post-discharge interviews were conducted in intermediate care settings or family homes. Semistructured interviews were digitally recorded and transcribed verbatim. Observations and go-along interviews were recorded through researcher field notes.

Analysis

Case histories were created through inductive analysis of transcripts and field notes, alongside listening to the original recordings of the interviews. These were organised around demographic details, data collection time point alongside accounts about experience, involvement, vulnerabilities and resilience and a participant summary was written.

Themes were identified through thematic analysis,[38] which included *within* case histories and how these changed over time and *between* case histories. Informed by our systematic review of patient involvement (see *Background*)[35] and the work of others in this area[39] we also undertook and published a more detailed but separate thematic analysis of involvement as a specific phenomenon.

Key findings

Overall, most patients reported being happy with their hospital care. They felt that staff were kind and caring. When people felt cared for, they were willing to 'overlook' issues with which they were less satisfied such as slow response times from staff.

People were generally satisfied with the care they received from primary and community healthcare professionals. Access was the main issue sometimes leading to a hospital re-admission. When primary care staff were proactive in receiving patients back into the community (e.g. by contacting patients), people felt more confident about staying at home. People also felt received when they had an active social support network, or when packages of care were resumed post discharge. People felt 'unreceived' if there was noone (formal services or informal) to help them transition from hospital back into their home in terms of practical and emotional support.

Six themes were identified (see *Appendix 2*, *Table 3* for a description of the content of themes). These were: a disappointing discharge; delivery and receipt of community care; involvement, choice and decision-making; information provision; physical and social environment; and medicines. Our more specific analysis on the phenomenon of patient involvement revealed that being involved in care in the hospital was a dynamic, interactional and relational process that was challenging 'work' for patients and often invisible as it combined cognitive (e.g. decision-making) and emotional (e.g. worrying about bothering staff with questions) and instrumental (e.g. getting dressed) dimensions (Hardicre *et al.*[40]). When in hospital, most patients entrusted their 'involvement work' to professionals and while most of the time this was desired, other times it became compliant behaviour so as not to be a burden to staff. A minority of patients attempted to retain their autonomy by resisting hospital processes; however, this was challenging and resource-intensive. In general, the data seemed to indicate that those who either entrusted their involvement work to professionals or

experienced failed attempts at retaining autonomy found managing at home during the early post-discharge period more difficult.

Limitations

Although some 'go-along interviews' were conducted, these were difficult to achieve. The movement of patients was often sudden and difficult to predict. Therefore, most of the data about patient experience of discharge came from interviews shortly after returning home, and ward-level observations of discharge. Despite attempts to capture evidence of resilience, narratives mostly captured individuals' vulnerabilities.

Relationship to other work packages

This WP was informed by earlier preparatory review work on patient and family involvement in care transitions (see *Background*). The findings from WP1 supported the development of the patient experience measure in WP3. WP1 also informed intervention development in WP4 by feeding into the functional resonanceanalysis method (FRAM) that identified the key activities undertaken by patients during transitions.

Further information

Full details of our findings in relation to the phenomenon of patient involvement have been published and are available as an open access paper.[40]

Methods for go-along interviews are available in Hardicre.[41]

Work package 2: Healthcare perspectives on excellence at transitions of care

Aims

- To explore strategies used by high-performing teams to deliver safe transitions of care to older people.
- To understand the contextual factors that are important in facilitating safe transitional care for older people.
- To understand the challenges to delivering safe transitional care for older people and to explore how high-performing teams demonstrate resilience to overcome these challenges.

Data collection

A positive deviance approach to explore what is done well to achieve safe care transitions was undertaken.[42] We used our previous experience of positive deviance and older people's wards to inform the protocol.[43] To identify high-performing hospital and general practice teams (with low or improved re-admission rates), we analysed 30-day emergency re-admission rates for patients aged ≥ 75 years. High-performing teams were purposively sampled to represent a range of healthcare contexts. From a sample of 151 GP practices and 85 hospital specialties across the north of England, we selected 6 high-performing GP practices and 4 hospital specialties. We aimed to recruit a minimum of six staff per site. Using purposeful and opportunity sampling, we recruited and interviewed 157 staff from different professional backgrounds (n = 58 matrons/nurses/healthcare assistants; n = 14 discharge coordinators; n = 30 doctors; n = 25 allied health professionals and n = 30 administrators/others). These represented 68 hospital staff, 68 primary care staff and 21 community staff. We primarily used focus groups to collect data which were recorded and transcribed verbatim. Single and two-person interviews were employed where staff were not available for interview. Contextual data about planning for discharge were gathered through observational work in hospitals.

Analysis

A pen portrait approach was used to analyse the data.[44] This helped us to synthesise large amounts of data from multiple methods into rich accounts of how transitions were achieved for each participating team. The higher-order themes were then identified in discussion with the wider team.

Key findings

We found that staff within the high-performing teams facilitated safe transitions in three interlinked ways: by getting to know their patients and needs well and sharing this within their own team and with others who would be responsible

for their care. They knew these wider team members well, valued their roles and trusted them and they bridged gaps within the system, predicting and eradicating problems, communicating what to expect and adapting continuously as things changed. Each of these factors contributed to safe transitions, but the safest transitions involved the enactment of all three. Unfortunately, this was rare, and these exceptionally safe transitions were only possible where significant time was invested by staff because patients had particularly complex needs (medical and/or social).

Limitations

The teams were selected based on rates of unplanned hospital re-admissions. However, re-admissions can be impacted by factors other than care quality. For example, re-admissions can vary depending on specialty[45] and levels of deprivation of the local population, alongside access to community-based services.[46,47] Participating General Practices and hospital Trusts were not all part of the same service, so it was not possible to understand how a system could contribute to safer transitions.

Relationship to other work packages

The knowledge garnered from WP2 was used continuously throughout the research as reminders of what staff did and did not do routinely within transitions. More directly it contributed to WP4 in the development of a theory for our intervention and in our scoping review work of interventions delivered in health and social care.

Further information

Full details of our WP2 protocol and findings have been published and are available as open access papers.[48,49]

Work package 3: Development and testing of a quality of transitions measure

Aims

The absence of a measure of the quality-of-care transitions that fit with the UK context and that addressed the whole transitional period led us to develop a new measure. We aimed:

- To develop a framework of core components of the transition from hospital to home.
- To develop, pilot and validate a measure to evaluate the quality and safety of care transitions relevant to older patients.

Data collection and analyses

We adapted an established four-stage measure development procedure[50] which included: (1) conceptualising the components of care transitions; (2) item development; (3) conducting a modified Delphi process to prioritise items; and (4) pilot-testing the measure for its acceptability. We subsequently undertook a validation study to explore factor structure and assess the measure's psychometric properties.

Measure development stages 1–4

Conceptualising the core themes of care transitions for the PACT programme of research involved combining data from a review of existing transitions measures and transitions interventions and data from WP1. This information was then reviewed within the team and by our PPIE panel to generate a transitions conceptual model with eight components for the future measure. Seventy-six items were mapped to the eight components, around half of which were about what patients knew, understood and were doing before leaving hospital to prepare for going home and the rest were about managing care at home afterwards. The items were reviewed, refined and assessed for comprehension and language (with our PPIE group) and then entered into two rounds of the Delphi process to prioritise items based on relevance and content validity with input from 25 experts including psychologists, sociologists, healthcare researchers and gerontologists.

A measure was developed with two versions: PACT-M1 (see *Report Supplementary Material 1*) capturing immediate post discharge and assessing preparedness for discharge and PACT-M2 (see *Report Supplementary Material 2*) capturing the experiences of managing at home. Both included eight items on five-point Likert scales and additionally captured adverse events.

We carried out pilot testing of the PACT-M1 with patients recruited from one NHS teaching hospital. Patients were recruited if they were 65 years and older, had spent at least one night in hospital, were expected to be discharged to their own homes, were English speaking and could provide informed consent. We recruited 28 participants and administered the PACT-M1 by telephone up to 1 week (n = 15) after discharge. Descriptive statistics and frequencies were calculated for each questionnaire item.

Validation study

Patient participants were recruited over a 6-month period from a large teaching NHS Foundation Trust across 10 wards covering a range of specialties mostly caring for older people. Inclusion criteria were: English-speaking population aged 65 years or older, with at least one overnight stay in hospital and due to be discharged to their own home. In total, 70% of the people approached agreed to participate, of whom 185 were recruited. The PACT-M was administered by post and telephone shortly after discharge (PACT-M1) and then at 30 and 90 days after discharge (PACT-M2). Response rates were 75% (n = 138) for the PACT-M1. For the PACT-M2, 110 participants (60%) responded.

Reliability was assessed by calculating Cronbach's alpha and exploratory factor analysis was performed to evaluate the dimensionality of the measure. Principal components analysis was used to examine the factor structure of the measure on correlation matrices, using pair-wise deletion. Subscales resulting from this analysis were assessed for reliability using Cronbach's alpha.

Key findings

The PACT-M captures perceptions of *preparedness* for managing at home as well as managing at home and this represents the whole transitional period which makes it novel. Pilot testing of PACT-M1 indicated it to be easy to understand and to be acceptable to older patients. Although most participants rated their experiences of care highly, they also reported problems (through adverse events reporting within the measure) in their care.

The validation study showed PACT-M1 to be a unidimensional scale with 'good' internal reliability and consistency. Similarly, PACT-M2 was also identified as a unidimensional scale with internal consistency and excellent internal reliability.

Limitations

The sample within the validation study was recruited from Oxford and was made up of White British patients with the cognitive capacity to consent, mostly living with their partners. Although this might reflect the characteristics of the patient population, this does mean that the measure requires further testing across more diverse patient populations.

Relationship to other work packages

This WP was underpinned by the knowledge and findings from WP1 and the review of reviews of transitions interventions. The measure was used in WP5 (trial feasibility study) within a booklet comprising other measures to assess questionnaire response rates and therefore future recruitment targets. It was also used in the full trial (WP6) as a secondary outcome measure assessing the clinical effectiveness of PACT intervention.

Further information

Full details of the development and validation of the PACT-M have been published and are available as open access papers.[51,52]

Work package 4: Development and pilot testing of the Partners at Care Transitions intervention

Aims

- To consolidate the evidence from WP1 to WP2 to develop a theory of change (stage 1).
- To develop an intervention using co-design methods (stage 2).
- To conduct a formative evaluation to assess the usability and acceptability of the intervention and to inform an implementation package (stage 3).

Stage 1: Developing a theory of change

Data analysis

We used findings from WP1 to WP2 and a method called FRAM[53] to understand and map the functional activities undertaken by patients and families over the transitional period (from hospital admission to 30 days post discharge). Discussions involving those who collected the data in WP1 and WP2 were convened to ensure that the model reflected their understanding. The model was finalised after a sense-checking exercise with key stakeholders including members of the wider research team, which included clinical staff, patient representatives, improvement scientists and academics.

Key findings

The resultant FRAM model (*Figure 2*) clearly depicted an approach to transition in which staff performed key care activities and that at the point of discharge responsibility for these activities was handed back to patients, caregivers and community services. This handover to patients and families was recognised as a safety gap whereby inadequate preparation for taking back responsibility of care led to difficulties in management of post-discharge activities. Four key activities were identified and these included managing take-home and ongoing medications, daily activities, their health conditions and escalation processes. This led to the development of a theory of change which postulated that patients must practise these activities while they are still in hospital to prepare them for being at home. By doing so, patients would experience a better and safer transition home which would in turn reduce the chances of an avoidable re-admission back into hospital.

Limitations

Functional analysis resonance method is normally applied at a more granular level than seen here. The scale of the transitional period meant that we had to abstract out to a higher level. The modelling was not undertaken in consultation with key stakeholders but was sense-checked with them after development.

Stage 2: Designing the intervention

Within our research programme, we identified key principles for intervention development. These were, in part, based on the need for an intervention to support involvement to be bidirectional (encouraging patients to 'reach in' and staff to 'reach out'). The result of this was the need for the intervention to include (1) tangible resources that enabled patients and families to reach into the system and (2) creating a scaffolding to help patients systematically reach in. The former referred to fixed visual components and the latter to the development of flexible staff-facing components. At this stage, the intervention development focused primarily on the fixed components.

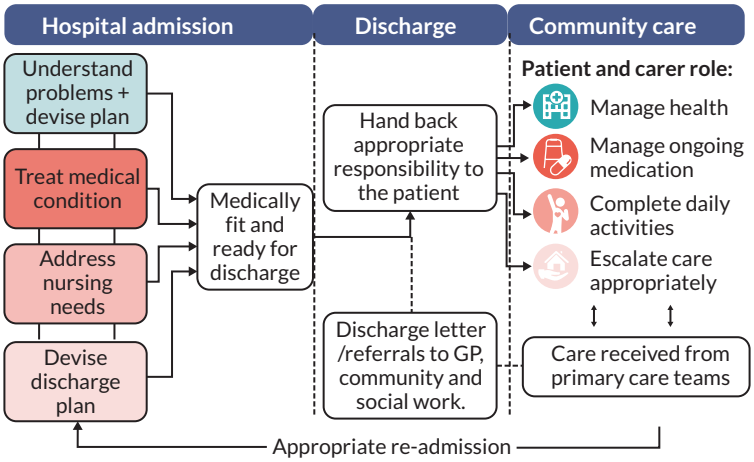

FIGURE 2 Simplified version of the FRAM model.

To inform and develop the fixed components, we held four co-design workshop sessions, performed a scoping review, and consolidated existing evidence (from WP1 to WP2). The four key activities represented within the FRAM model (see *Figure 2*, right-hand column) provided a framework to structure and boundary the intervention. The workshops were attended by patients and staff, and explored personal stories, identified facilitators to transitions, developed content and format ideas, and reviewed the prototype. Between the workshops we consolidated the evidence creating a list of 62 ideas for content and, through consultation, reduced these to 31. Through discussions with a design team who attended the stakeholder workshops we developed the prototype intervention which we called 'Getting Home, Staying Home'. This comprised:

- a patient-held booklet
- a ward induction leaflet
- a stand-up question card
- a 'your hospital record' sheet
- patient-friendly discharge letter.

These (see *Report Supplementary Material 3* for images of these components) represented the fixed components of the model. The flexible components (i.e. how staff might engage with each of the key activities such as encouraging patients to move more, practise managing medicines etc.) were intentionally left until WP5 as discussions with staff during training sessions.

Stage 3: Formative evaluation and iteration

Methods

The formative evaluation of the prototype fixed intervention components was conducted in one hospital Trust across three wards. We aimed to recruit 25 patients and 15 ward staff to interviews. Patients were eligible if they were aged 75 or over; likely to return to their own homes; were English-speaking; and an inpatient for at least one night. Patients were excluded if they: resided over a 30-mile radius of the hospital; were at the end of their life; or were unable to give informed. Caregivers of eligible patients were also invited to take part. Staff who were likely to interact with the intervention because of their roles were also recruited. Data were gathered through semistructured interviews (audio-recorded where possible), observations of care and intervention use (recorded on structured contact forms) and examining the physical intervention components. Data collection was informed by the capabilities, opportunities, motivation and behaviours (COM-B) model[54] where the behaviour of interest was engagement with the intervention components.

Analysis

Data analysis was iterative using a template approach structured around the main aims of the substudy. Regular team discussions during data collection of emergent findings in line with COM-B were held, leading to a consensus on areas for improvement and implementation.

Key findings

Twenty-five patient and caregiver participants and 15 staff were interviewed with an additional 20 visits to ward to observe intervention delivery. Engagement with various intervention components was variable and influenced by personal factors. Those who engaged were already more involved in their care. The hospital record sheet and question card were not used and were difficult to use, respectively. Although the intervention was viewed as important, the messages within the booklet did not convey strongly enough the need to get involved. Various challenges, including worry about providing the wrong information and lack of time, meant that the patient-friendly discharge summary was often not completed by staff.

To address these issues, we reduced the number of intervention components, the messages in the booklet were condensed and strengthened, the patient-friendly discharge summary simplified and implementation tools developed. The new intervention was called 'Your Care Needs You' (YCNY) and comprised a booklet, patient-friendly discharge summary and a short film. To support staff in introducing the intervention (increase self-efficacy), prompt cards were

designed, and a short training session was developed to educate staff on the benefits of the intervention for patient safety and to demonstrate the behaviours that would be helpful for supporting patient involvement.

Limitations

The study was intentionally small but lacked diversity across study participants. It was conducted across two specialties, so the generalisability of the intervention and implementation package to other ward types was unclear.

Relationship to other work packages

The findings from this WP contributed to the iteration of the fixed components within the intervention and informed the development of an implementation package in preparation for the feasibility trial in WP5.

Further information

Full details of the development and formative evaluation of the intervention have been published and are available as open access papers.[36,55–57]

Work package 5: Trial feasibility study

Aims

- To explore the feasibility of screening and recruitment processes and retention of patients for the full trial.
- To determine the most accurate way of collecting routine data at baseline, primary outcome data (hospital emergency re-admissions), secondary outcome and health economic data.
- To explore how feasible, acceptable and useful the YCNY intervention components are to patients, caregivers and staff, and to develop an enhanced implementation package via a qualitative evaluation.

Trial set-up and data collection

We ran a cluster randomised controlled feasibility trial (cRCT) between late 2019 and early 2020 on hospital wards (clusters) in England where > 40% of patients were routine > 75 years. Ten wards were randomised to YCNY or usual care using an unequal allocation ratio (3 : 2).

Implementation of the intervention was planned in four stages: introducing the intervention and exploring options for the flexible components alongside identification of a coach; roles and responsibilities decided; skills and knowledge training session; and follow-up support.

We aimed to recruit up to 20 patients per ward. Eligible patients were > 75 years old, planning to be discharged home, stayed overnight on participating wards and could read and understand English. The trial assessed the feasibility of delivering YCNY and the trial methodology through recruitment rates, and outcome completion rates, with follow-up at 5, 30 and 90 days, and a qualitative evaluation involving observations and interviews.

Analysis

All analyses were exploratory, and data were summarised descriptively. Categorical data were summarised by count and frequencies and continuous variables as means, standard deviations (SDs), medians and interquartile ranges (IQRs).

Key findings

Of the 14 randomised wards, 4 could not take part as planned [i.e. across the allotted time scale and/or were unable to deliver the intervention but were retained as allocated for analysis according to intention to treat (ITT)]. One further ward withdrew leaving nine participating wards. Routine data for the primary outcome were obtained for 148 patients (87 = intervention, 61 = control). Scrutiny of the data suggested that further manual checks would be required to ensure accuracy. We recruited 121 patients (72 = intervention, 49 = control) for the follow-up study. Data collection for the secondary outcome data stopped prematurely because of the COVID-19 pandemic. Completion rates for

questionnaires including health economic data were high and although response rates were lower than anticipated (75% vs. 85%), there were little missing data, including for health economic measures. Qualitative data were gathered from 9 patients, 19 ward staff and through 91 observations of care. Acceptability and usability of the booklet varied across patients and the discharge summary was challenging to complete. Staff were confused about their roles but again were keen on the principle of the intervention. They prioritised delivery of the fixed components, rarely focusing on developing and delivering the flexible components of the intervention. Changes were made to the research processes, intervention components and to the implementation package in preparation for the full trial. One of our recommended changes included involving hospital volunteers to support with delivery of intervention to avoid over burdening busy staff. However, COVID-19 meant that the implementation package needed to be delivered remotely, and some opportunities were lost such as involving hospital volunteers. To facilitate remote delivery of the intervention, we developed a microsite which included videos showing how to introduce the booklet, background information, downloadable prompt cards and a range of resources as incentives to take part. A separate online training session was developed with follow-up support. The final fixed intervention components are available here: https://pact.yqsr.org/patient/. The logic model for the final intervention is shown in *Figure 3*.

Limitations

Increasing pressures on wards (e.g. poor staffing, changes in leadership) meant that some participants felt unable to deliver the intervention. Due to these dropouts, the scope and depth of our qualitative evaluation were reduced. Our sample of recruited participants almost exclusively identified as White British, making it difficult to say how feasible the trial procedures and intervention would be for people from different ethnic backgrounds.

Relationship to other work packages

The feasibility trial informed the final intervention components and the implementation package, alongside trial processes for WP6.

Further information

Full details of the protocol and the findings from WP5 have been published and are available as open access papers.[58,59]

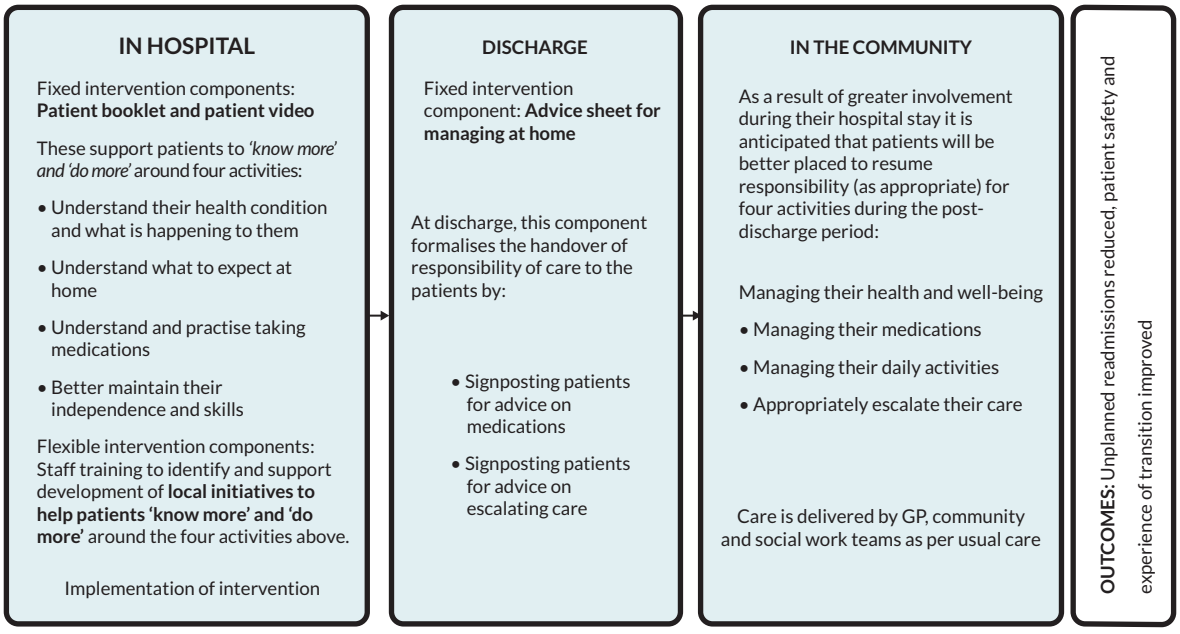

FIGURE 3 The intervention logic model.

Work package 6: Cluster randomised controlled trial assessing the clinical effectiveness, cost-effectiveness and fidelity of the 'Your Care Needs You' intervention including a process evaluation

Clinical effectiveness trial and fidelity assessment

Aims

- To assess the effectiveness of the YCNY intervention in reducing unplanned hospital re-admissions in patients aged 75 years and over.
- To assess the effectiveness of the YCNY intervention in reducing the time to, the number of, and duration of unplanned hospital re-admissions in patients aged 75 and over.
- To assess the effectiveness of the YCNY intervention at improving the quality and experience of transitions and quality of life in patients aged 75 years and over.
- To assess the fidelity of the YCNY intervention, exploring contextual factors that affected the way the intervention was used in practice and what was delivered and to the estimate the effect of the intervention when delivered as intended through a complier-average causal effect (CACE) analysis.

Methods

Trial set-up and data collection

We planned to recruit 40 wards that routinely provide care for people aged 75 years and older, from up to 11 NHS hospital Trusts in England (see *Appendix 3* for full details of methods). Wards were not eligible if they were: non-NHS funded/private inpatient wards; had few patients aged 75 years and over; did not have regular medical input such as discharge wards; were acute medical admission; were participating in an intervention trial which included similar follow-up time points to this trial. Wards were randomly allocated to one of two arms: YCNY or care-as-usual (control). Wards were stratified by ward type (specialty), the percentage of patients over 75 years (split by ≤ 66% and > 66%, based on the feasibility cRCT) and NHS trust.

The primary outcome was unplanned hospital re-admission (Y/N) at 30 days post discharge and secondary outcomes included: unplanned re-admission (Y/N) at 60 and 90 days; time to unplanned re-admission; number of unplanned re-admission; duration of unplanned re-admissions; quality of transition, including patient experience and adverse event rate measured using the PACT-M (see *Report Supplementary Material 3* and *Report Supplementary Material 4*) and Care Transition Measure-3 (CTM-3).[60] Hospital re-admissions, including time to, duration and number were assessed using routinely collected data. All other secondary outcome data were collected through a nested cohort study requiring individual patient consent and completion of questionnaires.

The sample size for the primary outcome was 5440 consisting primarily of non-individually consenting patients admitted to participating wards (pseudonymised sample) but also including those consented patients from the nested sample. The sample size for the secondary outcome of patient experience of transitions (the nested study) was 1000 participants (approximately 25 patients per ward). Eligible patients were those aged 75 years and older who were expected to be discharged back to their own homes; who stayed as an inpatient on a participating ward for at least one night; and who were able to give informed consent (or personal consultee if lacking in mental capacity). Patients were excluded if they met any of the following criteria: had previously been recruited to the study (e.g. during a different admission or on a different ward); required an interpreter (e.g. because they are unable to read or understand English); 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; identified as being at the end of their life/subject to fast-track discharge to palliative care; or were unable to give informed consent and where a suitable personal consultee could not be identified. Recruitment was undertaken by local research nurses and supported by the main research team where resources were scarce. Baseline data including patient demographics, admission information and comorbidities were collected in hospital after recruitment. Secondary outcomes (nested study) were collected via postal questionnaires administered shortly after discharge and at 30 and 90 days post discharge.

Intervention training and delivery

The impact of COVID-19 meant that we had to change our original plans of delivering training and implementation support on the wards to online. Our intervention wards received a 1- to 2-hour online interactive training session that was open to all staff who would have a lead role (acting as facilitators) in delivering the intervention. This included an introduction to patient involvement and the role of staff in this, a brief introduction to the fixed YCNY components (booklet, film and advice sheet for going home), and an open discussion session about how the fixed components could be delivered and plans for developing the flexible intervention components (to facilitate patients) to 'know more' (through asking questions) and 'do more' (e.g. with activities of daily living and practicing taking medications). Wards were free to decide upon how and when the fixed and flexible components were delivered; however, it was made clear that the intervention should be delivered at the ward level and that all components (except the advice sheet for managing at home) should be delivered early in the patient's stay on the ward. Posters advertising the ways in which patients could 'know more' and 'do more' were tailored to the wards after training sessions. These posters, alongside the advice sheets and booklets, were provided in hard copies to the wards. Follow-up support and monitoring were offered to the ward facilitators. The underlying aim of this training was to promote positive attitudes towards delivering the intervention by helping staff understand the benefits for patients of being prepared for being at home, to provide practical support (fixed components) and instructions for how to enact behaviours to deliver safer transitions and how they could model and support these behaviours. We also provided further online training offering more detailed information. After training, wards were offered a 1-month embedding period before the patient recruitment was due to commence.

Analysis of data to assess clinical effectiveness of the intervention, including CACE analysis

Ward and participant recruitment were presented in separate Consolidated Standards of Reporting Trials (CONSORT) flow diagrams for the primary (routine data) and nested cohorts. Response rates to participant questionnaires in the nested cohort were summarised overall and by treatment group (see *Appendix 3* for full details of analytical methods).

Ward and patient baseline characteristics were presented by treatment group for the primary and nested cohorts, as randomised.

The primary analysis model included treatment allocation, ward type, baseline ward re-admission rate, percentage of patients 75 and over and gender as fixed effects and trust and ward as random effects. Two sensitivity analyses were performed: (1) assessment of the robustness of the model to multicollinearity related to ward type ('Elderly and Intermediate Care' and 'Other') and (2) inclusion of index length of stay as a fixed effect. The impact of fidelity to YCNY (rated as 'low', 'moderate' or 'high' – see fidelity data collection and analysis methods below) was assessed using a secondary CACE analysis. A subgroup analysis (< 85 and ≥ 85 years of age) was conducted by including the interaction between age category and allocation in the primary analysis model.

The same fixed and random effects as specified in the primary analysis model were used in all secondary analyses unless otherwise stated. Re-admissions at 60 and 90 days were analysed using the same model specification as the primary analysis. Time to first re-admission was analysed using Cox's proportional hazards model and deaths were included using right censoring. The number of re-admissions across 90 days was analysed using a negative binomial, zero inflated model. Total duration of re-admissions across 90 days was analysed using a mixed-effects linear regression model and included the average length of stay at ward level as an additional fixed effect.

For the nested cohort data, CTM-3 and PACT-M experiences were analysed using the same covariates as the primary analysis using a mixed-effects linear regression. The primary time point of interest was pre-specified as 30 days post discharge. The PACT-M Safety (number of adverse events experienced) was analysed using a mixed-effects Poisson regression model due to severe deviations from the normality assumption and representing a count outcome. Sensitivity analyses were undertaken using the same models described above but restricted to those recruited during the first 5 months. No adjustments for multiple testing were applied across all analyses. Serious adverse events were reported descriptively.

Fidelity data collection

We adopted a modified version (for complex healthcare interventions) of the conceptual framework for fidelity implementation (CFIF)[61,62] to identify a set of criteria to measure the fidelity of the YCNY intervention (see *Appendix 4* for full details of methods). The criteria included measures of adherence (which patients received the intervention and frequency of delivery) and moderating factors (patient engagement, staff engagement, quality of delivery). We did not gather data on how the various intervention components were delivered in practice.

Fidelity assessment mainly captured delivery of the fixed components (i.e. booklet, advice sheet and film) but also attempted to capture some aspects of the flexible components (i.e. the ways in which ward staff supported patients to 'know more' and 'do more' in hospital in relation to the four key functions of the intervention). Data sources included researcher assessment of staff engagement in training sessions, research team observations intervention delivery, facilitator feedback and patient questionnaires.

Fidelity assessment analysis

The total fidelity assessment included 27 items (see *Appendix 6*, *Table 23*). Each fidelity item was scored from a range of zero to three. Scores of 0 to < 1 are indicative of 'low' fidelity, 1 to < 2 of 'moderate' fidelity and 2 to ≤ 3 of 'high' fidelity.[63] These findings were fed into the CACE analysis (see *Analysis of data to assess clinical effectiveness of the intervention, including CACE analysis*).

Key findings

Clinical effectiveness findings with sensitivity analysis

A total of 4947 patients from 39 wards (YCNY = 2525, care-as-usual = 2422) were included in the primary analysis cohort (see *Appendix 3* for a summary of findings and *Appendix 5*, *Figure 4*). Six hundred and thirteen participants from 35 wards were recruited to the nested cohort with 435 (71.0%) completing the T1, 400 (65.3%) completing T2 and 321 (52.4%) completing T3 (see *Appendix 5*, *Figure 5*). Baseline characteristics of wards and patients were generally balanced across treatment groups (see *Appendix 5*, *Tables 6–9)*.

There was no difference in the primary outcome of 30-day re-admission (Y/N) [odds ratio (OR): 0.93, 95% confidence interval (CI) 0.78 to 1.10; $p = 0.372$] and no evidence that treatment differed by age group (OR 0.89, 95% CI 0.66 to 1.20; $p = 0.447$) (see *Appendix 5*, *Tables 11* and *13*). There were no significant differences in re-admission (Y/N) at 60 and 90 days (OR 0.85, 95% CI 0.70 to 1.03; $p = 0.100$, and OR 0.82, 95% CI 0.67 to 1.01; $p = 0.061$, respectively), time to first re-admission [hazard ratio (HR) 0.87, 95% CI 0.75 to 1.01; $p = 0.076$] and total duration of re-admission (adjusted difference in means: −2.26, 95% CI −4.65 to 0.12; $p = 0.063$) (see *Appendix 5*, *Table 12*). However, all results were in favour of YCNY and there were larger differences in re-admissions (Y/N) at 90 days (18% reduction in unplanned re-admissions) providing evidence of a possible effect of YCNY. There was a 13% reduction in the number of re-admission across 90 days [incidence rate ratio (IRR) 0.87, 95% CI 0.76 to 0.99; $p = 0.039$] which was significant in favour of the intervention.

There was no significant difference in PACT-M experience across all time points and CTM-3 and PACT-M safety items at 7 and 90 days post discharge (see *Appendix 5*, *Tables 20* and *21*). At 30 days, a significant difference was observed for the CTM-3 (adjusted mean difference 4.93, 95% CI 0.46 to 9.40, $p = 0.031$) and PACT-M safety items in favour of the intervention (IRR 0.75, 95% CI 0.57 to 0.99, $p = 0.039$). There were no obvious differences in the number and type of serious adverse events across groups.

Fidelity assessment findings and impact on primary outcome

Overall fidelity to the intervention was moderate for the majority of wards ($n = 11$, 68.75%) and low for the remaining five (31.25%) (see *Appendix 6*, *Table 24*). The mean score for intervention fidelity was 1.26 (range 0.2–1.9; median = 1.35, maximum possible = 3). For 2 wards, 12/26 components were missed due to ward staff capacity. Removing these two wards made no difference to the CACE analysis findings. Fidelity to the intervention had no impact on re-admissions at 30 days.

Limitations

Clinical effectiveness trial

There may be potential bias of re-admissions data introduced by some patients not having re-admission data for a full 90 days as those admitted later would not have been followed up for as long; however, we would assume this would be

consistent across groups and would only impact some secondary analyses as the primary analysis only included those who had re-admission data for 30 days post discharge. Due to the nature of the intervention, cluster randomisation was used. This method of randomisation can be susceptible to selection bias; however, our primary cohort was comprised of all patients who met our eligibility criteria as we were able to extract routinely collected data for all of these patients. The nested cohort had a higher proportion of females and White British people than the primary cohort. There may also be variability in patients from different ward specialties which could influence re-admission rates. Ward specialty was included as a stratification variable in the randomisation and as a covariate in the analysis model to try and control for this.

No adjustment was made for multiple statistical testing, so any significant results should be interpreted with caution.

Within the nested cohort, the recruitment target was not met (613/1000; 61.3%) and, furthermore, follow-up was low, particularly at T3 (321/613; 52.4%). This meant that this part of the study was underpowered to detect our pre-specified effect size. The high attrition rate may also be a concern because those with worse outcomes may have been more likely to drop out of the study.

Fidelity assessment

Although the fidelity assessment of wards measured numerous components allowing for a general fidelity score, some assessments were not completed. For two intervention wards, no ward facilitator interviews were undertaken due to a combination of external factors, resulting in missing data from the ward's overall fidelity.

Only 5 of the 27 fidelity items more directly measured delivery of the flexible components. Four of these were captured through ward facilitator interviews ; where these could not be done, these data were wholly missing.

Due to fluctuating trust in COVID-19 policies, in-person assessment and measurement of intervention delivery was not possible, resulting in some assessments being based solely on self-reporting rather than a combination of methods.

Cost-effectiveness study

Aims

To assess the cost-effectiveness of the YCNY intervention compared to usual care in the

- short-term period (first 90 days post discharge according to the trial) and
- long-term lifetime horizon.

Data collection methods

Data for the short-term cost-effectiveness analysis were derived from: (1) the Routine data set , which includes variables such as unplanned hospital re-admissions at 30, 60 and 90 days, length of hospital stays, ward characteristics and other relevant variables; and (2) the case report form (CRF) data set, which contains patient characteristics and EuroQol-5 Dimensions (EQ-5D) measurements and some resource use utilisation (some hospital services, and primary care and social care) for a subsample of individuals from the Routine data set. In order to consolidate the unplanned hospital re-admissions, the EQ-5D and resource use measurements, all essential for the economic evaluation, we combined both data sets (Routine and CRF data sets) creating a Merged data set. Therefore, only patients contributing to both data sets (Routine and CRF data sets) were included in the analysis.

For the long-term economic evaluation, the same clinical and patient-reported outcomes data were utilised to maintain consistency and, to address long-term projections, external specialised literature and evidence were consulted.

Analytical methods

Individual patient-level data from the YCNY trial during the first 90 days post discharge was used to calculate the short-term cost-effectiveness of the YCNY intervention (see *Appendix 7* for full details of methods). This approach involved

calculating the mean costs and quality-adjusted life-years (QALYs) for each group (intervention and control), along with their adjusted mean differences, presented with 95% CIs.

For the base-case analysis, multilevel mixed-effects generalised linear models (MME-GLM) were estimated for analysing differences in mean costs and outcomes considering the hierarchical structure of the data (wards in hospitals as clusters). Seemingly unrelated regression (SUR) models with robust standard errors (SEs) were also considered to account for potential intragroup (cluster) correlations between costs and QALYs. Costs and QALYs were combined to calculate an incremental cost-effectiveness ratio (ICER).

Economic modelling techniques were used to estimate the long-term cost-effectiveness of the YCNY intervention over a lifetime horizon. For this, a de novo hybrid model was developed, comprising two components: (1) a decision-tree model mapping short-term outcomes across the cohort in three distinct health states: alive without re-admission, alive post re-admission and deceased, and (2) a partitioned survival model to estimate the expected quality-adjusted survival duration and lifetime beyond the trial period. For the extrapolation, we reflected the long-term impact of re-admission on mortality, the implications of survival for the accrual of healthcare costs and considered different mortality hazard assumptions.

Key findings

The short-term base-case results showed that the adjusted differences in total costs (i.e. the intervention delivery costs and the costs of the hospital re-admissions within the trial period) were −£268.78 (MME-GLM) and −£233.75 (SUR model), favouring the YCNY intervention (see *Appendix 7* and *Appendix 8* for full findings, tables and figures). The mean adjusted differences in QALYs were minimal yet positive, favouring the intervention at 0.0057 (MME-GLM) and 0.0071 (SUR model). Given that the YCNY intervention was associated with lower costs and a slight QALY increment, the intervention could be considered as cost-effective. The probability of the YCNY intervention being cost-effective at various QALY thresholds is relatively high (at least 80% probability of being cost-effective in the base case).

The long-term base-case results suggest that the YCNY intervention incurs a marginally higher cost (£38,555) compared to usual care (£38,544), with YCNY generating marginally higher QALYs (3.44 compared to 3.40) (see *Appendix 8*). The ICER for YCNY in this scenario is calculated at £285 per QALY gained. In our probabilistic sensitivity analysis, the YCNY intervention presented a 94% probability of being cost-effective at the £15,000 threshold. In our alternative scenarios, the ICER for YCNY increases to £4065 and £5755 per QALY gained, with a high probability of being cost-effective at the £15,000 threshold.

Limitations

This analysis has some limitations to mention. First, some crucial variables for the economic evaluation (such as the EQ-5D scores) are only available for a smaller cohort of individuals (the nested cohort). This introduces additional uncertainty in our analysis, impacting the precision of our findings. In addition, the presence of a high proportion of missing data for the EQ-5D scores introduced uncertainty and potential bias in the analysis. The high proportion of missing values for healthcare resource consumption in the primary health care and social care setting led us to focus mainly on inpatient hospital costs in our cost-effectiveness analysis. Finally, our long-term economic evaluation exercise heavily depends on external evidence from one study.[64] These limitations underscore the need for cautious interpretation of our findings.

Process evaluation

Aims

- To explore the mechanisms of action, specifically how it was received and used by patients, caregivers and staff.

Methods

Data were collected at eight intervention wards across four trusts. Data consisted of staff interviews (n = 23), patient interviews (n = 19 patients) and ethnographic observations (observations of key activities such as meetings and ward rounds; n = 94 hours).[65]

Two semistructured interviews were conducted per patient (*n* = 38), in the hospital (face to face) and again 6–11 days post discharge (via telephone). Interviews concerned patients' experiences of their health care and of YCNY. Patients (9 female, 10 male) were aged between 77 and 95 years (mean = 84.78 years). All patients were of white ethnicity. Patient data were unable to be collected on one ward.[65]

Semistructured interviews concerning the challenges and facilitators of YCNY implementation were conducted with relevant staff. Staff varied in their level of professional experience (mean years since qualifying = 13.31, range = 1–28 years) and time spent working on the ward (mean = 5.52 years, range = 1–15 years).

Data were analysed by two authors (SH and LS) using a constant comparison approach.[66] After data collection was complete for the first trust, both authors thoroughly read through the data (field notes and transcripts) and independently devised themes and subthemes. Through discussion, they reached consensus and refined the themes. For each subsequent trust, the themes and subthemes were compared to those of the trusts previously analysed, exploring which findings were commonalities and differences across trusts. Once data collection was complete, the two authors met to reach consensus on the overall themes and subthemes across the whole data set. At each stage, the themes and subthemes independently devised by the two authors were almost identical, indicating a high degree of consensus.

Key findings

Understanding the ethos of the intervention

Staff showed enthusiasm for the core aims of the intervention (achieving safe transitions and reducing avoidable re-admissions).[65] Due to pressures on staff's time, however, YCNY could become a task-based activity of giving out the fixed components (e.g. the booklet) rather than a catalyst for culture change. Some patients thought of YCNY as about receiving information via the fixed components, rather than viewing YCNY as a tool to support involvement. Constraints on time meant that staff often did not have the capacity to devise flexible intervention components. However, one ward in our sample was able to introduce an exercise class for patients and a sheet of exercises to enable patients to exercise independently. (See *Report Supplementary Material 4* for the image of key barriers and facilitators to implementing the YCNY intervention.)

Ward-wide, distributed understanding of YCNY was often not present, with responsibility for implementing YCNY sometimes limited to one or two staff members. Shift work and high staff turnover, particularly among non-nursing staff, could mean that there were some staff who had knowledge of YCNY present on the ward at any one time. For one ward, however, knowledge of YCNY was distributed throughout the ward. This was perhaps due to a high number of staff having attended the YCNY training, at the request of the ward manager.

Wider macro context

Pressures on staff time, such as understaffing and COVID-related pressures, were a major barrier to intervention delivery. Staff reported giving out the booklets and advice sheets to patients to some extent. However, most patients interviewed had not received YCNY materials and booklets were rarely visible in patients' rooms. Staff reported lacking the time to sufficiently explain the booklet to patients. Wider organisational policies could also be a barrier to YCNY implementation. For example, pressure to reduce falls did not necessarily sit well with encouraging patients to move.

Suitability for the patients and ward

Staff felt that YCNY was not suitable for patients with dementia and delirium, due to cognitive problems. We had intended for families to be involved by receiving and making use of the intervention to support patients who were less able; however, COVID-19 placed restrictions on visitor access. Staff sometimes felt YCNY was more appropriate for patients who are independent, fit and mobile. However, the patients interviewed often considered themselves to match this description yet did not tend to find YCNY materials relevant to them. These patients often felt that the YCNY materials contained information that was too basic.

Limitations

Limitations include a lack of a diverse and representative sample of patients, particularly in terms of ethnicity. Patients interviewed tended to consider themselves fit, mobile and independent and, as such, the patients interviewed may

not have been those most appropriate for the intervention. Several recruitment challenges impeded data collection including ward closures and staff leave due to the COVID-19 pandemic. As such, patient interview data were unable to be collected on one ward (L) resulting in a lack of patient perspectives for that ward. Family members/caregivers of those with dementia may have valuable perspectives on their role in engaging with YCNY; however, the perspectives of family members/caregivers were also not gained due to recruitment difficulties.

Relationship to other work packages

This WP was informed by work conducted in packages 1–5 and tested the clinical- and cost-effectiveness of the YCNY intervention in a cRCT.

Further information

Full details of the protocol for the main trial have been published and are available as an open access paper.[67] Full details of the methods and findings from the process evaluation are available as open access through Hampton *et al*.[65]

Summary of alterations to programme's original aims and design

We made a number of substantive changes to the design of the programme (see *Table 1*). There were no alterations to the aims of the programme.

TABLE 1 Summary of changes to programme

WP (change to aim or design)	Original plan	Change and scientific justification	Approvals
Preparatory work	To conduct a review of older patient's experiences during transitions	We conducted a systematic narrative review of older peoples' *involvement* during care transitions. A systematic review of older peoples' experiences during transitions had just been published. We felt that exploring the ways in which people experience involvement would be more informative to the programme and to future intervention development.	Not required
WP3	To interview 15 staff from a range of backgrounds	Instead of interviewing staff, we adopted a robust process to establish face validity, comprehensiveness and usability using round table discussions, a two-stage Delphi survey with GPs, geriatricians, research nurses and academics (n = 25), from the PACT research team and Programme Management Group (PMG) members, and consultations with PACT Patient Panel members to prioritise and refine items prior to piloting. This resulted in a much fuller development process than that described in the original application and has enabled us to prepare and submit an additional paper describing the full development process and early testing.	Not required
WP3	To explore the extent to which scores on the PACT-M were associated with the 'quality of the transition' through reviewing, for example completeness of discharge summaries, amount of follow-up care required, re-admissions. We said that we would use these data to define a cut-off point for a 'successful transition' for use in WP5/6	In WP1 and WP2 as well as discussions with clinical experts in the PMG, we questioned the value of this approach. The discharge summary offers very limited insight into the quality of the transition. We agreed to look at a nominal sample of 10 discharge letters to understand if our assumptions were correct. We randomly chose a small sample of 10 discharge letters from recruited participants (within the WP3 validation study). Information on discharge letters mostly referred to GPs, noting the diagnosis, treatment pathway and changes (if any) to patient medication plan. We also observed that the measure covers more domains than the observed discharge letter address.	Not required

TABLE 1 Summary of changes to programme (*continued*)

WP (change to aim or design)	Original plan	Change and scientific justification	Approvals
WP3	We planned to formally assess the quality of transitions with 100 patients over 75 years old across medical and surgical wards	During recruitment, we became aware that experience of transitions appeared to be very different for people who were relatively healthy at time of discharge as compared with those with more illness and disability. We therefore added a sample of 54 patients aged 65–75 in order to gain a better understanding of how the experience of transitions varies according to age and number of conditions. We therefore recruited 185 patients in total, of which 131 were over 75 years old. We believe that this enhanced our understanding of the experience of transitions and that the developed measure will have greater utility in future studies by other researchers who may wish to examine transition in a broader population. The increased sample ensured that we had a more robust statistical analysis and gave us a wider scope to examine additional questions such as how the experience of preparation for transition might impact subsequent self-management. Instead of recruiting participants from the wards specified in the protocol, we expanded our recruitment activities across several wards and we sought to further evaluate the usability of the measure by expanding recruitment to another NHS site. This enabled us to explore the usability of the PACT-M with a more diverse sample of 82 participants.	Not required
WP5 and WP6	To collect data at two time points: 30 and 90 days post discharge	The development of the PACT-M revealed that we needed to measure preparedness for managing at home and that this needed to be administered at home shortly after discharge hence the need to include an additional follow-up time point around 7 days post discharge.	Not required
WP6	Our sample size for the nested study was 782 participants	In WP5 we found that our attrition rate (which in part informed the original sample size) was higher (25%) than anticipated (15%). We adjusted the sample size accounting for this higher rate to 1000 participants.	NIHR was notified of this in the checkpoint report submitted after the completion of WP5
WP6	The original sample size for our primary outcome measure was 7000 participants allowing us to detect a 4% difference in unplanned re-admissions requiring 50 wards	We stipulated having 40 wards in the nested study and 50 in the primary outcome cohort. Restrictions, staffing issues and challenges with obtaining approvals meant that trying to recruit 10 extra wards purely for the primary outcome cohort was unsustainable. We adjusted the effect size to 4.5% (which was still within the expected effect size range) allowing for the same rate of attrition and consequently reduced the number of participants required for our primary outcome measure to 5440.	NIHR was notified of this in a contract to variation requesting an extension to the study due to COVID-19 delays

Reflections on the programme: successes, impacts and issues

Successes

Despite considerable delays to the trial which was due to commence in April 2020, we were able to use the COVID-19 period to refine the intervention, plan for its implementation within a changed healthcare context and ultimately deliver the trial with an extension of 18 months (including 3 months non-costed).

While there was an absence of an impact on the primary outcome of 30-day re-admission (Y/N), there were trends in the data in favour of the intervention and this was more pronounced at 60 and 90 days. This indicates the

fundamental importance of patient involvement in transitional care. In line with our findings, a recent meta-analysis of other transitions intervention trials for older people have shown significant reductions in hospital re-admissions at 90 days post discharge,[30] suggesting a 'lag' or 'investment' effect[27] of transition interventions where the intervention is assimilated into care over time. Our choice of the primary outcome of re-admission (Y/N) at 30 days post discharge was based on earlier work that identified re-admissions at this point as those being most avoidable via good hospital discharge processes.

Previous transitions interventions have included multiple elements for pre and post discharge, often including some kind of patient information, education or involvement (see *Background*). It has therefore been impossible to disentangle the effect of patient involvement from other elements or to understand the importance of those elements that are delivered prior to discharge compared to those that try to support patients when they return home. 'YCNY' focuses only on the involvement of patients and their carers during their hospital stay and planning for being at home. Thus, the demonstration of positive trends through our trial, particularly during extremely challenging times, shows that preparing patients for home by involving them in their care and discharge is an important element, that is, at least to some extent, within the control of the hospital team. Critical to this is the way in which we have conceived patient involvement as more than patient education and self-management and understood the key contextual influential factors. At a more granular level, while we now know that patient involvement is a key active ingredient in safe transitions, we do not fully understand what the key mechanisms of action were for YCNY. During intervention development, we anticipated that capturing how YCNY worked in practice might be challenging if the active ingredients were primarily the flexible components, for example short conversations between patients and staff that changed the dynamics of involvement. This was challenging to measure in the fidelity assessment as most of the measurement items focused on the fixed components and the assessment relied on a few individuals, not all of whom were ward-based. Similarly, the interviews and observations conducted in the process evaluation may not have picked up these subtle but potentially powerful interactions.

Impacts

Our PACT-M has been translated into several languages (Chinese, Danish, Swedish) and used in other transition research studies. We have been working alongside groups in Denmark and Sweden to ensure that all concepts translate in a meaningful way to retain face validity for other populations. There are plans to use the PACT-M as an outcome measure in these transition intervention studies.

We are making our intervention materials widely available and will track downloads. Our intention is to work with a number of organisations to expand our training offer. We are working with Re-engage, an organisation that supports older lonely adults nationwide, to adapt our messages for those living at home (and the volunteer supporters) in preparation for potential hospital admissions.

We have published and presented widely with, to date, 19 academic publications and 36 conference presentations resulting from this work.

Issues

Delivery of our trial was heavily impacted by COVID-19. Aside from delays, we experienced numerous challenges. These included obtaining timely local governance approvals, barriers to ward recruitment (e.g. ward and onsite research nurse staff shortages and redeployment) and patient recruitment (e.g. patients confined to beds and being more tired and unwell, research staff wearing masks and visors making communication more difficult). Delivery of training for the intervention and support for implementation were also hampered as staff did not want external staff coming onsite, other than research nurses at some sites to conduct patient recruitment. This reduced the opportunities to support staff to problem solve in relation to intervention delivery. Delivery of the intervention was also impacted because families and trust volunteers, who we saw as being key, were not allowed on wards. Further, the delivery of the flexible components to support patients in undertaking daily activities was restricted by infection control measures which meant that patients remained in or close to their beds. Nonetheless, over time, we did witness evidence of attempts to return to normal and a keenness among staff to do something new and exciting.

We recognised a recurring theme across a number of our WPs, which is the lack of ethnic diversity. We saw this in WPs 3, 4, 6 and the nested study and process evaluation in WP6. This may impact on the applicability and usability of our intervention and our PACT-M measure to minoritised ethnic groups. We will seek to explore how the measure and intervention materials can be adapted to support wider inclusion.

In WP2 we reported that re-admission rate as an outcome measure could be affected by many factors including hospital specialty, levels of deprivation and access to community services. In WP6 we could only feasibly stratify clusters (wards) by one of these factors (ward specialty). Most of the hospitals that took part in the trial were city-based, but they also serve semi-rural, rural areas and with varying levels of deprivation. Further exploration of the data to understand the relationship between deprivation and outcomes (hospital re-admissions and adverse safety events from the PACT-M) may be worth exploring. In the nested study, we did request information from participants on community healthcare resource consumption; however, there was a high proportion of missing responses. It remains unclear how we would have interpreted this in the health economic evaluation as low use of services may have been indicative of limited access to services in more deprived areas rather than low use of services due to the effect of the intervention.

A key learning point from WP5 was the temptation for staff to 'taskify' the intervention, that is to prioritise the delivery of the fixed components as a set of tasks rather than locally developing and delivering the flexible components. Within our WP6 training sessions, we deliberately held back on introducing the fixed components and instead front-ended the training session to orientate staff as to the thoughts and feelings of a patient who may lack autonomy on a ward. We then explored ways in which staff might support patients to 'know more' and 'do more' (to develop the flexible components) in relation to the four key activities of the intervention. When developing the intervention, we discussed the possibility that delivery of the flexible components might not be directly observable but could actually be the most powerful component because they encouraged a change in staff's attitudes and subsequent behaviours that granted 'permission' to patients to be active partners in their care. In constructing the fidelity assessment, we found the measurement of the flexible components to be more challenging to measure objectively and it is possible that our framework for intervention fidelity assessment did not adequately address the delivery and receipt of these flexible components, with only 5 of 26 fidelity items assessing these. This is worth further consideration in the evaluation of hybrid interventions[68] that might consist of fixed components and those that are more flexible and can be delivered differently by intervention sites. In our measure, we did not address this distinction adequately, but we will be considering in our future work, how to optimise this assessment.

Despite our attempts (through training) to avoid ward staff 'taskifying' the intervention, the process evaluation showed that this did happen. We were unable to enter wards (due to COVID-19 restrictions) to provide implementation support that could have reframed staff thinking and wards rarely took up our offer to provide ongoing offsite support. Neither the process evaluation nor the fidelity assessment was able to indicate the optimum application of the intervention. However, we think it reasonable to suggest that an initial training session followed by onsite support from, for example, a quality improvement team would be required.

Conclusions

We fully explored the phenomenon of patient involvement and developed a model demonstrating its enactment. We exposed the primarily and deleteriously passive role of older patients in hospital that appears to be, in general, acceptable to patients and unintentionally reinforced by staff behaviours. We developed and validated a measure of patient experience and safety during care transitions (PACT-M). Through the novel use of a modelling technique, we reconceptualised discharge as a handover in key care responsibilities back to patients which is not acknowledged and therefore not prepared for within the system. This understanding underpinned our theory and intervention development. Despite challenges mainly imposed by the COVID-19 pandemic, we ran a cRCT on a variety of ward specialties that routinely care for older people. Although there was no effect of the intervention on the primary outcome, we observed trends and significant findings in favour of the YCNY intervention, indicating the importance of patient involvement at transitions. The strongest evidence for transition interventions suggests the use of multiple elements across the whole transitional period. Here we intervened at depth on patient involvement only and we therefore anticipated a smaller impact on outcomes. The restrictions and challenges imposed by COVID-19

substantially exacerbated existing service resource issues. Our fidelity assessment and process evaluation showed that while staff valued the YCNY, they struggled to implement it indicating the need for training and local support for delivery. The intervention is, most likely, cost-effective.

Recommendations and implications

Patients often willingly relinquish their autonomy to become passive recipients of care in the hospital. This is a challenging dynamic to change as it appears, in general, to represent a tacit agreement between staff, patients and families that is rooted in society's relationship with health care as something that is provided for, and received by, the patient. It may be that retaining autonomy in hospital requires a more radical shift in thinking about society's relationship with health and health services. On a more practical level, it suggests perhaps that members of the public could be better prepared *for and encouraged to retain some autonomy, prior to* a hospital admission. We recommend therefore that further research is conducted to explore if being prepared for returning home from hospital, prior to an *unplanned* admission, improves patient safety and experience at transitions.

We recommend that interventions to support involvement of patients for a safer care transition focus on the four functions (tasks that patients are required to take on themselves) identified here: managing health, managing daily activities, managing medicines and escalating care.

Staff were engaged in YCNY training and bought into the concept of supporting patient involvement. We recommend that staff be offered training in supporting patient involvement.

The YCNY intervention was most likely cost-effective and demonstrated reductions in the number of re-admissions at 90 days post discharge and significant differences in self-reported patient safety benefits (fewer adverse events). We therefore cautiously recommend wider adoption and further evaluation of this intervention. It was unclear which ward specialties and which patient cohort was most suitable to receive YCNY. Similarly, we do not know if some patient groups (in relation to protected characteristics) benefitted more than others and therefore the impact of YCNY on health inequalities is unquantifiable. We will explore this going forward within our own data set and suggest that future research studies build in and intentionally question which groups, among the older population, are disproportionally affected by unsafe transitions to home. Further development of fidelity and quality of implementation assessments for complex interventions is warranted including exploration of contextual factors associated with variation in outcomes.

We made two attempts at implementing a patient-friendly discharge summary, both of which were unsuccessful despite patients, the public and staff acknowledging the need for improvements in standard discharge summaries. Our final approach which was tested in the trial was the advice sheet for managing at home which was tailored at the ward level. Although 60% of patients did not recall receiving this, which could be due to implementation failure or recall, 88% of patients who reported receiving it found it useful or very useful. On the one hand, this is encouraging, and we could support wider adoption of this advice sheet; however, it does represent a duplication of effort (wards would have to support delivery of a discharge summary *and* advice sheet) and this approach would not resolve the limitations of the current discharge summary, particularly in relation to its inability to support patients to enact patient involvement in the post-discharge period. As a priority, we recommend therefore that further research be undertaken to explore how systems-integrated discharge summaries can be improved to support patients and families navigate care safely in the early post-discharge period.

Additional information

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Acknowledgements

We are indebted to the committed members of our PPIE Group. We sadly acknowledge the passing of two PPIE members who brought humour and great insights to the sessions. We thank Café West Allerton which hosted a Stroke Survivors Group, West Bowling South Asian Women's Group and Denholme Elders and to the individual members of the public who helped us finalise our intervention prior to the final trial. We also acknowledge Lesley Hughes, Caroline Reynolds, Simon Walker, Jo Langley and Rebecca Partridge who contributed to individual WPs and to Liz Tomlin who supported PPIE during earlier phases of the research. We thank the various and numerous staff across primary care and community practices, and acute hospital Trusts who worked with us through every WP. In particular, we thank the local principal investigators who really embraced the intervention and supported the trial, troubleshooting

and steering us to completion of recruitment. We are also grateful to staff at the University of York who worked tirelessly to ensure the smooth running of the trial and who contributed to the analysis. Finally, we thank the research nurses and the R&D departments across the clinical research network who helped us to deliver the trial under very challenging circumstances.

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Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

Ethics statement

Work package 1 was approved by the Wales 7 Research Ethics Committee (reference: 17/WA/0057, provided 13 March 2017). WP2 received ethical approval from the University of Leeds (reference: 17–0202, provided 18 July 2017 and 17–0234, provided 30 August 2017). The development and validation studies within WP3 were approved by NHS London – Chelsea Research Ethics Committee (ref: 18/LO/0568 provided 27 March 2018). The formative evaluation study within WP4 was approved by the North West Greater Manchester East Research Ethics Committee (ref 18/NW/0636 provided 5 December 2018). WP5 feasibility trial was approved by Wales Rec 7 Research Ethics Committee, Confidentiality Advisory Group, and the Health Research Authority (references: REC 19/WA/0162, CAG 19/CAG/0105 provided 24 September 2019). The WP6 cRCT was approved by the North East Newcastle and North Tyneside 2 Research Ethics Committee, Confidentiality Advisory Group, and the Health Research Authority (references: 20/NE/0020, 21/CAG/0054 provided 26 February 2020).

Information governance statement

All personal information gathered within the course of this research was handled in line with the Data Protection Act (2018) and General Data Protection Regulation (EU GDPR) 2016/679. The data controller and processor was Bradford Teaching Hospitals NHS Foundation Trust. Bradford Teaching Hospitals NHS Foundation Trust organisation/institution is committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data

Protection Regulation (EU GDPR) 2016/679. Bradford Teaching Hospitals NHS Foundation Trust is the Data Controller, and you can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for our Data Protection Officer here: www.bradfordhospitals.nhs.uk/privacy-statement/.

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/KMNG5684.

Primary conflicts of interest: Laura Sheard was lead/co-applicant on two programmes of research funded by NIHR (2019–22) and the ESRC (2021–2). Professor Catherine Hewitt was a member of HTA Commissioning Sub-Board (EOI) 1 April 2016–31 March 2017, NIHR CTU Standing Advisory Committee 1 May 2020–1 May 2024, HTA Funding Committee Policy Group 1 February 2020–30 January 2023, HTA Commissioning Committee 1 November 2015–30 September 2022. Charles Vincent undertook consultancy work through RSM UK and was awarded small payments for guest talks through the Karolinka Institute and other universities. Robbie Foy was a member of Dissemination Centre Advisory Group 1 January 2015–31 December 2019. His institution also received funding from a number of NIHR programme grants. He was a member of the UK Harkness Fellowship Selection Committee, Chair of Independent Steering Groups and Data Monitoring Committees for 6 NIHR-funded studies, and Chair, NICE Implementation Strategy Group. Sarah Hampton was part funded through a NIHR Programme (reference NIHR133742). Beth Woods was a member of HTA Clinical Evaluation and Trials Committee 18 August 2020–30 November 2024. Yvonne Birks was a member of Covid-19 Reviewing Group 1 June 2020–30 September 2020, HTA Prioritisation Committee: Social Care 6 October 2022–31 October 2026. Yvonne also received funding for research from the NIHR School for Social Care, NIHR Research for Social Care, Policy research programme, NIHR Evidence Synthesis Centre, NIHR HS&DR and through ESRC.

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Appendix 1

TABLE 2 Review of reviews of transitions interventions

Study	Details	Intervention components and stage in transition	Main findings
Conroy *et al.* 2011[28]	Meta-synthesis of CGA for rapid discharge from AMUs. In five RCTs with older people	Comprehensive geriatrician-led assessments, pre discharge	CGA might result in lower risk of re-admission compared to nurse-led care but note CGA trials focus on falls only vs. nurse-led trials with multiple conditions
Hansen *et al.* 2011[24]	Narrative review of 16 experimental studies of mixed design mainly involving older people	Most interventions were single component including patient education, discharge planning, medicines reconciliation, appointment scheduling, transitions coaches, patient-centred discharge instructions, home visits or other types of planned follow-up (telephone/face to face), patient hotline. Delivered pre discharge, bridging or post discharge	No evidence of benefit in terms of mortality, re-admissions, functional ability and quality of life. Although post-discharge telephone calls were common types of successful bundled interventions, two RCTs testing them in isolation found no evidence of benefit
Hesselink *et al.* 2012[25]	Narrative review of patient handovers across 36 RCTs, half of which involved older people	Most transitions interventions included multiple components. None were single-component interventions. Components were medicines reconciliation, GP in-reach, telephone hotline, liaison nurse etc. Mainly delivered pre discharge and as bridging interventions	Evidence of benefit in terms of hospital use, patient status, primary care use and adverse events but one quarter of studies showing differences at baseline and use of inappropriate measures for measuring effective handovers
Laugaland *et al.* 2012[26]	Narrative review of studies and reviews exploring interventions to improve patient safety for older people at transitions. Included 12 reviews, 11 RCTs and 10 descriptive studies	Multiple-component interventions which included discharge planning with post-discharge support, educational sessions for patients and caregivers and medical students, key co-ordinators, mediation reviews, discharge counselling, pharmacist telephone follow-up, pharmacy transitions co-ordinators. Interventions delivered pre discharge, bridging and post discharge	Common feature across reviews is that discharge planning combined with discharge support yielded greatest effects. No evidence for the 'validity' of one component over another. Some suggest that interventions delivered early in hospital stay that were multidisciplinary, multicomponent and involved patients reduced adverse events
Allen *et al.* 2014[22]	Narrative review of 12 RCTs of transitions interventions for older people	Interventions included multiple components: patient self-management education, discharge assessment and care planning, medicines reconciliation, communication between providers, community follow-up. Interventions delivered prior to *and* after discharge	Despite self-management being a common type of intervention, there was limited outcome evidence in relation to this across studies. Evidence of significant reduction in hospital re-admission rates in some studies
Leppin *et al.* 2014[29]	Meta-analysis of 42 trials, many of which involved older people specifically focusing on patient capacity and capabilities	Most studies including between two and five intervention components. Components included telephone follow-up, telemedicine, education and self-management, home visits, medicines reconciliation, care co-ordinators and transitions coaches	Significant reduction in early re-admissions. Interventions with more components, including more staff involvement and supporting patient capacity for involvement more likely to be effective in reducing re-admissions
Burke *et al.* 2014[23]	Narrative review of 66 studies of mixed design mostly involving older people	Patient education, medicines reconciliation, improved communication across teams, telephone monitoring, telephone calls, telemedicine, visits in clinic, home visits, enlisting help of social and community support	Interventions covering more domains of the ideal transitions in care framework, associated with great success in reducing re-admissions

TABLE 2 Review of reviews of transitions interventions (*continued*)

Study	Details	Intervention components and stage in transition	Main findings
Rodakowski *et al.* 2017[21]	Meta-analysis of 15 RCTs of discharge planning for caregiver of older people	Most studies reported interventions with more than two components. Components included caregiver assessment, medicines reconciliation, demonstration of caregiver tasks, teachback techniques showing caregiver skills, follow-up visits and home visits, linking to community support. Intervention delivered pre discharge through to post discharge	Discharge planning with caregiver involvement resulting in significantly fewer hospital re-admissions at 3 and 6 months
Le Berre *et al.* 2017[30]	Meta-analysis of 92 RCTs of transitional care interventions for older people	Patient education, medicines reconciliation, phone calls, medication management, home visits, telemedicine. Many interventions involving pharmacy input	Significant reduction in hospital re-admission rates at 3, 6, 12 and 18 months post discharge. Some evidence that providing post-discharge telephone support and medicines management linked with better outcomes. Patient education and communication between different healthcare providers were the most frequent intervention components so unable to explore if they contributed to better outcomes

AMU, acute medical unit; CAG, comprehensive geriatric assessment.

Appendix 2

TABLE 3 Overview of findings and summary of themes identified in WP1

Theme	People struggled to get GP appointments. Calling ***999*** or NHS***111*** was done as an alternative by some people, resulting in admission to hospital. Getting things like continence pads and mobility aids could also be difficult. Sometimes new care packages started late, and this led to a few people being re-admitted. Overall, people felt in limbo, outside hospital care but not quite in any community care.
Overview	Most people said they felt safe and cared for in hospital, even when they had complaints about aspects of their stay. Patients especially valued relational aspects of care, like smiling, being listened to, and having a joke with staff. Going home was desired but the first week or so could be difficult. People felt more confident about being and staying at home when they had support from family and friends, and could access care from community services, like the GP.
Physical and social environment	In general, ward environments reduced peoples' autonomy and independence. Sedentary behaviour was common, often to reduce risk of falling; some people found it more difficult to walk and move around once back at home. Lots of things were done for people and so they lost confidence and were out of practice at doing their normal activities when they returned home. People struggled with levels of light and noise and the temperature of the wards.
Information provision	Being informed is a key facilitator of patient and carer involvement. For some people, it is the way that they want to be involved. Information needs to be given more frequently and in a way that is useful – avoiding overly technical medical language and not just given verbally (it is often forgotten and so it cannot be used later, or by caregivers who are often not present during key conversations between staff and patients).
Medicines	Most people did not understand their medicines – what they were, what they were for, or when and how to take them. This sometimes caused problems at home. Sometimes people chose not to take their new medicines because they were confused about them. Some people were worried about what to do with old medicines that had been stopped in hospital. A few people took their old medicine as well as, or instead of, their new ones.
Involvement, choice and decision-making	People wanted to be kept informed about their care and wanted to share information about their health concerns with staff but rarely voiced this. People did not want to be a nuisance and so didn't speak up even when asked if they had any questions. When it came to decisions about treatment/care most people left this to doctors. Being able to choose where they were discharged to was very important to people. People did want to be involved and have more control over things like using the toilet, washing themselves and moving about in hospital. Some family members described getting information about discharge and future care as a 'battle' and felt they were treated as a nuisance.
A disappointing discharge	Sometimes discharge from hospital was sudden and unexpected, and at times people felt ejected and unimportant. Discharge was also often delayed, and people spent a long time waiting to go home, often being moved to different wards; this was disorientating. Most people said neither they nor their caregivers were involved in making decisions about discharge.
Delivery and receipt of community care	People struggled to get GP appointments. Calling ***999*** or NHS***111*** was done as an alternative by some people, resulting in admission to hospital. Getting things like continence pads and mobility aids could also be difficult. Sometimes new care packages started late and this led to a few people being re-admitted. Overall, people felt in limbo, outside hospital care but not quite in any community care.

Appendix 3 Summary of analytical methods and findings from main trial (work package 6)

Abstract

Background: Transitions from hospital to home are risky for older people and those with complex needs. Systematic reviews of transitions interventions reveal that most include multiple components, but this is costly and evidence on which components contribute to outcomes is needed. Patient involvement may be an important component, but this requires confirmation.

Objective: To assess the clinical effectiveness of an intervention in improving the safety and experience of care transitions for older people.

Trial design: Cluster randomised controlled trial.

Participants: 11 National Health Service acute hospital trusts and 42 wards (clusters) routinely providing care for older people. Patients aged 75 years and older planning to transition from hospital to their own homes.

Intervention: A patient involvement intervention called Your Care Needs You delivered at the ward level.

Outcomes: The primary outcome was unplanned hospital re-admission rates within 30 days of discharge obtained through routine data. Secondary outcomes included re-admissions at 60 and 90 days post discharge from routine data and experience of transitions, patient-reported safety events, quality of life and healthcare resource use at 7, 30 and 90 days post discharge from a nested cohort of individuals.

Randomisation: Ward as the unit of randomisation from varying medical specialties randomised to Your Care Needs You or care-as-usual on a 1 : 1 basis.

Blinding: Due to the study design, it was not feasible to blind participants, ward staff, research nurses or members of the study team. Statisticians did not see primary outcome data until after the statistical analysis plan was signed off to minimise bias.

Results: There was no significant difference in unplanned 30-day re-admission *rates* or 60 or 90 days between intervention and control. However, at all time points, the rate was lower in the intervention group. The total number of re-admissions was also lower in the intervention group at all time points reaching statistical significance across 90 days post discharge with 13% fewer re-admissions than the control. At 30 days post discharge, patients in the intervention group reported a better experience of transitions (Coleman's Transition Measure-3) and significantly fewer safety events.

Conclusions: Patient involvement may be an important component of complex transitions interventions for older people.

Methods

Given that the YCNY intervention would involve patients and families receiving materials by the bedside as well as staff interacting with patients to support them to 'know more' and 'do more', we surmised that the risk of contamination between individuals (both patients and staff) on the same ward would be high. We therefore opted to randomise at ward level to minimise this risk.

Sample size

Based on similar interventions targeting re-admission (1) and an 18% baseline risk of re-admission for older patients, we anticipated a 4–6% absolute difference in re-admission rates at 30 days between control and intervention wards. Using a 4.5% reduction in re-admissions, 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.

A nested cohort for individual data was powered based on the secondary outcome of transition quality using the PACT-M (measures experience and safety at 7, 30 and 90 days post discharge).[52] With a mean difference of 2.7 points, SD of 9, and 80% power, α 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.

Randomisation

Wards were randomly allocated in an equal allocation ratio (1 : 1) independently by the York Trials Unit using minimisation software minimPy (2) and stratified by ward type (specialty), the percentage of patients over 75 years (split by ≤ 66% and > 66%, based on the feasibility cRCT) and NHS trust. Allocations were concealed until the PACT team (programme manager, research fellows and research nurses) notified wards about their allocation.

Analysis

Analyses were conducted in R (R Development Core Team, R Core Team. *R: A Language and Environment for Statistical Computing*. R Foundation for Statistical Computing [Internet]; 2011;**1**:409. URL: www.r-project.org) and Stata v18 (StataCorp. *Stata Statistical Software: Release 18*. College Station, TX, USA: Stata Press; 2023) following the principles of ITT and reported according to CONSORT guidelines for cluster randomised trials.[69] A detail statistical analysis plan was reviewed by the Trial Management Group and Trial Steering Committee and signed off prior to data analysis. This is available through the International Standard Randomised Controlled Trial Number Registry – https://doi.org/10.1186/ISRCTN17062524

Participant and data flow

Ward and participant recruitment have been presented in a CONSORT flow diagram for the primary and nested cohorts. Routinely collected data were received from trusts and included baseline and recruitment period measures for wards and re-admission data for patients within wards. Confidentiality Advisory Group (CAG) approval was given for the collection of routine data (ref: 21/CAG/0054). Data were requested via local research and development departments or via NHS Information Specialist. Patients were informed about the request for data via leaflets and posters on the ward and contact details were provided for patients to opt out. We requested data on all patients aged 75 years and who were coded as discharged to their usual place of residence. We then checking that usual place of residence did not include care home resident who were thereafter excluded. The sample was anonymised at the NHS trust before safe transfer back to the research tea. Total number of wards and patients with re-admission data were presented by treatment group as were the numbers and reasons for exclusion from the primary analysis.

Response rates to participant questionnaires were summarised overall and by treatment group.

Baseline characteristics

Ward and patient characteristics were presented by treatment group for the primary and nested cohorts, as randomised. No formal statistical comparisons were undertaken. Continuous measures were reported as means, standard deviations, median, minimum, and maximum and categorical data as counts and percentages.

Primary cohort

Primary analysis

The number of re-admissions and deaths at 30, 60 and 90 days were presented by treatment group.

The final analysis model included treatment allocation, ward type, baseline ward re-admission rate, percentage of patients 75 and over and gender as fixed effects and trust and ward as random effects. The pre-specified model (including hospital and ward as random effects) did not fit the structure of the data so were excluded. Two wards had missing baseline re-admission rates and were imputed using a simple linear regression model with ward type,

percentage of patients 75 and over and average age as predictors. Two sensitivity analyses were performed: (1) assessment of the robustness of the model to multicollinearity related to ward type ('Elderly and Intermediate Care' and 'Other') and (2) inclusion of index length of stay as a fixed effect. The impact of fidelity to YCNY at ward level ('low', 'medium' or 'high') was assessed using a secondary CACE analysis with a two-stage instrumental variable approach (random group allocation as the instrumental variable). A subgroup analysis (< 85 and ≥ 85 years of age) was conducted by including the interaction between age category and allocation in the primary analysis model.

Secondary analyses

All secondary analyses were analysed using the same fixed and random effects as specified in the primary analysis model unless otherwise stated. Re-admission at 60 and 90 days were analysed using the same model specification as the primary analysis. Time to first re-admission was analysed using a Cox's proportional hazards model and deaths were included using right censoring. The number of re-admissions over 90 days was analysed using a negative binomial, zero inflated model due to overdispersion. Total duration of re-admissions over 90 days was analysed using a mixed-effect linear regression model and included average length of stay at ward level as an additional fixed effect.

The Care Transitions Measure 3 items (CTM-3) is a patient-centred measure of the quality-of-care transitions and transforms onto a 0–100 scale with a higher score indicating a better-quality transition. The PACT-M is a validated measure of the experience and safety of moving from hospital to home. Scores on experience are calculated as the raw sum of each of the items and range from 0 to 32, with a higher score indicating a better-quality transition. Scores are considered valid if at least seven items are completed.

The PACT-M also measures the incidence of seven adverse events following discharge from hospital, which participants are asked to answer with a yes or no response, with the additional option of 'not applicable' for items four and six. Scores are calculated as the total number of adverse events reported by participants and range from 0 to 7, with a higher score indicating a greater number of adverse events experienced. Scores are considered valid if at least five items are completed.

Care Transitions Measure-3 and PACT-M experience were analysed using a mixed-effects linear regression using the same covariates as the primary analysis. The primary time point of interest for the nested cohort was pre-specified as 30 days. The PACT-M safety (number of adverse events experienced) was analysed using a mixed-effects Poisson regression model due to severe deviations from the normality assumption and representing a count outcome. Sensitivity analyses were undertaken using the same models described above but restricted to those recruited during the first 5 months. No adjustments for multiple testing were applied across all analyses.

Four questions that capture potential causes for post-hospital syndrome and serious adverse events were summarised descriptively by group using counts and percentages. Receipt of the intervention was summarised descriptively. The concurrent validity of the CTM-3 and PACT-M was assessed using Pearson's correlation coefficient for safety and experience score separately and by time point. A summary of ward moves was presented by treatment group.

Results

Participant flow

A total of 42 wards were randomised to either YCNY (n = 21) or care-as usual (n = 21). Three wards withdrew from the study completely and provided no data (YCNY = 2, care-as-usual = 1); one due to change in ward function and two due to concerns over staffing and recruitment from ward managers. Four wards (YCNY = 3, care-as-usual = 1) withdrew from the nested cohort but still provided routine data. Screening of participants for the nested cohort took place between 8 November 2021 and 31 March 2023; however, re-admissions were collected only for the first 5 months of recruitment at sites (between November 2021 and November 2022).

Primary cohort

Thirty-nine wards (YCNY = 18, care-as-usual = 21) from 11 trusts returned routinely collected data (see *Appendix 5*, *Figure 4*). During the first 5 months of recruitment, a total of 8906 patients were admitted to participating wards and re-admission data were returned for 5483 patients (YCNY = 2765, care-as-usual = 2718). However, 546 (YCNY = 240,

care-as-usual = 296) of the patients had to be excluded (152 were recruited outside 5-month recruitment window, 32 did not have an overnight index stay, 11 were followed up for < 30 day and 141 died during index stay).

A total of 5147 patients (YCNY = 2160, care-as-usual = 2537) were followed up for at least 30 days and 4947 of these patients (YCNY = 2525, care-as-usual = 2422) were included in the primary analysis which exceeded the target of 4896. Two-hundred (4%; YCNY = 85; 3%, care-as-usual = 115; 4.5%) patients were excluded as they died within 30 days and had no re-admission before death was recorded.

Nested cohort

Screening logs included 8319 patients across 35 wards (see *Appendix 5*, *Figure 5*). Wards screened on average 237 patients (mean = 237.7, minimum = 58, maximum = 600). Of the 8319 patients screened, 2542 (30.6%) were eligible, 625 (24.6%) consented and 613 (98.2%) were discharged and subsequently recruited [331 (54%) care-as-usual and 282 (46%) YCNY]. Reasons for ineligibility and refusal (where available) are given in *Tables 4* and *5* (see *Appendix 5*), respectively.

Baseline characteristics

Primary cohort

Wards and patients showed similar characteristics across treatment groups (see *Appendix 5*, *Tables 6* and *7*).

Nested cohort

Participants were admitted into hospital between 26 October 2021 and 27 March 2023. The nested cohort has more females (58%) (see *Appendix 5*, *Table 8*) compared to the primary cohort (41%) (see *Appendix 5*, *Table 7*). There are also more White British patients in the nested cohort (94%) when compared to the primary cohort (89%). Participants showed similar characteristics across treatment groups (see *Appendix 5*, *Tables 8* and *9*).

Primary cohort

Primary analysis

A total of 895/4947 (18%) patients had at least one unplanned hospital re-admission within 30 days post discharge, 436 (17%) in the YCNY and 459 (19%) in the care-as-usual group (see *Appendix 5*, *Table 10*). There were 289 (6%) deaths by 30 days (YCNY: 130; 5% and care-as-usual: 159; 6%).

There was no difference in 30-day re-admission (Y/N) between the two groups (OR 0.93, 95% CI 0.78 to 1.10; $p = 0.372$) (see *Appendix 5*, *Table 11*). Results were robust to sensitivity analyses and did not change findings when assessing multicollinearity, inclusion of index length of stay as a fixed effect and impact of fidelity to YCNY.

Secondary analysis

At 60 and 90 days, re-admission (Y/N) across groups were similar (OR 0.85, 95% CI, 0.70 to 1.03; $p = 0.100$, and OR 0.82, 95% CI, 0.67 to 1.01; $p = 0.061$) (see *Appendix 5*, *Table 12*). Although there was no significant difference, there is a larger difference at 90 days providing some evidence of a possible positive effect of YCNY.

There was no significant difference in time to first re-admission across 90 days (mean 30.06 days for YCNY and 30.67 days for care-as-usual; HR 0.87, 95% CI 0.75 to 1.01; $p = 0.076$) and total duration of re-admissions (adjusted mean difference: −2.26, 95% CI −4.65 to 0.12; $p = 0.063$). However, both results seem to support a positive intervention effect. There was a significant difference in total number of re-admissions (IRR 0.87, 95% CI 0.76 to 0.99; $p = 0.039$) showing a 13% reduction in the rate of re-admissions across 90 days post hospital discharge.

Subgroup analysis

There was no evidence that treatment differed by age group (OR 0.89, 95% CI 0.66 to 1.20; $p = 0.447$) (see *Appendix 5*, *Table 13*).

Nested cohort

Participant follow-up and retention

Of those consented, 448 (71.7%) remained full participants, 110 (17.6%) subsequently withdrew from the study, 50 (8.0%) died, 5 (0.8%) were lost to follow-up, 8 (1.3%) died prior to discharge, 2 (0.3%) withdrew prior to discharge and 2 (0.3%) were eligible but were not discharged within study time frames.

Overall, 435 (71.0%) participants completed the 7-day post discharge, 400 (65.3%) 30 days and 321 (52.4%) 90 days (see *Appendix 5*, *Table 14*).

There was a total of 177 study discontinuations [97 (54.8%) care-as-usual and 80 (45.2%) YCNY group]. Of those, 12 (6.8%) took place pre discharge and 165 (93.2%) took place post discharge (see *Appendix 5*, *Table 15*).

Secondary outcomes

Summaries of the potential causes for post-hospital syndrome, utility of the intervention at 7 days are provided in *Tables 16* and *17* (see *Appendix 5*), respectively, and the total CTM-3 score, PACT-M experience score and PACT-M safety score in *Table 18* (see *Appendix 5*). There was evidence of a difference in CTM-3 score, favouring the YNCY group at 30 days (adjusted mean difference 4.93, 95% CI 0.46 to 9.40, $p = 0.031$) but not at 7 (3.21, 95% CI −0.91 to 7.33, $p = 0.127$) or 90 days (2.59, 95% CI −2.08 to 7.27; $p = 0.277$) (see *Appendix 5*, *Table 19*).

There was evidence of a difference in the number of adverse events as measured by PACT-M safety (see *Appendix 5*, *Table 20*) with a decrease in the adverse event rate in the YCNY group (IRR 0.75, 95% CI 0.57 to 0.99, $p = 0.039$). Sensitivity analyses which restricted the population to those recruited and discharged within the first 5-month recruitment period reflected these results.

The correlation coefficients of the CTM-3 and PACT-M are presented in *Table 21* (see *Appendix 5*) with the direction of each correlation coefficient as expected.

Most participants did not experience a ward move during their index admission (see *Appendix 5*, *Table 22*). Sixty-nine intervention participants experienced at least one move to a control ward, compared to five control participants who experience at least one move to an intervention ward.

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 classified as related to YCNY or participation in the trial.

Limitations of the study

The limitations of the study include potential bias of re-admissions data introduced by differing length of follow-up depending on when patients were admitted to wards. Furthermore, we acknowledge that we have not adjusted for multiple statistical testing, so any significant results should be interpreted with care. Within the nested cohort, the recruitment target was not met and furthermore follow-up was low, particularly at T3. Combined PACT-M scores could not be presented due to poor model fit and CTM-3 is not thought to be a good measure of experience.

Appendix 4 Main trial fidelity assessment (work package 6)

Methods

Due to the complex nature of the YCNY intervention, an appropriate framework was required to assess and measure the fixed (booklet, advice sheet and film) and flexible (additional activities developed by wards in relation to the four YCNY core functions) components of the intervention. We used a modified version of the CFIF[61,62] which is appropriate for complex health interventions. The learning from the previous WP4 and WP5 of the PACT study enabled us to design a set of criteria to measure the components of fidelity from the CFIF framework. The criteria included elements of adherence: content, coverage, frequency and duration. It also included moderating factors which influence these adherence elements: participant responsiveness, comprehension of the intervention and how sufficiently this was described, quality of delivery, and context. We sought to consider fidelity beyond intervention delivery only, understanding that a fidelity relationship exists beyond its receipt and inclusive of enactment of the intervention. Following guidance that suggests using several measures of fidelity rather than one,[70] we undertook assessments of pre-intervention engagement as well as post-intervention interviews with the intervention implementers or 'ward facilitators'.

The multimethod approach for data collection included researcher assessment of staff engagement in training sessions, research team observations of intervention delivery (including displaying of posters), facilitator feedback, counts of booklets and advice sheets remaining and patient questionnaires. Implementation components, such as facilitator training or intervention materials, were standardised, but delivery was flexible according to needs and preferences of ward staff. The evaluation consisted of scores which reflected the occurrence or non-occurrence of 'Your Care Needs You' components and the ward facilitator interviews explored the different components of the CFIF in detail and attempted to ascertain the extent to which flexible components of the intervention had been implemented or amended as per localised approaches. We assessed fidelity at ward, ward staff and patient levels which followed recommendations from the previous PACT WP findings and from other fidelity assessments in complex interventions.[71]

We reviewed a variety of scoring systems for fidelity before opting for a four-point Likert for specific and relevant items to capture more nuanced information beyond receipt or non-receipt. This allowed us to assess the extent to which individuals perceived intervention components to be delivered. The fidelity assessment included 27 items (see *Appendix 6*, *Table 23*). To reduce subjectivity in the scoring process, a sample of items were used to measure inter-rater reliability as advocated by Frost *et al.*[72] and Lambert *et al.*[73] These comprised a sample of pre-intervention training engagement scores (40%) and a sample of post-intervention ward facilitator interviews (10%). Two coders independently scored fidelity items followed by discussions of discrepancies. Inter-rater agreement was 80% across all item scoring.

The items were often measured with differing upper and lower limits and range of values, for example delivery of the booklets was in part assessed by a count of remaining booklets at the end of the recruitment period and inversely scoring this. It was also assessed by ward facilitators perception of the extent to which all, some or few patients received the booklet on a count of zero to two. To calculate a final range on the same scale (i.e. between 0 and 3), we converted all items to have the same lower and upper values using the below formula:

$$Y = \left(\frac{X - X_{min}}{X_{range}}\right) n \tag{1}$$

A score of 3 is considered to represent 'competent delivery'.[63]

Findings

For 2 wards, 12 items were missed due to ward staff capacity, so their final score was assessed from 15 fidelity items. Each fidelity item was scored from 0 to 3 and an average was calculated across all 27 components for each ward (see *Appendix 6*, *Table 23*). Overall fidelity to the intervention was moderate for majority of wards (n = 11, 68.75%) and low for the remaining five (31.25%) (see *Appendix 8*, *Table 24*). The mean score for intervention fidelity was 1.26 (range 0.2–1.9; median = 1.35, maximum possible = 3).

Coverage of the intervention was not optimal, only 23% of eligible participants reported receiving a YCNY booklet and 29% received the advice sheet. However, of those who reported receiving the intervention, 77% found the booklet 'useful' or 'very useful' and 88% found the advice sheet 'useful' or 'very useful'. In a comparable study,[74] effectiveness of an intervention was evident despite the fact only 22% of participants received the complete intervention. Ward facilitators rated delivery of the booklet and advice sheets as moderate (mean scores of 1.7 and 1.74), meaning that probably about half of patients were thought to have been given these. This discrepancy between patient recollection of receipt and staff perception about delivery is not unexpected but not explained by the available data. Of further interest is how these components were introduced to patients. The advice sheet was given to patients with very little or no explanation with the fourth lowest mean fidelity score of 0.6. This suggests that the advice sheet was included with other materials (such as 'to take home medications') as a short handover. Despite this, the vast majority of patients who reported receiving this found it useful. The introduction of the booklet appeared to be more comprehensive but still was poorly rated (mean score of 1.1). Lack of explanation of the booklet is potentially more problematic, as there is a need for this to be used during the hospital stay. The short patient film was rarely delivered to patients, only 1.3% of patients reporting having seen the video. As a result, this accounted for the two lowest mean fidelity item scores, 0.03 and 0.2 coming from two different sources (patients and ward facilitators). Also, low (score of 0.48) was recruiter assessment of whether staff appeared to be engaging patients to be more informed about their medications. The highest rating item as assessed by the ward facilitator was giving the intervention to all patients regardless of age. Giving the intervention to all patients returning to their own homes, regardless of age, was emphasised in the ward facilitator training sessions as a way of simplifying delivery and avoiding confusion with research processes.

Conclusions

Although all intervention wards were provided with a tablet to enable patients to watch the short film, and a QR code was provided on the back of the patient-held booklet, access still ultimately relied on staff bringing the tablet to the patient bedside and also patients and families (when they were allowed onto the wards) understanding and being able to use the QR technology. Recruiter assessment of whether staff appeared to be engaging patients to be more informed about their medications unsurprisingly rated very low. Recruiters were on the ward often during the trial and after discussions with them it was considered that they had good insight into ward activities. However, ward facilitators delivered most of the intervention components, so recruiter's capacity to observe staff/patient engagement would have been limited. In the absence of any evidence to support weighting items or any indications from the previous WPs, we constructed an equally weighted fidelity score. Exploring this going forward in assessments of complex interventions may improve the accuracy of fidelity. The decision to divide the fidelity score into three categories (low, moderate, high) was based on avoiding a broad dichotomy of low versus high fidelity. However, the low fidelity scores reported for five wards could be a reflection of the reference values chosen and the number of fidelity items included in the assessment. Constructing final fidelity scores should be explored and reviewed going forward.

Appendix 5 Figures and tables from the main trial (work package 6)

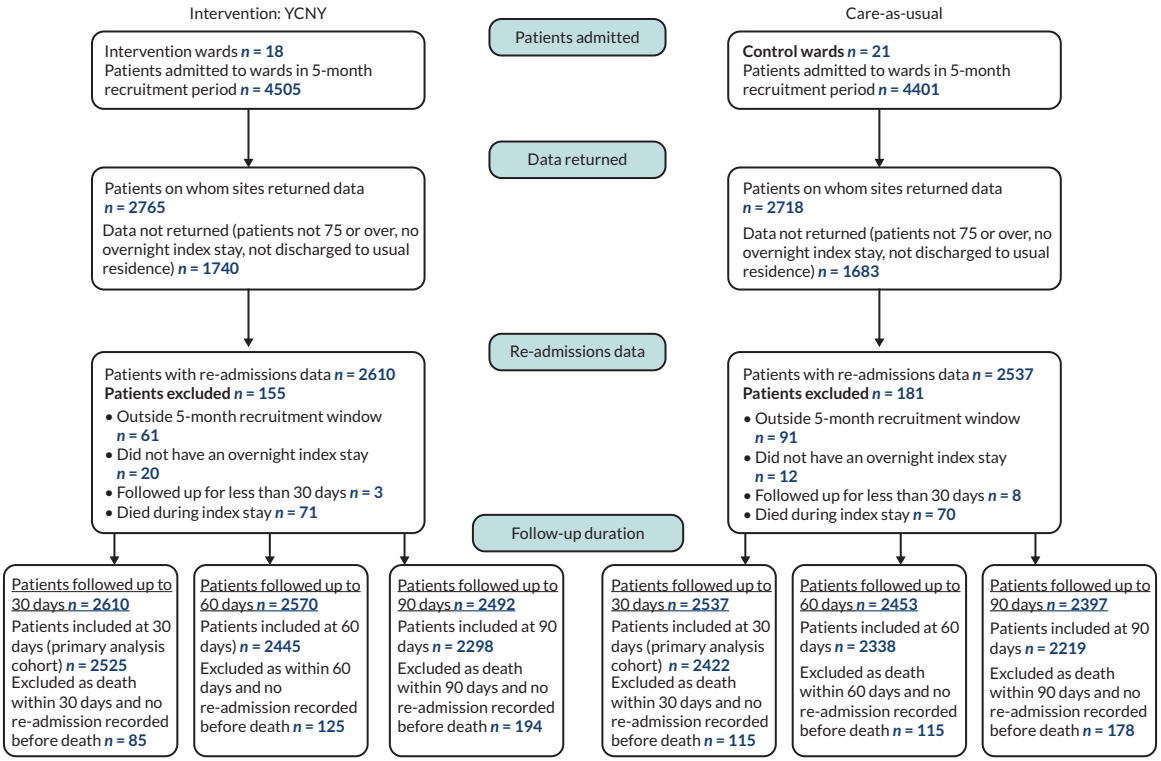

FIGURE 4 Consolidated Standards of Reporting Trials flow diagram showing flow of patients in the primary cohort study.

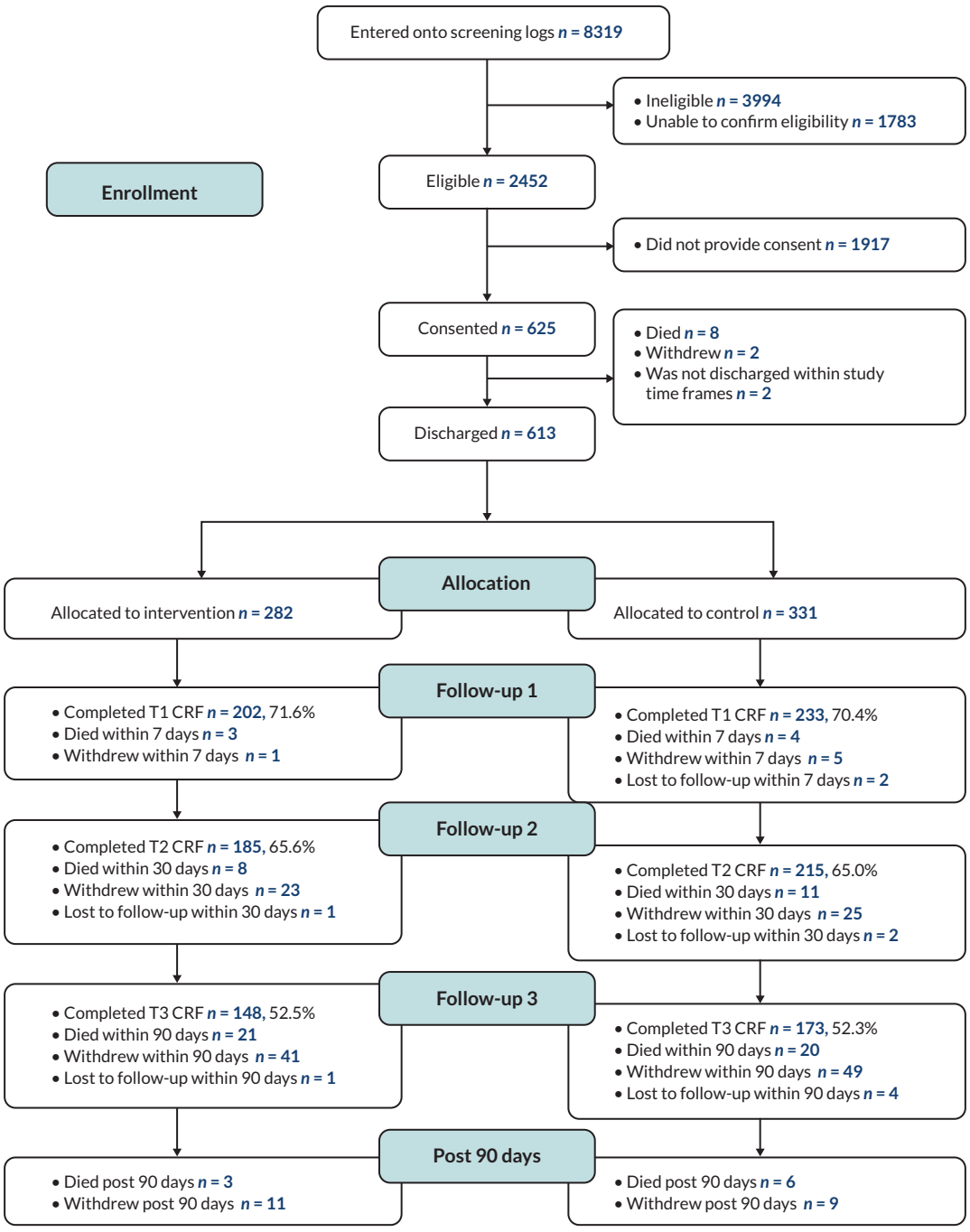

FIGURE 5 Consolidated Standards of Reporting Trials flow diagram showing flow of participants in the nested cohort study.

TABLE 4 Reasons for ineligibility in the nested cohort

	N	% of 3994 ineligible
Inclusion criteria (not met)		
Participant aged 75 or over	191	4.8
Expected discharge to own/relative's home	2003	50.2
Staying for least one night on participating ward	40	1.0
Able to give informed consent[a]	1172	29.3
Exclusion criteria (met)		
Requires an interpreter	130	3.3
Lives out of area	182	4.6
Expect transfer to another acute hospital or a community rehab unit	749	18.8
End of life/fast-track to palliative care	448	11.2
Nursing/residential home resident or to be discharged to a nursing/residential home permanently	1310	32.8
Admitted for psychiatric reason other than dementia or delirium	109	2.7
Already recruited into the study	31	0.8

a Of those 1172 patients who were unable to give informed consent, 498 (42.5%) were unable to provide a personal consultee, 231 (19.7%) were able to provide a personal consultee and 443 (37.8%) did not provide a response.

Note
Reasons for ineligibility are not mutually exclusive and therefore may not sum to 100%.

TABLE 5 Reasons for refusal to take part in the nested cohort study

Reasons for refusal	*N*	% of 1917 refusals
Not interested	430	22.4
Too poorly	27	1.4
Too much on or to worry about	192	10.0
Other	179	9.3
No reason given	36	1.9
Missing data	1053	54.9

TABLE 6 Baseline characteristics of wards who provided routine data

	YCNY (*N* = 18)	Care-as-usual (*N* = 21)	Overall (*N* = 39)
NHS Trust (ward codes[a])			
RN (M)	1 (6%)	1 (5%)	2 (5%)
RD (B, C, D and E)	4 (22%)	2 (10%)	6 (15%)
CLE (G and H)	2 (11%)	2 (10%)	4 (10%)
HTE (L)	1 (6%)	1 (5%)	2 (5%)
LL (I)	1 (6%)	2 (10%)	3 (8%)
DS (O and P)	3 (17%)	3 (14%)	6 (15%)
NLE (J and K)	2 (11%)	2 (10%)	4 (10%)
ON (F)	1 (6%)	3 (14%)	4 (10%)
LD (A)	1 (6%)	3 (14%)	4 (10%)
HS	1 (6%)	1 (5%)	2 (5%)
ND (N)	1 (6%)	1 (5%)	2 (5%)
Not reported	0	0	0
Type of ward			
Elderly care	8 (44%)	11 (52%)	19 (49%)
Orthopaedic	4 (22%)	3 (14%)	7 (18%)
Intermediate care	2 (11%)	2 (10%)	4 (10%)
Other	2 (11%)	2 (10%)	4 (10%)
Surgical	1 (6%)	1 (5%)	2 (5%)
Cardiology	0 (0%)	1 (5%)	1 (3%)
Respiratory medicine	0 (0%)	1 (5%)	1 (3%)
Stroke	1 (6%)	0 (0%)	1 (3%)
Not reported	0	0	0
Average age of patients on ward (2019) in years			
Mean (SD)	76.27 (10.02)	75.81 (10.54)	76.03 (10.15)
Median (Q1–Q3)	80.00 (69.55–84.60)	81.00 (66.50–85.00)	81.00 (69.00–84.80)
Min–max	55.00–86.70	57.00–86.40	55.00–86.70
Not reported	0	2	2
Percentage of patients who were 75 and over[a]			
Mean (SD)	74.28 (24.94)	76.67 (19.70)	75.56 (22.00)
Median (Q1–Q3)	85.00 (61.25–90.00)	85.00 (53.00–94.00)	85.00 (59.50–91.50)
Min–max	18.00–98.00	49.00–98.00	18.00–98.00
Not reported	0	0	0

continued

TABLE 6 Baseline characteristics of wards who provided routine data (*continued*)

	YCNY (*N* = 18)	Care-as-usual (*N* = 21)	Overall (*N* = 39)
Average length of stay on ward for patients aged 75 and over (2019)			
Mean (SD)	16.18 (7.09)	18.74 (10.57)	17.49 (9.01)
Median (Q1–Q3)	15.25 (10.35–22.23)	17.50 (11.15–23.00)	16.60 (11.00–22.30)
Min–max	6.00–30.00	6.00–43.60	6.00–43.60
Not reported	0	2	2
Number of patients discharged from ward (2019)			
Mean (SD)	382.28 (217.11)	316.16 (224.35)	348.32 (220.34)
Median (Q1–Q3)	344.00 (223.25–527.00)	320.00 (163.00–397.50)	322.00 (223.00–497.00)
Min–max	23.00–784.00	28.00–935.00	23.00–935.00
Not reported	0	2	2
Number of those patients who were re-admitted to hospital with 30 days			
Mean (SD)	66.61 (41.84)	57.42 (40.01)	61.89 (40.60)
Median (Q1–Q3)	61.50 (42.25–93.50)	51.00 (28.50–80.50)	59.00 (33.00–84.00)
Min–max	4.00–146.00	4.00–160.00	4.00–160.00
Not reported	0	2	2

Max, maximum; min, minimum.
a For cross referencing – these intervention wards took part in the fidelity assessment (see *Appendix 6*) and some also in the process evaluation.

TABLE 7 Baseline characteristics of patients (30-day primary cohort)

	YCNY (*N* = 2525)	Care-as-usual (*N* = 2422)	Overall (*N* = 4947)
NHS Trust (ward codes[a])			
RN (M)	136 (5%)	91 (4%)	227 (5%)
RD (B, C, D and E)	379 (15%)	179 (7%)	558 (11%)
CLE (G and H)	348 (14%)	276 (11%)	624 (13%)
HTE (L)	136 (5%)	108 (4%)	244 (5%)
LL (I)	387 (15%)	214 (9%)	601 (12%)
DS (O and P)	372 (15%)	323 (13%)	695 (14%)
NLE (J and K)	213 (8%)	170 (7%)	383 (8%)
ON (F)	183 (7%)	520 (21%)	703 (14%)
LD (A)	142 (6%)	357 (15%)	499 (10%)
HS	131 (5%)	52 (2%)	183 (4%)
ND (N)	98 (4%)	132 (5%)	230 (5%)
Not reported	0	0	0
Type of ward			
Elderly care	1317 (52%)	1284 (53%)	2601 (53%)
Orthopaedic	499 (20%)	319 (13%)	818 (17%)

TABLE 7 Baseline characteristics of patients (30-day primary cohort) (*continued*)

	YCNY (*N* = 2525)	Care-as-usual (*N* = 2422)	Overall (*N* = 4947)
Other	273 (11%)	199 (8%)	472 (10%)
Intermediate care	121 (5%)	179 (7%)	300 (6%)
Surgical	132 (5%)	109 (5%)	241 (5%)
Cardiology	0 (0%)	200 (8%)	200 (4%)
Stroke	183 (7%)	0 (0%)	183 (4%)
Respiratory medicine	0 (0%)	132 (5%)	132 (3%)
Not reported	0	0	0
Patient age in years			
Mean (SD)	84.30 (5.73)	84.53 (5.76)	84.41 (5.75)
Median (Q1–Q3)	84.00 (80.00–88.00)	84.00 (80.00–89.00)	84.00 (80.00–89.00)
Min–max	75.00–105.00	75.00–106.00	75.00–106.00
Not reported	0	0	0
Sex			
Female	1465 (58%)	1457 (60%)	2922 (59%)
Male	1060 (42%)	965 (40%)	2025 (41%)
Not reported	0	0	0
Ethnicity			
White – British	1176 (88%)	1102 (90%)	2278 (89%)
White – Any other white background	63 (5%)	41 (3%)	104 (4%)
Not stated	22 (2%)	24 (2%)	46 (2%)
Asian or Asian British – Indian	26 (2%)	19 (2%)	45 (2%)
White – Irish	12 (1%)	9 (1%)	21 (1%)
Asian or Asian British – Pakistani	11 (1%)	8 (1%)	19 (1%)
Black or Black British – Caribbean	3 (0%)	9 (1%)	12 (0%)
Any other ethnic group	6 (0%)	4 (0%)	10 (0%)
Asian or Asian British – Bangladeshi	7 (1%)	2 (0%)	9 (0%)
Asian or Asian British – Any other Asian background	8 (1%)	0 (0%)	8 (0%)
Black or Black British – Any other black background	3 (0%)	2 (0%)	5 (0%)
Asian or Asian British – Chinese	1 (0%)	2 (0%)	3 (0%)
Black or Black British – African	0 (0%)	2 (0%)	2 (0%)
Mixed – white and Asian	0 (0%)	2 (0%)	2 (0%)
Mixed – white and Black Caribbean	2 (0%)	0 (0%)	2 (0%)
Not reported	1185	1196	2381
Length of index stay (days)			
Mean (SD)	16.67 (16.33)	17.03 (18.10)	16.85 (17.22)

continued

TABLE 7 Baseline characteristics of patients (30-day primary cohort) (*continued*)

	YCNY (*N* = 2525)	Care-as-usual (*N* = 2422)	Overall (*N* = 4947)
Median (Q1–Q3)	12.00 (6.00–22.00)	12.00 (6.00–22.00)	12.00 (6.00–22.00)
Min–max	1.00–142.00	1.00–209.00	1.00–209.00
Not reported	0	0	0

Max, maximum; min, minimum.
a For cross referencing – these intervention wards took part in the fidelity assessment (see *Appendix 6*) and some also in the process evaluation.

TABLE 8 Baseline characteristics of nested cohort, as randomised

Variable		YCNY (*n* = 282)	Care-as-usual (*n* = 331)	Overall (*n* = 613)
Method of completion	Participant	320 (96.7)	265 (94.0)	585 (95.4)
	Carer	11 (3.3)	15 (5.3)	26 (4.2)
	Not reported	0 (0.0)	2 (0.7)	2 (0.3)
Method of admission	Emergency	303 (91.5)	258 (91.5)	561 (91.5)
	Elective	12 (3.6)	17 (6.0)	29 (4.7)
	Other	16 (4.8)	5 (1.8)	21 (3.4)
	Not reported	0 (0.0)	2 (0.7)	2 (0.3)
Age	Mean (SD)	83.5 (5.5)	83.3 (5.5)	83.4 (5.5)
	Median (IQR)	83.8 (8.9)	82.8 (8.5)	83.1 (8.7)
	Min–max	75.0–100.0	75.1–98.5	75.0–100.0
Gender	Male	132 (39.9)	126 (44.7)	258 (42.1)
	Female	199 (60.1)	156 (55.3)	355 (57.9)
Ethnicity	White British	318 (96.1)	261 (92.6)	579 (94.5)
	White Irish	1 (0.3)	4 (1.4)	5 (0.8)
	White (Other)	4 (1.2)	5 (1.8)	9 (1.5)
	Asian or Asian British (Indian)	0 (0.0)	1 (0.4)	1 (0.2)
	Black or Black British (Caribbean)	2 (0.6)	0 (0.0)	2 (0.3)
	Prefer not to say	5 (1.5)	7 (2.5)	12 (2.0)
	Not reported	1 (0.3%)	4 (1.4)	5 (0.8)
First language	English	320 (96.7)	272 (96.5)	592 (96.6)
	Other[a]	5 (1.5)	3 (1.1)	8 (1.3)
	Not reported	6 (1.8)	7 (2.5)	13 (2.1)
Live-in status	Alone	110 (33.2)	82 (29.1)	192 (31.3)

TABLE 8 Baseline characteristics of nested cohort, as randomised (*continued*)

Variable		YCNY (*n* = 282)	Care-as-usual (*n* = 331)	Overall (*n* = 613)
	Alone with regular support from family/friends	89 (26.9)	64 (22.7)	153 (25.0)
	With spouse/partner	112 (33.8)	105 (37.2)	217 (35.4)
	With son/daughter (in-law)	16 (4.8)	24 (8.5)	40 (6.5)
	With brother/sister	0 (0.0)	1 (0.4)	1 (0.2)
	Other[b]	3 (0.9)	3 (1.1)	6 (1.0)
	Not reported	1 (0.3)	3 (1.1)	4 (0.7)
Has daily caregivers	Yes	62 (18.7)	39 (13.8)	101 (16.5)
	No	265 (80.1)	237 (84.0)	502 (81.9)
	Not reported	4 (1.2)	6 (2.1)	10 (1.6)
How often per day?	1	20 (32.3)	6 (15.4)	26 (25.7)
(Of those who said Yes)	2	16 (25.8)	15 (38.5)	31 (30.7)
	3	8 (12.9)	8 (20.5)	16 (15.8)
	4 +	17 (27.4)	8 (20.5)	25 (24.8.)
	Not reported	1 (1.6)	2 (5.1)	3 (3.0)
Number of hospital admissions in the previous 12 months	Mean (SD)	1.3 (2.0)	0.9 (1.2)	1.1 (1.7)
	Median (IQR)	1.0 (2.0)	0.0 (1.0)	1.0 (2.0)
	Min–max	0–18	0–6	0–18
	Not reported	14 (4.2)	16 (5.7)	30 (4.9)

Max, maximum; min, minimum.
a Other languages included: Croatian (*n* = 1); French (*n* = 1); Hungarian (*n* = 1); Punjabi (*n* = 1); Spanish (*n* = 1); Welsh (*n* = 1); not reported (*n* = 2).
b Other living arrangements included; lives with friend (*n* = 1); lives with grandson (*n* = 1); lives with husband and daughter (*n* = 1); lives with nephew (*n* = 1); lives with spouse and son (*n* = 1); sheltered accommodation (*n* = 1).

TABLE 9 Baseline outcome measures, as randomised

Variable		YCNY (*n* = 282)	Care-as-usual (*n* = 331)	Overall (*n* = 613)
EQ-5D-5L	Mean (SD)	0.60 (0.27)	0.59 (0.28)	0.59 (0.28)
	Median (IQR)	0.66 (0.40)	0.67 (0.44)	0.66 (0.42)
	Min to max	−0.23 to 1	−0.22 to 1	−0.23 to 1
	Not reported	5 (1.77)	5 (1.47)	10 (1.61)
FCMI total	Mean (SD)	3.2 (2.0)	3.1 (2.0)	3.1 (2.0)
	Median (IQR)	3.0 (2.0)	3.0 (2.0)	3.0 (2.0)
	Min–max	0–10	0–12	0–12

continued

TABLE 9 Baseline outcome measures, as randomised (*continued*)

Variable		YCNY (*n* = 282)	Care-as-usual (*n* = 331)	Overall (*n* = 613)
	Not reported	2 (0.7)	0 (0.0)	2 (0.3)
Comorbidity	Arthritis (rheumatoid and osteoarthritis)	112 (39.7)	152 (45.9)	264 (43.0)
	Osteoporosis	40 (14.2)	55 (16.6)	95 (15.5)
	Asthma	28 (9.9)	49 (14.8)	77 (12.6)
	COPD, ARDS or emphysema	41 (14.5)	70 (21.2)	111 (18.1)
	Angina	33 (11.7)	33 (10.0)	66 (10.8)
	Congestive heart failure or heart disease	99 (35.1)	113 (34.1)	212 (34.6)
	Heart attack	27 (9.6)	26 (7.9)	53 (8.7)
	Neurological disease	9 (3.2)	9 (2.7)	18 (2.9)
	Stroke or TIA	77 (27.3)	46 (13.9)	123 (20.1)
	Peripheral vascular disease	30 (10.6)	17 (5.1)	47 (7.7)
	Diabetes (type 1 or 2)	82 (29.1)	74 (22.4)	156 (25.5)
	Upper gastrointestinal disease	53 (18.8)	49 (14.8)	102 (16.6)
	Depression	22 (7.8)	33 (10.0)	55 (9.0)
	Anxiety or panic disorders	33 (11.7)	32 (9.7)	65 (10.6)
	Visual impairments	85 (30.1)	111 (33.5)	196 (32.0)
	Hearing impairment	50 (17.7)	65 (19.6)	115 (18.8)
	Degenerative disk disease	36 (12.8)	50 (15.1)	86 (14.0)
	Obesity and/or BMI > 30 kg/m^2	30 (10.6)	29 (8.8)	59 (9.6)

ARDS, acute respiratory distress syndrome; BMI, body mass index; COPD, chronic obstructive pulmonary disease; EQ-5D-5L, EuroQol-5 Dimensions, five-level version; FCMI, functional co-morbidity index; max, maximum; min, minimum; TIA, transient ischaemic attack.

TABLE 10 Summary of re-admissions and deaths in the primary cohort

	YCNY	Care-as-usual	Overall
Re-admissions			
Re-admission at 30 days	436 (17%)	459 (19%)	895 (18%)
Re-admission at 60 days	612 (25%)	677 (29%)	1289 (27%)
Re-admission at 90 days	692 (30%)	779 (35%)	1471 (33%)
Deaths			
Death at 30 days	130 (5%)	159 (6%)	289 (6%)
Death at 60 days	229 (9%)	254 (10%)	483 (10%)
Death at 90 days	298 (12%)	327 (14%)	625 (13%)

TABLE 11 Primary analysis of the primary cohort

		Unplanned hospital re-admissions at 30 days *N* (%)			
	N in model	YCNY	Care-as-usual	OR (95% CI)[a]	*p*-value
Primary analysis model	4947	436 (17%)	459 (19%)	0.93 (0.78 to 1.10)	0.372
CACE analysis					
CACE analysis (based on fidelity scores of wards low, medium and high)[b]	4712			0.98 (0.92 to 1.05)	0.627

a Adjusting for ward type, baseline ward re-admission rate, percentage of patients 75 and over and gender as fixed effects and trust and ward as random effects. The ICCs were 0.004 for trust and 0.01 for ward.
b Fidelity scores were not able to be completed for two wards, so these were removed from this analysis.

TABLE 12 Secondary analysis of the primary cohort

		Unplanned hospital re-admissions at 60 and 90 days *N* (%)			
	n in model	YCNY	Care-as-usual	Estimate (95% CI) OR (95% CI)	*p*-value
60 days	4783	612 (25%)	677 (29%)	0.85 (0.70 to 1.03)	0.100
90 days	4517	692 (30%)	779 (35%)	0.82 (0.67 to 1.01)	0.061
		25th percentile[a] re-admission time in days (95% CI)	25th percentile[a] re-admission time in days (95% CI)	Cox's proportional HR (95% CI)	
Time to first re-admission	5158	67 (58 to 77.3 days)	50 (46 to 57 days)	0.87 (0.75 to 1.01)	0.076
		Mean number of re-admissions (SD)	Mean number of re-admissions (SD)	Incidence date ratio (95% CI)	
Total re-admissions	4517	0.39 (0.69)	0.46 (0.75)	0.87 (0.76 to 0.99)	0.039
		Mean duration of all re-admissions in days (SD)	Mean duration of all re-admissions in days (SD)	Adjusted difference in means (95% CI)	
Total duration of re-admissions (days)	1179	14.71 (17.31)	17.02 (18.42)	−2.26 (−4.65 to 0.12)	0.063

a 25th percentile re-admission time has been presented rather than median as less than half of patients experienced a re-admission.

TABLE 13 Subgroup analysis of the primary cohort

	n in model	OR (95% CI)	*p*-value
Unplanned hospital re-admission at 30 days post discharge			
Age (< 85 years) – treatment interaction	4947	0.89 (0.66 to 1.20)	0.447

TABLE 14 Postal questionnaire return rates, by trial arm and overall (of those who were discharged)[a]

	YCNY (*n* = 282)	Care-as-usual (*n* = 331)	Overall (*n* = 613)
Follow-up 1 (T1)			
Completed	202 (71.6)	233 (70.4)	435 (71.0)
Follow-up 2 (T2)			
Completed	185 (65.6)	215 (65.0)	400 (65.3)
Follow-up 3 (T3)			
Completed	148 (52.5)	173 (52.3)	321 (52.4)

a Participants will not have been sent a questionnaire if they withdrew or died prior to the follow-up time point.

TABLE 15 Study discontinuations by trial arm

	Pre discharge			Post discharge		
Type of withdrawal	YCNY (*n* = 285)	Care-as-usual (*n* = 340)	Total (*n* = 625)	YCNY (*n* = 285)	Care-as-usual (*n* = 340)	Total (*n* = 625)
Eligible[a]	0 (0.0)	2 (0.6)	2 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
Full withdrawal	0 (0.0)	2 (0.6)	2 (0.3)	52 (18.2)	58 (17.1)	110 (17.6)
Patient death	3 (1.1)	5 (1.5)	8 (1.3)	24 (8.4)	26 (7.6)	50 (8.0)
Lost to follow-up	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	4 (1.2)	5 (0.8)

a These participants were eligible and consented but were not discharged within study time frames.

TABLE 16 Questions that capture potential causes for post-hospital syndrome at T1

Post-hospital syndrome item		YCNY (*n* = 202)	Care-as-usual (*n* = 233)	Overall (*n* = 435)
While in hospital I slept well	Strongly disagree	36 (17.8)	43 (18.5)	79 (18.2)
	Disagree	64 (31.7)	65 (27.9)	129 (29.7)
	Neither agree nor disagree	40 (19.8)	41 (17.6)	81 (18.6)
	Agree	54 (26.7)	62 (26.6)	116 (26.7)
	Strongly agree	8 (4.0)	16 (6.9)	24 (5.5)
	Don't know/not applicable	0 (0.0)	2 (0.9)	2 (0.5)
	Not reported	0 (0.0)	4 (1.7)	4 (0.9)
While in hospital I ate well	Strongly disagree	16 (7.9)	22 (9.4)	38 (8.7)
	Disagree	39 (19.3)	49 (21.0)	88 (20.2)
	Neither agree nor disagree	25 (12.4)	37 (15.9)	62 (14.3)
	Agree	87 (43.1)	92 (39.5)	179 (41.2)
	Strongly agree	32 (15.8)	30 (12.9)	62 (14.3)
	Not reported	3 (1.5)	3 (1.3)	6 (1.4)

TABLE 16 Questions that capture potential causes for post-hospital syndrome at T1 (*continued*)

Post-hospital syndrome item		YCNY (*n* = 202)	Care-as-usual (*n* = 233)	Overall (*n* = 435)
While in hospital I had enough to drink	Strongly disagree	4 (2.0)	1 (0.4)	5 (1.2)
	Disagree	11 (5.5)	6 (2.6)	17 (3.9)
	Neither agree nor disagree	13 (6.4)	14 (6.0)	27 (6.2)
	Agree	134 (66.3)	153 (65.7)	287 (66.0)
	Strongly agree	40 (19.8)	54 (23.2)	94 (21.6)
	Not reported	0 (0.0)	5 (2.2)	5 (1.2)
While in hospital I was encouraged and supported to move more regularly	Strongly disagree	7 (3.5)	14 (6.0)	21 (4.8)
	Disagree	36 (17.8)	34 (14.6)	70 (16.1)
	Neither agree nor disagree	41 (20.3)	53 (22.8)	94 (21.6)
	Agree	96 (47.5)	109 (46.8)	205 (47.1)
	Strongly agree	20 (9.9)	20 (8.6)	40 (9.2)
	Don't know/not applicable	2 (1.0)	0 (0.0)	2 (0.5)
	Not reported	(0.0)	3 (1.3)	3 (0.7)

TABLE 17 Utility of the intervention summaries at T1

Utility of the intervention item		Total (*n* = 202[a])
Did you receive a 'Your Care Needs You' booklet?	Yes	77 (38.1)
	No	90 (44.6)
	Can't remember	32 (15.8)
	Not reported	3 (1.5)
If 'Yes', when did you use this?[b]	In hospital	24 (31.2)
	At home	35 (45.5)
	Not at all	10 (13.0)
	Can't remember	10 (13.0)
If you received the booklet, how useful did you find it?[c]	Very useful	12 (15.6)
	Quite useful	47 (61.0)
	Not useful	13 (16.9)
	Not reported	5 (6.5)
Did you or your family/friends watch the 'Your Care Needs You' film?	Yes	5 (2.5)
	No	178 (88.1)
	Can't remember	14 (6.9)

continued

TABLE 17 Utility of the intervention summaries at T1 (*continued*)

Utility of the intervention item		Total (*n* = 202[a])
	Not reported	5 (2.5)
Before you left hospital were you given a 'Patient advice to help you at home sheet'?	Yes	54 (26.7)
	No	108 (53.5)
	Can't remember	37 (18.3)
	Not reported	3 (1.5)
If 'Yes', what did you do with this?[b,c]	Read it	48 (88.9)
	Showed it to my GP, pharmacist, nurse etc.	0 (0.0)
	Nothing	3 (5.6)
	Don't know	2 (3.7)
If you received the 'Patient advice to help you at home' sheet, how useful did you find it?[c]	Very useful	15 (27.8)
	Quite useful	30 (55.6)
	Not useful	5 (9.3)
	Not reported	4 (7.4)

a The summaries provided have been restricted to participants in the intervention group who completed a postal questionnaire at T1.
b Responses here are not mutually exclusive and so percentages may not sum to 100.
c Percentages here are given out of those who answered 'yes' to the previous question.

TABLE 18 Descriptive summaries of the CTM-3 and PACT-M, by trial arm, at each time point

	YCNY		Care-as-usual	
Outcome measure	*n*	Mean (SD)	*n*	Mean (SD)
CTM-3				
T1	183	68.0 (20.5)	209	63.8 (20.7)
T2	165	69.3 (19.6)	191	63.7 (33.9)
T3	138	68.6 (19.9)	159	65.8 (20.6)
PACT-M (8 experience items)				
T1	189	20.7 (5.9)	218	19.6 (6.1)
T2	167	23.8 (4.5)	205	23.1 (5.1)
T3	144	24.3 (4.5)	165	23.7 (5.5)
PACT-M (7 safety items)				
T1	194	0.9 (1.3)	226	1.0 (1.2)
T2	177	1.0 (1.3)	208	1.3 (1.2)
T3	147	1.0 (1.1)	171	1.2 (1.3)

TABLE 19 Secondary analysis of CTM-3 scores

	Adjusted[a] mean difference between groups			
	YCNY Mean (95% CI)	Care-as-usual Mean (95% CI)	Difference (95% CI)	*p*-value
CTM-3				
T1	66.96 (63.01 to 70.91)	63.75 (60.04 to 67.46)	3.21 (−0.91 to 7.33)	0.127
T2	68.35 (64.58 to 72.13)	63.42 (59.92 to 66.93)	4.93 (0.46 to 9.40)	0.031
T3	68.50 (65.09 to 71.92)	65.91 (62.73 to 69.09)	2.59 (−2.08 to 7.27)	0.277
PACT-M (8-experience items)				
T1	20.23 (19.02 to 21.44)	19.55 (18.41 to 20.70)	0.68 (−0.50 to 1.87)	0.260
T2	23.74 (23.01 to 24.47)	23.17 (22.51 to 23.83)	0.57 (−0.41 to 1.56)	0.255
T3	24.24 (23.42 to 25.07)	23.77 (23.00 to 24.54)	0.47 (−0.66 to 1.61)	0.409
Sensitivity analysis (restricted to 5-month recruitment period)				
CTM-3				
T1	67.56 (63.22 to 71.91)	64.22 (60.19 to 68.25)	3.34 (−1.50 to 8.18)	0.176
T2	69.59 (65.84 to 73.34)	64.35 (60.83 to 67.87)	5.24 (0.21 to 10.28)	0.041
T3	68.48 (64.68 to 72.27)	67.15 (63.43 to 70.86)	1.33 (−4.03 to 6.68)	0.627
PACT-M				
T1	20.29 (19.01 to 21.57)	19.52 (18.32 to 20.71)	0.77 (−0.66 to 2.21)	0.290
T2	23.80 (22.92 to 24.68)	23.19 (22.40 to 23.98)	0.61 (−0.58 to 1.79)	0.318
T3	24.34 (23.32 to 25.36)	23.74 (22.76 to 24.72)	0.60 (−0.73 to 1.93)	0.376

a Adjusting for ward type, baseline ward readmission rate, percentage of patients 75 and over ans gender as fixed effects and trust and ward as random effects.

TABLE 20 Secondary analysis of PACT-M safety items

	Adjusted[a] IRR	
	IRR (95% CI)	*p*-value
PACT-M (7-safety items)		
T1	0.86 (0.66 to 1.10)	0.231
T2	0.75 (0.57 to 0.99)	0.039
T3	0.85 (0.69 to 1.04)	0.120
Sensitivity analysis (restricted to 5-month recruitment period)		
T1	0.87 (0.64 to 1.18)	0.383
T2	0.76 (0.58 to 1.01)	0.061
T3	0.84 (0.66 to 1.07)	0.149

a Adjusting for ward type, baseline ward readmission rate, percentage of patients 75 and over ans gender as fixed effects and trust and ward as random effects.

TABLE 21 Concurrent validity of the CTM-3 and PACT-M at each follow-up time point

		PACT-M safety score	PACT-M experience score
T1	CTM-3 Score	−0.2131	0.7011
T2	CTM-3 Score	−0.2126	0.4932
T3	CTM-3 Score	−0.1893	0.5278

TABLE 22 Summary of ward moves in nested cohort

	YCNY (*n* = 282)	Care-as-usual (*n* = 331)	Overall (*n* = 613)
Number of ward moves			
0	213 (75.5)	238 (71.9)	451 (73.6)
1	48 (17.0)	63 (19.0)	111 (18.1)
2	13 (4.6)	22 (6.7)	35 (5.7)
3	8 (2.8)	7 (2.1)	15 (2.5)
3 +	0 (0.0)	1 (0.3)	1 (0.2)
Number of ward moves			
Mean (SD)	0.3 (0.70)	0.4 (0.77)	0.4 (0.74)
Median (IQR)	0.0 (0.0)	0.0 (1.0)	0.0 (1.0)
Min–max	0.0, 3.0	0.0, 6.0	0.0, 6.0
Number of intervention participants who had at least one move to a control ward	69 (24.5)		
Number of control participants who had at least one move to an intervention ward		5 (1.5)	

Max, maximum; min, minimum.

Appendix 6 Fidelity assessment findings (work package 6)

TABLE 23 Fidelity grid with raw mean scores for each item

CFIF criteria	Source of measure	Fidelity assessment	Raw mean scores (0–3)
Adherence: content			
1.	Ward facilitator interview	To what extent have the YCNY booklets been delivered to all patients who were planning to return home?	1.70
2.	Ward facilitator interview	To what extent have the YCNY patient advice sheets been delivered to all patients going back to their own homes?	1.74
3.	Ward facilitator interview	How was the booklet introduced to patients?	1.10
4.	Ward facilitator interview	How was the advice sheet introduced to patients?	0.60
5.	Ward facilitator interview	How well do you think staff have used the booklet to encourage patient to ask questions?	1.05
6.	Patient follow-up questionnaires	If you received the booklet, how useful did you find it?	1.33
7.	Patient follow-up questionnaires	If you received the 'Patient advice to help you at home' sheet, how useful did you find it?	1.69
8.	Recruiter observations	Evidence of delivery of flexible components of intervention in relation to knowing more (e.g. asking questions, engaging with staff) and doing more (e.g. moving about)	1.78
Adherence: coverage			
9.	Patient follow-up questionnaires	Did you receive a 'Your Care Needs You' booklet?	0.71
10.	Patient follow-up questionnaires	Did you or your family/friends watch the 'Your Care Needs You' film?	0.03
11.	Patient follow-up questionnaires	Before you left hospital were you given a 'Patient Advice to help you at home sheet'	0.87
12.	Recruiter observations	On intervention wards I could see that people had their booklets	0.81
13.	Ward facilitator interview	Have you given the intervention to any patient regardless of age?	2.46
Adherence: duration/frequency			
14.	Intervention material counts	Remaining booklets	1.59
15.	Intervention material counts	Remaining advice sheets	1.87
16.	Recruiter observations	YCNY posters (no posters/posters on show/poster input and localised)	1.5
17.	Ward facilitator interview	To what extent have patients had the opportunity to watch the YCNY video during the YCNY delivery period?	0.2
18.	Recruiter observations	On the intervention wards I could see posters displayed related to the YCNY intervention	2.44
Moderator: participant responsiveness			
19.	Ward facilitator training	WF training engagement rating	1.49
20.	Recruiter observations	On intervention wards I could see that staff were trying to engage patients to be more informed about their medications	0.48
21.	Recruiter observations	On intervention wards patients seemed more engaged in their care	0.84

continued

TABLE 23 Fidelity grid with raw mean scores for each item (*continued*)

CFIF criteria	Source of measure	Fidelity assessment	Raw mean scores (0–3)
Moderator: comprehensiveness			
22.	Ward facilitator interview	To what extent did you do the things you thought you would do after the WF training?	1.60
Moderator: quality of delivery			
23.	Ward facilitator interview	To what extent do you think YCNY has helped staff make changes in relation to: patient understanding of their health and well-being?	1.15
24.	Ward facilitator interview	To what extent do you think YCNY has helped staff make changes in relation to: patient knowledge and skills in their medications?	1.47
25.	Ward facilitator interview	To what extent do you think YCNY has helped staff make changes in relation to: patient activity on the ward?	1.27
26.	Ward facilitator interview	To what extent do you think YCNY has helped staff make changes in relation to patient preparedness for managing going home?	1.21
Moderator: context			
27.	Ward manager interview	Since the study began, have you started any new initiatives or services to encourage more physical activity on the ward?	0.86

Note
These are raw mean scores across wards for each CFIF item.

TABLE 24 Fidelity scores for each intervention ward

Intervention ward	Fidelity score (0–3)
A	0.2
B[a]	1.7
C[a]	1.3
D[a]	1.4
E	1.9
F	1
G	1.4
H	1.4
I	1
J[a]	0.8
K[a]	1.3
L[a]	1.3
M	1.6
N	1.5
O[a]	1
P[a]	1.5

a These wards took part in the process evaluation.

Appendix 7 Health economic analysis and findings from main trial (work package 6)

Introduction

The economic analysis utilised individual patient-level data from the YCNY trial to calculate the short-term cost-effectiveness of the YCNY intervention versus usual care for the first 90 days post discharge. It also estimates the long-term cost-effectiveness over a lifetime horizon using decision modelling techniques. These calculations take into account both health outcomes and costs, thereby providing a nuanced understanding of the intervention's efficiency.

The primary analytical approach was cost-effectiveness analysis, which calculated the ICER based on the mean differences in costs and QALYs between the intervention and control groups.

Methods

General considerations

Health economics analysis plan

A health economics analysis plan (HEAP) was developed prior to conducting the economic evaluation to outline the specific methods and procedures. The HEAP is available upon request.

Reporting

The analysis adhered to established guidelines for reporting cost-effectiveness studies[75,76] (Gomes *et al.* 2012)[84] to ensure comprehensive and transparent reporting. Consolidated Health Economic Evaluation Reporting Standards 2022 Checklist is presented in *Table 25* (see *Appendix 8*).

Jurisdiction

This study was conducted in the UK which has an NHS, providing publicly funded health care, primarily free of charge at the point of use.

Perspective

The analysis was conducted from the perspective of the NHS and Personal Social Services, aligning with guidelines from the National Institute for Health and Care Excellence (NICE).[77]

Time horizon

The within-trial analysis focuses on a 90-day post-randomisation period. The longer-term analysis extends this to a lifetime horizon.

Discounting

For the short-term economic evaluation, costs and benefits were not discounted due to the trial's short duration (< 1 year). For analyses extending beyond 1 year, a discount rate of 3.5% per annum was applied, as recommended by NICE.[77]

Thresholds

Cost-effectiveness thresholds of £15,000,[78] £20,000 and £30,000 per QALY, as reported by NICE,[77] were used.

Short-term economic evaluation (within-trial analysis).

Participants

The inclusion and exclusion criteria for selecting participants in the YCNY intervention evaluation are detailed in previous sections. Notably, the clinical study excluded patients who died within 30 days without re-admission. To mitigate potential bias, these patients were incorporated into this economic evaluation, contributing to both cost and QALY calculations. A summary of the sample sizes across the data sets is provided in *Table 26* (see *Appendix 8*).

Data sets

The YCNY trial utilises two primary data sources: (1) the Routine data set, which includes variables such as unplanned hospital re-admissions at 30, 60 and 90 days, length of hospital stays, ward characteristics and other relevant variables; and (2) the CRF data set, which contains patient characteristics and EQ-5D measurements and some resource use utilisation (some hospital services, and primary care and social care) for a subsample of individuals from the Routine data set. These EQ-5D and resource use measurements were taken at baseline (collected in hospital during the initial admission and following patient recruitment), and at 10, 30 and 90 days post discharge.

In order to consolidate the unplanned hospital re-admissions, the EQ-5D and resource use measurements, all essential for the economic evaluation, we combined both data sets (Routine and CRF data sets) creating a Merged data set. Therefore, only patients contributing to both data sets (Routine and CRF data sets) were included in the analysis. The analysis of this Merged data set followed the 'intention-to-treat' principle.

Resource use measures and valuation

Resource use data collection involved the following categories/resources: (1) hospital services: unplanned re-admissions at 30, 60 and 90 days and the duration of inpatient stays, outpatient clinic, day case, and accident and emergency (A&E); (2) primary care services: GP at surgery, home and telephone, nurse at surgery, home and telephone, and therapist; and (3) social services: home care and social worker. While unplanned re-admissions at 30, 60 and 90 days and the duration of inpatient stays comes from a Routine data set, the information for rest of the health care and social services comes from the CRF to patients and caregivers.

Regarding the YCNY intervention cost, we considered the staff profile and time to be trained and to provide the YCNY intervention. This information was captured in a separate administrative documentation based on expert opinion. The staff profile involved mainly nurses/managers, and the main activities for deliver the YCNY intervention were to discuss with patient about care during admission and discharge, assisting with activities of daily living and provide instructions/education for patient and/or caregiver. For further details about the delivery of the YCNY intervention, see *Table 27* (see *Appendix 8*).

All resource utilisation was monetised and expressed in 2022 Great British pounds, using published UK unit cost estimates (Jones *et al.* 2023; NHS 2023).[85,86] The cost of implementing the YCNY intervention was calculated based on staff salary data (Jones *et al.* 2023).

Outcome measures and valuation

The primary economic outcome is QALYs, derived from health-related quality of life (HRQoL) scores obtained through the EuroQol-5 Dimensions, five-level version (EQ-5D-5L) instrument (for a complete-case analysis by arm and across time points, see *Appendix 8*, *Table 28*). These scores were mapped to the EuroQol-5 Dimensions, three-level version value set using the Hernandez-Alava *et al.* (2022)[87] mapping algorithm, following UK guidance. Outcome measurements were collected at baseline (during the initial hospital admission and post recruitment) and at 10, 30 and 90 days post discharge (via postal questionnaires). QALYs were calculated using the area under the curve approach.

Missing data

The data set was scrutinised for missing data. The nature and extent of the missing data were assessed to determine the most appropriate imputation method. For missing data at baseline, within-cluster mean imputation was used independently of the YCNY intervention allocation (Faria *et al.* 2014; Taljaard *et al.* 2008).[88]

In our base case, we assumed that data were missing at random (MAR) and multiple imputation methods through chained equations by arm were employed (White *et al.* 2011; Faria *et al.* 2014).[89,90] The number of imputed data sets

was defined according to the percentage of incomplete cases (White *et al.* 2011), and the analysis was conducted using the MI impute package in Stata. In the imputation model were considered the same variables as in the main analysis and the hierarchical structure of the data (Díaz-Ordaz *et al.* 2013; Gomes *et al.* 2013; Graham 2009).[91]

For the specific case of EQ-5D variables, the decision about imputing the domains or the EQ-5D index was based on the sample size and the proportion of missing data, as suggested by Simons *et al.* (2015).[92] Given the potential situation of missing values for the resource use information coming from CRFs, we conduct multiple imputation for resources with missing values lower than 60%, and these resources will be part of the main cost-effectiveness analysis. For the rest of resources, that is, those with a percentage of missing values higher than 60%, we will present a resource use comparison between YCNY intervention and usual care considering a complete-case analysis.

Statistical methods

Mean costs and QALYs for each group were presented alongside their adjusted mean differences, with 95% CIs around the differences in means (Willan *et al.* 2004).[93] In accordance with the clinical study, the mean differences for costs were controlled by ward specialty, re-admission rate at baseline (ward-level variable), percentage of patients over 75 years (ward-level variable) and sex (patient-level variable). The mean differences for QALYs were controlled by EQ-5D at baseline and the same variables as the analysis of mean difference for costs.

For the base-case analysis, MME-GLM were estimated for analysing differences in mean costs and outcomes considering the hierarchical structure of the data (wards in hospitals as clusters) (Gomes *et al.* 2012b). SUR models with robust standard errors were also considered to account for potential intragroup (cluster) correlations between costs and QALYs. Costs and QALYs were combined to calculate an ICER.

Non-parametric bootstrap was also used to produce the cost-effectiveness plane, representing the uncertainty in incremental cost and effect estimates, and the probability of YCNY intervention being cost-effective at different thresholds. Given that different approaches have been proposed to combine multiple imputation and bootstrap, we followed a possible approach consisting of drawing bootstrap samples from each of the imputed data set separately and then pooling the estimates (Leurent *et al.* 2018; Schomaker and Heumann 2018).[94,95]

Sensitivity analyses

Following Leurent *et al.* (2018), we modify the potentially multiply imputed data to reflect possible departures from the MAR assumption. In our case, we considered that the potential missing HRQoL data may be missing not at random (MNAR), while the MAR assumption is likely to hold for the potential missing cost data. This approach involves: use MI to impute the missing values under a MAR assumption, modify the MAR-imputed data to reflect a range of plausible MNAR scenarios by multiplying the imputed values by ± 10% (assumption), and analyse the resulting data set as one would a usual multiply-imputed data set.

Long-term economic evaluation (extrapolation and modelling)

Extrapolation and decision analytic modelling

Decision analytic modelling was undertaken to extrapolate costs and outcomes beyond the follow-up period of the trial, irrespective of statistical significance if there is potential for the cost-effectiveness of the intervention over a long-term time horizon.

Model structure

Figure 6 (see *Appendix 8*) illustrates the structure of the hybrid model developed for the long-term economic evaluation. The model initiates with a decision tree to represent the potential short-term outcomes of two strategies: YCNY and usual care. This decision tree, which captures the first 90 days consistent with the clinical trial duration, primarily serves to compute the proportion of patients in each of three health states (alive without experiencing re-admission, alive after experiencing re-admission, and deceased) for both the YCNY and usual care strategies. During this initial 90-day period, costs and QALYs were estimated based on the findings of the within trial analysis. The decision tree then informs the long-term extrapolation, providing foundational data for the subsequent stage of the model. In the second phase, we employed a partitioned survival model to project the expected quality-adjusted survival duration and lifetime costs for

each cohort beyond the trial period. This model, while estimating long-term survival duration and costs based on the patient's status at the conclusion of the trial, does not differentiate between the initial strategies beyond this point.

Key assumptions

The main assumptions underpinning the decision model are listed below:

- Our model predicts long-term survival duration and associated costs conditioned on the patient's health status at the end of the trial period.
- We assume that the intervention under consideration does not influence the rate of re-admissions after the trial period.
- We assume that the intervention does not exert a direct impact on mortality rates. Rather, its influence on mortality is mediated solely through its effect on re-admission rates.
- We assume that the relationship between 30-day re-admission and mortality rates, as described in Fluck *et al.*,[64] can be applicable to the 90-day re-admission rates examined in this study.

Relationship between unplanned hospital re-admissions and mortality

A key issue in our modelling proposal is how to extrapolate the potential 'short-term' benefits of the intervention (i.e. reduction in unplanned re-admissions in 90 days after discharge) to potential 'long-term' benefits (i.e. reduction in mortality). For this, we carried out a systematic review of the literature to identify studies that described this potential relationship in elderly patients in the context of the UK.

As a result of this systematic review, we only identified one relevant study titled 'Early emergency readmission frequency as an indicator of short-, medium- and long-term mortality post-discharge from hospital', conducted by Fluck *et al.*[64] in 2021. This study examines the associations of early emergency re-admission and all-cause mortality within 30 days and 6 months after discharge from hospital and over a 2-year period.

Using external general population data to simulate long-term survival probabilities

To extrapolate the survival probabilities beyond years 1 and 2, we followed the approaches suggested by Jackson *et al.*[79] In this study, the authors present methods for estimating parameters governing long-term survival when long-term evidence is available from different sources.

In our particular case, based on the short follow-up period of the YCNY trial (90 days), we adapted the approaches suggested by Jackson *et al.*[79] to combine two forms of external data: the first one, the survival probability data coming from Fluck *et al.*[64] for years 1 and 2 (external 'disease population' data), and the second one, the survival probability data coming from the UK life tables[80] for year 3 and beyond (external 'general population' data).

We implemented the three extrapolation scenarios after year 2 as suggested by Jackson *et al.*:[79] (1) Disease and general population have the same all-cause mortality. This approach is equivalent to assuming a hazard ratio (HR) = 1 after year 2 for the disease population and the general population and assumes that there is no difference in mortality beyond year 2 between patients re-admitted within 30 days and those not re-admitted within 30 days. (2) Proportional hazards for all-cause mortality between the disease and general populations. This approach assumes that the difference in mortality between patients re-admitted within 30 days and those not re-admitted within 30 days observed in Fluck *et al.*[64] is preserved across the time horizon of the model. (3) Additive hazards for all-cause mortality between the disease and general populations. This approach assumes that the difference in mortality between patients re-admitted within 30 days and those not re-admitted within 30 days observed in Fluck *et al.*[64] declines over the time horizon of the model.

Incorporating health-state utility values

We conducted an analysis of the EQ-5D scores for the YCNY patient cohort. This investigation was aimed at understanding the HRQoL specific to our study population, particularly in relation to the impact of ageing. Upon analysis, we found that the EQ-5D values in our patient population were closely aligned with the values reported by Ara and Brazier[81] for the same age profile groups. Ara and Brazier's approach, which utilises health-state utility values from the general population, serves as a proxy when specific data on the lifetime impact of ageing on HRQoL are not

available. Therefore, we leveraged on the approach suggested by Ara and Brazier to model the lifetime impact of ageing on HRQoL.

Incorporating future unrelated medical costs

We estimated healthcare costs beyond the trial period following the approach of including future unrelated medical costs, as proposed by Perry-Duxbury *et al.*[82] This approach recognises that a patient who receives an intervention, in our case the YCNY intervention, will potentially gain additional life-years and continue to consume healthcare resources during these life-years. According to this approach, it is possible to disaggregate the future unrelated medical costs into the sum of survivor and decedent unrelated medical costs, where survivor costs are costs at each age (excluding the age at which the individual dies) and decedent costs are costs incurred in the last year of life. Average unrelated medical costs are a weighted average of decedent and survivor costs in a certain year.

Main model inputs

Table 29 (see *Appendix 8*) shows the main inputs used in the long-term economic model with their mean values, standard error, probability distributions and source.

Results

Short-term economic evaluation (within-trial analysis)

Databases and sample size

Table 26 (see *Appendix 8*) offers a summary of the sample sizes across the various data sets described in *Methods*. In accordance with the inclusion criteria for this economic evaluation, the Merged data set comprises 468 individuals.

Merge data set: baseline characteristics

Table 33 (see *Appendix 8*) presents the baseline characteristics of 468 participants in the Merged data set, divided into intervention (N = 222) and control (N = 246) groups. Both groups are demographically similar in terms of the patient-level characteristics, such as age and gender. Some differences are observed in the ward-level variables: the intervention group shows a lower baseline re-admission rate and a lower percentage of patients over 75 years old compared to the control group.

Healthcare resource use, healthcare costs and total costs

Table 34 (see *Appendix 8*) focuses on the number and percentage of unplanned re-admissions within the trial follow-up period (90 days) for both the intervention and control groups in the Merged data set. In the intervention group, 72.97% of patients had zero re-admissions, compared to 67.48% in the control group. The percentage of participants with one re-admission was higher in the control group (22.76%) than in the intervention group (18.47%). Both groups were similar in the percentage of participants with two re-admissions, at approximately 7.3%. The control group had a higher percentage of participants with three or more compared to the intervention group.

On other hand, given the high percentage (over 60%) of missing values for the rest of hospital services, primary care and social policy services (all of the information of these resources coming from the CRF database), *Table 35* (see *Appendix 8*) presents a comparison of the resource utilisation of these services by arm using a complete-case analysis. The results suggest that, in general, the control group consumed more of these resources in comparison with the intervention group.

Table 36 (see *Appendix 8*) presents an unadjusted comparative analysis of the intervention costs, healthcare costs (inpatient hospitalisation costs) and total costs (intervention and healthcare costs) between the intervention and control groups using the Merged data set. Total costs are lower in the intervention group compared with the control group (difference of −£215.68).

Missing data

In our analysis of the Merge data set, we identified a high percentage of missing values in EQ-5D scores at various time points. For instance, at the 10-day mark, the intervention arm had 27% missing EQ-5D values (24% in the control arm),

29% missing values at 30 days (30% in the control group) and 37% at 90 days (38% in the control group). We identified that the missingness in EQ-5D measurements may be not at random, that is, there were an inverse association between the baseline EQ-5D scores and the presence of missing EQ-5D values at 10, 30 and 90 days.

Cost-effectiveness

Table 37 (see *Appendix 8*) presents a summary of the main results. For our base case (MME-GLM) the adjusted differences in costs were −£268.78 and for our alternative case (SUR model) −£233.75. In terms of QALYs, the mean adjusted differences are minimal yet positive, at 0.0057 and 0.0077 for the MME-GLM and SUR models, respectively. Given that the YCNY intervention is associated with lower costs and a slight QALY increment, the intervention could be considered 'Dominant' relative to the comparator (usual care).

Sensitivity analysis

Table 38 (see *Appendix 8*) presents the cost-effectiveness of the YCNY intervention under various assumptions regarding MNAR quality-of-life data, while *Figures 6* and *7* (see *Appendix 8*) show the corresponding cost-effectiveness planes and cost-effectiveness acceptability curves, respectively.

Table 38 compares different scenarios by rescaling the MNAR parameters for both the control and YCNY groups. In the base-case scenario (Scenario 1), which assumes MAR, the YCNY intervention is dominant, with a high probability of being cost-effective. Other scenarios adjust the rescaling parameters, for example, reducing imputed quality-of-life values by 5% or 10%. Across all scenarios (Scenarios 2–7), the YCNY intervention consistently remains dominant, and there is the high probability of cost-effectiveness underscoring the robustness of the YCNY intervention's cost-effectiveness under different assumptions of missing data. All of these results are based on imputed data.

Long-term economic evaluation (extrapolation and modelling)

Cost-effectiveness

Table 39 (see *Appendix 8*) presents a summary of the cost-effectiveness results under the different mortality hazard assumptions, comparing the YCNY intervention with usual care over a lifetime horizon. In our base-case scenario, where the hazard for all-cause mortality is assumed to be identical for both the external 'disease population' (referenced from Fluck *et al.*[64]) and the 'general population' (based on UK life-tables) beyond 2 years, YCNY incurs a marginally higher cost (£38,555) compared to usual care (£38,544), YCNY generating marginally higher QALYs (3.44 compared to 3.40), thereby generating 0.037 additional QALYS in the intervention. The ICER for YCNY in this scenario is calculated at £285 per QALY, suggesting higher probabilities of being cost-effective at the thresholds of £15,000 per QALY gained.

In the first alternative scenario, which posits a proportional hazard model, the cost associated with YCNY increases to £42,732, yielding 3.82 QALYs, while usual care costs £42,276 with 3.74 QALYs. Here, the ICER for YCNY increases to £5755 per QALY gained, yet it retains a high probability of cost-effectiveness at the aforementioned threshold. The second alternative scenario, adopting an additive hazard model, shows YCNY at a cost of £40,386 with 3.62 QALYs, compared to £40,139 with 3.56 QALYs for usual care. The ICER for YCNY in this scenario is £4065 per QALY, maintaining a high probability of cost-effectiveness at the £15,000 thresholds. *Figures 8–10* (see *Appendix 8*) present the cost-effectiveness planes and the cost-effectiveness acceptability curves for the base case and the alternative scenarios 1 and 2.

Conclusions

The study's findings provide insights into the short- and long-term costs and health outcomes associated with the YCNY intervention. In the short-term context, the YCNY intervention indicates a potential for cost savings with a slight improvement in health outcomes compared to usual care. For the long-term perspective, our analysis suggests that YCNY increases life expectancy, QALYs and costs and that improvements in QALYs are achieved at a cost that would be considered value for money using cost-effectiveness thresholds of £15,000–£30,000/QALY. Although changes in costs and outcomes associated with the intervention were small, this analysis suggests that the intervention may offer an efficient route to achieving health benefits in a resource-constrained environment.

However, our interpretation of these results must be tempered by acknowledging several limitations. The primary limitation is the 90-day follow-up period, which may not fully capture the medium- and long-term impacts of the intervention. This is a critical aspect, as medium- and longer-term effects can significantly influence the cost-effectiveness landscape. Additionally, the partial data availability, particularly the EQ-5D scores from a smaller subset of the cohort, introduces a layer of uncertainty. This limitation is compounded by the substantial missing data on these EQ-5D measurements. Besides, most of the healthcare resource consumption information (except for hospitalisation) was collected via CRFs from individuals. These resources include certain hospital services, primary care services and social services. Unfortunately, data on these resources, beyond hospitalisation (sourced from routine data), exhibited a high percentage of missing values, and therefore these were not included in the main cost-effectiveness analysis. However, an analysis of the healthcare consumption by control arm suggests that the control group used more primary care and social services compared to the intervention group. Consequently, we believe our cost-effectiveness results may be considered conservative. In addition, the reliance on external data sources for long-term projections, though necessary, brings with it inherent constraints that could affect the generalisability and robustness of our findings. Finally, in our modelling exercise we assumed that the intervention's effect is represented by the reduction in unplanned re-admission at 90 days (the trial period), and we modelled the impact of that reduction on mortality. However, the intervention could have an impact on reducing unplanned re-admissions beyond the 90-day period or directly reduce mortality, resulting in potential higher benefits attributable to the intervention. Nevertheless, we decided to take a conservative approach and adhere to the evidence provided by the trial.

Appendix 8 Figures and tables from the health economics evaluation in the main trial (work package 6)

TABLE 25 Consolidated Health Economic Evaluation Reporting Standards 2022 checklist

Topic	Number	Item	Location where item is reported
Title			
Title	1	Identify the study as an economic evaluation and specify the interventions being compared	Appendix 7, Introduction
Abstract			
Abstract	2	Provide a structured summary that highlights context, key methods, results and alternative analyses	N/A
Introduction			
Background and objectives	3	Give the context for the study, the study question and its practical relevance for decision-making in policy or practice	Appendix 7, Introduction
Methods			
Health economic analysis plan	4	Indicate whether a health economic analysis plan was developed and where available	Appendix 7, Methods, General considerations
Study population	5	Describe characteristics of the study population (such as age range, demographics, socioeconomic or clinical characteristics)	Described in the clinical study
Setting and location	6	Provide relevant contextual information that may influence findings	Described in the clinical study
Comparators	7	Describe the interventions or strategies being compared and why chosen	Described in the clinical study
Perspective	8	State the perspective(s) adopted by the study and why chosen	Appendix 7, Methods, General considerations
Time horizon	9	State the time horizon for the study and why appropriate	Appendix 7, Methods, General considerations
Discount rate	10	Report the discount rate(s) and reason chosen	Appendix 7, Methods, General considerations
Selection of outcomes	11	Describe what outcomes were used as the measure(s) of benefit(s) and harm(s)	Appendix 7, Methods, Outcome measures and valuation
Measurement of outcomes	12	Describe how outcomes used to capture benefit(s) and harm(s) were measured	Appendix 7, Methods, Outcome measures and valuation
Valuation of outcomes	13	Describe the population and methods used to measure and value outcomes	Appendix 7, Methods, Outcome measures and valuation
Measurement and valuation of resources and costs	14	Describe how costs were valued	Appendix 7, Methods, Resource use measures and valuation
Currency, price date, and conversion	15	Report the dates of the estimated resource quantities and unit costs, plus the currency and year of conversion	Appendix 7, Methods, Resource use measures and valuation
Rationale and description of model	16	If modelling is used, describe in detail and why used. Report if the model is publicly available and where it can be accessed	Appendix 7, Methods, Model structure

TABLE 25 Consolidated Health Economic Evaluation Reporting Standards 2022 checklist (*continued*)

Topic	Number	Item	Location where item is reported
Analytics and assumptions	17	Describe any methods for analysing or statistically transforming data, any extrapolation methods, and approaches for validating any model used	Appendix 7, Methods, Using external general population data to simulate long-term survival probabilities
Characterising heterogeneity	18	Describe any methods used for estimating how the results of the study vary for subgroups	N/A
Characterising distributional effects	19	Describe how impacts are distributed across different individuals or adjustments made to reflect priority populations	N/A
Characterising uncertainty	20	Describe methods to characterise any sources of uncertainty in the analysis	Appendix 7, Methods
Approach to engagement with patients and others affected by the study	21	Describe any approaches to engage patients or service recipients, the general public, communities or stakeholders (such as clinicians or payers) in the design of the study	N/A
Results			
Study parameters	22	Report all analytic inputs (such as values, ranges, references) including uncertainty or distributional assumptions	Appendix 7, Results
Summary of main results	23	Report the mean values for the main categories of costs and outcomes of interest and summarise them in the most appropriate overall measure	Appendix 7, Results
Effect of uncertainty	24	Describe how uncertainty about analytic judgements, inputs or projections affect findings. Report the effect of choice of discount rate and time horizon, if applicable	Appendix 7, Results
Effect of engagement with patients and others affected by the study	25	Report on any difference patient/service recipient, general public, community or stakeholder involvement made to the approach or findings of the study	N/A
Discussion			
Study findings, limitations, generalisability and current knowledge	26	Report key findings, limitations, ethical or equity considerations not captured, and how these could affect patients, policy or practice	Appendix 7, Conclusion
Other relevant information			
Source of funding	27	Describe how the study was funded and any role of the funder in the identification, design, conduct and reporting of the analysis	Described in the clinical study
Conflicts of interest	28	Report authors conflicts of interest according to journal or International Committee of Medical Journal Editors requirements	N/A

Reproduced from Husereau *et al.*[75]

TABLE 26 Sample sizes across data sets

Data set	Initial sample	Primary analysis cohort sample	Primary analysis cohort sample + patients who have died within 30 days and no re-admission recorded
Routine	5450	4947	5147
CRF	622	455	468
EE	615	455	468

CRF, complete-case form; EE, economic evaluation.

TABLE 27 Intervention delivery per patient

Activity	Duration (minutes)			Undertaken by
	Usual care wards	Intervention wards	Incremental	
Discussion with patient about care – on admission	5	5	0	Nursing/ manager
Discussion with patient about care – during admission	15	30	15	Nursing/ manager
Discussion with patient about care – during admission	15	25	10	Medical staff
Discussion with patient about care – discharge	15	20	5	Nursing/ manager
Assisting with activities of daily living	70	105	35	Nursing/ manager
Instructions/education for patient and/or caregiver	5	25	20	Nursing/ manager

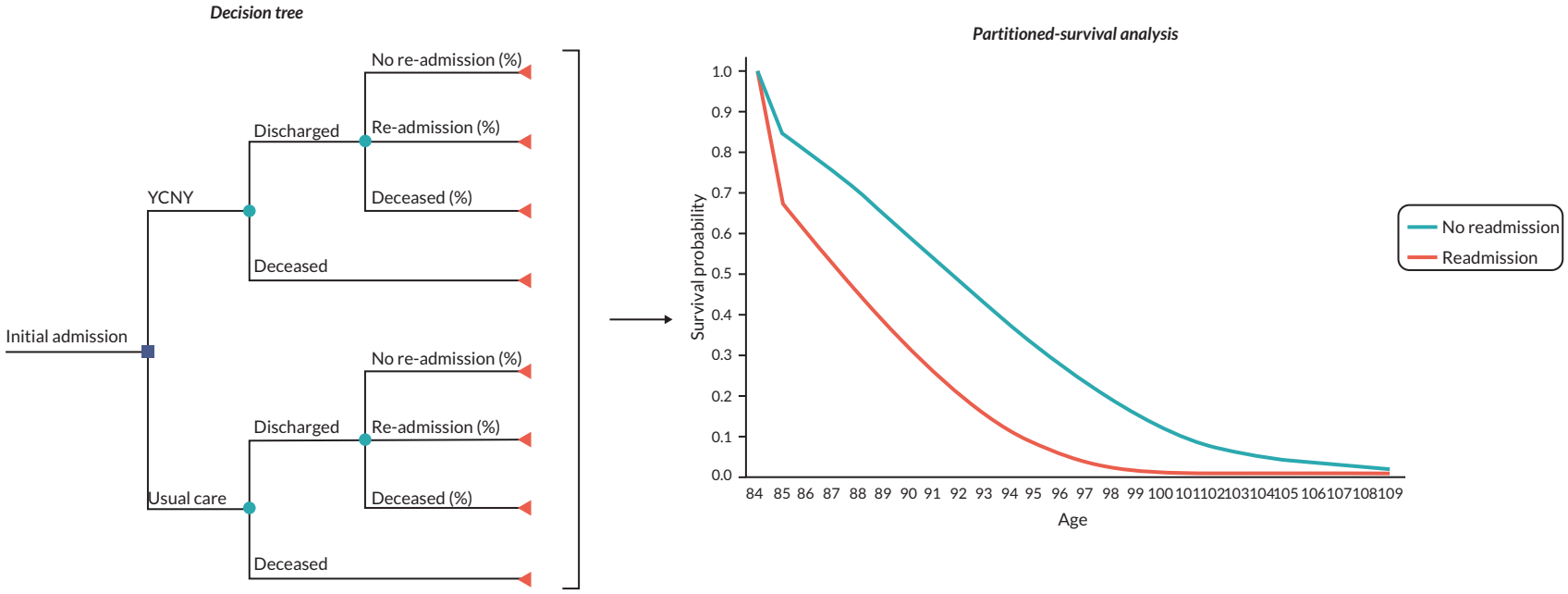

FIGURE 6 The health economic model.

TABLE 28 Unadjusted mean for EQ-5D-5L between arms

Variable	YCNY intervention	Control
EQ-5D at baseline	0.5999	0.5806
EQ-5D at 10 days	0.6007	0.5705
EQ-5D at 30 days	0.6271	0.5814
EQ-5D at 90 days	0.6590	0.5638

Note
Results based on complete cases.

TABLE 29 Main inputs of the long-term economic model

Description	Mean	SE	Alpha	Beta	Distribution	Source
Demographics						
Proportion age 70–79 years	0.23	–				YCNY trial data, Routine data set
Proportion female	0.59	–				YCNY trial data, Routine data set
Clinical parameters informing 90-day decision tree						
Probability of death at 90 days	0.13					
Probability of unplanned re-admission at 90 days in usual care	0.35	–	779	1440	Beta	YCNY clinical study
OR of YCNY intervention on unplanned re-admission at 90 days	0.82	1.00	–	–	Log-normal	YCNY clinical study
Mortality						
Probability of death at 2 years, 70–79 years	0.28	–	1699	4369	Beta	Own estimation based on Fluck *et al.* (2021)[64]
Probability of death at 2 years, 80 + years	0.38	–	3292	5464	Beta	Own estimation based on Fluck *et al.* (2021)[64]
HR of re-admission at 30 days on 2 years mortality, 70–79 years	2.50	1.00	–	–	Log-normal	Own estimation based on Fluck *et al.* (2021)[64]
HR of re-admission at 30 days on 2 years mortality, 80+ years	2.00	1.00	–	–	Log-normal	Own estimation based on Fluck *et al.* (2021)[64]
General mortality for age and sex	See table 'Gral. Mortality' below					UK Office for National Statistics
Costs (£)						
Adjusted total costs at 90 days in usual care at the individual level	1574	–				YCNY trial data, Merge data set
Adjusted incremental costs of YCNY intervention at 90 days at the individual level	−269	317	–	–	Normal	YCNY trial data, Merge data set
Adjustment for age and sex for the last and other years of life	See table 'Unrelated costs' below					Own estimation based on Perry-Duxbury *et al.* (2020)[82]
QALYs						
Adjusted total QALYs at 90 days in usual care at the individual level	0.0835	–				YCNY trial data, Merge data set
Adjusted incremental QALYs of YCNY intervention at 90 days at the individual level	0.0057	0.0084	–	–	Normal	YCNY trial data, Merge data set
Adjustment for age and sex	See table 'Health utility' below					Own estimation based on Ara and Brazier (2010)[81]
Other parameters						
Annual discount rate – outcomes	0.035	–				NICE
Annual discount rate – costs	0.035	–				NICE

TABLE 30 General mortality

Males			Females		Pop. weighted	
Age	qx	lx	qx	lx	qx	lx
0	0.004	100,000	0.004	100,000	0.004	100,000
1	0.000	99,578	0.000	99,650	0.000	99,613
2	0.000	99,555	0.000	99,628	0.000	99,591
3	0.000	99,542	0.000	99,617	0.000	99,579
4	0.000	99,532	0.000	99,608	0.000	99,569
5	0.000	99,523	0.000	99,601	0.000	99,561
6	0.000	99,516	0.000	99,594	0.000	99,554
7	0.000	99,508	0.000	99,587	0.000	99,546
8	0.000	99,501	0.000	99,581	0.000	99,540
9	0.000	99,494	0.000	99,575	0.000	99,534
10	0.000	99,488	0.000	99,570	0.000	99,528
11	0.000	99,480	0.000	99,564	0.000	99,521
12	0.000	99,473	0.000	99,558	0.000	99,514
13	0.000	99,463	0.000	99,553	0.000	99,507
14	0.000	99,451	0.000	99,544	0.000	99,496
15	0.000	99,438	0.000	99,534	0.000	99,485
16	0.000	99,421	0.000	99,523	0.000	99,471
17	0.000	99,401	0.000	99,510	0.000	99,454
18	0.000	99,370	0.000	99,494	0.000	99,431
19	0.000	99,330	0.000	99,473	0.000	99,399
20	0.001	99,285	0.000	99,452	0.000	99,366
21	0.001	99,233	0.000	99,433	0.000	99,330
22	0.000	99,182	0.000	99,412	0.000	99,295
23	0.001	99,133	0.000	99,388	0.000	99,258
24	0.001	99,081	0.000	99,366	0.000	99,221
25	0.001	99,026	0.000	99,344	0.000	99,182
26	0.001	98,966	0.000	99,318	0.000	99,140
27	0.001	98,906	0.000	99,293	0.000	99,097
28	0.001	98,844	0.000	99,262	0.000	99,051
29	0.001	98,777	0.000	99,231	0.001	99,002
30	0.001	98,705	0.000	99,197	0.001	98,950
31	0.001	98,629	0.000	99,159	0.001	98,893
32	0.001	98,546	0.000	99,120	0.001	98,833
33	0.001	98,462	0.000	99,074	0.001	98,768

continued

TABLE 30 General mortality (*continued*)

Males			Females		Pop. weighted	
Age	qx	lx	qx	lx	qx	lx
34	0.001	98,368	0.001	99,025	0.001	98,697
35	0.001	98,270	0.001	98,967	0.001	98,620
36	0.001	98,162	0.001	98,908	0.001	98,537
37	0.001	98,049	0.001	98,841	0.001	98,448
38	0.001	97,916	0.001	98,766	0.001	98,345
39	0.001	97,788	0.001	98,688	0.001	98,242
40	0.002	97,645	0.001	98,602	0.001	98,128
41	0.002	97,488	0.001	98,511	0.001	98,005
42	0.002	97,323	0.001	98,412	0.001	97,873
43	0.002	97,143	0.001	98,304	0.002	97,730
44	0.002	96,947	0.001	98,182	0.002	97,572
45	0.002	96,733	0.001	98,050	0.002	97,399
46	0.003	96,494	0.002	97,904	0.002	97,207
47	0.003	96,239	0.002	97,745	0.002	97,000
48	0.003	95,975	0.002	97,575	0.002	96,783
49	0.003	95,691	0.002	97,383	0.003	96,546
50	0.004	95,375	0.002	97,183	0.003	96,288
51	0.004	95,034	0.002	96,966	0.003	96,010
52	0.004	94,671	0.003	96,728	0.003	95,710
53	0.004	94,285	0.003	96,479	0.004	95,393
54	0.005	93,870	0.003	96,212	0.004	95,053
55	0.005	93,427	0.003	95,927	0.004	94,689
56	0.006	92,956	0.004	95,612	0.005	94,296
57	0.006	92,436	0.004	95,264	0.005	93,863
58	0.007	91,875	0.004	94,890	0.006	93,396
59	0.007	91,260	0.005	94,475	0.006	92,881
60	0.008	90,600	0.005	94,031	0.007	92,329
61	0.009	89,883	0.006	93,537	0.007	91,723
62	0.010	89,107	0.006	93,010	0.008	91,071
63	0.011	88,251	0.007	92,410	0.009	90,343
64	0.011	87,320	0.007	91,780	0.009	89,561
65	0.012	86,344	0.008	91,103	0.010	88,734
66	0.014	85,269	0.009	90,364	0.011	87,826
67	0.015	84,087	0.010	89,571	0.012	86,839
68	0.016	82,844	0.011	88,716	0.013	85,789

TABLE 30 General mortality (*continued*)

Males			Females		Pop. weighted	
Age	qx	lx	qx	lx	qx	lx
69	0.018	81,490	0.011	87,775	0.015	84,641
70	0.019	80,027	0.013	86,769	0.016	83,407
71	0.021	78,488	0.014	85,650	0.017	82,077
72	0.023	76,856	0.015	84,482	0.019	80,678
73	0.026	75,105	0.017	83,173	0.021	79,147
74	0.029	73,167	0.020	81,735	0.024	77,458
75	0.032	71,062	0.022	80,126	0.027	75,600
76	0.036	68,766	0.024	78,382	0.030	73,579
77	0.040	66,309	0.028	76,469	0.034	71,394
78	0.045	63,648	0.031	74,335	0.038	68,994
79	0.050	60,772	0.036	71,999	0.042	66,390
80	0.056	57,718	0.040	69,428	0.047	63,580
81	0.062	54,477	0.045	66,678	0.053	60,592
82	0.069	51,098	0.050	63,669	0.059	57,402
83	0.077	47,562	0.057	60,473	0.066	54,042
84	0.087	43,877	0.065	57,016	0.075	50,476
85	0.097	40,046	0.074	53,302	0.084	46,712
86	0.110	36,143	0.085	49,371	0.095	42,805
87	0.123	32,159	0.096	45,198	0.107	38,735
88	0.138	28,210	0.108	40,863	0.119	34,603
89	0.155	24,327	0.122	36,458	0.134	30,469
90	0.163	20,568	0.136	32,024	0.145	26,384
91	0.183	17,205	0.153	27,654	0.163	22,553
92	0.201	14,051	0.171	23,411	0.181	18,875
93	0.223	11,229	0.190	19,407	0.200	15,465
94	0.245	8725	0.208	15,728	0.220	12,367
95	0.269	6591	0.230	12,459	0.243	9650
96	0.290	4818	0.253	9590	0.265	7307
97	0.314	3418	0.278	7162	0.290	5369
98	0.336	2345	0.300	5172	0.311	3814
99	0.370	1558	0.320	3622	0.336	2627
100	0.391	982	0.351	2463	0.364	1744

Note
Notation.
qx: is the mortality rate between age *x* and (*x* + 1), that is the probability that a person aged *x* exact will die before reaching age (*x* + 1).
lx: is the number of survivors to exact age × of 100,000 live births of the same sex who are assumed to be subject throughout their lives to the mortality rates experienced in the 3-year period to which the National Life Table relates.
Source: Office for National Statistics.[80]

TABLE 31 Unrelated costs

	Men		Women		Overall (2018 price levels)		Overall (2022 price levels)	
Age	Other years of life	Last year of life	Other years of life	Last year of life	Other years of life	Last year of life	Other years of life	Last year of life
75	£3687	£6492	£3252	£5555	£3432	£5943	£3944	£6830
76	£3870	£6595	£3365	£5732	£3574	£6090	£4108	£6998
77	£4035	£6940	£3469	£5867	£3704	£6312	£4256	£7254
78	£4182	£7054	£3560	£5844	£3818	£6345	£4387	£7292
79	£4302	£7153	£3632	£5979	£3910	£6466	£4493	£7430
80	£4404	£7271	£3707	£6091	£3996	£6580	£4592	£7561
81	£4492	£7540	£3797	£6153	£4085	£6728	£4694	£7732
82	£4601	£7697	£3889	£6440	£4184	£6961	£4808	£7999
83	£4720	£8025	£4017	£6508	£4308	£7137	£4951	£8201
84	£4878	£8231	£4156	£6655	£4455	£7308	£5120	£8399
85	£5030	£8593	£4271	£7298	£4586	£7835	£5270	£9004
86	£5146	£8910	£4381	£7642	£4698	£8167	£5399	£9386
87	£5175	£9002	£4408	£7756	£4726	£8273	£5431	£9507
88	£5131	£8899	£4365	£7668	£4683	£8178	£5381	£9398
89	£5079	£8770	£4327	£7573	£4638	£8069	£5330	£9273
90	£5021	£8622	£4280	£7457	£4587	£7940	£5271	£9125
91	£4966	£8484	£4238	£7349	£4540	£7819	£5217	£8986
92	£4915	£8352	£4194	£7237	£4493	£7699	£5163	£8848
93	£4863	£8220	£4145	£7114	£4443	£7573	£5106	£8703
94	£4808	£8080	£4093	£6983	£4389	£7437	£5044	£8547
95	£4746	£7924	£4039	£6848	£4332	£7294	£4978	£8382
96	£4676	£7746	£3986	£6716	£4272	£7143	£4909	£8208
97	£4600	£7554	£3930	£6577	£4208	£6982	£4836	£8023
98	£4528	£7370	£3860	£6403	£4137	£6803	£4754	£7818
99	£4468	£7217	£3762	£6158	£4055	£6597	£4660	£7581
100	£4468	£7217	£3762	£6158	£4055	£6597	£4660	£7581
101	£4468	£7217	£3762	£6158	£4055	£6597	£4660	£7581
102	£4468	£7217	£3762	£6158	£4055	£6597	£4660	£7581
103	£4468	£7217	£3762	£6158	£4055	£6597	£4660	£7581
104	£4468	£7217	£3762	£6158	£4055	£6597	£4660	£7581
105	£4468	£7217	£3762	£6158	£4055	£6597	£4660	£7581
106	£4468	£7217	£3762	£6158	£4055	£6597	£4660	£7581
107	£4468	£7217	£3762	£6158	£4055	£6597	£4660	£7581
108	£4468	£7217	£3762	£6158	£4055	£6597	£4660	£7581

TABLE 31 Unrelated costs (*continued*)

	Men		Women		Overall (2018 price levels)		Overall (2022 price levels)	
Age	Other years of life	Last year of life	Other years of life	Last year of life	Other years of life	Last year of life	Other years of life	Last year of life
109	£4468	£7217	£3762	£6158	£4055	£6597	£4660	£7581
110	£4468	£7217	£3762	£6158	£4055	£6597	£4660	£7581

Note
Data from the Shinny app available at: https://imta.shinyapps.io/PAIDUKr/.
Source: Perry-Duxbury *et al.* (2020).[82]

TABLE 32 Health utilities

		EQ-5D		
Age	Cycle	HSUV (general population)	No re-admission	Re-admission
84	0	0.704	0.704	0.704
85	1	0.698	0.698	0.698
86	2	0.692	0.692	0.692
87	3	0.686	0.686	0.686
88	4	0.680	0.680	0.680
89	5	0.674	0.674	0.674
90	6	0.667	0.667	0.667
91	7	0.661	0.661	0.661
92	8	0.655	0.655	0.655
93	9	0.648	0.648	0.648
94	10	0.642	0.642	0.642
95	11	0.635	0.635	0.635
96	12	0.629	0.629	0.629
97	13	0.622	0.622	0.622
98	14	0.615	0.615	0.615
99	15	0.609	0.609	0.609
100	16	0.602	0.602	0.602
101	17	0.595	0.595	0.595
102	18	0.588	0.588	0.588
103	19	0.581	0.581	0.581
104	20	0.574	0.574	0.574
105	21	0.566	0.566	0.566
106	22	0.559	0.559	0.559
107	23	0.552	0.552	0.552
108	24	0.544	0.544	0.544
109	25	0.537	0.537	0.537

Sources: Ara *et al.*;[83] Ara and Brazier *et al.*[81]

TABLE 33 Merged data set: baseline characteristics

Variable	YCNY intervention Patients = 222 Wards = 16	Control Patients = 246 Wards = 19	Total Patients = 468 Wards = 35	*p*-value
Age	82.8 (5.4)	83.4 (5.5)	83.1 (5.4)	0.24
Dummy sex, 1 = male, %	48.2 (50.1)	39.4 (49.0)	43.6 (49.6)	0.056
EQ-5D at baseline	0.50 (0.31)	0.48 (0.33)	0.49 (0.32)	0.44
Ward: baseline re-admission rate, %	18.4 (6.6)	19.7 (5.6)	19.1 (6.1)	0.028
Ward: patients over 75 years old, %	69.5 (27.6)	74.3 (19.3)	72.0 (23.7)	0.028
Ward: patients re-admitted over 75 years old, %	67.9 (41.3)	70.4 (38.0)	69.1 (39.6)	0.50
Ward: dummy specialty, 1 = elderly and interm. care, %	53.2 (50.0)	55.7 (49.8)	54.5 (49.9)	0.58

TABLE 34 Hospital re-admissions within 90 days by arm

Re-admissions	YCNY intervention	Control	Total
0	162 (72.97)	166 (67.48)	328 (70.09)
1	41 (18.47)	56 (22.76)	97 (20.73)
2	16 (7.21)	18 (7.32)	34 (7.26)
3	2 (0.9)	5 (2.03)	7 (1.5)
4	1 (0.45)	0 (0)	1 (0.21)
5	0 (0)	1 (0.41)	1 (0.21)
Mean (SD)	0.3739 (0.6990)	0.4553 (0.7746)	0.4167 (0.7400)

Note
Data are presented as *N* (%).

TABLE 35 Other resource use within 90 days by arm and total, complete-case analysis

Healthcare resource use	Intervention		Control		Total	
	N	%	*N*	%	*N*	%
Hospital care						
Outpatient clinic	84	66.7	100	68	184	67.4
Day case	42	14.3	59	23.7	101	19.8
A&E	45	20	64	29.7	109	25.7
Primary care						
GP at surgery	82	51.2	97	54.6	179	53.1
GP at home	72	22.2	83	31.3	155	27.1
GP at telephone	83	62.6	90	70	173	66.5

TABLE 35 Other resource use within 90 days by arm and total, complete-case analysis (*continued*)

	Intervention		Control		Total	
Healthcare resource use	***N***	**%**	***N***	**%**	***N***	**%**
Nurse at surgery	79	43	91	49.4	170	46.5
Nurse at home	80	52.5	86	54.6	166	53.6
Nurse at telephone	74	33.8	76	27.6	150	30.7
Therapist	81	48.1	87	44.8	168	46.4
Social care						
Home care	79	40.5	85	51.8	164	46.3
Social worker	81	17.3	79	24	160	20.6

TABLE 36 Unadjusted mean intervention, healthcare and total costs between arms

Variable	Intervention	Control	Difference
Intervention costs	94.32	0.00	94.32
Hospitalisation costs	1502.44	1812.44	−310.00
Total costs	1596.76	1812.44	−215.68

Notes
Monetary values expressed in Great British pounds of 2022.
Results based on imputed values.

TABLE 37 Cost-effectiveness results

		Base case: MME-GLM	Alternative case: SUR model
Total costs	Adj. mean control[a]	1574.29	1576.43
	Adjusted mean YCNY intervention[a]	1305.51	1342.68
	Adjusted mean difference[a]	−268.78	−233.75
	SE difference	316.78	333.57
	95% CI difference	−889.67 to 352.11	−887.54 to 420.04
Total QALYs	Adjusted mean control[b]	0.0835	0.0841
	Adjusted mean YCNY intervention[b]	0.0892	0.0912
	Adjusted mean difference[b]	0.0057	0.0071
	SE difference	0.0084	0.0077
	95% CI difference	−0.0108 to 0.0223	−0.0080 to 0.0222
ICER		YCNY dominant	YCNY dominant

a Results adjusted by ward specialty, re-admission rate at baseline (ward-level variable), percentage of patients over 75 years (ward-level variable) and sex (patient-level variable).
b Results adjusted by EQ-5D at baseline ward specialty, re-admission rate at baseline (ward-level variable), percentage of patients over 75 years (ward-level variable) and sex (patient-level variable).

Notes
Within-trial analysis, 90-day time horizon. Monetary values expressed in Great British pounds of 2022.
Results based on imputed data.

TABLE 38 Cost-effectiveness of YCNY intervention under different MNAR assumptions for missing quality-of-life data

Scenario number	MNAR rescaling parameters[a]		Incremental cost[b] (£) (95% CI)	Incremental QALYs (95% CI)	NHB (95% CI)	Probability of cost-effective[c] (%)
	C control	C YCNY				
1 (base case, MAR)	1	1	−268.78 (−889.67 to 352.11)	0.0057 (−0.0108 to 0.0223)	0.0246 (−0.0190 to 0.0682)	89
2	1	0.95	−268.78 (−889.67 to 352.11)	0.0027 (−0.0135 to 0.0189)	0.0231 (−0.0205 to 0.0667)	87
3	0.95	1	−268.78 (−889.67 to 352.11)	0.0057 (−0.0103 to 0.0216)	0.0261 (−0.0174 to 0.0670)	90
4	0.95	0.95	−268.78 (−889.67 to 352.11)	0.0043 (−0.0117 to 0.0202)	0.0246 (−0.0189 to 0.0681)	89
5	0.95	0.90	−268.78 (−889.67 to 352.11)	0.0029 (−0.0130 to 0.0187)	0.0231 (−0.0204 to 0.0666)	87
6	0.90	0.95	−268.78 (−889.67 to 352.11)	0.0058 (−0.0098 to 0.0214)	0.0261 (−0.0174 to 0.0656)	90
7	0.90	0.90	−268.78 (−889.67 to 352.11)	0.0044 (−0.0111 to 0.0200)	0.0246 (−0.0189 to 0.0680)	89

NHB, net health benefit.
a How missing quality-of-life data are assumed to differ from the MAR-imputed values, for example, c control = 0.9 means that all imputed quality-of-life values in the control arm have been reduced by 10%.
b Missing costs assumed to be MAR in all scenarios.
c At a cost-effectiveness threshold of £15,000/QALY.

Notes
All results are based on imputed data and comparing the YCNY intervention arm to the control arm (n = 455).
Results based on imputed data.

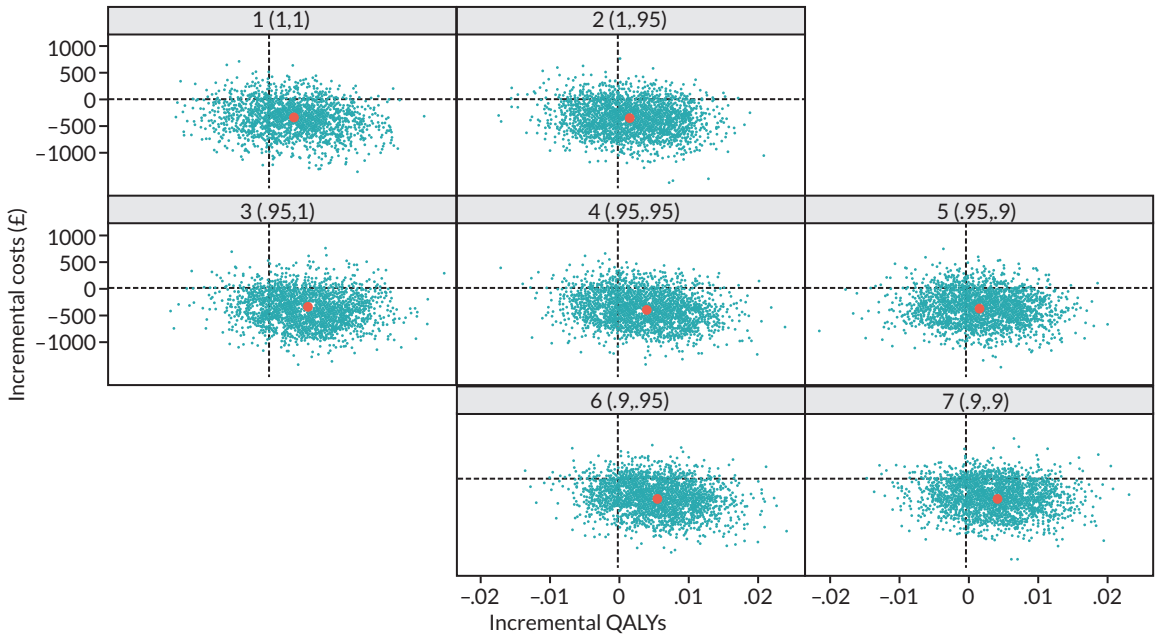

FIGURE 7 Cost-effectiveness planes of the YCNY intervention under different MNAR assumptions. Results based on imputed data. Notes: Headings in the top of each plane indicate the scenario number and the MNAR rescaling parameters (c control, c YCNY). For example, (.9, .9): imputed quality-of-life values have been reduced by 10% in both arms.

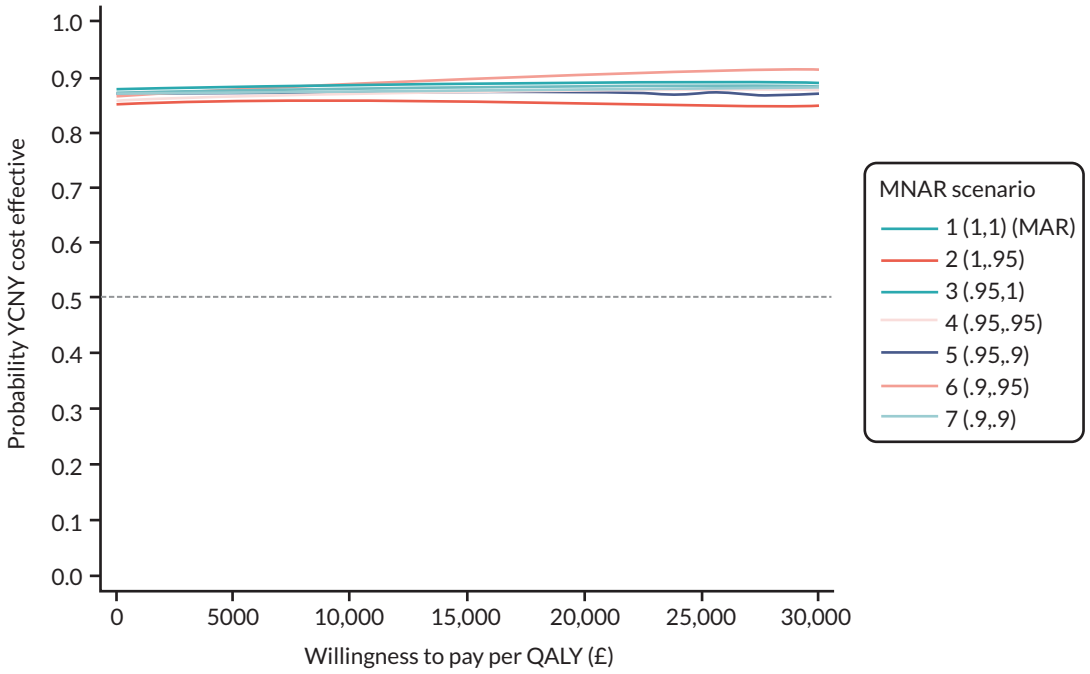

FIGURE 8 Cost-effectiveness acceptability curves.

TABLE 39 Summary of the cost-effectiveness results

			Incremental			Probability of cost-effective at threshold		
Arm	**Costs (£)**	**QALYs**	**Costs (£)**	**QALYs**	**ICER (£/QALY)**	**15,000 (%)**	**20,000 (%)**	**30,000 (%)**
Base case: Same hazard for all-cause mortality between the external 'disease population'[64] and external 'general population' (UK life-tables) for $t > 2$								
YCNY	38,555	3.44	10.65	0.0373	285.48	94	98	100
Usual care	38,544	3.40						
Alternative scenario 1: Proportional hazard for all-cause mortality between the external 'disease population'[64] and external 'general population' (UK life-tables) for $t > 2$								
YCNY	42,732	3.82	456.23	0.0793	5754.55	99	100	100
Usual care	42,276	3.74						
Alternative scenario 2: Additive hazard for all-cause mortality between the external 'disease population'[64] and external 'general population' (UK life-tables) for $t > 2$								
YCNY	40,386	3.62	247.24	0.0608	4065.41	97	100	100
Usual care	40,139	3.56						

Note
Within-trial analysis up to 90 days followed by model projections over lifetime.

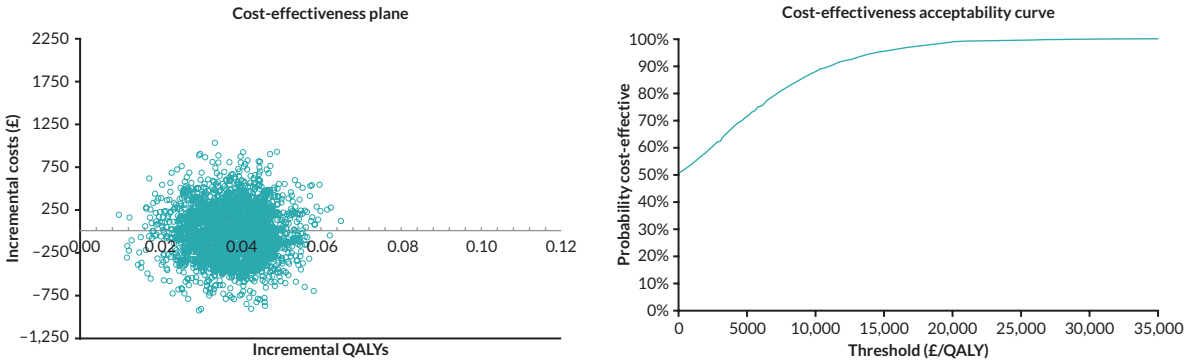

FIGURE 9 Cost-effectiveness plane and cost-effectiveness acceptability curve. Base case: same hazard for all-cause mortality between the external 'disease population'[64] and external 'general population' (UK life-tables) for $t > 2$.

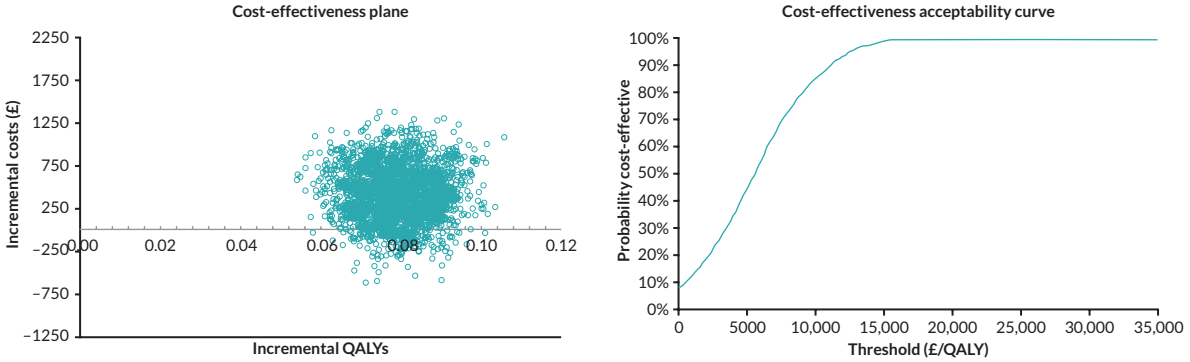

FIGURE 10 Cost-effectiveness plane and cost-effectiveness acceptability curve. Alternative scenario 1: proportional hazard for all-cause mortality between the external 'disease population'[64] and external 'general population' (UK life-tables) for $t > 2$.

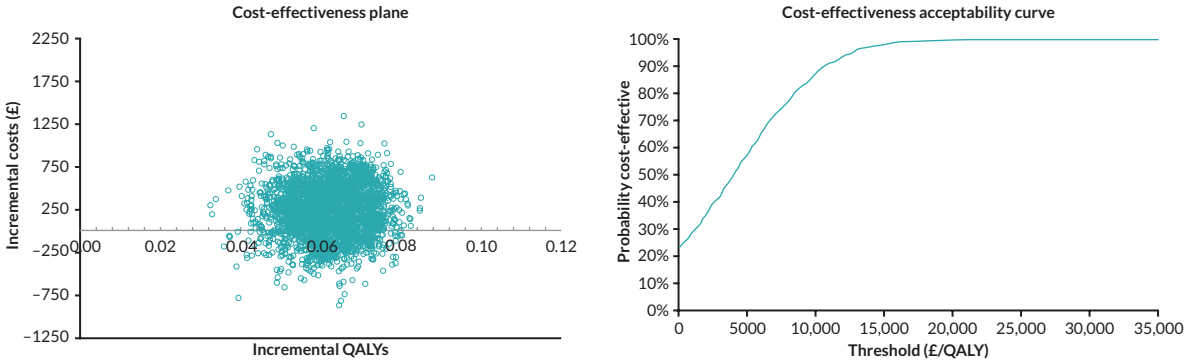

FIGURE 11 Cost-effectiveness plane and cost-effectiveness acceptability curve. Alternative scenario 2: additive hazard for all-cause mortality between the external 'disease population'[64] and external 'general population' (UK life-tables) for $t > 2$.

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