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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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Scientific summary

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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).

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