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FULL TITLE:

A cluster randomised controlled trial to assess the effectiveness and cost-effectiveness of the ‘Your Care Needs You’ intervention to improve safety and experience of care transitions.

SHORT TRIAL TITLE / ACRONYM:

PACT: Cluster randomised controlled trial of the ‘Your Care Needs You’ intervention.

**This protocol has regard for the HRA guidance**

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**RESEARCH REFERENCE NUMBERS**

IRAS number: 277060

ISRCTN number: To register prior to commencing study

Protocol version number and date:Version 1 - 12/12/19

Funders reference number: NIHR Programme Grant for Applied Research RP-PG-1214-20017

Sponsor reference number: Bradford Teaching Hospitals NHS Trust - BTHFT 2449

# SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the UK Policy Framework for Health and Social Care Research 2017, GCP guidelines, the Sponsor’s (and any other relevant) Standard Operating Procedures (SOP), and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor and the Chief Investigator.

I also confirm that I will make the findings of the trial publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies and serious breaches of GCP from the trial as planned in this protocol will be explained.

|  |
| --- |
| **For and on behalf of the Trial Sponsor:** |
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|  |  |  |
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# LIST OF ABBREVIATIONS

AE Adverse Event

BI Barthel Index

BIHR Bradford Institute for Health Research

DoB Date of Birth

CI Chief Investigator

CRF Case Report Form

CTM-3 Care Transitions Measure – 3 item

DMC Data Monitoring Committee

Eq5D EuroQol 5-Dimension Health Questionnaire

FCI Functional Co-morbidity Index

GCP Good Clinical Practice

ICF Informed Consent Form

IS Information Services

ISF Investigator Site File (This forms part of the TMF)

ISRCTN International Standard Randomised Controlled Trials Number

LoS Length of Stay

NHS R&D National Health Service Research & Development

PACT Partners At Care Transitions

PACT-M Partners At Care Transitions Measure

PI Principal Investigator

PIS Participant Information Sheet

cRCT Cluster Randomised Control Trial

REC Research Ethics Committee

SAE Serious Adverse Event

SOP Standard Operating Procedure

SSI Site Specific Information

TMF Trial Master File

TMG Trial Management Group

TSC Trial Steering Committee

YCNY Your Care Needs You!

YQSR Yorkshire Quality and Safety Research Group

YTU York Trials Unit

WP Work Package

# TRIAL SUMMARY

|  |  |
| --- | --- |
| Trial Title | A cluster randomised controlled trial to assess the effectiveness and cost-effectiveness of the ‘Your Care Needs You’ intervention to improve safety and experience of care transitions.  |
| Internal ref. no. (or short title) | PACT: a cluster randomised controlled trial of the YCNY intervention.Local Project Reference number : BTHFT 2449 |
| Clinical Phase  | Full trial  |
| Trial Design | Cluster Randomised Controlled Trial  |
| Trial Participants | Patients aged 75 years and over who are expected to be discharged back to their own home.The informal carers of patients aged 75 years and over who are expected to be discharged back to their own homes |
| Planned Sample Size | Consented patients: A minimum of 782 participants recruited across approximately 40 participating wards (approximately 20 patients per ward). If patients lack capacity, carers will act as a consultee. Anonymised routine data: on unplanned readmissions within 30 days (primary outcome), 60 and 90 days (secondary outcomes) for up to 7,000 non-consenting patients on participating wards. Process evaluation: nested sample of between 24 and 30 patients will be recruited to participate in the qualitative process evaluation with informal carers if relevant. Between 35 and 45 staff primarily interviewed across 8 wards and up to 5 control wards as part of the process evaluation. |
| Intervention duration | The intervention will be implemented by ward staff from admission to a participating ward until discharge from hospital (duration depends on each patient’s length of admission). Patients will be encouraged to take the intervention materials home for support following discharge.  |
| Follow-up duration | Up to three months post-discharge |
| Planned Trial Period | 18 months |
| Objectives  | 1. To assess the effectiveness of YCNY in reducing unplanned hospital readmissions in the over 75s
2. To assess the effectiveness of YCNY in improving quality and experience of transition and quality of life in the over 75s
3. To assess the cost effectiveness of the YCNY
4. To assess the fidelity of YCNY and explore the contextual factors that affect it.
5. To understand the mechanisms of action of YCNY
 |
| Intervention  | The YCNY Intervention is designed to support patients and families to prepare for discharge home following an inpatient hospital stay, with a view to improving the safety and experience of this transition. It comprises three core components: 1. A patient-facing ‘booklet’ which supports patients to ask questions and raise issues;
2. A patient-facing educational film;
3. Documents to enhance discharge letters.

Implementation of the intervention will be facilitated by researchers and coaches (nominated ward staff) supporting behaviour change among staff through education, training and provision of visual prompts. |

# FUNDING AND SUPPORT IN KIND

|  |  |
| --- | --- |
| **FUNDER(S)** | **FINANCIAL AND NON FINANCIALSUPPORT GIVEN** |
| National Institute for Health Research RP-PG-1214-20017 | Programme Grant for Applied Research £2,313,697.00 |

# TRIAL MANAGEMENT

The overall PACT programme of research is overseen by the Chief Investigator (CI), Rebecca Lawton, and managed on a day to day basis by the Programme Manager, Jenni Murray. The Operational team consists of two senior researchers, a junior researcher and research nurses who work across all work packages. The Operational team meet on a monthly basis planning, delivering the project and managing issues. The Operational team will be supported by a Clinical Lead based at each participating NHS Trust who will act as Principal Investigator (PI) for the study to support co-ordination and liaison with staff on each ward.

The Programme Management Group (PMG) comprises the Operational team, co-applicants, and a Patient and Public Involvement (PPI) panel representative (from a dedicated PACT PPI panel). The PMG meets quarterly to oversee the strategic direction of the programme and ensure that the conduct of all work packages (WPs) are methodologically and ethically sound.

The Trial Management Group (TMG) is a dedicated sub-group of the PMG and includes the CI, co-applicants, York Trials Unit (YTU) representatives, and core members of PACT operational team. The TMG meet on a regular basis, according to the needs of the study to assess trial progress and manage challenges as they arise.

A combined Trial Steering Committee (TSC) and Data Monitoring Committee (DMC) comprising 13 independent members meet annually to review study progress. Representatives include seven academics (including a statistician and a health economist), five people who work in health and social care or improvement, and a PPI leader. They feed back progress to the Sponsor using minutes from the meetings.

**Protocol contributors**

The protocol was developed by members of the Trial Management Group as well as members of the Patient Panel.

|  |  |
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| **KEY WORDS:** | Cluster randomised control trial InterventionPatient involvement Transitions of careDischarge |

# TRIAL FLOW CHARTS

Figure 1. Trial flowchart

Up to 9 participating hospitals

Wards with approx. 40% pts aged 75+. Randomisation at ward level (n=40-50)

**Intervention wards** (n=20-25)

Staff training. YCNY *becomes usual care*

**Control wards** (n=20-25)

Care as usual

Approx. 20 pts per ward recruited to the study. Pts receive the intervention (n=391)

Approx. 20 pts per ward recruited to the study. Pts receive usual care (n=391)

Pts discharged to ­own home (inc via intermediate care)

**3. Process evaluation**

* Assessment of fidelity across all intervention wards and in-depth ethnographic research on 8 wards
* Observations and interviews with 24-30 patients/carers and up to 45 staff
* Assessment of changes in care on control wards akin to intervention components

**Sept 2020- May 2021 (all sites) (4m recruitment period per site)**

**2. Post-discharge follow-up:** EQ5D-5L, PACT-M and health economics at discharge, 30 & 90 days post-discharge (includes re-admission data)

**1. Routine data** on unplanned readmissions (30, 60, 90 days post-discharge)

Screening patients for eligibility. Reruited on ward admission and baseline data collected.

 **Est Aug 2019 -March 2020**

**4. Routine data** (anonymised ward level sample of 7,000) on unplanned readmissions at 30, 60 and 90 days post-discharge.

Figure 2 Patient Identification, Recruitment and Follow-up Flowchart

Potential participants screened for eligibility according to inclusion / exclusion criteria.

Eligible patients screened to assess how and when to approach.

Eligible patients taken through consenting process. Re-screening for those initially not suitable to approach

Non-eligible patients excluded

Declined patients excluded

**T1 - Post discharge follow-up** to asses EQ5D-5L, PACT-M, post-hospital syndrome factors, Health Economics & rating of intervention

Patient consented.

Baseline data collected: demographics, EQ5D-5L, predictors of readmission

**Approach:**

* 4 attempts (postal + telephone call x2) to collect follow-up data.
* No response - record as missing data for that time point. Reattempt at next follow-up time point.

**T2 -30 day follow-up** to asses EQ5D-5L, PACT-M, Health Economics & rating of intervention

**T3 - 90 day follow-up** to asses EQ5D-5L, PACT-M, & Health Economics

Participant wishes to withdraw – participant excluded.

# BACKGROUND and RATIONALE

For older people and those with complex needs, the transitional period of moving from hospital back to their own homes is risky (Naylor et al, 1999; McMullan et al, 2010). As many as one in five patients experience an adverse event during this time, 62% of which could be prevented or ameliorated (Forster et al, 2003). In recent years emergency readmission rates have increased by 23% with around 30% of all readmissions estimated to be avoidable (Auchbach et al, 2016; Blunt et al, 2015; Van Walraven et al, 2011). A recent meta-analysis of 92 RCTs of transitions interventions for older people observed a significant reduction in hospital readmissions at multiple time points up to 12 months post discharge (Le Berre, 2017). The interventions are all highly complex, adopting multiple and variable components, commencing and ending at different time-points. As a consequence deciphering which components are the active ingredients is challenging (Hesselink et al, 2012; Radowoski et al, 2017, Laugaland et al, 2012). There is some suggestion however that interventions which seek to enhance patient capacity to reliably access and enact post-discharge care are most effective (Leppin 2014, Naylor et al, 2017). This would build on and facilitate the existing but unrecognised ‘work’ that patients and their carers already undertake in bridging the difficult transitional period. It further creates the opportunity to enhance safety and improve patient experience and reduce readmissions. The PACT research programme therefore asks the overarching question as to whether greater involvement of older patients and their families improves patient experience and safety at transitions of care. The programme comprises six work-packages (WPs):

* WP1 – Interviews and observations to gather information about patient experiences of care transitions.
* WP2 – Using routine data to identify wards and community teams who have low levels of readmissions and find out how they do this.
* WP3 - Developing a measure of the quality of transitions to be used in WP6.
* WP4 – Co-designing the new intervention called ‘**Your Care Needs You’** (YCNY) and initial piloting. YCNY includes three main components: a patient friendly booklet, a short patient film and enhanced discharge documents. The underpinning theory and intervention are described in Section 16.
* WP5 – Feasibility study of YCNY and trial methodology in three hospitals.
* WP6 – Assessing the effectiveness, cost-effectiveness and fidelity of the YCNY.

The current protocol relates to work package 6 within the programme of research.

# AIMS, OBJECTIVES, OUTPUTs

## Aim

To assess the effectiveness, cost-effectiveness of and fidelity to the YCNY intervention.

## Objectives

1. To assess the effectiveness of the YCNY intervention at reducing unplanned hospital readmissions in patients aged 75 years and over
2. To assess the effectiveness of the YCNY intervention at improving quality and experience of transitions and quality of life in patients aged 75 years and over
3. To assess the cost effectiveness of the YCNY intervention
4. To assess the fidelity of the intervention, exploring contextual factors that affect the way the intervention is used in practice and what is delivered
5. Exploring the mechanisms of action, specifically how it is received and used by patients, carers and staff.

## Endpoints

1. Primary: Hospital unplanned readmission rates at 30 days – selected because it indicates an important adverse outcome of transitions, it is policy-relevant and can be efficiently measured using routinely collected data.
2. Secondary: Quality of transition, including patient experience and adverse event rate measured using the PACT-M, hospital unplanned readmission rates; Health Related Quality of Life (EQ-5D-5L); self-reported health care resource use; and longer-term readmission rates (60 and 90 days) and cause of readmission.

# TRIAL DESIGN - overview

This is a cluster randomised controlled trial (cRCT) of the YCNY intervention versus usual care in older people during transition from hospital to home. We will identify approximately 50 wards from up to 9 hospital trusts in England which routinely have at least 40% of patients aged 75 years or above and consent wards to randomisation, training and intervention delivery (depending on allocation). Participating wards (approximately 40 selected from the identified 50) will be randomly allocated to one of two arms: YCNY and care as usual (control) on a 1:1 basis. Ward level randomisation will minimise the significant risk of contamination between patients (and staff) that might occur if individuals were randomised. The study aims to recruit approximately 782 patients from across participating wards. Recruitment of patients on each ward will last for approximately four months to coincide with the length of time necessary to collect sufficient data for the primary outcome: readmissions within 30 days. Patients will be individually consented to follow-up and will permit access to their electronic health records so that baseline and primary outcome data can be linked to their patient reported outcome measures.

On intervention wards, all staff will be informed of the study, the intervention, and their role in implementing the intervention. The implementation package will support behaviour change among staff through education, training and provision of visual prompts (e.g. posters). On usual care wards all staff will be informed of the study and their role in supporting research activities.

Patients may be given the booklet and shown the film prior to patient recruitment (see section 16.1.3 for more details on the intervention). As YCNY has been designed for those aged 75+ years returning to their own homes, staff will be asked to deliver the intervention to these individuals. Staff will be informed of the other inclusion criteria for the study however we anticipate that they may offer the intervention to a broader group of patients e.g. those aged less than 75 years.

Recruitment will be performed by Trust Research Nurses and Yorkshire Quality and Safety Research (YQSR) staff depending on resources. Informed consent to follow-up and access to electronic health records will take place at the patient bedside. If patients lack capacity, carers will act as a personal consultee and will support data collection. Follow-up will occur at three time-points: early post discharge (T1); 30 days (T2) and; 90 days (T3) after discharge from hospital. Follow-up will be conducted by YTU and YQSR research staff.

To assess the primary outcome (unplanned hospital readmission rates at 30 days post discharge) we will obtain anonymised ward level data for 7,000 patients discharged from participating wards during the period of recruitment.

A process evaluation will run alongside the trial to evaluate implementation and assess fidelity; to explore the mechanisms of action through the ongoing development of a logic model that has been developed in WP5; and to consider contextual factors which affect the way the intervention is used in practice and what is delivered. Research activities will begin during the study set-up stage. This is because WP5 revealed that decisions made by researchers and senior hospital staff during this period shape how the YCNY intervention is delivered and who is involved. Researchers will record field notes during this period and be interviewed by the process evaluator to capture information about these decisions and other important contextual information.

A fidelity assessment will be carried out across all intervention wards once the intervention period begins on each site, using a fidelity ‘grid’ developed in WP5. Information to complete the grid will be collected through observations, checks of how many YCNY booklets are given out and use of the intervention materials (e.g. whether posters have been put up), staff interviews with 20 YCNY coaches across the intervention wards, and the follow ups with patients. The fidelity grid will allow the creation of a quantitative score assessing the extent to which each intervention ward has delivered the intervention as intended. These scores will be input into a Complier-average Causal Effect (CaCE) analysis to estimate the effect of the intervention when it is delivered as intended. Up to five senior staff members (e.g. ward managers) will also be recruited from the control wards to assess whether any new care processes or quality improvement initiatives have been implemented which could ‘dilute’ the effect of the intervention in the trial.

To provide a more detailed account of what is delivered, the underlying mechanisms of action and contextual factors we will conduct an ethnographic study on eight wards. This will be necessary to accurately assess the YCNY intervention and to provide the learning to optimise the intervention after trial completion. The ethnographic research will start in a two week period before the intervention is delivered to enable the researchers to familiarise themselves with relevant ward processes and procedures, and to form relationships between researchers and staff. Implementation meetings and staff training will be observed, while we will also spend time observing usual care to see how the intervention is being delivered in practice and to identify contextual factors which shape delivery. Moreover, to assess how the intervention is being received by patients and their families, between 24 and 30 patients and family members will be recruited as part of the ethnographic research to complete in-depth patient-level observations and one interview. These interviews may take place after patient discharge to assess whether the YCNY booklet is being used after the hospital stay. Up to 20 staff members will also be recruited on the eight wards involved in the ethnographic study to ascertain their views on the training package and the intervention.

Data from the different qualitative methods used in the process evaluation will be analysed using a ‘pen portrait’ approach (Sheard & Marsh, 2019) in order to track each ward’s trajectory. These will subsequently be used to refine the logic model and to derive meta-level themes pertaining to the intervention’s effectiveness in the context of this trial, using thematic analysis techniques (Guest, 2012). This approach, along with the CaCE analysis, will provide a basis to interpret the final trial results, for example explaining why and how any improvement has (or has not) occurred.

# Ward eligibility

We will work with a range of specialities including elderly care, orthopaedics, respiratory medicine, cardiology, surgical and stroke / stroke rehabilitation.

## Inclusion criteria

Approximately 40 hospital wards that meet the following eligibility criteria will be invited to participate in this study.

* NHS funded, inpatient hospital wards within a participating NHS Trust
* Wards with approximately and routinely over 40% of patients aged 75 years and over

## Exclusion criteria

The following wards will be excluded from the study:

* Non-NHS funded / private inpatient wards
* Wards with routinely less than 40% of patients aged 75 years and over
* Wards that do not have regular medical input such as discharge wards and community rehabilitation wards
* Wards that are currently participating in an intervention trial which includes similar follow-up time points to the current trial.

## Ward Identification

Subsequent to board level agreement from approached NHS Trusts we will liaise with R&D offices regarding the best way to identify eligible and interested wards. This will likely include speaking with both information services within each trust and a range of speciality / ward staff. For interested wards, we will gather key characteristics that will be used for randomisation. Reasons for wards declining participation will be will be fully documented. Up to 50 wards will be identified in order to account for wards that may decline or withdraw during the study.

# Cluster randomisation

Wards will be randomised in equal allocation ratio (1:1) with 20 randomised to the Intervention and 20 to Care as Usual. Randomisation will be undertaken independently by the York Trials Unit with minimisation using minimPy (Saghaei and Saghaei, 2011). Minimisation will be conducted using the following key wards characteristics: ward type (speciality), the percentage of patients over 75 years, and NHS Trust.

## Post-randomisation procedures

Ward managers, senior managers, matrons, clinical leads, and trust research nurses will be informed about allocation. Staff will be asked not to discuss the intervention with other ward managers, particularly those in the control arm.

### Intervention arm only

We will discuss with the relevant ward leaders (e.g. ward managers, deputy ward managers, consultants, matrons) the main components of the intervention and identify with them suggestions for how these might be delivered within the context of their ward. More details regarding implementation of the intervention are provided in section 16.2.

### Control and intervention arms

We will arrange through ward managers a series of brief information sessions for all staff on the ward to inform them of research activities on the ward and participant recruitment. These sessions may take place during existing meetings (e.g. board rounds and handovers) or via drop-in sessions and will be repeated to capture various shifts. Wards (both intervention and control) will be offered access to the web-based versions (booklet and patient film on-line) of the intervention after the trial. We will feedback anonymous quantitative data from the follow-up assessments (see section17.4) to all wards one year after recruitment is completed for the purposes of quality improvement.

### Post-randomisation routine data collection

We will collect routine unplanned 30, 60 and 90-day readmission rates and average patient length of stay data at ward level for each participating ward. These data will be collected to facilitate adjustment for these factors in the primary analysis and to appropriately describe the ward characteristics. Please see section 17.7 for further details.

# Participant eligibility

## Patient inclusion criteria

Patients meeting all these criteria:

* Aged 75 and over
* Anticipated to be discharged to their own home or that of a relative’s (this can include a period of rehabilitation after hospital discharge)
* Stayed for at least one night on a participating ward
* Ability to read and understand English or has a carer that can read and understand English
* Willing and able to give informed consent (or personal consultee if lacking in mental capacity)

## Patient exclusion criteria

Patients meeting any of these criteria:

* Out of area patients and / or patients who are to be transferred to another hospital
* 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
* Less than one overnight stay (on the participating ward) at time of recruitment
* Identified as being at the end of their life / subject to fast-track discharge to palliative care
* Unable to read and understand English and without a carer who can read and understand English
* Unable to give informed consent and where a suitable personal consultee cannot be identified, or if no one is prepared to act as a consultee for the patient
* On an acute medical admission unit and to be transferred to another ward within the hospital

## Consultee and carer eligibility criteria

Consultees will fulfil the following eligibility criteria:

* A primary carer for the patient
* Provides informal care to the patient (i.e. not paid / professional)
* Willing to act as a consultee for the patient and support data collection throughout the study
* Ability to read and understand English

# Recruitment process

We will recruit and consent a minimum of 782 patients. Based on an average size ward of 28 beds and an average length of stay for elderly patients of 11 days and at least 40% of patients on a ward being over 75 years of age, we anticipate that each ward will discharge approximately 30 patients aged 75+ per month. We will create a recruitment schedule that will allow us to stagger recruitment for four months to achieve a cluster size of approximately 20 (meeting our inclusion/exclusion criteria).

## Participant identification and screening

Ward staff will be asked to confirm patient eligibility (which we anticipate will be readily available) and approachability with respect to patient wellbeing and capacity to provide informed consent. Staff will be reminded of the eligibility criteria at each visit to minimise the risk of post-randomisation selection bias. Researchers do not require access to identifiable personal information in order to assess eligibility and screen them for appropriateness to approach, however patient names will be recorded on screening logs to ensure that potential participants are not unnecessarily approached multiple times. Once recruitment on each ward is complete, the identifiable information (patient name) will be cut off the screening logs and destroyed confidentially to leave non-identifiable screening data.

## Initial approach

Senior ward nursing staff will determine whether staff or researchers will make the initial approach to patients. This will be on a ward by ward and, if necessary, patient by patient basis. Potential participants will be approached as soon as possible after screening. The researcher will briefly explain, to interested patients, the purpose of the research and what participation involves. The researcher will then provide patients with a written information sheet and discuss the study in further detail. All patients will have the opportunity to ask questions. Patients (and carers if needed) will then be given as much time as they need to decide whether or not to take part whilst they are on the ward. Previous research suggests that some patients prefer to decide whilst the researcher is still present, whilst others prefer to think about it or discuss it with family members. In the latter cases the researcher will agree a suitable time to return to the patient/carer. If people do decide to participate in the research the following consent procedures will be followed. All consent procedures are in line with the Mental Capacity Act Code of Practice and recommendations of good clinical practice within research. All researchers will have completed training on taking informed consent. Participants who consent to take part in the study will be given a unique study identification number which will be allocated to patients via the screening logs. The GPs of all participants will be informed via letter of their patient’s involvement in the study. They will be advised that the patient may show them parts of the intervention (enhanced discharge letter or booklet) but that they will not be expected to do anything different to usual care.

## Consent procedures for adults with capacity to consent

Although ward staff will have confirmed that the patient has capacity during the screening process, researchers will also use conversations during the initial approach to assess whether the patient has a suitable level of capacity to participate in the study.

If patients have capacity and agree to take part, they will be asked to complete a written consent form. Some patients with capacity may have difficulties completing the consent form. If they are unable to read or write, the researcher will complete the written parts of the form on their behalf and this will be witnessed (e.g. by another researcher or a member of staff). If patients are able to mark their own initials and sign the consent form themselves, but otherwise struggle to use a pen / write, the researcher will support them to complete certain aspects of the consent form (e.g. to print their name in a legible fashion or to date the form) in order to minimise burden. This will be documented using a file note. All participants will be given a copy of their completed consent form.

We will ask patients to provide consent for their data to be included in the study should they withdraw in the future. Participants will also be informed that, should they withdraw, they can request for their data to be removed from the study. Part pants are free to withdraw from the study at any point, without their care being affected and without needing to provide a reason, but we will collect this information where available.

## Consent procedures for adult who lack capacity to consent

Patients without capacity are often vulnerable and experience higher levels of patient safety incidents. Consequently, it is important to include them in this study. When an eligible patient lacking capacity to consent is identified, we will approach an informal carer (e.g. a relative or friend) to act as a personal consultee. The consultee will be asked to set aside their own views and provide guidance on the patient’s participation in the research, taking into consideration the patient’s wishes and interests.

The initial approach and information about the study will be provided in the same way as described above. The researcher will provide the carer with a written information sheet and discuss the study in detail including their role as a personal consultee and for supporting data collection. Carers will have an opportunity to ask questions and to consider their own and the patient’s participation. If the carer agrees to take part, they will be asked to complete the relevant sections of the Consultee Declaration Form. Written consent will only be taken once from a consultee at the beginning of their involvement in the research.

If a personal consultee cannot be identified for any reasons (for example, no family member or friend is available or willing, family members or friends live a distance away or are not in frequent contact, or the close contact is a paid carer or providing professional services) then the patient will not be recruited into the study.

## Consent procedures for participants who lose capacity during the study or are unable to complete follow-up outcome measures

Although the study involves collecting follow-up data from participants once they leave hospital, written consent written consent will be obtained at the start of the study, for patients who retain capacity throughout their involvement in the research. For participants who lose capacity or feel unable to complete outcome measures at follow-up, but who are otherwise happy to remain in the study, researchers will seek to identify a carer who can act as a consultee and support data collection on behalf of the patient. Information about the study will be given to the carer over the phone. If the carer is willing to act as a consultee, they will be asked whether they would like to receive information about the study in writing (via the post) or over the phone (then and there). If the carer opts to receive information via the post, a copy of the PIS and a postal version of the questionnaire will be sent out to them. Return of the questionnaire will be taken as implied consent. If the carer requests more information about the study over the phone, the researcher will use the verbal PIS script to explain the study. Following an opportunity to ask questions, if the carer is willing to fulfil the consultee role, we will digitally record consent using a verbal consent script.

## Payment

Participants will receive an unconditional £5 gift voucher with each questionnaire as a small token of our appreciation for their continued support of the study. This will be sent prospectively to participants with their questionnaire.

## Declined consent

Reasons for declining involvement in the research will be noted if provided by patients or their personal consultees. The right of a participant to refuse participation without giving reasons will be respected.

## Withdrawal

Participants are free to withdraw from the study at any point, without needing to provide a reason for their withdrawal. Similarly, consultees can also withdraw participants from the study at any point, without providing a reason. However, reason for withdrawal will be recorded if provided.

During the study, follow-up data will be collected at three time points post-discharge. Researchers will make up to four attempts to contact the participant at each time point. Failure to make contact will be recorded as missing data and the participant will be contacted again at the next scheduled follow-up. Participants will only be withdrawn from the study if they / their consultee inform the researcher of their wish to do so.

# INtervention and implementation

## The intervention

The intervention was co-designed by patients, staff and researchers during four workshops and was refined following a small formative evaluation across three wards within one NHS Trust. We are currently undertaking a trial feasibility study (REC ref: 19/WA/0162) across three NHS Trusts. While we do not anticipate that the intervention will change substantially, we do expect to learn much about its implementation. We will modify the study and intervention design/implementation package as needed and update the protocol and seek ethical approval as required. The structure and content of the intervention is described below using an adapted version of the TIDieR checklist (Hoffman et al, 2014).

### Name of the intervention

We will be testing the ‘Your Care Needs You’ intervention, which is designed to support patients and families to be better prepared for discharge home following an inpatient stay, with a view to improving the safety and experience of this transition.

### Aims and underpinning theory of the intervention

The overarching aim of YCNY is to improve the safety and experience of older people as they transition from hospital back to their own homes. The programme theory informing YCNY has been developed from findings in WPs 1 and 2. In this programme theory, we posit that by supporting patients whilst they are in hospital, to be prepared for four key activities that they will undertake after discharge, we may be able to support patients to stay at home safely, and reduce the likelihood of avoidable readmission to hospital. These activities are:

1) understanding their health and wellbeing;

2) retaining physical condition;

3) retaining knowledge and capability for taking medications and;

4) having an accurate understanding of when and how to escalate appropriately following discharge.

Evidence from our work and other empirical literature demonstrates that patients vary in the degree to which they are information seeking and receptive, and what they regard as their role whilst staying in hospital. Therefore, our intervention seeks to support patients and their caregivers to, where possible, take a more active role in these four key activities. Our programme theory suggests that, in order to adequately resource patients to manage these activities during the post-discharge period, the YCNY intervention needs to support patients to be involved in these key activities as early in their hospital stay as possible.

### Intervention components

The intervention comprises two fixed and one flexible core components.

* **Patient-friendly booklet -** This is a patient-held document which makes explicit the opportunities for patients to be more actively involved in their care whilst in hospital to support a smoother transition home. The booklet is structured around the four key activities that patients will need to manage at home. It is an A5 calendar style flip board that can be propped up on the bedside table to display ‘I would like to talk about …’ pages, to indicate that they have a question or something they wish to discuss with staff. There is space at the front of the booklet for patients to write their names if they wish. The booklet will be theirs and they will be able to take this home with them. The booklet will include the website address (and QR code) so that carers can access this online.
* **Short patient film -** The film will support the booklet and will be shown to patients as part of their introduction to YCNY. This film is based on real patients’ stories from our earlier qualitative work, and will bring to life, and seek to underline, our hypothesised links between playing an active role within hospital and better outcomes after discharge. Staff will show the film on whatever resources are available on the ward (e.g. tablets or computers on wheels). The film will also be available online for carers via provision of a website address (and QR code) in the booklet.
* **Enhanced discharge documents** (flexible) – These are designed to supplement existing discharge letters with key information to support patients in undertaking key post-discharge activities. They have a particular focus to support patients to navigate care after discharge. The documents come in two main forms: a) short educational guide for staff completing existing discharge letters or b) an additional separate patient-friendly care summary completed by staff. Staff can choose which option they prefer and who to involve in delivering this component of the intervention.

As part of the development of these intervention components we have explored and addressed a number of potential barriers and opportunities to implementation. For example the booklet includes a motivating message about why patients need to be involved. The use of large font, the provision of a pen with the booklet and the availability of the film creates further opportunities to engage. The short educational guide within the enhanced discharge documents overcomes some of the concerns that staff may have in needing to document additional information for patients during very busy discharge periods.

## Implementation

These core components will be supplemented with, and supported by, an ‘implementation package’. This package is based upon the barriers and facilitators to engagement that we have identified in earlier work packages and informed by the COM-B model (Michie et al, 2011).

### Facilitation of the intervention within the ward context

Initial set-up of the intervention will be facilitated by researchers and involve three key stages:

*Introducing the intervention -* After randomisation, we will meet with senior ward and clinical staff from the intervention wards to introduce the booklet, film, and enhanced discharge documents. We wil discuss with senior ward staff the requirements and options for delivering the intervention including who might act as a coach to take the lead. The coaches will have a supportive role in setting up the intervention and engaging in local problem solving to ensure that it runs smoothly by training staff, ensuring the booklets and film can be distributed by staff and encouraging staff to interact with the intervention. This person needs to be someone who is comfortable in this role.

Depending on staff availability and preferences we may meet with clinical staff separately to discuss implementation of the enhanced discharge documents, as this will be likely completed by junior doctors. These meetings will last up to one hour.

*Planning meeting -* We will work with a small group of ward staff, that includes the coach(es), on a roll-out plan that attempts to support delivery and embedding of the booklet, film and enhanced discharge. Within this meeting we will address known barriers to implementation by for example:

* Maximising opportunities to ensure that the intervention is delivered and used as planned through encouraging staff to plan appropriate times to introduce the booklet and film and consider specific roles for staff in interacting with the booklet
* Motivating staff to engage with the booklet by promoting it as a way to consistently support good patient involvement and to support better communication between staff and patients/carers
* Ensuring that staff feel confident to introduce the booklet and film and verbalise why it is important for patients to use through the provision of short guides.
* Ensuring that staff, patients and carers are prompted to engage with the intervention as a whole through the provision of ward posters

The meeting will last up to one hour.

*Training sessions* - We will train the coach(es) and ward manager to initiate the plan. This will include training the coaches so that they can train other ward staff to introduce YCNY booklet, apply the enhanced discharge documents and motivate them to engage. We will provide intervention/implementation materials (e.g. posters) and will offer support to coaches. Coaches will primarily be responsible for supporting others to embed the intervention. The meeting will last up to one hour. If possible / desired, we may merge the planning and training meetings. All meetings will be delivered flexibly to account for staff availability and ward context. Training of junior doctors in applying the enhanced discharge documents may occur in a separate, short meeting.

As part of the implementation support we will offer a Share & Learn meeting. This will enable coaches (and any ward staff ) within each NHS Trust to share and learn from each other’s experiences of delivering the intervention. Part of this meeting will involve exploring how staff have responded to patient’s or carer’s requests (such as moving more or practising medicines) that have been prompted by the YCNY intervention. We will offer advice and worked examples (e.g. known tools and initiatives) to those seeking support. The meeting will last for up to two hours.

Additional resources to support implementation will be offered to wards. These will include a range of staff posters to raise awareness of the key problems that patients experience after hospital discharge and to remind and motivate them to support patients to undertake the four key activities of the YCNY intervention.

### Training the ward team and delivering the intervention

Integrating of YCNY into the existing roles and responsibilities of team members is a known facilitating factor in the normalisation of an intervention into routine practice (Michie et al. 2005). Our earlier work packages indicate that YCNY is likely to be supported by staff in different ways and that this may vary across wards. We will use this information to guide the coaches.

*Introducing the patient booklet and film*

We have prepared a short script to explain the booklet and film and their purpose. Key to successful delivery of these components will be identifying staff / volunteers who can integrate introducing the booklet and film into existing routines. This might include a discharge co-ordinator whose role involves early engagement with patients as they come onto the ward. Equally possible might be volunteer networks within trusts that regularly visit specific wards and have a role that involves talking to patients or tasks such as getting drinks for patients. During site set up we will discuss the requirements for delivery of these components with ward managers who will ultimately make the decision.

*Encouraging patients and carers to use the booklet*

This will be an ongoing process that will start with the staff who introduce the booklet. Other opportunities to support patients to use the booklet might include helping patients to write down questions, reminding them to use / display the booklet and talk to their family, displaying the medications page before ward rounds. All staff will be encouraged to support patients to use the booklet in this way. Posters in the wards will also serve as a reminder to both staff and patients.

*Staff interacting with patients and carers using the booklet*

Interaction that is prompted by use of the booklet is likely to take many forms. For example staff may wish to respond to queries (either written in the booklet or verbal), write notes to the carers in the booklet or use the questions in the medications section of the booklet to structure their conversations. Because of the breadth of opportunities to use the booklet we will encourage all staff (nurses, medical staff, AHPs and discharge co-ordinators) about ways to use the booklet.

*Enhanced* *discharge* documents

These are most likely to be used by junior doctors but on some wards, for example step down wards that are primarily run by therapists and nurses, other staff may complete the enhanced discharge documents. We will speak to wards about who will be involved in using the enhanced discharge documents.

*Delivery*

We will ask ward staff to deliver the intervention to all patients that we consider eligible but will be pragmatic and support the ward team to deliver the intervention to any additional patients that they consider may benefit from it (e.g. those slightly younger than 75 years). Initial embedding of the intervention will last as long as is necessary and feasible on each ward (up to a maximum of 1 month). It is our aim for the YCNY to become usual care on the intervention wards. We anticipate that the booklet and film will be given/shown to patients when they are admitted to the ward (or at a suitable time there after). As such, all patients who are approached and consented to the study are likely to have already received the intervention, although this will not be a condition of their participation.

## Usual care

Usual care is defined as “The wide range of care that is provided in a community whether it is adequate or not, without a normative judgement” (Smelt et al. 2010). Usual care will be provided by secondary care, primary care, community and social services and will be available to both intervention and control participants.

## Contamination

Sources of contamination and the strategies used to reduce or minimise this are outlined in Table 1 and described below.

Contamination may occur in this study if patients are transferred from an intervention or control ward to another ward which has been allocated to a different arm in the study. This will result in either patients or staff being unintentionally exposed to the intervention. This is most likely to occur when patients are moved from an admissions unit on to a ‘base ward’ – a specialist downstream ward. To minimise this we will only recruit patients on these units who are due to be discharged directly to their own homes.

To reduce the possibility of contamination between staff, training materials and staff-facing intervention components will be restricted to intervention wards only and during staff training (on intervention wards) and briefings (on control wards) the importance of minimising contamination and the mechanisms used to minimise contamination will be stressed.

Table 1: Sources of contaminations and management strategies

|  |  |
| --- | --- |
| **Source of contamination**  | **Strategy to reduce or assess contamination**  |
| Patients are cared for by the same ward team.  | Randomisation at ward level rather than patient level. |
| Patients are moved between wards during their hospital admission. | Only including patients on admissions units if they are to be discharged straight home without admission to another wardResearchers will qualitatively and quantitatively explore how ward movement impacts contamination and the extent to which patients receive all intervention components (i.e. fidelity). |
| Staff work across and move between different wards.  | Staff will be briefed on the importance of minimising contamination and the mechanisms employed to do this.Training materials will be restricted to intervention wards only.Researchers will qualitatively assess the extent to which contamination occurs due to staff working across wards. |
| Components of the intervention may end up on control wards as patients are moved between wards (e.g. the booklet) | Although we would not want to stop a patient taking intervention components with them if they move wards, control wards will be briefed not to uptake / copy / adapt any of the intervention components on their ward during the trial.  |

# Data collection

## Overview

Information about the data required to support site randomisation and the screening of participants is outlined in sections 13 and 15.1 respectively. In this section we describe the time points and processes for data collection, outcome measures, and routine data required.

The Schedule of Events table (Table 2) below outlines the assessments to be undertaken during this study. Assessments will either be administered by a member of the research team or self-completed with or without support e.g. through telephone assistance from a member of the research team or by recording participants answers for them on a postal questionnaire. Where participants lack capacity, the consultee will complete the assessments for them. As part of study initiation, members of the research team will receive training on the completion of all study specific assessments to ensure standardised completion.

The assessments will be ordered within the questionnaire booklet to prioritise the collection of secondary outcome data. Researchers will consider participant fatigue during data collection, and will offer participants the opportunity to complete assessments over additional days if required. This will be at the discretion of the researcher and will be documented.

Paper Case Report Forms (CRFs) will be used to collect individual patient data for the study. Completed CRFs will be returned to York Trials (YTU).

**Table 2. Schedule of events**

|  |  |  |  |
| --- | --- | --- | --- |
| **Assessment** | **Type** | **Method of Completion \*** | **Timeline** |
| **Screening** | **Baseline** | **T1 (post-discharge)** | **T2 (30 days)** | **T2 (60 days)** | **T3 (90 days)** |
| Screening  | Screening log | Researcher / Trust RNs | x |  |  |  |  |  |
| Consent  | Consent Form | Researcher / Trust RNs | x |  |  |  |  |  |
| Baseline data collection - patient demographics, admission information and comorbidities | CRF | Researcher / Trust RNs / self-complete |  | x |  |  |  |  |
| Follow-up – PACT-M  | CRF | Researcher / self-complete |  |  | x | x |  | x |
| Follow-up – Post-hospital syndrome  | CRF | Researcher / self-complete |  |  | x |  |  |  |
| Follow-up – EQ5D-5L / proxy | CRF | Researcher / self-complete |  |  | x | x |  | x |
| Follow-up – Healthcare resource use | CRF | Researcher / self-complete |  |  | x | x |  | x |
| Follow-up – Utility of intervention | CRF | Researcher / self-complete |  |  | x | x |  |  |
| Routine data for consented patient participants – readmission, LoS, ward moves and length of stay on each ward for the index admission | CRF  | Information Services in each Trust |  | x |  | x | x | x |
| Tracking discharge dates | CRF | Trust RNs |  | x |  |  |  |  |
| Routine anonymised ward level data on admissions , discharges, LoS, unplanned readmissions  | CRF | Information Services in each Trust  |  | x |  | x | x  | x  |

* RN – research nurses;

## Blinding

Within this study it will not be possible to blind the ward staff, trust research nurses or YQSR researchers who are involved in recruitment to the treatment. The intervention will become usual care on the intervention wards and so it will also not be possible to blind participants as they may move wards during their hospital stay onto a ward where the intervention is not being used.

Where feasible we will ensure that researchers who conduct telephone follow-ups do not know the participants’ treatment group. However, all questionnaires will contain questions about intervention receipt and thereafter, use. This will allow us to identify potential contamination (through movement between control and intervention wards) and fidelity (extent to which eligible and recruited patients in the intervention received the intervention). These questions will be at the end of the questionnaire to minimise any potential bias in the measurement of the key outcomes.

## Baseline assessments

Once eligible participants have provided informed consent, the following baseline data will be collected:

**Table 3. Baseline data**

|  |  |  |
| --- | --- | --- |
| **Baseline data to be collected**  | **Collected from**  | **Reason**  |
| NHS number  | Ward Clerk | To link outcome data  |
| Index admission date | Ward Clerk | To link outcome data |
| Date of Birth | Patient  | For analyses (predictor of readmissions) |
| Gender | Patient  | For analyses (predictor of readmissions) |
| Ethnicity  | Patient | For analyses (predictor of readmissions) |
| First language | Patient | For analyses (predictor of readmissions) |
| Home address and telephone number (including preferred method for initial follow-up contact) | Patient / ward clerk if needed | To facilitate follow-up data collection. To assess patients SES (via postcode). |
| Living arrangements  | Patient  | For analyses (predictor of readmissions) |
| Carer arrangements | Patient  | For analyses (predictor of readmissions) |
| Functional Co-morbidity Index\* | Research Nurse / patient (patient notes) | For analyses (predictor of readmissions) |
| Barthel Index \* | Patient  | For analyses (predictor of readmissions) |
| EQ5D-5L (or EQ5D-5L proxy) | Patient | To assess baseline quality of life |
| Number of previous admissions over previous 12 months  | Research Nurse (patient notes) | For analyses (predictor of readmissions) |
| Method of index admission unplanned or planned | Research Nurse (patient notes) | For analyses (predictor of readmissions) |
| Reason for index admission | Research Nurse (patient notes) | For analysis (avoidablity of readmissions) |
| Date of discharge | Research Nurse (patient notes) | To enable tracking for the first post-discharge follow-up |

The majority of data will be collected from the participant themselves (or consultee). Where it is not possible to gather the information from the participant themselves (see table above) routinely collected data will be gathered via the ward clerk / nurse or via a trust Research Nurse. Participating patients will have provided consent for researchers to access this data.

**\*Two measures that will be used as baseline measures only are:**

**Functional Co-morbidity Index (FCI):** The FCI is a sum of 18 self-reported comorbid conditions with a score of 0 to 18 with each item scoring one (Groll et al., 2005). A higher FCI score indicates greater comorbidity and is associated with impairment in physical function one year later.

**Barthel Index (BI):** The BI consists of 10 items that measure a person’s daily functioning, particularly the activities of daily living (ADL) and mobility (Collin et al., 1988). Total possible scores range from 0 – 20, with lower scores indicating increased disability.

## Follow-up assessments

Following discharge from hospital, we will follow up recruited participants on control and intervention at three time points:

* T1 - post discharge: data collection will occur ideally between 5 and 14 days but up to a maximum of 21 days
* T2 - 30 days post discharge: data collection will occur ideally between 30 and 45 days
* T3 - 90 days post discharge: data collection will occur ideally between 90 and 105 days

At each follow-up point, four attempts will be made to contact the participant. All participants will be posted a follow-up questionnaire. A few days after, all will be telephoned to check receipt of the booklet and to offer support to complete over the phone if required. If there is no response then a reminder questionnaire will be sent in the post 14 days later and telephone support, offered one more time. Follow-up dates will depend upon when a participant is discharged. We will work with the clinical ward teams and trust research nurses to track discharge dates. In order to minimise any unnecessary distress or burden that may be caused by contacting patients who have died since the last point of contact, researchers will check the NHS Spine Portal prior to each follow-up to ensure that patients are still alive.

In total, participants will be asked to complete five measures at T1: PACT-M; Post-hospital syndrome, EQ5D-5L; health economics, and utility of the intervention (all measures are described in section 17.5). Four measures will be completed at T2 follow-up: PACT-M; EQ5D-5L; health economics, and utility of the intervention. Four measures will be completed at T3: PACT-M; EQ5D-5L; and health economics. Each follow-up is anticipated to take up to 30 minutes. This allows for participants to take their time, take breaks and for us to check their comprehension.

If a patient loses capacity during the trial and therefore cannot complete the outcome measures, recruitment procedures will be followed to identify a personal consultee. Follow-up data will only be collected about participants who have lost capacity if the appropriate consent is in place. Participants will be given an unconditional £5 voucher at each follow-up time point. If there is no response to the telephone call and if possible, a brief voicemail will be left with the participant detailing the name of the researcher calling, when they plan to ring again and what number they can be contacted on. For each telephone contact, we will only attempt to contact the participant by phone a maximum of two times (the initial attempt and then follow up call). Thereafter, if it is not possible to contact the participant, this will be reported as missing data. Subsequent follow-ups will be completed as planned.

## Outcome measures

Primary outcome measure for the trial is unplanned hospital readmissions at 30 days post-discharge. It will be assess using routinely collected data (see section 17.7.2)

Secondary outcome measures include a number of instruments and routinely collected data. The assessment instruments below will be used to collect outcome data for the feasibility trial.

**Patient At Care Transitions Measure (PACT – M):** The PACT-M is a validated measure of the quality and safety of moving form hospital to home (Oikinomou et al, 2019). It assesses patient perceptions of factors central to safety of transitional care namely; patient involvement, information sharing and medication management. In total, eight items are scored on a five point Likert scale: Strongly disagree, Disagree, Neither agree nor disagree, Agree, Strongly agree with an additional option of ‘Not applicable’. The PACT-M also measures the incidence of seven adverse events following discharge from hospital. Patients are asked to answer these questions with a yes or no response.

**Post-hospital syndrome:** There is currently no measure to capture this complex transient state of heightened vulnerability in the early post-discharge period (Krumholtz, 2013). Understanding more about this state may shed light on the causes of unplanned hospital readmissions. We ask four questions that capture potential causes for post-hospital syndrome using a five-point Likert Scale Strongly disagree, Disagree, Neither agree nor disagree, Agree, Strongly agree.

**EuroQol 5-Dimension Health Questionnaire (5 levels) (EQ5D-5L) and Proxy EQ5D-5L:** The EQ5D-5L is a measure of health state (quality of life comprising five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression (Janssen et al., 2013). Each dimension is scored on a five point Likert scale: no problems, slight problems, moderate problems, severe problems, unable. Scores are combined and converted into a summary index value which can be used to facilitate the calculation of quality-adjusted life years (QALYs). A proxy version of the EQ5D-5L will be completed by consultees.

**Healthcare Resource Use:** We will use an adapted version of Client Service Receipt Inventory (CSRI – Beecham and Knapp, 2001) to collect data from participants on their use of health related resources. This comprises five questions which have been adapted to assess the health resources that are pertinent to care transitions from hospital to home for older people.

**Utility of the intervention:** Patients will be asked five questions to assess receipt of the intervention and, thereafter, the usefulness of the intervention.

## Routine data required from Information Services (consented patients)

Once recruitment has finished in each NHS Trust the following data will be collected via Information Services for all participants who have consented to the study:

* Length of stay for the index admission – this will be calculated for each participant using the recorded admission and discharge dates for the index admission.
* Ward (including discharge wards) moves during the index admission. The names of the wards and lengths of stay on each ward.
* Unplanned hospital readmission dates: the dates of all unplanned hospital readmissions up to 90 days post-discharge from the participant’s index admission. These data will be used to assess our primary outcome (30 day readmissions) and secondary outcomes (60 and 90 day readmissions).
* The length of stay for any unplanned hospital readmissions. These data will be used to assess the cost-effectiveness of the intervention.
* Recorded discharge date for the index admission (this information will be collected here as well as above to ensure an accurate discharge date is recorded).
* Reason for all unplanned readmissions up to 90 days post-discharge from the index admission.

All data will be pseudonymised via the participants study ID. Baseline data will be recorded on CRFs. Routine data collected via Information Services will be provided to the YTU via secure electronic transfer via the following process. In order that NHS trusts can extract the routine data required at the end of recruitment, York Trials Unit will provide them with a data collection template. This template will be sent securely by YTU to the NHS Trust (via YQSR if necessary) and will be pre-populated with consented patients’ NHS number, Participant ID, ward admission date, and ward number. These details are needed so that Trusts can extract data for the correct patients and correct hosptial admission. The NHS trusts will enter the routine data into the template and delete the patients’ NHS number before returning it to YTU. NHS trusts will send data to YTU that has been pseudonymised using the Participant ID. All data will be sent securely to YTU (either via secure NHS email or Univeristy of York Dropoff, and via YQSR if necessary). Full details of data management are provided in Section 23.

## Routine data required from Information Services (non-identifiable data)

We need to collect routine, non-identifiable data for the participating wards to 1) provide baseline data for the participating wards to inform our analysis and 2) to assess the clinical effectiveness of the YCNY intervention on 30, 60 and 90-day unplanned hospital readmission rates (primary and secondary outcomes).

### Baseline data:

* Number of patients discharged by participating wards and the total number of 30-day, readmissions to any ward in the hospital trust reported on a monthly basis. These will be collected for up to 12 months *prior to the start of recruitment* and dichotomised by age (i.e., less than 75 years and aged 75+ years).
* Average length of stay reported monthly. Again, collected for up to 12 months *prior to the start of recruitment* and dichotomised by age (i.e., less than 75 years and aged 75+ years).

### After recruitment has finished:

* Total number of admissions to the ward during the recruitment period (to assess ward throughput for entry into a CONSORT diagram).
* Total number of patients discharged to their own homes by participating wards and of these, the total number of 30, 60 and 90-day, unplanned readmissions to any ward in the hospital trust reported on a monthly basis, over the recruitment period. These data will be used to assess our primary outcome and secondary outcomes.
* Average length of stay (by participating ward) during the recruitment period.

Information Services in each trust will conduct searches of their routine data to extract these data for the research team. They will provide the research team with completely anonymised and monthly and/or quarterly totals that have been aggregated to ward level. Under no circumstances will patient identifiable information will be given to the research team.

# Safety reporting procedures

## General Definitions

|  |  |
| --- | --- |
| **Term** | **Definition** |
| **Adverse Event (AE)** | Any undesirable clinical occurrence in a subject whether it is considered to be device/procedure related or not. |
| **Serious Adverse Event (SAE)** | Any untoward occurrence that:* results in death,
* is life-threatening,
* requires hospitalisation or prolongation of existing hospitalisation,
* results in persistent or significant disability or incapacity,
* consists of a congenital anomaly or birth defect,
* is otherwise considered medically significant by the investigator.

NOTE: The term "life-threatening" refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe. |
| **Related Unexpected Serious Adverse Event (RUSAE)** | Any SAE where in the opinion of the Chief Investigator the event was considered to be:* ‘Related’ that is, it resulted from the administration of any of the research procedures, and
* ‘Unexpected’ that is, the type of event is not listed in the protocol as an expected occurrence.
 |

## PACT operational definitions

**Expected AE and SAEs – Not Reportable**

In this patient population, incidents of hospitalisations, prolonged hospitalisation due to social reasons, disabling / incapacitating / life-threatening conditions, aging-associated diseases (such as cancer, cardiovascular disease, diabetes, arthritis, osteoporosis, dementia) other common illnesses such as depression, falls and deaths are expected in the study population due to the age of the cohort. A pre-existing condition (i.e., a disorder present at the start of the study) is not to be reported as an AE. In the context of this study, SAEs will only be reported if they appear to be related to an aspect of taking part in the study and it is an unexpected occurrence.

**Expected SAEs – Standard Reporting**

The death of some participants is expected within the study population. Information relating to this will be collected (at discharge and prior to each follow-up time point) from date of consent until the end of the participant’s involvement in the study via ongoing checks of survival status prior to the participant follow-ups.

Similarly, falls are expected within the study population. Information on these during the index stay will be collected through Datix reporting via the Risk Manager. We will request ward level data on a monthly basis and compare this to the average numbers of specified events for the preceding 12 months and the number of events in the same month of the previous year for the same ward. We will also collect participant reported adverse events including falls within the post discharge follow-up questionnaires (see 17.4).

As the death of and falls in some are expected, this event will not be subject to expedited reporting to the main Research Ethics Committee (REC), but will be reported annually to the REC (in routine annual progress reports) and reviewed regularly via emailed reports from the TMG to the TSC/DMC in accordance with the Trial Monitoring plan.

**Related and Unexpected SAEs – Expedited Reporting**

All potentially related and unexpected SAEs (identified through the monthly Datix reporting) will be reviewed by the CI and will be subject to expedited reporting to the Sponsor (dependent on Sponsor processes) and the main REC. These will be sent within 15 days of the Chief Investigator becoming aware of the event.

All RUSAEs occurring from the time of written informed consent until the end of the participant’s involvement in the study will be recorded on the RUSAE Form. Events will be followed up until the event has resolved or a final outcome has been reached.

For each RUSAE the following information will be collected:

* event duration (start and end dates, if applicable)
* full details in medical terms and case description
* action taken
* outcome
* seriousness criteria
* causality (i.e. relatedness to intervention), in the opinion of the investigator
* Whether the event would be considered expected or unexpected.

## Responsibilities

**Researchers and/or Principal Investigator:**

* Checking for SAEs when participants complete follow-up.
* Liaising with clinical team members (PI on site or clinical research colleagues) to make a judgement in assigning: seriousness; relatedness; expectedness.
* To ensure all RUSAEs are recorded and reported to the CI or their delegate within 24 hours of becoming aware and to provide further follow-up information as soon as available.
* To report RUSAEs to local committees in line with local arrangements.

**Chief Investigator (CI):**

* Assign relatedness and expected nature of SAEs where it has not been possible to obtain local assessment.
* Undertake SAE review*.*
* Review all events assessed as Related / Unexpected in the opinion of the local investigator*.* In the event of disagreement between local assessment and the CI, local assessment may be upgraded or downgraded by the CI prior to reporting to the main REC.

**YTU:**

* Expedited reporting of Related / Unexpected SAEs to the main REC and Sponsor within required timelines.
* Preparing annual safety reports to main REC and periodic safety reports to the TSC/DMC as appropriate.
* Notifying Investigators of Related / Unexpected SAEs which compromise participant safety.

**Trial Steering Committee (TSC) / Data Monitoring and Ethics Committee (DMC):**

* In accordance with the Trial Terms of Reference for the TSC/DMC, periodically reviewing safety data to determine patterns and trends of events, or to identify safety issues, which would not be apparent on an individual case basis.
* Consideration of trial continuation in light of safety concerns, and taking appropriate action to escalate issues of concern.

# Statistical Analysis

## Sample size calculation

We identified five UK studies of older patient discharge/transition interventions that provided a limited empirical basis for sample size calculations. A recent systematic of interventions to reduce early hospital readmissions identified features of interventions that explained variations in effectiveness (Leppin et al., 2014). Interventions that had both an inpatient and outpatient component demonstrated a relative risk of readmission of 0.77 (95% CI 0.65 to 0.92) and those rated to increase patient capacity of 0.68 (0.53 to 0.86). Both elements are components of our intervention. Thus, assuming the underlying risk of readmission is 18% for older patients (based on local hospital statistics), the Leppin findings translate into an absolute difference of 4% and 6% respectively. We therefore plan for a 4% reduction in readmissions at 30 days. Assuming 80% power, alpha=0.01, ICC=0.01, average cluster size=140 (30-40 older people discharged per month from 50 wards for 4 months) and 10% attrition rate, 7000 participants are needed.

It would not be efficient to design the study to recruit and consent 7000 patients. Instead we will use routinely collected data to explore readmission rates and include individual data collection of a nested cohort of participants within this larger sample. We will power the nested individual data collection cohort for our secondary outcome of quality of transitions. We will define a ‘successful’ transition at 30 days post discharge. A previous US study (Dedhia et al., 2009) observed a 68% success rate in the control group versus 89% in the intervention group. Assuming the most conservative success rate of 50% for the initial sample size calculation and planning to detect a 15% absolute difference (30% relative difference), we estimate 170 patients per group is required (80% power). Allowing for clustering this would increase to (assuming equal clusters of 20 patients and an ICC of 0.05) 332 patients per group. Allowing for 15% attrition (based on Townsend et al., 1988) we will recruit 391 patients per group (782 total). This requires 40 clusters, which will be randomly selected (from 50). We assume an ICC of 0.05 in the absence of published data indicating the most appropriate ICC for this setting and particular outcome.

## Statistical analysis plan

A CONSORT diagram will document the flow of hospitals, wards and participants through each stage of the trial. For each data collection point the amount of missing data will be calculated for each arm and rates compared.

Readmission rates will be summarised descriptively at each time-point by treatment group and overall. A repeated measures mixed model will be used to compare the treatment groups. This will also take account of the hierarchical nature of the data by including hospital and wards as random effects and the repeated measurements from participants will be modelled by the covariance structure. The outcome modelled will be readmission (yes/no) at 30, 60 and 90 days and the model will include important baseline covariates (e.g. minimisation factors), treatment group and time as fixed effects. An interaction term assessing whether the difference between the treatment groups changes over time will also be included in the model. Different covariance patterns for the repeated measurements will be explored and the most appropriate pattern will be used for the final model. Model assumptions will be checked and, if they are in doubt, the data will be transformed prior to analysis or alternative non-parametric analysis methods used.

The primary analysis will compare the groups at 30 days. Secondary analyses will compare the two groups at 60 and 90 days post-discharge. The secondary outcomes will also be analysed using similar methods as described above for the primary outcome. An additional exploratory analysis will be undertaken to investigate the impact of non-adherence on treatment effect estimates using a CACE (Complier Average Causal Effect) analysis.

Detailed statistical methods will be outlined in a separate Statistical Analysis Plan.

## Cost-effectiveness analysis

A cost-effectiveness analysis will be conducted alongside the RCT described above. The analysis will take the perspective of the NHS and Personal Social Services, consistent with the National Institute for Care Excellence (NICE). A within-trial analysis will be conducted initially examining the costs and outcomes observed within the trial period. We will extend the time horizon if there are substantial differences between the groups in re-admission rates and/or adverse events at the final follow-up (90 days). Where extrapolation beyond one year is conducted, discounting will be applied at recommended rates (currently 3.5% per annum on costs and effects). The extrapolated analysis to a longer time horizon will be the primary analysis.

### Measurement of outcomes

EQ5D-5L will be collected from patients at baseline and each trial follow-up and can be used to generate QALYs. Adjustment will be made for baseline imbalances in EQ5D scores. Data on other adverse events (such as falls, pressure ulcers) and factors that might contribution to post-hospital syndrome and therefore may contribute to re-admission/A&E attendance will be collected and will be used to extrapolate beyond the trial period where differences between groups are substantial.

### Measurement of costs

Resource use data will be collected alongside RCT data collection using postal/telephone follow up questionnaires and analysis of patient records as described above. This will include duration of inpatient stay, readmissions at 30, 60 and 90 days, and outpatient appointments. Primary and community based contacts with health and social care staff will also be collected at patient follow-up. Unit cost estimates from published sources (such as NHS Reference costs and Unit Costs of Health and Social Care) will be applied to the relevant resource use data to generate the resource specific cost . The intervention cost will also be estimated as part of WP5.

### Synthesising costs and outcomes

If appropriate, for both within trial and extrapolated analyses, cost and QALY data generated will be synthesised to create an incremental cost-effectiveness ratio (ICER) where the additional cost is compared with the additional benefit. This estimate can then be compared with a threshold value of a QALY to assess whether the intervention is likely to provide value for money. Probabilistic sensitivity analyses will be conducted to characterise the uncertainty around the adoption decision (depicted using cost-effectiveness acceptability curves) and to assess the value of further research in this area. Sensitivity analyses will determine the robustness of results to altering certain assumptions. For example, alternative forms of imputation of missing data or choice of discount rate could alter the assessment of cost effectiveness.

# Economic evaluation

We propose to assess the cost-effectiveness of the YCNY intervention by collecting data on the costs of the intervention, utilisation of health care, and key patient outcomes.

**Administered to patients or their proxy:**

* The EQ5D-5L will be administered at baseline and at the three post-discharge follow-ups (T1, T2, and T3).
* The number of presentations to healthcare professionals e.g. over-night stays in hospital, outpatient appointments, day case appointments, accident and unplanned attendances and use of community services.

**From routine data:**

* The number of readmissions and number of overnight hospital stays to the hospital trust following the index admission

**From published literature:**

* Unit costs of health care

**To estimate the cost of the intervention:**

* The costs associated with producing the booklet, and the enhanced discharge documents (a per-participant cost).
* The costs associated with developing the patient-film (a one-off cost).
* The costs associated with staff implementing the intervention i.e. introducing the intervention and in applying the enhanced discharge documents. We will record which staff are involved, their grade, and how many minutes of their time it takes (a per-participant cost).
1. **process evaluation**

This section will detail the scope of the process evaluation of YCNY.

* 1. **Aims and objectives**

The overarching aim of the process evaluation is to provide a comprehensive evaluation of the intervention in the context of this trial in order to complement the trial findings.

Following the guidance from Moore et al (2015), key objectives of the process evaluation is to investigate:

1. The implementation of the intervention, specifically what is delivered
2. The mechanisms of action, specifically how it is received and used by patients and staff
3. Contextual factors that affect the way the intervention is used in practice and what is delivered.
	1. **Process evaluation overview**

Process evaluation is commonly used to unpack the “black box” of RCTs and is vital, in the current study, to provide an accurate assessment of the YCNY intervention. YCNY is a complex intervention (Moore et al, 2015) and as such it is possible that trial outcomes will reflect variation in delivery rather than the intervention’s design. Interpreting trial outcomes therefore requires close attention to what is delivered. Information on the underlying mechanisms of action and contextual factors that shape the delivery and use of the YCNY intervention, will also be important for its optimisation after trial completion and for replicating any success that occurs in future delivery settings.

The process evaluation is designed to achieve the aims and objectives set out in 21.1. It includes the following key components:

* Research activities will begin prior to intervention delivery in order to collect key data during the study set-up period for the process evaluation. We will make field notes during this period and the researchers involved in study set-up processes will be interviewed by the researcher responsible for the process evaluation. This is in response to early findings from WP5 that high level discussions with Trusts, speciality leads and R&D departments can guide for example choice of local PI (their speciality potentially influencing who becomes involved in delivery of the intervention), use of volunteer networks and roles of allied health professionals. These may ultimately shape the success of the project at ward-level and the data collected during this period is necessary for assessing fidelity and for sampling decisions (see 21.3).
* To assess intervention fidelity we will collect the necessary data across all intervention wards. This will be guided by an intervention fidelity ‘grid’, based on existing guidance (Carroll et al, 2007) and developed as part of WP5. This consists of various measures for assessing fidelity, such as the numbers of staff attending implementation meetings or patients receiving the YCNY booklet (see 21.4).
* To provide a more detailed account of what is delivered, the underlying mechanisms of action and contextual factors we will conduct a more detailed ethnographic study on eight wards. A logic model, developed in WP5 using techniques for modelling the dynamics of complex interventions (Mills et al, 2019), will be refined in light of research findings and a thematic analysis will be undertaken of the data to draw out key themes regarding the intervention’s effectiveness in the context of the trial (see 21.5).
* At completion of the study period we will seek to undertake a semi-structured interview with a sample of up to 5 senior members of staff (e.g. ward manager) across the control wards. The interviews will assess whether any new care processes or quality improvement initiatives that resemble the four key activities of the YCNY intervention have been implemented on the control wards which could ‘dilute’ the effect of the intervention in the trial (see 21.6).

Table 4. Summary of data collection methods and proposed sample sizes. These are discussed in more detail in the sections 21.3 to 21.6.

**Table 4 Data collection methods and proposed samples**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Component of process evaluation** | **Method** | **Participant**  | **Sample size** | **Time point** |
| Set-up data supporting process evaluation | Note taking in study set up meetings | Staff involved in study set up meetings (notification of note taking) | Not applicable – this will vary  | During study set up at each site |
| Set-up data supporting process evaluation | Discussions with researchers involved in study set-up | Researchers (verbal consent) | Not applicable – this will vary  | At the mid- and end- points  |
| Fidelity assessment | Ward level observations | Ward staff and patients across all wards (verbal consent) | Not applicable – this will vary  | During the intervention period |
| Fidelity assessment | Staff interviews | Staff on intervention wards (written consent) | 20 YCNY coaches | At the mid- and end- points |
| Ethnographic study | Staff interviews  | Staff and hospital volunteers on eight wards (written consent) | Up to 20 | During or immediately after the intervention period |
| Ethnographic study | Patient level observations | Patient on the eight selected wards (written or witnessed consent) | 24-30 patients and associated carers  | At key moments during their hospital stay |
| Ethnographic study  | Patient interviews | Patient on the eight selected wards (written or witnessed consent) | 24-30 patients and associated carers | Shortly after discharge  |
| Ethnographic study | Documentary analysis  | Patients who take part in the post discharge interviews who share/return their booklet and any enhanced discharge documents | All those from the 24-30 who are interviewed, who return their YCNY booklets and enhanced discharge documents | During (if done face to face) or after (if done over the telephone) the post-discharge interview  |
| Assessment of care processes on control wards | Staff interviews | Control ward staff (written consent) | Up to 5 | End of the study |

* 1. **Collecting and utilising early study set-up data to support the process evaluation**

Process evaluations usually begin at the point when interventions are delivered but we are proposing various research activities during study set-up to collect data that is vital for the evaluation. WP5 revealed considerable variation in how the intervention was received and delivered by organisations. This was seen at multiple levels including:

* Trusts engagement at a senior level
* Local R&D processes for supporting the project
* Relationships between staff across organisational levels

The research team had to respond to this variation and adapt their approach accordingly. They obtained crucial information during the study set-up phase about the characteristics of each Trust and the ward environments. This included information on, for example, routes to accessing staff (e.g. through specific governance meetings or nursing meetings), the experiences of staff with quality improvement initiatives and research studies, staff pressures, envisaged roles in implementation (including the local PI) and general characteristics of patients on suggested wards. The success of the intervention was found to be affected by whether the implementation strategy was successfully adapted to each Trust on the basis of this information. Hence, the process evaluation will start during the study set-up stage and will involve researchers recording field notes to capture contextual information and the reasons for decisions made about the approach to intervention delivery. Researchers will explain to staff members who attend set-up meetings that notes will be kept in order to record such information. If staff object to this, notes will not be recorded for that meeting. Any notes taken will be fully anonymised and direct quotations made by staff will not be written down. To clarify issues and explore emergent themes, the process evaluator will also interview researchers involved in the study set-up at the mid- and end- point of the project. Because these interviews are internal to the research team, verbal consent will be taken from them but a PIS and consent form will not be required. The data obtained during study set-up is necessary for the fidelity assessment (see 21.4) because it is decided during this period who will be involved in the project at ward-level. The data may also be used to inform sampling decisions (see 21.4.1) and be analysed as part of the thematic analysis of process evaluation data (see 21.4.8).

## Fidelity Assessment

Research activities to assess intervention fidelity will be carried out in all of the Trusts and intervention wards involved in the trial. A fidelity ‘grid’, developed as part of WP5 and consisting of key measures for evaluating implementation, will guide the collection and analysis of fidelity information. A range of data collection methods will be utilised, including ward level observations undertaken by the research team and local research nurses, checks of how many booklets each ward give out and their use of intervention materials (e.g. whether posters have been put up) and interviews with key staff members involved. A prompt sheet to guide researcher observations will be agreed by the research team in advance of the study start date. Researchers collecting fidelity information will be instructed to anonymise all field notes and wards will be attributed pseudonyms prior to the study period. This will enable researchers to link their observations to wards but the wards, as well as specific patients and staff members, will not be named directly. Because of the centrality of the YCNY coach role to the intervention (see 16.2.1), all 20 YCNY coaches will be invited for interview. Mostly these will be short-structured interviews, although the coaches from the 8 wards involved in the ethnographic research will undergo more detailed, semi-structured interviews. Fidelity information will also be collected from patients during the follow-up questionnaires, for example whether they report receiving the booklet or had it explained to them by staff. The completed fidelity ‘grid’ will provide a basis for assessing variation in delivery across intervention wards. A Complier-average Causal Effect (CaCE) analysis (Hewitt et al, 2006) will then be undertaken to estimate the effect of the intervention when it is actually received by patients.

## Ethnographic Study

### Sampling

*Wards*

For the ethnographic study we will concentrate on eight wards across four hospital Trusts. These will be selected on a theoretical basis (Glazer, 1978) to allow for variation across important characteristics, such as the extent of MDT working or volunteer use. Precise criteria for involving Trusts in the ethnographic study will be informed by and decided after the study set-up period (see 21.3). At the ward level, sampling decisions will also be made on a theoretical basis but the sample will likely include diversity across ward size, specialty and patient mix. Process evaluation research activities will not be standardised across these eight wards but may concentrate on wards where the intervention is being delivered if, for example, other wards pull out during the implementation stage or do not deliver the intervention. This will ensure that resources are used optimally and the data collected is relevant to the research objectives.

*Patients*

On the eight wards involved in the ethnographic research, between 24 and 30 patients will be recruited to complete in-depth observation and one semi-structured interview. Where a participant has a carer that is involved in their care (e.g. spouse or friend), we will also seek to recruit them. A theoretical sampling approach (Glazer, 1978) will be adopted, aiming to recruit “information-rich” cases (Patton, 1990). Initially, sampling decisions will proceed on the basis of patient’s knowledge and use of YCNY materials but this may change in response to unanticipated events in the field and to allow emergent themes to be explored. The sample will also be monitored to ensure a diversity of gender and ethnicity, and we will attempt to include a range of ages within the target population of over 75s.

*Staff*

Purposive sampling will be employed to sample staff who are involved in the implementation of the intervention, including those who attended training sessions directly, YCNY coaches and staff who were informed and trained to support the intervention by YCNY coaches. Staff participants may include ward managers, nurses, healthcare assistants, doctors, allied health professionals and volunteers. It is anticipated that up to 20 staff (over and above the 20 coaches interviewed as part of the fidelity assessment across all wards) will be recruited from the 8 wards involved in the ethnographic research. As mentioned above, coaches on the wards involved in the ethnographic study will have a combined interview that will cover both the fidelity assessment and the ethnography.

### Consent

*Patients*

Patients recruited as part of the ethnographic research will be approached and consented to participate in the study through a separate qualitative consent process. Participants will be asked to consent to participation in observations and one interview, as well as the publication of any anonymised quotes. If patients have capacity and agree to take part, they will be asked to complete a written (or witnessed) consent form. Patients will be given a copy of their completed consent form. Because capacity can fluctuate within this group, it will be assessed at each visit. A carer can provide consent via consultee consent if a patient lacks capacity. Carer participants must also be willing and able to give informed consent to the qualitative aspects of the study if they want to be involved. If a carer declines to participate, this will not affect the participation of the patient.

Patients will be free to withdraw from the study at any point, without needing to provide a reason for their withdrawal, but we will collect this information where available. Patients will be informed that should they withdraw, any data already collected from them will be included in the final study data. However, they will also be informed that they can ask for their data to be removed at any point should they wish to, and that this would not affect their care in any way.

*Staff*

Researchers will approach staff members to invite them to take part, initially providing a short verbal description about what participation in the research involves. If staff members indicate that they are interested in being interviewed they will be given an information sheet, opportunity to ask questions and time to consider whether they would like to take part. Staff members that agree to participate will complete a consent form and be offered a copy.

### Payment

We are aware that we are asking patients to undertake a number of observations and interviews, at a time when their lives may contain additional complexities (e.g. upheaval due to illness, being admitted to hospital, and transitioning back home). As a sign of our gratitude for participating in the study we will offer patients (or the patient/carer dyad) £20 (in shopping vouchers). They will be informed about this during the consent process and will have the option of declining or accepting the vouchers. Participants will also receive an unconditional £5 voucher with each questionnaire as per all other participants in the study (see section 15.6 for details).

### Interviews

*Patients and Carers*

Semi-structured interviews will be used to explore the perspectives of patients recruited as part of the ethnographic research. Patient and carers will be asked about what they think and feel about the various YCNY intervention components and how these may be optimised, although questioning will adapt to explore any pertinent issues that arise during the trial in accordance with the principles of theoretical sampling (see 21.4.1). Ideally these interviews will take place within the first few days following discharge from hospital and be conducted at their own home or over the telephone if this is not feasible. Patient interviews will last between 30 and 60 minutes and, where possible, will be audio recorded or detailed field notes will be taken.

*Staff*

The interviews involving staff on the intervention wards will be semi-structured and will mainly take place during the intervention period. Questioning will focus on what staff think and feel about the YCNY intervention, as well as the way in which it was implemented and contextual factors that moderate its success. Where possible all staff interviews will be audio recorded or detailed field notes will be taken; they will last between 15 and 30 minutes, depending on the time available to staff; and they will most likely be conducted in a quiet room on the ward.

### Ward and patient level observations during intervention delivery

The research activities taking place across all intervention wards to assess fidelity (see 21.3 above) will be enriched with more detailed observational research on the eight wards involved in the ethnographic study. This will start in a two week period before the intervention is delivered. We will visit the wards between two and four times to form relationships with staff and familiarise themselves with relevant ward processes and procedures. It is expected that the ethnographic field notes taken during the training and intervention period will be more detailed than the other intervention wards. A ‘contact summary form’ will be completed at each point of contact – ‘contacts’ may be a discrete piece of observation or it may be something less bounded such as a day spent observing patient activity on the ward. These contact summary forms will be used to systematically collect and store the field notes, coordinate the ethnographic research and inform part of the initial data analysis through the suggestion of new or revised thematic codes (Miles & Huberman, 1994). The ethnographic research will also involve more detailed patient-level observations of the patients recruited into the process evaluation. These will be conducted at various points during the patient stay, for example during the introduction of the booklet to patients by staff or occasions where staff and patient interactions are expected as part of routine care (e.g. ward rounds, dispensing medicines and discharge). Observations are likely to be undertaken in the presence of others and at the point of care. Researchers will therefore remain sensitive when asking questions within this context. They will also minimise interruptions to the delivery of care so as not to intrude on standard care processes.

### Documentary analysis of booklets and enhanced discharge documents

As detailed in section 16.1.3, patients in the intervention group will be encouraged to take their booklets home at discharge and to use them in the post-discharge ‘transition’ period. During interview with patients we will ask them if they are willing to return their booklet to the research team by 30 days post discharge so that we can see how the booklet has been used. Patients will be given a stamped (and recorded delivery) addressed envelope for them to do this. In addition to collecting participants’ used booklets, we will gather copies of any ward documents that may or may not be part of the intervention but relate to its aims (i.e. understanding health and wellbeing, medications, escalation, and maintaining ADLs). Verbal consent will be obtained from an appropriate member of ward staff (e.g. ward sister) before taking copies / photographs of these documents. No documents containing patient identifiable information will be collected from the ward.

### Data analysis

Data from the different qualitative methods used in the ethnographic study (field notes, contact summary forms, interview data and document analysis) will be analysed using a ‘pen portrait’ method (Sheard & Marsh, 2019). Pen portraits are used to synthesise data across different sources. In this study they will be used to draw out key data (from observations, patient and staff interviews, and document analysis) for each participating ward. All data related to a ward will be drawn together to describe how the intervention was implemented, how staff and patients engaged with it, contextual factors which shaped its delivery/use and patients’ experiences and views of it. The pen portraits will be developed over the course of the study period and their ongoing analysis will inform sampling decisions and hone the research questions of the ethnographic study, in keeping with theoretical sampling (see 21.4.1). The pen portraits will also be the unit of analysis for a subsequent thematic analysis (Guest, 2012) which may also triangulate data collected during the study set-up stage and the fidelity assessment. Data coding will specifically pertain to a) refining the logic model developed in WP5 and b) drawing out meta-level themes concerning the intervention’s effectiveness in the context of the trial. This, in combination with the CaCE analysis (see 21.3 above), will provide a basis to interpret the final trial results, for example explaining why and how any improved outcomes has (or has not) occurred.

## Research on control wards

Researchers will be asked to observe control wards when they recruit patients to identify any new care processes or quality improvement initiatives that resemble the YCNY intervention and could ‘dilute’ the effect of the intervention in the trial. At the end of the trial period, the interviews with senior staff members on these wards will be interviewed about these initiatives. These interviews will take place in a quiet room on the ward or over the phone if this is preferred by them. It is anticipated that up to 5 senior members of staff (e.g. ward manager) will be interviewed on the control wards.

## Data transfer and storage

All process evaluation data, including observational and interview data, will be analysed and stored at the Bradford Teaching Hospitals NHS Foundation Trust (BTHFT). Field notes and contact summary forms will be stored in paper form in secure, locked filing cabinets form; where they have been written up as Word documents, they will be stored on secure, password protected servers at BTHFT. Similarly, audio data will be removed from recording devices as soon as is practicable and will be transferred and stored on secure, password protected servers at BTHFT. Audio files may be securely emailed to a UK-based third-party organisation for the purposes of transcription; in this case, we would ensure that an appropriate confidentiality and data security agreement is in place. Booklets that are returned by participants will be stored in a locked filing cabinet at BTHFT. Any identifiable information that patients have written in their booklets will be redacted. Copies of the booklets will be electronically scanned and stored on a secure, password protected drive which only the research team (YQSR) can access. Physical copies of the booklet will be confidentially destroyed following this. Only the research team members will have access to data. Both electronic and paper data will be stored for a period of 10 years, when paper data will be disposed of with confidential waste and electronic data no longer required for analysis will be deleted.

# End of trial Considerations

## Definition of end of trial

The end of the trial is defined as the date of completing the last follow-up assessment of the last patient in the trial which is anticipated to be at 90 day post-discharge.

The trial will be stopped prematurely if: funding for the trial ceases; following recommendation from the Trial Steering Committee; or as mandated by the Research Ethics Committee. The Research Ethics Committee will be notified in writing if the trial has been concluded or terminated early.

## Site and trial closure

At the end of the trial, all data (e.g. consent forms) will be removed from the trial sites to be securely stored at YQSR. All data held by the YQSR research team and YTU will be securely archived in line with the sponsor’s procedures for a minimum of 5 years. Following authorisation from the Sponsor, arrangements for confidential destruction will then be made.

# DATA MANAGEMENT

## Documentation of responsibilities between sponsor and other organisations

A model agreement (mNCA) will be used as the agreement between BTHfT as the sponsoring organisation and the participating organisations. A data sharing agreement between the sponsor and the YTU at the University of York will be put in place.

## Data collection tools and source document identification

All individual patient data required by the trial protocol will be recorded on CRFs. CRFs will be designed by the YTU to ensure that they facilitate adequate collection of data and to ensure proper audit trails can be kept to demonstrate the validity of the trial (both during and after the trial).

Data will be entered directly onto CRFs as detailed below:

* Baseline data will be entered by the research team and/or Trust Research Nurses
* Data collected through postal follow-ups will be entered directly onto the questionnaires by the participant or their carer
* Data collected through telephone follow-ups will be entered directly onto the questionnaires by members of the research team

The outcome measures that will be collected within the CRFs are detailed in section 17.5, and the methods that will be used to maximise completeness of data are outlined in section 17.4.

## Data handling and record keeping

All data will be completely anonymised for purposes of analysis and any subsequent reports or publications. For the purposes of ongoing data management, individual patients will only be identified by participant identification numbers. Study data will be recorded in a number of files for both the administration of the study and collection of patient data.

Wet ink copies of the CRFs will be sent to YTU in person or via post to be scanned into a secure web-based interface, specifically developed for this study. No personally identifiable information will be sent through the post. Trust Research Nurses and members of the YQSR research team will securely store CRFs at the participating trust or BTHFT until they can be sent to YTU. It is not necessary to retain copies of the CRFs at each NHS Trust as the data do not relate to the patient’s clinical treatment or care.

All data will be stored and transferred following YTU standard operating procedures. The staff involved in the trial (both at the sites and YTU) will receive training on data protection. The staff will be monitored to ensure compliance with privacy standards. Patient Reported Outcome Measures (PROMS) or other routinely collected data may also be received electronically; these data will not be subject to further validation. Data will be checked according to procedures detailed in the trial specific Data Management Plan.

All YTU data recorded electronically will be held in a secure environment at the University of York, with permissions for access as detailed in the delegation log. The Department of Health Sciences, in which YTU is based at the University of York, has a backup procedure approved by auditors for disaster recovery. Full data backups are performed nightly using rotational tapes, to provide five years’ worth of recoverable data. The tape backup sessions are encrypted and password protected, with tapes stored in a locked fire-proof safe in a separate secured and alarmed location. All study files will be stored in accordance with Good Clinical Practice guidelines. Study documents (paper and electronic) held at the YTU will be retained in a secure (kept locked when not in use) location for the duration of the trial. All essential documents, including source documents, will be retained for a minimum period of five years after study completion. The separate archival of electronic data will be performed at the end of the trial, to safeguard the data for the period(s) established by relevant regulatory requirements. All work will be conducted following the University of York’s data protection policy which is publically available (University of York, 2017).

## Access to data including final trial dataset

Direct access to data will be granted to members of the research team (YQSR and YTU), authorised representatives from the Sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections - in line with participant consent.

A statement of permission to access source data by study staff and for regulatory and audit purposes will be included within the participant consent form with explicit explanation as part of the consent process and participant information sheet.

Anonymised data (e.g. for patient reported outcome measures) will also be fed back to the participating wards to support them with their own improvement work and as a thank you for their involvement in the study.

Once YTU has completed the analysis and published in all intended scientific journals, the anonymised data may be made available for other researchers if requested. Each application for data will be reviewed by the Sponsor or the CI on a case by case basis.

In principle, anonymised data will be made available for meta-analysis and where requested by other authorised researchers and journals for publication purposes. Requests for access to data will be reviewed by the Chief Investigator, study Sponsor and trial team.

The Investigator(s)/Institutions will permit monitoring, audits, and REC review (as applicable) and provide direct access to source data and documents.

## Monitoring, Audit and Inspection

Data will be monitored for quality and completeness by the YTU, using established verification, validation and checking processes. Missing data, except individual data items collected via the postal questionnaires, will be chased via the follow-up process until they are received or confirmed as not available. The YTU / YQSR group and TMG will review the processes that relate to participant consent, eligibility, and the completeness, accuracy, and timeliness of data collection. This will be done by reviewing the trial data set.

Most of the data recorded on CRFs (except potentially Functional Comorbidity Index) will be collected directly from participants rather than from source documents (e.g., hospital records) and so, as such, it will not be possible for the YTU/Sponsor to conduct source data verification exercises. For the Functional Comorbidity Index CRF the Sponsor will reserve the right to intermittently conduct source data verification exercises on a sample of participants. This will be carried out by Sponsor staff and will involve direct access to patient notes at the participating sites.

# ETHICAL AND REGULATORY CONSIDERATIONS

## Regulatory Compliance and Research Ethics Committee (REC) review and reports

Before the study commences REC and HRA approval will be sought for the study protocol, all the informed consent forms and other relevant documents. Any substantial amendments that require review by the REC will not be implemented in practice at sites until the REC and HRA grants a favourable opinion for the trial.

Before the study commences the chief investigator will apply for NHS Research and Development permission (confirmation of capability and capacity) from the host sites. Any subsequent amendments that may affect permissions will be discussed with R&D departments at each site.

All correspondence with REC will be retained, annual reports will be produced by the chief investigator and REC will be notified at the end of the study and a final report will be submitted with the results and publications.

## Data protection and confidentiality

Patients should be confident that any data held about them will be stored securely and confidentially and will be handled in accordance with the 2018 Data Protection Act and the General Data Protection Regulation (GDPR). Patient names and contact details will be collected when a patient is registered into the study and they will be assigned a code that will be used instead of their name on any documentation referring to them. Following Caldicott principles we will only collect and store data that is necessary to the research and we will use the minimum necessary amount of personal confidential data. Data collected from patients will be stored securely for 10 years after which it will be securely destroyed. The following steps will be undertaken in order to safeguard data collected directly from patients:

* Identifiable patient information such as consent forms will be stored separately to anonymised data, such as transcripts and questionnaire data.
* De-identified physical data (using a separately stored patient ID), such as completed questionnaires or interview transcripts will be kept in a locked cabinet in a locked room at the YTU or YQSR.
* Any electronic data, such as electronic CRFs or audio recordings, will be held within password protected servers at YTU or YQSR. In electronically stored data, personal information, such as the participant’s name, will be replaced by a unique personal identification number. Names and other identifying information will never be used in films, reports or articles produced from the data collected directly from patients or staff. Only members of the research team who need access to confidential data will have access to it.
* Access to all data will be restricted to members of the research team to YQSR and YTU. The use of encryption and passwords to restrict access will be controlled to ensure that access to secure data is not compromised. Data will be stored on a network resource (e.g. server) that is effectively backed up by the University’s and/or NHS IT systems.

## Safeguarding study participants

If, during the course of the research, the researcher has concerns that the patient is at risk because of the actions or omissions of someone in their healthcare team, the researcher will ask the patient to report the detail as soon as possible to a relevant healthcare professional. If the patient appears to be at risk based on information they disclose during the research activities (e.g. the patient is found to be not taking their prescribed medicines), they will be advised by the research team to contact a relevant healthcare professional (NB. If the patient feels unable to report any risk, or lacks the capacity to do so, the researcher will act on behalf of the patient to communicate the risk to the relevant, local designated health professional). It is possible that, during discussions, participants may disclose information to the research team, or the research team may have concerns that the individual may be experiencing abuse, or is at risk of abuse. In such circumstances the researcher will follow the participant’s healthcare provider’s (NHS Trust or GP practice) Safeguarding Adults policy (or equivalent document).

## Peer review

The study is funded by a NIHR Programme Grant for Applied Research. The research design has been subject to the NIHR review process which involves two formal stages, each with a number of reports from subject and methods experts together with PPI review. At the later stages we received and responded to feedback from individual reviewers plus from the relevant NIHR panel. Copies of these reports can be requested from the study co-ordinators. This protocol has been reviewed by all members of our Programme Management Group which included academics and clinicians. The HRA Schedule of Events Cost Attribution Template and Organisation Information Document have been reviewed by our NHS R&D Lead, and the costs have been reviewed by the Sponsor’s Finance Lead and the CRN.

## Public and Patient Involvement

The Yorkshire Quality and Safety Research Group have an active patient panel who contributed to the development of the PACT research ideas and funding bid, including the focus on older patients, the grant proposal, and the research design of each work package within the PACT programme of work (including WP5 which this study relates to).

A patient panel dedicated to the PACT programme grant has been set up to support the programme of work. Panel members (n=8) are aged 75 and over and have been admitted to hospital within the last two years and/or are a family member or carer who is involved in the healthcare and social wellbeing of people aged 75 years and over. Over the course of this programme grant they have advised on: research questions and objectives, the design and wording of patient-facing documents, including information sheets, consent forms and interview guides, dissemination documents, providing feedback on initial intervention ideas, and attending programme and research meetings to provide service-user insight. The PACT patient panel have been consulted specifically to support the development of this protocol. The YCNY was co-designed by the PACT research group, health care professionals, and members of the PACT patient panel. Panel members will be involved through the analysis and dissemination of results.

## Amendments

If the research team needs to make a substantial amendment to the REC / HRA application or the supporting documents, they will submit a notice of amendment to the REC / HRA for consideration and to host site NHS R&D. The study co-ordinator and the chief investigator will decide whether to amend the protocol and the sponsor will decide whether an amendment is substantial using HRA definitions. The amendment history will be tracked using protocol version control and changes will be communicated to the HRA and site R&D using their established processes, for example the IRAS substantial amendments form.

## Protocol compliance and notification of serious breaches

Protocol non-compliances are considered to be departures from the approved protocol. Prospective, planned deviations or waivers to the protocol are not allowed. A protocol deviation can be defined as: any accidental or unintentional change to, or non-compliance with the research protocol that **does not** increase risk or decrease benefit or, **does not** have a significant effect on the participant’s rights, safety or welfare; and/or on the integrity of the data. Deviations may result from the action of the participant, researcher, or research staff. Examples of a deviation include, but are not restricted to:

* A rescheduled contact for data collection
* Participant refusal to complete scheduled research activities

Any accidental protocol deviations will be adequately documented and reported to the Chief Investigator and Sponsor via required sponsor/progress reports. Should deviations from the protocol frequently recur immediate action will be taken.

A “serious breach” is a breach which is likely to effect to a significant degree: a) the safety or physical or mental integrity of the participants of the trial; or b) the scientific value of the trial. The Sponsor will be notified immediately of any serious breaches that occur during the trial.

## Indemnity

This study is sponsored by the Bradford Teaching Hospitals NHS Foundation Trust and the NHS indemnity scheme will apply to meet the potential legal liability of the sponsor for negligent harm caused harm to participants arising from the management of the research. The NHS has a duty of care to patients treated, whether or not the patient is taking part in a research study, and the NHS remains liable for clinical negligence and other negligent harm to patients under this duty of care. The University of York will provide legal liability cover for their employed staff.

# DISSEMINIATION POLICY

The research team is committed to utilising a diverse range of dissemination methods to ensure that the research findings are widely shared with audiences including the research community, patients & the public, practitioners and policy makers. The PMG will agree a publication plan and will be consulted prior to release or publication of any study data. On completion of the feasibility trial, the data will be analysed and tabulated and a Final Trial Report will be prepared.

The NIHR will be notified of all outputs (i.e. publications) and all publications will acknowledge NIHR PGfAR as the study’s funding source and include an appropriate disclaimer regarding expressed views and opinions (example text is provided on the HTA website).

Authorship of the final study report and any additional publications associated with the research will follow the guidelines of the International Committee of Medical Journal Editors. A full study report will be made available and a synopsis will be sent to the REC and to participants on request.

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#  APPENDICIES

## Appendix 1 – Authorisation of participating sites

**16.3.1 Required documentation**

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| **Document** | **Version** | **Date** |
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## Appendix 2 – Amendment History

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| **Amendment No.** | **Protocol version no.** | **Date issued** | **Author(s) of changes** | **Details of changes made** |
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