PACT Work Package 6

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 (WP6).

ISRCTN: ISRCTN17062524

Registered: 11/02/2020

STATISTICAL ANALYSIS PLAN

Version 1

York Trials Unit
Department of Health Sciences
University of York
York, YO10 5DD

Version date: 30th March 2023

Author(s): Laura Mandefield, Kalpita Baird and Prof. Catherine Hewitt
Chief Investigator: Prof. Rebecca Lawton
Trial Coordinator: Dr Jenni Murray and Stephen Brearley

Contents

1. Document scope and relevant SOPs and guidance documents 4
2. Definition of terms/acronyms 4
3. Design 4
4. Trial Objectives 4
5. Sample Size 5
6. Randomisation 5
7. Outcomes 6
7.1 Primary outcome 6
7.2 Secondary outcomes 6
7.2.1 Patient Reported Outcomes 6
7.2.2 Outcomes from Routinely Collected Data 7
7.3 Follow-up 8
8. Data 11
8.1 Relevant SOPs and guidance documents 11
8.2 Sources of data (e.g. Case Report Forms (CRFs)) 11
8.3 Management of datasets and data verification 11
8.4 External datasets 12
8.4.1 Routine data collection 12
9. Analysis 13
9.1 Analysis populations 13
9.2 Participant Flow 13
9.3 Baseline data 13
9.3.1 Baseline Patient Level Data 13
9.3.2 Baseline Ward Level Data 14
9.4 Primary analysis 14
9.4.1 Estimating treatment effect 14
9.5 Sensitivity analysis 15
9.5.1 Intervention Compliance 15
9.5.2 Missing data 16
9.6 Secondary analyses on the primary population (n=5440) 16

9.6.1 Unplanned hospital readmission rates at 60- and 90-days post-discharge 16
9.6.2 Time to unplanned readmission 16
9.6.3 Number of unplanned readmissions 16
9.7 Secondary analysis on the nested cohort (n=1000) 17
9.7.1 Post hospital-syndrome (T1) 17
9.7.2 Quality of transition, including patient experience and adverse event rate 17
9.8 Subgroup analysis 17
9.9 Summary of intervention utility 17
9.10 Summary of ward moves (contamination) 18
9.11 Timing of follow up and readmissions 18
9.12 Adverse events 18
10. SAP amendment log 18
11. Signatures of approval 19
12. References 19
13. Appendices 20
13.1 Scoring of the PACT-M 20
13.1.1 9.1.1 Weighting 20
13.1.2 9.1.1 Missing data and N/A responses 20
13.2 Example tables and figures 0

1. Document scope and relevant SOPs and guidance documents

This statistical analysis plan (SAP) deals only with the statistical analysis of clinical effectiveness; the cost-effective analysis will be detailed in a separate plan. This SAP was written following completion of recruitment but prior to completion of data collection and database lock. The SAP was prepared according to York Trials Unit (YTU) standard operating procedures and guidance documents.

2. Definition of terms/acronyms

A definition of any terms or acronyms used in the SAP is provided in this section.

AE	Adverse Event
CAG	Confidentiality Advisory Group
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
cRCT	Cluster Randomised Controlled Trial
ICC	Intracluster Correlation Coefficient
NHS	National Health Service
PACT	Partners at Care Transitions
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SOP	Standard Operating Procedure
WP	Work Package
YTU	York Trials Unit

3. Design

PACT is a research programme comprising six work-packages (WPs). Work package six (WP6) is a cluster randomised controlled trial (cRCT) of the Your Care Needs You (YCNY) intervention vs care-as-usual in older adults during transition from hospital to home. Wards will be randomly allocated on a 1-1 basis. YCNY will become usual care on wards allocated to the intervention arm and individual consent will not be needed to access the intervention as this is across the whole ward.
Full details of the background and design of the trial are presented in the protocol (version 10).

4. Trial Objectives

The PACT WP6 objectives include:

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 YCNY in reducing the time to, the number of and duration of unplanned hospital readmissions in patients aged 75 and over.
3. 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
4. To assess the cost effectiveness of the YCNY intervention

5. To assess the fidelity of the intervention, exploring contextual factors that affect the way the intervention is used in practice and what is delivered
6. Exploring the mechanisms of action, specifically how it is received and used by patients, carers and staff.

This statistical analysis plan will cover objectives 1-3. Objectives 4-6 will be outlined in the health economic evaluation and process evaluation.

5. Sample Size

Five UK studies of older patient discharge/transition interventions were identified, that provided a limited empirical basis for sample size calculations. A recent systematic review 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 4.5% reduction in readmissions at 30 days. Assuming 80% power, alpha=0.05, ICC=0.01, average cluster size=140 (30-40 older people discharged per month from 40 wards for 5 months) and 10% attrition rate, 5440 participants are needed.
It would not be efficient to design the study to recruit and consent 5440 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. This will be measured by the PACT-M which produces an overall score between 0 and 67. Assuming a mean difference of 2.7 points, which equates to a reduction of around half an adverse event and a standard deviation of 9 (based on data from WP5), 170 patients per group are required (80% power, alpha=0.05). Allowing for clustering this would increase to (assuming equal clusters of 25 patients and an ICC of 0.05) 374 patients per group. Allowing for 25% attrition (based on projected results from our feasibility study) we will recruit 500 patients per group (1000 total) which would require 40 clusters. We assume an ICC of 0.05 in the absence of published data indicating the most appropriate ICC for this setting and particular outcome.

6. Randomisation

Wards will be randomised in an 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 (split by the median; <66% or ≥66% based on WP5), and NHS Trust.

7. Outcomes

7.1 Primary outcome

The primary outcome measure for the trial is unplanned hospital readmission rates at 30 days post-discharge. This will be assessed using routinely collected data and has been selected because it indicates an important adverse outcome of transitions, it is policy-relevant and can be efficiently measured using routinely collected data.

7.2 Secondary outcomes

Secondary outcome measures include:

From the routinely collected data (primary analysis population, n=5440)

1. Unplanned hospital readmission rates at 60- and 90- days post-discharge
2. Time to unplanned readmission
3. Number of unplanned readmissions
4. Duration of unplanned readmissions

From the nested cohort (n=1000)

5. Quality of transition, including patient experience and adverse event rate (PACT-M and CTM-3)
6. Health Related Quality of Life (EQ5D-5L)- to be used as part of the health economic analysis detailed elsewhere

7.2.1 Patient Reported Outcomes

- **Patient At Care Transitions Measure (PACT–M):** The PACT-M is a validated measure of the quality and safety of moving from hospital to home (Oikonomou *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. A detailed description of how the PACT-M measure is scored is given later in this document. We will report one overall score (0-67) and also the separate subscales; experience item score (8-40) and adverse events score (0-7).

- **Care Transitions Measure 3 items (CTM-3):** The CTM is a patient-centred measure of the quality of care transitions (Parry *et al.*, 2008). In this study we are using the CTM-3 due to its lower response burden, and ability to be added to existing surveys. Three items are scored on a four-point Likert scale ranging from strongly agree to strongly disagree. The CTM-3 will be scored by calculating the sum of responses across the three-items (responses are scored Strongly disagree = 1; Disagree = 2; Agree =3; Strongly Agree =4) The mean response will be calculated by dividing the sum of all responses by the number of questions answered. A linear transformation will then be used to convert the mean response to a 0-100 score. Don't know/don't remember/not applicable will be scored as 5 and will not contribute to the overall CTM score, similarly with missing data. This score reflects the overall quality of the care transition with lower scores indicating a poorer quality transition. This measure has been included to assess the concurrent validity of the PACT-M.
- **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 of post-hospital syndrome using a five-point Likert Scale Strongly disagree, Disagree, Neither agree nor disagree, Agree, Strongly agree.
- **Utility of the intervention:** Patients will be asked five questions to assess receipt of the intervention and, thereafter, the usefulness of the intervention.
- **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 indicated greater comorbidity and is associated with impairment in physical function one year later.

7.2.2 Outcomes from Routinely Collected Data

Once recruitment has finished in each NHS Trust the following routinely collected data will be collected via Information Services:

Data from consented participants in the nested sample:

- **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. The recorded discharge date for the index admission will be collected at baseline and from the routine data to ensure an accurate discharge date has been recorded.
- **Ward (including discharge wards) moves during the index admission:** The names of the wards and dates of admission to/move from each ward will be collected. These data will help us establish the level of contamination from patients moving between intervention and control wards

- **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; time to, number of and duration of readmissions)

Data from non-consented participants:

- Dates of admission to named participating wards, readmissions and discharges and types of admission (planned or unplanned) up to 90-days post-discharge from the first stay within the recruitment period.
- Death within 30, 60, or 90 days from index discharge date
- Gender, ethnicity and age at first admission during the recruitment period. These data will help us explore any differential impacts of the intervention according to these characteristics.

Ward level (baseline) data:

- Number of patients discharged by participating ward 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 the 12 month period of 2019 (prior to the COVID-19 pandemic. The data will be dichotomised by age (i.e., less than 75 years and aged 75+ years), as well as monthly average and median ages.
- Average length of stay reported monthly collected for the 12 month period of 2019 (prior to the COVID-19 pandemic) The data will be dichotomised by age (i.e., less than 75 years and aged 75+ years), as well as monthly average and median ages.

After recruitment has finished:

- Total number of admissions by participating wards during the recruitment period dichotomised by age (i.e., less than 75 years and aged 75+ years) and the average length of stay on participating wards during the recruitment period dichotomised by age (i.e., less than 75 years and aged 75+ years). (to assess ward throughput for entry into a CONSORT diagram).

7.3 Follow-up

Following discharge from hospital, we will follow up recruited participants as part of the nested sample 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 the point of recruitment, all consented participants will be advised that they will receive a questionnaire in the post and may receive a telephone call a few days later (as a reminder, to check receipt of the questionnaire or to offer support to complete). For participants who have not received the questionnaire we will offer to complete it over the phone or send another one out in the post (having checked the address). One more reminder phone call will be made after this point totalling up to four attempts to contact participants at each follow-up. Follow-up dates will depend upon when a participant is discharged. The trial team will work with the clinical ward teams and trust research nurses to track discharge dates. In order to minimise any unnecessary distress or burden on relatives 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 the start of each follow-up time point to ensure that patients are still alive. Participants will receive £5 as cash or a gift voucher with each questionnaire.

Table 1: Schedule of data collection

Assessment	Type	Method of Completion *	Screening	Baseline	T1 (post-discharge)	T2 (30 days)	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 – CTM-3	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
Follow-up – Utility of intervention	CRF	Researcher / self-complete			x			
Routine data for consented patient participants – readmission (dates and discharges/or death) and types, ward moves, dates on named wards 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 and discharges and readmission	CRF	Information Services in each Trust		x				
Routine pseudonymised individual level data (non-consented patients) on admissions, , wards, discharges/death, readmissions	CRF	Information Services in each Trust				x	x	x

8. Data

This section covers details of data collection, monitoring and validation.

8.1 Relevant SOPs and guidance documents

Title	Version	Date	Location
S01 Statistical Considerations	6.0	03 September 2020	https://ytu.york.ac.uk/SOPManager
DS02 Randomisation	2.0	24th July 2019	
DM06 Data Validation	7.0	29th October 2021	

Data and documents relevant to the statistician will be kept in a Statistical Master File following the directory structure detailed in the YTU SOP entitled “Directory structure and version control (at time of writing: SOP ID: DS01, version 5.0, 26th August 2022).

8.2 Sources of data (e.g. Case Report Forms (CRFs))

A copy of the CRFs with the variable names from the database (knowns as ‘specs’) will be kept by the Trial Statistician in their Trial Statistics folder. The CRFs to be used in the trial are:

- Screening and recruitment Log
- Initial Contact form
- Patient Baseline (M0)*
- Patient Contact Details (M0)*
- Follow-up 1 (T1)*
- Follow-up 2 (T2)*
- Follow-up 3 (T3)*
- Adverse Event reporting
- Serious Adverse Event reporting
- Adverse Event and Serious Adverse Event follow up form
- Change of Status form

CRF’s marked with an asterisk also have a carer/consultee equivalent CRF available.

8.3 Management of datasets and data verification

The following 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 CRFs by the participant or their carer
- Data collected through telephone follow-ups will be entered directly onto the questionnaire by members of the research team.

All data will be completely anonymised for purposes of analysis and any subsequent reports or publications. Electronic screening logs will be completed by the research team and/or Trust Research Nurses and transferred securely to YTU using DropOff. Trust Research Nurses will securely store CRFs at the participating trust until they can be sent to YTU. All data collected by sites using paper CRFs will be mailed to YTU, where it will be scanned into a secure web-based interface. Routinely collected data may also be received electronically. All data will be stored and transferred following YTU standard operating procedures. Data will be checked according to procedures detailed in the trial specific Data Management Plan, following validation plans authorised by the trial manager and trial statistician. All data recorded electronically at YTU will be held in a secure environment at the University of York. Full data backups are performed nightly, using rotational tapes, to provide years' worth of recoverable data.

8.4 External datasets

8.4.1 Routine data collection

Full details of the process of the routine data collection can be found in the protocol (v10).

In order to access the routinely collected individual level pseudonymised data on non-consented patients, we will create a template for the search which will be sent to a designated Information Services contact at each of the participating Trusts. They will be asked to conduct a search of patients who were admitted to the participating wards during the study recruitment period who were aged 75 years and older and who were coded as discharged to their 'usual place of residence'. The data file will include the items listed in this section above and will initially include NHS number and date of birth. The file will be internally transferred to a designated research nurse / trials assistant within the Trust and they will check the medical records to establish if the usual place of residence was their own home (or a carer's home) or a care home. Patients whose usual place of residence is a care home will be deleted from the file as they are not the sample of interest. For the remaining data set, NHS number and date of birth will be deleted from the file. Age at index admission will have been calculated by the information specialist at the time of doing the search and this will remain in the datafile. No identifiable information such as NHS numbers, dates of birth or dates of death will be given to the research team. This data file will be transferred securely back the research team for analysis.

9. Analysis

All analyses will be conducted in a validated statistical software such as R (R Development Core Team and R Core Team, 2011)or STATA v17 (StataCorp, 2017) following the principles of intention-to-treat with participants outcomes analysed according to their original randomised group, where data are available, irrespective of deviations based on non-compliance.

The trial will be reported according to the CONSORT (Consolidated Standards of Reporting Trials statement) guidelines.

9.1 Analysis populations

The PACT study has 2 main analysis populations.

1. ***The primary analysis population***- this comprises of the 5440 participants whose routinely collected data we will use.
2. ***The consented participants in the nested cohort*** - this comprises of the 1000 participants consented and recruited to the nested part of the trial.

For each part of the analysis we will specify which of the analysis populations will be used.

9.2 Participant Flow

The flow of wards and consented participants (the nested cohort, n=1000) through each stage of the trial, including reasons for non-eligibility, will be presented in a CONSORT diagram (see Appendix, Figure 1.). The CONSORT diagram will include an extension as this is a cluster randomised controlled trial (cRCT) .

Participants who are part of the routinely collected data (n=5440) will be presented separately. Number admitted to wards, number discharged and readmitted will be presented by treatment arm (Ref: 1).

A summary of study discontinuation (including withdrawals, deaths and lost to follow up) will be presented by treatment arm (Ref:Table 2).

9.3 Baseline data

9.3.1 Baseline Patient Level Data

The baseline demographics and clinical characteristics of the consented participants will be reported. For the continuous variables (e.g. age) either mean and standard deviation (SD) will be presented or median and inter-quartile range (IQR) depending on the distribution of the data. The number of observations used in each calculation will be presented alongside the summaries. For the categorical

variables, (e.g. ethnicity), the number and percentage of participants in each of the categories and the total number of observations will be presented.

All baseline summaries will be presented and reported for each treatment groups and in total *(Ref:* Table 4, Table 5). No formal statistical significance testing will be done to test baseline imbalances between the intervention arms, but any noteworthy differences will be descriptively reported.

The following summaries will be presented:

Demographics:	Age, Gender, Ethnicity, First language, Living arrangements, Carer arrangements
Patient reported outcomes:	Co-morbidities (as needed for the completion of the Functional Co-morbidity Index)
Other Measurements:	Number of previous admissions over the previous 12 months, Method of index admission (emergency or elective)

9.3.2 Baseline Ward Level Data

The following non-identifiable data for each participating ward over the most recent 12-month period will be presented by month and overall (Ref: Table 6):

- NHS Trust
- Ward type (specialty)
- Percentage of patients who are <75 years and ≥75 years.
- Size of ward
- Average length of stay for patients who are admitted to each participating ward (split by patients who are <75 years and ≥75 years with monthly totals)
- The number of patients discharged from a participating ward

The total number of these patients who are readmitted to the hospital trust within a 30-day period (split by patients who are <75 years and ≥75 years with monthly totals)

9.4 Primary analysis

9.4.1 Estimating treatment effect

The primary outcome is unplanned hospital readmissions rate at 30-days post-discharge and the population to be included in the primary analysis will be restricted to participants who are discharged and/or recruited during the first five months of the recruitment period (n=5440). This is to ensure a consistent and standardised time frame for intervention delivery is in place across all participating wards.

For the primary outcome, the between group difference in readmissions at 30 days, and its associated 95% confidence interval and p-value will be calculated using a mixed effects logistic regression. Minimisation factors (including ward type, trust, percentage of patients aged 75 years and over), gender, treatment group and baseline ward readmission rate will be included as fixed

effects. To account for the hierarchical nature of the data hospital and wards will be included as random effects.

The estimated treatment effect is an odds ratio and will be presented as is Table 8.

9.5 Sensitivity analysis

9.5.1 Intervention Compliance

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.

Compliance of wards will be assessed by members of the PACT study team. Each ward will be assessed through discussion. They will draw on communications with wards, the ward facilitator training, feedback from research nurses, whether posters were up, and responses to communications, and whether they indicated they were engaging with the flexible components or made their own suggestions. Three levels of compliance will be used; green, amber and red. The criteria that will be used to assign each level of compliance are described in the table below.

Level of compliance	**Criteria the must be met**
Green (good level of compliance)	• Ward staff engaged and attended training • Posters up on wards • Flexible component engagement by ward staff • Materials being given out to patients
Amber (medium level of compliance)	• Ward staff attended training • Posters up and as far as we are aware they are giving out the materials to patients. • Local Research Nurses are indicating variable levels of staff engagement with the intervention, but they are unlikely to be engaging with the flexible components of the intervention
Red (low level of compliance)	• Not delivering intervention, • Minimal or no engagement with training. • Posters may or may not be up

A two-stage instrumental variable approach will be used with random group allocation as the instrumental variable (Dunn, Maracy and Tomenson, 2005). The CACE analysis will be carried out on

the primary outcome only (readmission (Y/N) at 30 days post discharge). The three compliance categories will be used. If numbers are low, two categories may be combined.

9.5.2 Missing data

Due to the nature of the data collection, we expect to have very minimal missing data. Participants who do not have any readmissions are still included in the model. Some participants may have died during the follow up period and they will be presented separately.

9.6 Secondary analyses on the primary population (n=5440)

9.6.1 Unplanned hospital readmission rates at 60- and 90-days post-discharge

Secondary analyses will compare the two treatment groups at 60 and 90 days post discharge. The same model as used for the primary analysis will be used and the treatment estimate, 95% confidence interval and p-value will be presented (Ref: Table 9).

9.6.2 Time to unplanned readmission

Time to first readmission will be right-censored at the last point at which the readmission is known to have not taken place i.e. 90-days post-discharge or death. Kaplan-Meier survival curves will be produced for the two treatment groups and the median time to first readmission and a 95% confidence interval (CI) will be presented. A proportional hazards Cox regression model with shared frailty accounted for clustering by ward will be used to compare the time-to-readmission times between the treatment groups adjusting for similar covariates as the primary analysis
The proportional hazards assumptions will be assessed by considering plots of the Schoenfeld residuals and the Therneau and Grambsch test. A hazard ratio (HR) for the treatment effect will be presented with a 95% CI and associated p-value (Ref: Table 10).

9.6.3 Number of unplanned readmissions

The number of unplanned readmissions per person will be analysed using a mixed-effects Poisson regression adjusting for similar covariates as the primary analysis. Hospital and wards will be included as a random effect.

If the variance of the data is larger than the mean, this may give an indication that the data are over-dispersed. In this case, a negative binomial model will be run. Within this analysis in Stata, a likelihood ratio test of the overdispersion parameter alpha is conducted. A significant p-value indicates that the data are over-dispersed and therefore that Poisson regression is not appropriate. If the data are zero-inflated, then a zero-inflated Poisson or negative binomial model will be used.

The point estimate for the treatment effect in the form of an incidence rate ratio (IRR) and its associated 95% CI and p-value will be provided (Ref: Table 11).

9.7 Secondary analysis on the nested cohort (n=1000)

9.7.1 Post hospital-syndrome (T1)

A summary of responses to the four post hospital syndrome questions will be presented by trial arm for the nested cohort (n=1000) (Ref: Table 12).

9.7.2 Quality of transition, including patient experience and adverse event rate

PACT-M and CTM-3 produce scores which may be presented by treatment arm. As they are not being collected at baseline there will be no baseline adjustment. These outcomes will be analysed with a mixed effects model with treatment group, ward type, trust, percentage of patients aged 75 years and over and gender as fixed effects and hospital, ward as random effects. The treatment estimate and its associated 95% confidence interval and p-value will be presented (Ref: Table 13) for each of follow ups (T1, T2 and T3).

The nested cohort of consented participants was not restricted to a recruitment period of 5 months. So that we can compare the results to the primary analysis population, we will conduct a sensitivity analysis using the same models described above but restricted to those participants in the nested cohort who were recruited during the first 5 months of recruitment.

9.8 Subgroup analysis

The primary analysis model will be repeated with the inclusion of an interaction between treatment and age. This will be defined as follows:

- Younger patients- Median age of ward <85 years (Lee *et al.*, 2018)
- Older patients- Median age of ward $\geqslant$ 85 years

The regression coefficient for the interaction between treatment group and subgroup and its associated 95% confidence interval and p-value will be presented (Ref: Table 15). This analysis will be subject to adequate numbers per group.

9.9 Summary of intervention utility

Data collected on the intervention utility as collected in the CRFs in the nested cohort (n=1000) will be summarised descriptively (Ref: Table 14).

9.10 Summary of ward moves (contamination)

A simple summary of the number of consented participants who moved wards will be produced in the form of a table (Ref: Table 16). This will include the mean number of ward moves and whether they moved from control ward to intervention ward or vice versa.

9.11 Timing of follow up and readmissions

To check the timing of follow ups and how these might relate to readmissions, a plot will be produced by ward where dates of discharge, follow up and any readmissions will be shown (Ref: Figure 3). We will also present the proportion of consented participants who had a readmission before T1, T2 and T3.

9.12 Adverse events

Safety will be assessed by serious adverse events (SAEs) including deaths and Non-serious adverse events (AEs).. Details of definitions of SAEs and AEs are outlined in the study protocol. Descriptive statistics of SAEs and AEs will be presented by treatment arm. The following figures will be included (Ref: Table 174):

- The total number of SAEs/AEs, their outcome, relationship to study treatment and expectedness.
- The number and percentage of participants reporting at least 1 SAE/AE
- The number and percentage of participants reporting each type of SAE/AE;
- The number and percentage of participants reporting a treatment related SAE/AE.

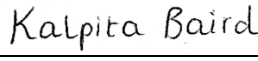
10. SAP amendment log

Please note all changes that are made to the Statistical Analysis Plan following initial sign-off in the box below. Include details of the changes made, any notes/justification for these changes, the new version number if applicable, who the changes were made by, and the date.

Amendment/addition to SAP and reason for change	New version number, name and date

11. Signatures of approval

Sign-off of the final approved version of the Statistical Analysis Plan by the principle investigator and trial statistician(s).

Name	**Trial Role**	**Signature**	**Date**
Rebecca Lawton	Chief Investigator		31/03/2023
Prof. Catherine Hewitt	Senior Statistician		30/03/23
Laura Mandefield	Senior Statistician		30/03/2023
Kalpita Baird	Statistician		30/03/2023

12. References

Dunn, G., Maracy, M. and Tomenson, B. (2005) 'Estimating treatment effects from randomized clinical trials with noncompliance and loss to follow-up: The role of instrumental variable methods', *Statistical Methods in Medical Research*. doi: 10.1191/0962280205sm403oa.

Groll, D. L. *et al.* (2005) 'The development of a comorbidity index with physical function as the outcome', *Journal of Clinical Epidemiology*. doi: 10.1016/j.jclinepi.2004.10.018.

Lee, S. B. *et al.* (2018) 'Differences in youngest-old, middle-old, and oldest-old patients who visit the emergency department', *Clinical and Experimental Emergency Medicine*. doi: 10.15441/ceem.17.261.

Leppin, A. L. *et al.* (2014) 'Preventing 30-Day Hospital Readmissions', *JAMA Internal Medicine*. doi: 10.1001/jamainternmed.2014.1608.

Oikonomou, E. *et al.* (2019) 'Developing a measure to assess the quality of care transitions for older people', *BMC Health Services Research*. doi: 10.1186/s12913-019-4306-8.

Parry, C. *et al.* (2008) 'Assessing the quality of transitional care: Further applications of the care transitions measure', *Medical Care*. doi: 10.1097/MLR.0b013e3181589bdc.

R Development Core Team and R Core Team (2011) 'R: A Language and Environment for Statistical Computing', *R Foundation for Statistical Computing*, 1, p. 409. doi: 10.1007/978-3-540-74686-7.

Saghaei, M. and Saghaei, S. (2011) 'Implementation of an open-source customizable minimization program for allocation of patients to parallel groups in clinical trials', *Journal of Biomedical Science and Engineering*. doi: 10.4236/jbise.2011.411090.

StataCorp (2017) 'Stata Statistical Software: Release 15', *2017*. doi: 10.2307/2234838.

13. Appendices

13.1 Scoring of the PACT-M

The PACT-M consists of eight experience items which are scored on five-point Likert Scale: Strongly Disagree, Disagree, Neither agree nor disagree, Agree, Strongly Agree with an additional option of 'Not applicable' for item six. The PACT-M also measures the incidence of seven adverse events following discharge from hospital, which patients are asked to answer with a yes or no response, with an additional option of 'Not applicable' for items four and six.

For the eight experience items, Strongly Agree will be coded as a 1 up to Strongly Disagree which will be coded as a 5. For these eight items the responses will be summed to give a score between 8 - 40 (or 7 – 35 if the N/A response is used), with a lower score indicating a more positive experience. If two consecutive numbers are circled, the higher number will be used. If the numbers are not consecutive, the item will not be scored and regarded as missing.

For the seven adverse event items a 'No' will be coded as 0 and a 'Yes' will be coded as 1. For these seven items the responses will be summed to give a score between 0 – 7 (or 0-5 if the N/A responses are utilised), with a lower score indicating a safer transition.

13.1.1 9.1.1 Weighting

Both sections of the PACT-M (eight experience items and seven adverse event items) are being treated as though they are of equal importance and therefore require the weighting of each section to be comparable. To ensure that each section has a similar weighting, the total score of the seven adverse event items (previously on a 0 – 7 scale) will be reweighted. This score will be transformed by adding one to the total score and multiplying by five. For example, a score of 3 would be transformed to a score of 20. This means that the previous 0 to 7 scale will now result in a 5 – 40 scale. Once the transformed score has been calculated this will be combined with the score of the eight experience items, resulting in an overall PACT-M score.

13.1.2 9.1.1 Missing data and N/A responses

There are five main eventualities to consider:

- no missing or N/A responses
- 1 N/A response from the eight experience items and no other missing items
- 1 missing response from the seven adverse event items and no other missing or N/A responses
- 1 missing or N/A response from the eight experience items and 1 missing response from the seven adverse event items.
- 1 N/A response from the eight experience items and 2 N/A responses from the seven adverse event items

If (from either of the PACT-M sections) one item or more is missing, in addition to the N/A response the value of the scale will be set to missing. For example, if a participant has used the N/A response and a further experience item is missing, the scale will be set to missing. Likewise, if both N/A

responses in the Adverse Event section are utilised and a further AE item is missing, the scale will be set to missing. This decision will be re-evaluated if it means excluding a large proportion of participants.

PACT-M Scoring Algoriithm

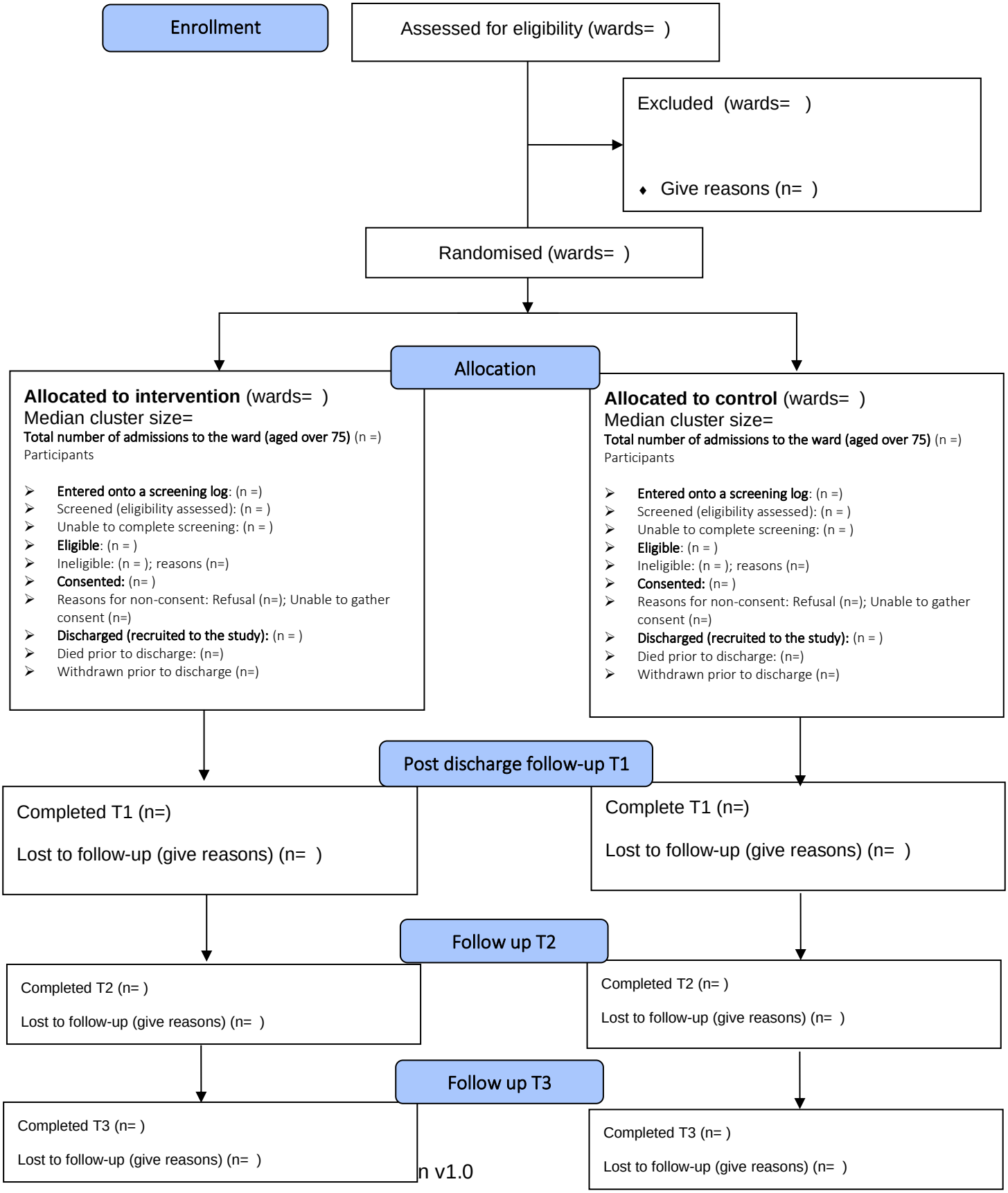
N/A / Missing	Component	Sum	Adjust Range	Further adjust (where needed) x	Final adjustment $Max\ value - x$
No N/A or missing responses	Experience	8 – 40	0 - 32	0 – 32	0 – 32
	Adverse events	5 – 40	0 - 35	0 - 35	0 - 35
	Total	**13 - 80**	**0 - 67**	**0 - 67**	**0 - 67**
1 N/A response OR 1 missing item (experience items)	Experience	7 – 35	0 – 28	0 – 32 (x32/28)	0 – 32
	Adverse events	5 – 40	0 – 35	0 – 35	0 – 35
	Total	**12 - 75**	**0 - 63**	**0 - 67**	**0 - 67**
1 missing item (AE items)	Experience	8 – 40	0 – 32	0 – 32	0 – 32
	Adverse events	5 - 35	0 – 30	0 – 35 (x35/30)	0 – 35
	Total	**13 - 75**	**0 - 62**	**0 - 67**	**0 - 67**
1 N/A response OR 1 missing item (experience items) AND 1 missing item (AE items)	Experience	7 – 35	0 – 28	0 – 32 (x32/28)	0 – 32
	Adverse events	5 – 35	0 – 30	0 – 35 (x35/30)	0 – 35
	Total	**12 – 70**	**0 - 58**	**0 - 67**	**0 - 67**
1 N/A response OR 1 missing item (experience	**Experience**	**7 – 35**	**0 – 28**	0 – 32 (x32/28)	0 – 32
	Adverse Events	**5 – 30**	**0 – 25**	**0 – 35 (x 35/35)**	0 – 35

items) AND 2 N/A responses (AE items)	**Total**	**12 - 65**	**0 - 53**	**0 - 67**	**0 - 67**

For each eventuality the total score will be reversed, resulting in a PACT-M score ranging from 0 – 67, with a higher score indicating a more positive and safe transition.

13.2 Example tables and figures

Figure 1: CONSORT style flow diagram showing ward and participant flow through the study for the nested cohort (n=1000)



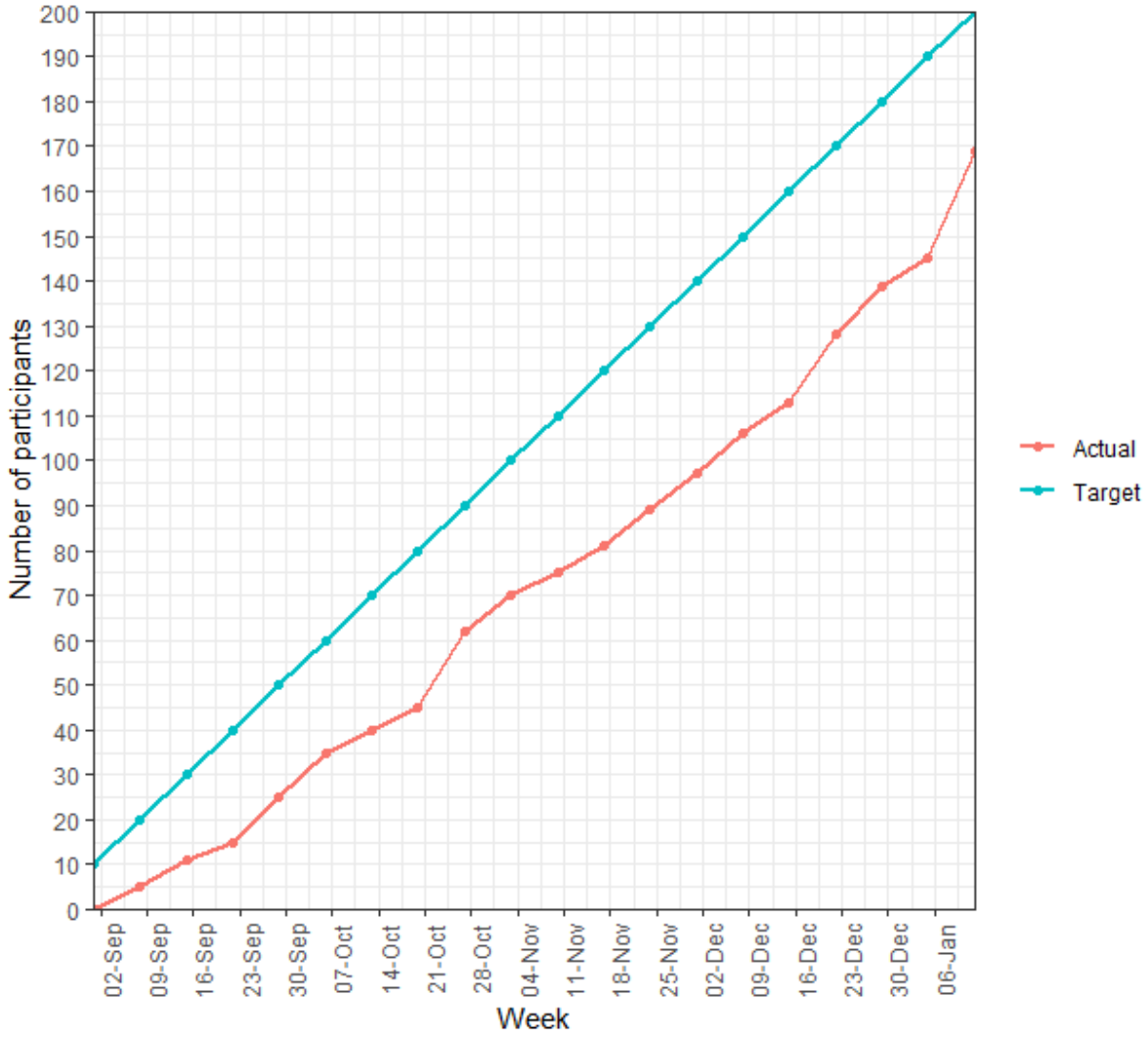


Figure 2: Recruitment of participants by month

Table 1: Summary of participant flow in the primary analysis population (n=5440)

	Intervention wards (n=xx)	Control wards (n=xx)	Overall (n=xx)
Patients admitted to wards in 5 month recruitment period	xxxxx	xxxx	xxxx
Patients who were discharged	xxxx(xx.x%)	xxxx(xx.x%)	xxxx(xx.x%)
Patients with primary outcome data (readmission data up to 30 days)	xxxx(xx.x%)	xxxx(xx.x%)	xxxx(xx.x%)

Table 2: Summary of study discontinuation

	Pre discharge			Post discharge		
Type of discontinuation	Intervention n=xx	Control n=xx	Total n=xx	Intervention n=xx	Control n=xx	Total n=xx
Withdrew from follow up	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Full withdrawal	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Lost to follow up	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Patient death	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)

Table 3: Attrition rates and study discontinuation summary

	Intervention	Control	Total
Number of participants recruited (discharged) into the study	xx	xx	xx
Number of participants who discontinued from the study post-recruitment	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reasons for discontinuation			
Patient death	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Withdrew from follow-up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Full withdrawal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost to follow up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Table 4: Baseline demographics of participants

Variable	Control	Intervention	All

		(n=xx)	(n=xx)	(n=xx)
Gender	Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not reported	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Age (years)	N	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median (IQR)	xx.x(xx,xx)	xx.x(xx,xx)	xx.x(xx,xx)
	Min., Max.	xx,xx	xx,xx	xx,xx
	Not reported	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ethnicity	White British	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	White Irish	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	…	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	…	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not reported	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
First language	English	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not reported	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Live in status	Alone	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	With spouse/partner	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	With son/daughter	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	With brother/sister	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not reported	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Has daily carers	Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not reported	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of previous hospital admissions in the previous 12 months	N	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median (IQR)	xx.x(xx,xx)	xx.x(xx,xx)	xx.x(xx,xx)
	Min., Max.	xx,xx	xx,xx	xx,xx
	Not reported	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Method of index admission	Emergency	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Planned	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not reported	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Table 5: Baseline patient outcome measures

Variable		Control (n=xx)	Intervention (n=xx)	All (n=xx)
Number of comorbidities	N	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median (IQR)	xx.x(xx,xx)	xx.x(xx,xx)	xx.x(xx,xx)
	Min., Max.	xx,xx	xx,xx	xx,xx
Comorbidity	Arthritis (rheumatoid and osteoarthritis)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Osteoprosis	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Asthma	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	COPD, ARDS or emphysema	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	…	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Table 6: Baseline characteristics of randomised wards

Variable		Control (n=xx)	Intervention (n=xx)	All (n=xx)
NHS Trust	…	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not reported	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Type of ward		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
		xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not reported	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ward size (number of beds)	N	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median (IQR)	xx.x(xx,xx)	xx.x(xx,xx)	xx.x(xx,xx)
	Min., Max.	xx,xx	xx,xx	xx,xx
	Not reported	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Patients <75	<75 years	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	≥75 years	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Average length of stay for patients who are admitted to each participating ward	N	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median (IQR)	xx.x(xx,xx)	xx.x(xx,xx)	xx.x(xx,xx)
	Min., Max.	xx,xx	xx,xx	xx,xx
	Not reported	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of patients discharged from a participating ward	N	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median (IQR)	xx.x(xx,xx)	xx.x(xx,xx)	xx.x(xx,xx)
	Min., Max.	xx,xx	xx,xx	xx,xx
	Not reported	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
total number of these patients who are readmitted to the hospital trust within a 30-day period	N	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median (IQR)	xx.x(xx,xx)	xx.x(xx,xx)	xx.x(xx,xx)
	Min., Max.	xx,xx	xx,xx	xx,xx
	Not reported	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Table 7: Questionnaire response rates by treatment arm

Follow-up time point	Intervention (n =xx)	Control (n = xx)	Total (n=xx)
T1 Questionnaire (Post-discharge)			
Sent	xx	xx	xx
Completed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
T2 Questionnaire (30-days post discharge)			
Sent	xx	xx	xx

Completed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
T3 Questionnaire (90-days post discharge)			
Sent	xx	xx	xx
Completed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Table 8 Primary analysis treatment effect on unplanned readmission (Y/N) at 30 days

	Mean estimates		Odds ratio (95% confidence interval)	p-value
	Control	Intervention		
Unplanned hospital readmission at 30 days post discharge				
Treatment effect estimate	xx.x	xx.x	x.x(x.x-x.x)	0.xxx
Sensitivity analysis				
CACE analysis			x.x(x.x-x.x)	0.xxx

Table 9: Secondary analysis treatment effect on number of unplanned readmissions at 60 and 90 days

	Mean estimates		Odds ratio (95% confidence interval)	p-value
	Control (n=xx)	Intervention (n=xx)		
Unplanned hospital readmission at 30 days post discharge				
Treatment effect estimate				
60 days post discharge	xx.x	xx.x	x.x(x.x-x.x)	0.xxx
90 days post discharge	xx.x	xx.x	x.x(x.x-x.x)	0.xxx

Table 10 Secondary analysis treatment effect on time to unplanned readmission

	Median time to first readmission (95% CI)		Hazard ratio (95% confidence interval)	p-value
	Control (n=xx)	Intervention (n=xx)		
Time to unplanned hospital readmission				
	xx.x (xx.x-xx.x)	xx.x(xx.x-xx.x)	x.x(x.x-x.x)	0.xxx

Table 11 Secondary analysis treatment effect on number of unplanned readmissions

	Number of unplanned hospital readmissions		IRR (95% confidence interval)	p-value
	Control (n=xx)	Intervention (n=xx)		
Unplanned hospital readmission at 30 days post discharge				
30 days post discharge	xx.x	xx.x	x.x(x.x-x.x)	0.xxx
60 days post discharge	xx.x	xx.x	x.x(x.x-x.x)	0.xxx
90 days post discharge	xx.x	xx.x	x.x(x.x-x.x)	0.xxx

Table 12: Summary of responses to post-hospital syndrome questions in the nested cohort (n=1000)

Post hospital syndrome question	*Control N(%)*	*Intervention N(%)*
Strongly disagree	*xx(xx.x%)*	*xx(xx.x%)*
Disagree	*xx(xx.x%)*	*xx(xx.x%)*
Neither agree nor disagree	*xx(xx.x%)*	*xx(xx.x%)*
Agree	*xx(xx.x%)*	*xx(xx.x%)*
Strongly agree	*xx(xx.x%)*	*xx(xx.x%)*
Strongly disagree	*xx(xx.x%)*	*xx(xx.x%)*
Disagree	*xx(xx.x%)*	*xx(xx.x%)*
Neither agree nor disagree	*xx(xx.x%)*	*xx(xx.x%)*
Agree	*xx(xx.x%)*	*xx(xx.x%)*
Strongly agree	*xx(xx.x%)*	*xx(xx.x%)*
Strongly disagree	*xx(xx.x%)*	*xx(xx.x%)*
Disagree	*xx(xx.x%)*	*xx(xx.x%)*
Neither agree nor disagree	*xx(xx.x%)*	*xx(xx.x%)*
Agree	*xx(xx.x%)*	*xx(xx.x%)*
Strongly agree	*xx(xx.x%)*	*xx(xx.x%)*
Strongly disagree	*xx(xx.x%)*	*xx(xx.x%)*
Disagree	*xx(xx.x%)*	*xx(xx.x%)*
Neither agree nor disagree	*xx(xx.x%)*	*xx(xx.x%)*
Agree	*xx(xx.x%)*	*xx(xx.x%)*
Strongly agree	*xx(xx.x%)*	*xx(xx.x%)*

Table 13 Secondary analysis treatment effect on PACT-M and CTM-3 scores at T1-T3 in the nested cohort (n=1000)

	Mean (SD)		Adjusted mean difference (95% confidence interval)	p-value
	Control (n=xx)	Intervention (n=xx)		
T1 (30 days post discharge)				
PACT-M total score	xx.x (xx.x)	xx.x (xx.x)	x.x(x.x-x.x)	0.xxx
PACT-M experience items score	xx.x (xx.x)	xx.x (xx.x)	x.x(x.x-x.x)	0.xxx
PACT-M adverse event score	xx.x (xx.x)	xx.x (xx.x)	x.x(x.x-x.x)	0.xxx
CTM-3 score	xx.x (xx.x)	xx.x (xx.x)	x.x(x.x-x.x)	0.xxx

	Mean (SD)		Adjusted mean difference (95% confidence interval)	p-value
	Control (n=xx)	Intervention (n=xx)		
T2 (60 days post discharge)				
PACT-M total score	xx.x (xx.x)	xx.x (xx.x)	x.x(x.x-x.x)	0.xxx
PACT-M experience items score	xx.x (xx.x)	xx.x (xx.x)	x.x(x.x-x.x)	0.xxx
PACT-M adverse event score	xx.x (xx.x)	xx.x (xx.x)	x.x(x.x-x.x)	0.xxx
CTM-3 score	xx.x (xx.x)	xx.x (xx.x)	x.x(x.x-x.x)	0.xxx
T3 (90 days post discharge)				
PACT-M total score	xx.x (xx.x)	xx.x (xx.x)	x.x(x.x-x.x)	0.xxx
PACT-M experience items score	xx.x (xx.x)	xx.x (xx.x)	x.x(x.x-x.x)	0.xxx
PACT-M adverse event score	xx.x (xx.x)	xx.x (xx.x)	x.x(x.x-x.x)	0.xxx
CTM-3 score	xx.x (xx.x)	xx.x (xx.x)	x.x(x.x-x.x)	0.xxx

This analysis will be repeated on participants recruited in the first 5 months (if numbers allow)

Table 14: Summary of the utility of the intervention in the nested cohort (n=1000)

Variable		Control (n=xx)	Intervention (n=xx)	All (n=xx)
Did you receive a 'Your Care Needs You' booklet?	Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Can't remember	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
If 'Yes', when did you use this?	In hospital			
	At home	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not at all	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Can't remember	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not applicable	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
If you received the booklet, how useful did you find it?	Very useful	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Quite useful	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not useful	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Did you or your family/friends watch the 'Your Care Needs You' film?	Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Can't remember	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Before you left hospital, were you given a 'Your Care Needs You' advice sheet?	Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Can't remember	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
If 'Yes', what did you do with this?	Read it	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Showed it to my GP, pharmacist, nurse etc	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Nothing	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Don't know	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
If you received the advice sheet, how useful did you find it?	Very useful	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Quite useful	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not useful	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Table 15: Subgroup analysis where average age on ward (<=80 and >80) is used as a subgroup

	Mean estimates		Odds ratio (95% confidence interval)	p-value
	Control	Intervention		
Unplanned hospital readmission at 30 days post discharge				
Treatment-Age group interaction estimate	xx.x	xx.x	x.x(x.x-x.x)	0.xxx

Table 16: Summary of ward moves (contamination) by consented participants

		Intervention (n=xx)	Control (n=xx)	Overall (n=xx)
Number of ward moves	0	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	…	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median (min, max)	xx.x(xx,xx)	xx.x(xx,xx)	xx.x(xx,xx)
Time spent off the original ward recruited from	n	xx	xx	xx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median (min, max)	xx.x(xx,xx)	xx.x(xx,xx)	xx.x(xx,xx)
Number of control participants who had at least 1 move to an intervention ward			xx (xx.x%)	
Number of intervention participants who had at least 1 move to a control ward		xx (xx.x%)		

Figure 3: Summary of events in the study for nested cohort participants (n=1000)

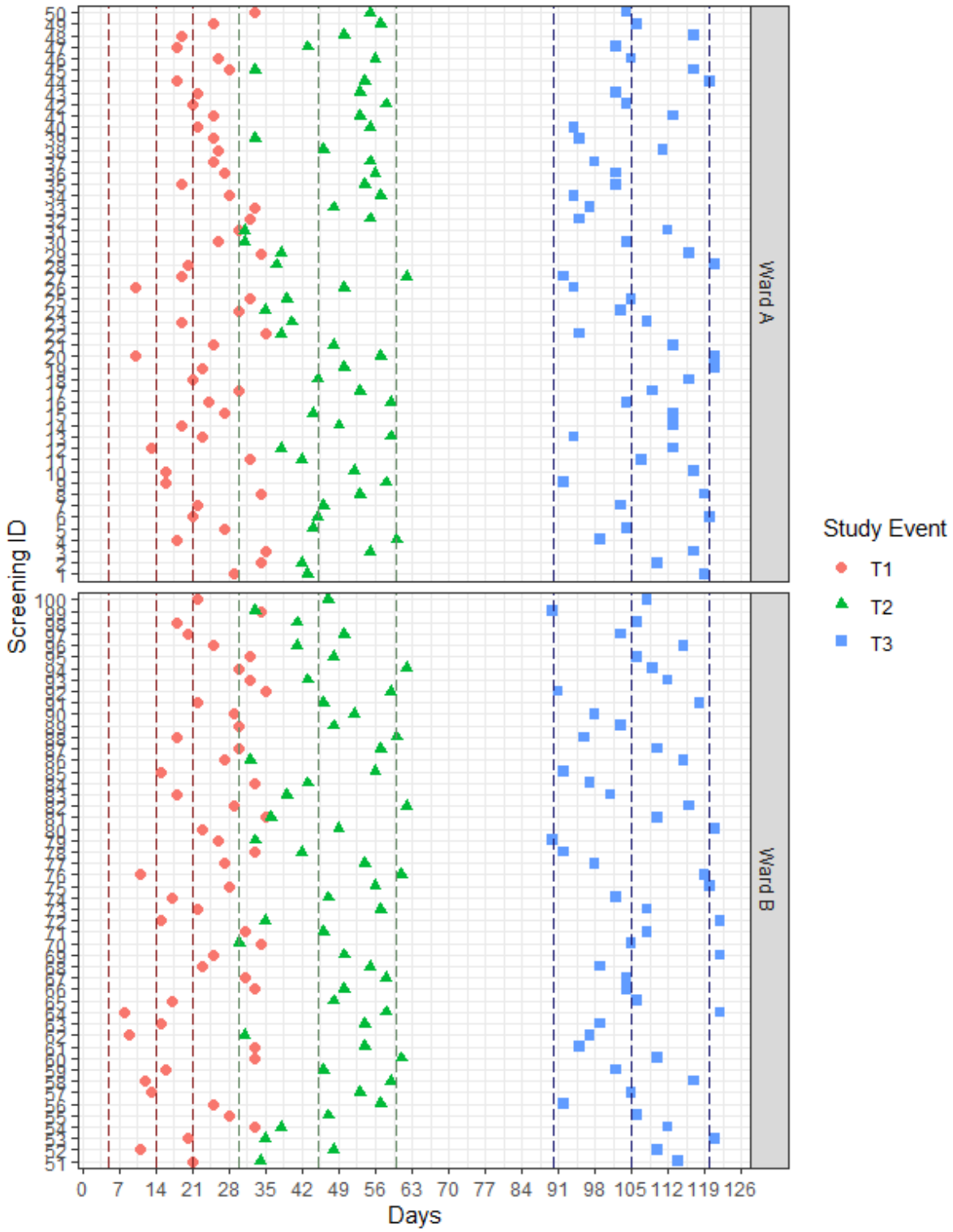

Screening ID
Ward A
Ward B
Days
0 7 14 21 28 35 42 49 56 63 70 77 84 91 98 105 112 119 126
Study Event
T1
T2
T3

Table 17: Summary of safety data

Event	Intervention group n=xx	Control group n=xx	Total n=xx
All Adverse events	xx (xx.x%)	xx(xx.x%)	xx(xx.x%)
Participants with at least 1 AE	xx (xx.x%)	xx(xx.x%)	xx(xx.x%)
…	xx (xx.x%)	xx(xx.x%)	xx(xx.x%)
…	xx (xx.x%)	xx(xx.x%)	xx(xx.x%)
	xx (xx.x%)	xx(xx.x%)	xx(xx.x%)