PCAT STATISTICAL ANALYSIS PLAN (SAP)
Version: 112525

Updates in 112525 version:
- Added Leslie Taylor
- Standardizing language around nursing units (pods)
- Update enrollment dates
- Clarify data source for discharge summary
- Update Per-Protocol to CACE analysis (& add Mplus to software)
- Updated timeline (Gantt)

Project Title: Impact of a novel post-discharge clinic on post-hospital follow-up among Veterans

Protocol ID: PCIL-DC-Clinic

Brief Title: Discharge Clinic

Project Team: Linnaea Schuttner, MD, MS, John Geyer, MD, Chelle Wheat, PhD, Leslie Taylor, PhD, Ashok Reddy, MD, Brinn Jones, Caitlin Harrington, MD, JD, Bryan Grigg, MD, Tinny Liang, MD, MS

Lead Author: Tinny Liang

Senior Author: Linnaea Schuttner

Principal Investigator(s): Linnaea Schuttner, MD, MS, John Geyer, MD,

Central Contact Backup: Brinn Jones

Sponsor: VA Puget Sound Health Care System

Collaborator: VHA Office of Primary Care

Conditions or Focus of Study: Discharge planning; care transitions

Keywords: discharge clinic; care transitions; post-hospital follow-up

Study Type: Interventional

Primary Purpose: Access

Study Phase: N/A

Interventional Study Model: Parallel

Number of Arms: 2

Masking: PI (Schuttner)

Allocation: Randomized

Enrollment: 13 RN pods/sites; 600 patients

Plan to Share IDP: No

Abstract/Brief Summary:

This is a randomized controlled quality improvement trial that will evaluate the difference in time to access to follow-up outpatient primary care following hospital discharge for Veterans in the VA Puget Sound.

1. STUDY SUMMARY AND AIMS

Study purpose:
To evaluate the effectiveness of a novel post-discharge multidisciplinary primary care clinic on post-hospitalization visit time to access among Veterans.

B. Study design:
This is a prospective, cluster-randomized quality improvement trial to evaluate the difference in time to access outpatient follow-up care in Veterans with a hospital discharge in the VA Puget Sound.

Current standard of practice is that primary care team nurses make phone outreach to empaneled patients recently discharged within 2 business days of nurse receipt of notification of hospital discharge. Notification to nursing staff is provided by centralized reporting (VSSC), with triggering by patient-self report during or after a non-VA hospitalization. Nurses can then opt to further arrange provider follow-up in clinic by any modality, based on triage of patient needs and complexity.

The unit of randomization will be pod (i.e., cluster, defined below) of affiliate nurses. Pods (i.e., clusters of nurses who share protocols for care within larger sites) in the VA Puget Sound will be identified by clinic leadership, if participating in a primary care teamlet (Patient Aligned Care Team, PACT) serving empaneled patients within affiliated VA primary care clinics. Among pods randomized to the active arm, team nurses will have the option to schedule Veterans with a recent hospitalization to a follow-up, dedicated multidisciplinary discharge clinic occurring twice weekly or usual care. Usual care arm-site team nurses will have the option to schedule Veterans recently discharged to existing primary care grid openings, which can include the continuity provider or non-continuity provider (acute, resident trainee grid openings) but will not have access to the dedicated discharge clinic.

A cluster-randomized trial is necessary due to high likelihood of contamination across patients based on nurse assignment (usual practice is nurse outreach to all team-empaneled patients, but nurses may cover multiple team panels within a clinic or a clinic-level cluster of nurses, called “pods”). Nurse pods will be assigned to either intervention or usual care arm following assessment of eligibility, in a 1:1 allocation using permuted block randomization (with random block sizes of 2 and 4). Randomization among 13 possible pods will be stratified by numbers of RNs serving per pod, as follows: small (2-5 RNs) vs. Large (>5 RNs).

1. **Active arm:** Dedicated discharge clinic
    a. **Intervention Type:** Other
    b. **Intervention Description:** Dedicated, post-hospital multidisciplinary discharge clinic.
2. **Control arm:** Usual care
    a. **Intervention Type:** As-available scheduling into continuity provider clinic, or utilization of non-usual provider grid options, as permitted by openings.

See Figure 1 for additional details.

Our primary outcome of interest will be days between nurse index phone call to recently discharged patient and outpatient post-discharge clinic visit with a clinician in primary care (general medicine service line, MD, DO, PA, or NP). Secondary outcomes of interest will include 30-day post-discharge readmission rate and ER visits within 30 days of nurse index phone call. Exploratory outcomes will be primary care utilization, combined ER/UC use, prescription medication outcomes (total, discontinued, and safety events), and discharge summary availability.

Enrollment in the trial will occur after 9/3/25.

C. Primary aims:

Aim 1:

Will test the hypothesis (H_{A1}) that Veterans in the intervention arm (via site-level RN team empanelment) will have different number of days to scheduled outpatient primary care follow-up appointment, than Veterans in the usual care arm, among those Veterans recently discharged from hospital stay.

D. Secondary aims:

Aim 2:

A) Will test the hypothesis (H_{A2}) that Veterans in the intervention arm (via site-level RN team empanelment) will have different 30-day readmission rates than Veterans in the usual care arm, among those Veterans recently discharged from hospital stay.
B) Will test the hypothesis (H_{A2}) that Veterans in the intervention arm (via site-level RN team empanelment) will have different ER visit rates then Veterans in the usual care arm, among those Veterans recently discharged from hospital stay.

E. Exploratory aims (non-hypothesis driven):

1. PC utilization post-intervention (outpatient visits - total, and by modality (in-person, VVC, telephone))
2. Combined ER / urgent care post-RN call
3. Total prescription medications (controlling for baseline/pre-intervention) at 28 days

4. Medications discontinued and by type of reason for discontinuation, between index RN call and 28 days.
5. Medication safety events (adverse drug / allergy events), between index RN call and 12 days
6. Post-hospital discharge summary availability by primary care clinician (MD, DO, NP, or PA) Licensed Independent Practitioner (LIP) appointment.

2. DATA SOURCES: *brief description of data sources.*

Table	**Time Period**	**Description**	**Analytic variables of Interest**
cdwwork.RPCMM.CurrentProviderTeamMembership cdwwork.ndim.RPCMMTeam	Screening	Provider/team info	TeamSta6a, StaffSID, STaffName, RPCMMTeam
cdwwork.RPCMM.CurrentRPCMMProviderFTEE	Screening		FTEEValue
[CDWWork].[Outpat].[Visit]	Post randomization		patientsid visitsid Visitdatetime, PrimaryStopCode, SecondaryStopCode
PACT_CC.econ.Outp_PCMM_SSN_Summary PACT_CC.econ.Inp_PCMM_SSN_Summary	Post randomization	Demographics	DOB, age, gender, marital status, DOD (if applicable), service connectedness, copay
SQL13.PACT_CC.[econ].[Outp_PCMM_SSN_Summary]	Post randomization		Age
SQL13.OABI_SHREC.[Demog].[SHREC_v3]	Post randomization		Race/Ethnicity
SQL13.PACT_CC.[SES].[pcmm_sesindex_2010_to_2018]	Post randomization		Neighborhood SES
RB03.VINCI_PSSG.VINC_PSSG	Post randomization		Drive distance
RB03.VINCI_CAN.[DOEx].[can_weekly_report_V2_5_history]	Post randomization		CAN score
SQL13.PACT_CC.[Comorb].[ConditionFlags_Last4Qtr]	Post randomization		AUD or SUD diagnosis, Charlson, Elixhauser (main), Gagne indices, hospice use/palliative care use
SQL13.PACT_CC.[econ].[Outp_PCMM_SSN_Summary]	Post randomization		Primary care visit count > 2 / < 2 in the past 12 month
SQL13.PACT_CC.[econ].[Outp_PCMM_SSN_Summary]	Post randomization		Gender
RB03.VINCI_PSSG.VINC_PSSG	Post randomization		ZIP code
SQL13.PACT_CC.[Demog].[marital]	Post randomization		Marital Status

SQL13.PACT_CC.[SES].[pcmm18_sesindex]	Post randomization		Education
SQL13.PACT_CC.[econ].[Inp_PCMM_SSN_Summary]	Post randomization		# hospitalization and/or ED visits in the past 12 months
SQL13.PACT_CC.[econ].[Outp_PCMM_SSN_Summary]	Post randomization		# hospitalization and/or ED visits in the past 12 months
SQL13.PACT_CC.[Dim].[VAST]	Post randomization		Primary care at CBOC or medical center
RB03.GEC_GECDACA.DOEx.JFI_VA_monthly	Post randomization		JenFrailtyIndex
[CDWWork].[STIUNotes].[TIUDocument_8925]	Post randomization		TIU notes that document nurse notification of discharge, discharge summary availability
CDWWork.Sstaff.sstaff	Screening		StaffSIDs match to name of nurses
Excel worksheet listing all nursing staff by pod	Screening		Randomization
IVC data	Post randomization		Community care hospitalization and urgent care/ ER data
Microsoft office metadata/radio button Y/N (JG has access) CDW: LIP first visit note template string (intervention group) CDW: RN index phone call template string (both groups)	Post randomization		Discharge summary availability for usual care LIP visits

3. STUDY POPULATION AND ELIGIBILITY
Pods (i.e., nursing clusters) will be eligible if there is > 1 active RN care manager serving assigned patients at that clinic, within VA Puget Sound. Nurse care managers (RN) will be identified via clinic leadership as eligible from 13 possible sites. RNs will be eligible if assigned to primary care teams (PACTs) with PCPs (primary care providers) delivering outpatient continuity care to patients with any FTE, and NOT on team type of: GERI, SCI, or HBPC. Providers will be excluded that had less than 1 patient visit during study timeframe.

All Veterans assigned to a PACT with an eligible team RN and receiving empaneled primary care from an eligible site in the VA Puget Sound as of May 26, 2025 with at least 1 outpatient visit in the past 24 months will be included. Eligible Veterans for the trial will include those discharged from a hospitalization on or after day 0 of the trial start date, who self-notify the VA Puget Sound of their hospitalization and are presented by internal data rosters to team RNs for standard post-discharge follow-up contact.

Sex: All
Gender based: No
Age limits: No
Accepts Healthy Volunteers: Yes

4. STUDY TIME PERIOD
The enrollment period for the study is September 3, 2025 (first training); first grid appointments onset on September 9, 2025. Data collection and analysis will continue through at least 6 months post-enrollment for the last Veteran evaluated.

5. STUDY OUTCOMES

Primary outcome measure:

Days between index and follow-up (patient-level), as defined below:

1. Nurse index phone call will be measured using search string within the Electronic Health Record (EHR), CPRS: '%Location of discharge: hospital%'
2. Follow-up discharge clinics will be measured by first stop code indicating any modality visit scheduled with a primary care clinician (licensed independent practitioner with MD, DO, NP, or PA degree types) following index phone call, within 45-days post-hospital index phone call.
3. Intervention clinic specifically will be measured for the per-protocol analysis by use of a specific discharge clinic note template in CPRS.

Secondary outcome measures:

1. 28-day count of VA and community care (IVC) hospital readmissions (patient-level),
2. 28-day count of ER visits, VA and community care (IVC) (patient-level)

Other prespecified outcome measures:

- PC utilization post-RN call (outpatient visits - total, and by modality (in-person, VVC, telephone)) within 45-days.
- Combined ER / urgent care post-RN call, by 28-days.
- Total prescription medications (controlling for baseline/pre-intervention) at 28 days.
- Medications discontinued and by type of reason for discontinuation, between index RN call and 28 days.
- Medication safety events (adverse drug / allergy events), between index RN call and 12 days
- Post-hospital discharge summary availability among patients with no discharge summary at time of index RN call, by first Licensed Independent Practitioner (LIP) appointment in primary care.

6. STUDY COVARIATES

Primary analysis:

A. Covariate of interest: intervention group indicator

B. Additional covariates: RN identifier

Secondary analysis:

A. Covariate of interest: intervention group indicator

B. Additional covariates: RN identifier

7. STATISTICAL ANALYSES AND DESCRIPTION OF MAIN TABLES

Sample size and power

Overall baseline (for 90 days period prior to trial) time from post-discharge index phone call by an RN to first primary care LIP scheduled visit was 10 days (SD = 13), from administrative data. Unit of cluster-randomization is pod, for calculations.

We find that given an α-level of 0.05, 80% power, an expected 10 days for the primary outcome in the control arm, and an intracluster correlation coefficient (ICC) of 0.02, the trial would need to have 600 total patients to be able to detect an absolute difference of 5 days. This is assuming the trial was split into 12 clusters with 50 patients each. 13 total clusters will be recruited to allow for attrition, aiming for a final sample of 12 clusters.

Descriptive analyses

The baseline comparability between groups will be assessed with regard to the variables as outlined in Table 1. Descriptive patient-level statistics will be presented

using the Pearson chi-square test for dichotomous variables and the Student's t-test for continuous variables. Missing data will be tabulated.

Primary analyses

The primary intention-to-treat analysis will use linear mixed-effects model (clustered on site) to test the association between randomization group and days to scheduled follow-up post hospital discharge. A random intercept will be included to capture cluster-level variation. The outcome will be reported as a difference in mean days between the treatment and control groups, adjusted for clustering. The final intracluster correlation coefficient will also be reported.

Complier Average Causal Effect (CACE) analysis:

Brief overview:

Given the nonadherence in the intervention arm (i.e., Veterans assigned to intervention nurses and who do not make a follow up appointment with the discharge clinic), we will estimate the "complier average causal effect" to estimate the causal effect of "discharge clinic appointment receipt" on primary and secondary outcomes where receipt refers to a discharge clinic appointment made and determined as detailed above.

More detailed:

Per-protocol and as-treated methods produce biased treatment effect estimates because they condition on observed intervention compliance measured after randomization (i.e., post-randomization selection bias). An alternative way to measure treatment effect when there is nonadherence is the "complier average causal effect" (CACE) which measures treatment effect among a subset of participants who are defined as "compliers" based on their potential behavior under both treatment assignments[1]. Since the intervention (discharge clinic access) is not available to control subjects, we know the compliance status of participants assigned to the intervention arm who make a discharge clinic appointment (compliers) and those assigned to the intervention arm who do not make a discharge clinic appointment and instead make an appointment with their regular PC (non-compliers). The remaining participants assigned to the control arm are a mixture of compliers and non-compliers (since their behavior under the intervention arm is unobserved and therefore treated as missing data). Observed compliance in the intervention group is defined as receipt of a discharge clinic appointment. Complier average causal effects (CACEs) are estimated using a mixed model approach implemented in Mplus[1]. We use (1) a multilevel logistic (or normal) regression model for binary (or normal) outcomes adjusting for the same variables used in the intent-to-treat analyses; and (2) a multilevel logistic regression model for binary compliance status adjusting for stratification variable size, a function of randomized

treatment arm and treatment receipt, patient- and site-level confounders, and a site random effect. For normal outcomes:

$$Y_{ij} = \beta_0 + \beta_1 C_i + \beta_2 C_i Z_i + \beta_3^T X_{Yi} + \beta_4^T X_{Yi} C_i + \beta_5 X_{Yi} C_i Z_i + \gamma_j + \epsilon_i$$

For Ci = 1 if Veteran *i* with site *j* is a complier and 0 if a non-complier; Zi = 1 if Veteran i's provider is randomly assigned to discharge clinic access and 0 otherwise; Xyi the same vector of covariates used in the adjusted ITT analyses; site random effect yj; and Ei a random error normally distributed. For binary outcomes,

$$logit(Y_{ij}) = \beta_0 + \beta_1 C_i + \beta_2 C_i Z_i + \beta_3^T X_{Yi} + \beta_4^T X_{Yi} C_i + \beta_5 X_{Yi} C_i Z_i + \gamma_j + \epsilon_i$$

Binary (latent) complier type is simultaneously modeled as:

$$logit(C_i) = \alpha_0 + \alpha_{Ci}^T X_{Ci} + \gamma_j$$

Where Xyi is the vector of covariates defined *a priori* to predict latent complier type.

Commented [WS1]: Having a problem with formatting.

All descriptive and main analyses will be performed using R version 4.3.1 and Mplus.

Subgroup analyses

The primary aim of the subgroup analysis is to explore if variation in treatment effect by level of patient comorbidity, to determine if there is consistency across illness burden.

Statistical tests for interaction will be used including CAN score (90-day hospitalization).

In the case of a low number of Veterans within a category (<10), the categories may be pooled. Given that these subgroup analyses will be considered exploratory, no adjustment for multiplicity will be made.

[1] https://mprc.isr.umich.edu/wp-content/uploads/2022/09/Little1998.pdf

[2] https://www.statmodel.com/

7Ai. Aim 1 Statistical Analyses

Aim 1: Will test the hypothesis (H_{A1}) that time to scheduling follow-up post hospital discharge among those who are randomized to a nurse visit with access to the dedicated discharge clinic differs compared to those who are usual care (active arm vs. control).

7Bi. Aim 2a Statistical Analyses

Aim 2: Will test the hypothesis ($H_{A2a\ \&\ A2b}$) that (a) count of ER visits and (b) count of rehospitalizations in 28-days post-index hospital discharge among those who are

randomized to a nurse visit with access to the dedicated discharge clinic differs compared to those who are usual care (active arm vs. control).

Primary outcome measure: Days between nurse index phone call to patient after hospital discharge and scheduled follow-up with primary care LIP.

Secondary outcome measures: a) count of hospital readmissions within 28-days post nurse index phone call to patient after index hospital discharge, b) count of ER visits within 28-days post nurse index phone call to patient after index hospital discharge.

Other prespecified outcome measures:

As above (section 5, exploratory outcomes).

7Aii. Adjustment of pre-specified variables
For increased precision, we will also complete analyses adjusting a priori for the following covariates:

- Patient level: Age, sex, race, prior primary care utilization count, site, CAN score (90-day hospitalization) at baseline
- RN level: Total panel size / paired provider FTE, RN FTE
- Site level: Total provider count (FTE)

8. TIMELINE

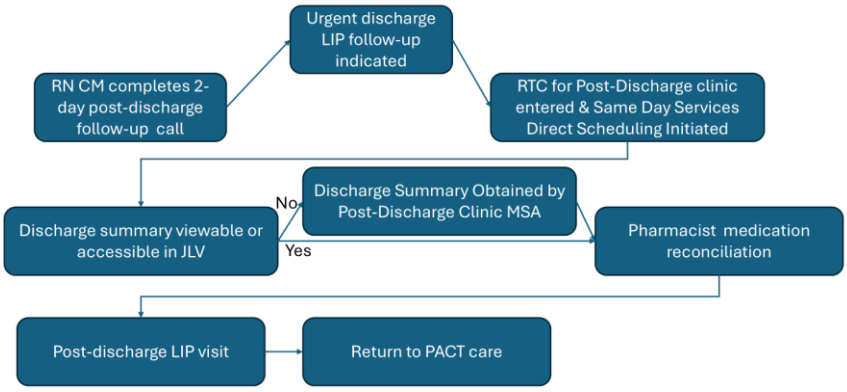
Activity	*Apr '25*	*May '25*	*Jun '25*	*Jul '25*	*Aug'25*	*Sep '25*	*Oct '25*	*Nov'25*	*Dec '25*	*Jan '26*	*Feb '26*	*Mar'26*	*Apr '26*	*May '26*
Obtain letter approval														
Develop & refine d/c workflows														
Preparation of trial data processes														
Sample size/power analysis														
Complete SAP, Register trial														
Identify & train RNs														
Trial enrollment and randomization														
Intervention														
Data analysis														

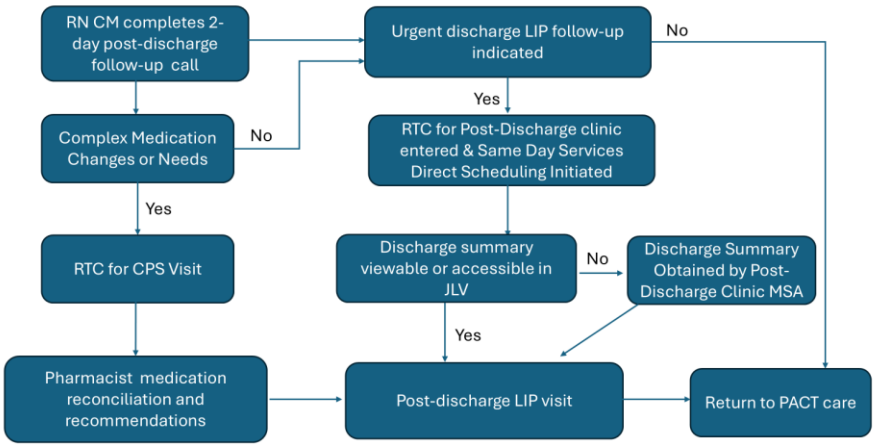
Manuscript preparation & deliverables														

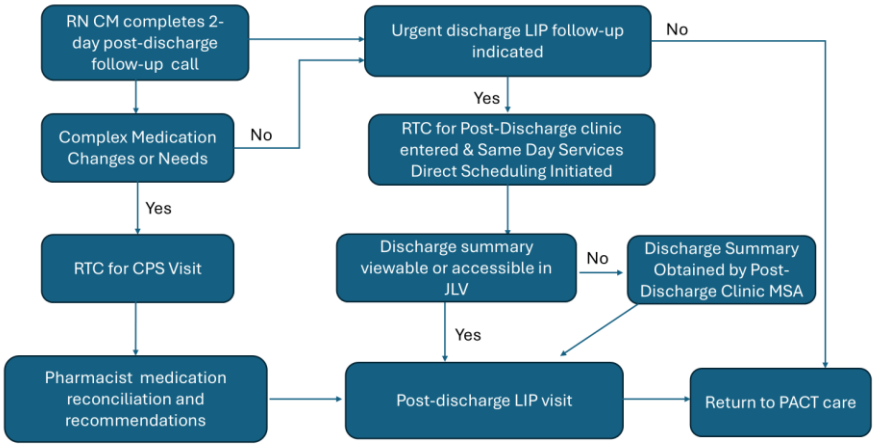
9. PROJECT LINKS *(project document locations to be updated after project initiation)*
1. Project Proposal *<location>*
2. Readme project description *<location>*
3. Data Summary Document *<location>* (Excel document containing work folder location, workplan location, source data description, dataset variables, data dictionary, cohort building script locations, journal/book references for project).

10. APPENDICES.

APPENDIX A: Workflows







APPENDIX B: SHELL TABLES AND FIGURES

Table 1: Baseline sociodemographic characteristics of Veterans by assigned arm

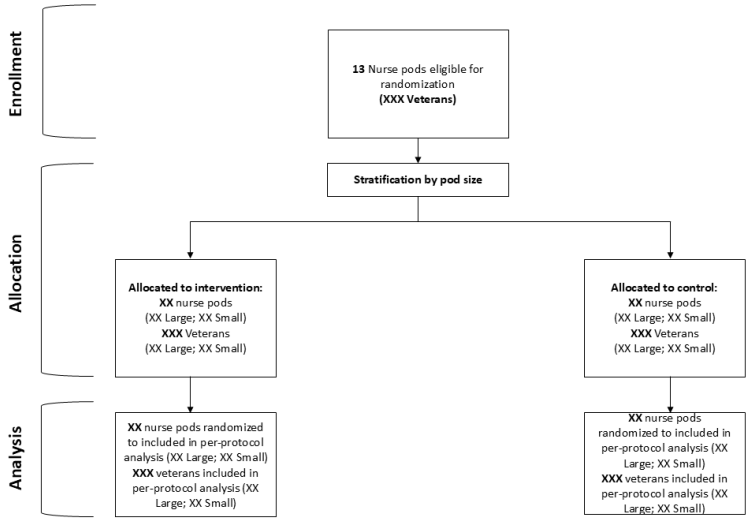
	Overall (N=XXX) % or M (SD)	Control arm (N= XXX) % or M (SD)	Intervention arm (N=XXX) % or M (SD)
Age (years) (SD)			
Sex			
Male			
Female			
Race/Ethnicity			
Non-Hispanic White			
Non-Hispanic Black			
Hispanic			
Asian/Pac Islander/Native Hawaiian			
Multi-race/other			
Marital status			
Married			
Other			
Service Connectedness			
100% SC			
>50% to <100% SC			
>0% to <50%			
NSC			
Copay (Y)			
SES index (decile)			
CAN Score (SD)			
Alcohol Use Disorder (Y)			
Substance Use Disorder (Y)			
Serious Mental Illness (Y)			
>2 primary care visits in the past 12 months (Y)			
Total hospitalizations in past 12 months (SD)			
Geography			
Urban			
Rural			
Highly Rural/Insular			
Drive time to nearest facility (SD)			
Facility Type			
CBOC			
VAMC			

Table 2: Adjusted

	Overall (95% CI)	Control arm (95% CI)	Intervention arm (95% CI)
ITT			
Age (years) (SD)			
Sex			
Male			
Female			
Race/Ethnicity			
Non-Hispanic White			
Non-Hispanic Black			

Hispanic			
Asian/Pac Islander/Native Hawaiian			
Multi-race/other			
CAN score – 90 day hospitalization			
Prior hospitalizations (12m)			
Prior primary care utilization (12m)			
Total panel size (PCP paired to RN)			
RN FTE			
Site level total provider FTE			
PP			
Age (years) (SD)			
Sex			
Male			
Female			
Race/Ethnicity			
Non-Hispanic White			
Non-Hispanic Black			
Hispanic			
Asian/Pac Islander/Native Hawaiian			
Multi-race/other			
Prior hospitalizations (12m)			
CAN score – 90 day hospitalization			
Prior primary care utilization (12m)			
Total panel size (PCP paired to RN)			
RN FTE			
Site level total provider FTE			

Figure 1: CONSORT diagram



APPENDIX C: ISRCTN additional information

US FDA regulated drug: No

US FDA regulated device: No

US FDA IND/IDE: No

Human Subjects Review: Board Status: Non-Applicable

Data Monitoring: No

FDA Regulated Intervention: No

APPENDIX D: Study randomization

A list of eligible participants will be generated using a SQL algorithm to extract data from the site's EHR repository. This list will then be randomized using the blockrand package in R version 4.3.1. A final list of eligible participants along with their randomized group assignment will be uploaded into an operational database that will then be shared electronically with operational partners responsible for post-discharge contact and scheduling.

References:

Fundamentals of Clinical Trials by Lawrence M. Friedman, Curt D. Furberg and David L. DeMets, 2010; p 158-159