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A Randomized Controlled Pragmatic Clinical Trial Evaluating the Effectiveness of a Discharge Follow-Up Phone Call on 30-Day Hospital Readmissions: Balancing Pragmatic and Explanatory Design Considerations

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ABSTRACT: (241 words)

Introduction*:* Hospital re-admissions within 30-days are a healthcare quality problem associated with increased costs and poor health outcomes. Identifying interventions to improve patients' successful transition from inpatient to outpatient care is a continued challenge.

Methods and Analysis: This is a single-center pragmatic randomized and controlled clinical trial examining the effectiveness of a discharge follow-up phone call to reduce 30-day inpatient readmissions. Our primary endpoint is inpatient readmission within 30-days of hospital discharge censored for death analyzed with an intention-to-treat approach. Secondary endpoints included observation status re-admission within 30-days, time-to-readmission, all-cause emergency department (ED) revisits within 30-days, patient satisfaction (measured as mean Hospital Consumer Assessment of Healthcare Providers and Systems or HCAHPS scores), and 30-day mortality. Exploratory endpoints include the need for assistance with discharge plan implementation among those randomized to the intervention arm and reached by the study nurse, and the number of call attempts to achieve successful intervention delivery. Consistent with the Learning Healthcare System model for clinical research, timeliness is a critical quality for studies to most effectively inform hospital clinical practice. We are challenged to apply pragmatic design elements in order to maintain a high quality practicable study providing timely results. This type of prospective pragmatic trial empowers the advancement of hospital-wide evidence-based practice directly affecting patients.

Ethics and Dissemination: Study results will inform the structure, objective and function of future iterations of the hospital's Discharge Follow-Up Phone Call program and be submitted for publication in the literature.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This is a randomized controlled trial performed at a single tertiary care referral center with a wide catchment area for complex medical cases with inclusion limited to the general medicine patient population to improve generalizability.
- The study is designed to demonstrate effectiveness with pragmatic concessions (including an anticipated 30% intervention delivery rate) limiting our ability to determine efficacy.
- Waiver of consent and use of clinical informatics resources permitted study feasibility and the planned enrollment of 2234 (80% power) to 3164 (90% power) patients in 7 months.
- The need to inform a time sensitive clinical practice decision in the context of clinical equipoise led to the appropriate selection of more pragmatic and less explanatory design elements including: an easily interpretable outcome with considerations for informed censoring, engaging clinical informatics with clinical and statistical partners to facilitate data capture from the electronic health record, considering whether post-randomization exclusions would contribute to or diminish generalizable results, employing sample size considerations and power calculations that include hospital administrative projections while maintaining conservative enrollment targets.
- Potentially obtaining external readmission data from a government funded regional health information exchange (The Vanderbilt Health Affiliated Network) is a data access innovation overcoming a major limitation (2-3 year data lag) to hospital readmission research.

INTRODUCTION

In 2010, The United States (US) Affordable Care Act tasked the Centers for Medicare and Medicaid Services to implement financial penalties for hospitals with excessive 30-day inpatient readmission rates.[1] Penalties are withheld reimbursements for select diagnoses designed to incentivize hospital to support higher quality discharge care transitions.[2] In 2016 penalties amounting to over $500 million were withheld from 2597 (47%) US hospitals.[3] In responses to this national quality improvement challenge Vanderbilt University Medical Center launched a nursing-based discharge follow-up phone call program to support more successful inpatient-to-outpatient transitions and improve patient satisfaction. Prior studies have attempted to determine whether a phone call can reduce hospital re-visits. The literature is limited as existing studies target very specific patient populations, are of insufficient design quality, or evaluate follow-up calls as part of a larger care bundle.[4-16] As our hospital system piloted this program, we found it crucial to rigorously quantify the impact of the intervention before it is launched as a health-system wide program. An impactful intervention could be adopted by other hospitals as an investment in quality, safety, and more effectively stewarding institutional resources. Our study team was challenged to embed a high quality clinical trial, specifically randomization and blinding, into the operations of daily inpatient care without disturbing the work flow of medical providers. Our null hypothesis is a follow-up phone call will have no impact on 30-day hospital readmissions. Here we discuss how we appropriately included pragmatic design elements for this superiority trial making the study practicable and results more timely than an explanatory trial approach.

METHODS AND ANALYSIS

Study Design

This is a single-center pragmatic randomized and controlled clinical trial examining the effectiveness of a discharge follow-up phone call on 30-day inpatient readmissions. The study began on February 13, 2017 with a 1 week informatics run-in period to assure the fidelity of our study dataflow as embedded into real-time clinical care at Vanderbilt University Medical Center (Figure 1). Trial initiation was on February 20, 2017 when enrollment began. The study was registered with clinicaltrials.gov (ID: NCT03050918) and IRB approval was received prior to study initiation. Our IRB granted a waiver of consent after several considerations. The trial examines the effectiveness of a newly established but existing clinical program. As a result the intervention is in active use, but its impact is unclear, thus demonstrating equipoise. The care to be received by control and intervention group patients is within the scope of acceptable practice, and poses minimal risk to patients exposed or withheld from the program. Consenting control group patients would have been logistically impracticable given available resources. In addition, the informed consent process would involve education on the risk of readmission targeted by the intervention. This could bias study results by prompting patient action to mitigate the risk and consequently make the results, for an important clinical question, uninterpretable. We randomize these 2 clinical practice options - discharge with and without a follow up call - to best examine the effectiveness of the program under actual clinical care conditions. Our study protocol is adherent to SPIRIT guidelines.[17]

Outcomes

Our primary endpoint is inpatient readmission within 30-days of hospital discharge censored for death. We considered the composite outcome of 30-day inpatient readmission or death. However, we found 30-day mortality rates in our general medicine population in the year prior to be 2.6%. This suggests death is not a significant competing risk and informative censoring[18] would be a minimal issue. Secondary endpoints include observation status re-admission within 30-days, time-to-readmission, all-cause emergency department (ED) revisits within 30-days, patient satisfaction (measured as mean Hospital Consumer Assessment of Healthcare Providers and Systems or HCAHPS scores), [19] and 30-day mortality. Exploratory endpoints include the need for assistance with discharge plan implementation among those randomized to the intervention arm and reached by the study nurse (See Table 1), and the number of call attempts to successful intervention delivery.

Study Population

We include all hospital adult inpatients discharged home from a general medicine service in our urban tertiary care hospital. We exclude in-hospital deaths since the study outcome was not applicable, patients who left the hospital against medical advice (AMA) due to the limited opportunity for discharge planning, and those transferred to a skilled nursing facility or another hospital since they were not discharged with the expectation their health maintenance will be managed from home and supported by clinic-based outpatient care. To improve the generalizability of our study findings to the typical general medicine patient population, we did not include those discharged from our medical sub-specialty services. Our hospital serves as a referral center for complex cases from a wide catchment. In addition, the patients admitted to a sub-specialty service are those requiring direct sub-specialist care. As a result, our sub-specialty service patients may have or require discharge planning not provided in a typical hospital setting.

Recruitment

We identify eligible patients via a custom programmed discharged patient report generated from the medical center's electronic health record (EHR) admission, discharge and transfer (ADT) system each weekday morning. This auto-generated report applies our inclusion and exclusion criteria using EHR ADT data documented during clinical care, and loads as a spreadsheet to a secure folder accessible to select study team members. It includes patient name, admission date, discharge date, discharging hospital provider team, age, address, primary phone number, and primary care doctor.

Study Procedure

Randomization and Blinding

Each weekday morning the list of eligible patients is randomized by a study team member (H.D., D.B. or M.Y.Y.) using the statistical program, R version 3.2.3's (R Foundation for Statistical Computing, Vienna, Austria, 2015, https://www.R-project.org) random sample function with a stable seed to promote reproducibility (see Supplement I). The study database was created in REDCap (Research Electronic Data Capitulation, https://www.project-redcap.org/), a secure web-enabled research data capture system designed to protect and secure protected patient health information.[20] REDCap's application program interface (API) was used to upload those randomized to each study arm (by R) into separate study databases. The study registered nurse (Phone Call RN, S.T.) was blinded to the control arm database, but used the intervention arm database as her work list (Figure 1). A form was created in the intervention database to displays the name, phone number, address, admission data, discharge date, discharge service, primary care doctor, and hours since discharge in a user-friendly format to aid the Phone Call RN's work flow (Supplement II). This replaces a similar discharge dashboard within the EHR that was built to support the hospital Discharge Phone Call Program. Constructing the intervention database form in REDCap was required to blind the Phone Call RN to the control group due to EHR information technology limitations making us unable to randomize or blind the existing dashboard. The REDCap form looks different in structure, but is identical in function while including only intervention group patients.

Post-Randomization Exclusions

During the study design phase we examined a historical cohort of patients who would have met our inclusion criteria and we found the discharge status of patients in our ADT system was not always correct. Chart review and discussion with physician and nursing staff indicated this occurred when there are late changes to the anticipated disposition plan, when the patient leaves the hospital before the care plan can be finalized, or during busy periods when non-care team members are proactively assisting with the discharge process. To permit a secondary per-protocol-analysis the Phone Call RN reviews the chart of each eligible patient to confirm they were truly discharged home. If this was not the case, the patient is identified as ineligible for a call, excluded from intervention delivery, but retained in the study for analysis. This same discharge verification process was repeated (by M.C.B.) in the control arm to ensure balance between study arms (Figure 1).

Discharge Plan Review

After confirming the discharge disposition, the Phone Call RN reviews the medical record to determine what was expected to occur after hospital discharge including medication changes, follow up appointments, education for new diagnoses, and symptoms for which to seek urgent care. The review provides a reference point from which to assess the patient's understanding and ability to "teach back"[21,22] each element of the care plan.

Intervention Delivery

The phone call intervention was designed to be consistent with the existing hospital program. It is a semi-structured discharge phone call assessment (Supplement III) delivered by the Phone Call RN. The Phone Call RN (S.T.) completed institutional training on discharge health coaching; interpreting discharge care plan documentation in the hospital EHR; and methods to contact discharge teams, visiting health assistance, pharmacists for assistance, durable medical equipment vendors, and follow-up providers. A first call attempt is made within 72 hours of discharge. If there is no answer, up to 4 call attempts are made until 7 days post-discharge.

The semi-structured script is used to guide a verbal clinical assessment obtaining information on potential causes of hospital readmission that can be identified and addressed to support a stable transition to outpatient care. Following the methods of health coaching,[22] the phone call focuses on assessing the patient's knowledge of their discharge diagnosis, discharge medication plan with attention to changes, follow-up appointments, and actualization of anticipated discharge supports (i.e., acquisition of durable medical equipment, visiting health assistance and medication procurement). Patients are asked to teach-back their discharge plan for these 3 domains. If any knowledge or care transition gaps are identified, the Phone Call RN provides re-education, and determines if additional discharge plan supports are needed. Additional supports include facilitating durable medical equipment acquisition, making a home health connection, referral to a primary care provider, referral to an emergency department, engagement of case management or social work assistance, medication education, medication changes, request for pharmacist assistance, request for other provider assistance, follow up appointment reminders, follow-up appointment scheduling, providing self-care teaching (wound care, diet, activity, etc).

A focused review of symptoms is conducted to identify conditions that could benefit from early attention including potential medication side effect, care plan failure, or new symptoms requiring provider evaluation. Depending on the issue identified, the Phone Call RN can engage the discharging provider, primary care doctor, hospital pharmacist, or follow up provider in addressing this medical need. When a provider cannot be contacted or identified for concerning symptoms, patients are referred to an urgent care facilities or emergency department to reconcile symptoms with the discharge status.

Patients in both the control and intervention arms may be contacted by non-study discharge follow-up care teams involved in their care as consultants or their primary care home as part of routine care. This may dilute our intervention effect, but replicates implementation scenario of real world care.

Data Collection

Patient and Initial Visit Data

Patient visit data are obtained from the hospital clinical data repository, the Research Derivative,[23] curated by a Vanderbilt Institute for Clinical and Translational Research Institute (VICTR) data management team. Our study team will share enrolled patients' date of service, medical record number, and hospital visit encounter number for the Research Derivative programmers to pull patient demographic, comorbidity, initial hospital visit, and discharge data. All data are uploaded to our study REDCap database.

Intervention Data
The outcome of each call attempt and intervention delivery encounter is recorded directly in the REDCap database. Prior to the study, the Phone Call RN was simultaneously documenting the outcomes of her calls (failures to reach patients and assistance provided to reached patients) in an administrative Microsoft Excel file used for daily reporting to supervisors. She will continue to complete her clinical documentation in the EHR as a clinical note. We, however, replaced her spreadsheet by adding her data collection fields into the intervention data collection form describe above (see Supplement II). At the end of each work day she downloads the call data from the intervention arm database as a Microsoft Excel file that looks identical to her prior spreadsheet. This permits consistent and maximal capture of intervention data within the study database without placing an additional data collection burden that could reduce her call attempt frequency and intervention delivery rate.

Re-Visit Data
We pull data related to any inpatient, observation, or ED revisit within 30 days to our hospital from the EHR including admitting and discharge diagnoses. This is done at 45 days to permit capture of delayed clinical documentation. It also permits us to monitor any re-admissions that occurred shortly after the standard 30-day window as part of our safety analysis. Visits occurring on days 31 or 32 would count as a non-event in our primary analysis but only reflect a slight re-admission delay without a clinically meaningful re-admission reduction. Patient satisfaction data are retrieved from the hospital Quality and Patient Safety Office at 60 days post-discharge. This follow-up interval was selected due to the historical maximum return rate of 27% being achieved at this follow-up period at our institution.

Existing readmission penalties are not limited to patients re-admitted to the original facility. A readmission reduction in our intervention arm could be attributed to shifting readmissions to an outside hospital more closely associated with the patient's outpatient care base. Attempting to surmount this problem was a priority given the wide catchment area of our tertiary care hospital. Acquiring external readmission data in a timely fashion is a major challenge given limited data sharing among hospitals and 2-3 year data lags for curated national databases including National Hospital Ambulatory Medical Care Survey (NHAMCS), Nation-wide Emergency Department Sample (NEDS), and Surveillance Epidemiology and End Result Medicare (SEER-Medicare) databases.

Given the need for a more timely result to inform institutional practice, we recognized this limitation and primarily planned to use provider documented EHR readmission data. Vanderbilt, however, is a hub for a Patient Centered Outcome Research Institute (PCORI) sponsored program to develop a health information exchange (HIE) within a regionalized health community called The Vanderbilt Health-Affiliate Network (VHAN).[24] Initial data sharing began shortly before our study and involved 3 area hospitals. Despite hospital referral patterns suggesting these hospitals were not a major source of our referred patients, we are pursuing this unique opportunity to obtain this external and typically unavailable data. VHAN is not yet organized for research data requests. This study is being used as a prototype to develop inter-institutional data sharing agreements. We are attempting to coordinate the transfer of ADT data into the HIE to meet our study timeline. The success of this effort is to be determined.

Mortality Data
We initially planned to obtain 30-day mortality data from our EHR which included deaths documented by institutional providers and the National Technology Information Services Death Master File[25,26] updated in our EHR with a 6 month data lag. Due to national regulatory

changes this data update became unavailable. Our alternative approach is to account for delayed notification and documentation with a 120-day window to assess 30-day mortality.

Sample Size Considerations

Using data for general medicine inpatients from the prior year, we estimate approximately 3048 patients will be eligible for the study over a 7 month study period with 1:1 randomization. Based on our experience with the current pilot, we have planned for a 30% intervention delivery rate. (See Figure 1). We expect this will be higher since 1:1 randomization will reduce the Phone Call RNs work load by 50% enabling more call attempts per patient thus increasing the likelihood of call success.

Study Length and Timeline

An informatics run-in period began February 7th, 2017 to test the integrity of the randomization and blinding procedure (Figure 2) and data collection plan (see Figure 3). Official study enrollment began on February 20th, 2017. We will obtain interim impact estimates of the discharge phone call intervention at 50% enrollment estimated to occur in July 2017 (3.5 months), and will conduct the definitive analysis at 100% enrollment expected in October 2017 (7 months). Data collection and the study analysis will account for a 30-day re-admission follow-up and the 45-day safety evaluation window. A preliminary analysis is expected in November 2017. We will close the study database after the inclusion of external readmission (if available) and mortality data.

Data Confidentiality, Sources and Sharing

Only key study personnel will have access to the full study dataset which will be maintained in REDCap. All data for this study is either documented by the Phone Call RN, or sourced directly from the EHR data repository. A de-identified version of the study database will be made available to other investigators upon request for IRB approved clinical research.

Data Quality and Safety Monitoring

The interim analysis will be conducted by an independent biostatistician (L.W.) and Data Quality and Safety Officer (T.H.). The results will be reviewed by a 3 member Safety Monitoring Committee including our Data Quality and Safety Officer; the hospital Chief Executive Officer; and Chief Quality, Patient Safety and Risk Prevention Officer. Given the minimal risk of the intervention there are no stopping rules. In addition to the study data analysis the Safety Committee will review 1) a 10% sample of the Phone Call Nurse's daily reports to her supervisors which is an element of clinical care reporting and 2) a summary of potential safety concerns from the office overseeing this clinical program, the Medicine Patient Care Center. The study team will remain blinded to outcome associated results.

Analysis Plan

General Approach

The primary analysis will examine our primary outcome and secondary outcomes via an intention-to-treat (ITT) analysis where comparisons will be made between the 2 study arms. We will follow with a secondary modified intention-to-treat (mITT) analysis of patients remaining after our post-randomization exclusions to permit a per-protocol analysis. Subgroup analyses will examine outcome differences by treatment assignment, age, gender, race, highest educational attainment, health literacy, established primary care status, patient satisfaction level, Medicare readmission penalty diagnosis status, and readmission risk score calculated at discharge as part of routine care at VUMC. Lastly, among patients in the intervention arm who

are called and reached, we will use descriptive statistics to quantify the need for patient assistance with discharge plan implementation (see Table 1).

Statistical Analysis

In our univariate analysis, differences among patient characteristic groups will be assessed using the continuity corrected chi-square test or Mann-Whitney test for continuous outcomes and the Kruskal-Wallis test for categorical outcomes. In our multivariate analysis, we will examine the relationship between treatment assignment and our secondary endpoints using logistic regression. The study is not powered for a time-to-event analysis; however, we will explore time-to-readmission using the Cox proportional hazard model to understand when readmissions occur. In order to provide hospital leadership with preliminary efficacy data, we will perform the interim analysis at 50% enrollment (approximately 3.5 months) followed by the final analysis after achieving 100% enrollment. We have a pre-specified α-level of significance of 0.05 with penalties for the mid-study interim analysis per the O'Brian-Fleming alpha spending function allowing for an α-significance level of 0.005 for the interim and 0.048 for the final analyses.

Power Calculation

The study design is targeted to achieve a minimum of 80% power before October of 2017 (see Table 1). Given the 0.048 alpha-level for our final analysis, and controls anticipated to have a 13.52% readmission rate based on estimates, this requires approximately 320 patients enrolled per month (n = 2234). We assessed this enrollment target as feasible after observing there were approximately 508 eligible patients per month based on medical center data collected from the year prior. We noted approximately 11% of these patient would need to be excluded from the mITT analysis after randomization due to mis-categorized hospital discharge status affecting study eligibility reducing potential monthly enrollment to 452 (n = 3164, or 1582 patients per arm). This 11% may be balanced if the hospital continues to experience its 11% annual growth in inpatient admissions, and opens a total of 45 new general medicine beds as scheduled to occur in months 3 and 6 of our study. In ***Table 1***, we illustrate conservative and ambitious enrollment scenarios with estimates for 80% and 90% power. Considering we have 1 Phone Call Study Nurse and will miss enrollment days for paid time off or sick days, we opted for a more conservative power target and detectable differences of 80% and 3.9% respectively. This carries an associated enrollment of 1117 patent per arm (n = 2234, or 11 patients per day).

DISCUSSION

We were challenged to design a high quality clinical trial while providing a definitive yet timely result to inform hospital clinical practice without disturbing active clinical care. Our research team has had to maintain high expectations while executing a pragmatic plan.[27] The engagement of administrative leaders as members of our study team has heightened the collaboration between clinical research and hospital operations. Hospital leadership has justified being more patient than administrative practice typically allows in anticipation of high quality results. If a benefit is demonstrate it can be expected to translate well as a clinical care program since it was tested in the context of real world clinical practice.

More Robust Results with Randomization

The hospital's original phone call program analysis compared re-admission rates in patients not called, those called by the Phone Call Nurse and reached, and those called and not reached (Figure 4). The results demonstrated lower readmission rates in those who we attempted to call, but never reached. Patients in the 3 groups, however, were not the same (Table 3). Specifically, those called and reached were younger, included fewer whites, had lower acuity visits (lower case mix index), included more transfers from an outside hospital, and were more often admitted from the emergency department. Patients not called had longer mean hospital length of stay (by 1.6 days), included more black patients, and were most likely to be admitted via the emergency department. University research leadership noted blinding and randomization within a clinical trial would producing 2 groups of patients with a near equal distribution of known and unknown characteristics, thus controlling for the confounding factors. Subsequent discussions led to the commission of this study.

Learning Health Care Partnership

VICTR and the hospital have recently engaged in a Learning Healthcare System[28] partnership where research directly informs practice and clinical practice informs our research. Our trial is a pilot for the Learning Healthcare System Platform, a center within the Institute to aid the development of high quality pragmatic studies and timely study completion through the provision of resources, expert consultation, and leadership facilitation. The platform will permit us to tackle significant gaps that arise between acquiring scientific evidence and the implementation of this evidence to advance health care delivery toward the goal of improving individual and population health. In some case existing evidence is not implemented. In the case of our study there is an unmet need for evidence despite the need to develop appropriate clinical practice. Improving health and healthcare requires careful focus on both the content and process of care. Bolstering learning healthcare will be part of the solution.

Enabling Pragmatic Design Elements

Enabling features of our study that can be considered to advance work in this area include waiver of consent, defining a feasible yet generalizable study population to produce results that can be translated to diverse care environments, engaging clinical informatics with clinical and statistical partners to facilitate data capture from the EHR, considering whether post-randomization exclusions would contribute or diminish generalizable results, employing sample size considerations and power calculations that include hospital administrative projections while maintaining conservative enrollment targets. More broadly, we have focused on the effectiveness of our intervention under real-world conditions and limitations, rather than efficacy. This involves accepting potential contamination of our effect from non-study related usual care. We expect that these factors will be distributed evenly among intervention and control patients by randomization. They may potentially dilute the intervention effect. We expect our large sample size will provide enough power to detect a clinically meaningful effect.

ETHICS AND DISSEMINATION

Our hospital leadership awaits the final results. We have their commitment that study results will directly affect hospital practice. Study conclusions will inform the structure, objective and function of future iteration of the Discharge Follow-Up Phone Call program and be submitted for publication in the literature.

CONCLUSIONS

The completion of large trials embedded into clinical practice that produce timely results can bridge the need for robust analyses and early answer to guide dynamic clinical practice decisions. Moreover, this type of prospective pragmatic study empowers the advancement of hospital-wide evidence-based practice directly affecting patients.

REFERENCES

1. Zuckerman, RB, Sheingold SH, Orav EJ, Ruhter J, Epstein AM. Readmissions, observation, and the hospital readmission reduction program. New England Journal of Medicine. 2016;374(16):1543-1551.

2. Center for Medicare and Medicaid Services. "Hospital Readmissions Reduction Program (HRRP)." AHRQ, CMS.gov. Available at: https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/readmissions-reduction-program.html. Accessed August 25, 2017.

3. American Hospital Association. Fast Facts on US Hospitals: 2017. Available at: http://www.aha. org/research/rc/stat-studies/fast-facts.shtml. Last Accessed: August 25, 2017.

4. Hansen, L. O., Young, R. S., Hinami, K., Leung, A. & Williams, M. V. Interventions to reduce 30-day rehospitalization: a systematic review. Annals of Internal Medicine. 2011;155:520–528.

5. Huffman M. Health Coaching: A new and exciting technique to enhance patient self-management and improve outcomes. Home Healthcare Now. 2007;25(4):271-274.

6. Huffman MH. Health Coaching: A fresh, new approach to improve quality outcomes and compliance for patients with chronic conditions. Home Healthcare Now. 2009;27(8):490-496.

7. Balaban RB, Weissman JS, Samuel PA, Woolhandler S. Redefining and Redesigning hospital discharge to enhance patient care: A randomized controlled study. Journal General Internal Medicine. 2008;23:1228-1233.

8. Weisman DS, Bashir L, Mehta A, Bhatia L, Levine SM, Mete M, Padmore JS. A medical resident post-discharge phone call study. Hospital Practice. 2012;40(2): 138–144.

9. Goldman LE, Sarkar U, Kessell E, Guzman D, Schneidermann M, Pierluissi E, Walter B, Vittinghoff E, Critchfield J, Kushel M. Support from hospital to home for elders: A randomized trial. Annals of Internal Medicine. 2014;161(7):472-81.

10. Wong FK, So C, Chau J, Law AK, Tam SK, McGhee S. Economic evaluation of the differential benefits of home visits with telephone calls and telephone calls only in transitional discharge support. Age and Ageing. 2014;44(1):143-7.

11. Mistiaen P, Poot E. Telephone follow-up, initiated by a hospital-based health professional, for postdischarge problems in patients discharged from hospital to home. The Cochrane Library. 2006. doi:10.1002/14651858.CD004510.pub3.

12. Soong C, Kurabi B, Wells D, Caines L, Morgan MW, Ramsden R, Bell CM. Do post discharge phone calls improve care transitions? A cluster-randomized trial. PloS One. 2014;9(11):e112230.

13. Chan B, Goldman LE, Sarkar U, Schneidermann M, Kessell E, Guzman D, Critchfield J, Kushel M. The effect of a care transition intervention on the patient experience of older multi-lingual adults in the safety net: results of a randomized controlled trial. Journal of General Internal Medicine. 2015;30(12):1788-94.

14. Wong FK, Chow SK, Chan TM, Tam SK. Comparison of effects between home visits with telephone calls and telephone calls only for transitional discharge support: a randomised controlled trial. Age and Ageing. 2013;43(1):91-97.

15. Harrison JD, Auerbach AD, Quinn K, Kynoch E, Mourad M. Assessing the impact of nurse post-discharge telephone calls on 30-day hospital readmission rates. Journal of General Internal Medicine. 2014;29(11):1519-25.

16. Dudas V, Bookwalter T, Kerr KM, Pantilat SZ. The impact of follow-up telephone calls to patients after hospitalization. The American Journal of Medicine. 2001;111(9):26-30.

17. Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Annals of Internal Medicine. 2013;158:200-207.

18. Wang, MC, Chiang CT. Analyzing recurrent event data with informative censoring. Journal of the American Statistical Association. 2001;96(455): DOI: 10.1198/016214501753209031.

19. Giordano LA, Elliott MN, Goldstein E, Lehrman WG, Spencer PA. Development, implementation, and public reporting of the HCAHPS survey. Medical Care Research and Review. 2010;67(1):27-37.

20. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. Journal of Biomedical Informatics. 2009;42(2):377-81.

21. DeWalt DA, Broucksou KA, Hawk V, Brach C, Hink A, Rudd R, Callahan L. Developing and testing the health literacy universal precautions toolkit. Nursing Outlook. 2011;59(2):85-94.

22. Rosenbloom ST, Harris P, Pulley J, Basford M, Grant J, DuBuisson A, Rothman RL. The mid-South clinical data research network. Journal of the American Medical Informatics Association. 2014;21(4):627-32.

23. Danciu I, Cowan JD, Basford M, Wang X, Saip A, Osgood S, Shirey-Rice J, Kirby J, Harris PA. Secondary use of clinical data: the Vanderbilt approach. Journal of Biomedical Informatics. 2014;52:28-35.

24 Jager AJ, Wynia MK. Who gets a teach-back? Patient-reported incidence of experiencing a teach-back. Journal of Health Communication. 2012;17(sup3):294-302.

25. Sesso HD, Paffenbarger RS, Lee IM. Comparison of national death index and world wide web death searches. American Journal of Epidemiology. 2000;152(2):107-11.

26. Williams BC, Demitrack LB, Fries BE. The accuracy of the National Death Index when personal identifiers other than Social Security number are used. American Journal of Public Health. 1992;82:1145–7.

27. Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. The PRECIS-2 tool: designing trials that are fit for purpose. British Medical Journal. 2015;350:h2147.

28. Olsen, L., Aisner, D., McGinnis, J.M. Institute of Medicine (US). Roundtable on Evidence-Based Medicine. The learning healthcare system: workshop summary. Washington (DC): National Academies Press (US); 2007. Roundtable on Evidence-Based Medicine. Available from: https://www.ncbi.nlm.nih.gov/books/NBK53492/

AUTHOR CONTRIBUTIONS

Dr. Yiadom is the Principal Investigator leading study design and implementation. Henry Domenico is the primary statistician for the project. Dan Byrne directly supervises data analysis and statistical plan implementation, and contributed to the study design. Michele Hasselblad contributed to the intervention design, study nurse training, and is actively involved in study implementation. Dr. Gatto is the scientific research coordinator for the study via the Learning Healthcare System Platform. Dr. Kripalani contributed to study design and the analysis plan. Dr. Choma contributed to the study design, implementation plan and the continued engagement of hospital leadership to support study implementation through completion. Johnston Morrison contributed to the study design. Monisha Bhatia contributed to the study design and data collection. Dr. Harrell provided senior guidance on the study design and the analysis plan. Ms. Dr. Hartert serves as the study safety officer and contributed to the study design, statistical analysis plan, and leading the blinded interim analysis along with Ms. Li Wang. Dr. Bernard provided senior scientific oversite for all aspects of the study. All authors reviewed and contributed to the final form of this manuscript.

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COMPETING INTERESTS

The authors have no competing interest to disclose.

Table 1 - Discharged Assistance Services for Intervention Group Patients "Reached" by Discharge Phone Call

Facilitating Durable Medical Equipment Acquisition
Making a Home Health Connection
Referral to a Primary Care Provider
Referral to the Emergency Department
Engagement of Case Management or Social Work assistance
Medication Education
Medication Changes
Request for Pharmacist Assistance
Request for Other Provider Assistance
Follow Up Appointment Reminder
Follow Up Appointment Scheduling
Providing Self-care Teaching (wound care, diet, activity, etc)
Intervention Group Patient Total

Table 2 - Power and Sample Size Scenarios

	Conservative		Ambitious	
Control Group Readmission Rate†	13.52%	13.52%	13.52%	13.52%
Intervention Group Readmission Rate	9.60%	9.10%	10.20%	9.70%
Power	80%	90%	80%	90%
Detectable Difference	3.9%	4.4%	3.3%	3.8%
Projected Study Sample Size	1117	1117	1582	1582

*2 group X^2 test of equal proportions (equal n's), 2-sided text, final analysis $\alpha = 0.048$

† Historical VUMC readmission rates

Table 3 – Distribution of Patient Characteristics from the Non-Randomized Pre-Trial Observational Study of the Phone Call Program and Readmission Rates

	Not Called (n=16,096)	**Called but Not Reached** (n=10,749)	**Called and Reached** (n=8,447)
Any Readmission within 30 days[1]	**15.1** (2,425)	7.4 (171)	8.8 (747)
Unplanned Readmission within 30-days[1]	**13.3** (2,133)	6.9 (158)	8.5 (719)
Gender (male)[1]	48.1 (7,742)	**41.7** (960)	46.5 (3,932)
Race[1]			
White	79 (12,711)	**77.5** (1,785)	80.5 (6,801)
Black	**15.9** (2,561)	14.9 (342)	14.1 (1,192)
Other	1.7 (280)	1.9 (44)	1.7 (142)
Unknown	3.4 (544)	5.7 (131)	3.7 (312)
Age[2]	50.8 (19.5)	**45.9** (18.5)	52.6 (182)
Hospital Length of Stay	**5.8** (7)	4.2 (4.7)	4.2 (4.6)
Case Mix Index[3]	2.0 (2.3)	**1.9** (2.0)	2.2 (2.3)
Transferred from Another Hospital[1]	18.7 (3017)	**21.1** (485)	17.4 (1470)
Admission from the Emergency Department[1]	**66.8** (10,756)	59.3 (1,366)	44.4 (3,752)

[1]Percentage and number of patients. [2]Mean and standard deviation (SD). [3]Case Mix Index is a complex measure of patient illness level and the intensity of services received during a hospital stay.

Figure Legend

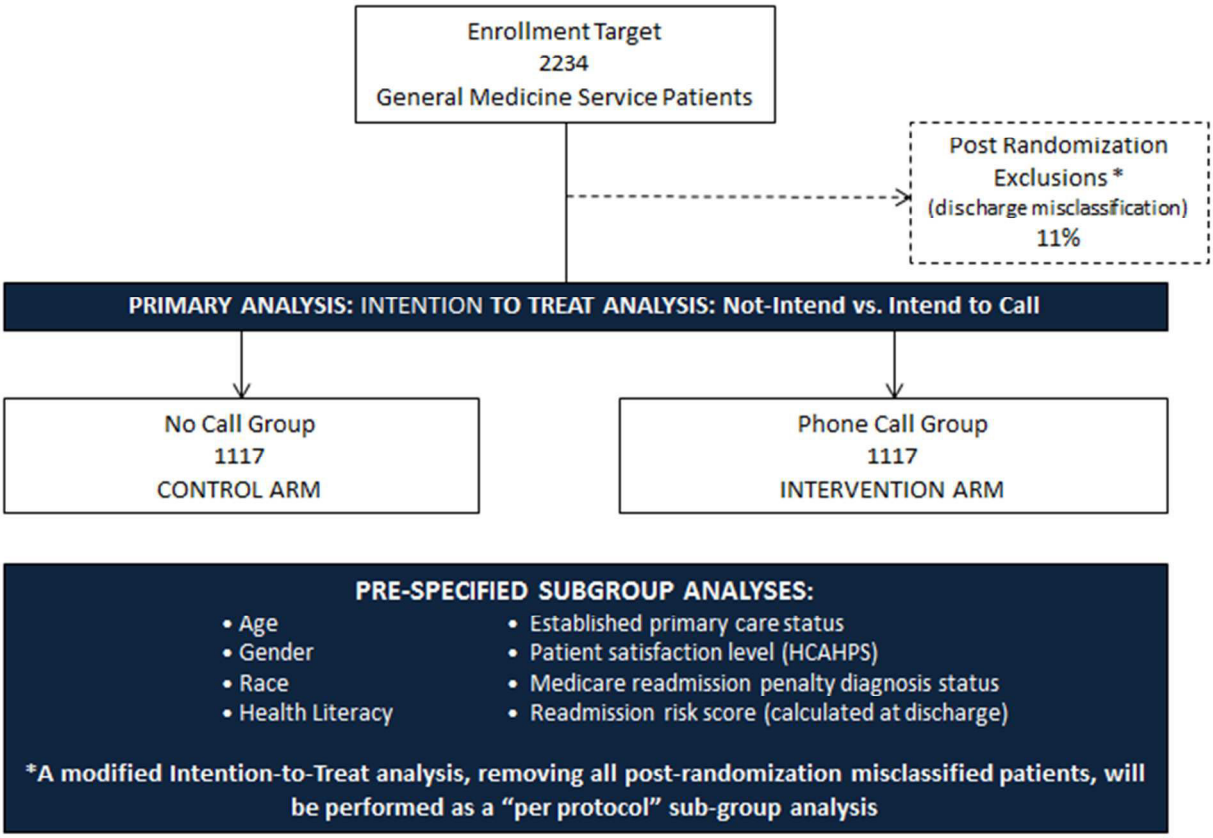
Figure 1 - Study Design Schematic and Enrollment Projection

Figure 2 - Operationalizing Randomization and Blinding within Dynamic Hospital Care

Figure 3 - Discharge Phone Call Study Data Sources and Flow

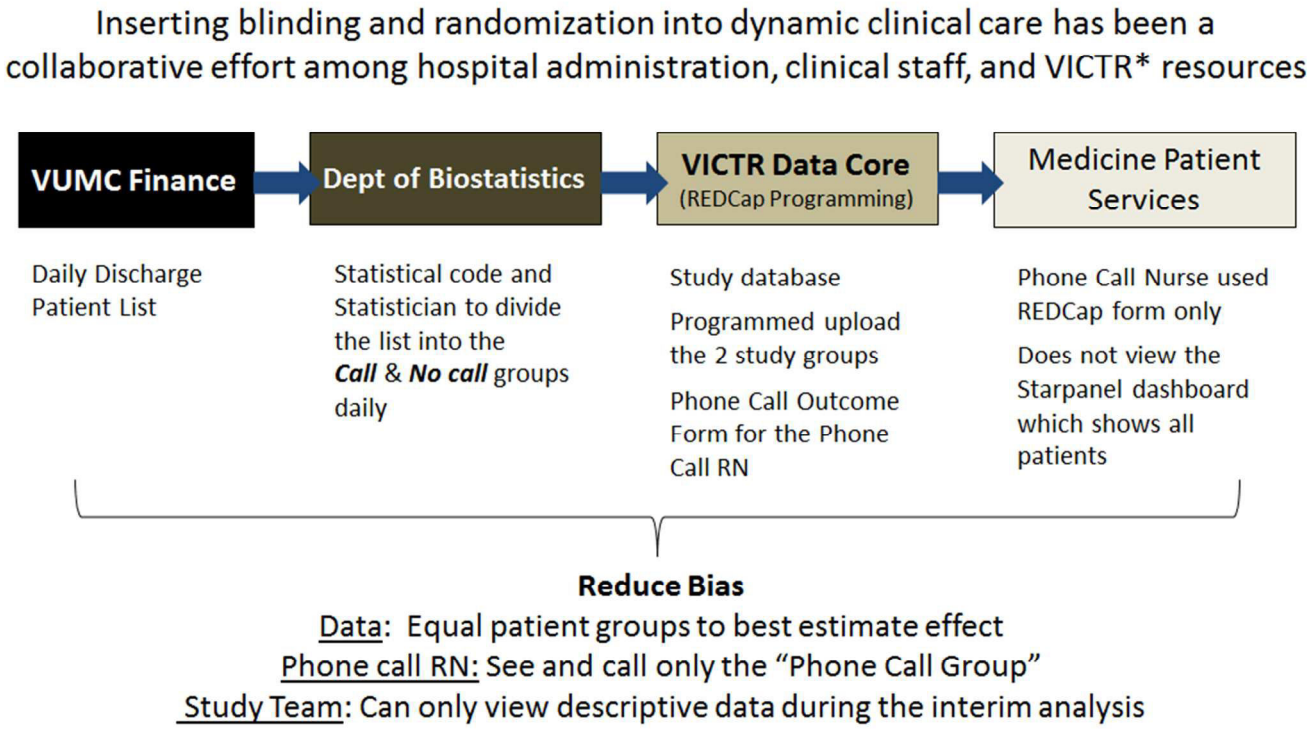
Figure 4 – Non-Randomized Pre-Trial 30-Day Readmission Rates by Phone Call Status

Figure 1 - Study Design Schematic and Conservative Enrollment Projection



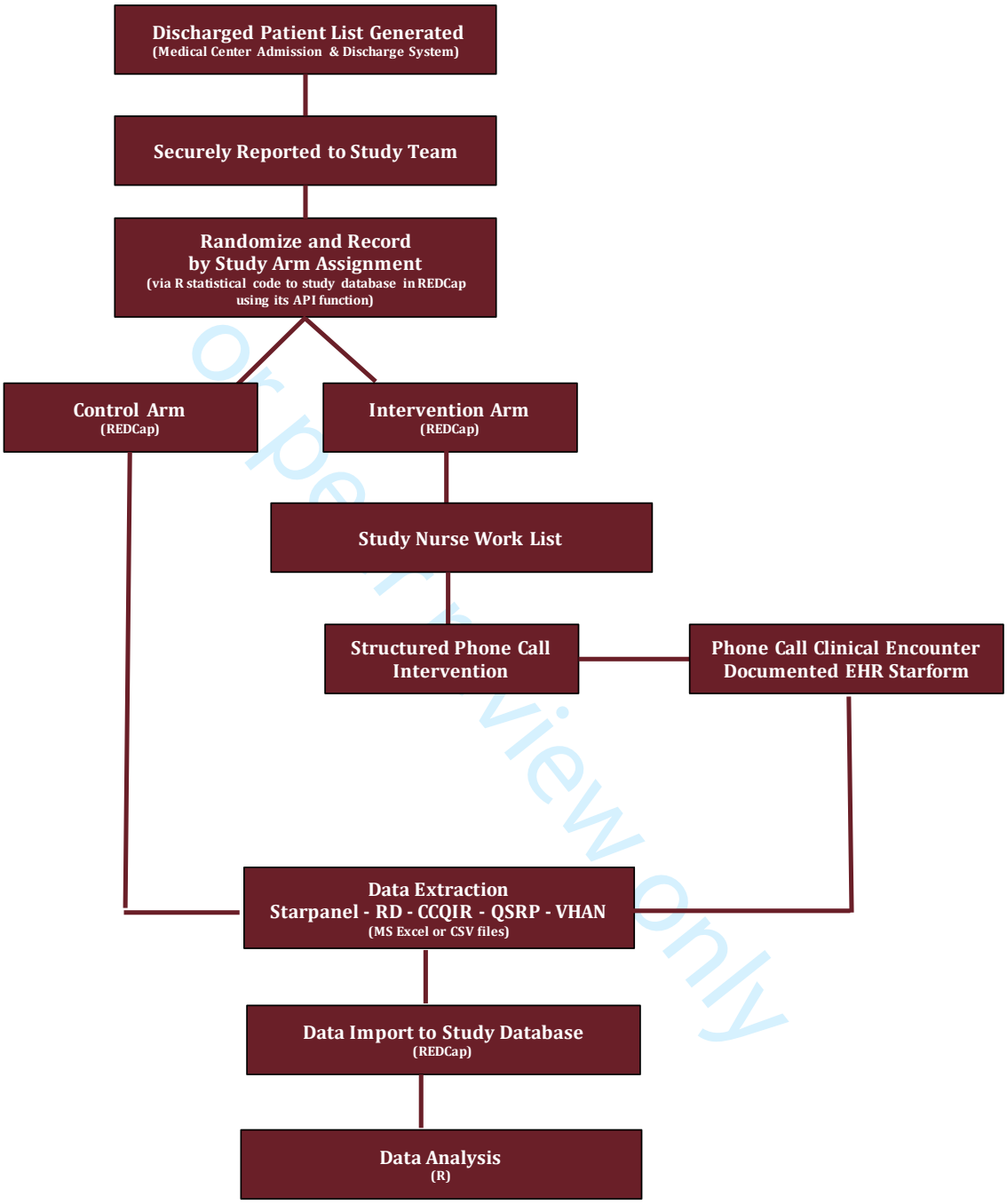
Historical readmission rate of 13.53%, chi-square α-level of significance = 0.05, 80% power to detect a statistically significant effect.

Figure 2 - Operationalizing Randomization and Blinding within Dynamic Hospital Care



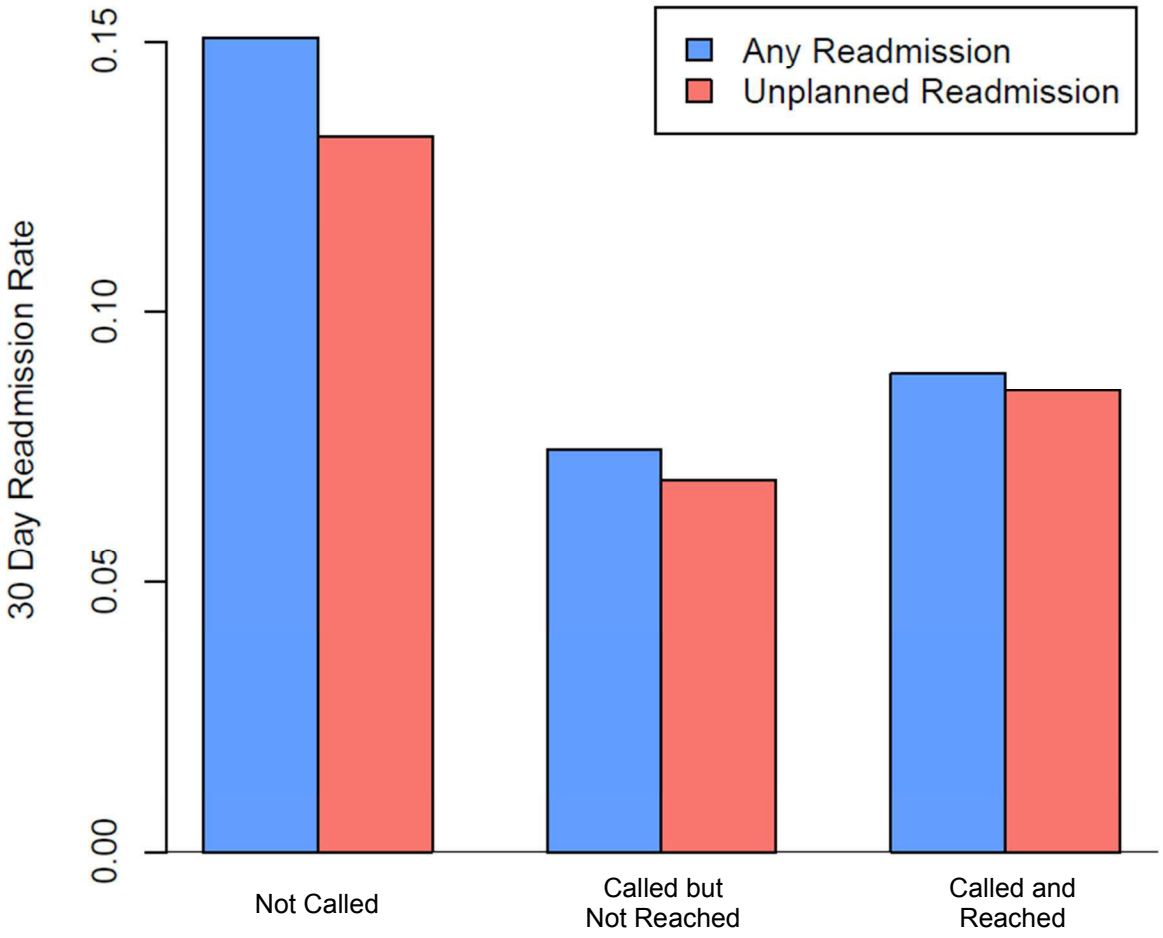
*VICTR = Vanderbilt Institute of Clinical and Translational Research

Figure 3 - Discharge Phone Call Study Data Sources and Flow



EHR = electronic health record, RD = Research Derivative Vanderbilt University Medical Center's curated clincial data archive, QSRP = Quality Safety and Risk Management Program that houses medical center Patient Satisfaction data. VHAN = the Vanderbilt Health Affiliated Network HIE, a potential source of external readmission data.

Figure 4 – Non-Randomized Pre-Trial 30-Day Readmission Rates by Phone Call Status



Supplement I – R Code Template for Daily Patient Cohort Randomization

```
#Load Necessary Libraries
library(RCurl)
library(readr)

#Set your file path to the folder where BOR report is stored
setwd("D:/Data/Documents/Temp Work computer/FU Phone Call/Randomization")

#Will upload BOR csv corresponding to today's date
filename <- paste("discharge_report_",format(Sys.Date(), "%m-%d-%Y"),".csv", sep = "")
filename <- paste("discharge_report_", Sys.Date(),".csv", sep = "")
data <- read.csv(file = filename)

#Sets a seed based on today's date for reproducibility
set.seed(floor(as.numeric(Sys.Date())^1.5))

#Samples a random 1/2 of rows to be included in the intervention group. Will randomly round up
or down if an odd number of rows.
sample_rows <- sample(1:nrow(data), sample(c(floor(nrow(data)/2), ceiling(nrow(data)/2)), 1),
replace = F)
random_group <- rep("B", nrow(data))
random_group[sample_rows] <- "A"
data <- data.frame(data, random_group)

#Saves intervention and control patients to separate datasets
data_intervention <- data[data$random_group == 'A',]
data_control <- data[data$random_group == "B",]

#Change directory to store intervention patients in Intervention Folder
setwd("D:/Data/Documents/Temp Work computer/FU Phone Call/Randomization/Intervention")

#Saves intervention patients with date stamp
write.csv(data_intervention, file = paste("data_intervention", Sys.Date(),".csv", sep = ""),
row.names = F)

#Creates data object containing the intervention patients that can be uploaded to REDCap
Data.INT <- read_file(paste("data_intervention", Sys.Date(),".csv", sep = ""))

#Uploads data to redcap, paste API token for project 2 below
result_intervention <- postForm(
  uri='https://redcap.vanderbilt.edu/api/',
  token='0F5278ECF8493BDA2A5FB71EBE828110',
  content='record',
  format='csv',
  type='flat',
  overwriteBehavior='normal',
  data=Data.INT,
  returnContent='count',
  returnFormat='json'
)
```

```
print(result_intervention)

#Change directory to store Control patients in Control Folder
setwd("D:/Data/Documents/Temp Work computer/FU Phone Call/Randomization/Control")

#Saves control patients with date stamp
write.csv(data_control, file = paste("data_control", Sys.Date(),".csv", sep = ""), row.names = F)

#Creates data object containing the Control patients that can be uploaded to REDCap
Data.Control <- read_file(paste("data_control", Sys.Date(),".csv", sep = ""))

#Uploads data to redcap, paste API token for project 1 below
result_control <- postForm(
  uri='https://redcap.vanderbilt.edu/api/',
  token='6EA859FA6C7F35B11CAAAA744ADAAC48',
  content='record',
  format='csv',
  type='flat',
  overwriteBehavior='normal',
  data=Data.Control,
  returnContent='count',
  returnFormat='json'
)

print(result_control)
```

Supplement II – Intervention Data Capture Form

Discharge Follow Up Phone Call

Editing existing Encounter Number **12345678901**

Encounter Number	**12345678901** To rename the record, see the record action drop-down at top of the Record Home Page.
Current Date and time	03-17-2017 1 Now M-D-Y H:M
Discharge Team	RIVEN HM 1
Discharge Team Group	RIVEN
MRN	2543577
Name	RICH, CARLA
BHLS	
Education	
Admit Date/Time	03-10-2017 1 Now M-D-Y H:M
Discharge Date and time	03-12-2017 1 Now M-D-Y H:M
Hours Since Discharge (auto-calculated)	119 View equation

Tele	6153851711
PCP Name	HABERMANN,
PCP ID	2515
Patients Preferred Language	ENGLISH
Date of First Contact	03-14-2017 Today M-D-Y
Call Attempts	Not eligible
Date of Last Contact	03-17-2017 Today M-D-Y
Status	Unsuccessful - No Answ er
Interventions Delivered (check all that apply)	☐ Durable Medical Equipment ☐ Facilitated Home Health Connection ☐ Referral to PCP (pt instructed to call) ☐ Referral to ED (pt instructed to go) ☐ Case Management/Social Work assistance requested ☐ Medication Change by Call RN ☐ Pharmacist assistance requested ☐ Provider assistance requested

Notes	 Expand
Form Status	
Complete?	Complete

Supplement III – Semi-Structured Phone Call Script and Clinical Note Template

Follow Up Phone Call Data Collection Form (Phone Call Starform)

Provider (indexing): Morrison, Johı (*** This will change the provider displayed in the all documents listing of StarPanel. ***)

***Standard Document Name:** Clinical Communication | Discharge Follow -up

Comment for Indexing (optional):

VANDERBILT UNIVERSITY MEDICAL CENTER
POST DISCHARGE TELEPHONE CALL

Date of Discharge: 12/12/2015

Patient Home Phone: (609) 122-222

CALL INFO:

Call Attempt Date and Time: 01/28/2016 12:12	**Pt Location:**	○ Call Successful ○ Call Unsuccessful ○ Call Unnecessary
Contact Attempts:		**Phone Call Occurred with:**
Caller: Morrison, Johı		
Pre-Call Prep Time:		
Call Duration:		

INTRODUCTION:

Hello, Barbara Ztest, this is Morrison, Johr from Vanderbilt. I am calling to follow-up with you after your recent visit to our hospital. I'd like to ask you a few questions to make sure everything is going ok. This could take 10 to 15 minutes - Is this a good time to talk?

- If Yes proceed;
- If No - can you give me a time that would be better and I will call you back?

I see you were in the Hospital for [x]. How are you feeling?

Comments:

DISCHARGE INSTRUCTIONS

Click HERE for Discharge Instructions

- I want to make sure the discharge instructions we gave you were clear and understandable... Can you please tell me in your own words how you are caring for yourself at home?
- What questions do you have about your discharge instructions?
  - If none... Great - if something were to come up, what would you do to get your questions answered?
- Are you having any unusual symptoms or problems? (Specific to problem *base this on the discharge summary* - i.e. dressing, PAIN, bruising or swelling, N/V; e.g., *Do your favorite pair of shoes still fit?*)

Patient can teach back self-care	☐ Yes ☐ No ☐ Partial
Provider contacted for pain/symptoms/complications	☐ Yes ☐ No

Comments:

FOLLOW-UP APPOINTMENT

- When is your follow-up appointment?

Follow-up appointment change made based on this call	☐ Yes ☐ No
Able to teach back follow-up appointment related to hospitalization	☐ Yes ☐ No

Comments:

MEDICATIONS:

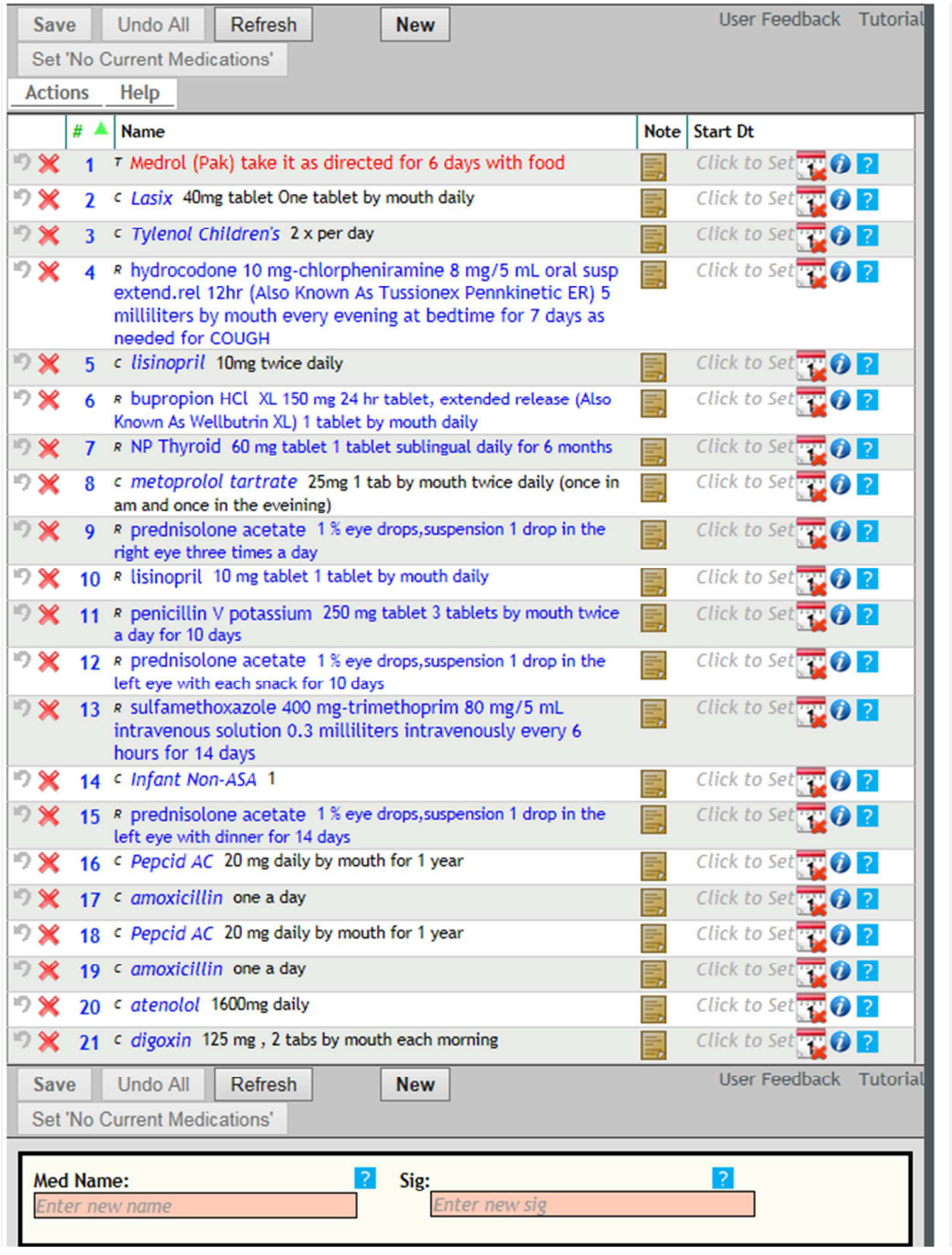
*Are new prescriptions identified on the discharge summary?

- **Yes** –
  - I see you have [number] new medicines from your hospital visit. How are you tolerating taking your [medication]? (follow protocol if you find patient has not filled prescriptions)
  - Would you talk through your daily plan for taking all your medicines
  - What questions do you have about your medicines
- **No** –
  - I see we didn't prescribe any new medicines when you left the hospital. Is that still correct?
  - Yes: Great – do you take any other medicines on a regular basis?
    - Would you talk through your daily plan for taking your medicines?
    - Do you have any questions about your medicines?
  - No: Ok, what medicines did you get? How are you tolerating taking your new medicines?
    - Would you talk through your daily plan for taking your new medicines and any others you take on a regular basis?
    - What questions do you have about your medicines?

Able to teach back medications	☐ Yes ☐ No

Has obtained medications prescribed at discharge	☐ Yes ☐ No ☐ Partial
Medication education or clarification was needed	☐ Yes ☐ No
Medication change made by caller/provider based on phone call	☐ Yes ☐ No
Comments:	

Meds Editor: (Click to expand/collapse)



CLOSING:

- Thank you for talking with me. We are always trying to get better at giving excellent care. Is there one thing that comes to mind for you that we can improve on?
- You will be getting a survey in the mail asking about your experience during your hospital stay. We would appreciate you taking the time to give us your feedback. It is very important to us and should only take you about five minutes.
- Do you need anything from us right now?
    - Ok we wish you all the best in your recovery. If you need anything, please contact us at [phone number]

Comments:

Save As Draft Complete

Form: post_discharge_telephone_call (Post Discharge Telephone Call)
Version: 2.4
Last modified: $Date: 2015/12/21 18:22:48 $

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	5
	2b	All items from the World Health Organization Trial Registration Data Set	5
Protocol version	3	Date and version identifier	?
Funding	4	Sources and types of financial, material, and other support	1,16
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	16
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	1,16
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	16

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
	6b	Explanation for choice of comparators	4
Objectives	7	Specific objectives or hypotheses	4
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	5,6
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	n/a
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	n/a
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	4
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	4,8

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	8
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	8,10
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	6
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	6
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	6
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	6,7
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	7,8
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	7,8

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	6,7,8
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	9,10
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	4,9,10
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	10
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	9
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	9
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	9
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	?
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	5
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	12

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	5
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	5
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	6,9
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	17
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	9
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	6,9
	31b	Authorship eligibility guidelines and any intended use of professional writers	15
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	9
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	n/a,5
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

A Randomized Controlled Pragmatic Clinical Trial Evaluating the Effectiveness of a Discharge Follow-Up Phone Call on 30-Day Hospital Readmissions: Balancing Pragmatic and Explanatory Design Considerations

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Primary Subject Heading:	Evidence based practice
Secondary Subject Heading:	Health services research
Keywords:	discharge phone call, pragmatic clinical trial, hospital readmission, transition of care

TITLE: A Randomized Controlled Pragmatic Clinical Trial Evaluating the Effectiveness of a Discharge Follow-Up Phone Call on 30-Day Hospital Readmissions: Balancing Pragmatic and Explanatory Design Considerations

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RUNNING TITLE: Discharge Phone Call RCT

WORD COUNT: 4277 (excluding abstract, strength and limitations, references, and supplements)

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CLINICAL TRIAL REGISTRATION: This study is registered with clinicaltrials.gov as NCT03050918

KEY WORDS: discharge phone call, pragmatic clinical trial, hospital readmission, transition of care

ABSTRACT: (241 words)

Introduction*:* Hospital re-admissions within 30-days are a healthcare quality problem associated with increased costs and poor health outcomes. Identifying interventions to improve patients' successful transition from inpatient to outpatient care is a continued challenge.

Methods and Analysis: This is a single-center pragmatic randomized and controlled clinical trial examining the effectiveness of a discharge follow-up phone call to reduce 30-day inpatient readmissions. Our primary endpoint is inpatient readmission within 30-days of hospital discharge censored for death analyzed with an intention-to-treat approach. Secondary endpoints included observation status re-admission within 30-days, time-to-readmission, all-cause emergency department (ED) revisits within 30-days, patient satisfaction (measured as mean Hospital Consumer Assessment of Healthcare Providers and Systems or HCAHPS scores), and 30-day mortality. Exploratory endpoints include the need for assistance with discharge plan implementation among those randomized to the intervention arm and reached by the study nurse, and the number of call attempts to achieve successful intervention delivery. Consistent with the Learning Healthcare System model for clinical research, timeliness is a critical quality for studies to most effectively inform hospital clinical practice. We are challenged to apply pragmatic design elements in order to maintain a high quality practicable study providing timely results. This type of prospective pragmatic trial empowers the advancement of hospital-wide evidence-based practice directly affecting patients.

Ethics and Dissemination: Study results will inform the structure, objective and function of future iterations of the hospital's Discharge Follow-Up Phone Call program and be submitted for publication in the literature.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- Single center trial conducted at a tertiary care referral center with inclusion limited to the general medicine population to improve generalizability.
- Designed to demonstrate effectiveness with pragmatic concessions (including an anticipated 30% intervention delivery rate) limiting our ability to determine efficacy.
- The need to inform a time sensitive clinical practice decision in the context of clinical equipoise led to the appropriate selection of more pragmatic and less explanatory design elements.
- Waiver of consent and use of clinical informatics resources permitted study feasibility.
- Potentially obtaining external readmission data from a health information exchange is a data access innovation overcoming a traditional hospital readmission research limitation.

INTRODUCTION

In 2010, The United States (US) Affordable Care Act tasked the Centers for Medicare and Medicaid Services to implement financial penalties for hospitals with excessive 30-day inpatient readmission rates.[1] Penalties are withheld reimbursements for select diagnoses designed to incentivize hospital to support higher quality discharge care transitions.[2] In 2016 penalties amounting to over $500 million were withheld from 2597 (47%) US hospitals.[3] In responses to this national quality improvement challenge Vanderbilt University Medical Center launched a nursing-based discharge follow-up phone call program to support more successful inpatient-to-outpatient transitions and improve patient satisfaction. Prior studies have attempted to determine whether a phone call can reduce hospital re-visits. The literature is limited as existing studies target very specific patient populations, are of insufficient design quality, or evaluate follow-up calls as part of a larger care bundle.[4-16] As our hospital system piloted this program, we found it crucial to rigorously quantify the impact of the intervention before it is launched as a health-system wide program. An impactful intervention could be adopted by other hospitals as an investment in quality, safety, and more effectively stewarding institutional resources. Our study team was challenged to embed a high quality clinical trial, specifically randomization and blinding, into the operations of daily inpatient care without disturbing the work flow of medical providers. Our null hypothesis is a follow-up phone call will have no impact on 30-day hospital readmissions. Here we discuss how we appropriately included pragmatic design elements for this superiority trial making the study practicable and results more timely than an explanatory trial approach.

METHODS AND ANALYSIS

Study Design

This is a single-center pragmatic randomized and controlled clinical trial examining the effectiveness of a discharge follow-up phone call on 30-day inpatient readmissions. The study began on February 13, 2017 with a 1 week informatics run-in period to assure the fidelity of our study dataflow as embedded into real-time clinical care at Vanderbilt University Medical Center (Figure 1). Trial initiation was on February 20, 2017 when enrollment began. The study was registered with clinicaltrials.gov (ID: NCT03050918) and institutional review board (IRB) approval was received prior to study initiation. The unit of study is each in-patient hospitalization, so a revisit after 30 days, but within the study period is included as a new observation.[17] We requested a waiver of consent from our IRB given several considerations. Usual care for patients discharge from the hospital includes reviewing documentation noting their new medication regimen with attention to changes, follow up appointment scheduling plan or dates, education on new diagnoses, and symptoms for which to seek care. The trial examines the effectiveness of a newly established but existing clinical program calling patients within 7 days of hospital discharge to support successful transition to outpatient care. As a result the intervention is in active use, but its impact is unclear, thus demonstrating equipoise. The care to be received by control and intervention group patients is within the scope of acceptable practice, and poses minimal risk to patients exposed or withheld from the program.[18] Consenting control group patients would have been logistically impracticable given available resources. In addition, the informed consent process would involve education on the risk of readmission targeted by the intervention. This could bias study results by prompting patient action to mitigate the risk and consequently make the results, for an important clinical question, uninterpretable.[19] Waiver of consent was granted. We randomize 2 clinical practice options - discharge with and without a follow up call - to best examine the effectiveness of the program under actual clinical care conditions. Our study protocol reporting is adherent to the CONSORT and Pragmatic Trials in Healthcare (Practihc) Groups' guidelines for pragmatic clinical trials and SPIRIT guidance for interventional trial protocols.[20, 21]

Outcomes

Our primary endpoint is inpatient readmission within 30-days of hospital discharge censored for death. We considered the composite outcome of 30-day inpatient readmission or death. However, we found 30-day mortality rates in our general medicine population in the year prior to be 2.6%. This suggests death is not a significant competing risk and informative censoring[22] would be a minimal issue. Secondary endpoints include observation status re-admission within 30-days, time-to-readmission, all-cause emergency department (ED) revisits within 30-days, patient satisfaction (measured as mean Hospital Consumer Assessment of Healthcare Providers and Systems or HCAHPS scores), [23] and 30-day mortality. Exploratory endpoints include the need for assistance with discharge plan implementation among those randomized to the intervention arm and reached by the study nurse, and the number of call attempts to successful intervention delivery.

Study Population

We include all hospital adult inpatients discharged home from a general medicine service in our urban tertiary care hospital. We exclude in-hospital deaths since the study outcome was not applicable, patients who left the hospital against medical advice (AMA) due to the limited opportunity for discharge planning, and those transferred to a skilled nursing facility or another

hospital since they were not discharged with the expectation their health maintenance will be managed from home and supported by clinic-based outpatient care. To improve the generalizability of our study findings to the typical general medicine patient population, we did not include those discharged from our medical sub-specialty services. Our hospital serves as a referral center for complex cases from a wide catchment. In addition, the patients admitted to a sub-specialty service are those requiring direct sub-specialist care. As a result, our sub-specialty service patients may have or require discharge planning not provided in a typical hospital setting.

Recruitment

We identify eligible patients via a custom programmed discharged patient report generated from the medical center's electronic health record (EHR) admission, discharge and transfer (ADT) system each weekday morning. This auto-generated report applies our inclusion and exclusion criteria using EHR ADT data documented during clinical care, and loads as a spreadsheet to a secure folder accessible to select study team members. It includes patient name, admission date, discharge date, discharging hospital provider team, age, address, primary phone number, and primary care doctor.

Study Procedure

Randomization and Blinding

Each weekday morning the list of eligible patients is randomized by a study team member (H.D., D.B. or M.Y.Y.) using the statistical program, R version 3.2.3's (R Foundation for Statistical Computing, Vienna, Austria, 2015, https://www.R-project.org) random sample function with a stable seed to promote reproducibility (see Supplement I). The study database was created in REDCap (Research Electronic Data Capitulation, https://www.project-redcap.org/), a secure web-enabled research data capture system designed to protect and secure protected patient health information.[24] REDCap's application program interface (API) was used to upload those randomized to each study arm (by R) into separate study databases. The study registered nurse (Phone Call RN, S.T.) was blinded to the control arm database, but used the intervention arm database as her work list (Figure 1). A form was created in the intervention database to displays the name, phone number, address, admission data, discharge date, discharge service, primary care doctor, and hours since discharge in a user-friendly format to aid the Phone Call RN's work flow (Supplement II). This replaces a similar discharge dashboard within the EHR that was built to support the hospital Discharge Phone Call Program. Constructing the intervention database form in REDCap was required to blind the Phone Call RN to the control group due to EHR information technology limitations making us unable to randomize or blind the existing dashboard. The REDCap form looks different in structure, but is identical in function while including only intervention group patients.

Post-Randomization Exclusions

During the study design phase we examined a historical cohort of patients who would have met our inclusion criteria and we found the discharge status of patients in our ADT system was not always correct. Chart review and discussion with physician and nursing staff indicated this occurred when there are late changes to the anticipated disposition plan, when the patient leaves the hospital before the care plan can be finalized, or during busy periods when non-care team members are proactively assisting with the discharge process. To permit a secondary per-protocol-analysis the Phone Call RN reviews the chart of each eligible patient to confirm they were truly discharged home. If this was not the case, the patient is identified as ineligible for a call, excluded from intervention delivery, but retained in the study for analysis. This same

discharge verification process was repeated (by M.C.B.) in the control arm to ensure balance between study arms (Figure 1).

Discharge Plan Review

After confirming the discharge disposition, the Phone Call RN reviews the medical record to determine what was expected to occur after hospital discharge including medication changes, follow up appointments, education for new diagnoses, and symptoms for which to seek urgent care. The review provides a reference point from which to assess the patient's understanding and ability to "teach back"[25,26] each element of the care plan.

Intervention Delivery

The phone call intervention was designed to be consistent with the existing hospital program. It is a semi-structured discharge phone call assessment (Supplement III) delivered by the Phone Call RN. The Phone Call RN (S.T.) completed institutional training on discharge health coaching; interpreting discharge care plan documentation in the hospital EHR; and methods to contact discharge teams, visiting health assistance, pharmacists for assistance, durable medical equipment vendors, and follow-up providers. A first call attempt is made within 72 hours of discharge on weekdays. If there is no answer, up to 4 call attempts are made until 7 days post-discharge.

The semi-structured script is used to guide a verbal clinical assessment obtaining information on potential causes of hospital readmission that can be identified and addressed to support a stable transition to outpatient care. Following the methods of health coaching,[25,26] the phone call focuses on assessing the patient's knowledge of their discharge diagnosis, discharge medication plan with attention to changes, follow-up appointments, and actualization of anticipated discharge supports (i.e., acquisition of durable medical equipment, visiting health assistance and medication procurement). Patients are asked to teach-back their discharge plan for these 3 domains. If any knowledge or care transition gaps are identified, the Phone Call RN provides re-education, and determines if additional discharge plan supports are needed. Additional supports include facilitating durable medical equipment acquisition, making a home health connection, referral to a primary care provider, referral to an emergency department, engagement of case management or social work assistance, medication education, medication changes, request for pharmacist assistance, request for other provider assistance, follow up appointment reminders, follow-up appointment scheduling, providing self-care teaching (wound care, diet, activity, etc).

A focused review of symptoms is conducted to identify conditions that could benefit from early attention including potential medication side effect, care plan failure, or new symptoms requiring provider evaluation. Depending on the issue identified, the Phone Call RN can engage the discharging provider, primary care doctor, hospital pharmacist, or follow up provider in addressing this medical need. When a provider cannot be contacted or identified for concerning symptoms, patients are referred to an urgent care facilities or emergency department to reconcile symptoms with the discharge status.

Patients in both the control and intervention arms may be contacted by non-study discharge follow-up care teams involved in their care as consultants or their primary care home as part of routine care. This may dilute our intervention effect, but replicates implementation scenario of real world care.

Data Collection

Patient and Initial Visit Data

Patient visit data are obtained from the hospital clinical data repository, the Research Derivative,[27] curated by a Vanderbilt Institute for Clinical and Translational Research Institute (VICTR) data management team. Our study team will share enrolled patients' date of service, medical record number, and hospital visit encounter number for the Research Derivative programmers to pull patient demographic, comorbidity, initial hospital visit, and discharge data. All data are uploaded to our study REDCap database.

Intervention Data

The outcome of each call attempt and intervention delivery encounter is recorded directly in the REDCap database. Prior to the study, the Phone Call RN was simultaneously documenting the outcomes of her calls (failures to reach patients and assistance provided to reached patients) in an administrative Microsoft Excel file used for daily reporting to supervisors. She will continue to complete her clinical documentation in the EHR as a clinical note. We, however, replaced her spreadsheet by adding her data collection fields into the intervention data collection form describe above (see Supplement II). At the end of each work day she downloads the call data from the intervention arm database as a Microsoft Excel file that looks identical to her prior spreadsheet. This permits consistent and maximal capture of intervention data within the study database without placing an additional data collection burden that could reduce her call attempt frequency and intervention delivery rate.

Re-Visit Data

We pull data related to any inpatient, observation, or ED revisit within 30 days to our hospital from the EHR including admitting and discharge diagnoses. This is done at 45 days to permit capture of delayed clinical documentation. It also permits us to monitor any re-admissions, occurring shortly after the standard 30-day window for our primary outcome, as part of our safety analysis. If there were a significant number of readmissions just after 30 days, we could achieve acceptable 30 day readmission performance. The binary outcome measure could mask a potential care quality issue occurring just beyond the boundary of measure. The additional 15 days permits the evaluation of this potential phenomenon. Patient satisfaction data are retrieved from the hospital Quality and Patient Safety Office at 60 days post-discharge. This follow-up interval was selected due to the historical maximum return rate of 27% being achieved at this follow-up period at our institution.

Existing readmission penalties are not limited to patients re-admitted to the original facility. A readmission reduction in our intervention arm could be attributed to shifting readmissions to an outside hospital more closely associated with the patient's outpatient care base. Attempting to surmount this problem was a priority given the wide catchment area of our tertiary care hospital. Acquiring external readmission data in a timely fashion is a major challenge given limited data sharing among hospitals and 2-3 year data lags for curated national databases including National Hospital Ambulatory Medical Care Survey (NHAMCS), Nation-wide Emergency Department Sample (NEDS), and Surveillance Epidemiology and End Result Medicare (SEER-Medicare) databases.

Given the need for a more timely result to inform institutional practice, we recognized this limitation and primarily planned to use provider documented EHR readmission data. Vanderbilt, however, is a hub for a Patient Centered Outcome Research Institute (PCORI) sponsored program to develop a health information exchange (HIE) within a regionalized health community called The Vanderbilt Health-Affiliate Network (VHAN).[28] Initial data sharing began shortly

before our study and involved 3 area hospitals. Despite hospital referral patterns suggesting these hospitals were not a major source of our referred patients, we are pursuing this unique opportunity to obtain this external and typically unavailable data. VHAN is not yet organized for research data requests. This study is being used as a prototype to develop inter-institutional data sharing agreements. We are attempting to coordinate the transfer of ADT data into the HIE to meet our study timeline. The success of this effort is to be determined.

Mortality Data

We initially planned to obtain 30-day mortality data from our EHR which included deaths documented by institutional providers and the National Technology Information Services Death Master File[29,30] updated in our EHR with a 6 month data lag. Due to national regulatory changes this data update became unavailable. Our alternative approach is to account for delayed notification and documentation with a 120-day window to assess 30-day mortality.

Sample Size Considerations

Using data for general medicine inpatients from the prior year, we estimate approximately 3048 patients will be eligible for the study over a 7 month study period with 1:1 randomization. Based on our experience with the current pilot, we have planned for a 30% intervention delivery rate. (See Figure 1). We expect this will be higher since 1:1 randomization will reduce the Phone Call RNs work load by 50% enabling more call attempts per patient thus increasing the likelihood of call success.

Study Length and Timeline

An informatics run-in period began February 7th, 2017 to test the integrity of the randomization and blinding procedure (see Figure 2) and data collection plan (see Figure 3). Official study enrollment began on February 20th, 2017. We will obtain interim impact estimates of the discharge phone call intervention at 50% enrollment estimated to occur in July 2017 (3.5 months), and will conduct the definitive analysis at 100% enrollment expected in October 2017 (7 months). Data collection and the study analysis will account for a 30-day re-admission follow-up and the 45-day safety evaluation window. A preliminary analysis is expected in November 2017 after the database is cleaned and locked. We will add external readmission (if available) and mortality data in March of 2018.

Data Confidentiality, Sources and Sharing

Only key study personnel will have access to the full study dataset which will be maintained in REDCap. All data for this study is either documented by the Phone Call RN, or sourced directly from the EHR data repository. A de-identified version of the study database will be made available to other investigators upon request for IRB approved clinical research.

Data Quality and Safety Monitoring

The interim analysis will be conducted by an independent biostatistician (L.W.) and Data Quality and Safety Officer (T.H.). The results will be reviewed by a 3 member Safety Monitoring Committee including our Data Quality and Safety Officer; the hospital Chief Executive Officer; and Chief Quality, Patient Safety and Risk Prevention Officer. Given the minimal risk of the intervention there are no stopping rules. In addition to the study data analysis the Safety Committee will review 1) a 10% sample of the Phone Call Nurse's daily reports to her supervisors which is an element of clinical care reporting and 2) a summary of potential safety concerns from the office overseeing this clinical program, the Medicine Patient Care Center. The study team will remain blinded to outcome associated results.

Analysis Plan

General Approach

The primary analysis will examine our primary outcome and secondary outcomes via an intention-to-treat (ITT) analysis where comparisons will be made between the 2 study arms. We will follow with a secondary modified intention-to-treat (mITT) analysis of patients remaining after our post-randomization exclusions to permit a per-protocol analysis. We will consider each re-visit beyond 30 days as an independent event during which the patient could be re-enrolled and randomized again to either study arm. This is consistent with the methodology of the US Center for Medicare and Medicaid Services.[17] The 2 primary statisticians used a dummy assignment variable to create the code to run the analyses. A 3rd un-blinded statistician will run the code with the real assignment variable replacing the dummy variable. This approach will be used for both the interim and final statistical analyses to reduce the potential for bias. Subgroup analyses will examine outcome differences by treatment assignment, age, gender, race, highest educational attainment, health literacy, established primary care status, patient satisfaction level, Medicare readmission penalty diagnosis status, and readmission risk score calculated at discharge as part of routine care at VUMC. Lastly, among patients in the intervention arm who are called and reached, we will use descriptive statistics to quantify the need for patient assistance with discharge plan implementation.

Statistical Analysis

In our univariate analysis, differences among patient characteristic groups will be assessed using the continuity corrected chi-square test or Mann-Whitney test for continuous outcomes and the Kruskal-Wallis test for categorical outcomes. In our multivariate analysis, we will examine the relationship between treatment assignment and our secondary endpoints using logistic regression. The study is not powered for a time-to-event analysis; however, we will explore time-to-readmission using the Cox proportional hazard model to understand when readmissions occur. In order to provide hospital leadership with preliminary efficacy data, we will perform the interim analysis at 50% enrollment (approximately 3.5 months) followed by the final analysis after achieving 100% enrollment. We have a pre-specified α-level of significance of 0.05 with penalties for the mid-study interim analysis per the O'Brian-Fleming alpha spending function allowing for an α-significance level of 0.005 for the interim and 0.048 for the final analyses.

Power Calculation

The study design is targeted to achieve a minimum of 80% power before October of 2017 (see Table 1). Given the 0.048 alpha-level for our final analysis, and controls anticipated to have a 13.52% readmission rate based on estimates, this requires approximately 320 patients enrolled per month (n = 2234). We assessed this enrollment target as feasible after observing there were approximately 508 eligible patients per month based on medical center data collected from the year prior. We noted approximately 11% of these patient would need to be excluded from the mITT analysis after randomization due to mis-categorized hospital discharge status affecting study eligibility reducing potential monthly enrollment to 452 (n = 3164, or 1582 patients per arm). This 11% may be balanced if the hospital continues to experience its 11% annual growth in inpatient admissions, and opens a total of 45 new general medicine beds as scheduled to occur in months 3 and 6 of our study. In ***Table 1***, we illustrate conservative and ambitious enrollment scenarios with estimates for 80% and 90% power. Considering we have 1 Phone Call Study Nurse and will miss enrollment days for paid time off or sick days, we opted for a more conservative power target and detectable differences of 80% and 3.9% respectively. This carries an associated enrollment of 1117 patent per arm (n = 2234, or 11 patients per day).

DISCUSSION

We were challenged to design a high quality clinical trial while providing a definitive yet timely result to inform hospital clinical practice without disturbing active clinical care. Our research team has had to maintain high expectations while executing a pragmatic plan.[31] The engagement of administrative leaders as members of our study team has heightened the collaboration between clinical research and hospital operations. Hospital leadership has justified being more patient than administrative practice typically allows in anticipation of high quality results. If a benefit is demonstrate it can be expected to translate well as a clinical care program since it was tested in the context of real world clinical practice.

More Robust Results with Randomization

The hospital's original phone call program analysis compared re-admission rates in patients not called, those called by the Phone Call Nurse and reached, and those called and not reached (Figure 4). The results demonstrated lower readmission rates in those who we attempted to call, but never reached. Patients in the 3 groups, however, were not the same (Table 2). Specifically, those called and reached were younger, included fewer whites, had lower acuity visits (lower case mix index), included more transfers from an outside hospital, and were more often admitted from the emergency department. Patients not called had longer mean hospital length of stay (by 1.6 days), included more black patients, and were most likely to be admitted via the emergency department. University research leadership noted blinding and randomization within a clinical trial would producing 2 groups of patients with a near equal distribution of known and unknown characteristics, thus controlling for the confounding factors. Subsequent discussions led to the commission of this study.

Learning Healthcare Partnership

VICTR and the hospital have recently engaged in a Learning Healthcare System[32] partnership where clinical practice informs our research and research directly informs practice. Our trial is a pilot for the Learning Healthcare System Platform, a center within the Institute to aid the development of high quality pragmatic studies and timely study completion through the provision of resources, expert consultation, and leadership facilitation. The platform will permit us to tackle significant gaps that arise between acquiring scientific evidence and the implementation of this evidence to advance health care delivery toward the goal of improving individual and population health. In some case existing evidence is not implemented. In the case of our study there is an unmet need for evidence despite the need to develop appropriate clinical practice. Timeliness is a critical quality for studies to most effectively inform hospital clinical practice. Improving health and healthcare requires careful focus on both the content and process of care. Bolstering learning healthcare will be part of the solution.

Enabling Pragmatic Design Elements

Enabling features of our study that can be considered to advance work in this area include waiver of consent, defining a feasible yet generalizable study population to produce results that can be translated to diverse care environments, engaging clinical informatics with clinical and statistical partners to facilitate data capture from the EHR, considering whether post-randomization exclusions would contribute or diminish generalizable results, employing sample size considerations and power calculations that include hospital administrative projections while maintaining conservative enrollment targets. More broadly, we have focused on the effectiveness of our intervention under real-world conditions and limitations, rather than efficacy.

This involves accepting potential contamination of our effect from non-study related usual care. We expect that these factors will be distributed evenly among intervention and control patients by randomization. They may potentially dilute the intervention effect. We expect our large sample size will provide enough power to detect a clinically meaningful effect.

ETHICS AND DISSEMINATION

Our hospital leadership awaits the final results. We have their commitment that study results will directly affect hospital practice. Study conclusions will inform the structure, objective and function of future iteration of the Discharge Follow-Up Phone Call program and be submitted for publication in the literature. The completion of large trials embedded into clinical practice that produce timely results can bridge the need for robust analyses and early answer to guide dynamic clinical practice decisions. Moreover, this type of prospective pragmatic study empowers the advancement of hospital-wide evidence-based practice directly affecting patients.

REFERENCES

1. Zuckerman, RB, Sheingold SH, Orav EJ, Ruhter J, Epstein AM. Readmissions, observation, and the hospital readmission reduction program. New England Journal of Medicine. 2016;374(16):1543-1551.

2. Center for Medicare and Medicaid Services. "Hospital Readmissions Reduction Program (HRRP)." AHRQ, CMS.gov. Available at: https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/readmissions-reduction-program.html. Accessed August 25, 2017.

3. American Hospital Association. Fast Facts on US Hospitals: 2017. Available at: http://www.aha. org/research/rc/stat-studies/fast-facts.shtml. Last Accessed: August 25, 2017.

4. Hansen, L. O., Young, R. S., Hinami, K., Leung, A. & Williams, M. V. Interventions to reduce 30-day rehospitalization: a systematic review. Annals of Internal Medicine. 2011;155:520–528.

5. Huffman M. Health Coaching: A new and exciting technique to enhance patient self-management and improve outcomes. Home Healthcare Now. 2007;25(4):271-274.

6. Huffman MH. Health Coaching: A fresh, new approach to improve quality outcomes and compliance for patients with chronic conditions. Home Healthcare Now. 2009;27(8):490-496.

7. Balaban RB, Weissman JS, Samuel PA, Woolhandler S. Redefining and Redesigning hospital discharge to enhance patient care: A randomized controlled study. Journal General Internal Medicine. 2008;23:1228-1233.

8. Weisman DS, Bashir L, Mehta A, Bhatia L, Levine SM, Mete M, Padmore JS. A medical resident post-discharge phone call study. Hospital Practice. 2012;40(2): 138–144.

9. Goldman LE, Sarkar U, Kessell E, Guzman D, Schneidermann M, Pierluissi E, Walter B, Vittinghoff E, Critchfield J, Kushel M. Support from hospital to home for elders: A randomized trial. Annals of Internal Medicine. 2014;161(7):472-81.

10. Wong FK, So C, Chau J, Law AK, Tam SK, McGhee S. Economic evaluation of the differential benefits of home visits with telephone calls and telephone calls only in transitional discharge support. Age and Ageing. 2014;44(1):143-7.

11. Mistiaen P, Poot E. Telephone follow-up, initiated by a hospital-based health professional, for postdischarge problems in patients discharged from hospital to home. The Cochrane Library. 2006. doi:10.1002/14651858.CD004510.pub3.

12. Soong C, Kurabi B, Wells D, Caines L, Morgan MW, Ramsden R, Bell CM. Do post discharge phone calls improve care transitions? A cluster-randomized trial. PloS One. 2014;9(11):e112230.

13. Chan B, Goldman LE, Sarkar U, Schneidermann M, Kessell E, Guzman D, Critchfield J, Kushel M. The effect of a care transition intervention on the patient experience of older multi-lingual adults in the safety net: results of a randomized controlled trial. Journal of General Internal Medicine. 2015;30(12):1788-94.

14. Wong FK, Chow SK, Chan TM, Tam SK. Comparison of effects between home visits with telephone calls and telephone calls only for transitional discharge support: a randomised controlled trial. Age and Ageing. 2013;43(1):91-97.

15. Harrison JD, Auerbach AD, Quinn K, Kynoch E, Mourad M. Assessing the impact of nurse post-discharge telephone calls on 30-day hospital readmission rates. Journal of General Internal Medicine. 2014;29(11):1519-25.

16. Dudas V, Bookwalter T, Kerr KM, Pantilat SZ. The impact of follow-up telephone calls to patients after hospitalization. The American Journal of Medicine. 2001;111(9):26-30.

17. Centers for Medicare & Medicaid Services. CMS 2017 Procedure-Specific Measures Updates and Specifications Report Hospital-Level 30-Day Risk-Standardized Readmission Measures. Version 6. “Multiple Readmissions.” March 2017:13.

18. Code of Federal Regulations. "Protection of Human Subjects." National Institutes of Health Office for Protection from Research Risks. 2009;Title 45:Part 46.116:d1-4.

19. Department of Health and Human Services, Secretary's Advisory Committee on Human Research Protections, “SACHRP letter to HHS Secretary: Recommendations related to waiver of informed consent and interpretation of ‘minimal risk’,” January 31, 2008, available at: https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2008-january-31-letter/index.html Accessed: December 1, 2017.

20. 13. Zwarenstein M, Treweek S, Gagnier JJ, Altman DG, Tunis S, Haynes B, Oxman AD, Moher D, Grp C, Pragmatic Trials Healthcare P: Improving the reporting of pragmatic trials: an extension of the CONSORT statement. BMJ. 2008;337: a2390

21. Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Annals of Internal Medicine. 2013;158:200-207.

22. Wang, MC, Chiang CT. Analyzing recurrent event data with informative censoring. Journal of the American Statistical Association. 2001;96(455): DOI: 10.1198/016214501753209031.

23. Giordano LA, Elliott MN, Goldstein E, Lehrman WG, Spencer PA. Development, implementation, and public reporting of the HCAHPS survey. Medical Care Research and Review. 2010;67(1):27-37.

24. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. Journal of Biomedical Informatics. 2009;42(2):377-81.

25. DeWalt DA, Broucksou KA, Hawk V, Brach C, Hink A, Rudd R, Callahan L. Developing and testing the health literacy universal precautions toolkit. Nursing Outlook. 2011;59(2):85-94.

26. Jager AJ, Wynia MK. Who gets a teach-back? Patient-reported incidence of experiencing a teach-back. Journal of Health Communication. 2012;17(sup3):294-302.

27. Rosenbloom ST, Harris P, Pulley J, Basford M, Grant J, DuBuisson A, Rothman RL. The mid-South clinical data research network. Journal of the American Medical Informatics Association. 2014;21(4):627-32.

28. Danciu I, Cowan JD, Basford M, Wang X, Saip A, Osgood S, Shirey-Rice J, Kirby J, Harris PA. Secondary use of clinical data: the Vanderbilt approach. Journal of Biomedical Informatics. 2014;52:28-35.

29. Sesso HD, Paffenbarger RS, Lee IM. Comparison of national death index and world wide web death searches. American Journal of Epidemiology. 2000;152(2):107-11.

30. Williams BC, Demitrack LB, Fries BE. The accuracy of the National Death Index when personal identifiers other than Social Security number are used. American Journal of Public Health. 1992;82:1145–7.

31. Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. The PRECIS-2 tool: designing trials that are fit for purpose. British Medical Journal. 2015;350:h2147.

32. Olsen, L., Aisner, D., McGinnis, J.M. Institute of Medicine (US). Roundtable on Evidence-Based Medicine. The learning healthcare system: workshop summary. Washington (DC): National Academies Press (US); 2007. Roundtable on Evidence-Based Medicine. Available from: https://www.ncbi.nlm.nih.gov/books/NBK53492/

AUTHOR CONTRIBUTIONS

Dr. Yiadom is the Principal Investigator leading study design and implementation. Henry Domenico is the primary statistician for the project. Dan Byrne directly supervises data analysis and statistical plan implementation, and contributed to the study design. Michele Hasselblad contributed to the intervention design, study nurse training, and is actively involved in study implementation. Dr. Gatto is the scientific research coordinator for the study via the Learning Healthcare System Platform. Dr. Kripalani contributed to study design and the analysis plan. Dr. Choma contributed to the study design, implementation plan and the continued engagement of hospital leadership to support study implementation through completion. Sarah Marlow is the stud nurse delivering the phone call intervention. Monisha Bhatia contributed to the study design and data collection. Johnston Morrison contributed to the study design. Dr. Harrell provided senior guidance on the study design and the analysis plan. Ms. Dr. Hartert serves as the study safety officer and contributed to the study design, statistical analysis plan, and leading the blinded interim analysis along with Ms. Li Wang who is he study's unblinded statistician. Dr. Bernard provided senior scientific oversite for all aspects of the study. All authors reviewed and contributed to the final form of this manuscript.

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COMPETING INTERESTS

The authors have no competing interest to disclose.

Table 1 – Power and Sample Size Scenarios

	Conservative		Ambitious	
Control Group Readmission Rate†	13.52%	13.52%	13.52%	13.52%
Intervention Group Readmission Rate	9.60%	9.10%	10.20%	9.70%
Power	80%	90%	80%	90%
Detectable Difference	3.9%	4.4%	3.3%	3.8%
Projected Study Sample Size	1117	1117	1582	1582

2 group X^2 test of equal proportions (equal n's), 2 sided test, final analysis $\alpha = 0.048$.

† Historical Vanderbilt University Medical Center readmission rates.

Table 2 – Distribution of Patient Characteristics from the Non-Randomized Pre-Trial Observational Study of the Phone Call Program and Readmission Rates

	Not Called (n=16,096)	**Called but Not Reached** (n=10,749)	**Called and Reached** (n=8,447)
Any Readmission within 30 days[1]	**15.1** (2,425)	7.4 (171)	8.8 (747)
Unplanned Readmission within 30-days[1]	**13.3** (2,133)	6.9 (158)	8.5 (719)
Gender (male)[1]	48.1 (7,742)	**41.7** (960)	46.5 (3,932)
Race[1]			
White	79 (12,711)	**77.5** (1,785)	80.5 (6,801)
Black	**15.9** (2,561)	14.9 (342)	14.1 (1,192)
Other	1.7 (280)	1.9 (44)	1.7 (142)
Unknown	3.4 (544)	5.7 (131)	3.7 (312)
Age[2]	50.8 (19.5)	**45.9** (18.5)	52.6 (182)
Hospital Length of Stay	**5.8** (7)	4.2 (4.7)	4.2 (4.6)
Case Mix Index[3]	2.0 (2.3)	**1.9** (2.0)	2.2 (2.3)
Transferred from Another Hospital[1]	18.7 (3017)	**21.1** (485)	17.4 (1470)
Admission from the Emergency Department[1]	**66.8** (10,756)	59.3 (1,366)	44.4 (3,752)

[1]Percentage and number of patients. [2]Mean and standard deviation (SD). [3]Case Mix Index is a complex measure of patient illness level and the intensity of services received during a hospital stay.

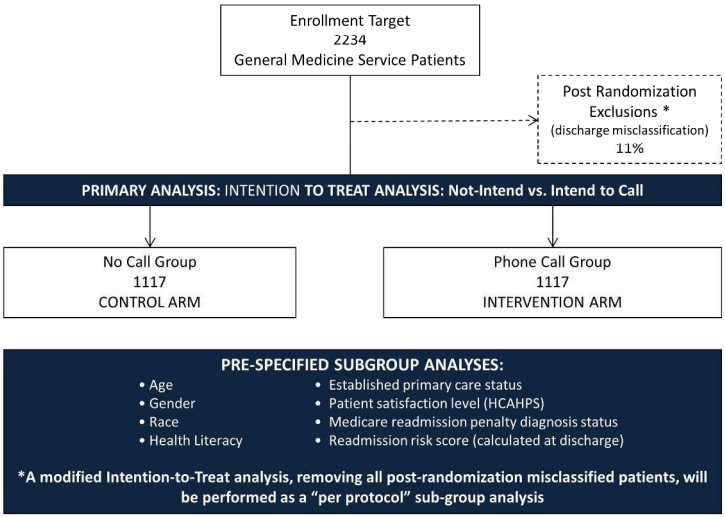
FIGURE LEGEND

Figure 1 - Study Design Schematic and Enrollment Projection

Figure 2 - Operationalizing Randomization and Blinding within Dynamic Hospital Care

Figure 3 - Discharge Phone Call Study Data Sources and Flow

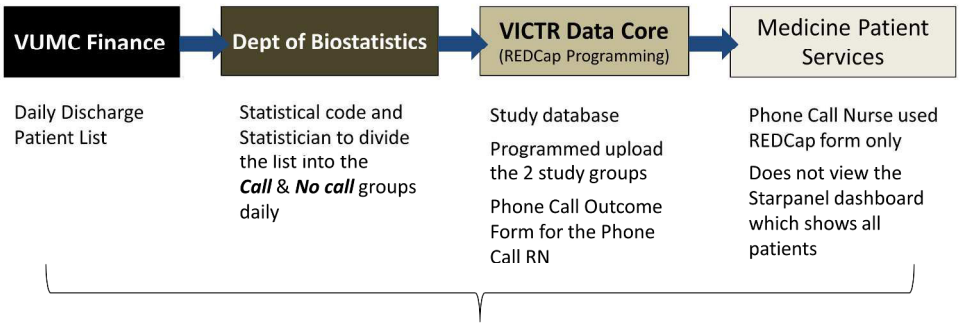
Figure 4 – Non-Randomized Pre-Trial 30-Day Readmission Rates by Phone Call Status



Historical readmission rate of 13.53%, chi-square α-level of significance = 0.05, 80% power to detect a statistically significant effect

254x190mm (300 x 300 DPI)

Inserting blinding and randomization into dynamic clinical care has been a collaborative effort among hospital administration, clinical staff, and VICTR* resources



Reduce Bias

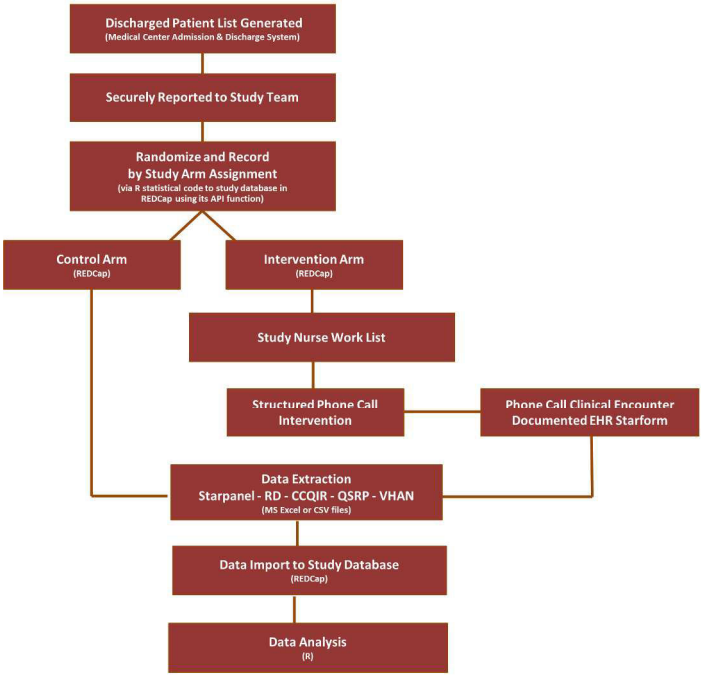
Data: Equal patient groups to best estimate effect

Phone call RN: See and call only the "Phone Call Group"

Study Team: Can only view descriptive data during the interim analysis

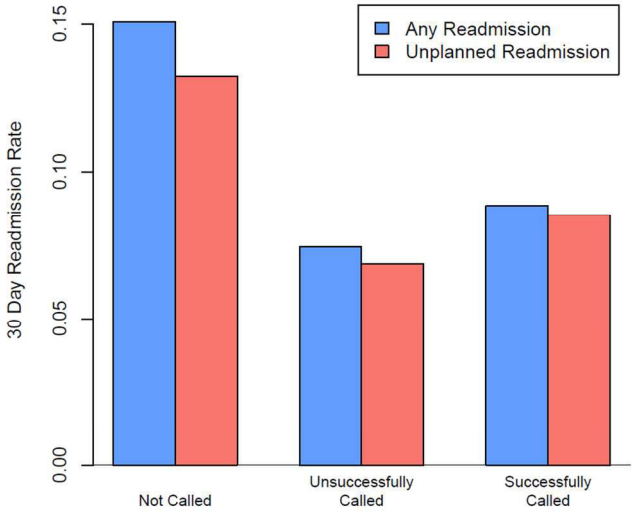
*VICTR – Vanderbilt Institute for Clinical and Translational Research

254x190mm (300 x 300 DPI)



EHR = electronic health record, RD = Research Derivative Vanderbilt University Medical Center's curated clincial data archive, QSRP = Quality Safety and Risk Management Program that houses medical center Patient Satisfaction data. VHAN = the Vanderbilt Health Affiliated Network health information exchange, a potential source of external readmission data.

254x190mm (300 x 300 DPI)



254x190mm (300 x 300 DPI)

Supplement I – R Code Template for Daily Patient Cohort Randomization

```
#Load Necessary Libraries
library(RCurl)
library(readr)

#Set your file path to the folder where BOR report is stored
setwd("D:/Data/Documents/Temp Work computer/FU Phone Call/Randomization")

#Will upload BOR csv corresponding to today's date
filename <- paste("discharge_report_",format(Sys.Date(), "%m-%d-%Y"),".csv", sep = "")
filename <- paste("discharge_report_", Sys.Date(),".csv", sep = "")
data <- read.csv(file = filename)

#Sets a seed based on today's date for reproducibility
set.seed(floor(as.numeric(Sys.Date())^1.5))

#Samples a random 1/2 of rows to be included in the intervention group. Will randomly round up
or down if an odd number of rows.
sample_rows <- sample(1:nrow(data), sample(c(floor(nrow(data)/2), ceiling(nrow(data)/2)), 1),
replace = F)
random_group <- rep("B", nrow(data))
random_group[sample_rows] <- "A"
data <- data.frame(data, random_group)

#Saves intervention and control patients to separate datasets
data_intervention <- data[data$random_group == 'A',]
data_control <- data[data$random_group == "B",]

#Change directory to store intervention patients in Intervention Folder
setwd("D:/Data/Documents/Temp Work computer/FU Phone Call/Randomization/Intervention")

#Saves intervention patients with date stamp
write.csv(data_intervention, file = paste("data_intervention", Sys.Date(),".csv", sep = ""),
row.names = F)

#Creates data object containing the intervention patients that can be uploaded to REDCap
Data.INT <- read_file(paste("data_intervention", Sys.Date(),".csv", sep = ""))

#Uploads data to redcap, paste API token for project 2 below
result_intervention <- postForm(
  uri='https://redcap.vanderbilt.edu/api/',
  token='0F5278ECF8493BDA2A5FB71EBE828110',
  content='record',
  format='csv',
  type='flat',
  overwriteBehavior='normal',
  data=Data.INT,
  returnContent='count',
  returnFormat='json'
)
```

```
print(result_intervention)

#Change directory to store Control patients in Control Folder
setwd("D:/Data/Documents/Temp Work computer/FU Phone Call/Randomization/Control")

#Saves control patients with date stamp
write.csv(data_control, file = paste("data_control", Sys.Date(),".csv", sep = ""), row.names = F)

#Creates data object containing the Control patients that can be uploaded to REDCap
Data.Control <- read_file(paste("data_control", Sys.Date(),".csv", sep = ""))

#Uploads data to redcap, paste API token for project 1 below
result_control <- postForm(
  uri='https://redcap.vanderbilt.edu/api/',
  token='6EA859FA6C7F35B11CAAAA744ADAAC48',
  content='record',
  format='csv',
  type='flat',
  overwriteBehavior='normal',
  data=Data.Control,
  returnContent='count',
  returnFormat='json'
)

print(result_control)
```

Supplement II – Intervention Data Capture Form

Discharge Follow Up Phone Call

Editing existing Encounter Number **12345678901**

Encounter Number	**12345678901** To rename the record, see the record action drop-down at top of the Record Home Page.
Current Date and time	03-17-2017 1 Now M-D-Y H:M
Discharge Team	RIVEN HM 1
Discharge Team Group	RIVEN
MRN	2543577
Name	RICH, CARLA
BHLS	
Education	
Admit Date/Time	03-10-2017 1 Now M-D-Y H:M
Discharge Date and time	03-12-2017 1 Now M-D-Y H:M
Hours Since Discharge (auto-calculated)	119 View equation

Tele	6153851711
PCP Name	HABERMANN,
PCP ID	2515
Patients Preferred Language	ENGLISH
Date of First Contact	03-14-2017 Today M-D-Y
Call Attempts	Not eligible
Date of Last Contact	03-17-2017 Today M-D-Y
Status	Unsuccessful - No Answer
Interventions Delivered (check all that apply)	Durable Medical Equipment Facilitated Home Health Connection Referral to PCP (pt instructed to call) Referral to ED (pt instructed to go) Case Management/Social Work assistance requested Medication Change by Call RN Pharmacist assistance requested Provider assistance requested

Notes	Expand
Form Status	
Complete?	Complete

Supplement III – Semi-Structured Phone Call Script and Clinical Note Template

Follow Up Phone Call Data Collection Form (Phone Call Starform)

Provider (indexing): Morrison, Johr (*** This will change the provider displayed in the all documents listing of StarPanel. ***)

***Standard Document Name**: Clinical Communication | Discharge Follow-up

Comment for Indexing (optional):

VANDERBILT UNIVERSITY MEDICAL CENTER
POST DISCHARGE TELEPHONE CALL

Date of Discharge: 12/12/2015

Patient Home Phone: (609) 122-222

CALL INFO:

Call Attempt Date and Time: 01/28/2016 12:12 **Contact Attempts:** **Caller:** Morrison, Johr **Pre-Call Prep Time:** **Call Duration:**	**Pt Location:**	○ **Call Successful** ○ **Call Unsuccessful** ○ **Call Unnecessary** **Phone Call Occurred with:**

INTRODUCTION:

Hello, Barbara Ztest, this is Morrison, Johr from Vanderbilt. I am calling to follow-up with you after your recent visit to our hospital. I'd like to ask you a few questions to make sure everything is going ok. This could take 10 to 15 minutes - Is this a good time to talk?

- If Yes proceed;
- If No - can you give me a time that would be better and I will call you back?

I see you were in the Hospital for [x]. How are you feeling?

Comments:

DISCHARGE INSTRUCTIONS

Click HERE for Discharge Instructions

- I want to make sure the discharge instructions we gave you were clear and understandable... Can you please tell me in your own words how you are caring for yourself at home?

- What questions do you have about your discharge instructions?
  - If none... Great - if something were to come up, what would you do to get your questions answered?

- Are you having any unusual symptoms or problems? (Specific to problem *base this on the discharge summary* - i.e. dressing, PAIN, bruising or swelling, N/V; e.g., *Do your favorite pair of shoes still fit?*)

Patient can teach back self-care	○ Yes ○ No ○ Partial
Provider contacted for pain/symptoms/complications	○ Yes ○ No

Comments:

FOLLOW-UP APPOINTMENT

- When is your follow-up appointment?

Follow-up appointment change made based on this call	○ Yes ○ No
Able to teach back follow-up appointment related to hospitalization	○ Yes ○ No

Comments:

MEDICATIONS:

*Are new prescriptions identified on the discharge summary?

- **Yes** –
  - I see you have [number] new medicines from your hospital visit. How are you tolerating taking your [medication]? (follow protocol if you find patient has not filled prescriptions)
  - Would you talk through your daily plan for taking all your medicines
  - What questions do you have about your medicines
- **No** –
  - I see we didn't prescribe any new medicines when you left the hospital. Is that still correct?
  - Yes: Great – do you take any other medicines on a regular basis?
    - Would you talk through your daily plan for taking your medicines?
    - Do you have any questions about your medicines?
  - No: Ok, what medicines did you get? How are you tolerating taking your new medicines?
    - Would you talk through your daily plan for taking your new medicines and any others you take on a regular basis?
    - What questions do you have about your medicines?

Able to teach back medications	○ Yes ○ No

Has obtained medications prescribed at discharge	○ Yes ○ No ○ Partial
Medication education or clarification was needed	○ Yes ○ No
Medication change made by caller/provider based on phone call	○ Yes ○ No
Comments:	

Meds Editor: (Click to expand/collapse)

CLOSING:

- Thank you for talking with me. We are always trying to get better at giving excellent care. Is there one thing that comes to mind for you that we can improve on?
- You will be getting a survey in the mail asking about your experience during your hospital stay. We would appreciate you taking the time to give us your feedback. It is very important to us and should only take you about five minutes.
- Do you need anything from us right now?
    - Ok we wish you all the best in your recovery. If you need anything, please contact us at [phone number]

Comments:

Save As Draft Complete

Form: post_discharge_telephone_call (Post Discharge Telephone Call)
Version: 2.4
Last modified: $Date: 2015/12/21 18:22:48 $

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	5
	2b	All items from the World Health Organization Trial Registration Data Set	5
Protocol version	3	Date and version identifier	?
Funding	4	Sources and types of financial, material, and other support	1,16
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	16
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	1,16
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	16

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
	6b	Explanation for choice of comparators	4
Objectives	7	Specific objectives or hypotheses	4
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	5,6
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	n/a
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	n/a
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	4
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	4,8

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	8
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	8,10
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	6
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	6
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	6
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	6,7
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	7,8
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	7,8

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	6,7,8
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	9,10
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	4,9,10
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	10
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	9
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	9
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	9
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	?
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	5
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	12

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	5
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	5
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	6,9
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	17
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	9
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	6,9
	31b	Authorship eligibility guidelines and any intended use of professional writers	15
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	9
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	n/a,5
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.