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Rationale and design of a randomized controlled trial of home-based primary care versus usual care for high-risk homebound older adults

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1.0 Introduction

Over two million Americans are currently homebound.[1] This number will continue to grow as the U.S. population ages and increasing numbers of older adults develop significant functional impairment.[2] As compared to their non-homebound counterparts, the homebound have more chronic conditions and higher symptom burden.[2,3] Yet even when these baseline clinical differences are accounted for, the homebound have higher rates of hospitalization and higher mortality rates.[4,5] This may be because the homebound often have limited social supports and face various challenges accessing routine office-based health care. The burden

of care often falls to their informal caregivers, who themselves may experience caregiver stress as they struggle to help.[6]

Home-based primary care (HBPC) programs attempt to meet the complex clinical, functional, and social needs of the homebound by bringing the expertise of an interdisciplinary care team into the home.[7] Evidence suggests that HBPC programs can improve quality of care for vulnerable patients while simultaneously supporting their caregivers.[8,9] Importantly, HBPC programs may also be cost effective. Early analysis of data from the Independence at Home Demonstration project found HBPC programs lowered costs for high risk homebound patients, largely by preventing unnecessary hospitalizations.[10] As a result, the number of HBPC programs is growing and national efforts are underway to expand the number of HBPC providers and establish quality metrics to evaluate the care they provide.[7,11]

Despite its promise, the existing evidence base for HBPC is largely limited to observational studies.[8] There is one randomized controlled trial of HBPC performed in the Veterans Affairs Health System, but this study did not require patients to be homebound, had high rates of patient discharge from the intervention (early 60% at 6 months), and had significant variability in intervention at the 16 sites over the 4 years of the trial.[12] Adoption of HBPC may be limited by the lack of high quality data from randomized clinical trials. For this reason, we designed a pragmatic randomized controlled trial of HBPC versus office-based primary care (OBPC) for homebound older adults at high risk for hospitalization. The purpose of the study is to determine the impact of HBPC vs. OBPC on patients' hospitalization and emergency room use and quality of life, and on the quality of life of their informal caregivers. We will also assess healthcare costs. In addition, we will conduct a rigorous dissemination and implementation evaluation of HBPC to inform HBPC implementation efforts elsewhere.

This study will provide valuable data for policymakers and guide decision making for health systems considering adoption and implementation of HBPC.

2.0 Design and Methods

2.1 Study Overview and Guiding Frameworks

The "Home or Office-based primary Medical care for the homebound Elderly" (HOME) study is a pragmatic randomized controlled trial of home-based primary care (HBPC) versus usual office-based primary (OBPC) for homebound adults ages 65 years and older. The study seeks to determine the impact of HBPC on healthcare services use, quality of life, and costs of care. Additionally, we will conduct a dissemination and implementation evaluation of HBPC based on the RE-AIM framework that assesses the following domains: (1) Reach, breadth of program reach and extent of patient engagement; (2) Program efficacy, program outcomes and processes that are important to patients, caregivers, and systems; (3) Adoption, acceptability of program services to patients, caregivers, and systems; (4) Implementation, consistency of service delivery; (5) Maintenance, patient-level retention in care and feasibility of program integration into the larger health system.

2.2 Inclusion and Exclusion Criteria

Patient inclusion criteria will be: (1) age ≥65 years; (2) requires assistance with 2 or more activities of daily living; (3) meets the Medicare definition of homebound, specifically, the subject leaves the home infrequently for non-medical purposes or cannot leave the home without assistance; (4) ≥1 hospitalization or ≥2 emergency room visits in the prior 12 months; (5) speaks English or Spanish; and (6) is willing to accept a HBPC physician as their primary care physician. In addition, eligible patients must meet existing criteria for enrollment in the clinical program that is providing the HBPC services, the Mount Sinai Visiting Doctors (MSVD) program. MSVD only accepts individuals residing in Manhattan and will not accept individuals receiving office-based hemodialysis and those previously discharged from the MVSD program for safety reasons. Like the Mount Sinai Health System in general, MSVD accepts private insurance, Medicaid, Medicare, and most Medicare Advantage and Managed Long Term Medicaid plans. Finally, the HOME study will exclude individuals with a terminal illness with death anticipated in <2 weeks or those currently enrolled in home hospice.

Upon enrollment, patients will be asked if they have a primary informal caregiver. Caregivers are included in the study if they are the patient's primary informal caregiver, defined as the unpaid family member or friend who by patient or proxy report is most involved in assisting the patient with their care, is aged ≥18 years, and speaks English or Spanish.

2.3 Setting for Recruitment

Patients will be recruited from the Mount Sinai Healthcare System adult primary care and geriatrics practices in Manhattan. These practices care for ethnically diverse patients in predominantly low-income communities, and several are teaching sites for medicine residents or geriatric medicine fellows. While the precise team structures vary, most practices utilize an interdisciplinary team to provide primary care. Patients randomized to OBPC will continue to receive care in their respective practice. In line with our pragmatic study design, the variability in OBPC setting will help ensure that our findings are applicable to other health systems across the country where variability in office-based care is typical.

2.4 Intervention

The HBPC intervention will be administered through Mount Sinai Visiting Doctors (MSVD.) Described elsewhere in detail, MSVD is the largest academic HBPC program in the country and uses interdisciplinary teams to care for 1,700 patients in Manhattan each year and admit approximately 360 patients to the program each year.[13] Patients are typically referred to MSVD through their health providers, community agencies, or word of mouth. All referred patients receive a phone call from a practice triage nurse who reviews program eligibility as described above, answers questions about the program, and conducts a triage assessment. This assessment evaluates life expectancy, environmental and social support, caregiver burden, and individual health needs including health care utilization and uncontrolled symptoms. Patients with the highest needs are prioritized for provider visits. Average wait list time is about 6 month, though patients with high needs based on their

triage are often seen much sooner. For example, those identified to have significant unmet palliative care needs are seen within 2 weeks from triage. MSVD physicians are assigned for initial patient visits based on geography and availability. During the initial visit, the physician makes a final determination of the patient's appropriateness for MSVD, including whether or not the home is safe for ongoing home visits.

Patients enrolled in MSVD are assigned a primary care provider (PCP) who visits approximately every 6-10 weeks. During visits PCPs assess patients to confirm they remain appropriate for MSVD services, though discharges due to patients no longer being homebound are rare. Next-day urgent visits are available to patients with urgent issues and extensive telephonic support is available 24 hours a day, 7 days a week. PCPs work in one of six interdisciplinary teams, comprised of 2-4 physicians, one nurse practitioner, one social worker, and one administrative assistant.[14] Nurse practitioners conduct select urgent, follow-up visits, and post-discharge visits, but primarily work in the office and provide extensive telephonic management of patients on their team while PCPs provide direct patient care in the community. Program social workers assess each new patient either in person or by phone. They provide ongoing assistance as needed and make referrals to community resources to address a variety of psychosocial issues such as entitlement and insurance access, homecare, and caregiver burden.[15] Biweekly team meetings alternate with biweekly full practice clinical meetings.

MSVD team members refer to outside providers as needed for specialist consults and additional home based services including nursing, physical therapy, occupational therapy, home hospice, home blood draws, psychotherapy, and radiographic imaging.

Procedure

3.0 Recruitment and Informed Consent

Potentially eligible patients will be identified by reports from the Mount Sinai Health System Data Warehouse. The reports list patients ages ≥65 years with ≥1 hospitalization or ≥2 emergency room visits in the MSHS in the prior 12 months. Patients on the list will be filtered by practice location and grouped by Mount Sinai Healthcare System adult primary care and geriatrics primary care provider. Patients will then be stratified for priority outreach based on risk for future hospitalization as determined by: (1) a modified Hierarchical Conditions Category (HCC) score that the MSHS generates for all patients based on ICD-10 diagnoses on record; (2) risk of a fall based on the Morse Fall Scale[16] that is often documented during preventive health screening; (3) increasingly higher number of hospitalizations.

Consent from each patient's current PCP will be obtained prior to patient outreach. To facilitate this process, presentations will be made to clinicians in participating practices to introduce the study, its rationale, objectives and protocols, and to answer questions. Following the introduction, PCPs will be contacted by email with a list of patients who are potentially eligible for the study. The email message will ask the PCP to mark the patients that meet the Medicare definition of homebound and is expected to remain homebound for at least 12 months, indicate if the patient has capacity to consent, and provide their permission

for the team to reach out to the patient. If the PCP is unsure about patient's capacity to consent, one of the study physicians will review the medical record for documentation of incapacity. If none exists, a study physician will administer an in-person assessment using the University of California San Diego Brief Assessment of Capacity to Consent (UCSDBACC) tool.[17] If patients do not have capacity to consent, all subsequent recruitment will be conducted through their proxy.

Once permission has been obtained to recruit the patient or proxy, the research assistant will mail a letter to them describing the study, followed by a telephone call 7 days later to provide additional details of the study. Research assistants also confirm study eligibility criteria, including confirmation of homebound status and recent hospitalization/ emergency room visits as well as determination of need for assistance with 2 or more activities of daily living by self-report. If eligible, a baseline interview is scheduled and at that time patients/ proxies will be asked to identify the patient's primary informal caregiver, who will then be recruited separately.

3.2 Randomization and Blinding

After enrollment and completion of the baseline interview, the project manager will generate a computer-generated random treatment assignment and notify the patient/proxy of the assignment by phone. Patients will be randomized 1:1 (intervention, control) in permutated blocks of 4 and 6 based on (1) eligibility for the Independence at Home demonstration[18] (eligible vs. not eligible; 2 strata), and (2) dementia severity as determined by the Montreal Cognitive Assessment (MoCA)[19] during initial interview (none/mild, moderate, or severe; 3 strata) for a total of six strata. There is no documentation of randomization in the electronic medical record and the study personnel are not involved in the clinical care of enrolled patients. Those randomized to OBPC will continue to see their office-based primary care provider unless the provider is a medical resident or intern, in which case they are offered the option to change to an attending level physician within their practice to ensure that the patients in the two study arms have physicians with similar years of training. Those randomized to HBPC will be referred to MSVD. All standard MSVD program enrollment procedures will be followed with the exception that study patients will receive a new patient appointment within 4-6 weeks of program referral regardless of their triage score. Patients randomized to HBPC will transfer their primary care to MSVD after their first visit with an MSVD provider. Twelve months after randomization, patients assigned to OBPC will be offered expedited referral to the MSVD program pending continued clinical eligibility.

All physicians and multidisciplinary team members providing care to study patients, research assistants, and study investigators will be blinded to treatment assignment.

3.3 Data Collection

Quantitative interviews will be conducted in English or Spanish with patients/proxies and informal caregivers in-person at baseline, six months, and twelve months. To minimize response burden, interviews were designed to last 30 minutes or less. Qualitative interviews with randomly selected patients/proxies, caregivers, and clinicians in the HBPC arm will occur in the patient's home throughout the study period and are limited to 45 minutes.

Data will be obtained from the New York State Statewide Planning and Research Cooperative System (SPARCS) to determine hospitalization and emergency department visits for patients enrolled in the trial. In addition, Medicare and Medicaid claims will be obtained to determine spending. Finally, non-billed costs associated with HBPC will be obtained from administrative records of the MSVD program following methods in a previously published study of MSVD program costs.[20]

4.0 Measures

4.1 Patient and Caregiver Outcome Variables

The primary patient outcome is hospitalization as reported by data from the SPARCS data set. The secondary outcomes are emergency room use; quality of life (Quality of Life in Alzheimer's Disease, QOL-AD);[21] symptoms (Edmonton Symptom Assessment Scale, ESAS);[22] general health (Short Form-1 general health measure, SF-1);[23] depression (patient health questionnaire, PHQ-2[24] for patients and the Cornell Depression Scale[25] for proxies); and satisfaction with care (The Family Satisfaction with End-of-Life Care, FAMCARE.)[26]

The primary caregiver outcome is caregiver burden (Caregiver Burden Inventory, CBI).[27] The secondary caregiver outcomes are opportunity costs of caregiving (National Study of Caregiving Employment and Caregiving module);[28] depression (PHQ-2);[24] general health (SF-1);[23] and satisfaction with care (FAMCARE).[26]

4.2 Patient and Caregiver Independent Variables

Independent variables to be collected for both patients and caregivers are: sociodemographic variables (age, race, ethnicity, education, income); social support variables (marital status, Lubben Social Support Scale);[29] clinical and function variables (presence of chronic diseases, ability to perform activities of daily living and instrumental activities of daily living Montreal Cognitive Assessment.)[19] Additional independent variables for patients are: type and accessibility of housing number of household members and household composition, home care services (nursing physical therapy, home health aide), use of assistive devices, day program participation, and clinical conditions and medications as recorded in the electronic medical record. Additional independent variables for caregivers are: relationship of caregiver to patient, distance between patient and caregiver's homes, and the caregiver's time spent with patient.

3.1 Cost Variables

We will obtain 3 years of Medicare claims data (MedPAR, Outpatient, HHA, Carrier, Hospice, DME, Part D, and Beneficiary Annual Summary standard analytic files) for each patient to determine Medicare spending 12 months preceding the study, during the study, and following the study. We will also obtain 3 years of Medicaid claims data (Medicaid Person Summary File, inpatient, long term care, other services, and prescription drugs standard files). For patients enrolled in Medicare Advantage plans, we will seek to obtain claims from the commercial insurers directly.

4.4 Process Measures

Process measures will be identified in collaboration with MSVD leadership and staff, using the RE-AIM framework as a guide. Examples include: (1) Reach, percentage of the target population screened for the study and frequency of patient/ proxy telephonic communication with the program team; (2) Program efficacy, study outcomes, such as hospitalization rates; (3) Adoption, percent of eligible recruits who accept HBPC and self-reported acceptability of program services to patients, caregivers, and systems; (4) Implementation, differences in rates of visits, skilled nursing referrals, and flu vaccination among various MSVD providers; (5) Maintenance, HBPC attrition.

5.0 Analysis Overview

We will conduct intention-to-treat analyses of all outcomes. Characteristics of patients who drop out, cross-over to HBPC or OBPC, or who are lost to follow-up will be evaluated. We will examine missing data patterns for all variables and determine whether rates vary by patient characteristics. Success of randomization will be evaluated by comparing baseline characteristics of patients using the chi-square test, t-test, and Wilcoxon test, for discrete and continuous variables. A descriptive summary of subjects and practices will also be generated.

5.1 Sample Size and Power Calculations

We estimated a sample size of 175 per treatment arm by Poisson regression (counts of hospitalization events per 6-month period; power=80%, alpha=5%; two-tailed.) This estimate was based on reports that hospital admissions decreased 38% for patients in HBPC[30] and the unadjusted 6-month hospitalization rate for MSVD patients is 1.5. In addition, we applied a 30% inflation rate for attrition from death or nursing home/ skilled nursing facility transfer based on existing rates of these events at MSVD. Given 79% of MSVD patients have informal caregivers, we estimate 120 informal caregivers per study arm. Caregiver burden index (CBI) scores average 32 points (SD 15)[31–33] and we will have >80% power to detect a difference of ≥8 units (16%) in CBI scores, which we expect based on data from the VA study.[12]

5.2 Quantitative Analysis

We will use Poisson or negative binomial (based on the data) regression to assess differences in the rates of hospitalization and ED visits in the two arms using the incidence density after adjusting for randomization strata. If there are imbalances in baseline patient characteristics, we will adjust for these differences in the regression models. In secondary analyses, we will compare ED re-visit and hospital readmission rates in both groups using similar methods.

The QOL-AD, ESAS, SF-1, PHQ-2, and FAMCARE scores will be analyzed as continuous measures, measured at baseline, 6-and 12-months. Appropriate transformations will be applied if the scores are not normally distributed. We will first examine the relative change in score from baseline to last follow-up using ordinary least squares regression, then test score variation over time in repeated measures analyses using generalized linear mixed models (random patient intercepts) with intervention assignment, time, and a time by

assignment interaction as the predictor variables while accounting for site-level clustering. We will adjust effect estimates for any imbalance of variables between subjects in the 2 study arms. We will also conduct analyses adjusted for comorbidities and functional status to account for the potential effect of these factors on patient survival. For adjusted analyses, we will fit linear mixed models with logit and Poisson link functions using the log of person-weeks of observation as the offset. Standard regression diagnostics will be employed. Continuous measures for caregiver outcomes will be similarly conducted.

We will sum total costs from the Medicare claims data, Medicaid claims data, and insurer Medicare Advantage data for the observation period. We will report total costs, and average and median quarterly and per-month costs, for both the 12-month pre-study and post-enrollment periods. We will also examine costs by area: inpatient, ED, hospice, skilled nursing facility, home-based, office-based, durable medical equipment, medication, adult day care, residential care, case management. We will conduct bivariate tests of associations between per-month costs and the independent variables. Multivariate analysis will be conducted using a two-part model for each measure of cost with a significant number of zeros. For positive costs, we will consider models with logarithmic transformations and gamma regressions estimated via GLM or maximum likelihood methods. We will report the annual average per-person cost and illness-severity adjusted per-person costs across both programs to provide a benchmark for HBPC planning. In exploratory analyses, we will report adjusted differences in employment-related caregiver opportunity costs, expressed as annual hours of missed work due to provision of unpaid caregiving.

5.4 Missing Data

Twenty-five percent of homebound adults die each year.[34–38] The resulting missing data are non-ignorable because the mechanism generating incomplete data is not random. We will examine death rates between patients in each study arm using the chi-square test and Kaplan-Meier methods. If differences in death rates do exist we will use 2 strategies to address the missing data concern: multiple imputation and competing risks analysis. We will report results from both approaches in papers and other presentations of study findings.

5.5 Qualitative Analyses

All qualitative interviews with randomly selected patients/proxies, caregivers, and clinicians in the HBPC arm will be recorded, transcribed, and analyzed using Atlas.ti software. Each transcript will be coded independently by two individuals, using thematic, exploratory analysis. Coders will review transcripts, update and revise themes, and update the interview guide as needed. This iterative process will enable the team to determine when new themes that require further probing arise and when thematic saturation in patient/caregiver interviews occurs. We will continue to randomly sample and interview 6 patient/caregiver dyads or individuals biannually, including those who complete and drop out of the study, to identify new issues that may arise in the latter part of the study.

After analyzing the qualitative and quantitative data, we will perform a convergent analysis by comparing and contrasting our quantitative results with the qualitative results at both the individual caregiver and thematic levels. Convergent analysis allows for different but

complementary data to be integrated, compared and contrasted to create richer, more informed findings than examining quantitative and qualitative data separately.[39,40]

5.6 Analysis of Process Measures

This study is not designed to be powered to detect statistically significant differences in process measure rates. However, we will present summary descriptions for all quantitative process and program measures as well as rates stratified by groups when applicable (HBPC vs. OBPC; MD vs. NP vs. RN) and conduct appropriate bivariate tests of association. We will also stratify process measure rates by illness severity and goals of care (e.g., stability of chronic illness vs. palliation) because they may influence the types and intensity of services received.

6.0 Patient safety

All recruited patients will receive primary care from a well-established primary care practice within the Mount Sinai Health System: those randomized to OBPC will continue with their office based practice and those randomized to HBPC will receive care with the Mount Sinai Visiting Doctors Program. Risks to patients who take part in the interventional arm are minimal. Regular study oversight by a Data and Safety Monitoring Board DSMB will be in place throughout the study.

7.0 Conclusion

HBPC is an emerging modality of health care delivery that may effectively serve the needs of medically complex, homebound, elderly adults and their caregivers. This HOME Study is the first randomized controlled trial of HBPC in a Medicare population and will directly inform the ongoing expansion of HBPC programs in the US. This pragmatic randomized controlled trial will provide data on the impact of HBPC vs. usual care, as well as data to information dissemination of the model and its implementation in other healthcare systems.

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