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A pragmatic randomized comparative effectiveness trial of transitional care for a socioeconomically diverse population: Design, rationale and baseline characteristics

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ABSTRACT

Transitional care programs have been widely used to reduce readmissions and improve the quality and safety of the handoff process between hospital and outpatient providers. Very little is known about effective transitional care interventions among patients who are uninsured or with Medicaid. This paper describes the design and baseline characteristics of a pragmatic randomized comparative effectiveness trial of transitional care. Northwestern Medical Group- Transitional Care (NMG-TC) care model was developed to address the needs of patients with multiple medical problems that required lifestyle changes and were amenable to office-based management. We present the design, evaluation methods and baseline characteristics of NMG-TC trial patients. Baseline demographic characteristics indicate that our patient population is predominantly male, Medicaid insured and non-white. This study will evaluate two methods for implementing an effective transitional care model in a medically complex and socioeconomically diverse population.

1. Introduction

In 2012, the Centers for Medicare and Medicaid Services, under the Affordable Care Act, launched the Hospital Readmissions Reduction Program that reduced payments to hospitals for excessive 30-day readmissions [1]. These factors are amplified in patients of low socioeconomic status (SES). The period of transition from hospital to home is often wrought with fragmentation of care, poor communication and coordination, and inadequate patient education leading to adverse events, avoidable readmissions, and increased costs [2,3]. Addressing readmissions in this population is particularly challenging due to lower health literacy, competing social and economic needs, lack of social support, and higher rates of unmet behavioral health needs [4–9].

Efforts to enhance care transitions have addressed the multitude of factors from the pre- to post-discharge period that may contribute to readmission. These factors vary widely in type, intensity, and patient population. While several evidence-based care transition programs have succeeded in improving outcomes, many have had minimal to no success, with results dependent on the target patient population [10–15]. A recent meta-analysis of care transition interventions found an 18% reduction in 30-day readmissions [16]. However, many of these interventions focused on elderly Medicare enrollees or privately insured populations with access to a usual source of primary care. Very little is known about effective interventions among patients who are uninsured or with Medicaid.

Furthermore, the majority of studies that included large proportions of patients with low SES failed to significantly reduce the rate of 30-day readmissions [9,12,17,18].

The combined medical and social complexity of these patients may require a more holistic approach to reduce readmissions. The goal of this manuscript was to present the design, evaluation, methods, and baseline characteristics of a pragmatic, randomized, comparative effectiveness trial of NMG-TC and routine patients. We conclude that the comparison of patient level outcomes of transitional care to routine care can determine if this transitional bridge was effective at reducing readmissions. Once the study is complete, we plan to publish analysis results in a future manuscript.

Abbreviations: NMG-TC, Northwestern Medical Group- Transitional Care; ACS, American Community Survey

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2. Materials and methods

2.1. Study design and participants

The study goal was a pragmatic, randomized, comparative effectiveness trial with analysis to be completed at the patient-level to compare two groups: [1] (NMG-TC care): a short term intense intervention to address long-standing poor health management problems with multidisciplinary services provided in parallel to rapidly support, stabilize and empower patients so they can function successfully in a traditional 15-minute office visit, versus [2] (Routine care): referral to a partner clinic for follow up. Patients who had a new cancer diagnosis were excluded from the study but were still cared for in the NMG-TC.

2.2. Enrollment flow

In our standard and existing organizational workflow, acute care providers entered an order for follow-up care in the electronic medical record in instances when they felt it was clinically appropriate. The scheduling system determined the type of follow-up needed based on the order and then scheduled the appointment and placed the information into the discharge papers provided to the patient. The scheduling system scheduled patients to be seen in NMG-TC if they needed follow-up and did not have a primary care provider or requested a new primary care provider. During the study's enrollment phase—September 2015 through February 2016—the initiation of an appointment in the NMG-TC triggered an automated randomization process, as described below.

2.3. Randomization and blinding

When the scheduling team initiated scheduling of a patient in the NMG-TC, a randomization feature embedded in the scheduling system was cued in which patients were randomized to be seen in the NMG-TC. In order to maintain the NMG-TC referral base, patients were randomized to an appointment at the NMG-TC or a local federally qualified health center (FQHC) for care at a 3:1 ratio (i.e., 75% of those enrolled were randomized to the NMG-TC). The scheduling system automatically notified the acute care provider of all appointments and printed appointment information into the discharge paperwork. The scheduling team member also made telephone contact with the patient prior to discharge whenever possible. Hospital personnel and scheduling team members were unable to modify randomization assignments. Prior to study implementation, the NMG-TC director spoke with referral team members and clinicians in the inpatient department, observation units and emergency departments to explain the study objectives, protocols and importance of adherence with assigned randomization.

2.4. Data collection and outcomes assessment

Study data were collected from institutional patient-level databases, telephone surveys and public sources of geographic-level data. A study programmer queried Northwestern Medicine databases to collect data on each study enrollee's hospital ‘index visit’ (i.e. the ED visit, observation stay or inpatient admission that preceded study inclusion during which the randomization occurred) and health care utilization measures. Variables collected from the index visit included patient age, sex, insurance, race/ethnicity, index visit type, length of stay, hospital visits during the prior year (counts of ED visits, observation stays and inpatient admissions) and primary International Classification of Diseases (ICD) billing diagnosis code. Diagnosis codes were individually reviewed by two study authors and grouped. If there was a disagreement the authors discussed the codes to determine grouping together. In addition to collecting counts of visits to the NMG-TC following discharge, we also collected four outcomes for the 30-, 90-, 180- and 365-day periods following discharge: 1) ED visits, 2) observation stays, 3) inpatient admissions, and 4) total hospital visits (sum of ED, observation and inpatient). The primary study outcomes were the four hospital visit count measures for the 90-day period following discharge.

We also obtained neighborhood-level characteristics for each study subject. Non-homeless subjects with valid address data were linked to census block groups—subdivisions of U.S. Census tracts containing 600–3000 people—through their home address at the time of the index visit. We then linked each subject's block group to American Community Survey (ACS) 2015 five-year estimates for block-level characteristics [19], including median household income, unemployment rate, proportion married, proportion who had completed high school and proportion with a bachelor's degree. If ACS block group-level data were unavailable due to large margins of error, we imputed missing data using census tract-level values. We also measured proximity to Northwestern Memorial Hospital by calculating travel time to the hospital campus from each patient's home address via driving and public transit.

Approximately 90 days after discharge, a research assistant called each study enrollee to obtain self-reported outcome data through a patient survey utilizing validated instruments. Research assistants attempted telephone contact with each patient up to six times. Patients who were reached via phone and interested in participating provided verbal consent prior to the phone interview. Patients who participated in the interview provided self-reported information on questions assessing health care use, barriers to care, and physical and mental health status.

We also collected data on regional health care utilization. We obtained data on whether subjects attended any primary care visits at local FQHC network partners, which was used as a proxy measure of establishing a primary care home following index visit discharge. We captured data on regional hospital visits during follow-up by obtaining data from hospitals in the Chicago Area Patient-Centered Outcomes Research Network (CAPriCORN) [20]. CAPriCORN data on hospital visits were combined with study outcome data from Northwestern Medicine databases to create more comprehensive measures of subjects' use of hospital care throughout Chicago following the index visit at Northwestern Memorial Hospital.

2.5. Interventions

2.5.1. Routine care arm

Patients whose acute care providers indicated a need for follow-up and were randomized to routine care were scheduled to be seen by a primary care provider partnered with the Northwestern medical system. Providers were located throughout Chicagoland and patient assignments were determined by the patient's insurance and proximity to home. Patients who were not insured were scheduled at a FQHC partner clinic and continued to receive specialty care within the health system.

2.5.2. NMG-TC care model

Patients who were randomized to the NMG-TC and attended the appointment were seen in a multidisciplinary comprehensive care practice which aimed to identify critical medical and psychosocial needs and address them concurrently with onsite multidisciplinary resources. NMG-TC visits typically occurred weekly for two to six weeks, lasted longer than traditional office visits and were designed to create brief intense interactions to stabilize medical and psychosocial issues, create positive behavior change and empower patients to better manage their conditions. Patients were then connected to a community-based primary care provider for longitudinal care. Critical components of the NMG-TC care model included: 1) a multidisciplinary team who saw the patients in a shared space and provided real time integrated care, 2) development of a patient-centered and individually tailored care plan to meet the needs of each patient, 3) a judgement free community to