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Tele-transitions of care. A 12-month, parallel-group, superiority randomized controlled trial protocol, evaluating the use of telehealth versus standard transitions of care in the prevention of avoidable hospital readmissions

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ABSTRACT

Introduction: Comprehensive transitions of care, reduce dangerous hospital readmissions. Telehealth offers promise, however few guidelines aid clinicians in introducing it in a feasible way while addressing the needs of a multi-comorbid population. Physician adoptability remains a significant barrier to the use of Telehealth due to data overload, concerns for disruptive workflows and uncertain practices. The methods proposed aid clinicians in implementing Telehealth training and research with limited resources to reach patients who need clinical surveillance most. This study introduces a new workflow for addressing tele-transitions of care, using risk stratification, remote patient monitoring, and patient-centered virtual visits. We propose a new communication tool which facilitates adoption. We take a clinically meaningful approach in assessing avoidable hospital readmissions, which can lead to further quality improvements and improved patient care.

Methods: This study design is a parallel-group, superiority, randomized controlled trial in which 180 patients are enrolled in the standard of care or Telehealth arms and evaluated for 30-days post hospitalization. The Telehealth group receives daily vitals surveillance with a "teledoc", a senior resident physician, who performs weekly virtual visits. The endpoint is 30-day hospital readmission. Patient data is collected on hospital utilization, patient self-management, physician and patient experience.

Discussion: Our protocol introduces a novel study design with existing clinical trainees, to provide comprehensive tele-transitions of care to reduce avoidable readmissions.

1. Introduction

Telehealth offers great promise in addressing the triple aim objectives [1], while helping reduce avoidable readmissions. In the advent of new data sources and technologies, clinical practice must evolve to ensure high patient satisfaction and quality care. The first 30 days after hospital discharge offers an important opportunity for telehealth intervention allowing for daily surveillance of vitals, weekly virtual visits and review of all available electronic data [2]. This practice of Telemedicine may potentially reduce dangerous adverse events through improved patient–provider communication, medicine reconciliation, patient education, and assurance of patient hemodynamic stability. Many Telehealth studies thus far, have had inconsistent findings in regards telemedicine's impact on readmissions [3–8]. The lack of evidence is likely due to the paucity of studies, the lack of standardization in telehealth interventions, as well as a focus on evaluation of telehealth to reduce all cause readmissions for a subgroup of patients with a specific admission diagnosis [9]. We propose, that Telehealth, as primarily a tool of surveillance and communication, should be evaluated for patients with multiple co-morbidities, with a primary outcome of avoidable readmissions. Avoidable readmission is defined as a hospital readmission due to violation of evidenced based Transitions of Care notably 1) medication error 2) lack of clinical follow up 3) lack of appropriate response to clinical “red flags” and 4) lack of appropriate patient-centered documentation or the HIE. It is clear from published studies that preventable readmissions are due to failure of overall clinical management, not simply admission diagnosis management [10] and that Telehealth, has the most beneficial impact on mixed chronic conditions, using multi-function interventions [7,9].

The aim of this paper is to share our research and clinical processes, to help overcome the barrier to the adoption of telemedicine practice and research [11–13]. We introduce a feasible, replicable approach

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Table 1
World health organization trial registration data set.

Data category	Information
Primary registry and trial identifying number	ClinicalTrials.gov NCT03528850
Date of registration in primary registry	18 May 2018
Secondary identifying numbers	IRB 970227
Source of monetary or material support	Stony Brook Medicine Information Technology
Primary sponsor	Stony Brook Medicine Information Technology
Secondary sponsor(s)	None
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Public title	Stony Brook Telehealth Trial
Scientific title	Stony Brook Telehealth Study. Tele-transitions of Care. An Approach to Reduce 30-day Readmission Using Tele-Health Technology; A Randomized Controlled Trial
Countries of recruitment	United States
Health condition(s) or problem(s) studied	Multi-comorbid disease in the Post-hospitalization period
Intervention(s)	Telehealth: 30 days Biometric Surveillance of blood pressure, heart rate, oxygen saturation and weight. Weekly virtual visits with a telehealth physician and weekly surveys during the 30 day period.
Key inclusion and exclusion criteria	Inclusion criteria: adult patients (≥30 years), patients hospitalized and discharged to the care of the Family Medicine clinical practices from Stony Brook University Hospital, patients able to provide consent for their own care, English speakers (able to comprehend and speak English), patients with good cognitive function (as evidence by ability to answer a mild cognitive screen (age, telephone, current date, name of facility), patients living within reasonable commute to the Family Medical Group clinics, patients with a life expectancy greater than 6 months, patients with a clinical disposition to home after hospital discharge, patients that are able to turn on the telehealth technology and follow prompts. Patients with two or more diseases Exclusion criteria: Uninsured patients, Patients whose physical limitations prohibit the use of the telehealth equipment, Patients involved in another research study, Pregnant patients (patients actively trying to conceive), Admission for a psychiatric primary diagnosis
Study type	Interventional Allocation: randomized Intervention model: parallel assignment Masking: None Primary purpose: prevention
Date of first enrollment	June 1, 2017
Target sample size	180
Recruitment status	Recruiting
Primary outcome(s)	Readmissions (HIE and Electronic Medical Record Data)
Key secondary outcomes	Emergency Department Utilization (Electronic Medical Record data), Patient Satisfaction (Survey data), Medication Adherence (Patient Self Report), Biometric Reading Adherence (Vendor Portal Data), Adverse Health Events (Physician Survey), Physician Satisfaction (Physician Survey)
Ethics Review	IRB Approved Trial, 970227 Date of Approval Date: 02/06/2017
Completion Date	June 1, 2018

using clinical trainees and direct involvement of the patient's primary care provider (PCP). This protocol follows the SPIRIT guidelines to establish a transparent, thorough and guideline based study methodology [14]. The results of this trial will be disseminated by publication in peer reviewed medical journals, conference presentations, national meetings and with faculty, staff and the patients studied.

2. Objective

Our objective is to provide reliable evidence as to whether Telehealth interventions using remote patient monitoring, weekly virtual visits and access to the HIE, will reduce avoidable readmissions in comparison to standard of care.

3. Overview

This trial was a 12-month, parallel-group, superiority randomized controlled trial to evaluate the effect of Telehealth on avoidable readmissions. 180 multi-comorbid patients who fulfilled the eligibility criteria, were randomized to receive either Telehealth or Standard of Care (Table 1). The standard of care upon hospital discharge, was the provision of a discharge summary and patient instructions encouraging follow up with the PCP within 7–14 days and scheduled specialist appointments as indicated. A clinical summary with detailed instructions were provided by the discharge nurse. The Telehealth intervention involved the provision of a smart phone device and Bluetooth-enabled blood pressure monitoring cuff, weighing scale, and pulse oximeter (Fig. 1). Telehealth patients measured their vitals daily using the tele-equipment and had weekly virtual visits with a transition of care physician (teledoc). Upon consent, patients participated in the trial for the length of thirty (30) days following hospital discharge. The teledoc in this trial, was a senior resident physician of the family, population and preventive medical division. The virtual visits and remote monitoring was performed by the resident who, in turn, reported the patient status to the PCP. The role of the teledoc can be fulfilled by a trained resident, fellow, nurse-practitioner or a primary care physician.

The intervention began two days after hospital discharge, when the patient received the delivered “tele-kit” and began daily vitals. The teledoc then began once daily surveillance of vitals, conducted weekly virtual visits, and wrote detailed Electronic Medical Record (EMR) documentation with the use of validated risk stratification measures [15,16] as well as data from the HIE.

We hypothesized that in comparison to the “standard care” that:

1. Preventable hospital readmissions will be reduced through patient centered virtual visits, daily biometric surveillance, and increased data access.
2. Patient satisfaction during the transition of care period will be improved
3. Adverse healthcare outcomes will be reduced

The primary outcome of the study was to determine the effect of telehealth on avoidable hospital readmissions within 30 days of the index hospitalization discharge as defined by clinical review of two independent physicians according to the definition aforementioned, as well as calculation of overall unplanned hospital readmission. In