Tele-transitions of Care (TTOC). A 12-month, Randomized Controlled Trial evaluating the use of Telehealth to achieve Triple Aim Objectives

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Abstract

Background: Poor transitions of care leads to increased health costs, utilization and poor outcomes. This study evaluated Telehealth feasibility in improving transitions of care. Methods: This is a 12-month randomized controlled trial, evaluating the use of telehealth (remote patient monitoring and video visits) versus standard transitions of care with the outcomes of over utilization, access to care, medication management and adherence and patient engagement. Results: The study conducted between June 2017 and 2018, included 105 patients. Compared with the standard of care, Telehealth patients were more likely to have medicine reconciliation ($p = 0.013$) and were 7 times more likely to adhere to medication than the control group ($p = 0.03$). Telehealth patients exhibited enthusiasm ($p = 0.0001$), and confidence that Telehealth could improve their healthcare ($p= 0.0001$). Telehealth showed no statistical significance on ED utilization ($p = 0.691$) nor for readmissions ($p = 0.31$). 100% of Telehealth patients found the intervention to be valuable, 98% if given the opportunity, reported they would continue using telehealth to manage their healthcare needs, and 94% reported that the remote patient monitoring technology was useful. Conclusions: Telehealth can improve transitions of care after hospital discharge improving patient engagement and adherence to medications. Although this study was unable to show the effect of Telehealth on reduced healthcare utilization, more research needs to be done in order to understand the true impact of Telehealth on preventing avoidable hospital readmission and ED visits.

Background

Telehealth has the potential to improve transitions of care, through enhanced connections among patients and their clinicians, during a vulnerable period after hospital discharge (1). To achieve triple aim objectives, reducing unnecessary hospital readmissions is desirable for payers and patients alike(2). Several key studies have shown the values of telehealth in reducing avoidable hospital readmissions(1, 3-7), while others have reported inconsistent findings in regards to overall healthcare utilization: Emergency Department (ED) visits and readmissions (4, 5, 8-11). Telehealth interventions using primarily communications and surveillance technologies, show most promise in counseling and enhancing patient compliance(12). It is unlikely that telehealth alone, can reverse disease pathology or predictable courses of disease(13). Despite this, the majority of published telehealth studies, have focused on patient populations selected by diagnosis, such as heart failure, with limited generalizability regarding the effects of Telehealth in regards to patients with multiple co-morbidities(12). With this in mind, this study aims to evaluate telehealth (remote patient monitoring coupled with weekly video visits), for a population of patients identified by clinical disposition rather than by diagnosis.

Patients in this trial, have an existing primary care provider (PCP) within our health system and received telehealth services from either their PCP or a clinical trainee reporting to their PCP. Patients were enrolled in the study at the bedside, prior to hospital discharge to their homes. The intervention's primary endpoints were in attempts to reduce hospital readmissions and ED utilization with an overall aim of reducing adverse events through improved patient–provider communication, medicine reconciliation, patient education, and assurance of patient hemodynamic stability. The Telehealth Transitions of Care

intervention, or TTOC, was designed in concordance with Coleman's four pillars of transitional care: 1) medication self-management 2) clinical follow up 3) knowledge of clinical "red flags" and 4) Increased access to patient-centered documentation or the HIE. TTOC follows the strength of evidence of maximal patient benefit for patients with mixed chronic conditions, by use of a multi-functional approach (remote patient monitoring and video visits) (5, 12). TTOC was designed to enhance PCP services, while also providing training opportunities for physicians in Telehealth. In doing so, TTOC provided a major benefit to our academic hospital system, helping to overcome known barriers to telehealth adoption(14-16). We introduce a feasible, replicable approach using clinical trainees and direct involvement of the patient's PCP. The protocol and study design has been published in the peer reviewed literature(17).

Methods

Aim, Design and Setting of the study

The aim of the study was to evaluate the effects of TTOC (weekly video visits with daily remote patient monitoring), to standard of care. The primary outcomes of the study were to determine the effect of telehealth on hospital readmissions and ED visits within 30 days of the index hospitalization discharge. Secondary analysis, included evaluation of risk score, patient attitudes, medicine adherence and management, qualitative patient experience, patient self-management and self-efficacy attitudes (Figure 3). This study was performed by the Family and Internal Medicine Departments at Stony Brook Medicine, which is a 603-bed teaching institution on the northern part of Long Island, New York. The hospital mostly services the population of Suffolk County with an annual admission of 31,715 patients. The Family Medicine and Internal Medicine departments. Over 75 percent of patients were serviced by the Family Medicine physicians, in an ambulatory practice serving about 32,000 patients annually, who do not currently serve uninsured patients (whom are referred to our affiliated FQHCs and our free student run clinic not officially part of the Family Medicine practice).

Participant Characteristics

105 patients who fulfilled the eligibility criteria, were randomized to receive either TTOC or Standard of Care (Figure 1). Eligible patients were adult patients (≥ 30 years), with 2 or more disease processes, English speakers, with good cognitive function, a life expectancy greater than 6 months, with an ability to provide consent. All patients were hospitalized at Stony Brook University Hospital and discharged to the patient home, with the follow up care in either the Family or Internal Medicine clinical practices. Patients self-identified as living within reasonable commute to the Family or Internal Medical Group clinics, and were able to complete a technological aptitude test of turning on the telehealth technology and following the prompts. Patients were excluded if they had physical limitations prohibiting the use of the telehealth equipment, were uninsured (who received referrals elsewhere for follow up care), if involved in another research study, were pregnant or actively trying to conceive, or if admitted for a primary psychiatric diagnosis.

Study Design

We conducted a 2-arm, parallel group, randomized controlled trial between June 1, 2017 to June 1, 2018. 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 within 48 hours after hospital discharge (Figure 2)(18). 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. All patients were consented and enrolled in the Health Information Exchange.

Data Collection

Study data was collected and managed using REDCap (19) electronic data capture tools hosted at Stony Brook Medicine.

Data Analysis

Frequencies and percentages were calculated for categorical variables, e.g. Re-admission and ED visit for each randomized group. Means and standard deviations (SD) were calculated for continuous variables if the data followed a normal distribution (e.g. age). If the data did not follow the normal distribution, medians and ranges were calculated instead. Chi-square tests or Fisher's exact tests were used to compare the percentages of categorical variables between the Telehealth and control groups. T tests or Wilcoxon rank sum tests were used to compared means and medians between the two randomized groups. To evaluate the associations between Readmission, ED visit and adhere with telehealth and other factors, multivariable logistic regression models were performed and odds ratios and their 95% confidence intervals were estimated.

SAS v9.3 (Cary, NC) and SPSS v25 (Chicago, IL) were used to conduct all statistical analyses.

Results

451 patients were assessed for eligibility for the trial. 105 patients met inclusion criteria for study participation, gave informed consent, and were enrolled in the study prior to discharge. 47 patients were randomized to the TTOC group while 58 patients received the standard of care. Patients were excluded if their hospitalization course worsened, whereby they were no longer eligible, as they were discharged to subacute rehabilitation centers (SAR). A small proportion of patients later refused to participate in the trial when discharged to the home (Figure 1).

The average age at enrollment was 65 years. Overall, the study arms were balanced by characteristics as there were no statistically significant differences between the groups in regards to gender, race and education. 68.5% of individuals in the control group had higher than high-school level of education in

comparison to 76.1% of individuals in the telehealth intervention group. In addition, the employment rate was similar in both groups: 43.1% in the control group and 38.3% in the intervention group. No significant difference was seen in the presence of a computer at home: 77.6% for the control group and 63.8% for the telehealth intervention group. Over 97% of study participants had internet in their home, while over 94% owned a cell phone. Both groups had high percentages of patients who used a computer on a regular basis 63.8% in the control group and 77.6% of the TTOC group. Both groups showed high confidence in using smart phones or tablets. On average both groups spent about 4 hours on the computer per day. Similar percentage of individuals in both groups reported their health as either good or very good: 60.3% in the control group and 48.9% in the intervention group. The median scores, on a questionnaire scale of 1-10, were also similar between the 2 groups for the confidence with health management and comfort with technology measures. Patients had an average of 9 diagnoses, and a moderate severity risk score and a moderate rating of disability.

(Table 1).

Patients had a statistically significant improvement in enthusiasm and confidence that Telehealth helped patients ($p = 0.0001$). There was no statistically significant difference in the perception of difficulty in participating in the trial ($p > 0.072$).

(Table 2)

There was no statistically significant difference in follow up with the PCP ($p > 0.096$). However, 94% of patients in the Telehealth arm felt that the remote patient monitoring technology was helpful in managing their healthcare needs. 98% if given the opportunity would continue to use the technology to manage their health needs. 100% of the Telehealth patients found the intervention to be valuable. Also, Patients in the Telehealth arm, were about 7 times more likely to adhere to their medications (OR = 6.925, 95% CI: 1.2-39.9, $p = 0.03$).

(Table 3)

There were no statistically significance regarding ED utilization or Hospital readmissions. Patients with a greater number of diagnoses were more likely to go to the ED (controlling for age, gender and Telehealth).

Discussion

Our trial shows that when patients receive high quality tele-transitions of care, they are more adherent to their medications, and can be engaged in their healthcare. Telehealth provided great value for patients after hospital discharge. The trial was underpowered to evaluate hospital readmissions and ED utilization; however, it is important to recognize that telehealth patients received safe well-coordinated care for their medical conditions. There were no adverse events reported resulting from the Telehealth

intervention in regards to patient injury, harm, error or death, despite patients suffering multiple co-morbidities and health changes. 4 patients were successfully and actively referred to the hospital after having life threatening clinical situations including: stroke, acute airway and oxygen desaturation, reflecting their late-stage non-modifiable pathologies. Telehealth has shown promise in regards to reducing readmissions. However new literature also questions the validity of hospital readmissions as an endpoint, as some studies show increased death related to lower rates of readmission(20, 21). The coordinated care of our telehealth patients in a setting with a shared EMR, also allowed for improved diagnosis, cohesive patient histories validated by clinicians with supportive bio-monitored data (blood pressure, heart rate, O2 saturation, weight).

There were other many benefits of this study, including the 18 residents formally trained in Telehealth, and resulting in 15 Primary care providers requesting formal credentialing for Telehealth from our institution in Family and Internal Medicine. The clinician engagement and training is an important achievement as physician adoption remains a considerable barrier to telehealth implementation(15).

This study lends itself to generalizability in academic medical systems as Stony Brook Medicine, itself is a large academic center with advanced biomedical informatics and Information Technology resources and willing residents available for telehealth training. One limitation of the study may be in implementing this design in smaller healthcare settings without clinical trainees. It is also important to note that clinical trainees were in their last year of training and therefore, the seniority of trainees involved in the role of the teledoc, should be taken into account. Furthermore, the volume of patients followed by the Teledoc must be tailored to clinical experience and aptitude. Larger well powered, multi-institutional trials are required to make definitive conclusions regarding the ability of the intervention to reduce hospital readmissions.

As digital technologies become increasingly more important in patient's lives and with the increased consumerism of both IT and healthcare itself, health care systems are faced with stronger demands for virtual health services. Our trial shows feasibility in implementing Telehealth within existing clinical workflows. TTOC has shown tremendous value for patients, clinicians and the hospital system, irrespective of being underpowered for readmissions and ED utilization. Further studies and large clinical trials in collaboration with several health systems, will allow for true return on investment for Telehealth for transitions of care.

Conclusion

Telehealth has great value in providing safe transitions of care, increasing patient satisfaction and improving patient adherence to medication. More research is needed to evaluate the true impact of Telehealth on preventing avoidable hospital readmission and ED visits.

Trial Registration And Status

ClinicalTrials.Gov ID: NCT03528850 Date Registered: 5/18/2018

Status: Completed

IRB #: 970227

Abbreviations

Tele-Transitions of Care (TTOC), Primary care provider (PCP), Emergency Department (ED), Telehealth transition of care physician (teledoc), standard deviations (SD), subacute rehabilitation centers (SAR)

Declarations

Ethics Approval and Consent to Participate:

Our study and all of its components were approved by the Stony Brook University Institutional Review Board (IRB #: 970227). Written Consent was obtained by all participants.

Availability of Data and Materials: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing Interests: The authors: Dr. Kimberly Noel, Dr. Catherine Messina, Dr. Gerald Kelly, Dr. Elinor Schoenfeld, and Dr. Wei Hou, declare to possess no conflict of interest and no competing financial interests exist.

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Author's Contributions: All authors listed above have contributed to this work equally. All authors were involved in study design. GK, KN were involved in data collection and overall supervision of the trial. WH and CM analyzed the statistical methodology. All authors analyzed and interpreted the findings. All authors read and approved the final manuscript.

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Tables

Table 1. Baseline Demographics

Basic Demographics	Standard of Care n = 57	Treatment n =45	P value
Age, Mean(SD) [a]	63.67 (14.78)	65.66 (13.24)	0.483
Female, n (%) [b]	35 (63%)	29 (64%)	0.840
Education, n (%) [b]			
High School	16 (30%)	11 (25%)	0.807
Some College	21 (40%)	20 (45%)	
Completed College	16 (30%)	13 (30%)	
Race, n (% Non-Caucasian) [a]	10 (18%)	6 (13%)	0.561
Employed n (%) [b]	25 (44%)	17 (38%)	0.535
Sick/Disability			
Readmission Risk Score [a, d]	45.29 (11.82)	45.28 (14.28)	0.997
Number of Diagnoses, Median [c]	8	9	0.401
Median Number of Follow Up Appointments on Discharge [c]	3	2	0.348
How would you rate your health? n (% Good/Very Good) [b]	34 (60%)	22 (49%)	0.278
(0 = Good/Very Good, 1 = Poor/Fair)			
General Health Rating, Median [c]	2 (0 ,4)	1 (0 ,4)	0.141
(Poor =0, Fair =1, Good=2, Very Good=3, Excellent =4)			
Access to Care			
Emergency Contact Person, Yes n (%) [b]	57 (100%)	42 (93%)	0.083
Full-time Caregiver, Yes n (%) [b]	5 (9%)	7 (16%)	0.291
Self-Efficacy			
Confidence in Health Management, Median [c]	9 (4 ,10)	8 (2 ,10)	0.146
Computer/Tech Savviness			
Do you use a computer on a regular basis? Yes n (%) [b]	45 (79%)	29 (64%)	0.103
How comfortable are you with using technology like a smart phone or tablet? Median (Range) [c]	8 (0 ,10)	7 (0 ,10)	0.225
Do you own a cell phone? [b] Yes n (%)	54 (95%)	43 (96%)	0.999
Do you have internet service in your home? Yes n (%) [b]	56 (98%)	44 (98%)	0.999
Do you have difficulties with your cell service, whereby you experience dropped calls or poor reception? Yes n (%) [b]	2 (4%)	2 (4%)	0.999
How many hours per day do you use the computer? Mean (SD) [a]	3.57 (2.90)	4.95 (5.25)	0.154
Telehealth			
How enthusiastic are you about the Telehealth program, Median [c]	8 (0 ,10)	9 (1 ,10)	0.124
How confident are you that Telehealth may help your healthcare, Median [c]	9 (0 ,10)	8 (3 ,10)	0.970

[a] based on t-tests comparing difference in means. The data shows mean (SD) in each randomized group.

[b] based on Chi-square or Fisher's exact test comparing difference in %. The data shows n (%) in each randomized group.

[c] based on Wilcoxon rank sum tests comparing medians. The data shows median (min, max) in each randomized group.

[d] Risk scores are calculated by using a proprietary algorithm by Cerner© that includes about 40 + data points from groups, based on the patient history and admitting physical exam, diagnosis related group codes, patient demographics, procedures, utilization, lab tests, medications, and exploratory variables. The score uses a scale (0–100 scale) that it easier for clinicians to understand.

Table 2. Patient experience

	Standard of Care n = 43	Treatment 30 day n= 31	P Value
How Difficult was participation in the Study for you? [a] n (%) (0 = Very Easy 4 =Very Difficult)	0 (0,2)	0 (0,2)	0.072
How enthusiastic are you about the Telehealth program? [a] Median (Range)	7 (0,10)	10 (5,10)	<0.0001*
How confident are you that Telehealth may help your healthcare? [a] Median (Range)	7.5 (0,10)	9 (5,10)	<0.0001*
How confident are you with managing your own healthcare? [a] Median (Range)	9 (1,10)	9 (5,10)	0.914

a. based on Wilcoxon rank sum tests comparing medians

Statistical Methods

Frequencies and percentages were calculated for categorical variables, e.g. Re-admission and ED visit for each randomized group. Means and standard deviations (SD) were calculated for continuous variables if the data followed a normal distribution (e.g. age). If the data did not follow the normal distribution, medians and ranges were calculated instead. Chi-square tests or Fisher’s exact tests were used to compare the percentages of categorical variables between the Telehealth and control groups. T tests or Wilcoxon rank sum tests were used to compared means and medians between the two randomized groups. To evaluate the associations between Readmission, ED visit and adhere with Telehealth and other factors, multivariable logistic regression models were performed and odds ratios and their 95% confidence intervals were estimated.

Table 3: Clinical Endpoints for Telehealth

Effect	Point Estimate	95% Wald Confidence Limits		P value
ED Utilization [a]	0.749	0.180	3.115	0.691
Readmission [a]	2.645	0.404	17.328	0.311
Medication Adherence [a]	6.925	1.203	39.856	0.030*

	Standard of Care n = 57	Treatment n =45	P value
Medicine Reconciliation [b]	47 (82%)	31 (100%)	0.013*
PCP Follow-up Visit, Yes n(%) [b]	31 (60%)	34 (76%)	0.096
Death [b]	1 (2%)	0 (0%)	0.372

1. based on logistic regression controlling for age, gender, number of diagnoses
2. based on Chi-square or Fisher's exact test comparing difference in %. The data shows n (%) in each randomized group.

*Logistic regression models failed to converge for Medicine Reconciliation and PCP F/u due to data sparsity, therefore, no odds ratio was estimated for the two outcomes.

Figures

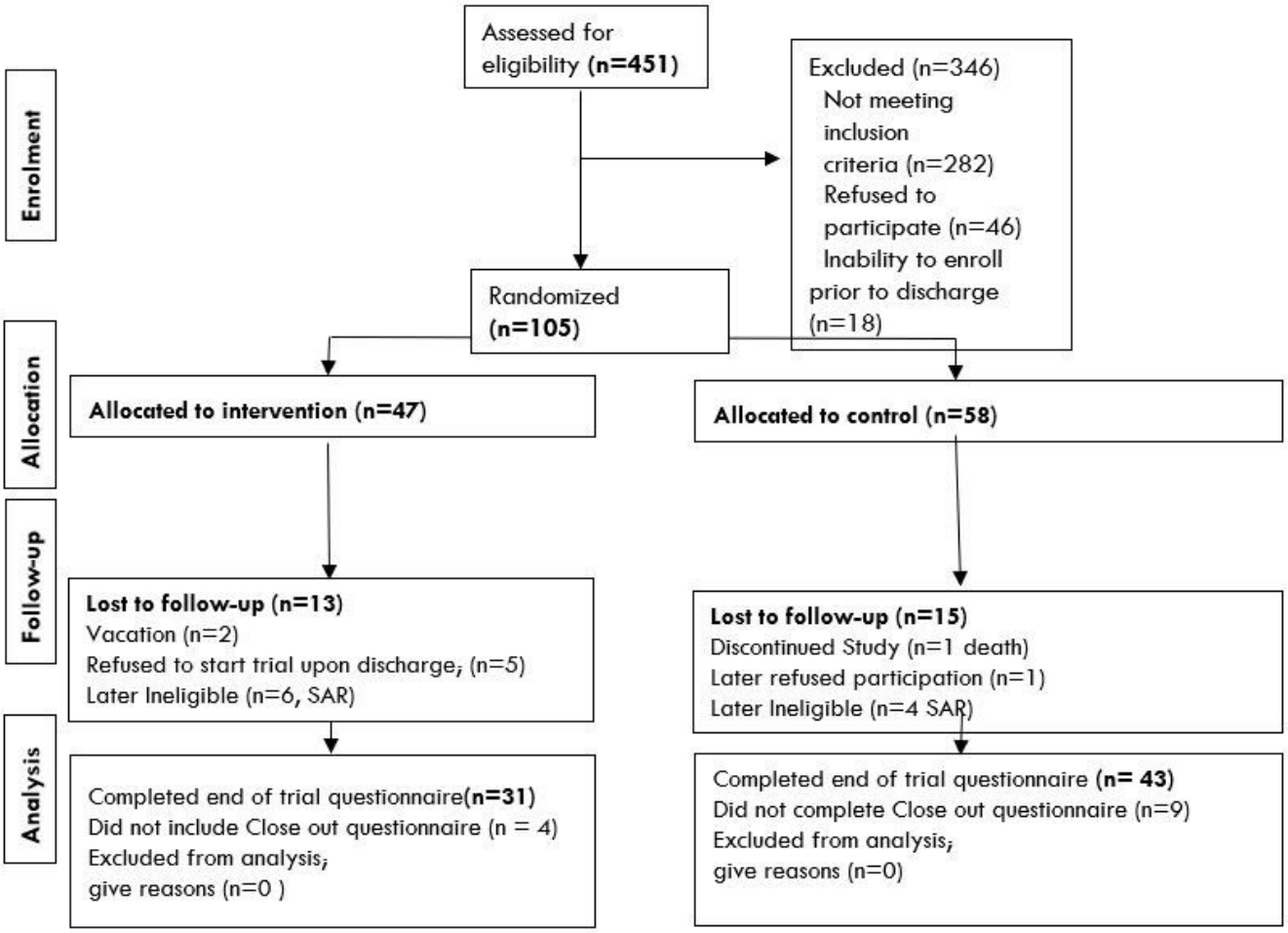

Figure 1

Total CONSORT Statement Flow Diagram

Telemedicine Device Specs

Telemedicine Tablet Monitor	Manufacturer	Model	Certification
	LG	G-Pad 7 in.	FCC Cleared - VZW
	LG	VK 815 8 in.	FCC Cleared - VZQ

Blood Pressure Monitor	Manufacturer	Model	Certification
	A&D Medical	UA-767PBT	FDA Class II
	Fora Care	P20	FDA Class II

Pulse Oximeter	Manufacturer	Model	Certification
	NONIN Medical	ONYX II 9560 BT Smart 3230	FDA Class II

Weight Scale	Manufacturer	Model	Certification
	A&D Medical	UC-321PBT	FDA Class I, FCC
	Fora Care	ForaW310	FDA Class II

Courtesy of Vital Care Services©

Figure 2

Telehealth Equipment