

## Article

# The Diabetes Transition of Hospital Care (DiaTOHC) Pilot Study: A Randomized Controlled Trial of an Intervention Designed to Reduce Readmission Risk of Adults with Diabetes

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**Abstract:** Hospital readmission within 30 days of discharge (30-day readmission) is a high-priority quality measure and cost target. The purpose of this study was to explore the feasibility and efficacy of the Diabetes Transition of Hospital Care (DiaTOHC) Program on readmission risk in high-risk adults with diabetes.

This was a non-blinded pilot randomized controlled trial (RCT) that compared usual care (UC) to DiaTOHC at a safety-net hospital. The primary outcome was all-cause 30-day readmission.

Between 10/16/2017 and 05/30/2019, 115 patients were randomized. In the intention-to-treat (ITT) population, 14 (31.1%) of 45 DiaTOHC subjects and 15 (32.6%) of 46 UC subjects had a 30-day readmission ( $p=0.88$ ) while 35.6% DiaTOHC and 39.1% UC subjects had a 30-day readmission or ED visit ( $p=0.72$ ). The Intervention:UC ratio of cost was 0.33 (0.13-0.79)95%CI ( $p<0.01$ ). Among the 69 subjects with baseline HbA1c  $>7.0\%$  (53 mmol/mol), 30-day readmission rates were 23.5% (DiaTOHC) and 31.4% (UC,  $p=0.46$ ) and composite 30-day readmission or ED visit rates were 26.5% (DiaTOHC) and 40.0% (UC,  $p=0.23$ ). In this subgroup, the Intervention:UC cost ratio was 0.21 (0.08-0.58)95%CI ( $p=0.002$ ).

The DiaTOHC Program is feasible and may decrease combined 30-day readmission/ED visit risk as well as healthcare costs among patients with higher HbA1c levels.

**Keywords:** rehospitalization; transition care; pilot study; prospective randomized trial

## 1. Introduction

Hospital readmission within 30 days of discharge (30-day readmission) is a high-priority quality measure and cost target [1]. People living with diabetes are at higher 30-day readmission risk than those without diabetes [2-4]. Several interventions have shown promise for reducing readmission risk of diabetes patients in mostly observational studies [4]. Selecting patients at high readmission risk for intervention may enable more efficient use of resources than applying interventions broadly without regard to readmission risk. No previously published randomized controlled trials (RCTs) have tested an intervention designed to reduce readmission risk in patients with diabetes and high readmission risk as predicted by a validated tool. We previously reported on the development and validation of the Diabetes Early Readmission Risk Indicator (DERRI™)[5-7], which predicts 30-day readmission risk in diabetes patients. The aim of the current pilot RCT was to explore the feasibility and potential efficacy of a novel, multi-component intervention, the Diabetes Transition of Hospital Care (DiaTOHC) Program, on 30-day readmission risk in adult patients with diabetes at high risk based on the DERRI™.

## 2. Materials and Methods

### 2.1. Study design, setting, and ethics

This was a non-blinded pilot RCT with two parallel arms that compared usual care (UC) to the DiaTOHC Program (Intervention) at Temple University Hospital, an urban, academic, safety-net hospital in Philadelphia, PA. The protocol was registered in the National Clinical Trials Registry (NCT03243383) and approved by the Temple University Institutional Review Board (#24306). This study was carried out in accordance with the Declaration of Helsinki. Written informed consent was obtained from all subjects. The study was registered on ClinicalTrials.gov (NCT03243383), where the protocol is accessible.

### 2.2. Participants and randomization

Inclusion criteria were an established diagnosis of diabetes, defined by pre-admission use of a diabetes-specific medication and/or documentation of the diagnosis in the medical record, age  $\geq 18$  years, high predicted risk of 30-day readmission ( $\geq 27\%$ ) based on the DERRI™[6], and hospital admission to a non-critical care unit. Exclusion criteria were pregnancy, binge drinking ( $\geq 5$  alcoholic drinks for males or  $\geq 4$  alcoholic drinks for females on the same day), drug abuse within 3 months before admission, receiving palliative care during the hospitalization, participation in another readmission risk reduction program, planned or actual transfer to another hospital or subacute facility, discharge expected within 12 hours, lack of access to a phone, living more than 30 miles away from the hospital, HbA1c  $< 5.7\%$  (39 mmol/mol), and inability to speak English. Subjects were withdrawn from the study upon transfer to another hospital or subacute facility, discharge to hospice or a long-term care facility, signing out against medical advice, or inpatient death. We screened a computer-generated list of patients who were admitted to non-critical care units with orders for routine point-of-care blood glucose testing. If the primary hospital team approved, then potentially eligible patients were approached in their hospital room for further screening and informed consent.

Subjects were randomly assigned with a computer-generated randomization scheme 1:1 in randomly permuted blocks of 2, 4, or 6 to receive either the Intervention or UC. The study statistician (H.Z.) generated the random allocation sequence. Group assignments were placed in sealed envelopes and revealed sequentially as subjects were randomized. Study coordinators enrolled participants and assigned them to interventions based on the allocation sequence.

### 2.3. Interventions

Subjects in the UC group received the standard discharge instructions, education, medication reconciliation and follow-up according to routine practice. Discharge instructions were generated using the Epic Hyperspace® (Verona, WI) electronic health record (EHR), which is integrated between the inpatient and outpatient settings. Education was

provided by bedside nurses and hospital providers at their discretion using stock materials in the EHR (ExitCare Clinical References). Subjects received training by a bedside nurse on using a glucometer and insulin as needed. Diabetes therapy upon discharge was determined by the primary team. Discharge instructions were routinely sent to the primary care provider either by fax or EHR. Subjects received a phone call within 4 days after discharge from a hospital-employed community health worker that included checking on the health of the subject, confirming follow up appointments and access to medications, and answering questions. Problems were referred to a Nurse Navigator, all of whom had a Nurse Practitioner degree, for further management. A transition-of-care appointment was scheduled for all patients with a primary care provider within 10 days of discharge. This appointment focused on medication reconciliation, review of discharge instructions, and updating care needs since hospital discharge.

Subjects in the Intervention group received the DiaTOHC Program in addition to the UC described above. The DiaTOHC Program has three components: 1) patient-centered discharge education, 2) HbA1c-based adjustment of diabetes therapy upon discharge, and 3) post-discharge support.

### 2.3.1. Patient-centered discharge education

The education consisted of two parts delivered by one of three study team Navigators over the phone before discharge or 1 to 3 days after discharge according to subject availability. The first part was focused, customizable, diabetes discharge instructions and education using a 19-page booklet based on American Diabetes Association (ADA) guidelines that includes information on diet, physical activity, and self-care guidance, such as how to recognize and treat hypoglycemia and hyperglycemia [8]. The instructions addressing post-discharge use of diabetes medications were adapted from previously published work [9]. All the concepts tested in the revised Diabetes Knowledge Test (DKT2) are covered in the booklet [10]. Subject who had not completed a formal outpatient diabetes education program in the prior 12 months were referred to a Diabetes Care and Education Specialist at the Temple Diabetes Center. The second part of discharge education was a comprehensive review of the discharge plan. A Navigator reviewed the discharge plan with subjects, covering the treatment plan, how to take medications, reasons for and importance of follow-up appointments and testing, and how to reach post-hospital providers.

### 2.3.2. HbA1c-based adjustment of diabetes therapy

Diabetes therapy upon hospital discharge was determined by a study Endocrinologist (C.V. or D.R.) using an algorithm based on previously published work and ADA guidelines (Supplementary Table S1) [8, 11]. For subjects with baseline HbA1c <7.0% (53 mmol/mol), the pre-admission treatment regimen was continued unless adjustments were needed for safety. For subjects with baseline HbA1c >7.0% (53 mmol/mol), pre-admission non-insulin diabetes therapy was optimized, defined as using the next higher dose up to the maximum tolerated dose. Only FDA-approved diabetes therapies were used in the study. Metformin was started in subjects with Type 2 Diabetes who did not have a contraindication to using it. Depending on the baseline HbA1c level, insulin was adjusted or added to the pre-admission regimen.

### 2.3.3. Post-discharge support

One to 3 days after discharge, a Navigator called subjects to assess their status, confirm receipt of and compliance with medications, verify follow-up appointments, assess barriers to following the discharge plan, determine the need for a community health worker, and review BG levels. Similar phone calls were made weekly for four weeks following discharge or until the first unplanned readmission. Subjects who were discharged on non-insulin regimens were asked to check their BG levels at least once a day, and subjects discharged on insulin at least twice a day. If a subject reported BG levels <70 or >240 mg/dL, then the Navigator notified a study physician, who contacted the subject by phone

to adjust diabetes therapy per protocol (Supplementary Tables S2 and S3). In addition, all intervention subjects received a referral for a nursing visit in the home to assess medical needs for support at home. Referral to a community health worker was made if subjects were found to have non-medical needs and/or obstacles to maintaining self-care and attending follow-up appointments, including transportation, food, housing, financial and legal issues.

#### 2.4. Data collection, measures, and sample size

The primary outcome was all-cause unplanned hospital readmission within 30 days of discharge. Secondary outcomes assessed at 30 days after discharge were time to unplanned readmission (stratified by the number of Navigator phone calls completed), rate of any emergency department (ED) visit not associated with a hospital admission, composite rate of unplanned readmission or ED visit, cost of post-discharge acute care and the intervention (details below), daily frequency of self-monitored blood glucose (SMBG) testing, and three categories of hypoglycemia defined as any SMBG level <70, <54, or <40 mg/dL (Intervention group only). Data on hypoglycemia in the Intervention group were obtained during the follow-up Navigator phone calls. Because the UC group did not receive Navigator calls, comparable data on hypoglycemia were not available. Baseline characteristics were recorded based on self-report and review of the medical record.

Approximately 5 weeks after discharge, a study coordinator called subjects in both groups to assess readmissions, ED visits, and the frequency of SMBG testing. Healthcare encounters were confirmed in the EHR, which is integrated with several other healthcare systems in the region by Epic Care Everywhere. Readmissions that could not be confirmed in the EHR were confirmed by obtaining discharge records. Change in HbA1c level from baseline (hospital admission) was assessed 3 months after discharge.

The cost of post-discharge acute care was based on the sum of the estimated cost of all planned and unplanned readmissions and ED visits within 30 days of discharge. The cost of each readmission was based on the observed length of stay and a unit cost of \$3,045 USD per hospital day in 2017 among patients with diabetes [12]. The cost of each ED visit was based on a unit cost of \$1,110 [12]. The cost of the intervention was based on the value of time spent by the Navigators and study physicians. Based on the average annual income of a Navigator working 2,000 hours per year, Navigator time was valued at \$58 per hour. Similarly, based on the Fiscal Year 2018 median income of an Assistant Professor in Endocrinology working 2,300 hours per year in the United States, physician time was valued at \$101 per hour [13].

A target of 60 subjects per group was the largest deemed feasible. The last date of enrollment was determined by Navigator availability. As a pilot trial, this study is not powered to detect statistically significant differences in outcomes.

#### 2.5. Statistical analysis

Distributions of the data were assessed by descriptive statistical and graphical methods. Summary statistics are reported as mean  $\pm$  standard deviation or median (interquartile range). To assess the randomization procedure, baseline values of all variables were compared between the Intervention and UC groups. Between-group differences for continuous variables were compared using the t-test or Wilcoxon rank-sum test, and proportions were compared using the chi-square test or exact test.

The primary outcome (readmission rate) was compared between Intervention and UC groups with the chi-square test. Time to readmission was estimated by Kaplan-Meier curve and compared between groups by the log-rank test, with the Intervention group stratified by the number of Navigator phone calls completed (<3 or 3 to 5). Multivariable Cox regression was used to estimate the risk of readmission adjusted for baseline differences with the Intervention group stratified by the number of Navigator calls. Continuous secondary outcomes were compared using the Wilcoxon rank-sum test. Categorical secondary outcomes were compared using the chi-square test. Because of skewed

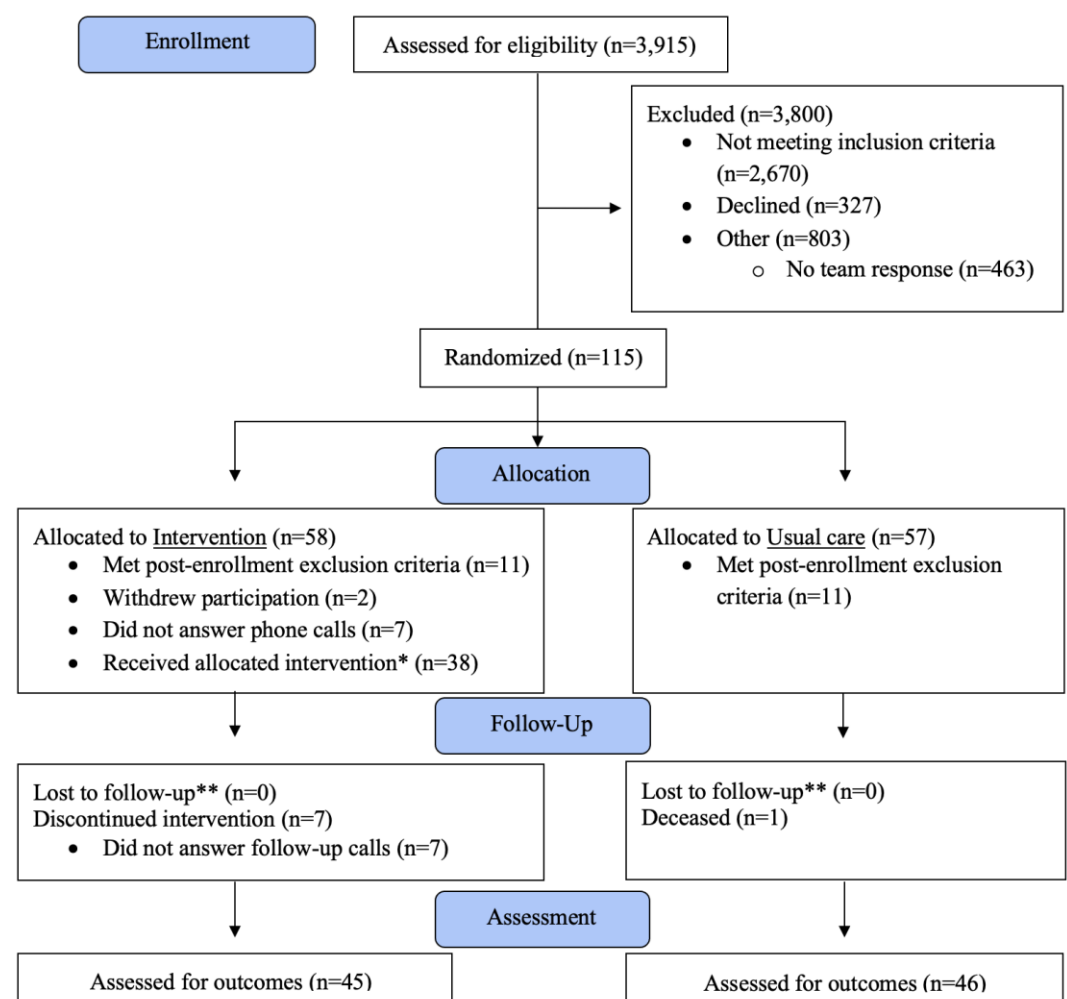
distributions, the ratio of estimated costs between groups was compared using log-transformed gamma regression [14].

The primary analyses for all outcomes were performed in the intention-to-treat (ITT) population, defined as having been randomly assigned to a study group and not meeting post-enrollment exclusion criteria. In pre-specified analyses, outcomes were assessed in the ITT subgroup of subjects with a baseline HbA1c >7.0% (53 mmol/mol). Statistical significance is claimed at an alpha level of 0.05. There is no adjustment for multiple comparisons given that this is a pilot study.

### 3. Results

#### 3.1. Participant flow

Between 10/16/2017 and 05/30/2019, a total of 3,915 patients were assessed for eligibility and 3,800 were excluded (Figure 1). The remaining 115 patients were randomized, and 58 were allocated to Intervention, 57 to UC. The analyzed ITT cohort had 45 Intervention subjects and 46 UC subjects.



**Figure 1. Flow of patients in trial.** \*Subject received education, adjustment of diabetes therapy upon discharge, and at least 1 follow-up phone call; \*\*Electronic health record used for follow-up if subject could not be contacted

#### 3.2. Baseline characteristics

Mean age was  $58.7 \pm 12.7$  years, duration of diabetes  $15.1 \pm 10.0$  years, and median HbA1c 8.7% [7.1%-10.6%], 72 mmol/mol [54-92 mmol/mol] (Table 1). The cohort was 71% Black, 28% White, 14% Hispanic and mostly low-income (86%). Most patients (95%) had Type 2 Diabetes. There were some baseline differences between groups, including a recent



hospital discharge, preadmission insulin use, depressive symptoms, and diabetes distress. Predicted 30-day readmission risk was not different between groups (38.4±7.6% Intervention, 37.5±7.5% UC).

**Table 1.** Baseline characteristics of Intervention and Usual Care groups.

Variable	All Patients N=91	Intervention N=45	Usual care N=46	P value
Age, years	58.7 ± 12.7	58.5 ± 13.7	58.9 ± 11.7	0.88
Female	47 (51.6)	21 (46.7)	26 (56.5)	0.35
Income, USD				0.52
Less than \$12,060	25 (27.5)	9 (20.0)	16 (34.8)	
\$12,060-\$16,239	16 (17.6)	8 (17.8)	8 (17.4)	
\$16,240-\$24,599	15 (16.5)	9 (20.0)	6 (13.0)	
\$24,600-\$49,999	22 (24.2)	11 (24.4)	11 (23.9)	
\$50,000 or more	13 (14.3)	8 (17.8)	5 (10.9)	
Race				0.16
Black	65 (71.4)	29 (64.4)	36 (78.3)	
Other	1 (1.1)	0 (0.0)	1 (2.2)	
White	25 (27.5)	16 (35.6)	9 (20.0)	
Hispanic	13 (14.3)	9 (20.0)	4 (8.7)	0.12
Education, years	12.6 ± 2.5	13.0 ± 3.0	12.1 ± 1.8	0.07
Employment Status				0.50
Disabled	64 (70.3)	32 (71.1)	32 (69.6)	
Employed	1 (1.1)	1 (2.2)	0 (0.0)	
Retired	16 (17.6)	6 (13.3)	10 (21.7)	
Unemployed	10 (11.0)	6 (13.3)	4 (8.7)	
Insurance				0.82
Medicaid only	16 (18.0)	9 (20.9)	7 (15.2)	
Medicare and Medicaid	17 (19.1)	9 (20.9)	8 (17.4)	
Medicare only	24 (27.0)	10 (23.3)	14 (30.4)	
None	3 (3.4)	2 (4.7)	1 (2.2)	
Private	29 (32.6)	13 (30.2)	16 (34.8)	
Smoking				0.99
Current smoker	18 (19.8)	9 (20.0)	9 (19.6)	
Former smoker	40 (44.0)	20 (44.4)	20 (43.5)	
Never	33 (36.3)	16 (35.6)	17 (37.0)	
Body mass index (kg/m <sup>2</sup> )	35.2 ± 10.9	36.2 ± 11.7	34.2 ± 10.0	0.38
Type of Diabetes				0.63
Type 1	5 (5.5)	3 (6.7)	2 (4.3)	
Type 2	86 (94.5)	42 (93.3)	44 (95.7)	
Diabetes duration, years	15.1 ± 10.0	13.6 ± 8.5	16.6 ± 11.2	0.16
A1c at admission	8.7 [7.1-10.6]	8.9 [7.2-11.1]	8.5 [7.1-10.0]	0.26
A1c at admission >7.0% (53 mmol/mol)	69 (76.7)	34 (77.3)	35 (76.1)	0.89
Preadmission Home Medication Route				0.08
Insulin only	52 (57.1)	27 (60.0)	25 (54.3)	
No medications	7 (7.7)	1 (2.2)	6 (13.0)	
Oral & insulin	19 (20.9)	13 (28.9)	6 (13.0)	

Variable	All Patients N=91	Intervention N=45	Usual care N=46	P value
Oral only	11 (12.1)	3 (6.7)	8 (17.4)	
Other	2 (2.2)	1 (2.2)	1 (2.2)	
Preadmission sulfonylurea use	8 (8.8)	3 (6.7)	5 (10.9)	0.48
Preadmission metformin use	19 (20.9)	9 (20.0)	10 (21.7)	0.84
Preadmission insulin use	73 (80.2)	42 (93.3)	31 (67.4)	0.002
Preadmission statin use	64 (70.3)	28 (62.2)	36 (78.3)	0.09
Preadmission glucocorticoid use	18 (19.8)	8 (17.8)	10 (21.7)	0.64
Preadmission blood pressure medications				0.06
None	14 (15.4)	9 (20.0)	5 (10.9)	
ACE-i or ARB and Non-ACE/ARB	25 (27.5)	13 (28.9)	12 (26.1)	
Only ACE-i or ARB	23 (25.3)	6 (13.3)	17 (37.0)	
Only non-ACE or ARB	29 (31.9)	17 (37.8)	12 (26.1)	
History of severe hypoglycemia	34 (37.8)	17 (37.8)	17 (37.8)	1.00
Current or prior DKA or HHS	9 (9.9)	5 (11.1)	4 (8.7)	0.70
Microvascular complications				0.69
0	35 (38.5)	15 (33.3)	20 (43.5)	
1	35 (38.5)	20 (44.4)	15 (32.6)	
2	15 (16.5)	7 (15.6)	8 (17.4)	
3	6 (6.6)	3 (6.7)	3 (6.5)	
Macrovascular complications				0.69
0	25 (27.5)	13 (28.9)	12 (26.1)	
1	38 (41.8)	20 (44.4)	18 (39.1)	
2	21 (23.1)	9 (20.0)	12 (26.1)	
3	6 (6.6)	2 (4.4)	4 (8.7)	
4	1 (1.1)	1 (2.2)	0 (0.0)	
Anemia diagnosis	62 (68.1)	33 (73.3)	29 (63.0)	0.29
Discharged within 90 days before index admission	81 (89.0)	45 (100.0)	36 (78.3)	<0.001
ED visit within 90 days before index admission	24 (30.4)	10 (26.3)	14 (34.1)	0.45
Admission priority				1.00
Emergent	75 (82.4)	37 (82.2)	38 (82.6)	
Planned	4 (4.4)	2 (4.4)	2 (4.3)	
Urgent	12 (13.2)	6 (13.3)	6 (13.0)	
Home zip code within 5 miles of hospital	78 (85.7)	40 (88.9)	38 (82.6)	0.39
Discharge status				0.69
Against medical advice	1 (1.1)	0 (0.0)	1 (2.2)	
Home with nursing care	28 (30.8)	14 (31.1)	14 (30.4)	
Home without additional services	56 (61.5)	29 (64.4)	27 (58.7)	
Subacute facility (rehabilitation or skilled	5 (5.5)	2 (4.4)	3 (6.5)	
No discharge within prior year	1 (1.1)	0 (0.0)	1 (2.2)	
Predicted risk of readmission within 30 days, %	38.4 ± 7.6	39.2 ± 7.8	37.5 ± 7.5	0.28
Admission blood glucose, mmol/L	208.1 ± 107.7	188.7 ± 95.6	227.1 ± 116.4	0.10
Admission serum sodium, mmol/L	136.0 ± 4.9	136.3 ± 4.9	135.7 ± 5.0	0.54
Admission serum potassium, mmol/L	4.3 ± 0.8	4.3 ± 0.9	4.2 ± 0.7	0.91
Admission serum creatinine, mg/dL	1.7 [1.1-3.2]	2.0 [1.1-3.2]	1.5 [1.1-3.2]	0.91
Admission eGFR, mL/min	39.8 ± 20.6	39.8 ± 20.5	39.8 ± 20.9	0.99

Variable	All Patients N=91	Intervention N=45	Usual care N=46	P value
Admission hematocrit, %				0.08
High	2 (2.2)	2 (4.4)	0 (0.0)	
Low	69 (75.8)	30 (66.7)	39 (84.8)	
Normal	20 (22.0)	13 (28.9)	7 (15.2)	
Brief Health Literacy Screen Score	11.9 ± 2.9	12.3 ± 3.0	11.6 ± 2.7	0.26
PHQ-2 Score	1.0 [0.0-2.0]	1.0 [0.0-2.0]	2.0 [1.0-3.0]	0.013
Diabetes Knowledge Test Score	57.3 ± 15.6	59.1 ± 15.7	55.5 ± 15.5	0.28
Problem Areas in Diabetes Score	30.6 ± 24.3	36.3 ± 25.1	25.1 ± 22.4	0.028
Predicted risk of readmission within 30 days, %*	38.4 ± 7.6	39.2 ± 7.8	37.5 ± 7.5	0.28

Values are mean ± SD, median [IQR], or n (%) unless otherwise stated. \*Predicted risk based on Diabetes Early Readmission Risk Indicator (DERRI™).

IQR (interquartile range), ACE-i (angiotensin-converting enzyme inhibitors), ARB (angiotensin II receptor blockers), DKA (diabetic ketoacidosis), HHS (hyperosmolar hyperglycemic state), eGFR (estimated glomerular filtration rate), PHQ (patient health questionnaire)

### 3.3. Outcomes

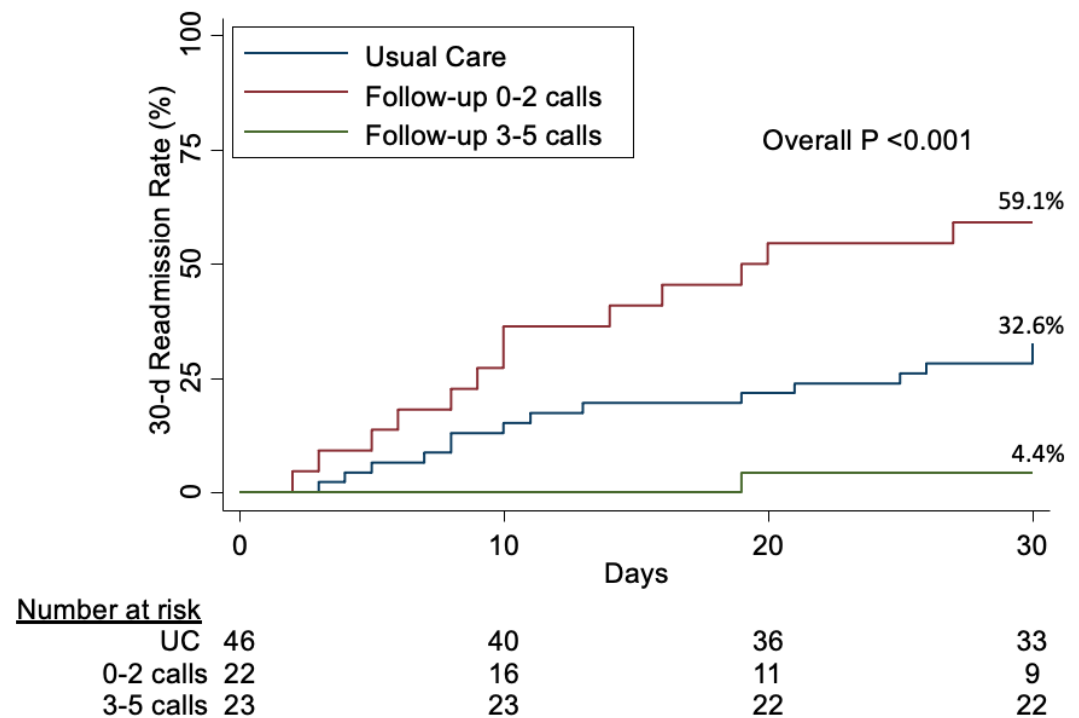
The 30-day readmission rate was 31.1% in the Intervention group and 32.6% in the UC group (p=0.88, Table 2). Time to readmission varied significantly by number of follow-up navigator calls completed (Figure 2). Among Intervention patients who completed 3-5 follow-up calls, only one patient (4.3%) was readmitted, whereas 13 (59.1%) of Intervention patients who completed <3 follow-up calls were readmitted (p<0.001). Adjusted for baseline differences, completing 3-5 follow-up calls was associated with significantly lower risk of readmission relative to UC (HR 0.12, 95%CI [0.02–0.98], p=0.048). There were no significant differences in secondary outcomes except costs, which were lower in the Intervention group.



**Table 2.** Outcomes in Intervention and Usual care groups.

<b><u>Intention-to-treat cohort</u></b>				
Variable <sup>a</sup>	All Patients N=91	Intervention N=45	Usual care N=46	P value
Readmission	29 (31.9)	14 (31.1)	15 (32.6)	0.88
ED visit	8 (8.8)	4 (8.9)	4 (8.7)	0.97
Readmission or ED visit	34 (37.4)	16 (35.6)	18 (39.1)	0.72
Costs, USD	--	5,542 ± 10,970	6,657 ± 16,969	--
Costs, USD	--	172 [127-5,546]	0 [0-5,667]	--
Costs, Intervention:Usual Care ratio (95%CI)		0.33 (0.13-0.79)		0.01
Hypoglycemia				
-Blood glucose <70 mg/dL	--	5 (11)	--	--
-Blood glucose <54 mg/dL	--	2 (4)	--	--
-Blood glucose <40 mg/dL	--	1 (2)	--	--
Number of daily SMBG tests	2.1 ± 1.5	2.4 ± 1.6	1.8 ± 1.4	0.12
Change in HbA1c at 3 months, %	-0.9 [-1.6-0.2]	-1.0 [-1.6-0.2]	-0.9 [-1.4-0.2]	0.78
Change in HbA1c at 3 months, mmol/mol	-10 [-18-2]	-11 [-18-2]	-10 [-15-2]	0.78
<b><u>Subgroup with baseline HbA1c &gt;7.0%</u></b>				
	All Patients N=69	Intervention N=34	Usual Care N=35	P value
Readmission	19 (27.5)	8 (23.5)	11 (31.4)	0.46
ED visit	7 (10.1)	3 (8.8)	4 (11.4)	0.72
Readmission or ED visit	23 (33.3)	9 (26.5)	14 (40.0)	0.23
Costs, USD	--	3,657 ± 8,230	6,967 ± 18,863	--
Costs, USD	--	154 [126-1,246]	0 [0-5,661]	--
Costs, Intervention:Usual Care ratio (95%CI)		0.21 (0.08-0.58)		0.002
Hypoglycemia				
-Blood glucose <70 mg/dL	--	5 (14.7)	--	--
-Blood glucose <54 mg/dL	--	2 (5.9)	--	--
-Blood glucose <40 mg/dL	--	1 (2.9)	--	--
Number of daily SMBG tests	2.2 ± 1.6	2.5 ± 1.6	2.0 ± 1.5	0.23
Change in HbA1c at 3 months, %	-1.0 [-2.2-0.0]	-1.1 [-2.2-0.0]	-0.9 [-2.3-0.1]	0.82
Change in HbA1c at 3 months, mmol/mol	-11 [-24-0]	-12 [-24-0]	-10 [-25-1]	0.82

Values are mean ± SD, median [IQR] or n (%) unless otherwise stated. IQR, interquartile range; CI, confidence interval. <sup>a</sup>Within the 30 days after hospital discharge. \*Costs of 30-day readmissions, ED visits, and the intervention. SMBG, self-monitored blood glucose.



**Figure 2.** Time to readmission in Intervention and Usual care (UC) groups stratified by number of follow-up calls completed by Intervention participants.

#### 3.4. Ancillary analysis

Among the 69 patients with baseline HbA1c >7.0% (53 mmol/mol), the 30-day readmission rate was 23.5% in the Intervention group and 31.4% in the (UC) group ( $p=0.46$ , Table 2). There were no significant differences in secondary outcomes except costs, which were lower in the Intervention group.

#### 4. Discussion

This pilot RCT shows the DiaTOHC intervention is feasible and suggests that the intervention may decrease readmission/ED visit risk among patients with a baseline HbA1c >7.0% (53 mmol/mol). In this subgroup, Intervention subjects experienced a non-significant 34% relative risk reduction in readmission/ED visit risk and absolute risk reduction of 13.5%. Furthermore, completing more follow-up calls was associated with an 88% lower risk of readmission in the ITT cohort. Although there was no difference in readmission/ED visit risk, frequency of SMBG testing, or HbA1c between study groups, costs were significantly lower in the Intervention group. Hypoglycemia during the intervention was uncommon, with 11% of Intervention participants reporting any SMBG <70 mg/dL. Other trials with similar HbA1c-based discharge treatment algorithms reported post-discharge hypoglycemia rates of 23-29% [11, 15].

Several mostly observational studies have investigated the effect of various interventions on readmission risk in diabetes patients [4], categorizable as inpatient diabetes education only, inpatient diabetes management by a dedicated service, and multi-component programs consisting of education, transition-of-care support, and/or outpatient follow-up. The relative risk reductions of these interventions vary considerably from zero to 71%, with most studies showing benefit.

The current study adds to the small number of related published RCTs with a novel approach: combining multi-component intervention with selection of high-risk patients using a validated tool. This pilot study, however, is limited by lacking power for detecting differences between groups for most of the outcomes. Because observation of the UC group was limited, we were unable to compare hypoglycemia rates or office visits

between groups. Given the nature of the Intervention, blinding was not feasible. Lastly, the findings may not generalize to other sites and other settings.

In conclusion, the non-significant but promising reduction in readmission/ED visit risk in the higher HbA1c subgroup merits further investigation in a larger, multi-center RCT.

**Supplementary Materials:** The following supporting information can be downloaded at: [www.mdpi.com/xxx/s1](http://www.mdpi.com/xxx/s1), Table S1: HbA1c-based adjustment of diabetes therapy; Table S2: Outpatient basal insulin dose adjustment; Table S3: Outpatient prandial/pre-meal insulin dose adjustment based on subsequent mealtime/HS BG values.

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