Improving Transplant Med Safety through a Pharmacist -Led, mHealth-Based Program

Principal Investigator: David J Taber, PharmD, MS, BCPS
Professor
Medical University of South Carolina
Department of Surgery
96 Jonathan Lucas Street; CSB HE426E
Charleston, SC 29425
Tele: 843 792 2724
Fax: 843 792 8596
Email: taberd@musc.edu

Team Members: James Fleming, PharmD; co-investigator
Mulugeta Gebregziabher, PhD; co-investigator
Frank Treiber, PhD; co-investigator
John McGillicuddy, MD; co-investigator
Zemin Su, MS; biostatistician
Morgan Overstreet, MS; study coordinator
Jason Hirsch, BS; study coordinator

Organization: Medical University of South Carolina
171 Ashely Avenue
Charleston, SC 29425

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Federal Project Officer: Emily Chew
Phone: (301) 427-1305
Email: emily.chew@ahrq.hhs.gov

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Abstract

Purpose: The goal of this study was to examine the efficacy of improving medication safety through a pharmacist-led, mobile health–based intervention.

Scope: Clinical trial.

Methods: This was a 12-month, single-center, prospective, parallel, two-arm, single-blind, randomized controlled trial. Adult kidney recipients 6–36 months post-transplant were eligible. Participants randomized to the intervention received supplemental clinical pharmacist–led medication therapy monitoring and management via a mobile health–based application, integrated with risk-guided televisits and home-based BP and glucose monitoring. The application provided an accurate medication regimen, timely reminders, and side effect surveys. Both the control and intervention arms received usual care.

Results: 136 were included. The mean age was 51 years, 57% were , and 64% were Black. Participants receiving the intervention experienced a significant reduction in medication errors (61% reduction in risk rate; incident risk ratio, 0.39; 95% confidence interval, 0.28 to 0.55; P, 0.001)and a significantly lower risk of Grade 3 or higher adverse events (incident risk ratio, 0.55, 95% confidence interval, 0.30 to 0.99; P 0.05). The intervention arm also demonstrated significantly lower rates of hospitalizations (incident risk ratio, 0.46; 95% confidence interval, 0.27 to 0.77; P 0.005) and lower healthcare costs.

Keywords: Kidney Transplant, Medication Safety, Hospitalizations, mHealth, Pharmacist Interventions

high acceptability of mobile health (mHealth) technology to bridge communication gaps that often lead to med safety issues. Our transplant recipients have doubled smartphone use to over 60% from 2012 to 2015. Almost 90% of survey respondents indicated t K D W Whey were comfortable with mHealth monitoring and felt W K D W it improved patient-provider communication. Transplant recipients were central to successful development of a mHealth medical regimen self-management program which the proposed program builds upon. These data establish that a pharmacist-empowered, patient-centered, mHealth-based intervention provides an innovative and promising opportunity to improve med safety in kidney transplantation. Our mHealth programs and that of others have been successful in improving physical markers for various chronic diseases, including those present in transplant recipients (e.g. BP for hypertension); however, costeffectiveness of these efforts have yet to be adequately demonstrated.

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H O L J L E O H I R U the study. Multiorgan recipients were excluded, as were patients incapable of measuring their own BP and blood glucose (if applicable) self-administering medications; speaking, hearing, and reading English; or utilizing the mobile health application (app) after sufficient training. Patients who were eligible and agreed to study participation were consented and randomized by research personnel using a random number generator in a simple blocked manner (blocks of eight) into one of the two study arms. Only study coordinators and clinical pharmacists assessing medication errors, AEs, and clinical outcomes were blinded to study assignment.

Intervention

Participants randomized to the intervention arm were provided the same usual care as the control cohort. As part of usual care, kidney transplant recipients are seen by pharmacists while in the hospital and during routine clinic visits for the first 6 months post-transplant. After this, pharmacists see patients only when requested by a provider for medication-related issues. In addition to usual care, the intervention group received clinical pharmacist–led supplemental medication therapy monitoring and management utilizing a smartphone-enabled mobile health app, integrated with risk-driven televisits and home-based BP and blood glucose monitoring (when applicable). The mobile health app, developed by our group, provided participants with an accurate list of their medication regimen W K D W was automatically updated from the elec- tronic medical record (EMR), timely medication reminders, automated messages triggered by missed doses or scheduled health monitoring, medication side effect tracking, and BP and blood glucose trends (when applicable). Monthly and subject-initiated surveys were delivered through the app regarding the frequency and severity of common side effects. The intervention included clinical pharmacist telemonitoring of medications, medical appointment adherence, weekly BP/ Jucose readings, and scheduling R I telehealth visits with participants. The clinical pharmacist was notified of any medication changes

' D W D R Q P H G L F D W L R Q H U U R U Vwere collected by clinical study coordinators and clinical pharmacists who did not have access to the randomization module within the electronic case report form system

7 Z participants withdrew from the study intervention arm before completing the study for a 99% retention rate; both participants are included in this intent-to-treat analysis.

Baseline characteristics were mostly comparable between the two study arms. The mean age was 51 years, 57% of participants were P H Q, and 64% were Black individuals. The primary etiologies of kidney failure were diabetes and hypertension, followed by polycystic kidney disease and lupus. History of hypertension was similar between groups however, 52% of participants in the control group had a history of diabetes compared with 28% in the intervention group. On average, participants spent 4 years on dialysis, and 84% of participants were on dialysis at the time of transplant. More participants in the intervention group experienced delayed graft function compared with the control group (27% versus 13%). In the intervention group, 27% had donor-positive, recipient-negative CMV serostatus (high risk) versus 12% in the control group. The 6-month ambulatory procedure history, hospitalization history, and mean number of clinic visits were comparable between groups.

All 68 participants in both arms experienced at least one medication error during the study. There were 904 separate assessments in the 136 participants over the 12-month study (of the 952 potential assessments, 48 were missed 95% completion rate). In total, there were 1385 medication errors in the control arm (mean 20.4±14.0) and 614 in the intervention arm (mean 9.0±5.9), leading to a 56% reduction in medication errors in the treatment arm. In the multivariable model, total adjusted medication errors were reduced by an average of 0.11 per month in the intervention arm (95% confidence interval [95% CI], 0.05 to 0.17; P<0.001) compared with the control arm, leading to a 61% reduction in the risk rate of medication errors over the 12-month study (incident risk ratio [IRR], 0.39; 95% CI, 0.28 to 0.55; P<0.001). Common administrative errors included omissions, additions, and prescribing errors. Clinical errors were largely due to non- or undertreated conditions, primarily electrolyte abnormalities. Using the Overhage criteria, most medication errors were categorized as significant but ranged from minor to serious.

All study participants in the treatment and control arms reported at least one AE. Rates of Jrade 1 and Jrade 2 AEs were comparable between treatment arms. Participants in the intervention arm experienced numencsmtere 1lstudyate J

important to recognize W K D W all mobile health apps are not created equal. Many existing platforms are narrowly focused on adherence unidirectionally with patients and fail to incorporate clinicians; we believe this inhibits the development of a partnership between patients and clinicians that is a central theory behind the potential effectiveness of mobile health. Future research should focus on comparing mobile health apps, such as