Submission Id: 5451

Title

Collaboration Oriented Application to Controlling High blood pressure (COACH) Multisite Pragmatic Trial Design and Evaluation

Priority 1 (Research Category)

Hypertension

Presenters

Richelle Koopman, MD, MS, Elise Russo, MPH, Parijat Ghosh, PhD, Shannon Canfield, PhD, MPH, David Dorr, MD, MS, Aisha Ghumman, MPH, Abigail Rolbiecki, PhD, MPH, MSW, Victoria Shaffer, PhD, Blake Johnson, JD, MBA

Abstract

Context: 40% of diagnosed hypertension in the United States is uncontrolled, creating excess risk for cardiovascular morbidity and mortality. COACH is an innovative patient-facing blood pressure (BP) control decision support system that includes reporting, data visualization, and analysis of both clinic and home BP data, as well as lifestyle risk-reduction goal setting. COACH is a modular app using Fast Healthcare Interoperability Resources (FHIR), facilitating implementation across EHR vendor platforms. COACH is accessed via the EHR or patient portal via desktop, tablet, or mobile devices. Objective: Create a protocol for a highly pragmatic trial of COACH decision support system in the EHR/patient portal for patient and clinician shared management of hypertension. Study Design: Pragmatic multi-site randomized trial, intent-to-treat analysis. Setting: Family Medicine and General Internal Medicine practices at 3 US academic health centers in Tennessee, Missouri, and Oregon, and across the 2 largest US EHR platforms. Population Studied: 550 non-pregnant adults with uncontrolled hypertension who are patient portal users at one of the 3 study sites. Intervention: COACH app with messaging informed by behavioral economics principles and integration of home BP data into patient and clinician workflow vs. control condition of home BP monitoring and recording without reminders. Outcome Measures: Informed by RE-AIM framework and assessment with the PRECIS-2 instrument. Primary: proportion with controlled BP at 6 months. Secondary: absolute change in BP, days to BP control, number of home BPs entered, messages to care team, episodes of hypotension, patient engagement with app, emergency visits, hospitalizations. Pragmatic trial assessed with the PRECIS-2 instrument. Results: PRECIS-2 assessment of the degree of pragmatic approach in the COACH trial protocol reveals scores of 4/5 for pragmatism in 4/9 domains and 5/5 in the other 5 domains. Results indicate sufficient clinical staffing for implementing COACH due to flexible delivery protocols. While the “digital divide” is ever shrinking, digital interventions retain the limitation of excluding those who do not have the digital literacy to access them; COACH mitigates this limitation with accessibility via a range of devices including mobile

phones. Conclusions: The COACH trial is designed to be highly pragmatic with the goal that results will translate well to clinical practice, increasing scalability and impact.