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The E-Coach transition support computer telephony implementation study: Protocol of a randomized trial

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ABSTRACT

Background: Patients requiring complex care are at high risk during the transition from one setting of care to another. Effective interventions to support care transitions have been designed but are very resource intensive. Telemonitoring has been considered as an approach to enhance care transition support, but many telemonitoring systems require special equipment or web-based interfaces to interact with patients and caregivers.
Methods/design: In this paper we report our protocol for developing and testing E-Coach, an interactive voice response (IVR)-enhanced care transition intervention that monitors patients at home using their personal phone. The elements described include 1) development of an IVR monitoring system that will be based on Coleman's four pillars of care transition support; 2) development of a web-based "dashboard" of IVR responses that alert care transition nurses (CTN) of patient/caregiver concerns after discharge and allow documentation by the CTN when patients/caregivers are called; 3) pilot testing of the IVR system by patients and providers with refinement of the system based on patient/provider input; and 4) a pragmatic protocol for formal testing through a randomized controlled trial (RCT) of the E-Coach intervention in congestive heart failure (CHF) and chronic obstructive pulmonary disease (COPD) patients admitted to a large tertiary hospital.
Trial Registration: CT.gov#: NCT01135381.

1. Introduction

Patients with complex care needs experience increased vulnerability when transitioning from one setting of care to another. In particular, the transition from the hospital setting to home places complex patients in jeopardy of adverse events and increases their risk for loss of community tenure. Approximately 20% of recently discharged patients experience adverse events, [1,2] often precipitated by ineffective communication. Among over 15,000 hospitalized patients, 11.9% reported new or worsening symptoms within 3 to 5 days of leaving the hospital [3]. One-quarter of post-hospitalization Medicare beneficiaries experienced one or more transfers from lower- to higher-intensity care environments within the first 30 days post-discharge meeting the definition of a complicated care transition. Eight percent of these care transitions resulted in death during the 30-day post hospitalization time period [4].

Interventions have been tested to improve care transitions for complex hospitalized patients. Coleman and colleagues

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designed the Care Transitions Model based on focus groups demonstrating gaps in 4 domains at discharge: 1) medication self-management, 2) lack of a patient-centered health record owned and maintained by the patient to facilitate cross-site information transfer, 3) inconsistent follow-up with primary or specialty care, and 4) lack of knowledge by the patient or caregiver regarding warning signs and symptoms indicative of a worsening condition and instructions on how to respond to them. Coleman's intervention was coordinated by a transition nurse coach and included an in-hospital meeting with the patient prior to discharge, then patient follow-up, first by home visit and then by telephone 3 times during a 28-day post hospitalization discharge period. In a randomized controlled trial, the intervention reduced rehospitalization rates by 30% and 26% at 30 and 90 days respectively. Although the intervention reduced hospital costs compared to the control ($2058 vs. $2546), the intervention required intensive resource allocation, due to the requirement that the transition coach make home visits and proactive phone calls, and therefore could only take care of 24 to 28 patients at any given time [6].

Interactive voice response (IVR) systems allow interaction between patients and databases using a standard telephone. IVR systems can obtain information from patients and deliver recorded telephone messages, instructions, reminders, or tailored education. IVR systems have the distinct advantage of being accessible around the clock without geographic restriction [5,7,8]. IVR systems have been extensively studied for monitoring of chronic conditions and to support health behavior change [5]. Despite the flexibility of this technology, use of IVR to support health care transitions remains relatively underdeveloped [9]. Using the core elements of the Care Transition Model, we developed the "E-Coach" interactive voice response (IVR) system, an IVR-enhanced coaching and monitoring program. We chose this model because it utilizes the telephone, a means of communication more ubiquitous than the Internet that is not limited by geographic distance. Further, the use of this system facilitated efficient use of care transition nurse resources, because it gathered relevant clinical information to prompt transition nurses to call only those patients with concerns and need for transitional support, while providing a mechanism to monitor patients who are doing well without necessitating a personal follow-up call.

In this report we present the general study protocol for E-Coach, a pragmatic clinical trial. We also present preliminary data from pilot testing of the system and subsequent system refinements. This trial is pragmatic in several aspects, including a strong partnering and co-funding relationship with our collaborating Health Care System. In light of recent interest in pragmatic trials from the NIH Director's office, we focus on the pragmatic aspects of our study using the pragmatic–explanatory continuum indicator summary (PRECIS) [10] tools to visually demonstrate where we view this protocol on the continuum.

2. Methods/design

2.1. Study design

E-Coach is a multi-phase study that includes 1) development of an IVR monitoring system that is based on Coleman's four pillars of care transition support; 2) development of a web-based "dashboard" for care transition nurses, with alerts of patient/caregiver concerns after discharge; 3) pilot testing of the IVR system by patients and providers with refinement of the system based on patient/provider input; and 4) formal testing through a randomized controlled trial (RCT) of the E-Coach intervention in congestive heart failure (CHF) and chronic obstructive pulmonary disease (COPD) patients admitted to a large tertiary hospital.

This study is designed as a pragmatic trial, and in that vein, is co-supported by the hospital which employs the care transition nurse during the RCT phase of the study. Specifically, the IVR system is developed with research funds, but the web-based "dashboard" for nurses is developed by the Health Care System with operational dollars. The care transition nurses are funded by the Health Care System and we have provided them additional training in care transition support. Thus, our funding from AHRQ was targeted solely to the development and testing of the IVR computer telephony system, the integration of the IVR with the dashboard developed by the clinical system, and the rigorous data collection described in our study protocol.

2.2. Development of an IVR monitoring system

The E-Coach IVR system is designed to actively call patients at multiple intervals after discharge. In a stepped-care approach, the IVR system is monitored by a care transition nurse who reviews IVR-collected data via the dashboard and supports patient self-management through telephone-based health coaching when needed, up to 2 months (60 days) after discharge.

The E-Coach IVR is designed to perform three primary functions: 1) collect data from patients, 2) alert the care transition nurse about possible patient warning signs, and 3) provide ongoing patient education and motivation during the IVR calls. The IVR is programmed with a brief questionnaire assessing patient symptoms, issues with medications, maintenance of a personal health record, and issues with scheduling follow-up care. Patient-entered IVR data generate "red flags" notifying the care transition nurse to contact the patient to offer additional support. IVR calls are designed to have a typical duration of less than 5 min, but could last longer, depending on the user's responses. IVR calls occur daily for the first 7 days; after which participants are given the options to continue with daily calls or to receive a call every 3 days for a total of 28 calls (Fig. 1).

IVR development has occurred in partnership with the hospital Health System Information Services (HSIS), which is responsible for the operational clinical and administrative systems to support patient care. We have worked collaboratively with programmers in the HSIS department to develop the IVR and link it securely to a system-compatible dashboard (see below). We built an accessible user interface for the IVR (using TeleSage SmartQ™) that begins with a simple root menu of the primary system functions and then includes branching logic based on patient responses. We have developed and recorded a voice bank of recorded messages and queries comprising the IVR content. We conducted extensive usability testing using "best practices" for script design, development, and piloting as described by Abu-Hasaballah and colleagues [11].