



CREATE Wellness: A multi-component behavioral intervention for patients not responding to traditional Cardiovascular disease management



Chris Miller-Rosales^a, Stacy A. Sterling^b, Sabrina B. Wood^b, Thekla Ross^b, Mojdeh Makki^b, Cindy Zamudio^b, Irene M. Kane^b, Megan C. Richardson^b, Claudia Samayoa^b, Nancy Charvat-Aguilar^b, Wendy Y. Lu^b, Michelle Vo^b, Kimberly Whelan^b, Connie S. Uratsu^b, Richard W. Grant^{b,*}

^a University of California at Berkeley, Berkeley, CA, USA

^b Division of Research, Kaiser Permanente, Oakland, CA, USA

ARTICLE INFO

Keywords:

Patient-centered
Intervention research
Stakeholder engagement research

ABSTRACT

Background/Aims: Cardiovascular disease (CVD) is the leading cause of death in the US. Many patients do not benefit from traditional disease management approaches to CVD risk reduction. Here we describe the rationale, development, and implementation of a multi-component behavioral intervention targeting patients who have persistently not met goals of CVD risk factor control.

Methods: Informed by published evidence, relevant theoretical frameworks, stakeholder advice, and patient input, we developed a group-based intervention (Changing Results: Engage and Activate to Enhance Wellness; “CREATE Wellness”) to address the complex needs of patients with elevated or unmeasured CVD-related risk factors. We are testing this intervention in a randomized trial among patients with persistent (i.e. > 2 years) sub-optimal risk factor control despite being enrolled in an advanced and highly successful CVD disease management program.

Results: The CREATE Wellness intervention is designed as a 3 session, group-based intervention combining proven elements of patient activation, health system engagement skills training, shared decision making, care planning, and identification of lifestyle change barriers. Our key learnings in designing the intervention included the value of multi-level stakeholder input and the importance of pragmatic skills training to address barriers to care.

Conclusions: The CREATE Wellness intervention represents an evidence-based, patient-centered approach for patients not responding to traditional disease management. The trial is currently underway at three medical facilities within Kaiser Permanente Northern California and next steps include an evaluation of efficacy, adaptation for non-English speaking patient populations, and modification of the curriculum for web- or phone-based versions.

ClinicalTrials.gov Identifier: NCT02302612.

1. Introduction

Cardiovascular disease (CVD) represents an enormous burden of disease in the US, accounting for one-third of U.S. deaths per year [1]. With improved survival rates, there are now over 80 million Americans living with CVD [2]. Diagnosis and treatment of modifiable CVD risk factors such as hypertension and hyperlipidemia represent one of the major successes in the effort to reduce CVD-related morbidity and mortality in the US [3]. Despite promising trends, however, the majority of patients with CVD still do not reach evidence-based risk

reduction goals [4]. New primary care delivery strategies are therefore needed to ensure more effective implementation of evidence-based CVD risk reduction therapies.

Disease management programs have been widely implemented for common conditions such as hypertension, diabetes, and heart failure [5–7]. These programs generally include tools such as population-level screening, laboratory result monitoring, telephone-based outreach by nurses, and disease-specific medication titration protocols to achieve evidence-based and disease-specific clinical goals. While often successful for single conditions or inter-related risk factors, traditional

* Corresponding author. Present address: Kaiser Permanente, Division of Research 2000 Broadway, Oakland, CA, 94612, USA.
E-mail address: Richard.W.Grant@kp.org (R.W. Grant).

<http://dx.doi.org/10.1016/j.conctc.2017.10.001>

Received 5 July 2017; Received in revised form 15 September 2017; Accepted 2 October 2017

Available online 04 October 2017

2451-8654/ © 2017 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).

disease management has often not been sufficient for patients with health issues and care barriers that extend beyond a narrow disease-specific focus [8].

Management of CVD risk factors is complicated by the increasingly high prevalence of concurrent comorbid diagnoses [9]. Among Medicare beneficiaries, for example, 40% suffer from at least 3 chronic comorbid conditions and over 20% have more than 4 conditions [10]. Multiple comorbidity does not necessarily preclude effective CVD risk reduction, but within the CVD patient population there exists a subset of patients with characteristics (e.g. lower patient activation and engagement with health care, lower levels of motivation) and/or mental health comorbidities (e.g. depression, anxiety, alcohol misuse) that may present modifiable barriers to effective care.

Further progress in CVD risk factor control in these patients with complex conditions will require new approaches to care. We hypothesized that a coordinated behavioral approach designed to address common underlying barriers and to provide patients with self-management skills and techniques applicable across multiple different chronic diseases would result in better CVD outcomes compared to usual care. In this paper, we describe the rationale, development, and implementation of an evidence-based, patient-centered behavioral intervention targeting patients within a CVD disease management program who have persistently not met goals of CVD risk factor control.

2. Material and methods

2.1. Setting

Kaiser Permanente Northern California (KPNC) is an integrated health care delivery system serving more than 4.1 million members. The membership is demographically and socioeconomically diverse [11] and includes more than 350,000 members with CVD risk factors (e.g., hypertension, elevated lipids, poor glycemic control). These patients are automatically enrolled in the successful Preventing Heart Attacks and Strokes Everyday (PHASE) program, a robust, population-based CVD management program implemented in 2005. Key features of PHASE include a continuously updated CVD registry, provider performance feedback, system-wide efficiencies, population management, and evidence-based practice guidelines. Although approach has produced impressive population-level benefits [12], approximately 15% of patients remain persistently uncontrolled over time and are the focus of this intervention.

2.2. Conceptual models for intervention

We hypothesized that patients failing traditional disease management may require a multi-component intervention focused on patient self-care knowledge, skills, and confidence, rather than additional disease-specific education or treatment. We therefore sought to create an integrated program designed to activate core patient self-management skills and to introduce self-management strategies for overcoming barriers to care. Based on a scoping review of the literature, we identified four areas of opportunity for supporting patients who are failing traditional disease management. These domains were identified based on evidence of clinical impact among complex patients. Below we describe each of these domains and provide key citations that support their relevance to our intervention development goals.

Increasing Patient Activation Levels: Patient activation is defined as understanding one's role in the care process and having the knowledge, skill and confidence to manage one's health and health care [13]. As patients become more "activated," they build their capacity to take greater responsibility for achieving health-related goals [14–16]. Patient activation can be reliably measured across adult age ranges and racial/ethnic groups using the Patient Activation Measure (PAM), a 13-item questionnaire that correlates with health outcomes and self-management behaviors including medication adherence [17]. Patients with

lower PAM scores are more likely to miss appointments, report lower confidence and knowledge, and apply fewer strategies for problem solving [18]. Interventions based on shared decision making, group learning and motivational interviewing (MI) have successfully raised PAM scores [19,20], and randomized trials have shown that interventions designed specifically to increase PAM scores result in better clinical outcomes, such as increased minutes of walking among older adults [21] and decreased heart failure hospitalization rates [22].

Improving Patient Engagement/System Navigation Skills: Patient engagement is defined as the actions individuals must take to obtain the greatest benefit from the health care services available to them [23]. Because "activated" patients must still find ways to successfully navigate an often convoluted medical system, pragmatic skills training is an essential component to overcoming barriers to care. Prior work has demonstrated the value of training in system navigation (e.g. use of electronic patient portals to communicate with providers) [24] and in problem-solving (e.g. disease-specific education about how to manage home data, symptoms, and side effects; and more general training in how to communicate with providers and to prioritize for decision-making) [25–28].

Screening for Behavioral Risk: Among patients with poor disease control, factors such as risky alcohol use, depressed or anxious mood, sedentary lifestyle and poor diet are prevalent, detrimental, and yet often clinically under-recognized [29]. Because of the challenges to effective health care navigation posed by co-occurring mental health and substance use problems, interventions to activate and engage patients with complex conditions should include activities designed to help identify and address these concerns. Prior work has demonstrated the feasibility and effectiveness of comprehensive screening for clinically unrecognized and untreated behaviors that can undermine attempts to manage complex clinical conditions [30]. Moreover, while more severe behavioral health disorders (e.g. chemical dependency, major depression) identified through screening will require specialty referral, mild or moderate mental health symptoms and substance use can often be effectively addressed through brief group counseling and motivational interviewing [31–33].

Care Planning: One challenge of designing interventions for patients with complex conditions is that while there are clear commonalities in the experience of chronic disease self-management that transcend specific diagnoses, each patient nonetheless presents a unique history of barriers, strengths, preferences, knowledge, skills and goals. Priority-setting through shared decision making can make subsequent clinical encounters more efficient and productive by focusing clinical efforts on the most amenable targets [34–36]. For patients with complex medical comorbidities, a key benefit of this approach is the ability to collaboratively establish a care plan suited to the patient's level of self-management activation [37,38]. Matching intervention activities to the patient's level of activation can have lasting impacts on accomplishing and maintaining overall health goals. For example, creating a care plan which builds on the patient's own skills, strengths and preferences can translate the general benefits of interventions into specific actionable goals that each patient can share with his or her care team.

We created an intervention program that combines elements of these four proven, evidence-based domains. The resulting intervention is designed to augment rather than replace the existing disease management program (Fig. 1). To date there have been no published randomized trials of patient-centered interventions that integrate all four of these components into an intervention for patients with complex conditions not meeting care goals.

2.3. Study design considerations

We chose a pragmatic, parallel group, randomized controlled trial design to test our intervention. In keeping with our pragmatic framework, patients randomized to control arm will continue to receive usual care, including the established PHASE disease management program,

Download English Version:

<https://daneshyari.com/en/article/5549630>

Download Persian Version:

<https://daneshyari.com/article/5549630>

[Daneshyari.com](https://daneshyari.com)