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Design and methods of "diaBEAT-it!": A hybrid preference/randomized control trial design using the RE-AIM framework

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ABSTRACT

Background: Diabetes prevention is a public health priority that is dependent upon the reach, effectiveness, and cost of intervention strategies. However, understanding each of these outcomes within the context of randomized controlled trials is problematic.
Purpose: To describe the methods and design of a hybrid preference/randomized control trial using the RE-AIM framework.
Methods: The trial, which was developed using the RE-AIM framework, will contrast the effects of 3 interventions: (1) a standard care, small group, diabetes prevention education class (SG), (2) the small group intervention plus 12 months of interactive voice response telephone follow-up (SG–IVR), and (3) a DVD version of the small group intervention with the same IVR follow-up (DVD–IVR). Each intervention includes personal action planning with a focus on key elements of the lifestyle intervention from the Diabetes Prevention Program (DPP). Adult patients at risk for diabetes will be randomly assigned to either choice or RCT. Those assigned to choice (n = 240) will have the opportunity to choose between SG–IVR and DVD–IVR. Those assigned to RCT group (n = 360) will be randomly assigned to SG, SG–IVR, or DVD–IRV. Assessment of primary (weight loss, reach, & cost) and secondary (physical activity, & dietary intake) outcomes will occur at baseline, 6, 12, and 18 months.
Conclusion: This will be the first diabetes prevention trial that will allow the research team to determine the relationships between reach, effectiveness, and cost of different interventions.

1. Introduction

The prevention of Type 2 diabetes is a public health priority due to its prevalence, negative influence on health, and lack of a known cure [1]. The results of the Diabetes Prevention Program (DPP) indicated that modest weight loss achieved through diet and exercise was effective in delaying the onset of Type 2 diabetes [2]. Given the potential public health impact of DPP a number of efforts have been made to translate the lifestyle intervention into practice. A recent

Abbreviations: RE-AIM, reach effectiveness adoption implementation maintenance; PA, physical activity.

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review reported on 28 effectiveness trials based on the DPP lifestyle intervention or its principals [3]. On average, across healthcare or community setting and whether delivered by health professionals, lay leaders, or interactive technology, these interventions were able to facilitate a similar percent reduction in body weight as the original DPP [3].

While the findings from these trials are promising and certainly speak towards the potential for diabetes prevention activities to be effective in community and clinical practice, there is a paucity of information on other key factors necessary to determine if these interventions can truly be translated into practice [4]. Specifically, Glasgow and colleagues suggested that when planning and evaluating lifestyle interventions, the translation of research evidence into practice will be better informed by assessing information across a number of outcomes represented by the RE-AIM framework [5]. This includes reporting on **r**each, **e**ffectiveness, and **m**aintenance of effects at the individual level and **a**doption, **i**mplementation and **m**aintained delivery at the organizational level. Similarly, Abrams and colleagues proposed that to understand the overall impact of evidence-based strategies, two factors are critical to the overall impact on the target population—reach and effectiveness [6]. Specifically, if an effective intervention cannot reach a significant and representative proportion of the target population it will have limited impact. The evidence that key elements of the DPP lifestyle intervention can be successfully applied in multiple community and clinical settings is extremely promising, but to date there is a lack of literature related to the reach of diabetes prevention strategies beyond simply reporting on the number of participants or a participation rate based on an inconsistent denominator [4]. In fact, the calculation of actual reach is never possible within the traditional RCT designs where participants must consent to being randomized to one of the available conditions. As such, innovative designs that allow researchers to investigate both reach and effectiveness of diabetes prevention programs are needed.

Applications of the RE-AIM framework also recommend understanding the costs of intervention delivery in terms of reach and effectiveness [7]. To date, determining the cost-effectiveness of diabetes prevention has been tied solely to information gleaned from the outcomes of the DPP trial [8–11]. In nearly every case, translational diabetes prevention trials in the United States were adapted to reflect the DPP key elements using a lower frequency of sessions (e.g., 11 to 16 sessions), typically delivered to groups rather than to individuals [12–20]. These adaptations are made as a method to reduce intervention costs, but only three studies reported cost explicitly and those that do have simply reported on the cost of the intervention rather than on cost-effectiveness in achieving outcomes [13,18,21]. Studies that determine the relationships between reach, effectiveness and cost of diabetes prevention programs delivered in typical clinical or community settings are needed.

2. Primary research goals

The diaBEAT-it! project used the RE-AIM framework to plan potential interventions that had the potential to: (1) reach a high proportion of patients at risk for Type 2 diabetes, (2) effectively support patients to reduce body weight by 5%, (3) be scalable in order to improve potential adoption across healthcare settings, (4) be implemented at a reasonable cost, and (5) lead to weight loss maintenance and be sustained in typical healthcare settings. Based on this five-fold focus we developed two potentially scalable interventions that could, after appropriate testing, be broadly adopted, easily implemented, and sustained in typical healthcare settings. Both interventions are 12 months in duration and include a live call to assist participants in initiating changes and 22 interactive voice response (IVR) follow-up support calls. The interventions differ in the initial patient contact—one is initiated with a small group, in-person session (SG/IVR) and the other is initiated with a DVD (DVD/IVR).

The primary purposes of the project are to determine the reach of each active intervention (i.e., the number, proportion, and representativeness of patients enrolled), the effectiveness of the strategies in supporting patients to lose and maintain a 5% weight loss, and the cost-effectiveness of the interventions in achieving standard weight loss. Secondary purposes include reporting on the adoption rate of family and community medicine clinics and physicians approached to participate and the degree to which the interventions are delivered as intended, as well as determining whether participant preference impacts intervention effectiveness when compared to a control group.

3. Methods

3.1. Design overview

To achieve our study goals we will conduct a pragmatic clinical trial [22–24] that employs a hybrid preference/randomized control trial (RCT) design [25–27] (see Fig. 1). Patients at risk for developing diabetes will be randomly assigned to either a Choice group or a Randomization group. Choice group participants ($n = 240$) will have the ability to select which of the two interventions they prefer, while those in the Randomization group ($n = 360$) will be randomly assigned to one of three groups (including a standard care control (SC) consisting of only the diabetes prevention class). This hybrid 2 group preference and 3 group randomized controlled trial design [25–27] allows us to determine the effectiveness of two interventions relative to SC in reducing body weight within the context of a traditional RCT, while still determining the relative reach of SG/IVR and DVD/IVR within the context of the 2 group preference design components. This design maximizes efficiency in testing of new interventions by capitalizing on the strengths of both the RCT and preference designs [25–27]. This study and protocol were approved by the Carilion Clinic Institutional Review Board and is registered at clinicaltrials.gov (NCT02162901).

3.2. Participant eligibility and recruitment

Carilion Clinic serves 18 counties and six cities in Western and Southwestern Virginia and employs nearly 600 physicians across 160 practices. The total patient population (~1 million patients) includes a range of racial and economic diversity. Patients who receive care at the Carilion Clinic Family and Community Medicine Clinics in the greater Roanoke Metropolitan area in southwest Virginia will be invited to