Preventive Medicine Reports 4 (2016) 107–112

Contents lists available at ScienceDirect

Preventive Medicine Reports

journal homepage: http://ees.elsevier.com/pmedr

A pilot randomized trial of technology-assisted goal setting to improve physical activity among primary care patients with prediabetes☆

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ARTICLE INFO

Article history:
Received 29 October 2015
Received in revised form 17 May 2016
Accepted 19 May 2016
Available online 21 May 2016

Keywords:
Applied informatics
Medical informatics
Primary care
Electronic health records
Prediabetes
Behavior change
Goal setting
Clinical decision support

ABSTRACT

Lifestyle behavior changes can prevent progression of prediabetes to diabetes but providers often are not able to effectively counsel about preventive lifestyle changes. We developed and pilot tested the Avoiding Diabetes Thru Action Plan Targeting (ADAPT) program to enhance primary care providers' counseling about behavior change for patients with prediabetes. Primary care providers in two urban academic practices and their patients with prediabetes were recruited to participate in the ADAPT study, an unblinded randomized pragmatic trial to test the effectiveness of the ADAPT program, including a streamlined electronic medical record-based goal setting tool. Providers were randomized to intervention or control arms; eligible patients whose providers were in the intervention arm received the ADAPT program. Physical activity (the primary outcome) was measured using pedometers, and data were gathered about patients' diet, weight and glycemic control. A total of 54 patients were randomized and analyzed as part of the 6-month ADAPT study (2010–2012, New York, NY). Those in the intervention group showed an increase total daily steps compared to those in the control group (+1418 vs −598, $p = 0.007$) at 6 months. There was also a trend towards weight loss in the intervention compared to the control group (−1.0 lbs. vs. 3.0 lbs., $p = 0.11$), although no change in glycemic control. The ADAPT study is among the first to use standard electronic medical record tools to embed goal setting into realistic primary care workflows and to demonstrate a significant improvement in prediabetes patients' physical activity.

1. Background

The 2014 prevalence and incidence of type 2 diabetes mellitus (DM2) is increasing worldwide with 29 million Americans (9.3% of the population) and 347 million Europeans (9.5%) diagnosed with diabetes (Danaei et al., 2011; CDC, 2014). The worldwide prevalence rate is estimated to almost double from 2.8% in 2000 to 4.4% in 2030(Danaei et al., 2011; Writing Group Members et al., 2007; Wild et al., 2004). Moreover, in the United States, an additional 86 million adults are estimated to have prediabetes (a condition defined by blood sugar levels greater than normal but below thresholds for diabetes) (CDC, 2014). Several studies have established that DM2 can be prevented through lifestyle behavior changes (ADA, 2008). The landmark Diabetes Prevention Program (DPP) demonstrated that a comprehensive, intensive behavioral change program can reduce progression to DM2 by 58% in people with prediabetes, and this evidence has translated into recommendations that weight control through small increases in physical activity and small reductions in caloric intake can make a significant impact on preventing diabetes (Hill et al., 2003; Craig et al.; Diabetes Prevention Program Research Group, 2002).

For primary care providers (PCPs), counseling patients with prediabetes about lifestyle modification can consume the majority of time during a clinical encounter, often because traditional clinical encounters do not support effective behavior change (Haire-Joshu and Klein, 2011). Providers have limited training on effective behavior change techniques,(Kushner, 2010) and the provider–patient encounter is often brief and consumed by mandatory documentation and reporting requirements. The time remaining to counsel on behavior change is therefore short, unstructured, and ineffective. Consequently, PCPs spend little time discussing physical activity and lifestyle changes (Eakin et al., 2005; Glasgow et al., 2001).

Recent studies have shown that using health technologies including electronic medical records (EMR), the internet or text messaging can help improve behavioral management of diabetes (Holbrook et al., 2011; Hunter et al., 2008; Christian et al., 2008; Welch and Shayne, 2006; Jackson et al., 2005; Dick et al., 2011; Franklin et al., 2006; Richardson et al., 2005). Device technologies such as pedometers have also been shown to improve diabetes related behaviors (Richardson et al., 2005; Yates et al., 2009; Diedrich et al., 2009; Booth et al., 2008).

☆ Clinicaltrials.gov.: NCT01473654.

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http://dx.doi.org/10.1016/j.pmedr.2016.05.012

Furthermore, interventions that appear to be most effective in sustaining behavior changes include those that use goal-setting, physical activity prescriptions and reminders via telephone calls (Ammerman et al., 2002; Spink et al., 2008; Eakin et al., 2007).

We developed the Avoiding Diabetes Thru Action Plan Targeting (ADAPT) program to create a streamlined shared goal-setting tool embedded in the EMR to help PCPs more effectively counsel patients with prediabetes to improve lifestyle behaviors. This paper describes the results of a 6-month pilot randomized pragmatic trial to evaluate the effectiveness of the ADAPT program on lifestyle behaviors (physical activity, diet) and clinical outcomes (hemoglobin A1C, weight).

2. Methods

The ADAPT study introduced a novel electronic medical record (EMR)-based tool to embed goal setting into primary care provider counseling for patients with prediabetes. The full details of the study design have been previously published (Mann and Lin, 2012; Lin and Mann, 2012).

Patients were recruited between 2011 and 2012 from two urban, academic primary care practices in New York City. Eligible participants were recruited from practice databases and all study procedures were situated within the context of already scheduled clinical visits (Challenges in Clinical Research, 2010). Eligibility criteria included: age 18 or older, English-speaking, and a diagnosis of prediabetes defined as having a glycosylated hemoglobin A1C (A1C) of 5.7–6.4% or a fasting glucose of 100–125 mg/dL. Patients were excluded if they had a diagnosis of diabetes, had ever been prescribed a diabetic medication, were unable to walk, or did not have access to email. A research assistant obtained informed consent with interested participants and administered a standardized survey at enrollment and at 6 months. All participants were given a pedometer to wear for at least one week upon enrolling in the study. All study activities including baseline and follow-up surveys, laboratory assessments and pedometer disbursements were conducted within the context of ongoing primary care clinical activities. This study was approved by the Institutional Review Board at Mount Sinai Hospital.

2.1. Design

The study was a pragmatic randomized clinical trial whose unit of randomization was at the level of the primary care provider. PCPs were randomly assigned in a 1:1 ratio to intervention or control; their patients were subsequently in the intervention or control arm depending on the group to which their PCP had been randomized. Blinding was infeasible due to the nature of the intervention. Patients were offered a 3 month follow-up with their PCP but it was not mandated since every 3-month visits are not a requirement of routine clinical care for prediabetes follow-up. A 6 month follow-up visit was scheduled for all participants.

2.2. Intervention

Just prior to a routine office visit with their PCP, patients in the intervention arm completed a short survey to identify one diet and one physical activity behavior they were willing to change and would be willing to discuss with their PCP. The survey also assessed their current level of pre-specified lifestyle behaviors. During the office visit, the EMR alerted the PCP about the previously-selected diet and physical activity behaviors that their patient was willing to change and the EMR-embedded action planning tool helped guide PCPs to engage in a conversation about lifestyle behavior change along the SMART goal setting framework (see Appendices for screenshots) (Locke and Latham, 1990). The purpose of the action planning tool was to help PCPs and patients set one concrete diet and one concrete activity goal at the close of the visit (for example, “reduce intake of sweetened beverages to one daily” or “get off one bus stop earlier to walk”). In subsequent visits, the EMR tool would display patient progress on these behaviors to the PCP. A pedometer was given to all patients in the intervention arm to assist them in achieving the physical activity goals set with their PCP.

Patients in the control arm followed the same visit schedule as those in the intervention arm but the EMR tools were not available for their PCPs during their visits and they did not receive a pedometer for the duration of the study. Patients in this group did receive printed information on prediabetes and how to change their lifestyle to treat it.

2.3. Measures

All participants completed a baseline survey that assessed sociodemographics, medical history, family history, self-reported physical activity and attempts to change physical activity, confidence/self-effectiveness to change eating habits and physical activity, and assessed their stage of change regarding diet and physical activity behaviors (Prochaska and Velicer, 1997). Prediabetes knowledge and diabetes risk perception were measured using validated instruments consisting of 8 and 5 item 5-point scales respectively (Weymiller et al., 2007; Walker et al., 2007). Prediabetes knowledge and diabetes risk perception scores were calculated as number of points divided by the maximum number of points in each scale for a maximum value of 1, which would indicate strong knowledge or risk perception.

2.4. Diet

Self-reported diet behavior was assessed using a 13 item 3-point scale subset of the short Rapid Eating and Activity Assessment for Patients (REAP-S) tool, a 16-item instrument to address dietary intake and behavior (Gans et al., 2003, 2006). Diet behavior scores were calculated as a 13 item sum with a maximum value of 39 and higher scores indicating better diets.

2.5. Physical activity

All participants were required to wear a pedometer (portable activity monitor, Omron HJ-720ITC) to measure their daily steps at baseline and after the 6 month study visit. The pedometer was then retained by intervention participants for the duration of the study but collected from control patients and then given back to them at 6 months to collect closeout activity assessment. During the pre and post assessment the LCD display of the pedometer was blinded in both groups. To be considered a valid measure of activity, a participant's pedometer data needed to consist of (1) at least 10 h of non-zero activity per day and (2) at least 2 days of activity (Bodenheimer and Handley, 2009). Hours of activity and days worn could be continuous or interrupted. Steps-per-day were then calculated for each patient for each valid day. At baseline and 6 month primary care office visits, weight, A1C, and fasting lipid panels were measured as part of routine clinical care.

2.6. Statistical analysis

Differences between participants in the control vs. intervention arms were compared using t-test, Wilcoxon Rank Sum, chi-square or Fisher's exact test, as appropriate. Changes between baseline and six months were calculated for average daily steps (measured by pedometer), weight, and A1c levels. Differences between groups with respect to these changes between baseline and 6 months were assessed via t-test or Wilcoxon Rank Sum for normally and non-normally distributed variables, respectively. For all tests, p-values less than 0.05 were considered statistically significant. All analyses were conducted using SAS 9.2 (SAS Institute, Cary, North Carolina).