


RESEARCH - QUANTITATIVE

Assessment of a National Diabetes Education Program diabetes prevention toolkit: The D2d experience

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Keywords

Diabetes type 2; disease prevention; evaluation; patient education; behavior modification; adults; chronic illness.

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Received: 8 February 2017;

revised: 20 June 2017;

accepted: 26 June 2017

doi: 10.1002/2327-6924.12499

*The D2d Research Group membership is presented in the D2d design paper Pittas et al. (2014).

Abstract

Background and purpose: The National Diabetes Education Program created the *Small Steps. Big Rewards. GAME PLAN.* toolkit to deliver basic type 2 diabetes prevention information to individuals at risk. The purpose of this study is to test the impact of *GAME PLAN* on diabetes prevention knowledge and behavioral readiness in the vitamin D and type 2 diabetes (D2d) study and participant satisfaction with toolkit materials.

Methods: Three hundred sixty adults at risk for diabetes participating in the D2d study were enrolled. Participants took a pretest, were sent home with the *GAME PLAN*, then took a posttest at their next visit, 3 months later. The Wilcoxon-signed rank test was used to examine changes in knowledge and behavioral readiness between scale scores pre- and posttest.

Conclusions: There were modest increases in composite diabetes prevention knowledge scores ($p < .05$) and behavioral readiness scores ($p < .001$) from pre- to posttest. Participants also reported at posttest that the toolkit materials were appropriate, comprehensive, and relevant.

Implications for practice: The *GAME PLAN* health education materials improve knowledge and behavioral readiness among adults at risk for diabetes. Providers can use *GAME PLAN* as one component of diabetes prevention education.

Introduction

Type 2 diabetes is a serious disease that has reached epidemic proportions among Americans in the past decade (Centers for Disease Control and Prevention, 2014). An array of prevention tools and programs are available for individuals at risk to learn about the disease and how to make lifestyle changes to prevent or delay diabetes onset. Furthermore, various delivery mechanisms and approaches to reaching those at risk with these critical resources have been explored for effectiveness.

Nishigaki, Sato, Ochiai, Shibayama, and Kazuma (2011) delivered susceptibility and prevention information to adults with type 2 diabetes and their offspring using a combination of genetic counseling and/or a computerized behavioral program. Both parents and offspring experienced positive changes in attitudes and behaviors regarding

diabetes prevention, but using patients as the information channel had limited effectiveness.

Additionally, various programs and tools exist to address prevention of a broader range of chronic diseases through awareness and lifestyle changes. For example, the Families Sharing Health Assessment and Risk Evaluation (SHARE) Workbook is a plain language “educational tool outlining disease risk and healthy guidelines to reduce risk of heart disease, diabetes, breast cancer, and colorectal cancer” (Koehly, Morris, Skapinsky, Goergen, & Ludden, 2015). This family health history tool was developed at a Grade 8 reading level and evaluated by key stakeholders for later use in intervention studies among individuals at risk for these diseases; however, the tool was neither tailored nor intended to be diabetes specific.

While information delivery mechanisms described above show promise, primary care providers, especially

nonphysicians, are uniquely positioned to counsel patients at risk for type 2 diabetes on the risk factors and lifestyle changes to prevent or delay the onset of disease. However, primary care providers are increasingly pressed for time during patient visits, and “supplementary” counseling around prevention of chronic diseases like diabetes may not be a priority during the time available (Østbye et al., 2005). In a study by Campbell-Scherer et al. (2014), family physicians, nurse practitioners, nurses, and dieticians set out to develop guidelines and tools best suited for the primary care setting through the BETTER trial: Building on Existing Tools to Improve Chronic Disease Prevention and Screening in Family Practice. However, the effort was limited by a lack of quality evidence and high-quality tools.

Diabetes prevention information must be accessible, culturally tailored, engaging, contain high-impact information, and be delivered at an appropriate readability level. One assessment of diabetes prevention materials among a Northern Plains Tribe found that prevention materials, including pamphlets, booklets, and fact sheets, were written at a readability level higher than recommended (Simonds, Rudd, Sequist, & Colditz, 2011). This study highlights the need to tailor materials to target audiences and engage audience members in testing and evaluation studies to ensure materials are appropriate.

This study was designed to assess how *Small Steps. Big Rewards. GAME PLAN.*, an evidence-based diabetes prevention resource, performs in a clinical trial setting. Objectives of this study were to:

- determine if diabetes prevention knowledge increased after exposure to the toolkit;
- determine if readiness for diabetes prevention behaviors increased after exposure to the toolkit; and
- gather feedback on the toolkit’s appropriateness, comprehensiveness, and usability.

To conduct the study, the National Diabetes Education Program (NDEP) partnered with the vitamin D and type 2 diabetes (D2d) study, which used the paper booklet *GAME PLAN* toolkit as a standardized educational tool at the start of study participation. The D2d study sought to enroll approximately 2400 participants at risk for type 2 diabetes across 22 sites in the United States to test whether vitamin D supplementation is safe and effective at lowering the risk of progression to diabetes (Pittas et al., 2014). Diabetes risk was defined as meeting two of three glycemic criteria for prediabetes established in 2010 by the American Diabetes Association. Using *GAME PLAN* in this setting provided a cost-effective opportunity for the NDEP to obtain data on the effectiveness of its resource, as the initial component of a long-term diabetes education effort, for adults at risk for diabetes.

This article is the second in a two-part series highlighting results from evaluation studies of NDEP patient education resources in clinical trial settings (Devchand et al., 2017). The first article evaluated the impact of a diabetes management booklet on participant knowledge and self-efficacy around diabetes management behaviors among participants already diagnosed with diabetes, while this study focuses on an at-risk population and a toolkit designed for diabetes prevention.

Methods

All participating sites obtained Institutional Review Board approval and written consent to administer the *GAME PLAN* assessment. D2d participants underwent a two-visit screening process to determine eligibility. Following the second visit, eligible participants were randomized to receive once daily vitamin D or placebo, and returned for the first follow-up visit at 3 months.

Investigators developed two short questionnaires used for the pre- and posttest assessment. The questionnaire used existing, validated items to the extent possible, such as those from the Michigan Diabetes Research and Training Center’s (MDRTC) Diabetes Knowledge Test and the Stanford Patient Education Research Center’s (SPERC) Diabetes Self-Efficacy Scale (MDRTC, 1998a, 1998b; SPERC, n.d.). Both English and Spanish language materials were included in the study. Both have incorporated plain language principles and include colorful images and graphics to enhance appeal and comprehension, and the Spanish language materials have been culturally adapted. The pretest questionnaire contained seven questions, and all items were close-ended.

The composite knowledge score was determined by four multiple choice items and four true–false items related to diabetes prevention, calculated as one point for each correct answer. Knowledge items assessed key diabetes prevention information contained in *GAME PLAN*, such as weight loss recommendations, blood glucose, related health complications, and physical activity. The composite behavioral readiness score was determined by seven stages of change items associated with diabetes prevention behaviors, with more points assigned to answers conveying more advanced stages of readiness. Stage of change responses ranged from precontemplation (“I do not intend to”) to maintenance (“I started this 6 months ago or longer”). Behavioral readiness items assessed lifestyle factors such as physical activity and diet. Information about gender, highest education level, race/ethnicity, and age of participants was obtained. These factors were controlled for in analyses.

The posttest questionnaire included 20 items, 7 identical to the pretest questionnaire, plus 13 additional

close- and open-ended items to assess the quality of the *GAME PLAN* materials, such as whether the materials were appropriate, comprehensive, relevant, and to identify areas for improvement. Both the pre- and posttest questionnaires were pretested for comprehension among a small sample of at-risk adults; however, the pretesting sample was too small to evaluate the validity and reliability of the instruments.

At the second screening visit of the D2d study, participants ($n = 680$) completed the pretest in English (95%) or Spanish (5%), and were then provided with the *GAME PLAN* toolkit to take home. When randomized participants returned for their first follow-up visit at 3 months, they completed the posttest questionnaire ($n = 360$). Sites were instructed to stop administering the pretest when at least 300 matched posttests had been submitted study wide. Data collection was conducted between October 2013 and March 2015. All participants who were asked to complete the posttest did so.

Data analysis

Data were analyzed in MS Excel Data Analysis Tools Add-In, within Office 365 ProPlus suite. The Wilcoxon-signed rank test was conducted to detect significant differences between individuals' knowledge and behavioral readiness at pre- and posttest. This nonparametric test converts scores to ranks and compares pre- and posttest ranks for participants and was used instead of a *t*-test for matched pairs in the absence of an assumption for a normally distributed population. Sample size and power were calculated for paired-sample *t*-tests using G*Power 3.1.5. A sample size of 272 people completing pre- and posttests would provide a confidence interval of 5.522 and allow detection of small effects ($d > .20$) at $\alpha = .05$ and power = .95. Effect sizes were calculated as the *z*-value divided by the square root of the number of observations and categorized using Cohen (1988) criteria of .1 = small effect, .3 = medium effect, and .5 = large effect.

Open-ended responses were reviewed and analyzed with the goal of identifying common themes, areas of consensus, and differences of opinion among participants regarding the appropriateness of toolkit materials.

Results

The analyzed sample included 360 D2d study participants recruited from 16 D2d sites (out of 22). A description of sites can be found in the D2d design paper by Pittas et al. (2014). Participants who completed the questionnaires were majority female (53%), non-Hispanic (90%), White (68%) or African American (27%), and 82% reporting at least some college. See Table 1 for a description of the sample.

Table 1 Participant demographic characteristics

Variable	N	Range	Mean
Age	360	(32–85)	58.6
Variable	N		(%)
<i>Gender</i>			
Male	168		46.7
Female	192		53.3
<i>Ethnicity</i>			
Hispanic	36		10.0
Not Hispanic	324		90.0
<i>Primary race</i>			
American Indian or Alaska Native	2		0.6
Asian	11		3.1
Black or African American	98		27.2
Native Hawaiian or other Pacific Islander	2		0.6
White	243		67.5
Other	4		1.1
<i>Education Level</i>			
Elementary (1–8)	11		3.1
High school (9–12) no diploma	9		2.5
High school (9–12), GED, or equivalent diploma	45		12.5
Some post high school education, no degree	56		15.6
Some post high school education, AA	53		14.7
Bachelor's degree	94		26.1
Graduate or professional degree	91		25.3
Prefer not to say	1		0.3
<i>Primary language</i>			
Spanish	19		5.3
Not Spanish	341		94.7

Note. GED, Certificate of High School Equivalency; AA, Associate of Arts degree.

Knowledge

Out of a range of possible scores from 1 to 8, participants' pre- and posttest knowledge scores ranged from 2 to 8. Analyses showed a statistically significant increase in individual composite knowledge scores at posttest with a small effect size ($r = .16$), based on Cohen (1988) criteria. While the median knowledge score remained the same from pretest (median = 6.0) to posttest (median = 6.0), the mean knowledge score increased from pretest (mean = 5.5) to posttest (mean = 5.7; $p = .03$). Subgroup analyses will be the focus of future studies (Figure 1).

The knowledge questions revealing the largest shifts from pre- to posttest were those related to (Figure 2):

- weight loss recommendations (16% increase in correct responses); and
- physical activity recommendations (11% increase in correct responses).

Behavioral readiness

Out of a range of possible scores from 0 to 35, participants' pretest behavioral readiness scores had a range

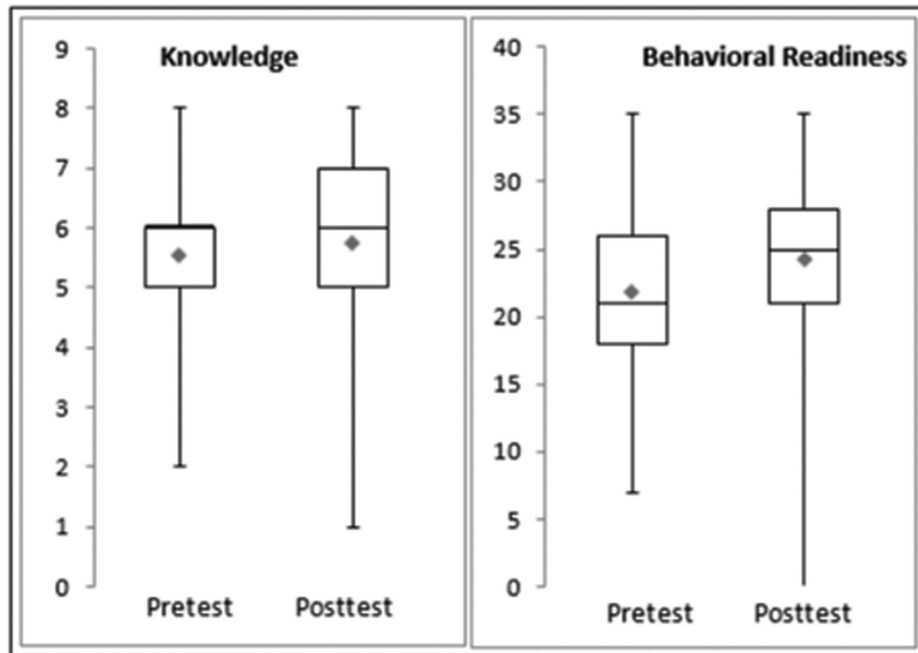


Figure 1 Distributions and means of participants’ pre- and posttest knowledge and behavioral readiness scores.
 Notes. The box-and-whisker plots in the figure above display the first quartile (25th percentile), median, and third quartile (75th percentile) with the boxes, while the upper and lower whiskers indicate minimum and maximum scores. The “*” symbol indicates the mean score of the sample for each time point.

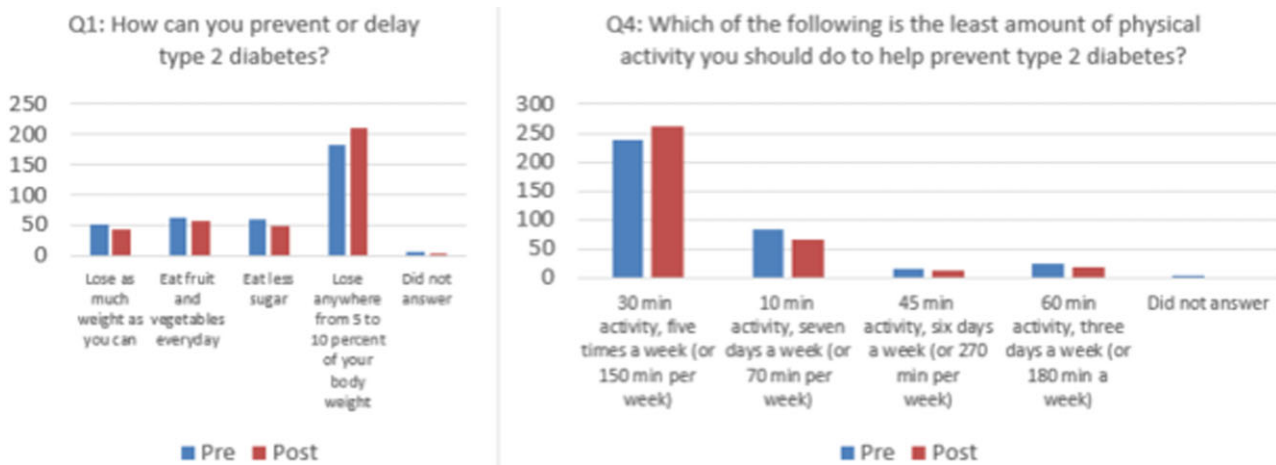


Figure 2 Knowledge question summaries.

of 7–35, and posttest behavioral readiness scores ranged from 0–35. Analyses revealed a statistically significant increase in individual composite behavioral readiness scores at posttest with a medium effect size ($r = .41$), based on Cohen (1988) criteria. The median behavioral readiness score increased from pretest (median = 21) to posttest (median = 25), and the mean behavioral readiness score increased from pretest (mean = 21.9) to posttest (mean = 24.2; $p < .001$; Figure 1).

The behavioral readiness questions with the largest shifts in scores from pre- to posttest were those related to (Figure 3):

- reducing the number of calories consumed (70% increase in those reporting action or maintenance of behavior);
- tracking food and beverage consumption and physical activity (64% increase in those reporting action or maintenance of behavior); and

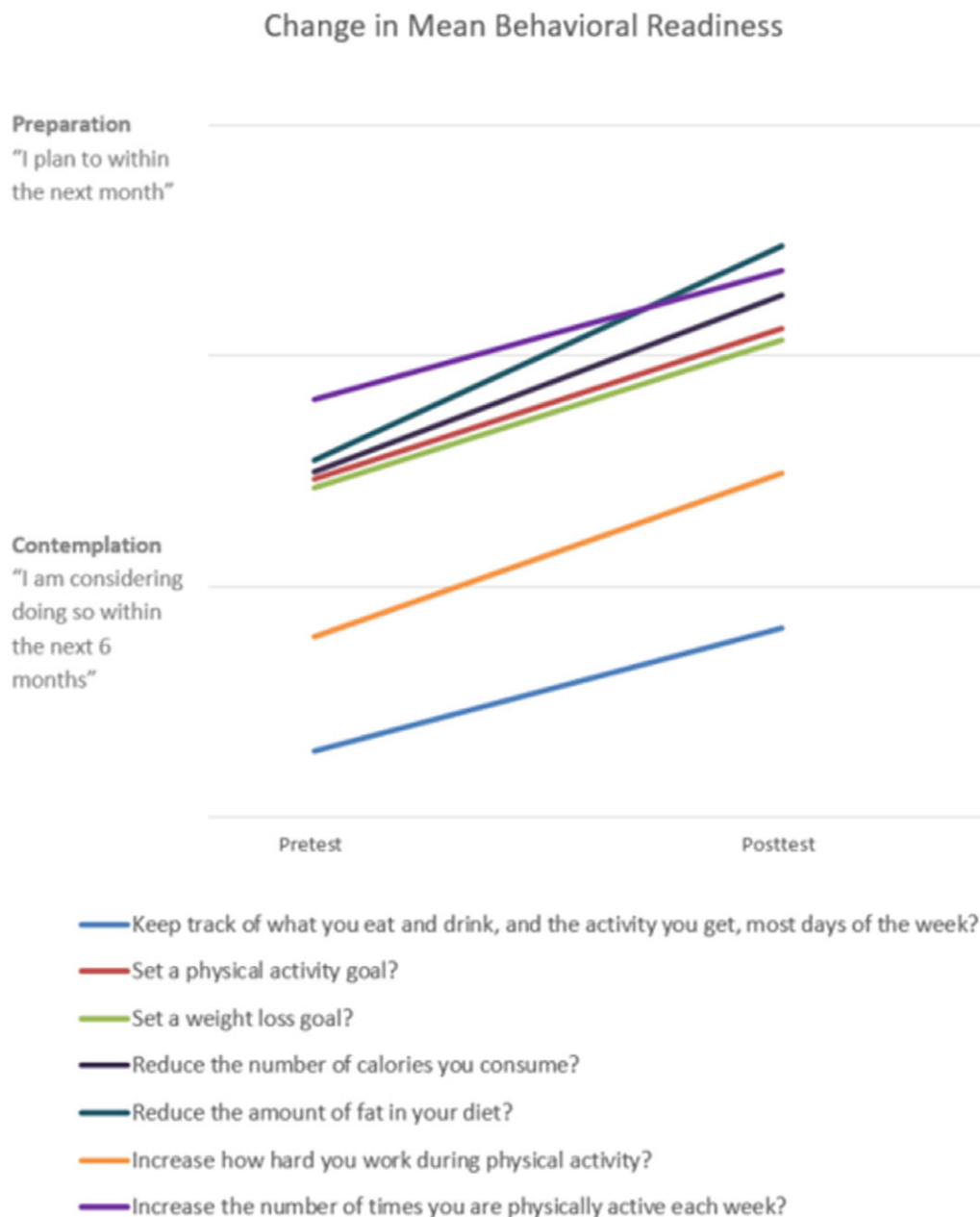


Figure 3 Behavioral readiness question summaries.

- reducing the amount of dietary fat (61% increase in those reporting action or maintenance of behavior).

Appropriateness, comprehensiveness, and usability of materials

Participants generally agreed with the appropriateness of the *GAME PLAN* toolkit materials, as measured by

questions regarding the format of materials, and the amount and comprehensiveness of information included. The majority of participants preferred the *GAME PLAN* toolkit materials in a paper booklet format (73%), compared to the possibility of a smartphone/mobile app (16%) and computer web-site formats (20%).

The majority of participants (79%) strongly agreed or agreed that the *GAME PLAN* toolkit materials provided adequate information to reach four specific objectives: set a

weight loss goal, plan healthier meals, start a physical activity program, and set a physical activity goal.

Discussion

The results above highlight several important findings. Participants experienced no change in overall type 2 diabetes prevention knowledge from pre- to posttest, but certain knowledge topic areas improved, such as weight loss and physical activity recommendations. Participants also experienced an increase in readiness for diabetes prevention behaviors from pre- to posttest. The behavioral readiness areas showing the most gain were the following: reducing calorie consumption, tracking diet and activity, and reducing dietary fat. Participants also generally found the *GAME PLAN* toolkit materials to be appropriate, comprehensive, and relevant.

The limitations of this study included factors outside of the *GAME PLAN* toolkit that may have impacted pre- and posttest scores, as well as repeated measurement effects in which the participants' exposure to the pretest affected posttest results. For example, investigators could not control for diabetes information obtained by participants from sources outside of the study and other than *GAME PLAN*. The 3-month period between being provided the *GAME PLAN* and the posttest may have been too long to assess short-term retention, and it is unknown if the participants read the materials. Without a control group—individuals not receiving the *GAME PLAN* toolkit—it was not possible to control for these confounding variables. The participants represented a highly educated cohort, where 82% had at least some college education, which may have resulted in outcomes that are less representative of the larger population. Future research should be conducted to support the use of this toolkit with less educated populations. In addition, the cohort may have been inherently ready for diabetes prevention behaviors as all the participants took the initiative to participate in the diabetes prevention study. As a result, a possible ceiling effect in the pretest could have impacted posttest scores. Finally, only a small percentage of Spanish toolkits were assessed, limiting investigators' ability to compare outcomes for English- versus Spanish-speaking audiences.

Because of constraints in time and funding, investigators were not able to expand the study to follow participants longer term to assess whether changes in knowledge or behavioral readiness early in the trial impacted long-term knowledge and behaviors or clinical outcomes. Additionally, an analysis of differences between those who did and did not complete a posttest may offer a different perspective to the study. The NDEP will consider these expansions and more robust evaluation approaches in the future.

Although the majority of participants preferred the paper booklet format of the toolkit, it is worth noting that the mean age of participants was 58.6 years old. Further research may explore if younger patients have a preference for digital/online formats.

Implications for practice

The NDEP's *GAME PLAN* was a moderately effective but easy-to-deliver standardized educational tool and could be used successfully in other settings. Health care providers can use the *GAME PLAN* toolkit to support patients at risk for type 2 diabetes to increase diabetes prevention knowledge and behaviors.

Diabetes education requires a variety of interventions and tools, and diabetes prevention programs should continue to produce accessible, evidence-based information and toolkits for patients, providers, and partners to help prevent and delay diabetes and its complications.

Acknowledgments

The evaluation of the NDEP *Small Steps. Big Rewards. GAME PLAN* toolkit was funded by the National Institute of Diabetes and Digestive and Kidney Diseases under contract number HHSN276201200001U. This evaluation was conducted as an ancillary study to the vitamin D and type 2 diabetes (D2d) study, with support from a U01 research grant (U01-DK-098245) from the National Institute of Diabetes and Digestive and Kidney Diseases. We would like to thank Pauline Tran for her literature review assistance in preparing this manuscript. RD contributed to the design, writing, and critical review of the manuscript. PS contributed to the design, writing, and critical review of the manuscript. JMG contributed to the design, writing, and critical review of the manuscript. DMT contributed to the design, writing, and critical review of the manuscript. CN contributed to the design, writing, and critical review of the manuscript. RD is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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