Lowering HbA1c in Food Insecure Type 2 Diabetics through a Fruit and Vegetable Prescription Program.

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Abstract

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14 food insecure diabetics with uncontrolled diabetes enrolled in a six-month Fruit and Vegetable Prescription (FVRx) program. Participants were screened and recruited by their Primary Care Provider and referred to the FVRx program coordinator. Participants met with a diabetes health educator monthly for nutritional education as well as SMART goal setting towards improving their diet. Food vouchers for local farmers' markets valued at $1 per day per household member were dispersed during these visits. The number of food vouchers redeemed were tracked for each participant for data analysis. HbA1c levels were measured before (May) and after (November) the program. The average HbA1c change was -1.85% ($p = 0.0004$; 95% CI: -2.69, -1.01) after the six-month program was completed. After adjusting for participants' pre-program HbA1c level, a $10 increase in the average amount redeemed per month was associated with a 1.4% (p-value: 0.006; 95% CI: 0.5, 2.4) decrease in HbA1c. This reveals a strong relationship between improving food security and improving diabetes management.

Introduction

Over 30 million Americans have Type 2 Diabetes and approximately another 84 million have prediabetes and are more likely to develop Type 2 Diabetes within their lifetime[1]. Type 2 Diabetes is a disease where cells develop a resistance to insulin, the hormone that promotes the absorption of sugar in the bloodstream into the body's cells. When the amount of blood sugar is chronically high, cells become desensitized and require more insulin to absorb the same amount of sugar[3]. While there is no cure for Diabetes, those diagnosed with it can control their disease primarily through dietary improvements and increasing their physical activity level[2]. Glycated hemoglobin, also known as HbA1c, is a form of hemoglobin with glucose bound to it. The higher a person's blood sugar over the previous 90 days, the higher the percentage of hemoglobin will have glucose bound to it. Although HbA1c reflects the average blood glucose over the entire 120-day lifespan of the red blood cell, it correlates best with the average blood glucose over the previous 8 to 12 weeks[4,5].

A well-balanced diet is crucial to controlling blood sugar levels and, therefore, adequately managing diabetes[6,7,8,9,10]. Yet 48 million Americans live in households that lack reliable access to a sufficient quantity of affordable and nutritious food[11,12]. These are known as food insecure households and those identified as food insecure are at higher risk for many diseases, including obesity and diabetes[13,14,15,16]. Food security is a measurement of whether a household's diet has a sufficient quantity and quality of food. Those that are food insecure tend to eat less fruits and vegetables than those that have food security[17]. Additionally, diabetics that are food insecure are more likely to have uncontrolled diabetes which leads to a higher rate of mortality, comorbidities, and hospitalization[18,19,20]. Some populations, such as those with a lower socioeconomic status, are at higher risk for either diabetes or food insecurity[21,22]. A study in 2012 found that those living in a rural area is 8.6% more likely to be diagnosed with Type 2 Diabetes than those living in urban areas even after controlling for income, age, gender, ethnicity and BMI[23]. Gamm, et al., Rural Healthy People 2010: A Companion Document to Healthy People 2010[24] specifically analyzes the effect diabetes has on rural America. While living in a rural area is not thought in and of itself to be a cause of increased risk for developing Type 2 Diabetes, rural areas typically house low-income, older, and ethnic populations which are more at risk for diabetes than the general population[25,26]. Similar associations are seen with the comorbidity and mortality rates of diabetes; once adjusted for socioeconomic status, age, and ethnicity, the mortality rates for urban and rural areas are similar. Another area where rural diabetics are at a disadvantage is education. As well as being uninsured, living in a rural area decreases the chance a diabetic would receive pertinent diabetes education[27].

There have been many approaches to combatting food security in rural areas. A prominent approach is the Fruit and Vegetable Prescription (FVRx) Program by Wholesome Wave[28]. This program is a comprehensive framework for a food voucher program aimed at those facing food insecurity. The framework is flexible and involves Primary Care Providers recruiting overweight patients to a program where participants are provided food vouchers, or prescriptions, in order to improve fruit and

vegetable consumption. During the program, participants meet with their PCP on a monthly basis to set goals for fruit and vegetable consumption. This is done while simultaneously providing a basic education on nutrition[28]. Previous FVRx programs have promising results in improving participants' immune systems, lowering weight, increasing fruit and vegetable intake, improving food security, lowering HbA1c, and better grocery shopping habits[29,30,31,32,33,34]. One practice employed by the Wholesome Wave FVRx program to make lasting changes in participants' shopping habits is motivational interviewing. This invokes patients to change unhealthy behaviors and has proven effective with patients with diabetes[35,36,37,38]. The combination of education, motivational interviewing, and fruit and vegetable vouchers address the barriers to improving participants' diets and engages them to make lasting changes[39,40,41,42]. A diverse diet rich in fruits and vegetables has proven to better manage diabetes but whether it is simply a matter of access has yet to be determined. The specific aim of this study is to evaluate the effectiveness of a FVRx program tailored towards diabetes management in lowering HbA1c in food insecure diabetics.

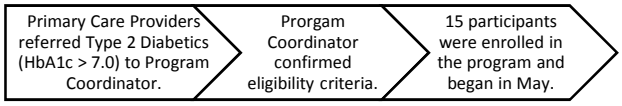
The Setting

The program was set in two PeaceHealth primary care clinics in Skagit County, Washington; One in Sedro-Wooley and another in Burlington, Washington. The majority of Skagit County is considered rural with an average of 67.5 people per square mile, a poverty rate of 11.3%, and the last reported prevalence of diabetes in 2013 was 9.1%[1,43].

Participants

PeaceHealth Primary Care Providers (PCPs) recruited patients with Type 2 Diabetes and an HbA1c reading greater than 7.0 in the past 3 months to the program coordinator. The coordinator called these patients to explain the program, verify the inclusion and exclusion criteria, and the responsibilities of the participants. During this call, the coordinator administered the USDA Food Security Survey in order to ensure participants were food insecure. The USDA's Food Security Survey determines if a family has fewer meals than needed or relies on low-cost/low-quality food due to a limited budget[44]. Those that could not speak English or Spanish as well as having a household size of greater than seven were excluded as well due to financial constraints. The remaining criteria were to ensure the HbA1c readings were valid and accurate. This includes not being pregnant, a current smoker, or diagnosed with the following: Thalassemia, Sickle Cell disease, Iron deficiency, splenic disease, kidney disease, liver disease, or alcoholism[4,5,45]. All participants had to be older than 18 years old and mentally capable of giving an informed consent to participate.

Figure 1. Recruitment Process



The Program

The Skagit County FVRx program recruited participants as early as February for the program to start in May when the local farmers' markets opened. Participants were given basic nutrition and cooking education and trackable produce vouchers in the amount of $1 per day per household member. Participants met monthly in order to cover new nutritional topics, disburse

produce vouchers, and set nutritional goals through motivational interviewing. HbA1c was tested before and after the program to assess diabetes control levels and participants were asked if they had consumed at least half of the produce purchased.

Candidates were identified by their PeaceHealth PCP in early February and referred to the program's coordinator. The program coordinator then confirmed eligibility, explained the program's requirements, and obtained a verbal consent to participate. Participants were asked to meet with the program's health educator at the Skagit PeaceHealth Family Practice Clinic once a month for six months, consume (rather than waste) at least half of the fruits and vegetables bought with the program's vouchers, and have an HbA1c test before and after the program. In exchange, participants are given food vouchers redeemable at any of the three local farmers markets equal to $1 per day per household member. The program provided vouchers for every household member because the family would eat together and, otherwise, participants with larger households would have fewer vouchers for themselves. Vouchers were returned to the program coordinator each month and had the participants' program ID number on them. Vouchers were then tallied to track how much each participant spent each month.

The first visit was conducted in May to coincide with the opening of the local farmers' markets. During this visit, informed consent was obtained, participants were educated about nutritional labeling, and an initial HbA1c level was obtained before vouchers were distributed. Blood was collected by a Certified Medical Assistant and processed by an Abbott Afinion 2 analyzer. Participants were educated on differing nutritional subjects during subsequent visits (June: MyHealthyPlate, July: Sugar, August: Salt, September: Fiber, October: Fats) and for each nutritional topic, motivational interviewing and SMART (Specific, Measurable, Attainable, Relevant, Time-sensitive) goal setting were used to encourage participants to improve their grocery shopping habits. Participants were educated on the basics of nutrition to make better choices outside of the farmers' markets as well. A recipe book "Good and Cheap: Eat Well on $4/Day"[46] was given complimentary to each participant as well as cooking classes throughout the program. Participants completed an open-ended questionnaire each visit assessing the amount of physical activity (sports, hobbies, employment, and other physical activities) and produce waste in order to assess their potential as confounders. Participants were categorized as either having wasted over 50% of purchased produce or changed physical activity levels for that month. During the final visit, participants were only given food vouchers and an HbA1c reading was taken before the program concluded.

Where the Skagit County FVRx Program differs from the traditional Wholesome Wave FVRx program is in the delivery method. PCP's in Skagit County FVRx simply referred their patients to the program where participants met with a diabetes health educator. Participants were then educated on basic nutrition, taught how to cook simple meals, and given food vouchers to build new grocery shopping habits. This contrasts with the Wholesome Wave model where the PCP would fill the role of meeting with participants rather than a health educator. This change was made due to the lack of available providers as well as avoiding the additional cost to the program. The traditional Wholesome Wave model focused on obesity rather than diabetes. The Skagit County FVRx made it a priority to

focus on diabetics due to diet's significant influence on the management of diabetes in such a short time.

Statistical Analysis

Descriptive analyses were conducted to assess the means, standard deviations, medians, minimums, maximums, and ranges of the pre-program HbA1c, post-program HbA1c, and changes in HbA1c. One-sample t-tests were performed to compare the average change in HbA1c levels to determine if the change was significantly different from zero. This test has the null hypothesis that the average change in HbA1c levels is equal to zero, and the two-sided alternative hypothesis that it is not zero.

A linear model was also fitted to the data to analyze the association between vouchers redeemed and the subsequent change in HbA1c after factoring the participants' pre-program HbA1c. This is due to the participants' pre-program HbA1c influencing the magnitude of the associated change in HbA1c level. The program provided vouchers for every household member instead of just the participants based on the assumption that the family would eat together. As a result, rather than modeling the total dollar amount redeemed, the exposure variable was modeled as the average dollar amount redeemed per person per month (i.e., total redeemed amount / number of family members / months).

All analyses were completed using R 3.5.1[47].

Results

Of the 15 participants that began that program, one person's data was excluded due to discovering her pregnancy during the study. The majority of the 14 remaining participants were female (n = 13) and the age ranged from 24 – 71 with a mean age of 53.7 (SD = 15.5). Household size varied from 2 – 7 with a mean size of 3.8 (SD = 1.4). Participants were primarily Caucasian apart from one Hispanic woman. One participant's HbA1c level had lowered to 6.0 at the beginning of the program but had an HbA1c > 7.0 at the time of recruitment to include him in the study.

Table 1 presents the summary statistics for the one sample t-tests on pre- and post-program HbA1c levels and their corresponding changes. This table summarizes both the central tendency and variability of the data. The testing results the estimated average change in HbA1c level during the study was -1.85 (p = 0.0004; 95% CI: -2.69, -1.01).

Table 1. Summary Statistics of Pre- and Post-Program HbA1c and Changes

	Pre-HbA1c	Post-HbA1c	Changes in HbA1c
Mean	9.11	7.26	-1.85
Std. Deviation	1.98	1.62	1.45
Median	9.20	6.70	-1.95
Minimum	6.00	5.30	-3.90
Maximum	13.60	11.10	0.10
Range	7.60	5.80	4.00

Figure 2. Pre/Post HbA1c Levels Boxplot

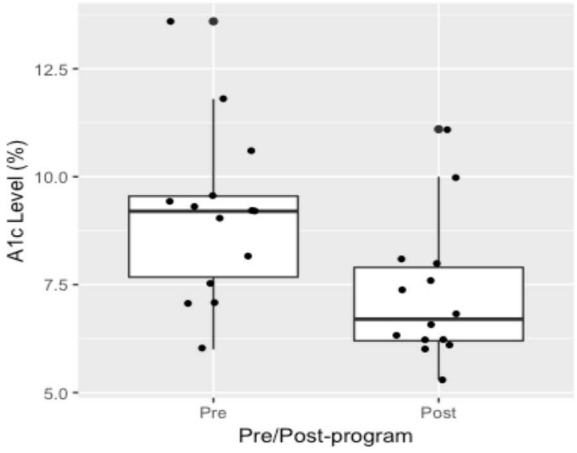
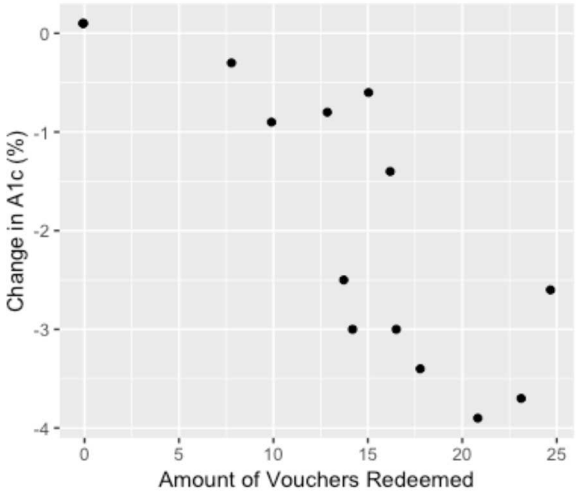


Figure 3. Scatterplot of Changes in HbA1c Level by Redeemed Vouchers



The boxplots of pre/post program HbA1c levels in Figure 2 outline the patterns and outliers of the dataset. There is a general decreasing trend in the subjects' HbA1c levels. It can be observed that the variabilities for pre- and post-program HbA1c levels do not differ much from each other, although the medians and quartiles of these two plots have significantly decreased. Figure 3 presents a scatterplot of the change in HbA1c level (post-pre) as a function of the redeemed vouchers to explore the relationship between these two variables. There were no changes in physical activity levels or instances where more than 50% of purchased produce were wasted.

The linear model evaluating the association between vouchers redeemed and the decrease in HbA1c after adjusting for the participants' pre-program HbA1c shows that a $10 increase in the average amount redeemed per month is associated with a 1.4% ($p = 0.006$; 95% CI: 0.5, 2.4) decrease in HbA1c.

Discussion

The pre-post change analysis showed a statistically and clinically significant HbA1c reduction of 1.85% over the course of the program. Furthermore, a dose-response effect with the number of vouchers redeemed was demonstrated. A $10 increase in the average amount redeemed per month per household member was associated with a 1.4% decrease in HbA1c after adjusting for pre-program HbA1c levels. With the analysis focusing on the dose-response effect, the potential for significant confounding are partly mitigated.

The Skagit County FVRx Program focused on managing diabetes rather than the Wholesome Wave's focus on obesity. The Skagit County FVRx Program also relied on other healthcare workers to run the program rather than the PCP being the main point of contact. This was due to financial restraints and difficulty in recruiting PCPs to take on the additional workload. The staff of the FVRx program were from PeaceHealth or United General District 304 and were paid their normal wages to run the program. Further analysis is needed to assess the cost of running a similar program to the amount saved in healthcare related costs.

Limitations

Without a control group, the cohort study design is not as strong as a traditional controlled study design in proving that the observed decrease is caused by participation in the program. The potential for this, having relatively few participants, and the short time frame in which the program operated lead to a smaller statistical power. Unfortunately, the program's length, lack of follow-up, and number of participants were limited due to funding. Additionally, one participant was not aware of her pregnancy when the study began. This meant the HbA1c data collected from this participant was unreliable and would have to be excluded due to the participant's ineligibility for the study. It also wasn't possible to empirically track how much produce was consumed rather than wasted. This meant that participants had to be asked about their eating habits for the previous month and this has the potential for significant recall bias. Lastly, the nature of the program relies on farmers' market to be open and provide quality produce. This limits the applicability of this program to areas with farmers' markets that are open and have a steady supply of produce all year.

Conflict of Interest

The authors of this study declare no conflict of interest.

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