CEHD Grant Application

Personalized intervention for controlling blood glucose through diet in prediabetic individuals

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Project purpose

The goal of this project is to seek a personalized intervention to control blood glucose levels through diet modification in newly diagnosed prediabetes patients. The researchers will assist the participants to figure out what foods in their diet contributed the most to their high blood glucose levels. Thus, they would be able to control their blood glucose levels in the safe range by eliminating or reducing the amount of those specific foods to avoid developing type II diabetes. Those individuals with prediabetes could stay healthy without requiring medicine and can avoid drug side effects and reliance.

Background

Diabetes is a major health problem all over the world. In 2019, the International Diabetes Federation released the 9th edition of the World Diabetes Map (https://diabetesatlas.org/data/en/world/). In addition, to show the data for 2019, they also predicted the diabetic incidence of the world in 2030 and 2045. In 2019, there were 463 million diabetic patients worldwide. By 2030, it could reach 578 million and by 2045, there may be nearly 700 million diabetic patients. For the U.S., the National Diabetes Statistics Report 2020 (https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf) revealed that an estimated 34.2 million people of all ages (10.5% of the U.S. population) have diabetes. Approximately 88 million adults equal or above 18 years old had prediabetes in 2018 based on their fasting glucose or hemoglobin A1c (HbA1C) level, which means 34.5% of all U.S. adults had prediabetes. It was widely recognized that people with prediabetes have a higher risk of developing type II diabetes. Within five years, 15-30% of them will eventually develop type II diabetes if lack lifestyle changes.

High blood glucose and high blood pressure can damage capillaries and cause vascular dysfunction to organs rich in capillaries, such as kidneys, heart, and eyes (Rask-Madsen and King 2013). The common complications of diabetes include cardiovascular disease, kidney damage, nerve damage, eye damage, foot damage, hearing impairment, skin conditions, Alzheimer's disease, and so on. High blood sugar can cause permanent organ damage and reduce lifespan.

In addition to the patients suffering from the long-term torture caused by the complications, the cost of diabetes treatment became the burden of patients and society. In 2017, the total cost of diabetes diagnosed in the United States was approximately US$327 billion ($237 billion in direct medical costs plus $90 billion in reduced productivity, absenteeism,

and inability to work.
(https://www.cdc.gov/chronicdisease/resources/publications/factsheets/diabetes-prediabetes.htm).

What's more sad is, since the pandemic of COVID-19 from the beginning of 2020 and regrettably still going on, diabetic and obese patients have been regarded as high-risk groups for developing serious symptoms and high risks of death. Thus, they need special protection. Codo and the co-workers explained that diabetic and obese patients with uncontrolled blood glucose levels are at greater risk of severe forms of COVID-19 (Codo et al. 2020). The cytokine storm they observed in critically ill patients was believed to be related to dysfunctional adaptive immune responses and epithelial cell death. In this article, they showed that elevated glucose and continuous aerobic glycolysis in monocytes directly promote virus replication.

It has been well known that blood glucose mainly came from the digestion and absorption of carbohydrates include simple sugar and starch. Foods and beverages contain a high amount of simple sugar (e.g. candies, cookies, sweet treats, cakes, sodas, sweetened drinks, etc.) and starch (e.g. white rice, fined wheat bread, bagels, doughnuts, most breakfast cereals, mashed potatoes, and fries, etc.) could increase our blood sugar dramatically and quickly. If people consume a large amount of these foods or beverages for a long time, they are at high risk of developing type II diabetes. Currently, we focus the emphasis on carbohydrate count and low glycemic index foods, which means those foods are unlikely to trigger the large increase in our blood glucose (e.g. most fruits and vegetables, whole grains, beans, pasta, dairy products, nuts, etc.). With the innovation and maturity of continuous glucose monitoring (CGM) technology, research in the diabetic area made great progress and blood glucose management indicators have been updated also. Dr. Eran Segal is a computational biologist scientist at the Weizmann Institute of Science. He and his team conducted research by continuously monitoring 800 healthy volunteers' blood glucose responses to foods via CGM (Zeevi et al. 2015). For a week-long observation of glucose levels response to 46,898 meals, they found high variability in their response to identical meals. For example, some people had a low blood glucose response to rice intake but showed a high blood glucose response to ice cream. While others may have the opposite situation. However, how a person responds to the same food was pretty consistent. They claimed that recommending a universal dietary suggestion might have limited usefulness due to differences in genetic backgrounds, gut microbiota, and lifestyles among populations. However, a personalized diet could modify increased postprandial blood glucose and its metabolic consequences efficiently.

The latest American Diabetes Association's "Standards of Medical Care in Diabetes 2020" (DOI: 10.2337/dc20-S006) introduced a new standard for evaluating blood glucose regulation- Time in Ranges (TIR), which means the time when blood glucose is within the target range. The TIR control target for patients with type I and type II diabetes is >70%. However, the TIR goal is not static, it should be highly individualized while paying attention to hypoglycemia and blood glucose fluctuations. Managing patients' blood glucose according to this high-profile new standard can help reduce diabetes complications and avoid serious issues such as inability to take care of themselves or disability due to acute brain injury caused by hypoglycemia.

Majeed's team published a systematic review article in 2020 that evaluated the utility of CGM in type I and type II diabetes and showed remarkable enhancement in the levels of HbA1c as compared to non-CGM (Azhar et al. 2020). They reported type II diabetes including senior patients obtained benefits by using the CGM since it provided comprehensible information of glucose variableness as well as HbA1c levels. This allows the health care professional workers to escort patients in terms of their glucose levels. However, wearing the device for longer periods for the participants was an inconvenience, which minimized its utilization.

Based on the knowledge that each person's postprandial blood glucose responses to the identical food were pretty consistent but different people showed variation, individuals could figure out what foods are "good" for them and what foods are "bad" for their blood glucose maintain. This study hypothesizes that people could screen their "bad" foods through CGM and eliminate or reduce the amount of those food categories to better control their blood glucose levels and avoid damages to their health.

Methods and plan of work

If the proposal is funded, we will submit the documents to the Institutional Review Board to obtain approval. We will recruit ten or more volunteers (based on financial support) of newly diagnosed prediabetic individuals with the cooperation of the Ascension Borgess Hospital Borgess Diabetes & Endocrine Center in Kalamazoo, Michigan. We have contacted the registered dietitians there and will meet them on Nov. 22nd, 2021 to discuss the cooperation. This pilot study starts with newly diagnosed prediabetic individuals because the drug effects could be eliminated.

After the recruiting process, the socio-demographic data, body composition data, and medical history data will be collected before the intervention. The socio-demographic data include age, gender, race, education level, marital status, working status, smoking status, alcohol consumption, supplement usage, and so on. We will collect their body weight, body height, physical activity, fasting plasma glucose (FPG) data & HbA1c (historical measurements in the medical history), symptoms of diabetics, history of gestational diabetes, histories of heart disease or stroke, medicine usage data, and family history of diabetes, etc.

Next, we purchase the CGMs (https://www.freestyle.abbott/us-en/myfreestyle.html) and will request each participant to wear them for two weeks and write down or take pictures of what the person eats. For the first three days, they just do normally as what they usually eat. This will provide an accurate description of participants' typical daily diet. They will see how their blood glucose change after each meal and snack and when the blood glucose level reaches the highest point as well as the lowest point. The food components and the Healthy Eating Index (HEI) will be analyzed using the same methods that we have and got publication on it (Rojhani et al. 2021).

For the following three days, we will let the participants just consume those low glycemic index foods and beverages, such as vegetables, some low carbohydrate fruits, beans, dairy products, nuts, eggs, meats, fish, milk, tea, dark coffee, etc. They will see their blood glucose levels stay stable within the recommended range. Next, they will add those starch-rich foods (such as rice, bread, spaghetti, ice cream, cakes, and so on) one by one as the usual amount they consumed. If a food category causes blood glucose to spike, the person could reduce the amount or eliminate the food according to their willingness to make sure their postprandial blood glucose stays in the target range. Sweetened beverages that contain a high amount of simple sugar could increase blood glucose dramatically. People can see that effect visually and learn to limit the intake. The participants will be required to consume their "good" foods in the tolerant amounts they found and continue for three months.

After three months, we will conduct another survey to collect their body weight, three-day food record, physical activity, FPG and HbA1c, symptoms of diabetics, etc. to evaluate the effects of blood glucose control through their diet change.

When finishing the data collection, we will analyze the data. Dietary component data will be analyzed using the Food Processor Nutrition Analysis Software stalled in the computers in the FCS department. HEI will be calculated based on the results obtained. Each individual's BMI, FPG, and HbA1c will be analyzed by t-test. Socio-demographic data and other data would be analyzed to see the correlation of the success or failure of the blood glucose control through personalized diet intervention.

Budget

(Redacted)

Anticipated outcomes

Each participant will learn how his/her blood glucose change after eating different foods and figure out what foods are hard for the person to remain in the target blood glucose range. Thus, participants know how to eliminate or reduce those "bad" foods intake to avoid developing type II diabetes in the future. Via this pilot study, we could evaluate the efficiency of blood glucose control through personalized diet modification, understand the difficulties the participants might have, and improve the intervention process. We could assist people with similar health issues with personalized strategies more efficiently.

We will write manuscripts for publication and present our results at academic conferences. The preliminary data we obtained will help us to seek external funding to do more research in this area.

A graduate assistant who involves in this project will obtain training in conducting research, as well as collecting, analyzing, and reporting data. This could be his/her thesis for getting the degree.

Plans for continuing research

Diabetes is a complex situation affected by many factors such as genetic background, age, body weight, diet, gut microbiota, physical activities, stress, sleep, support team, and so on. People may not be able to change their age and genetic background, but they can change their lifestyle and eating habits if they understand and observe the benefits to their health. We will conduct studies on individuals with type II, gestational diabetes, and type I diabetes in the future. Through providing nutrition and healthy lifestyle education to assist them better control their blood glucose levels via personalized diet modification to avoid or reduce the complications and medicine usage. This will help patients to improve their living quality and longevity as well as reduce the financial burden for individuals and society.

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