EJSIT
European Journal of Science, Innovation and Technology
ISSN: 2786-4936
www.ejsit-journal.com
Volume 3 | Number 4 | 2023

Curcuma Longa Therapy for the Management and Treatment of Type 2 Diabetes: Quasi Experimental Pilot Study Design

Dr. Fouad E El Hachimi, DCN, Dr. Kim Lien Le, DCN
Department of Nutrition, Maryland University of Integrative Health, United States

ABSTRACT

Background: Diabetes mellitus is a chronic metabolic condition defined by consistent hyperglycemia. By 2017, about 462 million individuals worldwide between the ages of 15 and 79 had type 2 diabetes mellitus (T2D). This global public health burden is expected to increase by 200 million by 2040. Curcumin, which is considered the active ingredient in turmeric, has been extensively researched concerning T2D. However, this pilot study will evaluate the efficacy of daily intake of turmeric root powder as a food agent in the management and treatment of T2D.

Method: This is a quantitative quasi-experimental pilot study design, with the primary objective to answer the following question: Can daily intake of turmeric root powder instead of curcumin effectively control blood glucose in persons with T2D?

Conclusion: This study aligns with principles and practices of complementary and integrative health we aim to show the efficacity and effectiveness of whole food agents as a nutritional intervention in the management and treatment of medical conditions such as T2D.

Keywords: diabetes, type 2 diabetes, turmeric, curcumin, nutrition, nutrition intervention

BACKGROUND

Diabetes mellitus is a chronic metabolic condition defined by consistent hyperglycemia. About half a billion people worldwide live with diabetes, which means that over 10% of the world's adult population is now diabetic. The projected number for 2030 will increase by 25% and up to 51% in 2045, while in 2015, about 415 million individuals worldwide between 20 and 79 had diabetes mellitus. This global public health burden is expected to increase by 200 million by 2040 (Zheng et al., 2018). Concerning the U.S, in 1994, *the Centers for Disease Control and Prevention* (CDC), announced that diabetes had reached epidemic levels and should be dealt with as a significant public health crisis. Since 2012, about 30 million individuals in the U.S. were thought to have T2D which is approximately more than 9 percent of the population, and 27% of those individuals have not been diagnosed and are not receiving any treatment. This is happening despite all the scientific progress achieved in the field of pathophysiology, diagnosis and treatment in the past 50 years.

One of the top 10 causes of mortality globally is diabetes, along with cancer, respiratory disease, and cardiovascular disease. These conditions together account for approximately 80% of all premature noncommunicable diseases and deaths worldwide (GBD 2015 Risk Factors Collaborators, 2016). Diabetic individuals have 2 to 3 times more risk of all-cause mortality (Yang et al., 2019). In addition, diabetes is linked to increased death from cancer, CVD, infections, stroke, chronic kidney disease, and chronic liver disease (Bragg et al., 2017; Policardo et al., 2015). Finally, diabetes is the second most significant negative total effect on decreasing global health adjusted life expectancy worldwide (Chen et al., 2019).

For individuals, a persistently high blood glucose level leads to significant life-changing and life-threatening complications such as kidney failure, blindness, and loss of limbs. A recent study of 2551 diabetic patients, with median diabetes duration of four years,

showed that 52% of participants developed hypertension, 40% had dyslipidemia, 37% developed microalbuminuria, and, 5% had apparent diabetic nephropathy. CVD complications were also common in participants up to10% (Al-Lawati, 2017). Diabetes mellitus prematurely kills 5 million people annually worldwide (IDF Diabetes Atlas, n.d.). Beside complications, the financial burden on the diabetic individuals is significant since over 3 in 4 adults with diabetes live in low and/or middle-income countries (IDF Diabetes Atlas, n.d.).

Healthcare costs for diabetic individuals are on average twice as much as for individuals without diabetes. According to *the International Diabetes Federation*, the total cost of diabetes treatment amounted to 15% of the total health care cost in certain regions in the world, which is a staggering cost by any standards. Diabetes in certain regions of the world is the cause of 9% of all adult hospital admissions, 12% of all hospital bed occupancy, and 20 to 30% of all outpatient attendance in regional hospitals (Al-Lawati, 2017).

T2D is about 90% of all cases of diabetes mellitus. In this condition, the insulin sensitivity is decreased over time, leading to what's known as insulin resistance, which makes insulin ineffective and causes an increase in insulin synthesis to maintain glucose balance. Over time, the pancreas function is impaired, and insulin synthesis decreases, leading to type 2 diabetes (Goyal & Jialal, 2020). Oral diabetic medications tend to delay the total pancreas burnout and the need for insulin injections. Nevertheless, over time, the condition deteriorates, and insulin injections become inevitable.

THE ORIGINS OF T2D THERAPY

From the very beginning, frequent and excessive urination was considered a diagnosis of diabetes mellitus. Physicians at that time used horseback riding as a therapy (Reece & Homko, 1998). Centuries later, Rollo discovered the association between food intake and the amount of glucose in the urine (Blaslov et al., 2018). He noticed that excessive intake of carbohydrates increased glucose levels, while the consumption of animal products resulted in less glucose (Guthrie & Humphreys, 1988), (Eknoyan & Nagy, 2005). Thus, in 1877 he proposed that the therapy should be based on a protein rich, high fat diet with low carbohydrates. This diet therapy became the recommended therapy for diabetes until the discovery of insulin in Torento, in 1921 (Blaslov et al., 2018). However, since the first proposal in 1877, many other approaches have been experimented with, such as the "potato therapy," the "oat-cure," and the "starvation diet." This experiment lasted until 1916 when Elliot Joslin published a book entitled: The Treatment of Diabetes Mellitus. In this book, Joslin stated that a fasting diet with consistent moderate physical activity could significantly decrease the risk of death in diabetic individuals (Joslin, 1916). Even though the physical activity and diet concept went through many changes, they still are the two official fundamental therapy approaches for T2D, beyond pharmacological treatment ("Introduction," 2017).

The root of the pharmacological treatment started with the French lilac plant (Galega officinalis), which was used during medieval times as a therapy to remedy diabetes mellitus symptoms with success (Blaslov et al., 2018). This treatment was stopped at the beginning of the 20th century after the anti-hyperglycemic agent in the plant, guanidine, was isolated, synthesized, and named Synthalin. It was then discovered to be a hepatotoxic synthetic drug. Several decades later, a resurgence of interest in the biguanides occurred, and metformin was first introduced in 1959 in Europe and approved in the United States in 1990. Metformin is the only biguanide therapy still used today that primarily reduces the output of hepatic gluconeogenesis and glycogenolysis (Rodbard et al., 2007). Other drug therapies have been introduced in the past two decades, including the sulfonylureas and the class of thiazolidinediones.

HYPOTHESIS

Our project reintroduces a natural food agent in the therapeutic path of T2D. Turmeric root powder is safe and is available worldwide. It is an affordable food agent that if applied properly, may play a crucial role in alleviating the complications and financial burden of diabetes. Our project is a quantitative quasi-experimental study with the primary objective of answering the following question or hypothesis: Can a daily intake of turmeric root powder effectively control and treat T2D subjects' blood glucose? Answering this question may be vital in determining how much we can further control T2D without ever getting to the insulin injection stage. This would relieve the global public health burden, including the cost of medication. This study will be conducted in any clinic worldwide that offers us the necessary help and support to conduct our research.

CASE REPORT

A 45 years-old male came with T2D, obesity, dyslipidemia, and asthma. He was not taking any medication and his fasting blood sugar was hovering around 155 mg/dL. Due to his busy lifestyle and travelling schedule, he was not interested in a full nutritional intervention. He agreed to take one teaspoon of regular turmeric powder that he bought himself from the market, once after each meal and one before bedtime. After four weeks the patient’s fasting blood glucose levels dropped from 155 mg/dl to 115-110 mg/dl.

DESIGN AND METHOD

This study is a longitudinal quantitative quasi-experimental study to estimate the efficacy of an intervention on a target population without random assignment and longitudinal research because it looks at one population over a period of time. This method is well-matched to our research aims because we are looking to assess the intervention of adding daily turmeric root powder intake to the T2D population that fits specific criteria without having a comparison group or random assignments. We will also be following our group for a period of time and compare initial baseline values to the end of the study period results.

To test acceptability, feasibility, and safety, this study will start with a small number of participants. Twenty participants will be enrolled from the patients referred to us by endocrinologists. To build a realistic sample group, participants from various ethnic groups and social status may be able to participate as follows:

Inclusion criteria will include:

- Adult patients without age restriction
- Type 2 diabetes diagnosis
- Fasting blood glucose above 125 mg/dL
- Post prandial blood glucose above 150 mg/dL
- HbA1c above 6.5%
- Oral diabetic medication

Exclusion criteria will include:

- Blood thinner medication
- Gallbladder stones
- Kidney dialysis
- Type 1 diabetes diagnosis
- Insulin injection

THE INTERVENTION

The participants will be enrolled in a 3-month–long study. They will all be instructed not to make any changes to their daily routine, including their diet and physical activity. They will also be instructed to take one teaspoon of turmeric powder which is the equivalent of 3 to 5 g of turmeric, directly with water or mixed with 2 ounces of water orally after each meal, and once before bed time. Up to 12g curcumin daily intake is considered safe, well-tolerated (Chuengsamarn et al., 2012, p. 2; Lao et al., 2006). While, one teaspoon of turmeric powder has around 200 mg of curcumin. All participants will be made aware of any signs or symptoms of hypoglycemia and will be directed to contact their endocrinologist to adjust medication dosage accordingly. For adherence, we will be contacting participants once a week to check on them and keep them motivated.

THE OUTCOME MEASURE

To assess the outcome of the intervention: all participants will be asked to collect data about both their fasting blood glucose and postprandial blood glucose daily for one week prior to the start of the intervention, so that we have a baseline data for the study. From day one of the intervention, all participants will log in to Google Docs and register their blood glucose two times a day for the first week of the study: before breakfast, two hours after dinner. After the first week, the study participants will be measuring and recording one-time fasting blood sugar and one time postprandial after dinner, three times every week. The freestyle blood sugar monitor is used for ease of use and accuracy. The device can hold a week's data; if some of the participants forget to upload their daily measuring, they can easily find it saved on the monitor. For those who cannot use Google Docs, they can use Glooko's MeterSync Blue which is a hardware that enables patients to upload data via Bluetooth to Android and they simply plug the MeterSync Blue adapter into their meter to send data wirelessly to the app.

HbA1c levels will be tested once before the intervention, once when it is over, and three months after the intervention. The data collected will help us assess the progress of the intervention, the percentage that blood sugar levels have dropped or increased, and what the long-lasting effects are. Data collected will be compared to baseline data for each subject individually, and as a group result. For further analysis we will seek the help of a statistician in RSCH841. Future studies should be conducted to assess long-term adherence feasibility and barriers. This study will also assess secondary objectives, including medication reduction, sleep improvement, stress reduction, and weight loss.

ADVERSE EVENTS

Four RCTs reported adverse events, but two showed no severe related side effects in two groups. In two studies, Asadi et al. used 80 mg of nano-curcumin supplementation for eight weeks. The results showed a significant reduction in glycated hemoglobin, fasting blood glucose, the total score of neuropathy, and depression compared to the placebo. Only two cases reported stomach pain in the first few days but did not specify the group (Asadi et al., 2019 & 2020). Another randomized placebo-controlled clinical study from Srinivasan et al., 2019 of 136 patients with type 2 diabetes showed that one patient had upper abdominal pain.

In our clinic and in the past fourteen years of using turmeric powder, no adverse events have been reported concerning this intervention. Therefore, we believe using turmeric powder in our experiment will enhance the curcumin studies without causing any major side effects.

CONCLUSION

This study aligns with principles and practices of complementary and integrative health we aim to show the efficacity and effectiveness of whole food agents as a nutritional intervention in the management and treatment of medical conditions such as T2D.

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