Whether Fasting-Mimicking Diet Improves management of Type-1 and Type-2 Diabetes

Mellitus? A Research Proposal

Whether Plant-Based Fasting-Mimicking Diet (PBFMD) is effective in preventing and reversing

Type-1 and Type-2 Diabetes Mellitus"? A Research Proposal

Topic to Be Pursued

The topic I wish to pursue is the 'role of plant-based diet in preventing and reversing

type-1 and type-2 diabetes mellitus." Recent studies suggest that novel dietary interventions

might alleviate the risk and complications of both type-1 and type-2 DM. Cheng et al. (2017)

showed that fasting mimicking diets (FMD) induce prenatal-development gene expression

(PDGE) in the adult pancreas. The authors showed that FMD could reverse beta cell failure and

rescue murine species from type-1 and type-1 DM. The authors grounded their research on the

assumption that animals are able to withstand fasting conditions by developing different adaptive

responses. One such adaptive response is the atrophy of different tissues that help to minimize

energy loss during fasting. However, a reversal of normal dietary plan causes such tissues to

regenerate and proliferate. Hence, it is contended that Plant-Based Fasting-Mimicking Diet

(PBFMD) could prevent and reverse DM.

Reason of Interest

The increased prevalence of Diabetes Mellitus (DM) over the past few decades has raised

significant concerns across healthcare professionals around the globe. Both type-1 and type-2

DM predisposes the risk of different cardiovascular disorders. On the other hand, uncontrolled

diabetes mellitus is associated with different complications. The major complications of DM

include nephropathy, reticulopathy, and neuropathy. Moreover, such complications may lead to

end-organ failure and may increase the risk of mortality in the respective individual. Hence,

healthcare professionals and scientists are on a quest for innovative and effective strategies for

managing DM. Although hypoglycemic drugs are effective in managing DM, tolerance can reduce their effectiveness over the long term. As a result, dosage titration of hypoglycemic agents imposes significant concerns in patients and healthcare professionals (Brereton et al., 2014).

Bradhorst et al. (2015) highlighted that stem-cell-based therapy was effective in regenerating hemopoietic and nervous tissues. Cheng et al. (2017) showed that FMD could induce regeneration and cellular programming in the pancreas. Such programming led to the functional lineage of pancreatic beta cells. As a result of such altered lineage, both insulin secretion and insulin sensitivity increased in murine samples. On the other hand, plant-based dietary interventions are becoming popular in developed and developing nations. The present study would explore the role of Plant-based fat mimicking diets (PBFMD) in alleviating the risk of uncontrolled DM.

A plant-based diet consisting of nuts and soya proteins would provide high fats, low carbohydrates and low protein quality-a situation that mimics fasting. As a result, pancreatic cell lineage can get altered to increase expression of pancreatic beta-cells upon re-introduction of the individual into the feeding state. The impact of this novel dietary intervention can be evaluated through changes in Hb1Ac and blood glucose levels. The Cheng et al.s (2017) study provided the role of FMD in murine models and related those to the histopathological changes in the pancreatic cell lineage. However, the present study would be conducted on humans as a clinical trial. This is because Cheng et al. (2017) highlighted that FMD should be evaluated in T1DM and T2DM patients.

Target Audience

The target population for the proposed study would include patients suffering from uncontrolled T1DM or T2DM. Novel interventions such as plant-based diet may ensure tight control of blood sugar in the respective target population. Hence, the proposed intervention might benefit such individuals who are refractory or unresponsive to oral hypoglycemics. The proposed study would be conducted as a randomized control trial. The study participants (n=120) would be randomly allocated to four experimental groups. All study participants should be diabetics and must belong to the age-range of 40 to 50 years. The study population would include individuals from diverse ethnic, religious, socioeconomic, and cultural backgrounds. Such assumptions would reduce the confounding effects of different demographic variables in the proposed study. The first experimental group would receive only oral hypoglycemics as prescribed by their physician. The second experimental group would receive a combination of oral hypoglycemic and PBFMD. On the contrary, the third experimental group would only consume PBFMDs. Finally, the fourth experimental group would be asked to fast for two days.

Problem Statement

The proposed study would explore one main research question "Whether Plant-Based Fasting-Mimicking Diet (PBFMD) is effective in preventing and reversing Type-1 and Type-2 Diabetes Mellitus"?

Research Questions

The proposed study would explore one main research question and different sub-research questions. The SRQs would help to address the main research question in a comprehensive manner.

Main research question
Whether PBFMD is effective in preventing and reversing T1DM and T2DM?
Sub-research Questions
Whether PBFMDs significantly lower blood glucose levels in diabetics?
Whether PBFMDs significantly lower glycosylated hemoglobin levels (Hb1Ac) in diabetics?
Whether PBFMDs significantly improve insulin levels in diabetics?
Whether PBFMDs significantly reduce the risk of nephropathy, neuropathy, and retinopathy in diabetics?
Whether PFMDs are effective alone or in combination with oral hypoglycemic drugs in reducing blood glucose levels?
Whether PFMDs significantly increase the risk of CVD and dyslipidemia in diabetic patients?
Whether consumption of PFMDs is associated with more adverse effects compared to oral hypoglycemics?

Table 1: The research questions and their respective hypothesis

Hypothesis Testing

Both the main and sub-research questions would be interpreted based on the acceptance or rejection of the null hypothesis (Ho) or the alternative hypothesis (Ha) respectively. The research questions and their respective hypotheses are presented in Table 1. The Ho contends

that there is no difference between the means or correlation between two observations. Any noted difference or correlation is attributed to chance factors of random sampling. The Ho is accepted if the p-value for the statistical test of inference is greater than 0.05. The Ha contends that there is a significant difference between the means or correlation between two observations. Any noted difference or correlation is not attributed to chance factors of random sampling. The Ha is accepted if the p-value for the statistical test of inference is lesser than 0.05. Hence, the Ho for the proposed study contends that PBFMD is not effective in preventing and reversing T1DM and T2DM. Likewise, the Ha the Ho for the proposed study contends that PBFMD is effective in preventing and reversing T1DM and T2DM.

Identification of Variables and Interpretation of Relationship

The end-points and interventions are aligned to the research questions that were framed for the proposed study. Such parameters include fasting blood glucose levels, Hb1Ac levels, history of adverse effects, and incidences of cardiovascular mortality and morbidity. The intervention that would be explored in the proposed study is a plant-based fat mimicking diet. The diet will comprise of low protein, low carbohydrate, and a high-fat content. The diet would consist of a higher proportion of nuts and a lower proportion of milk and meat products. Although the novel diet would also comprise fewer amounts of cereals, the study participants would be encouraged to consume whole grains during the entire phase of the study. Inferential statistics such as the Mann-Whitney U test and Student's t-tests would be undertaken to report the findings of the proposed study. The IBM-SPSS software would conduct all statistical calculations for the present study.

References

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