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A Prospective Study on the Impact of Intermittent Fasting on Insulin Sensitivity and Metabolic Markers in Overweight and Obese Adults with Type 2 Diabetes- Study protocol

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ABSTRACT

Background: The obesity and Type 2 Diabetes Mellitus (T2DM) epidemic in the world is a critical community health issue, which majorly is a result of insulin resistance. Intermittent fasting (IF) is a new dietary therapy with a prospective to become a viable solution through its alternating phases of starvation and food intake in the effort to enhance metabolic health. Although short term studies are positive, there is a lack of long-term data on its effectiveness in enhancing insulin sensitivity and other important metabolic indicators in overweight and obese diabetic patients.

Aim: To evaluate the treatment of insulin sensitivity and a full range of metabolism indicators in overweight and obese adults with T2DM on the effect of a 24-month intermittent fasting program.

Methods: The prospective observational study will involve 210 participants who have T2DM (BMI 25 kg/m2). The participants will be subjected to a time-limited diet (16:8) (8-hour to eat, 16 hours to starve). At baseline and after the 24-month study period, anthropometric measurements (weight, BMI, waist/ hip circumference), biochemical measures (fasting plasma glucose, HbA1c, lipid profile, leptin, beta-hydroxybutyrate, high-sensitivity C-Reactive Protein), and dietary adherence will be measured. Paired t-tests and correlation analysis based on the SPSS version 25.0 will be used to perform statistical analysis.

Conclusion: The current study will attempt to give strong, sustainable evidence on the sustainability and metabolic advantage of intermittent fasting. It is hoped that the findings will be used to inform evidence-based lifestyle interventions in the management of T2DM and the minimization of the effects of obesity complications..

KEYWORDS: Intermittent Fasting, Insulin Resistance, Type 2 Diabetes, Obesity, Metabolic Syndrome, Time-Restricted Feeding.

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INTRODUCTION

Overweight and obesity among the population worldwide have almost tripled since 1975 and this contributes to the number of non-communicable diseases especially Type 2 Diabetes Mellitus (T2DM) (1, 2). The primary cause of insulin resistance, which is a pathophysiological condition of cell failure to respond to insulin, is obesity (3). This resistance is of the essence to the formation of the metabolic syndrome, T2DM, and cardiovascular diseases, establishing an acute necessity of efficient and lasting interventions (4, 5).

The conventional method of dieting, which is sustained on a constant calorie reduction, tends to be challenging. Intermittent fasting (IF) has been considered as an option that can be used as an alternative instead of eating. Some of the common regimens such as alternate-day fasting and time-restricted feeding (TRE) have been proven effective in a short-term study to improve body composition, glycemic control, and lipid profiles (6, 7). Indicatively, time-restricted feeding (16:8 protocol) has been demonstrated to lower the fat mass and enhance insulin sensitivity, which are at times not dependent on weight loss (8, 9).

Critical knowledge gaps still exist in spite of a positive outcome. A good number of the available studies are relatively short-term and their results cannot be extrapolated to a long-term clinical practice (10). It is also necessary to gain a better insight on the mechanistic impact of IF on particular metabolic pathways, such as inflammatory and oxidative stress indicators, in a specified group of overweight and obese patients with T2DM.

The proposed research is aimed to fill these gaps and to assess the effects of 24 months of IF intervention on insulin sensitivity and a wide range of metabolic parameters. Our hypothesis is that an IF diet will result into major differences in insulin sensitivity, glycemic control, lipid, and inflammatory markers in adults with T2DM who are overweight and obese..

MATERIALS AND METHODS

Design and Setting: The study design is a prospective observational study that will be done at the Department of Medical Physiology, Jawaharlal Nehru Medical College, Sawangi (Meghe), Wardha, between the years 2023 and 2025.

Participants:

Inclusion Criteria: Patients aged 18-65 years with a minimum of 6 months of diagnosed T2DM, a Body Mass Index (BMI) 25 kg/m 2 and an intention to follow the 16:8 intermittent fasting plan.

Exclusion Criteria: Type 1 or gestational diabetes, severe hepatic/renal/cardiovascular disease, active malignancy, intake of drugs that have a pronounced impact on the lipid metabolism, and the inability to provide informed consent.

Calculation of the sample size: Given the suspected moderate effect (Cohens d = 0.5), the power of 90 per cent and a dropout rate of 20 per cent in 24 months, 105 participants in each group (n=210) was calculated to be statistically significant.

Intervention: The norms to be adhered to will be the 16:8 time-restricted feeding regime that includes eating all day calories in 8-hour interval and starving the rest of the 16. Compliance will be ensured by using self-administered daily diet and fasting records.

DATA COLLECTION:

Anthropometric Measures: The anthropometric measurements that will be taken in this study include body weight, height, BMI, and waist/hip circumference with the help of standardized methods.

Biochemical Analysis: To analyze: Fasting blood samples will be investigated.

Glycemic Markers: HbA1c, Fasting Plasma Glucose (FPG).

Lipid Profile: Total Cholesterol, LDL-C, HDL-C, Triglycerides.

Hormones and Metabolites: Leptin, Beta-Hydroxybutyrate (bHB).

Inflammatory Marker: High-sensitivity C-Reactive Protein (hs-CRP).

Statistical Analysis: SPSS version 25.0 will be used to analyze the data. The data will be summarized using descriptive statistics (mean, standard deviation, frequencies). There will be a comparison of the pre and post-intervention results through inferential statistics which will be mainly paired t-tests. The correlation by Pearson will be used to determine relationships between variables (e.g., leptin, bHB, and lipid levels). The p-value of less than 0.05 will be taken as statistically significant.

Ethical Considerations: The research protocol will be passed through the Institutional Ethics Committee of Datta Meghe Institute of Higher Education and Research. All the participants will be informed (written consent) before enrolment and confidentiality will be assured and the right to withdraw at will without any penalty.

DISCUSSION

This study protocol represents a prospective study content on the metabolic impact of intermittent fasting over an extended period of time. The period of 36 months is a major strength as it has addressed a major limitation of the past studies. The study aims a high-risk group (adults with established T2DM) as it specifically targets the population of overweight and obese individuals who can be benefited by effective lifestyle interventions.

Outcome measures are chosen to have a holistic view of the metabolic health. In addition to usual glycemic indices (FPG, HbA1c, HOMA-IR), leptin and bHB should be considered a particularly valuable inclusion. One of the important ketones, bHB, is the direct biomarker of metabolic switching and compliance to fasting state (12). Leptin is a crucial hormone released by adipose tissue that provides a window into the relationship between IF, adiposity, and the regulation of appetite (11). βHB, a key ketone body, serves as a direct biomarker of metabolic switching and adherence to the fasting state (12). The measurement of hs-CRP will help quantify the potential anti-inflammatory effects of IF, a crucial mechanism in breaking the link between obesity, inflammation, and insulin resistance (13).

Potential challenges include ensuring long-term adherence and managing the variability inherent in a free-living population. The use of dietary logs, while practical, relies on participant honesty. Future analyses could incorporate more objective adherence measures.

This study is poised to make a valuable contribution to the field of nutritional science and metabolic medicine. If the hypothesis is supported, the findings will provide strong evidence for incorporating structured intermittent fasting as a non-pharmacological strategy to improve metabolic health and reduce the risk of complications in a growing diabetic population.

CONCLUSION

This research protocol describes a rigorous investigation into the sustained impact of a 16:8 intermittent fasting regimen on insulin sensitivity and metabolic health. By providing long-term data on a comprehensive set of biomarkers in a clinically relevant population, the study aims to bridge a critical gap in the current literature. The results have the potential to validate IF as a sustainable and effective dietary strategy, empowering individuals and guiding healthcare providers in the management of T2DM and obesity-related metabolic dysfunction**.**

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