

Research Protocol
Title: Influence of Diet
and Exercise on the
Overall Quality of Life,
Health, and Wellness
Outcomes of the Patients
Affected with Type II
Diabetes Mellitus

Background and Justification

Evidence-based literature reveals the influence of physical activity on the quality of life, mortality rate, cardiovascular events, blood pressure, and blood cholesterol level of the patients affected with type II diabetes mellitus (Colberg, et al., 2010). The qualitative assessment by Advika, et al. (2017) reveals the requirement of comprehensive approaches for improving exercise adherence of the diabetic patients in the context of enhancing their wellness outcomes. The analysis by Malpass, et al. (2009) also advocates the need for disseminating physical activity and dietary information to the type II diabetes patients to effectively improve their lifestyle changes and overall healthcare experience. The case-control study by Al-Mountashiri, et al. (2017) reveals the improvement in glycemic control of type II diabetes patients under the influence of dietary modification. The limited consumption of fat and elevated consumption of fruit results in improvement in the blood glucose levels. The study also advocates the need for consuming a balanced diet in the context of normalizing the BMI and HbA1c level of diabetic patients. Scientific opinion by Asif (2014) emphasizes the influence of different food items on the glycemic indices of the patients affected with type II diabetes mellitus. For example, the consumption of peas, beans, whole grains, peaches, and dark leafy vegetables substantially reduces the glycemic index of diabetic patients. The scientific opinion also signifies the need for exercise interventions in the context of enhancing the LDL (low-density lipoprotein): HDL (high-density lipoprotein) ratio in type II diabetes patients.

The analysis by Sami, et al. (2017) reveals the significance of dietary knowledge enhancement of the diabetic patients in the context of effectively controlling their disease manifestations. The assessment also reveals the positive influence of dietary modification measures on the quality of life and self-care pattern of the diabetic patients. Individuals affected with glucose intolerance need to implement fat and calorie intake restrictions in the context of minimizing their risk of hyperglycemia and associated clinical manifestations (Appuhamy, et al., 2014). The assessment by Clark (2015) emphasizes the impact of metabolic stress on type II diabetes manifestations in the affected individuals. Accordingly, the exercise and dietary management approaches must focus on stabilizing the body mass indices, hormone levels, and blood lipid levels of the diabetic patients to effectively improve their overall health outcomes. The study findings indicate the effectiveness of a hypocaloric and protein-rich diet on the metabolic outcomes of type II diabetes patients. However, evidence-based literature exhibits gaps in relation to the assessment of combination interventions (including exercise and diet approaches) and their impact on the metabolic demand of the diabetic patients. The study by

Hamasaki (2016) emphasizes the positive influence of regular walking on the metabolic outcomes of the patients affected with type II diabetes mellitus. Walking also reduces the risk of mortality and cardiovascular disease in diabetic patients. The study also advocates the influence of walking and standing on the non-esterified fatty acid, insulin, and glucose responses of the diabetic patients. Furthermore, the study also emphasizes the potential of non-exercise activity thermogenesis or daily physical activity on the anabolic and catabolic processes of diabetic patients. The study signifies the requirement of undertaking a range of exercise, diet, and environmental modification approaches to effectively control the health, wellness, quality of life and treatment outcomes of diabetic patients.

Evidence-based literature undoubtedly reveals the significance of diet and exercise in terms of improving the treatment and management outcomes of the patients affected with type II diabetes mellitus. However, serious research gaps exist in terms of delineating the exact potential of diet and exercise approaches for type II diabetes patients. The researchers still struggle to standardize various diets and exercise strategies for their coadministration with the conventional treatment modalities to improve the overall health and wellness of the type II diabetes patients. Prospective research studies need to identify the significant patient attributes and health outcomes that could exhibit substantial improvement under the influence of dietary modification strategies and exercise interventions for a predetermined duration. The proposed study will proceed a step further to identify the influence of aerobic exercise, walking, and dietary modification interventions on the quality of life and overall treatment, health, and wellness outcomes of the type II diabetes patients. The proposed study will attempt to evaluate the physical function, clinical symptoms, psychological well-being, social well-being, satisfaction/personal constructs level, cognitive function, glycemic control, and lipid control of diabetic patients in relation to the administration of predetermined diet and exercise measures.

Study Hypothesis

The 4-monthly administration of dietary and exercise interventions substantially improves the overall well-being, personal constructs, and psycho-socio-somatic outcomes of the patients affected with type II diabetes mellitus.

Methodology

Study Design

The proposed study will deploy a mixed method approach in the context of determining the improvement in patient attributes and lab outcomes under the sustained influence of diet and exercise interventions. The mixed method interventions utilize the quantitative and qualitative research approaches in accordance with the research questions/hypothesis to

retrieve scalable, precise, and generalizable findings (Tariq & Woodman, 2013). Investigators will deploy cohort intervention with the objective of observing clinical/lab outcomes of diabetic patients at regular intervals during and after the administration of the preselected dietary and exercise interventions. Cohort intervention effectively indicates the incidence and prevalence of various disease manifestations (NCOR, 2014). The presented study will follow the same trend and identify the variation in glycemic control and lipid levels of diabetic patients after dietary/exercise administration. The study will also deploy semi-structured interviews to evaluate the dependent variables, including physical function, personal constructs, and psychosocial outcomes of diabetic patients. The open-ended questions through the semi-structured interviews will assist the researchers in understanding the subjective experience of the participants in relation to the preselected dependent variables (Jamshed, 2014). However, the independent variables will include the diet plan, exercise sessions, and walking interventions recommended by the healthcare professionals in coordination with the study investigators.

Study Population and Methods of Recruitment

The researchers will utilize the purposive sampling strategy in accordance with the following prerequisites.

1. Affirmatory diagnoses of type II diabetes mellitus [uncontrolled state]
2. Ongoing diabetes conventional treatment
3. The age range of 45-65 years
4. The absence of cardiovascular abnormalities
5. The absence of physical and mental deformities
6. Male and female participants

Uncontrolled diabetes state of participants will assist in determining the extent of glycemic control that they might acquire after receiving the preconfigured interventions. The absence of patients' comorbidities and physical challenges will reduce the risk of clinical complications and facilitate the administration of appropriate diet/exercise interventions.

The researchers will retrieve the data of diabetic patients of the selected age range and clinical characteristics through the databases of the selected hospitals (after acquiring due approval). The participants will be contacted through telephone calls and email. The final shortlisting of candidates will be based on their initial clinical assessment and analysis of the individualized prescriptions.

Sample Size

The researchers will deploy 500 type II diabetes patients at the selected location in accordance with the study protocol. The selection of a substantial sample size will facilitate the extrapolation of the study outcomes to the entire type II diabetes patients in the selected age group (Faber & Fonseca, 2014). The power of the study substantiates with the selected sample size. However, many studies with small sample size also provide relevant findings based on the precise methodology and focussed research objectives. The researchers in the presented scenario might need to adjust or optimize the sample size based on the study duration and should adjust the false negatives rate prior to the study initiation (Gupta et al., 2016).

Methods of Data Collection

The researchers will utilize the embedding approach with the objective of collecting the desired data across numerous preselected points across the research location (Fetters, et al., 2013). The researchers will record the interview sessions and transcribe the audio transcripts for deriving the study theme. Lab outcomes will be recorded in the electronic health record for analysis. The tagging and coding of the qualitative data will be performed in accordance with the grounded theory (Foley & Timonen, 2015).

Ethical Considerations

The researchers will require obtaining approval from the concerned ethical review board before initiating the proposed study in the context of safeguarding the rights and dignity of the participants (Grady, 2015). The participants will need to fill in the informed consent form detailing the entire procedures and conventions related to the study intervention (Nijhawan, et al., 2013). The researchers will explain the expected outcomes of the study to the participants. However, they will refrain from undue deception at any point in time during the study intervention. The researchers will execute debriefing interventions after study accomplishment to effectively record participants' overall experience and satisfaction level in relation to the study course (Gardner, 2013). The participants will be allowed to leave the study at any point in time without providing any explanation. The researchers will preserve the confidentiality of the participants' information and study data to reduce the risk of biasing. The study recruiters and investigators will advise the participants in their best interest and without any conflict of interest.

Statistical Analysis

Thematic assessment of the qualitative data will be undertaken through the utilization of the grounded theory method. The theoretical sampling of outcomes will substantially help in comparatively analyzing the dependent variables (Sbaraini, et al., 2011). The robust

statistical approach will be utilized to retrieve the robust average of blood glucose and lipid profile of the participants before and after receiving the nutrition and exercise interventions (Zhong, et al., 2016).

Timetable

Milestone	Duration
Participants' recruitment	1-month
Data collection	1-month
Administration of study procedures	4-months
Qualitative data analysis	15-days
Quantitative Data analysis	15-days
Assessment of findings	15-days
Publishing of results and report writing	15-days

Critical Evaluation of Research Design

The greatest strength of the proposed study relates to its mixed method design and utilization of multiple variables for evaluating the research hypothesis. The substantial sample size of the study will increase the scalability of outcomes larger groups of the population. The study recruitment strategy, ethical conventions, and data collection/analysis measures will effectively reduce the risk of bias and inappropriate outcomes. The thematic assessment of information through grounded theory approach minimizes the risk of misrepresenting the retrieved data. The study triangulation will substantially enhance its rigor and authenticity of the retrieved findings. However, the study limitations will be based on the challenges encountered in training the research team to conduct the mixed methods study to reduce the risk of conflicting results. Participants' dropout at any point in time during the study execution will challenge the generalizability of findings and impact the statistical power to a considerable extent. The engagement of multidisciplinary researchers will increase the risk of manual errors during data collection and analysis.