**Diet and Exercise vs Antidiabetic Medications for Type II Diabetic Management**

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**Diet and Exercise vs Antidiabetic Medications for Type II Diabetic Management**

Type 2 diabetes mellitus is a chronic disease that results from impaired blood glucose control. The etiology of type 2 diabetes includes inadequate production of insulin by the pancreas and poor response of cells to insulin. The predisposing factors include being overweight or obese, leading a sedentary lifestyle, a positive history of the disease, ethnicity, age, and blood lipid levels among other factors (Al-Sahouri et al., 2019). There is no treatment for type 2 diabetes, therefore, management entails pharmacological interventions as well as lifestyle modifications that involve diet and exercise.

Poorly controlled type2 diabetes is a significant public health problem due to an increased risk of diabetic complications. Some of the complications associated with type 2 diabetes include diabetic retinopathy, nephropathy, foot ulcers, poor wound healing, neuropathy, skin conditions, and cardiovascular disease (Fekadu et al., 2019). Thus, there is a need to manage type 2 diabetes to avoid these complications. The main challenges associated with the pharmacological management of type 2 diabetes include adverse side effects associated with the medications, leading to non-adherence and poor glycemic control (Gouda et al., 2018). The high cost of diabetic medications may be prohibitive for patients of low-socioeconomic standing (Fekadu et al., 2019). Exercise and dietary interventions are beneficial in the management of diabetes because they do not have adverse effects and are cost-effective. However, it is unknown whether dietary changes and exercise achieve the same levels of glycemic control as those observed in pharmacological interventions. There is a need to ascertain this issue to promote dietary and exercise interventions in diabetic patients who cannot afford drug therapy or are experiencing intolerable side effects from the same.

**PICO Question**

In adults with type 2 diabetes, do exercise and diet lead to better glycemic control compared to drug therapy as primary treatment?

**Discussion of Findings**

The table of findings of the research critically reviewed by the authors is found in the appendix. A particular theory that was used to guide the research was the Health Belief Model. The research revolved around the idea that current treatment of diabetes is not as effective as it could be. Rather than simply taking pills or injecting insulin, other methods are available that would be effective in type 2 diabetes management, ones that can help them understand the gravity of their condition, motivate them to play a larger role in their treatment, and provide them with what they may need to change for more effective therapy (Rosenstock, Stretcher, & Becker, 1988). Although the findings of the research confirmed the important of exercise and diet for better glycemic control, only a small amount of evidence was found that exercise and diet lead to a better glycemic control than does drug therapy (Blickle et al., 2009; Knowler et al., 2002). Much of the research found that it was a combination of antidiabetic agents and lifestyle modifications, including diet and exercise routines along with diabetes-centered patient education, which yielded positive results, reduced hemoglobin A1c, and improved glycemic control.

**Current Use of Research Findings**

When researching diet and exercise vs antidiabetic medications, there was an obvious best glycemic control standard of care practice. Regardless of the setting, we found that the best glycemic control for newly diagnosed Type II diabetics is a combination of lifestyle change with antidiabetic medication use. The benefits of using lifestyle modifications with moderate intensity as the primary intervention was found to be most beneficial for those who were diagnosed as prediabetic.

In interviewing nurses, Nurse Practitioners, and physicians in a primary care setting, where multiple Type II diabetics are newly diagnosed and treated; it was found that they practice in a comprehensive diabetes self-management which includes instructions on nutrition, physical activity and metformin as first line therapy for newly diagnosed diabetes. Most providers follow the American Diabetes Association guidelines which include current clinical practice guidelines and general treatment goals. They begin their patients on metformin with an A1c of > 7.5-8% along with diet and exercise education being as equally important in the patient’s standard of care. Metformin is the preferred initial drug therapy because of glycemic efficacy. The providers goal of therapy is a A1c of <7% to protect against micro and macrovascular complications of uncontrolled diabetes.

Through interviewing new graduates (n=6) it was determined that in current programs across the domain of educational programs including nursing, chiropractic, and podiatric medicine disciplines, the importance of proper nutrition and adequate exercise was taught as a component of type 2 diabetes management. The students state that included in their education on diabetes risk management there were certain principles of nutrition and exercise such as avoidance of sugary drinks and highly processed foods, following the MyPlate.gov recommendations for macronutrient ratios, and regular exercise of 30 minutes per day at least 5 days of the week.

Here there are ethical implications of the research findings, namely beneficence. Beneficence in healthcare seeks to reduce and mitigate harm a patient might receive from a disease or therapy while enhancing and increasing the benefits a patient may receive through treatment of a disease (Strickland & Stoops, 2018). Regular exercise and diet modifications are not without significant in reducing hemoglobin A1c and improving glycemic control in type 2 diabetes (Coppell et al., 2010; Otten et al., 2017). It is important that providers incorporate such interventions into the care plan of their patients. Withholding measures that reasonably improve the efficacy of treating a chronic disease is unjust and goes against the ethical principle of beneficence.

**Recommendations for Nursing Practice**

Recommendations for nursing practice should include several educational aspects. First, intensive diet education, such as foods to avoid, healthy snack options, need for snacks or drinks for low glucose readings, and emergency medications for critical lows. Discussion of how to recognize signs and symptoms of low glucose and what medications the patient has on hand at home for low glucose. Strict medication management regimen should be implemented for the patient. Nurses could consider discussing the need for a dietitian consult with the physician if they are not already completed and or if further education is deemed necessary. Assuring that the patient understands when and how to give their medications is important. Family should be involved in all aspects of education for diabetics as well. Patients need to feel empowered to make their own choices, particularly healthy ones, to self-manage this disease in a positive way (Wilson, 2021). Assessing outcomes to determine a patient’s understanding of the education would include asking questions on how frequent the blood glucose is checked, what medications are taken and at what times, asking scenario questions to assess how to treat a low glucose. Allowing a patient to keep a food log that they bring to appoints is another way they can be held accountable to their choices and provides the physician and nurses to guide the patients care based on their health literacy.

**Recommendations for Future Research**

Recommendations for further research in this area should include more in-depth studies. Many of the studies found were over brief periods of time and directed toward diabetics who have had the disease for less than five years. Better results could come from longer trials with diabetics who have had this condition for longer time frames. Less exclusion of diabetics with chronic complications could prove or disprove that those patients may have better quality of life and glycemic control with modifications in diet, exercise, and pharmacological adherence.

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**Appendix**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Article | Purpose | Conceptual  Framework | Sample/  Setting | Variables | Design | Threat | Measurement | Analysis | Findings | Level of Research/Replication |
| Castaneda, C., Layne, J. E., Munoz-Orians, L., Gordon, P. L., Walsmith, J., Foldvari, M., Roubenoff, R., Tucker, K. L., & Nelson, M. E. (2002). A Randomized Controlled Trial of Resistance Exercise Training to Improve Glycemic Control in Older Adults with Type 2 Diabetes. Diabetes Care, 25(12), 2335–2341. https://doi.org/10.2337/diacare.25.12.2335 | To determine the efficacy of high-intensity progressive resistance training (PRT) on glycemic control in older adults with T2D | not explicitly stated but self-efficacy is implied | Sixty-two community-dwelling Latinos >Fifty-five years old with T2D for at least three years who were randomly placed in control or PRT group. Took place at General Clinic Research Center at New England Medical Center and Human Nutrition Research Center on Aging at Tufts University (HNRCA) over sixteen weeks | Independent variable- PRT dependent variable- glycemic control with PRT | Randomized control trial | Small sample size and short duration of study. Self- reporting was not observed by researchers and only done by self- reported checklists | postprandial glucose before and after exercise with One Touch Glucometer for treatment group, Control group received phone calls every other week and came to HNRCA during baseline, mid, and poststudy. Both groups had pre, mid and post study biochemical measurements (not explicitly stated as to the tests). Both groups were given weekly symptom checklist to document glucose, diabetic control, medical visits, med changes, acute illnesses, hospitalizations, BMI measurements | statistical analysis based on intent to treat approach using SPSS 10.0 for Windows. | PRT as adjunct to standard care is effective in increasing glycemic control. | Level IV and is possible for replication |
| Hashim, S. A., Mohd Yusof, B.-N., Abu Saad, H., Ismail, S., Hamdy, O., & Mansour, A. A. (2021). Effectiveness of Simplified Diabetes Nutrition Education on Glycemic Control and Other Diabetes-Related Outcomes in Patients with Type 2 Diabetes Mellitus. Clinical Nutrition ESPEN, 45, 141–149. https://doi.org/10.1016/j.clnesp.2021.07.024 | To evaluate the effectiveness of the Simplified Diabetes Nutrition education (SDNE) on glycemic control | Health Belief Model | Two hundred and eight T2D studied from June to December 2019 at Faiha Specialized Diabetes, Endocrine, and Metabolism Center (FDEMC) in Basrah, Iraq. study completed via lecture-based Power point, whiteboards, group discussions, interactive videos, household measurements and food models | Independent variable- Weekly diabetic nutrition module Dependent variable- improved glycemic control | Randomized control trial | Short study over twenty-two total weeks. Study ended two weeks early due to conflict in Iraq so only ten weekly modules given. | The primary outcome measure of the U-TURN study was change in HbA1c from baseline to twelve-month follow-up. The secondary outcome was reduction in anti-diabetic medications from baseline to twelve months follow as evaluated according to the pre-specified algorithm | Statistical analyses conducted using SPSS software, independent t-test to determine difference of continuous variables, Chi-square test for categorical variables, General Linear model and two-way repeated measure ANCOVA to measure changes over time, intention to treat analysis for nonadherence and missing data | SDNE was beneficial in improving glycemic control in Iraqi patients with T2D. | Level IV and is possible for replication |
| Vieira, E. R., Cavalcanti, F. A. da C., Civitella, F., Hollifield, M., Caceres, S., Carreno, J., Gaillard, T., Huffman, F. G., Mora, J. C., & Queiroga, M. R. (2021). Effects of Exercise and Diet on Body Composition and Physical Function in Older Hispanics with Type 2 Diabetes. International Journal of Environmental Research and Public Health, 18(15). https://doi.org/10.3390/ijerph18158019 | To assess the effects of diet and exercise on body composition and physical function in older Hispanics with T2D | Not explicitly stated | Twenty-nine Hispanics ≥ sixty-five years old with T2D, able to pass the Mini Cog test, and score > seventeen on Mini Nutritional assessment. They were from three senior centers in poor neighborhoods. Divided into three groups: Control group, diet group, and diet + exercise group | Independent variable- diet and exercise for one arm, and diet for the second arm. | Cluster-randomized trial with three arms | Short duration Food consumption, daily physical activity, adherence to medication was not objectively measured, study ended early due to COVID, high attrition rate, groups were uneven: diet and exercise had eight, diet had six, and control had fifteen | Height measured using SECA Stadiometer, weight in light clothing and no shoes, BMI, waist and hip circumference using flexible, non-elastic metric tape measure, grip strength using dynamometer, sit to stand test without arm rests, two blood pressure checks while sitting, Capillary glucose and HbA1C | Shapiro-Wilk test to verify data normality and Levene test for equal variances. Comparison of three groups performed with ANOVA and Tukeys multiple comparison test HSD. P values were all two sided and the analyses done in SPSS software | No improvement in variables of diabetes management but showed slight improvement in physical abilities from baseline to three months | Level IV and is possible for replication |
| Blonde, L., Meneghini, L., Peng, X. V., Boss, A., Rhee, K., Shaunik, A., Kumar, S., Balodi, S., Brulle-Wohlhueter, C., & McCrimmon, R. J. (2018). Probability of Achieving Glycemic Control with Basal Insulin in Patients with Type 2 Diabetes in Real-World Practice in the USA. Diabetes Therapy, 9, 1347-1358. https://doi.org/10.1007/s13300-018-0413-5 | To determine the probability of achieving glycemic control over twenty-four months in patients taking oral antidiabetic agents after basal insulin initiation in patients with T2DM in the USA  To determine the importance of basal insulin in treating T2DM | Quantitative study. None explicitly stated. | 6597 patients, reflective of US population with T2DM in terms of age, race, insurance coverage, most common comorbidities, who were started basal insulin following OADs and had at least one valid glycated hemoglobin (HbA1c) result within 90 days before and 720 days after basal insulin initiation | Changes in HbA1c, glycemic control over twenty-four months. | Epidemiological, retrospective cohort study | No randomization threatens external validity.  Intervention of intensive basal insulin treatment uncommon in routine clinical care.  Only selecting patients with a HbA1c >9% baseline not entirely reflective of all patients diagnosed with T2DM. | Changes to HbA1c every six months (every quarter) measured over a twenty-four-month period, likelihood of lowering HbA1c to < 7% if glycemic control not reached each quarter, likelihood of reaching glycemic control over twenty-four months, statistical analysis to determine demographic data | Descriptive statistics of HbA1c change from baseline were calculated every 180 days following basal insulin initiation, percentage of patients who had not reached glycemic control. Probably of achieving glycemic control was a) estimated quarterly as the conditional probability of achieving glycemic control among those who had not previously achieved glycemic control and b) the cumulative probability of patients reaching first glycemic control over time using Kaplan-Meier curves for the whole study cohort | 6597 patients selected from clinical EMR database, mean HbA1c decreased 1.49 percentage points from baseline-6month after basal insulin introduction and 38% reached glycemic control in the first 12 months, no significant reduction later in time. Post basal insulin initiation, 22% reached HbA1c <7% in the first quarter. Estimated that 25%, 38%, 42% and 64% of eligible patients achieved HbA1c < 7% by 6, 12, 18, and 24 months respectively after basal insulin initiation. Likelihood of achieving glycemic control after 6-12 months on an unmodified regimen is low. Maintaining a basal insulin regimen over 12-24 months in a patient who has not yet reached HbA1c < 7% yields little to no benefit of reaching this goal. | Level IV, replication is possible |
| Heine, R. J., Van Gall, L. F., Johns, D., Mihm, M. J., Widel, M. H., & Brodows, R. G. (2005). Exenatide versus Insulin Glargine in Patients with Sub optimally Controlled Type 2 Diabetes. Annals of Internal Medicine, 143, 559-569. https://doi.org/10.7326/0003-4819-143-8-200510180-00006 | The change in hemoglobin A1c from baseline was the foremost factor used to determine the efficacy of the interventions. SAS software used to conduct likelihood-based mixed-effect model repeated measures (MMRM) analysis. | Study guided by quantitative framework although non explicitly stated. | eighty-two outpatient study centers in thirteen countries  five hundred fifty-one patients with T2DM and inadequate glycemic control (HbA1c level 7.0%-10.0%) despite combination metformin and sulfonylurea therapy. | Variables studied, exenatide, ten micrograms BID, or insulin glargine, one daily dose titrated to maintain fasting blood glucose levels of less than 100 mg/dL. | 26-week multicenter, open-label, randomized, controlled trial | Open-label study design because of one treatment group receiving titrated medication (glargine) while the other treatment group received a fixed-dose. Patients receiving insulin glargine were also taking metformin or combination oral therapy. It is not clear if weight reduction in the exenatide group was due to higher incidence of GI disturbances. More patients dropped out of the exenatide group due to side effects. | Hemoglobin A1c level, fasting plasma glucose level, body weight, seven-point self-monitoring blood glucose, standardized test-meal challenge, safety, and tolerability. | The change in hemoglobin A1c from baseline was the foremost factor used to determine the efficacy of the interventions. SAS software used to conduct likelihood-based mixed-effect model repeated measures (MMRM) analysis. | At week 26, both exenatide and insulin glargine reduced hemoglobin A1c levels by 1.11%. Exenatide reduced postprandial glucose excursions greater than insulin while glargine reduced fasting glucose concentrations more than exenatide. Body weight decreased 2.3kg with exenatide and increased 1.8kg with insulin glargine. Rates of symptomatic hypoglycemia were similar, but nocturnal hypoglycemia occurred less frequently with exenatide. GI symptoms, including nausea, vomiting, and diarrhea, occurred more frequently in the exenatide group. | Level II, replication is possible. |
| Otten, J., Stomby, A., Waling, M., Isaksson, A., Tellstrom, A., Lundin-Ollson, L., Brage, S., Ryberg, M., Svensson, M., & Olsson, T. (2017). Diabetes/Metabolism Research and Reviews, 33(1). DOI: 10.1002/dmrr.2828 | Reducing the risk of complications associated in patients with diabetes are needed. Following a certain diet may allow for glycemic control and improve insulin sensitivity and supervised exercise may reduce the risk of cardiovascular disease. | Quantitative, none explicitly stated. | Subjects from northern Sweden. Patients diagnosed with T2DM w/n past 10 years, BMI of 25-40kg/m^2 and had stable weight for 6 months with HbA1c of 6.5-10.8% and using lifestyle modification and or metformin for diabetes who had sedentary lifestyles (<30 min exercise 5 days/week). | Fat mass, insulin sensitivity, HbA1c, leptin maximum oxygen uptake, lean mass in male participants were all studied in the study subjects in two groups, one with paleolithic diet with a standardized exercise recommendation (PD) and one with paleolithic diet with a 1-hr supervised exercise session (PD-EX). | Single-blinded randomized controlled trial with two arms. A secondary analysis included a non-randomized observational group as reference | Small sample size of 32, selection effect limiting the application of the study results to the general population. | Food was weighed, trained dietician converted food weight into estimated energy and nutrient intake. Resting energy expenditure measured via indirect calorimetry. Energy expenditure over 7-day period estimated using accelerometer and heart rate monitor. Fat mass and lean mass analyzed by dual-energy x-ray absorptiometry. Fasting venous samples used to determine HbA1c, serum insulin, serum cholesterol, HDL, serum triglyceride and CRP levels all tests run at university hospital lab. Insulin sensitivity calculated: homeostatic model assessment of insulin resistance (HOMA-IR) = fasting glucose x fasting insulin / 22.5 and the revised quantitative insulin sensitivity check index (Revised QUICKI) = 1/(log fasting glucose + log fasting insulin + log NEFA). LDL calculated as (serum cholesterol – serum HDL – serum triglycerides) / 2.2. | Primary analysis compared treatment effects between PD and PD-EX groups. The change over time of each group determined by Wilcoxon rank-sum test. Secondary analysis compared treatment effect in each group with the observational group. All statistical analysis performed using R version 3.1.1. | PD-EX had higher fasting glucose and HDL levels than the PD group. Insulin sensitivity and glycemic control improved in both groups, no difference between groups. The HOMA-IR and revised QUICKI improved in both intervention groups, HbA1c decreased in both PD (19%) and PD-EX (20%). HbA1c of PD change from 7.1 to 6.2 (-0.9 % points), fasting glucose from 8.0 to 7.1 (change of -0.9 mmol/L), and fasting insulin 23 to 15 (change of -8 mIU/L); HbA1c of PD-EX 7.3 to 6.2 (change -1.1 points), fasting glucose from 8.9 to 6.9 (change of -2.0 mmol/L), and fasting insulin of 16 to 12 (change of -4 mlU/L). | Replication is possible. Level III research. |
| Blicklé, J.-F., Hancu, N., Piletic, M., Profozic, V., Shestakova, M., Dain, M.-P., Jacqueminet, S., & Grimaldi, A. (2009). Insulin glargine provides greater improvements in glycaemic control vs. intensifying lifestyle management for people with type 2 diabetes treated with OADS and 7-8% A1C levels. The Tulip Study. Diabetes, Obesity and Metabolism, 11(4), 379–386. <https://doi.org/10.1111/j.1463-1326.2008.00980.x> | Determine if early administration of insulin glargine in combinations with oral antidiabetics (OADs) vs. lifestyle management and OADs improves glycemic control in type II diabetics. | Not explicitly stated. Behavior change framework | Two hundred and eleven randomized patients with a mean age of 60.7, weight 84.5, BMI 29.9, and A1c 7.6. | Independent- Insulin glargine & lifestyle management  Dependent- outcome of glycemic control | Open-label, multinational, multicenter, comparative, parallel-group, randomized study. | 9 month and twelve visit was short for this study. 6 visits were telephone consultations, and the patient was not seen in office. Fourteen patients withdrew from the study for adverse events. Some patients did not have A1c measurements and were counted as non-responders. | Adjusting baseline A1c was used to determine the percentage of patients achieving A1c<6.5% at the end of treatment. The change in A1c was measured between baseline and end by analysis of covariance (change in A1c as the dependent variable, treatment as the fixed effect, and A1c value as the covariate). | Logistic Regression Model (predictive analysis). | Insulin initiation with glargine was more effective with 60% of the patients reaching A1c <7% while lifestyle modifications were effective in only 38% of patients. | Level IV and is possible for replication. |
| Knowler, W., Barret-Connor, E., Fowler, S., Hamman, R., Lachin, J., Walker, E., Nathan, D., & Diabetes Prevention Program Research Group. (2002). Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. New England Journal of Medicine, 346(6), 393–403. https://doi.org/10.1056/nejmoa012512 | To determine if lifestyle modification or the administration of metformin would delay development of diabetes. | Not explicitly stated. Behavior Change Framework | 3234 nondiabetic persons with elevated fasting and post-load plasma glucose. | Independent: standard lifestyle recommendations plus metformin (Glucophage) at a dose of 850 mg twice daily, standard lifestyle recommendations plus placebo twice daily, or an intensive program of lifestyle modification  Dependent: delay development of diabetes | Double-blind randomized control trial. | Exclusion criteria: comorbidities were not taken into consideration in this study. Some metformin participants developed GI symptoms and were unable to take full metformin dose. There were also many documented participants with musculoskeletal complaints in the lifestyle management group that could have impeded on exercise. | Participants were assigned to one of three groups which included: standard lifestyle recommendations plus metformin at a dose of 850 mg twice daily, standard lifestyle recommendations plus placebo twice daily, or intensive program of lifestyle modifications (with a goal to achieve a 7% weight loss reduction from initial bodyweight). The data was measured by fasting plasma glucose test <140 and measurement of glucose and glycosylated hemoglobin (HbA1c) | Quantitative data were analyzed. Multiple linear regression modeling was used to determine results. | Lifestyle changes and treatment with metformin both reduced the incidence of diabetes in persons at high risk. The lifestyle intervention was more effective than metformin. | Level IV and is possible for replication. |
| Johansen, M. Y., MacDonald, C. S., Hansen, K. B., Karstoft, K., Christensen, R., Pedersen, M., Hansen, L. S., Zacho, M., Wedell-Neergaard, A.-S., Nielsen, S. T., Iepsen, U. W., Langberg, H., Vaag, A. A., Pedersen, B. K., & Ried-Larsen, M. (2017). Effect of an intensive lifestyle intervention on glycemic control in patients with type 2 diabetes. JAMA, 318(7), 637. https://doi.org/10.1001/jama.2017.10169 | To determine if intensive lifestyle intervention can achieve glycemic control compared to standard care in patients with type II diabetes. | Not explicitly stated. Behavior Change Framework | Ninety-eight adult participants with non-insulin dependent type II diabetes diagnosed for less than 10 years. | Independent- Lifestyle intervention or conventional multi-factorial care on glycemic control and anti-diabetic medications  Dependent- Glycemic control | Randomized, assessor-blinded, single-center study within Region Zealand and the Capital Region of Denmark. | Exclusion criteria: Types of antidiabetic medications used were not specified. | The primary outcome measure of the U-TURN study was change in HbA1c from baseline to 12-month follow-up. The secondary outcome was reduction in anti-diabetic medications from baseline to 12 months follow as evaluated according to the pre-specified algorithm | Repeated-measures linear mixed models, an analysis of covariance model. | A lifestyle intervention compared with standard care resulted in a change in glycemic control that did not reach the criterion for equivalence but was in a direction consistent with benefit. Further research is needed. | Level IV and cannot be replicated. |
| Coppell, K. J., Kataoka, M., Williams, S. M., Chisholm, A. W., Vorgers, S. M., & Mann, J. I.  (2010). Nutritional intervention in patients with type 2 diabetes who are hyperglycaemic  despite optimised drug treatment—Lifestyle Over and Above Drugs in Diabetes  (LOADD) study: Randomised controlled trial. BMJ,  341.https://doi.org/10.1136/bmj.c3337 | To determine the degree  of the impact  of intensive  dietary interve  ntion on glycemic control as well  as the risk  factors for  cardiovascular  disease in  patients with  type 2 diabetes with hyperglycemia  in spite of optimized  drug treatment | Not explicitly stated. | Ninety-three patients aged  ≤ seventy years old with type 2 diabetes and a  HbA1c of more  than 7% despite  using optimized drug therapy  in addition to at  least two others  complications,  such as hypertension,  obesity, or  dyslipidemia. | Intensive individualized dietary advice, exercise advice, HbA1c, Adiposity, blood pressure and lipid profile | Randomized control trial | Attrition (some participants dropped out of the trial) | HbA1c the primary outcome. Secondary  outcomes were  measures of blood pressure, adiposity, and lipid profile. | Data analysis was done by standard deviation, correlations, and analysis of covariance. HbA1c was the primary outcome. Measures of blood pressure, adiposity, and lipid profiles were secondary outcome | There was  significant difference in HbA1c between the  treatment and control groups at six months in terms of weight, BMI, and weight circumference. The  authors concluded  that intensive dietary advice leads to substantial improvements in  glycemic control as  well as anthropometric  measures in patients  with type 2 diabetes.  This was in spite of  prior unsatisfactory  HbA1c with  drug treatment | Level IV, possible for replication |
| Jung, C. H., Park, C. Y., Ahn, K. J., Kim, N. H., Jang, H. C., Lee, M. K., ... & Park, S. W.  (2015). A randomized, double‐blind, placebo‐controlled, phase II clinical trial to  investigate the efficacy and safety of oral DA‐1229 in patients with type 2 diabetes  mellitus who have inadequate glycaemic control with diet and exercise.  Diabetes/Metabolism Research and Reviews, 31(3), 295-  306.https://doi.org/10.1002/dmrr.261 | To assess the  optimal dose,  efficacy and  safety of DA 1229, in Korean subjects with  type 2 diabetes  mellitus that was poorly  controlled with  diet and exercise | Not explicitly stated. | The subjects were enlisted  from twenty-six university hospitals in  Korea. They  included men  and women aged twenty and seventy-five with type 2 diabetes a HbA1c of 7-10%, with a diagnosis of  diabetes four weeks before  screening;  should not have been treated with oral glucose-lowering  agents in the  last 6 weeks | A twelve-week active treatment period and placebo, 2.5mg, 5mg, or 10mg of DA 1229, mean change in HbA1c | Randomized, double- blind, placebo- controlled, phase II clinical trial | Attrition of some participants | The primary measure  was the average change in HbA1c at  week 12. | Data analysis involved ANOVA or Kruskal-Wallis test for continuous variables. Chi-square test or Fisher's exact test for categorical variables. | All three doses of DA-1229 led to significant reductions  in HbA1c from baseline compared to the control (no drug).  There was better glycemic control in  participants subjects  who used diet, exercise, and drugs than those who used the exercise and diet  alone. The conclusion  was that a combination of diet, exercise, and  medication was the  best intervention | Level IV, possible for replication |
| Andrews, R. C., Cooper, A. R., Montgomery, A. A., Norcross, A. J., Peters, T. J., Sharp, D. J., & Dayan, C. M. (2011). Diet or diet plus physical activity versus usual care in patients with newly diagnosed type 2 diabetes: the Early ACTID randomised controlled trial. The Lancet, 378(9786), 129-139. https://doi.org/10.1016/S0140-6736(11)60442-X | To study the  effects of diet  and physical  activity on  blood pressure and glucose  concentrations  in diabetic  patients. | Not explicitly stated | The setting was  southwest  England. The  subjects were  adults between thirty and eighty  years with a  diagnosis of  type 2 diabetes in the last five to eight months. | Initial dietary consultation and follow-up every six months; an intensive diet intervention via consult every three months with nurse support, dietary intervention plus pedometer-based activity program, HbA1c, blood pressure | Randomized Control Trial | Participant selection and attrition | Primary measure was improvement in HbA1c levels and blood pressure at six months. | Data analysis done by descriptive statistics and multivariable linear regression. | The glycemic control worsened in the control group but improved in the diet group and diet plus activity groups. These differences persisted to twelve months with minimal use of diabetes drugs. The authors concluded that an intensive diet intervention n just after diagnosis can enhance glycemic control. | Level IV, possible for replication |