Research Article

EFFECT OF LIFESTYLE INTERVENTION COUNSELING ON BLOOD GLUCOSE, MEDICAL TREATMENT COST AND QUALITY OF LIFE IN DIABETES MELLITUS

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A R T I C L E   I N F O

A B S T R A C T

Objectives: A systematic review of original research articles analyzed to evaluate the effect of lifestyle modification counseling on glycemic control, treatment cost, and quality of life in Type 2 Diabetes Mellitus (T2DM) patients.

Methods: Original articles searched through PubMed, Medline, Scopus, and EMBASE and database published between 2007 and 2017. This systematic review has been searched for total 242 research articles on the effect of lifestyle based counseling in diabetes patients. Out of 242 total 40 articles (18 articles for glycemic control, 8 diabetes treatment cost and 14 article for HR-QoL) matched the inclusion criteria and remaining (n=202) articles excluded due to irrelevant to study objectives.

Results: All included and discussed studies on lifestyle-based counseling showed significant improvement in glycemic control, reduction in medical treatment with significant improvement in the Quality of Life in T2DM patients.

Conclusion: Reviewed studies conclude that lifestyle modification counseling is an effective, noninvasive, cost-effective intervention procedure to prevent and control type 2diabetes mellitus. Below stated studies have some limitations and suggestion which conclude the further requirement of multi-centric randomize controlled studies in India with special reference to treatment cost for diabetes and long-term effects on quality of life in T2DM patients with comprehensive lifestyle holistic approaches.

INTRODUCTION

Diabetes mellitus is a silent, chronic, non-infectious metabolic disorder has attained epidemic proportions globally. Type 2 diabetes has become a leading cause of premature death and disability around the world, and significantly increases the risk for both macro vascular; atherosclerosis, and micro vascular complications; retinitis, diabetic neuropathy, and renal disease [1-2]. International Diabetes Federation (2015), reports 8.8% or 415 million people diagnosed with diabetes mellitus globally, and it is further predicted that this number will increase to 642 million by 2040. According to Diabetes Altus (2015), India has 69.1 million diabetes cases and it is estimated that the second highest number in the world. The diabetes burden can affect the individual, family, society and the healthcare systems. The rising prevalence of diabetes and its related complications can profoundly impact on the healthcare costs and QoL (Quality of Life) of T2DM patients. According to IDF, around 19% of global health expenditure on diabetes is being used up in the low- and middle-income economies [3-4].

Diabetes mellitus leads to fatal complications that are associated with increased medical treatment costs and diminish the QOL. The long-term complications of diabetes affect almost every system in the body, especially the eyes, kidneys, heart, feet, and nerves [5]. Sedentary lifestyle, urbanization, socio-demographic changes, industrialization, and globalization are the major cause for the developing and increasing the prevalence of diabetes in India, with attendant factors such as unhealthy food, lack of physical activity, consumption of tobacco and excess alcohol, chronic stress, impaired sleep, population growth, being the main driver of the epidemic [6-11].

Diabetes mellitus is a heterogeneous group of metabolic disorders characterized by chronic hyperglycemia [12]. It is basically three types; Type 1 diabetes, Type 2 diabetes, and Gestational diabetes mellitus. Type 1 DM is an autoimmune disease mostly occurs in children and called juvenile or childhood diabetes and is characterized by stop insulin secretion due to viral infection, atrophy or degeneration of beta-cells of the pancreas, insulin insufficiency. Thus, T1DM requires daily administration of insulin to remain life [13]. T2DM is a lifestyle disorder, characterized by insulin

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deficiency and a combination of insulin resistance.T2DM patients do not require insulin injections to alive, that's known as NIDDM. More than 90% of people suffered from T2DM around the world [14]. Gestational diabetes usually occurs during pregnancy (second or third trimester of pregnancy) referred as hyperglycemia and recover or disappear after delivery [15].

According to Forsen *et al*, age, gender, family history, race and ethnicity, genetic factors and low birth-weight are major non-modifiable risk factors for T2DM. According to Wilson and Zimmet *et al* unhealthy diet, obesity, physical inactivity, smoking, use of tobacco and alcohol, stress and non-adherence of medical checkups and medication are the major modifiable risk factors which can be managed through lifestyle management [16-17]. Progression and development of diabetes mellitus, leads to various life-threatening complications such as retinopathy (loss of vision or blindness), nephropathy (kidney failure), peripheral neuropathy (nerve damage and foot ulceration or amputation), neuropathy (gastrointestinal, genitourinary, and sexual dysfunction), hypertension, heart failure, stroke, heart attack, slow healing of cuts or bruises, gum disease, bladder infections, anxiety and depression that can complicate the management of the diabetes. Diabetes and its related complications increase medical treatment cost, disability, morbidity, mortality, and decrease the quality of life of T2DM patients [18-20]. Lifestyle management is an essential step to prevent and control diabetes and includes diabetes self-management education, healthy and balanced diet therapy, increase physical activity, smoking and alcohol cessation counseling, and stress management counseling with routine medical checkups and medication adherence [21]. Lifestyle modification counseling programs facilitate the coping skills, knowledge about diabetes and how to manage it properly, improves self-care behaviors, clinical outcomes, health status, and quality of life in a cost-effective manner [22]. Below stated lifestyle modification counseling based diabetes research studies described the effect of lifestyle intervention in T2DM patients.

METHODS

Search: A systematic review of original studies published globally since 2007 to 2017 in the English language was searched. The literature was searched to evaluate the effect of lifestyle modification counseling on glycemic control, cost of medical treatment and health-related quality of life in type-2 diabetes mellitus patients using relevant databases including Pub Med Central, Scopus, Medline, EMBASE, Google Scholar and National Health Services Economic Evaluation (NHSEE) resources. A flow chart of identification, searched and included is given in Table 1.

Inclusion Criteria: Quasi-experimental, pre and post-test designed studies, Randomized Control Trial (RCT), prospective and retrospective studies on lifestyle modification counseling on glycemic control, medical treatment cost and health-related quality of life in type-2 diabetes mellitus patients were included.

Exclusion Criteria: Case studies, review and meta-analysis studies on lifestyle modification counseling were excluded from the study because those were not relevant to study objectives.
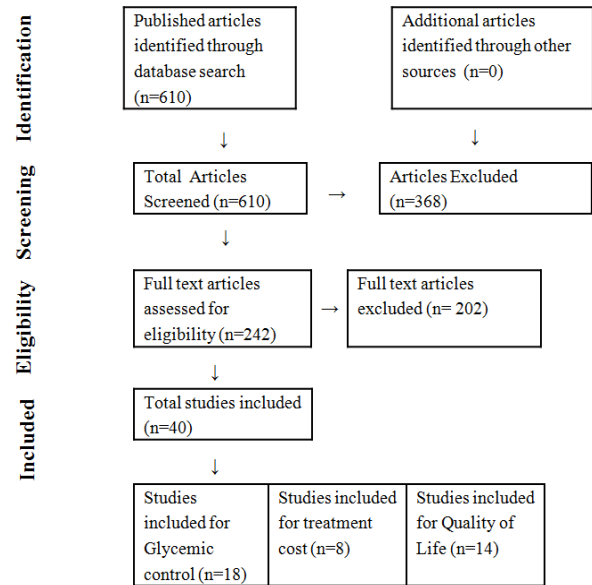

Table 1 Flow chart of identification of included studies

RESULTS

Effect of Lifestyle Modification Counseling on Glycemic Control in T2DM Patients

Ji-SooYoo *et al* (2007) was carried out an experimental study with 48 T2DM patients to assess the effects of a lifestyle modification program on glycemic control. The intervention group received educational counseling on exercise, diet, stress management, and self-management. The result of this study showed statistically significant improvement in fasting blood sugar and HbA1c levels between the two groups. The author concluded that lifestyle modification counseling was effective in improving and maintaining glycemic control [23].

Kuchake VG *et al* (2009) conducted a randomized controlled study with 35 T2DM patients to assess the effect of patient counseling on nutrition and exercise in T2DM patients. All subjects were received educational counseling about the disease, diet medication, and exercise for three months. The result demonstrated statistically significant reductions in HbA1c, FPG, total cholesterol, serum triglyceride and LDL cholesterol. The author revealed that glycemic control can be improved through patient counseling about the disease, diet, exercise, medication, and personal hygiene [24].

Fritha Morrison *et al* (2012) was performed a retrospective cohort study including 30,897 type 2 diabetes Patients to determine the long-term effectiveness of lifestyle counseling on patients. A Significant improvement was observed in glycemic control in lifestyle intervention patients. The author reveals that lifestyle counseling was strongly associated with faster improvement in HbA1C, blood pressure, and LDL cholesterol control [25].

Sanghani *et al* (2013) conducted a randomized intervention study with 279 patients with T2DM to assess the effect of exercise training counseling and physical activity interventions on glycemic control. This study concluded that increase physical activity was beneficially associated with a significant HbA1c decline [26].

Table 2 Effect of Lifestyle Modification Counseling on Glycemic Control in T2DM patients

S.No	Author & Study Years	Title of Study	Sample Size	Study design	Findings & Conclusion
1	Ji-SooYoo et al (2007)[23]	The effect of a comprehensive lifestyle modification program on glycemic control and body composition in patients with type 2 diabetes	48	Experimental design with random assignment	Significant improvement in fasting blood sugar and HbA1c observed. Comprehensive lifestyle modification for glycemic control.
2	Kuchake V.G et al(2009)[24]	Assessment of impact of Patient Counselling, Nutrition and Exercise in patients with Type 2 Diabetes Mellitus	35	Randomized controlled study	Glycemic control of type-2 diabetic patients can be improved through patient counseling. In this study significant reductions were found in HbA1C, FPG, cholesterol, serum triglyceride and LDL cholesterol.
3	Fritha Morrison et al (2012)[25]	Lifestyle counseling in routine care and long-term glucose, blood pressure, and cholesterol control in patients with diabetes	30,897	Retrospective cohort study	Good achievement in HbA1C, blood pressure, and LDL cholesterol has been seen in this study.
4	Sanghaniet al(2013)[26]	Impact of lifestyle modification on glycemic control in patients with type 2 diabetes mellitus	279	Randomized intervention study	Author concludes that supervised structured training was more effective in HbA1c control. Lifestyle intervention program was effective.
5	Salwa A Mohamed et al (2014)[27]	Effect of lifestyle intervention on health behaviors,weight and blood glucose level among patients with diabetes mellitus.	50	A quasi-experimental research design	Significant improvement in blood glucose levels, decrease weight, improve blood glucose level and health behaviors in the study group had been observed.
6	Krishnan D et al (2015)[28]	The Impact of Diet Counselling on Type 2 Diabetes Mellitus: An Indian Case Study	150	Pre and post-test experimental design	After six-month counseling program clearly indicated that intervention had a positive effect on the management of glycemic control in T2DM patients.
7	Islam et al. (2015)[29]	Diabetes knowledge and glycemic control among patients with type 2 diabetes in Bangladesh	515	A cross-sectional study	Author concludes that strategies to improve the quality of diabetes education and identifying other potential factors for glycemic control are important for ensuring optimum management of diabetes in Bangladesh.
8	NaoshiHosomuraet al (2015)[30]	Electronic Documentation of Lifestyle Counseling and Glycemic Control in Patients With Diabetes	10,870	Retrospective study	In this study Lifestyle counseling program was effective and significant improvement in glycemic control was observed.
9	Sarah Abdi1et al. (2015)[31]	Behavioural Lifestyle Intervention Study (BLIS) in patients with type 2 diabetes in the United Arab Emirates: A randomized controlled trial	35	Randomized controlled trial	Author revealed that lifestyle intervention programme was effective in improving glycaemic control the HbA1c levels of the T2DM patients
10	Merakou K et al (2015)[32]	Group patient education: effectiveness of a brief intervention in people with type 2 diabetes mellitus in primary health care in Greece: a clinically controlled trial	193	Controlled trial study	After 6 months, significant differences in changes in HbA1c and Quality of life in T2DM patients were observed.
11	Browning C et al. (2016)[33]	Management of type 2diabetes in China: the Happy Life Club, a pragmatic cluster randomized controlled trial using health coaches	41	Randomized controlled trial(RCT)	Study showed statistically significant improvement in HbA1c triglycerides, LDL cholesterol and HDL cholesterol.
12	Shareef J et al (2016)[34]	Evaluating the Effect of Pharmacist's Delivered Counseling on Medication Adherence and Glycemic Control in Patients with Diabetes Mellitus	106	Prospective, interventional study	Significant improvement in medication adherence and glycemic control (fasting and post prandial plasma glucose) in patients with diabetes mellitus in intervention group as compared to the usual care group (p<0.005) was observed in this study.
13	Sonomtseren S et al. (2016)[35]	Lifestyle modification intervention improves glycemic control in Mongolian adults who are overweight or obese with newly diagnosed type 2 diabetes	80	Prospective study	A significant difference in mean HbA1c decreased from 8.5 ± 2.7% to 6.0 ± 1.8% p<0.0001 has been observed with marked improvements in cardiovascular risk factors, including total cholesterol, triglycerides, reductions in systolic and diastolic blood pressure with p<0.05. The remarkable improvement in glycemic control and lipid profile in participants had been observed.
14	Okada H. et al. (2016)[36]	Effects of Lifestyle Intervention Performed by Community Pharmacists on Glycemic Control in Patients with Type 2 Diabetes: The Community Pharmacists Assist (Compass) Project, a PragmaticCluster Randomized Trial	132	Prospective, cluster-randomized, controlled trial	After 6 months, patients had shown significantly improvement in HbA1c. The number of drugs also reduced . Brief lifestyle intervention by community pharmacists improved glycemic control in patients with T2DM.
15	GhadaAsaad et al. (2016)[37]	Effectiveness of a Lifestyle Intervention in Patients with Type 2 Diabetes: The Physical Activity and Nutrition for Diabetes in Alberta (PANDA) Trial	73	Single-arm, pre-post intervention study	The significant improvements in A1c, BMI and lipids were maintained at six months. The results suggest that a dietary intervention incorporating interactive education sessions focused on menu planning with familiar, accessible foods may be effective for diabetes management

16	Samah M. *et al* (2017) [38]	Effect Of Tele-Nursing (Phone-Based Follow-Ups) On Self-Efficacy, Healthy Lifestyle, And Glycemic Control In Diabetic Patients	100	Quasi - experimental study	Study revealed that tele- nursing was effective to improve self- efficacy, healthy lifestyle and blood glucose level in type 2 diabetic patients. The mean level of FBS & PPG was significantly reduced after lifestyle intervention.
17	Takuya Yamamoto *et al.* (2017) [39]	Effect of a newly-devised nutritional guide based on self-efficacy for patients with type 2diabetes in Japan over 2 years: 1-year intervention and 1-year follow-up studies	74	Observational study	Author revealed that decreases in glycated hemoglobin levels were more pronounced in the E-Guide group. E-Guide is more effective and powerful than the conventional methods for glycemic control and self-care behavior among patients with type 2 diabetes in Japan.
18	Figueira ALG *et al.* (2017) [40]	Educational interventions for knowledge on the disease, treatment adherence and control of diabetes mellitus	82	Before and after design study	In this study , knowledge on the disease (p<0.001), the medication treatment (p=0.0318) and the glycated hemoglobin rates (p=0.0321) improved significantly

Salwa A Mohamed *et al* (2014) carried out a quasi-experimental study among 50 T2DM patients to assess the effect of lifestyle intervention on blood glucose level. This study concluded that health education about diabetes and its management was effective methods to improve blood glucose level, knowledge, and health of diabetes patients [27].

Dharini *et al* (2015) performed a pre and post-test experimental study includes 150 subjects with T2DM to investigate the effect of diet counseling on T2DM patients. The results of the investigation showed improvement in glycemic control and reduce the risk of complications. The author concludes that six-month counseling program clearly indicated that intervention had a positive effect on the management T2DM [28].

Islam *et al* (2015) performed a cross-sectional study among 515 T2DM patients to investigate the association between knowledge of diabetes and glycemic control inT2DM patients. This study concluded that patients who have good knowledge about diabetes and its management have better glycemic control and manage risk factors for progressing diabetes [29].

NaoshiHosomura *et al* (2015) was carried out a retrospectively study among 10,870 diabetes patients to establish the quantitative effect of lifestyle counseling documentation associated with the improved glycemic control. As per this study, lifestyle counseling was considered to improve glycemic control in T2DM patients [30].

Sarah Abdi1 *et al* (2015) performed a translational randomized controlled trial including 35 type 2 diabetes patients to evaluate the effect of behavioral lifestyle program in improving glycemic control. A significant reduction has been reported in the HbA1c in the intervention group with sustained for 1 year [31].

Merakou *et al* (2015) performed a study with 193T2DM patients to assess the impact of patient group education intervention in T2DM patients. This study showed significant improvements in HbA1c, BMI, triglycerides, and LDL in the intervention group as compared to control group. As per this study, group-based patient education is effective in controlling people with type 2 diabetes [32].

Browning C *et al* (2016) carried out a cluster randomized controlled trial among 41 T2DM patients to assess the effectiveness of the coach-led motivational interviewing intervention to glycemic control in T2DM patients. The result of this study showed statistically significant improvement in HbA1c triglycerides, LDL cholesterol and HDL cholesterol [33].

Shareef J *et al* (2016) conducted a prospective, interventional study including 106 T2DM patients to assess the impact of pharmacist-delivered counseling on medication adherence and glycemic control. A Significant improvement in glycemic levels and medication adherence was observed in the intervention group. The study revealed that educational counseling made a significant influence on medication adherence and glycemic control in T2DM patients [34].

Sonomtseren S *et al* (2016) was carried out a study with 80 newly diagnosed type 2 diabetes patients to evaluate the effectiveness of the intervention in Mongolian. In this study, improvements have been observed in cardiovascular risk factors, body weight, blood sugar levels, total cholesterol, triglycerides, systolic and diastolic blood pressure. The author concluded that a lifestyle modification intervention may be highly effective for early diabetes treatment and prevention [35].

Okada H *et al* (2016) was conducted a prospective, cluster-randomized, controlled trial with 132 patients with T2DM to examine the effects of lifestyle intervention coaching on glycemic control. A significant improvement had been observed in HbA1c in the intervention group after 6 months and the number of drugs was also reduced. Hence it was concluded that lifestyle intervention by community pharmacists was effective and improved glycemic control in patients with T2DM [36].

GhadaAsaad *et al* (2016) conducted a study with 73 participants with T2DM to evaluate the effect of the lifestyle intervention on glycemic control with dietary adherence. The author revealed that intervention was effective in improving glycemic control and diet adherence [37].

SamahM *et al* (2017) was performed a quasi-experimental study among 100 patients with type 2 diabetes to assess the effect of telenursing on self-management and glycemic control. A significant improvement has been shown in fasting and PP blood sugar in the intervention group as compared to control group and author revealed that telenursing was effective to improve glycemic control [38].

Takuya Yamamoto *et al* (2017) carried out an interventional study among 74 T2DM patients to examine the effects of E-Guide use on glycemic control. A Significant reduction was observed in HbA1c levels in the E-Guide group and the author concludes that intervention guidance through "E-Guide" was more effective and powerful as compared to conventional methods for glycemic control in T2DM patients [39].

Table 3 Effect of Lifestyle Modification counseling on treatment cost of diabetes in T2DM patients

S.No	Author	Title of Study	Sample Size	Study design	Findings & Conclusion
1	Anne M *et al* (2007) [41]	Effects of Lifestyle Intervention on Health Care Costs: Improving Control with Activity and Nutrition (ICAN)	147	Randomized controlled trial	Author conclude that lifestyle management counseling lead by an experienced dietitian was effective and did not increase health care costs among obese patients with type 2 diabetes
2	Chidambaram D *et al* (2013) [42]	Cost- of- Illness Analysis of Type 2 Diabetic Patients in a Multispeciality Hospital at Coimbatore	120	Prospective observational study	Author conclude that the factors which affects the treatment cost of diabetes was mainly medicine, lab, hospitalization and related complications cost.
3	Png ME, Yoong JS-Y *et al.* (2014) [43]	Evaluating the Cost-Effectiveness of Lifestyle Modification versus Metformin Therapy for the Prevention of Diabetes in Singapore	Not defined	Decision-based model study	Author revealed that cost of lifestyle modification was cost-effectiveness as compare to metformin intervention.
4	SmitaSontakke *et al* (2015) [44]	Educational interventions for knowledge on the disease, treatment adherence and control of diabetes mellitus	150	Prospective, cross-sectional study	Author revealed that higher cost of medicine and lack of awareness the importance of medicine was the reason non- adherence to medicine. Hence, the awareness about medicine is necessary.
5	Mash A R *et al.* (2015) [45]	Cost-effectiveness of a diabetes group education program delivered by health promoters with a guiding style in underserved communities in Cape Town, South Patient Education and Counseling	Not defined	Randomized controlled trial (RCT)	The group education program performed by trained healthcare personnel was cost-effective.
6	Fadare J *et al.* (2015) [46]	Medication adherence and direct treatment cost among diabetes patients attending a tertiary healthcare facility in Ogbomosho, Nigeria	129	Cross-sectional study	Adherence of diabetes patients in the study sample to their medications was satisfactory. There is a need for the integration of generic medicines into routine care as a way of further reducing the burden of healthcare expenditure on the patients.
7	Upadhyay *et al.* (2016) [47]	Does pharmacist-supervised intervention through pharmaceutical care program influence direct healthcare cost burden of newly diagnosed diabetics in a tertiary care teaching hospital in Nepal: a non-clinical randomised controlled trial approach	162	Pre-post non-clinical randomised controlled study	In this study, pharmacist supervised intervention through pharmaceutical care program significantly decreased direct healthcare costs of diabetics
8	Odnoletkova , Ramaekers D *et al.* (2016) [48]	Delivering Diabetes Education through Nurse- Led Tele-coaching, Cost-Effectiveness Analysis	574	Randomized clinical trial	Repeating the intervention for lifetime had the greatest impact on the cost-effectiveness

Figueira ALG *et al* (2017) carried out a "before and after" designed study in 82 T2DM patients to assess the effect of educational interventions, medication adherence, and glycemic control. The result of this study revealed the significant improvements in HbA1c with adherence to medication. The author concluded that educational interventions showed the positive contribution to the participants' diabetes knowledge, medication adherence and glycemic control [40].

Effect of Lifestyle Modification Counseling on Medical Treatment Cost in Type 2 Diabetes Patients

Anne M *et al* (2007) conducted a randomized controlled trial among 147 T2DM patients to evaluate lifestyle program effectiveness on health care costs. In this study intervention group received lifestyle management education and the author concluded that lifestyle management intervention counseling was effective for reducing the risk of life-threatening complications and reduction of diabetes treatment cost in T2DM patients [41].

Chidambaram D *et al* (2013) conducted a prospective observational study to determine annual per patient direct cost for management of T2DM. The study reveals that medicine, lab and admission cost were the factors affected the health care cost of diabetic patients.

This study revealed that cost of illness can provide a framework for estimation of diabetic cost and lifestyle intervention may reduce diabetes treatment cost in T2DM patients [42].

Png ME, Young *et al* (2014) conducted a study to assess the effectiveness of lifestyle modification and metformin among pre-diabetic subjects. In this study author concluded that lifestyle modification and metformin intervention are cost-effective and can prevent or delay the risk of T2DM [43].

SmitaSontakke *et al* (2015) conducted a prospective, cross-sectional, questionnaire-based study in 150 T2DM patients to evaluate adherence therapy and study factors associated with non-adherence in patients. The result of the study demonstrated that due to high-cost patients not buying all medicines, actions to provide free medicines to non-affording patients need to be implemented [44].

Mash R *et al* (2015) performed a cluster randomized controlled trial (RCT) to assess the cost-effectiveness of diabetes education program. This education program was focused on healthy diet, physical activity; avoid the use of tobacco, smoking, alcohol, foot care, and stress. In this study, the author concluded that a group education program

performed by trained healthcare personnel was cost-effective [45].

southwestern Nigeria. The results of this study showed 40.6%, patients have good medication adherence.

Table 4 Effect of Lifestyle Modification Counseling on Quality of Life in T2DM patients

S.No	Author	Title of Study	Sample Size	Study design	Findings & Conclusion
1	Thomas D *et al.* (2009) [49]	Effect of patient counseling on quality of life of hemodialysis patients in India	56	Prospective interventional study	Medication therapy with patient counseling focusing on diet exercise and regular medications are an effective way to improve health-related QoL of T2DM patients.
2	Al Mazroui N R *et al.* (2009)[50]	Influence of pharmaceutical care on health outcomes in patients with Type 2 diabetes mellitus	240	randomized, prospective controlled study	Pharmaceutical care improved glycaemic control with reduced cardiovascular risk scores in Type 2 diabetes patients over a 12-month period
3	Adepu Ramesh *et al.* (2009) [51]	Impact of Community Pharmacy based Patient Education on Quality of Life in Type 2 Diabetes Mellitus	70	Prospective, open label, randomized study	Patient counseling in this study had improved overall quality of life in diabetic patients
4	Adepu *et al.*(2011) [52]	Influence of post discharge counselling on health outcomes in diabetic and hypertensive patients	158	Prospective randomized study	A statistically significant (p<0.05) improvement in HRQoL was observed Pharmacist provided post discharge counselling has shown positive impact on therapeutic outcomes and health related quality of life.
5	Ramune Jacobsen *et al* (2012) [53]	Predictors of Effects of Lifestyle Intervention on Diabetes Mellitus Type 2 Patients	143	Randomized clinical trial	Statistically significant improvements in patients systolic blood pressure, waist circumference, exercise capacity, glycemic control had been observed in this study.
6	Maxwell O. Adibe (2013) [54]	The Impact of Pharmaceutical Care Intervention on the Quality of Life of Nigerian Patients Receiving Treatment for Type 2 Diabetes	110	Randomized, controlled study	Overall HRQOL significantly improved at 12 in patients with type 2 diabetes.
7	Saleh *et al.* (2014) [55]	Non-adherence to self-care practices & medication and health related quality of life among patients with type 2 diabetes: a cross-sectional study	500	Cross-sectional study design	As per this study , T2DM patients who have a non-adherence rate also have a lower quality of life.
8	MarziehKargar Jahromi1 *et al* (2015) [56]	Effectiveness of Diabetes Self-Management Education on Quality of Life in Diabetic Elderly Females	90	Interventional study	Author concludes that the diabetic individuals can be significantly improved following instruction by health care providers to quality of life
9	AlirezaDidarloo *et al.* (2016) [57]	Impact of Educational Intervention Based on Interactive Approaches on Beliefs, Behavior, Hemoglobin A1c, and Quality of Life in Diabetic Women	90	Prospective interventional study	Instructional interventions based on interactive approaches can be useful, and applicable for behavior modification and improvement of HbA1c level and HRQOL in people with DM
10	Shareef *et al.* (2016) [58]	Impact of Pharmacist's Intervention on Improving Quality of Life in Patients with Diabetes Mellitus	106	Prospective interventional study	The study shows that clinical pharmacist guided appropriate interventions were found to be effective in achieving better glycaemic control and better quality of life in patients with diabetes mellitus
11	Sriram S *et al* . (2016) [59]	Impact of pharmaceutical care activities on diabetic patients at a private corporate hospital	120	Prospective comparative study	Author concludes that pharmacist mediated patient counseling of the disease, medications and lifestyle modifications will improve the Quality of life and Glycemic control. The assessment of quality of life in patients with diabetes could help to improve patient's wellbeing
12	Sofa D *et al.* (2016) [60]	Medication Adherence Contributes to an Improved Quality of Life in Type 2 Diabetes Mellitus Patients: A Cross-Sectional Study	91	Cross-sectional study	Adherence to prescribed medication showed a positive effect on Diabetes-specific QOL in patients. The result is important not only in developing intervention programs for patients but also in improving their QOL through sustainable health promotion.
13	Ibrahim N *et al* (2016) [61]	Effects of a Community-Based Healthy Lifestyle Intervention Program (Co-HELP) among Adults with Prediabetes in a Developing Country: A Quasi- Experimental Study	268	Quasi-experimental study	Co-HELP participants showed significant improvement in fasting plasma glucose, HbA1C , diastolic blood pressure , waist circumference and HDL cholesterol with Significant improvements in HRQOL for both physical component .
14	Reza Nabi-Amjad *et al.* (2016) [62]	Comparison of Effectiveness of Self-Empowerment Through Educational Package and Workshop in Quality of Life of Diabetic Patients Jundishapur	40	Randomized clinical trial	Study revealed that lifestyle based education program can promote self-care skills and improve the quality of life in diabetic patients.

Fadare1 J *et al* (2015) conducted a cross-sectional study including 129 patients to assess the level of adherence to anti diabetic drugs among outpatients in a teaching hospital in

Total costs for medication was 72.3% and laboratory investigations cost was17.6% in T2DM patients. A significant improvement has been observed in glycemic control, reduction

in short and long-term diabetes complications and treatment cost of those patients who adherence to anti- diabetic medicines and self-management [46].

Upadhyay *et al* (2016) carried out an interventional, pre-post non-clinical randomized controlled study among 162 T2DM patients to assess the effect of pharmaceutical care program on healthcare costs of diabetes. The author concludes that lifestyle intervention guided by pharmacist significantly decreased direct healthcare costs and improves the glycemic control of T2DM patients [47].

Odnoletkova *et al* (2016) collected a randomized clinical trial involving 574 participants with the aim to analyze the lifelong cost-effectiveness of the tele coaching program. It has been observed that repeated lifestyle intervention had the greatest impact on the cost-effectiveness. Author of this study concludes that patient education programs can improve diabetes control in the short term but their cost-effectiveness is indefinite [48].

Effect of Lifestyle Modification Counseling on Quality of Life in Type 2 Diabetes Patients

Thomas D *et al* (2009) performed a prospective interventional study, to assess the impact of patient counseling in health-related quality of life (HR-QoL). This study concluded that medication therapy with patient counseling focusing on diet, exercise and regular medications were an effective way to improve health-related QoL of T2DM patients [49].

Al Mazroui NR *et al* (2009) conducted a randomized, prospective controlled study including 240 T2DM female, to assess the influence of a pharmaceutical care program on disease control and health-related quality of life. The author concluded that pharmaceutical care improved glycemic control with reduced cardiovascular risk scores in T2DM patients [50].

Adepu Ramesh *et al* (2009) did a prospective, open-label, randomized study with 70 South Indian T2DM patients to assess the influence of pharmacist counseling on patients' perception of the disease management and quality of life in T2DM patients. The significant improvement was observed in knowledge and QoL in the intervention group. The results of the study suggest that patient counseling improved the overall quality of life of diabetic patients [51].

Adepu *et al* (2011) conducted a prospective, randomized study with 158 T2DM patients to assess the impact of counseling on health outcomes in diabetic and hypertensive patients. The results of this study showed a significant improvement in HRQoL, blood pressure and blood glucose levels in the test group. The author revealed that counseling has the positive effect on therapeutic outcomes and health-related quality of life [52].

Ramune Jacobsen *et al* (2012) carried out a retrospective randomized clinical trial with 143 T2DM patients to identify predictors of the effects of lifestyle intervention in T2DM patients. The result of lifestyle intervention studies showed statistically significant improvements in glycemic control, systolic blood pressure, exercise capacity, waist circumference, and health-related quality of life of type 2 diabetes patients [53].

Maxwell O Adibe *et al* (2013) carried out a randomized, controlled study with 110 T2DM patients to evaluate the impact of pharmaceutical care intervention on health-related quality of life (HRQOL). Significant improvement was observed in HR-QoL in lifestyle intervention group and these results sustained for 12 months [54].

Farzana Saleh *et al* (2014) conducted a cross-sectional study with 500 T2DM patients to assess the association between non-adherence to self-care practices, medication and health-related quality of life among T2DM patients. The author concludes that non-adherence of lifestyle modification increases the risks of complication and also promotes a poorer quality of life [55].

MarziehKargar Jahromi1 *et al* (2015) conducted an interventional study including 90 T2DM patients to assess the effectiveness of diabetes self-management education on quality of life in T2DM females. The result showed significant improvement in QoL in the intervention group. The author concludes that the behavioral intervention may improve the quality of life outcomes of the diabetic elderly females [56].

AlirezaDidarloo *et al* (2016) carried out an interventional study with 90 T2DM female to examine the effect of an educational program on behavior, glycemic control indicator, and QoL among diabetic women. This study reveals that educational approaches can be useful and applicable for behavior change and improvement in HbA1c and HRQOL in T2DM females [57].

Shareef J *et al* (2016) conducted a prospective, interventional study among 106 T2DM patients to assess the impact of pharmacist-led interventions in the quality of life. The significant improvement was observed in quality of life in the intervention group. In this study author revealed that educational intervention through clinical pharmacist was effective in achieving the better quality of life and glycemic control in T2DM patients [58].

Sriram S *et al* (2016) carried out a prospective comparative study among 120 T2DM patients to evaluate the impact of pharmaceutical care and to give information about the disease and lifestyle modification. A significant improvement was observed in the quality of life BMI, and blood glucose. The author concluded that pharmacist mediated patient counseling about disease, medications and lifestyle modifications may improve the quality of life and glycemic control in T2DM patients [59].

Sofa D *et al* (2016) conducted a cross-sectional study to analyze the association between adherence to prescribed diabetes medication and diabetes-specific QoL in patients. This study showed that intervention programs can improve T2DM patients QoL [60].

Ibrahim N *et al* (2016) conducted a quasi-experimental study including 268 pre-diabetes participants to determine the effects of lifestyle interventions delivered in pre-diabetes patients. Participants in Co-HELP group received lifestyle counseling while the usual care group received health education. The result of this study shown a significant improvement in glycemic control (fasting, PP HbA1C) and HRQOL of LMC group. This study provides evidence that lifestyle based diabetes counseling programs may improve glycemic control and HR-QoL [61].

Reza Nabi-Amjad *et al* (2016) conducted a randomized clinical trial with 40 T2DM patients. A significant difference was observed in the quality of life before and after the intervention in T2DM patients. The author concludes that lifestyle based education program may promote self-care skills

and improve the quality of life in diabetic patients [62]. The summary of all included and discussed studies are given in Table 2, Table 3 and Table 4.

DISCUSSION

A Significant improvement has been observed in glycemic control, health-related quality of life, treatment cost for diabetes and its complications in T2DM in almost all above discussed studies. Lifestyle modification programs also showed improvement in adherence to lifestyle management but limited to strictly follow the program because of the complexity of the model, face difficulties to understand and follow the model and most of the patients were unaware of self-management practice for diabetes. The Management and control of diabetes in India face so many problems, such as lower levels of awareness about diabetes and its management, lack of trained medical and paramedical staff, non-adherence behavior of patients and unable to afford of diabetes medicines and other medical services. Patients not strict to regular intake of medicines because of out of pocket cost of diabetes medicines and very few studies were published to evaluate the effectiveness of lifestyle intervention in the reduction of diabetic economic burden. Rarely any Indian study was found to assess the effect of lifestyle modification counseling or diabetes awareness program to control diabetes economic burden in India.

CONCLUSION

There is a need of multi-centric randomized control trials to evaluate lifestyle modification programs with comprehensive holistic approaches which should be easy to follow by illiterate, rural and urban patients and that will help to reduce diabetes cost and diabetes complications along with improving long-term quality of life in T2DM patients.

CONFLICT OF INTEREST

The researchers have no conflicts of interest related to the material presented in this article.

Acknowledgments

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