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Effect of lifestyle intervention holistic approach on blood glucose levels, health-related quality of life and medical treatment cost in type 2 diabetes mellitus patients

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ABSTRACT. Type 2 Diabetes Mellitus (T2DM) is a costly, lifestyle-related disorder, its management is very critical and challenging hence lifestyle intervention may a cornerstone in the reversal and management of T2DM. This study designed to assess the impact of lifestyle intervention holistic (LIH) Model on blood glucose levels (BGL), Health-Related Quality of Life (HRQOL), and medical treatment cost in T2DM patients. This prospective, quasi-experimental study was conducted among 224 T2DM patients in Delhi Diabetes Research Center (DDRC), New Delhi. The study participants were allocated into two groups-Lifestyle Intervention Counseling (LIC) group received lifestyle-based counseling through the LIH model while the Usual-care group received only standard treatment. Study outcomes were assessed at baseline, 3rd, 6th, and 12th month and data were analyzed through SPSS. Study results revealed that LIC participants had decreased in fasting blood glucose 0.26 mg dL^{-1} (-4.37 to 4.89), blood glucose postprandial -70.16 mg dL^{-1} (-85.15 to - 55.16), HbA1C -2.82% (-5.26 to - 0.37), medicine cost ($p < 0.004$), hospitalization cost ($p < 0.011$), and cost of surgery ($p < 0.0005$). A significant improvement also observed in HRQOL and adherence towards a holistic model in LIC group. The study concludes that lifestyle-based counseling and its adherence was cost-effective and significantly improves BGL, HRQoL, and medical treatment in T2DM patients.

Keywords: lifestyle intervention counseling; type 2 diabetes mellitus; blood glucose levels; treatment cost, HRQoL; holistic model.

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Introduction

The prevalence of diabetes mellitus is increasing rapidly at an alarming rate and documented as an epidemic disease of the 21st century, affecting millions of people around the world. Type 2 diabetes mellitus is more dominant than other forms of diabetes (type 1 and gestational diabetes), and the main driver of the diabetes epidemic (Huizinga & Rothman, 2006).

Type 2 Diabetes Mellitus is one of the major chronic health problems especially in low and middle-income countries, such as India, cover approximately 77% of all cases of diabetes (Kumari, Singh, & Dahiya, 2018). Diabetes mellitus is a silent, life-threatening disorder mainly characterized by a high blood glucose level with deregulations of, fat and protein metabolism consequential defects in insulin secretion and insulin action (The InterAct Consortium, 2012; Rabito & Kaye, 2013). According to the report of the International Diabetes Federation [IDF] (2017), the global prevalence of diabetes is estimated to increase, about 451 million people suffering from diabetes around the world and this number will be estimated to increase to 693 million by 2045. Due to increasing prevalence and, the higher population, India has become the 'Diabetic Capital' of the world and has the second-highest number of diabetes patients after China. According to IDF (2017) report, around 72.946.400 people live with diabetes in India and the Prevalence of diabetes mellitus in adults is 8.8% (IDF, 2017; Tripathy et al., 2017). T2DM is a very lavish metabolic disorder, because of chronic nature, multi-organ complications and co-morbidities such as obesity, hypertension, amputations, kidney failure, blindness, nerve disorders and the major risk factor for developing cardiovascular disease. Approximately 65% of diabetic deaths occur due to cardiovascular disease (Lloyd-Jones et al., 2009).

Lifestyle characters, such as high calories diet, obesity, physical inactivity smoking, stress, and ignorance of self-care are the major risk factors that influence the development and prognosis of T2DM (American Diabetes Association, 2016). So the first-line treatment of T2DM might be a plant-based balanced diet, physical activity (walking, running, cycling, yoga practice, etc.), weight loss, meditation, stop smoking, and tobacco before or in parallel with pharmacological therapy (Heidemann, Paprott, Haftenberger, Rathmann, & Scheidt-Nave, 2015; Najafipour, Mobasseri, & Yavari, 2017). However the pharmacological hypoglycemic medication is effective in lowering blood glucose levels (Gorter, Laar, Janssen, Houweling. & Rutten, 2012) in T2DM but it is associated with potential adverse drug reaction (Holman et al., 2007), discomforts, (Prasad-Reddy & Isaacs, 2015) increase economic costs (Espeland, Glick & Bertoni, 2014) and deteriorate the HRQoL of T2DM patients (Tracey, McHugh, Buckley, & Kearney, 2015). So the urgent solutions for reducing and reversing, the prevalence of diabetes is especially investment in the modifiable factors (diet, physical activity, stress, and weight) through lifestyle interventions that are capable to maintain glycemic control, quality of life and reduce the economic burden of disease. Several studies exposed that lifestyle intervention is a very effective, non-invasive approach, more controlling than costly pharmacological treatment which slows the prevalence of diabetes, reduces the sequence of various short and long-term diabetes complications, and decreased the need for medications to treat diabetes (Hartley, 2014; Ali et al., 2013; Asaad, Soria-Contreras, Bell, & Chan, 2016).

Various lifestyle studies concluded that lifestyle interventions, combines with plant-diets, regular physical activity with meditation may significantly reduce the incidence of diabetes (Lambrinou, Hansen, & Beulens, 2019; Kumari, Singh, Dahiya, Jhingan, & Chhajer, 2018). Several clinical trials illustrate that lifestyle interventions are effective in treating diabetes, obesity, hypertension, cardiovascular disease, and other chronic diseases (Mohan et al., 2006; Ibrahim, Moi, Awalludin, Ali, & Ismail, 2016). To date, in India rarely any study which, combined all five lifestyle intervention components (plant-based balanced diet, physical activity, stress management, risk factors management, Routine medical checkups, and Medication adherence) and observed the effect of lifestyle intervention on blood glucose levels, HRQOL) and medical treatment cost with the evaluation of adherence toward lifestyle interventions in T2DM patients (Chhajer, Singh, Kumari, & Lohmor, 2018). Therefore this study was opted to assess the effect of lifestyle intervention holistic approaches on blood glucose levels, HRQOL, and medical treatment cost in T2DM patients.

Methodology

This hospital-based, quasi-experimental, prospective study was carried out in the Delhi Diabetes Research Center (DDRC) New Delhi, among 224 T2DM patients who were attending the outpatient department at DDRC New Delhi and fulfilled all study eligibility criteria and agree for one-year follow-ups. The consecutive sample technique was used to enroll the patient by face to face interaction and the total duration of the study was 3 years (April 2015 to November 2018) with follow-ups.

Inclusion criteria were clinically and diagnostically confirmed T2DM patients of either sex, aged between 35 to 70 years, patients having blood sugar fasting (BSF) more than 120 mg dL^{-1}, blood sugar postprandial (BSPP) more than 180 mg dL^{-1}, and glycated hemoglobin (HbA1c) above 7%, patients having at least one co-morbidity of obesity, hypertension, coronary heart disease, patients having diabetes at least more than 1 year, and patients who were willing to participate and follow-ups along with able to give both oral and written consent. Exclusion criteria were patient having diabetes less than 1 year, Type 1 and Gestational Diabetes, severe heart, liver and kidney failure, hospitalized, visual-hearing problems, severe diabetes complications in the foot or unable to do physical activities, the patient received more than one time or multiple lifestyle intervention counseling over the last 1 year, and the patient unwilling to participate or unable to give written consent.

Data collection and Lifestyle Intervention

The data collection process was completed in one year and 6 months (6 months for enrollment of the study participant and, one year of follow-up). The data collection process started with the screening of T2DM participants. First of all total 312 patients were screened, according to eligibility criteria. Out of 312 patients, 88 patients were excluded from the study because they were not fulfilling all study requirements. Finally, 224 patients were enrolled as they fulfill all study eligibility criteria and agree to participate with a one-year follow-up. Patients were allocated into two groups (LIC and UC group), based on participants were

receiving or not receiving lifestyle intervention counseling (LIC). The first group was a lifestyle intervention counseling (LIC) group, receive lifestyle intervention counseling sessions with pharmacological treatment and the second group was usual care (UC) group, they were not received lifestyle intervention counseling only taking pharmacological treatment. Each group had 112 patients. The data collection process was completed in three phases- baseline assessment, lifestyle intervention counseling, and study follow-ups (3rd, 6th, and 12th months).

Phase-1 Baseline assessment

The data collection was carried out using pre-designed questionnaires which included the following parts:

The socio-demographic information of the study participants was collected through face to face interview, on the first day of contact by asking questions related to their age, locality, duration of diabetes, the present status of co-morbidity, family history of diabetes, food habits, Stress, type of medication.

Then the baseline anthropometric (Height, Weight, BMI) and physiological (BP, Pulse) measurements of the study participants were done through standard methods by lab technicians. The height of the participants was measured in centimeters using a stadiometer and SECA digital scale. The weight of the study participants was measured in kilograms using Krupp's weighing machine. The BMI calculated by using Quetelet's formulae, weight in kilograms divided by the square of the height in meters. BMI = kg m^{-2}. The body Fat percentage of participants was measured with the help of a body fat caliper.

The systolic and diastolic BP of the participants was recorded by using an automatic digital blood pressure monitor of Diamond Company by trained personnel. Pulse was measured using ChoiceMMed MD300C2D pulse oximeter.

Blood Glucose levels: Blood Sugar Fasting and PP of the patients were performed by using the GOD-POD method and HbA1c was assessed using an immune-turbidimetry method. Total cholesterol level was assessed by using the CHOD-PAP method, triglyceride by GPO method, HDL- cholesterol by immune inhibition method was done and LDL was calculated with the help of a standard formula [LDL = Total Cholesterol - HDL - (Triglycerides/5)].

Treatment Cost Assessment: Baseline medical treatment cost for diabetes and its related complications was analyzed by a personal discussion with the administration of pre-designed diabetes and its related complications questionnaire by the participants. This questionnaire contains a total of 20 questions on the expenditure on the treatment and management of diabetes and its related complications per month. This expenditure includes doctor consultation fees, laboratory test cost, medicine cost, hospitalization/surgery cost, and traveling cost.

Health-Related Quality of Life (HR-QoL) assessment: HR-QoL of both the groups was assessed using short-form health survey (SF-36) and appraisal of diabetes scale (ADS). These questionnaires (SF-36 and ADS) contain questions related to daily life problems such as mobility, personal care, housework, family, study, free time activities, soreness, distress and nervousness/hopelessness, etc. The responses of the participants were recorded as the answer to the questions. SF-36 is a general health assessment tool; consist of 36 questions, with eight health measurement domains. These eight domains were scored from 0 to 100, indicative of worst to best possible health outcomes.ie high score of SF-36 defines better health outcomes of patients. ADS is a diabetes-specific questionnaire for assessing HRQOL of T2DM diabetes patients consists of 7 questions covering uncertainty; diabetes-related stress, diabetes control, expected future decline, coping skill, and effect of diabetes on life goals. The total score for this scale range from 0 to 35. 0 is the best level of health and to 35 is the worst level of health. Thus, the lesser score of ADS suggests better health and a better quality of life, on the other hand, a higher score indicates poor quality of life.

Phase-2 Lifestyle intervention counseling (LIC)

After completion of baseline investigations, a comprehensive Lifestyle intervention Counseling (LIC) was given to only LIC group patients with the help of the Lifestyle Intervention Holistic (LIH) Model which we have developed during the study. The LIH Model concepts and contents were taught and explained in the step by step manner through the experts (diabetes educator, dietitian, endocrinologists, and physical trainer, yoga, and meditation teachers). LIH model was used as a holistic approach in the management and treatment of T2DM. This model is very easy to understand and follow by the patients, it consists of five key components that are located at our fingertips. These components were explained in the local language, with

the help of pictures, posters, videos, and face to face interaction with participants. Lifestyle intervention counseling was repeated every month for 6 months.

Five components of lifestyle intervention counseling

'The first component' was a plant-based balanced diet located on the thumb. Diet counseling was delivered by an experienced dietician, she educates the participants, how can the balanced diet maintains blood sugar levels, weight, blood pressure, and reduce the risks of diabetes-related complications and medication. She motivated the participants to cut down a high calorie, fatty, salty and sugary food and increase the amount of fibrous diet, like as whole grain, green leafy vegetables, and fibrous fruits which reduce the blood sugar and cholesterol level and also fill up the stomach for a longer period. The dietitian also provided a diet chart to all study participants and motivated them to the follow this diet chart strictly and give strict instruction to divide their meal into six small and regular portions at proper time intervals (take breakfast, lunch, and dinner at the regular and appropriate time and also take small snacks in between these meals).

'The second component' was physical activity located on the index finger, which is very essential to maintain BSL, BP, and reduce the risks of other fetal life-threatening complications. The physical trainer and yoga teacher was advised the participants to increase their physical activities, such as brisk walk and yogic exercises for 30 minutes per day. They were educating the participants about the importance of regular physical activities and how can it help in the management of diabetes because it helps to reduce the blood glucose level, LDL cholesterol and triglycerides burns extra calories, boost energy level, maintain body weight, improve blood flow, and improve the response of the anti-diabetic drugs and ability to cope with diabetes and stress, decrease anxiety and depression, blood pressure, etc. Yoga teacher explained the impotence of yogic exercise (Mudrasana, Balasana, Vajrasana, Paschimottanasana, Ardha Matsyendrasana, Supta Vajrasana, Dhanurasana, Shavasana) and taught how to perform yoga asanas. They motivated the participants for making their walking groups and use pedometers to measure their walking progress, and also provoked participants to take the stairs in place of using a lift or elevator and advised to go office and market by walk if nearer to home.

'The third component' was the management of risk factor (obesity, smoking, tobacco, and alcohol) which located on the middle finger. Participants were motivated by diabetes educators to quit Tobacco (smoking and chewing tobacco) and alcohol by face to face interaction and taught these are the major risk factors for developing type 2 diabetes. She educated participants, smoking and chewing tobacco can cause respiratory problems, lung and mouth cancer, damage blood vessels, decrease blood flow to the legs and feet, and increase the risk of heart attack and amputation. She advised the participants to join smoking and tobacco cessation clinics which provide counseling with some medication to quit these habits.

'The fourth component' was stress management, placed upon ring finger. The stress management sessions were provided by a mediation guru and diabetes educator in the form of a psychological technique called motivational interviewing. The purpose of this was to encourage the participants to develop inherent motivation to produce a change in behavior and spread awareness about meditation and breathing exercises in terms of stress management. They educate the participants, that diabetes and stress have direct relation, and how stress hormones (adrenaline and cortisol) increase the blood glucose level, and therefore the participants were encouraged to do daily meditation and breathing exercise at least for 15 minutes to control their stress and advised to take proper sleep. They were made familiarize educated that during meditation the level of stress hormone (adrenaline and cortisol) reduced thereby reducing the blood sugar level.

'The fifth component' was routine medical checkups and medication adherence is a very important and necessary point in the treatment and management of diabetes, placed on the little finger. The diabetologist was encouraged to the participants for routine medical checkups (blood sugar fasting, PP, HbA1c, lipid profile) and advise them to take their medicine at the proper time.

Usual care group - Participants in the UC group received only standard care (Pharmacological treatment). Besides, they have also received the pamphlets and booklets for self-management of diabetes and record their all parameters at the 3rd, 6th and12th months. The same diary was given to UC participants to record their weights, diets, physical activities, and other blood test results as it also provided to the intervention group.

Phase-3 Follow ups

The follow-up and assessment of anthropometric, physiological, and biochemical parameters have been done at 3rd, 6th, and 12 months with the same methods which we have used during baseline assessment for both groups. After that, the medical treatment cost and health-related quality of life of both the groups were done at 3rd, 6th, and 12 months through the same procedure and same quality of life (SF-36 and appraisal of diabetes scale) and medical treatment cost questionnaire (diabetes and its related complications questionnaire).

Lifestyle Holistic Model Adherence

Adherence to the lifestyle intervention holistic model was assessed through a diabetes lifestyle intervention adherence questionnaire. This questionnaire contained 5 items for adherence, including adherence to a balanced diet, physical activity, and risk factor management, meditation to control stress, and routine medical checkups & medication. Each item had 4 questions that mean the whole questionnaire consist of 20 questions. Every question had 7 options out of which one option was appropriate; each answer carried a score of that marked options range from 0-7. The follow-up and assessment of LIH model adherence in the intervention group (LIC group) patients were done at 3rd, 6th, and 12 months, through the diabetes lifestyle intervention adherence questionnaire.

Statistical analyses approach

The statistical package for the social sciences (SPSS) software version 21 was used for all statistical analyses. Participants' demographic and socioeconomic measurements were compared between groups using independent t-test. Mean, percentage, and standard deviation were used to analyze the socio-demographic and clinical variables. Frequency, percentage distribution means, and the standard deviation was used to analyze the anthropometric, physiological biochemical parameters of T2DM patients. Multi-variant analysis was done to assess the effect on glycemic control. Medical treatment cost was assessed through Wilcoxon scores (rank-sum) test to calculate p-value as data were not normally distributed. Health-related Quality of life was assessed by using a sample t-test. The adherence to holistic model was assessed through median and p-value less than 0.05 ($p < 0.05$) was considered as a significant value for the effective changes in the intervention.

Ethical approval and informed consent

The ethical clearance for this study was obtained from the concerned authorities of the Delhi Diabetes Research Center (DDRC), New Delhi, and SAAOL Heart Center, New Delhi. The written informed consent was obtained from all study participants before initiation of the study. The signed informed consent from study participants showed the agreement of participants to participate in the study without any force.

Results

Recruitment and response rate of participants

A total of 312 T2DM patients were screened from DDRC, New Delhi. Out of 312 patients, 224 patients were registered as they fulfill study eligibility criteria and agree to complete one-year follow-ups. Enduring 88 patients were excluded from the study because of 27 patients were refuse to give informed consent, 33 patients refused to participate and one year follow up, 12 patients having diabetes less than one year, and 16 patients having time obligation difficulty. Final enrolled 224 patients were allocated to LIC (test group) and UC group (control group). Each group had 112 patients. Furthermore, 10 patients from LIC group and 12 patients from the UC group were excluded because they were not completed one year follow up because of some patients have no interest to follow LIH model, some migrate to different places, some patients have no trust in intervention therapy, and some having time commitment difficulty. Finally, 202 ($n = 100$ in the UC group and $n = 102$ in LIC group) patients have completed the whole study with all 3, 6, and 12 months the follow-ups.

Demographic profile and baseline assessment of LIC and UC groups

In the present study, the data of 202 participants were analyzed. The mean age of the LIC group patients was 51.4 ± 9.3 and UC group patients were 54.0 ± 8.6 with an age range from 35 to 70 years.

The number of male participants was higher 118 (58.4%) than females' participants 84 (41.6%). A maximum number of participants belonged from urban (111) areas as compared to rural and semi-urban 42 and 49 respectively. The average duration of diabetes of the LIC group was 7.93 ± 6.4 and the UC group was 7.88 ± 5.9. In this study out of 202 patients, 127 patients were obese, 150 having hypertension, 68 patients were having heart disease. Out of 202 patients, 77 patients were having a history of diabetes, in which 39 patients from the LIC group and 38 from the UC group. Out of total patients, 112 patients were Non-vegetarian, 89 was a vegetarian and one was Vegan. Out of total patients, 31 patients were smokers, 24 patients had the habit of tobacco chewing, and 51 patients consumed alcohol in excess amount and 114 patients had no personal habits of tobacco and alcohol. At baseline assessment, 87 patients were physically active, in which 43 patients in the LIC group and 44 in the UC group. Out of 202 patients, only 23 patients were performing meditation to control stress and only 35 patients have monitored their blood glucose regularly at baseline. The data of demographic profile and baseline assessment of LIC and UC are summarized in Figure 1.

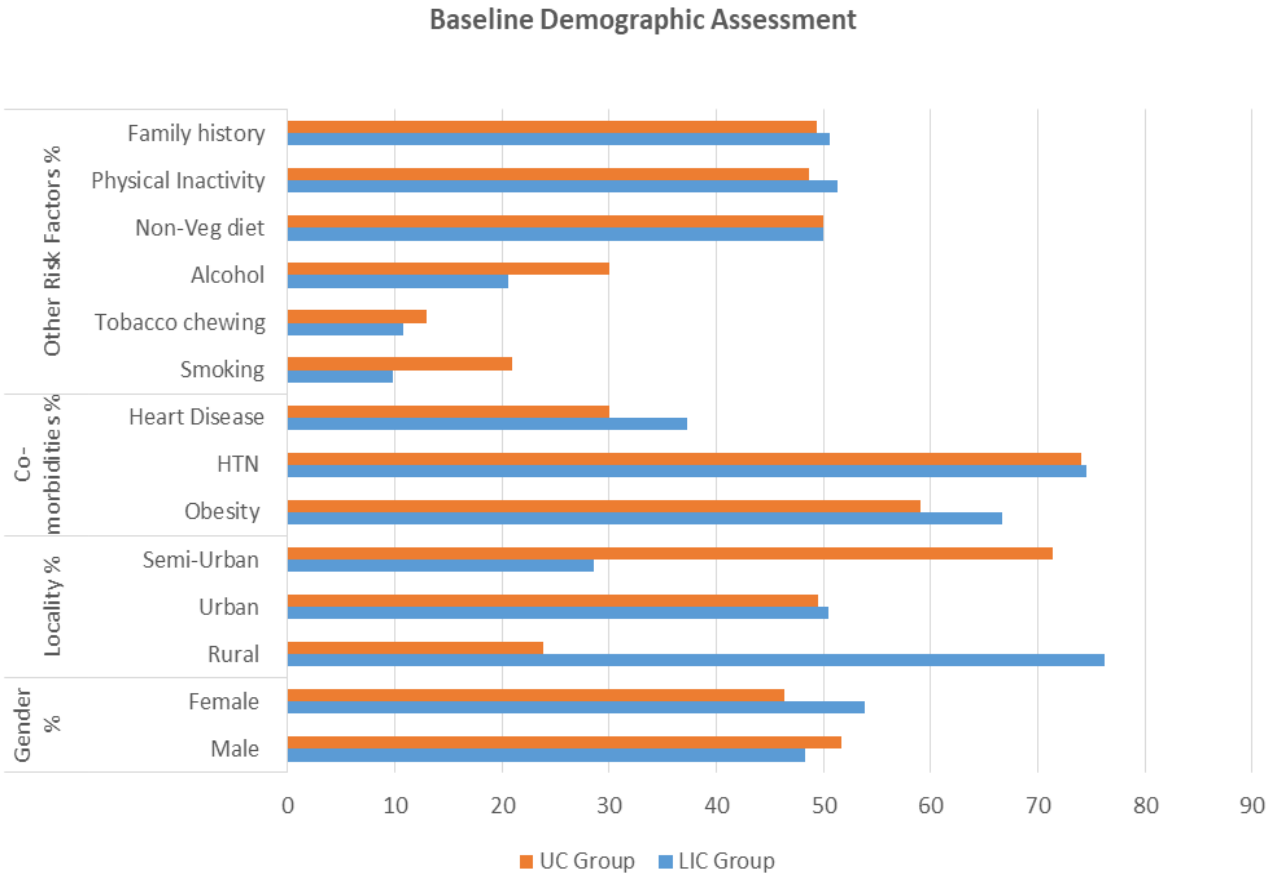

Figure 1. Demographic and Baseline characteristics for the LIC and UC group participants.

Socioeconomic profile of LIC and UC groups

Out of 202 patients, 69 patients were 12th or diploma holders followed by 63 were Graduate/Postgraduate, 45 Up to class 10 education, 10 Up to class 5 education, 2 Illiterate, and 2was Ph.D./Doctorate. In this study, participants belong to various types of occupations. Out of 202 patients, 70 (34.6%) patients were unemployed (retired and females) followed by41 (20.2%) clerical/shop owner, 36 Semiprofessional, 21 skilled workers, 18 skilled workers, 13 skilled workers, and 3 was Professional. Out of 202 patients, 75 patients from the income group of 19291-38599 INR followed by 61 patients from income group of > 38,600 INR, and 25 patients from the income group of 14463-19290 INR. Out of 202 patients, 96patients belong to the Upper Middle class followed by77 Upper Class, 25 Lower Middle class, Upper Lower class, and 1 from the Lower class. Out of 202 patients, 125 patients were self-supporting for their finances for Diabetes however 72 patients were supported by their families, 3 by the health care provider, and one by the Insurance Company. The socioeconomic profile of LIC and UC groups are summarized in Figure 2.

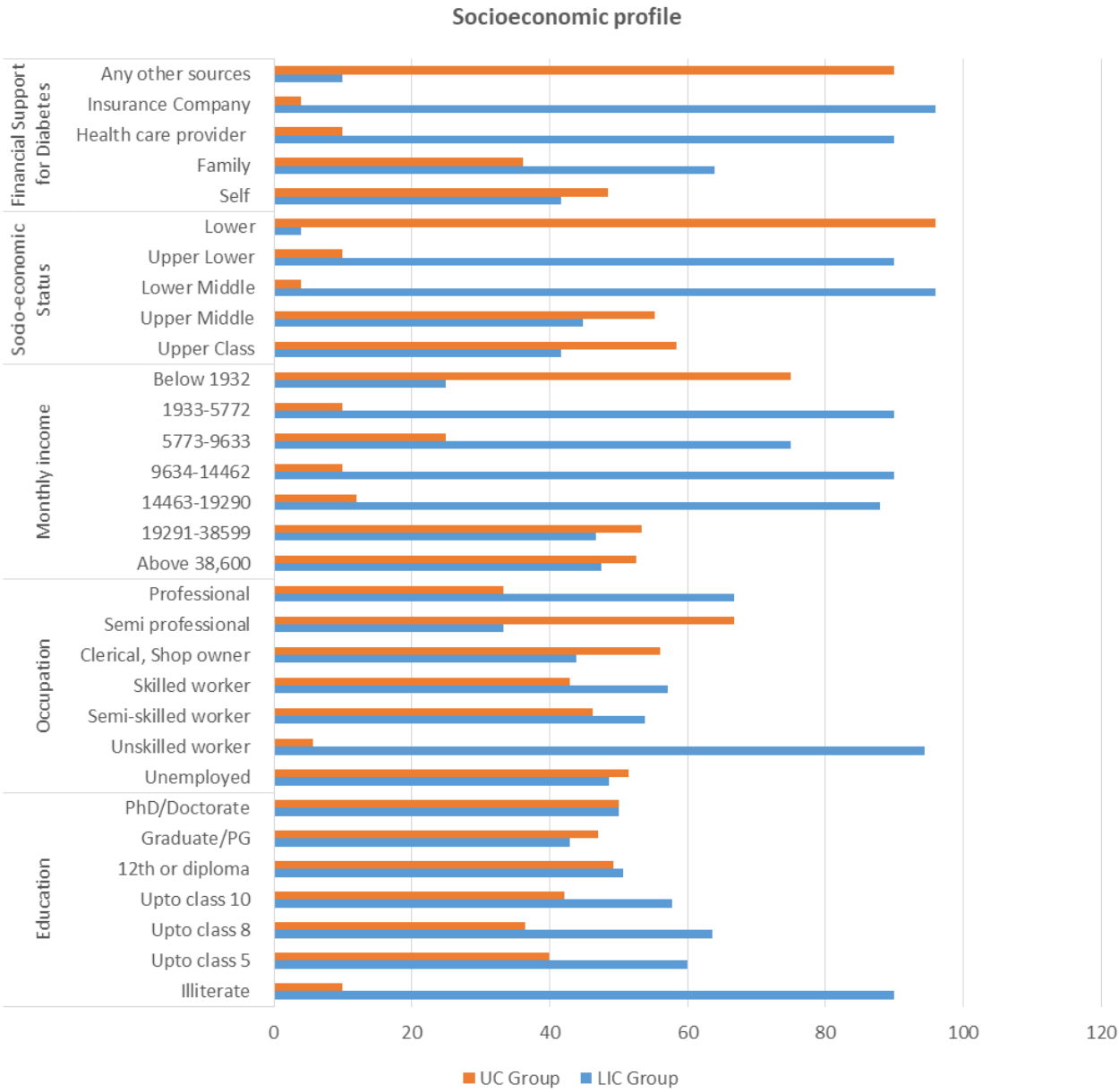

Figure 2. Socioeconomic profile for the LIC and UC group participants.

Anthropometric Physiological Profile for the LIC and UC group

A statistically significant improvement was observed in Body Fat% at 3rd (30.7 ± 5.5 to 29.9 ± 5.1) 6th month (30.7 ± 5.5 to 29.4 ± 4.4) and 12 month (30.7 ± 5.5 to 29.2 ± 3.8) from baseline, within the LIC Group. A significant improvement was observed in SBP at 6th (125.5 ± 9.7 vs 130.9 ± 11.3) and 12 month (124.7 ± 9.5 vs 131.1 ± 11.9) between the LIC and UC Group and also a significant improvement was observed in DBP at 3rd (134.9 ± 16.0 to129.5 ± 13.1), 6th month (134.9 ± 16.0 to 125.5 ± 9.7) and 12month (134.9 ± 16.0 to 124.7 ± 9.5) from baseline. There was a statistically significant improvement observed in pulse rate from baseline to 3rd (82.6 ± 7.0 to 80.3 ± 6.04), 6th month (82.6 ± 7.0 to 78.9 ± 4.8) and 12month (82.6 ± 7.0 to 79.4 ± 6.1). The follow ups of physiological parameters (BMI, Body fat, SBP, DBP and pulse) of the LIC and UC groups are represented in Figure 3.

Effects of lifestyle modification counseling on glucose metabolism

An intention-to-treat analysis of between groups at 12-month (mean difference, 95% CI) revealed that the LIC participants had decreased in the BSF 0.26 mg dL^{-1} (-4.37 to 4.89), BSPP -70.16 mg dL^{-1} (-85.15 to - 55.16) and HbA1C -2.82% (-5.26 to - 0.37), with all p-values < 0.001. The BSF in the LIC group significantly decreased at 3, 6- and 12-month follow-up by 16.93 (12.53 to 21.32) mg dL^{-1}, 33.44 mg dL^{-1} (28.42 to 38.46), and 29.29 mg dL^{-1} (22.26 to 36.32) respectively, with p < 0.00. In contrast, the usual

care group also showed a decrease in FPG at 6-month and 12 month, but there was no decrease observed at 3 month follow up. Relative to the usual care group, the LIC group demonstrated a substantial decrease in BSPP by 35.93 mg dL^{-1}, (29.92 to 41.93) 75.16 mg dL^{-1}, (66.87 to 83.46) and76. 53 mg dL^{-1} (66.04 to 87.03) at 3, 6, and 12-month respectively with significant $p < 0.001$. Similar patterns of changes were observed for HbA1C where by the LIC group demonstrated a decrease of 0.51% (0.4 to 0.61) 0.87% (0.75 to 0.99) and 0.97% (0.86 to 1.08) ($p < 0.001$) as compared to an increase of 0.17% (-0.02 to 0.36) 0.21% (0.02 to 0.39) and -1.30% (-3.63 to 1.01) ($p > 0.05$) for the UC group at 3, 6 and 12-month follow-up respectively. The data of effects of lifestyle modification counseling on glucose metabolism of LIC and UC are summarized in Table 1.

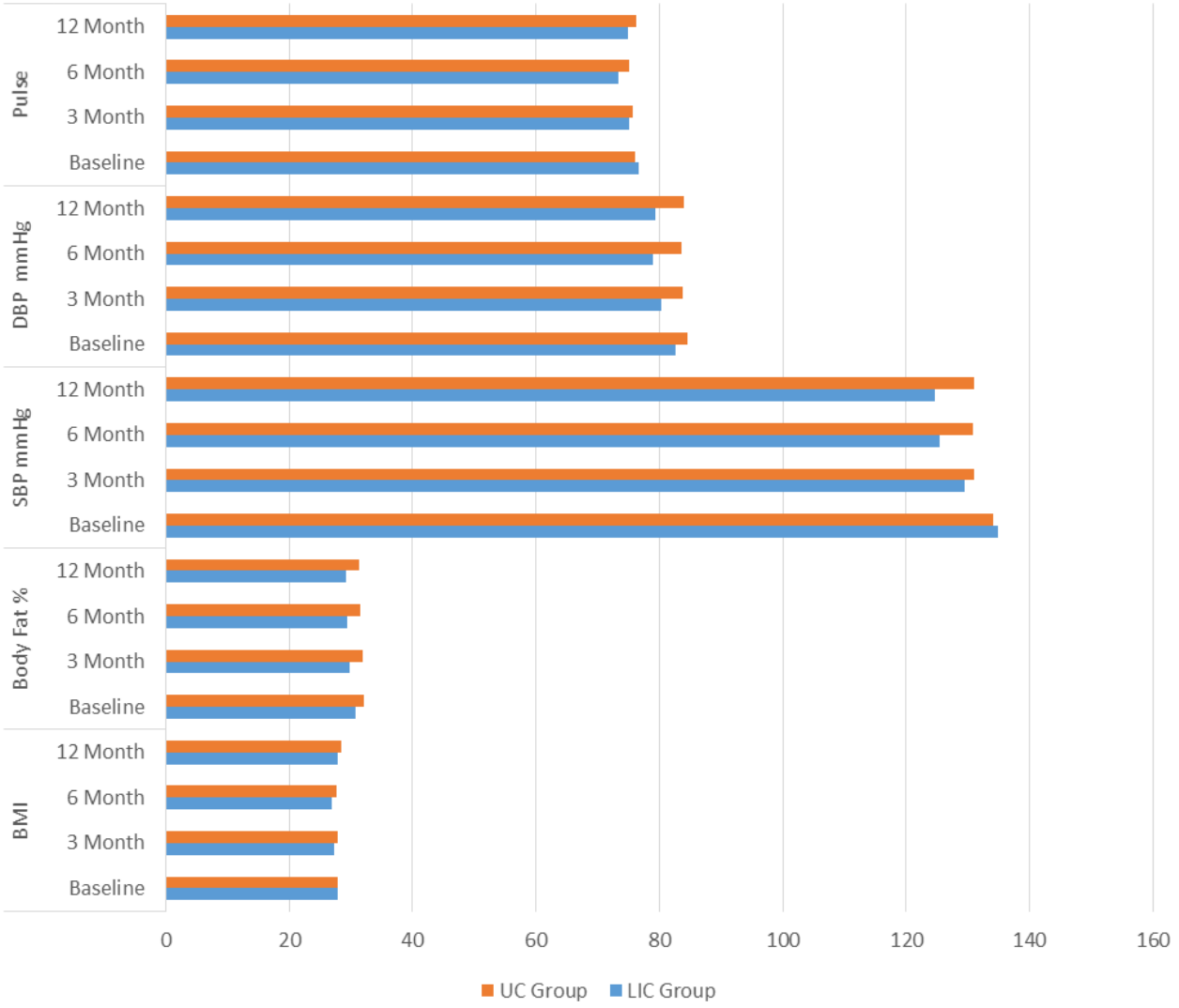

Figure 3. Changes in Physiological parameters.

Table 1. Changes in blood sugar levels between and within LIC and UC group from baseline to 3, 6-and 12 month follow-up.

Outcome	LIC Group (n=102)			UC Group (n=100)			Mean difference (95% CI) between groups		
	Mean change (95% CI) from baseline			Mean change (95% CI) from baseline					
	3-month	6-month	12-month	3-month	6-month	12-month	3-month	6-month	12-month
BSF	16.93 (12.5-21.32)	33.44 (28.42-38.46)	29.29 (22.26-36.32)	3.28 (-2.09-8.65)	11.35 (5.74-16.96)	9.89 (3.83-15.94)	7.73 (-0.08-15.54)	-0.60 (-7.84-6.64)	0.26 (-4.37-4.89)
p value	S	S	S	NS	S	S	S	NS	NS
BSPP	35.93 (29.92-41.93)	75.16 (66.87-83.46)	76.53 (66.04-87.03)	20.52 (9.54-31.49)	40.68 (27.74-53.62)	31.21 (17.92-44.49)	-39.75 (-57.39- -22.10)	-59.26 (-74.90- - 43.61)	-70.16 (-85.15- - 55.16)
p value	S	S	S	S	S	S	S	S	S
HbA1c	0.51 (0.4-0.61)	0.87 (0.75-0.99)	0.97 (0.86-1.08)	0.17 (-0.02-0.36)	0.21 (0.02-0.39)	-1.30 (-3.63-1.01)	-0.86 (-1.30- - 0.43)	-1.20 (-1.60- - 0.79)	-2.82 (-5.26- - 0.37)
p value	S	S	S	NS	S	NS	S	S	S

BSF-Blood sugar fasting, BSPP- Blood sugar postprandial, HbA1c- Glycated hemoglobin, S-Significant, NS-Non-significant, Means differences within and between-group are in mean (95% Confidence Interval), a negative change indicates a fall on average from baseline to 3 months, baseline to 6 months and baseline to 12 months. Determined repeated measures ANOVA within and between groups comparison and multi-variant analysis for significant change at $p < 0.05$.

Lipid Profile

A statistically significant reduction in total cholesterol was observed at 3rd (286.4 ± 103.2 to 247.1 ± 80.1), 6th month (286.4 ± 103.2 to 213.2 ± 83.9) and 12month (286.4 ± 103.2 to 205.8 ± 56.9) from baseline, within the LIC group while there was an insignificant incensement observed in the UC group. A significant improvement in triglyceride and HDL was observed at 3rd, 6th, and 12month from baseline, within the LIC group while no statistically significant differences observed in the usual care group. There was a statistically significant difference was observed in LDL cholesterol at 6th (119.5 ± 80.7 vs 183.7 ± 96.5) and 12 month (111.9 ± 54.8 vs151.5 ± 77.4) between the LIC Group and UC Group. There was a statistically significant difference observed in VLDL cholesterol at 3rd (47.13 ± 22.9 to 40.64 ± 17.4), 6th month (47.13 ± 22.9 to 34.57 ± 12.5) and 12month (47.13 ± 22.9 to 35.0 ± 8.2) from baseline, within the LIC group while no statistical significant differences observed in the usual care group. The data of lipid profile (Cholesterol, Triglycerides, HDL, LDL and VLDL) and follow ups (baseline, 3, 6, and 12th month) of the LIC and UC groups are summarised in Figure 4.

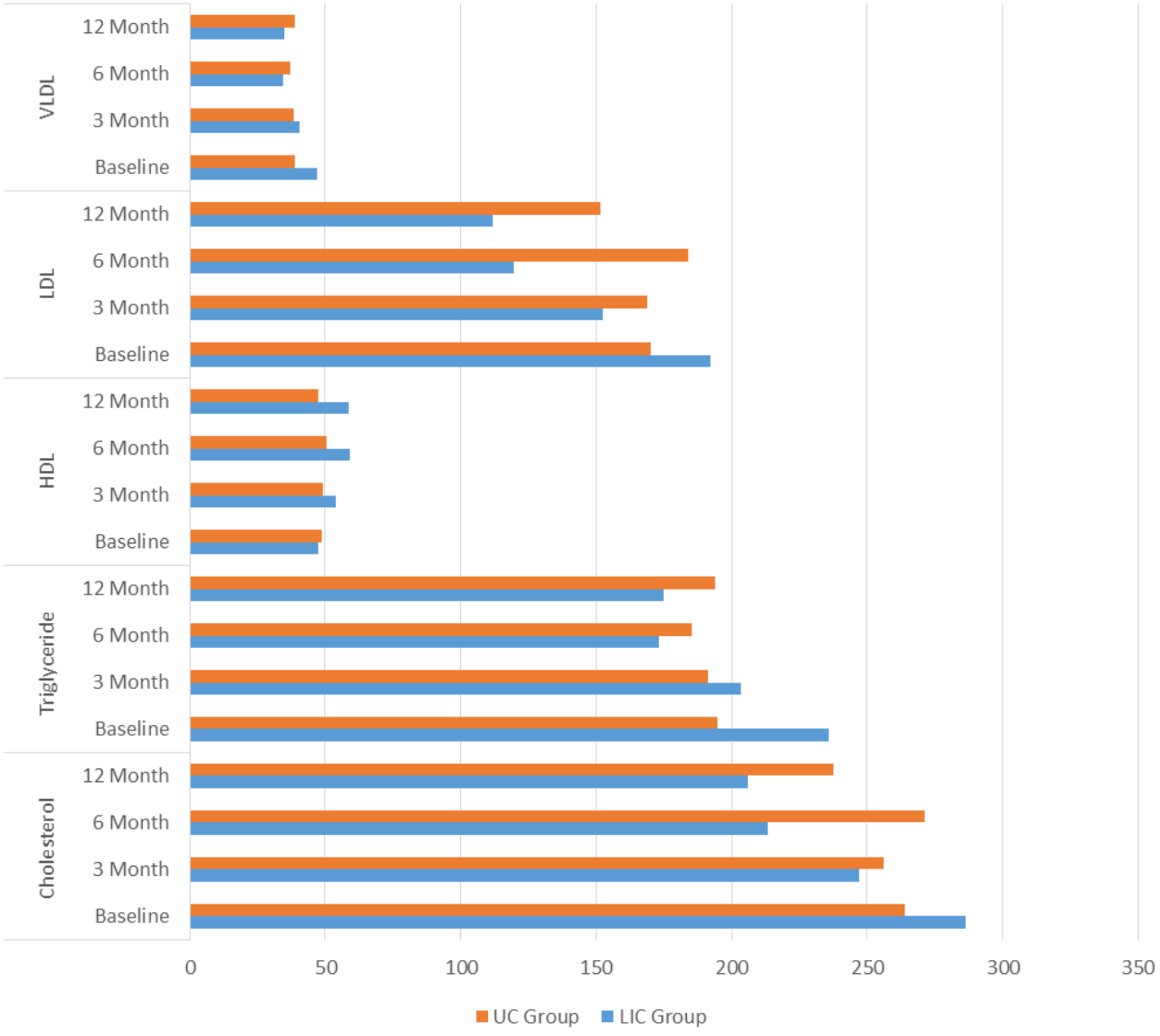

Figure 4. Lipid profile assessment.

Assessment of Lifestyle intervention counseling on HRQoL (SF-36) of LIC and UC group

There were no significant changes observed in HRQoL between LIC and UC group at baseline but there was a statistically significant improvement was observed in the emotional well-being, physical functioning, energy/fatigue, role limitation due to emotional problems, and social functioning in the LIC group as compared to the UC group at 6th month follow up. After one year following lifestyle intervention counseling instructions, the LIC group showed a significant improvement in all of the domains except bodily pain. In the domain of bodily pain, there was improvement observed in the mean (68.70 to 75.12) but not reach a statistically significant level. A significant improvement was observed in the mean of the following domains from baseline to 12 months, physical functioning (62.402 to 83.676), energy/fatigue (54.31 to 80.75), Role limitation due to physical health (35.30 to 64.50), emotional well-being (63.06 to 85.79), social functioning (38.848 to 65.54) role limitation due to emotional problem (37.90 to 71.46), and general health (54.51 to 82.398) as compared to the UC group. So that the results of the present study showed significant improvement in the overall health-related quality of life in LIC group patients after following lifestyle intervention counseling. The effect of lifestyle intervention counselling on HRQoL using SF-36 scale for LIC and UC group and it follow ups (baseline, 3,6, and 12th month) are summarised in Figure 5.

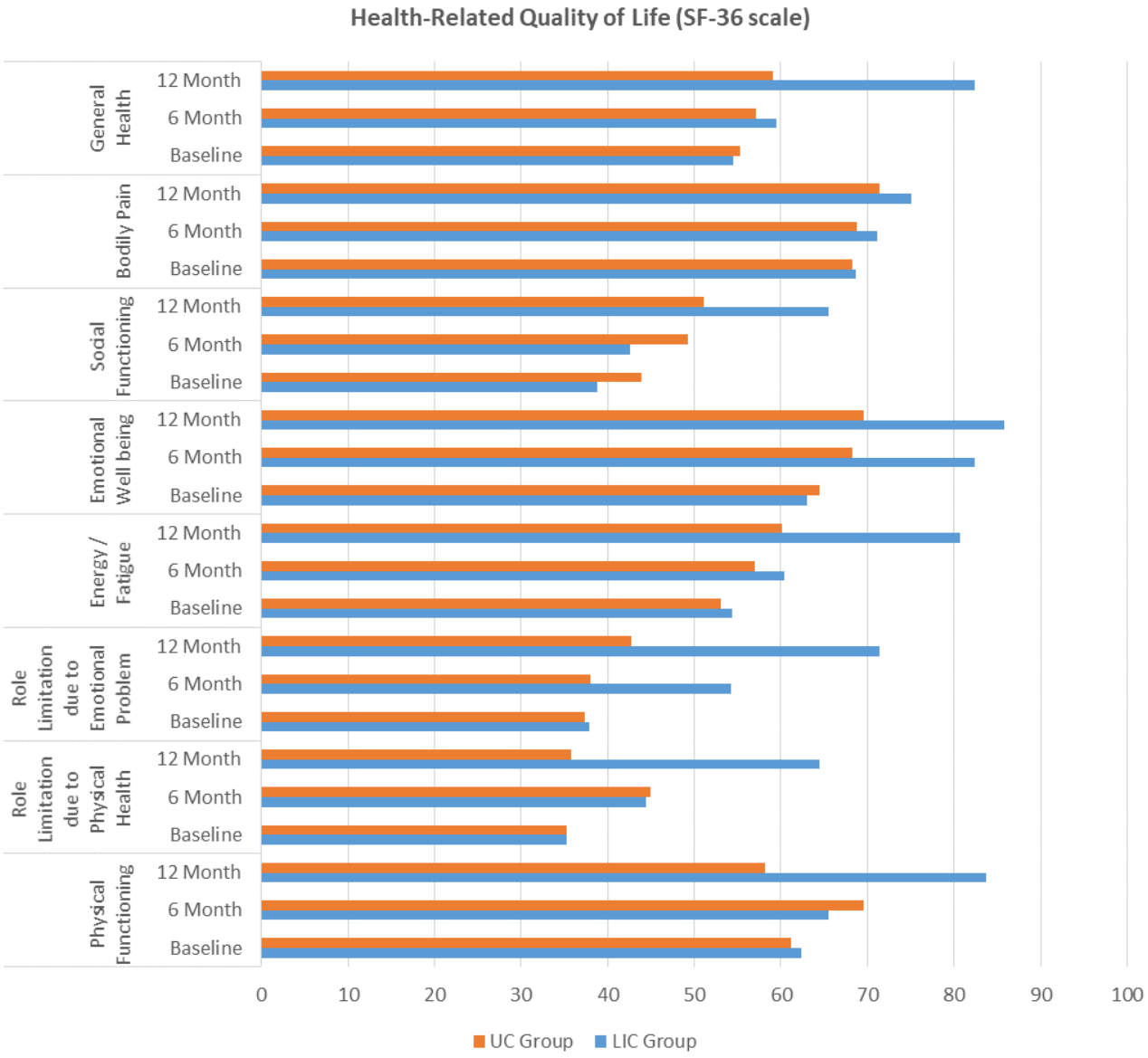

Figure 5. Changes in Health-Related Quality of Life (SF-36 scale) of LIC and UC group.

According to the ADS scale, LIC group patients showed a significant improvement in the following variables- control over diabetes, uncertainty due to diabetes, copying skills, anticipated future

deterioration, and effect of diabetes on life goals after following lifestyle intervention counseling instructions but there was no significant improvement was observed in one variable (distress caused by diabetes) at 6 months. After one year follows up most of the patients of LIC group showed significant improvement in all domains such as distress caused by diabetes (3.9 to 2.8), uncertainty due to diabetes (4.8 to 3.1), control over diabetes (2.4 to1.1.5), anticipated future deterioration (3.7 to 1.9), coping skills (2.9 to 2.09) and effect of diabetes on life goals (3.4 to 2.1) with statistically significant p values, from baseline to one-year follow-up. The effect of lifestyle intervention counseling on HRQoL using ADS scale for LIC and UC group and it follow ups are summarized in Figure 6.

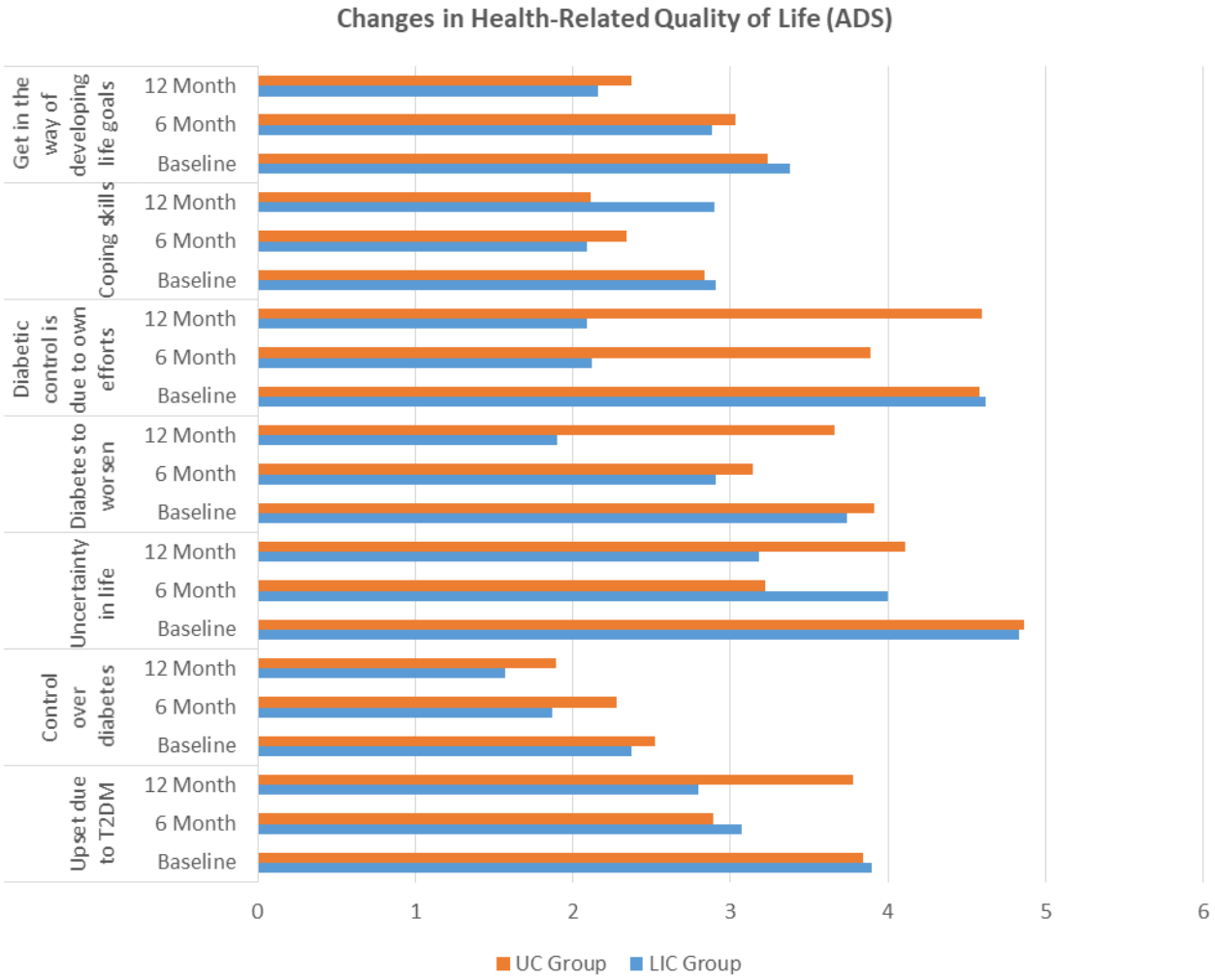

Figure 6. Changes in Health-Related Quality of Life (ADS scale) of LIC and UC group.

Assessment of Medical Treatment cost after lifestyle intervention counseling in LIC & UC Group at 12 months

At 12 month follow up, a significant reduction was found in diabetes medicine cost, surgery cost, and hospitalization cost of LIC group as compared to the UC group. The result of the present study concludes that the UC group spends more money (10534 INR) on diabetes medicine as compared to the LIC group (9627.5 INR) with significant p-value 0.0038. The surgery cost of the LIC group (3186.3 INR) was lesser as compared to the UC group (9212.0 INR) with a significant difference p 0.0046. The average hospitalization cost of the UC group (39580 INR) was approximately four times higher as compared to the LIC group (10569 INR). The anti-diabetes medicine cost, hospitalization, and surgery cast of LIC group were lesser due to the lesser number of co-morbidities and complications; it may be due to the effect of lifestyle intervention counseling.

There was a mean change observed in some other variables cost in INR such as diabetic neuropathy expenses (UC vs LIC) (307 *vs* 184.3), hypertension medicines cost (257.8 *vs* 173.8), diabetes retinopathy expenses (39.0 *vs* 14.7), foot complication related treatment cost (305.5 *vs* 137.8), other expenses for

diabetes (340.0 *vs* 173.5), but these changes or reduction did not reach to the statistically significant level. Although the LIC group spends more money for doctor's consultation fees for diabetic complications because of the LIC group have more participants with comorbidities and diabetes-related complications. The cost of travel, diabetes complication diagnosis and heart disease medication was a little higher in the LIC group due to the higher number of heart disease participants in the LIC group as compared to the UC group. The data of medical ttreatment cost of LIC & UC groups are summarized in Figure 7.

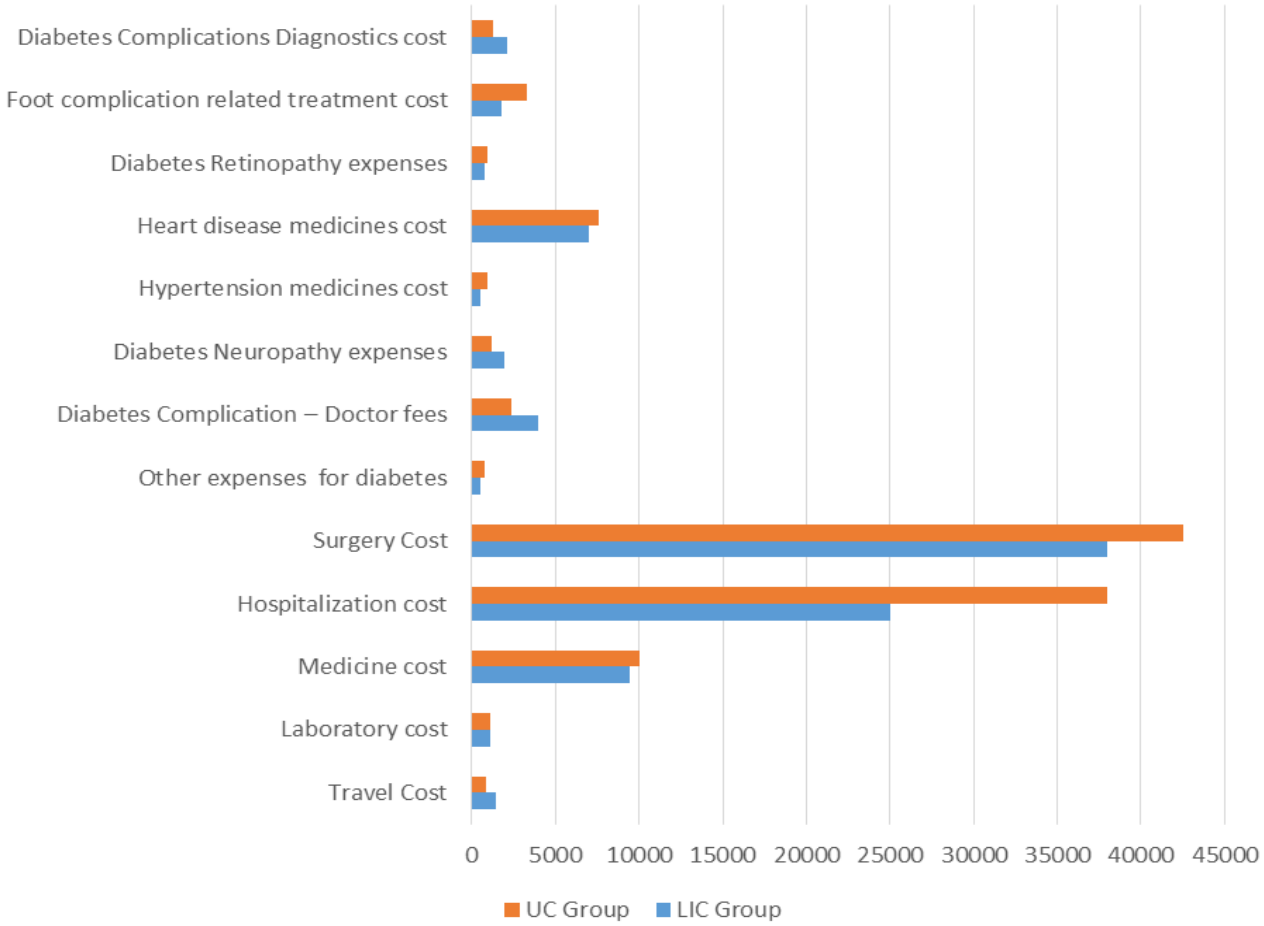

Figure 7. Medical treatment cost assessment.

Lifestyle Modification Holistic Model adherence status

After lifestyle modification counseling the adherence was assessed through seven-point liker scale which showed the significant improvement in diet chart adherence (Q1), eating a generous amount of fibrous diet (Q2), reduce to take sugar-rich products(Q 3), reduce to eat junk foods(Q4), walk for 30 minutes per day (Q5), take stairs instead of using lift or elevator (Q7), walk by feet to the market or office (Q8), reduce tobacco consumption (Q9), leave tobacco even you had a strong feeling to consume it (Q10), reduce consumption of alcohol (Q11), leave alcohol even you had a strong feeling to drink it (Q12), get proper sleep(Q14), feel relax and happy (Q15), check your feet for any symptom of diabetes complication(Q20). The adherence was increased from 3rd month to 6th-month follow-up but not sustained until the 12th month except tobacco and alcohol cessation. In short, this study results demonstrate good adherence to the diet, physical activity, and tobacco and alcohol cessation but lower the adherence to meditation for stress management, regular checkups, and medication adherence.

A detailed description of lifestyle adherence (lifestyle intervention holistic model) through LIC and UC group participants is given below:

In concern with (1)Diet chart adherence at the first follow up after lifestyle intervention counseling (3 months) the mean ± SD (days) of diet chart adherence was 5.21 ± 0.59, at second follow (6 month) it became 6.30 ± 0.76 and at 12 months follow up it was 5.32 ± 0.65. Hence the maximum adherence was observed at 6 month with higher mean. These results indicate that continuous counseling is necessary for improving the

adherence status of participants. The status of lifestyle modification holistic model adherence of LIC group at 3rd, 6th and 12th month is represented in Figure 8.

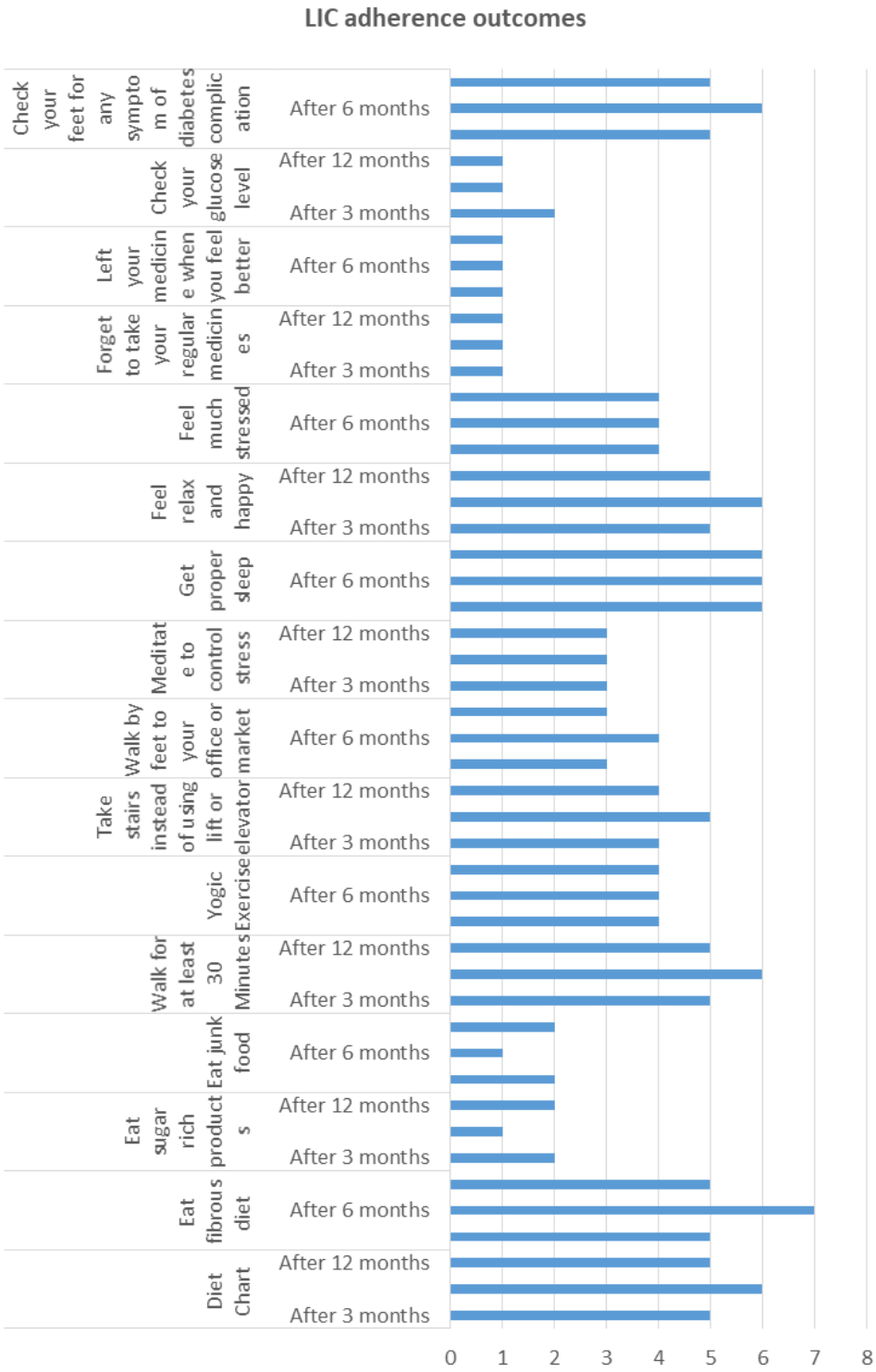

Figure 8. Changes in LIHM adherence outcomes based on a weekly time frame in seven points Likert scale over the three follow-ups (3rd, 6th and 12 month).

Similarly, the improvement also observed in (2) Eat fibrous diet (5.15 ± 0.64, 6.44 ± 0.66 and 5.37 ± 0.77), (3) patients reduce the intake of sugar-rich products (1.65 ± 0.920, 0.96 ± 0.72 and 1.80 ± 0.88) and (4) Eat junk food (1.66 ± 0.68, 1.06 ± 1.03 and 1.53 ± 0.56). A significant improvement was observed in the adherence to walking for at least 30 minutes (3 month-5.19 ± 0.94, 6 month- 6.07 ± 0.75 and 12 month-5.31 ± 0.95), and Yogic exercise (3 month-4.33 ± 1.08, 6 month 4.30 ±1.08 and 12 month 4.20 ± 1.19) per day scores from 3rd month to 6th month of follow-ups was increased but decrease at 12 month follow-up.

The patients' adherence to taking stairs instead of using lift or elevator (4.38 ±1.15 6 month-4.89 ± 1.13 and at 12 4.35 ± 1.21) and they use to take feet to go to their office or market (3.08 ± 0.75 6 month 4.05 ± 1.17 and 12 month 3.06 ± 0.76). Also significantly increased from 3rd month to 12 month of follow-ups. A significant adherence also observed in LIC group patients, they reduce smoking, chewing tobacco, and alcohol consumption after motivational counseling by the diabetes educator They left tobacco, smoking, and alcohol even they had a strong feeling to consume it. At baseline, very few patients were adhering to do meditation, after meditation counseling few more patients follow meditation practice but not reach the statistical level. After motivational counseling, the patient gets proper sleep as compare to before and feel relax and happy. The mean difference observed in the adherence to taking regular medicines in the LIC but not reach the statistically significant level from 3rd month to 12 month of follow-ups. Minimum days to forget to take medicines were observed at 3 month with lower mean and almost similar at 6 month. Few patients left medicine when you feel better but Maximum improvement was observed at 6 month. A significant adherence to check feet for any symptom of diabetes complications was observed LIC group patient but the Maximum adherence scores were observed at 6 month about 6 days out of 7 days of a week.

Discussion

A number of encouraging findings observed in the present study, with significant improvements in blood glucose levels, medical treatment cost, and health-related quality of life at the 3rd, 6th, and 12th-month follow-ups. A significant reduction was seen in body fat%, systolic and diastolic blood pressure, pulse, BSPP, HbA1C, medicine, surgery and hospitalization cost, and an improvement in HDL-cholesterol, and health-related quality of life (most of the domains). A significant improvement was also observed in lifestyle intervention holistic model the adherence components especially in - follow Diet Chart, Eat fibrous diet, reduce to take sugar-rich products, and junk foods, increase Yogic Exercise, Take stairs instead of using lift or elevator, Meditate to control stress, Get proper sleep, Check your glucose level and Check your feet for any symptom of diabetes complication and which was increased from 3rd month to 12th month of follow-up.

Effect of LIC on blood glucose levels in T2DM patients

The present study showed a significant improvement in blood sugar levels (BSF, BSPP, and HbA1c) on the LIC group as compared to the UC group. A study by Ades, Savage, Marney, Harvey and Evans (2015) showed a significant reduction in BSF by 20%, and HbA1c by 0.6% after adhering a six-month intervention, these findings support the present study. Several studies were done by Jorge, Oliveira and Resende (2011), Sasakabe, Haimoto, Umegaki and Wakai (2010) and Balducci, Zanuso, Nicolucci and Cardelli (2010) showed similar results to the present study with a significant decrease in blood glucose fasting, HbA1c, and cholesterol level, after following diet and exercise intervention. Several other studies conducted by Lee, Pei, Chi and Jeng (2015) and Bibra et al. (2014) support the present study and found improvements in glycemic control in the participants after adhering structured diet and aerobic training program. Two communities based comprehensive intervention studies by Koniak-Griffin et al. (2015) and Pérez-Escamilla et al. (2015) found significant improvement in glycemic control and lipid levels after lifestyle intervention practices.

Similarly, studies were done by Krishnan et al. (2015) showed significant improvement in glycemic control, and reduce the risk of complications after diet and exercise counseling program for six-months. A study by Okada et al. (2016) found significant a reduction in fasting and PP blood sugar, HbA1c, and the number of drugs in the intervention group after 6 months of lifestyle intervention coaching by community pharmacists and nurses. A study by Yamamoto, Moyama and Yano (2017) showed a significant reduction in HbA1c levels after receiving intervention guidance through E-Guide. Two studies were done by Shareef, Fernandes and Samaga (2016) and Sriram, Damodharan, Arjun, Latha and Raghuram (2016) show significant improvements in quality of life, BMI, and glycemic control in T2DM patients after following lifestyle intervention counseling through clinical pharmacist about diabetes, its complications, risk factors medications and lifestyle modifications. Studies by Ibrahim et al. (2016) and Nabi-Amjad et al. (2016) provide evidence that lifestyle-based counseling programs may significantly improve glycemic control and HRQOL of the test group.

Effect of LIC on medical treatment cost in T2DM patients

The results of the present study showed a significant reduction in diabetes medicine cost, surgery cost, and hospitalization cost of LIC group patients after following one-year lifestyle intervention counseling. A study revealed that lifestyle intervention with routine care reduces the risk of life-threatening complications and health care costs received lifestyle management education through experienced dietitians (Wolf et al., 2007). A study by Upadhyay, Ibrahim, Mishra, Alurkar and Ansari (2016) demonstrated a statistically significant reduction in diabetes medication cost, anti-hypertension medication cost, and hospitalization cost, in T2DM patients after following the pharmaceutical care program in which lifestyle intervention provided by the pharmacist. Similarly in the present study, we observed that patients of usual care group who have not received lifestyle modifications counseling spent more money on diabetes medicines, hospitalization and surgery cost due to diabetic complications as compared to LIC group. Studies by Png and Yoog (2014), and Mash, Kroukamp, Gaziano, and Levitt (2015) concluded that lifestyle intervention program focused on a healthy diet, physical activity; avoid the use of tobacco, smoking, alcohol, foot care, and stress management, performed by trained healthcare personnel was cost-effective and reduce the medical treatment cost and can prevent or delay the risk of T2DM and related complications.

Studies done by Cranor, Bunting, and Christensen (2003) and Garrett and Bluml (2005) defined a significant reduction in direct medical treatment costs and per patient direct health care cost after following a pharmacist-led lifestyle intervention program. Another similar lifestyle intervention study was done by Sevick et al. (2000), and Eakin, Reeves, and Winkler (2013), which provide evidence that lifestyle interventions were cost-effective, improves the quality of life and reduces the risk of diabetes-related complications. A study by Lin et al. (2006) demonstrated that adherence to self-management decrease the disease burden, health care cost, and frequent hospitalizations.

Effect of LIC on health-related quality of life in T2DM patients

A study by Kuznetsov concludes that there is a very strong relationship between glycemic control and HRQoL which means if the patient has a high blood glucose level experience a poor HRQoL due to the complications. The present study showed a significant improvement in HRQoL in all the domains of the LIC group as compared to the UC group follow-ups. Studies conducted by Guldbrand et al. (2014) and Snel et al. (2012) support the present study and found a significant improvement in HRQoL after adhering to a low fat and calorie diet, with physical exercise for 12 months.

A study carried out by Davis, Tomuta, Isasi, Leung and Wylie-Rosett (2012) found similar findings of the present study that low calories diet with physical activity decrease body fat percentage so indirectly had beneficial effects on HRQoL, because a physical appearance may have negative impacts on social interactions and activities of daily life, thus a decrease in body fat percentage resulted in an improvement in HRQoL. Two studies were done by Shareef et al. (2016) and Sriram et al. (2016) showed significant improvements in the quality of life, BMI, and glycemic control in T2DM patients after following lifestyle intervention counseling through clinical pharmacist about diabetes, its complications, risk factors, medications and lifestyle modifications. Studies by Ibrahim et al. (2016) and Nabi-Amjad et al. (2016) provide evidence that lifestyle-based counseling programs may significantly improve glycemic control and HRQOL of test group. A study done by Jacobsen, Vadstrup and Frolich (2012) showed significant improvements in glycemic control, SBP, physical capacity, waist circumference, and health-related quality of life in T2DM patients after adhering lifestyle intervention for one year.

Patient's adherence to lifestyle intervention and LIH model

The result of this study showed significantly good adherence to some variables such as a prescribed healthy diet(follow diet chart), take a generous amount of fibrous diet, minimum days eat junk food, and very rarely eat sugar-rich products), physical activity(regular walking and yoga at least 5 days, walk by feet to your office or market, take stairs instead of using lift or elevator), and regular checkup but the participants did not show significant adhere for regular medication, quit tobacco and alcohol, and patients did not adhere to regular meditation for stress management, but some patients still reported a range of reasons for non-adherence. Lin et al. (2006) in their studies demonstrated that adherence to lifestyle practice minimizes the burden of diabetes and improved clinical and physiological parameters which further reduced the hospitalization rate and economic burden. Several studies showed a significant improvement in

HRQOL, glycemic control, and observed reduction in medical treatment cost due to the reduction in both short and long-term diabetes complications of those patients who were adherence to antidiabetic medicines and self-management practice. The studies were done by Figueira, Villas Boas, Coelho, Freitas and Pace (2017), Fadare, Olamoyegun and Gbadegesin (2015) and Alfian, Sukandar, Lestari and Abdulah (2016) shown significant improvements glycemic control, QoL and reduce the risks of complications and treatment cost after adhering interventions counseling about medication, diet and physical activity adherence. The studies indicated that lack of awareness and adherence to self-care, and self-management associated with more diabetic-related complications which deteriorate the HRQoL (Shayeghian et al., 2015; Smalls, Gregory, Zoller, & Egede, 2015).

Conclusion

The findings of the present study discovered that lifestyle intervention counseling through LIH model and its adherence among T2DM patients was effective and significantly improved the physiological parameters (BMI, body fat, pulse, SBP, and DBP), blood glucose level (BSF, BSPP, and HbA1c), lipid profile, HRQoL, and reduced medical treatment cost in the LIC group as compared to the UC group. Hence there is an urgent need to arrange such types of easy and understandable lifestyle interventions programs in the rural communities to make people aware of diabetes and its related complications and how to control it at a very lower cost and improve their quality of life. Furthermore, several patients do not strictly adhere to regular intake of medicines because of the higher cost of diabetes medicines, there are very few studies were published in India to evaluate the effectiveness of lifestyle intervention in the reduction of diabetic economic burden.

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