Therapeutic Effects of Yoga on Quality of Life Outcomes in Patients with Type 2 Diabetes Mellitus - A Prospective Randomized Trial

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ABSTRACT

BACKGROUND

Psychosocial variables characterized by different emotional, cognitive and behavioural changes are highly persistent / or recurrent in diabetics. An important aspect of diabetes care is assessing symptoms related to these with the use of reliable and valid instruments. Treatment and control of Type 2 diabetes mellitus (T2DM) focuses on lifestyle changes. Yoga practice, a cost-effective method has a role in the prevention of diabetes, lowering glucose levels, and in improving health. We studied the effects of yoga practice on psychosocial factors and Quality of Life (QoL) in participants of T2DM.

METHODS

This is a prospective randomized hospital based trial. It was conducted on 104 participants of T2DM (age of study participants 30 - 65 years of both gender) which were randomized into two study groups viz. Control and Yoga active group. Approximately 40 minutes of yogasana, five days (minimum) a week for six months was performed in yoga active group. Fasting & postprandial serum glucose and glycated haemoglobin were analysed by using auto-analyser. Various questionnaires for assessing stress, depression (stressful life events, stress at home, at work, autonomy and for depression DSM IV CIDI questionnaire)* and QoL (SF - 36)* were filled by study participants. Psychosocial stress was evaluated by obtaining questionnaire related to major stressful life episodes in the previous years, work stress, home stress, financial stress and autonomy. Statistical analysis was done by using paired and two independent samples t test. Relative risk was reported as odds ratio and with 99 % Confidence Intervals (CI).

RESULTS

A significant improvement in mental wellbeing, self-control and QoL was observed as compared to control group. Serum glucose and glycated haemoglobin were significantly decreased in participants of yoga active group as compared to the control group participants.

CONCLUSIONS

Yoga therapy intervention in the present study positively addressed QoL of the diabetic participants and also achieved adequate glycaemic control.

KEYWORDS

Diabetes Mellitus, Quality of Life (QoL), Psychosocial Factors

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BACKGROUND

Type 2 Diabetes mellitus (T2DM) is a prevalent lifestyle problem. It has been assumed that by the year 2030 incidence of T2DM will rise by 7.7 % in adult population of the world and hence will affect around 439 million population.[1] Disorders like anxiety and depression are highly persistent / or recurrent in diabetes.[2] Up to 23 % of people with both types of diabetes in developed countries and about 58 % in developing and undeveloped countries report anxiety symptoms, predominantly Generalized anxiety disorders (GAD) symptoms.[3] An important aspect of diabetes care is assessing symptoms related to anxiety and depression with use of reliable and valid instruments because these psychiatric disorders significantly affect Quality of life (QoL) and capacity to function.[4] Effects of Psychosocial factors are critical to management of diabetes and yoga can prove to be a potential therapy for achieving positive changes in behaviour and lifestyle. It has been quoted by Alexis Carrel that "Quality of life is more important than Life itself." [5]

The World Health Organization (WHO) defined health as a new perspective in year 1948, that it is not just absence of disease but also health is presence of physical, mental and social well-being. Good QoL is the one which has perfect balance between the health status of mind, body and soul.[6] Findings of the study by O'Connor et al[7] provides evidence that the complications caused by diabetes result in causes reduction in cognitive skills, memory and attention by extending to the brain.

Management and treatment of T2DM focuses on lifestyle modifications like diet, increase in physical activity, self-management of sign and symptoms, also reducing regular medications. Yoga practice is a cost-effective method which has various health related benefits including physical fitness, body relaxation, self - awareness also results overall well-being of an individual.[8,9] Yogasana and practice of various pranayama helps in management of T2DM and an adjunct to medical therapy.[10] It is rooted on the principle that the body and mind are closely associated and positively impacts health.[11]

Health related quality of life (HRQoL) is a popular and important measurement in the research field. This provides data about patient's perspective of their HRQoL and supports to design improve treatment and prevention.[12]

The QoL measures satisfaction and importance in various life domains (physical functioning, role limitations due to physical health, emotional problems, general health, body pain, social functioning and emotional wellbeing). Association between diabetes mellitus (DM) and poor glycaemic control with worsened cognitive function and major decline suggesting contribution of DM severity to accelerated cognitive aging.[13] The need for cognitive assessments in different stages of diabetes and intervention for enhancement and maintenance of the cognitive QoL for care of diabetes has been suggested.[14]

There are few studies reporting the effect of 6 months yoga for evaluation of QoL and mental wellbeing in patients with diabetes.[15,16] This study was undertaken with the aim to find out whether yoga intervention and meditation improves QoL and symptoms of anxiety in type 2 diabetics.

METHODS

Study Participants

This study was a prospective randomized trial of yoga intervention conducted among 104 type 2 diabetics, in the Department of Biochemistry, RUHS CMS, Jaipur. Ethical clearance for this study was taken from the Institutional Ethics committee [DCG (I) Registration No. ECR / 762 / Inst / RJ / 2015]prior to study. Present study was carried out in accordance with the approved guidelines and was registered on Clinical Trials Registry-India (CTRI); CTRI / 2017 / 08 / 009447.

The diagnosis of diabetes was based on American diabetes Association (ADA) / European Association of Study of Diabetes Criteria (EASD).[17] Participants with infections (acute and chronic), connective tissue disease, bronchial asthma, various viral infections (in the last one year), cancer, haemolytic disease, pulmonary tuberculosis, chronic obstructive pulmonary disease (COPD), rheumatoid arthritis, psychiatric illness, myalgia, myositis, myopathy, diabetics already practicing yoga or regular physical activity, seriously ill participants and can't give informed consent were excluded from the present study. Age group of participants was 30 - 65 years.

Sample Size Formula

The minimum sample size formula based on mean and standard deviation (SD) is

$$n = \frac{(z_\alpha + z_\beta)^2 (S1^2 + S2^2)}{(\bar{X}_1 - \bar{X}_2)^2}$$

Where Z_α is linked with the level of significance and Z_β is linked with the power of the test. For 5 % level of the significance Z_α =1.96, Z_β = 0.84 for 80 % power of the test. β - Error is 20 %. $\bar{X}_1$ is the mean blood glucose (fasting) of first sample and $\bar{X}_2$ is the mean blood glucose (fasting) of second sample. X1=167.40, X2=133.77. S1 is the SD of the first sample and S_2 is the SD of the second sample. S1=37.32, S2=38.77. According to this minimum sample size was 40 patients of T2DM (20 Patients of each group). Since the sample size was very small and for convenient grouping, sample size was increased to 104 subjects (52 Patients of each group).[18]

Randomization of Participants

To achieve randomness in the selection among the two study groups; simple computer generated randomisation was applied to assign the participants into two respective groups. First participant was randomly assigned thereafter, each participant was assigned alternatively to each group. Total of 127 T2DM participants of both gender were screened and out of these 12 participants were excluded

from the study. Then total 115 participants were randomized into two study groups viz. Control group without yoga intervention (n=52), active group with yoga intervention (n=63). 8 participants of yoga active group did not adhere to yoga intervention schedule and 3 participants of yoga active group were not available for follow up. Hence 104 participants (52 participants for each group) were studied.

Intervention

Intervention involved approximately 40 minutes practice of yogasana. These were performed minimum 5 times in a week for a period of 6 months in yoga active group. Measures were taken to provide yoga support to participants so as to overcome large dropout in the training sessions, fear of injury, failure to achieve follow up and to address motivational barrier. Participants of both groups continued their hypoglycaemic, other medicines and dose of these medicines remained constant throughout the whole study period. Yoga schedule included Prayer, various asanas and pranayamas. Yoga sessions were organized in yoga lab by authorized and experienced single yoga instructor. Participants were relaxed after yoga session by meditation practice.

Yogasana	Rounds	Time Duration (Seconds)
Prayer	Omkar 3 times	60
Asanas		
Trikonasana	6	60
Katichakrasana	6	60
Surya Namaskaras	9	90 seconds each
Arthamatsyendrasana	Each side 90 seconds x 2	180 x 2
Pavanamuktasana	4	90 seconds each
Bhujangasana	2	90 x 2
Dhanurasana	2	90 x 2
Padachakrasana	Clock/anti-clock 15 +15	120
Breathing exercise		
Pranayamas	i. Rechaka, Puraka	20 rounds* 60
	ii. Bhastrika	5 rounds** 60
	iii. Nadi Shodhana	1-24 x 2 90
Prashantha Asana / Meditation	-	10 minutes
Yoga Schedule		

*One Inhale and One Exhale = One round ** Four Expulsions and One Long Breath = One round

Analysis of Psychosocial Factors and QoL

All the study participants were explained regarding aims of the study. A written informed consent was filled by all participants. Detailed physical and clinical examinations were taken at baseline and after six months. History of the participants (disease history, treatment, dosage, duration, sex and gender) was noted. Questionnaire for Psychosocial factors [19] and QoL; 36 - Item Short Form Survey Instrument (SF-36)[20, 21] was filled by participants of the study at baseline and after six months of follow up by both the groups. Questionnaire was self - administered if respondents had sufficient ability, otherwise interviewer assisted.

Psychosocial Factors Questionnaire

Psychological factors include stress and depression. Psychosocial stress is explained as feeling irritable or fill up with anxiety, or as having trouble as a result of conditions at work or at home or autonomy for organizing the events. Psychosocial stress was evaluated by asking questionnaire about major stressful life events in the past years; work stress and home stress, financial stress and autonomy.[22] We assessed depression by asking simple questionnaire i.e., during the past 1 year, study participant had felt depressed, sad for 2 weeks or more. There were 7 no - yes questions for assessing depression, Q.1 was lose interest in most things like hobbies, work or activities that usually give pleasure, feel low energy, increase or decrease weight, more difficulty in falling asleep than usually, more trouble in concentrating than usual, always thinking about own or someone else's death, feeling worthless — out of 7 questions if five or more than five positive answers were defined as presence of depression. It is a modification of the short form Diagnostic and statistical Manual of Mental Disorders, Composite International Diagnostic Interview (DSM - IV CIDI) questionnaire for assessing depression.[23]

QoL

SF - 36 questionnaire was used to evaluate change in QoL. This self-administered and validated measures, QoL through various domains. These are physical functioning, role limitations due to physical health, role limitations due to emotional problems, energy / fatigue, emotional well - being, social functioning, pain and general health. The evaluator was uninformed regarding group allocation of the diabetics.

Biochemical Analysis

After 10 - 12 hours fasting venous blood samples of participants were withdrawn under aseptic condition. The samples were collected into plain and EDTA coated vacutainers for serum glucose fasting (F) and post prandial (PP) and HbA_{1c} respectively and estimated at baseline and end of six months.

Statistical Analysis

For each study variable the groups mean ± SD was calculated. Using the paired and independent samples student's 't' test, significant difference between means were evaluated. The independent samples student's 't' test was used to compare control and active groups at both baseline and follow up, whereas the paired 't' test was used to compare the means at baseline and follow up within control and yoga active groups. Statistical Package for Social Science (SPSS) version 22.0 software for windows was used, with $p < 0.05$ considered as statistically significant. Relative risk estimates are reported as odds ratio and accompanying 99% Confidence Intervals (CI). The two proportions Z test was used to compare the sex ration both the study groups.

RESULTS

The distribution of T2DM participants as per age and gender is shown in Table 1. Out of 104 study participants 57 (55 %) and 47 (45 %) were male and female respectively. In control group 25 were males and 27 were females and in yoga active group 32 were males and 20 were females. The sex ratio in both the groups is similar (Z = 1.39, p=0.164). The association between age groups and sex was tested in both the control and yoga groups. No significant association between age and sex in both the study groups (p > 0.05) (Table 1). The recruited participants had disease duration of 2 to 8 years.

Age (Years)	Group 1 Control (n= 52)			Group 2 Yoga Active Group (n= 52)		
	Male	Female	p value	Male	Female	P Value
30 - 40	2 (8 %)	1 (4 %)	0.4082	2 (6.25 %)	1 (5 %)	0.05823
40 - 50	8 (32 %)	11 (41 %)		12 (37.5 %)	2 (10 %)	
50 - 60	11 (44 %)	14 (51 %)		11 (34.37 %)	15 (75 %)	
60 - 70	4 (16 %)	1 (4 %)		7 (21.87 %)	2 (10 %)	
Total	25	27		32	20	

Table 1. Age and Gender - Wise Distribution of T2DM Participants

*significant at 5%

Parameters		Control (n=52) Mean ± SD	Yoga Active Group (n=52) Mean ± SD	P Value
Serum glucose (Fasting) (mg / dl)	Baseline	183.04 ± 53.00	182.05 ± 54.00	0.9253
	After 6 months	173.11 ± 47.00	130.01 ± 36.00	0.000168**
	p - value	0.12161	0.000001**	
Serum glucose (Post Prandial) (mg / dl)	Baseline	234.00 ± 52.00	235.00 ± 62.00	0.9298
	After 6 months	225.12 ± 65.00	174.01 ± 66.00	0.00595*
	p - value	0.07883	0.000001**	
HbA_{1c} (%)	Baseline	8.19 ± 2.11	8.29 ± 2.13	1.0000
	After 6 months	8.16 ± 2.04	7.11 ± 1.5*	0.00283*
	p - value	0.15703	0.00628*	
QoL	Baseline	49.93 ± 14.56	50.73 ± 13.17	0.7693
	After six months	48.76 ± 14.32	58.17 ± 14.34	0.001932**
	p - value	0.1824	0.00683*	
Psychosocial factors	Baseline	36.50 ± 4.80	36.76 ± 5.20	0.7926
	After six months	36.06 ± 4.90	35.20 ± 5.53	0.05821
	p - value	0.3927	0.05823	

Table 2. Glycaemic Parameters, QoL and Psychosocial Factors in Control and Yoga Active Groups of Study Participants

*significant at 5%

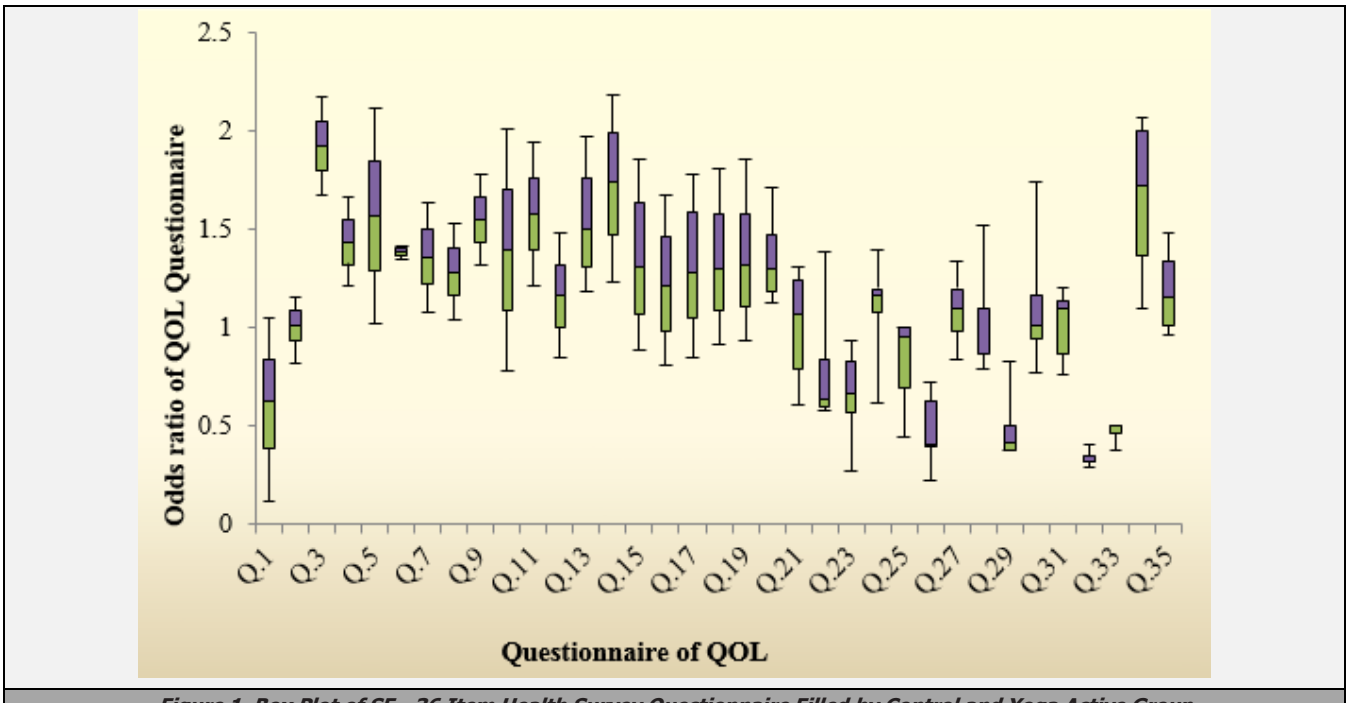

Figure 1. Box Plot of SF - 36 Item Health Survey Questionnaire Filled by Control and Yoga Active Group

	Control (n=52)		Yoga Active Group (n=52)	
	Baseline	After 6 Months	Baseline	After 6 Months
Marital separation / divorce	0	0	1	1
Major personal injury or illness	6	8	7	6*
Loss of Job / Retirement	2	2	2	2
Death / Major illness of a close family member	3	3	6	6
Loss of Crop / Business Failure	8	9	3	3
Death of Spouse	0	0	0	0
Violence	10	12	8	7*
Major intra family conflict	11	12	12	10*
Other	5	5	4	4

Table 3. Effect of 6 Months Yoga Therapy on Physical, Emotional Role and Social Functioning of Study Participants

*Decrease after 6 months of follow - up

	Number of Control (%) After 6 Months	Number of Cases (%) After 6 Months	Odds Ratio (99 % CI)
Work Stress			
Never	13 (25 %)	16 (30.77 %)	1
Sometimes	22 (42.31%)	26 (50 %)	0.83 (0.63 -1.09)
Several period	12 (23.08 %)	8 (15.39 %)	1.41 (1.19 -1.63)
Permanent	5 (9.62 %)	2 (3.85 %)	2.5 (2.15 - 2.79)
Home Stress			
Never	18 (34.6 %)	21 (40.4 %)	1
Sometimes	24 (46.2 %)	25 (48.1 %)	0.97 (0.76 -1.22)
Several period	7 (13.5 %)	4 (7.7 %)	1.8 (1.44 - 2.05)
Permanent	3 (5.7 %)	2 (3.8 %)	1.5 (1.21 - 1.76)
Financial Stress			
Little / None	21 (40.4 %)	25 (26.92 %)	1
Moderate	23 (44.2 %)	22 (50 %)	1.04 (0.82 - 1.30)
High	8 (15.4 %)	5 (23.08 %)	1.63 (1.28 -2.04)
Autonomy			
None	14 (26.92 %)	18 (34.62 %)	1
Little	7 (13.46 %)	13 (25 %)	1.4 (.455 - 4.581)
Moderate	18 (34.62 %)	21 (40.38 %)	0.9 (.354 -2.324)
Substantial	7 (13.46 %)	0	0
Complete	6 (11.54 %)	0	0
Not Applicable	0	0	0
Feeling Depressed			
No	38 (73.1 %)	43 (82.7 %)	1
Yes	14 (26.9 %)	9 (17.3 %)	1.55 (1.28-1.69)

Table 4. Psychosocial Factors in Participants of Control and Yoga Active Group

It can be observed from table 2, in yoga active group, significant decrease in serum glucose (F and PP) and HbA_{1c} ($p < 0.05$) was observed after regular practice of yogasanas for 6 months when compared to control group participants. QoL was improved significantly ($p < 0.05$) after 6 months of yoga practice in type 2 diabetics of yoga active group when compared to type 2 diabetics of control group. A non - significant difference ($p > 0.05$) in psychosocial factors in yoga active group was found when compared to control group (Table 2).

Among psychosocial factors, major personal injury or illness, violence and major intra family conflict were decreased after 6 months of yoga therapy in type 2 diabetics (Table 3). Table 4 shows psychosocial factors in experienced practitioners of yoga active group and control group with odd ratios. For all categories of work stress, home stress, financial stress, autonomy and feeling depressed, odds ratio values are mentioned. The value of odd ratio greater than 1 shows more risk in control in comparison to experienced practitioners of yoga and less than 1 value shows less risk in control as compared to cases. Figure 1 shows the distribution of QoL data for both groups at follow up. Most of the box plots minimum value is near to 1. It indicates better QoL in yoga active group after 6 months as compared to control group.

DISCUSSION

This study was performed to assess effect of non-pharmacological intervention i.e. Yoga therapy on QoL and psychosocial factors in type 2 diabetics. Biochemical parameters to assess glycaemic control in diabetics, i.e. Serum glucose (F and PP) and HbA_{1c} were significantly decreased in yoga active group at six months follow up (Table 2).

HRQoL has generated immense interest due to many reasons which includes evidences of effect of psychosocial factors on physical health as well as delivery of health. In diabetes, poor QoL results in lack of self - care, leading to poorer glycaemic control thus increasing risks for developing complications and expansion of poor QoL.[24] Yoga influences the mental state in different ways and has role in the management diseases, including obesity, hypertension, asthma, neuromuscular diseases and psychiatric illnesses. One of the diseases which adversely affect QoL is DM. Exercise has been reported as a therapeutic modality in treatment of DM.[25]

In the present study, non - significant difference was seen in research variables at baseline. This shows that the study groups were formed with no sampling bias. At follow up after 6 month, QoL was improved significantly in yoga active group when compared to diabetics of control group. No significant difference in psychosocial factors was observed in yoga active group when compared to control (Table 2). Similar trends was shown in the study performed by Latha S et al[26] in which yoga practice enhances subjective wellbeing and QoL among T2DM patients, enhances sprit and mood concentration, attain adequate glycaemic control. A study performed on patients with non - communicable diseases also reported that yoga group showed significantly better wellbeing, psychological and total QoL when compared with the control group.[27] Bazzano et al[28] in their study reported significant improvement in QoL by yoga intervention group as compared to the control.

Yoga is considered as one of the preventive and alternative treatment in diabetes management and is an area of research for controlling both the symptoms and complications associated with T2DM. Chronic psychological stress leads to insulin resistance, increase blood pressure and risk of cardiac diseases. Yoga practice effectively reduces stress, thus adding in control of diabetes.

Since effect of exercise on the uptake of glucose is up to 48 hours asana based yoga should be performed regularly or alternate days, so as to achieve the desired effect on serum glucose.[29] Our results show that practice of yoga for 6 months significantly decreased serum glucose (F& PP) and HbA_{1c} levels in type 2 diabetics (Table 2). A study of Mikus et al[30] stated that short term daily exercise reduces serum glucose and glycaemic variability in T2DM. Boule et al[31] found that exercise training improves serum glucose levels and results in reduction in HbA_{1c}. A study by Connie et al[32] stated that increased physical activity significantly related to lower serum glucose and greater insulin sensitivity.

Yogasanas aids in improvement in the sensitivity of β - cells to glucose which results in improvement in secretion and enhanced supply of blood to the muscle and muscle relaxation thus improving glucose uptake.[33] Yoga which is a non-pharmacological intervention may also prove to achieve improved glycaemic control in diabetes.[34]

In the present study, major personal injury or illness, violence and major intra family conflict were found to be decreased in type 2 diabetics after 6 months of yoga therapy (Table 3). Figure 1 shows the distribution of QoL data for both groups at follow up. Most of the box plots minimum value is near to 1. It indicates better QoL in yoga group as compared to the control group. These results are in accordance with Hadi Ne et al[35] who reported improvements

in all 8 components of the SF - 36 after practicing yoga for a period of six months, showing a statistically significant difference ($p < 0.05$). Similar observations were seen in the summary scores for both mental and physical components. SW Lee et al [36] examined health before and after yoga as a mind-body training using SF - 36 questionnaire and found improvements in all domains. H Valerie et al[37] performed a randomized control trial for assessment of QoL using SF - 36 in type 2 Diabetic participants. They reported improvements in both subscales that are QoL physical component subscale (PCS) and general health (GH) when compared with the control group. The control and exercise group did not show any difference in the mental component summary. Another study analysed 150 type 2 diabetics with poor glycaemic control and reported lower mean SF-36 scores in various domains.[38]

Stress, anxiety and negative moods are improved by regular practice of yogasana. Yogic practice enhances the level of serotonin level in body that is known to facilitate the cognitive performance.[39] Yogasana and meditation reduce stress hormones and catecholamines. During stress, dysfunctions occur in the nervous system (sympathetic), leading hypothalamic – pituitary - adrenal axis (HPA) to consequently increase serum cortisol levels and change insulin resistance.[40] Delight and happiness during practice of yoga are because of raised β-endorphin levels, serotonin and dopamine levels. Increased in arginine - vasopressin levels results in reduction of gamma - aminobutyric acid (GABA) - ergic inhibition of the supra - optic area of the hypothalamus resulting in improvements in arousal. The calming effect is attributed to melatonin hypothalamic stimulation arising while performing yoga practice results in ecstatic and blissful feelings. The reduction in spatial orientation and out-of-body experiences during the period of meditation are attributed to decrease in levels of GABA and increase in N - acetyl aspartyl glutamate and 5 - methoxy dimethyl tryptamine levels (from pineal enzymes).[41]

CONCLUSIONS

Yoga therapy intervention in the present study positively addressed QoL of the diabetic participants and also achieved adequate glycaemic control. Results of the study indicate that holistic yoga therapy for diabetes self-management improves psychological health in the era of a global decrease in HRQoL.

Limitations

Dietary data was not recorded and its effect was not considered in the study. Long term study was not conducted due to threat of non-compliance of the participants.

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