

The Effect of Yoga and Peer Support Interventions on the Quality of Life of Women with Diabetes: Results of a Randomized Controlled Trial

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Abstract

Objective: This was an interventional study to understand the effect of two low-cost interventions; yoga and peer support on the quality of life (QOL) of women with type 2 diabetes. **Methodology:** An open label parallel three-armed randomized control trial was conducted among 124 recruited women with diabetes for 3 months. Block randomization with a block length of six was carried out. In the yoga arm, sessions by an instructor, consisting of a group of postures coordinated with breathing were conducted for an hour, 2 days a week. In the peer support arm, each peer mentor after training visited 13–14 women with diabetes every week followed by a phone call. The meeting was about applying disease management plans in daily life. At the beginning and end of the study, QOL was assessed by the translated, validated World Health Organization QOL-BREF in four domains physical, psychological, social, and environmental domains. **Results:** The majority (96%) of the study participants perceived the peer support and yoga intervention to be beneficial. Paired *t*-test revealed significant increases in the social and environmental domain in the peer group and in the environmental domain in the yoga group, though this disappeared in the between-group comparison perhaps due to poor glycemic control (hemoglobin A1c varied from 9.4 to 9.6) and the short duration of 3 months of the study. **Conclusion:** Peer support and yoga improved perceptions of QOL though its impact on scores was not significant due to a short period of study among women with poor glycemic control.

Keywords: Quality of life, randomized control trial, type 2 diabetes, women

INTRODUCTION

The quality of life (QOL) is an important health outcome^[1] in chronic diseases such as type 2 diabetes.^[2] Considerations of QOL are gaining increasing importance in the evaluation of health policy, medical intervention,^[3] and in providing a multidimensional viewpoint.^[4] The World Health Organization (WHO) defines QOL as “an individual’s perception of their position in life in the context of the culture and value systems, in which they live in relation to their goals, expectations, standards, and concerns.”^[5] Health-related QOL has been found to be far worse among those with diabetes^[6] as health-care regimen requires ongoing self-care behavior that can interfere with patients’ desired lifestyle.

Studies show relatively low correlations between clinical measures of disease activity (hemoglobin A1c [HbA1c] results for diabetes) and patients’ perceptions of health and

well-being.^[7,8] There is an inherent cost-benefit trade-off between the disease and treatment burden.^[9] This was also recognized in the Diabetes Control and Complications Trial also where intensive insulin therapy yielded a significant reduction in diabetic complications compared to traditional insulin therapy,^[9] but did not lead to improved QOL.^[10]

Women are uniquely, severely affected by diabetes and have worse QOL and mental well-being compared with men with diabetes.^[11,12] Studies on clinical and educational interventions suggest that improving patient’s health status and perceived

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ability to control their disease results in improved QOL.^[13] Yoga and peer support are two such low-cost interventions that can empower the patient to adhere to the complex and demanding nature of this chronic disease. The theoretical basis of yoga and peer support are empowerment and social support,^[14] respectively. Peer support has been defined as the support from an individual with experiential knowledge based on a sharing of similar life experiences or prevention plans in daily life.^[15]

Yoga, an ancient Indian psychological, physical and spiritual exercise regimen has been studied for control of symptoms and complications associated with type 2 diabetes mellitus and has been found to improve QOL among people with diabetes.^[16]

Hence, the effect of yoga and peer support on the QOL of women with type 2 diabetes was studied as part of a bigger study on glycaemic outcomes.

METHODOLOGY

The estimated sample size based on earlier study^[17] on the variables-fasting blood sugar, glycosylated HbA1c, and QOL at 95% confidence, and 80% power varied from 5 to 40 with an anticipated fall in fasting plasma glucose (FPG) of 32 mg/dl and a fall in HbA1c of at least 0.5%. The maximum sample size being 40, the required sample size for the study is 40 for each group totaling 120 for the open label three-armed randomized trial.

Study population and recruitment

The study was conducted in a rural area of Kerala, India, at a rural health training center. The interventions, yoga and peer support, were administered for 3 months. From a population of 19,000 residing in the local self-administration-unit (panchayat), 1042 cases of type 2 diabetes were listed on the basis of a baseline survey in the area (hospital records, Rural Community Health Training Centre). The women from this list in the 30–65 age groups were contacted, and the first 250 women with diabetes were identified and invited to participate in the study. After clinical screening, willingness, and applying the inclusion and exclusion criteria, 124 women were enrolled in the study and randomized into three groups [Figure 1].

Inclusion criteria

Women with type 2 diabetes mellitus diagnosed within the last 8 years, and between 30 and 65 years of age, and HbA1c between 7% and 10% were included.

Exclusion criteria

Those already practicing yoga, meditation, chronic alcohol consumption, known diabetes complications, pregnant and lactating women, treatment with alternate system of medicine, body mass index (BMI) >35 kg/m² and with serious medical and psychiatric conditions were excluded from the study.

After obtaining written informed consent, the women underwent a baseline assessment by a physician. Those on pharmacologic or nonpharmacologic treatment continued with

the same. All the study participants were given an education on diet and were advised exercise for at least 10 min/day.

Randomization

The participants were randomized by block randomization of fixed block length of six. All possible permutations of the three arms A, B, and C were listed. A list of independent identically distributed random numbers was generated and chosen. Each number in this list was then replaced by the block. The random allocation sequence was generated by a person not connected with the study at the main hospital and handed over to the research assistant at the health center in numbered opaque sealed envelopes. The allocation ratio was approximately 1:1:1.

Ethics Committee Approval was obtained from the Institutional Ethics Committee of the Institution dated August 8, 2011. The trial was registered with the CTRI/2011/12/002227.

The primary outcomes studied were FPG, HbA1c, QOL, and pharmacological adherence (Morisky's Medication Adherence Scale-8).^[18] This paper discusses the QOL outcome, the paper on glycaemic outcomes has been accepted for publication. QOL was measured by the widely used WHOQOL-BREF validated in the local language^[19] in four domains, namely, social, physical, environmental, and psychological. QOL was assessed by the health center staff not directly associated with the study, at the beginning and end of the study. FPG, HbA1c, and pharmacological adherence and the secondary outcomes such as BMI, waist-hip ratio, and blood cholesterol have been discussed elsewhere.

Statistical methods

Mean and standard deviation were computed for all the measurable study variables for each intervention group. To test the significance of the differences in mean values of the study variables, from basal to the follow-up period; within each group, paired *t*-test was applied, and among the three groups, one-way analysis of variance was applied.

Yoga intervention

Instructor driven yoga sessions were conducted for 60 min on 2 days a week. On the other days, the women were instructed to practice at home and maintain a daily log. The 60-min sessions consisted of 25 min-Surya namaskara-12 steps, 5–7 min-deep relaxation-muscle relaxation technique, and 15 min asana or yoga postures. The postures consisted of Pavanamuktasana in the supine position, Bhujangasana and Shalabhasana in the prone position, and Ardhamatsyaendrasana in the sitting position as recommended by yoga experts for diabetes.^[20] This was followed by 15 min of pranayama. A record of the food eaten, drugs consumed, and exercise particulars were also maintained for 2 days a week considered to be representative of the entire week. This was reviewed every month.

If any of the study participants were found to have hypoglycemia (random plasma glucose [RPG] <70 g/dl) in the monthly review with or without symptoms, the oral drugs were reduced by 20%–50%.

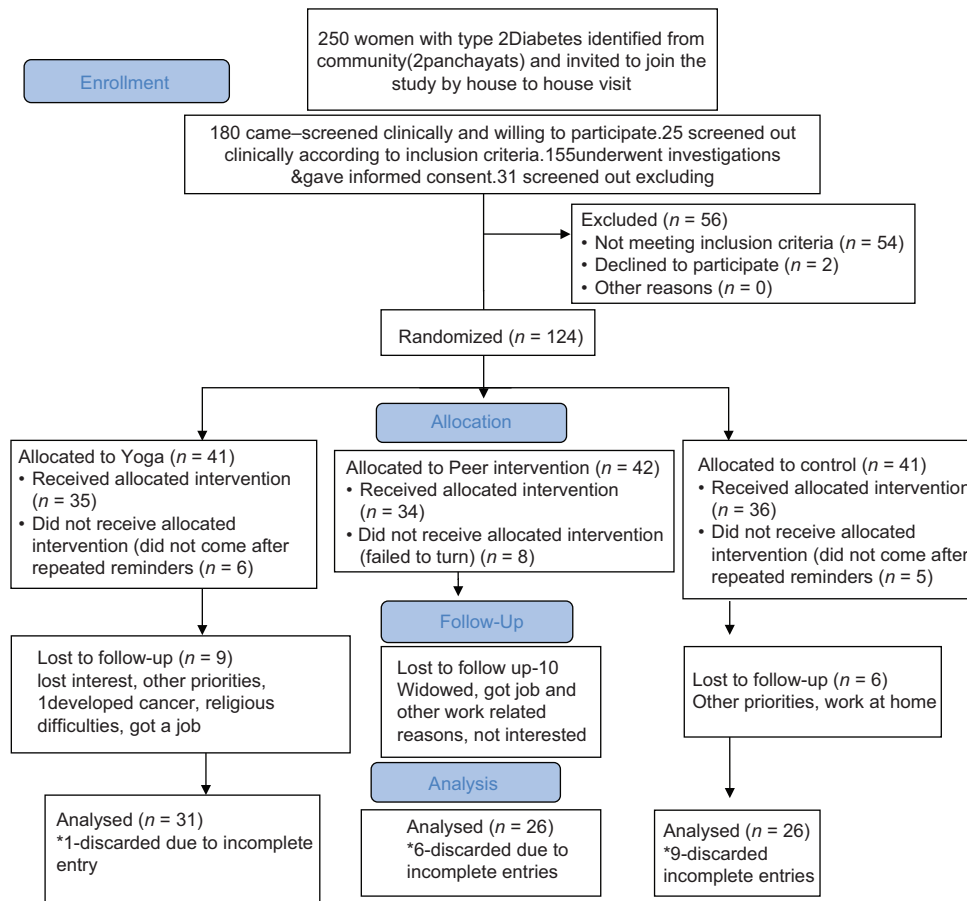


Figure 1: Flow diagram of enrollment, follow up and analysis

Peer support intervention

Three peer mentors were identified from the community and trained. The criteria for eligibility was; having had type 2 diabetes for at least 1 year with a RPG < 250 mg/dl in the last reading, judged by the investigation team to be generally adherent to treatment and behavior change regime, capacity and commitment to undergo the training required, an understanding of patients confidentiality, undertaking to liaise with the concerned doctor if unanticipated problems arose during the course of their peer support activity. Peer mentors underwent a 2 days training program consisting of a physician who explained the etiology of diabetes, changes taking place in the body due to diabetes, complications due to poor glycemic control and an outline on the drugs used, and its mechanism of action and the synergies with physical activity. The nutrition specialist explained all the nutritional and dietary aspects of diabetes; psychologist trained the peer mentors on communication skills, empathy, and confidentiality. A training manual was prepared for the peer mentors based on the peers for progress handbook and handed over to the mentors for future reference.

Peer support meetings

Each peer mentor would visit 13–14 women with diabetes. A face-to-face meeting with the woman with diabetes in a week

for about 45–60 min on the functions of peer support, namely, assistance in applying disease management or prevention plans in daily life, providing emotional and social support, linkage to clinical care, and proactive, flexible ongoing support. This was followed up by a telephone call in the same week. The principal investigator also undertook a monthly review of the activities. During the first visit, the peer mentor collected the treatment details including drugs, diet, and physical activity. In the follow-up visits, the peer mentor advised and monitored the woman regarding diet, exercise, timely consumption of drugs, emotional stress, symptoms, foot care, etc., During the last visit in the 3rd month, the peer mentor conducted a final assessment regarding the entire process, its acceptability, difficulties, and usefulness to the participants. The participants were also given a diary to record the visit, advice of the peer mentor, and the changes brought about.

All the patients were reviewed monthly and necessary care given. The control group was given the usual standard of care. A pretested, semi-structured questionnaire was used to collect sociodemographic and other information.

RESULTS

The mean age of the study group in the three groups varied from 51.92 to 51.97 years and the mean duration of diabetes varied

from 5.1 to 5.8 years. The glycosylated hemoglobin levels in the groups varied from 9.4% to 9.6% indicating poor control among women at baseline. The three groups were statistically comparable at baseline with respect to age, duration of diabetes, occupation, income, and type of family [Table 1].

The QOL scores measured by WHOQOL-BREF in the social and environmental domains were consistently higher in all the three groups than in physical and psychological scores before intervention. Paired *t*-test showed that in the peer support group, there was a significant increase in the social and environmental domain of QOL with an increase in scores by 7.69 (15) and 4.07 (8.76) at $P = 0.014$ and $P = 0.019$ respectively. The difference was the least in the psychological domain. In the yoga group, the increase in scores of environmental domain just about achieved significance at $P = 0.05$ [Table 2]. Surprisingly, the yoga group showed a decrease in QOL scores in the physical and social domains. This was in contrast to the feeling of well-being expressed by yoga participants. Perhaps, a longer period is required before this is reflected in QOL scores. Between groups, the improvement of environmental domain scores was almost the same at 4.45 (12.78), 4.07 (8.76), and 4.12 (14.94) in the yoga, peer, and control group, respectively. In the psychological domain, the yoga and peer group showed marginal increase compared to control which showed a fall in scores. In the social domain, the peer group showed a marked increase by 7.69 (15.03) compared to control by 4.29 (23.38) compared to a marginal fall in yoga group. In the physical domain, peer group scores increased by 3.98 (19.2) points compared to 1.43 (17.5) in the control group whereas surprisingly, the yoga group showed a decline by 2.47 (14.3). In spite of the trends, none of these achieved significance [Table 3].

The feedback from the study participants regarding the interventions was as follows. The yoga group (96.8%) found the whole process interesting and useful. Many of the study participants said that they felt much better physically and mentally. Symptoms such as dryness of mouth, polyuria at night, joint pain reduced considerably for (25/32) study

participants. The patients also said that they felt more alert and energetic with less aches and pains. Some patients (10/32) also remarked that their blood sugar decreased. A few participants also were sad that the project was over. One of them also recounted that attending yoga classes reminded her of school.

Peer support

The mentors and mentee found this a rewarding program with the peer mentors stating in their final assessment that 96.1% liked this novel program of peer support, had a favorable attitude, and accepted advice from peer mentors readily (25/26). In terms of assistance in daily management, the peer mentor was able to influence the mentees to adhere to diet, exercise, and drugs and was able to see for themselves the impact of adherence to diet, drugs, and exercise on aspects of disease control, including reducing blood sugar levels in the next visit. Diet modification in terms of decreasing rice intake and instead opting for wheat-based products was also brought about. A few patients (6/26) also observed that opting for wheat products and increasing exercise helped to control blood sugar. In a population with cultural predilection for rice, less consumption of rice and adding wheat, vegetables were positive outcomes that helped to decrease sugar levels. Although some women (15/26) wanted to bring about changes in their dietary habits, it was difficult because of family food patterns. As far as, the function of social and emotional support was considered; few (8/26) study participants confessed to feeling much relieved after discussing family issues with the peer mentor. The function of linkage to clinical care was delivered but not taken up well by the patients due to competing family priorities. Ongoing availability of support was ensured during the study by giving the phone number of the peer mentor whom the mentee could call up at any time, and linkages were also established between the peer mentors and the investigators whom they could contact at any time.

The peer mentors found this an extremely fruitful and intensely satisfying exercise as being a diabetic; they could themselves see the changes brought about by adhering to diet, exercise, and drugs. Mentors were happy that they could find solutions

Table 1: Comparison of baseline values in yoga, peer support, and control groups

	Yoga			Peer support			Control			P
	n	Mean	SD	n	Mean	SD	n	Mean	SD	
Age (years)	35	51.97	7.40	33	51.92	8.32	38	51.92	6.57	0.99
Per capita income (INR)	35	986.57	1992.32	33	715.03	1356.35	38	1602.13	4927.7	0.49
FPG (mg/dl)	35	163.27	46.56	31	177.99	70.39	38	186.69	73.02	0.29
HbA1c% (mmol/mol)	35	9.5 (80)	1.65	31	9.4 (79)	1.62	38	9.6 (82)	1.85	0.89
BMI (kg/m ²)	34	24.83	3.89	31	25.54	4.52	36	24.68	4.1	0.67
Waist hip ratio	34	0.97	0.05	32	0.97	0.04	37	0.9	0.05	0.42
BP systolic (mmHg)	34	134.76	20.63	32	128.69	18.07	38	124.63	15.7	0.06
BP diastolic (mmHg)	34	84	11.43	32	83.5	9.5	38	79.63	7.64	0.11
Adherence	31	5.46	1.92	27	5.36	1.74	37	5.08	1.67	0.66
Total cholesterol (mg/dl)	35	220.65	53.29	31	234.98	38.23	38	216.63	63.39	0.34
Diabetes duration (years)	32	5.8	2.78	34	5.34	2.75	37	5.1	3.04	0.62

FPG: Fasting plasma glucose, HbA1c: Glycosylated hemoglobin, BP: Blood pressure, BMI: Body mass index, SD: Standard deviation, INR: Indian rupee

to problems affecting other women with diabetes which gave them strength, walking to visit them gave them exercise, insights that stress increases disease, understood others difficulties, and got an opportunity to interact with others and understand others thought processes. Helping others was another useful facet. The difficulties included two women with diabetes (2/10) did not like the visits and opted for Ayurveda, frequent unavailability of patients at home due to employment and other requirements, frequent change in phone numbers which made follow-up over phone difficult.

DISCUSSION

A significant improvement in QOL scores in the social and environmental domain in the peer group and in the environmental domain in the yoga group was observed though these differences disappeared in the between-group comparison. Most (96%) of the participants in the intervention groups found it useful.

The main objective of treating all chronic diseases such as diabetes mellitus is to improve well-being and attain a satisfactory QOL. Pooled analysis of population-based surveys

in countries like Germany has shown that type 2 diabetes has negative consequences for health-related QOL,^[21,22] and good QOL is significantly related to good compliance.^[23] The mean total score of QOL in physical, mental-emotional, feelings of well-being, and behavioral activity dimension were significantly higher in the healthy population than in the diabetes mellitus group.^[24] Consideration of psychosocial issues are therefore important for good diabetes care as it determines self-management behaviors and other pertinent psychosocial variables such as depression. They are also strong predictors of the presence of complications.^[21]

A similar interventional study on yogic breathing exercise (Sudarshanakriya) conducted by Jyotsna *et al.* has shown an improvement in physical, psychological and social domains at 3 months^[16] and in total scores and environmental domain at 6 months.^[25] This study differs from our study in that the participants belonged to both the sexes, had better control with HbA1c values between 7 and 7.29, and was for a longer duration. A significant improvement in QOL at 3 and 6 months following yoga has also been reported though between-group analysis has not been mentioned (only abstract available).^[26] Systematic reviews conclude that yoga may be efficacious in improving QOL but well-designed, randomized control trial is necessary to prove its efficacy.^[13] More limited data suggest that yoga may also enhance QOL.^[27]

Peers can serve as role models for sustained behavior change and provide coaching and leadership.^[28] In Thailand and three countries in Sub-Saharan Africa an improvement in patients, QOL was observed after peer support.^[29] Peer supporters who talk with patients provide daily, credible, practical assistance in initiating and maintaining the behavior patterns that are central to management of chronic disease.^[29] This may be the reason why in the peer support before and after group significant increase was seen in the environmental and social domains though this disappeared in the between-group comparison. In a study conducted in Austria with peers providing coaching and leadership, no significant improvement in QOL in the intervention group was observed which was attributed to well-controlled baseline levels.^[28] Here, a stable HbA1c was interpreted as success. Due to the participation of more motivated and better self-managed patients, these results may also not be generalizable to all diabetic patients,^[28] particularly this study where the HbA1c levels were high to start with.

Table 2: Quality of life scores before and after the intervention

	QOL	Mean difference	SD	P
Control	Prephysical/postphysical	1.433	17.52	0.68
	Prepsychological/postpsychological	-1.21	18	0.73
	Presocial/postsocial	1.28	23.38	0.78
	Preenvironmental/postenvironmental	4.12	14.94	0.17
Yoga	Prephysical/Postphysical	-2.47	14.3	0.34
	Prepsychological/postpsychological	0.39	16.34	0.89
	Presocial/postsocial	-1.16	20.52	0.75
	Preenvironmental/postenvironmental	4.45	12.78	0.06
Peer	Prephysical/postphysical	3.98	19.2	0.3
	Prepsychological/postpsychological	0.0007	17.9	1.00
	Presocial/postsocial	7.69	15.03	0.015
	Preenvironmental/postenvironmental	4.07	8.76	0.026

SD: Standard deviation, QOL: Quality of life

Table 3: Quality of life score differences between the groups

	Yoga		Peer		Control		P
	Mean difference	SD	Mean difference	SD	Mean difference	SD	
Physical difference	-2.47	14.3	3.98	19.2	1.43	17.5	0.344
Psychological difference	0.39	16.34	0.0007	17.9	-1.21	18	0.94
Social difference	-1.16	20.52	7.69	15.03	4.29	23.38	0.107
Environmental difference	4.45	12.78	4.07	8.76	4.12	14.94	0.99

SD: Standard deviation

An educational intervention among elderly men and women with diabetes and hypertension showed an increase in QOL scores using the WHOQOL-100 though the between-group comparison is not mentioned.^[13] Gender differences have also been observed with obese women feeling that the disease was more overwhelming than obese men.^[30] Complications of disease have been found to affect QOL in the landmark UKPDS study whereas therapeutic policies known to reduce the risk of complication had no effect on QOL.^[31]

The study participants appreciated the effects of both the interventions; peer support and yoga. Peer support helped the peer mentors and patients themselves to delve into the problems faced by individual patients and also helped to find incremental solutions which from feedback appears to be immensely satisfying for both peer mentors and mentees. The Yoga group participants reported a reduction in symptoms related to diabetes, good sleep, reduced anxiety, and a reduction in arthritic aches and pains. The results of the effect of Yoga and peer support on glycaemic outcomes show decreasing trends of fasting plasma glucose and glycated haemoglobin in the yoga group and on fasting plasma glucose in the peer group.^[32] Though, further studies need to be carried out for longer period to explore this divergence in perception and QOL scores.

CONCLUSION

QOL assessment in health care is a complex, multidimensional construct,^[33] and the perceptions; scores reflect a divergent picture in this study. A longer period of study is required among this challenging group of women with poor glycemic control.

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Conflicts of interest

The authors declare a potential conflict of interest in the funding support from Peers for Progress however; results obtained from this study were in no way influenced by this funding body. The study sponsor had no role in (a) study design; (b) the collection, analysis, and interpretation of data; (c) the writing of the report; or (4) the decision to submit the manuscript for publication.

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