

Effect of Community-Based Structured Yoga Program on Hba1c Level among Type 2 Diabetes Mellitus Patients: An Interventional Study

Abstract

Context: In view of the rising burden of type 2 diabetes mellitus (DM) cases in India, there is an urgent need for an effective, low-cost, sustainable intervention controlling diabetes thus preventing complications. **Aims:** This study aimed to assess the effect of structured yoga programs on diabetes. **Subjects and Methods:** This was a community-based interventional study that was conducted in an urban resettlement colony of Delhi, India. Known diabetes patients with glycated hemoglobin (Hb1Ac) $\geq 6.5\%$ were enrolled from 12 randomly selected blocks of the community with a sample size of 192 in each intervention and wait-listed control arm. The intervention was structured yoga of 50 min daily, 2 consecutive weeks in a nearby park and health center followed by twice a week home practice up to the 3rd month. The primary outcome measure was HbA1c% and secondary outcome measures were lipid profile and fasting blood glucose. **Statistical Analysis Used:** A per-protocol analysis was done. Mean, standard deviation (SD), and 95% confidence interval were estimated. The level of significance was considered for 0.05. **Results:** There was a significant decrease of Hb1Ac (0.5%, SD = 1.5, $P = 0.02$), total cholesterol (11.7 mg/dl, SD = 40.5, $P < 0.01$), and low-density lipoprotein (3.2 mg/dl, SD = 37.4, $P < 0.01$) from baseline to end line in the intervention group. These changes in intervention group were also significantly different from the change in the wait-listed control group. The other variables did not change significantly. **Conclusions:** It revealed that structured yoga program improved glycemic outcome and lipid profile of individuals in a community-based setting. Yoga can be a feasible strategy to control hyperglycemia, lipid levels, and can help better control type 2 DM.

Keywords: Community, diabetes mellitus, type 2, yoga

Introduction

Type 2 diabetes mellitus (DM) is one of the fastest-growing global health emergencies of the 21st century. Nearly half a billion people (463 million) of the world population are suffering from diabetes and this number is projected to reach 578 million by 2030 and 700 million by 2045. India follows this global trend with a prevalence of 77.0 million in 2016 that is projected to reach 101.0 million by 2030 and 134.2 million by 2045.^[1]

The pace of diabetes prevalence in many countries and regions has been boosted by rapid urbanization and dramatic changes toward a sedentary lifestyle.^[2] One of the earliest multicentric studies carried out by the Indian Council for Medical Research (ICMR INDIAB) in India to estimate the prevalence of diabetes in urban and rural areas of 15 Indian cities

reported a mean prevalence of 11.2% in urban areas and 5.2% in rural areas.^[3] With this rising burden of diabetes in the country, the prevalence of diabetes in urban metros is a cause of concern. The Center for Cardiometabolic Risk Reduction in South-Asia Study conducted in cohorts of three metropolitan urban cities, namely Chennai, Delhi, and Karachi reported that overall 47.3%–73.1% of the population had either diabetes or prediabetes. In Delhi, overall 72.7% (70.6%–74.9%) population had either diabetes or prediabetes where the prevalence of diabetes was 25.2% (23.6%–26.8%) and for prediabetes, it was 47.6% (45.6%–49.5%).^[4] This prevalence is much higher than reported in the ICMR INDIAB study. In light of the above situation, there is a need to look for low-cost sustainable lifestyle interventions that are effective in offsetting

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diabetes and can empower the patient to institute behavior change and adhere to the complex and demanding nature of this chronic disease. Yoga, as a lifestyle intervention, has been reported to lead to beneficial health outcomes related to cardiovascular and metabolic disorders including T2-DM.^[5-7] Some studies suggest the role of yoga in the management of diabetes and other conditions.^[8,9] The promising benefits of yoga interventions for T2-DM have also been recorded in a recent systematic review.^[7] Collectively, findings suggest that yogic practices may promote significant improvements in several indices in T2-DM management, including glycemic control, lipid levels, and body composition and overall quality of life of diabetes patients.^[5,10-12]

With limited research on the usefulness of yoga in the management of diabetes, most of the studies are either facility based or have an inadequate sample size or may have lesser yoga sessions and time and short follow-up period. Hence, there is a lack of adequate scientific evidence to see its beneficial effect when practised at community-level settings, where we can find out its role in the long term with sustainable effect at no cost or with fewer resources for recreational activities and healthy lifestyle. With this background, a study was planned to see the effect of yoga in a real-life community-based setting among known diabetes rather than a facility-based setting. Hence, a community-based yoga trial was conducted to assess the effect of structured yoga program on diabetes in a population living in an urban resettlement colony that migrated from various places in Delhi in search of a better life.

Subjects and Methods

Subjects

This community-based yoga trial was carried out in an urban resettlement colony located in South Delhi District, Delhi. The area had a total population of about 36,000 in the year of the study. Most of the population in the area belonged to lower-middle socioeconomic status.^[13] People living in the community for at least 6 months and ≥ 18 years of age with already diagnosed Type 2 DM and HbA1c $\geq 6.5\%$ were included in the study. Those who were practising yoga of any type earlier, pregnant women and people with known diabetes complications such as chronic kidney disease, moderate-to-severe cardiovascular conditions; any known medical condition under treatment such as angina pectoris, asthma, bronchitis, renal diseases which prevent the participants doing yoga practice and known psychiatric conditions which prevent following yoga instructions, and physical disabilities were excluded from the study. Known diabetes patients with Hb1Ac ≥ 6.5 were enrolled from the 12 selected blocks of the urban community as per the estimated sample size. An estimated sample size of 192 in each arm assuming 0.5% mean

difference change (in intervention and wait-listed control arm) in HbA1C with a combined standard deviation (SD) of 1.5%, at 95% confidence, 80% power, and 20% loss to follow-up in both arms was taken.^[14] Ethics Committee Approval was obtained from the Institutional Ethics committee (IEC-557/03.11.2017).

Participant recruitment and group allocation

A total of 12 selected blocks were randomly divided with 6 blocks each in intervention and wait-listed control block. The term wait-listed control implied the group of participants who will not receive the intervention but put on a waitlist list to receive intervention after the active treatment group does. The blocks for intervention and wait-listed control were situated in the locality in a way where mixing could be avoided to the maximum between the study participants. The research team conducted a household survey of 7779 houses, where we could find 849 patients with a history of diabetes. Out of these 849 diabetes patients, 235 patients were excluded as they did not meet the inclusion criteria [Figure 1]. Out of the remaining 614 patients, 401 patients consented to be part of the study. Of these 401 participants, 209 participants were residing in the intervention block, while 192 participants were in the wait-listed control block.

Intervention procedure

Participants enrolled from the selected intervention block were given an instructor-driven structured yoga program in different batches for 50 min early morning, daily for 2 consecutive weeks in an urban health center and nearby park located in the study area. It was advised to keep bowel and bladder emptied before yogic practice. The yoga module was prepared by professional yoga therapists from the study institution. It was 50 min in duration and consisted of stretching and breathing exercises, light exercises, asanas in sitting and standing position (Vakrasana, Ardhamatsyendrasana, Trikonasana, etc.) as recommended by yogic experts in diabetes, Pranayama (Nadi Shuddhi, Vibhagiya Pranayam, etc.), dhyaan, and "Aum" chanting [Figure 2]. The yoga sessions were conducted by a qualified yoga instructor having a professional qualification in Yoga Arts. For each participant for the initial 2 weeks, the yoga sessions were practised under the supervision of a yoga instructor in the designated center. Out of 14 sessions in the 2 weeks, at least 80% attendance was required. Those participants completing $\geq 80\%$ of sessions at center were requested to continue practice at home at least two sessions/week for the rest of the period of 3 months. The yoga instructor and field research team visited each participant twice a week to record the compliance of home practice sessions, recording any side effects and motivating them. The assessment of the biochemical variables was done at baseline and at the end of 3 months periods for the participants of both intervention and wait-list controlled

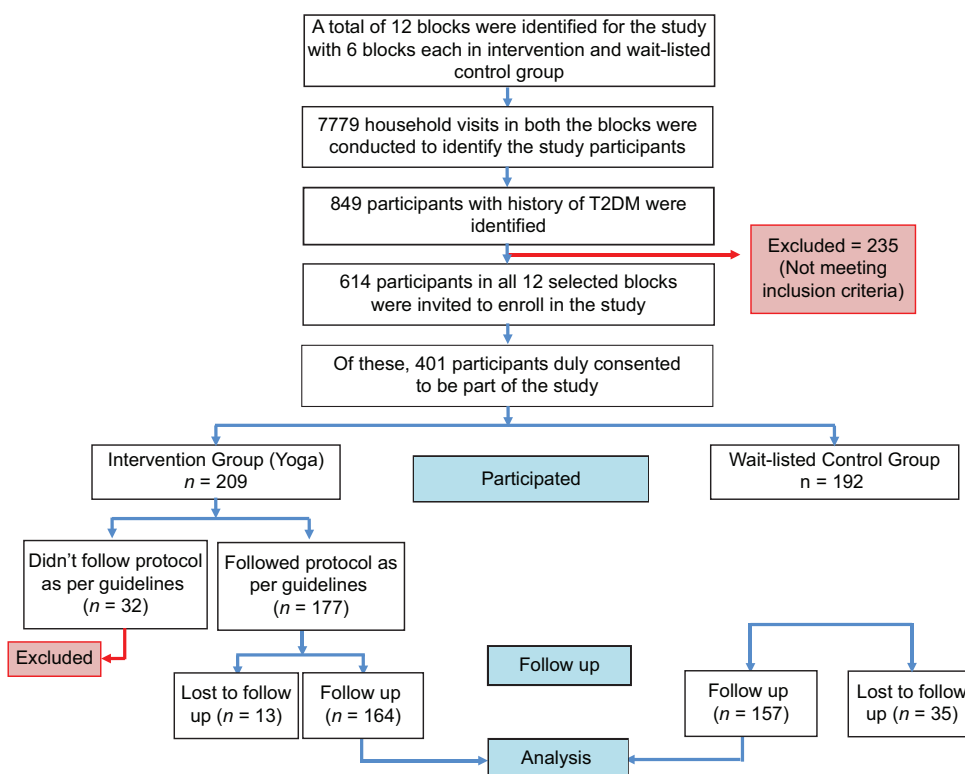


Figure 1: Flow diagram of study participant enrollment and follow up

groups. The details of the structured yoga program are attached in Figure 2.

Participants enrolled in the selected control block (taking medication as prescribed by their physicians) were not given any intervention; however, they were kept as the wait-listed control group and were asked to join the program after 3 months of follow-up. Similar biochemical parameters were recorded at the baseline and at 3 months and were compared with the intervention group to see the effect of yoga on diabetes management.

Outcome measures

The primary outcome measure was glycated hemoglobin (HbA1c). A mean change of 0.5% was expected in each arm, i.e. intervention and wait-listed control arm. The secondary outcome (considered as other markers of diabetes management) measures were fasting blood glucose (FBG), total cholesterol, triglycerides, high-density lipoprotein (HDL), and low-density lipoprotein (LDL). All the biochemical parameters were analyzed using a standardized method. All the participants were informed a day before to come in empty stomachs for the blood sampling. Five milliliter of venous blood from the median cubital vein was drawn in the morning fasting state to conduct abovementioned blood investigations. HbA1c% was measured by high-performance liquid chromatography (HPLC) method (Machine name: Arkray Hplc Hba1c Analyzer, Ha-8180 v). The serum lipid profile was measured by

selective inhibition and the CHOD-PAP method (Machine name: BIOLIS 24i).

Data management and statistical analysis

Data entry was done using Epi Info software. Following data cleaning, data analysis was done using Stata software version 13. Mean, SD, proportion, and 95% confidence interval (CI) were computed for all the continuous and categorical variables. Paired *t*-test was applied to compare within-group baseline value to end line of the continuous variables with normal distribution. Independent *t*-test was applied to compare the normally distributed variables between intervention and wait-list group, whereas Wilcoxon rank-sum test and Wilcoxon signed-rank test were used to test the variables with nonnormal distribution between two groups and within-group respectively. The level of statistical significance considered for this study was 0.05. A per-protocol analysis was done in view of the lost to follow-up.^[15]

Results

The number of total enrolled participants was 401, out of which 209 participants were in the intervention group and 192 participants in the wait-listed control group. In the intervention group, out of 209 participants, 177 participants completed the minimum 80% supervised sessions. Hence, these 177 participants were included in the home practice. The remaining 32 participants who did not complete were excluded from the study. Hence, the total number of

participants considered in the analysis at the beginning of the study was 177 participants in the intervention group and 192 participants in the wait-listed control group. After 3 months, follow-up of 164 participants in the intervention group and 157 participants in the wait-listed control group was completed. The reasons for lost to follow-up were mostly personal reasons related to household work, children, migration, the issue of time, etc.

The mean age of the participants in the intervention group was 52.8 years (SD 10.1) with 59.9% female and 40.1% male participants. The mean age of the participants in the wait-listed control group was 54.2 years (SD 11.2) years with 56.8% female and 43.2% male participants. The distribution of age and sex was comparable between the intervention and wait-listed control group [Table 1].

The baseline biochemical parameters of the study participants such as mean FBG, HbA1c, HDL, and LDL between the two groups were comparable [Table 2].

The analysis of the baseline and end-line biochemical variables within each group [Table 3] showed that there

Figure 2: Structured Yoga Program (Name and duration of asanas included in yogic practice)

Practice	Duration
Prayer	1 min
Practice breathing	
Stretching and breathing	2 min
Hands in and out	2 min
Ankle breathing	2 min
Breathing process	1 min
Leg straightening breathing process	2 min
IRT (Immediate Relaxation Technique)	1 min
Light exercise	
Slow jogging/slow jogging	2 min
Walking process	1 min
QRT (Quick Relaxation Technique)	3 min
Asanas (Asanas in standing position)	
Ardhakti Chakrasan (Half wheel)	1 min
Ardha Chakrasan	1 min
Vakrasan (spinal twist)	1 min
Trikonasana (triangle pose)	1 min
Asana (Asana in sitting position)	
Vakrasana (Half twist)	1 min
Ardhamatsyendrasana	1 min
DRT (Deep Relaxation Technique)	7 min
Pranayama (yogic breathing)	
Vibhagiya Pranayam	5 min
Nadi shuddhi	1 min
Nabanasandha posture	5 min
Bhramari pranayam	2 min
Dhyaan	
“Aum” chanting or any other prayer as per their religious beliefs	7 min
Total time	50 min

was a significant decrease of FBG from 193.7 ± 80.0 mg/dl to 174.6 ± 74.3 mg/dl in the intervention group ($P < 0.01$), whereas the wait-listed control group did not show any significant changes ($P = 0.68$). The HbA1c in the intervention group decreased from 8.8 ± 1.8 to 8.2 ± 1.9 and the change was statistically significant ($P < 0.01$), but in the waitlisted control group, there were no significant changes ($P = 0.22$). The serum cholesterol in the intervention group decreased from 195.5 ± 43.3 to 183.7 ± 40.9 significantly ($P < 0.01$). The LDL also decreased significantly from 116.7 ± 37.3 to 103.4 ± 36.5 ($P < 0.01$) in the intervention group. There was no significant change found in the TGL and HDL variables of the intervention group. The wait-list control group also did not show any significant changes in any variables after 3 months compared to the baseline value [Table 3].

Baseline to end-line difference within group showed that there was a decrease of 19.1 mg/dl (95% CI: 7.2–31.0) in FBG level in the intervention group and an increase of 1.1 mg/dl (95% CI: 14.9–12.6) in the wait-list control group [Table 4]. These baseline to end-line changes were not statistically different between the intervention and wait-list control group ($P = 0.08$). The mean decrease of HbA1c level in the intervention group was 0.5 (95% CI: 0.3–0.8) compared to 0.1 (95% CI: 0.1–0.4) decrease in the waitlisted control group. These changes of HbA1c were different between the two groups with statistical significance ($P = 0.02$) [Table 4].

Among the secondary outcomes, in the intervention group, the mean decrease of cholesterol from baseline was 11.7 mg/dL (95% CI 5.5–18.0) compared to an increase of 2.6 mg/dl (95% CI: 9.3–4.1) in the wait-list group. The changes were different between the groups with statistical significance ($P < 0.01$) [Table 4].

Serum LDL in the intervention group decreased by a mean of 13.2 mg/dl (95% CI: 7.5–19.0), whereas in the wait-list control group, there was a mean increase of 2.9 mg/dl (95% CI: 9.1–3.3). These changes were different between the two groups with statistical significance ($P < 0.01$). In the intervention group, there was an increase of 0.9 mg/dl (95% CI: 16.5–14.7) of mean serum triglyceride level compared to a decrease of 4.0 mg/dl (95% CI: 8.2–16.3) in the

Table 1: Baseline demographic information of study participants in intervention group and wait-listed control group

Variables	Intervention group (n=177)	Wait-listed control group (n=192)	Total (n=369)
Age (years), mean±SD	52.8±10.1	54.2±11.2	53.3±10.7
Sex, n (%)			
Female	106 (59.9)	109 (56.8)	215 (58.2)
Male	71 (40.1)	83 (43.2)	154 (41.8)

SD=Standard deviation

waitlisted control group. The changes were not statistically significant ($P = 0.65$) between the two groups. The HDL level in the intervention group showed an increase of 1.3 mg/dl (95% CI: 3.0–0.4) compared to a rise of 0.4 mg/dl (95% CI: 2.3–1.5) in the waitlisted control group; however, these changes were not statistically significant between the groups ($P = 0.48$) [Table 4]. No side effects due to yoga practice were reported by the participants.

Discussion

This current study was one of the very few community-based studies with an adequate sample size conducted in the urban setting of Delhi to see the effect of yoga among adults with type 2 diabetes.

Table 2: Description of baseline values of different biochemical variables in intervention and wait-listed control group

Variables	Mean±SD	
	Intervention group (n=177)	Wait-listed control group (n=192)
FBG (mg %)	194.1±79.2	201.6±83.5
Hb1Ac (%)	8.8±1.8	9.0±1.9
Cholesterol (mg/dL)	197.2±43.4	185.3±47.4
Triglycerides (mg/dL)	200.1±98.2	184.0±96.9
HDL (mg/dL)	39.7±10.2	38.0±9.9
LDL (mg/dL)	117.4±37.2	110.4±40.6

FBG=Fasting blood glucose, Hb1Ac=Glycosylated hemoglobin, HDL=High-density lipoprotein, LDL=Low-density lipoprotein, SD=Standard deviation

The present study found a favorable role of yoga in the glycemic control of diabetes. From the statistical analysis of the results obtained in the present study and their comparison with other published research, it can be said that yoga helps in reducing Hb1Ac and fasting blood glucose levels and improve other indices of importance in DM2 management.

In the present study, there was a significant decrease in glycosylated hemoglobin (Hb1Ac) and fasting blood glucose levels among known diabetes practising yoga regularly. These findings are concordant with the findings reported in previous studies^[14,16-18] whereas in contrast to some other studies.^[19] Studies in countries outside India give mixed reports with some reporting a significant improvement in HbA1c and fasting blood glucose profiles, whereas another exploratory study in the UK showed only a marginal decline in HbA1c.^[20,21] However, the exact cause of the reduction in HbA1c is not known. As per the review by Mahajan, yoga practice has a physiological mechanism reducing stress, influencing the hypothalamopituitary–adrenal axis, and improving the balance of the autonomic nervous system and hormonal system.^[22] It also protects the patients from early development of various vascular complications of DM.^[17]

Other findings showed an improvement in lipid profile among the intervention group compared to the waitlisted control group. In the yoga group, there was a decrease in cholesterol and LDL levels that may help prevent the early development of comorbid conditions such as hypertension

Table 3: Within-group analysis of the baseline and end-line values of the biochemical variables in the intervention group and the wait-list control group

Variables	Intervention group (n=164)		Wait-listed control group (n=157)	
	Mean±SD	P ^a	Mean±SD	P ^a
FBG (mg %) ^b				
Baseline	193.7±80.0	<0.01	203.1±82.4	0.68 ^b
End line	174.6±74.3		204.3±92.5	
Hb1Ac %				
Baseline	8.8±1.8	<0.01	9.1±1.9	0.22
End line	8.2±1.9		8.9±2.1	
Cholesterol (mg/dL)				
Baseline	195.5±43.3	<0.01	186.1±48.1	0.44
End line	183.7±40.9		188.7±43.3	
TGs ^b (mg/dL)				
Baseline	194.0±95.6	0.56	185.2±98.0	0.97 ^b
End line	195.0±103.6		181.2±79.6	
HDL (mg/dL)				
Baseline	39.9±10.4	0.12	38.2±9.9	0.64
End-line	41.3±11.2		38.7±9.9	
LDL (mg/dL) ^b				
Baseline	116.7±37.3	<0.01	110.7±40.8	0.26 ^b
End line	103.4±36.5		113.7±39.4	

^aPaired *t*-test was applied for the variables assessed at baseline and end line, ^bWilcoxon signed-rank test was applied. TGs=Triglycerides, FBG=Fasting blood glucose, Hb1Ac=Glycosylated hemoglobin, SD=Standard deviation, HDL=High-density lipoprotein, LDL=Low-density lipoprotein

Table 4: Between-group comparisons of mean differences in biochemical parameters from baseline to end line

Variables	Intervention group	Wait-list control group	Difference of Δ^a (95% CI)	P^b
Δ FBG ^c (mg %), mean \pm SD	19.1 \pm 77.3	-1.1 \pm 87.3	-20.3 (-38.4--2.1)	0.08 ^c
FBG (0 month-3 months), 95% CI	7.2-31.0	-14.9-12.6		
Δ Hb1Ac %, mean \pm SD	0.5 \pm 1.5	0.1 \pm 1.8	-0.4 (-0.7--0.04)	0.02
Hb1Ac (0 month-3 months), 95% CI	0.3-0.8	-0.1-0.4		
Δ Cholesterol (mg/dl), mean \pm SD	11.7 \pm 40.5	-2.6 \pm 42.7	-14.3 (-23.5--5.2)	<0.01
Cholesterol (0 month-3 month), 95% CI	5.5-18.0	-9.3-4.1		
Δ TG ^c (mg/dl), mean \pm SD	-0.9 \pm 101.4	4.0 \pm 78.1	4.9 (-15.0-24.8)	0.65 ^c
TG (0 month-3 months), 95% CI	-16.5-14.7	-8.2-16.3		
Δ HDL (mg/dl), mean \pm SD	-1.3 \pm 11.2	-0.4 \pm 12.1	0.9 (-1.6-3.4)	0.48
HDL (0 month-3 months), 95% CI	-3.0-0.4	-2.3-1.5		
Δ LDL ^c (mg/dl), mean \pm SD	13.2 \pm 37.4	-2.9 \pm 39.4	-16.2 (-24.7--7.8)	<0.01 ^c
LDL (0 month-3 months), 95% CI	7.5-19.0	-9.1-3.3		

^a Δ =Mean difference (0th month value 3rd month value), ^bUnpaired *t*-test was applied, ^cWilcoxon rank-sum test was applied. FBG=Fasting blood glucose, Hb1Ac=Glycosylated hemoglobin, SD=Standard deviation, HDL=High-density lipoprotein, LDL=Low-density lipoprotein, CI=Confidence interval

and coronary artery disease in case of type 2 DM patients. The study findings are in line with the several studies conducted around the world.^[23-26]

In addition to this, among the intervention group, the study results showed a decrease in triglyceride levels and a rise in HDL levels. However, there was no statistical significance within these parameters. These findings are consistent with the findings reported by Azami *et al.* wherein no significant change was observed in triglyceride and HDL levels after 26 weeks of yoga intervention.^[25] However, another study conducted by Shantakumari *et al.* reported contrary findings wherein a significant change in TG and HDL levels of diabetic patients was observed.^[26,27]

The structured yoga program has designed after an extensive literature review by professional yoga therapists which was a combination of asana and breathing exercises targeted at the disease under study. Since more than one-third of the urban population of most of the Indian cities are from low socioeconomic slum areas,^[28] this home-based yoga practice by the community people increases the generalizability of the result. Compliance with the intervention protocol was found in more than two-third of the study participants. The sample size of the study was adequate and the dropout rate was comparatively less than expected. The ease of use, safety, and potential benefits of yoga in a community setting has led it to be more widely accepted.

Since the study population chosen from the community also included migratory population, hence lost to follow-up of the study participants was expected, which is not the case with a small sample size and facility-based studies. The sustainability of the home-based yoga practice after the study period without follow-up could not be assessed. The long-term control of diabetes and lipid profile was not assessed. We faced challenges during the recruitment phase and during follow up due to practical and motivational barriers among the participants to adhere to the yoga

intervention. Moreover, choosing the participants randomly could have been improved the strength of evidence.

Conclusion

The current study reveals a favorable role of yoga to improve glycemic outcome and lipid profile of individuals with diabetes even in community based setting. It can be considered as a feasible strategy in resource-constraint settings and low socioeconomic areas. However, rigorously designed randomized controlled trials are needed to examine the long-term efficacy of yoga in this population. Future studies should include assessments of behavioral (e.g. diet, physical activity) and psychological (e.g. stress, depression) factors which may act as potential mediators of the effect of yoga for improved clinical outcomes in patients with T2DM and its complications.

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Ethical clearance

Ethics Committee Approval was obtained from the Institutional Ethics committee of All India Institute of Medical Sciences (IEC-557/03.11.2017).

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Conflicts of interest

There are no conflicts of interest.

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