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Feasibility of yoga as a complementary therapy for patients with type 2 diabetes: The *Healthy Active and in Control* (HA1C) study

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ABSTRACT

Objectives: This study:*Healthy Active and in Control* (*HA1C*), examined the feasibility and acceptability of yoga as a complementary therapy for adults with Type-2 Diabetes (T2DM).
Design: A 2-arm randomized clinical trial comparing Iyengar yoga with a supervised walking program.
Setting: Hospital based gym-type facility and conference rooms.
Interventions: Participants were randomized to a 12-week program of either; (1) a twice weekly Iyengar yoga, or (2) a twice-weekly program of standard exercise (SE).
Main Outcome Measures: Primary outcomes assessed feasibility and acceptability, including enrollment rates, attendance, study completion, and participant satisfaction. Secondary outcomes included HbA1c, physical activity, and measures of diabetes-related emotional distress, self-care and quality of life (QOL). Assessments were conducted at baseline, end of treatment, 6-months and 9-months post-enrollment.
Results: Of 175 adults screened for eligibility, 48 (30 women, 18 men) were eligible and enrolled. The most common reasons for ineligibility were orthopedic restrictions, HbA1c levels < 6.5 and BMI > 42. Session attendance was high (82% of sessions attended), as was follow-up completion rates (92%). Program satisfaction rated on a 5-point scale, was high among both Yoga (M = 4.63, SD = 0.57) and SE (M = 4.77, SD = 0.52) participants. Overall 44 adverse events (26 Yoga, 18 SE) were reported. Of these, six were deemed "possibly related" (e.g., neck strain, back pain), and 1 "probably related" (ankle pain after treadmill) to the study. Yoga produced significant reductions in HbA1c. Median HbA1c at 6 months was 1.25 units lower for Yoga compared to SE (95% CI: -2.54 -0.04).

Greater improvements in diabetes self-care, quality of life, and emotional distress were seen among Yoga participants than among SE participants. Increases in mindfulness were seen in Yoga but not in SE.
Conclusions: The yoga intervention was highly feasible and acceptable, and produced improvements in blood glucose and psychosocial measures of diabetes management.

1. Introduction

Diabetes affects more than 29 million American adults and is the seventh leading cause of death in the United States.[1] The American Diabetes Association states that regular physical activity is critical to the management of blood glucose and overall health for individuals with Type 2 diabetes (T2DM).[2] However, individuals with T2DM typically find compliance with this recommendation difficult.[3,4] In the United States, there remains a need for effective, acceptable, feasible and empirically validated strategies to promote physical activity among those with T2DM.

Yoga practice involves a physical activity component (postures/*asana*), and a relaxation component (meditation, *shavasana*). With its focus on controlling breath, holding postures, and meditation, yoga increases the practitioner's attention to bodily sensations and present moment experiences, thus contributing to yoga as a mindfulness-based activity.[5,6] Mindfulness may help improve diabetes management by increasing individuals' ability to recognize emotional stress and to respond with more effective coping strategies.[7,8]

Randomized controlled trials (RCT) with healthy adults and those with T2DM have shown a benefit of yoga on stress reduction.[9–14] Since empirical studies show that stress leads to poor food choices,[15,16] yoga

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may benefit diabetics by improving dietary control. RCTs in non-diabetics have shown improved dietary outcomes after yoga interventions.[17–20]

A systematic review of yoga studies among adults with T2DM (found 12 RCTs encompassing 864 patients),[21] concluded that while overall results showed a significant reduction in HbA1c and fasting blood glucose (FBG), there was significant heterogeneity among studies due to methodological weaknesses. A more recent review (included 8 RCTs with a total of 842 participants) reiterated this same conclusion;[22] that while studies of yoga as a method for improving glycemic control have shown promise overall, there is great heterogeneity between studies. Moreover, of the 13 unique studies included in those systematic reviews[21,22] most studies (N = 9) were conducted in India and none in the U.S. There is sufficient evidence to suggest that yoga has the potential to positively impact stress, diet and other self-care tasks that contribute to improved glycemic control; however, this has not yet been tested among individuals with T2DM. Additionally, it is not clear whether a yoga intervention would be both feasible and acceptable to American adults with T2DM.

2. Materials and methods

2.1. Design

This study examined the feasibility and acceptability of a yoga intervention among U.S. adults with T2DM. In this pilot RCT, participants were randomly assigned to a 12-week program of either; (1) Iyengar yoga, or (2) standard exercise (SE: e.g., walking, stationary cycling). Both interventions were delivered in group format in two consecutive cohorts. Assessments were conducted at enrollment (baseline), end of treatment (EOT = week 12), and at 3- and 6-months post-intervention.

2.2. Recruitment and eligibility

Participants were recruited through diabetes clinics, flyers posted at clinics and retail outlets, and internet ads. Individuals were screened by trained research staff for eligibility. Inclusion criteria were: age > 18 years with T2DM for at least 6 months, HbA1c levels > 6.5. Individuals with serious co-morbid conditions (e.g. uncontrolled hypertension, heart failure, angina), serious psychiatric disorder, orthopedic problem limiting exercise, BMI > 42 kg/m2, or pregnancy were excluded. Individuals were also excluded who had engaged in yoga, Tai Chi or similar practice in the past month or who attended > 3 such classes in the past six months. The revised Physical Activity Readiness Questionnaire (PAR-Q+) was used to screen for exercise safety.[23] If one or more items were endorsed on PAR-Q+, physician consent was required for study participation.

2.3. Enrollment and randomization

After providing written consent, participants completed baseline surveys, and laboratory assessments to verify HbA1c levels. Participants were scheduled for a second visit to receive their randomized assignment. Randomization assignments were implemented with the aid of a computer program and were delivered by the study statistician to the study research assistant in sealed opaque envelopes with consecutively ordered ID numbers. Only the study statistician had access to the randomization list. The study statistician delivered envelopes to the RA on the day that new participants were to receive randomization. We used a permuted-block randomization procedure to ensure that HbA1c levels (< 9 vs. > 9) and genders were evenly distributed between study arms. All participants were given handouts on diabetes management (e.g., basics of diabetes, symptom & management of hypoglycemia, hydration), and advised to continue with medication plans prescribed by their physician.

2.4. Interventions

The Yoga intervention consisted of two 60-minute sessions weekly for 12 weeks. Classes were conducted by certified Iyengar yoga instructors. We chose Iyengar yoga because it uses props such as wooden blocks, blankets, etc. that help students achieve and maintain postures with relative ease and thus may reduce the risk of injury. Each class consisted of: guided meditation and breath-work, active and passive asanas (including standing, sitting, twists and restorative postures), and guided relaxation. Participants were encouraged to practice yoga at home and workbooks, props and a DVD were provided to aid home practice.

Standard Exercise (SE) consisted of a 60-minute session twice weekly for 12 weeks to match the dose and duration of the yoga condition. Sessions were held at a gym-type facility that included an indoor walking track, treadmills, ellipticals, and stationary bicycles. Each session included a 5-minute warm-up (i.e. stretches), 50 min of moderate-intensity exercise and a 5-minute cool-down. All sessions were supervised by staff trained in exercise physiology. Participants were instructed to exercise in a perceived exertion range of “fairly light” to “somewhat hard” (11–13 on the Borg perceived exertion scale).[24]

2.5. Assessments

Data were collected from participants at screening/enrollment, EOT (week 12), and at 6 months and 9 months post-enrollment. All assessments were conducted by staff blinded to randomization.

2.6. Feasibility and acceptability

The primary focus of this pilot study is to accumulate evidence of feasibility and acceptability of the yoga intervention for adults with T2DM. Feasibility was assessed by enrollment, attendance and completion of assessments. Session attendance (Yoga/SE) and follow-up visits were logged throughout the study. Study completion is calculated as the number of participants randomized minus the number who completed the final assessment. Acceptability was assessed by an anonymous program satisfaction survey at EOT. Participants indicated their satisfaction with the intervention using a 1–5 scale (1 = “not at all satisfied” to 5 = “very satisfied”).

2.7. Diabetes-related measures

Blood draws to assess HbA1c, and FBG were conducted at baseline and EOT. Adherence to diabetes management was assessed using the Summary of Diabetes Self-Care Activities Measure,[25] which has subscales addressing exercise, diet, foot care, blood sugar testing and medications. The degree to which participants felt that challenges surrounding controlling diabetes were affecting their quality of life (QOL) was assessed using the Diabetes-39 instrument,[26] which assesses five distinct dimensions: Diabetes Control, Anxiety/Worry, Social Burden, Sexual Functioning, and Energy & Mobility. Participants also rated diabetes-related emotional distress on the Problem Areas in Diabetes (PAID), shown to correlate strongly with self-care behaviors and glycemic control.[27–29]

2.8. Other covariates

Demographic information was collected at baseline along with the interviewer administered 7-day Physical Activity Recall (PAR).[30,31] The Five Facet Mindfulness Questionnaire (FFMQ) was used to measure mindfulness.[32] To calculate Body Mass Index (BMI), height was measured at baseline and weight (using a calibrated balance beam scale) was assessed at each assessment visit.

2.9. Subject compensation, ethical and safety oversight

Participants received $50 compensation for completing follow up assessments. Study procedures and materials were approved by the Institutional Review Board of The Miriam Hospital (IRB registration #TMH IRB-00000482). All participants were actively monitored for adverse events by study staff at each visit. Staff actively asked participants about any change in health status and medications since the previous interaction. All medical events, related and unrelated to the study were documented and reported to the concerned authorities. A Data Safety Monitoring Board (DSMB), comprised of individuals not affiliated with the study reviewed all procedures and adverse event reports annually.

2.10. Statistical analyses

Differences between eligible and ineligible participants were compared using Analysis of Variance (ANOVA) and chi-squared tests where appropriate. Between-group differences in baseline demographic and diabetes-related variables were examined using chi-square tests (categorical variables), ANOVA (continuous variables) or non-parametric tests as appropriate. Feasibility and acceptability, were examined descriptively and using ANOVA to examine between-group differences. Although statistical power to detect intervention effects was limited, we explored between-group differences in diabetes-related outcomes and important psychosocial variables. First, overall changes in diabetes outcomes baseline to EOT, EOT to 6 m, and 6 m to 9 m were examined using parametric and non-parametric paired tests in the aggregate sample and then separately by intervention arm. Next, between-group differences in diabetes outcomes and physical activity were examined using a series of quantile regression models with bootstrapped standard errors controlling for baseline. As self-reported physical activity is subject to high variability, particularly in smaller samples, the median is a more appropriate measure of central tendency (as opposed to the mean). We explored potential moderating effects of baseline values on associations between group and outcomes at follow-ups by including an interaction between baseline value and group. Between-group differences in psychosocial constructs at each follow-up were examined using longitudinal mixed analysis of covariance (ANCOVA), adjusting for baseline values. Effect sizes and 95% confidence intervals were calculated to better understand the intervention effects. Mixed models accommodate missing values under the assumption of missing at random to allow maximum use of available data from each time point.

2.11. Sample size and power calculations

The primary focus of this pilot study was to examine feasibility and acceptability of the yoga intervention for adults with T2DM. Thus, we did not conduct a formal power analysis on traditional T2DM outcome variables. The sample size (N = 48) was based on a number sufficient to measure feasibility and to allow us to obtain initial estimates of effect size for our outcome variables.

3. Results

3.1. Recruitment and demographics

Of 175 callers screened 29 were eligible but declined to participate and 98 were not eligible. The most common reasons for ineligibility were medical reasons (37.7% of all ineligible: most commonly orthopedic concerns limiting physical activity [n = 14], denied physician consent [n = 4] and recent hospitalizations [n = 4]), scheduling conflicts (22.4%), HbA1c values below 6.5 (18.4%), and BMI > 42 (14.3%). See Fig. 1 Consort Diagram. There were no demographic differences between eligible and ineligible participants.

Thirty women and 18 men were eligible and randomized to Yoga (n = 24) or SE (n = 24). One SE participant withdrew from the study after randomization prior to the start of the exercise intervention sessions. Participants averaged 55.7 years old (SD = 8.8, range 32–74), 72.9% were non-Hispanic white, and had some college (37.5%) or were college graduates (25%). There were no baseline differences between intervention arms (Table 1).

3.2. Primary outcomes

3.2.1. Feasibility and acceptability

Overall, 82% of Yoga and 74.8% of SE classes were attended with no significant difference in attendance between groups (p = .312). At EOT 87.5% of Yoga participants reported engaging in home practice in addition to intervention classes. Follow-up assessments were completed by 90% of participants (N = 43) through the final follow up. Among Yoga participants 50% were taking additional classes in yoga and 54.2% were practicing at home at the 6 m follow-up. At 9 m only 12.5% were still taking yoga classes, however 45.8% continued to practice at home. Among SE participants, 67% reported walking on their own at follow-up. There was no contamination of intervention during the study in that none of the SE participants reported taking yoga classes or practicing yoga at home during the study. Program satisfaction was high among both Yoga (M = 4.63, SD = 0.57) and SE (M = 4.77, SD = 0.52) participants.

3.2.2. Adverse events

Overall 44 adverse events (26 Yoga, 18 SE) were reported. Of these, six AEs (in 5 participants) were deemed “possibly related” (4 yoga participants reported back pain, knee pain, neck strain, bone spurs in heel and pulled muscle; and 1 SE participant reported a foot injury), and 1 AE was “probably related” (ankle pain after treadmill, SE condition) to the study. All seven events were musculoskeletal injuries anticipated as a result of yoga or exercise, and all resolved without medical intervention. No serious adverse events were detected.

3.3. Secondary outcomes

3.3.1. HbA1c ad FBG

Unadjusted values are presented in Table 2. Significant reductions in FBG from 6 m to 9 m were observed in the aggregate sample (p = .04). When stratifying by intervention group, there were no significant within-group changes in diabetes outcomes among SE participants. However, among Yoga participants, there were significant reductions in FBG from 6 m to 9 m (p = .05) and borderline significant reductions in HbA1c from EOT to 6 m (p = .06). A similar pattern of results was observed when comparing median scores within group over time.

Longitudinal models suggest significant effects favoring Yoga on reductions in HbA1c from baseline to 6 m among those with elevated HbA1c at baseline (> 8; median value in the sample). Median HbA1c at 6 m was 1.25 units lower for Yoga participants compared to SE (95% CI: −2.54 −0.04).

3.3.2. Diabetes self-care

Yoga participants improved from baseline to EOT on self-care issues surrounding exercise (p = 0.001), diet (p = .03), and foot care (p = 0.001). These improvements remained significant through the final follow-up. SE participants also improved significantly on self-care issues surrounding exercise (p = 0.001), however this change was not sustained at either follow-up. Data on psychosocial variables are presented in Table 3.

3.3.3. Quality of life

Yoga participants showed reductions in *Concern* about being able to control their diabetes from baseline to EOT (p = 0.06), 6 m (p = 0.009) and 9 m follow-up (p = 0.015). The SE group also showed

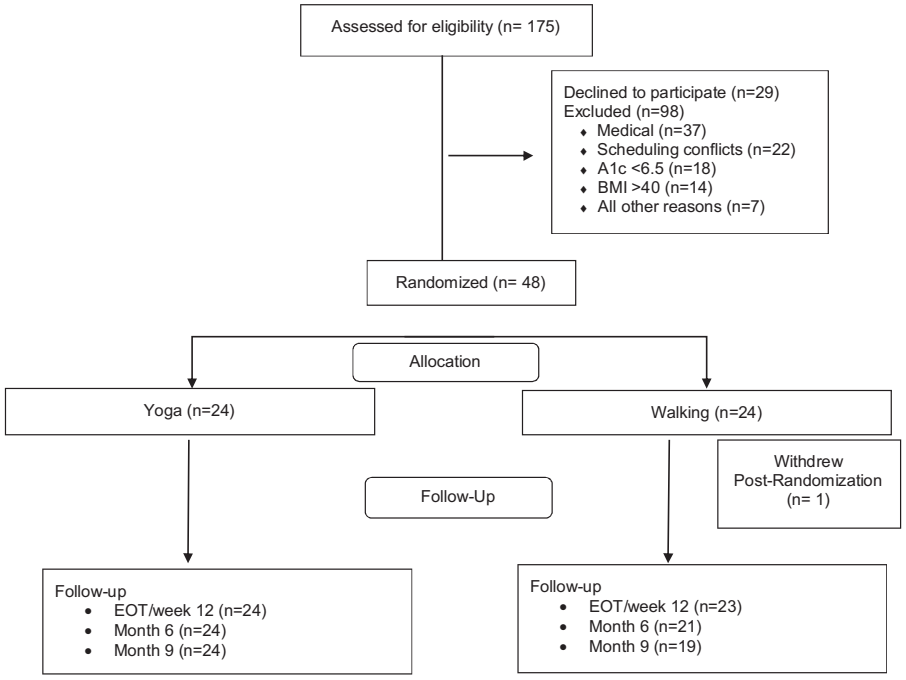

Fig. 1. Consort Diagram.

Table 1
Participant characteristics at baseline(N = 48).

Measure	Overall (n = 48) Percent (N) or Mean (SD)	Yoga (n = 24)	Walking (n = 24)
Gender, %Female	62.5%(n = 30)	62.5%(n = 15)	62.5%(n = 15)
Education			
< High School Graduate	6.2% (n = 3)	0 (0)	12.5 (n = 3)
High School Graduate	14.6% (n = 7)	20.8% (n = 5)	8.3% (n = 2)
Some College	37.5% (n = 18)	41.7% (n = 10)	33.3% (n = 8)
College Graduate	25.0% (n = 12)	29.2% (n = 7)	20.8% (n = 5)
Advanced Degree	16.7% (n = 8)	8.3% (n = 2)	25.0% (n = 6)
Hispanic/Latino	8.3% (n = 4)	4.2% (n = 1)	12.5% (n = 3)
Race			
Non-Hispanic White	72.9% (n = 35)	70.8% (n = 17)	75.0% (n = 18)
Marital Status			
Single	29.2% (n = 14)	37.5% (n = 9)	20.8% (n = 5)
Single, Live with Partner	2.1% (n = 1)	0 (0)	4.2% (n = 1)
Married	47.9% (n = 23)	37.5% (n = 9)	58.3% (n = 14)
Separated or Divorced	20.8% (n = 10)	25.0% (n = 6)	16.7% (n = 4)
Employment Status			
Employed Full-time	45.8% (n = 22)	45.8% (n = 11)	45.8% (n = 11)
Employed Part-time	14.6% (n = 7)	16.7% (n = 4)	20.8% (n = 5)
Unemployed	18.8% (n = 9)	16.7% (n = 4)	20.8% (n = 5)
Age	55.7 (8.8)	57.5 (6.7)	53.8 (10.3)
Currently use Insulin	52.1% (n = 25)	50.0% (n = 12)	54.2% (n = 13)
HbA1C	8.3 (1.4)	8.3 (1.6)	8.4 (1.1)
Fasting Blood Glucose	168.1 (51.0)	167.8 (45.6)	168.3 (56.9)

improvements in *Concern* from baseline to EOT (p = 0.02) and 6 m (p = 0.02), however differences were no longer significant at the 9 m follow-up. SE participants showed significant improvement in Anxiety/ Worry at EOT, and both Yoga and SE participants showed improvements from baseline in *Anxiety/ Worry* that were significant at the 6 m and 9 m follow-ups (p values < 0.05).

Table 2
Unadjusted Median Values of Dependent Variables over Time by Group.

	Yoga	Walking
Moderate-to-Vigorous Physical Activity	Baseline 0(370.00) 12 W 75.00(390.00) 6M 30.00(370.00) 9 M 105.00(620.00)	Baseline 10.00(190.00) 12 W 165.00(880.00) 6M 80.00(480.00) 9 M 60.00(690.00)
Glycated Hemoglobin (%)	Baseline 7.70(5.30) 12 W 8.10(6.30) 6M 7.85(4.90) 9 M 7.40(5.80)	Baseline 8.10(5.10) 12 W 8.00(5.90) 6M 8.00(6.10) 9 M 8.10(7.30)
Fasting Blood Glucose (mg/dL)	Baseline 168.00(175.00) 12 W 168.00(242.00) 6M 168.50(298.00) 9 M 158.00(190.00)	Baseline 160.00(223.00) 12 W 163.50(253.00) 6M 160.00(261.00) 9 M 155.00(364.00)

Median (Range) are presented. NOTE: unadjusted median values by group and timepoint are presented. Sample size for this study was small and as with small pilot studies, variances are large and unadjusted values should be interpreted with caution.

3.3.4. Diabetes-Related emotional distress (PAID)

Yoga participants experienced a significant reduction in emotional distress between baseline and EOT (p < 0.05), which continued through the final follow-up (p values < 0.001). SE participants also experienced a significant reduction in emotional distress at EOT (p = 0.048), but differences were no longer significant at follow-ups.

3.3.5. Mindfulness

Increased mindfulness scores were observed among Yoga participants between baseline and the month 9 follow-up (p = 0.006). A slight increase in mindfulness scores was also observed among SE participants at the month 9 follow up, although this change was not statistically significant.

3.3.6. Body mass index

Yoga participants showed a slight decrease in BMI between baseline (M = 33.6 (SD = 5.2) and EOT (M = 33.2, SD = 5.8), which remained

Table 3
Means, Standard Deviations, Paired *t*-test p-values, and Effect Sizes for Baseline to 12 weeks, Baseline to 6 months & Baseline to 9 months, for the Yoga and SE groups.*

Variable	Baseline	12 weeks	p-value	Cohen's d (95% C)	6 M	p-value	Cohen's d (95% C)	9 M	p-value	Cohen's d (95% C)
Yoga	40.6 (23.5)	35.1 (24.9)	.029	−.23	31.9	< .001	−.36	28.6	< .001	−.50
Problem Areas in Diabetes (PAID)				(-.65, .20)	(19.7)		(-.79, .08)	(22.5)		(-.94, -.05)
Walking	34.5 (23.1)	27.6 (19.4)	.048	−.29	24.9	.068	−.38	23.7	.073	−.35
Problem Areas in Diabetes (PAID)				(-.72, .15)	(18.6)		(-.85, .09)	(16.9)		(-.85, .14)
Yoga	51.6	52.1	.702	.06	52.3	.569	.07	54.8	.006	.36
FFM: Mindfulness	(8.7)	(9.4)		(-.36, .47)	(9.5)		(-.35, .49)	(9.5)		(-.07, .79)
Walking	53.4	54.8	.340	.16	55.6	.177	.22	56.2	.081	.31
FFM: Mindfulness	(8.5)	(7.3)		(-.28, .60)	(6.3)		(-.25, .69)	(7.3)		(-.20, .81)
Yoga	32.5	26.4 (21.8)	0.06	−.27	22.2 (16.6)	.009	−.52	24.6 (23.8)	0.015	−.35
Diabetes 39: Diabetes Concern	(21.4)			(-.71, .17)			(-.99, -.05)			(-.80, .09)
Walking	32.1	20.2	.020	−.45	23.1	.022	−.36	23.6	.122	−.26
Diabetes 39: Diabetes Concern	(25.5)	(19.4)		(-.90, .003)	(20.3)		(-.83, .11)	(22.0)		(-.75, .23)
Yoga	41.1	40.1	.787	−.04	34.0	.020	−.26	33.5	.054	−.28
Diabetes 39: Anxiety & Worry	(26.1)	(27.6)		(-.46, .38)	(24.2)		(-.69, .16)	(26.5)		(-.71, .15)
Walking	48.6	33.9	.001	−.46	34.3	.009	−.47	30.5	< .001	−.52
Diabetes 39: Anxiety & Worry	(30.9)	(30.6)		(-.91, -.01)	(29.8)		(-.95, .01)	(26.7)		(-1.04, -.01)
Yoga	1.0	3.0	< .001	1.51	2.1	.013	.90	2.0	.053	.77
Diabetes Self-Care: Exercise	(1.3)	(1.8)		(.86, 2.16)	(1.9)		(.35, 1.44)	(2.2)		(.22, 1.33)
Walking	2.2	3.5	.001	.60	2.6	.431	.19	2.4	.632	.18
Diabetes Self-Care: Exercise	(2.1)	(1.7)		(.14, 1.06)	(2.0)		(-.23, .62)	(1.6)		(-.24, .60)
Yoga	2.0	3.8	< .001	.99	3.7	< .001	.94	3.9	< .001	1.09
Diabetes Self-Care: Foot Care	(1.7)	(1.7)		(.47, 1.51)	(2.3)		(.43,1.46)	(2.3)		(.55, 1.63)
Walking	3.3	3.6	.385	.11	4.0	.348	.23	3.9	.420	.16
Diabetes Self-Care: Foot Care	(2.6)	(2.5)		(-.32, .54)	(2.5)		(-.23, .69)	(2.5)		(-.32, .64)
Yoga	2.9	3.6	.033	.37	3.9	.006	.52	3.7	.004	.41
Diabetes Self-Care: Diet	(1.9)	(1.8)		(-.07, .80)	(1.7)		(.07, .97)	(1.5)		(-.03, .85)
Walking	2.4	3.1	.079	.35	2.9	.384	.20	3.1	.318	.24
Diabetes Self-Care: Diet	(2.1)	(2.4)		(-.09, .79)	(2.0)		(-.25, .66)	(2.6)		(-.24, .73)

*One participant randomized to the SE condition never appeared for any intervention session or follow up after randomization.

consistent through 6 m (M = 33.2, SD = 5.8) and 9 m (M = 33.2, SD = 5.6), although this did not achieve statistical significance (p = .13). SE participants showed a slight, non-significant *increase* in BMI between baseline (M = 33.5, SD = 4.7) and EOT (M = 33.8, SD = 4.8) through the final follow-up (M = 33.7, SD = 5.1), p = .34.

Longitudinal Models suggested no significant *between-group* differences in Diabetes Self-Care, Quality of Life, emotional distress, mindfulness, and BMI (all p > .05).

3.3.7. Physical activity

Unadjusted median min/week of moderate to vigorous physical activity (MVPA) at baseline and follow-ups are presented in Table 2. Results suggest significant group effects favoring Yoga among those with higher baseline MVPA. Specifically, median min/week of MVPA at EOT was significantly higher among Yoga participants compared to SE (controlling for baseline) among those with higher MVPA at baseline (> 175 min/week), p < .05. Although baseline MVPA was treated continuously in the moderator model, 175 min/week was the value at which the lines crossed. For those with lower MVPA rates at baseline, SE outperformed Yoga with respect to median min/week of MVPA at EOT.

4. Discussion

Results of this study support the feasibility of an Iyengar yoga intervention for American adults with T2DM. Adherence to the yoga classes was favorable (82%) with high retention rates (N = 43; 90%) at final follow-up. Participant satisfaction surveys also indicated high program acceptability.

This study also examined the effect of yoga on psychological and behavioral parameters among adults with T2DM. There was a significant decrease in diabetes distress and improvement in quality of life. The proportion of Yoga participants with distress scores (PAID) above 40, which is the clinical cutoff for diabetes-related distress, dropped from 46% at baseline to 33% at EOT.[33,34] While improvements were also seen in the comparison arm, this change did not persist through follow up. Overall, the Yoga intervention led to a clinically meaningful 12-point decrease in diabetes distress, that persisted through follow up. The reduction in distress observed in this study was similar to past interventions that incorporated cognitive behavioral therapy[35] or intensive medical and educational program for diabetes management.[36]

Yoga participants showed increases in mindfulness scores. Increased mindfulness has been shown to improve dietary decision making resulting in improved weight loss.[37,38] Indeed mindfulness-based approaches appear most effective in addressing binge eating, emotional eating and eating in response to external cues.[39] Mindfulness may help improve diabetes management by increasing the individual's ability to respond to challenges with more effective coping strategies.[7,8] However, in the current study changes in mindfulness among Yoga participants became statistically significant only by month 9, while other changes in self-care and diabetes-related distress changed by the end of treatment.

Though there have been multiple studies examining the effect of yoga on clinical and physiological outcomes, relatively few studies have examined the psychological benefits of yoga among adults with diabetes. Consistent with our results, past studies have shown improvements in anxiety/worry,[40,41] distress,[42] and quality of life after yoga intervention. [40,41,43,44] In addition, assessment of behavioral parameters including self-care activities was unique to this study and is essential to explore the mechanism by which yoga could influence diabetes management. Yoga participants showed improvements in self-care activities related to diet, foot care and physical activity that were maintained for 6-months after the end of intervention. Though there were some improvements in the comparison arm, effects in this group

did not persist through follow-up. The improvement in foot-care among Yoga participants may be of special relevance given its importance to health maintenance among those with T2DM. Perhaps because yoga is practiced in bare feet, it may draw attention to this type of care.

BMI showed indications of slight improvements among Yoga participants and slight worsening among Standard participants, however neither of these changes were statistically significant. Given the relatively short timeline of the intervention and the lack of statistical power, it is premature to draw conclusions regarding the effects of yoga on BMI among adult diabetics. A systematic review that included 30 studies and 2133 participants [45] indicated that among overweight/obese individuals yoga interventions did promote reduced BMI. However, this meta-analysis also indicated that these effects were not robust against selection bias; and publication bias could not be ruled out. Given the strong positive effects that weight loss can produce on T2DM,[46] additional research on the effects of yoga on BMI warranted justified.

There was an initial increase in HbA1c and FBG values for both groups from baseline to EOT. It should be noted that the EOT assessment was conducted in December during the holiday season, which could have affected participants' diet and subsequently, their glucose levels. Participants also reported that it took 3–4 weeks for them to be able to practice yoga poses comfortably, thus a 12-week intervention may be insufficient to observe changes in HbA1c. An extended intervention of at least 16-weeks may be more ideal. Nonetheless, Yoga participants had better long-term glycemic control compared to SE participants.

This pilot study has a number of strengths. We used random assignment to study conditions, long-term follow-up, and objective measures for glycemic control. Participants demonstrated good treatment adherence and retention, with no differential adherence between groups. We also observed changes in psychological (diabetes distress, quality of life, mindfulness) and behavioral factors (diet, foot care, physical activity) that could explain the effect of yoga for diabetes management. Moreover, we used validated measures specifically developed for adults with diabetes.

The study also has limitations that should be noted and may need to be addressed in future research. First, the recruitment rates (29%) was limited due in part to strict eligibility criteria. Over 40% of interested individuals were excluded for orthopedic limitations, elevated BMI and HbA1c values indicating pre-diabetes (5.7–6.4). Since Iyengar yoga can accommodate individuals with elevated BMI and with orthopedic limitations, these exclusions were necessitated only by the chosen comparison condition.[47] Feasibility would be enhanced by selecting an alternate comparison arm such as an attention-control. The use of an exercise control group with equal contact time provided us with a contrast between yoga and an ideal situation: supervised standard exercise, however, the SE protocol was far more intensive than usual care for patients with T2DM. Second, as yoga may also benefit those with pre-diabetes and metabolic syndrome, generalizability would be enhanced by including these individuals.[48] Finally, although there were improvements in self-reported diet, without appropriate nutrition counseling, participants may not be aware of what exactly to change and how to change. This could have restricted improvements in glucose levels. Future interventions might benefit by incorporating diet counseling into the yoga program.

5. Conclusion

This study highlights several benefits of yoga for adults with T2DM. Yoga was found to be a generally safe and highly feasible intervention. The findings suggest the need for further research with larger samples and multiple sites to prove the efficacy of yoga as a complementary therapy for diabetes management.

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