



A Randomized Controlled Trial to Evaluate Changes in Quality of Life after Adopting Yoga Protocol and Brisk Walking in the Patients of *Madhumeha* with Special Reference to Type 2 Diabetes Mellitus

*¹Dr. Kiran Jha and ²Dr. Sarvesh Kumar Agrawal

^{*1}Assistant Professor, Department of Swasthavritta & Yoga, Dalia Ayurved College and Hospital, Kanera, Kheda, Gujarat, India.

²Associate Professor, Department of Swasthavritta & Yoga, National Institute of Ayurveda, Jaipur, Rajasthan, India.

Abstract

Introduction: *Madhumeha* (DM) is a chronic disease in which patients take long time/life-long medicines. In *Madhumeha* (DM) or any other chronic diseases the quality of life (QOL) is hampered due to factors like long duration of therapy, dietary restrictions, co-morbidities and complications of disease. Yoga Practices might be beneficial for such patients. No study has been conducted on the practice of Yoga Protocol for such patients. Yoga Protocol (YP) is combination of Yoga, Asana, Pranayama, Dhyana and Prayer which has potential to improve QOL of patients on its entire Domain which cannot be achieved only with medicines. It may have more effect on QOL in comparison to Brisk Walking (BW), a form of exercise.

Objectives: Primary- To evaluate the difference in QOL among the patients of *Madhumeha* (Type 2 Diabetes Mellitus) after adopting Yoga Protocol and Brisk walking, Secondary- To evaluate the difference in reduction of FBS, PPBS, HbA1C among the patients of *Madhumeha* (Type 2 Diabetes Mellitus) after adopting Yoga Protocol and Brisk walking.

Methodology: A screening proforma was used for enrolment of patients. Sample size was 80, 40 in each group. A Case Record Form/Questionnaire was prepared for gathering details. MDQOL Scale, for the assessment of changes in Quality of Life was used. Wilcoxon and Mann Whitney tests were used for Subjective parameter (MDQOL Scale) and Paired and Unpaired t tests were used for Objective parameter (FBS, PPBS, HbA1c).

Results: Group A has shown more percentage improvement in subjective parameter (MDQOL) as compared to Group B, but the difference is not statistically significant. Group A has shown more statistically significant improvement in objective parameter (FBS, PPBS, HbA1c) as compared to Group B.

Conclusion: YP had shown more percentage improvement in subjective parameter (MDQOL) as compared to BW, but the difference was not statistically significant. YP had shown more statistically significant improvement in objective parameter (FBS, PPBS, HbA1c) as compared to BW. Both the therapies are very easy to use, safe and have multiple psychological benefits hence it can be accepted more widely in the society, also it is a low-cost intervention for the control of various lifestyle disorders.

Keywords: Diabetes Yoga Protocol, *Madhumeha*, Quality of Life.

Introduction

Madhumeha (DM) is a chronic disease in which patients take long time/life-long medicines. In *Madhumeha* (DM) or any other chronic diseases the quality of life (QOL) is hampered due to various factors like long duration of therapy, dietary restrictions, co-morbidities and complications of disease. Therefore, a programme to improve QOL is required for such patient. Yoga Practices may be beneficial for such patients. However, various trials have been found successful to reduce blood sugar level or symptomatic improvement or to improve QOL of such patients but no study has been conducted on the practice of Yoga Protocol for such patients. Yoga Protocol is combination of Yoga, Asana, Pranayama, Dhyana and Prayer which also has potential to improve QOL of patients on its entire Domain which cannot be achieved only with medicines.

It may have more effect on QOL in comparison to Brisk Walking, a form of exercise.

Aims & Objectives

Aim: To evaluate the role of Yoga protocol on Quality of life (QOL) among the patients of *Madhumeha* (Type 2 Diabetes mellitus)

Primary: To evaluate the changes in Quality of life (QOL) among the patients of *Madhumeha* (Type 2 Diabetes Mellitus) after adopting Yoga Protocol and Brisk walking

Secondary: To evaluate the difference in reduction of FBS, PPBS, HbA1C among the patients of *Madhumeha* (Type 2 Diabetes Mellitus) after adopting Yoga Protocol and Brisk walking

Materials and Methods

1. Trial Design

- Type of Study – Interventional Study
- Allocation Concealment- SNOSE
- There were no important changes in methods after commencement of trial.

2. Selection of Cases

The study was conducted on 80 clinically and pathologically diagnosed patients of *Madhumeha* (Type-2 DM). The selection of patients was made from OPD of, National Institute of Ayurveda and SSBH, Jaipur (Raj.).

3. Inclusion Criteria

- Patients between the Age group 18-60 yrs.
- Irrespective of gender, religion & occupation.
- Known patients of *Madhumeha* (Type II DM) taking medicines and not doing any exercise or Yoga at least since the last one year.

4. Exclusion Criteria

- Patients not willing to participate in the study.
- Pregnant and lactating mothers.
- Known case of any illness in which performing yoga/Brisk walking is contraindicated viz, cervical/lumber spondylitis, arthritis of Knee Joints, post-surgical cases, pyrexia, IHD or any acute condition.

5. Study Setting: Study was conducted on the patients registered from associated Institute Hospital.

Methods of Intervention

Group A: Yoga Protocol practice was advised daily for 60 minutes per day in morning (empty stomach) or evening (before meal) for 12 weeks.

Group B: Brisk walking was advised daily for 30 minutes per day in morning (empty stomach) or evening (before meal) at

approximate speed of 4 Km/hr for 12 weeks.

Criteria of Assessment: Both subjective and objective parameters were employed for assessment of the impact of the treatment. Subjective criteria of evaluation included the Modified Diabetes Quality of life Scale (MDQOL) assessment. Objective criteria of evaluation included FBS, PPBS and HbA1C - Before and after the trial.

Assessment of Objective Parameters: FBS, PPBS and HbA1C - Before and after the trial

Outcomes

Primary: There is a significant improvement in Quality of life after adopting Yoga Protocol in the patients of *Madhumeha* (Type 2 Diabetes Mellitus) as compared to Brisk Walking.

Secondary: There is reduction in FBS, PPBS & HbA1C in the Patients of *Madhumeha* (Type 2 Diabetes Mellitus) after adopting Yoga Protocol and brisk walking

Sample size: 40 in each group

Randomization: Computer generated table of Random number

Allocation Concealment Method: SNOSE

A Computer-generated table of Random number was generated by the researcher and the randomization of patients in both the groups was done by SNOSE method. Each patient was allowed to choose an envelope, sealed with the name of the group either A or B.

Statistical Methods

Wilcoxon and Mann Whitney for Subjective and One tailed & two tailed t test for Objective parameters

- **Statistical Calculation:** GraphPad Instat
 ‘p’ values between 0.5-0.1 = Insignificant
 ‘p’ values between 0.05-0.01= Significant
 ‘p’ values between 0.005-0.001 = Highly Significant

Results

Table 1: Effect of Diabetes Yoga Protocol Practice and Brisk Walking on Subjective Parameter

Variable	Group	Mean Score		Mean Difference	% Relief	S.D.	S.E.	P Value	S
		B.T.	A.T.						
MDQOL	A	21.72	65.15	43.425	66.65	11.381	1.800	<0.0001	ES
	B	22.75	63.95	41.175	64.386	8.193	1.295	<0.0001	ES

Table 2: Effect of Diabetes Yoga Protocol Practice and Brisk Walking on Objective Parameters

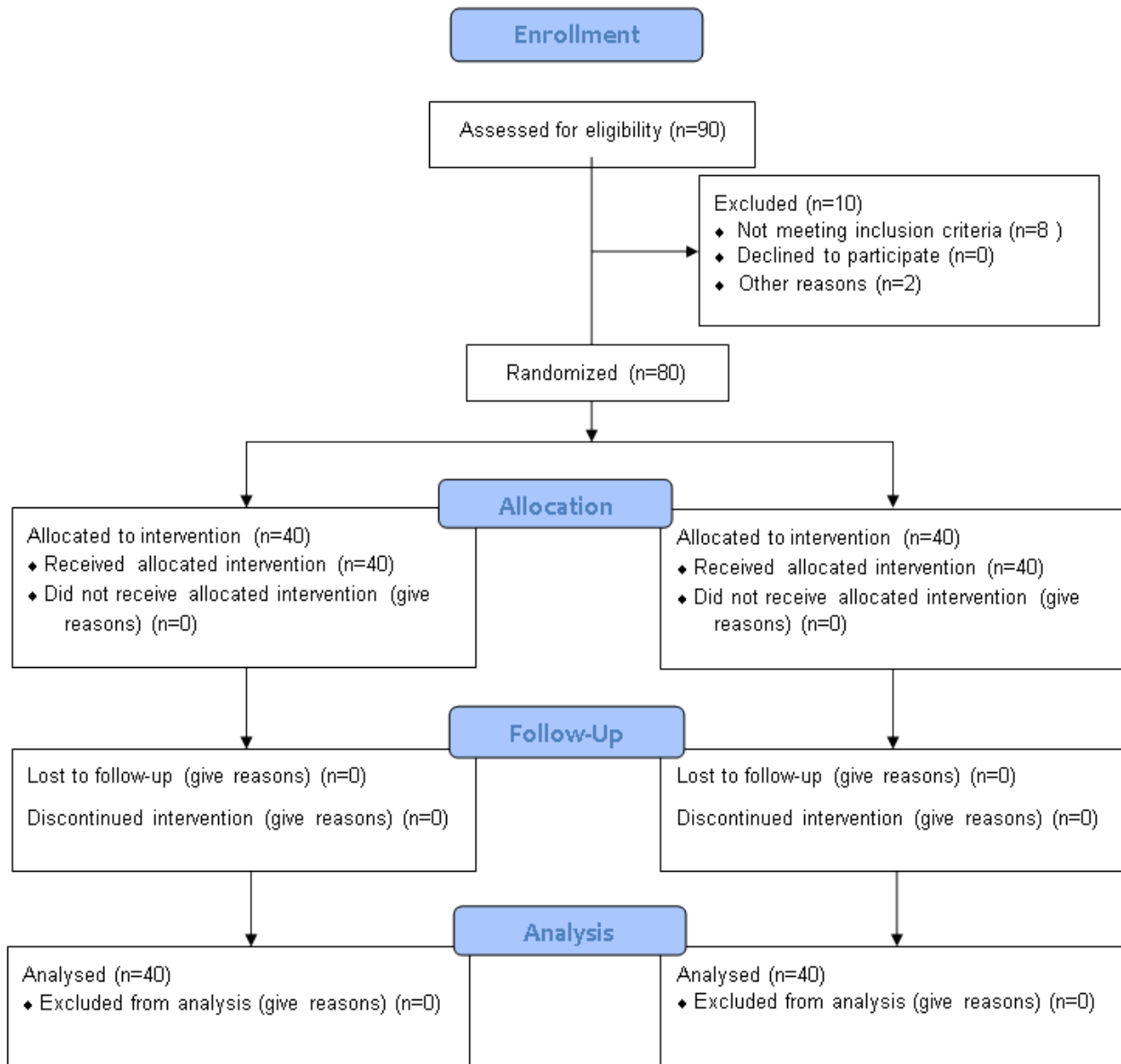
Variable	Group	Mean		Mean Difference	% Relief	S.D.	S.E.	P Value	T	S
		B.T.	A.T.							
FBS	A	199.34	157.31	42.028	21.08%	37.9425	5.99992	<0.0001	7.005	ES
	B	160.35	140.50	19.851	12.37%	28.602	4.52222	<0.0001	4.389	ES
PPBS	A	266.11	210.56	55.548	20.87%	67.8289	10.7257	<0.0001	5.179	ES
	B	214.60	186.45	28.150	13.11%	36.787	5.817	<0.0001	4.840	ES
HbA1c	A	9.163	8.0781	1.09	11.89%	0.6238	0.09863	<0.0001	11.051	ES
	B	7.990	7.300	0.69	8.63%	0.6953	0.1099	<0.0001	6.276	ES

Table 3: Intergroup Comparison of Group A & Group B for Subjective Parameters

Variable	Groups	Mean	SD±	SE±	“U” Value	P	S
MDQOL Score	A	43.425	11.381	1.800	944.50	0.1655	NS
	B	41.175	8.193	1.295			

Table 4: Intergroup Comparison of Group A & Group B for Objective Parameter

Variable	Groups	Mean	SD±	SE±	P	T	S
FBS	A	42.028	37.943	5.999	0.0042	2.952	S
	B	19.851	28.602	4.522			
PPBS	A	55.548	67.829	10.725	0.0276	2.246	S
	B	28.150	36.787	5.817			
HbA1c	A	1.09	0.6238	0.09863	0.0083	2.708	S
	B	0.69	1.6953	0.1099			

CONSORT Flow Diagram

Total Duration of Trial: 18 Months

Recruitment Period: One year

Trial Period: 12 Weeks

Follow-Up Period: At every four weeks

Dropouts: There was no specific reasons for dropouts, recorded during the clinical trial.

Adverse effects: Any adverse event, observed during treatment period or during follow up visits will be clearly documented and appropriate and timely management will be done consulting the physician associated in the trial. The Investigating team will report the same to the Ethics committee at the earliest.

Discussion

Diabetes is a chronic metabolic condition that has an adverse effect on quality of life. The main causes of T2DM include factors like poor diet, inactivity, obesity, genetic factors, and psychological stress. The fundamental principle of yoga is the idea that the body and mind are intrinsically connected. Flexibility, muscle strength, blood flow, and oxygen uptake are all improved. Yoga can increase physical fitness, relaxation, and self-awareness, among other things. Given acceptable high levels of adherence, yoga can be used to manage a variety of lifestyle disorders, including diabetes. Yoga results in improvements in physiological, psychological & behavioural changes.

Psychological stress and depression have a bidirectional effect on diabetes control. Stress increases the risk and severity of diabetes by stimulating the hypothalamic-pituitary-adrenal (HPA) and sympathetic axes, as well as parasympathetic withdrawal, leading to a rise in cortisol, epinephrine, norepinephrine, growth hormone, glucagon, catecholamines, prolactin, leptin, and neuropeptide Y levels. Chronic activation of the HPA axis has been linked to poor diabetes control and consequences such as diabetic neuropathy. In type 2 diabetes patients, an increase in inflammatory cytokines leads to insulin resistance. Chronic mental stress can cause insulin resistance, hypertension, and an elevated risk of cardiovascular events. Yoga effectively reduces stress, which aids with diabetes management.

The numerous health advantages of yoga therapy are related to changes in the levels of different hormones and neurotransmitters: improvements in arousal are due to increased arginine-vasopressin levels, which reduce the gamma-aminobutyric acid (GABA) inhibition of the supraoptic area of the hypothalamus; joy and euphoria during yoga therapy; and; Melatonin is responsible for its calming effects, lateral hypothalamic stimulation is responsible for the ecstatic and blissful feelings experienced during yoga, and decreased spatial orientation and out-of-body experiences during meditation are caused by higher levels of N-acetyl aspartyl glutamate and 5-methoxydimethyltryptamine (from pineal enzymes) than GABA.

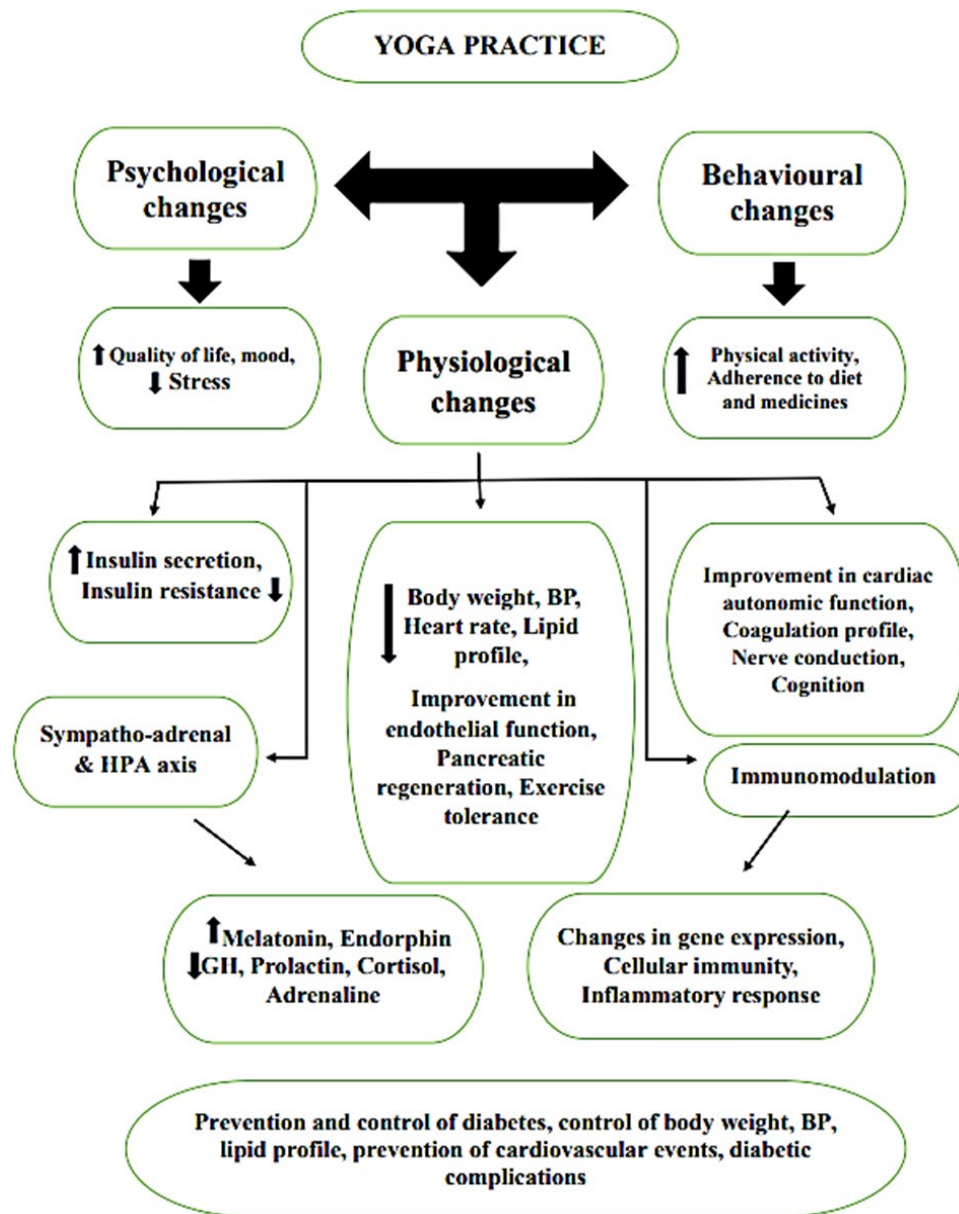
Yoga asana also alter gene expression, which has positive effects on body weight, adiposity, dyslipidaemia, and insulin resistance. They also increase muscle activity, strength, endurance, flexibility, and balance. Yoga lowers oxidative stress, as shown by improvements in adiponectin levels and decreases in serum levels of leptin, interleukin-6, and malondialdehyde. In diabetic patients, yoga therapy increases the proportion of receptor binding as well as the number of insulin receptors. By lowering fasting insulin levels, shifting

the peak insulin level to the left, and bringing the insulin-to-glucose ratio back to normal, it enhances insulin kinetics. Indirectly indicating improved insulin sensitivity or decreased insulin resistance, it also lowers levels of free fatty acids.

Yoga enhances cell-mediated immunity, as shown by improvements in type 2 diabetics' lymphocyte migration test results. In high-risk individuals, yoga also delays the onset of diabetes. It was discovered to lower symptom scores in diabetics. Additionally, it results in decreased requirements for anti-diabetic medication, HbA1c, postprandial blood sugar, and fasting blood sugar, indicating improved glycaemic control. Yoga improves high density lipoprotein cholesterol levels while lowering triglyceride, free fatty acid, and low-density lipoprotein cholesterol levels. It encourages discipline around eating and exercise. It has been demonstrated that regular yoga practice increases exercise tolerance, increases treadmill test performance from eight metabolic equivalents (METS) to twelve METS, and delays the anaerobic threshold. According to some studies, people who practice yoga have lower systolic and diastolic blood pressure. Regular yoga practice lowers the chance of complications from diabetes. Patients with diabetes mellitus are thought to experience sudden death as a result of cardiac autonomic dysfunction. Clinical studies have demonstrated that consistent yoga practice decreased the risk of cardiovascular events and enhanced cardiac autonomic function without regard to glycaemic control. Additionally, yoga therapy reduces blood clotting, which helps diabetic patients' nerve conduction and cognitive function.

Weight gain occurs in patients with type 2 diabetes when glycaemic control is not improved with diet or exercise that leads to increase in the insulin dosage. Yoga, on the other hand, enhances glycaemic control while not causing an increase in body weight, and some studies have even found that it causes weight loss.





Limitations of the Study

- This study, which evaluated the therapeutic benefits of yoga and brisk walking in managing diabetes, was constrained by the small sample size and brief duration of the intervention.
- In this study only diagnosed case of *Madhumeha* (Type 2 Diabetes Mellitus) were included, irrespective of the medicines they were taking, if the patient might be treated with same medicine or drug then the evaluation of the overall effect of medicine along with yoga was supposed to be determined more accurately.

Interpretation

Both the interventions, Diabetes Yoga Protocol and Brisk walking show positive response on objective parameters but not on subjective parameter, which indicates that both of this can be used in the management of diabetes but comparatively Diabetes Yoga Protocol is more effective than Brisk Walking.

Registration

Ethical Clearance: This study was approved by Institutional Ethics Committee (IEC) of National Institute of Ayurveda, Jaipur via letter no. IEC/ACA/2021/02-109 dated 01/09/2021

CTRI Registration: This study has been registered in Clinical Trial Registry of India (CTRI) with CTRI Reg. No.

“CTRI/2022/03/040765”

Funding: National Institute of Ayurveda provided funding for this study and the patients were enrolled and registered from NIA OPD itself.

References

1. Sharma GS, commentator. *Atharvaveda Samhita*. 1st ed. New Delhi: Sanskrita Sahitya Prakashana; 2015.
2. Vyasa MV. *Agnipurana*. Gorakhpur: Geeta Press.
3. Vyasa MV, Kaushik VS. *Garud puran*. 12th ed. Pooja Prakashan.
4. Pandey K, Chaturvedi G, editors. *Agnivesha Charak Samhita*. Sutra sthan, C.Su. 17/78-80. Varanasi: Chaukhambha Bharti Academy; 2009.
5. Datta KA. *Sushruta Samhita of Maharshi Sushruta*. Chaukhambha Sanskrit Sansthan; 2010.
6. Mitra J, ShivPrasad, editors. *Vridha Vagbhata, Astangsamgraha Samhita*. Choukhambha Sanskrit Series Office; 2008.
7. Katyayan A, commentator. *Bhela Samhita*. Varanasi: Chaukhambha Surbharati Prakashan; 2022.
8. Tripathi H, editor. *Harita Samhita*. Varanasi: Choukhambha Krishnadas Academy; 2005.
9. Sarma H, Bhisagacharya S, translators. *Kashyapa Samhita or Vrddhajivakiya Tantra*. Chaukamba Sanskrit

- Sansthan; 2006.
10. Tripathi B. *Madhavanidanam of Madhavakara*. Varanasi: Chaukhambha Surbharati Prakashan; 2001.
 11. Tewari P, editor and translator. *Vrinda Madhav or Siddha Yoga*. Varanasi: Chaukhambha Visvabharati; 2007.
 12. Tripathi B. *Ashtanga Hridayam; Vagbhata*. Delhi: Chaukhambha Sanskrit Pratistahan; Chowkhamba Vidyabhawan; 2022.
 13. Misra BS, editor. *Bhavaprakasa of Shri Bhav Mishra*. Chaukhambha Sanskrit.
 14. Tripathi JP, commentator. *Chakradutta*. Varanasi: Chaukhambha Sanskrit Series; 1983.
 15. Shrivastava S, commentator. *Sarangadhara Samhita, Jwanprada Hindi Commentary*. Varanasi: Chaukhambha Orientalia; 2013.
 16. Misra BS, editor. *Bhavaprakasa of Shri Bhav Mishra*. Vranasi: Chaukhambha Sanskrit Sansthan; 2003.
 17. Sen KGD. *Bhaisajya Ratnavali*. Rao GP, translator. Vol 2. Varanasi: Chaukhamba Orientalia; 2014.
 18. Radha Kant SR. *Shabda Kalpadrum*. Varanasi: Devi Chaukhambha Sanskrit Series.
 19. *Davidson's Principle and Practice of Medicine*. 21st ed. Churchill Livingstone.
 20. *Harrison Principles of Internal Medicine*. 19th ed. Vol 2. McGraw Hill Education.
 21. World Health Organization. *Global Report on Diabetes*. World Health Organization; 2016.
 22. *IDF Diabetes Atlas*. 8th ed. 2017.
 23. 100 growth in diabetes patients in India in the last 15 years. NDTV Food. Available from: <http://food.ndtv.com/health/100-growth-in-diabetes-patients-in-india-in-the-last-15-years-1292926>
 24. Kaveeshwar SA, Cornwall J. The current state of diabetes mellitus in India. *Australas Med J*. 2014; 7(1): 45–48.
 25. *Guyton and Hall: Textbook of Medical Physiology*. 11th ed. Elsevier Saunders.
 26. World Health Organisation. *WHOQOL: Measuring Quality of Life*. Available from: <https://www.who.int/tools/whoqol/whoqol-bref>
 27. Melam GR, Alhusaini AA, Buragadda S, Kaur T, Khan IA. Impact of brisk walking and aerobics in overweight women. *J Phys Ther Sci*. 2016 Jan; 28(1): 293-7.
 28. Ministry of Ayush. *Yoga Based Life Style Module for Diabetic*. Available from: <https://antidiabetesayus.files.wordpress.com/2017/05/yoga-based-life-style-module-for-diabetic.pdf>
 29. Raveendran V, Deshpandae A, Joshi S. Therapeutic Role of Yoga in Type 2 Diabetes. *Endocrinology and metabolism (Seoul, Korea)*. 2018; 33(3): 307-317.
 30. Duraiswamy V, Balasubramaniam G, Subbiah S, Veeranki SP. Role of yoga in the management of Type 2 Diabetes Mellitus. *International Journal of Students' Research*. 2011; 1(3): 80-84.
 31. Mahajan M, Mahajan Y. Role of yoga in type 2 diabetes mellitus. *Indian Journal of Clinical Anatomy and Physiology*. 2023; 10(1): 6-9.
 32. International Diabetes Federation. *IDF Diabetes Atlas*. 8th ed. Brussels: International Diabetes Federation; 2017.
 33. Thangasami SR, Chandani AL, Thangasami S. Emphasis of yoga in the management of diabetes. *J Diabetes Metab*. 2015; 6: 613.
 34. Liu XC, Pan L, Hu Q, Dong WP, Yan JH, Dong L. Effects of yoga training in patients with chronic obstructive pulmonary disease: a systematic review and meta-analysis. *J Thorac Dis*. 2014; 6: 795-802.
 35. Browning RC, Kram R. Energetic cost and preferred speed of walking in obese vs. normal weight women. *Obes Res*. 2005; 13: 891–899.
 36. Fogelholm M, Kukkonen-Harjula K, Nenonen A, et al. Effects of walking training on weight maintenance after a very-low-energy diet in premenopausal obese women: a randomized controlled trial. *Arch Intern Med*. 2000; 160: 2177–2184.
 37. Wang X, Hu Y, Qin LQ, Dong JY. Meal frequency and incidence of type 2 diabetes: A prospective study. *British Journal of Nutrition*. 2021; 128: 1-18.
 38. Choudhary A, Sunda P, Agrawal R, Meena B, Meel J, Vyas S. Association of sleep time with diabetes mellitus and impaired glucose tolerance. *International Journal of Medical and Biomedical Studies*. 2021; 5(7).
 39. Pitta S, Devi KP, Shailaja B. Diabetes mellitus (Madhumeha)-an Ayurvedic review. *International journal of pharmacy and pharmaceutical sciences*. 2014; 6.
 40. Agarwal V, Kumar N, Arya BC. A Review on role of exercise and yoga in the prevention of Madhumeha (Diabetes Mellitus). *Int J App Ayu Res*. 2017 Mar 15; 2(11): 1623-7. Available from: <https://ijaar.in/index.php/journal/article/view/355>
 41. Karimi H, Ur Rehman S. Exercise and Type-2 Diabetes Mellitus. *Journal Riphah College of Rehabilitation Sciences*. 2016.