

Yoga or Mindfulness on Diabetes: Scoping Review for Theoretical Experimental Framework

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Parole chiave: Yoga; Mindfulness; Diabete Mellito; Promozione della Salute; COVID-19

Abstract

Background. About one in 11 adults worldwide suffers from diabetic disease with constantly increasing prevalence; from the 529 million patients registered in 2021, the number of people with diabetes was predicted to rise to approximately 1.31 billion in 2050. In Italy, 5.9% of the population is diabetic, with a higher prevalence with increasing age and in the South of the country. Yoga and Mindfulness could represent a valid support for the care of diabetic subjects especially in a stressful caring context such as the Covid-19 pandemic.

Study Design. A scoping review was conducted to achieve the goals of the study. Yoga or Mindfulness interventions on diabetic subjects were specifically analyzed and qualitative-quantitative data collected in the selected randomized controlled trials were extensive for possible meta-analysis.

Methods. The review was conducted by two independent practitioners and a third one was consulted in case of conflict. The PRISMA method was used for both the selection and reporting of the studies to be included. Specific PICOS and search strategies have been developed on PubMed, Embase and PsycINFO databases. Included in the review were: randomised controlled trials, full dissertation articles and papers in English with a time limit on May 31, 2022.

Results. The Review included 22 studies; 12 on Mindfulness, 9 on Yoga and one about both disciplines; among these, one studied patients with Type 1 Diabetes, 14 with Type 2 Diabetes, 6 with both and one with Gestational Diabetes. Only one paper studied adolescent subjects while the other 21 focused on a range of adult subjects. The studies showed that Yoga and Mindfulness have strong potential not only on stress management, but also on clinical-metabolic parameters.

Conclusions. The recent Covid-19 pandemic has certainly redesigned a new way of treating and managing chronic diseases, such as diabetes. An increasingly fragile population, and with the growing need to reduce overall stress levels, could find alternative practices in Yoga and Mindfulness to support conventional therapies.

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Introduction

Worldwide, about one in 11 adults is affected by diabetic disease with proportions that are constantly increasing; from the 529 million patients registered in 2021, the number of people with diabetes was predicted to rise to approximately 1.31 billion in 2050 (1–3). In Italy, 5.9% of the population is suffers from diabetes, with a higher prevalence with increasing age and a wider spread in the South of the country (4). Familiarity, age and incorrect lifestyles (especially unbalanced diet, smoking, alcohol, daily increase in caloric intake, increased consumption of refined cereals, and sedentary lifestyle) are the main risk factors for several noncommunicable diseases, including diabetes and for the related complications and socioeconomic change (5–11). The role of a better lifestyle and diet has proven to be crucial for the prevention of disease outcomes and complications pre and post Covid-19 era (12–18). A third of diabetic patients use some type of complementary or alternative therapy and, among these, 3–20% use it as the only form of treatment (19, 20). Yoga is an ancient Indian practice with more than 20 million practitioners in the United States and it is one of the most common complementary therapies used by american adults (21). The benefits of practising Yoga on adult diabetic patients, in addition to the reduction of stress, have been shown to favour a better glycaemic, lipid and overall body composition of the subject (22–24). The use of Mindfulness in diabetic individuals supported directly the management of stress, anxiety, depression and favoured patient self-care, preventing any clinical and social care complications from a perspective of overall well-being (25–28). Like Yoga, Mindfulness also derives from remote Eastern practices based on calm, stress management and conscious breathing that improves focus on the present in a non-judgmental way with relevant effect on frail population (29). Yoga and Mindfulness could represent a valid support for the care of diabetic subjects especially in a stressful care context such as the Covid-19 Pandemic.

Methods

The main objective of the study was to evaluate Yoga or Mindfulness interventions on diabetic subjects while the qualitative and quantitative data collected from the included studies were specifically

analyzed. The review aimed to answer the following questions:

- What complementary effect to traditional diabetes treatment can Yoga and/or Mindfulness?
- What quali/quantitative clinical-metabolic outcomes can support patients treated with complementary Yoga and/or Mindfulness therapy?

The Review – was performed Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) extension for Scoping Reviews (PRISMA-ScR) (30) – was conducted by two independent operators and a third one was consulted in case of a conflict. Specific Population, Intervention, Comparison, Outcomes and Study (PICOS) and inclusion criteria were declared; English articles with complete dissertation with time limit on 31 May 2022 and which met the quality requirements of the PRISMA Statement (30) (Fig. 1 and 2). Research strategies on PubMed, Embase and PsycINFO databases have been conducted for the selection of the studies. Through the use of Boolean operators AND/OR, the following keywords were applied: “Yoga”, “Mindfulness”, “Diabetes Mellitus”, “Diabetes Gestational”, “Diabetes Mellitus Type 2”, “Diabetes Mellitus Type 1”, “Diabetes Complications”. Of the 265 randomized controlled trials (RCTs) identified, 108 were excluded because duplicate or ineligible for Title or Abstract. Of 157 eligible, 103 were removed because not pertinent and, for the 54 papers retrieved, 10 were excluded initially and 22 after comparison by researchers and expert opinion.

Results

Twenty-two studies were included (Tab. 1); 12 on Mindfulness, 9 on Yoga and one concerning both disciplines; among them, one work studied patients with Type 1 Diabetes (T1D), 14 with Type 2 Diabetes (T2D), 6 with both and one with Gestational Diabetes (GD). Only one work studied adolescents, while the other 21 focused on a range of adult patients. The included studies took place in different care settings; 1 in Pakistan, 1 in Canada, 3 in the USA, 1 in Iran, 1 in South Korea, 7 in India, 1 in Australia, 1 in New Zealand, 1 in Cuba, 2 in Thailand and 3 in the Netherlands. The experimental cohort with the smallest sample size included 13 subjects, while the largest one 150. Five studies focused mainly

on qualitative aspects, 8 on quantitative, 9 on both quali-quantitative aspects. The main quantitative parameters investigated were: Glycated Haemoglobin (HbA1c) and Fasting Blood Glucose (FBG) in 11

studies, Waist-Hip Ratio (WHR) in 3 studies, Body Mass Index (BMI) in 7, Waist Circumference (WC) in 2, Blood Pressure (BP) in 6 and lipid profile in 7 studies.

P Adults or young adults (no children) with diabetes
I Yoga or Mindfulness intervention
C Yoga or Mindfulness intervention or no Yoga or Mindfulness intervention or none
O Primary or secondary outcomes (stress factors, wellness, quality of life, glycemic control, lipid profile, pain or anthropometric measures)
S RCTs in English version with temporal limit on 31 May 2022

Figure 1. Picos and Inclusion criteria

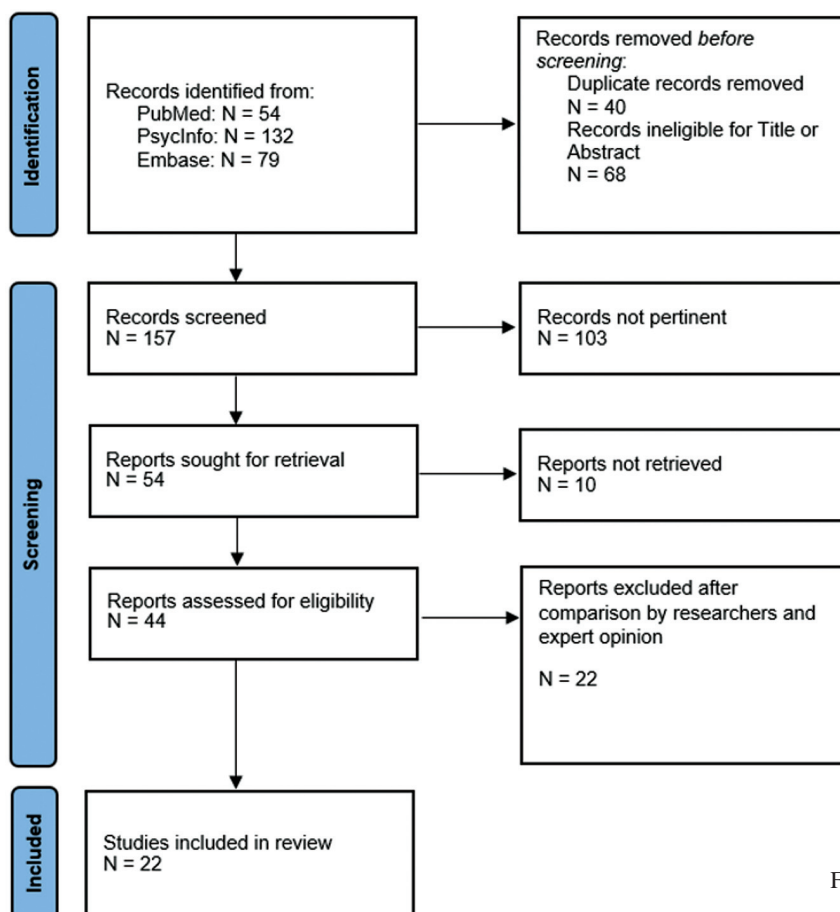


Figure 2. PRISMA Method Flowchart

Table 1. Synthesis of included studies.

| First Author and Year of publication | Setting | Practice | Intervention and control groups | Psychological and General Health Support | Quantitative Outcome | Qualitative Outcome | Main Results and Conclusion | Quality of the Study |
|--------------------------------------|--|--|---|---|---------------------------------------|---|---|----------------------|
| Hussain et al (31) (2019) | Pakistan Older Female Patients with Neuropathy in Type 1 Diabetes (T1D) and Type 2 Diabetes (T2D) | Mindfulness-Based Meditation (MM) or Progressive Relaxation Meditation (PM) or Control Meditation (CM) | Group MM 36 / Group PM 32 / Group CM 37 8 weeks | The MM sessions combined meditation exercises with elements of cognitive therapy | Not observed | Painful Diabetic Peripheral Neuropathy (BPI-DPN Q4) and the Patient Global Impression of Change (PGIC) | MM and PM experienced significant ($p < 0.05$) reduction in average daily pain in last 24 hours at study end compared with baseline (28.7% and 39.7%). MM significant ($p < 0.01$) reduction of pain compared with control (a score of 5.2 ± 1.2 dropped to 3.0 ± 1.1 by week 12 of treatment) | Low |
| Rozworska et al (32) (2020) | Canada Adults T1D and T2D with peripheral painful diabetic neuropathy (PDPN) | Mindfulness Based Stress Reduction (MBSR) | Intervention group 30 / Control group waiting list 32 8 weeks (2 weeks and 3 months follow up) | Combined Mindfulness intervention with didactic sessions, group discussions and homework | Not observed | Mindfulness with Five Facet Mindfulness Questionnaire (FFMQ), Pain Catastrophizing with Pain Catastrophizing Scale (PCS), Pain Severity with Brief Pain Inventory Subscale for multidimensional pain (BPI), Physical Quality with Short Form 12 Health Survey [version 2 (SF-12)] and Mental depression level with Patient Health Questionnaire 9 (PHQ-9) | The mediation effect of pain catastrophizing was not significant. Linear moderated trends were also found. Post-hoc moderated mediation analyses suggested that MBSR patients with longer histories of diabetes might increase their mindfulness levels more, which in turn leads to improved pain severity and physical quality of life | Low |
| Ellis et al (33) (2019) | USA Young adults (16-20 years old) T1D | MBSR | 16 case MBSR / 32 control group 16 control 1 in Cognitive Behavioural Stress Management (CBSM) 16 control 2 diabetes Support Group (DSG) (16 for each group were analysed three-month follow-up) 9 weeks | Stress support and walking meditation, body scan, and mindful movement/gentle Yoga, learning pay attention moment-to-moment, understanding stress reactions and home practice was recommended | Glycated Haemoglobin (HbA1c) | Treatment Effects with Diabetes Management Scale (DMS), Stress with 10-item version of the Perceived Stress Scale (PSS), Socioeconomic status (SES) with MacArthur Scale of Subjective Socioeconomic Status (SSSS), Depression with Center for Epidemiologic Studies Depression Scale (CES-D) | MBSR reduce self-reported stress at the end of treatment ($p = 0.03$) and three-month follow-up ($p = 0.01$). No relevant effects on diabetes management and glycaemic control in the intervention group were obtained. In DSG had improved glycaemic control at the end of the treatment ($p = 0.01$) and reduced depressive symptoms at t3 month follow-up ($p = 0.01$) | Moderate |
| Armani et al (34) (2018) | Iran Adults with T2D | MBSR | 29 MBSR group / 30 control group 8 week (3 months follow up) | Each session includes selective and sustained concentration practices, introduction of new concepts, reflection on poetry or readings, mindful listening practice and opportunity for questions | HbA1c and Fasting Blood Glucose (FBG) | Mental health, depression, and anxiety were measured with: General Health Questionnaire (GHQ-28), Hamilton Depression Rating Scale (HDRS), and Hamilton Anxiety Rating Scale (HARS) | In comparison with the control group, the MBSR intervention group showed a significant reduction in all outcome measures including FBG, HbA1C, HARS, and HDRS scores ($p < 0.05$) | Low |

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|-------------------------------|---|--|---|---|---|--|--|----------|
| Pearson et al (35) (2018) | Australia Adults with T2D | Mindfulness | Intervention group allocated 38 (31 analysed) / Control group allocated 36 (36 analysed) 8 weeks (follow up at 8 and 12 weeks the end of intervention) | Not specified | Blood Pressure (BP) and HbA1c | Depression, anxiety and stress with 21-item Depression, Anxiety and Stress Scale (DASS-21), Diabetes spe cific emotional problems with Problem Areas in Diabetes in Survey (PAID) scale and self-management using the Summary of Diabetes Self-Care Activities Scale (SDSCA) | Significant reductions in depres sion ($p = 0.02$) and stress ($p = 0.03$) in the intervention group compared with the control group. At the 12-week follow-up, there was reduction in depression by 4.1 units and stress by 3.4 units in the case group relative the control. There was an overall improvement in blood glucose monitoring but it was not significant ($p = 0.06$) | Low |
| Haenen et al (36) (2016) | Netherlands Adults with T1D and T2D | Mindfulness Based Cognitive Therapy (MBCT) | 70 intervention groups, 69 control randomised / 51 in the intervention group and 55 controls completed six month follow up 8 weeks | Stress support, generic mental symptoms management (coping with thoughts/feelings) and home practice recommended | Not observed | Psychological distress with PSS and Profile of Mood States (POMS-SF). To evaluate the practice of MBCT, FFMQ was adopted | MBCT group showed larger decreases in perceived stress, depression, and anxiety and had significantly improvements in health related quality of life compared control group | Low |
| Nyklicek et al (37) (2016) | Netherlands Adults with T1D and T2D | MBCT | MBCT 70 patients allocated and analyzed / Control group 69 allocated and analyzed 8 week (6 months follow up) | Not specified | Not observed | Hospital Anxiety and Depression Scale (HADS) was used to assess symptoms of anxiety and depression, perceived stress with PSS, shorted Eysenck Personality Questionnaire (EPQ-RSS) used for personality measurement, Dutch version FFMQ for Mindfulness skill | Mixed models analyses showed that sex and baseline acting with awareness were significant moderators of effectiveness. In the MBCT group, women showed larger decreases in anxiety and depression across time (large effects) compared with men (medium to small effects) | High |
| Gainey et al (38) (2016) | Thailand Adults with T2D | Buddhist Walking Meditation (WM) | Walking Traditional Exercise group (WE) 13 (11 analyzed) / WM 14 (analyzed 12) 12 weeks | Not specified | Body Mass Index (BMI), Flow-mediated dilatation (FMD), Pulse wave velocity (PWV), Ankle-brachial index (ABI), Blood analyses, Body Fat (%), Heart rate (bpm), BP, FBG, HbA1c | Not observed | FBG level decreased significantly in both groups ($p < 0.05$). Significant decrease in HbA1c and BP were observed only in the WM group. FMD increased significantly ($p < 0.05$) in both groups but arterial stiffness was improved only in the WM group. Serum Cortisol (SC) level was reduced ($p < 0.05$) only in the WM group | Low |
| Fris et al (39) (2016) | New Zealand Adults with T1D and T2D | Mindful Self-compassion (MSC) | 71 randomised / completed 31 in the intervention group and 30 control analyzed 8 weeks | formal meditation together with formal and informal self-compassion practices aimed at developing the cognitive, behavioural, and physical capacities to soothe and comfort oneself when distressed | HbA1c | Self-compassion using the Self-Compassion Scale (SCS), depressive symptoms with the PHQ-9 and diabetes-specific distress with Diabetes Distress Scale (DDS) | MSC produced in the interven tion group statistically effect on self-compassion ($p < 0.001$ on T1 – T2 and T1 – T3), depression ($p < 0.05$ on T1 – T2 and $p < 0.001$ on T1 – T3), diabetes distress ($p < 0.001$ on T1 – T2 and T1 – T3) and HbA1c between baseline and follow-up ($p < 0.001$ on T1 – T3) | Moderate |

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| Jung et al (40) (2015) | South Korea Adults with T2D | Korean Mindfulness- Based Stress Reduc- tion (K-MBSR) | 84 pre-test recruited: 28 inter- vention group, 28 controls group 1 and 2 allocated (21 intervention, 18 control 1 and 17 control 2 completed) 8 weeks | Stress, diet, walk and home practice was recommended | SC, FBG and Vascular inflammatory responses | Stress response with DDS and Psychological response with Perceived Stress Response Inventory (PSRI) | All groups showed no statistically differences between the effects in the stress, glycemic control, or vascular inflammation. In K-MBSR and walking groups significant reductions in the levels of SC and vascular inflammatory responses ($p < 0.05$) | Moderate |
| Miller et al (41) (2014) | USA Adults with T2D | Mindful Eating Inter- vention in Diabetes (MB-EAT-D) | 32 randomised in MB-EAT-D group and 27 completed study / 36 randomized in Smart Choices control group and 25 completed the study 8 weeks (follow up at 1 and 3 months) | MB-EAT-D also included basic information regarding diet, physical activity, weight regulation, and glycaemia; however, no specific diet or activity goals were provided | Weight and Energy intake | The 110-item Block 2005 Food Frequency Questionnaire to assess usual intake, the 18- item diabetes-specific nutrition self-efficacy questionnaire to assess promoters of diabetes self-management, the 25-item Eating Self-Efficacy Scale was to assess difficulty in controlling overeating in various situations, the Three- Factor Eating Questionnaire (TFEQ) to assess cognitive control of food intake susceptibility to nonphysical hunger and disinhibition of control of food, the 21-item Beck Anxiety Inventory measures symptoms of anxiety and FFMQ for Mindfulness | At 3-month follow-up: significant improvement in qualitative outcome for both groups ($p < 0.0125$). Smart Choices increase in nutrition knowledge and self-efficacy than MB-EAT-D group ($p < 0.05$). MB-EAT-D had significant increase in Mindfulness, whereas the Smart Choices had significant increase in fruit and vegetable | Low |
| Tovote et al (42) (2014) | Netherlands Adults with T1D and T2D | MBCT and Cognitive Behaviour Therapy (CBT) | 94 randomized: 31 intervention MBCT, 32 intervention CBT, 31 control waiting list (9 drop out for MBCT and CBT, 2 lost to follow-up in MBCT and 4 lost to follow-up in CBT and in the waiting list) 8 weeks | Daily homework support and stress mediation | HbA1c | Well-being with Well- Being Index (WHO-5), Depression Rating Scale, anxiety with Generalized Anxiety Disorder 7 (GAD-7), diabetes related distress with PAID | MBCT and CBT reported significant reductions in depressive symptoms compared with waiting list (respectively: $p = 0.004$ and $p < 0.001$ respectively). Positive effects on anxiety, well-being, and diabetes-related distress in two intervention groups. Are not available effect on HbA1c value | Low |
| Youngwanichsetha et al (43) (2014) | Thailand Pregnant women with Gestational Diabetes Mellitus | Mindfulness Eating and Yoga exercise | 90 allocated intervention group (analyzed 85) / 90 allocated control group (analyzed 85) 8 weeks | Support Nutrition inter- vention and support for homework | FBG, 2-h postprandial blood glucose, and HbA1c | Not observed | The intervention group showed significantly reduced FBG, 2-h postprandial blood glucose and HbA1c value ($p < 0.05$) | Low |

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| Danasegaran et al (44) (2021) | India Adults (males) with T2D | Yoga | Yoga group 42 / control group 46 12 weeks | The subjects of study group were instructed to practice yoga in addition to Oral Antidiabetic Drugs (OAD) | Cardiometabolic and biochemical parameters measures: BP, Rate Pressure Product (RPP), Total Power (TP) of Heart Rate Variability (HRV), Low-Frequency to High-Frequency (LF-HF) ratio of HRV, Homeostatic Model of Insulin Resistance (HOMA-IR), lipid profile and lipid risk factors, Malondialdehyde (MDA), and high-sensitive C-reactive protein (hsCRP) | Not observed | LF-HF ratio ($p < 0.001$) were decreased in the study group after 12 weeks compared with the control group Biochemical parameters There was a significant decrease in the study group to FBG ($p < 0.001$), insulin ($p < 0.001$), HOMA-IR ($p < 0.001$), Total Cholesterol (TC) ($p < 0.001$), Low Density Lipoprotein (LDL) ($p < 0.001$), Triglycerides (TG) ($p = 0.006$) and High Density Lipoprotein (HDL) ($p = 0.014$) | Moderate |
| Viswanathan et al (45) (2021) | India Adults with T2D | Yoga | Yoga group 150 control group 150 3 months | Additional motivational intervention for homework practice | BMI, FBG, HbA1c, BP, LDL, HDL, VLDL, TG, BP, TC, Thio-Barbituric Acid Reactive Substances (TBARS), Prostacyclin synthase (PTGIS) and Superoxide dismutase (SOD) | Sleep quality using the Pittsburgh Sleep Quality Index (PSQI) | There was a significant reduction in BMI, FBG, HbA1c and TG ($p < 0.05$) in Yoga group as compared with non-Yoga group. There was marked improvement in the levels of Adiponectin, PTGIS and sleep quality (total score 3.4 ± 2.7 ; $p < 0.05$) among subjects practising Yoga | Low |
| Sharma et al (46) (2020) | India Adults with T2D | Yoga | Yoga group 52 / No Yoga 52 6 months | Not specified | BMI, waist-to-hip ratio (WHR), FBG and post-prandial serum glucose, TC, TG, HDL, LDL, Very Low Density Lipoprotein (VLDL) | Not observed | Significant improvement was observed in the yoga group when compared before and after yoga intervention. BMI showed a similar trend. A statistically significant decrease in TC, TG, LDL, VLDL, BMI, WHR and glycaemic control was observed in the experimental group compared with control ($p < 0.001$) | Moderate |
| Hegde et al (47) (2020) | India Adults with T2D | Hatha Yoga (HY) | HY group 20 / Sham Yoga group as control 20 3 months follow up | Printed and video supported the interventions | HbA1c, BMI, FBG, Waist circumference (WC), Systolic Blood Pressure (SP), Diastolic Blood Pressure (DP), MDA, Glutathione (GSH), Vitamin C and SOD | Not observed | There were significant reductions in MDA and SOD with both groups. MDA decreased by 12% in the Yoga group and by 8.5% in the Sham Yoga group. GSH and vitamin C improved in both groups. Yoga participants had a significant improvement in GSH (14%) than did the Sham Yoga group (5%). No significant differences between groups in FBG, HbA1c, WC, BMI and BP. DP did not show a significant reduction in the Yoga group unlike in Sham Yoga | Low |

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|-----------------------------------|---|---|--|---|---|--|--|----------|
| Bock et al (48) (2019) | USA Adult T2D | Yoga | 48 randomised: 24 Yoga group / 24 Standard Exercise Walking group (SE) 12 weeks (follow up 6/9 months) | Specified that only home practice was recommended | HbA1c, FBG and BMI | Quality of life with Diabetes- 39 Instrument, emotional distress on Diabetes area with PAID, FFMQ to measure Mindfulness | Median HbA1c at 6 months was 1.25 units lower for Yoga compared to SE (95% CI: -2.54 -0.04). Yoga group observed improvement in diabetes self-care, quality of life, and emotional distress. Increases in mindfulness were seen in Yoga but not in SE | Low |
| Datey et al (49) (2018) | India Adults (males) prisoner T2D | Ayurveda Rasahara Juice and Yoga combined | Group 1: Rasahara Juice and yoga 38 Group 2: Yoga 37 Group 3: control 37 3 months | Supplemented Ayurveda herbal juices | FBG and Post Prandial Blood Sugar (PPBS) levels, HbA1c and lipid profile | Not observed | Significant decreases FBG (-21.13 ± 21.16 mg/dL) and PPBS levels (-15.02 ± 14.89 mg/dL) in group 1 (p < 0.0001) and FBG level (20.62 ± 32.68 mg/dL) in group 2 (p = 0.0005). Increases in group 3 significance for PPBS level (9.62 ± 21.83 mg/dL) (p = 0.0022), HbA1c: group 1 -0.044 ± 0.059 mg/dL (p = 0.0002), group 2 +0.024 ± 0.456 mg/dL (not significant) and group 3 +0.365 ± 0.369 mg/dL (p < 0.0001) | Moderate |
| Sreedevi et al (50) (2017) | India Adults (females) T2D | Yoga or Peer Support (PS) | Randomised 124: Yoga group 41 (Analyzed 32) / Peer Support 42 (Analyzed 32) / Control 38 (Analysed 35) 3 months | Diet, Lifestyle support and home practice was recommended | HbA1c %, FBG, TC, BP (DP and SP), WHR, BMI | Quality of life with Morisky Medication adherence scale (MMAS-8) and pharmacological adherence | There was a trend in decline of FBG in the PS and Yoga group and of HbA1c in the Yoga group but not statistically relevant. A significant decrease was observed in DP and WHR in the Yoga group | Moderate |
| Shantakumari et al (51) (2013) | India Adults with T2D | Yoga | Yoga group 50 / Control group 50 3 month | Not specified | WC, WHR, BMI, TG, TC, HDL and LDL | Not observed | Non-significant decrease in BMI from 25.12 ± 1.54 to 23.59 ± 1.38 kg/m2. There was a significant reduction in TC, TG and LDL. Mean TC before yoga was 244.86 ± 28.09 mg/dl and was reduced to a mean of 219.56 ± 32.02 mg/dL. TG significant reduction from 151.88 ± 43.08 mg/dL to 130.11 ± 28.82 mg/ dL while the LDL reduced from 144.74 ± 28.45 to 120.51 ± 34.31 mg/dL. There was a non-significant elevation in HDL from 44.63 ± 9.35 mg/dL to 47.15 ± 8.17 mg/dL | Moderate |

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|--------------------------------|----------------------|----|---|--|---|--------------|--|----------|
| C. Cangelosi et al (52) (2008) | Cuba Adults with T2D | HY | HY group 77 / Conventional Physical Training (PT) 77 / Control group 77 24 weeks | Diabetes education, fundamental instructions of the management of disease and home practice were recommended | FBG, TC, LDL, VLDL, HDL and Oxidative stress indicators: MDA, protein oxidation (POX), Phospholipase A2 (PLA2), SOD and catalase activity | Not observed | FBG in the HY and PT groups after six months decreased by 29.48% and 27.43% respectively ($p < 0.0001$) and there was a significant reduction in TC in both groups ($p < 0.0001$). VLDL in the managed groups after six months differed significantly from baseline values ($p = 0.036$). MDA significantly decreased by 19.9% and 18.1% in the HY and PT groups respectively ($p < 0.0001$). SOD significantly increased by 24.08% and 20.18% respectively ($p = 0.031$). There was no significant difference in the baseline and 6 months activities of PLA2 and catalase after six months although the latter increased by 13.68% and 13.19% in the HY and PT groups respectively ($p = 0.144$) | Moderate |
|--------------------------------|----------------------|----|---|--|---|--------------|--|----------|

Mindfulness

Hussain et al (31) randomized 105 women over 55 with T1D and T2D with diabetic peripheral neuropathy [Mindfulness-Based Meditation (MM) 36, Progressive Relaxation Meditation (PM) 32 and Control Meditation (CM) 37] into three intervention groups. All the proposed interventions lasted 8 weeks and the 16 sessions of the MM group were supported with cognitive-behavioural therapy exercises. The MM and PM groups showed statistically significant effects ($p < 0.05$) on the average pain perceived in the last 24 hours compared with the start of treatment (28.7% MM and 39.7% PM). Regarding the reduction of pain, the MM group observed a reduction ($p < 0.01$) compared with the control group. According to the study by Rozworska et al (32) – which followed 32 subjects with T1D and T2D suffering from symptomatic diabetic peripheral neuropathy for eight weeks – it was shown that in the Mindfulness Based Stress Reduction (MBSR) group the quality of life and painful sensation improved even at three months of intervention. The researchers have observed how the time variable can influence the intervention, especially in subjects with a longer history of diabetic neuropathy. In the Ellis et al (33) study, young adolescents with T1D were enrolled in three study subgroups (16 for each group): MBSR, Cognitive Behavioral Stress Management (CBSM) and Diabetes Support Group (DSG). Measurements of the effects of the practice were carried out at the end of the intervention and after three months. MBSR has been shown to significantly reduce stress at the end of treatment ($p = 0.03$) and at the three-month follow-up ($p = 0.01$) but found no relevant effects in terms of glycaemic control. The DSG Group statistically improved glycaemic control at the end of the treatment and depressive symptoms at the three-month follow-up ($p = 0.01$). According to Armani et al (34) – who followed 29 patients with T2D (30 controls) for eight weeks with a weekly MBSR lesson and supported with specific awareness interventions – statistically significant benefits were observed in the experimental group compared with the control group, concerning FBG, HbA1C and on the qualitative stress management scales Hamilton Depression Rating Scale (HARS) and Hamilton Anxiety Rating Scale (HDRS) ($p < 0.05$). The study by Pearson et al (35) was developed for eight weeks through audiovisual material on 31 subjects with T2D (36 controls) and showed that the experimental group statistically significantly reduced depressive symptoms ($p = 0.02$) and stress ($p = 0.03$), while for glycaemic values

there was an overall but not valid improvement ($p = 0.06$). The study by Haenen et al (36) followed for eight weeks the experimental group of T1D and T2D patients (70 cases and 69 controls) with Mindfulness Based Cognitive Therapy (MBCT) and the support of a workbook that facilitated the repetition of the practice at home. The MBCT group demonstrated a major improvement in stress, depression, anxiety and in quality of life perceived. Mixed model analysis from the study by Nyklíček et al (37) – who followed 70 patients with both T1D and T2D (control group, $n = 69$) for 8 weeks – showed that gender and mindful acting were important moderators of efficacy of the proposed intervention. In the MBCT group, women showed greater decrease in anxiety and depression over time, than men. According to the study by Gainey et al (38) – who followed the experimental group of Buddhist Walking Meditation (WM, $n = 12$) for 12 weeks [11 controls in Walking Traditional Exercise group (WE)] – statistically significant improvements for FBG were observed in both groups ($p < 0.05$). Improvements for HbA1c and BP were observed only in the WM group. Flow-mediated dilatation (FMD) improved significantly in both groups ($p < 0.05$) but arterial stiffness improved only in the WM group. Blood cortisol was statistically significantly reduced only in the WM group ($p < 0.05$). In the Friis et al (39) study, the experimental group of subjects with T1D or T2D (32 subjects) and 31 controls were followed for eight weeks with specific cognitive-behavioural practices for stress management. MSC produced statistically significant effects both at the end of 8 weeks (T2) and at the three-month follow-up (T3) for self-compassion ($p < 0.001$ between T1 - T2 and between T1 - T3), depression ($p < 0.05$ between T1 - T2 and $p < 0.001$ between T1 - T3), diabetes stress management ($p < 0.001$ between T1 - T2 and T1 - T3) and for HbA1c between initiation of practice and follow-up ($p < 0.001$ on T1 - T3). The study by Jung et al (40) included 28 subjects with T2D for each subgroup: Korean Mindfulness-Based Stress Reduction (K-MBSR), walking and educational group (important drop out). The intervention lasted eight weeks and all groups had an educational basis in diabetes management and minimal practice and stress management techniques. No statistically significant differences were observed between the groups in terms of stress, glycaemic control and vascular inflammation. The experimental group and the control group observed a reduction in cortisol levels and in the vascular inflammatory response ($p < 0.05$). A reduction in the stress response was observed in the two control groups. The study

by Miller et al (41) enrolled 27 subjects with T2D in the intervention group and 25 in the control group. The main intervention focused, with a duration of eight weeks, on a specific Mindfulness program on the management of correct food intake and the consequent reduction in weight and change in quality of life. Qualitative and quantitative measurement follow-ups of the intervention were planned at the end of the course, one month and three months. At three months, significant improvements in qualitative outcomes were observed by specific surveys for both groups ($p < 0.0125$). The group of Smart Choices controls increased nutritional and self-care knowledge compared with the intervention group ($p < 0.05$). The Mindful Eating Intervention in Diabetes (MB-EAT-D) group observed an improvement in mindfulness. In the study by Tovote et al (42), three groups of patients were followed for eight weeks: MBCT, Cognitive Behavior Therapy (CBT) and the waiting list. In the MBCT group, the subjects involved were followed with single practice sessions of 45-60 minutes and supported for daily practice for about 30 minutes. The variations in terms of depression, anxiety, general well-being and pathology were evaluated with specific qualitative scales and under the quantitative aspect through the variation of HbA1c. MBCT and CBT observed a significant reduction from the checklist for depressive symptoms ($p = 0.004$ and $p < 0.001$, respectively). No relevant differences regarding pre-post-surgery HbA1c. In the study by Youngwanichsetha et al (43) – who analysed 85 women with gestational diabetes via Mindfulness Eating and Yoga support (85 controls) – demonstrated a statistically significant improvement in the overall glycaemic picture by reducing FBG, 2-h postprandial blood glucose and HbA1c ($p < 0.05$).

Yoga

In the study by Danasegaran et al (44) – who followed, after an initial specific preliminary training, the experimental group for 12 weeks with 5 weekly meetings and favoured home practice at the weekend – observed a statistically significant improvement on cardio-metabolic parameters in the post-test Low-Frequency (LF) to High-Frequency (HF) ratio ($p < 0.001$), compared with the control group and on biochemical parameters [FBG ($p < 0.001$), insulin ($p < 0.001$), Homeostatic Model of Insulin Resistance [HOMA-IR ($p < 0.001$)], Total Cholesterol [TC ($p < 0.001$), Low Density Lipoprotein [LDL ($p < 0.001$)], Triglycerides [TG ($p = 0.006$) and High

Density Lipoprotein [HDL ($p = 0.014$)]. According to Viswanathan et al (45) – who concluded the study with 150 subjects affected by T2D followed by 5 lessons of 50 minutes per week for three months – statistically valid reductions were observed for BMI, FBG, HbA1c and TG ($p < 0.05$) in the experimental group compared with the control group. Improvements were also observed in Adiponectin, Prostacyclin synthase (PTGIS) and quality of sleep in subjects who practiced Yoga (total score 3.4 ± 2.7 ; $p < 0.05$). According to Sharma et al (46), who followed the experimental group of T2D subjects (52 subjects in the intervention group and 52 control) with an intensive approach of 5 meetings per week for six months, statistically significant improvements ($p < 0.001$) were found in the group Yoga versus non-Yoga in terms of lipid profile [TC, TG, LDL, Very Low Density Lipoprotein (VLDL)], BMI, WHR and glycaemic control (FBG and post prandial serum glucose). The study by Hegde et al (47) followed two groups for 3 months: Hatha Yoga (HY) for the experimental group ($n = 20$) and simulated Yoga for the control group ($n = 20$). Significant reductions in Malondialdehyde (MDA) and Superoxide Dismutase (SOD) values were observed for both groups; those of MDA decreased by 12% in the Yoga group and by 8.5% in the control group. Glutathione (GSH) and vitamin C showed improvement in both groups. Participants in the Yoga group had a significant improvement in GSH (14%) compared with the control group (5%). No significant differences between groups for FBG, HbA1c, Waist Circumference (WC), BMI, and BP; Diastolic Blood Pressure (DP) values did not show a significant reduction in the Yoga group unlike the control group. In the Bock et al study (48) on subjects affected by T2D (24 in Yoga group and 24 controls) predicted that the group of cases was inserted in the Yoga arm while that of the controls in that of standard exercises at different intensities of physical activity (exercise bike, walking or treadmill). Six months after the end of the bi-weekly intervention lasting 60 minutes each for 12 weeks, the Yoga group demonstrated a reduction in HbA1c up to 1.25 compared with the control group (95% CI: $-2.54 - 0.04$). The Yoga group also observed improvements in self-care, quality of life, stress management and perceived well-being thanks to Mindfulness. According to Datey et al study (49), who divided in three subgroups [Yoga Rasahara Juice (group 1), Yoga (group 2) and control group (3)] for three months a population of male inmates with T2D, observed a significant reduction in about the levels of FBS [-21.13 ± 21.16 mg/dL] and post prandial blood

sugar [PPBS (-15.02 ± 14.89 mg/dL) in group 1 ($p < 0.0001$) and for the levels of FBG (20.62 ± 32.68 mg/dl) in group 2 ($p = 0.0005$)]. Significant increase was noticed for group 3 for PPBS levels (9.62 ± 21.83 mg/dL; $p = 0.0022$). Recorded changes in HbA1c were: group 1, -0.044 ± 0.059 mg/dL ($p = 0.0002$), group 2, $+0.024 \pm 0.456$ mg/dL (not significant) and group 3, $+0.365 \pm 0.369$ mg/dL ($p < 0.0001$). The study by Sreedevi et al (50) randomised women with T2D in three arms in an age group between 35 and 65 years, followed for three months; Yoga group was formed by 41 women (analyzed 32), Peer Support by 42 women (analyzed 32), and control group by 38 women (analyzed 35). Nutritional and healthier lifestyle information from industry experts has been added to the Yoga group. A reduction in FBG was observed in the Peer group and in the Yoga group and in HbA1c in the Yoga group but not in a statistically significant manner. A reduction in DP and WHC values were observed in the Yoga group. According to Shantakumari et al (51) – who followed 50 diabetic patients with dyslipidaemia for three months and compared them to a control arm – they observed statistically significant improvements in the pre- and post-test intervention group for WC and TG ($p < 0.05$) and $p < 0.001$ for TC and LDL. In the study by Gordon et al study (52), who followed three intervention arms for 24 weeks after the randomisation of subjects with TD2, a statistically significant reduction was observed for glycaemia in the Hatha yoga (HY) and Conventional Physical Training (PT) groups ($p < 0.0001$). Regarding oxidative stress: MDA statistically significant reduction in the HY and PT groups ($p < 0.0001$), SOD statistically significantly increased ($p = 0.031$) respectively by 24.08% PT and 20.18% in HY, Phospholipase A2 (PLA2) and catalase activity, although increased after six months 13.68% PT and 13.19% in HY, they did not find significant values ($p = 0.144$).

Discussion

The review conclude that Yoga and Mindfulness could support traditional treatments and promote a holistic approach to self-care of diabetes. The stakeholder could consider Yoga or Mindfulness a valid support of diabetes care. The RCTs included in the review demostred that Yoga and Mindfulness provide a protective stress management (33, 35–37, 39, 42, 48) but have a positive effect on clinical metabolic parameters such as HbA1c (33, 34, 39, 43, 45, 48, 49), FBG (34, 38, 43–45, 49, 52), BMI (45, 46), lipid

profile (44–46, 51, 52) and oxidative stress (38, 40, 47, 52). Although further molecular investigation is required, a mechanism has been proposed for such benefits of Yoga in the management of T2D. A study found that Yoga has a beneficial effect on DNA damage in T2D patients in peripheral blood mononuclear cells, mediated by the mitigation of oxidative DNA damage and enhancement of DNA repair (53). For possible experimental framework primary DNA damage might be employed as a useful biomarker in that context, also adopting non-invasive sampling procedures to obtain mononuclear leukocytes from alternative specimens (*e.g.*, saliva) which may be better accepted by individuals in the absence of risk perception (54). Moreover, as overweight/obesity and metabolic syndrome are often associated with diabetes and/or diabetes risk (55, 56), such beneficial activities might also be proposed to obese patients, regardless of the presence of diabetes. The recent Covid-19 pandemic has certainly redesigned a new way of treating and managing both emergencies and several chronic diseases (57–59), and Yoga or Mindfulness can improve a complex care and support specific Clinical Pathway of Diabetes for all health workers (60–62). The development of specific care networks organized on several levels of assistance is an increasing prerogative for the management of chronic diseases in general - but above all - for the diabetes (63–65). Structured organizational methods could favour the assistance and prevention of complications for diabetics and patients with chronic diseases in general (63, 66). It could be strategic to care for operators who direct their assistance interventions on lifestyle disciplines, consequently favouring attention to fragile subjects such as diabetic patients (67). The review has the limit of not being able to standardise the Yoga and Mindfulness interventions to be included in the study also because the disciplines themselves have both applicative and theoretical variability that does not allow easy comparisons. Another significant limitation was having included extremely heterogeneous papers, both in terms of the study populations and the age of the participants.

Conclusions

Due to its low operating costs and the almost absolute impossibility of incurring major side effects, the managers of personal services could consider Yoga and Mindfulness as valid complementary alternatives to support conventional diabetes care and for a slower

chronicity. An increasingly fragile population with a growing need to reduce overall stress levels could find alternative practices in Yoga and Mindfulness to support conventional therapies. This review is also proposed as a theoretical summary of future experimental paths that may involve diabetic subjects who intend to consider Yoga and Mindfulness as a valid support for the treatment and prevention of possible post-Covid-19 stress complications and Clinical Care Pathway.

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Not applicable.

Riassunto

Yoga o Mindfulness per il Diabete: una scoping review per un progetto sperimentale

Introduzione. Nel mondo circa un adulto su 11 soffre di diabete con un'incidenza in costante aumento; dai 529 milioni di malati registrati nel 2021, le proiezioni salgono a circa 1.31 miliardi nel 2050. In Italia è diabetico il 5,9% della popolazione, con una prevalenza più elevata con l'aumentare dell'età e nel Sud del Paese. Lo Yoga e il Mindfulness potrebbero rappresentare un valido supporto per la cura dei soggetti diabetici soprattutto in un contesto assistenziale stressante come la pandemia da Covid-19.

Disegno dello studio. Per il raggiungimento degli obiettivi dello studio è stata condotta una revisione di scopo della letteratura. Gli interventi di Yoga o Mindfulness su soggetti diabetici sono stati analizzati in modo specifico e i dati quali-quantitativi raccolti nei trial controllati randomizzati selezionati sono stati approfonditi per un'eventuale meta-analisi.

Metodi. La revisione è stata condotta da due ricercatori indipendenti e un terzo è stato consultato in caso di conflitto. Il metodo PRISMA è stato utilizzato sia per la selezione che per l'appropriatezza degli studi da includere. PICOS specifici e strategie di ricerca sono stati sviluppati sui database PubMed, Embase e PsycINFO. I criteri di inclusione scelti sono stati: trial controllati randomizzati, dissertazioni complete e documenti in inglese, pubblicati entro il 31 maggio 2022.

Risultati. La revisione ha incluso 22 studi; 12 sulla Mindfulness, 9 sullo Yoga e uno su entrambe le discipline. Di questi, uno ha studiato pazienti con diabete di primo tipo, 14 con diabete di secondo tipo, 6 con entrambi e uno con diabete gestazionale. Solo uno ha studiato soggetti adolescenti, mentre gli altri 21 si sono concentrati su soggetti adulti. Dallo studio è emerso che lo Yoga e la Mindfulness hanno un forte potenziale non solo sulla gestione dello stress, ma anche su importanti parametri clinico-metabolici.

Conclusioni. La recente pandemia da Covid-19 ha sicuramente ridisegnato un nuovo modo di trattare e gestire le malattie croniche come il diabete. Una popolazione sempre più fragile, e con la crescente necessità di ridurre i livelli complessivi di stress, potrebbe trovare pratiche alternative nello Yoga e nella Mindfulness per supportare le terapie convenzionali.

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