Indian J Med Res 161, January 2025, pp 72-80
DOI: 10.25259/IJMR_1227_2024

Original Article

The effect of progressive muscle relaxation therapy on diabetes distress & anxiety among people with type 2 diabetes

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Received August 20, 2024; Accepted November 26, 2024; Ahead of print February 7, 2025; Published February 14, 2025

***Background & objectives*: Diabetes distress (DD) is a mental condition that can develop in people with diabetes and shares characteristics with stress, anxiety, and depression. The aim was to determine the effect of Jacobson's Progressive Muscle Relaxation (PMR) therapy on DD, anxiety, glycemic control, hemodynamic and lipid measures among people with type 2 diabetes (T2DM).**

***Methods*: A total of 80 participants were recruited for this prospective randomised intervention study and divided into two groups equally; group 1 (Control) (n=40) received general counselling for stress reduction and group 2 (Intervention) (n=40) received PMR therapy and general counselling for stress reduction. A pre-, and post-test was done with diabetes distress Scale (DDS) and generalized anxiety disorder (GAD) Scales. Baseline data on anthropometric, hemodynamic, biochemical details were collected and repeated after three months. Thirty-six participants, with four dropouts in each group, reported for follow up. Diabetes medication regimens in both groups remained unchanged throughout the study period.**

***Results*: There was a significant reduction in the total mean scores of DDS (Pre *vs*. Post) (3.8 *vs*. 1.6) and GAD Scale (17.9 *vs.* 6.3; *P*<0.0001) in the intervention group. The PMR therapy group showed a significant reduction in HbA1c, fasting and post prandial (PP) glucose levels with HbA1c (baseline *vs.* follow up; 9.2% *vs*. 7.6%), fasting (194.5 mg/dl *vs*. 142.4 mg/dl) and PP glucose levels (266.5 mg/dl *vs*. 175.5 mg/dl) (*P*=0.001) whereas control group showed an increase in HbA1c, fasting and PP glucose levels. The impact of PMR therapy was also reflected in the lipid profile. Seventy per cent of the intervention group participants followed PMR therapy regularly.**

***Interpretation & conclusions*: Our study findings highlighted that PMR therapy had a positive effect on diabetes distress and anxiety among people with T2DM. It also improved glycemic control and can be used as an adjunctive to the medications for better management of T2DM.**

Key words Anxiety - diabetes distress -glycemic control - Jacobson's PMR therapy - T2DM

Type 2 Diabetes (T2DM) has reached epidemic proportions in India. About one-third of individuals with diabetes face social, psychological, or both challenges that hinder their ability to self-manage their

condition[1]. People with diabetes are prone to distress in their day-to-day lives. Diabetes has a significant influence on both physical and mental health[2,3].

Diabetes distress (DD) is characterised by patients' emotional burden about the management of their disease; crucial factors that set distress apart from depression are emotional despair, support, and access to care. DD is the emotional distress caused by living with diabetes and the difficulty of constant daily self-management. Such emotional distress causes stress hormones like cortisol, epinephrine and glucagon to rise, which triggers the sympathetic nervous system. It can be an additional reason for elevated blood glucose levels in individuals with diabetes[4]. DD was reported to be a substantial health issue for adults with T2DM[5]. DD management involves monitoring glucose levels, following a nutrition plan, exercising regularly, and taking proper medications.

Generalized anxiety disorder (GAD) is one of the most common anxiety disorders, with lifetime prevalence rates estimated at 5.7 per cent[6]. Early recognition, and providing appropriate treatment may reduce individual distress, disability status and associated cost of GAD to the society. The prevalence of GAD was higher among people with T2DM than in the general population[7].

Several non-pharmacological therapies are available such as breathing exercises, thermotherapy, meditation through guided imagery *etc*., which bring a positive impact on an individual's mind and body. Progressive muscle relaxation (PMR) technique proposed by Dr. Edmund Jacob in 1976 for a duration of 15 min helps people unwind, become more at ease, lessen their anxiety, tension and rage[8]. It uses a gradual, continuous practice approach and thereby reduces the tension and produce a calming effect to the mind[8]. PMR can be used as an adjunctive therapy which is easy to learn, cost effective, and is based on procedures with no side effects.

Screening and treating mood disorders is crucial, as they can negatively impact an individual's well-being[9]. PMR has been proven to alleviate anxiety and depression in a variety of illnesses, including asthma[10], pulmonary artery hypertension[11], coronary bypass surgery[12], multiple sclerosis[13], chemotherapy-induced nausea[14]. The benefits have been proved on various other disease conditions. However, the impact of Jacobson's PMR on DD, GAD and glycemic control in individuals living with diabetes has not been evaluated. In the Indian context, there isn't much literature available on this topic. Hence, this study was aimed to determine the effect of PMR therapy on diabetes distress and anxiety and also on the glycemic control, hemodynamic, and lipid profile of people with T2DM.

Materials & Methods

This prospective randomised intervention study was conducted by the department of Psychology, Prof. M Viswanathan Diabetes Research Centre, Chennai after obtaining the ethical approval by the Ethics Committee of the Institution. This randomised study screened 578 participants aged 25-60 yr with T2DM from MV Diabetes and Prof. M Viswanathan Diabetes Research Centre for diabetes in north Chennai, India, between July to August 2023 and were followed up till October 2023.

Study design: Out of 578 participants those with HbA1c >10 per cent (n=124), severe complications (n=56), and other serious illnesses (n=12) were excluded and the remaining 386 (209M:177F) participants were screened with Diabetes Distress Scale (DDS)[15] and Generalized Anxiety Disorder (GAD) Scale[16]. The participants with DDS score of <3 and with a GAD score of Zero indicated that they did not have DD and Anxiety; hence, they were excluded. The remaining participants were enrolled into two study groups through computer-generated random numbers after screening (Figure). A written informed consent was obtained from all the participants after discussing the benefits and steps of PMR therapy.

Inclusion and exclusion criteria: People with HbA1c between eight per cent and 10 per cent, those who were assessed for DD and anxiety by DDS and GAD Scale and those who had never undergone PMR in the past and were willing to participate in the therapy session were included. People with HbA1c >10 per cent and with severe microvascular complications or any other serious illness were excluded.

Sample size: Forty participants in each group are required to detect a mean difference of 0.8 of HbA1c per cent with 90 per cent power, five per cent precision, and assuming a 20 per cent dropout rate[17].

Study groups: A total of 80 participants were included after screening based on the criteria mentioned above and were enrolled into group 1 (Control group) (n = 40) (M 26:F14) and group 2 (Intervention group) (n =

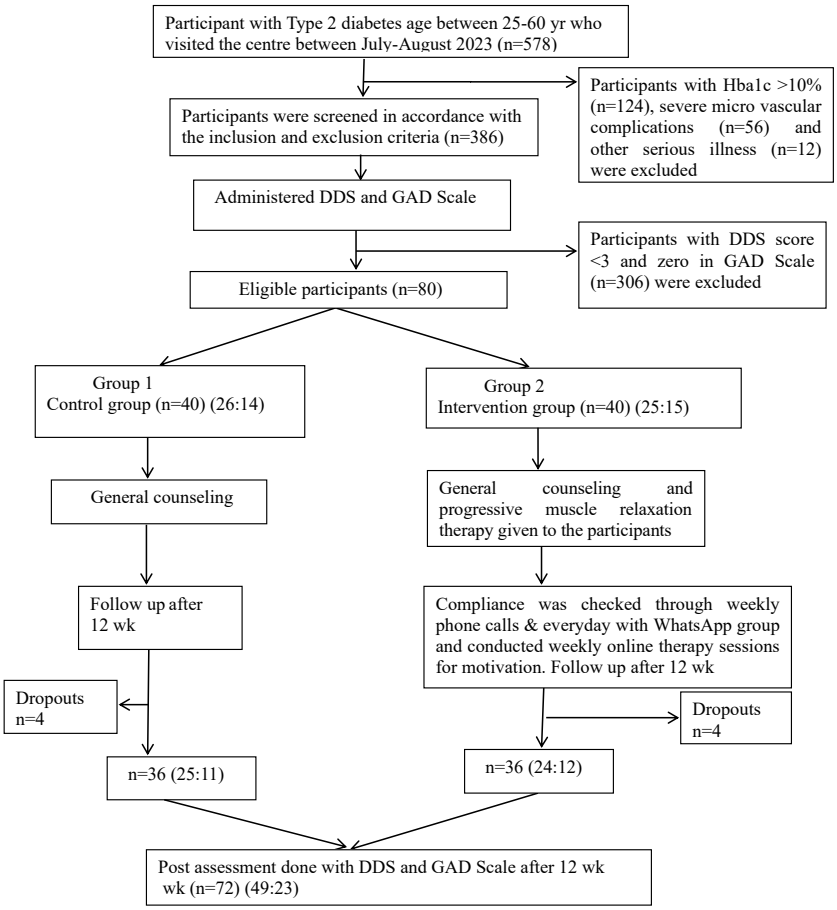

Figure. The flowchart shows the screening and recruitment of the participants, and the procedure followed in the study. DDS, diabetes distress Scale; GAD, generalized anxiety disorder Scale.

40) (M 25:F15) through computer-generated random numbers. After 12 wk, 36 participants from group 1 with four dropouts (2 due to personal reasons,1 due to migration and 1 due to non-response to repeated calls) and 36 participants from group 2 with four dropouts (2 dropouts due to non-adherence to therapy, 2 due to migration and personal reason) reported for follow up. Anthropometric, hemodynamic and biochemical parameters were repeated after three months. The final analysis was carried out with 72 participants. During the study period, the treatment regimen for diabetes remained unchanged in both the study groups (Figure).

Data collection: Data on educational, economic status, hypertension, tobacco use, alcohol consumption, and smoking behaviour, anthropometric measurements like height and weight were collected using a semi-structured questionnaire. Body mass index (BMI) (kg/m^2) was calculated. Blood pressure was monitored using a standard mercury sphygmomanometer.

Tools: The DDS is a standardised 17-item self-report measure. The scores for each item range from 1 (no distress) to 6 (severe distress), reflecting the level of distress the respondent experienced in the previous month. This DDS17 yields a total score with four subscale scores, each addressing different kinds of distress. A mean item score of three or more is regarded as a clinically significant level of distress[15]. The seven-item GAD-7 self-report Scale was used to evaluate the key symptoms of generalized anxiety disorder[16]. A 4-point Likert-type Scale has been applied to rate the items (0 being not at all and 3 being almost every day). More severe GAD symptoms are indicated by higher scores, which range from 0 to 21.

Methodology: Blood samples were collected, and HbA1c, fasting, postprandial (PP) glucose and lipid levels were measured at baseline and follow up. Baseline data on anthropometric, hemodynamic, and biochemical details were collected and repeated after three months.

Intervention: The group 1 participants were given general counselling for stress reduction and advised to use regular oral hypoglycemic agents (OHA). The group 2 participants were instructed to do PMR by tensing the appropriate muscle group and sustaining the tension for up to 5 sec before relaxing it for 10 sec, along with general counselling and advised to continue the therapy every day with OHA. Both the groups were advised to follow the prescribed diet throughout the study period.

Progressive muscle relaxation therapy: The sequence used in PMR therapy was toes, left foot, left lower leg, left upper leg, and the same sequence for the right leg, hip and buttocks, stomach, chest, shoulders and shoulder blades, back, left hand, left lower arms, and left upper arms, and the same procedure followed for the right hand followed by the neck, forehead, eyes, cheeks, mouth, and jaw. After this, 15 min procedure, the participants were asked to relax in a meditative state for 5 min in the lying position. The whole procedure was taught by the trained psychologist, and a recorded voice version of the therapy was given to each participant for daily practice.

Compliance: The participants were advised to do PMR daily. They were considered as 100 per cent compliant if they did PMR every day. The group 2 participants were joined in a WhatsApp group and asked to drop a done symbol every day after doing the therapy. Weekly therapy sessions were conducted for these participants through video conferencing to motivate them to do the therapy.

Statistical analysis: Per protocol analysis was used and the final analysis was carried out with 72 participants. Mean ± Standard deviations (SD), number and percentages were reported for continuous and categorical variables, respectively. Chi-square, independent and paired t-test were employed for comparison between and within the groups. A *P* value of <0.05 was considered significant. The analysis was done using SPSS software version 28 (IBM Corp., Armonk, NY, USA).

Results

Table I summarises the baseline characteristics of the study groups. The mean age was similar in both the groups. Sixty-four per cent of the participants in the control and 47 per cent of them in the intervention group completed school-level education. The duration of diabetes was similar in the study groups. Both the study groups were matched for their age and duration of diabetes. The mean age was 50.9 yr in group 1 and 50.1 yr in group 2, respectively. The mean duration of diabetes was 6.7 yr in group 1 and 6.9 yr in group 2. Most of the participants in both groups were from middle-class economic status, followed by upper-middle-class, and very few respondents were from lower socioeconomic status. Fifty-three per cent from the control and 44 per cent of participants from the intervention group reported walking as a form of physical exercise and following dietary advice. About a third (30.6%) of group 1 participants were on sulphonylureas, 25 per cent used biguanides, and 44.4 per cent used a combination of both, while 33.3 per cent were on sulphonylureas, 16.7 per cent used biguanides and 50 per cent used both in group 2. Nearly 70 per cent participants in the intervention group practiced the PMR therapy regularly and the remaining practiced twice or thrice in a week.

Smoking and alcohol consumption were similar in both groups. The presence of hypertension was significantly higher in group 1 (28%) than in group 2 (8%; P=0.032). Eleven per cent of participants in group 1 and 17 per cent of participants in group 2 were confirmed to have dyslipidemia. Nineteen per cent in both groups had the presence of both hypertension and dyslipidemia.

Table II compares the anthropometric, hemodynamic, and biochemical details of the study groups at baseline and follow up. In both groups, no significant reduction was noted in BMI and systolic blood pressure. No change was noted in diastolic blood pressure in group 1, whereas a significant reduction was noted in group 2 (*P*=0.001) at follow up.

Both the groups were matched for HbA1c at baseline. The group who received the PMR therapy showed a statistically significant reduction in HbA1c percentage (baseline *vs*. follow up; 9.2 *vs*. 7.6), fasting (194.5 *vs*. 142.4) and PP glucose levels in mg/dl (266.5 *vs*.175.5; *P*=0.001).The control group showed an increase in HbA1c, fasting and PP glucose levels. The impact of PMR therapy was also reflected in the lipid profile of the group 2 participants, which showed a significant reduction in lipid parameters like triglycerides, total and LDL cholesterol. HDL cholesterol increased significantly in group 2 (*P*=0.005). Lipid profile did not show any significant difference in control group except for HDL cholesterol which decreased significantly (*P*=0.009).

Table I. The baseline characteristics of the control and intervention groups

Variables	Group 1 (Control) n=36	Group 2 (Intervention-PMR therapy) n=36	Chi-square value	*P* value
Age in yr (mean±SD)	50.9±6.9	50.11±7.1		0.627
Age categories (yr)				
25-35	1 (3)	1 (3)	0	1
36-45	5 (14)	7 (19)	0.4	0.527
46-55	19 (53)	20 (56)	0.056	0.813
>55	11 (31)	8 (22)	0.644	0.422
Gender				
Male	25 (69)	24 (67)	0.064	0.8
Female	11 (31)	12 (33)	0.064	0.8
Educational status				0.527
Primary school	4 (11)	3 (8)	0.158	0.69
Secondary school	19 (53)	14 (39)	1.399	0.236
Under graduation	7 (19)	10 (28)	0.693	0.405
Post graduation	6 (17)	9 (25)	0.758	0.383
Duration of diabetes (yr)	6.7±3.6	6.9±4.3		0.847
Monthly family income (INR)				
< 50000	4 (11)	5 (14)	0.127	0.721
=50000 to 100000	17 (47)	15 (42)	0.225	0.635
>100000	15 (42)	16 (44)	0.057	0.811
Physical activity				
Walking	19 (53)	16 (44)	0.5	0.417
Exercise	-	2 (6)		-
Yoga	1 (3)	1 (3)	0	1
Comorbidities				
Hypertension	10 (28)	3 (8)	4.599	0.032
Dyslipidemia	4 (11)	6 (17)	0.465	0.495
Hypertension/dyslipidemia	7 (19)	7 (19)	0	1
Smoking				
Ex- users	3 (8)	1 (3)	1.059	0.303
Current users	1 (3)	1 (3)	0	1
Alcohol consumption				
Ex- users	5 (13)	4 (11)	0.127	0.722
Current users	2 (6)	3 (8)	0.215	0.643

Values are n (%). INR, Indian rupees; PMR, progressive muscle relaxation; SD, standard deviation

Table III shows the mean item scores of the DDS and GAD-7 within the study groups. The scores of four subscales of DDS: emotional, physician-related, regimen-related, and interpersonal distress were significantly decreased at follow up in group 2 participants as compared to baseline and a significant decrease was also noted in the total score of DDS (3.8 *vs*. 1.6) and GAD Scale (17.9 *vs*. 6.3) (P<0.0001) among the participants who followed the PMR therapy. In group 1 participants, the emotional, interpersonal and regimen-related distress scores showed a minimal increase in the follow up mean scores, whereas physician-related distress showed a minimal decrease among the participants. The total scores of DDS (3.9 *vs*. 4.4; P=0.001) and GAD Scale (17.4 *vs*. 18.6; P=0.015) showed a significant increase in group 1 participants.

Table II. Comparison of anthropometric, haemodynamic and biochemical details of the study groups at baseline and follow up visit

Characteristics	Group 1 (control) n=36				Group 2 (Intervention-PMR therapy) n=36				Comparing between the groups			
	Baseline (mean±SD)	Follow up (mean±SD)	t value	*P* value	Baseline (mean±SD)	Follow up (mean±SD)	t value	*P* value	Baseline		Follow up	
									t value	*P* value	t value	*P* value
BMI (Kg/m^2)	27.5±3.4	27.7±3.5	1.07	0.237	27.1±4.3	27.2±4.4	0.33	0.517	0.50	0.55	0.54	0.562
Systolic BP (mm/Hg)	122.2±12.1	121.7 ±11.9	0.73	0.561	122.4±9.9	121.4 ±3.5	0.76	0.576	0.09	0.649	0.13	0.936
Diastolic BP (mm/Hg)	73.8±7.7	74.4±6.4	0.66	0.377	75.2± 7.5	71.1±3	3.68	0.001	0.78	0.647	2.83	0.004
HbA1c (%)	9.0±0.8	9.4±1.3	2.14	0.063	9.2±0.5	7.6± 1.1	8.69	0.001	1.16	0.140	6.34	0.001
Fasting glucose (mg/dl)	165.6±53.4	176.3±50.6	1.43	0.216	194.5±47.8	142.4±45.7	6.73	0.001	2.42	0.016	2.98	0.003
PP glucose (mg/dl)	227.5±74.9	238.3±72.4	0.98	0.363	266.5 ±71.4	175.5±63.9	7.59	0.001	2.26	0.017	3.9	0.001
Total cholesterol (mg/dl)	145.6±35.7	149.2±48.6	0.64	0.681	173.0±52.6	157.1±34.5	1.91	0.087	2.59	0.027	0.79	0.386
LDL cholesterol (mg/dl)	74.6±25.2	78.6±32.7	0.92	0.521	85.6±28.9	78.7±23.5	1.31	0.228	1.72	0.102	0.02	0.735
HDL cholesterol (mg/dl)	47.1±7.7	43.8±9.4	2.73	0.009	48.1±7.5	50.6±7.7	2.97	0.005	0.56	0.844	3.33	0.004
Triglycerides (mg/dl)	129.3±50.9	133.9±56.1	0.57	0.309	165.9±92	123.5±57.4	3.91	0.001	2.09	0.123	0.78	0.275

Values are mean±SD. BMI, body mass index; BP, blood pressure; PP, post prandial; LDL, low density lipoprotein; HDL, high density lipoprotein

Table IV compares the mean difference of DDS and GAD-7 scores between the baseline and follow up visit in emotional burden, physician-related, regimen-related, interpersonal distress. Total DDS score was significantly different in group 2 when compared to group 1.The mean difference score of GAD between the groups was also statistically significant, with a greater reduction in group 2 (P=0.001). Overall, there was a greater reduction in the total DD score and anxiety disorder score in the participants of the PMR therapy group. Seventy per cent participants in group 2 followed PMR therapy everyday and the remaining 30 per cent followed six days per week. Out of the 40 participants all joined the weekly therapy sessions for 10 wk, two were absent for the 11th wk and three were absent for the 12th wk but they continued their regular therapy practice.

Discussion

People living with diabetes are more likely to experience stress because of the anguish of their disease. This condition leads to DD and anxiety. This study helped to determine the effectiveness of PMR therapy on DD and anxiety among people with T2DM. Numerous measurements such as anthropometric, lipid, hemodynamic parameters and glycemic control were used to evaluate the effectiveness of the therapy. This study also examined the impact of PMR therapy along with medications on the above parameters and demonstrated an encouraging impact on a number of outcome indicators. The findings illustrated that consistent practice of PMR therapy combined with conventional medication showed a significant improvement in glycemic control, and reduction in lipid and hemodynamic parameters. There was a greater reduction noted in the total DD and anxiety scores among those who followed the PMR therapy. Similar educational backgrounds and having identical socioeconomic status, BMI, age, glycemic status, and duration of diabetes between the study groups prevented confounding effect on intervention outcomes. Using a successful follow up strategy of sending daily messages through WhatsApp groups and making phone calls, our study yielded a response rate of 90 per cent. In our study, the impact of PMR therapy was most apparent in relation to glycemic status and the decrease in diabetes distress and anxiety scores. More than 70 per cent of the participants in the intervention group practised PMR therapy regularly to achieve favourable outcomes.

Table III. Comparison of mean item scores of DDS and GAD-7 anxiety Scale between the study groups

Characteristics	Group 1 (control) n=36				Group 2 (Intervention-PMR therapy) n=36			
	Baseline (mean±SD)	Follow up (mean±SD)	t value	*P* value	Baseline (mean±SD)	Follow up (mean±SD)	t value	*P* value
Emotional burden	5.1±0.7	5.5±0.4	4.54	0.001	4.8±0.9	1.8±0.6	20.9	0.001
Physician related distress	1.3±0.6	1.2±0.6	2.77	0.008	1.3±0.4	1.0±0.2	3.81	0.001
Regimen related distress	4.8±0.6	5.0±0.6	2.47	0.023	4.4±1.1	4.3±1	3.4	0.003
Interpersonal distress	3.1±1.1	3.6±1.2	5.48	0.001	3.2±4.1	1.5±0.6	2.57	0.001
Diabetes distress Scale total score	3.9±0.6	4.4±0.7	7.01	0.001	3.8±0.6	1.6±0.5	27.28	0.001
Generalized anxiety disorder Scale total score	17.4±3	18.6±2.6	2.33	0.015	17.9±2.6	6.3±3.3	19.05	0.001

Values are mean±SD

Table IV. Comparison of mean difference of DDS and GAD-7 anxiety Scale scores between the study groups

Characteristics	Group 1 (control) n=36; (mean±SD)	Group 2 (intervention-PMR therapy) n=36; (mean±SD)	*P* value
Emotional burden	0.4±0.6	-3.0±0.9	0.001
Physician related distress	-0.1±0.2	-0.2±0.4	0.061
Regimen related distress	0.2±0.4	-0.1± 0.2	0.001
Interpersonal distress	0.5±0.5	-1.7±4.1	0.001
Diabetes distress Scale total score	0.5±0.4	-2.1±0.5	0.001
Generalized anxiety disorder Scale total score	1.3±3.2	-11.6±3.7	0.001

Values are mean±SD

Our findings were consistent and similar to the previous reports from other populations[18,19]. A very recent study from Indonesia showed that PMR reduced stress and glucose levels in people with T2DM. The authors suggested that Jacobson's PMR approach could help individuals with diabetes reduce stress, anxiety, and depression while also promoting sustainable stress prevention strategies[19]. PMR can also reduce sadness, anxiety, stress, and glucose levels and improve quality of life. The study done in Egypt showed a remarkable difference in DD and anxiety among the study participants[20]. Also, PMR technique was found to be effective in reducing depression in people with diabetes[21], supporting the evidence generated from our study. PMR may reduce anxiety and depression by regulating the central and peripheral nervous systems, potentially blocking physiological and psychological responses to anxiety.

Our study findings showed promising results on the effect of PMR therapy in reducing glucose levels, HbA1c and lipid parameters. Similarly, in another study, the PMR technique and a structured exercise programme were effective in reducing HbA1c in individuals with T2DM. The study conducted in Indonesia also proved the effectiveness of progressive relaxation in reducing glucose levels[18]. Another study in older people, suggested that the use of evidence-based complementary therapies in general health care services may enhance quality care and promote positive health care service delivery[22]. Our study findings contrast with the research conducted in Iran, which indicated that PMR had no impact on glycemic control and quality of life in individuals with T2DM[23].

The effectiveness of PMR therapy was evident from the above studies. In one of our previous reports, it was proved that women had high levels of distress in managing diabetes as compared to men[4]. This study used the same DDS-17 item Scale to assess DD. It was reported that 55 per cent of women had moderate to high diabetes related distress on DDS-17 Scale[4]. Women may be targeted and guided to practice PMR in order to reduce DD and anxiety. Another study conducted on Indian population reported the prevalence of DD as 42 per cent and it was significantly and negatively associated with the domains of self-management such as dietary control, glucose management and health care use[24]. One of the recent studies from eastern India also showed a high prevalence of DD in 77 per cent participants and emotional distress was more common[25].

In our study, there were no adverse events reported and few participants from the intervention group participated enthusiastically in the therapy session and mentioned that they experienced a calm and peaceful attitude. This anti-stress benefit of PMR therapy may contribute to greater control over their glucose levels. The limitations of the study were as follows: the sample size was small and the findings of this study have to be confirmed by further evaluating the effect of PMR therapy in a larger sample. It is also necessary to assess the long-term sustainability of PMR therapy's effect on glycemic control, DD and anxiety. The study was conducted in a single centre, thus restricting the generalizability of the findings.

Overall, the findings in this study suggested that PMR therapy had a positive effect on diabetes distress and anxiety among people with T2DM. The study indicates that PMR can enhance their glycemic control. Therefore, regular use of PMR therapy in conjunction with conventional medications may be advantageous for better diabetes management and improve the quality of life of people with T2DM. This can be implemented by reinforcing the practice of PMR therapy for all people with T2DM at every follow up visit.

***Financial support & sponsorship*:** None.

***Conflicts of Interest*:** None.

***Use of Artificial Intelligence (AI)-Assisted Technology for manuscript preparation*:** The authors confirm that there was no use of AI-assisted technology for assisting in the writing of the manuscript and no images were manipulated using AI.

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