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Beneficial effects of mindfulness based stress reduction (MBSR) on bio-physiological and psychological parameters among type 2 diabetics

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Diabetes is an illness that affects every aspect of a person's life. The poor glycemic control is the main reason for the development of diabetes related complications and the stressful life.The nature of the disorder, age, lifestyle practices and psychosocial factors are playing an important role in the management of diabetes. Mindfulness based stress reduction (MBSR) is a meditation therapy which promotes positive mindset, feeling of wellbeing and good medical outcomes without any side effects. Study was done to evaluate the beneficial effects of MBSR therapy on HbA1C, blood pressure, BMI, stress, depression and mindfulness among 138 type 2 diabetics. Participants were randomly assigned for intervention group and control group. The intervention group participants received 8 weeks MBSR and the control did not receive intervention. All participants in both groups received their routine medical treatment. Dependent variables were measured before andsix week after intervention. Follow-up was done at 10th week. Study results showed that MBSR had beneficial effect on HbA1C, blood pressure, BMI, stress, depression and mindfulness among participants in the intervention group.

Keywords: Bio-physiological, Mindfulness based stress reduction, Psychological, Type 2 diabetics

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All over the world diabetes mellitus is a major public health problem that requires consistent medical treatment. International Diabetes Federation (IDF) reported that currently there are 463 million people living with diabetes. It may increase to 578 million by 2030 and 700 million by 2045. An expanding economy, social aging, unsatisfactory diet, sedentary lifestyle and increasing urbanization are most important influencing factors of diabetes in the world[1,2]. The World Health Organization (WHO), 2016 has reported that India is the diabetic capital of the world and majority of deaths are attributable to increases in blood glucose before the age of 70 years. In 2016, there were 1.6 million deaths directly caused by diabetes[3]. Hypertension is a significant risk factor for type 2 diabetes. There is considerable evidence that insulin resistance has causal link with hypertension[4]. Even obesity is a condition strongly associated with the development of many more ailments; insulin resistance and type 2 diabetes by block the signals of insulin receptors, thus gradually causing the cells to become resistant to insulin[5]. Along with hyperglycaemia, the stress and depression are also one of the associated health problems of individuals with type 2 diabetes. Worldwide 43 million people with diabetes have symptoms of stress and depression. Depression is common and highly prevalent conditions in adults with type 2 diabetes mellitus as compared to those not having diabetes[6]. Also medications for the treatment of diabetics may have short or long term side effects[7]. So an effective management strategy is required to reduce the diabetes related complication, drug and hospitalization cost and balancing of pharmacologic and non-pharmacologic interventions. Mindfulness therapies is one of the non-pharmacological intervention that focus on mindful attention and awareness that helps to treat various disease and disorders and improved mental health and wellness. MBSR was applied in many psychological and physical problems such as stress, anxiety, depression, chronic pain, headache, sleep disorders and cancer. It is an 8 week program and developed by Jon Kabat-Zinn in 1979[ref 8-9].

So the present study was done to evaluate the beneficial effects of MBSR on bio-physiological and psychological parameters among type 2 diabetics.

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Methodology

The study was done after getting the Institutional Ethics Committee written approval from Saveetha University (008/01/2015/IEC/SU), Vydehi Institute of Medical Science and Research Centre (VIEC/2015/APP/098). Anonymity and confidentiality of the data was maintained. Research design adopted was a true experiment with pre-test, post-test design. The study was done in selected rural communities in Bengaluru. The sample size was estimated with 90% power and 5% significance level. The estimated sample size was 60 for each group and expecting a drop out of 10% the sample was rounded off to 66 in each group using Sigma Plot 13.0 version Systat Software, USA. But a maximum available sample of 138 who met the study inclusion criteria and willing to participate in the study were selected. They were assigned in the control group and the intervention group (69+69) using computer generated random number after getting informed consent. Both male and female aged 30-65 years were interviewed at first and as the second step, the blood pressure and blood glucose was measured followed by assessment of perceived stress and depression. The eligible sample was decided based on their blood pressure, blood glucose and cut off scores of the PSS; that is ≥15 and CEDS ≤ 20 in the sub-scales. The fasting blood glucose was estimated using a glucometer by finger prick method. The participants were selected if he/she was already diagnosed with type 2 diabetes and fasting capillary blood glucose was ≥ 110 mg/dL and ≤ 275 mg/dL, with a current systolic blood pressure of ≥ 140 mm Hg or diastolic blood pressure of ≥ 90 mm Hg with or without anti-hypertensive medication. There were no restrictions on routine pharmacological, diet and fluid management. A brief questionnaire, semi-structured interview schedule, Perceived Stress Scale (PSS), Centre for Epidemiologic Studies Depression (CESD), Mindfulness Attention Awareness Scale (MASS), blood glucometer, blood glucose measurement using glycated hemoglobin test (HbA1C), sphygmomanometer, weighing machine and measuring tape was used. BMI was calculated from height and weight (kg/m^2) measured using standard methods. The content validity of the tool was obtained by sending the tool to the experts in the field of community medicine, general medicine, nursing and clinical psychology. After establishing the content validity, the language validity was done. The tool was pre-tested on 10 type 2 diabetics. Reliability of the tools was established. The data collection methods and observations were phased into the survey, assessment of pre-test, post-test and follow-up. Prior to MBSR session, the goal of mindfulness practice was explained to the participants. In this study, the Intervention group received 20-30 min MBSR practice in a week for 5 days over the period of 8 weeks. It includes mindfulness breathing, mindfulness body scan, mindfulness sounds and mindfulness feelings and thoughts. Intervention group participants were divided into subgroups. For each group the time slot was given for MBSR intervention. The intervention was delivered by the investigator who had received training in MBSR at village under health training centre. The control group participants did not receive any intervention. But at the end of the study the control group participants also received MBSR. There were 6 dropouts in the control group and 5 dropouts in the intervention group. Finally, 127 participants were analyzed (63+64) in both control and experimental group, respectively. Overall there was 8% attrition.

Analysis of data

The repeated measures analysis of variance was used to compare the means from the pre-test to follow up for both the groups. Bonferroni post hoc test also computed to determine the difference between the time points. The p-value ≤0.05 is being considered as significant. The chi-square test was done to find homogeneity between the groups based on their baseline demographic and clinical variables (p>0.05). It was done by using Statistical Package for Social Sciences (SPSS) 16.0 version software.

Results

The findings showed that the demographic variables of participants in the control and the intervention group were not significant. This emphasized that there was homogeneity between the control group and the intervention group participants at the pre-test (Table 1).

Bio-physiological parameters

The data given in Table 2 shows that the intervention group mean pre-test HbA1c (8.8) was slightly higher than post-test HbA1c (8.2). The intervention group mean post-test HbA1c (8.2) was lesser than the control group mean posttest HbA1c (8.9). There was no change in mean HbA1C of control group whereas in the intervention group, the mean HbA1C was decreased by 1.1%. Though changes of HbA1c were mild in intervention group, a

Table 1 — Homogeneity test of demographic data for the control and Intervention group N=127

S. No	Demographic Variable	Control group (n=63)		Intervention group (n=64)		Chi-square	'p' value
		f	%	f	%		
1.	**Age (in years)**						
	35-39	5	7.94	3	4.69	0.362	0.985
	40-44	23	36.51	27	42.19		
	45-49	19	30.16	21	32.81		
	50-54	10	15.87	8	12.5		
	55-59	6	9.52	5	7.81		
2.	**Gender**						
	Male	26	41.27	29	45.31	0.211	0.646
	Female	37	58.73	35	54.69		
3.	**Religion**						
	Hindu	46	73.02	49	76.56	1.262	0.532
	Muslim	11	17.46	7	10.94		
	Christian	6	9.52	8	12.5		
4.	**Educational profile**						
	Primary	21	33.33	19	29.69	0.639	0.887
	Secondary	35	55.56	39	60.94		
	Higher Secondary	5	7.94	06	9.37		
	Undergraduate	2	3.17	00	00		
5.	**Occupation**						
	Farmer/coolie	44	69.84	42	65.62	1.536	0.463
	Private employee	12	19.05	10	15.62		
	Homemaker	07	11.11	12	18.75		
6.	**Type of family**						
	Joint family	09	14.29	06	9.37	0.735*	0.391
	Nuclear family	54	85.71	58	90.63		
7.	**Dietary pattern**						
	Vegetarian	09	14.28	07	10.94	0.438	0.803
	Pure vegetarian	03	4.76	01	1.56		
	Mixed diet	51	80.95	56	87.5		
8.	**Habits of Tea/coffee**						
	Yes	61	96.82	64	100	0.524	0.469
	No	02	3.17	00	00		
9.	Habits of addiction						
	a. Smoking status	44	69.84	39	60.94	2.93	0.231
	Non-Smoker	14	22.22	12	18.75		
	Smoker	05	7.94	13	20.31		
	Ex-smoker						
10.	**b. Alcohol status**						
	No	58	92.06	53	82.81	1.699	0.192
	Yes	05	7.94	11	17.19		
11.	**c. Use of Tobacco**						
	No	49	77.78	52	81.25	0.235	0.628
	Yes	14	22.22	12	18.75		

significant interaction effect between group and time (df = 2, 250; F = 49.207; p<0.001) was found. Between the groups, there was also a time influence. After the intervention duration, there was a significant difference in mean HbA1c scores between intervention and control groups. MBSR training was successful in substantially lowering HbA1c from pre training (8.8±1.36), post training (8.2±1.22) to follow-up (7.9±1.13), according to a post hoc test using the Bonferroni correction.

RMANOVA revealed that the intervention group's HbA1c was significantly lower than that of the control group's (Fig. 1).

In terms of systolic blood pressure (SBP) the intervention group's mean pre-test SBP (146.9) was higher than post-test SBP (145.4). There was a major

Table 2 —Beneficial effects of MBSR on bio-physiological parameter in the control and the intervention group (N=127)

Parameters	Groups	Pre-test M±SD	Post-test M±SD	Follow-up M±SD	Variables	Significance (0.05)		
						df	F value	p Value
HbA1C								
	Control group	8.9±1.31	8.9±1.27	8.9±1.31	Group	1,125	8.134	0.005
	Intervention group	8.8±1.36	8.2±1.22	7.9±1.13	Time	2,250	41.034	0.000
					Group x Time	2,250	49.207	0.000
SBP								
	Control group	147.1±4.06	146.7±3.35	146.8±3.96	Group	1,125	5.966	0.016
	Intervention group	146.9±4.08	145.4±3.75	143.6±3.75	Time	2,250	48.277	0.000
					Group x Time	2,250	35.209	0.000
DBP								
	Control group	94.6±2.75	94.8±2.75	94.4±3.4	Group	1,125	3.511	0.063
	Intervention group	94.3±2.73	93.7±2.76	93.3±2.86	Time	2,250	6.607	0.002
					Group x Time	2,250	8.915	0.000
BMI								
	Control group	26.2±3.06	26.2±2.99	26.2±2.93	Group	1,125	0.741	0.391
	Intervention group	25.9±3.13	25.7±2.89	25.6±2.79	Time	2,250	5.672	0.004
					Group x Time	2,250	7.782	0.001

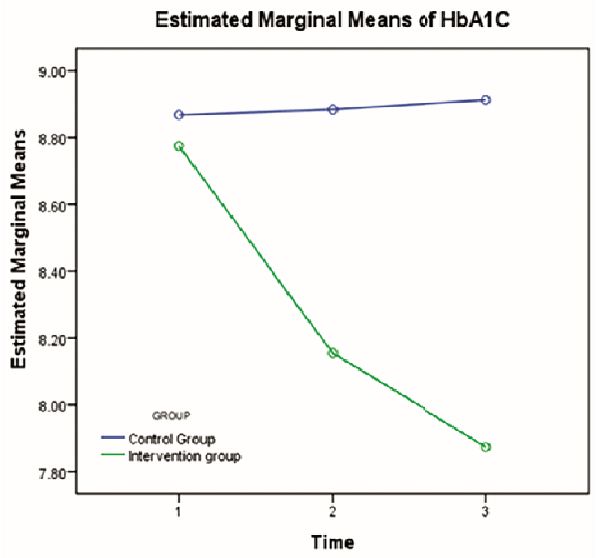

Fig. 1 — Repeated measures ANOVA for HbA1c on MBSR

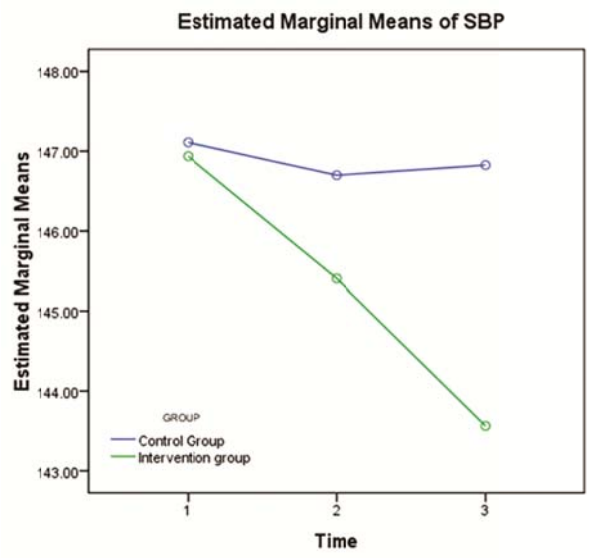

Fig. 2 — Repeated measures ANOVA for SBP on MBSR

interaction effect between group and time (df = 2, 250; F=35.209; p<0.001), as well as time effect between the groups. After the intervention there was a significant difference in mean SBP between the intervention and control group. MBSR training was effective in significantly decreasing SBP from pre-training (146.9±4.08), post-training (145.4±3.75) to follow-up (143.6±3.75), according to a post hoc test using the Bonferroni correction. In the intervention group, the systolic blood pressure was decreased by 3.3 mm Hg. RMANOVA revealed that the intervention group's SBP was a significantly lesser than the control group's (Fig. 2)

MBSR showed slight difference of mean diastolic blood pressure (DBP) in the intervention group from pre-test DBP (94.3) to post-test DBP (93.7). The mean post-test of intervention group's DBP (93.7) was lesser than the mean post-test of control group's DBP (94.8). Between the groups, there was a substantial interaction effect between group and time (df = 2, 250; F=8.915; p 0.001) as well as a time effect. After the intervention time, there was a significant

difference in mean DBP between the intervention and control groups.The findings of a post hoc test that used the Bonferroni correction showed that MBSR training was effective in lowering DBP significantly from pre-training levels. There was also no substantial reduction in the intervention community (F=5.966, p=0.063). The results of the RMANOVA revealed that the intervention group's DBP was significantly lower than the control group's (Fig. 3)

Within the intervention group only there was slight reduction in mean BMI from pre-test (25.9) to post-test BMI (25.7). This post-test BMI (25.7) was lower than the control group's mean post-test BMI (26.2). There was a major interaction effect between group and time (df = 2, 250; F=7.782; p 0.001), as well as a time effect between the groups (df = 2, 250; F = 7.782; p 0.001). There was also no major difference in group (F=0.741; p=0.391) according to the findings.

MBSR training was successful in substantially lowering BMI from pre-training (25.9±3.13), post-training (25.7±2.89) and follow-up (25.6±2.79), according to a post hoc test using the Bonferroni correction. RMANOVA revealed that the intervention group's BMI was significantly lower than the control group's (Fig. 4).

However, intervention group showed statistically significant improvements in terms of HbA1c, blood pressure and BMI but does not seem to be of any clinical significance.

Psychological parameters

Table 3 indicates that the intervention group's mean pre-test stress score (18.39) was higher than the post-test stress score (13.65). The intervention group had a lower mean post-test stress score (13.65) than the control group (18.73). A substantial interaction effect between group and time (df = 2, 250; F=127.125; p<0.001) and time effect was found between the groups. Significant difference in mean stress scores was observed between intervention and control group after intervention. MBSR training was successful in substantially reducing stress from pre-training (18.39±2.87), post-training (13.65±2.23), and follow-up (11.38±2.65), according to a post-hoc test using the Bonferroni correction (Fig. 5).

In terms of depression, the intervention group had a lower mean post-test depression score (12.88) than the control group (18.38). In addition, the intervention group's mean post-test depression score (12.88) was lower than the control group's score (18.49). Between the groups, there was a substantial interaction effect

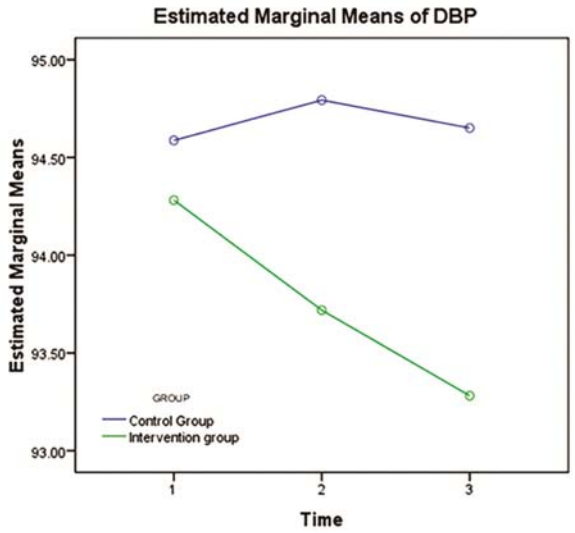

Fig. 3 — Repeated measures ANOVA for DBP on MBSR

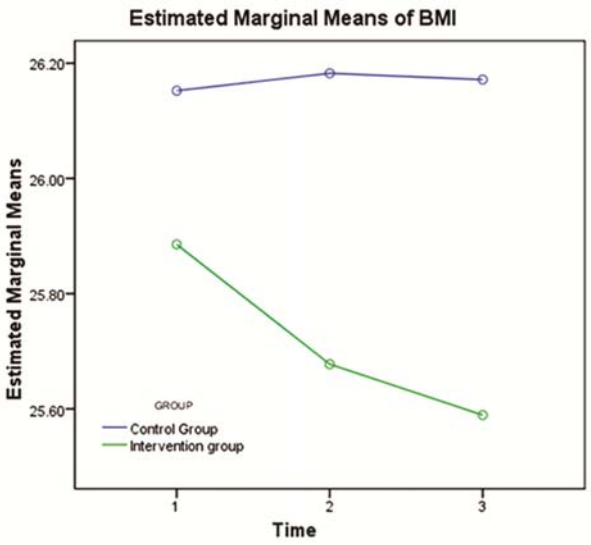

Fig. 4 — Repeated measures ANOVA for BMI on MBSR

between group and time (df = 2, 250; F=499.212; p 0.001) as well as time effect. After the intervention, there was a significant difference in mean depression scores between the intervention and control groups. MBSR training was effective in significantly reducing depression from pre training (18.38±2.7), post training (12.88±2.2), and follow-up (11.7±2.29), according to a post hoc test using the Bonferroni correction (Fig. 6).

MBSR improved the mean mindfulness score in the intervention group from pre-test (48.06) to post-test (60.64). The intervention group had a higher mean post-test mindfulness score (60.64) than the control group (48.32). There was a major interaction

Table 3 — Beneficial effects of MBSR on psychological parameter in the control and the intervention group (N=127)

Parameters	Groups	Pre-test M±SD	Post-test M±SD	Follow-up M±SD	Variables	Significance (0.05)		
						df	F value	p Value
Stress								
	Control group	18.79±2.93	18.73±2.36	18.37±2.37	Group	1,125	115.296	0.000
	Intervention group	18.39±2.87	13.65±2.23	11.38±2.65	Time	2,250	157.691	0.000
					Group x Time	2,250	127.125	0.000
Depression								
	Control group	18.65±2.59	18.49±2.46	18.6±2.5	Group	1,125	103.97	0.000
	Intervention group	18.38±2.7	12.88±2.2	11.7±2.29	Time	2,250	527.808	0.000
					Group x Time	2,250	499.212	0.000
Mindfulness								
	Control group	48.64±8.49	48.32±7.9	48.59±7.75	Group	1,125	59.867	0.000
	Intervention group	48.06±7.05	60.64±5.41	64.42±4.99	Time	2,250	303.024	0.000
					Group x Time	2,250	313.531	0.000

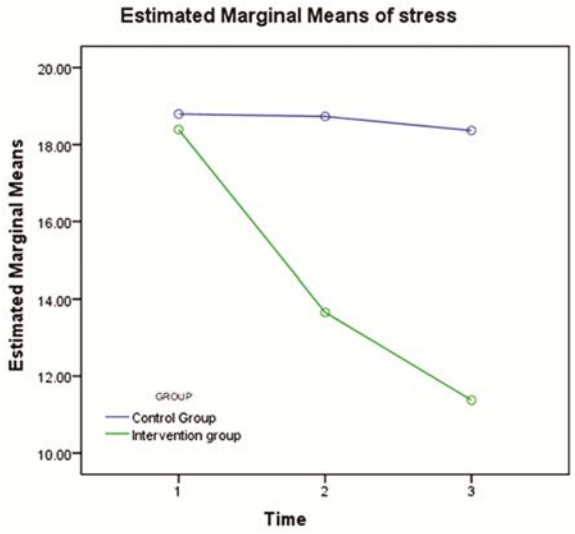

Fig. 5 — Repeated measures ANOVA for stress on MBSR

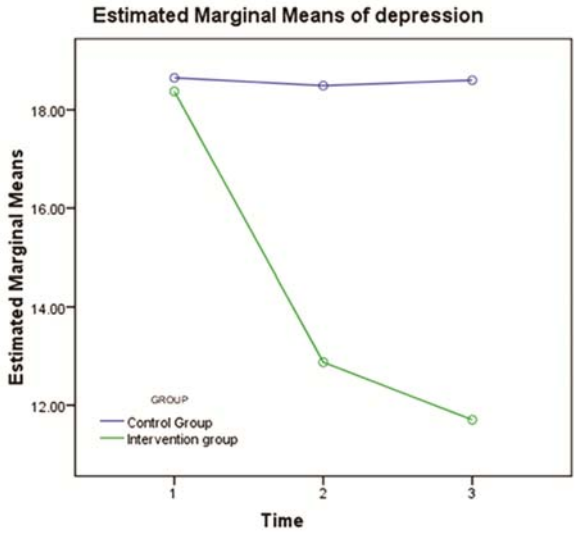

Fig. 6 — Repeated measures ANOVA for depression on MBSR

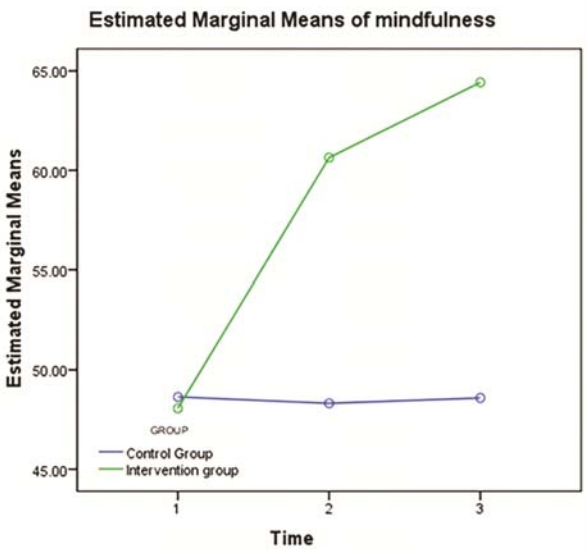

Fig. 7 — Repeated measures ANOVA for mindfulness on MBSR

effect between group and time (df = 2, 250; F=313.531; p 0.001), as well as a time effect between the groups (df = 2, 250; F=313.531; p 0.001). After intervention, there was a significant difference in mean mindfulness scores between the intervention and control groups.

The Bonferroni correction test revealed that MBSR training was successful and effective in significantly improving the mindfulness from pre training (48.06±7.05), post training (60.64±25.41) to follow-up (64.42±4.99) (Fig. 7).

The RMANOVA findings revealed that the intervention group had a substantial decrease in stress and depression levels, as well as an increase in mindfulness scores, when compared to the control group.

Discussion and Conclusion

The study findings indicate that MBSR has beneficial effects on psychological variables. However, the changes observed in physiological variables were statistically significant they may not be of much significance from clinical point of view**.** Present study findings are in agreement with other studies reported that the mindful meditation had a remarkable improvement on physical and emotional wellbeing, glycemic control, HbA1C, depression, anxiety and reduces the diabetes related distress of patients with type 2 diabetes[10-12]. The practicing of MBSR along with Yoga showed very good effects on reduction of blood pressure by reducing the activity of sympathetic nervous system and cortisol level in diabetics[13,14]. The mindfulness practice is beneficial for self-regulation to limit excessive food consumption. It promotes weight maintenance, reduction of BMI, eating behavior and emotional eating[15-18] and also it shows long term improvement in metabolic health due to obesity[19]. Diabetes mellitus gives a major life stress so physical, emotional and psychological coping is required. Mindfulness therapy helps in relieving stress, depression and improve self-awareness, mindfulness awareness and self-acceptance abilities of the individual with diabetes mellitus[20-22]. Mind- body practices are offered as novel therapeutic approaches for adolescents with psychiatric disorders[23]. The reduction of stress and depression is due to decreased gray-matter density in the amygdala, a group of subcortical structure that plays a key role in emotion resulting in anxiety, stress, fear and depression. MBSR decreased amygdala response and help for morphologic change includes increased cortical thickness and grey matter density in the posterior and anterior cingulate cortex and insula[24,25]. Mindfulness-based interventions has impact on reduction of stress, depression and anxiety among back pain patients[26], women with breast cancer[27] and elderly population in residential homes[28] and reduce unnecessary panic towards any threat[29].

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Conflict of Interest

Authors declare that they do not have any conflict of interest.

Authors'Contributions

SKS and PS have been actively involved in conceptualization, design of the study, collection of necessary documents and interpretation of the same. SKS drafted the initial paper, PS has done critical revision and necessary corrections. All the authors approved the final version of the article which was submitted to the Journal, IJTK.

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