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Efficacy of GSR Biofeedback Relaxation on Aggression and Blood Pressure in Patients with Type II Diabetes Mellitus: A Randomized Controlled Trial

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Abstract

To verify the effect of GSR biofeedback (GSR-BF) relaxation training on aggression, blood pressure, and blood glucose levels, we conducted a randomized controlled trial among type II diabetes patients (TIIDPs). 228 TIIDP were selected from the various hospitals of Raipur, Chhattisgarh. Sixty participants who were found to have scores above the 75th percentile on the aggression inventory were included in the sample. Participants with higher aggression were invited for intervention and out of them, 50 randomly divided into two groups: the biofeedback relaxation group and the sham-control group. The 25 TIIDPs in the treatment group were given training on the use of the GSR-BF device for the management of stress parameters, with a total of 20 sessions (30 minutes each). The 25 TIIDPs in the control group didn't receive any training on biofeedback relaxation. Aggression, blood pressure, and blood glucose were assessed before and after the intervention. Aggression was recorded on follow-up too. The SPSS 16th version was used for the analysis. The GSR-BFgroup reported a significant change in systolic blood pressure (p = 014), blood glucose levels (P = 005) and in the dimensions of aggression (p = 001) on the post-intervention test. On the other hand, the control group reported a moderate increase in aggression. The biofeedback group had a significant reduction in the levels of aggression and blood pressure, while the control group had a significant increase in aggression. These findings will be helpful for the promotion of overall health in hyperglycemic TIIDPs.

Keywords: Aggression, blood pressure, GSR biofeedback, hyperglycaemia, relaxation.

Introduction

Worldwide, there are millions of people living with diabetes, and this is expected to rise to 54% by 2030. In India, there are higher numbers of people living with diabetes as compared to other countries. In India alone, there are 61.3 million people living with diabetes, which leads to increased diabetes problems among adults. The prevalence of non-communicable diseases is on the rise even after the government's meticulous efforts for early diagnosis and treatment. The diabetes population in India is impacted by one or more mental health issues. Anger and anxiety are often experienced by people who deal with chronic illnesses like diabetes. Numerous research have discovered a connection between poor self-control and low glucose levels (1). Bushman et al. have discovered that higher aggression is predicted by low glucose levels (2).

The conduct known as aggression is typified by verbal or physical assault. Suicidal or self-destructive behaviours may result from it, depending on whether it is focused inside or outwards against oneself. Berkowitz has defined Aggression is defined as any behavior meant to cause physical or psychological harm to another person (3). In comparison to men, women exhibit less overt aggression and more suppressed aggression (4). Younger adolescents exhibit much higher levels of physical aggression, while older adolescents exhibit significantly higher levels of other forms of aggression (5). There is a high degree of demographic variability in the prevalence and presentation of the aggression problem.

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Patients with diabetes frequently experience severe changes in their physical and mental well-being that they are ill-equipped to handle. Disrupted physiology, relationships with parents, elders, and peers, academic failure versus high expectations, and substance misuse are the main causes of the psychological issues during this time. For instance, people find it more difficult to focus when their blood sugar is low (6), controlling their emotions (7-8), and suppressing their need to act aggressively (9). Low blood sugar levels have even been linked to an increased risk of violent crimes, such as domestic violence, according to some research. Tilov et al. have discovered that patients with arterial hypertension exhibited the highest levels of aggression toward other (10). Diabetes patients had the greatest average levels of verbal aggression. Those with hypertension showed the highest degrees of anger and hostility. Patients with musculoskeletal diseases and those with hypertension and diabetes differed statistically significantly on the four aggressiveness questionnaire scales. Aggression and physiological morbidity are related, either directly or indirectly. With the increasing prevalence rates of mental health disorders among diabetes type 2 patients, apart from drug therapy, psychological intervention is very important. A review of the literature indicates that not much research has been done in India on managing aggression in people with type 2 diabetes. Emotion regulation study is one of the key areas of scientific inquiry (11), and One of the key protective elements that people can use to maintain their personal well-being is emotional regulation (12). The human-computer interaction (HCI) model can provide the necessary solution while looking for the pertinent answer to emotional regulation. Medical professionals are interested in this expanding field. It is described as a potentially effective technology-based intervention to improve emotional control (13). Among its many intriguing qualities is the potential application of technology to the field of mental health (14) and the proliferation of widely deployable biofeedback devices and affordable wearable health monitors (13).The examination of the potential design space and the demonstration of the practicality of digital emotion regulation assistance in a range of contexts and demographics have occupied a substantial amount of recent HCI research (15). But there's still work to be done in terms of fully integrating innovative HCI intervention approaches with state-of-the-art psychological therapy (16). To the best of our knowledge, numerous research have previously examined the impact of GSR-BF relaxation training on emotional regulation (stress & anxiety) (17-21); Few studies, meanwhile, have looked into the impact of type II diabetes on aggression. As a result, the goal of the current study was to find out how type II diabetes patients' blood pressure, blood glucose, and aggression were modified by GSR-BF relaxation training.

Methodology

Sample

In this study, 228 TIIDPs were initially selected by incidental sampling technique from the outpatient departments (OPD) of different state funded and private clinics of Raipur, India. All the TIIDPs were well controlled with antidiabetic drugs. Firstly, TIIDPs were evaluated by the aggression inventory, and those who scored more than the 75th percentile on the aggression inventory participated in the intervention. G∗Power computer software, based on the power of 0.80, effect size of 0.80, and alpha of 0.05 for a priori power analysis, suggested 21 participants were required per group (22).

The following exclusion and inclusion criteria we used in our study:

Inclusion Criteria: -

- The participants were diagnosed with Type II diabetes mellitus and well controlled with antidiabetic drugs.
- Who were willing to participate in the study
- Who were able to read and speak Hindi and English
- Who scores above the 75th percentile on the aggression inventory

Exclusion Criteria: -

- Participants with associated severe psychiatric problems and severe medical problems (CHD, CVA, cancer, dementia, etc.) were excluded.
- Who were not interested in participating; and
- Who were not able to understand Chhattisgarhi or Hindi.

After evaluation of inclusion and exclusion criteria, we used the random sequence generation technique for random assignment in the experimental and control groups.

Study Design: Randomized controlled trial

Randomization

After the enrolment, 50 participants were equally divided into: the experimental (Group1) and the control group (group2). Twenty sessions (30 minutes each) training of GSR-BF were provided to the group1 and not to the group2. 24 TIIDP in the group2 and 21 TIIDP in the group1 had completed the study. A CONSORT diagram indicating each stage of this study is shown in Figure 1.

Tools:

Information about socio-demographic characteristics of the TIIDP was collected through the demographic proforma sheet.

Aggression Inventory (AI): Aggression of the TIIDP were evaluated by a Hindi translated aggression inventory. The originally inventory was developed by the Buss-Durkee (23). Inventory consists of a total of 67 items, which assess the eight different dimension of aggression. The test-retest reliability of the aggression inventory was 0.82 for males and 0.79 for females. The construct validity of the inventory was 0.45 for males and 0.46 for females.

GSR Biofeedback: Assessment of galvanic skin resistance (GSR) and for relaxation training we

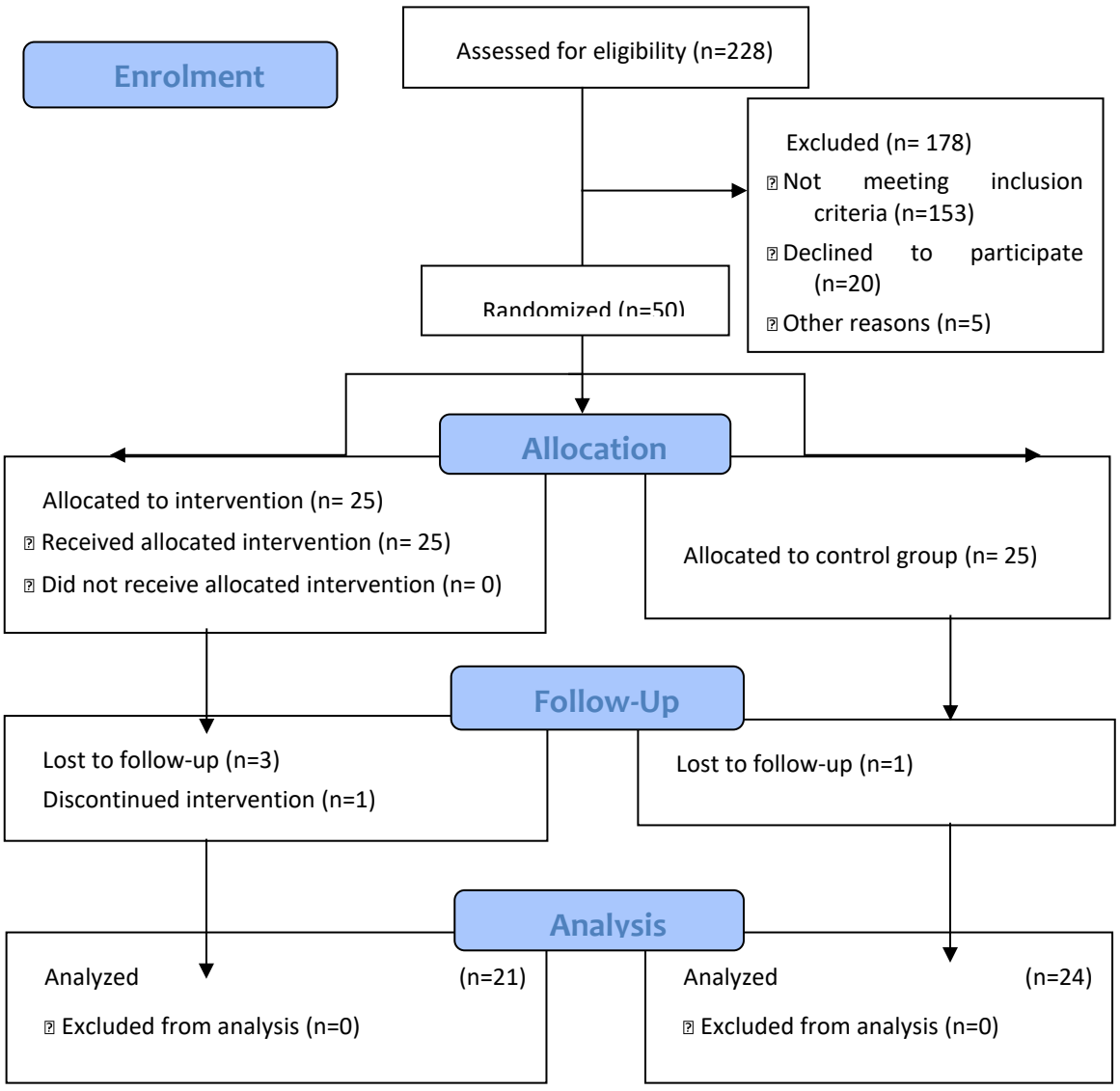

Figure 1: CONSORT diagram with flow chart of the participants

used GSR biofeedback machine (Biotrainer GPF-2000, Medicaid Chandigarh, India). The feedback of the relaxation is provided by two coloured bars (1. green and 2. Red), and the numerical display of skin resistance in Ohms also reported.

Blood Pressure: Automatic digital blood pressure monitor instrument (Oscillometric system) was used to measure systolic blood pressure (SBP) and diastolic blood pressure (DBP). Before assessment of DBP and SBP, readings were validated by health professional with standard measures. The manufacturer of this instrument and British Hypertension Society were also validated for clinical use.

Procedure

Before starting the intervention, we had obtained signed consent forms from all the subjects who had participated in the current study. They were given questionnaires individually. The instructions for each questionnaire were explained to the participants, and they were requested to fill out the questionnaires. [Aggression Inventory]. After the assessment of the aggression levels, the participants were invited for intervention, and 50 of them were randomly divided into two groups by using a computer: [Experimental group (n = 25) and Control group (n = 25)]. The benefits and consequences of the study were explained to the participants before starting the experiment.

Intervention Procedure

Every participant was sit comfortably in a chair, and then the GSR-BF was positioned in front of them. The GSR-BF Biotrainer GPF-2000 was used for relaxation and to measure the baseline GSR records and post-value GSR of each participant. The left index and ring fingers were used as the electrode locations for the GSR recording. The GSR-BF equipment was kept in an isolated room, which was quiet and comfortable. Every participant were used the same biofeedback apparatus under the same settings. In this study, the experimental group's members were told to lower the sounds' frequency and intensity, and increase the amount of green bars that glowed in tandem with digital numbers, and refrain from causing the red bars to illuminate. GSR-BF was administered for 20 sessions (30 minutes each) at sensitivities of 2%, 5%, and 10%. Participants in control group did not get any instruction for relaxation. After the 20-session intervention, all the parameters were recorded for both groups, respectively.

Statistical Analysis

The 16th edition of SPSS was used for statistical analysis of data. The data were analyzed using parametric tests as the data distribution was normal. The data's normal distribution was ascertained using the Kolmogorov-Smirnov test. Descriptive statistics like mean and standard deviation as well as inferential statistics like an ANOVA and t-test for two samples were employed in the data analysis.

Results

Out of the 60 subjects with high aggression levels, 15 were males (25.0%) and 45 were females (75.0%). The participants' mean age was 56.81 years (SD: -7.71). Maximum number of participants [51.7% (n = 31)] belonged to the 61–70 years age category. The participants who were found to have high aggression levels were 88.3% married (See Table-1).

Blood pressure and blood glucose comparisons between pre- and post-intervention

Significant change were found in the score of systolic blood pressure (pre-intervention: 125±14.99; post-intervention: 116±11.54; t=2.602; P=.014) and blood glucose (pre-intervention: 179±74.21; post-intervention: 135±35.56; t=3.010; P=.005) at 0.05 level of significance between pre- and post-intervention. Experimental group reported a lower level of systolic blood pressure and blood glucose levels over 20 sessions of relaxation training (Table 2).

In the score of systolic blood pressure (pre-intervention: 121±14.51; post-intervention: 120±13.39; t=.556; P=.581) and diastolic blood pressure (pre-intervention: 73.20±11.35; post-intervention: 73.033±11.32; t=.113; P=.911), no significant change were found at 0.05 level between pre- and post-intervention. However, the control group had reported a significant decrease in the blood glucose (pre-intervention: 186±92.96; post-intervention: 142±43.39; t = 4.661; P =.000) (Table 2).

Table 1: TIIDP Demographic Characteristics

Socio-demographic Variable	Categories	Frequency	(%)
1. **Age groups (Years)**	31-40	3	5.0
	41-50	13	21.7
	51-60	13	21.7
	61-70	31	51.7
2. **Sex**	Man	15	25.0
	Women	45	75.0
3. **Status of Marriage**	Married	53	88.3
	Widow	7	11.7
4. **Locality**	Rural	15	25.0
	Urban	45	75.0
5. **Education**	Primary	12	20.0
	5^{th} to 8^{th}	22	36.7
	8^{th} to 12^{th}	8	13.3
	12^{th} to Graduation	18	30.0
6. **The effected Year of Diabetes**	1-10	43	71.7
	11-20	16	26.7
	21-30	1	1.7
7. **Diabetes Complication**	No complication	18	30.0
	Eye	6	10.0
	Neuropathy	24	40.0
	Kidney	8	13.3
	Heart	4	6.7

Table 2: Comparison of blood pressure, blood glucose in Control vs. Experimental groups during pre and post-intervention tests

	Time of recording	Control group		Experimental group	
		Mean±(SD)	t-test and p value	Mean±(SD)	t-test and p value
Systolic blood pressure	Pre-intervention	121±14.51	t=556; p>0.05	125.1±14.99	t=2.602; p<0.05
	Post-intervention	120±13.39		116.00±11.54	
Diastolic blood pressure	Pre-intervention	73.20±11.35	t=.113; p>0.05	74.83±10.62	t=.238; p>0.05
	Post-intervention	73.33±11.32		74.16±11.52	
Glucose	Pre-intervention	186±92.96	t=4.611; p<0.01	179.0±74.21	t=3.010; p<0.01
	Post-intervention	142±43.39		135.4±35.56	

Aggression and their dimensions scores comparison between pre-, post, and follow-up tests

The score of assault (pre-intervention: 5.56±1.71; post-intervention: 5.26±2.08; follow-up condition: 3.33±2.00; F=11.34; P=.000), indirect aggression (pre-intervention: 5.033±2.07; post-intervention: 4.76±2.96; follow-up test: 1.66±1.84; F=19.085; P=.000), irritability (pre-intervention: 5.033±1.99; post-intervention: 4.76±2.14; follow-up test: 1.56±1.61; F=30.006; P=.000), negativism (pre-intervention: 2.76±1.52; post-intervention: 1.90±1.29; follow-up test: 1.30±.87; F=10.256; P=.000), resentment (pre-intervention: 5.33±1.66; post-intervention: 4.90±2.77; follow-up test: 2.30±2.46; F=14.645; P=.000), suspicions (pre condition: 5.26±1.65; post-intervention: 5.30±2.00; follow-up test: 3.80±2.41; F=5.247; P=.07), verbal aggression (pre condition: 4.36±2.28; post-intervention: 3.66±2.27; follow-up test: 2.56±1.81; F=5.413; P=.06), guilt (pre condition: 2.63±1.40; post-intervention: 1.76±1.13; follow-up test: 2.066±1.43; F=3.279; P=.042), and total aggression scores (pre-intervention: 36.00±3.96; post-intervention: 32.33±10.11; follow-up test: 18.60±4.35; F=55.23; P=.000) were found statistically significant change among pre-,post-intervention and follow-up test. A significant decrease we found in the mean value of all dimension and total aggression scores over 20 sessions of relaxation training (Table 3).

The scores of indirect aggression (pre-intervention: 3.63±2.44; post-intervention: 4.33±2.26; follow-up condition: 4.70±2.03; F=1.735; P=.183), negativism (pre-intervention: 1.93±1.22; post-intervention: 2.60±1.65; follow-up condition: 2.80±1.51; F=2.83; P=.230), resentment (pre-intervention2.73±1.79; post-intervention: 3.66±1.76; follow-up condition: 4.03±2.04; F=3.838; P=.230), suspicions (pre-intervention: 5.70±1.72; post-intervention: 5.20±1.80; follow-up condition: 5.33±1.76; F=.644; P=.528), and guilt (pre-intervention: 2.10±1.02; post-intervention: 2.26±1.63; follow-up condition: 2.60±1.37; F=1.033; P=.360) were reported no significant change between pre, post and follow-up test. However, the control group had reported a significant increase in assault (pre-intervention: 4.13±2.19; post-intervention: 5.23±1.59; follow-up test: 5.50±1.59; F=4.784; P=.011), irritability (pre-intervention: 3.20±2.18; post-intervention test: 4.36±1.65; follow-up test: 4.866±2.08; F=1.562; P=.005), verbal aggression (pre-intervention: 2.28±2.00; post-intervention test: 3.53±2.16; follow-up test: 3.60±2.25; F=1.180; P=.011), and total aggression scores (pre-intervention: 29.26±4.99; post-intervention: 31.20±5.12; follow-up test: 33.43±3.96; F=18.92; P=.000) (Table-3).

Table-3: Aggression score comparison of Control vs. Experimental groups during pre-, post and follow-up tests

Aggression dimensions	Time of recording	Control group		Experimental group	
		Mean±SD	F & p value	Mean±SD	F & p value
Assault	Pre-intervention	4.13±2.19	F=4.78;	5.56±1.71	
	Post-intervention	5.23±1.59	p<0.05	5.26±2.08	F=11.34;
	Follow-up	5.50±1.59		3.33±2.00	p<0.01
Indirect	Pre-intervention	3.63±2.44		5.033±2.07	
Aggression	Post-intervention	4.33±2.26	F=1.735;	4.76±2.96	F=19.085;
	Follow-up	4.70±2.03	p>0.05	1.66±1.84	p<0.01
Irritability	Post-intervention	3.20±2.18	F=5.562;	5.033±1.99	
			p<0.01		F=30.006;
	Post-intervention	4.36±1.65		4.76±2.14	p<0.01
	Follow-up	4.86±2.08		1.56±1.61	
Negativism	Pre-intervention	1.93±1.22	F=2.83;	2.76±1.52	
	Post-intervention	2.60±1.65	p>0.05	1.90±1.29	F=10.256;
	Follow-up	2.80±1.51		1.30±.87	p<0.01
Resentment	Pre-intervention	2.73±1.79		5.33±1.66	

	Post-intervention	3.66±1.76	F=3.838;	4.90±2.77	F=14.645;
	Follow-up	4.03±2.04	p>0.05	2.30±2.46	p<0.01
Suspicion	Pre-intervention	5.70±1.72	F=.644;	5.26±1.65	
	Post-intervention	5.20±1.80	p>0.05	5.30±2.00	F=5.247;
	Follow-up	5.33±1.76		3.80±2.41	p<0.01
Verbal	Pre-intervention	2.28±2.00	F=1.180;	4.36±2.28	
Aggression	Post-intervention	3.53±2.16	p<0.05	3.66±2.27	F=5.413;
	Follow-up	3.60±2.25		2.56±1.81	p<0.01
Guilt	Pre-intervention	2.10±1.02	F=1.33;	2.63±1.40	
	Post-intervention	2.26±1.63	p>0.05	1.76±1.13	F=3.279;
	Follow-up	2.60±1.37		2.066±1.43	p<0.05
Total	Pre-intervention	26.26±4.99	F=18.92;	36.00±3.96	
Aggression	Post-intervention	31.20±5.12	p<0.01	32.33±10.11	F=55.23;
	Follow-up	33.43±3.96		18.60±4.35	p<0.01

Post intervention comparisons between the intervention and control groups on aggression

The aggression status of experimental and control group in post intervention condition is shown in (table 3). We calculated ANOVA for post intervention comparison between experimental and control group. The F value for Assault (F=8.141), Indirect Aggression (F=31.709), Irritability (F=61.948), Negativism (F=19.161), Resentment (F=5.505), Suspicion (F=4.419) and total Aggression (F=142.66) were significant, consequently, it can be concluded that the experimental and control groups' on post-intervention conditions differed significantly. Assault, Irritability, Indirect Aggression, Negativism, Resentment, Suspicion, and Total Aggression were higher in the control group compared to the experimental group (Table 3).

Discussion

This study has tried to find out the effect of GSR-BF on aggression, blood pressure, and blood glucose. Numerous previous laboratory experiments have reported the effect of biofeedback relaxation on the better management of blood glucose levels and stress. In the current study participants of the experimental group who had practiced GSR-BF relaxation training, reported significant reduction in aggression and its dimensions as compared to the control subjects. The findings of this study of the GSR-BF effect on aggression are similar to the other reports available on various relaxation effects. Numerous research works have reported a noteworthy impact of relaxation on autonomic activity in relation to GSR, EMG, and RR (17–21, 24). Sympathetic activity is shown by the GSR, EMG, and blood pressure, which all point to physiological arousal (25). Feedback from the EMG is indicating the contraction pattern which is generated by his or her skeletal muscles. Those TIIDP who underwent GSR-BF relaxation training was significantly reduced Aggression and its all dimension. The current study's findings are consistent with the prior research (26, 27). It also confirms the results of another study that reported relaxation is short-term, proactive interventions for aggressiveness reduction. In one study, impulsivity and aggression were significantly reduced after 10 weeks of meditation (28). These findings suggest that biofeedback intervention may be helpful in lowering the frequency and seriousness of domestic abuse cases in addition to other crimes involving rage (21). Before intervention, high aggressions were observed in TIIDP. Conversely, the control group reported a slight rise in aggression during the 20 sessions of consistent activity without receiving biofeedback relaxation. Anger and stress are typically linked, and research has shown that both can have detrimental consequences on one's health (29–36). The reason behind this is that when glucose levels are not under control, People find it more difficult to restrain their focus, regulate their emotions, and suppress their violent inclinations. Additional studies have also demonstrated a link between increased aggression and heightened diabetes symptoms. DeWall et al. have found that

individuals with diabetes have the highest average levels of verbal aggression (9). According to a recent meta-analysis, there was a strong correlation between hostility and anger and an elevated risk of coronary heart disease (CHD) in both healthy and pre-existing CHD populations (37). More research with bigger sample sizes is required. GSR-BF relaxation can be an alternative therapy for the management of anger among diabetes patients and the control of blood glucose levels in hyperglycemic type II diabetes patients. This will be helpful in the promotion of overall psychological health. The current study supports the use of GSR-BF relaxation in patients with high aggression. The promotion of psychological wellness will benefit from this study. In patients who exhibit high levels of aggressiveness, the current study supports the efficacy of GSR-BF relaxation.

Abbreviations

Nil

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Author Contributions

Study design: Dr. Mahendra Kumar and Dr. Priyamvada Shrivastava. Data collection: Dr. Mahendra Kumar, Analysis and interpretation: Mahendra Kumar, Mahesh Kumar, Dr. Yanjana. Drafting of the manuscript: Dr. Mahendra Kumar.Dr. Yanjana,Dr. Alka Chhandrakar, Dr. Manoj K Sahu,Critical revision of the manuscript:Dr. Mahendra Kumar.Dr. Yanjana,Dr. Alka Chhandrakar, Dr. Manoj K Sahu, Sannet Thomas, Antony Willson, Approval of the final version for publication: all co-authors.

Conflict of Interest

No any conflicts of interest are disclosed by the authors.

Ethics Approval

The current study was approved by the Pt. Ravishankar Shukla University, Raipur India [Institutional Ethics Committee, IEC Ref. No.:194/IEC/PRSU/2017].

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