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Original Article

The Effect of GSR Biofeedback Relaxation on Anxiety and Stress in Patients with Type II Diabetes Mellitus: A Randomized Controlled Trial

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ABSTRACT

Background: Anxiety disorders have high prevalence in diabetes patients and low-middle income countries like India. Research has provided evidence about biofeedback effectiveness on stress-related psychophysiological parameters. This study aimed to verify the impact of GSR biofeedback relaxation on stress-related psychophysiological parameters (galvanic skin resistance, stress, and anxiety) among type II diabetes patients with high levels of anxiety.

Methods: The present study was a single-blinded randomized controlled trial. Initially, 228 type II diabetes patients were assessed with the state trait anxiety inventory (STAI). Seventy participants identified as having high anxiety with STAI scores above the 75th percentile were invited to participate. Patients were randomly divided into a biofeedback relaxation and a sham-control group. Participants of the biofeedback group received training on how to use the GSR biofeedback device for management of stress parameters for twenty 30-minute sessions. The sham-control group received no intervention. Both groups were assessed before and after the biofeedback relaxation training program. The results of the STAI, GSR, and the inventory of stress for type II diabetes patients were compared. SPSS 16 version was used for analysis.

Results: The biofeedback group reported a significant change in the state of anxiety ($t=5.089$; $P<0.001$), GSR ($t=-2.199$; $P<0.035$), and stress ($F=46.850$; $P<0.001$) post-test. The control group reported a moderate increase in stress and trait anxiety at the same time. These results are consistent with previous studies.

Conclusion: Biofeedback relaxation is a useful technique for managing stress and anxiety in diabetes type II patients. During an emotional disturbance, it may also be helpful in promoting overall psychological health. Further research is necessary to determine the long-term effects of GSR biofeedback relaxation and the effects of cortisol on mood among diabetes patients.

Introduction

The incidence of type II diabetes (TIID) is increasing worldwide. India has the largest TIID population in the world, and the number of TIID patients in India is expected to increase to 69.9 million by 2025 [1]. The prevalence of TIID mellitus is 2.4% in India's rural population and 11.6% in its urban population [2]. In India, the diabetes population is affected by one or more mental health disorders. Anxiety is common among TIID patients compared to normal healthy controls and associated with worse diabetes outcomes. Diabetic patients experience higher levels of anxiety compared to

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normal healthy controls [3]. Grigsby et al. reported that the incidence of mood and anxiety disorders is higher in individuals with TIID compared to the general population [4]. Stress and anxiety disorders are significant predictors for psychological and physiological illnesses [5-8]. Stress can both directly and indirectly affect the control of diabetes [9]. Anxiety is correlated with poor glycemic control [10-13], and similarly, mental stress is associated with the damage of cognitive function [14]. This review summarizes the association between anxiety and diabetes and suggests that an innovative and evidence-based psychological intervention is needed for these conditions.

An overview of the effects of biofeedback on stress and anxiety are provided herein, A pilot study was conducted before this study [15] for the management of anxiety, and it was found that GSR biofeedback (GSR-BF) is effective in treating anxiety [16, 17]. Electroencephalography (EEG) and electromyography (EMG) also showed that biofeedback training is helpful in treating GAD (Generalized Anxiety Disorder) [18]. EMG biofeedback is a more valuable technique compared to GSR [19]. GSR-BF and progressive muscular relaxation training were found to have significant effects on anxiety and pulse rate [20]. Computerized biofeedback relaxation effects on different psychophysiological parameters, including GSR, EMG, RR, and stress, showed a significant difference between before and after intervention [21]. Human physiological parameters such as heart rate, EEG, GSR, EMG, and facial expressions are highly related to stress levels [22-29].

Anxiety is associated with poor metabolic outcomes and increased medical complications among TIIDM patients. Stress and anxiety in TIID patients need to be managed at each clinical contact, particularly in the urban population. Various alternative treatment modalities are available for the management of mental health problems [30], but they have not been used frequently in TIID patients. The effect of GSR-BF relaxation training on stress and anxiety levels has been investigated in the past by many studies, but only a few of them have investigated scientifically through the measurement of psychophysiological parameters. Therefore, the present study was designed to examine the role of GSR-BF relaxation training on stress-related psychophysiological parameters (state trait anxiety, perceived stress and GSR) among TIID patients.

Materials and Methods

In the present study, 228 TIID patients were initially assessed using the State Trait Anxiety Inventory (STAI). Patients were selected through the incidental sampling method from the outpatient departments of various government and private hospitals in Chhattisgarh, India. Out of 228 patients, 70 high anxiety participants with scores above the 75th percentile on the STAI were invited to participate in intervention. Fifty participants who fulfilled the inclusion criteria were randomly assigned to the experimental or sham-control group (20 declined to participate).

The G*Power computer program was used to select subjects based on a priori power analysis [31, 32]. Using parameters of 0.80 power, 0.80 large effect size, and 0.05 alpha, the t-test sample size was 21 participants per group.

Inclusion Criteria

- Known case of TIID mellitus, well controlled with antidiuretics drugs.
- Diagnosis of type II diabetes.
- Willingness to participate.
- Knowledge of Hindi and English languages.
- Ability to read and speak.

Exclusion Criteria

- Diagnosis or association of severe psychiatric illness or severe medical problem (cardiovascular, cerebrovascular accident, cancer, Alzheimer's, dementia, depression, suicide, psychosis, other).
- Receiving any other psychotherapy or medication for any psychiatry illness.
- Not interested in participating.
- Inability to understand Hindi.

Study Design

The present single blinded randomized controlled trial was approved by the Institutional Ethics Committee (IEC Ref. No.:194/IEC/PRSU/2017), Pt. Ravishankar Shukla University, Raipur, India. Written informed consent forms were signed by all subjects participating in the study.

Randomization

After enrollment and following the random sequence generation technique, 50 participants were divided into two groups: 1. Experimental group, and 2. Sham-control group, each comprised of 25 participants. Biofeedback relaxation training was given to the experimental group, but not the sham-control group, in twenty 30-minute sessions for 3 weeks. Twenty-four patients in the sham-control group and twenty-one patients in the experimental group completed the study. A flow chart of participants through each stage of the trial is shown in Figure 1.

Tools

Demographic Checklist

Socio-demographic data of diabetes patients was gathered through the demographic Performa sheet.

Perceived Stress Scale (PSS)

Stress was assessed by the perceived stress scale (PSS), a valid and reliable tool developed by Cohen, Kamarck, and Mermelstein [33]. The PSS is a 10-item self-reporting tool that has been used to measure perceived stress in daily life.

State and Trait Anxiety Inventory (STAI)

The STAI, developed by Pal and Tiwari, was used to assess state and trait anxiety [34]. This inventory consists of 60 items; 30 items measure state anxiety, and 30 items measure trait anxiety. The split-half reliability of the scale was 0.71, 0.78, and 0.76 for the state, trait, and total tests, respectively [34].

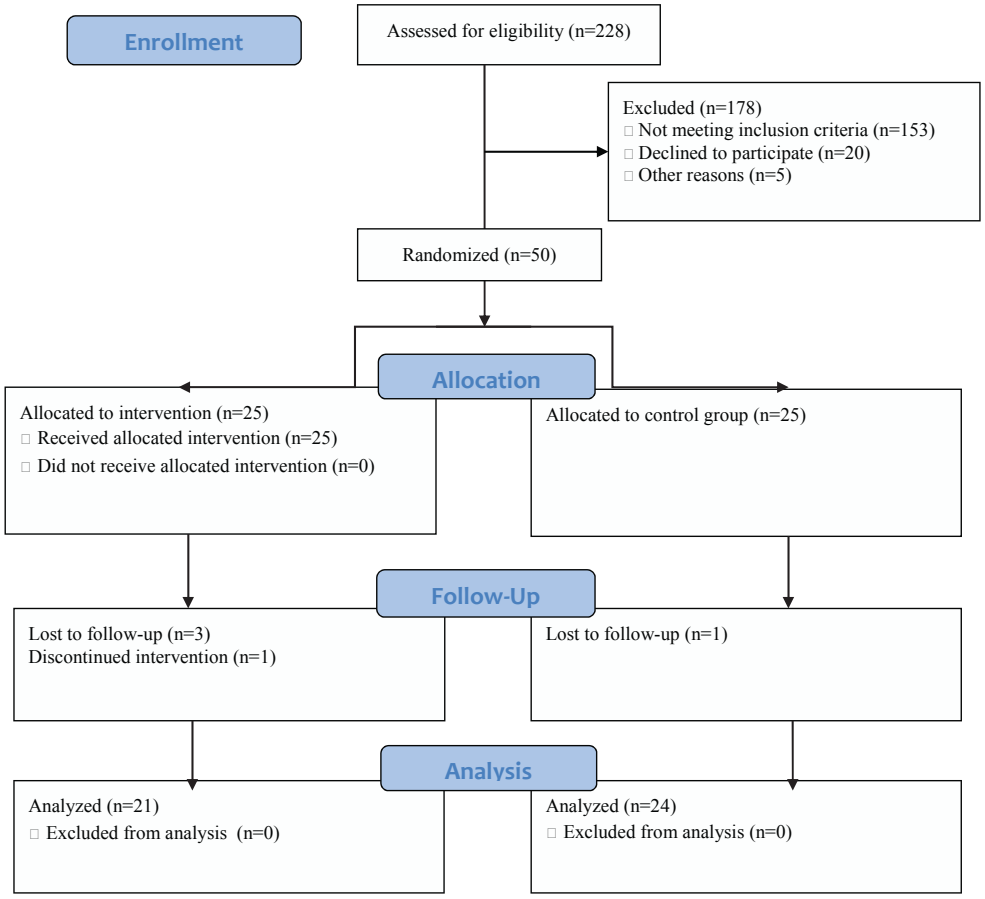

Figure 1: CONSORT diagram with flow chart of participants

GSR Biofeedback

Biofeedback relaxation training (BF-RT) is a method that helps a person learn and modify his/her physiological activity to improve health and performance [35]. GSR biofeedback is a relaxation technique that uses monitoring devices to measure and give "feedback" of autonomic activity (e.g., galvanic skin response), allowing one to gain some voluntary control over those functions. BF-RT has been utilized to help with various psychophysiological conditions [36, 37]. GSR biofeedback Biotrainer GPF-2000 (Medicaid Chandigarh, India) was used for the relaxation training and measurement of galvanic skin resistance (GSR). In GSR biofeedback, feedback for audio is a pure tone, and feedback for visual is a graphic green bar. The GSR biofeedback machine provided visual feedback in the form of glowing bars in two colors (1. Green, indicating relaxation; 2. Red, indicating tension) with a numerical display of skin resistance in Ohms, which increased on relaxation.

Procedure

Initially, 228 patients (117 male and 38 female) were selected for assessment of anxiety. The age range was between 39 and 70 years (mean age=57.14; SD=7.17). Male patients ranged in age from 39 to 70 years old (mean age 57.38; SD 7.70), while female patients had an age range of 46 to 68 (mean age=56.62; SD=5.87). The duration of diabetes ranged between 1 and 30 years (mean duration, 9.00 years; SD=7.18). A patient was high in1 to 10 years of duration with 71.1%, and a patient was low in 21 to 30 years of duration with 5.3%. Patients were given questionnaires individually and instructed in completing the STAI and PSS questionnaires. After the assessment of high anxiety on STAI, 70 high anxiety participants were invited to participate in intervention. Fifty interested participants who fulfilled the inclusion criteria were randomly selected for two groups using the random sequence generation technique by computer [Group 1: biofeedback relaxation (n=25) and Group 2 sham-control group (no relaxation, n=25)]. All patients were taking anti-diabetes medication prescribed by physicians and not receiving any other psychotherapy or medication for psychiatry illness. All participants were TIID patients, and no incentives were provided at any time.

Before starting the study, the nature and possible consequences of the study were described to the participants. During intervention, subjects were made to sit comfortably on a chair, and GSR biofeedback was placed in front of the subject. A baseline record and post-value of GSR were measured on a GSR biofeedback Biotrainer GPF-2000. The electrode for GSR recording was placed on the left index and ring finger or two alternate fingers. The GSR biofeedback equipment was situated in an isolated, quiet, and comfortable room. Similar conditions and the same biofeedback apparatus were used for all participants. Subjects in the biofeedback experimental group were instructed to decrease the intensity and frequency of the sound, increase the number of glowing green bars and digital numbers, and avoid getting the red bars to glow. GSR-biofeedback was given at 2%, 5%, and 10% sensitivity for twenty 30-minute sessions. Participants in the sham-control group were not

Table 1: Pre-intervention score for biofeedback and sham-control groups

	Time of recording	Experimental		Control		P value
		Mean	Std. Deviation	Mean	Std. Deviation	
State Anxiety	Pre	55.61	4.47	53.62	5.58579	0.198
Trait Anxiety	Pre	55.71	6.26	55.20	5.34041	0.771
GSR	Pre	326.8	1373.5	386.1	759.21955	0.075
Stress	Pre	32.04	2.80	31.87	2.69157	0.834

given any training for relaxation. After the intervention, all parameters were again recorded from both groups (experimental group and sham-control group).

Statistical Analysis

Data was statistically analyzed using SPSS, 16th version (Company IBM). The Shapiro–Wilk test was used to determine the normal distribution of data. The Levene test was used to check the homogeneity of variance. Because of the normality of data and homogeneity of variance distribution, parametric tests were used. Data did not fit the normal distribution and homogeneous of variance, so non-parametrical tests had to be chosen. In analyzing the data, descriptive statistics comprised mean, standard deviation, and inferential statistics, including a set of variance (ANOVA), F-test, t-test, and Mann–Whitney test for two samples. A P value (two-tailed) <0.05 was considered statistically significant.

Results

Out of 70 high anxiety subjects, 25.0% were males and 75.0% were females. The mean age of diabetes patients was 56.81 years (SD-7.71). Patients comprising the age group of 61–70 years had a high percentage with 51.7%. The majority of the high anxiety participants (88.3%) were married.

The F-test showed no significant differences on pre-intervention scores for state anxiety, trait anxiety, or stress between the biofeedback group and the sham-control group (Table 1). Mann–Whitney's test showed no significant differences on pre-intervention scores for GSR between the biofeedback group and the sham-control group (Table 1).

The results for state anxiety showed a significant decrease post-intervention for the biofeedback group and a small non-significant decrease in the sham-control group (Figure 2). For the biofeedback group, the mean post-intervention state anxiety score (M 55.61; SD=4.47) was lower than the mean pre-intervention state anxiety score (M 43.85; SD=6.06). A dependent sample t-test showed a significant decrease in state anxiety scores (t=6.786; P=0.000). For the sham-control group, the mean of post-intervention state anxiety scores (M 52.75; SD=7.77) was slightly lower than the mean of pre-intervention state anxiety scores (M 53.62; SD=5.58). A dependent sample t-test shows no significant difference in state anxiety scores (t=-0.500; P=0.622).

The results for trait anxiety showed a non-significant decrease post-intervention for the biofeedback group (t=1.974; P=0.062) and a small non-significant increase in the sham-control group (t=-.599; P=0.555) (Figure 3). For the biofeedback group, the mean post-intervention trait anxiety score (M 51.76; SD=7.42) was lower than the mean pre-intervention trait anxiety score (M 55.71; SD=6.26). For the sham-control group, the mean post-intervention trait anxiety score (M 56.20; SD=5.80) was slightly higher than the mean pre-intervention trait anxiety score (M 55.20; SD=5.34).

In GSR, the results indicate a significant increase post-intervention for the biofeedback group and a small non-significant increase for the sham-control group (Figure 4). In the biofeedback group, the mean post-intervention GSR score (M 389.4; SD=78.2) was higher than the mean of pre-intervention GSR score (M 326.8; SD=13.7). A paired sample Wilcoxon test showed a significant increase in GSR scores (Z=1.801; P=0.050). For the sham-control group, the mean post-intervention GSR

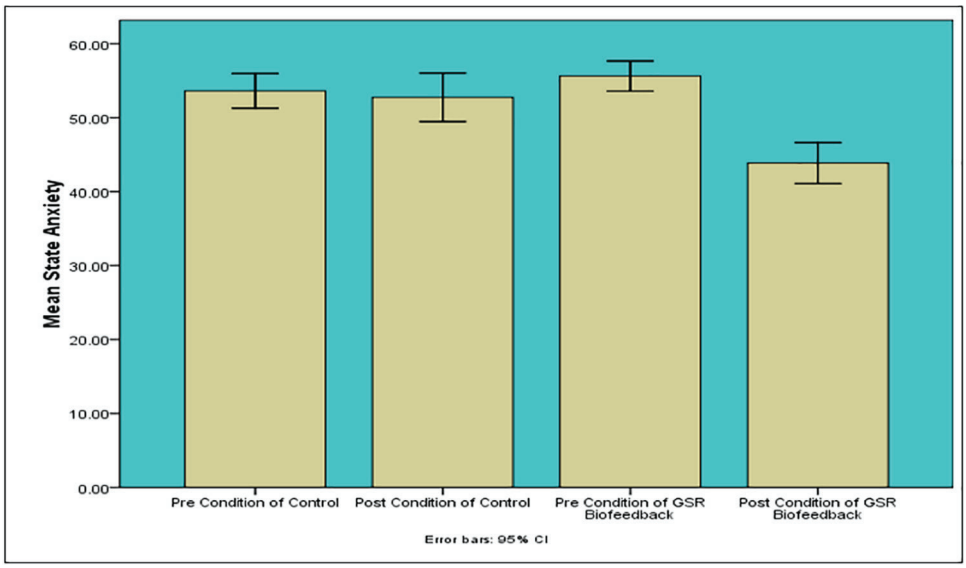

Figure 2: Difference between pre- and post-scores for state anxiety (GSR: (Galvanic skin resistance

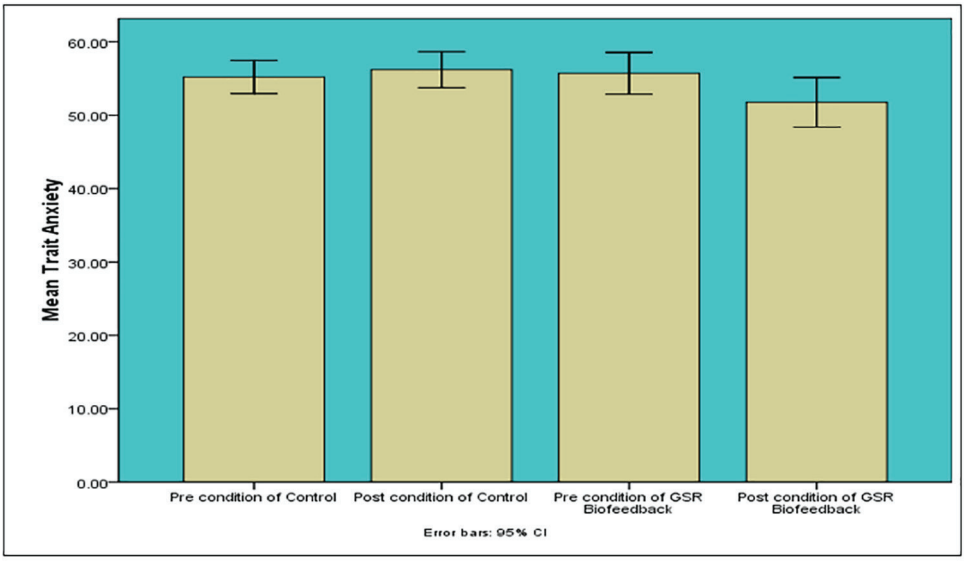

Figure 3: Difference between pre- and post-scores for trait anxiety (GSR: (Galvanic skin resistance))

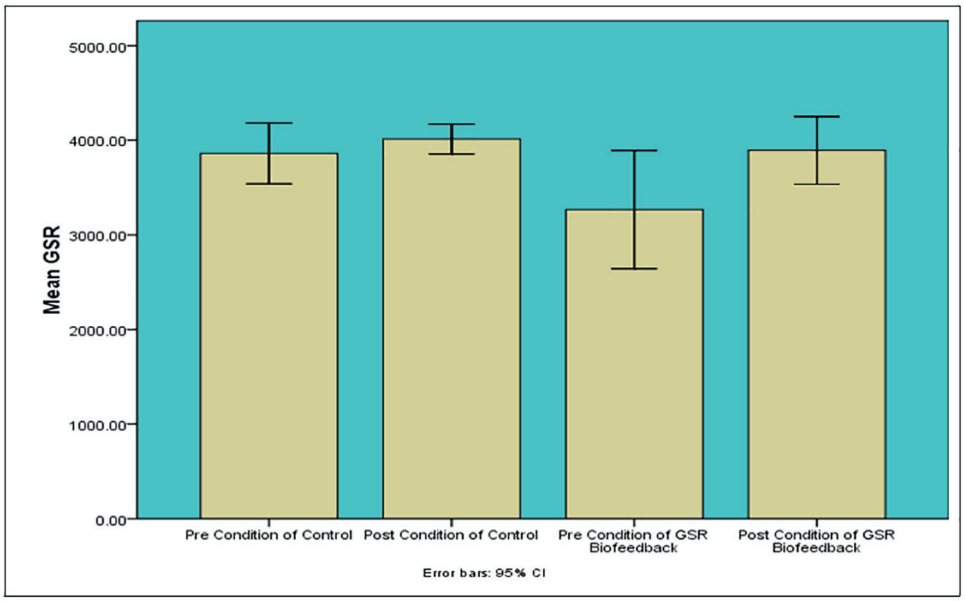

Figure 4: Difference between pre- and post-scores for galvanic skin resistance (GSR)

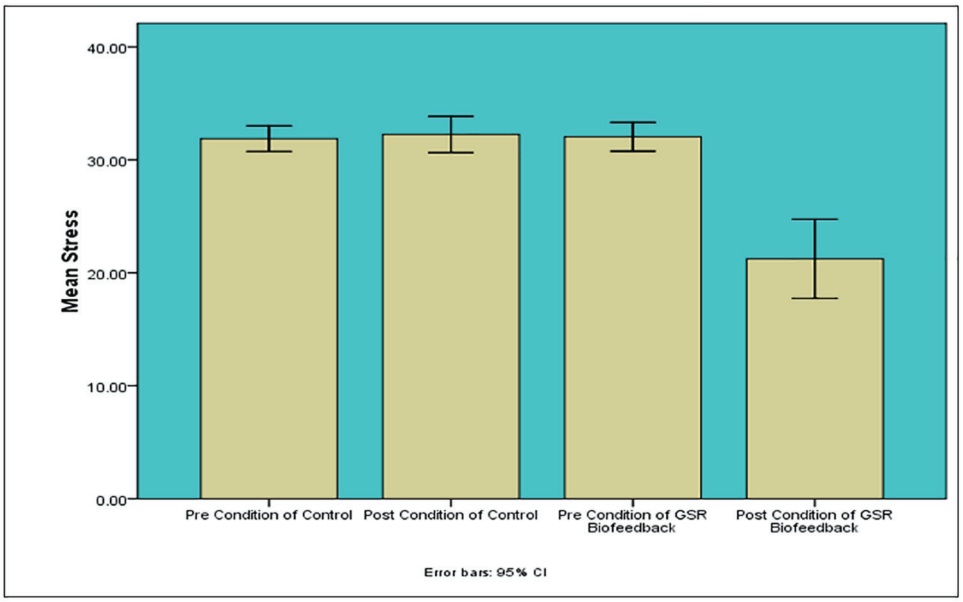

Figure 5: Difference between pre- and post-scores for stress (GSR: (Galvanic skin resistance))

score (M 401.1 SD=37.0) was slightly higher than the mean pre-intervention GSR score (M 386.1; SD=75.9). A paired sample Wilcoxon test showed no significant differences in GSR scores (Z=−1.069; P=0.285).

For stress, the results indicated a significant decrease post-intervention for the biofeedback group and a small non-significant decrease for the sham-control group (Figure 5). For the biofeedback group, the mean post-intervention stress score (M 21.23; SD=7.70) was lower than the mean pre-intervention stress score (M 32.04; SD=2.80). A dependent sample t- test showed a significant decrease in stress scores (t=6.371; P=0.000). For the sham-control group, the mean post-intervention stress score (M 32.25; SD=3.80) was slightly higher than the mean pre-intervention stress score (M 31.87; SD=2.69). A dependent sample t-test showed no significant deference in stress scores (t=−0.379; P=0.708).

A between-group comparison was made using the F-test to determine whether post-intervention differences existed between the biofeedback and sham-control groups on state anxiety, trait anxiety, GSR, and stress. Significant differences were found in state anxiety (F=17.906; P=0.000), trait anxiety (F=5.076; P=0.029), and stress (F=7.663; P=0.008).

Discussion

The growing number of mental health disorders among TIID patients, with particular emphasis on stress and anxiety pathologies, makes TIID patients a population at risk [30]. This risk could be considered higher among urban diabetes patients, because of the sadness and high stress associated with adaptation to this specific situation [38]. Considering that most health services have inadequate resources, it is important to find solutions to help patients to manage daily stress, reduce anxiety, and promote well-being.

The main objective of the present study was to confirm the role of GSR biofeedback relaxation training on state and trait anxiety and stress. The GSR biofeedback program was demonstrated to be very useful in helping anxious patients reduce their high state anxiety and stress levels. The control group also showed small changes in psychophysiological responses (GSR, stress, anxiety). The control group reported a moderate increase in trait anxiety and stress over the 20 sessions with regular activity and without relaxation training. The percentage of decrease in state anxiety scores post-condition was higher in the biofeedback group compared to the control group. Moderate reductions in trait anxiety have been also observed in the biofeedback group. This result is consistent with those of a previous study [39]. A significant immediate decrease in state anxiety was observed with alpha biofeedback training [40]. Analogous results in state and trait anxiety with EMG and thermal biofeedback have also been reported [41, 42]. The results of the current study on biofeedback relaxation training effects on stress-related parameters can be compared with other reports available on various relaxation effects, as they are similar. Several studies have been found that show the significant effect of relaxation on autonomic activity with reference to GSR, EMG, and RR [17, 21, 32, 43, 44]. GSR, EMG, and blood pressure are indicators of sympathetic activity, denoting physiological arousal. EMG feedback is the process of monitoring and displaying to an individual the ongoing contraction patterns generated by his or her skeletal muscles. Because stress is stored in the form of muscle tension, EMG is found to be raised in the event of stress. Palekar et al. reported GSR-aided biofeedback training as a successful technique for reducing pulse rate, respiratory rate, BP, and perceived stress [41]. Ghazavi et al. reported that muscle relaxation techniques are effective to decrease blood glucose levels [45]. The current findings confirmed the effect of relaxation on stress and anxiety reported in several other studies [46]. Hence, the results indicate the significant effect of biofeedback relaxation on anxiety and stress-related parameters in TIID patients.

Stress and trait anxiety were increased in the control group post-condition, because patients did not practice relaxation and did not receive psychotherapy at home. When glucose levels are not controlled, people have more difficulty controlling their attention and emotions and overriding their aggressive impulses [47]. Emotional state is affected by the adrenaline or epinephrine hormone during response to stress. The hormones adrenaline and cortisol are released, and the sympathetic nervous system is activated; after that, perspiration, heartbeat, and breathing rate increase. Constricting blood vessels allows more oxygen into the blood and more blood to the core of the body instead of the extremities [48]. Biofeedback training works with operant conditioning, and it has been found to be very useful in modifying brain functions associated with mental health and medical disorders [49]. Four weeks of relaxation training affects the HPA-axis by decreasing the level of salivary cortisol as a reliable physiological marker of stress [50]. Further research with bigger samples is necessary to determine the long-term effects of GSR biofeedback relaxation and the effects of mood on patients' responses to treatment.

Conclusion

GSR biofeedback relaxation is a useful technique for managing stress and state anxiety and reducing symptoms of emotional disturbance in diabetes patients. During stressful periods of diabetes type II patients, this technique may also help promote overall psychological health. This study supports the use of GSR biofeedback relaxation in patients with emotional disturbance.

Conflict of Interest: None declared.

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