



Protocol

Effect of EMG, RESP, and TEMP Biofeedback Training to reduce Anxiety among Undergraduate Students

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Abstract

Background: It is evident that anxiety and stress are two of the main predominant issues that cause several mental health problems and disorders in university students, causing a negative impact on this population. Higher educational institutes in Pakistan have limited access and resources to face these issues. It is suggested that biofeedback-aided relaxation training has been effective in alleviating anxiety and stress symptoms among undergraduate students, especially during their examination season. Recent research has proven biofeedback to be effective training for anxious students. The current randomized control trial is planned to investigate the effectiveness of Electromyography-EMG, Respiration Rate-RESP, and Skin Temperature-TEMP biofeedback training for reducing anxiety symptoms among nursing students by receiving 8 sessions for 4 weeks.

Methodology: This study is planned to investigate the effectiveness of EMG, RESP, and TEMP Biofeedback Training in reducing symptoms of anxiety among the nursing students from one school, and to determine whether biofeedback training is associated with relaxing the minds and bodies of the anxious nursing students to cope with the distressing situation. Study subjects meeting the eligibility criteria will be randomized into two groups using randomly generated numbers: the Biofeedback training group and the Control group. Biofeedback training will be used as an intervention vs. the control. All the study subjects who give consent to participate will be made to complete the study questionnaires (Demographic, Screening for Anxiety using the State-Trait Anxiety Inventory – STAI) at baseline and post-intervention (after 4 weeks).

Discussion: This study might help us determine biofeedback as a possible effective and useful technique in helping nursing students manage their anxiety. Moreover, it is suggested that Individuals receiving biofeedback training tend to show significant changes for the three psychophysiological modalities, i.e., EMG, RESP, and TEMP. This study might also give us insight into the efficacy of biofeedback in the Pakistani population seeking help for stress and anxiety.

Keywords

Biofeedback Training, Anxiety, Nursing Students, EMG, Respiration, Temperature.



Introduction

Biofeedback is a process/technique in which an individual can see the real-time recording of one or more physiological systems. Information from the psychophysiological recording from biofeedback training can be used to help manage several physical and mental health issues with optimal functioning. Biofeedback helps manage several disorders/diseases, including stress, depression, anxiety, pain, urinary incontinence, etc¹. Using biofeedback, one can learn to control the physical and psychological effects of stress, anxiety, and depression. Moreover, it helps people relax their minds and bodies to cope with the distressing situation.

The normal reaction of the body to stress is anxiety. It is a sensation of dread for what is ahead. Most people may experience dread and nervousness on the first day of school, during a job interview, before tests, or when giving a speech². It is suggested that anxiety belongs to a group of mental health diagnoses that cause excessive trepidation, fear, worry, or apprehension^{2,3}. Studies suggest that computer-based biofeedback systems help reduce anxiety in college and university students. Moreover, nursing students experience anxiety and stress throughout their education and training. Several factors might increase their anxiety, including academic, clinical, financial, interpersonal, family, physical and mental health issues. Above all, poor coping skills of an individual may contribute the most to developing anxiety³⁻⁵. Several studies have shown effective and significant use of biofeedback in reducing anxiety symptoms in undergraduate and nursing students^{4,5}.

The transition to university happens for most students near the end of adolescence, a

period marked by mental instability due to the need to cope with psychological and psychosocial changes⁶. Although reasonable amounts of stress are prevalent and adaptable in students' lives, excessive and ongoing stress may be linked to increased anxiety, and depression symptoms, among other manifestations^{7,8}. The effects of psychological morbidity far-reaching effects, not only on students' health, development, scholastic success, and quality of life, but it is suggested to extend to their families, institutions, and even other people's lives⁹. Depression and anxiety are two of the most typical psychological responses to stressful events encountered in university. During these times, students may experience a variety of emotional disturbances, including an increase in depressive and anxiety symptoms, which may drive them to engage in incorrect coping strategies, self-medication, or needed professional care¹⁰.

Regarding biofeedback, limited research using this on students has been conducted but has shown promising results. A computer-based biofeedback system was found to be beneficial in lowering anxiety in college students by Henriques et al. in 2011, and they recommended an interventional decrease in anxiety levels¹¹. In a similar vein, research indicates that EMG biofeedback and relaxation training may help students avoid anxiety-related academic failures and that therapy sessions can successfully lessen physical and mental signs of worry¹². Similarly, experimental studies show lower state anxiety in the experimental group compared to the control when augmented with GSR biofeedback¹³. Similarly, biofeedback-assisted relaxation training, including diaphragmatic breathing and progressive muscle relaxation training, is also shown to help improve physiological measures using an influential training



strategy, improving respiratory, skin, temperature, and pulse rate of the nursing students¹⁴. Still, the effectiveness and efficacy of Biofeedback intervention training compared to other intervention training and programs are under discussion, and studies are being done to investigate whether it is effective in reducing anxiety traits and stress among undergraduate students. This randomized control trial aims to investigate the effectiveness of biofeedback training for reducing anxiety symptoms among the nursing students who are associated with anxiety.

Methodology

Study Design

This study will be conducted as a randomized control trial using subjects from one nursing school. Study subjects meeting the eligibility criteria will be randomized into two groups: the Biofeedback training group receiving EMG, RESP, and TEMP Biofeedback Training. While second group is the Control group in which subjects will be asked to take three 20-minute writing sessions and write about the given control topic about their daily events of the past week. All the study subjects providing the consent to participate will be made to complete the study questionnaires (Demographic, Screening for Anxiety using the State-Trait Anxiety Inventory - STAI)^{15,16,17} at baseline and post-intervention (after 4 weeks).

Ethical Concerns

The study protocol was consulted and approved by AEIRC Committee on Ethics with the approval number ERC/S20/P-015. And registered by the Clinicaltrial.gov (Registration number NCT05508919)

Participants

Study participants will be recruited from the School of Nursing, Koohi Goth Women

Hospital, Karachi-Pakistan. Students from a variety of ethnic backgrounds who reported to be anxious during the pre-screening utilizing the anxiety scale will make up our targeted population and will be considered eligible for participation. Through an advertisement on the institute's notice board, students would be contacted and asked to take part in the study. Each participant will be informed of the study's aims, length, and purpose before obtaining their written consent.

Eligibility Criteria

Inclusion Criteria

All subjects fulfilling the below given criteria will be included.

1. The subject must not have any evidence of any metastatic disease.
2. Must be able to properly write and speak Urdu or English Language.
3. Must be a first- or second-year student.
4. Should have high anxiety that will be assessed using the State-Trait Anxiety Inventory-STAI.

Exclusion Criteria

1. The subject must not have any evidence of any metastatic disease.
2. Must be able to properly write and speak Urdu or English Language.
3. Must be a first- or second-year student.
4. Should have high anxiety that will be assessed using the State-Trait Anxiety Inventory-STAI.

Study participants who match the requirements will be randomly divided into two groups: the Biofeedback training group and Control group

Interventions

The experimental intervention

The Alive Pioneer with the GP8 Amp (Biofeedback device) will be used for this study. GP8 Amp can record ECG Heart Rate,



EMG for muscle tension, Hand Temperature, and Skin conductance.

The sequence of the biofeedback training sessions is given below:

1. Subjects in this group will get biofeedback intervention training.
2. The training consists of a total of 8 sessions for every individual, with 2 sessions per week for 4 weeks.
3. Each session will be approximately 1 to 1.30 hours.
4. Subjects will be instructed not to use chocolate, coffee, tea, and cocoa drinks at least 3 hours before the training session.
5. Since it is suggested that anxiety tends to change with time so we might consider a one-month pretreatment measure as well as a just before treatment measure; that way, we can be sure if our baseline is stable or not.
6. Baseline session: The subject will be asked to sit quietly for 15 minutes, and their breathing rate, skin temperature, and muscle tension using EMG will be measured without any intervention.
7. Subjects will then be given biofeedback training gradually to control their breathing rate and relax their muscle activity and temperature through RESP biofeedback, assisted EMG biofeedback, and TEMP biofeedback, from the 1st session till their 8th session.

The control intervention

In control intervention, the subjects will be asked to take three 20-minute writing sessions¹⁸ and write about the given control topic about their daily events of the past week.

1. For example, in Session 1, we may ask the Subjects to write about how they will use their time.

2. Similarly, we will ask the subject to give more detail and write briefly about the given control condition in sessions 2 and session 3.
3. At the end of three writing sessions, we will measure their EMG, RESP, and TEMP to compare with the Biofeedback training group.

At the end of biofeedback training and writing sessions, the participants of both groups will also be asked to again fill the State-Trait Anxiety Inventory -STAI scale.

Recruitment and Assessment Procedure

One or more researchers will be involved in the process of recruitment and evaluation. The principal investigator will conduct prior training sessions regarding study aims and procedures for all the researchers involved in the study. An information sheet including the subject's socio-demographic characteristics will be provided to each individual. Written informed consent will be taken from each subject before the initiation of the study. Confidentiality will be maintained during and after the study for the Biofeedback training group and the control group. A baseline questionnaire (Demographic, Screening for Anxiety using the State-Trait Anxiety Inventory - STAI)^{15,16,17} at baseline and post-intervention (after 4 weeks) will be conducted.

Procedure

The Screening questionnaire will be utilized for assessment. Subjects reporting experiencing anxiety with the cut-off score at or above the 75th percentile on the STAI will be kept inclusive.

Study Hypothesis

1. We hypothesized to determine biofeedback as a possible effective and useful technique in helping individuals manage their anxiety.



2. Moreover, individuals receiving biofeedback training will show significant changes for the three psychophysiological modalities, i.e., EMG, RESP, and TEMP.
3. Throughout training of 4 weeks, study subjects will be trained to decrease EMG and RESP while they will be able to increase their skin TEMP.

Measures

Anxiety

The State-Trait Anxiety Inventory-STAI will be used for anxiety screening. Higher scores indicate a greater level of anxiety. It consists of 20 items on a 4-point Likert scale (1 for "almost never" to 4 for "almost always"). The STAI Y has been widely used in numerous studies and is regionally tailored. The STAI Y-2's psychometric results in Portuguese are favorable: with the reliability Cronbach's alpha .90, while the test-retest Pearson correlation coefficient of .8818. Subjects reporting experiencing anxiety with the cut-off score at or above the 75th percentile on the STAI will be kept inclusive.

Electromyography Biofeedback (EMG)

The surface EMG disposable sticky sensors will be attached to the bicep or flexor muscle. The ground sensor will be attached to the subjects' fingertips to read the heart rate. To enhance the connection on hairy places, a conductive paste, such as Ten20 Conductive Paste can be used. The electrodes can be set up consecutively. To view the EMG signals, the white, black, and green leads from the GP8 Amp will be connected to the disposable electrodes.

Respiration Biofeedback (RESP)

In this training, the GP8 Amp RepARATION belt will be used. To gauge the subject's breathing, the Respiration Belt is wrapped over the chest or abdomen. The belt expands somewhat with each breath the subject takes, and this stretch (near the middle of the belt)

is measured. In the breath pacer region of the Alive Bottom Graphs, the respiration data is displayed as a yellow line. The subject's breathing impacts his or her heart rate and smoothness, as seen by the yellow respiration line.

Temperature Biofeedback (TEMP)

As suggested, the temperature in hand increases when one gets to relax. Using GP8 Amp, we can teach the subjects to increase their hand temperature dramatically. The mini-USB slot closest to the 4 leads is where the temperature sensor is connected to the GP8 Amp. Using one of the skin conductance Velcro finger straps to secure the temperature sensor, the other end will be placed on the subject's finger. The temperature will need to calibrate for 30 to 60 seconds or until it stops rising before the training can start.

Expected Outcomes

Primary outcomes

We hypothesized to determine Biofeedback as a possible effective and useful technique in helping individuals to manage their anxiety

Secondary Outcomes

1. Individuals receiving biofeedback training will tend to show significant changes for the three psychophysiological modalities i.e., EMG, RESP, and TEMP.
2. Over the duration of training of 4 weeks, study subjects will be trained to decrease EMG and RESP, while they will be able to increase their skin TEMP.

Sample Size

The participants of this study will consist of 50 second-year nursing students, both males, and females, from the School of Nursing, Koochi Goth, Karachi-Pakistan. The age range of study subjects will be between 18-21



Years. This sample size is selected based on the Glantz book's prior power analysis.

Randomization

According to the eligibility requirements, subjects will be randomly assigned in a 1:1 ratio to the Biofeedback Training Group or control group. Randomization will be accomplished using computer-generated numbers. The study center will provide each participant a special code after collecting the necessary information from them. Each form for each subject will have a reference to the code.

Statistical Analysis

All STAI and biofeedback measurements (EMG, RESP, and TEMP) will be entered into

the SPSS version 22.0 program, and all data will be analyzed using a Multivariate Analysis of Covariance (MANCOVA) to compare pre- and post-measures of the STAI scale, as well as a Repeated Measures Analysis of Variance (ANOVA) to compare the experimental group in two physiological modes during the baseline (0) and eighth sessions of the biofeedback training. Moreover, to determine which subject met the criteria for learning the skills during biofeedback training, we will be using percent change scores while analyzing changes in anxiety. Wilcoxon signed-rank test will be done to compare the measures among the subjects.

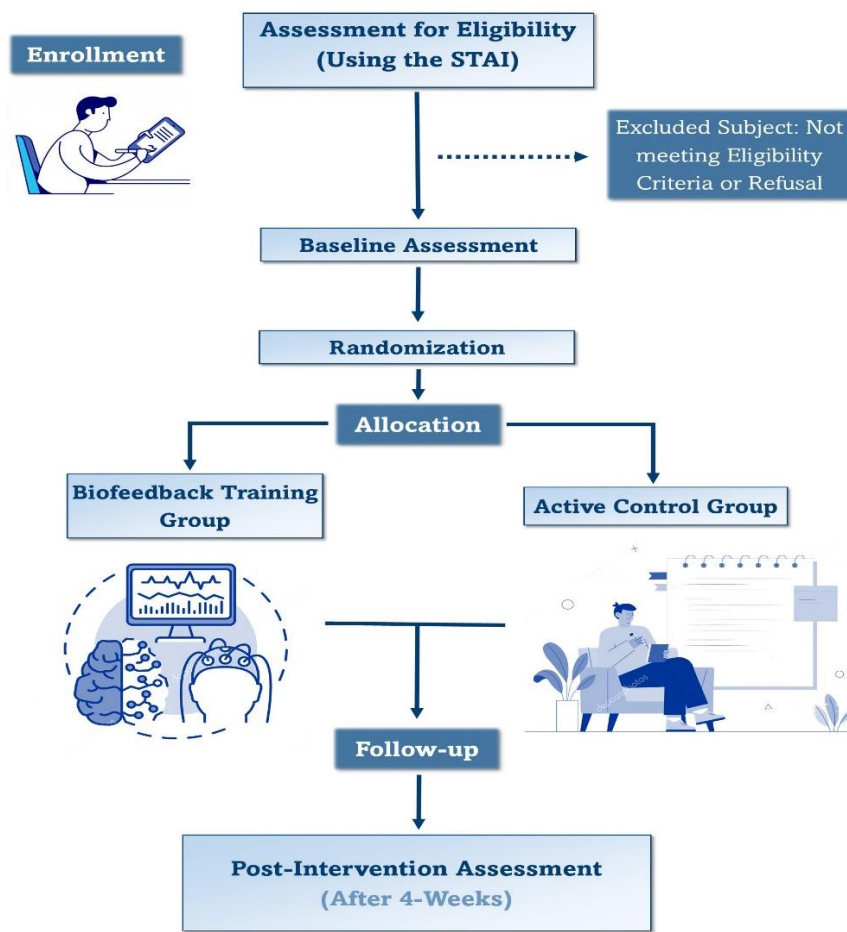


Figure 1: Flowchart of the study procedure



Discussion

Using biofeedback, one can learn to control the physical and psychological effects of stress, anxiety, and depression. Moreover, it also helps people to relax their minds and bodies to cope with a distressing situation. Psychophysiological studies have demonstrated that biofeedback training can help in reducing symptoms (psychological and psychophysiological) of stressful academic scenarios in undergraduate students. Biofeedback training and different therapeutic sessions for anxious students seem to help them in reducing the muscle tension and respiration rate, especially during the time of their final examinations.

Biofeedback training/treatment is considered a self-regulation technique, suggesting an association of stress and anxiety features with sympathetic arousal of the nervous system. Subjects getting biofeedback training are taught to alter the performance of their autonomic nervous system, which results in a reduction of activity of the sympathetic nervous system. This is done by giving the subjects an awareness session regarding their physiological functioning. Moreover, such biofeedback training is suggested to increase the individual's control over their involuntary actions and help them to dominate their activities. Overall, biofeedback training is suggested to improve the symptoms of anxiety, stress, and depression in undergraduate students.

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