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The effect of brainwave-based feedback on anxiety and stress in college students

Submission date
14/10/2025

Recruitment status
No longer recruiting

Registration date
16/10/2025

Overall study status
Ongoing

Last Edited
15/10/2025

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
College students commonly face anxiety and stress issues, yet there is currently a lack of real-time, non-invasive monitoring and intervention methods. This study aims to explore, through two experiments, the capability of electroencephalogram (EEG) in predicting stress biomarkers (such as cortisol and alpha-amylase) and anxiety states, and to develop an EEG-based closed-loop neurofeedback training system to help individuals with anxiety regulate their emotions and alleviate symptoms.

Who can participate?
1. Anxiety Disorder Participants: College students aged 17-30 with current anxiety symptoms only, no history of other mental disorders, and no current use of psychiatric medications.
2. Healthy Participants: College students aged 17-30 with no history of mental or psychological disorders and no significant physical illnesses.
All participants must have normal vision and hearing (or corrected to normal) and sign an informed consent form.

What does the study involve?
Study 1: Participants will complete a modified version of the Montreal Stress Test, with the core task being mental arithmetic training. The experimental group will perform the task under time pressure, while the control group will have no time constraints. Electroencephalogram (EEG) data will be recorded simultaneously, and saliva samples will be collected for analysis of cortisol and alpha-amylase levels.
Study 2: Participants were randomly assigned to two groups: The experimental group received EEG-based closed-loop neurofeedback training to learn negative emotion suppression through real-time feedback during an emotional image recognition task. The control group performed the same task without receiving neurofeedback. All participants completed anxiety scale assessments and EEG recordings both before and after the intervention.

What are the potential benefits and risks of participation?
Potential Benefits:
1. Helps participants better understand and regulate their emotional states;
2. Accesses professional psychological assessments and EEG monitoring;

3. May alleviate anxiety symptoms and enhance emotional regulation skills.
Potential Risks:
1. Temporary discomfort or anxiety caused by task pressure during the experiment;
2. Mild discomfort from wearing EEG devices;
3. Some participants may experience fatigue or cognitive load during training.

Where is the study conducted?
Hefei Fourth People's Hospital (Anhui Mental Health Center) (China)

When does the study start and how long is it expected to last?
January 2022 to December 2027

Who is funding this research?
Anhui Province Key Research and Development Program Project (China)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
PID 205866

Study information

Scientific Title
A randomised controlled trial of a closed-loop EEG neurofeedback intervention for anxiety: targeting emotion regulation and event-related potential biomarkers

Study objectives
Experiment 1 aims to explore the predictive capability of EEG feature models for cortisol and α-amylase levels by integrating different machine learning models and feature importance analysis methods, with the goal of providing novel solutions for real-time, non-invasive stress monitoring. Experiment 2 aims to focus on specific ERP components during states of anxiety and to explore a brainwave feature model capable of monitoring and predicting anxiety states (diagnostic model).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/01/2023, Medical Research Ethics Committee of Hefei Fourth People's Hospital (316 Huangshan Road, Shushan District, Hefei, 230026, China; +86 (0)551 6361 6193; 2514331322@qq.com), ref: HFS-IRB-PJ-WL (2022002)

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Anxiety disorder

Interventions
Study 1:
The participants underwent two identical experimental procedures: Day 1: the first montreal imaging stress task (MIST) with EEG recording. Day 4: the second MIST task with EEG recording. The MIST task included four 3-minute blocks: the first and third blocks were control blocks and

the second and forth blocks were experimental blocks , with saliva collection completion after each block. A final saliva collection was completed after a 15-minute rest.
Saliva was collected six times: after MIST training (following a 5-minute rest) and at the end of each 3-minute block (four times), with a final collection after a 15-minute rest. A total of 12 saliva samples were collected before and after the intervention (Figure 1). Saliva samples were collected via standardized time points, cryopreserved at -80°C, and tested for cortisol and alpha-amylase levels using kits.

Study 2:
All participants were randomly assigned to one of the following two groups:
Experimental group (n=30): Participants exhibiting anxiety symptoms receive closed-loop neurofeedback training based on electroencephalogram (EEG). During training, participants performed an emotion image recognition task (positive/negative) while actively suppressing negative emotions triggered by viewing negative images. Task-related EEG signals were collected in real-time, and real-time neural feedback was provided based on event-related potential components (e.g., N2/P3/LPP). Each training session lasted approximately 30 minutes, with multiple sessions conducted (specific number determined by experimental design). Control group (n=30): Received identical intervention content to the experimental group but without neural feedback. Participants performed the same emotion image recognition task while EEG data was collected.
All participants completed clinical scale assessments (e.g., Self-Rating Anxiety Scale) and baseline EEG recordings prior to intervention. EEG data collection and scale assessments were repeated post-intervention.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Study 1:
Prediction of cortisol and α-amylase levels using machine learning models based on electroencephalogram features.

Study 2:
1. Change in amplitude of anxiety-specific Event-Related Potential (ERP) components (e.g., N2, P3, or Late Positive Potential (LPP)) during the emotional regulation task.
Timepoint: From baseline (pre-intervention) to immediately after the completion of the closed-loop training sessions.
2. Change in high-frequency beta wave power during the emotional regulation task.
Timepoint: From baseline (pre-intervention) to immediately after the completion of the closed-loop training sessions.

Key secondary outcome(s))
Study 1:
1. Performance comparison of different machine learning models in predictive tasks: Specific metrics include accuracy, which evaluates the performance of multilayer perceptrons, support vector machines, and linear discriminant analysis in predicting elevated/low cortisol and α-amylase levels.
2. Importance contribution of EEG features to predictive models: Quantification of relative contributions from different frequency bands (e.g., Delta, Theta, Alpha, Beta, Gamma) to cortisol and α-amylase prediction using SHAP values. Quantification of relative contributions from different brain regions (e.g., right prefrontal cortex, occipital cortex, parietal cortex) to

predicting these biomarker levels through SHAP values.
3. Regression prediction accuracy of machine learning models for cortisol and α-amylase levels: Evaluation metrics include R^2 (coefficient of determination) and mean absolute error to measure models' ability to predict continuous physiological parameter values.
4. Differences in EEG feature model prediction effectiveness across time points (first and second MIST tasks): Assess whether temporal factors during stress task interventions affect the classification performance of EEG feature-based models.

Study 2:
1. Change in self-reported anxiety scores as measured by standardized anxiety scales (e.g., GAD-7, SAS).
Timepoint: From baseline (pre-intervention) to immediately after the completion of the training sessions.
2. Change in behavioral performance during the emotional regulation task, including:
Reaction time to positive and negative stimuli.
Accuracy of emotion identification.
Timepoint: From baseline to post-intervention.
3.Change in scores from the closed-loop training task (where a higher score indicates better ability to suppress negative emotions and greater emotional stability).
Timepoint: Measured after each training block and compared across the training course.
4.Changes in other EEG/ERP components not listed as primary outcomes, such as P1, N1, and Error-Related Negativity (ERN/ΔERN), and their correlation with anxiety reduction.
Timepoint: From baseline to post-intervention.
5.Participant's subjective experience and strategy use, assessed through post-training questionnaires or interviews, regarding:
5.1. Attention concentration level.
5.2. Cognitive load.
5.3. Emotional state.
5.4. Fatigue level.
5.5. Self-regulation strategies developed.
Timepoint: After each training session or at the end of the entire intervention.
6.Performance and generalizability of the predictive EEG-based anxiety diagnostic model, evaluated by:
The model's accuracy, sensitivity, and specificity in classifying or predicting anxiety states.
Timepoint: Upon completion of data collection and analysis.

Completion date
31/12/2027

Eligibility

Key inclusion criteria
Anxiety disorder participants:
1. Age 17-30 years old college students;
2. Able to comprehend questionnaire content and complete all scales independently;
3. Currently experiencing only anxiety symptoms without other DSM-5-confirmed mental disorders;
4. No history of psychiatric medication use (within 6 months);
5. Normal vision and hearing or corrected vision/hearing;

6. No severe physical illnesses, no history of head trauma, no metal implants in the head, no epilepsy, no episodes of transient loss of consciousness; willing to participate and have signed an informed consent form.

Healthy participants:
1. Age 17-30 years old college students
2. Normal hearing, normal or corrected vision
3. Right-handed
4. No previous diagnosis of mental or psychological illness
5. No history of major physical illness

Participant type(s)
Learner/student

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
17 years

Upper age limit
30 years

Sex
All

Key exclusion criteria
Exclusion criteria for anxiety disorders:
1. The questionnaire results contain significant logical inconsistencies;
2. Confirmed diagnosis of mental illness or family history of psychiatric disorders;
3. History of head trauma or implanted devices in the head;
4. If participants show marked improvement in anxiety levels or nearly perfect scores during closed-loop training before the assessment, they may be preliminarily excluded from the anxiety group as they may not meet the diagnostic criteria for anxiety.

Date of first enrolment
02/03/2023

Date of final enrolment
15/04/2024

Locations

Countries of recruitment
China

Study participating centre
Hefei Fourth People's Hospital
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Sponsor information

Organisation
Affiliated Psychological Hospital, Anhui Medical University

Funder(s)

Funder type
Government

Funder Name
Anhui Provincial Key Research and Development Plan

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Wan Li (wanli@ahmu.edu.cn) after the publication of the article

IPD sharing plan summary
Available on request