Musically-Guided Paced Breathing Improves Mental Health in War-Affected Adolescents

Study Protocol and Statistical Analysis Plan

NCI Number: NCT06988800

January 21, 2024

Participants

Students were included in this study if they were children aged 13-17 years and enrolled at a school in a war-torn area in the West Bank in the Middle East. Students were excluded if they had a known diagnosis that may have impeded their participation (e.g., epilepsy, substance abuse, attention-deficit/hyperactivity disorder). In order to have 90% power to detect a medium effect size (f = .25), 130 participants would be required, and the total number enrolled was 213. Consent forms stated that the goal of the intervention was to reduce anxiety and manage stress.The study protocol was approved by an Institutional Review Board that consisted of two independent researchers in the study region.

Procedure

Participants were randomly assigned, stratified by age and gender, to an intervention or control condition. After all consents were collected, an individual external to the study team divided participants into near equal groups based on age and gender, which were then used to assign participants to one of the three conditions. Only the individual who randomized the participants and the group facilitators were provided access to the document linking the name and de-identified participant identifier.

Participants in the control condition completed other typical after-school activities while participants in the intervention condition completed one of two breathing interventions: paced breathing (paced), or mindful breathing (mindfulness). Participants in the control condition were given the opportunity to complete the intervention after the study ended. All participants in the intervention and control conditions completed a pre-intervention measure of anxiety, depression, and self-efficacy. Participants in the intervention condition then completed 12 sessions of the guided paced breathing audiovisual intervention, held 2 times a week for 5 weeks. After the 4th

week of the intervention, all participants in both the intervention and control conditions completed a mid-intervention measure of anxiety, depression, and self-efficacy. The study was then paused for one month during Ramadan, and resumed at the beginning of the following month. After the 5th total week of the intervention, all participants in both the intervention and control conditions completed a post-intervention measure of anxiety, depression, and self-efficacy.

Guided Paced Breathing Audiovisual Intervention

Each intervention session was conducted by the school teacher, who guided groups of approximately ten participants in classrooms. The groups were separated by gender and age (e.g., 16-year-old boys). Participants were seated comfortably with a clear view of a screen displaying the audiovisual intervention, and the audio was played at a comfortable volume. Each session began with an educational introduction, which outlined the benefits of paced breathing, such as how it can positively impact well-being and mental health (e.g., "A strong sense of well-being helps you to feel good about yourself and the way your life is going, which can have a hugely positive impact on your mental health").

Following the introduction, the intervention transitioned into a three-minute audiovisual guided paced breathing exercise. The paced breathing condition used timed auditory and visual cues to guide participants through breathing cycles at a rate of five breaths per minute, designed to stimulate the parasympathetic nervous system and promote relaxation. The audiovisual cues included spoken instructions, music, and breath-like sounds. The tonal audio cues rose in pitch during inhalation and fell during exhalation, creating a clear auditory signal for breath pacing. The same harmonic drone used in the mindfulness intervention provided a calming background, though here it was combined with the rhythmic pacing. Visually, the pacing was synchronized

with the image of a lotus flower opening during inhalation and closing during exhalation, reinforcing the breathing rhythm.

Mindfulness Intervention

The mindfulness intervention employed a similar visual setting, featuring the same lotus flower graphic. However, instead of rhythmic pacing, the lotus flower remained open at the start of the session and gradually closed over the course of the 3 minute exercise. This visual served as a symbolic anchor for the participant's growing awareness and focus.

The audio component of the mindfulness intervention featured a female narrator guiding participants through mindfulness exercises, focusing on breath awareness and cultivating non-judgmental attention to thoughts and feelings. Ambient tonal sounds, including a harmonic drone with slow timbral changes, played softly in the background to support relaxation. Importantly, no rhythmic audio cues were included to avoid inducing breathing entrainment. This setup emphasized passive, mindful observation rather than active breath control, encouraging participants to observe their bodily sensations and thoughts without judgment.

Measures

Demographics. Participant age and gender were collected from families as part of the student's involvement in the after-school program.

Revised Children's Manifest Anxiety Scale (RCMAS). To measure the level and nature of anxiety symptoms, the RCMAS Arabic version was administered to participants via a web-based survey. The RCMAS is a self-report questionnaire that lists feelings or actions and was administered to all participants pre- and post-intervention. Participants answer "yes" if that item is generally descriptive of their own feelings or actions, or "no" if not. The RCMAS produces a total anxiety score based on 28 items, with three subscales: physiological anxiety,

worry/oversensitivity, and social concerns/concentration. Higher scores represent more anxiety symptoms. Both the English and Arabic versions of the RCMAS have been shown to have acceptable reliability and validity in school-aged children. Similar to previous studies using the RCMAS, if at least 80% of items for each scale was present, missing data was imputed using the within-subject mean of the non-missing items in the same scale. In the current sample, the total score showed good internal consistency ($\alpha = .82$).

The Self-Efficacy Questionnaire for Children (SEQ-C).

The Self-Efficacy Questionnaire for Children (SEQ-C) measures three types of self-efficacy: (1) social self-efficacy, measuring children's capability to deal with social challenges; (2) academic self-efficacy, measuring children's perceived capability to master academic affairs; and (3) self-regulatory efficacy, measuring children's ability to resist peer pressure to engage in high risk activities.

Translated PHQ-9

A validated measure of depressive symptoms, consisting of nine items assessing the frequency of depressive symptoms over the past two weeks. The PHQ-9 has demonstrated strong psychometric properties, including reliability and validity in clinical and non-clinical populations, including the translated Arabic version.

Data Analysis

Analyses were conducted using R. Group differences at baseline in anxiety, depression, and self-efficacy scores were examined using ANCOVAs and post hoc Tukey pairwise tests. For the primary analyses, four analyses of covariance (ANCOVAs) were conducted. For each ANCOVA, the independent variables were condition (paced breathing or mindfulness intervention vs. control) and time of observation (before or after the intervention), the dependent

variable was the behavioral scale (RCMAS, SEQ-C, PHQ-9) at post-intervention, and the covariate was gender. Exploratory general linear models (GLMs) were conducted to examine whether gender moderated the relationship between condition and anxiety or depression symptoms. For significant GLMs, post-hoc GLMs were conducted to examine the relationship between condition and anxiety or depression symptoms within each subgroup. All tests were two-tailed, no test assumptions were violated, and findings were considered significant at $p < .05$.