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A pilot study evaluating the effects of a guided paced breathing audiovisual intervention for children aged 6 - 10 years old in the Levant Region

Submission date
20/10/2021

Recruitment status
No longer recruiting

Registration date
22/10/2021

Overall study status
Completed

Last Edited
30/12/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Palestinian youth disproportionately experience high rates of anxiety and other mental health disorders, a mental health crisis heightened as war and political turmoil have left mental health personnel and infrastructure in Palestine scattered and underfunded. Additionally, occupation and exposure to conflict are unique causes of anxiety for Palestinian youth, further contributing to high anxiety rates among the population and burdening the severely inadequate mental health infrastructure.
Access to mental health specialists in this region is impacted by a number of factors, including but not limited to the high cost of administration, limited mobility, poverty, war and cultural differences in the treatment of mental health disorders. This study aims to bridge this gap with a targeted intervention designed specifically for children in this region.
Recent clinical studies demonstrate that slow, rhythmic breathing positively impacts the brain and calms the stress response. Slow-paced breathing hence presents itself as a component in a potential low-cost, scalable, and accessible health resource for stress regulation and anxiety management. The aim of this study is to investigate the effects of a digital guided breathing intervention on anxiety in children at the Middle East Children's Institute. This digital intervention uses visual and auditory cues to guide a calming paced breathing pattern, which may help alleviate anxiety. The 8-week pilot study will evaluate the effects of a regular weekly practice of the intervention designed to help manage symptoms of anxiety and improve overall well-being in Palestinian children.

Who can participate?
Children aged 6-10 years enrolled at the Middle East Children's Institute after-school program. There will be an equal number of male and female participants across all ages.

What does the study involve?
Participants will be randomly assigned to the intervention and waitlist groups. One-half of the body of participants will receive a guided breathing intervention, while the other half will be put

on a waitlist to receive the intervention in the future and, for the purposes of this study, will serve as the control group. Every participant, both in the intervention group and the waitlist group, will complete questionnaires at the start and the end of the 8-week study period. Participants in the intervention group will engage in three sessions with the software per week, with each session lasting up to 5 minutes. Before and after each interaction with the intervention, participants in the intervention group will complete a brief survey (about 2 minutes) communicating their stress and comfort levels at the time.

What are the possible benefits and risks of participating?
The benefit which may reasonably be expected to result from this study is a reduction in stress and/or anxiety. There are no known risks associated with direct participation in this study. Responding to the questionnaires and surveys may cause participants to think of situations that make them anxious or sad, which some may find uncomfortable.

Where is the study run from?
The Middle East Children's Institute (USA)

When is the study starting and how long is it expected to run for?
March 2021 to December 2021

Who is funding the study?
The Middle East Children's Institute (USA)

Who is the main contact?
Victoria Grace CEO
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
U1111-1269-2145

Study information

Scientific Title
A pilot study in the effects of a digital guided breathing intervention on measures of state-trait anxiety in healthy participants aged 6-10: Breathing Entrainment for Anxiety Management (BEAM)

Acronym
BEAM

Study objectives
The primary aim of this study is to evaluate the potential for impact of guided breathing interventions for anxiety or stress delivered through a digital medium. The researchers expect to see improvements in all primary and secondary outcome measures at the post-intervention timepoint relative to baseline

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/02/2022, Institutional Review Board consisting of two independent consultants in the region: an expert in special education (Dr. George Elias Malki) and a professor in psychology (Professor Taisir Abdallah, PhD) (Al-Quds University, Abu Dis, Palestine; no telephone number; no email), no reference

Study design
Single-center single-blinded waitlist-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
School

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Symptoms associated with anxiety in individuals in high-stress environments

Interventions
Recruitment concludes with the appropriate number of qualifying participants having provided written consent to participate in the study. The names of participants will be entered into a digital form that is password protected and can only be accessed by the trial lead supervisor. Once the form is populated with names, the names are randomized using a randomize range function. This will allocate study participants randomly into experimental and control groups for the study.

Participants will be delivered digital therapy featuring mindful breath awareness and paced breathing through audiovisual stimuli designed to support anxiety management. Three digital therapy breathing interventions will be delivered each week to the participants in the trial group over a total of 8 weeks.

Baseline and post-study assessment of anxiety using RCMAS will be conducted before stimulus presentation.

Participants will be shown the stimuli in a familiar classroom environment using television and speakers playing sound at a safe volume.

The first week will serve as an introductory week teaching breath awareness and guided breathing best practices. This week will feature audio-only stimuli.

The second week until the end of the trial will feature audio/visual stimuli featuring slow-paced breathing interventions.

The control group will be waitlisted to receive the intervention at a later date after the trial.

Intervention Type
Behavioural

Primary outcome measure
Participants' persistent (trait) anxiety measured by an Arabic translated version of the Revised Children's Manifest Anxiety Scale (RCMAS) validated for use with the population participating in this study, prior to and following the 8-week study period

Secondary outcome measures
Participants' self-reported relaxation measured by a pictorial Likert scale immediately prior to and following each digital intervention

Overall study start date
11/03/2021

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Aged 6-10 years
2. Any gender
3. A student at the Middle East Children's Institute (MECI) Comprehensive After-School Program

Participant type(s)
Other

Age group
Child

Lower age limit
6 Years

Upper age limit
10 Years

Sex
Both

Target number of participants
160

Total final enrolment
144

Key exclusion criteria
1. A diagnosis of epilepsy
2. A history of substance abuse

Date of first enrolment
22/10/2021

Date of final enrolment
30/10/2021

Locations

Countries of recruitment
Palestine, State of

Study participating centre
Middle East Children's Institute / Palestine
Deir Ghassana Women's Society Building
Bani Zeid Al-Gharbia
Palestine, State of
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Sponsor information

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Muvik Labs

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Sponsor type
Industry

Website
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Funder(s)

Funder type
Charity

Funder Name
Middle East Children's Institute

Results and Publications

Publication and dissemination plan
This study is planned to be published in a high-impact peer-reviewed journal as soon as possible following the completion of data analysis, estimated to be in February 2022. Additional documents will not be made available until after publication after which they may be made available upon request.

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The datasets generated by this study will be available 3 months after the publication of the study and indefinitely thereon upon request from Victoria Grace (contact@muviklabs.io) following the publication of the main trial findings. Data may be shared with other research teams for the purpose of contributing to systematic reviews and meta-analyses upon the proposal of a methodologically sound proposal, whose use of this data has been approved by an independent review committee identified for this purpose and a signed data use agreement. Participant consent has been sought for this and shared data will be fully anonymised. There are no other considerations or comments relating to this.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/12/2022	30/12/2022	Yes	No