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Promoting better learning at school

Submission date
13/12/2022

Recruitment status
No longer recruiting

Registration date
03/01/2023

Overall study status
Completed

Last Edited
10/06/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Children in the school district this trial will take place in frequently suffer from poverty and neglect. Domestic violence is common as is alcohol abuse. Wives and children are frequently physically abused when the husband/father drinks. Verbal abuse is commonplace. Alcohol abuse and drug abuse are not uncommon in this middle school population and there is pressure to join gangs. It is common for fathers to leave the family for long periods of time to find work in the fields in the United States. Frequently the men create second families in the United States and some never return. Teachers are usually high school graduates but are very concerned about children dropping out and using alcohol and drugs.
The study aims to reduce trauma in children who are likely to be exposed to trauma on a regular basis and hopefully mitigate symptoms of trauma that interfere with their learning and social life.

Who can participate?
Children in middle school whose caregivers have given consent for them to participate, and then, have given consent to participate will be included in the study

What does the study involve?
There will be two middle schools that participate in the study. The children in participating classrooms in one school will have 10 minutes of unguided free art activity every morning at a teacher-determined time. Children participating in another classroom will have 10 minutes of teacher-lead acupoint self-treatment every morning at a teacher-appointed time.
Aside from participating in the above daily activities, the children will be assessed during the school semester on three occasions by graduate students from the Universidad Intercultural Indigena de Michoacan (UIIM). The first assessment will take place at the beginning of the school semester, the second assessment will be 6 weeks later, and the third will take place at the end of the semester. The caretaker (if they agree to also participate) and the child (assessed separately and at different times in the day than the caretaker) will be answering questions on a tablet, and no one will have access to the questions and answers except the statistician, and the statistician will see only numbers representing each child. No one else at the University or anywhere will ever see the child's questions and answers.

What are the possible risks and benefits of participating?
The possible benefits to a child as a result of participating in this study may be a reduction in

stress and improved grades. The possible risks might be that a child may think about difficult things while doing the art activity or the acupoint exercise or during the assessment and temporarily feel some emotional upset.

When is the study starting and how long is it expected to run for?
January 2022 to July 2023

Who is funding the study?
Association for Comprehensive Energy Psychology (ACEP)

Who is the main contact?
Ms Suzanne Connolly, smc@suzanneconnolly.com

Contact information

Type(s)
Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
Promoting better learning at school using a 10-minute teacher-led exercise to reduce stress, a controlled double-blind study

Acronym
PBLS

Study objectives
The authors hypothesize that a 10-minute teacher-led group exercise of thought field therapy (TFT) will significantly reduce symptoms of trauma in middle school children in the TFT intervention group, as measured by the CATS assessment (Appendices 1 &2) when compared to the ten-minute per-school-day intervention of art activity for the active waitlist group of middle school children.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/11/2022, Intercultural Indigenous University of Michoacan (Universidad Intercultural Indigena de Michoacan) (Km3 HWY Hueorio, s/n Quinta La Tzipecua, Patzcuarto, Michoacan, P.C., 58010, Mexico; +52 (0)61614, 5591860948; pedro.reygadas@uiim.edu.mx), ref: 10548974

Primary study design
Interventional

Study design
Pre-post-controlled multicentered double-blinded intervention study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of and reduction of symptoms of adverse childhood experiences and improved learning

Interventions
Current interventions as of 28/09/2023:
Co-researcher, Suzanne Connolly, LCSW, was contacted by a board member of a Mexican non-profit, Asociacion San Andreas Pescador whose mission is helping underprivileged children in Mexico. The non-profit board member was in contact with two university professors from UIIM, who were also concerned about the adverse experiences of children in Mexico. They wondered if a stress reduction technique (TFT) they had learned could be helpful if introduced in classrooms in Mexico. Suzanne Connolly agreed to help as she had some informal experience doing this intervention in a school in the United States and was experienced professionally as a researcher. The idea of an active waitlist group was suggested to limit variables. There was some difficulty in

finding two schools to participate in as this area is known to be dangerous and people are suspicious. The idea of a cluster randomized trial was dropped but this will be a double-blinded controlled study.

This study will be a pre-post-controlled multicentered double-blinded intervention study with a pretest, a posttest 1 at midterm, and a posttest 2 at semester end. Children in two middle schools in an area with similar demographics but geographically separated have accepted an invitation to participate. (Teachers in one school could not agree to attend the longer training so they will be in the art-activity group so it will be a non-randomized controlled trial. The study was planned to be randomized but will now be a non-randomized controlled study). Ideally, each middle school will have approximately 50 students whose caregivers will agree for them to participate in this trial and who themselves agree to participate in this trial. Recruitment for classroom participants will begin prior to the beginning of the school semester and end two weeks after the first week of the school semester.

Both schools will receive a 10-minute daily intervention that the researchers predict will reduce stress in the classrooms. The principals, the teachers, the caretakers, and the children will be told we are testing two possibilities for reducing stress in the classroom.

The participating children in both schools will meet with a UIIM graduate student for assessment at pretesting, mid-semester, and semester end. At each assessment, they will meet with the assessor at a private designated space at the school and the child will be given a tablet pre-programmed by the statistician with the questions and the choice of answers. The graduate student will reassure the child that they know neither the questions nor the answers and that the only person who will see the answers will be the statistician who will not know their name but only a number. No one will ever see their names and their answers. The questions will appear one at a time on the tablet and as soon as answered will disappear into a databank, created by the statistician. The statistician will have access to only numbers. Only one person, Lic. Leonor Zarazua Menchaca will have the key to the child's names and numbers and that document will be stored in a separate locked file cabinet at the University.

The children in one school will receive a ten-minute teacher-guided group intervention of TFT (self-acupoint tapping) guided by their teacher every school day; the children in the second school will participate in an active waitlist group. TFT is a specific self-administered acupoint tapping procedure where the children will tap with their fingers on five specific acupoints on their face, one on their side, two on their fingers, and two on their hand.

The participating students in the second middle school will receive a ten-minute intervention of a teacher-initiated non-directed art activity consisting of free drawing with colored pencils and art paper provided to the students through the grant. The teachers will be trained to not critique the artwork or interpret the artwork in any way.

Both schools will be informed that we are testing possible ways to reduce the effects of trauma and enhance the learning ability of middle school children by increasing their ability to focus on the classroom. The children will be assessed using the Spanish version of the Child and Adolescent Trauma Screen for Children (CATS) Ages 7-17 (see Appendix 1 at BLS-project.org) and their caregivers (see Appendix 2 at BLS-project.org).

Lic. Leonor Zarazua Menchaca, study coordinator representing the non-profit study sponsor Asociacion San Andrés Pescador, will arrange for the utilization of cell phone cameras to video-record teacher-led interventions in the two groups videoing the teachers only (no children). These will be assessed for intervention fidelity by study coordinators, Lic. Leonor Zarazua

Menchaca and Suzanne Connolly, LCSW by weekly live supervision by Lic. Leonor Zarazua Menchaca. If the classes are online, the assessment of intervention fidelity will all be conducted remotely.

Previous interventions:
Co-researcher, Suzanne Connolly, LCSW, was contacted by a board member of a Mexican non-profit, Asociacion San Andreas Pescador whose mission is helping underprivileged children in Mexico. The non-profit board member was in contact with two university professors from UIIM, who were also concerned about the adverse experiences of children in Mexico. They wondered if a stress reduction technique (TFT) they had learned could be helpful if introduced in classrooms in Mexico. Suzanne Connolly agreed to help as she had some informal experience doing this intervention in a school in the United States and was experienced professionally as a researcher. The idea of an active waitlist group was suggested to limit variables. There was some difficulty in finding two schools to participate in as this area is known to be dangerous and people are suspicious. The idea of a cluster randomized trial was dropped but this will be a double-blinded controlled study.

This study will be a pre-post-controlled multicentered double-blinded intervention study with a pretest, posttest, and one follow-up. Children in two middle schools in an area with similar demographics but geographically separated have accepted an invitation to participate. (Teachers in one school could not agree to attend the longer training so they will be in the art-activity group so it will be a non-randomized controlled trial. The study was planned to be randomized but will now be a non-randomized controlled study). Ideally, each middle school will have approximately 50 students whose caregivers will agree for them to participate in this trial and who themselves agree to participate in this trial. Recruitment for classroom participants will begin prior to the beginning of the school semester and end two weeks after the first week of the school semester.

Both schools will receive a 10-minute daily intervention that the researchers predict will reduce stress in the classrooms. The principals, the teachers, the caretakers, and the children will be told we are testing two possibilities for reducing stress in the classroom.

The participating children in both schools will meet with a UIIM graduate student for assessment at pretesting, post-testing, and follow-up. At each assessment, they will meet with the assessor at a private designated space at the school and the child will be given a tablet pre-programmed by the statistician with the questions and the choice of answers. The graduate student will reassure the child that they know neither the questions or the answers and that the only person who will see the answers will be the statistician who will not know their name but only a number. No one will ever see their names and their answers. The questions will appear one at a time on the tablet and as soon as answered will disappear into a databank, created by the statistician. The statistician will have access to only numbers. Only one person, Lic. Leonor Zarazua Menchaca will have the key to the child's names and numbers and that document will be stored in a separate locked file cabinet at the University.

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Intervention Type
Behavioural

Primary outcome(s)
Stressful experiences, trauma symptoms, and how problems interfere with life, measured using the Child and Adolescent Trauma Screen (CATS) for Youth and Caregivers ages 7-17 at baseline (start of the school semester), 6 weeks after the school semester begins, and just before the school semester ends

Key secondary outcome(s)
Child behavioral disturbances, absenteeism and grades measured using classroom teacher reporting throughout the study

Completion date
07/07/2023

Eligibility

Key inclusion criteria
Two middle school principals from the Pascuala area of Michoacan will have consented for their schools to participate in this controlled (not randomized) study.
Children eligible to participate in this study will be:
1. In participating classrooms
2. Children whose caregivers have granted free consent
3. Children who have given their free consent, following their caretaker's consent
Note: All ages in middle school will be included

Participant type(s)
Other

Healthy volunteers allowed
No

Age group

Child

Sex
All

Key exclusion criteria
1. Children not in one of the two consenting/participating schools
2. Children whose caregivers have not signed free consent
3. Children whose caregivers have given free consent but they have not given free consent

Date of first enrolment
28/11/2022

Date of final enrolment
27/01/2023

Locations

Countries of recruitment
Mexico

Study participating centre
Escuela Telesecundaria ESTV16466
Alheli- (no street address)
Caracha, municipio de Ziracuaretiro, Michoacán
Mexico
61703

Study participating centre
Escuela Telesecundaria N 301
Zirimicuaro Domicilio conocido
Zirimicuaro Domicilio conocido
Mexico
61703

Sponsor information

Organisation
Association for Comprehensive Energy Psychology

Funder(s)

Funder type
Research organisation

Funder Name
Association for Comprehensive Energy Psychology (ACEP)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (https://bls-project.org). The database (no names) relevant to the main objectives gathered by the statistician, Dr Hector Figueroa Palofox, will be available at the repository. The URL repository will be updated and maintained for a minimum time of 5 years.

Raw data and results of analyses will be shared upon request. No children's names or caretaker's names will ever be available or able to be connected to any data. Only one researcher in the study will have access to both names and numbers and that researcher will not be able to connect any data to names. Any data posted will be nontraceable to any individual child or caregiver. The two groups, not individuals will be compared by a statistical method that will be established by the statistician.

Teachers are told the following and teachers, caretakers and students will have a basic understanding of how the intervention they received helped or did not help. The following is a quote from the caretaker's consent form: (Appendices 5 & 6)
"Your child is being asked to be a participant in a study. Two different approaches to creating a calm learning environment will be explored at two different schools. The approach at your child’s school is intended to gather information about the use of a technique called... (the Acu treatment or art activity is described briefly only one or the other depending on which school) which could potentially increase your child’s ability to focus on schoolwork and learn. At the study’s finish, if the improvement in one school classroom, significantly surpasses the improvement in the other school’s classroom, all teachers who wish to participate, will be given the opportunity to be trained to conduct more effective treatment in their classrooms for the following semesters."

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		09/06/2025	10/06/2025	Yes	No
Basic results			27/08/2024	No	No
Statistical Analysis Plan			30/12/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes