

APPLICATION FOR THE CONDUCT OF RESEARCH INVOLVING HUMAN PARTICIPANTS

TITLE OF STUDY:		DATE SUBMITTED (today's date):	
Promoting Better Learning at School Project		11/03/2022	
PURPOSE OF STUDY: Check all that apply.			
KA	<input checked="" type="checkbox"/>	X	<input type="checkbox"/>
	Pilot Study	Dissertation	Research Project
			Institutional Research

RESEARCHER'S NAME:	SCHOOL (ELC, HOD, PSY):	PROGRAM (Clinical, OMOD, etc.):
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CO-RESEARCHER INFORMATION – Include name, address, and contact information

Dr. Josefina Guzmán Díaz, UIIM, El Tiempo que Resta C.A

DESCRIPTION OF PROPOSED RESEARCH –

1. Provide a brief description of the background and purpose of your research.

1.The problem: Children in the Mexican educational system today are facing many challenges. Absenteeism, bullying, poor grades, smoking, alcohol and drug use, behavioral problems, and dropout rates are epidemic in our schools. Mexico ranked last in education among the 35 Organization for Economic Cooperation and Development (OECD) countries. Mexican children leave school with the worst literacy, math, and science skills, with around half failing to meet the most basic standards.
<https://www.asherfergusson.com/raising-a-family-index>
 Additionally, the Covid-19 pandemic has caused many thousands of children to miss classes and fall behind in their schoolwork. <https://www.children.org/learn-more/contact-us/faq/about-child-details/my-school>

Many of these problems are due, in part, to the effects of Adverse Childhood Experiences (ACEs). ACEs (childhood traumas) include physical, emotional, or sexual abuse; physical or emotional neglect; parental substance abuse; parental mental illness or, suicide attempt; violence between parents; parental separation; bullying; and parental criminal conviction. ACEs have been associated with lower educational attainment,

[Type here]

and higher risk of anxiety, depression, smoking, and alcohol and drug use in teenagers.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6220625/>

ACEs are also associated with negative adult health outcomes, including cancer, diabetes, obesity, cardiovascular disease, substance abuse, depression, and premature death. Although the effects of ACEs are widely recognized, up until recently there have been no effective methods for treating it.

<https://jamanetwork.com/journals/jama/article-abstract/2755266>

2. Provide a brief description of the **basic research question/issue**.

3. The study will include a ten-minutes per-school-day tapping intervention Our question is: Will thought field therapy (TFT), significantly reduce symptoms of trauma in middle school children in the TFT intervention group, as measured by the CATS assessment, when compared to the ten-minutes per-school-day intervention of an art activity for the active waitlist group of middle school children? Secondary aims of the study are to improve the overall learning environment by reducing absenteeism, reducing disciplinary actions, and improving reading and math scores as noted by the teachers.

4. Provide a description of the **design and procedure** of your research. Be sure to describe **all activities** that participants will engage in, and the total time required. Also, at each step in the procedure that you describe, list **all of the means you will use to collect data** during that step in the procedure (e.g., instruments, measures, tests, questionnaires, surveys, interview schedules, focus group questions, observations).

3.a. Provide a listing that has the name followed by a brief description of the tests, instruments, or measures and **attach copies of instruments and questionnaires for review**.

3a. Study Design: This study will be a pre-post-controlled study with one-follow-up. Children in two middle schools in an area with similar demographics but geographically separated have accepted an invitation to participate. Ideally each middle school will have approximately 30 students. The children in one school will receive an intervention of ten-minutes of TFT (acupoint tapping) guided by their teacher every school day; the children in the second school will participate in an active waitlist group. The participating students in that middle school will receive an intervention of ten-minutes of a teacher led art activity consisting of colored pencil artwork, on the same schedule. 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 in the classroom. The children will be assessed using the Spanish version of the CATS (Child and Adolescent Trauma Screen) for children (Appendix 1) and their caretakers. (Appendix 2). Children and their caretakers participating in the study will complete a signed consent form. 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 with periodic live supervision by Lic. Leonor Zarazua Menchaca. If the classes are online, assessment of intervention fidelity will all be conducted remotely.

Timing: The study starting time is planned for the beginning of the winter -2023 school session and will take place in on-site classrooms. (However, we can also prepare for the possibility that the study will take place online.)

Training of Teachers: The middle school, San Bertolo Pareo, municipality of Pátzcuaro and Jarácuaro, municipality of Erongarícuaro, Michoacán will be the site of the TFT intervention group.

Two teachers from the San Bertolo Pareo school and any school counselors and/or others from the San Bertolo Pareo school, who want to be trained in Thought Field Therapy (TFT) will participate in a one and a half day training prior to the start of the school semester. (Extra people are being included to insure plenty of practice time). The two-day training for the teachers (and others) will be conducted by Suzanne Connolly, LCSW with Lic. Leonor Zarazua Menchaca serving as co-instructor and interpreter.

During the duration of the semester, the teacher will lead the classroom for ten minutes of self-help intervention (TFT) each morning.

The children in the middle school classroom(s) in the school (yet to be named) in the art-activity group will receive a teacher-led intervention where the teacher will guide the students for the duration of the semester, in ten minutes of free expression artwork encouraging them to express their feelings through artwork. This teacher will receive a half-day training on the importance supporting the students during the activity but not directing or criticizing their artwork in any way. Art therapist Maria Luisa De La Garza, will provide the training.

After the semesters end, the teachers and others from the art-activity school will be invited to attend an additional training in TFT if the intervention proves to be significantly superior in measurable outcomes to the art-activity intervention school and likewise the teachers from the TFT intervention school will be invited to learn the importance of a daily ten-minute period of drawing in the classroom if the art-activity school proves significantly superior in measurable outcomes to the TFT intervention school.

3b. The Assessment Instrument: The CATS (Child Adolescent Trauma Screen) is an excellent assessment for this study. It will be conducted for both children and adults via confidential self-test style. The CATS has been validated in Spanish. <https://psyarxiv.com/d8pht/> and is in the public domain.

Description and training of Assessors: The CATS will be administered to the schoolchildren and their caretakers by six trained graduate students from the Universidad Intercultural Indígena de Michoacán (UIIM). The six UIIM students will be trained to administer the CATS at the UIIM in a 4-hour training which will be led by Dr. Pedro Reygadas, Suzanne Connolly, LCSW, and Lic. Leonor Zarazua. The six graduate students will receive University credit for their participation. The students will be supervised professionally throughout the study by the study lead investigators, Josefita Guzman, and Dr. Pedro Reygadas head of the Department of Language and Culture, UIIM, with on the ground practical assistance from Lic. Leonor Zarazua Menchaca.

The Assessment Process: Six graduate students from UIIM will be trained to administer the CATS, using the Spanish version of the Child and Adolescent Trauma Screening (CATS) for 7–17-year-olds for both children and their caretakers (Appendices 1 and 2). The graduate students will be trained in the assessment process, but they will be “blind” to the questions being asked and the answers the children and their parents/caretakers provide via tablet.

The students and their caretakers will be assessed at school in a secluded area with only the student or caretaker (never both at the same time) and the graduate-student-assessor present at appointed times. The student will be assured of confidentiality by the graduate-student-assessor and the graduate-student-assessor will ask the student to answer each question carefully. The graduate-student-assessors will not see the

children's questions or answers. The tablet, programed by the statistician, will allow the child to read and answer one question at a time, it will disappear into a secure database and bring the child to the next question and so on to the end of the survey. The child will not be asked to talk about any of the questions but if they do the graduate-student-assessor will listen carefully and be empathetic and supportive to the students.

The testing instrument will be the Spanish version of the Child and Adolescent Trauma Screening (CATS) for 7-17-year-olds, for both children and their caretakers.

There will be a pretest at the beginning of the study a posttest at six weeks, and a follow up close to the end of semester. Teachers will track students' grades, behavioral problems, and absenteeism, and report this information without names or coded numbers to Dr. Hector Figueroa Palafox, the study's statistician. The CATS will be administered using a tablet as described above. The key code to the names and numbers will be available only to Lic. Leanora Zarazua Menchaca, who will not have access to the children's answers. The key code will be kept securely in a locked file cabinet at UIIH. The graduate-student-assessors will not see the children's answers as the children will be responding to the questions on a tablet that will require an answer on each item, in order to move on to the next.

Graduate-student-assessors might potentially be aware of some problems as there is some chance the child might decide to talk about something that happened to them during the assessment. If this should happen, the graduate-student-assessors will respond with empathy and support and normalize as much as possible. They will be taught to do this during their training as recommended by CATS recommended standards. The graduate-student-assessors will visit the children for the assessments at their schools at specified times and their caretakers, separately at the school at specified times.

Assessment Student Hours per schools involved (1 TX group and 1 active waitlist group)

	Hrs. to test 60 families (2 hours each)	6 Assessors
Pretest Start of fall semester 2022	120	20 hrs. each
Posttest 1 6 weeks into study 2022)	120	20 hrs. each
Follow up	120	20 hrs. each
Subtotal 3 assessments	360	

The above assumes 60 middle-school children and their caretakers enrolled in the study (30 in the TFT intervention group and 30 in the art-activity group). It allows one hour for the child assessment and one hour for the caretaker assessment at pretest, posttest, and follow-up. The assessments will be conducted by six UIIH graduate-student-assessors.

3.b. In addition to describing the design and procedure of your research, please indicate the methods that your research will include by checking all that apply. This list is neither preferred nor comprehensive. Please let us know if you are using another method or methods:

<input checked="" type="checkbox"/>	Descriptive	<input checked="" type="checkbox"/>	Quantitative	<input type="checkbox"/>	Oral history	<input type="checkbox"/>	Grounded action	<input checked="" type="checkbox"/>	Field work
<input checked="" type="checkbox"/>	Experimental	<input type="checkbox"/>	Ethnographic	<input type="checkbox"/>	Phenomenological	<input type="checkbox"/>	Grounded theory	<input type="checkbox"/>	Longitudinal
<input checked="" type="checkbox"/>	Qualitative	<input type="checkbox"/>	Formative	<input type="checkbox"/>	Narrative	<input type="checkbox"/>	Action research	<input checked="" type="checkbox"/>	RCT

4. Indicate whether recruitment of participants and/or data collection will involve the use of any of the following.	X	Audiotapes, videotapes, digital recordings, or photographs
	x	Electronic communications (e.g., E-mail, Internet) for reminders and initial Letter of Invitation.
		Archival data that is publicly available
	x	Archival data that is not publicly available
<p>If your response is "yes" to any item in #4, state what specifically will be used, describe how the media will be used (e.g., coded and then destroyed, kept for publication, or broadcast, etc.), how the media will be stored and for how long. If you are using archival data, discuss what permissions are required (if any) and include a copy of the permission to use the archival data in your appendices.</p>		
<p>The study coordinator, Lic. Leonor Zarazua Menchaca, will videotape teacher-only leading a class through the intervention (art-activity or tapping exercise) on occasion to insure intervention fidelity. No children will be videotaped,</p> <p>The children will answer questions via tablet out of sight of student-graduate-assessors, and in a secluded and secure area. The statistician, Dr. Hector Figueroa Palafox, will program tablets to automatically enter a secure database as the child answers. There will be no trace of the answers on the electronic device. The test itself will only have a number with no name attached and the statistician will not have access to the name-number key. Only Lic. Leonor Zarazua Menchaca will have access to the name-number key which will be kept in a secure locked location at UIIM.</p>		
5. Does the proposed research require that you deceive participants in any way?	NO	
<p>If your response is "yes," describe the type of deception you will use, indicate why it is necessary for this study, and provide a copy of the debriefing script.</p>		
<p>Research has been conducted that demonstrates the usefulness of both techniques as a form of therapy for children. The principals of both groups will be told in their invitation that: Children in two middle schools in an area with similar demographics but geographically separated have accepted an invitation to participate. Both schools will be informed that we are testing possible ways to reduce the effects of trauma, enhance the learning ability of middle school children, and increase their ability to focus in the classroom.</p> <p>Two different approaches to creating a calm learning environment will be studied and compared at two different schools. The students in each of the two classrooms would participate in one of two interventions throughout the 2023 Spring semester. We predict that 10-minutes of art activity will lead to some improvement in the predicted outcomes, but that TFT will lead to significantly greater outcome improvements. Also, as we inform the principals in their invitation "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 the more effective intervention in their classrooms for the following semesters. See Principles Invitation for TFT group and art-activity group (Appendices 3, 4), Parent/Caretaker Permission Forms (Appendices 5,6), and Child's Permission Forms (Appendices 7,8,).</p>		
6. Name any source(s) of funding for the proposed research. If an application for funding is under review, enter Pending.		
<p>The Association for Comprehensive Energy Psychology is an international, non-profit organization headquartered in the USA. Its mission is to educate, research and promote energy psychology techniques among health professionals and the public throughout the world.</p> <p>They have funded \$10,000 in member donations to this humanitarian project.</p>		

Asociacion San Andrés Pescador is a non-profit civil association, founded in Mexico in 2006 with the mission of providing tools that support emotional well-being for the development of healthier social relationships in middle and low-income communities. Our goal is for each family to have access to social emotional learning tools for achieving a better quality of life.

They have donated a meeting room, lodging, and meals for those taking the two-day TFT training at their facility. They have also donated a meeting room, lodging, and meals for the three assessors who will be staying there for three days at pre-test, three days at posttest, and three days at follow-up.

7. Conflict of Interest: Is any conflict of interest (COI) associated with your study? Enter Yes or No.		NO
7. a. Do funding source(s) listed in #6 above, have any potential for financial or professional benefit from the outcome of this study? If yes, please explain:		Yes: Only a study to list on resumes.
7. b. Do any other organizations with which you are affiliated (e.g., your employer) have any potential for financial or professional benefit from the outcome of this study? If yes, please explain:		No
8. Benefits: Is there any potential for benefit from the outcome of this study? Definition of benefit: A research benefit is considered to be something of health-related, psychosocial, or other value to an individual research participant, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participation in research is not considered a benefit, but compensation for research-related inconveniences. Compensation: Will participants receive compensation for their participation in your study? If you answer yes to either question, please explain:		YES Children may experience less anxiety, fewer days absent, fewer behavioral problems and better grades,
9. Has this research been through previous IRB review, or is anticipated to undergo IRB review, at another location		No
10. Indicate the total number of participants you plan to include or enroll in your study.	60	Indicate the age range of the participants that you plan to enroll in your study. 11-13
11. Will participants include individuals from any of the following groups?	<input checked="" type="checkbox"/> x	i. Minors (persons under the age of 18) ii. Prisoners <input checked="" type="checkbox"/> x iii. Persons with legal guardians, or those otherwise unable to provide informed consent: Please describe All will have a primary caretaker that can give consent

12. Describe the inclusion and exclusion criteria for your participants and how these will be sensitively communicated to potential participants. What will you say to potential participants who do not meet your inclusion criteria? Please attach copies of any letters or scripts you will use to **exclude potential participants**.

Caregiver consents, child consents are attached (Appendices 3,4,5,6,7,8)


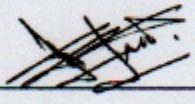
13. Please describe the steps you will take to **minimize risks and/or ameliorate the impact** of any harm.

The statistician, Dr. Hector Figueroa Palafox, has devised a way that the children's answers will be strictly confidential. They will not be known to caretakers, teachers, principals, statistician, assessors, or researchers. The statistician will have access to only the answers and the child's number but not their name. Also see Adverse Events Form (Appendix 9).

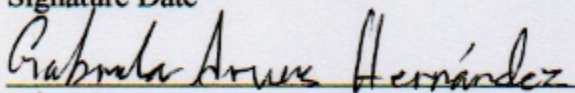
14. Indicate how your data will be used. Enter Yes or No for each item.		Dissertation		Publication/journal article/presentations
		Pilot Study for Dissertation		Aggregate data/summary of results released to participants/parents
		Knowledge Assessment (KA)		Aggregate data/summary of results released to employer or school
		IF KA, TYPE KA # HERE		Aggregate data/summary of results released to agency or other organization
		Capstone Project:	Other (please describe here):	

15. Attached Informed Consent Form: (See; Appendices 8,9,10,11,12,13)

This document was reviewed and approved by the Ethics Committee of the Intercultural Indigenous University of Michoacán created for the supervision of this research project and made up of:
 C. Dra. Elizabeth Téllez Juanpedro, UIIM (Academy of Language and Culture, academic body Nature and Ancestral and Regional Knowledge) C. Dr. Gabriela Arias Hernández (Sustainable Development Academy, Nature, and Ancestral Knowledge academic body)

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Signature
 17-Nov-2022
 Signature Date


 Printed name

Elizabeth Téllez Juanpedro

Appendices

Appendix 1: CATS for 7-17 yr. Youth Version pp. 9-10

Appendix 2: CATS Caretakers of 7-17 yr. version pp.11-12

Appendix 3: Principles Invitation TFT group version pp.13-15

Appendix 4: Principles Invitation Art-Intervention group version pp. 16-18

Appendix 5: Caretakers Permission Form TFT group version pp 19-20

Appendix 6: Caretakers Permission Form Art-Activity version pp.21-22

Appendix 7: Youth Permission Interview TFT group version p. 23

Appendix 8: Youth Permission Interview Art-Activity group version p.24

Appendix 9: Adverse Experience Form p.25

