Augmented Mindfulness Training for Resilience in Early Life (A-MindREaL) Study

April 11, 2019

Laureate Institute for Brain Research, Tulsa, Oklahoma

Parent Permission for Child to Act as a Research Subject

Augmented Mindfulness Training for Resilience in Early Life (A-MindREaL) Study:
Laureate Institute for Brain Research

TITLE:	A-MindREaL: Augmented Mindfulness Training for Resilience in Early Life
PROTOCOL NO.:	2019-003-00 WIRB® Protocol #20190946
SPONSOR:	National Institute of General Medical Sciences (NIGMS)
INVESTIGATOR:	Namik Kirlic, PhD 6655 S Yale Ave Tulsa, Oklahoma 74136 United States 918-502-5747 nkirlic@libr.net
STUDY-RELATED PHONE NUMBER(S) AND EMAIL:	Elisabeth Akeman 918-805-7274 (24 Hours) mindreal@libr.net

RESEARCH CONSENT SUMMARY

You are being asked for your consent for your child to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether their children take part in this research. Later sections of this document will provide all relevant details.

What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary for you and your child. Whether you take part is up to you and your child.
- If you or your child don't take part, it won't be held against you or your child.
- Your child may decline participation even if you provide consent.

- You and your child can take part now and later drop out, and it won't be held against you or your child
- If you and your child don't understand, ask questions.
- Ask all the questions you want before you and your child decide.

How long will my child be in this research?
We expect that your child taking part in this research will last approximately two weeks.

Why is this research being done?
The purpose of this research is to investigate the relationship between brief mindfulness training and brain function in youth between ages 13 and 16. Mindfulness training has evidence of being helpful in coping with stress and attention.

What happens to me if I agree to take part in this research?
If you and your child decide to take part in this research study, the general procedures for your child include filling out surveys, learning a mindfulness practice focused on the breath, and practicing mindfulness while having activity in your child's brain recorded in an MRI machine and potentially displayed to them.

Could being in this research hurt me?
The most important risks or discomforts that your child may expect from taking part in this research include becoming tired or bored, feeling uncomfortable answering questions about feelings, loss of confidentiality, discomfort from wearing an EEG cap, and risk of injury in the MRI magnet if the child has any metal implants or fragments in their body.

Will being in this research benefit me?
The most important benefits that your child may expect form taking part in this research include potential improvement in attention and coping with stress. Possible benefits to others include a better understanding of the relationship between mindfulness training and brain function.

What other choices do I have besides taking part in this research?
This is not a treatment study. Your child's choice is to not participate in this research.

DETAILED RESEARCH CONSENT

This consent form describes a research study. Research studies involve only individuals who choose to participate. Please take your time to make your decision about participating in the study.

This consent form may contain words that you do not understand. Please ask the Principal Investigator or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who is conducting the study, why your child has been asked to participate, and what is the approximate number of participants in the study?
Dr. Namik Kirlic and the Laureate Institute for Brain Research (LIBR) investigators are conducting a research study to learn more about how to help teens become more resilient. Your child has been asked to participate in this study because your child is between ages 13 and 16. This study will enroll approximately 120 youth at LIBR from the Tulsa area.

Why is this study being done?
The purpose of this research study is to investigate the relationship between brief mindfulness training and brain function in youth between ages 13 and 16. The researchers will also aim to determine the relationship between this brief mindfulness training and emotional functioning in youth. In particular, researchers are interested in identifying whether mindfulness training will help with stress reactions. Mindfulness training has been successfully used with youth to help them improve attention and coping with stress. The results of this study may help in improving current and designing new interventions for youth. These interventions could prevent negative outcomes in young people's lives and increase positive outcomes.

What devices are involved in this study?
The Magnetic Resonance Imaging (MRI – use of a magnetic field to produce an image) is used to look at brain function and anatomy. LIBR is using the MRI scanner in a research (experimental) mode. U.S. Food and Drug Administration (FDA) approval has not been obtained for the particular ways that information about interpersonal interaction from the MRI may be used in this research; however, the MRI scanner will not be used for purposes outside its intended application. It is considered to be a non-significant risk investigational device.

A physiological recording system will also be used to monitor bodily sensations, such as heart rate and breathing.

What are the study procedures?
If your child takes part in the study, they may be asked to complete the following procedures at the Laureate Institute for Brain Research:

Questionnaires
We may ask you to provide information about your child and your family including his/her phone number, address, and email, and contact information of relatives or friends. Contact information will only be used to help find you and your child for the follow-up studies. Relatives and friends are told only that this is a research study being conducted at Laureate Institute for Brain Research and no other information about the study or about your family is given.

We may give your child questionnaires on paper and the computer about his/her thoughts, mood and feelings, behavior, personality, and past and current life experiences. We do not share any information your child tells us; this helps to keep the privacy needed so we get honest answers. Your child may skip questions that make him/her uncomfortable.

One week after completion of these questionnaires, we may contact you and your child to complete similar brief follow-up questionnaires.

Mindfulness Practice Session

Your child will take part in a mindfulness practice session during which they will be given a brief introduction to mindfulness, followed by a guided, traditional mindfulness practice focused on the breath. Your child will then complete the same mindfulness practice in the mock scanner. During both practice sessions, your child will be assessed on how they feel, difficulty of performing the task, and have an opportunity to ask any questions. Finally, your child will be given instructions for the neuroimaging session, including whether or not they will receive neurofeedback, as well as instructions to help minimize movement in the MRI. Mindfulness practice sessions may be video and audio recorded and may be reviewed by the research team. The recordings will be destroyed at the end of the study.

Electroencephalography (EEG)

Your child may also be asked to have an EEG at the same time as the MRI scan. After they are familiarized with the equipment, a cap consisting of multiple MRI-compatible EEG electrodes with gel in them will be placed on their scalp and a few electrodes with gel in them will be placed on their back. While they lie in the MRI scanner, the electrodes will be connected to a data collection system and EEG signals will be collected and stored on the computer of the recording system. The prep time for an EEG takes approximately half an hour.

Magnetic Resonance Imaging (MRI)

For MRI studies, you will be given a brief medical history questionnaire and screening form about your child to complete. Undesirable medical findings may arise during the interview, screening, or MRI scanning. If so, these findings will remain confidential and will be discussed with you by a researcher of this study.

Before MRI scanning, your child will learn tasks that will involve practicing mindfulness. Training for the MRI tasks will last approximately 30 minutes. Your child will then be placed in the MRI scanner to perform the tasks. The MRI scanner rapidly takes pictures of the brain. The MRI scanner is a metal tube surrounded by a strong magnetic field. During the MRI, your child will lie on a table that can slide in and out of the tube. They will be asked to lie still during scanning. Earplugs will be provided to lessen the loud “knocking” sounds that the scanner makes while it is imaging your child’s brain.

First, your child will receive a series of short scans that allow us to know where their head is inside the tube. Your child will then receive a scan lasting 5 to 15 minutes that gives us more detailed pictures of their brain. Finally, they will undergo a series of scans lasting about 60 minutes during which they will perform the tasks. During these tasks, your child may receive information about the activity (or blood oxygen levels) in his or her brain that is related to mindfulness practice. They may also be then asked to control their brain activity by practicing mindfulness (neurofeedback), view words that may describe them, or simply resting. During all of these scans, it will be very important to remain still. Their time in the scanner will be about 1.5 hours.

If your child is a female, a urine pregnancy test will be obtained. An over-the-counter urine pregnancy test will be completed just prior to any MRI scanning. They will not be allowed to participate in the study if the pregnancy test reads positive.

How much time will each study procedure take, what is your child's total time commitment at each time point, and how long will the study last?
The table below is an estimate of the amount of time it will take to complete each study component. The study is expected to last two weeks in total.

Assessment	Mindfulness Training And EEG Preparation	Scanning	Follow up	Total
15 minutes	1 hour	1.5 hours	15 minutes	3 hours

Your child will not be asked to miss any school for this study. Snacks may be available.

How will my child's confidentiality and privacy be protected? Will other people have access to my child's data and biological samples?
Research records will be kept confidential. This means that what your child tells us will not be shared with you, his/her school, family, or friends. Your child's records with his/her name and contact information will be stored separately from data collected from your child in locked cabinets or a secure password protected computer and file, with access restricted to limited study personnel. Your child's records may be reviewed by the Western Institutional Review Board and the people who support this study at the Laureate Institute for Brain Research.

All results of your child's assessments (e.g., all of the responses to questions or tasks, scores, or task results) will be identified only by a unique participant code that contains no information about his or her identity. Only the research team will have the information that matches the anonymous code to traditionally used identifying information, such as name, address, and phone number. Dr. Kirlic and his collaborators will keep the information that matches the code to this commonly used identifying information in a password protected database for approximately 10 years or as long as the study has funding. Only very few, authorized people, who have agreed to protect your identity, will have access to this information that matches your personal information to the anonymous code.

After having identifiers removed, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent. In the anonymous coded form, the data will be entered into a database. This database will be accessible to the study researchers at LIBR. Individuals who request access to your child's data will have to agree not to try to identify any individuals who have participated in the study. However, there is a small possibility that in the future an unauthorized attempt to identify your child as a participant in the study could succeed.

To help us protect your child's privacy, Dr. Kirlic and the LIBR Investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, the research team cannot be forced (for example by court order) to share research information that may identify your child in any Federal, State, local, civil, criminal, administrative, legislative, or other proceedings. Sharing may be necessary if the DHHS does a review of the study. Your child should understand that a Certificate of Confidentiality does not prevent him/her from voluntarily releasing information about him/herself. If an insurer, employer, or other person obtains your child's written assent and your permission to receive research information, then the researchers may not use the Certificate to withhold that information. If your child requests the study data be released to his/her doctor, this information may then become part of your child's medical record. Insurance companies may have access to such records. This might then hurt your child's access to health or other insurance. However, we will not release information about your child to your child's doctor without his/her assent and your permission.

Finally, your child should know the research team can take steps, such as telling authorities (for example, the Police) if 1) your child tells us of plans to really hurt him/herself, 2) your child tells us of plans to really hurt another person, or 3) we learn that a child or elder has been or is being abused or neglected. If your child decides at a later time that he/she does not want his/her data or specimens to be used for future research, your child, or you on his/her behalf, may tell this to Dr. Kirlic, who will use his best efforts to stop any additional studies. However, it may be impossible to locate and stop such future research once the materials have been shared with other researchers.

What risks are associated with this study?
Participation in this study may involve risks or discomforts. These include the following:

1. It is possible your child may become tired, bored, or frustrated during the study sessions. Your child can take a break and/or stop the testing at any time.

2. It is possible that being asked about feelings, mood, or behaviors may make your child feel uncomfortable. Your child may skip questions that make him/her feel uncomfortable.

3. There is risk of possible loss of confidentiality. The study will be conducted under a Certificate of Confidentiality. However, if some of the information collected, such as use of illegal substances, were to become known outside of this research setting, it may place your child at risk for criminal or civil liability or may be damaging to his/her ability to get a job, affect personal reputation, or have otherwise unknown outcomes.

4. There are no significant risks expected from the MRI-compatible EEG. However, there may be minor discomfort from wearing an EEG cap, which is similar to wearing a tight hat. Your child may feel local pressure points and minor skin irritation from the electrode patches. This will be minimized by the use of gel in each electrode, and foam pads placed under and surrounding their head.

5. People are at risk for injury from the MRI magnet if they have any of the following metal implants or fragments:
   - pacemakers or other implanted electronic devices
   - brain stimulators
   - dental implants
   - aneurysm clips (metal clips on the wall of a large artery)
   - metallic prostheses (including metal pins and rods, heart valves, and cochlear implants)
   - permanent eyeliner
   - implanted delivery pump
   - shrapnel fragments

Your child will be asked to complete an MRI screening form for the MRI scan. Your child will be screened for these implants or metal fragments before the study, and if they have any of them, they will not receive an MRI scan and cannot be in the study. Tell the study doctor if you are uncertain whether they have any metal objects in their body. In addition, all magnetic objects (for example, watches, coins, jewelry, and credit cards) must be removed before entering the MRI scanner room. Clinically relevant research results, including individual research results, will be disclosed to you,

Welders and metal workers are also at risk for injury because they may be unaware of small metal fragments in the eye.

There are no known long-term risks or consequences of MRI scans. However, your child may become uncomfortable because they will be lying in a small space. Some people are bothered by the loud thumping noises made by the scanner. Your child will wear earplugs to reduce the noise and increase their comfort during scanning. LIBR study staff will closely and continuously monitor your child throughout the scanning procedure. Your child will be able to use an emergency call button at all times during the scan. Your child will be removed from the scanner immediately if they request to be removed.

6. Risks for mindfulness training

There are minimal risks in practicing mindfulness. However, we will ask your child about their experiences and monitor them for any change in their mood.

7. Additional Risks Associated with Loss of Privacy
   While we believe that the risks to you and your family are very low, we are unable to tell you exactly what all of the risks are. Below are some potential risks:

   - Your child's privacy is very important to us and we will use many safety measures to protect his/her privacy. However, even with all the safety measures that we use, we cannot guarantee that your child's identity will never become known.

   - While the controlled-access databases used to share data from this project will not contain information that is traditionally used to identify your child, such as his/her name, address, and telephone number, people may develop ways in the future that would allow someone to link your child's genetic or medical information in these databases back to him/her. For example, someone could compare information in our databases with information from your child (or a blood relative) in another database and be able to identify your child (or a blood relative). Individuals who request access to your child's data will have to agree not to try to identify your child or any of his or her relatives, or to contact your child or relatives. However, there is a small possibility that in the future an unauthorized attempt to identify your child as a participant in the study could succeed.

What benefits can be reasonably expected?
The types of mindfulness practice utilized in this study has been shown by previous research to improve attention, coping with stress, and resilience. Therefore, there is a possibility that your child will benefit from this training. In addition, your child's participation should help us better understand the relationship between mindfulness training and brain function.

What alternatives do my child and I have?
This study is for research purposes only. Your and your child's alternative is to not participate in this research. While the mindfulness training provided in this study has evidence from previous research to improve attention, coping with stress, and resilience for some people, there are other options to obtain similar treatments.

Can you withdraw your permission or can your child choose to withdraw from the study without penalty or loss of benefits?
Participation in research is entirely voluntary. Your child may refuse to participate or withdraw at any time without penalty or loss of benefits to which he/she is otherwise entitled. Likewise, you may withdraw your permission for your child to participate at any time without penalty or loss. If your child decides to no longer continue in this study, or if you withdraw your permission, you or your child must notify Dr. Kirlic in writing at the Laureate Institute for Brain Research, 6655 S. Yale

Ave, Tulsa, OK 74136, or email to nkirlic@libr.net. Your child will be told if any important new information is found during the course of this study that may affect your child's wanting to continue.

Can your child be withdrawn from the study without his/her assent?
Your child may be withdrawn from the study if Dr. Kirlic or the LIBR investigators believe it is in his/her best medical interest or if your child does not follow the instructions from the study personnel.

Will your child be compensated for participating in this study?
Your child will be compensated for his/her time participating in the study. Each assessment payment (see below) will be paid once the assessment is completed. If your child does not finish a study session, he/she will be paid $10 for every hour completed.

- Assessment: $20.00
- Mindfulness training and EEG preparation: $50.00
- Scanning: $150.00
- Follow-up: $20.00

The payment will be given as a ClinCard, a reloadable credit card that can be used at stores, online, or for cash at local banks. The ClinCard will be available for use within 1 to 2 business days after each interview and/or study visit.

We may give your child snacks and/or a meal during study appointments.

Are there any costs associated with your child participating in this study?
Neither you nor your health insurance will be charged for any of the study tests, procedures, or activities. If you need to be hospitalized, voluntarily or involuntarily, Laureate Institute for Brain Research does not intend to provide payment for this, and you or your insurance provider will be billed for these costs.

What if your child is injured as a direct result of being in this study?
In case your child gets hurt or sick resulting from this study, emergency medical treatment is available. In the event of an emergency, you should call 911. Be sure to tell the emergency staff and other healthcare providers of your participation in this study. Contact the Principal Investigator of this study, Namik Kirlic, PhD as soon as possible at 918-502-5747. You can call the Principal Investigator if you have questions or concerns. Your health insurance provider may be billed to cover the cost of the medical or emergency services provided. No funds have been set aside by the Laureate Institute for Brain Research to compensate you in the event you are hurt or get sick.

Whom can you call if you have questions?
Namik Kirlic, PhD and/or another study staff has explained this study to you and your child and answered any questions. If there are other questions, concerns or complaints about the research or

research-related problems, now or in the future, contact Dr. Kirlic at 918-502-5747, nkirlic@libr.net or Elisabeth Akeman at 918-805-7274 (24 Hours), mindreal@libr.net.

You or your child may call the Western Institutional Review Board at 1-800-562-4789 or 360-252-2500 to inquire about rights as a research subject or to report research-related problems or if you have questions, concerns, or complaints about the research. You may also write to them at:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Your Signature and Consent
Consent:
For children, consent is provided by the parent or guardian

Assent:
Written assent is required for children ages 13-16 years using the Child Assent Form. The person obtaining assent to document assent on the assent form. You have received a copy of this consent document. You agree to allow your child,
_____ to participate.
(PRINT FIRST AND LAST NAME)

_____	_____	_____
Parent/Guardian Name (print)	Parent/Guardian Signature	Date
_____	_____	_____
Name of Person Obtaining Informed Consent (print)	Signature of Person Obtaining Informed Consent	Date

We may inform you about other studies that you or your child could participate in, check the box below if you do not give permission to be contacted.

☐ NO, I do not wish to be contacted about other studies.

If your child has been a participant in other LIBR research studies, do you give your permission to have your child's data in those studies shared with the researchers who are conducting this study?

☐ YES, my child's data from other LIBR studies can be shared with the researchers conducting this study.
☐ NO, I do not want my child's data from other LIBR studies to be shared with the researchers conducting this study.

IRB APPROVED
Apr 11, 2019

Laureate Institute for Brain Research, Tulsa, Oklahoma

Child Assent to Participate

Augmented Mindfulness Training for Resilience in Early Life (A-MindREaL) Study:
Laureate Institute for Brain Research

TITLE: A-MindREaL: Augmented Mindfulness Training for Resilience in Early Life

PROTOCOL NO.: 2019-003-00
WIRB® Protocol #20190946

STUDY-RELATED PHONE NUMBER(S) AND EMAIL:
Elisabeth Akeman or Namik Kirlic, PhD
918-502-5747
918-805-7274 (24 Hours)
mindreal@libr.net
nkirlic@libr.net

Why are you in this study and who else is in the study?
You are being asked if you want to be part of this study because you are 13, 14, 15, or 16 years old. About 120 youth from Tulsa area are being asked to be in this study, and we hope that youth will stay in the study for 2 weeks.

Why is this study being done?
We are trying to learn about ways in which we can help teens become resilient. Specifically, we want to find out if a brief mindfulness training can help with being more resilient. To help us study that, we are interested in learning about your thoughts, feelings, behaviors, as well as your brain.

What will happen in the study?
Questionnaires
You will answer questions either on a computer, tablet, paper, or with a researcher about your thoughts, feelings, and behaviors. Finally, we may ask your parent (or the person who takes care of you) some questions about you and your family.

Mindfulness Training
You will participate in a mindfulness training session. Mindfulness training will consist of a practice session in which mindfulness will be first described to you, followed by a session in which

you will focus on your breath. This activity is focused on purposely paying attention to your breath and staying in the present moment. The practice will be introduced to you by a licensed clinical psychologist and/or clinical psychology doctoral student under supervision. They will also ask you some questions about this practice and answer any questions you might have. Each training session will be video and audio recorded and may be reviewed by the research team. The recordings will be destroyed by the end of the study.

Electroencephalography (EEG)

You will be asked to have an EEG at the same time as the MRI. During EEG, a cap will be placed on your head using gel connected electrodes to your scalp, as well as one on your back. The EEG cap fits like a tight hat and is not painful. While you lie in the MRI scanner, the electrodes will record activity in your brain and transmit the EEG signal to a data collection system on a computer for storage. The prep time for an EEG takes approximately half an hour.

Magnetic Resonance Imaging (MRI)

For MRI studies, your will be given a brief medical history questionnaire and screening form to complete in order to ensure that you are safe to go in the scanner.

Before MRI scanning, you will learn tasks that will involve practicing mindfulness. Training for the MRI tasks will last approximately 15 minutes. You will then be placed in the MRI scanner to perform the tasks. The MRI scanner rapidly takes pictures of your brain. The MRI scanner is a metal tube surrounded by a strong magnetic field. During the MRI, you will lie on a table that can slide in and out of the tube. You will be asked to lie still during scanning. Earplugs will be provided to lessen the loud “knocking” sounds that the scanner makes while it is imaging your brain.

First, you will receive a series of short scans that allow us to know where your head is inside the tube. You will then receive a scan lasting 5 to 15 minutes that gives us more detailed pictures of your brain. Finally, you will undergo a series of scans lasting about 60 minutes during which you will perform specific tasks. During these tasks, you may receive information about the activity in your brain that is related to your mindfulness practice. You may be then asked to control the activity in your brain by practicing mindfulness, view words that may describe you, or simply rest. During all of these scans, it will be very important to remain still. Your time in the scanner will be about 1.5 hours.

If you are a female, a urine pregnancy test will be obtained. An over-the-counter urine pregnancy test will be completed just prior to any MRI scanning. You will not be allowed to participate in the study if the pregnancy test reads positive.

How much time does the study take and will I be paid?

The table below is an estimate of the amount of time it will take to complete all visits for this study. The study is expected to last 2 weeks in total.

Assessment	Mindfulness Training And EEG Preparation	Scanning	Follow up	Total
15 minutes	1 hour	1.5 hours	15 minutes	3 hours

You will be compensated for your time participating in the study as outlined below. If you do not finish a study session, you will be paid $10 for every hour completed.

- Assessment: $20.00
- Mindfulness training and EEG preparation: $50.00
- Scanning: $150.00
- Follow-up: $20.00

Do I have to be in the study?
You do not have to be in this study unless you want to. Even if your parent (or guardian, or caretaker) agrees to be in the study, you can still choose to not be in the study. No one will be upset if you decide to not do the study. You can also stop at any time. You can ask questions at any time and if you change your mind about doing something, you can stop right away. If we think that something is unsafe for you, we will not ask you to do it. It is very important to us that you feel comfortable and safe during the study. Tell us if something does not feel right, and we will fix it or you can stop doing it.

Will other people find out about me?
We will do all we can to keep your information private. Soon after you participate, we will put all of the information in a computer, on paper forms, or in a storage place, but the information will only have a number to identify it, not your name. That way only a very small number of the scientists will know which information is yours and they will be very careful to keep this secret. We will not tell anyone about your answers or about the other information, not even your parents or caregiver, unless we feel that something very bad could happen to you or someone else if we did not tell.

All of the information will be made available to many other scientists so that they can use it to answer questions, solve problems, and make new things. But this information will not have your name on it, so the people who use it will not know you were in the study.

This form explains the research study. Please read it carefully. Ask questions about anything you do not understand. If you do not have questions now, you may ask later.

Put an "X" by the choice you want:

_____ Yes, you want to be in the study.

_____ No, you don't want to be in the study.

Please write your first and last name: _____

In my judgment, the participant is voluntarily and knowingly giving assent and possesses the legal capacity to give assent to participate in the study.

_____ _____
Signature of Person Obtaining Informed Assent Date