

Transcranial Photobiomodulation for reducing autism symptoms in children.

May 1, 2022

Parental Permission for Research Participation

Study title	Transcranial Photobiomodulation for reducing autism symptoms in children
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The Research Team:

Name	Phone Number	E-mail	Role
Dr. Yuli Fradkin	201-731-6244	yf155@ubhc.rutgers.edu	Principal investigator
Dr. Eugenia Steingold	347-779-2473	dr.eugenia.steingold@gmail.com	Researcher
Katya Sverdlov	917-566-8151	Katya.sverdlov@gmail.com	Project Coordinator

We're asking you if you will allow your child to participate in a research study. This document describes the information that we believe most people need to decide whether to take part in this research.

Participation is completely voluntary. If you agree to let your child participate now, you can always change your mind later. Whatever you decide, there are no negative consequences if you decide not to have your child participate.

Parents/Guardians: You are being asked if you want your child to join a research study. This is a parental consent form. It provides a summary of the information the research team will discuss with you. If you decide that your child can take part in this study, you will sign this form to confirm your decision. If you sign this form, you will receive a signed copy for your records.

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

What is the purpose of this study? We want to see if brain LED therapy (photobiomodulation) can help children with Autism Spectrum Disorder (ASD). The use of LED therapy has not been approved for the ASD and its use in this study is experimental.

When your child will wear the headband, the child will be exposed to LED lights. The lights will be near infra-red. The lights will have the frequency of 850 MHz.

What will my child do?

The study will last 9 weeks. During that time, we will ask you or another caregiver to bring your child to Dr. Steingold's office twice a week, for approximately 30 minutes at a time.

Initial Assessment

- During the very first visit, the clinician will conduct 1 separate assessments:
 - Childhood Autism Rating Scale (CARS2)
- This interview will take place in Dr. Steingold's private office.

There will be one study group.

- All children who participate in this research study will receive the LED therapy.

While in Dr. Steingold's office:

- First, we will ask your child to wear a Smart EEG headband (such as Brainbit <https://brainbit.com/>) for 10 minutes to collect your child's electroencephalogram (EEG) which measures your child's brain activity. This is a painless procedure, and the measuring device is designed for young children.
- Second, We will ask your child to wear a headband which will have some LED lights inside it. The child will wear this headband for approximately 10 - 15minutes.
 - This is an experimental device that has not been approved by the Food and Drug Administration (FDA)
 - The child may, if he wishes, also simultaneously play with toys and listen to music.
 - While the child is playing, we will ask you some questions about your child's recent behavior.
 - The LED lights will be turned on.
- Third, we will again ask your child to wear a Smart EEG headband for another 10 minutes, to measure the effect of the light penetration.

At home afterward:

- We will ask you to keep a daily diary of how many words your child says per day, his comprehension of instructions, his sleep, how many tantrums the child had, his social interaction and his eating.
- We will check in with you on a weekly basis regarding your observations, either by phone or in person.

Final Assessment:

- At the end of this 9-week study, the clinician will again conduct 1 separate assessment:
 - Childhood Autism Rating Scale (CARS2)

Will it cost me money to take part in this research?

- Taking part in this research may lead to added costs to you, such as transportation and parking for which you will not be reimbursed.

What are my responsibilities if I take part in this research?

- You will have to take the assessments.
- You will have to arrange for your child to visit Dr. Steingold's office twice a week.
- You will have to keep a daily diary of your child's activities.
- You will have to answer a weekly questionnaire with the researcher, either in person or over the phone
- You will have to report any side effects to the researcher.

Could being in this Research Hurt My Child / Risks

Possible risks or discomforts	How we're minimizing these risks
Some questions may be very personal or upsetting to you	<ul style="list-style-type: none"> • You can skip any questions you don't want to answer.
Your child may feel uncomfortable wearing the headband and may want to take it off early	<ul style="list-style-type: none"> • If the child wants to take off the headband, we will first encourage him to wear it, by attempting to divert his attention to other things, such as toys and music. • If, however, the child insists on taking off the headband, he / she will not be forced to wear it and he / she may be able to take it off before the conclusion of the session. • If the child consistently refuses to wear the headband, then the child will discontinue participation in the study.
Breach of confidentiality (your child's data being seen by someone who shouldn't have access to it)	<ul style="list-style-type: none"> • We'll keep your child's identifying information separate from the research data, but we'll be able to link it by using a study ID. We will destroy this link after we finish collecting and analyzing the data.
If you are in the group that receives placebo (no active treatment), your child's symptoms or condition may not improve.	<ul style="list-style-type: none"> • Your child can continue their existing treatment(s) while participating in this study
Risks of intervention from LED	<ul style="list-style-type: none"> • Some prior participants have reported mild headaches after the first 1 or 2 treatments.
Risks of EEG test	<ul style="list-style-type: none"> • An EEG is a test that measures brain activity and detects potential abnormalities.

	<ul style="list-style-type: none"> • The EEG has been used for many years and is considered a safe procedure. The test causes no discomfort. The electrodes record activity. They do not produce any sensation. In addition, there is no risk of getting an electric shock. • The child may feel uncomfortable while wearing the device on the head.
There may be risks that we do not know about yet.	<ul style="list-style-type: none"> • Throughout the study, we'll tell you if we learn anything that might affect your decision to let your child participate.

Other Study Information

Possible benefits	<ul style="list-style-type: none"> • We cannot promise any benefits to you or others from your taking part in this research. • However, the possible benefit your child may experience while in this research may include improvement of speech, improvement of responsiveness, reduction of tantrums, improvement of sleep, and improvement of eye contact. However, there is no guarantee that your child will benefit from being in this research. • The results of this research may guide the future treatment of autism in children and adults.
Estimated number of participants	25 children
How long will it take?	<ul style="list-style-type: none"> • 9 weeks total. • The participant child is expected to come into the office twice a week for a period of 30 minutes. • The parent is expected to keep a daily diary and to answer questions about the child's behavior (which will take about 5 minutes). • The parent is also expected to speak to the researcher about these observations on a weekly basis, which will take another 10 minutes.
Costs	You'll pay for your own transportation and parking
Compensation	<p>Neither you nor your child will be financially compensated.</p> <p>However, upon completion of the study, if you wish, you will receive, free of charge:</p> <ol style="list-style-type: none"> a) Consultation with a psychologist (Dr. Steingold) about the symptoms, conditions and progress of your child. b) The final EEG map of your child's brain. c) The initial and the final results of your child's

	assessments
Future research	You may be contacted to participate in follow up research after several months. You will not be obligated to participate.
Removal from the study	In order for our data to be useful, it is important that your child attend every session. If your child misses a session and can't reschedule within 4 days, we'll have to take them out of the study.
Funding source	JelikaLite Corp. is funding this research study. JelikaLite Corp. has applied for an NSF grant.

Alternative Procedures or Courses of Treatment

You should speak to your doctor and / or social worker regarding available procedures and treatments for autism. At this point there is no one-size-fits-all treatment.

Currently available evidence-based therapies include Applied Behavior Analysis (ABA), occupational therapy, speech therapy, physical therapy, sensory integration therapy, floor-time therapy, and certain medications to help control symptoms of autism.

Confidentiality and Data Security

We'll collect the following identifying information for the research: your child's name, birth date, gender, type and amount of therapy received and diagnosis. This information is necessary so that we can compile all your child's data and compare children by age and gender when we analyze the data. We may also contact you in the future to request participation in a follow up study. You will not be obligated to participate.

Where will data be stored?	Cloud storage
How long will it be kept?	For a period of 6 years.

What if my child is harmed from being in this study?

If your child is harmed while being in this study, let us know immediately. If it's an emergency, get help from 911 or your child's doctor right away and tell us afterward. We can help you find resources if your child needs psychological help.

Who can see my data?	Why?	Type of data
The Researcher Team at JelikaLite Corp.	To analyze the data and conduct the study	Coded (names removed and labeled with a study ID)
The IRB (Institutional Review Board) The Office for Human Research Protections (OHRP) or other federal agencies The Food and Drug Administration (FDA)	To ensure we're following laws and ethical guidelines	All, including identifying information
Anyone (public)	If we share our findings in publications or presentations	<ul style="list-style-type: none"> • Aggregate (grouped) data • De-identified (no names, birthdate, address, etc.) • If we quote you or your child, we'll use a pseudonym (fake name)
Independent data analyst	To analyze the effect of treatment	<ul style="list-style-type: none"> • Coded (names removed and labeled with a study ID)

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

Financial Disclosure

Both researchers have a financial interest in the Company that makes the device. If the device is successfully developed, the researchers may benefit financially. If you have any questions about this, please talk to Dr. Steingold or the study staff.

Can my child be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your child's best interest.
- Child has a side effect that requires stopping the research.
- Child needs a treatment not allowed in this research.
- The research is canceled by the FDA or the sponsor.
- You are unable to keep your child's scheduled appointments.

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?

If you decide to leave this research, contact the research team. Your participation is voluntary and you may withdraw at any time. Your withdrawal or decision not to participate will not result in any penalty and will not otherwise affect any of your existing or future benefits to which you or your child may be entitled to.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page or below.

For questions about the research	Dr. Yuli Fradkin	yf155@ubhc.rutgers.edu 201-731-6244
	Dr. Eugenia Steingold	dr.eugenia.steingold@gmail.com 347-779-2473
	Katya Sverdlov	katya@jelikalite.com 917-566-8151 (24 hours)
For complaints or concerns	Dr. Yuli Fradkin	yf155@ubhc.rutgers.edu
	IRB	WCG IRB researchquestions@wcgirb.com 855-818-2289

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

Signatures

If you have had all your questions answered and give permission for your child to participate in this study, sign on the lines below. Remember:

1. Your child's participation is completely voluntary;
2. Refusal to participate will involve no penalty or loss of benefits to which you or your child is otherwise entitled;
3. You're free to remove your child from the study at any time; and
4. Discontinued participation will not result in any penalty or loss of benefits to which you or your child is otherwise entitled.
5. Assent of children is not required

Your signature documents your permission for you, or the individual named below to take part in this research.

Name of Child (print)

Name of Parent or Legally Authorized Representative / Guardian (print)

Signature of child subject's parent, or individual authorized

Date

under state or local law to consent to the child

subject's general medical care

Name of Researcher obtaining consent (print)

Signature of Researcher obtaining consent

Date