Transcranial Photobiomodulation for reducing autism symptoms in children.

October 1, 2020

Parental Permission for Research Participation

IRB #: 120200004

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Study title	Transcranial photobiomodulation for reducing autism symptoms in children.

The Research Team:

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

We're asking your child to participate in a research study. This document describes the key 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 would 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).

What will my child do?

The study will last 8 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, we will ask you (the parent) to fill out a CARS2 test, which is a Childhood Autism Rating Scale. This interview will take place in Dr. Steingold's private office.

There will be two separate study groups.

- One group will receive a placebo and one group will receive an intervention.
    - The purpose of having different study groups is to test the efficacy of the proposed intervention.
- You will be put into a study group by chance (like a coin toss). You have a 50% chance (15 out of 30) of being placed in any particular group. You cannot choose your study group.
- During the research, you and the study doctor will not know which group you are in. (Your study doctor can find out in case of an emergency).

While in Dr. Steingold's office:

- We will ask your child to wear a headband which will have some LED lights inside it. The child will wear it for approximately 10 - 20 minutes.
    - 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.
- If your child is in the placebo group, he/she will wear the headband, but with the light technology turned off. The child may listen to music and / or play with toys.

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 8-week study, we will ask you to fill out a CARS2 test again.

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 initial and final CARS2 assessment
- 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	• 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	• 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.
Breach of confidentiality (your child's data being seen by someone who shouldn't have access to it)	• 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.	• Your child can continue their existing treatment(s) while participating in this study
Risks of intervention	• Some prior participants have reported mild headaches after the first 1 or 2 treatments.
There may be risks that we do not know about yet.	• 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. • After years of study, there are no known negative

	side effects of photobiomodulation. Exposure to LED lights is not known to have any negative side effects. • 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	• We cannot promise any benefits to you or others from your taking part in this research. • However, the possible benefit your child may experience from the device described in this research includes 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	30 children
How long will it take?	• 8 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	None. Neither you nor your child will be compensated.
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 a 3 days time, we'll have to take them out of the study.
Funding source	JelikaLite LLC is funding this research study. JelikaLite LLC 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?

The study is not expected to have harmful effects. 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 LLC	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	• 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	• 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

The researcher has 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 will not result in any penalty and will not 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.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (800) 232-9570, info@neirb.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.

For questions about the research	Dr. Eugenia Steingold Katya Sverdlov	dr.eugenia.steingold@gmail.com katya.sverdlov@gmail.com
For questions about your child's rights as a research participant	IRB (Institutional Review Board; provides ethics oversight)	(800) 232-9570, info@neirb.com
For complaints or problems	Dr. Eugenia Steingold	dr.eugenia.steingold@gmail.com
	IRB	(800) 232-9570, info@neirb.com

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 Guardian (print)

_____ _____

Signature of child subject's parent, or individual authorized under state or local law to consent to the child subject's general medical care — Date

_____

Name of Researcher obtaining consent (print)

_____ _____

Signature of Researcher obtaining consent — Date