Study Name: Bifocal Lenses In Nearsighted Kids (BLINK) Study
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The Ohio State University Parental Permission For Child's Participation in Research

Study Title: Bifocal Lenses in Nearsighted Kids (BLINK) Study

Principal Investigator: Jeffrey J. Walline, OD PhD

Sponsor: National Eye Institute

- **This is a parental permission form for research participation.** It contains important information about this study and what to expect if you permit your child to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to permit your child to participate.
- **Your child's participation is voluntary.** You or your child may refuse participation in this study. If your child takes part in the study, you or your child may decide to leave the study at any time. No matter what decision you make, there will be no penalty to your child and neither you nor your child will lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you or your child is a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **Your child may or may not benefit as a result of participating in this study.** Also, as explained below, your child's participation may result in unintended or harmful effects for him or her that may be minor or may be serious depending on the nature of the research.
- **You and your child will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you permit your child to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider permitting your child to participate in this study for the reasons explained below.

1. Why is this study being done?

This study is being done to determine whether soft bifocal contact lenses (contact lenses typically used to help people older than 40 see up close) slow the progression of nearsightedness (difficulty seeing far away) and to see how they work in order to better be able to slow the progression of nearsightedness in the future.

2. How many people will take part in this study?

A total of 294 children ages 7-11 are expected to participate. Two clinical centers – The Ohio State University College of Optometry and the University of Houston College of Optometry – are each expected to enroll approximately 147 children.

3. What will happen if my child takes part in this study?

Your child will be randomly assigned to wear one of three contact lenses. Neither you nor the study team determines which lenses your child will wear; a computer basically flips a coin to determine which lenses your child wears. One contact lens has no reading power (a regular contact lens), one has medium reading power, and one has high reading power. (The lenses with reading power are the bifocal contact lenses.) If you or your child were to look at the contact lenses, you would not be able to tell the difference. All three are made of the same material, and the care is exactly the same for each of them. We ask your child to wear the contact lenses as often as comfort allows, but the study contact lenses must be removed nightly, cleaned, and stored in solution. Your child should never sleep in these lenses.

We will examine your child for a minimum of three years (please see the description of each visit below). Measurements include things that are involved in routine eye exams, plus four other measures. We will measure where light focuses and eye shape throughout the back of the eye by having your child look in various directions while we measure the prescription with machines that do not touch the eye. We will also measure two parts of the eye by taking pictures and measuring the images.

At the first visit and at each annual visit, we will dilate your child's pupils. When we do that, we put drops in each eye. For about four hours, lights will seem brighter than usual and things close to the eyes will be blurry. We will give your child sunglasses to help the brightness, and your child can remove eye glasses to see clearly up close.

If either birthparent wears glasses or contact lenses, we would like to be given a copy of that parent's spectacle prescription. If this is not available, and the birthparent can bring the eye glasses to the clinic, we can obtain the prescription from a machine that "reads" the eye glasses. If this information cannot be obtained please let us know. It will not affect your child's participation in the study.

4. How long will my child be in the study?

There are at least nine visits over a minimum of three years. Below is a brief description of each visit.

Visit	When	Time	Dilate?	Description
1	1 Day	2:30	Yes	Full eye exam, read eye charts, measure eye shape and where light focuses, surveys, fit with contact lenses
2	1 week	1:00	No	Dispense contact lenses and teach care
3	3 weeks	0:45	No	Check eye health, read eye charts, surveys
4	6 months	0:45	No	Check eye health, read eye charts, surveys
5	1 year	2:00	Yes	Full eye exam, read eye charts, measure eye shape and where light focuses, surveys
6	18 months	0:45	No	Check eye health, read eye charts, surveys
7	2 years	2:00	Yes	Full eye exam, read eye charts, measure eye shape and where light focuses, surveys
8	30 months	0:45	No	Check eye health, read eye charts, surveys
9	3 years	2:00	Yes	Full eye exam, read eye charts, measure eye shape and where light focuses, surveys

If your child has any problems with his/her eyes, you may need to bring him/her to the clinic for an unscheduled visit so we can determine if it is safe to continue contact lens wear.

We expect all children will participate in the study for three years, but it is possible the study could be stopped early or continue beyond this time period.

5. Can my child stop being in the study?

Your child may leave the study at any time. If you or your child decides to stop participating in the study, there will be no penalty and neither you nor your child will lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can my child expect from being in the study?

The risks are similar to any contact lens wear outside the study. Your child may not see as clearly with contact lenses as s/he does with eye glasses. Your child may experience red, uncomfortable eyes. Although it is very rare, your child could get an eye infection, which could lead to permanent vision loss. If your child gets red, uncomfortable eyes, has excessive tearing, or experiences vision changes, he or she should remove the contact lenses, and you should call the clinic.

We will put drops in your child's eyes to dilate the pupils. For about four hours, your child will notice brighter lights and blurry vision up close. We will provide sunglasses to help with bright lights, and your child can remove his or her glasses to see clearly up close.

Below is a list of additional problems that may occur while wearing contact lenses:

- Burning, stinging, and or itching of the eyes
- Less comfort after all day wear
- A feeling like there is something in the eye
- Inflammation of the cornea (clear window on the front of the eye) and/or scratch of the cornea
- Swelling of the cornea
- Small blood vessels growing into the cornea
- Small defects in the corneal surface (corneal staining)
- Redness
- Bumps on the inside of the eye lid (tarsal abnormalities)
- Inflammation of the inner eye (iritis)
- Excessive watering, unusual eye secretions, or redness of the eye
- Blurred vision
- Rainbows or halos around objects
- Sensitivity to light
- Dry Eyes

7. What benefits can my child expect from being in the study?

Your child may or may not benefit from participating in this study. The study contact lenses might help correct your child's vision while s/he is wearing them, but there is no guarantee that this study will help your child. Your child's participation might help him/her become less nearsighted in the future.

8. What other choices does my child have if he/she does not take part in the study?

You or your child may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. If you don't want your child to participate, you can ask your primary eye doctor to prescribe contact lenses for your child.

9. Will my child's study-related information be kept private?

Efforts will be made to keep your child's study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your child's participation in this study may be disclosed if required by state law.

Also, your child's records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your child's medical care, your child's study-related information may be placed in their permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that your child is participating in a research study and have access to your child's information.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your child's protected health information.

10. What are the costs of taking part in this study?

There are no costs to you for your child taking part in this study.

If you do not own an OSU parking permit, a parking pass will be provided for the visitor's garage, if needed.

11. Will I or my child be paid for taking part in this study?

Neither you nor your child will be compensated for study participation. However, your child will receive, at no cost to you, eye care, contact lenses, contact lens solutions, and contact lens cases during his/her study participation. Your child will also receive free or very discounted eye glasses, depending on the frames you choose (we will provide a frame allowance for purchase of glasses at The Ohio State University College of Optometry Eyewear Gallery).

If your eye care practitioner is a member of the BLINK Study Network and directly referred you to the BLINK study, you will have the option of purchasing your child's eye glasses and using a frame allowance at this practitioner's office.

By law, payments to subjects are considered taxable income.

12. What happens if my child is injured because he/she took part in this study?

If your child suffers an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if your child should obtain medical treatment at The Ohio State University Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

13. What are my child's rights if he/she takes part in this study?

If you and your child choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights your child may have as a participant in this study.

You and your child will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You or your child may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable,

according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact any of the following individuals: OSU Clinic Coordinator, Jill Myers, at 614-292-0200 or blinkstudy@osu.edu; OSU Clinic Site Principal Investigator, Dr. Donald Mutti, at 614-247-7057 or mutti.2@osu.edu; or the Study Chair, Dr. Jeffrey Walline, at 614-247-6840 or walline.1@osu.edu

For questions about your child's rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If your child is injured as a result of participating in this study or for questions about a study-related injury, you may contact the OSU Clinic Site Principal Investigator, Dr. Donald Mutti at 614-247-7057 or mutti.2@osu.edu or the Clinic Coordinator, Jill Myers, at 614-292-0200 or blinkstudy@osu.edu.

If you have a study related medical problem after our regular office hours please call: 614-292-3354.

Signing the parental permission form

I have read (or someone has read to me) this form and I am aware that I am being asked to provide permission for my child to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to permit my child to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of subject	
Printed name of person authorized to provide permission for subject	**Signature of person authorized to provide permission for subject**
Relationship to the subject	**Date and time** **AM/PM**

<u>Investigator/Research Staff</u>

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	Date and time **AM/PM**

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	Date and time **AM/PM**
Printed name of witness	**Signature of witness**
	Date and time **AM/PM**