Study Name: Bifocal Lenses In Nearsighted Kids (BLINK) Study
NCT: NCT02255474
Date of consent – University of Houston clinical site 08/01/2014

UNIVERSITY OF HOUSTON
PARENTAL PERMISSION FOR CHILD'S PARTICIPATION IN RESEARCH

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

Sponsor: National Eye Institute

Principal Investigator: David A. Berntsen, OD PhD
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Houston, TX 77204-2020
713-743-5836

- **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 University of Houston. If you or your child is a student or employee at the University of Houston, your decision will not affect your grades or employment status.

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 University of Houston College of Optometry and The Ohio State University 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 the following additional 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 and eye length with instruments that do not touch the eye. We will use clinical instruments that do not touch the eye to take pictures inside of the eye and will measure 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 University of Houston.

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 glasses or 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:

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The University of Houston Committees for the Protection of Human Subjects; and
- The sponsor supporting the study, their agents or study monitors.

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.

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

Neither you nor your child will be paid for study participation. However, your child will receive, at no cost to you, study-related eye care, contact lenses, contact lens solutions, and contact lens cases during his/her study participation. The visits include a free complete eye examination for your child each year. If a contact lens is lost or damaged during the study, it will be replaced at no cost to you. Your child will also receive free or very discounted eye glasses, depending on the frames you choose (we will provide a $150 frame allowance for the purchase of glasses at the University of Houston Optical Services). Your child will also receive a small toy or gift (roughly $10 in value) at each of the three annual visits after being enrolled in the study.

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

If your child suffers an injury while participating in this study, you should notify the study doctor immediately, who will determine if your child should be seen by a study doctor or should obtain medical treatment at a nearby clinic, hospital, or emergency center.

If a referral to a doctor outside of the study is needed for treatment, the cost for this treatment will be billed to you or your medical or hospital insurance.

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 University of Houston 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.

The study doctor or sponsor can withdraw your child from the study at any time, even if your child wants to continue to be in the study. This could happen if:

- The study doctor believes it is best for your child to stop being in the study.
- Your child does not follow directions about the study.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact one of the following individuals: UH Clinic Coordinator, Laura Cardenas, at 713-743-1994 or blink@uh.edu or UH Clinic Site Principal Investigator, Dr. David A. Berntsen, at 713-743-5836 or dberntsen@uh.edu.

This study was reviewed by the Insitutional Review Board (IRB) at the University of Houston called the Committee for the Protection of Human Subjects (CPHS). CPHS at the University of Houston is a group of people who review the risks and benefits of a study. If your child wants to asks questions about what it means to be in a research study or if you have questions about your child's rights as a research participant, you or your child can contact CPHS at 713-743-9204.

SUBJECT RIGHTS

1. I understand that parental consent is required of all persons under the age of 18 participating in this project. I understand that my child (student) will also be asked to agree to participate.
2. All procedures have been explained to me and I have been provided an opportunity to ask any questions I might have regarding my child's (student's) participation.
3. Any risks and/or discomforts have been explained to me.
4. Any benefits have been explained to me.
5. I understand that, if I have any questions, I may contact Dr. David Berntsen at 713-743-5836.
6. I have been told that my child or I may refuse to participate or to stop his/her participation in this project at any time before or during the project. My child may also refuse to answer any question.
7. ANY QUESTIONS REGARDING MY CHILD'S RIGHTS AS A RESEARCH SUBJECT MAY BE ADDRESSED TO THE UNIVERSITY OF HOUSTON COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS (713-743-9204).
8. All information that is obtained in connection with this project and that can be identified with my child (student) will remain confidential as far as possible within legal limits. The results may be published in scientific journals, professional publications, or educational presentations without identifying my child (student) by name.

NAME OF CHILD: _____

I agree to allow my child to participate in this research project:

YES_____ NO_____

_____
Printed Name of Parent/Legal Guardian

_____ _____
Signature of of Parent/Legal Guardian Date

I attest that the participant had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

_____
Printed Name of Study Personnel Obtaining Consent

_____ _____
Signature of Study Personnel Obtaining Consent Date