CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Automated digital photoscreening for amblyogenic risk factors in children aged 18-48 months

Name of Principal Investigator:
Dr. Inas Makar M.D., FRCS (ED)
Ivey Eye Institute
St. Joseph's Hospital
268 Grosvenor Street
London, Ontario   N6A 4V2
Phone: 519 646-6100 ext. 58281
Fax: 519 646-6149

Co-Investigators
Afua Oteng-Amoako. OD, MPH, MSc. Coordinator,
iSee Research Program

Name of Sponsor
St. Joseph's Health Care Foundation - London, Ontario

Introduction
You are being invited as the parent(s) of a minor child to participate in this research study that aims to detect visual conditions that cause a lazy eye (amblyopia) or eye turn (strabismus) using a special digital camera called the PlusOptix S12 photoscreener. You are being asked to participate in this research study because your child is between the ages of 18 months and 4 years and lives in London, Ontario or a surrounding community. The majority of eye conditions in children typically start to affect vision in this age group which is usually preverbal and difficult to examine by the traditional methods of vision testing. For these reasons, we would like to include your child in this study.

The aim of this research study is to assess the effectiveness of the Plusoptix as a vision screening tool for children aged 18 months to 4 years in London, Ontario and surrounding communities. This study aims to identify the risk factors of amblyopia in children and evaluate the reliability of Plusoptix photoscreener as a screening tool. A questionnaire provided to you in this study aims to identify the barriers associated with parent’s inability to follow up with eye care professionals.

Children found through screening to have a potential vision problem will be referred to an optometrist (eye doctor) to confirm screening findings and to provide further management including glasses with or without patching.

Version: 15Oct2015
Background/Purpose
Children aged 18 months to 4 years can be challenging to examine reliably by primary care providers with traditional vision testing, hence the role for photoscreening. Delay in detecting significant refractive errors (long sightedness, short sightedness and astigmatism) can cause vision loss from lazy eye (amblyopia) and eye turn (strabismus). The earlier lazy eye (amblyopia) and its risk factors are detected in young children, the better the outcome. Photoscreeners require minimal cooperation from the child and are not dependent on examiner professional expertise in conducting an eye examination.

The purpose of this study is to test the PlusOptix S12 photoscreener as a reliable, simple and user friendly screening tool in detecting eye conditions leading to a lazy eye or an eye turn (strabismus). Currently, there is no mandated routine eye examination for this age group (18 months-4 years old) which ensures that eye conditions are detected in a timely manner by professional eye care providers. The training of family doctors, who currently provide screening in Ontario, does not cover detecting refractive errors that can lead to a lazy eye or an eye turn. Photo screening flags children needing a more detailed eye examination by an optometrist and identifies conditions that would have likely gone undetected. By participating in this study you will help us collect data that will highlight the role and effectiveness of photoscreening in this challenging age group.

Up to 5,000 children will participate in this study and it will take 3 year(s) to complete. It is expected that you may be in the study for up to 3 years

Study Procedures
Your child’s vision will be screened using a Plusoptix S12 vision screening camera at an early year center or at your child’s day care facility. Screening will be done by trained volunteers accompanied by research staff. After the test, a "pass" or "refer" screening result is provided immediately by the camera. A “refer” result indicates your child should see an eye care professional for a comprehensive, dilated eye exam. A “pass” result indicates that your child’s eye health is very likely good for now, but a retest would be necessary as the eyes change rapidly with growth. The information obtained from vision screening is preliminary only, does not constitute a diagnosis of vision problems and does not replace a full, comprehensive eye exam provided by an eye care professional.

A referral package will be provided for parents of children who are referred after the screening test. This package will contain a list of instructions to help with booking a follow-up appointment with an eye care professional – including a letter informing you on the results of the screening test, a list of optometrists in the area participating in our research program and a referral report with results of the screening for the optometrist. Also included in the package will be a paper questionnaire. We would like for you to complete the questionnaire after the screening, but you may take it home with you and mail it to the study center if preferred. A self-addressed and stamped envelope will be provided for this purpose. A questionnaire will also be completed 3-months after the screening by phone. Questionnaires are for research purposes and completion is voluntary. You may refuse to answer any question you do not want to answer.
There is no charge to participate in this vision screening event. If your child is referred to an eye care professional, you will be contacted by telephone and/or email two weeks after the screening by the iSee study center staff regarding the referral eye exam for research purposes. Please understand that email is not a secure form of communication; e-mail messages sent over the Internet are not encrypted once the leave the hospital e-mail system. Therefore, we cannot guarantee the security of messages sent/received by email.

By consenting your child for this study, you are giving permission for your eye doctor (optometrist/ophthalmologist) to share the evaluation results with the iSee Research Program for research purposes. These results will be the glasses prescription given to your child (if any), diagnosis of condition and type of treatment. Results will be provided to you by the Optometrist examining your child to be mailed to the study center after your child’s examination. A self-addressed and stamped envelope will be provided for this purpose. We may request for your optometrist to send a copy of the results to the study center directly, if we do not receive your copy in the mail. This will only be requested if you have granted permission by signing the top section of the referral report.

If your child is referred to an eye care specialist or ophthalmologist at St. Joseph’s Hospital, the research team may access your child’s electronic health records to review the examination results and reports. You may receive a phone call 6-months after screening, if your child is referred to see a specialist.

Examinations

Plusoptix S12 Vision Screening: The PlusOptix S12 vision screener will be used to obtain a measurement and image. The device captures an image, in a non-contact, non-threatening manner and provides a report determining the level of risk for the presence of an eye turn (strabismus) and refractive errors (long sightedness, short sightedness and astigmatism). No drops, puffs of air or medication are required. Measurements are performed from 3.3 feet (1 meter) away. Screening is as simple as getting your child’s picture taken. Results from the device do not provide a diagnosis, and only points to the need for further evaluation.

Voluntary Participation

Your participation in this study is voluntary. You can withdraw from the study at any point. No new information or data will be collected from that point on. There will not be a penalty or loss of benefits to which you or your child are otherwise entitled if you do. The decision to stop will not affect your child’s legal rights.

Risks

No risks are anticipated. Procedure is non-invasive.

Potential Benefits

There are no direct benefits for participating in this research program.

Privacy & Confidentiality

We wish to assure you that privacy is very important to us. When you join the study, your child will be given an ID number. Researchers will use this ID number to organize the data, instead of your child’s
name or other information that can identify them directly. This ID number will also be used on the
referral report to your optometrist, instead of your child’s name. Any data collected for study purposes
that could potentially identify your child, will be stored in a highly secure manner and never be released
or disclosed in a form that could identify you. Data collected through this study will be available to
researchers in this study and may also be used in scientific publications and/or presentations, but no
personal details will be released without your permission. The study data will be electronically (by means
of a computer) or manually analysed together with other participant’s data to report the results.

Costs
There is no charge for the screening test or for follow-up examinations with an eye care professional. The
Ontario Health Insurance Plan (OHIP) covers people less than 20 years of age, for a routine
comprehensive eye examination provided by either an optometrist or physician once every 12 months,
plus any follow-up assessments that may be required.

Compensation
The screening and the professional care your child will receive related to their participation in this study
will not result in any cost to you or your child. Your child will not be paid for participation. However,
your child will be given a 5-inch plastic frisbee as a token of appreciation.

Questions about the Study
You will receive a signed copy of this Letter of Information and Consent Form to keep for your records. It
is important that you understand all details of the study before consenting your child to participate. If you
have any questions regarding:

Your responsibilities as a parent, attached consent form or other specific details about this program,
please contact:
iSee Study Center, Ivey Eye Institute; St. Joseph’s Hospital: (519) 646-6000 ext. 65101 or
iseevision@sjhc.london.on.ca

Your rights as a research participant, please contact:
Dr. David Hill, Scientific Director – c/o Lawson Health Research Institute at (519)667-6649.

Injury or adverse events related to the study, please contact:
Dr. Inas Makar, Primary Investigator, St. Joseph’s Hospital: 519 646-6100 ext. 58281
Consent.
Informed Consent

I have read the Letter of Information, have had the nature of the study explained to me and I hereby give permission for my child/ward, named below, to participate in the research program. All questions have been answered to my satisfaction.

☐ If my child is referred for further testing, I would like to opt out of completing the paper and telephone questionnaires and receiving a follow-up phone calls and an email which will be used for research.

Please print or type the information requested below, it is important that you provide all information requested.

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