What is intermittent exotropia?

Intermittent exotropia is the medical term used when the eyes drift out some of the time and are straight at other times.

How common is intermittent exotropia?

Intermittent exotropia is the most common form of childhood onset exotropia (eyes drifting out), affecting about 32 out of 100,000 children under 19 years of age every year.

What causes intermittent exotropia?

The cause of intermittent exotropia is unknown.

What are overminus glasses?

Intermittent exotropia is often treated using glasses with special lenses (overminus glasses). These glasses make the eyes work harder in order to see clearly. The extra work is thought to help make the eye drift out less frequently. We believe that overminus glasses may help your child, but we do not know this and the study is being done to find out.

What is the Pediatric Eye Disease Investigator Group (PEDIG)?

The study is being conducted by the Pediatric Eye Disease Investigator Group (PEDIG). Your child's eye doctor is a member of this group. The study will include about 450 children at pediatric eye care centers across North America.

The Jaeb Center for Health Research is the coordinating center (data center) that is organizing the study. The National Eye Institute is providing the funding for the study.

What are the study procedures?

If your child is in the study, he or she will be treated one of two ways. Your child will be treated either with overminus glasses or with no treatment other than regular glasses. A computer program will be used to decide whether your child will receive the overminus glasses treatment.

With the overminus glasses treatment:

- Your child will be prescribed new glasses with overminus lenses to be worn for all waking hours. After one year, the strength of the overminus lenses will be reduced for 3 months, followed by regular glasses for 3 months.

With no treatment other than regular glasses:

- Your child will be prescribed new glasses to be worn for all waking hours. If your child doesn't need glasses that have a prescription, he or she will be prescribed glasses with clear lenses that have no correction. Your child's glasses will be updated after one year and again 3 months later.

You should not agree to have your child be in the study unless you are willing to have your child receive either the overminus glasses or no treatment other than regular glasses. You will not be able to choose which treatment your child gets.

Your child will need to undergo an enrollment examination to verify that he or she is eligible for the study. Your child will also need to return for follow-up visits 6, 12, 15, and 18 months after enrolling in the study.

At the enrollment and subsequent follow-up visits, you will be asked how often your child is wearing their glasses. The eye doctor will measure how well your child can hold his/her eyes straight. At most visits, you and/or your child will be asked to complete a brief questionnaire.

What will be my responsibilities if I agree to have my child participate in the study?

If you agree to have your child be a part of the study, you will be expected to speak with study staff on phone calls 1, 3, 9, and 13 months after enrollment, as well as to bring your child in for the aforementioned follow-up visits. You will be expected to try your best to make sure that your child wears the glasses during all waking hours.

A study like this takes a lot of effort from everyone involved. You and your child will be a very important part of the research team, and like its other members, you will have a commitment to the study.

What costs will be my responsibility?

The National Eye Institute will provide funds for services specific to the research study, but will not cover patient services considered to be routine care. The study will pay for visits that are done just for the research study. Any additional visits that are part of routine care would be your or your insurance company's responsibility.

If your child receives the overminus glasses treatment, the study will provide a pair of overminus glasses at no cost to you. If your child receives no treatment other than regular glasses, the study will provide a pair of regular glasses. Your child will receive a second pair of glasses after one year, and a change in lenses three months later, again at no cost to you.

To cover travel and other visit-related expenses, you will be given $50 for completion of each of the following visits: the enrollment,

repeated enrollment (if required), 6-, 12-, 15-, and 18-month exams, and any additional visit the study requires. You will receive payment for completed visits even if your child leaves the study before the end. If you are unable to complete study visits without additional funds due to travel costs, please discuss this with the study staff. Additional funds may be available.

Why should I volunteer to have my child take part in the study?

You and your child will be part of a research study designed to provide answers about how to best treat intermittent exotropia. Although the results may not be of direct benefit to your child, other children with intermittent exotropia are likely to benefit from the results of the study.

What do I need to do to have my child take part in the study?

Contact Dr. Marjean Kulp if you would like to schedule an appointment to see if your child is eligible for the study. If you want your child to be in the study, you will be asked to sign a form (Informed Consent Form) giving your consent. This form will provide you with more details about the study.

Principal Investigator at Ohio State:
Marjean Kulp, OD, MS
The Ohio State University College of Optometry
338 W. 10th Ave.
Columbus, OH 43210
(614) 688-3336 or Kulp.6@osu.edu

Coordinating Center:
Jaeb Center for Health Research
Phone: 888-79PEDIG
Email:pedig@jaeb.org

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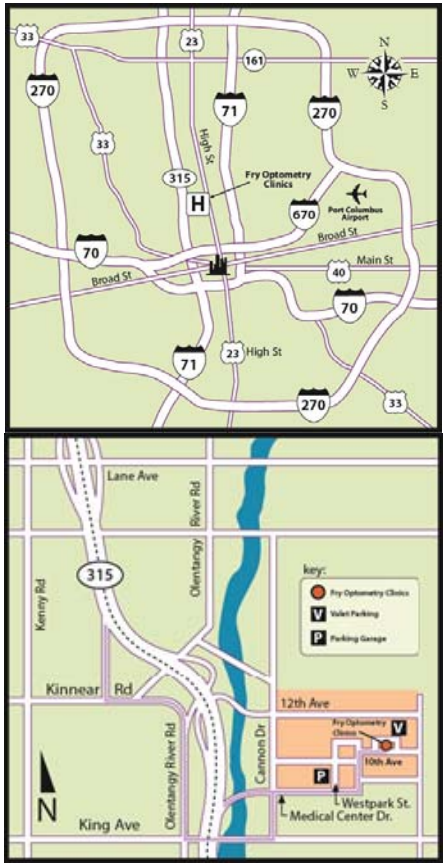
From the North:
Take State Route 315 S to King/Kinnear exit.
Turn left onto Kinnear Rd (Kinnear turns into Olentangy)
Take Olentangy River Road to King Ave. (3rd light).
Turn left onto King Ave.
Take King Ave. to Cannon Drive.
Turn left onto Cannon Drive.
Take Cannon Drive to Medical Center Drive.
Turn right onto Medical Center Drive.

From the South
Take State Route 315 N to Medical Center Dr. exit.
Continue to go straight onto Medical Center Drive.

Parking-Hospital Garage:
Follow Medical Center Drive to Westpark St. Turn Left onto Westpark St.
The Hospitals Parking Garage is located on your left.



Intermittent Exotropia Study 5

A Randomized Clinical Trial of Overminus Spectacle Therapy for Intermittent Exotropia

Information for Parents

Pediatric Eye Disease Investigator Group

National Eye Institute
NATIONAL INSTITUTES OF HEALTH