Dichoptic Treatment for Amblyopia in Children 8 to 12 Years of Age

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 8 years to 12 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

1. Age 8 to <13 years.
2. VA, measured in each eye without cycloplegia in current refractive correction (if applicable) using the E-ETDRS VA protocol on a study-approved device displaying single surrounded optotypes, as follows:

    1. VA in the amblyopic eye 20/40 to 20/200 inclusive (33 to 72 letters with E-ETDRS).
    2. VA in the fellow eye 20/25 or better (≥ 78 letters with E-ETDRS).
    3. Interocular difference ≥ 3 logMAR lines (≥ 15 letters) i.e., amblyopic eye VA at least 3 logMAR lines worse than fellow eye VA).
3. Amblyopia associated with strabismus, anisometropia, or both (previously treated or untreated).

    1. Criteria for strabismic amblyopia: At least one of the following must be met:

* Presence of a heterotropia on examination at distance or near fixation (with optical correction), must be \<=5 prism diopters (Δ) by SPCT at distance and near fixation.
* Documented history of strabismus which is no longer present (which in the judgment of the investigator could have caused amblyopia).

1. Criteria for anisometropia: At least one of the following criteria must be met:

* ≥1.00 D difference between eyes in spherical equivalent (SE).
* ≥1.50 D difference in astigmatism between corresponding meridians in the two eyes.

1. Criteria for combined-mechanism: Both of the following criteria must be met:

* A criterion for strabismus is met (see above).
* ≥1.00 D difference between eyes in SE OR ≥1.50 D difference in astigmatism between corresponding meridians in the two eyes.

1. No more than 2 weeks (cumulative) of prior dichoptic treatment
2. No treatment with cycloplegic eyedrops (e.g., atropine) in the past 2 weeks; other treatments allowed up to enrollment but then must be discontinued.
3. Refractive correction is required (single vision lenses or contact lenses) for any of the following refractive errors based on a cycloplegic refraction completed within the last 7 months:

- Hypermetropia of 2.50 D or more by SE
- Myopia of amblyopic eye of 0.50D or more SE
- Astigmatism of 1.00D or more
- Anisometropia of more than 0.50D SE

NOTE: Children with cycloplegic refractive errors that do not fall within the requirements above for refractive correction may be given refractive correction at investigator discretion but must follow the study-specified prescribing guidelines, as detailed below.

NOTE: Monocular or binocular contact lens wear is allowed provided the contact lenses meet the refractive error correction requirements below. For each child, all testing must be performed using the same form of optical correction (i.e., no changing between contacts and spectacles).
1. Spectacles/contact lens correction prescribing instructions referenced to the cycloplegic refraction completed within the last 7 months:

* SE must be within 0.50D of fully correcting the anisometropia (if new glasses are prescribed, reduction in plus sphere must be symmetric in the two eyes).
* SE must not be under corrected by more than 1.50D SE.
* Cylinder power in both eyes must be within 0.50D of fully correcting the astigmatism.
* Axis must be within +/- 10 degrees if cylinder power is ≤1.00D, and within +/- 5 degrees if cylinder power is \>1.00D.
* Myopia must not be under corrected by more than 0.25D or over corrected by more than 0.50D SE, and any change must be symmetrical in the two eyes.

1. Spectacles/contact lens correction (with or without other treatment such as patching) meeting the above criteria must be worn:

* For at least 18 weeks OR until VA stability is documented (defined as \<1-line change by the same testing method measured on 2 consecutive exams at least 9 weeks apart).
* For determining VA stability (non-improvement):

    * The first of two measurements may be made 1) in current correction, or 2) in trial frames with or without cycloplegia or 3) without correction (if new correctio n is prescribed),
    * The second measurement must be made without cycloplegia in the correct spectacles/contact lens correction that has been worn for at least 9 weeks.
    * NOTE: Because this determination is a pre-randomization, the method of measuring VA is not mandated.

1. Participant is willing to wear a headset.
2. Participant is willing to continue full-time spectacles/contact lens wear (if needed).
3. Interpupillary distance of 52mm to 72mm inclusive.

4. Investigator is willing to prescribe continued spectacles/contact lens correction (if needed) or either dichoptic device per protocol.
5. Participant is willing to accept assignment to either continued spectacles/ contact lens wear alone, dichoptic movies/shows (view 1 hour per day 6 days per week) OR dichoptic games (play approximately 25 minutes per day, 6 days per week) for 19 weeks.
6. Parent understands the protocol and is willing to accept randomization.
7. Parent has phone (or access to phone) and is willing to be contacted by JAEB Center staff.
8. Relocation outside of area of an active PEDIG site for this study within the next 36 weeks is not anticipated.

Exclusion Criteria:

1. Heterotropia more than 5Δ at distance or near (measured by SPCT in current correction)
2. Prism greater than a total of 8 diopters horizontal and 1 diopter vertical in the refractive correction at time of enrollment.
3. Current bifocal spectacles (eligible only if bifocal discontinued 2 weeks prior to enrollment).
4. Myopia greater than -6.00D spherical equivalent in either eye.
5. Ocular co-morbidity that may reduce VA determined by an ocular examination performed within the past 7 months (Note: nystagmus per se does not exclude the participant if the above visual acuity criteria are met using patch occlusion. Fogging is not permitted).
6. Diplopia more than once per week over the last week prior to enrollment by parental report.
7. History of light-induced seizures.
8. Known simulator sickness.
9. Severe developmental delay that would interfere with treatment or evaluation (in the opinion of the investigator). Participants with mild speech delay or reading and/or learning disabilities are not excluded.
10. Immediate family member (biological or legal guardian, child, sibling, parent) of investigative site personnel directly affiliated with this study or an employee of the JAEB center for Health Research.

Conditions & Interventions

Interventions:
DEVICE: Vivid Vision, DEVICE: Luminopia, DEVICE: Optical Correction
Conditions:
Amblyopia
Keywords:
Dichoptic, Luminopia, Vivid Vision, Game, movie, glasses

More Information

Description:
Participants eligible for the study will be randomly allocated (1:1:1) to receive either Luminopia dichoptic treatment while wearing optical correction if needed, Vivid Vision dichoptic treatment while wearing optical correction if needed, or continued optical correction alone if needed, with clinical assessments at 9- and 18-weeks post-randomization. At the 18-week primary outcome visit, participants who were randomly assigned to receive optical correction alone if needed with an IOD of 1 logMAR line (5 letters) or more, will be offered randomization to Luminopia or Vivid Vision dichoptic therapy and if they accept, followed forward with visits at 27- and 36-weeks post-randomization. The study will end for all other participants at 18 weeks.

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