



Binocular treatment for childhood amblyopia using a handheld electronic device

We are offering children (5-15 years) and adults (16+ years) who may have previously tried conventional amblyopia therapies an opportunity to try a new binocular treatment. This "binocular-balanced viewing" treatment was approved as a medical device in 2018 and is currently undergoing Phase II clinical trial in the UK (ClinicalTrials.gov Identifier: NCT03754153).

Treatment involves watching movies or cartoons on a handheld Nintendo device, with the non-amblyopic eye seeing a blurred image and the amblyopic eye seeing a clear image. The amount of blur will be tailored to match the visual acuity of the amblyopic eye. Treatment will be done at home, for 1 hour/day, on a Nintendo 3DSXL device that we will loan to participants during the study.

The study includes follow-up vision checks every 6 weeks at the Grafton Campus Optometry Clinic. It has two phases:

Phase 1) Refractive adaptation: We will first assess the stability of visual acuity and stereoacuity in refractive correction only before starting the binocular treatment. Participants will need to wear their full refractive correction and will be asked to not do any other amblyopia treatment for at least 12 weeks. We will check their vision every 6 weeks. After stable visual acuity is confirmed across 3 or more visits, those who still meet the visual acuity criteria will enter the second phase.

Phase 2) Binocular treatment: Participants will be loaned the Nintendo device to watch binocular movies/cartoons for 1 hour/day at home. We will check their vision every 6 weeks. Treatment can be continued until there is no further improvement, or up to 36 weeks maximum.

After participating in this study, we will refer participants back to you for on-going care.

Inclusion criteria:

- 5 year of age or older, including adults.
- Unilateral amblyopia associated with strabismus and/or anisometropia.
- Best-corrected visual acuity (VA) of 6/12 or worse in the amblyopic eye, and 6/7.5 or better in the fellow eye.
- Currently wearing correction for the full amount of their anisometropia, myopia, and/or astigmatism (where relevant). Hyperopia can be under-corrected by up to +1.50 DS from the cycloplegic refraction, as long as the reduction in plus sphere is equal in both eyes.
- Correction can be in glasses or soft contact lenses or some combination of the two. Must be worn for >50% of waking hours on average, every day.
- If strabismic: manifest strabismus of ≤ 10 prism dioptres at near.
- Healthy eyes with no ocular diseases.
- No previous intraocular surgery. Strabismus surgery and uncomplicated corneal refractive surgery is fine.
- Not currently doing any therapy for amblyopia apart from wearing refractive correction.

For further information or to refer a patient, please contact:

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Approved by the University of Auckland Human Participants Ethics Committee on 26 August 2019 for six years. Reference Number 20609 (023137).