



PARTICIPATION INFORMATION SHEET – For adult participants ≥ 16 years of age at the Christchurch study site

Multiple case study of binocular treatment for childhood amblyopia using a handheld gaming device

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Why are we asking you for your help?

We are testing a new binocular movie-watching treatment to improve vision in amblyopia (“lazy eye”). This treatment aims to encourage the brain to use visual information from the two eyes together, through watching movies or videos with blurry images in the better-seeing eye and clear images to stimulate the “lazy” eye. We need adult and child volunteers with suitable types of amblyopia to try this new treatment. This document provides information to help you decide whether this study is something you would like to be a part of.

How do you know if you will be eligible?

We need adults (16 years and older) with reduced best-corrected vision in one eye (6/12 or worse) due to amblyopia and normal visual acuity (6/7.5 or better) in the other eye. Your amblyopia must be associated with anisometropia (a difference in prescription between eyes), strabismus (an eye-turn or misalignment of the two eyes), or both of these conditions. You should have healthy eyes with no other conditions that affect vision. If you have an eye-turn, the angle of the eye-turn must be 10 prism dioptres or less when looking up close. This is because binocular amblyopia treatment is not suitable for people with larger angle eye-turns.

To confirm your eligibility and that this treatment is suitable for you, we will need to know about your previous eye-related history, current vision, refraction, binocular vision, and eye health. If you have had an eye test with an eye-care professional (such as optometrist or ophthalmologist) recently, we will ask for your permission to look up the records of this eye test. If you have not had an eye test recently or if you do not want us to access your previous records, then we will ask you to attend a comprehensive eye exam either with your current eye-care professional or at Anstice Optometrists, Christchurch. This exam may vary in length from 0.5-2 hours depending on how many tests need to be done to check your eligibility. Pupil-dilating eye drops that relax your focusing may be needed to confirm whether your current glasses or contact lenses prescription is appropriate and to check the health of the back of the eyes. The drops can cause temporary stinging, blurry vision, and light sensitivity. If you have had a dilated fundus exam and cycloplegic refraction within the last 6 months and you’re happy for us to access the records, then you will not need to have eye drops again. The clinician who assesses your eyes can find out if you are eligible and can refer you to our study.

What should you expect?

Participation in this study includes two phases. Everyone eligible will start in Phase 1, where you will be asked to just wear up-to-date glasses or contact lenses. Once we have confirmed that your visual acuity is stable and that you are able to wear lenses (where needed) full-time, then we will assess whether you can continue to the binocular movie treatment in Phase 2.

Phase 1) Refractive adaptation (lenses only):

Most people with amblyopia have refractive error and will need to wear corrective lenses before doing any other therapies like patching or binocular treatment. If you are not currently wearing an up-to-date prescription, then we'll ask you to update your glasses and/or contact lenses before taking part in this study. You are free to choose where you would like to purchase glasses or contact lenses from, as long as the prescription is appropriate for amblyopia treatment. This study will not be covering any costs of updating or replacing glasses or contact lenses.

During the "refractive adaptation" phase we ask that you do not do any other amblyopia treatment (like patching or atropine eye drops), and only continue to wear your glasses or contact lenses every day for as much of the day as you can. Some adults will experience improvements in vision just from wearing up-to-date glasses or contact lenses for a few months. In this study we want to separate this potential effect of wearing lenses from the effects of the binocular movie treatment that we are testing, so we will check that your vision in lenses is stable before starting the binocular movie treatment. This involves vision checks every 6 weeks at Anstice Optometrists, for up to 3 visits (12 weeks). Each follow-up visit can take up to 1 hour, and will include the standard clinical tests that would normally be done during amblyopia treatment.

If after 12 weeks your vision improves until it is better than 6/12 in your amblyopic eye, then by current clinical standards you will not need any additional treatment for amblyopia. If this happens, then you will not be eligible for the binocular movie treatment phase. We will refer you back to your current eye-care professional for on-going care.

Phase 2) Binocular movie treatment:

This phase involves watching movies or cartoons on a handheld Nintendo device for a total of 1 hour/day at home. We will loan you the Nintendo device for the treatment. You will be able to choose from a selection of cartoons and movies, and the videos will be adjusted specifically to blur the vision in your better eye to match your amblyopic eye. Because the treatment is individually tailored, we ask that you do not share the device with anyone else. You should continue to wear your full prescription in glasses or contact lenses during this phase, including when not doing the binocular treatment. We will ask you to take care of the Nintendo device to the best of your ability and to return the device after finishing the treatment.

To measure how well the binocular treatment works, we will ask you to attend follow-up visits every 6 weeks at Anstice Optometrists to check your vision using standard clinical tests, and we will download data from the Nintendo device to see how well you have been doing the treatment. We will also ask you to fill in a feedback questionnaire to tell us your thoughts about the treatment. At each visit, we can change the cartoons or movies loaded onto your device if you wish. We will continue the binocular treatment until your vision stops improving, or up to 36 weeks maximum. After completing the binocular treatment, we will refer you back to your existing eye-care professional for on-going routine care.

Benefits of taking part:

There are no definite long-term benefits of your participation in this study, however there is the potential for the vision in your amblyopic eye and your 3D vision to improve.

Costs of taking part:

The clinical assessments and follow-up visits involved in this study will be provided at the normal cost for services at Anstice Optometrists. We expect that you would need to attend the same number of visits for this study as you would need if you undertook standard amblyopia therapies such as patching or atropine eye drops, so the cost of treatment will be similar regardless of whether you take part in this study or if you undergo standard amblyopia treatments at Anstice Optometrists. There is no reimbursement for the cost of any prescription glasses or contact lenses, or for attending visits.

Risks:

During the binocular treatment you may experience mild tiredness of the eyes, similar to other handheld electronic devices like smartphones. If this occurs we recommend taking short (1-2 minute) breaks and looking into the

distance.

There is also a rare possibility of developing double vision as a result of your amblyopia being treated. This can occur with any type of amblyopia treatment, including conventional therapies like patching and new therapies like binocular treatment. Double vision can have a negative impact on vision and health and sometimes cannot be treated, though most of the time it is only temporary. The binocular treatment being tested in this trial has not led to any cases of double vision to date, however it remains a theoretical possibility. If you experience any double vision, you should stop using the treatment device immediately and contact the study researchers. You will be asked to attend the University Optometry Clinic for an assessment of the double vision. If the double vision persists, then we will make appropriate referrals for management.

Data storage/retention/destruction/future use

All data collected as part of this study will be de-identified by assigning a unique ID code for you. The digital data will be backed up and stored securely on password-protected computers or servers. Paper records will be stored in locked filing cabinets. The data will be accessible only to the named investigators. Paper records will be stored for 6 years and then destroyed using appropriate confidential document destruction services. De-identified digital data will not be destroyed, as this data will be useful for developing better amblyopia treatments in the future.

Confidentiality

At the end of the study we hope to publish our findings in a scientific journal. This will be done in a way that does not identify you.

Participation is your choice

Please take your time to read this document and to decide whether you wish to take part, and feel free to discuss your decision with your current eye-care provider and your whānau, family or other support people. Taking part is completely voluntary (your choice). We want to make sure that you are happy to participate before we start.

Please note that if you are currently under the care of an eye-care professional either at the University Optometry Clinic, Anstice Optometrists, or elsewhere, your decision to participate in this study, or not, will have no impact on the standard of care you receive from these clinics. If you are a student or colleague of the researchers, your participation or non-participation will likewise have no bearing on your grades or relationship with the University. If you are concerned about these issues, please contact Dr Andrew Collins or Prof John Fraser (details at the end of this document).

Right to withdraw

If you do agree to take part, you are free to withdraw from the study at any time without having to give a reason. You also have the right to withdraw any data collected as part of the study from the time of your participation up to six months after the last visit that you attend.

What information will you receive?

Although it is unlikely, if any of the clinical tests we perform discover new or different findings about your eye health or vision status, we will inform you of this and make appropriate referrals if necessary. At the end of your study participation (either after Phase 1 or Phase 2), we will refer you back to your eye-care provider (if you have one) with a report of any changes in your vision during the study. If you are an existing patient at Anstice Optometrists, then you can choose whether to continue receiving routine care at this practice or go elsewhere. You will also receive a copy of this report to keep for your own reference. If you do not wish to be referred, then we will just send you the report for you to keep.

If you would like a summary of the overall project findings, please indicate this on the consent form. Note that this study will be run over a long period of time and there is often quite a delay between when the data is collected and when a paper is published, so there may be a gap in time between when you participate and when you receive the summary. This summary will not contain any identifying details for any participants.

Who should I contact about this study?

If you would like to take part in this study or have any further questions, please contact Kim Stedman, the clinical contact person for the Christchurch site, or the study co-ordinator Dr Tina Gao.

Contact details:

Christchurch site clinical contact

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

For any concerns regarding ethical issues you may contact the Chair, the University of Auckland Human Participants Ethics Committee, at the University of Auckland, Research Office, Private Bag 92019, Auckland 1142. Telephone 09 373-7599 ext. 83711. Email: humanethics@auckland.ac.nz