School of Optometry and Vision Science
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The University of Auckland,
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PARTICIPATION INFORMATION SHEET – For parent/guardians of child participants 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 and your child would like to be a part of.

How do you know if you will be eligible?
We need children (5-15 years) 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 child's 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. Your child should have healthy eyes with no other conditions that affect vision. If your child has an eye-turn, the angle of their 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 eligibility and that this treatment is suitable for your child, we will need to know about your child's previous eye-related history, current vision, refraction, binocular vision, and eye health. If your child has had an eye test with an eye-care professional (like an optometrist or ophthalmologist) recently, we will ask for your permission to access the records of this eye test. If your child has not had an eye test recently or if you do not want us to access your child's previous records, then we will ask you to take your child to their eye-care professional or the Anstice Optometrists, Christchurch for a comprehensive eye exam. This exam may vary in length from 0.5-2 hours depending on how many tests need to be done to check your child's eligibility. Pupil-dilating eye drops that relax your child's focusing may be required at the initial assessment to confirm whether your child's 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 your child has had a dilated fundus exam and cycloplegic refraction within the last 6 months and you're happy for us to access the records, then your child will not need to have eye drops again. The clinician who assesses your child can find out if they are eligible and refer them to our study.

What should you expect?
Participation in this study includes two phases. Everyone eligible will start in Phase 1, where your child will be asked to just wear their up-to-date glasses or contact lenses. Once we have confirmed that your child's visual acuity is stable and that your child is able to wear lenses (where needed) full-time, then we will assess whether they 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 your child is not currently wearing an up-to-date prescription, then we'll ask you to update their glasses and/or contact lenses before taking part in this study. You may choose which provider 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 your child does not do any other amblyopia treatment (like patching or atropine eye drops), and only continue to wear their glasses or contact lenses every day for as much of the day as possible. Some children will experience improvements in vision just from wearing up-to-date glasses or contact lenses every day 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 child's vision in their 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 child's vision improves until it is better than 6/12 in their amblyopic eye, then by current clinical standards your child will not need any additional treatment for amblyopia. If this happens, then your child will not be eligible for the binocular movie treatment phase. We will refer your child back to their 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 your child to do the treatment. You and your child 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 child's better eye to match their amblyopic eye. Because the treatment is individually tailored, we ask that your child does not share the device with anyone else. Your child should continue to wear their 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 your child to attend follow-up visits every 6 weeks at Anstice Optometrists to check their vision using standard clinical tests, and we will download data from the Nintendo device to see how well your child has been doing the treatment. We will also ask you to fill in a feedback questionnaire to tell us your and your child's thoughts about the treatment. At each visit, we can change the cartoons or movies loaded onto your child's device if you wish. We will continue the binocular treatment until your child's vision stops improving, or up to 36 weeks maximum. After completing the binocular treatment, we will refer your child back to their existing eye-care professional for on-going routine care.

Benefits of taking part:
There are no definite long-term benefits of your child's participation in this study, however there is the potential for your child's vision in the amblyopic eye and their 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 your child would need to attend the same number of visits for this study as they would need if they were undergoing standard amblyopia therapies such as patching or atropine eye drops, so the cost of treatment will be similar regardless of whether your child takes part in this study or undergoes standard amblyopia treatment 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 your child 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 your child developing double vision as a result of their 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 your child experiences any double vision, they should stop using the treatment device immediately and you should contact the study researchers. You and your child 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 your child. 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 only accessible only by 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 or your child.

Participation is your choice
Please take your time to read this document and to decide whether you and your child wish to take part, and feel free to discuss your decision with your child's 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 and your child are happy to participate before we start.

Please note that if you or your child are currently under the care of an eye-care professional 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 or your child receives. If you are a student or colleague of the researchers, your child's 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 and your child 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 your child attends.

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

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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)

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