PARTICIPANT INFORMATION SHEET

Project: Effect of refractive blue on a novel retinal birefringence scanning device - the Blinq handheld fixation screener

Names of Researchers:

This research is conducted by staff and students at the School of Optometry and Vision Science (SOVS), University of Auckland (UOA).

Principle Investigator:

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To Participant and Whānau

We would like to invite you to participate in our study investigating the effect of refractive error on the reliability of a novel birefringence scanning device, the Blinq (Rebion Inc).

The Blinq device is a non-invasive method of screening for eye misalignments that can contribute to amblyopia (lazy eye) - a common childhood vision disorder that, if left untreated, can lead to long-term vision problems. The Blinq uses a new technology to check for amblyopia, and may be better than current methods of vision screening. Refractive error is a very common condition that happens when light is not focused correctly at the back of the eye, causing blurry vision. This blur may also cause the Blinq scan to become inaccurate, which affects how useful the device will be if used for vision screening or as part of an eye exam. We want to investigate exactly how much blur is needed to impact the accuracy of the Blinq device, so that this can be accounted for when interpreting results from this device.

This study will be conducted in two parts. Part 1 will assess the device's reliability using your natural refractive error (if you have any). After completing Part 1, we will confirm whether you are eligible to take part in Part 2. Part 2 will involve a series of contact lenses to change the focusing of your eyes, so that we can test the Blinq on known amounts of refractive error.

You are eligible to participant in Part 1 if you

- Are 16 years or older
- Have vision in both eyes (regardless of level of vision)

You are eligible to participate in Part 2 if you

- Meet all criteria for Part 1
- Have normal best corrected visual acuity of 6/7.5 or better in each eye
- Have normal stereoacuity (3D vision)
- Have no strabismus (squint or eye-turn) at near viewing
- Have a spherical refractive error only with low or no astigmatism (≤1.00 DC)
- Are willing and able to wear soft contact lenses, and can put in and remove the contact lenses by yourself
- Can achieve a "pass" result on the Blinq at least once during Part 1, either with unaided vision or wearing your own soft contact lenses

You are not eligible to participate if you

- Have a current ocular disease or any condition that impacts the ocular media clarity, pupil, or the central retina. These diseases and conditions will prevent the Blinq from obtaining scans of the macula.

What does the study involve?

If you are interested in participating, we will email you a link to an electronic Consent Form. Once you have submitted this Consent Form, we will contact you to a) send you a link to a short questionnaire about your eyes and any prescription lenses you currently wear; and b) book an appointment for Part 1 of this study.

Part 1 involves a visit at the Grafton Campus, where a clinical assessment will be conducted to confirm your refractive error and binocular vision status. Afterwards, you will be asked to focus with your eyes on a small target inside the handheld Blinq device while your eyes will be scanned 5 times, taking approximately 2-5 seconds per scan. Your pupil size will then be measured. If you normally wear contact lenses, we will also take 5 Blinq scans through your contact lenses. The appointment will take 40-60 minutes.

Part 2 will take 2 hours, and can be split into multiple sessions. You will be asked to wear soft contact lenses which will correct your eyes to 7 predetermined levels of refractive errors, in a random order. At each level of refractive error, you will be asked to wear the lenses for at least 10 minutes before your eyes are scanned 5 times with the Blinq. We will be using daily disposable contact lenses, which we will ask you to put in and take out by yourself. Some of the lenses will not be your normal prescription, so you will have temporary blurry vision while wearing the lenses, but your vision will return to normal when you remove the lenses. You are welcome to take breaks between contact lenses or whenever needed.

Is there any cost to participate?

Participating in this study will not cost you anything other than your time.

Benefits

There are no direct benefits to you for participating. However, as a gratuity for your participation, you will receive a $20 petrol or Westfield voucher for completing Part 1, and an additional $40 petrol or Westfield voucher for those who also complete Part 2.

Right to Withdraw from Participation

Participation is entirely voluntary and your personal identity will remain confidential. The data we collect will be reported in an anonymous manner. You can withdraw from the study at any time without reason or penalty. You may also withdraw any of your data collected as part of the study up to 3 months after your last study visit.

Risks

Incidental findings: During the course of the study, the researchers may identify abnormalities with your eyes that are not related to the study. In such an event, you will be informed of this and referred for further assessment at an appropriate clinic (e.g. at an optometrist, ophthalmologist, or your GP). If you do not wish to know about this type of finding, please do not participate.

Data storage

All data collected for the purposes of this study will be stored securely; paper records and electronic data will be stored in protected cabinets and computers only accessible by named investigators. The results of this study will only be published in a manner that does not identify you.

Consent to Participate

We will ask you to complete an electronic Consent Form to affirm your agreement to participate.

The Academic Director of SOVS has given an assurance that your participation or non-participation will have no impact on your grades or relationship with the University. You may contact your Head of Department/School should you feel that this assurance has not been met.

If you or your whānau are a patient at the UOA Optometry Clinic, your participation or non-participation will not impact the quality of care you receive, and you/your whānau can request to be seen by a different optometrist supervisor or student if you feel there may be a conflict of interest with the study investigators.

What will happen after the study

The data collected in this study will be used to evaluate whether the Blinq will be used in vision screening and outreach programs offered by SOVS, and for the improvement of childhood vision screening programs in New Zealand and internationally. The de-identified study data will be kept for at least 10 years, until all publications using this data are complete, and then the data will be deleted. The study results will be analysed by the student researchers as part of their honours year written reports, and also published in a scientific journal and presented at conferences.

If you wish to receive a summary of the study findings upon completion of the study, please indicate this on the Consent Form and provide a valid email address where results can be sent.

Thank you for giving us your time to consider your participation in this study. If you have any questions about this study or would like to participate, please contact one of us: gmck923@aucklanduni.ac.nz

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For concerns of an ethical nature, you can contact the Chair of the Auckland Health Research Ethics Committee at ahrec@auckland.ac.nz or at 373 7599 x 83711, or at Auckland Health Research Ethics Committee, The University of Auckland, Private Bag 92019, Auckland 1142

Approved by the Auckland Health Research Ethics Committee on 20/03/23 for three years. Reference number AH25623