PLAIN LANGUAGE STATEMENT AND CONSENT FORM

TO: Participant

Plain Language Statement

Date:

Full Project Title: Investigating ocular markers of diabetic neuropathy

Principal Researchers: Luke Chong, Amanda Douglass and Geoff Sampson

Associate Researcher(s): Cassandra Dimian, Samuel Dent and Madeline Baker

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Introduction

The following information describes the purpose, procedures, benefits and risks associated with this study. It also describes your right to refuse to participate or withdraw from the study at any time. In order to decide whether you wish to participate in this research study, you should be aware of the risks and benefits to be able to make an informed decision and give consent. Please ask any questions you may have regarding the study and ensure all your questions have been answered to your satisfaction, before opting to sign the consent form.

Purpose

Diabetic peripheral neuropathy is a risk factor for falls and is typically measured by endocrinologists via peripheral nerve response in the feet. This neuropathy also affects the eye, and the structure and function of ocular nerves can be assessed by primary eye care professionals. This study will extend current clinical measures and combine them to apply novel analyses in people with varying levels of diabetic peripheral neuropathy severity. Improved understanding of these factors may result in a unique non-invasive biomarker for diabetic peripheral neuropathy and may consequently help to mitigate falls risk.

Procedures

The following procedures will be conducted during the study:

(1) Screening

The screening procedure consists of two parts; firstly, you will be asked to complete a screening checklist that asks for presence of any conditions that may affect the tests being conducted such as stroke, glaucoma, congenital colour deficiency, multiple sclerosis and optic neuritis. The checklist also asks if you are currently taking any medication that may affect the test results. The checklist needs to be completed before attending your first session.

The second part of the screening procedure will be conducted at Deakin University Waurn Ponds to further determine eligibility. Screening will involve a brief and relevant history regarding your vision and general health, assessment of visual acuity and assessment of the health of the eyes.

(2) Simple assessment of neuropathy in the feet

We will conduct a series of tests to assess your nerve responses in the feet such as your ability to differentiate between a blunt and pointy sensation, vibration and temperature-sensation sensitivity and the Achilles tendon reflex response. None of these tests cause discomfort.

The “Achilles Tendon Test” involves applying a light tap with a small medical rubber mallet to the back of your ankle to assess whether your foot moves in response to the tap in the way that is expected in a healthy person. The “Vibration Detection Test” involves placing a tuning fork against your big toe and asking you to respond as to whether you think the tuning fork is vibrating or not. Both tests are quick and neither test involves any discomfort for you.

(2) Computerised measurement of peripheral (side) vision

We will test your central and side vision. You will be asked to look at a central white target and respond by pressing a button whenever you see a light appear anywhere in your side vision. This test is well accepted and widely used tests in clinical research. This test will be repeated once in each visit to the clinic. You can take breaks at any time. There are no known risks or discomfort associated with this test.

(3) Imaging of your retina

Optical coherence tomography (OCT) will be used to take pictures of your retina. OCT is a standard clinical test that is well tolerated. You will be asked to sit at a camera-like machine and to look at small fixation targets inside the instrument. This instrument uses a light beam to obtain high resolution images of your retina. This is a non-contact and safe procedure which is no more uncomfortable than having a flash photograph taken. You may experience a brief after-image which may last up to 30 seconds.

(4) Colour vision

Your ability to perceive different colours will be tested by indicating when you see a moving coloured target against a grey background on a computer screen. You will be asked to press a button to indicate the direction the coloured target has moved. There are no known risks or discomfort associated with this test.

In total these four procedures are anticipated to take up to 2 hours. This will be completed across two visits to the Deakin Collaborative Eye Care Clinic located at the Deakin Waurn Ponds campus.

Benefits

Since this study does not provide diagnosis or treatment, there is no direct benefit to you. However, the results of this study may benefit society by providing data to help clinicians increase their ability to assess and detect diabetic peripheral neuropathy. This study is NOT designed to replace regular eye or general health examinations and results from this study will not be used for clinical care. However, if we find a result which suggests that clinical care may be required, we will provide you with a referral to your regular healthcare professional for appropriate management.

Risks

All of the vision tests and measurements are standard procedures that are carried out in routine eye examinations. The overall level of risk is minimal and similar to that of a full eye examination in an optometrist's office. All procedures used in this study are considered low-risk clinical tests. Since the OCT involves light flashes, you may experience brief (lasting for less than 30 seconds) after-images (shadows in your vision) like those experienced from a camera flash.

All equipment is disinfected between participants to maintain hygiene. As part of our clinic COVID protocol you will be asked to wear a mask and fill in a COVID declaration. This helps to protect both our research participants and our staff.

Confidentiality

Your study data will be handled confidentially. If results of this study are published or presented, individual names and other personally-identifiable information will not be used.

All information relating to the study and its details will remain strictly confidential. Each participant will be assigned an ID number to ensure anonymity of all recorded data. All written and electronic data will be coded using the participant ID number and maintained in a database or on restricted instruments in the clinic. The results based on the collected data in this investigation may be submitted for publication.

Return of Research Findings

If you would like a summary of the research findings, the average group data can be provided to you upon request once data collection and analysis is complete.

Alternatives to Participation

Your participation in this research is voluntary and you have a right withdraw from our study. If you choose to take part then change your mind, please contact the researchers via email advising your wish to withdraw. Please note we are only able to withdraw your data up until it has been analysed. This analysis will occur two weeks after data collection is completed. Your decision to participate or not participate will not affect your relationship with Deakin University or future participation in other research studies.

Compensation

You will be compensated for your time and travel expenses with a $30 Coles gift card for each session that you attend ($60 total). You will receive your gift card immediately upon completion of each attended session.

Questions

If you have any questions or concerns about this study, please contact Dr. Luke Chong at luke.chong@deakin.edu.au

Complaints

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact:

The Human Research Ethics Office, Deakin University, 221 Burwood Highway, Burwood Victoria 3125, Telephone: 9251 7129, research-ethics@deakin.edu.au

Please quote project number HEAG-H 105_2022.

PLAIN LANGUAGE STATEMENT AND CONSENT FORM

TO: Participant

Consent Form

Date:

Full Project Title: Investigating ocular markers of diabetic neuropathy

Reference Number:

I have read, and I understand the attached Plain Language Statement.

I freely agree to participate in this project according to the conditions in the Plain Language Statement.

I have been given a copy of the Plain Language Statement and Consent Form to keep.

The research team has advised that my identity and personal details will not be revealed, including where information about this project is published, or presented in any public form.

Participant's Name (printed) ……

Signature …… Date ……

PLAIN LANGUAGE STATEMENT AND CONSENT FORM

TO: Participants

Withdrawal of Consent Form

(To be used for participants who wish to withdraw from the project)

Date:

Full Project Title: Investigating ocular markers of diabetic neuropathy

Reference Number:

I hereby wish to **withdraw** my consent to participate in the above research project and understand that such withdrawal will not jeopardise my relationship with Deakin University, the Deakin Collaborative Eye Care Clinic or the researchers listed.

Participant's Name (printed) …….

Signature ……. Date ……

Please email this form to Dr Luke Chong, luke.chong@deakin.edu.au