Dunedin Multidisciplinary Health & Development Study

Concept Paper Form

Provisional Paper Title: Are macular drusen in midlife a marker of ageing?
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P.I. Sponsor: (if the proposing author is a student or colleague of an original PI)
Today's Date: April 2019

Objective of the study:

To determine if study members with macular drusen are biologically older than other study members. In simple terms, are macular drusen a bio-marker of biological age in midlife or of the pace of ageing?

Data analysis methods:

Straightforward analyses of association between drusen and other measures of aging can be accomplished using analysis of variance and multiple regression.

Variables needed at which ages:

- Drusen in retinal photography P45
- Facial age P45
- 18-biomarker measure of Pace of ageing phase 45,

Analyses with Phase 45 variables asks if drusen are associated with other measures of ageing, taken at the same time, a validation of the hypothesis that drusen are a sign of ageing.

Significance of the Study (for theory, research methods or clinical practice):

Drusen are yellow deposits under the retina made up of lipids that are easily identifiable on clinical examination or retinal photography. Drusen are the hallmark of the early stages of age-related maculopathy (ARM). ARM remains the number one cause of blindness in Western nations. 1 in 7 people over the age of 50 years is affected in some way and 1 in 4 people over the age of 80 have some vision loss.1 A recent Deloitte's report in NZ (funded from Gisborne) reported the total cost of vision loss from AMD was estimated to be $391.1 million in 2016, or $19,727 per person with ARM (economic costs which were mainly healthcare were $89.6 million, lost wellbeing was $301.5 million).2 In addition to economic costs, the loss of wellbeing was estimated to cost an additional 1,800 Disability adjusted life years (DALYs). ARM may be considered as a classic chronic disease of ageing and the risk factors for ARM are considered to be the same as those for cardiovascular disease. In particular, the risk factors are ageing, smoking, nutritional and genetic.

The DS is a novel approach to studying ageing longitudinally by tracking a cohort of young adults into middle of their life course. The DS also has a measure of the pace of ageing. To date over 100 SM have been identified with drusen on digital retinal photography.

This investigation provides a unique opportunity to evaluate a classic disease of ageing in midlife!
If drusen in midlife are found to be associated with advanced biological ageing or can be used as a marker of pace of ageing, then this would translate to:

1. Improved Individual care and interventions to prevent blindness and ageing
2. Use of retinal photographs in clinical trials of anti-ageing interventions
3. Using drusen as a marker to help identify factors that slow/speed the pace of ageing

References:

References:

1. Macular Degeneration NZ http://mdnz.org.nz/
2. https://www2.deloitte.com/nz/en/pages/economics/articles/socioeconomic-cost-macular-degeneration-in-nz.html

Data Security Agreement

Provisional Paper Title	
Proposing Author	
Today's Date	

Please keep one copy for your records and return one to the PI Sponsor

Please initial your agreement: (customize as necessary)

	I am current on Human Subjects Training [CITI www.citigrogram.org] or equivalent.
	My project is covered by the Dunedin Study's ethics approval OR I have /will obtain ethical approval from my home institution (please specify).
	I will treat all data as "restricted" and store in a secure fashion. My computer or laptop is: • encrypted (recommended programs are FileVault2 for Macs, and Bitlocker for Windows machines) • password-protected • configured to lock-out after 15 minutes of inactivity AND • has an antivirus client installed as well as being patched regularly.
	I will not "sync" the data to a mobile device.
	In the event that my laptop with data on it is lost, stolen or hacked, I will immediately contact my PI Sponsor or Study Director, Richie Poulton (richie.poulton@otago.ac.nz).
	I will not share the data with anyone, including my students or other collaborators not specifically listed on this concept paper.
	I will not post data online or submit the data file to a journal for them to post. *Some journals are now requesting the data file as part of the manuscript submission process. The Dunedin Study Members have not given informed consent for unrestricted open access, so we have a managed-access process. Speak to your PI Sponsor or Richie Poulton for strategies for achieving compliance with data-sharing policies of journals.*
	I will delete all data files from my computer after the project is complete. Collaborators and trainees may not take a data file away from the office. The data remains the property of the Study and cannot be used for further analyses without an approved concept paper for new analyses.

Signature: _____

CONCEPT PAPER RESPONSE FORM

A To be completed by the proposing author:

Provisional Paper Title	
Proposing Author	
Other Contributors	
Potential Journals	
Today's Date	
Intended Submission Date	

Please keep one copy for your records and return one to the proposing author

B. To be completed by potential co-authors:

☐ Approved ☐ Not Approved ☐ Let's discuss, I have concerns

Comments: _____

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Please check your contribution(s) for authorship:

	Conceptualizing and designing the longitudinal study
	Conceptualizing and collecting one or more variables
	Data collection
	Conceptualizing and designing this specific paper project
	Statistical analyses
	Writing
	Reviewing manuscript drafts
	Final approval before submission for publication
	Acknowledgment only, I will not be a co-author

Signature: _____