

Effects of lutein and omega-3 fat enriched egg consumption on visual function in older adults: Implications for age-related macular degeneration

Submission date 25/06/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/06/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/06/2018	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Despite ample research showing the ability of lutein, zeaxanthin and omega-3 docosahexaenoic acid (DHA) to benefit retina (eye) function, research using whole foods as a vehicle for these nutrients is lacking. As age-related macular degeneration (AMD) is common among Caucasian older adults, this study investigates whether DHA-enriched egg consumption can improve retina function in this population.

Who can participate?

Healthy Caucasian adults aged 50-80

What does the study involve?

Participants consume two lutein and DHA enriched eggs daily for six weeks, while avoiding supplements and foods high in eye-related nutrients. Rod and cone (eye) cell function is assessed by full field electroretinogram (an eye test). Blood DHA, lutein and lipid levels are measured at the start of the study and after 6 weeks.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Richardson Centre for Functional Foods and Nutraceuticals (Canada)

When is the study starting and how long is it expected to run for?

May 2013 to September 2014

Who is funding the study?

1. Agri-Food Research and Development Initiative's (ARDI) Growing Forward program
2. Manitoba Egg Farmers
3. Burnbrae Farms Inc.

Who is the main contact?

Mrs Chelsey Walchuk
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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

J2013:104

Study information

Scientific Title

Effects of lutein and docosahexaenoic acid enriched egg consumption in older adults: Implications for age-related macular degeneration

Acronym

Egg and Vision Study

Study objectives

Lutein and DHA enriched egg consumption will improve retina function in Caucasian older adults by increasing egg-nutrient associated blood profiles while not adversely affecting plasma lipid profiles. More specifically, in Caucasian older adults, lutein and DHA enriched egg consumption will:

1. Improve self-assessed health and vision status
2. Improve electrophysiological retina function
3. Not influence TC and TAG concentrations
4. Not influence HDL-C/LDL-C particle size
5. Increase DHA in plasma and erythrocytes
6. Increase lutein in plasma

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Manitoba Joint-Faculty Research Ethics Board, 02/08/2013, Protocol #J2013:104

Study design

Single-centre 6-week intervention trial with a repeated measure design

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

General health of the retina and prevention of age-related macular degeneration

Interventions

Avoidance of retina/eye related food items for one month prior and throughout the duration of the trial (6 weeks) including: eggs; oysters; liver (chicken, beef, veal, etc.); sweet potato; pumpkin; carrots; kale; fish and caviar; spinach; supplements that contain zinc, choline, vitamin A, lutein, zeaxanthin and DHA.

Limit retina/eye related food items for one month prior and throughout the duration of the trial (6 weeks) including: pork ham, bacon, beef, lamb, butternut squash, collard greens, turnip greens, baked beans and green peas

Treatment: 2 medium (92g) lutein and docosahexaenoic acid enriched eggs (0.87 mg lutein/day, 220 mg DHA/day) daily for 6 weeks to be consumed/cooked at the discretion of the participant.

Control: No control group as participants acted as their own control from PRE to DURING and POST assessment following consumption of enriched eggs.

Rod and cone cell function was assessed by full field electroretinogram. Plasma and red blood cell (RBC) DHA, plasma lutein, lipid profiles, and lipoprotein subfractions were assessed at day 0 (PRE) and 6 wks (POST).

Intervention Type

Supplement

Primary outcome(s)

1. Self-assessed health and vision status measured using a modified version of the National Eye Institute Visual Functioning Questionnaire at PRE (week 0), DURING (week 3) and POST (week 6) assessment
2. Plasma lipid profiles (Total cholesterol, HDL-cholesterol, LDL-cholesterol, Triglycerides), measured using a Cobas C 111 Analyzer at PRE (week 0), DURING (week 3) and POST (week 6) assessment
3. Plasma fatty acids, measured by gas chromatography at PRE (week 0), DURING (week 3) and POST (week 6) assessment
4. Plasma lutein, measured using high performance liquid chromatography at PRE (week 0),

DURING (week 3) and POST (week 6) assessment

5. Retina function, measured using a full field electroretinogram at PRE (week 0), DURING (week 3) and POST (week 6) assessment

Key secondary outcome(s)

1. Average dietary intake, measured using a 3-day food record analyzed using The Food Processor software between DURING (week 3) and POST (week 6) assessment

2. LDL/HDL particle size, measured using polyacrylamide gel electrophoresis (Lipoprint Lipoprotein Subfractions Testing System, Quantimetrix, California, US) at PRE (week 0) and POST (week 6) assessment

Completion date

01/09/2014

Eligibility

Key inclusion criteria

1. Individuals between 50-80 years of age
2. Caucasian ethnicity
3. Good English written and oral communication skills

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

1. Individuals with an egg allergy
2. Individuals diagnosed with a chronic disease (ie. diabetes, cardiovascular disease etc)
3. Individuals diagnosed with mental cognitive disorders
4. Individuals diagnosed as hypercholesterolemic
5. Individuals taking statins and other lipid lowering medications
6. Individuals diagnosed with eye related disease (i.e. glaucoma, AMD, retinitis pigmentosa, etc)

Date of first enrolment

01/07/2013

Date of final enrolment

01/03/2014

Locations

Countries of recruitment

Canada

Study participating centre

Richardson Centre for Functional Foods and Nutraceuticals

196 Innovation Drive

University of Manitoba, SmartPark

Winnipeg

Canada

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Sponsor information

Organisation

University of Manitoba

ROR

<https://ror.org/02gfys938>

Funder(s)

Funder type

Research organisation

Funder Name

Agri-Food Research and Development Initiative's (ARDI) Growing Forward program

Funder Name

Manitoba Egg Farmers

Funder Name

Burnbrae Farms Inc.

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Miyoung Suh (miyoung.suh@umanitoba.ca) and Chelsey Walchuk (umwalchu@myumanitoba.ca).

IPD sharing plan summary

Available on request