Can an increase in fruit and vegetable intake improve/change your skin colour and appearance?

Submission date	Recruitment status No longer recruiting	Prospectively registered		
05/10/2013		[_] Protocol		
Registration date	Overall study status	[] Statistical analysis plan		
20/11/2013	Completed	[X] Results		
Last Edited 28/01/2019	Condition category Nutritional, Metabolic, Endocrine	Individual participant data		

Plain English summary of protocol

Background and study aims

Regular consumption of fruit and vegetables has been linked to a decrease in a number of longterm conditions such as obesity, stroke, type 2 diabetes, cardiovascular disease (CVD) (heart disease) and some cancers. Despite the beneficial effects of eating fruit and vegetables, the majority of the Australian population are not meeting the current recommended servings. In New South Wales (NSW), only 10% of young adults eat adequate amounts of vegetables and 50% do not eat enough fruit. There are several reasons such as sensory appeal, habit, cost, availability, time constraints, peers and social interactions, highlighting that it is a complex process. Various approaches have been tried to increase fruit and vegetable intake amongst the adult population. Although these are effective to some extent, more research or other strategies are required. Recent studies have investigated the effects of fruit and vegetable consumption on skin colour. Skin colour is influenced by three key pigments: haemoglobin, melanin and carotenoids. Carotenoid pigments are found in skin layers and contribute to normal human skin colour. These yellow-red pigments can only be obtained from vegetables and fruit. A recent study investigated the dietary effects of fruit and vegetable consumption on skin colour appearance. The study found that changes in fruit and vegetable consumption were significantly correlated with skin redness and yellowness after 6 weeks. If the consumption of fruit and vegetables can influence carotenoid levels that lead to skin colour change this in turn may improve the appearance of healthy skin colour and overall health. The beneficial effects on appearance thus may influence individuals who are motivated by appearance, typically adolescents and younger adults, to make changes to their diet and to increase their fruit and vegetable intake. The aim of this study is to find out if an intake of high carotenoid fruit and vegetables for four weeks improves skin colour appearance.

Who can participate?

Women aged 18-30 years with low fruit and vegetable intake can participate in this study.

What does the study involve?

Participants are randomly allocated to one of two groups. Every week for 4 weeks one group will receive a box of fruit and vegetables that are high in dietary carotenoids, and the other group

will receive a box of fruit and vegetables that are low in dietary carotenoids. The box is equivalent to seven servings a day and participants are asked to consume the fruit and vegetables that are provided. In addition they need to collect the fruit and vegetables from the university each week. They are asked to attend four measurement sessions at the University of Newcastle Nutrition & Dietetics Anthropometry lab. They have a blood test at each assessment, which requires them to fast overnight, and they will complete an online questionnaire before the assessment session about them, their health, their skin type and their perception on appearance. Following a 2-week break the groups will swap over and receive the alternative fruit and vegetable box every week for 4 weeks. Participants are asked to refrain from using any tanning lotions, creams or sunbathing during the study.

What are the possible benefits and risks of participating?

Participants will receive information on their body composition, blood pressure, fruit and vegetable intake, and skin carotenoid and melanin levels. They will also receive a \$25 gift voucher for participating in the study to cover travel costs. They will receive a weekly complementary fruit and vegetable box for 8 weeks. Blood collection may cause some individuals to feel light headed, faint or experience some bruising at the site of the blood collection. Breakfast will be provided after measurements and blood collection has taken place. Participants may experience some discomfort from having their blood pressure taken. The spectrophotometer used to measure skin carotenoids is safe and involves pressing the device to the skin surface to measure the level of carotenoid and melanin compounds that are in the skin. All other measures in the study use standard tools that have been widely used in research. Some questions in the online survey and questionnaires are of a sensitive nature (e.g. requesting information about prescribed medication, acne, feelings about your personal appearance and the questions in relation to the photographs). All information collected will be kept confidential and names will not be stored alongside responses.

Where is the study run from? The University of Newcastle, Callaghan Campus, Australia.

When is study starting and how long is it expected to run for? The study started in October 2013 and is expected to run until April 2014.

Who is funding the study? The University of Newcastle (Australia).

Who is the main contact? Professor Clare Collins clare.collins@newcastle.edu.au

Contact information

Type(s) Scientific

Contact name Prof Clare Collins

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Impact of high versus low carotenoid intakes from vegetables and fruit on skin colour and appearance: a randomised cross-over trial

Study objectives

It is hypothesised that an increased consumption of high carotenoid fruit and vegetables will be associated with a significantly greater increase in skin yellowness compared to increased consumption of low carotenoid fruit and vegetables. The null hypothesis is that there will be no difference between the groups.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The University of Newcastle Human Research Ethic Committee; initial approval 11/10/2012; variation approved 09/09/2013; ref: H-2012-0338

Study design

Randomised 4-week cross-over trial with a 2-week washout

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Other

Study type(s) Other

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Young women from the general population not following any dietary restriction due to medical conditions

Interventions

Participants will be required to be in the study for 11 weeks. There will be two interventions phases (4 weeks each) and a 2-week washout period.

In phase 1 the participants will be randomly assigned to receive one of the two interventions: a weekly fruit and vegetable box.

Box 1: High in carotenoids

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Box 2: Low in carotenoids

The box will contain a total of two servings of fruit and five servings of vegetables per day (including tinned products and sauces). There will be a two-week wash-out period (half life of carotenoids).

In phase 2, participants will cross-over and receive the alternative fruit and vegetable box.

In both intervention phases, the participants will be blinded as to what level of carotenoids the fruit and vegetable boxes contain, the boxes will be identified as Box 1 or Box 2. During each of the two intervention phases, participants will be required and encouraged to consume the fruit and vegetables that are provided to them. Participants will be required to abstain from using any tanning products, lotions/sprays or sunbathing for the 11-week period, because this will have an impact on their skin colour and the results. Participants will be required to attend the Nutrition and Dietetics Anthropometry lab in the Hunter Building (HC57) during week 1, 5, 7, 11 in which the following measurements will be taken:

1. Height, weight, body composition (fat mass and fat free mass), blood pressure

2. Have a blood test at each assessment, in which we will require you to fast overnight

3. Have a photograph of the face taken

4. A food frequency questionnaire (FFQ) on eating habits and 24-hour recall and quality of life (QoLSF12) survey

5. Skin carotenoid and melanin measurements taken on the skin at shoulders, arms, face, hand, foot sole and hip using a spectrophotometer to measure carotenoids in the skin 6. Complete an acceptability evaluation survey in weeks 5 and 11

The fruit and vegetable consumption tests periods are 2 x 4-week periods (week 1 to 4 and weeks 7 to 10).

Intervention Type

Other

Phase Not Applicable

Primary outcome measure

Skin carotenoid content as measured by spectrophotometer. Time point: Baseline, Week 5. Week 7 and Week 11

Secondary outcome measures

1. Plasma carotenoids: fasting blood sample (2 x 2 ml ETDA), time point: baseline, week 5, week 7 and week 11

2. Daily fruit and vegetable intake:

2.1. Australian Eating Survey 2010, 137-item semi-quantitative food frequency questionnaire, time points: baseline, week 5, week 7 and week 11

2.2. 24-hour recall, time points: baseline, week 5, week 7 and week 11

3. Quality of life (SF12), time points: baseline, week 5, week 7 and week 11

Overall study start date

01/10/2013

Completion date

01/04/2014

Eligibility

Key inclusion criteria

1. Females aged 18-30 years

2. Low fruit and vegetable consumption (vegetables with evening meal <3-4 per week and <5-6 pieces fruit per week)

3. Able to attend the Callaghan campus on four occasions (baseline and 4 weeks, cross over)

4. Proficient in English

5. Abstain from using tanning/lotions/sprays and sunbathing for 11 weeks

Participant type(s)

Patient

Age group

Adult

Lower age limit 18 Years

Upper age limit

30 Years

Sex

Female

Target number of participants

30

Key exclusion criteria

- 1. BMI <18.5kgm2
- 2. Current smoker
- 3. Current eating disorder
- 4. Liver disease
- 5. Special diet: Coeliac, Fermentable, Oligo-, Di-, Mono-saccharides And Polyols (FODMAPS), low

fibre diet

6. Metabolic disorders: type 2 diabetes, hypertension/hypotension, renal disease

7. Cardiovascular disease (CVD)

8. Gastrointestinal tract disease

9. Currently pregnant or lactating

Date of first enrolment 01/10/2013

Date of final enrolment 01/04/2014

Locations

Countries of recruitment Australia

Study participating centre HA12 Hunter Building Callaghan Australia 2308

Sponsor information

Organisation The University of Newcastle (Australia)

Sponsor details

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Sponsor type University/education

Website http://www.newcastle.edu.au/ ROR https://ror.org/00eae9z71

Funder(s)

Funder type University/education

Funder Name

The University of Newcastle (Australia) - Priority Research Centre for Physical Activity and Nutrition

Results and Publications

Publication and dissemination plan Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2016	28/01/2019	Yes	No