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Effects of fish consumption on cardiovascular risk factors

Submission date	Recruitment status	[_] Prospectively registered
08/05/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/05/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/01/2019	Circulatory System	

Plain English summary of protocol

Background and study aims
Consuming fish is a good source of omega-3 fatty acids. Omega-3 fatty acids are good for the heart and can help those who are at high risk of cardiovascular disease (CVD). Fish plays an important role in many diets. The atherogenic index is a tool to identify people with CVD risk. Lipids (fats in the drugs) are usually lowered by a diet rich in fish which can decrease the risk of heart diseases. However, there are many lifestyle and social/economic backgrounds that can impact CVD risk. The aim of this study is to evaluate the lipid profile in healthy people with different fish consumption habits to assess their CVD risk level.

Who can participate?
Healthy adults aged 23 to 30 years old.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group eat curried fish (containing coconut cream) daily (300g weekly) for six months. Those in the second group are fed daily with fish fried in coconut oil (300 grams per week) for six months. Participants are assessed before and after the study to assess their lipids levels, body mass index, and blood pressure.

What are the possible benefits and risks of participating?
There are no notable benefits or risks with participating.

Where is the study run from?
Eastern University, Sri Lanka (Sri Lanka)

When is the study starting and how long is it expected to run for?
August 2015 to April 2016

Who is funding the study?
Eastern University, Sri Lanka (Sri Lanka)

Who is the main contact?
Mrs Chandravathany Devadawson

Study website
www.esn.ac.lk

Contact information

Type(s)
Scientific

Contact name
Mrs Chandravathany Devadawson

ORCID ID
http://orcid.org/0000-0002-0557-6274

Contact details
Department of Zoology
Eastern University, Sri Lanka
Chenkalady
Battcialao
Sri Lanka
30350

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT03111784

Secondary identifying numbers
N/A

Study information

Scientific Title
Effects of fish consumption on cardiovascular risk factors: a quasi-experimental study

Study objectives
The aim of this study is understand the relationship of fish consumption and its pattern in cardiovascular disease (CVD) from the Eastern Sri Lankan community.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee Faculty Of Health Care Sciences Eastern University, Sri Lanka, 21/10/2014, ref: EUSL/FHCS/ERC/2014/27

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Screening

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
Cardiovascular diseases

Interventions
Participants undergo a baseline examination for lipid profiles, body mass index (BMI), blood pressure (BP). Participants take a pre-tested questionnaire used to collect data on dietary habits including fish consumption and other socio-demogrpahic characteristics.

Participants are randomly allocated to one of two groups.

Group 1: Participants are fed daily with fish prepared as a curry containing coconut cream (300 grams per week for six months).

Group 2: Participants are fed daily with fish fried in coconut oil (300 grams per week for six months).

Fasting blood samples are collected from healthy people for lipid profile estimations with an automated analyzer after the intervention. Detailed information regarding physical and atherogenic parameters was collected from each participant. Participant’s lipid profiles, body mass index (BMI) , blood pressure (BP) are measured at the end of the six months.

Intervention Type
Other

Primary outcome measure
1. Type of fish consumption is measured using participant records at six months
2. Amount of fish consumption is measured using participant records gram at six months
3. Time of consumption is measured using the participant records at six months

4. Processing type of fish is measured using the participant record at six months
5. Sociodemographics are measured using the pretested semi –structured questionnaire at baseline

Secondary outcome measures
Cardiovascular risk profiles are measured using blood samples and biochemistry lab automatic analysis at baseline and six months.

Overall study start date
01/08/2015

Completion date
30/04/2016

Eligibility

Key inclusion criteria
Healthy adults aged 23 to 30 years old.

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
599

Key exclusion criteria
People who do not eat fish

Date of first enrolment
31/08/2015

Date of final enrolment
01/09/2015

Locations

Countries of recruitment
Sri Lanka

Study participating centre
Department of Zoology
Eastern University, Sri Lanka

Chenkalady
Batticaloa
Sri Lanka
30350

Sponsor information

Organisation
Eastern University, Sri Lanka

Sponsor details
Vanthrumoolai
Chenkalady
Battcaloa
Sri Lanka
30350

Sponsor type
University/education

Website
www.esn.ac.lk

ROR
https://ror.org/01jrs3715

Funder(s)

Funder type
University/education

Funder Name
University Grant Commission Sri Lanka

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer reviewed journal.

Intention to publish date
01/10/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Mrs Chandravathany Devadawson chand_oo@yahoo.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article			29/01/2019	Yes	No