ORIGINAL ARTICLE

Impact of coconut and palm oils on cardio-metabolic risk factors: study protocol for a human study

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Abstract

Background

Although the traditional Sri Lankan diet is low in fat content, the incidence of cardiovascular diseases is high. This probably correlate with high saturated fat and cholesterol intake. This study is to investigate the impact of coconut oil and palm oil as cooking oil media, which are the primary dietary saturated fat sources among Sri Lankans, on cardio-metabolic risk factors.

Methods:

The study will be conducted as a sequential feeding clinical trial. The study has been approved by the Ethics Review Committee of Faculty of Medicine, University of Colombo (EC/19/046). A total of 40 healthy adults from the general community will be recruited. The study will be divided into two feeding periods of 8 weeks each for coconut oil and palm oil. Participants will be provided the first test oil for the first feeding period and then, the second test oil will be continued for another 8 weeks keeping 4 weeks of washout period in between. The anthropometric and biochemical investigations will be done at the beginning of the first feeding period, at the end of the first feeding period (8th week), at the beginning of the second feeding period (12th week), and at the end of the second feeding period (20th week) of the study. The primary outcome index will be the difference in the change in serum low-density lipoprotein cholesterol concentration between the two feeding periods. Secondary outcome measures include the serum concentrations of, total and high-density lipoprotein cholesterol (TC and HDL-C), TC/HDL-C ratio, triglycerides, very low-density lipoprotein cholesterol, fasting plasma glucose, liver enzymes, anthropometry, blood pressure, dietary and physical activity assessment. Data will be analyzed using SPSS v 22.

Discussion

The expected outcome of the study is an improved understanding of the differences in cardiometabolic risk factors between the consumption of coconut oil and palm oil.

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Background

The latest World Health Organization (WHO) report has highlighted that Non-Communicable Diseases (NCDs) account for 41 million deaths each year, equivalent to 71% of all global mortality [1]. Among the different NCDs, cardiovascular diseases (CVDs) account for most of NCD fatalities, which is around 17.9 million per year. While the risk factors for CVDs are multifactorial, an unhealthy diet is one of the most common modifiable risk factors [2]. Among unhealthy dietary habits, fat in the diet plays a key role in the incidence and severity of CVDs. A multinational study from 7 countries examined the relationship between diet and CVD in different populations living in different parts of the world [3]. Results from this study showed that higher fat intake, especially higher intake of saturated fatty acids (SFAs) was directly associated with a high prevalence of CVD. Several lines of evidence indicate that sources and types of fat have a more important role in determining the risk of CVD than the total amount of fat in the diet [4]. The high SFA content in the diet is considered as one of the several reasons that explain the relatively high incidence of CVDs in the South Asian region [5]. Coconut and palm oils are primary dietary SFA sources among South Asians [6]. The World Health Organization's 2003 report stated that there is convincing evidence that palm oil consumption contributes to an increased risk of developing CVD [7]. However, due to the low cost, palm oil is increasingly used in the household as well as in the food industry [8]. Although both oils have a high content of SFA, they differ in their fatty acid composition. Coconut oil contains a high proportion of lauric acid, a medium-chain fatty acid, that has been shown to increase serum high-density lipoprotein (HDL) cholesterol and low-density lipoprotein (LDL) cholesterol [9,10]. Palm oil on the other hand, contains not only longer chain saturated fatty acids but also mono unsaturated fatty acids and some poly-unsaturated fatty acids. Hence the type of saturated fatty acids as well as the degree of unsaturation in the two oils may result in different effects on blood lipids when compared side by side.

To date, several clinical trials have investigated the effect of coconut oil over palm oil on cardiovascular health. One randomized controlled trial found that a palm oil-enriched diet did not lead to negative effects on the lipid profile compared to a coconut oil-enriched diet [11]. Furthermore, two clinical trials conducted in Malaysia [12,13] demonstrated that there was a significant increase of LDL-cholesterol by coconut oil compared to palm oil. However, subsequent study from the same country [14] indicated that coconut oil decreased LDL-cholesterol over palm oil. Findings from various countries may not be directly applicable to another country due to variations in genetic factors, cooking methods, dietary habits, and other environmental factors [15,16].

Data on the effects of coconut oil or palm oil as replacement fats is limited, and this lack of evidence hinders the ability to provide clear public health guidelines. The public health relevance of the proposed study is expected to be important as this study aims to examine the real-world situation and not using the oils as a supplement, but as routine cooking media among free-living adults. Further, although the addition of oil to cooked food is commonly seen in studies, this is not a culturally acceptable food consumption practice in the world as a whole. The real-world applications of this study include recognizing existing culture and cooking methods that oil is used for in different processing methods such as deep-frying, shallow frying, and heating at relatively high temperatures until vaporization especially with tempering. Such processing can form trans fats, carcinogens, and other metabolites that can negatively affect cardiometabolic health. A trial performed in real-world situations with commonly used cooking methods has the potential to shed light on how the different oils in their processed forms would impact cardiometabolic risk factors. Therefore, we will plan our menus ensuring that all the processing methods with both coconut and palm oil are carried out at the same level. Data on coconut versus palm oil is lacking and clinical trials provide the strongest evidence to study a replacement effect of coconut versus palm oil.

Objectives and hypothesis

Objectives: This study aims to investigate and compare the effects of daily consumption of coconut and palm oil on lipid profile (Total Cholesterol (TC), LDL-cholesterol, triglycerides (TG), HDL-cholesterol, TC/HDL-C ratio, very-low-density lipoprotein cholesterol (VLDL-cholesterol), and other cardio-metabolic risk factors (glycemic parameters, liver function tests, anthropometric parameters, and blood pressure) in healthy adults in Sri Lanka. Furthermore, dietary intake and physical activity levels will also be evaluated as potential confounding variables.

Hypothesis: Coconut oil would have a beneficial effect on lipid profile and other cardio-metabolic risk factors compared to palm oil in healthy adults in Sri Lanka.

Methods

Study design

The study will be carried out in the model of a sequential feeding clinical trial for a period of 8 weeks for each feeding period separated by 4 weeks washout period. Figure 1 provides an overview of the study.

Figure 1: Schematic representation of study design.

Sample size

The sample size to detect a 25 mg/dL difference in the change of serum LDL-cholesterol (primary outcome measure) between the two feeding periods of coconut oil and palm oil, while maintaining a type one error (α) of 0.05 and type 2 error (β) of 0.1 is 32. The expected difference of 25 mg/dL in LDL-cholesterol between the two groups in sample size calculation was based on the differences observed in the reference study used (Mean LDL-cholesterol change in coconut oil feeding group was +10 mg/dL while mean LDL-cholesterol change in palm oil feeding group was -15 mg/dL) [17]. Assuming a compliance rate of 80% for subjects, approximately 40 subjects will be recruited. Equal gender distributions will be maintained and the sample will be stratified to represent all categories of the adult population such as young adults (18-35 years), middle-aged adults (35-55 years), and older adults (>55 years) to ensure equal age distribution.

Study setting and population

Participants will be non-institutionalized healthy adults living in the community. They will be invited through a public announcement, using fliers and by inviting prospective participants. The volunteering subjects will be initially interviewed for medical history and lifestyle information via a screening questionnaire. Those who meet the initial inclusion criteria will be invited for a health screening session including medical examination and biochemical profile.

Inclusion and exclusion criteria

Inclusion criteria

- Free-living or non-institutionalized (having an independent life-style) healthy adults who are more than 18 years old.
- Willing to consume both coconut and palm oil sequentially and follow the dietary instructions.
- Consumes all three main meals at home and willing to continue this throughout the study period.
- Willing to maintain their usual dietary habits and physical activities.

Exclusion criteria

- Those who have a medical history of cardiovascular diseases, stroke, thyroid disease, diabetes mellitus, liver or renal dysfunction (acute or chronic), peptic ulceration, cancer.
- Individuals on medications for dyslipidemia, hypercholesterolemia, or inflammation, receiving tetracycline therapy.

- Those with high lipid profile values according to the treatment guidelines [18] at the screening test.
- Those who use herbal supplements, antioxidants, vitamins, minerals, omega 3 or omega 6 supplements.
- Those who follow any prescribed diet and weight loss diets.
- Those who are unable to speak, read or write either in Sinhala, English or Tamil language.
- Those who frequently consume foods from outside (at least 2 days per week).
- Pregnant and lactating mothers.
- Those who are suffering from any other disorder that might affect lipid profile.
- Frequent use of alcohol and/or tobacco or plans to change alcohol/tobacco consumption habits during the trial period

Suspension criteria

- Subject's demand to discontinue the study.
- Serious adverse events or unusual changes in clinical test results.
- Principal investigator's decision to terminate the study (low rates of compliance, complications, or unable to continue the study due to unavoidable reasons).

Screening

Interested volunteers will be provided with an outline of the study. Socio-demography and general lifestyle pattern, medical history, and co-morbidities of each subject will be collected using a standard interviewer-administered screening questionnaire. Potentially suitable participants will be identified and those who meet all the inclusion criteria will be invited to attend a screening session during which anthropometric measurements and blood pressure will be measured and a fasting venous blood sample for biochemical analysis will be drawn with informed written consent. The screening blood sample (6-10 mL) will be analyzed for blood lipids, glucose, and liver function tests. Individuals who have 'abnormal' blood biochemistry based on standard clinical cut-offs [18] will be excluded from the study.

Outcomes

Primary outcome: Difference of the change in serum LDL-cholesterol between the two feeding periods of coconut and palm oil.

Secondary outcome: Change in each of the following variables within the groups consuming coconut and palm oil (baseline to follow-up)

- a. TC, HDL-cholesterol, TC/HDL-cholesterol ratio, TG, VLDL-cholesterol, FPG, ALT, and AST
- b. Weight, BMI, waist circumference, and waist to hip ratio
- c. Systolic and diastolic blood pressure

Interventions

The study will be divided into two feeding periods of 8 weeks each. Participants will be provided one test oil (either coconut or palm oil) for the first feeding period by the investigator. After 4 weeks of washout period, the second oil will be continued for another 8 weeks. This wash-out period of 4 weeks in between two testing periods, will allow the effects of the test oil to cease and plasma lipids and lipoproteins to return to baseline levels.

A 24-hour dietary recall will be applied to all subjects before the commencement of the study to test their usual dietary intake. As this is a 'real-world' study, participants will be fed according to their usual dietary intake and will be advised to follow their routine physical activity practices as well. Individualized calorie requirements using Harris-Benedict equation [19] will be calculated to test any deviation between their usual calorie intake and the requirement. The macronutrient profiles of the daily calorie intake will be based on a typical Sri Lankan intake [20] and therefore, 19% of daily energy is considered to be from the total fat of the diet, and, 50% of energy will be assumed to be through the treatment oil. Therefore, to fulfill this requirement, nearly 10% of daily energy will be provided by the test oil. We do not hope to alter the effect of their habitual diet on the outcome because the effect of their habitual intake on outcome measures during both the coconut oil feeding period and the palm oil feeding period can be assumed to be the same. The minimum dosage of desired oil volume required per day will be calculated for every individual separately.

The diets will consist of foods containing one of the two experimental fats (coconut oil or palm oil) for breakfast, lunch, dinner, and snacks during each of the two intervention periods. Both oils will be provided for the entire family for food preparation. Every household will be expected to use only the test oil provided during the whole intervention period. This will ensure the participant's

compliance with the test oil. While the quantity of oil to be used by the participant will be indicated, the rest of the family will be permitted to take their usual quantity as they desire. All participants will be provided with measuring cups to quantify the volume of oil used at each meal. They have to maintain the record book to mention the quantity of oil used during each meal.

Initially, the information regarding the profile of the family, their usual intake of oil (approximate volume required per week/month for the entire family) will be collected. Then the quantity of oil required to be given to each household without having any shortage will be decided. The amount of oil for all residents will be included in sealed containers and distributed once every two weeks.

The composition of fatty acids of coconut oil and palm oil, their level of purity, and type will be analyzed by the Industrial Technology Institute (ITI) in Sri Lanka which is accredited with ISO 17025.

Monitoring compliance

Adherence to the desired amount of oil to be taken within a day by the subject will be ensured through the following measures:

- Checking the volume of test oil used while visiting the houses and through photographs (compliance calculation is given below).
- Checking the recording books.
- Conducting food recalls and regular interviews once a week.
- Communication by telephone calls and messaging apps to encourage participants to adhere to test oil volume.

During the experimental period, the subjects will be required to maintain their normal dietary and physical activity pattern. There will be a 4 week washout period in between the two treatment oils. Participants will be allowed to use their usual oil during this period.

The compliance will be evaluated by using the formula given below.

$$\text{Compliance \%} = \frac{(\text{number of days with treatment oil} - \text{number of days without treatment oil}) \times 100}{\text{Number of days with treatment oil}}$$

Individual data with a compliance rate of more than 80% will be considered for final analysis.

Proposed assessment plan

The detailed items that will be measured at every visit are described in Table 1.

Table 1. A brief study schedule for each visit

	Visit 1 (screening visit)	Visit 2 (8 th week)	Visit 3 (12 th week)	Visit 4 (20 th week)
Informed written consent form	•			
Recording demographic data	•			
Medical history taking	•			
Physical examination ¹	•	•	•	•
Fasting Plasma Glucose	•	•	•	•
Liver Enzymes ²	•	•	•	•
Lipid profile ³	•	•	•	•
Blood pressure	•	•	•	•
Food Frequency Questionnaire	•		•	
IPAQ*	•		•	

*IPAQ: International physical activity questionnaire.

¹Body weight, height, waist circumference and hip circumference; ²AST, ALT, ³total cholesterol, triglyceride, LDL cholesterol, and HDL cholesterol, VLDL cholesterol, TC: HDL ratio

Anthropometric assessments

Height will be taken to the nearest 0.1 cm, as the maximum distance to the uppermost position on the head from heels, with the individual standing barefoot and in full inspiration using an upright plastic portable calibrated stadiometer (SECA. 217 by SECA Gmg H & Co. Kg., Hamburg, Germany) adhering to standard protocol. Bodyweight will be measured to the nearest 0.1 kg using a calibrated electronic floor scale (SECA 815 by SECA GmbH & Co. Kg, Hamburg, Germany) with the participants wearing indoor light clothing. BMI will be calculated as weight (in kilograms) divided by the square of height (in meters). Waist circumference (WC) will be measured midway between the iliac crest and the lower rib margin at the end of normal expiration using a plastic flexible tape (SECA 203 by SECA GmbH & Co. Kg., Hamburg, Germany) to the nearest 0.1 cm. Similarly, the hip circumference also will be measured at the widest part of the buttocks at the intertrochanteric level to the nearest 0.1 cm. All anthropometric measurements will be made by using standardized equipment and protocol based on WHO guidelines [21].

Dietary assessments

Food intake will be assessed using a 7-day diet diary and estimating portion weight using a food atlas developed for Sri Lankan foods [22] at the middle of both feeding periods separately. The daily energy and nutrient intake will be calculated using Nutri-Survey 2007 (EBIS pro, Willstaett, Germany) nutrient analysis software, modified with Sri Lankan food. To calculate the intake of energy and nutrients, all 7 analyzed days divided by seven for each person will be used to represent that person's daily dietary intake. A validated food frequency questionnaire will be used to report the consumption of each food according to (1) frequency per day; (2) frequency per week; or (3) frequency per month to ensure whether the subject is following a similar diet during both the intervention periods [23,24]. Participants will be asked to record oil volume used in everyday cooking in the recording paper throughout the intervention period. If the oil is used for deep frying and residual volume of oil is discarded, participants will be instructed to record the discarded volume with a minus (-) sign.

Physical activity assessment

Physical activity will be assessed by the validated version of the International Physical Activity Questionnaire (IPAQ) for Sri Lankans. In addition to that, a 3-day activity diary of usual days will be obtained.

Statistical analysis

Data entry and statistical analysis will be done using SPSS version 22 (SPSS Inc., IL, USA). Comparison of baseline values for the outcome measures before the administration of the 2 test oils (between the start of the study and following the 4 week washout period) will be tested using a t-test, and significance will be set at $p < 0.05$. Changes in study outcome measures over the course of the intervention will be tested by comparing all parameters end of 8 week intervention period of the 2 oils using analysis of covariance (ANCOVA) technique with Tukey's as post-hoc test for multiple comparisons. Baseline weight, age, and gender will be used as covariates in the ANCOVA statistical analysis. The main statistical analysis will essentially be a per protocol analysis, in which it will include only those volunteers who have completed the study, defined as those having vascular activity, fasting blood parameters measured at baseline and post-intervention and the pre-specified covariates measured at baseline. Therefore, volunteers with missing values for these parameters will be excluded from the primary analysis. If participants have any other missing values, for example for secondary endpoints, this will not preclude them from the primary analysis. Measures will be taken to minimize withdrawals from the study and non-compliance amongst volunteers ensuring that the per protocol analysis, as defined here, gives an accurate estimate of the effect of oil consumption in this population.

Adverse effect evaluation and termination rules

Our prescribed amount of oil together with any additional amounts is unlikely to attain levels higher than that recommended by the WHO recommendation, which is up to 30% of total energy intake from fat (which includes Asian adults) [25]. The 19% of daily energy will be the expected intake for the participants and will be well within this value and near typical consumption patterns in Sri Lanka [20]. However, in the event of an adverse event, the following precautions would ensure timely identifications and management of participants.

- Reporting mechanisms will be put in place to ensure direct reporting of probable adverse events to the investigator by participants (via telephone).
- During follow-up visits, probable adverse events will be noted by history and examination and investigated in detail. All adverse effects observed will be documented separately.

- All adverse events will be attended to by a physician, and any serious adverse event will be referred for treatment and appropriate care.
- All serious adverse events will be reported to the Ethics Review Committee, Faculty of Medicine, University of Colombo.
- A Data and Safety Monitoring Board (DSMB) identified by the investigators will evaluate all the adverse events at regular intervals.

In the event of major adverse effects occurring in a significant proportion of the study population, the study would be terminated pending further investigation.

Data collection, processing, storage, and access

Data collection will be performed according to the standard operating procedures by trained research assistants. All the collected data will be kept as an electronic version. Participants will be identified using codes at all stages of the analysis. All their data will be stored in a computer specially allocated for the study. The information on this computer will be only accessible by password, known only by the chief investigator and a key researcher. Only the chief investigator and members of the research team will have access to the data. Personal data of the participants (e.g. name) and their consent forms will be securely stored and discarded after 5 years under the standard protocol.

Discussion

In this article, we present a clinical trial design to assess the impact of coconut versus palm oils on cardio-metabolic risk factors. Both coconut and palm oils are used for domestic cooking as well as in the manufacturing of food [19-21]. In parallel with the recent rising trend in CVD, we observe an increase in palm oil consumption in Sri Lanka as in other countries in the region. Clinical trials provide the strongest evidence to study the replacement effect of coconut and palm oils. Though coconut and palm oils are the most popular fat sources among Sri Lankans, a comparison of the effect of daily consumption of coconut oil and palm oil on CVD risk has not been studied. To our knowledge, this is one of the first well-designed clinical trials evaluating the effects of coconut oil versus palm oil on cardio-metabolic health in Sri Lanka. This study will provide the necessary groundwork for future clinical trials assessing the effect of different forms of coconut and palm oil available in the market.

Trial status

Protocol version number 3.0 (18th July 2019). Participant recruitment will be commenced at the end of 2020.

List of abbreviations

ALT: Alanine aminotransferase; AST: Aspartate aminotransferase; BMI: Body mass index; CVD: cardiovascular diseases; DBP: Diastolic blood pressure; DSMB: Data and safety monitoring board; ERC: Ethics review committee; FFQ: Food frequency questionnaire; FPG: Fasting plasma glucose; HC: Hip circumference; HDL: High-density lipoprotein; hs-CRP: high sensitive C reactive protein; IPAQ: International physical activity questionnaire; LDL: Low-density lipoprotein; NCD: non-communicable diseases; RA: Research assistant; SBP: Systolic blood pressure; SFA: saturated fatty acids; SLCTR: Sri Lanka clinical trial registry; VLDL: very-low-density lipoprotein; WC: Waist circumference; WHO: World Health Organization; WHR: Waist to hip ratio.

Declarations

Ethics approval

Ethical clearance was obtained (Reference No: EC/19/046) from the Ethics Review Committee of the Faculty of Medicine, University of Colombo. The trial was also registered at the Clinical Trial Registry of Sri Lanka Medical Association (SLCTR/2019/034). The study will be conducted in compliance with the Declaration of Helsinki and the Good Clinical Practice (GCP) guidelines.

Authors' contributions

RJ and HS substantially contributed to the general idea and design of the study. HS, RJ, and PR took part in designing the protocol. HS drafted the manuscript. RJ and PR revised the manuscript. All authors have read and consented to the manuscript.

Consent for publications

Not applicable. No data collected.

Availability of data and materials

Not applicable.

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