Randomized, Quadruple-blind, Placebo-controlled, Clinical Trial to determine the effects of Coffee (caffeine) supplementation on Hepatic Steatosis and Fibrosis in Metabolic dysfunction-associated Steatotic Liver Disease(MASLD)

Principal Investigator:

Vidyajothi Prof. A.P. De Silva

Senior Professor, Department of Medicine

Faculty of Medicine, University of Kelaniya

Co-Investigators:

- Prof. M.A. Niriella, Professor in Gastroenterology
- Prof. A.S. Dassanayake, Professor
- Dr. Uditha Dassanayake, Senior Lecturer (Grade II)
- Vidya Jyothi Prof. H. Janaka de Silva, Emeritus Professor of Medicine
- Dr. Krishanni Prabagar, Research Assistant
- Dr. Prathibha Wijesinghe, Research Assistant

Affiliation:

Faculty of Medicine, University of Kelaniya

Colombo North Teaching Hospital, Ragama, Sri Lank

Contents

List of Annexures

List of Tables

1.	**Title:**	Randomized, Quadruple-blind, Placebo-controlled, Clinical Trial to determine the effects of Coffee (caffeine) supplementation on Hepatic Steatosis and Fibrosis in Metabolic dysfunction-associated Steatotic Liver Disease(MASLD)
2.	**Objective**	**Primary Objective:** • To assess the effect of coffee (caffeine) supplementation on hepatic steatosis and fibrosis in NAFLD patients measured by CAP score using Fibro scan and Hepatic fibrosis measured by TE using Fibro scan and FIB-4 score **Secondary Objectives:** • To assess changes in liver enzymes (ALT, AST, GGT) with caffeine supplementation. • To assess the impact on metabolic markers(HbAIC, lipid profile, BMI). • To assess potential side effects of caffeine supplementation.
3.	**Study design**	Randomized, Quadruple blinded, Placebo-controlled
4.	**Study setting**	Gastroenterology Clinic, University Medical Unit, Colombo North Teaching Hospital, Ragama, Sri Lanka.
5.	**Study population**	Patients attending the clinic
6.	**Definition of intervention/main exposure variable**	Caffeine supplementation in the form of a 400 mg caffeine capsule taken orally once daily for 6 months. The control group will receive a placebo capsule identical in appearance.
7.	**Definition of primary outcome**	Is the reduction in hepatic steatosis and fibrosis in non-alcoholic fatty liver disease (NAFLD) patients which is measured by Liver stiffness measurement (LSM) via Fibro scan, Controlled attenuation parameter (CAP) scores via Fibro scan and FIB-4 score calculation. All comparisons will be from baseline to week 24.
8.	**Sample size**	110 participants
9.	**Data collection method**	It would be conducted by two MBBS-qualified researchers trained in the study protocol. Interviewer-administered questionnaires will collect demographic and clinical data. Case Report Forms (CRFs) will document medical history, anthropometric measurements, clinical findings and investigation findings. **Monthly** follow-ups will include: • Physical exams, monitoring of adherence, side effects, and lifestyle factors (diet, exercise, alcohol intake) In **3 months and 6 months** • Blood investigations, fibro scan and US scan findings
10.	**Proposed data analysis**	Data will be analyzed using SPSS software version 21
11.	**Main ethical issues**	**Informed consent:** Obtained twice (for eligibility and enrollment). **Confidentiality**: Participants' personal data will be anonymized. **Risk-benefit balance**: Potential side effects of caffeine (e.g., palpitations, insomnia, high blood pressure) will be monitored. **Adverse events reporting**: Participants can report symptoms anytime, and serious adverse events will be immediately reported to relevant authorities.

1. Introduction and Literature Review

Non-alcoholic fatty liver disease (NAFLD) is an increasingly prevalent clinical disorder and a public health concern, significantly contributing to the global burden of chronic liver disease(1). It has emerged as the leading cause of chronic liver disease worldwide and is associated with serious complications, including fibrosis, cirrhosis, and hepatocellular carcinoma (HCC)(2).

NAFLD is characterized by abnormal lipid deposition in the liver and is diagnosed when hepatic steatosis is present in >5% of hepatocytes, as confirmed by liver biopsy, without secondary causes of liver injury or excessive alcohol intake(3). It has also been strongly associated with metabolic disorders such as type 2 diabetes mellitus, obesity, and insulin resistance and has the potential to progress to non-alcoholic steatohepatitis (NASH), fibrosis, cirrhosis, and ultimately HCC, increasing both morbidity and mortality among affected individuals(2,3).

The pathogenesis of NAFLD and its progression to NASH is complex and not yet fully understood, but it is widely recognized as a two-step process. The first step involves hepatic fat accumulation (steatosis), where lipid deposition in hepatocytes occurs due to increased fat synthesis, decreased lipid export, and impaired mitochondrial function. The second step consists of cellular and molecular changes leading to inflammation and fibrosis, driven by the oxidation of fatty acids, which induces oxidative stress and triggers cytokine-mediated injury, immune system dysregulation, mitochondrial dysfunction, lipotoxicity, and chronic inflammation. These mechanisms contribute to the progression from NAFLD to advanced fibrosis(4,5). Both genetic predisposition and environmental factors influence disease progression(6).

It affects nearly 38% of the global population, and its prevalence is increasing—particularly among younger individuals who are being exposed to risk factors such as poor dietary habits, sedentary lifestyles, and obesity at an earlier age(7). In addition, improving socioeconomic status in low-income regions has led to an increased availability of calorie-dense, unhealthy foods, further exacerbating the rise in NAFLD cases(8). This prevalence also parallels the increasing incidence of cirrhosis, cirrhotic complications, and HCC, which adds to the global healthcare burden(9).

1.1. Benefits of Caffeine to health

Coffee is one of the most widely consumed beverages worldwide and has been associated with numerous health benefits, including a reduced risk of type 2 diabetes, Parkinson's disease, prostate cancer, hepatitis C, and HCC(10,11,12). Large-scale epidemiological studies have shown that increased coffee consumption is linked to a modest reduction in all-cause mortality(13).

1.2. Supplementation of Caffeine in Liver conditions

Specifically, coffee has demonstrated beneficial effects on liver-related conditions. Regular coffee consumption has been linked to a reduced risk of cirrhosis and chronic liver disease, a lower severity of viral liver diseases (e.g., hepatitis C) and decreased levels of liver enzymes (ALT, GGT, bilirubin), indicating improved liver function(14,15).

These protective mechanisms of coffee are thought to stem from its antioxidant, anti-inflammatory, and anti-adipogenic properties(16). Coffee consumption has been associated with reduced production of reactive oxygen species (ROS), inflammatory cytokines (TNF-α, TGF-β), and oxidative stress, thereby protecting hepatocytes from damage(17). It has also been associated with the inhibition of hepatic stellate cell activation, thereby reducing liver fibrosis(18) . Moreover chlorogenic acids, which is a constituent of coffee, also improve glucose metabolism, reduce insulin resistance, and help mitigate the risk of NAFLD progression(19).

Several studies have suggested an inverse relationship between coffee consumption and NAFLD prevalence and severity. A study reported that individuals who drank coffee regularly had a 29% reduced risk of developing NAFLD and a 30% lower risk of liver fibrosis in NAFLD patients compared to non-coffee drinkers(20,21). Experimental studies have also shown that coffee upregulates mitochondrial and endoplasmic reticulum (ER) chaperone proteins**,** such as glucose-related protein 78 (GRP78), which modulates ER homeostasis and prevents metabolic stress-induced liver injury(22). Coffee's polyphenols, which have a structure similar to silymarin (a known hepatoprotective compound), can increase the production of antioxidant proteins such as periredoxin-1 (PRDX-1), which helps counteract oxidative damage in hepatocytes(23).

Additionally, non-caffeine components of coffee, such as cafestol, kahweol, and chlorogenic acid, have been shown to reduce triglyceride and cholesterol deposition in hepatocytes. And prevent hepatocellular carcinoma development(24).

Studies have been done to identify the type of coffee that provide beneficial effect. Anty et al. found that regular filtered coffee, but not espresso coffee, was associated with a lower level of fibrosis(25). This is supported by numerous studies that have shown a hepatoprotective role for filtered coffee, while unfiltered coffee may be potentially harmful(25). Differences in preparation methods certainly result in differences in the composition of coffee, with chlorogenic acids being better preserved in filtered coffee compared with espresso coffee, but filtering coffee also removes the beneficial cafestol and kahweol.

While numerous epidemiological and observational studies have suggested that coffee may reduce the risk of NAFLD and fibrosis progression(26,27), these findings are limited by their inability to establish causality. The optimal dose and formulation of coffee for therapeutic benefits remain unknown. Furthermore, the ideal amount of coffee needed to maximize liver health benefits, the role of additives (milk, sugar, water) in influencing coffee's bioactive properties, the potential adverse effects or contraindications in specific populations (e.g., pregnant women, individuals with cardiovascular conditions) have yet to be identified.

2. Hypothesis, Objectives, Outcomes and End points

2.1. Hypothesis:

- **Null Hypothesis**: Coffee (caffeine) supplementation has no effect on hepatic steatosis and fibrosis in NAFLD patients.
- **Alternative Hypothesis:** Coffee (caffeine) supplementation reduces hepatic steatosis and fibrosis in NAFLD patients**.**

2.2. Objectives:

Primary Objective:

- To assess the effect of coffee (caffeine) supplementation on hepatic steatosis and fibrosis in NAFLD patients measured by CAP score using Fibro scan and Hepatic fibrosis measured by TE using Fibro scan and FIB-4 scores

Secondary Objectives:

- To assess changes in liver enzymes (ALT, AST, GGT) with caffeine supplementation.
- To assess the impact on metabolic markers(HbAIC, lipid profile, BMI).
- To assess potential side effects of caffeine supplementation.

2.3. The Outcomes:

- **Primary Outcome**

  The primary outcome is to compare the reduction of Hepatic steatosis measured by CAP score using Fibro scan and Hepatic fibrosis measured by TE using Fibro scan and FIB-4 scores
- **Secondary Outcome**

  The secondary outcome is to compare the reduction of AST and ALT levels

2.4. End Points:

Primary endpoints

1. Reduction in Liver stiffness measurement (LSM) as determined by fibroscan of liver from baseline to week 24.
2. Reduction in Hepatic steatosis with controlled attenuation parameter (CAP) as determined by fibroscan from baseline to week 24.
3. Reduction in Fib-4 score as determined by calculation from baseline to week 24.

Secondary endpoints

1. Reduction in Anthropometric parameters: waist circumference, weight and body mass index (BMI) from baseline to week 24.
2. Reduction in levels of Aspartate Transaminase (AST), Alanine Transaminase (ALT) and Gamma Glutamyl Transpeptidase (GGT) from baseline to week 24.
3. Reduction in fatty liver index (FLI) from baseline to week 24.

Exploratory endpoints

1. Changes in Lipid profile as determined by total cholesterol (TC), triglycerides (TG), high density lipoproteins (HDL) and low-density lipoproteins (LDL) from baseline to week 24.
2. Changes in Metabolic parameters: (FBS) and (HbA1c) from baseline to week 24.
3. Changes in Beta cell function using HOMA-IR from baseline to week 24.

3Justification

Given that NAFLD currently has no FDA-approved pharmacological treatment, there is an urgent need for safe, cost-effective, and accessible interventions. A well-designed RCT is essential to establish a causal relationship between coffee consumption and liver health., determine whether coffee can be an effective dietary intervention for NAFLD management. If proven effective, this could serve as a simple, affordable, and widely accepted dietary intervention for NAFLD management. Given its accessibility and tolerability, incorporating coffee into clinical guidelines could provide a practical solution to help mitigate the economic and healthcare burden of NAFLD. Thus, the aim of our study is to prove that coffee is a safe and effective dietary intervention for managing NAFLD, with the goal of providing evidence that could shape future guidelines.

3.1. Justification for Use of Placebo:

The use of a placebo is necessary to control the psychological effects of caffeine supplementation, ensuring that observed effects were solely due to the active ingredient. By employing a Quadruple-blind design, the placebo also would help eliminate bias.

3.2. Justification for Using Biological Samples:

Biological samples are essential for objectively assessing the physiological effects of caffeine supplementation. They provide measurable biomarkers, reducing reliance on self-reported data and enhances the study's accuracy and reliability.

4. Study Method, Patient Recruitment, Data collection

4.1. Study Design:

This study will be a randomized, quadruple-blinded, placebo-controlled trial with parallel-group allocation

4.2. Study Duration:

Six months.

4.3. Study Setting and Population:

The study will be conducted at the Gastroenterology Clinic, University Medical Unit, Colombo North Teaching Hospital, Ragama, Sri Lanka. Participant recruitment and follow-up will be done at this venue. Medical investigations and scanning will be done at the Colomb North Teaching Hospital, Ragama which has a SLAB accredited laboratory and a calibrated liver fibro scan. All patients with ultrasonically proven fatty liver disease will be recruited for the study.

4.3.1. Inclusion Criteria

- Both male and non-pregnant, non-lactating female patients aged 18 - 65 years who provide written informed consent before starting the study
- Patient diagnosed with type 2 diabetes based on American Diabetes Association (ADA) definition or who only take oral antidiabetic drug.
- CAP score >263
- Fulfilling 2/3 USS criteria for fatty liver

4.3.2. Exclusion Criteria

- History of unsafe alcohol consumption
- Other liver disease (chronic viral/autoimmune/hereditary)
- Use of steatogenic medications
- History of drug dependence
- Body mass index (BMI) ≥35 kg/m2

- A restrictive diet or weight change ≥ 5 kg during the 3 months prior to study
- Pregnancy or lactation
- Patients with sensitivity to caffeine intake
- Patients with symptomatic ischaemic heart disease, arrythmia's
- Any condition that, in the opinion of the clinician, would contraindicate the patient's participation.

4.4. Sample Size Calculation and Statistics:

Sample size(n)

n = σ2(Zα/2+Zβ)2/delta

where,

- Zα/2=1.96 (for **α = 0.05**, two-tailed test)
- Zβ=0.84Z_{\beta} = 0.84Zβ=0.84 (for **80% power**)
- σ=5\sigma = 5σ=5 (**Standard Deviation**)
- Δ=3\Delta = 3Δ=3 (**Expected Mean Difference**)

Calculation,

n=(3)22×(5)2×(1.96+0.84)2
n=2×25×(2.8)29
n=43.56=44

Adjusting for Dropout (20%)

N final=441−0.20=440.80=55

Final Sample Size

- 55 participants per group
- Total: 110 participants (both groups combined)

4.5. Participant recruitment

- Participants will be recruited on a voluntary basis after obtaining informed written consent from patients with NAFLD by one of the investigators.

Patient Selection: Screening and eligibility assessment

- Advertisement about the details of the study and contact number of PI will display in all three languages (Sinhala/English/Tamil)at the Liver Clinic of Gastroenterology & Hepatology Department at CNTH-Ragama .Volunteering participants will contact PI and they will asked to come to Faculty medicine, University of Kelaniya, and they will approach by a trained medically qualified research assistant. First, the patients will be provided detailed information about the study and will be given an opportunity to discuss their concerns/questions in their preferred language (Sinhala/English/Tamil) with the medical investigator.
- Once the patient is satisfied with the information given, he/she will be screened for eligibility to participate in the trial. Informed written consent will be obtained from all patients with ultrasonically proven fatty liver disease for the eligibility assessment.
- All consenting patient's eligibility assessment for inclusion and exclusion criteria will be recorded in CRF by RA and reviewed by medical investigator in the team.
- Patients complied with inclusion exclusion criteria will be recruited to study and patients who are not eligible will be directed to Liver Clinic of Gastroenterology & Hepatology Department at CNTH-Ragama to receive standard care of treatment.

4.6. Data collection:

- Data collection will be done by a two MBBS qualified graduates, who can converse in Sinhala, English and Tamil and are trained by the consultant hepatologist.
- An interviewer administered questionnaire will be used to record basic demographic details of the patient in addition to the data on clinical features. Patient identification data is collected for the purpose of tracing the patient in an adverse event or a medical

emergency. However, personal identification will not be used in the database, and the serial numbers will be used instead of names.

- Data collection will be done using a Case Report Form developed by the investigators. During each monthly visit, investigators will query regarding any adverse effects. Patients will also undergo clinical examination on visits.

History

- A detailed clinical history will be taken regarding the basic demographic details such as age, gender marital status, selected socioeconomic variables, relevant family history, relevant past medical history, drug history, allergic history and consumption of alcohol and tobacco will be recorded in CRF

Anthropometric measurements

- Height, weight and waist circumference will be measured, and BMI will be calculated. All anthropometric measurements will be made by trained personnel. This will be done to check the eligibility for the study, at baseline and each monthly follow up visit.

Clinical examination

- Seated blood pressure is to be recorded on two occasions after at least a 10-min rest. A full physical examination will include head, ears, eyes, nose, mouth, skin, heart and lung examinations, lymph nodes, gastrointestinal, musculoskeletal, and neurological systems. This will do for checking the eligibility to the study, at baseline and each monthly follow up visit.

Laboratory investigations

- Serum fasting plasma glucose, Lipid profile, Liver enzymes will be done to assess the baseline fasting blood glucose for recruitment into the study to comply with inclusion criteria. Serum HCG will be tested for female participants to exclude pregnancy. Abdomen ultrasound scan will be performed to assess eligibility to the study.

- After recruitment baseline testing will be done for HbA1c,serum Insulin level, fasting plasma glucose, Lipid profile, Liver enzymes. Serum creatinine, full blood count, serum electrolytes and urine analysis will be done for safety assessments.

Ultrasound and Fibro scan

- At the baseline Ultrasound scan will be performed to confirm the diagnosis of NAFLD. After recruitment at the baseline and at the end of six months a fibro scan will be done to assess the efficacy parameters. The ultrasound and fibro scan will be done at North Colombo Teaching hospital

Collection of blood samples

- Table 1 summarizes the blood sample collection. The investigations will be done at the North Colombo Teaching hospital which is an accredited laboratory. These tests are required to assess the efficacy and safety of the medications in an objective manner.

Table 1: Summary of Blood Sample Collection

Day	**Blood volume**	**Investigations**
Enrolment	6 ml	FBS, Liver profile Lipid profile, Serum HCG (Female participants only)
Allocation Visit - Beginning of 1st Month	6 ml	FBS Serum HbA1c Fasting serum insulin

		Lipid profile, Liver profile, Total bilirubin Serum creatinine FBC Serum electrolytes
3rd month and 6th month	6 ml	FBS Serum HbA1c Fasting serum insulin Lipid profile, Liver profile, Total bilirubin Serum creatinine FBC Serum electrolytes

4.7. Randomization, blinding and code breaking

This is a Quadruple-blind study and either the Participant, Care Provider, Investigator, Outcomes Assessor will be aware of treatment assignments prior to the final database locks at the conclusion of the study.

Computer-generated random numbers will be used for randomization. Both caffeine tablets and placebo tablets will be packed into identical white HDPE (High Density Polyethylene) plastic bottles numbered from 1 to 110 by a pharmacist or an independent third party. according to the list of computer-generated random numbers. After packing each bottle according to this list with either Caffeine tablets or placebo tablets, the list will be placed in a sealed envelope until completion of the trial. The label of each bottle will indicate only the patient's random number and the direction

for taking the tablets. This number will be clearly noted on each patient's CRF forms and tablets would be provided hence.

The caffeine and placebo tablets will be manufactured in identical shape and size and will be film coated to give the same appearance.

Bottles containing 60 caffeine tablets will be issued on day of allocation and will contain medication required for 30 days. The packed and sealed bottles will be stored at the University of Kelaniya, Faculty of Medicine, under recommended storage conditions specified by the manufacturer and kept under lock and key and released in small batches to be given to patients. Therefore, all investigators and patients will be blinded.

The codes can be accessed any time and in the event of a Serious Adverse Effect(SAE) or a Serious Adverse Reaction(SAR) the code of that patient will be broken. All eligible participants are randomly assigned to the two groups according to patient recruitment order.

4.8. Data analysis:

Data will be analyzed using SPSS software version 21. Baseline patient characteristics will be described using descriptive statistics. Continuous variables will be expressed using mean and standard deviation or median with range depending on the distribution of data. Categorical variables will be expressed using frequency and percentage. Primary analysis will be done using a modified intention to treat (mITT) analysis where only subjects with at least one follows up assessment done will be included in the analysis.

Mean change in CAP score and LSM from baseline to 6 months will be compared between the 2 groups (Caffeine tablets vs placebo) using Independent T test or Mann Whitney U test depending on the distribution of data. For the secondary endpoints continuous variables will be compared using Independent T test or Mann Whitney U test and categorical variables will be compared using Chi square test. Repeated measures ANOVA will be used for analysis of change in variables from baseline till end of study. P value less than 0.05 will be considered statistically significant.

Safety outcomes will be described using descriptive statistics. For patients who were lost to follow up, the last available value will be used for analysis.

Safety and adverse event data analysis

Vital sign measurements and laboratory biochemical test data will be presented as mean and standard deviation.

A listing of all adverse events by participants including % of participants who experienced adverse events will be presented. This list will include adverse event (actual term and preferred term), event start and end dates, category as per the ICH Topic E 2 A Clinical Safety Data Management: Definitions and Standards for Expedited Reporting,relationship to study drug/procedure, seriousness, and outcome.

Procedures for Reporting any Deviation(s) from the Original Statistical Plan

Deviations from the original statistical plan are unlikely. However, should they occur, then approval for such changes will be sought from the ERC and these changes will be reported in the final report and papers.

4.9. Data/Sample storage and disposal

Data will be entered and saved in a dedicated computer with password protection. Hard copy of data will be stored in a secure place and accessible only to investigators. Samples of blood of volunteers after testing would be stored in a secure facility, under suitable conditions during storage. Samples will be disposed of immediately after completion of the study publication. No samples would be used for any analysis other than the ones stipulated in the study proposal.

4.10. Dissemination of results

Results will be disseminated widely through peer reviewed scientific communications and publications in indexed journals. Dissemination and presentation of results will be done irrespective of the positive or negative nature of results.

Sharing data with study participant

The results of this study will be shared with the volunteer participants after completion of the study, by the investigators at an open forum, without compromising confidentiality or identity of the participant.

5. Intervention, Monitoring of compliance to treatment

Caffeine tablets and placebo tablets required for the trial would be sourced from Nutricost, a U.S.-based company that specializes in high-quality dietary supplements. Nutricost products are manufactured in GMP-compliant facilities and undergo third-party testing to ensure purity and consistency. The caffeine tablets specifically contain caffeine anhydrous, a dehydrated form of caffeine that provides a standardized and effective dosage and placebo are manufactured using starch ensuring that it is inert and does not affect the study's outcomes.

The study groups will receive one bottle on the day of allocation, and it will contain either caffeine tablets or placebo required for a month. The test group will receive the caffeine tablet while the control group will receive the placebo .Tablet bottles will be issued to participants according to their random number mentioned in the Case Report Form (CRF).

Patients will be asked to take the medication every day after dinner. Recommended dose and directions for use will be given verbally when dispensing the tablet pack, and written instructions will be clearly mentioned on the label of the bottle in Sinhala, Tamil and English. The patients will be asked to take the tablets home. At each monthly visit, the participants will be asked to bring tablet bottles with balance tablets, to count at the monthly visit to assess compliance. The required tablets for next month will be issued during this visit.

Participants who have < 80% compliance will be re-educated on the importance of daily administration of investigational product, as much as possible: with the overall aim to maintain ≥ 80% compliance over the study period.

5.1. Lifestyle modification and standard care during the study period

There is currently no approved pharmacological treatment which can reverse NAFLD or control disease progression. Hence current treatment strategies are focused on lifestyle modifications. All patients in the two groups will receive standard diet modification and exercise and physical activity recommendations according to Clinical Practice Guidelines developed by Sri Lanka College of

Endocrinologists, Sri Lanka society of Gastroenterology, 2019. However, management of comorbid conditions such as diabetes and hypertension will be as per routine hospital practice based on guidelines. If patients are already on pharmacological treatment for NAFLD, such patients will not be recruited to study.

Before recruitment all participants will be made aware of the required lifestyle modification during the study period as per standard management schedule.

5.2. Dietary measurements

All patients will be instructed on a balanced diet, including decreased intake of saturated and trans fats and increased intake of fiber. In overweight patients, dietary intervention will focus on a calorie restricted diet, attained over a 6-month period. The calorie-restricted diets will be planned to create a deficit of 500- 1000 kcal/day and will be individualized for each study subject. A culturally validated Food Frequency Questionnaire (FFQ) will be used to obtain habitual intake of calories, macronutrients and micronutrients. This will be assessed monthly to monitor dietary measurements of participants.

Medical RA will meet individual patients for counselling on dietary intervention. All patients are asked to maintain food logs and ask to bring it on follow up visits and food logs will be reviewed monthly, and diet plans will be adjusted as needed.

Dietary measurements will be monitored at the baseline and during each follow up monthly visits.

5.3. Physical activity

Physical activity will be evaluated by using the International Physical Activity Questionnaire (IPAQ) short Version, which is a user-friendly measurement tool that comprises of 7 questions that considers the level of physical activity in the past 7 days. This will be assessed monthly to monitor the physical activity of participants. Moderate-intensity exercise for 30 – 60 minutes (ex: 30 minutes of walking/day) on 3–5 days per week is recommended during the study period.

5.4. Alcohol consumption

Intake of alcohol is not recommended and if consumed should not exceed the limit mentioned in exclusion criteria 20 g/day for women and 30g/day for men ≥ 2 units alcohol/day for women and >3 units for men during the study period.

The Alcohol Use Disorders Identification Test (AUDIT) is a 10-item screening tool developed by the World Health Organization (WHO) to assess alcohol consumption, drinking behaviors, and alcohol-related problems. This is validated questionnaire and Sinhala and Tamil translations are freely available to use. Frequency of alcohol consumption will be assessed monthly using AUDIT questionnaire in all patients.

5.5. Follow up assessment

The recruited patients will be advised to come for monthly assessments and will be asked to attend the nearest hospital, if they develop any complications and inform the study team of such incidence.

The degree of adherence to prescribed lifestyle changes and diet will be recorded at the baseline and monthly follow-up visits. Physical activity and alcohol consumption will also be monitored at the baseline and monthly follow-up visits.

Anthropometric measurements, physical examination and vital sign measurements (BP, HR, RR etc..) will be monitored at the baseline and each monthly visit. Details on concomitant medications will be recorded in monthly visits.

Liver profile, Lipid profile, Full blood count, Serum creatinine, fasting blood glucose, HbA1c, serum insulin, serum electrolytes and urine analysis and serum insulin will be investigated at the baseline, at 3 months and 6 months.

Fibro scan will be done at the baseline and after 6 months at the completion of the study.

The details of items which will be measured on every visit are described in Table 2.

Table 2: Summary of follow up

	Enrolment	**Allocation 1**	**Subsequent visits**					
TIME POINT		0	1st month	2nd month	3rd month	4th month	5th month	6th month
ENROLMENT								
Eligibility screen	×							
Informed consent	×							
Allocation		×						
INTERVENTIONS								
caffeine or placebo		×	×	×	×	×	×	
ASSESSMENTS								
Medical history taking	×	×	×	×	×	×	×	×
AUDIT	×	×	×	×	×	×	×	×
FFQ and IPAQ	×	×	×	×	×	×	×	×

Height, weight and waist circumference			×	×	×	×	×	×
Blood pressure	×	×	×	×	×	×	×	×
Physical examination[1]	×	×	×	×	×	×	×	×
USS scan	×							
Fibro scan		×						×
FBG	×	×			×			×
Fasting serum insulin		×			×			×
HCG only female	×							
Serum HbA1c		×			×			×
Lipid profile	×	×			×			×
Liver enzymes	×	×			×			×
Total bilirubin	×				×			×
Serum creatinine		×			×			×
Serum electrolytes		×			×			×

FBC		×			×			×
UFR		×			×			×

6. Ethics approval and related issues

Ethics approval will be obtained from the Ethics review committee, university of Kelaniya, to conduct the study, and the clinical study will be registered at the Sri Lanka Clinical Trials Registry. The trial will be conducted in compliance with the Good Clinical Practice guidelines

6.1. Benefits and the risks of the study

Benefits

The study will provide high quality clinical evidence on the effects of caffeine supplementation on hepatic steatosis and fibrosis. It would help establish a causal relationship and propose an alternative or complementary strategy to diet and exercise in the treatment of NAFLD.

Risks

There is a risk of participants experiencing side effects of caffeine such as palpitations, high blood pressure, gastrointestinal discomfort, insomnia and anxiety

6.2. Obtaining informed Written consent

Informed written consent will be obtained in their preferred language by a medically qualified research assistant. Informed written consent will be taken twice from the volunteer participants. Once for participation in eligibility assessment to check the suitability of the person for the study, and later at the time of enrolling into the study. They will be informed that recruitment to the study will be based on the inclusion and exclusion criteria.

If any changes are made to the study protocol during the study, participants will be informed of such change and possible impact of those changes, and consent will be obtained again

Patients who have expressed willingness to participate in the study will be informed about the study, both verbally and in writing, in their preferred language (English, Sinhalese or Tamil) The information provided will include aims of the study, relevant clinical and laboratory procedures,

follow up, patient responsibilities, potential benefits to the individual and to society, risks involved and ability to withdraw from the study at any time without giving any reasons.

6.3. Fair participant selection

Fair participant selection will be ensured through objective inclusion criteria, avoiding unjustified exclusions. Randomization balanced key characteristics, minimizing bias.

6.4. Protection of rights of participants and provision of medical and psychological support

Participant rights would be protected through strict ethical guidelines. Participation would be entirely voluntary, with individuals informed of their right to refuse or withdraw at any stage without penalty. Informed consent would be obtained. Confidentiality would be maintained, and data handled securely. Additionally, medical and psychological support would be available throughout the study to address any adverse effects or concerns, prioritizing participant well-being and safety.

6.5. Volunteer participation and confidentiality

A personal ID number will be allocated to selected volunteers. Names of volunteers will not be used in data collection and report writing. Personal identification data would be stored separately, maintaining strict confidentiality with the chief investigator and used only for the purpose of identification during follow-up if necessary. Personal identity will be disclosed only in the event of a medical emergency or if required by law. Data will be provided to the appropriate health authority in the state hospital in the event of an adverse event when further management is required.

Responsibilities of the researchers

Researchers would ensure ethical conduct, participant safety, and protocol adherence.

7. Safety assessment and adverse event (AE) reporting

The study participants will be carefully screened before enrollment in the study regarding their health status and suitability. Inclusion and exclusion criteria have been chosen appropriately to minimize possible risks for volunteers participating in this trial. This will be done by an MBBS and a qualified research assistant trained by the principal investigator. During the study, the volunteers will be closely monitored for safety parameters including AE reporting, physical examination, biochemical, hematology, vital signs measurements, and urinalysis.

The volunteers will be provided with a card stating that they are participating in a clinical study, giving the investigational product, the duration of the study, the address and telephone numbers of the principal investigator. These cards are useful if the study participants consult a physician during their study participation or for emergencies.

The PI and the study team will meet every 4 weeks to review the study procedures, enrollment, screening, implementation, data collection, investigations, and adverse events. The following precautions will be in place to ensure timely detection and identification of adverse reactions and management of such volunteers.

1. Participants will be given contact numbers of the PI and another medical investigator who can be reached at any time for reporting or inquiry about any AE or any query related to the study.
2. Information on adverse events will be obtained by questioning the participants in general terms such as "How do you feel?" or “How have you been feeling since the last questioning?" or by subjects' spontaneous complaints.
3. Medically qualified investigators will obtain appropriate information to determine the outcome of the AE and to assess whether it meets the criteria for classification as a Suspected Unexpected Serious Adverse Reaction (SUSAR) requiring immediate notification..

7.1. The severity of adverse events is characterized as follows

Mild: Any symptom of which the subject is aware, but which is easily tolerated.

Moderate: Any symptom which is discomforting enough to cause interference with a volunteer's usual activity.

Severe: Any symptom which causes a volunteer's inability to perform usual activity

For all AEs, information will be obtained to determine causality.

The causal relationship between the investigational caffeine product and the AE will be characterized according to the following:

Not related – there is not a reasonable possibility that the study drug caused the AE.

Unlikely – suggests that only a remote connection exists between the study drug and the event. Other conditions, including concurrent illness, progression or expression of the disease state or reaction to concomitant medication, appear to explain the AE.

Possible – suggests that the association of the AE with the study drug is unknown, however the event is not reasonably supported by other conditions.

Probable – suggests that a temporal sequence of the AE with drug administration exists and, in the Investigator's clinical judgment, it is likely that a causal relationship exists between the drug administration and the AE, and other conditions (concurrent illness, progression or expression of the disease state, or concomitant medication reactions) do not appear to explain the AE.

Events where a causal relationship is classified as probable or possible will be regarded as related.

7.2. Outcome

The outcome of the adverse event will be classified according to the following definitions:

Recovered / resolved: the event has resolved (no further symptoms are present, and no treatment is being received by the subject).

Recovered / resolved with sequelae: the event has resolved but lingering effects may be present.

Fatal / life threatening: the subject died as a result of the event. This code should only be used for the event that caused the death, not any event that was present at the time of the subject's death.

Unknown: will be used in the event that the subject is lost to follow-up and no reliable data can be obtained.

All observed AEs will be reported as described in the following sections.

Medically qualified investigators will obtain appropriate information to determine the outcome of the AE and to assess whether it meets the criteria for classification as a Suspected Unexpected Serious Adverse Reaction (SUSAR) requiring immediate notification.

The codes can be accessed all 24hrs and in the event of a SAE when the code of that patient will be broken.

7.3. Reporting

Mechanisms for direct reporting of probable adverse events to investigator by patients will be in place (via direct contact). In addition, during evaluation visits probable adverse events, if any will be noted and relevant volunteers will be investigated in detail to determine any association with the drug.

Any serious adverse event as defined in GCP guidelines will be reported to the National ADR monitoring center in the Department of Pharmacology, Faculty of Medicine, Colombo within 24 hours and the Ethics Review Committee as soon as possible. Data Safety Monitoring Board (DSMB) will evaluate all data and adverse events, if any at intervals during the trial as stipulated by the DSMB.

7.4. Reporting Period

All AEs, whether serious or non-serious, observed and/or spontaneously reported, beginning from the time the informed consent is signed and dated, are collected on the source document.

All adverse drug reactions that are both serious and unexpected (SUSAR) will be reported.

The researcher will report any serious unexpected adverse drug reaction (as defined in the Good Clinical Practices (GCP) Guidelines in CIOMS-I format as soon as possible, but no later than

fifteen calendar days after the sponsor is made first aware of such reaction to the Ethics Review Committee and the investigators participating in the clinical trial.

Any fatal or life-threatening serious unexpected adverse drug reaction will be reported by the researcher to the Ethics Review Committee and the investigators participating in the clinical trial as soon as possible, but not later than seven calendar days

7.5. Investigation

Any adverse events/reactions will be investigated in detail.

7.6. Management

In the event of an adverse event or adverse reaction such events will be managed as soon as possible under the direct supervision of a Consultant Physician with no cost to the volunteer. After the research is completed, the volunteers can reach the investigators for any concerns about health.

7.7. Termination of Study and withdrawal from the study

The principal investigator will terminate a volunteer participant from the trial in the following cases. In such an event, Principal investigator will inform the participant about termination of the study and the reason for termination.

• Occurrence of an adverse event which does not justify continuation of the study

• Protocol violation which jeopardizes the performance of the study

If a volunteer is not adhering to the proposed medication protocol a detailed discussion will be held to understand the reason for non-adherence to determine whether it is tablet related or due to another reason such as forgetfulness or does not want to continue with the medication on personal preference which is unrelated to the product. No intimidation or force would be used to improve compliance if the participant refuses to provide any information

Criteria for stopping the trial or discontinuation of study intervention

Individual subjects dosing will be stopped immediately if clinically relevant allergic reaction/ hypersensitivity occurs which needs medical intervention.

1. Dosing will be stopped if liver enzymes increases > 3 x normal range
2. Dosing will be stopped if conjugated bilirubin increases > 1.5 x normal range
3. Dosing will be stopped if serum creatinine increases > 1.5 x normal range
4. Dosing will be stopped if subjects suffer from a drug related (assessed as possibly or probably) and clinically relevant AE of moderate or severe intensity.
5. Any clinically significant values outside the reference ranges with major deviation and/or possible pathological relevance in physical examination, biochemical examination, hematology, vital signs measurements, electrocardiogram (ECG), and urinalysis.
6. Patients with AUDIT score > 8.

A volunteer can decide to withdraw from study participation at any time, for any reason, specified or unspecified, and without penalty or loss of benefits to which the subject is otherwise entitled. In this case, the subject must immediately contact the investigator and state that he is leaving the study.

Reasons for the withdrawal of the study (AE, ineffective treatment, inability to comply with the study requirements etc.) will be sought, if the patient is willing to provide that information. They will be made aware that their decision will in no way affect their treatment, and that they will be free to withdraw from study at any time. To respond to questions and record complaints during the study, contact details of two investigators will be provided to the study participants. Patient can be withdrawn from the study upon the principal investigator’s decision to terminate the study, based on study compliance and adverse reactions development such as low rates of compliance, complications, or inability to tolerate the medication etc.

7.8. Data Safety Monitoring Committee(DSMB)

This clinical trial will be monitored by a Data and Safety Monitoring Board (DSMB) which will comprise the following members:

A physician, a clinical pharmacologist, hepatologist, and a statistician, The DSMB will meet bimonthly.

The DSMB will review and evaluate the data on clinical safety collected during the study and assesses reports on serious adverse events and adverse events. DSMB will meet every month to review and evaluate safety data and to give recommendations based on the evaluation.

Responsibilities of DSMB

1. Provide independent, sound, and timely review of clinical trial safety data.

2. Advice investigators on whether to continue, modify or stop the clinical trial for safety or ethical reasons.

3. Safeguard the interests of the study participants.

4. Oversee the timely analysis, review, and publication of the results.

5. Ensure ongoing scientific validity, integrity, and clinical and scientific relevance of the study.

7.9. Seeking clarifications

The participants will be told that they will have the opportunity to seek clarifications and to register complaints at any stage of the study. Study participants will be provided with contact details of two investigators (one of whom is the principal investigator), and the ERC for immediate contact (in case of an emergency) during the course of the study or to seek clarifications or register any complaints.

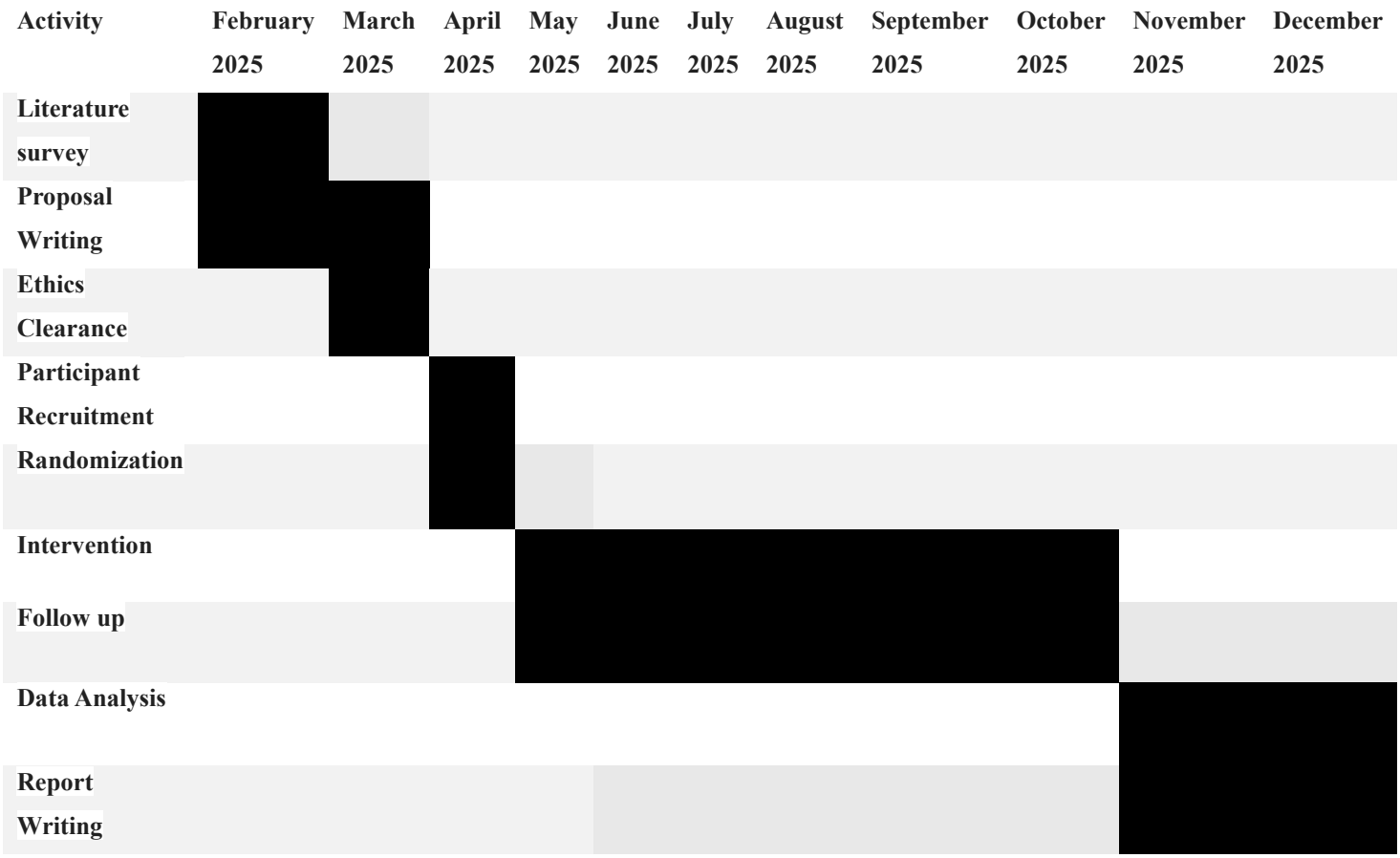
8. Budget

Category	Total (LKR)
1. Participant Costs	**60,000**
2. Study Medications	**1,091,000**
3. Equipment & Supplies	**30,000**
4. Ethics & Administrative Costs	**35,000**
Subtotal	**1,216,000**
7. Contingency (10%)	**121,600**
Grand Total	**1,337,600**

8.1. Source of funding

Funding for the clinical trial will be provided with the personal funds of Prof AP de Silva and Prof MA Niriella.

9. Timeline


Activity
February 2025
March 2025
April 2025
May 2025
June 2025
July 2025
August 2025
September 2025
October 2025
November 2025
December 2025
Literature survey
Proposal Writing
Ethics Clearance
Participant Recruitment
Randomization
Intervention
Follow up
Data Analysis
Report Writing

10. References

1.Xian YX, Weng JP, Xu F. MAFLD vs. NAFLD: shared features and potential changes in epidemiology, pathophysiology, diagnosis, and pharmacotherapy. Med Nexus Open Access. 2021 May 27.

2. Lonardo A, Mantovani A, Lugari S, Targher G. NAFLD in some common endocrine diseases: prevalence, pathophysiology, and principles of diagnosis and management. Int J Mol Sci. 2019;20(11):2841. doi:10.3390/ijms20112841.

3. Hashimoto E, Taniai M, Tokushige K. Characteristics and diagnosis of NAFLD/NASH. J Gastroenterol Hepatol. 2013;28(S4):64-70. doi:10.1111/jgh.12271.

4. Arab JP, Arrese M, Trauner M**.** Recent insights into the pathogenesis of nonalcoholic fatty liver disease. Annu Rev Pathol. 2018;13:321-350. doi:10.1146/annurev-pathol-020117-043617.

5. Pafili K, Roden M. Nonalcoholic fatty liver disease (NAFLD) from pathogenesis to treatment concepts in humans. Mol Metab. 2021;50:101122. doi:10.1016/j.molmet.2020.101122.

6. Dongiovanni P, Romeo S, Valenti L. Genetic factors in the pathogenesis of nonalcoholic fatty liver and steatohepatitis. Biomed Res Int. 2015;2015:460190. doi:10.1155/2015/460190.

7.Wong VW-S, Ekstedt M, Wong GL-H, Hagström H. Changing epidemiology, global trends and implications for outcomes of NAFLD. J Hepatol. 2023;79(3):842-852.

8. Riazi K, Azhari H, Charette JH, Underwood FE, King JA, Ehteshami Afshar E, et al. The prevalence and incidence of NAFLD worldwide: a systematic review and meta-analysis. Lancet Gastroenterol Hepatol. 2022;7(9):851-861.

9. Younossi ZM, Koenig AB, Abdelatif D, Fazel Y, Henry L, Wymer M. Global epidemiology of nonalcoholic fatty liver disease—meta-analytic assessment of prevalence, incidence, and outcomes. Hepatology. 2016;64(1):73-84. doi:10.1002/hep.28431.

10. Kolb H, Martin S, Kempf K. Coffee and lower risk of type 2 diabetes: arguments for a causal relationship. Nutrients. 2021;13(4):1144. doi:10.3390/nu13041144.

11. Lee LK, Mhd Rodzi NA**.** Addressing the neuroprotective actions of coffee in Parkinson's disease: an emerging nutrigenomic analysis. Antioxidants. 2022;11(8):1587. doi:10.3390/antiox11081587.

12. hen X, Zhao Y, Tao Z, Wang K. Coffee consumption and risk of prostate cancer: a systematic review and meta-analysis. BMJ Open. 2021;11(2):e044049. doi:10.1136/bmjopen-2020-044049.

13. Tybjærg Nordestgaard A, Grønne Nordestgaard B. Coffee intake, cardiovascular disease and all-cause mortality: observational and Mendelian randomization analyses in 95,000-223,000 individuals. Int J Epidemiol. 2016;45(6):1938-1952. doi:10.1093/ije/dyw325.

14.Chen S, Teoh NC, Chitturi S, Farrell GC**.** Coffee and non-alcoholic fatty liver disease: brewing evidence for hepatoprotection? J Gastroenterol Hepatol. 2014;29(3):435-441.

15. Klatsky AL, Morton C, Udaltsova N, Friedman GD. Coffee, cirrhosis, and transaminase enzymes. Arch Intern Med. 2006;166(11):1190-1195. doi:10.1001/archinte.166.11.1190.

16. Wijarnpreecha K, Thongprayoon C, Ungprasert P**.** Coffee consumption and risk of nonalcoholic fatty liver disease: a systematic review and meta-analysis. Metab Genet. 2017;66:e8. doi:10.1097/MEG.0000000000000776.

17. Jung S, Kim MH, Park JH, Jeong Y, Ko KS. Cellular antioxidant and anti-inflammatory effects of coffee extracts with different roasting levels. J Med Food. 2017;20(6):585-591. doi:10.1089/jmf.2017.39.

18. Shim SG, Jun DW, Kim EK, Saeed WK, Lee KN, Lee HL, Lee OY, Choi HS, Yoon BC. Caffeine attenuates liver fibrosis via defective adhesion of hepatic stellate cells in cirrhotic model. J Gastroenterol Hepatol. 2013;28(12):1877-1884. doi:10.1111/jgh.12317.

19. Kennedy OJ, Roderick P, Poole R, Parkes J. Coffee, caffeine and non-alcoholic fatty liver disease? Ther Adv Gastroenterol. 2016;9(1):3-16. doi:10.1177/1756283X15615976.

20. Bambha K, Wilson LA, Unalp A, Loomba R, Neuschwander-Tetri BA, Brunt EM, Bass NM; for the Nonalcoholic Steatohepatitis Clinical Research Network (NASH CRN). Coffee consumption in NAFLD patients with lower insulin resistance is associated with lower risk of severe fibrosis. Liver Int. 2014;34(8):1250-1258. doi:10.1111/liv.12379.

21. Hayat U, Siddiqui AA, Okut H, Afroz S, Tasleem S, Haris A. The effect of coffee consumption on non-alcoholic fatty liver disease and liver fibrosis: A meta-analysis of 11 epidemiological studies. Ann Hepatol. 2017;16(6):802-810. doi:10.1016/j.aohep.2017.05.004.

22. Perumpail BJ, Li AA, Iqbal U, Sallam S, Shah ND, Kwong W, Cholankeril G, Kim D, Ahmed A. Potential therapeutic benefits of herbs and supplements in patients with NAFLD. Diseases. 2018;6(8):e38. doi:10.3390/diseases6030038.

23. Kositamongkol C, Kanchanasurakit S, Auttamalang C, Inchai N, Kabkaew T, Kitpark S, Chaiyakunapruk N, Duangjai A, Saokaew S, Phisalprapa P. Coffee consumption and non-alcoholic fatty liver disease: An umbrella review and a systematic review and meta-analysis. Front Pharmacol. 2021;12:786596. doi:10.3389/fphar.2021.786596.

24. Shen H, Rodriguez AC, Shiani A, Lipka S, Shahzad G, Kumar A, Mustacchia P. Association between caffeine consumption and nonalcoholic fatty liver disease: A systemic review and meta-analysis. Ther Adv Gastroenterol. 2021;14:17562848211020415. doi:10.1177/17562848211020415.

25. Anty R, Marjoux S, Iannelli A, Patouraux S, Schneck AS, Bonnafous S, Gire C, Amzolini A, Ben-Amor I, Saint-Paul M-C, Mariné-Barjoan E, Pariente A, Gugenheim J, Gual P, Tran A**.** Regular coffee but not espresso drinking is protective against fibrosis in a cohort mainly composed of morbidly obese European women with NAFLD undergoing bariatric surgery. *J* Hepatol. 2012;57(5):1090-1096. doi:10.1016/j.jhep.2012.05.022.

26. Zelber-Sagi S, Salomone F, Webb M, Lotan R, Yeshua H, Halpern Z, Santo E, Oren R, Shibolet O. Coffee consumption and nonalcoholic fatty liver onset: a prospective study in the general population. Liver Int. 2014;34(12):1889-1895. doi:10.1111/liv.12616.

27. Setiawan VW, Porcel J, Wei P, Stram DO, Noureddin N, Lu SC, Le Marchand L, Noureddin M. Coffee drinking and alcoholic and nonalcoholic fatty liver diseases and viral hepatitis in the multiethnic cohort. Clin Gastroenterol Hepatol. 2017;15(8):1305-1307. doi:10.1016/j.cgh.2017.02.038.

11. Annexures

11.1. Annexure 1A

Randomized, Quadruple-blind, Placebo-controlled, Clinical Trial to determine the effects of Coffee (caffeine) supplementation on Hepatic Steatosis and Fibrosis in Metabolic dysfunction-associated Steatotic Liver Disease(MASLD)

Participant Information Sheet

I, Prof Arjuna Priyadarsin De Silva, Senior Professor in Medicine and Consultant Physician to the University Medical Unit, Colombo North Teaching Hospital and the Faculty of Medicine, University of Kelaniya, would like to invite you to take part in the research project titled Randomized, double-blind, placebo-controlled, clinical Trial to determine the effects of coffee (caffeine) supplementation on hepatic steatosis and fibrosis in non-alcoholic fatty liver disease. The other investigators in this study are Prof Madunil Anuk Niriella, Professor of Gastroenterology and Consultant Physician, Colombo North teaching Hospital and the Faculty of Medicine, University of Kelaniya, Prof Anuradha S Dassanayake, Professor of Pharmacology, and Consultant Physician Faculty of Medicine, University of Kelaniya.Dr. Uditha Dassanayake, Senior Lecturer and Consultant Gastroenterologist, Department of Medicine, Faculty of Medicine, University of Kelaniya, P Prof Janaka De Silva, Emeritus Professor of Medicine, Faculty of Medicine, University of Kelaniya, Dr. Krishanni Prabagar, Research Assistant, Faculty of Medicine, University of Kelaniya, Dr. Prathibha Wijesingha, Research Assistant, Faculty of Medicine, University of Kelaniya. The study would be conducted at the Gastroenterology Clinic, University Medical Unit, Colombo North Teaching Hospital, Ragama, Sri Lanka.

1.Purpose of the study

The purpose of this study is to find out if caffeine supplementation can help improve liver health in individuals with non- alcoholic fatty liver disease(NAFLD). Specifically, we aim to determine if caffeine can reduce liver fat(hepatic steatosis) and Liver fibrosis

2. Voluntary participation

Your participation in this study is voluntary. You are free not to participate at all or to withdraw from the study at any time despite consenting to take part earlier. There will be no loss of medical care or any other available treatment for your illness or condition to which you are otherwise entitled. If you decide not to participate or withdraw from the study, you may do so at any time.

3. Participant Selection

You are being invited to participate in this research because you have been diagnosed with non-alcoholic fatty liver disease (NAFLD)

4. Duration, procedures of the study and participant's responsibilities

a) You will be interviewed by trained personnel who will obtain your basic details like age, educational level, lifestyle, dietary habits, and consumption of alcohol and tobacco. They will go through your clinic medical records as well.
b) At the start of the study and monthly for 6 months, your Blood pressure, height, weight, and waist circumference will be measured.
c) Full blood count, fasting plasma glucose, glycosylated haemoglobin A1c, fasting serum lipids, ALT, AST, serum creatinine, full blood count and serum electrolytes will be assessed at the start and in three months and six months. In addition an ultra sound scan of the abdomen and fibroscan would be performed at recruitment and in the end of six months.
d) You will be given either caffeine/placebo tablets to be consumed every day for six months. In addition you would be instructed on health lifestyle practices to be followed in these six months

5. Potential benefits

Participation in this study may benefit you in several ways.

a) Your blood pressure, height, weight, and waist circumference will be measured at no additional cost.
b) Your diabetes control, cholesterol, liver functions and renal functions will be accessed free of charge

c) You will be instructed on lifestyle modifications for improvement of liver function free of charge
d) It is likely that there will be reduction in liver fat(hepatic steatosis) and liver fibrosis with the consumption of caffeine tablets

6. Risks, hazards, and discomforts

While Caffeine is widely consumed and generally safe within recommended limits, participants may experience certain side effects

Mild to Moderate Side effects

Palpitations, Restlessness, Insomnia, headaches, Stomach discomfort

Rare but serious risks

Arrythmias, Allergic reactions

Participants would be expected to follow dietary and exercise guidelines and daily supplement schedule. They would also be expected to visit the university medical unit every month for monthly checkups which might be inconvenient.

7. Risk management and Safety Precautions

Participants will be screened for any severe heart disease and other high-risk conditions at recruitment, if identified they will not be included in the study.

Participants will be instructed to not consume any amount of coffee, tea or energy drinks while participating in the study.

Participants will receive a study ID card with contact details of study doctors for reporting any adverse effects and care would be provided immediately.

A data and Safety Monitoring board(DSMB) will oversee the study.

8. Confidentiality

Confidentiality of all records is guaranteed and no information by which you can be identified will be released and only anonymous data will be published. These data will never be used in such a way that you could be identified in any way in any public presentation or publication without your express permission. Data without identification information may be shared with other researchers as many journals expect the authors to make their data available to other researchers.

9. Sharing the Results

If needed, we can make necessary arrangements to share the results of the study with you. Please notify the investigators that you wish to know the results of the study.

10. Termination of study participation

You may withdraw your consent to participate in this study at any time, with no penalty or effect on medical care or loss of benefits. Please notify the investigator as soon as you decide to withdraw your consent.

11.Clarification

If you have questions about any of the tests / procedures or information, please feel free to ask any of the persons listed below.

Prof Arjuna Priyadarsin De Silva	0777572379
Prof Madunil Anuk Niriella	0714820948
Dr. Krishanni Prabagar	0779175034
Dr. Prathibha Wijesinghe	0764750654

11.If you have any complaints about unethical conduct related to this research, you may make a complaint to ethics review committee, Faculty of Medicine, University of Kelaniya using information given below.

ERC Office Address: Ethics review committee, Faculty of Medicine, University of Kelaniya. Telephone no: 0112961267 Email: ercmed@kln.ac.lk

Randomized, Quadruple-blind, Placebo-controlled, Clinical Trial to determine the effects of Coffee (caffeine) supplementation on Hepatic Steatosis and Fibrosis in Metabolic dysfunction-associated Steatotic Liver Disease(MASLD)Version 1.

28.02.2025

11.2 Annexure 1A

පරිවෘත්තීය අක්‍රමිකතාව ආශ්‍රිත අක්මාවේ මේදය තැම්පත් වීමේ රෝගයේදී (MASLD), අක්මාවේ ස්ටියටෝසිස් (steatosis) සහ ෆයිබ්‍රෝසිස් (fibrosis) යන තත්ව වලට කෝපි (caffeine) භාවිත කිරීමෙන් ඇතිවන බලපෑම අධ්‍යයනය කිරීම සඳහා සිදුකෙරෙන සසම්භාවී(randomized), සිව් අන්ධ(quadruple-blinded),ප්ලැසිබෝ පාලිත (placebo- controlled) පරීක්ෂණය.

සහභාගි වන්නන් සඳහා වන තොරතුරු පත්‍රය

කොළඹ උතුරු ශික්ෂණ රෝහලේ සහ කැලණිය විශ්ව විද්‍යාලයේ වෛද්‍ය පීඨයේ වෛද්‍ය විද්‍යාව පිළිබඳ ජ්‍යෙෂ්ඨ මහාචාර්ය සහ උපදේශක වෛද්‍ය මහාචාර්ය අර්ජුන ප්‍රියදර්ශන් ද සිල්වා වන මම, පරිවෘත්තීය අක්‍රමිකතාව ආශ්‍රිත අක්මාවේ මේදය තැම්පත් වීමේ රෝගයේදී (MASLD), අක්මාවේ ස්ටියටෝසිස් (steatosis) සහ ෆයිබ්‍රෝසිස් (fibrosis) යන තත්ව වලට කෝපි (caffeine) භාවිත කිරීමෙන් ඇතිවන බලපෑම අධ්‍යයනය කිරීම සඳහා සිදුකෙරෙන සසම්භාවී(randomized), සිව් අන්ධ(quadruple-blinded),ප්ලැසිබෝ පාලිත (placebo- controlled) පරීක්ෂණයට සහභාගි වන ලෙස ඔබට ආරාධනා කිරීමට කැමැත්තෙමි. මෙම අධ්‍යයනයේ අනෙකුත් විමශර්කයින් වන්නේ උතුරු කොළඹ ශික්ෂණ රෝහලේ සහ කැලණිය විශ්ව විද්‍යාලයේ වෛද්‍ය පීඨයේ ආමාශ ආන්ත්‍ර විද්‍යාව පිළිබඳ මහාචාර්ය සහ උපදේශන වෛද්‍ය මහාචාර්ය මදුනිල් අතුක් නිරිඇල්ල, කැලණිය විශ්ව විද්‍යාලයේ ඖෂධවේදය පිළිබඳ මහාචාර්ය සහ උපදේශන වෛද්‍ය මහාචාර්ය අනුරාධ එස් දසනායක, සහ කැලණිය විශ්ව විද්‍යාලයේ වෛද්‍ය පීඨයේ සම්මානිත මහාචාර්ය ජනක ද සිල්වා, කැලණිය විශ්වවිද්‍යාලයේ වෛද්‍ය පීඨයේ පර්යේෂණ සහයක ක්‍රිෂානි ප්‍රභාගර්, කැලණිය විශ්වවිද්‍යාලයේ වෛද්‍ය පීඨයේ පර්යේෂණ සහයක ප්‍රකිභා විජේසිංහ.

1. අධ්‍යයනයේ අරමුණ

මෙම අධ්‍යයනයේ අරමුණ වන්නේ පරිවෘත්තීය අක්‍රමිකතාව ආශ්‍රිත අක්මාවේ මේදය තැම්පත් වීමේ රෝගය (MASLD ඇති පුද්ගලයින්ගේ අක්මා සෞඛ්‍යය වැඩි දියුණු කිරීමට කෑමෙන් අතිරේකය උපකාරී වේද යන්න සොයා බැලීමයි. විශේෂයෙන්, කෑමෙන් අක්මාවේ මේදය (හෙපටික් ස්ටීටෝසිස්) සහ අක්මා ෆයිබ්‍රෝසිස් අඩු කළ හැකිද යන්න තීරණය කිරීම අපගේ අරමුණයි.

2.ස්වේච්ඡා සහගත සහභාගිත්වය

මෙම අධ්‍යයනයට ඔබගේ සහභාගිත්වය සම්පූර්ණයෙන්ම ස්වේච්ඡා සහගත වේ. මෙම අධ්‍යයනයට සහභාගි නොවී සිටීමට තීරණය කිරීමට හා, පළමුව සහභාගි වීමට කැමැත්ත ප්‍රකාශ කර තිබීම නොහැකා අධ්‍යයනයෙන් ඉවත් වීමට තීරණය කිරීමට ඔබට මුලුමනින්ම නිදහස ඇත. ඔබ අධ්‍යයනයට සහභාගි නොවීමට අදහස් කරන්නේ වුවද, ඔබට ලැබෙන වෛද්‍ය සත්කාරවල හෝ ඔබගේ රෝගී තත්ත්වයට ලැබෙන චෙනත් ප්‍රතිකාර වල කිසිදු අඩුවක් සිදු නොවනු ඇත. ඔබ සහභාගි නොවී සිටීමට හෝ, අධ්‍යයනයෙන් ඉවත් වීමට තීරණය කරන්නේ නම්, ඕනෑම වෙලාවක ඔබට එසේ කළ හැකිය.

3 . සහභාගි වන්නන් තෝරා ගැනීම

ඔබට පරිවෘත්තීය අක්‍රමිකතාව ආශ්‍රිත අක්මාවේ මේදය තැම්පත් වීමේ රෝගය (MASLD) ඇති බව හඳුනාගෙන ඇති බැවින් මෙම පරීක්ෂණයට සහභාගි වීමට ඔබට ආරාධනා කෙරේ.

4. කාල සීමාව, අධ්‍යයනයේ ක්‍රියාපටිපාටිය සහ සහභාගි වන්නන්ගේ වගකීම්

අ) වයස, අධ්‍යාපන මට්ටම, ජීවන රටාව, ආහාර සුරුදු සහ මධ්‍යසාර හා දුම්කොළ පරිභෝජනය වැනි ඔබේ මූලික තොරතුරු, සුහුඹු සුද්ගලයින් විසින් ඔබව සම්මුඛ සාකච්ඡාවට ලක් කර ලබා ගනු ලැබේ. ඔවුන් ඔබේ සායනික වෛද්‍ය වාර්තා ද පරීක්ෂා කරනු ඇත.

ආ) අධ්‍යයනය ආරම්භයේදී සහ මාස 6ක් සඳහා මාසිකව, ඔබේ රුධිර පීඩනය, උස, බර සහ ඉණ වට ප්‍රමාණය මනිනු ලැබේ.

ඇ) සම්පූර්ණ රුධිර පරීක්ෂාව, නිරාහාර ප්ලාස්මා ග්ලූකෝස්, ග්ලයිකෝසිලේටඩ් හිමොග්ලොබින් A1c (HbA1c) නිරාහාර සීරම් ලිපිඩ (Fasting lipid profile), ALT, AST, සීරම් ක්‍රියේටිනින්, සීරම් ඉලෙක්ට්‍රොලයිට් ආරම්භයේ දී සහ මාස තුන සහ මාස හයකින් පරීක්ෂා කරනු ලැබේ. ඊට අමතරව බඳවා ගැනීමේදී සහ මාස හය අවසානයේ උදරයේ අල්ට්‍රා සවුන්ඩ් ස්කෑන් (ultra sound scan) පරීක්ෂණයක් සහ ෆයිබ්‍රෝ ස්කෑන් (fibroscan) පරීක්ෂණයක් සිදු කරනු ලැබේ.

ඈ) මාස හයක් සඳහා සෑම දිනකම පරිභෝජනය කිරීමට ඔබට කෑෆේන්/ප්ලැසිබෝ පෙති ලබා දෙනු ඇත. ඊට අමතරව මෙම මාස හය තුළ අනුගමනය කළ යුතු සෞඛ්‍ය ජීවන රටා පිළිවෙත් පිළිබඳව ඔබට උපදෙස් දෙනු ලැබේ.

5. ලැබිය හැකි ප්‍රතිලාභ

මෙම අධ්‍යයනයට සහභාගිවීම මඟින් ඔබට පහත ප්‍රතිලාභ ලැබේ .

a) අ) ඔබගේ රුධිර පීඩනය, උස, බර සහ ඉණ වට ප්‍රමාණය කිසිදු අමතර වියදමකින් තොරව මනිනු ලැබේ.
b) ආ) ඔබගේ දියවැඩියාව පාලනය, කොලෙස්ටරෝල්, අක්මා ක්‍රියාකාරිත්වය සහ වකුගඩු ක්‍රියාකාරිත්වය නොමිලේ ලබා ගත හැකිය
c) ඇ) අක්මාවේ ක්‍රියාකාරිත්වය වැඩි දියුණු කිරීම සඳහා ජීවන රටා වෙනස් කිරීම් පිළිබඳව ඔබට නොමිලේ උපදෙස් දෙනු ලැබේ
d) ඈ) කෑෆේන් පෙති පරිභෝජනය සමඟ අක්මාවේ මේදය (අක්මා ස්ටීයටෝසිස්) සහ අක්මා ෆයිබ්‍රෝසිස් අඩු වීමට ඉඩ ඇත.

6. අවධානම්, ප්‍රතිලාභ සහ අපහසුතා

කෑෆේන් බහුලව පරිභෝජනය කරන අතර නිදෙර්ශිත සීමාවන් තුළ සාමාන්‍යයෙන් ආරක්ෂිත වුවද, සහභාගිවන්නන්ට ඇතැම් අතුරු ආබාධ අත්විඳිය හැකිය

කුණු සිට මධ්‍යස්ථ අතුරු ආබාධ

හෘද ස්පන්දනය දැනීම, නොසන්සුන්තාවය, නින්ද නොයාම , හිසරදය ,බඩේ අපහසුතාව

දුලර්භ නමුත් බරපතල අවදානම්

හෘද ස්පන්දන රටාවේ වෙනස්කම්, අසාත්මිකතා

සහභාගිවන්නන් ආහාර සහ ව්‍යායාම මාර්ග උපදේශන සහ මෙදනික අතිරේක කාලසටහන අනුගමනය කරනු ඇතැයි අපේක්ෂා කෙරේ. මාසික පරීක්ෂණ සඳහා ඔවුන් සෑම මසකම විශ්වවිද්‍යාලයේ මෙවැද්‍ය ඒකකයට පැමිණිමට ද අපේක්ෂා කෙරේ, එය අපහසුතාවයක් විය හැකිය.

7. අවදානම් කළමනාකරණය සහ ආරක්ෂිත පූර්ව **ආරක්ෂාවන්**

බඳවා ගැනීමේදී සහභාගිවන්නන් දරුණු හෘද රෝග සහ අනෙකුත් අධි අවදානම් තත්ත්වයන් සඳහා පරීක්ෂා කරනු ලැබේ. හදුනාගත හොත් ඔවුන් අධ්‍යනයට ඇතුළත් නොකෙරේ.

සහභාගිවන්නන්ට පරීක්ෂණය සිදුකරන කාලය පුරාවට කෑෆේන් (caffeine) අඩංගු කෝපි, තේ හෝ ශක්තිජනක පෑන හාවිත නොකිරීමට උපදෙස් දෙනු ලැබේ.

අභිතකර බලපෑම් වාර්තා කිරීම සඳහා සහභාගිවන්නන්ට අධ්‍යයන මෙවැද්‍යවරුන්ගේ සම්බන්ධතා තොරතුරු සහිත අධ්‍යයන හැඳුනුම්පතක් ලැබෙනු ඇති අතර වහාම ප්‍රතිකාර ලබා දෙනු ඇත.

දත්ත සහ ආරක්ෂණ අධීක්ෂණ මණ්ඩලයක් (DSMB) අධ්‍යයනය අධීක්ෂණය කරනු ඇත.

8 රහස්‍යභාවය

සියලුම වාර්තාවල රහස්‍යභාවය සහතික කෙරෙන අතර ඔබව හදුනාගත හැකි කිසිදු තොරතුරක් නිකුත් නොකරන අතර නීත්‍යානුකූල දත්ත පමණක් ප්‍රකාශයට පත් කෙරේ. ඔබේ අවසරයකින් තොරව ඕනෑම ඉදිරිපත් කිරීමක දී හෝ ප්‍රකාශනයක දී ඔබව කිසිදු ආකාරයකින් හදුනාගත හැකි ලෙසින් මෙම දත්ත කිසිවිටෙකත් භාවිතා නොකෙරේ. විද්‍යාත්මක සඟරා විසින් මෙම ප්‍රකාශන වලට අදාළ දත්ත අනෙකුත් පර්යේෂකයින් සමඟ බෙදා ගැනීම අපගෙන් බලාපොරොත්තු වන බැවින් හදුනාගැනීමේ තොරතුරු නොමැති දත්ත අනෙකුත් පර්යේෂකයින් සමඟ බෙදාගත හැකිය.

9 ප්‍රතිඵල බෙදාගැනීම

අවශ්‍ය නම් අධ්‍යයනයේ ප්‍රතිඵල ඔබ සමඟ බෙදාගැනීමට අපට අවශ්‍ය කටයුතු සම්පාදනය කළ හැක. එසේ අවශ්‍ය නම්, කරුණාකර ඔබට අධ්‍යයනයේ ප්‍රතිඵල දැනගැනීමට අවශ්‍ය බව පරීක්ෂකයින්ට දන්වන්න.

10. අධ්‍යයන සහභාගිත්වය අවසන් කිරීම

ඔබට ඕනෑම වෙලාවක මෙම අධ්‍යයනයට සහභාගිවීමට ඔබ දුන් කැමැත්ත ඉල්ලා අස්කරගත හැකිය. එසේ කිරීමෙන් ඔබට ලැබෙන වෛද්‍ය ප්‍රතිකාර වලට බලපෑමක් හෝ ප්‍රතිලාභ අහිමිවීමක් නිදුනොවේ. ඔබ දුන් කැමැත්ත ඉල්ලා අස්කර ගැනීමට තීරණය කළ වහාම විමර්ශකයින්ට දන්වන්න.

11. පැහැදිලි කිරීම්

ඔබට කිසියම් පරීක්ෂණයක්/ ක්‍රියාපටිපාටියක් හෝ ඉහත තොරතුරු පිළිබඳව ප්‍රශ්න ඇත්නම් පහත සඳහන් ඕනෑම අයෙකුගෙන් විමසිය හැකිය.

මහාචාර්ය අර්ජුන ප්‍රියදර්ශන් ද සිල්වා 0777572379

මහාචාර්ය මදුනිල් අතුක් තිරිඇල්ල 0714820948

වෛද්‍ය ක්‍රිෂානි ප්‍රභාගර් 0779175034

වෛද්‍ය ප්‍රතිභා විජේසිංහ 0764750654

මෙම අධ්‍යයනයේ යම් සදාචාර විරෝධී පවත්වා ගැනීමක් සම්බන්ධයෙන් ඔබට කිසියම් පැමිණිල්ලක් තිබේනම්, කැලණිය විශ්වවිද්‍යාලයේ, වෛද්‍ය විද්‍යා පීඨයේ ආචාරධර්ම සමාලෝචන කමිටුවට, ඔබේ පැමිණිල්ල පහත තොරතුරු භාවිතා කර ඉදිරිපත් කරන්න.

ආචාරධර්ම සමාලෝචන කමිටු කාර්යාලයේ ලිපිනය:
ආචාරධර්ම සමාලෝචන කමිටුව, වෛද්‍ය විද්‍යා පීඨය, කැලණිය විශ්වවිද්‍යාලය.
දූ.අ.: 0112961267
විද්‍යුත් තැපෑල: ercmed@kln.ac.lk

11.3. Annexure 1A

வளர்சிதை மாற்ற செயலிழப்புடன் தொடர்புடைய ஸ்டீடோடிக் கல்லீரல் நோயில் (MASLD) கல்லீரல் ஸ்டீடோசிஸ்(Steatosis) மற்றும் ஃபைப்ரோசிஸில்(fibrosis) காபி (காஃபின்) கூடுதல் விளைவுகளைத் தீர்மானிக்க சீரற்ற, நான்கு மடங்கு குருட்டு, மருந்துப்போலி கட்டுப்படுத்தப்பட்ட, மருத்துவ சோதனை.

பங்கேற்பாளர் தகவல் தாள்

கொழும்பு வடக்கு போதனா மருத்துவமனை மற்றும் களனி பல்கலைக்கழக மருத்துவ பீடத்தின் மருத்துவப் பிரிவின் மூத்த பேராசிரியரும் ஆலோசகர் மருத்துவருமான பேராசிரியர் அர்ஜுன பிரியதர்சின் டி சில்வா, ஆல்கஹால் அல்லாத கொழுப்பு கல்லீரல் நோயில் காபி (காஃபின்) சப்ளிமெண்டேஷன் கல்லீரல் ஸ்டீடோசிஸ்(steatosis) மற்றும் ஃபைப்ரோஸிஸில்(fibrosis) ஏற்படுத்தும் விளைவுகளைத் தீர்மானிக்கும் சீரற்ற, இரட்டை-குருட்டு, மருந்துப்போலி கட்டுப்படுத்தப்பட்ட, மருத்துவ சோதனை என்ற ஆராய்ச்சி திட்டத்தில் பங்கேற்க உங்களை அழைக்க விரும்புகிறேன். இந்த ஆய்வில் உள்ள மற்ற ஆய்வாளர்கள் கொழும்பு வடக்கு போதனா மருத்துவமனை மற்றும் களனி பல்கலைக்கழக மருத்துவ பீடத்தின் இரைப்பை குடல் மற்றும் ஆலோசகர் மருத்துவர் பேராசிரியர் மதுனில் அனுக் நிரியெல்லா, மருந்தியல் பேராசிரியர் பேராசிரியர் அனுராதா எஸ் தசநாயக்க, களனிப் பல்கலைக்கழக மருத்துவ பீடத்தின் மருத்துவத் துறையின் மூத்த விரிவுரையாளர் மற்றும் ஆலோசகர் இரைப்பை குடல் நிபுணர் டாக்டர் உதித தசநாயக்க, களனி பல்கலைக்கழக மருத்துவ பீடத்தின் ஆலோசகர் மருத்துவர். களனி பல்கலைக்கழக மருத்துவ பீடத்தின் ஓய்வுபெற்ற பேராசிரியர் பேராசிரியர் ஜனக டி சில்வா, களனிப் பல்கலைக்கழக மருத்துவ பீட ஆராய்ச்சி உதவியாளர் டாக்டர் கிருஷானி பிரபாகர், களனிப் பல்கலைக்கழக மருத்துவ பீட ஆராய்ச்சி உதவியாளர் டாக்டர் பிரதிபா விஜேசிங்க.

1. ஆய்வின் நோக்கம்

இந்த ஆய்வின் நோக்கம், மது அருந்தாத கொழுப்பு கல்லீரல் நோய் (NAFLD) உள்ள நபர்களில் காஃபின்(caffiene) கல்லீரல் ஆரோக்கியத்தை மேம்படுத்த உதவுமா என்பதைக் கண்டறிவதாகும். குறிப்பாக, காஃபின் கல்லீரல் கொழுப்பை (கல்லீரல் ஸ்டீடோசிஸ்) மற்றும் கல்லீரல் ஃபைப்ரோஸிஸைக் குறைக்க முடியுமா என்பதை கண்டறிவதாகும்

2. தன்னார்வ பங்கேற்பு

இந்த ஆய்வில் பங்கேற்பது முழுமையாக உங்களது விருப்பம். பங்கேற்பதற்கான ஒப்புதலை அளித்த பின்னரும், எப்போது வேண்டுமானாலும் பங்கேற்பை நிறுத்த அல்லது பங்கேற்க மறுக்க உங்களுக்கு சுதந்திரம் உள்ளது. இதில் பங்கேற்காமையாலோ, பங்கேற்பை நிறுத்தியதாலோ உங்களுக்கு உரிய மருத்துவ சேவையில் எந்த குறையும் ஏர்படாது.

3. பங்கேற்பாளர் தேர்வு

உங்களுக்கு மதுசாரமற்ற கொழுப்பு கல்லீரல் நோய் (NAFLD) இருப்பது கண்டறியப்பட்டுள்ளதால், இந்த ஆராய்ச்சியில் பங்கேற்க அழைக்கப்படுகிறீர்கள்.

4. ஆய்வின் காலம், நடைமுறைகள், மற்றும் பங்கேற்பாளரின் பொறுப்புகள்

a) வயது**,** கல்வி நிலை**,** வாழ்க்கை முறை**,** உணவுப் பழக்கம் மற்றும் மது மற்றும் புகையிலை நுகர்வு போன்ற உங்கள் அடிப்படை விவரங்களைப் பெறும் பயிற்சி பெற்ற பணியாளர்களால் நீங்கள் நேர்காணல்

செய்யப்படுவீர்கள். அவர்கள் உங்கள் மருத்துவ மருத்துவ பதிவுகளையும் மதிப்பாய்வு செய்வார்கள்.

b) ஆய்வின் தொடக்கத்திலும் 6 மாதங்களுக்கும் மாதந்தோறும், உங்கள் இரத்த அழுத்தம், உயரம், எடை மற்றும் இடுப்பு சுற்றளவு அளவிடப்படும்.

c) முழு இரத்த எண்ணிக்கை, உண்ணாவிரத பிளாஸ்மா குளுக்கோஸ், கிளைகோசைலேட்டட் ஹீமோகுளோபின் H**A**1**c**, உண்ணாவிரத சீரம் லிப்பிடுகள், **ALT, AST,** சீரம் கிரியேட்டினின், முழு இரத்த எண்ணிக்கை மற்றும் சீரம் எலக்ட்ரோலைட்டுகள் தொடக்கத்திலும் மூன்று மாதங்கள் மற்றும் ஆறு மாதங்களுக்குப் பிறகும் மதிப்பிடப்படும். கூடுதலாக, ஆட்சேர்ப்பு மற்றும் ஆறு மாதங்களின் முடிவில் வயிறு மற்றும் ஃபைப்ரோஸ்கானின்(fibroscan) அல்ட்ரா(US scan) சவுண்ட் ஸ்கேன் செய்யப்படும்.

d) ஆறு மாதங்களுக்கு ஒவ்வொரு நாளும் உட்கொள்ள காஃபின்/மருந்துப்போலி மாத்திரைகள் உங்களுக்கு வழங்கப்படும். கூடுதலாக, இந்த ஆறு மாதங்களில் பின்பற்ற வேண்டிய சுகாதார வாழ்க்கை முறை நடைமுறைகள் குறித்து உங்களுக்கு அறிவுறுத்தப்படும்.

5. சாத்தியமான நன்மைகள்

இந்த ஆய்வில் பங்கேற்பது உங்களுக்கு பல வழிகளில் பயனளிக்கும்.

a) உங்கள் இரத்த அழுத்தம், உயரம், எடை மற்றும் இடுப்பு சுற்றளவு கூடுதல் செலவு இல்லாமல் அளவிடப்படும்.

b) உங்கள் நீரிழிவு கட்டுப்பாடு, கொழுப்பு, கல்லீரல் செயல்பாடுகள் மற்றும் சிறுநீரக செயல்பாடுகள் இலவசமாக அணுகப்படும்

c) கல்லீரல் செயல்பாட்டை மேம்படுத்துவதற்கான வாழ்க்கை முறை மாற்றங்கள் குறித்து உங்களுக்கு இலவசமாக அறிவுறுத்தப்படும்

d) காஃபின் மாத்திரைகளை உட்கொள்வதன் மூலம் கல்லீரல் கொழுப்பு (கல்லீரல் ஸ்டீடோசிஸ்) மற்றும் கல்லீரல் ஃபைப்ரோஸிஸ் குறையும் வாய்ப்பு உள்ளது.

6. சாத்தியமான ஆபத்துகள்

காஃபின் பரவலாக உட்கொள்ளப்படுகிறது மற்றும் பரிந்துரைக்கப்பட்ட வரம்புகளுக்குள் பொதுவாக பாதுகாப்பானது என்றாலும், பங்கேற்பாளர்கள் சில பக்க விளைவுகளை அனுபவிக்கலாம்

லேசான முதல் மிதமான பக்க விளைவுகள்

- படபடப்பு, அமைதியின்மை, தூக்கமின்மை, தலைவலி, வயிற்று அசௌகரியம்

அரிதான ஆனால் கடுமையான ஆபத்துகள்

- அரித்மியா, ஒவ்வாமை எதிர்வினைகள்

பங்கேற்பாளர்கள் உணவு மற்றும் உடற்பயிற்சி வழிகாட்டுதல்கள் மற்றும் தினசரி துணை அட்டவணையைப் பின்பற்றுவார்கள் என்று எதிர்பார்க்கப்படுகிறது. அவர்கள் ஒவ்வொரு மாதமும் பல்கலைக்கழக

மருத்துவப் பிரிவிற்கு மாதாந்திர பரிசோதனைகளுக்காக வருகை தருவார்கள், இது சிரமமாக இருக்கலாம்.

7.இடர் மேலாண்மை மற்றும் பாதுகாப்பு முன்னெச்சரிக்கைகள்

பங்கேற்பாளர்கள் ஆட்சேர்ப்பின் போது ஏதேனும் கடுமையான இதய நோய் மற்றும் பிற உயர் ஆபத்து நிலைமைகளுக்கு பரிசோதிக்கப்படுவார்கள், அடையாளம் காணப்பட்டால் அவர்கள் ஆய்வில் சேர்க்கப்பட மாட்டார்கள்.

ஆய்வில் பங்கேற்கும் போது பங்கேற்பாளர்கள் காபி, தேநீர் அல்லது எனர்ஜி பானங்களையும் உட்கொள்ளக்கூடாது என்று அறிவுறுத்தப்படுவார்கள்.

பங்கேற்பாளர்கள் ஏதேனும் பாதகமான விளைவுகளைப் புகாரளிக்க ஆய்வு மருத்துவர்களின் தொடர்பு விவரங்களுடன் ஒரு ஆய்வு அடையாள அட்டையைப் பெறுவார்கள் மற்றும் உடனடியாக பராமரிப்பு வழங்கப்படும்.

தரவு மற்றும் பாதுகாப்பு கண்காணிப்பு வாரியம் (DSMB) ஆய்வை மேற்பார்வையிடும்.

8. ரகசியத்தன்மை

உங்கள் அடையாளம் தெரியாத விதத்தில் மட்டுமே தரவுகள் வெளியிடப்படும்.

9. முடிவுகள் பகிர்தல்

முடிவுகளை தெரிந்துகொள்ள விரும்பினால், ஆராய்ச்சியாளர்களுக்கு தெரிவிக்கவும்.

10. பங்கேற்பு நிறுத்தம்

பங்கேற்பை எப்போது வேண்டுமானாலும் நிறுத்தலாம்.

11. விளக்கம் தேவைப்பட்டால்

தேனும் சோதனைகள் / நடைமுறைகள் அல்லது தகவல்கள் குறித்து உங்களுக்கு ஏதேனும் கேள்விகள் இருந்தால், கீழே பட்டியலிடப்பட்டுள்ள நபர்களில் யாரிடமாவது தயங்காமல் கேளுங்கள்.

பேராசிரியர் அர்ஜுன பிரியதர்சின் டி சில்வா 0777572379

பேராசிரியர் மதுனில் அனுக் நிரியெல்லா 0714820948

டாக்டர் கிருஷானி பிரபாகர் 0779175034

டாக்டர் பிரதிபா விஜேசிங்கே 0764750654

12.முறைசார் புகார்

ஈதிக்ஸ் ஆய்வுக்குழு(ERC), கேளனிய பல்கலைக்கழக மருத்துவ பீடம்,
தொலைபேசி: 0112961267
மின்னஞ்சல்: ercmed@kln.ac.lk

11.4. Annexure 1B

Randomized, Quadruple-blind, Placebo-controlled, Clinical Trial to determine the effects of Coffee (caffeine) supplementation on Hepatic Steatosis and Fibrosis in Metabolic dysfunction-associated Steatotic Liver Disease(MASLD)

Consent Form

a. By the participant

The participants should complete the whole of this sheet himself/herself.

1.Have you read the information sheet? (Please keep a copy for yourself.)	Yes	☐	No	☐
2.Have you had an opportunity to discuss this study and ask any questions?	Yes	☐	No	☐
3.Have you had satisfactory answers for all your questions?	Yes	☐	No	☐
4.Have you received enough information about the study?	Yes	☐	No	☐
5.Who explained the study to you?				
6.Do you understand that you are free to withdraw from the study at any time without having to give a reason and without affecting your future medical care?	Yes	☐	No	☐
7.Sections of your medical notes including those held by the investigator relating to your participation in this study may be examined by other research assistants. All personal details will be treated as STRICTLY CONFIDENTIAL. Do you give your permission for these individuals to have access to your records?	Yes	☐	No	☐
8.At the initiation and every month till the completion of the study your height, weight, BMI, waist circumference and blood pressure will be measured. Do you give permission for it?	Yes	☐	No	☐
9. At initiation of the study and in 3 months and 6 months from initiation blood tests would be taken do you consent to that?	Yes	☐	No	☐
10. At initiation of the study and in 6 months an ultrasound scan of the abdomen and fibroscan would be done, do you consent to that?	Yes	☐	No	☐
11.Would you consent to Taking either caffeine/ placebo tablets every day for 6 months?	Yes	☐	No	☐
12. Would you provide contact details to our research team and agree to be contacted by them for any inquiries related to the study?	Yes	☐	No	☐
13.Have you had sufficient time to come to your decision?	Yes	☐	No	☐

14.Do you agree to take part in this study?	Yes ☐	No ☐

Participant's

Signature: ……

Name: ……..... Date: .....

b. Should be completed by the Investigator/person who took consent

I have explained the study to the above participant, and he/she has indicated willingness to take part.

Signature:

……

Date: …….

Name: ……

11.5. Annexure 1B

පරිවෘත්තීය අක්‍රමිකතාව ආශ්‍රිත අක්මාවේ මේදය තැම්පත් වීමේ රෝගයේදී (MASLD), අක්මාවේ ස්ටියටෝසිස් (steatosis) සහ ෆයිබ්‍රෝසිස් (fibrosis) යන තත්ව වලට කෝපි (caffeine) භාවිත කිරීමෙන් ඇතිවන බලපෑම අධ්‍යයනය කිරීම සඳහා සිදුකෙරෙන සසම්භාවී(randomized), සිව් අන්ධ(quadruple-blinded),ප්ලැසිබෝ පාලිත (placebo- controlled) පරීක්ෂණය.

mrSCIKhg සහභාගි වීමට කැමැත්ත ලබාගැනීමේ පෝරමය

A). mrSCIKhg සහභාගිවන්නන් තමන් විසින්ම මෙම පත්‍රිකාව සම්පූර්ණ කළ යුතුය.

1.ඔබ තොරතුරු පත්‍රිකාව කියවා තිබේද? (කරුණාකර ඔබ වෙනුවෙන් පිටපතක් තබා ගන්න.)	ඔව් ☐	නැත ☐
2. මෙම අධ්‍යයනය ගැන සාකච්ඡා කිරීමට සහ ප්‍රශ්න ඇසීමට ඔබට අවස්ථාවක් ලැබී තිබේද?	ඔව් ☐	නැත ☐
3.ඔබේ සියලුu ප්‍රශ්න සඳහා සතුටුදායක පිළිතුරු ලැබී තිබේද?	ඔව් ☐	නැත ☐
4.අධ්‍යයනය පිළිබඳ ප්‍රමාණවත් තොරතුරු ඔබට ලැබී තිබේද?	ඔව් ☐	නැත ☐
5. ඔබට මෙම අධ්‍යයනය පැහැදිලි කළේ කවුද?	.....	
6. හේතුවක් දැක්වීමකින් තොරව සහ ඔබේ අනාගත වෛද්‍ය ප්‍රතිකාරවලට බලපෑම් නොකර ඕනෑම වේලාවක අධ්‍යයනයෙන් ඉවත් වීමට ඔබට නිදහස ඇති බව ඔබට වැටහෙනවාද?	ඔව් ☐	නැත ☐
7.මෙම අධ්‍යයනයට ඔබගේ සහභාගීත්වය සම්බන්ධයෙන් විමර්ශකයා සතු දත්ත ඇතුළුව ඔබගේ වෛද්‍ය සටහන් වල කොටස් වෙනත් පර්යේෂණ සහායකයින් විසින් පරීක්ෂා කරනු ලැබිය හැක. සියලුම පුද්ගලික තොරතුරු දැඩි ලෙස රහසිගත ලෙස සලකනු ලැබේ. මෙම පුද්ගලයින්ට ඔබගේ වාර්;d වෙත ප්‍රවේශ වීමට ඔබ ඔබගේ අවසරය ලබා දෙනවාද?	ඔව් ☐	නැත ☐
8. අධ්‍යයනය ආරම්භයේදී සහ අධ්‍යයනය අවසන් වන තෙක් සෑම මසකම ඔබේ උස, බර, ශරීර ස්කන්ධ ද¾Yකය, ඉණ වට ප්‍රමාණය සහ රුධිර පීඩනය මනිනු ලැබේ. ඔබ ඒ සඳහා අවසර දෙනවාද?	ඔව් ☐	නැත ☐

9. අධ්‍යයනය ආරම්භයේදී සහ ආරම්භයෙන් මාස 3ක් සහ මාස 6ක් ඇතුළත රුධිර පරීක්ෂණ සිදු කරනු ලැබේ'ඔබ එයට එකඟද?	ඔව් ☐	නැත ☐
10. අධ්‍යයනය ආරම්භයේදී සහ මාස 6 කට පසු උදරයේ අල්ට්රා සවුන්ඩ් ස්කෑන් පරීක්ෂණයක් සහ ෆයිබ්‍රොස්කෑන් පරීක්ෂණයක් සිදු කරනු ලැබේ, ඔබ එයට එකඟද?	ඔව් ☐	නැත ☐
11. මාස 6ක් පුරාවට දිනපතා කැෆේන්/ප්ලේසෙබෝ පෙති වලින් එකක් ගැනීමට ඔබ එකඟ වෙනවාද?	ඔව් ☐	නැත ☐
11.මෙම අධ්‍යයනය සම්බන්ධයෙන් කිසියම් තොරතුරක් ඔබගෙන් ලබා ගැනීමට අවශ්‍ය වුවහොත් අප ප¾fhaෂණ කණ්ඩායම විසින් ඔබගේ දුරකථන අංකය ඔස්සේ ඔබව සම්බන්ධ කරගන්නවාට ඔබ කැමතිද?	ඔව්	නැත
12.ඔබේ තීරණයට පැමිණීමට ඔබට ප්‍රමාණවත් කාලයක් තිබේද?	ඔව්	නැත
13.මෙම අධ්‍යයනයට සහභාගි වීමට ඔබ එකඟද?	ඔව්	නැත

සහභාගිවන්නාගේ,

අත්සන :.....

නම :.....

දිනය :.....

ප¾fhaIK සහායකයා /කැමැත්ත ගැනීමේ ප්‍රකාශනය ලබාගත් පුද්ගලයා විසින් සම්පූ¾K කළ යුතුය.

B) මෙම ස්වේච්ඡාවෙන් ඉදිරිපත් වන පුද්ගලයා හට මෙම අධ්‍යනය පිළිබඳව පැහැදිලි කර ඇති අතර ඔහු /ඇය සහභාගි වීමට කැමැත්ත පළ කර ඇත .

p¾fhaIK සහයකයාගේ අත්සන
.....දිනය.....
නම.....

wdpdr O¾u සමාලෝචන කමිටුව වෛද්‍ය පීඨය කැලණිය කැලණිය විශ්ව විද්‍යාලය.

11.6. Annexure 1B

வளர்சிதை மாற்ற செயலிழப்புடன் தொடர்புடைய ஸ்டீடோடிக் கல்லீரல் நோயில் (MASLD) கல்லீரல் ஸ்டீடோசிஸ்(Steatosis) மற்றும் ஃபைப்ரோசிஸில்(fibrosis) காபி (காஃபின்) கூடுதல் விளைவுகளைத் தீர்மானிக்க சீரற்ற, நான்கு மடங்கு குருட்டு, மருந்துப்போலி கட்டுப்படுத்தப்பட்ட, மருத்துவ சோதனை.

ஒப்புதல் படிவம்

a. பங்கேற்பாளர் மூலம் இந்த அட்டவணையை முழுவதையும் தாங்கள் முடிக்க வேண்டும்.

1. நீங்கள் தகவல் அட்டவணையை படித்துள்ளீர்களா? (தயவுசெய்து உங்கள் நகலை வைத்துக்கொள்ளவும்.) ஆம் /இல்லை
2. நீங்கள் இந்த ஆராய்ச்சியைப் பற்றி விவாதிக்க மற்றும் கேள்விகள் கேட்க வாய்ப்பு பெற்றுள்ளீர்களா? ஆம்/ இல்லை
3. உங்கள் அனைத்து கேள்விகளுக்கும் உங்களுக்கு திருப்திகரமான பதில்களைப் பெற்றுள்ளீர்களா? ஆம் /இல்லை
4. இந்த ஆராய்ச்சி பற்றி போதிய தகவல்களைப் பெற்றுள்ளீர்களா?

   ஆம் /இல்லை
5. இந்த ஆராய்ச்சியை உங்களுக்கு யார் விளக்கினர்?.....
6. நீங்கள் இந்த ஆராய்ச்சியில் எப்போது வேண்டுமானாலும் காரணம் கொடுக்காமல், உங்கள் எதிர்கால மருத்துவ பராமரிப்பினை பாதிக்காமல் விலகுவதைப் பற்றி புரிந்துள்ளீர்களா? ஆம் /இல்லை
7. உங்கள் மருத்துவ குறிப்புகள், ஆராய்ச்சியில் பங்கேற்பு தொடர்பானவை உள்பட, ஆராய்ச்சி உதவியாளர்களால் பரிசோதிக்கப்படலாம். அனைத்து தனிப்பட்ட விவரங்களும் கடுமையாக இரகசியமாக கையாளப்படும். இந்த பதிவுகளுக்கு அணுகலை அளிக்க நீங்கள் அனுமதி அளிக்கிறீர்களா? ஆம் /இல்லை

8. ஆரம்ப கட்டத்திலும், ஆய்வு முடியும் வரை ஒவ்வொரு மாதமும் உங்கள் உயரம், எடை, உடல் நிறை குறியீட்டெண் (BMI), இடுப்பு சுற்றளவு மற்றும் இரத்த அழுத்தம் ஆகியவை அளவிடப்படும். அதற்கு நீங்கள் அனுமதி அளிக்கிறீர்களா? ஆம் /இல்லை
9. ஆய்வின் தொடக்கத்திலும், துவக்கத்திலிருந்து 3 மாதங்கள் மற்றும் 6 மாதங்களுக்குப் பிறகும் இரத்தப் பரிசோதனைகள் எடுக்கப்படும், அதற்கு நீங்கள் சம்மதிக்கிறீர்களா?ஆம் /இல்லை
10. ஆய்வின் தொடக்கத்தில், 6 மாதங்களுக்குப் பிறகு, வயிற்றுப் பகுதியின் அல்ட்ராசவுண்ட் ஸ்கேன்(US scan) மற்றும் ஃபைப்ரோஸ்கேன்(Fibro scan) செய்யப்படும், அதற்கு நீங்கள் சம்மதிக்கிறீர்களா? ஆம் /இல்லை
11. 6 மாதங்களுக்கு ஒவ்வொரு நாளும் காஃபின்/மருந்துப்போலி மாத்திரைகளை எடுத்துக்கொள்ள நீங்கள் சம்மதிப்பீர்களா?

    ஆம் /இல்லை
12. நீங்கள் எங்கள் ஆராய்ச்சி குழுவிற்கு தொடர்பு விவரங்களை வழங்கி, இந்த ஆராய்ச்சியுடன் தொடர்புடைய எந்தவொரு விசாரணைகளுக்கும் தொடர்புகொள்வதற்கு ஒப்புக்கொள்கிறீர்களா? ஆம் /இல்லை
13. நீங்கள் உங்கள் முடிவை எடுக்க போதிய நேரம் பெற்றுள்ளீர்களா? ஆம் /இல்லை
14. இந்த ஆராய்ச்சியில் பங்கேற்க நீங்கள் ஒப்புக்கொள்கிறீர்களா? ஆம் /இல்லை

பங்கேற்பாளரின் கையொப்பம்: .....
பெயர்: .....
திகதி: .....

b. ஒப்புதல் பெற்ற ஆராய்ச்சியாளர் அல்லது நபரால் பூர்த்தி செய்யப்பட வேண்டும்
நான் மேலே உள்ள பங்கேற்பாளருக்கு இந்த ஆராய்ச்சியை விளக்கி, அவர்/அவள் பங்கேற்க விருப்பம் தெரிவித்துள்ளார்.

கையொப்பம்: .....
திகதி: .....
பெயர்: .....

11.7. Annexure 1C

Case Report Form

Participant ID: _____ Visit Date:_____

Participant Random Number:_____

Review No: ☐

History:

1. Introduction:

- Age:_____
- Gender:_____
- Marital Status:_____
- Occupation:_____

2. Systemic Review:

- CVS:_____
  _____
  _____
- RS:_____
  _____
  _____
- Nervous:_____
  _____
  _____
- Gastrointestinal:_____
  _____
  _____
- Genitourinary:_____
  _____
  _____
- Musculoskeletal:_____
  _____
  _____

3. **Past Medical/Surgical History**:_____
   _____
   _____
4. **Drug History**:_____
   _____
   _____
5. **Family History**:_____
   _____
   _____
6. **Allergic History:**_____
   _____
   _____
7. **Social History**:_____
   _____
   _____

Alcohol:	None: ☐	Moderate: ☐	Heavy: ☐
Smoking:	None: ☐	Moderate:☐	Heavy: ☐

Examination:

General examination:

- Height(cm):_____
- Weight(kg):_____
- Waist Circumference(cm):_____
- BMI:_____
- Other
  Findings:_____
  _____
  _____

CVS examination:

- Blood Pressure(mmhg):_____
- Heart Rate:_____
- Other
  Findings:_____
  _____
  _____

Respiratory Examination:

- Respiratory rate:_____
- Other
  Findings:_____
  _____
  _____

Abdomen Examination:

Findings:_____
_____
_____

Other Important Findings:_____

_____

_____

Investigations:

- FBC:

  _____
  _____
  _____
- Serum Electrolytes:

  _____
  _____
  _____

Liver Assessments:

- AST (IU/L): _____
- ALT (IU/L): _____
- GGT (IU/L): _____
- Total Bilirubin:_____
- CAP Score: _____
- LSM (Fibro scan): _____
- FIB-4 Score: _____
- US scan
  Findings:_____
  _____
  _____
- Fibro scan
  Findings:_____
  _____
  _____

Metabolic Assessments:

Lipid Profile:

- Total Cholesterol (mg/dL): _____
- Triglycerides (mg/dL): _____
- HDL (mg/dL): _____
- LDL (mg/dL): _____

Blood glucose:

- Fasting Blood Sugar (FBS) (mg/dL): _____
- HbA1c (%): _____
- Fasting Serum Insulin: _____

Others:

- Serum Creatinine:_____
- UFR:_____

Adherence to Intervention:

Degree of adherence to Treatment:

Over the past month,

- **Tablet:**

No adherence ☐	Poor adherence☐	Moderate adherence☐	Good adherence☐	Complete adherence☐

- **Diet:**

No adherence ☐	Poor adherence☐	Moderate adherence☐	Good adherence☐	Complete adherence☐

- **Alcohol and Smoking intervention:**

No adherence ☐	Poor adherence☐	Moderate adherence☐	Good adherence☐	Complete adherence☐

Reason for Non Adherence:

_____
_____
_____
_____

Followed treatment

- *0–6 days → No adherence*
- *7–13 days → Poor adherence*
- *14–20 days → Moderate adherence*
- *21–27 days → Good adherence*
- *28 days (Every day) → Complete adherence*

Adverse Events (AE) Reporting:

- Any AE observed? ☐ Yes ☐ No
- If yes,

1. **Degree:**

Mild: ☐ Moderate: ☐ Severe: ☐

2. **Relation to treatment:**

Non Related: ☐	Unlikely: ☐	Possible: ☐	Probable: ☐

3. **Outcome:**

Recovered/resolved: ☐

Recovered/resolved with sequelae: ☐

Fatal/Life threatening: ☐

Unknown: ☐

4. **Action Taken:**

No action☐ Medical Intervention☐

Discontinued☐

Reported: ☐

Summary of the event:

_____

_____

_____

_____

_____

11.8. Annexure 1D.

Patient Identification Form.

Participant ID: _____

Participant Random Number:_____

1. Name:

   _____

2. Gender: ☐ Male ☐ Female
3. Age:

   _____

4. Ethnicity:

   _____

5. Occupation:

   _____

6. Contact Number:

   Home:_____

   Office:_____

   Mobile:_____

7. Address:_____
   _____
   _____
   _____

11.9. Annexure 1E

Patient Information Card

Participant Name: _____

Study Title: **Randomized, Quadruple-blind, Placebo-controlled, Clinical Trial to determine the effects of Coffee (caffeine) supplementation on Hepatic Steatosis and Fibrosis in Metabolic dysfunction-associated Steatotic Liver Disease(MASLD)**

Investigational Product: **Caffeine 400mg**

Trial Start Date: End Date:

Contact Information

Principal Investigator:

Prof Arjuna P De Silva

Institution: Faculty of Medicine, University of Kelaniya

Address: P.O Box 6, Thalagolla Road, Ragama, Sri Lanka

Contact Number: 0777572379

Investigator:

Prof Madunil A Niriella

Institution: Faculty of Medicine, University of Kelaniya

Address: P.O Box 6, Thalagolla Road, Ragama, Sri Lanka

Contact number:0714820948

IMPORTANT INFORMATION: This individual is a participant in a clinical research study. If medical attention is required, please contact the principal investigator at the number listed above before administering treatment. In case of emergencies, follow standard medical procedures and notify the study team as soon as possible.

For Healthcare Providers: Please be aware that this participant may be under specific study-related restrictions. For further information, contact the principal investigator.

In case of loss, please report to the study team immediately.

11.10. Annexure 1F

Front Label

Participant ID:

Random Number:

Contents: 60 capsules (200mg each)

Ingredients: Caffiene anhydrous

Suggested use: Take two capsules daily after dinner

This recommended dose of this product contains as much caffeine as 4 cups of coffee. Do not consume more than 400 mg of caffeine from any source in a 24 hour period. It may cause nervousness, irritability, sleeplessness and occasional rapid heart rates. In case of accidental overdose, seek professional assistance or contact a poison control center immediately

Storage: Store in a cool, dry place away from sunlight
Warnings: Keep out of reach of children. Do not use if the seal is broken.

Manufactured by: Nutricost

Back Label

This medication is part of a clinical trial. Do not share with others. If you experience any adverse effects, contact the study team immediately.

CURRICULUM VITAE

Vidya Jyothi Senior Professor ARJUNA P.DE SILVA,
MBBS,MD,MRCP(UK)MSc(Oxford),FRCP(Lond),FCCP, AGAF,FNASSL

Personal Details:

Name : Arjuna Priyadarsin De Silva
Address : 126, Cotta Road, Colombo 08. Sri Lanka
Sex : Male
Date of Birth : 13th June 1965
Nationality : Sri Lankan
Registration : Sri Lanka Medical Council (SLMA) 11202
General Medical Council (UK) 5206625

Education & Credentials:

Education:

Primary & Secondary:

1971-1980: St. Thomas' Preparatory School – Colombo 3
1981-1984: St. Thomas' College Mt Lavinia.

Prizes
Class prize 1980, 1983,
Buddhism 1977, Social Studies1978, 79
Botany prize 1984,
Class prize 1984

Senior Prefect
Captain of St. Thomas' College Rowing Team 1983
Represented Sri Lanka in Rowing 1983, 84

University:

Undergraduate
North Colombo Medical College (NCMC)

Academic Record:

2nd MBBS	**First Class with Distinction in Anatomy and Physiology**
3rd MBBS	**Second Class with Distinctions in Microbiology and Pharmacology**
Final MBBS	**Second Class 1993**

Postgraduate

1997-1999 **MD**	Postgraduate Institute of Medicine, University of Colombo. **1st in Order of Merit (Part I)**
2001	Royal College of Physicians United Kingdom .**MRCP (UK)** Green College, University of Oxford. **MSc** (Oxon)

DEGREES & CERTIFICATIONS

MBBS	North Colombo Medical College- 1993
MD	University of Colombo - 1999
MRCP	Royal College of Physicians London - 2001
MSc	University of Oxford - 2001

Board Certified as a Specialist in General Medicine (1999)

Board Certified as Trainer in Gastroenterology (2008)

FCCP 2009

FRCP (Lond) 2010

FNASSL 2017

AGAF 2018

HONOURS, AWARDS, PRIZES, SCHOLARSHIPS

Vidya Joythi -2018
FNASSL -2017

Presidential Research Award - National Research council, Colombo
2019, 2018, 2016, 2013, 2012, 2010, 2006, 2001

Vice Chancellors Award for the most outstanding researcher in Medicine 2010, 2014
Top ten researchers in University of Kelaniya 2017,2018, 2019, 2020,2021

Poster of distinction APSL 2011

Oral free paper prize for Best presentation in the Spotlight Session on Risk factors for non-acoholic fatty liver disease at **UEG Week Vienna – October 2016**

Kumaradas Rajasuriya Prize for the Best Paper in Tropical Medicine 2016 Sri Lanka Medical Association Annual Sessions, Colombo 2016

S E Seneviratna Prize for research paper 2016 Sri Lanka Medical Association Annual Sessions, Colombo 2016

Wijerama Award for best research paper 2010, Sri Lanka Medical Association Annual Sessions, Colombo 2010

Wijerama Award for best research paper 2014, Sri Lanka Medical Association Annual Sessions, Colombo 2014

Professor Rajasuriya Prize for research paper 2010, Sri Lanka Medical Association Annual Sessions, Colombo 2010

Professor Rajasuriya Prize for research paper 2000, Sri Lanka Medical Association Annual Sessions, Colombo 2000

Rajasuriya Oration Medal, Ceylon College of Physicians 2012

EV Peiris Oration Medal, Ceylon College of Physicians 2009

Sir Markus Fernando Oration Medal, Sri Lanka Medical Association 2008

Sir Markus Fernando Oration Medal, Sri Lanka Medical Association 2003

Poster of Distinction DDW 2002

National Science Foundation Research Grant (2004)

University of Kelaniya Research Grant (2008)

MEMBERSHIP AND APPOINTMENTS IN SOCIETIES, COUNCILS, REVIEW BOARDS & OTHER BODIES

Ceylon college of Physicians – Council Member (2002-2004)

Student Councilor University of Kelaniya 2006- to date

Sri Lanka University Games Medical Sub Committee member 2007

Life Member: Sri Lanka Medical Association

Member of Oxford Society

Member of Green College (Oxford) Alumni 2001 to date

North Colombo Medical College Alumini Asscociation 1993 to date

Gastroenterological and Digestive Endoscopy Society of Sri Lanka: Secretary (2003-2007)

Gastroenterological and Digestive Endoscopy Society of Sri Lanka Council Member 2008 to date

Member of the American Gastroenterology Association (AGA) 2010-

Member of the Board of Study in Dermatology Post Graduate Institute of Medicine 2009

Committee Member of the Sri Lanka Sports Ministry Disciplinary Enquires Board (2007) Reviewer Journal of Neuro gastroenterology, Scandianvian Journal of Gastroenterology 2010, Hepatology International 2007 to date

Committee Member for preparation of National Clinical practice Guide lines for Gastroenterology and Hepatology 2007 – to date

Committee member for preparation code of conduct /of University Teachers University of Kelaniya 2008

Hon Consultant Physician Sports Ministry 2007- to date

Member of Board of Directors Consumer Affairs Authority, Ministry of Trade, Marketing Development Co-operatives and Consumer Services, Sri Lanka. 2007 to 2010

Honorary Consultant Physician and Gastroenterologist – Sri Lanka Police Hospital 2007 to date

Senior Superintendent of Police Reserve Police Force Sri Lanka 2007 to date

Member of the Council, National Institute of Education Sri Lanka 2011

Director General of Sports Medicine Sri Lanka 2011 to 2013

Chairman of Sri Lanka Anti-Doping Agency (SLADA) **2011 September to date**

Team physician London Olympics 2012

Medical Advisory panel of Sri Lanka Cricket 2015 to date

PROFESSIONAL EXPERINCE

2021: Chairman Sri Lanka cricket management committee

2016 to 2019: Chairman SARADO (south Asian regional anti-doping organization

Asian games Incheon – 2014 – Team Physician

August 2013 to August 2016: **Head of Department of Faculty of Medicine University of Kelaniya**

Nov 2011 to 2013:	**Director General** Institute of Sports Medicine Sri Lanka,
2019- to date :	**Senior Professor in Medicine**
Sep 2009- 2019:	**Professor in Medicine**, Faculty of Medicine, University of Kelaniya
July 2004 to Sep 2009:	**Senior Lecturer in Medicine**, Faculty of Medicine, University of Kelaniya
July 2004 to 2011:	**Clinical Co-ordinator**, Faculty of Medicine, University of Kelaniya
Nov 2002-June 2004:	**Consultant Physician** (Resident Physician) National Hospital (NHSL) Colombo
29 April -30 October 2002:	**Consultant Physician** GH Ampara
Oct 2000-March 2002:	**Registrar & Research Fellow** in Gastroenterology at Radcliffe Infirmary Oxford, UK. (Supervisor Prof D.P. Jewell, Professor of Gastroenterology and Consultant Gastroenterologist).

Oct 1999-Oct 2000:	**Senior Registrar in General Medicine**. National Hospital Colombo. (Supervisor Dr W.K.Balasuriya MD, FRCP, FCCP, Consultant Physician.)
Jan 1997- June 1999:	**Registrar in Medicine.** Colombo North Teaching Hospital. Department of General Medicine and Gastroenterology. (Supervisor Prof H.J.De Silva MD,FRCP,DPhil(Oxon).
Rotational appointments in specialized units	
	* Cardiology unit (NHSL) * Neurology unit (NHSL) * Respiratory Medicine unit (NHSL) * Rheumatology unit (NHSL) * Dermatology unit (NHSL)
1995-1996	**Senior House Officer in Psychiatry**, Colombo North Teaching Hospital (Supervisor Dr N. Fernando MD, Consultant Psychiatrist)
April 1994-April 1995	**Intern Medical Officer**, General Hospital Kalutara. Surgery (Supervisor Dr R Badurdeen, FRCS, Consutant Surgeon. Paediatrics (Supervisor Dr. A.T.W. Guneratne, MD, FRCP, Consultant Paediatrition.
Aug 1993- April 1994	**Demonstrator in Physiology**, Faculty of Medicine, University of Ragama.

Experience in Teaching, Examining and Supervision

Teaching:

Undergraduate: Medicine, Theraputics, Clinical Physiology, History of Medicine to medical students of the Faculties of Medicine **University of Kelaniya.**
Supervisor on research projects.
BSc Speech and Language therapy students

Post Graduate: Post graduate lectures for MD

Supervision:

Under graduate: Clinical medicine,

Post graduate: MD General Medicine
MD Gastroenterology
PhD 1 Rear Admiral Shamal Fernando
Msc 3

Examining:

Undergraduate: MBBS examiner to the Faculty of Medcine, Kelaniya, Colombo, Ruhuna,Sri Jayewardenapura , Peradeniya.
Examiner in the Act 16 Examination for Medical graduates with foreign qualifications conducted by Sri Lanka Medical Council.

Postgraduate: Clinical coordinator MD part II examination 2003, 2004
Examiner MD part I OSCE November 4. 2008
MD Part II VIVA 2014
MD Part II 2015, 2016, 2017
MRCP Paces Examiner 2016

Orations, Guest Lectures National and International Meetings & Events

1. **Ceylon College of Physicians**: Young Physicians Lecture "The Management of acute upper gastrointestinal haemorrhage" Colombo Feb2000

2. **Ceylon College of Physicians**: Recent Advances in Inflammatory Bowel Disease. Colombo 2002

3. **Sir Markus Fernando Oration**: From bench to bedside –The role of TNF-α polymorphisms in inflammatory bowel disease **Sri Lanka Medical Association** Colombo 2003

4. **International Inflammatory Bowel Disease** (IBD) conference: Colombo Feb 2005

5. **Sri Lanka College of Haematologists**: Aneamea in Liver Disease. Colombo August 2006

6. **College of General Practitioners of Sri Lanka**: GORD. Colombo October 2007

7. **United Nation Development Programme (UNDP)** : Lecture on Child abuse . Embilipitiya. June 2008

8. **Sir Markus Fernando Oration**: Colitis in Sri Lanka – From microscopic to macroscopic . **Sri Lanka Medical Association**. Colombo Nov 2008

9. The first conference on Endobolism 2011 Xiemen China

10. IBD in Asia. Ceylon Collage of Physicians annual academic sessions 2014. 5th to 8th October 2014

11. 5th World Congress of Science and Medicine in Cricket March 2015

12. Ceylon College of Physicians, Specialty update programme 2014

Resource Person in Seminars and Workshops

Main Organizer MD part 1 MCQ course Ceylon College of Physicians 2004, 2005

Main Organiser , International IBD conference , **Gastroenterological and Digestive Endoscopy Society of Sri Lanka.** February 2006.

Annual Meeting of Clinical Teachers -Medical Education Centre, Faculty of Medicine, University of Kelaniya. March 2006

Sri Lanka Medical Association 39th Annual Academic Sessions : Symposium-Gastroenterology – Chairperson. Colombo, September 2006

Development of Best Practice guidelines in Histopathology reporting Consensus Meeting, College of Pathologists Sri Lanka, January 2007

International conference on gastrointestinal pathology "ICON_GI 2007" September 2007

Resource person Ceylon College of Physicians MCQ course for MD part I 2008 May 2008

Ceylon College of Physicians and Galle Medical Association Joint Sessions August 2008 Guide lines on management of Hepatic encephalopathy

Resource person Kandy Society of Medicine Annual Academic Session February 2009. "Anaemia of gastrointestinal origin in the elderly"

Resource person Ceylon College of Pathologist Annual Academic Sessions 2010. "The Management of IBD"

Research & Publications

Publications in Refereed Journals

1. Effects of probiotics combined with dietary and lifestyle modification on clinical, biochemical, and radiological parameters in obese children with nonalcoholic fatty liver disease/nonalcoholic steatohepatitis: a randomized clinical trial.
   Rodrigo T, Dulani S, Nimali Seneviratne S, **De Silva AP**, Fernando J, De Silva HJ, Jayasekera, Wickramasinghe VP.Clin Exp Pediatr. 2022 Jun;65(6):304-311. doi: 10.3345/cep.2021.00787. Epub 2021 Nov 11.PMID: 34773939

2. The association between steatosis and liver damage in transfusion-dependent beta thalassaemia patients.
   Padeniya P, Ediriweera D, **De Silva AP**, Niriella M, Premawardhena A.Br J Haematol. 2022 Oct 4. doi: 10.1111/bjh.18492.

3. Multiple imputation approaches for handling incomplete three-level data with time-varying cluster-memberships.
   Wijesuriya R, Moreno-Betancur M, Carlin J, **De Silva AP**, Lee KJ.Stat Med. 2022 Sep 30;41(22):4385-4402. doi: 10.1002/sim.9515. Epub 2022 Jul 27.PMID: 35893317

4. Alcohol availability and prevalent Chlamydia trachomatis in young Australians: a multi-level analysis.
   Bingham AL, **De Silva AP**, Vaisey AM, Temple-Smith MJ, Spark SY, Hocking JS.Sex Health. 2022 Jan;18(6):460-465. doi: 10.1071/SH21098.PMID: 34844665

5. Postdischarge outcomes of COVID-19 patients from South Asia: a prospective study.
   Abeysuriya V, Seneviratne SL, **De Silva AP**, Mowjood R, Mowjood S, de Silva T, de Mel P, de Mel C, Wijesinha RS, Fernando A, de Mel S, Chandrasena L.Trans R Soc Trop Med Hyg. 2022 Apr 28:trac039. doi: 10.1093/trstmh/trac039. Online ahead of print.PMID: 35483750

6. Taming Tris(bipyridine)ruthenium(II) and Its Reactions in Water by Capture/Release with Shape-Switchable Symmetry-Matched Cyclophanes.

Yao C, Lin H, Daly B, Xu Y, Singh W, Gunaratne HQN, Browne WR, Bell SEJ, Nockemann P, Huang M, Kavanagh P, **de Silva AP.**J Am Chem Soc. 2022 Mar 23;144(11):4977-4988. doi: 10.1021/jacs.1c13028. Epub 2022 Mar 11.PMID: 35274938 .

7. Chronic nausea and vomiting: a diagnostic approach.
Niriella MA, Jayasena H, Withanage M, Devanarayana NM, **De Silva AP.**Expert Rev Gastroenterol Hepatol. 2022 Apr;16(4):311-320. doi: 10.1080/17474124.2022.2056016. Epub 2022 Mar 22.PMID: 35303783 Review

8. An analytical cross-sectional study to describe the mental health status of doctors in three selected tertiary care hospitals and medical undergraduates, Colombo, Sri Lanka during the first wave of COVID-19 pandemic.
Gallhenage J, Perera I, Rupasinghe P, **De Silva AP**, Suraweera C.Asian J Psychiatr. 2022 Jan;67:102945. doi: 10.1016/j.ajp.2021.102945. Epub 2021 Nov 26.PMID: 34879322

9. Multiple molecular logic gate arrays in one system of (2-(2'-pyridyl)imidazole)Ru(ii) complexes and trimeric cyclophanes in water.
Yao CY, Lin HY, Morgenfurt P, Keyes TE, **de Silva AP.**Chem Sci. 2022 Aug 26;13(36):10856-10867. doi: 10.1039/d2sc03617g. eCollection 2022 Sep 21.PMID:

10. Combination of cycle threshold time, absolute lymphocyte count and neutrophil:lymphocyte ratio is predictive of hypoxia in patients with SARS-CoV-2 infection.
Abeysuriya V, Seneviratne SL, **de Silva AP**, Mowjood R, Mowjood S, de Silva T, de Mel P, de Mel C, Chandrasena L, Wijesinha RS, Fernando A, de Mel S.Trans R Soc Trop Med Hyg. 2022 Jul 6;116(7):628-635. doi: 10.1093/trstmh/trab182.PMID: 34894631

11. Emerging inflammatory bowel disease demographics, phenotype, and treatment in South Asia, South-East Asia, and Middle East: Preliminary findings from the Inflammatory Bowel Disease-Emerging Nations' Consortium.
Banerjee R, Pal P, Hilmi I, Ghoshal UC, Desai DC, Rahman MM, Dutta U, Mohiuddin SA, Al Mohannadi M, Philip M, Ramesh GN, Niriella MA, **De Silva AP**, de Silva HJ, Pisespongsa P, Limsrivilai J, Aniwan S, Nawarathne M, Fernandopulle N, Aye TT, Ni N, Al Awadhi S, Joshi N, Ngoc PTV, Kieu TV, Nguyen AD, Abdullah M, Ali E, Zeid A, Sollano JD, Saberi B, Omar M, Mohsin MN, Aftab H, Wai TM, Shastri YM, Chaudhuri S, Ahmed F, Bhatia SJ, Travis SPL; Inflammatory Bowel Disease-Emerging Nations' Consortium (IBD-ENC) study group.J Gastroenterol Hepatol. 2022 Jun;37(6):1004-1015. doi: 10.1111/jgh.15801. Epub 2022 Mar 17.PMID: 35178742

12. Letter to the Editor: On the Proposed Definition of Metabolic-Associated Fatty Liver Disease.
Niriella MA, **De Silva AP**, de Silva HJ.Clin Gastroenterol Hepatol. 2022 May;20 (5):1186. doi: 10.1016/j.cgh.2021.05.019. Epub 2021 May 14.PMID: 34000380 No abstract available.

13. Dengue and leptospirosis infection during the coronavirus 2019 outbreak in Sri Lanka.
Niriella MA, Ediriweera DS, **De Silva AP**, Premaratlna BHR, Jayasinghe S, de Silva HJ.Trans R Soc Trop Med Hyg. 2021 Sep 3;115(9):944-946. doi: 10.1093/trstmh/trab058.PMID: 33823550

14. Short-term Oral Steroids Significantly Improves Chronic Rhinosinusitis Without Nasal Polyps.
De Silva AP, Schembri MA, Sarah AH, Chao J, Yip KH, Cildir G, Lopez A, Tumes DJ, Pant H.Laryngoscope. 2021 Oct;131(10):E2618-E2626. doi: 10.1002/lary.29495. Epub 2021 Mar 4.PMID: 33660850

15. Fluorescent Molecular Logic Gates Driven by Temperature and by Protons in Solution and on Solid.
West MES, Yao CY, Melaugh G, Kawamoto K, Uchiyama S, **de Silva AP.**Chemistry. 2021 Sep 15;27(52):13268-13274. doi: 10.1002/chem.202101892. Epub 2021 Aug 1.PMID: 34233035

18. Outcomes of NAFLD and MAFLD: Results from a community-based, prospective cohort study.
Niriella MA, Ediriweera DS, Kasturiratne A, De Silva ST, Dassanayaka AS, **De Silva AP**, Kato N, Pathmeswaran A, Wickramasinghe AR, de Silva HJ.PLoS One. 2021 Feb 3;16(2):e0245762. doi: 10.1371/journal.pone.0245762. eCollection 2021.PMID: 33534815

19. A Colorimetric Method for Quantifying Cis and Trans Alkenes Using an Indicator Displacement Assay.
Valenzuela SA, Crory HSN, Yao CY, Howard JR, Saucedo G, **de Silva AP**, Anslyn EV.Angew Chem Int Ed Engl. 2021 Jun 14;60(25):13819-13823. doi: 10.1002/anie.202101004. Epub 2021 May 13.PMID: 33723888

20. Evaluation of approaches for accommodating interactions and non-linear terms in multiple imputation of incomplete three-level data.
Wijesuriya R, Moreno-Betancur M, Carlin JB, **De Silva AP**, Lee KJ.Biom J. 2021 Dec 16. doi: 10.1002/bimj.202000343. Online ahead of print.PMID: 34914127

21. Sugammadex, neostigmine and postoperative pulmonary complications: an international randomised feasibility and pilot trial.
Leslie K, Chan MTV, Darvall JN, **De Silva AP**, Braat S, Devlin NJ, Peyton PJ, Radnor J, Lam CKM, Sidiropoulos S, Story DA.Pilot Feasibility Stud. 2021 Nov 9;7(1):200. doi: 10.1186/s40814-021-00942-9.PMID: 34753515

22. The clinical utility of accurate NAFLD ultrasound grading: Results from a community-based, prospective cohort study.
Niriella MA, Ediriweera DS, Kasturiratne A, Gunasekara D, De Silva ST, Dassanayaka AS, **De Silva AP**, Kato N, Pathmeswaran A, Wickramasinghe AR, de Silva HJ.Eur J Radiol. 2021 Mar;136:109516. doi: 10.1016/j.ejrad.2020.109516. Epub 2021 Jan 2.PMID: 33421884

23. Volatile anaesthesia and peri-operative outcomes related to cancer: a feasibility and pilot study for a large randomised control trial.
Dubowitz JA, Cata JP, **De Silva AP**, Braat S, Shan D, Yee K, Hollande F, Martin O, Sloan EK, Riedel B; Global Onco-Anaesthesia Research Collaboration Group.Anaesthesia. 2021 Sep;76(9):1198-1206. doi: 10.1111/anae.15354. Epub 2021 Jan 13.PMID: 33440019 .

25. Changing phenotype, early clinical course and clinical predictors of inflammatory bowel disease in Sri Lanka: a retrospective, tertiary care-based, multi-centre study.
Niriella MA, Liyanage IK, Kodisinghe SK, **De Silva AP**, Jayatissa AVGAM, Navarathne NMM, Peiris RK, Kalubovila UP, Kumarasena SR, Jayasekara RW, de Silva HJ.BMC Gastroenterol. 2021 Feb 16;21(1):71. doi: 10.1186/s12876-021-01644-5.PMID: 33593289

26. Multiple imputation methods for handling missing values in longitudinal studies with sampling weights: Comparison of methods implemented in Stata.
De Silva AP, De Livera AM, Lee KJ, Moreno-Betancur M, Simpson JA.Biom J. 2021 Feb;63(2):354-371. doi: 10.1002/bimj.201900360. Epub 2020 Oct 25.PMID: 33103307

27. Masks in COVID-19: let's unmask the evidence.
De Silva AP, Niriella MA, de Silva HJ.Expert Rev Respir Med. 2021 Mar;15(3):293-299. doi: 10.1080/17476348.2021.1838277. Epub 2020 Nov 1.PMID: 33054448 Review.

28. 'Is there racism in academic medical publishing?'.
Niriella MA, **De Silva AP**, de Silva HJ, Jayasinghe S.BMJ Evid Based Med. 2021 Dec;26(6):e3. doi: 10.1136/bmjebm-2020-111487. Epub 2020 Jul 28.PMID: 32723765 No abstract available.

29. Fluorescent molecular logic gates based on photoinduced electron transfer (PET) driven by a combination of atomic and biomolecular inputs.
Wright GD, Yao CY, Moody TS, **de Silva AP.**Chem Commun (Camb). 2020 Jun 23;56(50):6838-6841. doi: 10.1039/d0cc00478b.PMID: 32432237

30. Metabolic syndrome, but not non-alcoholic fatty liver disease, increases 10-year mortality: A prospective, community-cohort study.
Niriella MA, Kasturiratne A, Beddage TU, Withanage SA, Goonatilleke DC, Abeysinghe CP, De Mel RT, Balapitiya TL, De Silva ST, Dassanayake AS, **De Silva AP**, Pathmeswaran A, Wickramasinghe AR, Kato N, de Silva HJ.Liver Int. 2020 Jan;40(1):101-106. doi: 10.1111/liv.14237. Epub 2019 Sep 25.PMID: 31472085

31. Patterns and predictors of mortality in a semi-urban population-based cohort in Sri Lanka: findings from the Ragama Health Study.
Kasturiratne A, Ediriweera DS, De Silva ST, Niriella MA, Thulani UB, Pathmeswaran A, Dassanayake AS, **De Silva AP**, Chackrewarthy S, Ranawaka U, Kato N, Wickremasinghe AR, de Silva HJ.BMJ Open. 2020 Sep 29;10(9):e038772. doi: 10.1136/bmjopen-2020-038772.PMID: 32994253

32. The impact of empirical hydrocortisone therapy on clinical outcomes in dengue fever: a retrospective chart review.
de Mel S, Thilakawardana BU, de Mel P, **de Silva AP**, de Mel C, Chandrasena L, Seneviratne SL, Abeysuriya V.Trans R Soc Trop Med Hyg. 2020 Aug 1;114(8):632-634. doi: 10.1093/trstmh/traa049.PMID: 32562423

33. COVID-19 and gastroenterology: clinical insights and recommendations for gastroenterology care providers.
Niriella MA, **De Silva AP**, Liyanage KI, Sarin SK, de Silva HJ.Scand J Gastroenterol. 2020 Aug;55(8):1005-1011. doi: 10.1080/00365521.2020.1789896. Epub 2020 Jul 10.PMID: 32650675 Review.

34. Clinical research during the COVID-19 pandemic: gastroenterology researchers' perspective.
Niriella MA, **De Silva AP**, de Silva HA, de Silva HJ.Frontline Gastroenterol. 2020 Jul 29;12(3):252-254. doi: 10.1136/flgastro-2020-101585. eCollection 2021.PMID: 33907620

35. Low-dose melatonin for sleep disturbances in early-stage cirrhosis: A randomized, placebo-controlled, cross-over trial.
De Silva AP, Niriella MA, Ediriweera DS, De Alwis JP, Liyanage IK, Ettickan U, Liyanapathirana KV, Undugodage C, de Silva HA, de Silva HJ.JGH Open. 2020 May 18;4(4):749-756. doi: 10.1002/jgh3.12356. eCollection 2020 Aug.PMID: 32782966

36. Hydroxychloroquine for post-exposure prophylaxis of COVID-19 among naval personnel in Sri Lanka: study protocol for a randomized, controlled trial.
Niriella MA, Ediriweera DS, **De Silva AP**, Premarathne R, Balasooriya P, Duminda KD, Malavige NG, Wanigasuriya K, Lekamwasam S, Kularathne SA, Siribaddana S, de Silva HJ, Jayasinghe S.Trials. 2020 Aug 27;21(1):748. doi: 10.1186/s13063-020-04659-7.PMID: 32854751

37. A Personal Journey across Fluorescent Sensing and Logic Associated with Polymers of Various Kinds.
Yao CY, Uchiyama S, **de Silva AP.**Polymers (Basel). 2019 Aug 14;11(8):1351. doi: 10.3390/polym11081351.PMID: 31416199 .

38. Fixed Low-Dose Triple Combination Antihypertensive Medication vs Usual Care for Blood Pressure Control in Patients With Mild to Moderate Hypertension in Sri Lanka: A Randomized Clinical Trial.
Webster R, Salam A, de Silva HA, Selak V, Stepien S, Rajapakse S, Amarasekara S, Amarasena N, Billot L, **de Silva AP**, Fernando M, Guggilla R, Jan S, Jayawardena J, Maulik PK, Mendis S, Mendis S, Munasinghe J, Naik N, Prabhakaran D, Ranasinghe G, Thom S, Tisserra N, Senaratne V, Wijekoon S, Wijeyasingam S, Rodgers A, Patel A; TRIUMPH Study Group.JAMA. 2018 Aug 14;320(6):566-579. doi: 10.1001/jama.2018.10359.PMID: 30120478

39. Acute Dermato-Lymphangio-Adenitis Following Administration of Infliximab for Crohn's Disease.
Liyanage IK, Niriella MA, **de Silva AP**, de Silva N, de Silva HJ.ACG Case Rep J. 2019 Jun 25;6(6):e00075. doi: 10.14309/crj.0000000000000075. eCollection 2019 Jun.PMID: 31616760

40. Performance of critical care prognostic scoring systems in low and middle-income countries: a systematic review.
Haniffa R, Isaam I, **De Silva AP**, Dondorp AM, De Keizer NF.Crit Care. 2018 Jan 26;22(1):18. doi: 10.1186/s13054-017-1930-8.PMID: 29373996 .

41. Precise Proton Mapping near Ionic Micellar Membranes with Fluorescent Photoinduced-Electron-Transfer Sensors.
Uchiyama S, Yano K, Fukatsu E, **de Silva AP.**Chemistry. 2019 Jun 26;25(36):8522-8527. doi: 10.1002/chem.201806270. Epub 2019 May 15.PMID: 30947361

42. A data platform to improve rabies prevention, Sri Lanka.
De Silva AP, Harischandra PL, Beane A, Rathnayaka S, Pimburage R, Wijesiriwardana W, Gamage D, Jayasinghe D, Sigera C, Gunasekara A, Cadre M, Amunugama S, Athapattu PL, Jayasinghe KSA, Dondorp AM, Haniffa R.Bull World Health Organ. 2017 Sep 1;95(9):646-651. doi: 10.2471/BLT.16.188060. Epub 2017 May 19.PMID: 28867845

45. Lighting-up protein-ligand interactions with fluorescent PET (photoinduced electron transfer) sensor designs.
McLaughlin B , Surender EM , Wright GD , Daly B , **de Silva AP** .Chem Commun (Camb). 2018 Feb 1;54(11):1319-1322. doi: 10.1039/c7cc05929a.PMID: 29210385

46. How native yeasts may influence the chemical profile of the Brazilian spirit, cachaça?
Portugal CB, **de Silva AP**, Bortoletto AM, Alcarde AR.Food Res Int. 2017 Jan;91:18-25. doi: 10.1016/j.foodres.2016.11.022. Epub 2016 Nov 22.PMID: 28290322

47. Experiences of ICU survivors in a low middle income country- a multicenter study.
Pieris L, Sigera PC, **De Silva AP**, Munasinghe S, Rashan A, Athapattu PL, Jayasinghe KSA, Samarasinghe K, Beane A, Dondorp AM, Haniffa R.BMC Anesthesiol. 2018 Mar 21;18(1):30. doi: 10.1186/s12871-018-0494-8.PMID: 29562877

48. Addressing the information deficit in global health: lessons from a digital acute care platform in Sri Lanka.
Beane A, **De Silva AP**, Athapattu PL, Jayasinghe S, Abayadeera AU, Wijerathne M, Udayanga I, Rathnayake S, Dondorp AM, Haniffa R.BMJ Glob Health. 2019 Jan 29;4(1):e001134. doi: 10.1136/bmjgh-2018-001134. eCollection 2019.PMID: 30775004

49. Multiple imputation methods for handling missing values in a longitudinal categorical variable with restrictions on transitions over time: a simulation study.
De Silva AP, Moreno-Betancur M, De Livera AM, Lee KJ, Simpson JA.BMC Med Res Methodol. 2019 Jan 10;19(1):14. doi: 10.1186/s12874-018-0653-0.PMID: 30630434

52. Non-resolution of non-alcoholic fatty liver disease (NAFLD) among urban, adult Sri Lankans in the general population: A prospective, cohort follow-up study.
Niriella MA, Kasturiratna A, Beddage T, Ediriweera DS, De Silva ST, Perera KR, Subasinghe CE, Kodisinghe SK, Piyaratna TC, Rishikesawan V, Dassanayaka AS, **De Silva AP**, Pathmeswaran A, Wickramasinghe AR, Kato N, Janaka de Silva H.PLoS One. 2019 Oct 29;14(10):e0224474. doi: 10.1371/journal.pone.0224474. eCollection 2019.PMID: 31661524

53. Fixed-combination, low-dose, triple-pill antihypertensive medication versus usual care in patients with mild-to-moderate hypertension in Sri Lanka: a within-trial and modelled economic evaluation of the TRIUMPH trial.
Lung T, Jan S, de Silva HA, Guggilla R, Maulik PK, Naik N, Patel A, **de Silva AP**, Rajapakse S, Ranasinghe G, Prabhakaran D, Rodgers A, Salam A, Selak V, Stepien S, Thom S, Webster R, Lea-Laba T; TRIUMPH Study Group.Lancet Glob Health. 2019 Oct;7(10):e1359-e1366. doi: 10.1016/S2214-109X(19)30343-2. Epub 2019 Aug 30.PMID: 31477545

54. Molecular memory with downstream logic processing exemplified by switchable and self-indicating guest capture and release.
Daly B, Moody TS, Huxley AJM, Yao C, Schazmann B, Alves-Areias A, Malone JF, Gunaratne HQN, Nockemann P, **de Silva AP.**Nat Commun. 2019 Jan 21;10(1):49. doi: 10.1038/s41467-018-07902-7.PMID: 30664631

55. Incidence and risk factors for metabolic syndrome among urban, adult Sri Lankans: a prospective, 7-year community cohort, follow-up study.
De Silva ST, Niriella MA, Ediriweera DS, Kottahachchi D, Kasturiratne A, **de Silva AP**, Dassanayaka AS, Pathmeswaran A, Wickramasinghe R, Kato N, de Silva HJ.Diabetol Metab Syndr. 2019 Aug 14;11:66. doi: 10.1186/s13098-019-0461-7. eCollection 2019.PMID: 31428204

56. The incidence, prevalence and trends of Chronic Kidney Disease and Chronic Kidney Disease of uncertain aetiology (CKDu) in the North Central Province of Sri Lanka: an analysis of 30,566 patients.

Ranasinghe AV, Kumara GWGP, Karunarathna RH, **De Silva AP**, Sachintani KGD, Gunawardena JMCN, Kumari SKCR, Sarjana MSF, Chandraguptha JS, De Silva MVC.BMC Nephrol. 2019 Aug 28;20(1):338. doi: 10.1186/s12882-019-1501-0.PMID: 31462219

57. Critical Care Junior Doctors' Profile in a Lower Middle-income Country: A National Cross-sectional Survey.
De Silva AP, Baranage DDS, Padeniya A, Sigera PC, De Alwis S, Abayadeera AU, Mahipala PG, Jayasinghe KS, Dondorp AM, Haniffa R.Indian J Crit Care Med. 2017 Nov;21(11):733-739. doi: 10.4103/ijccm.IJCCM_268_17.PMID: 29279633

58. Lean non-alcoholic fatty liver disease (lean NAFLD): characteristics, metabolic outcomes and risk factors from a 7-year prospective, community cohort study from Sri Lanka.
Niriella MA, Kasturiratne A, Pathmeswaran A, De Silva ST, Perera KR, Subasinghe SKCE, Kodisinghe SK, Piyaratna TACL, Vithiya K, Dassanayaka AS, **De Silva AP**, Wickramasinghe AR, Takeuchi F, Kato N, de Silva HJ.Hepatol Int. 2019 May;13(3):314-322. doi: 10.1007/s12072-018-9916-4. Epub 2018 Dec 11.PMID: 30539516

59. Traumatic brain injury (TBI) outcomes in an LMIC tertiary care centre and performance of trauma scores.
Samanamalee S, Sigera PC, **De Silva AP**, Thilakasiri K, Rashan A, Wadanambi S, Jayasinghe KSA, Dondorp AM, Haniffa R.BMC Anesthesiol. 2018 Jan 8;18(1):4. doi: 10.1186/s12871-017-0463-7.PMID: 29310574

60. Simplified prognostic model for critically ill patients in resource limited settings in South Asia.
Haniffa R, Mukaka M, Munasinghe SB, **De Silva AP**, Jayasinghe KSA, Beane A, de Keizer N, Dondorp AM.Crit Care. 2017 Oct 17;21(1):250. doi: 10.1186/s13054-017-1843-6.PMID: 29041985

61. Non-alcoholic fatty liver disease and its associations among adolescents in an urban, Sri Lankan community.
Rajindrajith S, Pathmeswaran A, Jayasinghe C, Kottahachchi D, Kasturiratne A, de Silva ST, Niriella MA, Dassanayake AS, **de Silva AP**, de Silva HJ.BMC Gastroenterol. 2017 Nov 29;17(1):135. doi: 10.1186/s12876-017-0677-7.PMID: 29187144

62. Evaluation of the feasibility and performance of early warning scores to identify patients at risk of adverse outcomes in a low-middle income country setting.
Beane A, **De Silva AP**, De Silva N, Sujeewa JA, Rathnayake RMD, Sigera PC, Athapattu PL, Mahipala PG, Rashan A, Munasinghe SB, Jayasinghe KSA, Dondorp AM, Haniffa R.BMJ Open. 2018 Apr 27;8(4):e019387. doi: 10.1136/bmjopen-2017-019387.PMID: 29703852

63. Association of the Quick Sequential (Sepsis-Related) Organ Failure Assessment (qSOFA) Score With Excess Hospital Mortality in Adults With Suspected Infection in Low- and Middle-Income Countries.
Rudd KE, Seymour CW, Aluisio AR, Augustin ME, Bagenda DS, Beane A, Byiringiro JC, Chang CH, Colas LN, Day NPJ, **De Silva AP**, Dondorp AM, Dünser MW, Faiz MA, Grant DS, Haniffa R, Van Hao N, Kennedy JN, Levine AC, Limmathurotsakul D, Mohanty S, Nosten F, Papali A, Patterson AJ, Schieffelin JS, Shaffer JG, Thuy DB, Thwaites CL, Urayeneza O, White NJ, West TE, Angus DC; Sepsis Assessment and Identification in Low Resource Settings

(SAILORS) Collaboration.JAMA. 2018 Jun 5;319(21):2202-2211. doi: 10.1001/jama.2018.6229.PMID: 29800114

64. Pre-event quality of life and its influence on the post-event quality of life among patients with ST elevation and non-ST elevation myocardial infarctions of a premier province of Sri Lanka. Mahesh PKB, Gunathunga MW, Jayasinghe S, Arnold SM, Haniffa R, **De Silva AP.**Health Qual Life Outcomes. 2017 Aug 1;15(1):154. doi: 10.1186/s12955-017-0730-9.PMID: 28764724

65. A comparison of multiple imputation methods for handling missing values in longitudinal data in the presence of a time-varying covariate with a non-linear association with time: a simulation study. **De Silva AP**, Moreno-Betancur M, De Livera AM, Lee KJ, Simpson JA.BMC Med Res Methodol. 2017 Jul 25;17(1):114. doi: 10.1186/s12874-017-0372-y.PMID: 28743256

66. Niriella MA, Kobbegala VJ, Karalliyadda HN, Ranawaka CK, **de Silva AP**, Dassanayake AS, de Silva HJ. Sero-prevalence and vaccination status of hepatitis A and hepatitis B among adults with cirrhosis in Sri Lanka: a hospital based cohort study. BMC Res Notes. 2017 Jul 21;10(1):303. doi: 10.1186/s13104-017-2634-5.

67. Gunathilaka ML, Niriella MA, Luke NV, Piyarathna CL, Siriwardena RC, **De Silva AP**, de Silva HJ. Possible gasoline-induced chronic liver injury due to occupational malpractice in a motor mechanic: a case report. J Med Case Rep. 2017 Jul 3;11(1):179. doi: 10.1186/s13256-017-1352-x.

68. Niriella MA, Pathmeswaran A, De Silva ST, Kasturiratna A, Perera R, Subasinghe CE, Kodisinghe K, Piyaratna C, Rishikesawan V, Dassanayaka AS, **De Silva AP**, Wickramasinghe R, Takeuchi F, Kato N, de Silva HJ. Incidence and risk factors for non-alcoholic fatty liver disease: A 7-year follow-up study among urban, adult Sri Lankans. Liver Int. 2017 May 19. doi: 10.1111/liv.13478. [Epub ahead of print]

69. Piyarathna T A, Niriella M A, **de Silva AP**, de Silva H J. Duodenal xanthelasmata Ceylon Med J. 2016 Dec 30;61(4):191. doi: 10.4038/cmj.v61i4.8389.

70. **De Silva AP**, Niriella MA, Nandamuni Y, Nanayakkara SD, Perera KR, Kodisinghe SK, Subasinghe KC, Pathmeswaran A, de Silva HJ. Effect of audio and visual distraction on patients undergoing colonoscopy: a randomized controlled study. Endosc Int Open. 2016 Nov;4(11):E1211-E1214. Epub 2016 Oct 20.

71. Niriella MA, Kodisinghe SK, **De Silva AP**, Hewavisenthi J, de Silva HJ. Intestinal tuberculosis masquerading as difficult to treat Crohn disease: a case report. BMC Res Notes. 2016 Aug 24;9(1):417. doi: 10.1186/s13104-016-2222-0.

72. Amarasiri DL[1], Pathmeswaran A, Dassanayake AS, **de Silva AP**, Adikari MD, Sanjeewa PA, Jayaratne A, de Silva HJ.
The prevalence of upper respiratory symptoms in a cohort of adults presenting with symptoms of gastro-oesophageal reflux disease. Ceylon Med J. 2016 Jun;61(2):63-7. doi: 10.4038/cmj.v61i2.8301.

73. Subasinghe SK, Nandamuni Y, Ranasinghe S, Niriella MA, Mithithinda JK, Dassanayake A, de Silva AP, de Silva HJ
Association between road accidents and low-grade hepatic encephalopathy among Sri Lankan drivers with cirrhosis: a prospective case control study. BMC Res Notes. 2016 Jun 13;9:303. doi: 10.1186/s13104-016-2106-3.

74. Kumarasena RS, Niriella MA, Ranawaka CK, Mithithinda JK, **de Silva AP**, Dassanayaka AS, de Silva HJ. Predicting acute liver failure in dengue infection. Ceylon Med J. 2016 Mar;61(1):35-6. doi: 10.4038/cmj.v61i1.8260

75. Kasturiratne A, Akiyama K, Niriella MA, Takeuchi F, Isono M, Dassanayake AS, **de Silva AP**, Wickremasinghe RA, Kato N, de Silva HJ. Association of genetic variants with non-alcoholic fatty liver disease in an urban Sri Lankan community. Liver Int. 2015 Feb;35(2):676-9. doi: 10.1111/liv.12624. Epub 2014 Jul 10.

76. Wijewantha H S, **de Silva A P**, Niriella M A, Wijesinghe N, Waraketiya P, Kumarasena R S, Dassanayake A S, **, Hewawisenthi J de S** , de Silva H J. Usefulness of Routine Terminal Ileoscopy and Biopsy during Colonoscopy in a Tropical Setting: A Retrospective Record-Based Study. Gastroenterology Research and Practice. 2014 (2014)

77. Kasturiratne A, Mufeena MN, Mettananda KC, Fernandopulle N, Rajindrajith S, Waraketiya PR, Weerasinghe SK, Ranaweera A, Hewavisenthi SJ, **de Silva AP**, de Silva HJ. Incidence of inflammatory bowel disease in Gampaha district: details of the Sri Lankan component of the Asia-Pacific Crohn's and Colitis Epidemiology Study. Ceylon Med J. 2014 Mar;59(1):16-8

78. Ranawaka CK, Mithithinda JK, Senanayake SM, de Alwis WR, Mufeena MN, Niriella MA, Dassanayake AS, **de Silva AP**, Pathmeswaran A, de Silva HJ. Validation of the Sinhala version of the Chronic Liver Disease Questionnaire (CLDQ) for assessment of health related quality of life among Sri Lankan cirrhotics. Ceylon Med J. 2013 Dec; 58(4):156-62

79. Senanayake SM[1], Fernandopulle AN, Niriella MA, Wijesinghe NT, Ranaweera A, Mufeena MN, Pathmeswaran A, Nawarathne NM, **de Silva AP**, de Silva HJ. The long-term outcomes of a cohort of Sri Lankan patients with ulcerative colitis: a retrospective study at twonational referral centers and review of literature. Clin Exp Gastroenterol. 2013 Sep 20;6:195-200. doi: 10.2147/CEG.S49202. eCollection 2013

80. Amarasiri WA[1], Pathmeswaran A, **de Silva AP**, Dassanayake AS, Ranasinha CD, de Silva HJ. Gastric motility following ingestion of a solid meal in a cohort of adult asthmatics. J Neurogastroenterol Motil. 2013 Jul;19(3):355-65. doi: 10.5056/jnm.2013.19.3.355. Epub 2013 Jul 8

81. Senanayake SM, Niriella MA, Weerasinghe SK, Kasturiratne A, de Alwis JP, de Silva AP, Dassanayake AS, de Silva HJ. Survival of patients with alcoholic and cryptogenic cirrhosis without liver transplantation: a single center retrospective study. BMC Res Notes. 2012 Dec 2;5:663

82. Amarasiri DL, Pathmeswaran A, Dassanayake AS, de Silva AP, Ranasinha CD, de Silva HJ. Esophageal motility, vagal function and gastroesophageal reflux in a cohort of adult asthmatics. BMC Gastroenterol. 2012 Oct 12;12:140

83. Kasturiratne A, Weerasinghe S, Dassanayake AS, Rajindrajith S, de Silva AP,Kato N, Wickremasinghe AR, de Silva HJ. Influence of non-alcoholic fatty liver disease on the development of diabetes mellitus. J Gastroenterol Hepatol. 2013;28:142-7.

84. De Silva AP, Nandasiri SD, Hewavisenthi J, Manamperi A, Ariyasinghe MP, Dassanayake AS, Jewell DP, de Silva HJ. Subclinical mucosal inflammation in diarrhea-predominant irritable bowel syndrome (IBS) in a tropical setting. Scand J Gastroenterol. 2012 Jun;47(6):619-24.

85. De Silva AP, Kumarasena RS, Perera Keragala SD, Kalubowila U, Niriella M,Dassanayake AS, Pathmeswaran A, de Silva HJ. The prone 12 o'clock position reduces ileal intubation time during colonoscopy compared to the left lateral 6 o'clock (standard) position. BMC Gastroenterol. 2011 Aug 4;11:89.

86. Dassanayake AS, Kasturiratne A, Niriella MA, Kalubovila U, Rajindrajith S, De Silva AP, Kato N, Wickremasinghe R, de Silva HJ. Prevalence of Acanthosis Nigricans in an urban population in Sri Lanka and its utility to detect metabolic syndrome. BMC Res Notes. 2011 Jan 28;4(1):25.

87. De Silva AP, Niriella MA, Perera H, Aryasingha S, Kalubovila U, Manchanayake J, Dassanayake AS, Devanarayana NM, Pathmeswaran A, De Silva HJ. Is a six hour fast after a rice meal sufficient before upper gastrointestinal endoscopy? Scand J Gastroenterol. 2010 Mar 24.

88. RS Kumarasena,M Nirella,U Kalubowilla, AP De Silva, AS Dassanayake,HJ de Silva Bleeding from oesophageal ulceration after variceal band ligation for primary prophylaxis for oesophageal varices. *Gut* accepted Sep 2010 ;59(11):1586.

89. R S Kumarasena, S M Senanayake, K Sivaraman, AP de Silva, A S Dassanayake, R Premaratna ,B Wijesiriwardena, H J de Silva.Intravenous N-acytelcystine in dengue associated acute liver failure.
Hepatol inter accepted 2010.

90. Niriella MA, De Silva AP, Dayaratne AH, Ariyasinghe MH, Navarathne MM, Peiris RS, Samarasekara DN, Satharasinghe RL, Rajindrajith S, Dassanayake AS, Wickramasinghe AR, de Silva HJ. Prevalence of inflammatory bowel disease in two districts of Sri Lanka: a hospital based survey. BMC Gastroenterol. 2010 Mar 19;10:32.

91. de Silva AP, Karunanayake AL, Dissanayaka TG, Dassanayake AS, Duminda HK, Pathmeswaran A, Wickramasinghe AR, de Silva HJ. Osteoporosis in adult Sri Lankan inflammatory bowel disease patients. World J Gastroenterol. 2009 Jul 28;15(28):3528-31.

92. Amarasiri LD, Pathmeswaran A, De Silva AP, Dassanayake AS, Ranasinha CD, De Silva J. Comparison of a composite symptom score assessing both symptom frequency and severity with a score that assesses frequency alone: a preliminary study to develop a practical symptom score to detect gastro-oesophageal reflux disease in a resource-poor setting. Eur J Gastroenterol Hepatol. 2009 May 30.

93. Dassanayake Anuradha S, Kasthuriratne Anuradhani, Rajindrajith Shaman, Kalubowila Udaya, Chakrawarthi Sureka, De Silva A P, Makaya Miyuki, Mizoue Tetsuya, Kato Norihiro, Wickremasinghe A Rajitha, de Silva H Janaka Prevalence and risk factors for non alcoholic liver disease (NAFLD) in adults in an urban Sri Lanakan population. J Gastroenterol Hepatol 2009

94. De Silva AP, Amarasiri L, Kottachichi M, Dassanayake A, De Silva HJ. A one hour fast for water and a six hour fast for solids provides good endoscopic vision and provides minimum patient discomfort. J Gastroenterol Hepatol 2009

95. Mettananda , de Silva AP, de Silva HJ
Acute systemic paraquat intoxication: survival without long term complications . **Ceylon Med J**. 2008; **53**:136-7.

96. de Silva HJ, de Silva NR, de Silva AP, Jewell DP.
Emergence of inflammatory bowel disease 'beyond the West': do prosperity and improved hygiene have a role? *Trans R Soc Trop Med Hyg* 2008;**102**:895-7.

97. de Silva AP, Aryasingha S, Dassanayake AS, Hevavisenthi J, Ratnasena BG, de Silva HJ. Ménétrier's disease treated with gastrectomy. **Ceylon Med J**. 2008 Mar;53(1):22-3.PMID: 18590266 [PubMed - in process]

98. de Silva AP, Kasturiratne A, Liyanage DL, Karunanayaka TK, de S Hewavisenthi SJ, Dassanayake AS, Farrell GC, de Silva HJ. Is past exposure to hepatitis A protective against progressive fibrosis in non-alcoholic fatty liver disease?
Liver Int. 2008 Jan;28(1):147-9. No abstract available.
PMID: 18173565 [PubMed - indexed for MEDLINE]

99. de Silva HJ, Dassanayake AS, Manamperi A, de Silva AP.
Treatment of lamivudine-resistant hepatitis B infection in post-renal transplant patients with adefovir dipivoxil: preliminary results.
Transplant Proc. 2006 Nov;38(9):3118-20.
PMID: 17112914 [PubMed - indexed for MEDLINE]

100. Armuzzi A, Ahmad T, Ling KL, de Silva A, Cullen S, van Heel D, Orchard TR, Welsh KI, Marshall SE, Jewell DP.
Genotype-phenotype analysis of the Crohn's disease susceptibility haplotype on chromosome 5q31.
Gut. 2003 Aug;52(8):1133-9.
PMID: 12865271 [PubMed - indexed for MEDLINE]

101. Ahmad T, Armuzzi A, Bunce M, Mulcahy-Hawes K, Marshall SE, Orchard TR, Crawshaw J, Large O, de Silva A, Cook JT, Barnardo M, Cullen S, Welsh KI, Jewell DP. The molecular classification of the clinical manifestations of Crohn's disease.
Gastroenterology. 2002 Apr;122(4):854-66. Erratum in: Gastroenterology. 2003 Jul;125(1):281.
PMID: 11910336 [PubMed - indexed for MEDLINE]

102. van Heel DA, Udalova IA, De Silva AP, McGovern DP, Kinouchi Y, Hull J, Lench NJ, Cardon LR, Carey AH, Jewell DP, Kwiatkowski D.
Inflammatory bowel disease is associated with a TNF polymorphism that affects an interaction between the OCT1 and NF(-kappa)B transcription factors.
Hum Mol Genet. 2002 May 15;11(11):1281-9.
PMID: 12019209 [PubMed - indexed for MEDLINE]

103. Ganeshwaran Y, Seneviratne SM, Jayamaha R, De Silva AP, Balasuriya WK.
Dengue fever associated with a haematoma of the rectus abdominis muscle.
Ceylon Med J. 2001 Sep;46(3):105-6. Review.
PMID: 11732298 [PubMed - indexed for MEDLINE]

104. Seneviratne SM, Ganeshwaran Y, Jayamaha R, De Silva AP, Balasuriya WK.
A man with thyrotoxicosis, lymphoma and thymic hyperplasia.
Ceylon Med J. 2001 Sep;46(3):102-3.
PMID: 11732296 [PubMed - indexed for MEDLINE]

105. Deen KI, de Silva AP, Jayakody M, de Silva HJ.
Saphenoperitoneal anastomosis for resistant ascites in patients with cirrhosis.
Am J Surg. 2001 Feb;181(2):145-8.
PMID: 11425056 [PubMed - indexed for MEDLINE]

106. de Silva AP, Seneviratne SL, Gunatilake SB, Fonseka M, Jayasekera R, de Silva HJ. A family with alkaptonuria showing quasidominant inheritance.
Ceylon Med J. 1999 Sep;44(3):130-2. No abstract available.
PMID: 10675999 [PubMed - indexed for MEDLINE]

107. Gunatilake SB, de Silva AP, Jayamanne SF, de Silva HJ.
Two cases of Creutzfeldt-Jakob disease.

Ceylon Med J. 1998 Dec;43(4):246-7. No abstract available.
PMID: 10355185 [PubMed - indexed for MEDLINE]

108. de Silva AP, Molagoda A, Fernando PL, de Silva HJ.
The young woman who could not stop vomiting.
Postgrad Med J. 1998 Nov;74(877):691-2. No abstract available.
PMID: 10197201 [PubMed - indexed for MEDLINE]

109. de Silva AP, Premaratne R, Gunatilake SB, Fonseka MM, de Silva HJ.
Red (wo)man syndrome.
Ceylon Med J. 1998 Mar;43(1):33. No abstract available.
PMID: 9624841 [PubMed - indexed for MEDLINE]

Presentations at Conferences, Meetings of Professional Associations and other forums* Published in Abstract Form

Abstracts:

1. De Silva AP, de Silva HJ, Fonseka C. Effect of music on blood pressure in healthy young men. **Proceedings of the Second International Medical Congress, University of Peradeniya** 1994;120.

2. De Silva AP, de Silva HJ. A study of malignancies operated on in surgical units of General Hospital Kalutara. **Proceedings of the Kandy Society of Medicine** 1995; 22-23.

3. De Silva AP, de Silva HJ. Analysis of histological compostion of solitary nodules of the thyroid in females. **Proceedings of the Kandy Society of Medicine** 1995; 20-22.

4. KI Deen, de Silva AP, Jayakody M, de Silva HJ. Saphenous vein – peritoneal shunts in treatment of resistant ascites. XIth world Congress of Gastroenterology, **Digestion 1998**; 59 (suppl 3):342-3

5. Deen KI, Jayakody M, De Silva AP, Bodhipakse S, de Silva HJ. Saphenoperitioneal shunting for treatment of resistant ascites. **Sri Lanka Medical Association**, 1998.

6. Pharmacogenetics of Infliximab in Crohn's Disease: The 5q31/ IBD5 Risk Haplotype Predicts Response. Arjuna P De Silva, Severine Vermeire, Tariq Ahmad, Armuzzi Alexandro, Koon Ling, Simon Travis, Susan Cullen. *Gastroenterology. DDW 2002* (Poster of distinction).

7. The genetic prediction of the clinical response to infliximab in Crohn's disease (CD): a role for polymorphisms in the TNFA and LTA genes?
A PlDe Silva, T Ahmad, S Vermeire, Armuzzi A, Ling K, Travis S, Welsh K, RutgeertsP, Jewell D. *Gut*2002. *BSG 2002*.

8. TNF gene promoter polymorphisms show significant associations with inflammatory bowel disease - a family based study. AP de Silva, DA

van Heel, NJ Lench, D McGovern, DP Jewell. *E J Gastro Hep* 2002. Oral presentation UEGW 2001.

9. A molecular classification of the clinical manifestations of Crohn's disease Tariq Ahmad, Alessandro Armuzzi, Mike Bunce, Kim Mulcahy-Hawes, Sara E Marshall, Timothy R Orchard, Jonathan Crawshaw, Oliver Lange, Arjuna De Silva, Julia T Cook, Martin Barnardo, Sue Cullen, Ken I Walsh, Derek P Jewell. *Gut* 2002. Oral presentation BSG 2002.

10. Inflammatory bowel disease is associated with a *TNF* polymorphism that affects an interaction between the OCT1 and NF-κB transcription factors. David A. van Heel, Irina A. Udalova, Arjuna P. De Silva, Dermot P. McGovern, Yoshitaka Kinouchi, Jeremy Hull, Nicholas J. Lench, Lon R. Cardon, Alisoun H. Carey, Derek P. Jewell, Dominic Kwiatkowski. *Gut* 2002. Oral presentation BSG.

11. No Association between NOD2(CARD 15) polymorphisms and susceptibility to, or progression of, primary sclerosing cholangitis. SN Cullen, T Ahmad, A Armuzzi, A De Silva, Li Jin Hong, RW Chapman, DP Jewell. *Gut* 2002. BSG 2002 poster.

12. Haplotype Analysis of Heat Shock Protein 70(HSP70) Single Nucleotide Polymorphisms(SNPs) in Susceptibility and Phenotype of inflammatory Bowel Disease (IBD). Armuzzi A, Ahmad T, Marshall S, Mulcahy-Hawes K, large O, Crawshaw J, Ling KL, De Silva AP, Bunce M, Welsh K, Jewell D. *Gut* 2002. BSG 2002 oral presention.

13. The IBD 5q31/IBD 5 risk haplotype determines perianal phenotype in Crohn's disease. Armuzzi A, Ahmad T, De Silva AP, Ling KL, Cullen SN, Van Heel D, Jewell D. *Gut* 2002. BSG oral presentation.

14. Inflammatory bowel disease is associated with a *TNF* polymorphism that affects an interaction between the OCT1 and NF-κB transcription factors. David A. van Heel, Irina A. Udalova, Arjuna P. De Silva, Dermot P. McGovern, Yoshitaka Kinouchi, Jeremy Hull, Nicholas J. Lench, Lon R. Cardon, Alisoun H. Carey, Derek P. Jewell, Dominic Kwiatkowski. *Gastroenterology* 2002. Oral presentation DDW 2002.

15. A molecular classification of the clinical manifestations of Crohn's disease Tariq Ahmad, Alessandro Armuzzi, Mike Bunce, Kim Mulcahy-Hawes, Sara E Marshall, Timothy R Orchard, Jonathan Crawshaw, Oliver Lange, Arjuna De Silva, Julia T Cook, Martin Barnardo, Sue Cullen, Ken I Walsh, Derek P Jewell. Oral presentation DDW 2002.

16. The IBD 5q31/IBD 5 risk haplotype determines perianal phenotype in Crohn's disease. Armuzzi A, Ahmad T, De Silva AP, Ling KL, Cullen SN, Van Heel D, Jewell D. ***Gastroenterology 2002***. DDW 2002 poster.

17. Haplotype Analysis of Heat Shock Protein 70(HSP70) Single Nucleotide Polymorphisms(SNPs) in Susceptibility and Phenotype of inflammatory Bowel Disease (IBD). Armuzzi A, Ahmad T, Marshall S, Mulcahy-Hawes K, large O, Crawshaw J, Ling KL, De Silva AP, Bunce M, Welsh K, Jewell D. *Gastroenterology 2002*. DDW 2002 poster.

18. Dassanayake AS, De Silva AP, De Silva HJ.Aetiology of cirrhosis in tertiary referral centre in Sri Lanka. **15th Asia Pacific Association for Study of the Liver, Liver International** 2005;37.

19. De Silva AP, Mettananda KCD, Dassanayake A, Aryasinghe S, Deen KI, de Silva HJ. Inflamatory bowel disease (IBD) in a tertiary referral centre in Si Lanka. **Sri Lanka Medical Association, Ceylon Medical Journal** 2005;50 (suppl 1): 24.

20. De Silva AP, Amarasiri WADL, Kottachchi DC, Dassanayake A, de Silva HJ,. One hour of fast for liquids prior to endoscopy is safe effective and results in minimum patient discomfort. **Digestive Disease Week, Amercian Gastroenterology Association**, Los Angeles, USA,2006.

21. De Silva AP, Amarasiri L, Kottahachchi DC, Dassanayake A, de Silva HJ. One hour fast for liquids prior to upper gastrointestinal endcscopy is safe, effective and results in minimum discomfort. **Sri Lanka Medical Association, Ceylon Medical Journal** 2006;51 (suppl 1):21

22. De Silva AP, Dassanayke AS, Hewavisenthi J, Liyanage DLMN, Dissanayake TGI, Duminda HKKT, de Silva HJ. Microscopic colitis not otherwise specified (NOS) in patients with diarrhoea predominant IBS in a tropical setting . **Digestive Disease Week, Amercian Gastroenterology Association**, Los Angeles, USA,2007.

23. De Silva AP, Karunanayake AL, Dissanayka TGI, Dassanayke AS, Duminda HKKT, Pathmeswaran A, de Silva HJ. Is osteoporosis more common among adult Sri Lankans with Inflammatory Bowel Disease (IBD)? **Sri Lanka Medical Association** 2008; 69. (oral presentation)

24. De Silva AP, Dassanayke AS, Hewavisenthi J, Liyanage DLMN, Dissanayake TGI, Duminda HKKT, de Silva HJ. Microscopic colitis not otherwise specified (NOS) in patients with diarrhoea predominant IBS in a tropical setting . **Sri Lanka Medical Association** 2008; 68.(oral presentation)

25. De Silva AP, Dassanayke AS, Hewavisenthi J, Liyanage DLMN, Dissanayake TGI, Duminda HKKT, de Silva HJ. Microscopic colitis not otherwise specified (NOS) in patients with diarrhoea predominant IBS in a tropical setting . **Sri Lanka Medical Association** 2008;(Pathology) (oral presentation) OP 50.

26. De Silva AP, Karunanayake AL, Dissanayka TGI, Dassanayke AS, Duminda HKKT, Pathmeswaran A, de Silva HJ. Is osteoporosis more common among adult Sri Lankans with Inflammatory Bowel Disease (IBD)? **Sri Lanka Medical Association** 2008; (Musculoskelettal Disorders) (oral presentation) OP 38.

27. Dassanayake AS, Rajindrajith S, Kasthuriratne A, Kalubowila U, De Silva AP, De Silva HJ. Epidemiology of non – alcoholic fatty liver disease (NAFLD) in an urban Sri Lankan population. . **Sri Lanka Medical Association** 2008. (Oral)

28. Anuradha S Dissanayake, Hiranthi Mendis, Arjuna P De Silva, Janaka H De Silva. Gastric Antral Vascular Ectasia (GAVE) in patients with cirrhosis. **Hepatology International** 2007, P-0968, 1:3-242;237.

29. Dassanayake AS, Rajindrajith S, Kasthuriratne A, Kalubowila U, De Silva AP, De Silva HJ. Epidemiology of non – alcoholic fatty liver disease (NAFLD) in an urban Sri Lankan population. **Diegstive Disease Week , Amercian Gastroenterology Association**, USA,2008.

30. A.P. De Silva, A.S. Dassanayake, A. Kasthuriratne, D.N. Liyanage, T.P. Karunanayake, S.J.Hewavisenthi, G.C. Farrell, H.J De Silva. Is Past Exposure to Hepatitis A Protective against Progressive Fibrosis in non Alcoholic Fatty Liver Disease (NAFLD)? **Hepatology International** 2008,PE 1368; 298

31. H Janaka De Silva, Anuradha Dissanayake, Arjuna P De Silva. Adefoir Dipivoxil In The Treatment Of Lamivudine –Resistant Hapatitis B Infection In Post Renal Transplant patients : Preliminary Results. **Journal of Gastroenterology and Hepatology** 2006;21: (pls check)

32. De Silva AP, Karunanayake AL, Dissanayka TGI, Dassanayke AS, Duminda HKKT, Pathmeswaran A, de Silva HJ. Osteoporosis among adult Sri Lankans with Inflammatory Bowel Disease (IBD) Gut 2008; 57 (Suppl II) A129.

33. AP De Silva, MA Niriella, NJAHD Perera, JVS Aryasingha, KVU Kalubowila, AS Dassanayake, A Pathmeswaran, HJ de Silva. Is a six hour fast after a rice meal sufficient before upper gastrointestinal endoscopy? 21st March 2009 – 122nd Annual Scientific Sessions,SLMA **Oral Presentation: OP 30**

34. MA Niriella, AS Dassanayake, KVU Kalubovila, S Rajindrajith, AP De Silva, AR Wickramasinghe, N Kato, M Makaya, HJ De Silva Are alanine transaminase (ALT) levels useful to screen for Non-alcoholic Fatty Liver Disease (NAFLD) in the community?" 21st March 2009 - 122nd Annual Scientific Sessions, SLMA **Oral Presentation: OP 34**

35. MA Niriella, AS Dassanayake, KVU Kalubovila, AP De Silva, AR Wickramasinghe, N Kato, M Makaya, HJ De Silva. IS ACANTHOSIS NIGRICANS A USEFUL CLINICAL SCREENING TEST FOR NON-ALCOHOLIC FATTY LIVER DISEASE (NAFLD) IN RESOURCE POOR SETTINGS?" *April 25th 2009 -* ***44th Annual Meeting of the EASL*** **Poster Presentation:** A-158-0030-**00353**

36. AP De Silva, MA Niriella, NJAHD Perera, JVS Aryasingha, KVU Kalubowila, AS Dassanayake, A Pathmeswaran, HJ de Silva. Is a six hour fast after a rice meal sufficient before upper gastrointestinal endoscopy? **DDW 2009** June 1

37. MA Niriella, AS Dassanayake, KVU Kalubovila, AP De Silva, AR Wickramasinghe, N Kato, M Makaya, HJ De Silva Alanine transaminase (ALT) levels in normal adult Sri Lankans" *2nd June 2009,* ***DDW 2009***

Poster Presentation: (585946)

38. A P De Silva, RS. Kumarasena, S P. Keragala, K V Udayapushpa, M.A. Niriella, A.S. Dassanayake, A Pathmeswaran, H.J. De Silva. The Prone 12 O'Clock Position Reduces Illeal Intubation Time During Colonoscopy Compared to the Left Lateral 6 O' Clock (Standard) Position. ***DDW 2010*** Poster Presentation:

39. A P De Silva, Aresha Manamperi, Shivanthi J Hewavisenthi, Madurangi P ariyasinghe, A.S. Dassanayake, Derek P Jewell, H.J. De Silva. Sub Clinical Intestinal Mucosal Inflammation Diarrhea Predominant Irritable Bowel Syndrome (IBS) is a Tropical Setting. ***DDW 2010*** Poster Presentation

40. L Amarasiri, A Pathmeswaran, C D Ranasinghe, A P De Silva, A.S. Dassanayake, HJ De Silva. Peristaltic Dysfunction in Asthma is Secondary to Increased Gastro-Oesophageal Reflux. ***DDW 2010***.

41. AP De Silva, Keragala BSBD, Kasthurirathna A, Kumarasena RS, Dassanayake AS, Premaratne R, Dassanayake KMNP, De Silva HJ.
The Utility of ALT: AST ratio as an early screening test for dengue fever.
123rd Annual Scientific sessions SLMA 2010. oP

42. AP De Silva, Kumarasena RS, Keragala BSDP, Kalubowila KUV, Niriella MA, Dassanayake AS, Pathmeswaran A, De Silva HJ.The Prone 12 O'Clock position reduces ileal intubation time during colonoscopy compared to the left lateral 6 O' Clock (Standard position.). 123rd Annual Scientific sessions SLMA 2010. oP

43. De Silva AP, Mannamperi A, Ariyasinghe MP, Nandasiri ASD, Hewavisenthi J, Dassanayake AS, Jewell DP, De Silva HJ .Subclinical intestinal mucosal inflamantion in diarrhea predominant irritable bowel syndrome in a tropical setting. 123rd Annual Scientific sessions SLMA 2010. oP

44. Kumarasena RS, De Silva AP, Keragala BSBD, Premarathna BAHR, Thilakaratne PMYI. Premawardena AP, De Silva ST, Jayamanne SF, De Silva HJ.Liver Syfunction and its outcome in patients with dengue infection.123rd Annual Scientific sessions SLMA 2010. oP

45. Kumarasena RS, Senayanake SM, De Silva AP, Biyanwala C, Dassanayake As, Premaratne R, Wijesiriwardena B, De Silva HJ.Intravenous N-aceylcysteine in acute liver failure associcated with dengue infection. 123rd Annual Scientific sessions SLMA 2010. oP

46. Senanayake SM, Hewawasam SP, Kumaraena RS, Kasturiratne A, De Alwis JPN, Nandasisri ASD, Dassanayake AS, De Silva AP, De Silva HJ.Comparison of outcomes with patients with alcoholic cirrhosis and non alcoholic steatohepatistis (NASH) related cirrhosis. 123rd Annual Scientific sessions SLMA 2010. oP

47. Premarathna R, Jayasinghe KGNU, Liyanaarchchi EW, Weerasinghe OMS, Pathmeswaran A, Williams HSA, De Silva ST, De Silva AP, De Silva HJ.

Effect of single dose methyl prednisolone in severe illness associated with dengue fever. 123rd Annual Scientific sessions SLMA 2010. oP

48. Prevalence and risk factors for non-alcoholic fatty liver disease among adults in an urban Sri Lankan population
Anuradha S Dassanayake · Anuradhani Kasturiratne · Shaman Rajindrajith · Udaya Kalubowila · Sureka Chakrawarthi · Arjuna P De Silva · Miyuki Makaya · Tetsuya Mizoue · Norihiro Kato · A Rajitha Wickremasinghe · H Janaka de Silva - **Journal of Gastroenterology and Hepatology** 05/2009; 24(7):1284-8

49. Prevalence and risk factors for metabolic syndrome among aging adults in an urban Sri Lankan population
KATT Kasturiratna · MA Niriella · ST De SIlva · KR Perera · SKCE Subasinghe · SK Kodisinghe · TACL Piyaratna · K Vithiya · D Kottachchi · UK Ranawaka · C Jayasinghe · S Rajindrajith · AS Dassanayaka · AP De Silva · A Pathmeswaran · HJ de Silva
Annual Academic Sessions, Sri Lanka Medical Association, Colombo, Sri Lanka; 07/2015

50. Association between road accidents and minimal hepatic encephalopathy in cohort of Sri Lankan cirrhotic drivers
Asia Pacific Digestive Week; 01/2014

51. Recurrent vs. First Presentation with Acute Coronary Syndrome in a Tertiary Care Hospital
GMTR Bandara · VNRM Fonseka · DST Danansuriya · RLP Harshanie · K Thirumavalavan · G Premawansa · SMSB Samarakoon · AP De Silva · ST De Silva UK Ranawaka
Annual Academic Sessions, Sri Lanka Medical Association, Colombo, Sri Lanka; 07/2012

52. Pre-admission antiplatelet therapy in patients presenting with acute coronary Syndrome
DST Danansuriya · K Thirumavalan · G Pemawansa · S Samarakoon · AP De Silva · ST De Silva · UK Ranawaka
Annual Academic Sessions of the Sri Lanka Medical Association, Colombo, Sri Lanka; 06/2011

53. Delay in presentation and management of acute myocardial infarction in a tertiary referral centre
A P De Silva · R L P Harshanie · M L Harshini · S P K H M A T Gammulla · K Thirumavalan · G Pemawansa · S Samarakoon · S T De Silva · U K Ranawaka
Annual Academic Sessions of the Ceylon College of Physicians, Colombo, Sri Lanka; 09/2010

54. Acute Coronary Syndrome in a Teaching Hospital – One Year Analysis
Shamila Thivanshi De Silva · RLP Harshanie · ML Harshin · SPKHMAT Gammulla · K Thirumavalavan · G Premawansa · S Samarakoon · AP de Silva UK Ranawaka

Annual Academic Sessions of the Ceylon College of Physicians, Colombo, Sri Lanka; 09/2010

55. Comparison of body fat percentage of Sri Lankan National rugby players Based on their playing positions
122nd Annual scientific sessions SLMA 2009; 01/2009

56. Prevalence of eosinophilic oesophagitis among adult Sri Lankan patients with refractory upper gastrointestinal symptoms - a prospective study Arjuna P De Silva
122nd Annual Scientific sessions SLMA 2009; 01/2009

57. Prevalence and risk factors for non-alcoholic fatty liver disease among adults in an urban Sri Lankan population Anuradha S Dassanayake · Anuradhani Kasturiratne · Shaman Rajindrajith · Udaya bKalubowila · Sureka Chakrawarthi · Arjuna P De Silva · Miyuki Makaya · Tetsuya Mizoue · Norihiro Kato · A Rajitha Wickremasinghe · H Janaka de Silva - **Annual Academic Sessions, Sri Lanka Medical Association, Colombo, Sri Lanka;** 07/2015

58. Prevalence and risk factors for metabolic syndrome among aging adults in an urban Sri Lankan population KATT Kasturiratna · MA Niriella · ST De SIlva · KR Perera · SKCE Subasinghe · SK Kodisinghe · TACL Piyaratna · K Vithiya · D Kottachchi · UK Ranawaka · C Jayasinghe · S Rajindrajith · AS Dassanayaka · AP De Silva · A Pathmeswaran HJ de Silva

Annual Academic Sessions, Sri Lanka Medical Association, Colombo,

Sri Lanka; 07/2015

59. Recurrent vs. First Presentation with Acute Coronary Syndrome in a Tertiary Care Hospital GMTR Bandara · VNRM Fonseka · DST Danansuriya · RLP Harshanie · K Thirumavalavan · G Premawansa · SMSB Samarakoon · AP De Silva · ST De Silva UK Ranawaka **Annual Academic Sessions, Sri Lanka Medical Association, Colombo, Sri Lanka**; 07/2012

60. **The prevalence of cirrhosis in adult with evidence of immunity against Hepatitis A**
Kobbegala KGVJ[1], Karalliyadda HN[1], Niriella MA[1], Ranawaka CK[2], de Silva AP[1], Dassanayake AS[1], de Silva HJ[1]
OP - 001
Sri Lanka Medical Association (SLMA) 129th Annual Academic Sessions - July 2016

61. **Clinical predictors of poor disease outcome for IBD in Sri Lanka**

Niriella MA[1], Kodisinghe SK[2], Dinamithra NP[3], Rajapakshe N[1], Nanayakkara SD[1], Luke HPDP[1], Silva KTM[1], De Silva AP[1], Navarathne NMM[3], Jayasekara RW[4], de Silva HJ[1]

OP - 006

Sri Lanka Medical Association (SLMA) 129th Annual Academic Sessions - July 2016

62. **Incidence and predictors of metabolic syndrome in an urban, adult Sri Lankan population – a community cohort follow-up study**

    De Silva ST[1,2], Niriella MA[1,2], Kasturiratna A[1], D Kottahachchi[1], Ranawaka UK[1,2], Dassanayaka AS[1], de Silva AP[1,2], Pathmeswaran A[1], Wickramasinghe AR[1], Kato N[3], de Silva HJ[1,2]

    OP - 015

    Sri Lanka Medical Association (SLMA) 129th Annual Academic Sessions - July 2016

63. **Incidence and risk factors for non-alcoholic fatty liver disease in an urban, adult Sri Lankan population – a community cohort follow-up study**

    Niriella MA[1], KasturiratnaA[1], De Silva ST[1], Perera KR[2], Subasinghe SKCE[2], Kodisinghe SK[2], Piyaratna TACL[2], Vithiya K[2], Dassanayaka AS[1], De Silva AP[1], Pathmeswaran A[1], Kato N[3], de Silva HJ[1]
    OP - 018
    Sri Lanka Medical Association (SLMA) 129th Annual Academic Sessions - July 2016

64. **Anthropometric correlates of total body fat, visceral adiposity and cardio-metabolic health risk: a community cohort study of urban, adult Sri Lankans**

    Niriella MA[1], De Silva ST[1], Kasturiratna A[1], Kottachchi D[1], Ranawaka UK, Dassanayaka AS[1], De Silva AP[1], Pathmeswaran A[1], de Silva HJ[1]
    OP - 035
    Sri Lanka Medical Association (SLMA) 129th Annual Academic Sessions - July 2016

65. **Lean non-alcoholic fatty liver disease (Lean-NAFLD): characteristics and risk factors from a community cohort follow up study**

    Niriella MA[1], De Silva ST[1], Kasturiratna A[1], Perera KR[2], Subasinghe SKCE[2], Kodisinghe SK[2], Piyaratna TACL[2], Vithiya K[2], Dassanayaka AS[1], De Silva AP[1], Pathmeswaran A[1], Wickramasinghe AR[1], Kato N[3], de Silva HJ[1]
    Poster in spotlight (oral presentation) and Poster presentation – PP 1102
    United European Gastroenterology Week (UEGW) 2016, Vienna, Austria – October 2016

66. **Prevalence of irritable bowel syndrome in an urban adult Sri Lankan population**

    Rishikesavan V, Arjuna P De Silva, Mendis WAS, Ruston SM, Madunil A Niriella, Pathmes Pathmeswaran, Hithanadura Janaka de Silva

    PP - 043
    Sri Lanka Medical Association (SLMA) 129th Annual Academic Sessions - July 2016

67. **Lean non-alcoholic fatty liver disease (Lean-NAFLD): characteristics and risk factors from a community cohort follow up study**

    Niriella MA[1], De Silva ST[1], Kasturiratna A[1], Perera KR[2], Subasinghe SKCE[2], Kodisinghe SK[2], Piyaratna TACL[2], Vithiya K[2], Dassanayaka AS[1], De Silva AP[1], Pathmeswaran A[1], Wickramasinghe AR[1], Kato N[3], de Silva HJ[1]

PP - 047
Sri Lanka Medical Association (SLMA) 129th Annual Academic Sessions - July 2016

68. **Changing phenotype of IBD in Sri Lanka**
Niriella MA[1], Kodisinghe SK[2], Dinamithra NP[3], Rajapakshe N[1], Nanayakkara SD[1], Luke D[1], Silva KTM[1], De Silva AP[1], Navarathne NMM[3], Jayasekara RW[4], de Silva HJ[1]
PP - 054
Sri Lanka Medical Association (SLMA) 129th Annual Academic Sessions - July 2016

69. **Early clinical course of IBD in Sri Lanka**
Niriella MA[1], Kodisinghe SK[2], Dinamithra NP[3], Rajapakshe N[1], Nanayakkara SD[1], Luke HPDP[1], Silva KTM[1], De Silva AP[1], Navarathne NMM[3], Jayasekara RW[4], de Silva HJ[1]
PP - 054
Sri Lanka Medical Association (SLMA) 129th Annual Academic Sessions - July 2016

70. **Comparison of cryptogenic and hepatitis B related hepatocellular carcinoma**
Siriwardena RC[1], Niriella MA[1], Dassanayake AS[1], De Silva AP[1], Gunathilake B[1], Chok KSH [2], Lo CM [2], Chan SC[2], Fan ST [2],de Silva HJ [1]
PP - 096
Sri Lanka Medical Association (SLMA) 129th Annual Academic Sessions - July 2016

71. **Significance of pre-treatment serum alpha-fetoprotein in hepatocellular carcinoma of non-viral aetiology**
Siriwardena RC [1], Niriella MA [1], Dassanayake AS [1], De Silva AP [1], Gunathilake B [1], de Silva HJ
PP - 122
Sri Lanka Medical Association (SLMA) 129th Annual Academic Sessions - July 2016

72. Niriella MA, De Silva ST, Kasturiratna A, Kottachchi D, Ranasinghe RMAG, Dassanayaka AS, De Silva AP, Pathmeswaran A, Wickramasinghe AR, Kato N, de Silva HJ. **Lean-NAFLD is the strongest predictor of future obesity among urban adult Sri Lankans: results from a prospective, community cohort follow-up study**
United European Gastroenterology Week 2017, Barcelona, Spain; 10/2017

73. Niriella MA, Kodisinghe SK, De Silva AP, Rajapakshe N, Nanayakkara SD, Luke HPDP, Silva KTM, Navarathne NMM, Dissanayake VHW, Jayasekara RW, de Silva HJ. **Genetic associations of inflammatory bowel disease in Sri Lanka: a case-control study of phenotypes and selected genetic polymorphisms.**
United European Gastroenterology Week 2017, Barcelona, Spain; 10/2017

74. De Silva ST, Niriella MA Kasturiratna A, Kottahachchi D, Ranawaka UK, Dassanayaka AS, de Silva AP, Pathmeswaran A, Wickramasinghe AR, Kato N, de Silva HJ. **Incidence and predictors of metabolic syndrome among urban, adult Sri Lankans: a community cohort, 7-year follow-up study.**
European Association for the Study of Diabetes (EASD) 53rd Annual Meeting, Lisbon, Portugal – 09/2017

75. Niriella MA, De Silva ST, Kasturiratna A, Kottachchi D, Ranasinghe RMAG, Dassanayaka AS, De Silva AP, Pathmeswaran A, Wickramasinghe AR, Kato N, de Silva HJ. **Incidence, Prevalence and Demographic and Life Style Risk Factors for Obesity Among Urban, Adult Sri Lankans: A Community Cohort Follow-Up Study**
Sri Lanka Medical Association (SLMA) 130th Annual Academic Sessions; 07/2017 – OP27

76. Niriella MA, De Silva ST, Ediriweera DS, Kasturiratna A, Jayasinghe C, Rajindrajith S, De Silva AP, Pathmeswaran A, de Silva HJ. **Prevalence of obesity and its associations among adolescents: an urban community-based birth cohort.**
Sri Lanka Medical Association (SLMA) 130th Annual Academic Sessions; 07/2017 – OP36

77. Niriella MA, De Silva ST, Ediriweera DS, Kasturiratna A, Jayasinghe C, Rajindrajith S, De Silva AP, Pathmeswaran A, de Silva HJ. **Prevalence of obesity and its associations among adolescents: an urban community-based birth cohort.**
Sri Lanka Medical Association (SLMA) 130th Annual Academic Sessions; 07/2017 – OP36

78. Niriella MA, Kodisinghe SK, De Silva AP, Rajapakshe N, Nanayakkara SD, Luke HPDP, Silva KTM, Navarathne NMM, Dissanayake VHW, Jayasekara RW, de Silva HJ. **Changing Phenotype, Early Clinical Course And Clinical Predictors Of IBD In Sri Lanka: A Prospective, Multi-Center Descriptive Study.**
Sri Lanka Medical Association (SLMA) 130th Annual Academic Sessions; 07/2017 – OP50

79. Siriwardena HDRC, Niriella MA, Dassanayake AS, De Silva AP, Gunathilake B, Pathmeswaran A, de Silva HJ. **Clinical Predictors of Poor Outcomes in Hepatocellular Carcinoma of Non-Viral Aetiology.**
Sri Lanka Medical Association (SLMA) 130th Annual Academic Sessions; 07/2017 – OP45

80. Niriella MA, Kodisinghe SK, Dassanayake SUB, Rajapakshe N, Nanayakkara SD, Luke HPDP, Silva KTM, De Silva AP, Navarathne NMM, de Silva HJ. **Serious thiopurine adverse effects and discontinuation among IBD patients in Sri Lanka.**
Sri Lanka Medical Association (SLMA) 130th Annual Academic Sessions; 07/2017 – PP45

81. Niriella Madunil A, Siriwardana Rohan C, Dassanayake Anuradha, De Silva Arjuna, Gunathillake Bhagya, Pathmeswaran Arunasalam, de Silva Hithanadura J. **Clinical predictors of mortality in hepatocellular carcinoma of non-viral aetiology.** Digestive Diseases Week 2017, Chicago, Il, Unites States; 05/2017

82. Niriella MA, Udeshika AKMA, IK Liyanage, De Silva AP, De Silva HJ

Early hepatitis is the strongest risk factor for the development of sever Dengue infection: a points-based risk score to predict critical disease in Dengue fever
Asia-Pacific Digestive Week (APDW) 2018, 15-18, November, 2018, Seoul, South Korea (OE-0233)

83. Niriella MA, , De Silva ST, Kasturiratna A, Perera KR, Subasinghe SKCE, Kodisinghe SK, Piyaratna TACL, Vithiya K, Dassanayaka AS, De Silva AP, Pathmeswaran A, Wickramasinghe AR, Kato N, de Silva HJ

Alcoholic fatty liver disease among unsafe drinkers: a prospective, community cohort, 7-year follow-up study
Asia-Pacific Digestive Week (APDW) 2018, 15-18, November, 2018, Seoul, South Korea (OE-0236)

84. Withanachchi AD, Thalagala TAES, Liyanage IK, Dasanayake AS, De Silva AP, Gunathilake BM, Siriwardana RC, Niriella MA

Perioperative outcomes following establishment of deceased donor liver transplantation: a single center experience in Ragama, Sri Lanka

Asia-Pacific Digestive Week (APDW) 2018, 15-18, November, 2018, Seoul, South Korea (OE-0284)

85. Niriella MA, Kasturiratna KATT, De Silva ST, Ranasinghe A, Perera KR, Subasinghe SKCE, Kodisinghe SK, Piyaratna TACL, Vithiya K, Dassanayaka AS, De Silva AP, Pathmeswaran A, Wickramasinghe AR, Kato N, de Silva HJ

Non-resolution of non-alcoholic fatty liver disease (NAFLD) in urban, adult Sri Lankans: a prospective, community-based, 7-year follow-up study
The Liver Meeting [(of American Association for the Study of Liver Disease (AASLD)], 9-13 November, 2018, San Francisco, California, USA

86. Thalagala TAES, Withanachchi AD, Liyanage IK, De Silva AP, Niriella MA
Prevalence and correlates of colonic diverticular diseases in patients undergoing colonoscopy at a tertiary referral centre in Sri Lanka
131st Anniversary International Medical Congress (of SLAM), Colombo 27-29 July 2018 – OP044

87. Fernando PNJ, Pigera S, Rashani SAN, Fernando R, Weerasinghe DPP, Godakumbura KKDTD, Niriella MA, Jayawickreme S, De Silva AP

Do common "arishta" preparations manufactured in Sri Lanka contain Anabolic Androgenic Steroids (AAS), stimulants or ethanol?
131st Anniversary International Medical Congress (of SLAM), Colombo 27-29 July 2018 – PP108

88. Withanachchi AD, Thalagala TAES, Liyanage IK, Dasanayake AS, De Silva AP, Gunathilake BM, Siriwardana RC, Niriella MA

Perioperative outcome following establishment of deceased donor liver transplantation: A single centre experience in Ragama, Sri Lanka
131st Anniversary International Medical Congress (of SLAM), Colombo 27-29 July 2018 – PP153

Chapters published

1. New Developments in Endoscopy - **"Endoscopy - Innovative Uses and Emerging Technologies"**, Edited by Somchai Amornyotin, 09/2015: chapter New Developments in Endoscopy; , ISBN: 978-953-51-2172-5

2. Ileoscopy; How and Why to Do It - **Endoscopy of GI Tract**, Edited by Somchai Amornyotin, 03/2013: chapter Ileoscopy; How and Why to Do It; , ISBN: ISBN 978-953-51-1034-7

3. Evidence Based Guidelines for Preparation Before Upper Gastrointestinal Endoscopy (UGIE) - **Gastrointestinal Endoscopy**, 07/2011; , ISBN: 978-953 307-385-9

Books

1. **The role of TNF alpha polymorphisms in inflammatory bowel disease: TNF Polymorphims in IBD**
08/2010; VDM Verlag Dr. Müller., ISBN: ISBN-13: 978-3639258530

Creative work

Design of the new logo of the Medical Faculty,University of Kelaniya , Sri Lanka 2008

Extra-Curricular Activities

Rowing

- **Represented Sri Lanka, 1983-84**
- **Represented Colombo Rowing Club 1982**
- **Winner HMS Enterprise Trophy 1982**
- **Represented St Thomas's College 1981-83**
- **Captain 84**
- **Vice captain 83**
- **Secretary 82**

Karate Purple belt

Interests: Golf, Art, Dancing

Date: 28.02.2025 **Signature:** 

NIDA Clinical Trials Network

Certificate of Completion

is hereby granted to

Prof. Arjuna De Silva

to certify your completion of the six-hour required course on:

GOOD CLINICAL PRACTICE

MODULE:	STATUS:
Introduction	N/A
Institutional Review Boards	Passed
Informed Consent	Passed
Confidentiality & Privacy	Passed
Participant Safety & Adverse Events	Passed
Quality Assurance	Passed
The Research Protocol	Passed
Documentation & Record-Keeping	Passed
Research Misconduct	Passed
Roles & Responsibilities	Passed
Recruitment & Retention	Passed
Investigational New Drugs	Passed

Course Completion Date: 31 July 2024

CTN Expiration Date: 31 July 2027

Eve Jelstrom

Eve Jelstrom, Principal Investigator

NDAT CTN Clinical Coordinating Center

Good Clinical Practice, Version 5, effective 03-Mar-2017

This training has been funded in whole or in part with Federal funds from the National Institute on Drug Abuse, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN27201201000024C.