

## Effect of Sacha Inchi Oil on Human Blood Pressure and Lipid Profile: A Preliminary Study in Malaysia

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### ABSTRACT

This uncontrolled pre-post study aimed to assess changes in blood lipid profiles and blood pressure resulting from a 2-month consumption of Sacha Inchi Oil (SIO) (*Plukenetia volubilis*). Investigating the effects of SIO on Malaysians is essential for tailoring interventions to the local context, considering genetic, cultural, and dietary differences. A total of 13 adult participants, comprising 8 males and 5 females aged 35 to 74 years old, took part in this intervention study. Each participant was instructed to consume 2 softgels daily, with each softgel containing 530 mg of SIO. Blood lipid profiles and blood pressure were measured at baseline and at the end of the 2-month period, utilizing venipuncture for blood tests and a sphygmomanometer for blood pressure assessment. The results indicated a significant reduction in Systolic Blood Pressure (SBP) levels following SIO supplementation (2 softgels daily) ( $p < 0.05$ ). However, there were no notable improvements in Diastolic Blood Pressure (DBP), Total Cholesterol (TC), Low-Density Lipoprotein Cholesterol (LDL-C), High-Density Lipoprotein Cholesterol (HDL-C), and Triglycerides (TG) after the 2-month supplementation. In conclusion, the daily supplementation of 2 softgels of SIO (1,060 mg) for 2 months demonstrated a beneficial effect on blood pressure, particularly in reducing SBP. These findings serve as preliminary data for future research into the potential health benefits of SIO in the Malaysian population.

**Keywords:** blood lipid profile, blood pressure, sachu inchi oil

### INTRODUCTION

Sacha inchi (*Plukenetia volubilis*) is an indigenous plant of the Euphorbiaceae family, originates from the Peruvian rainforest and is cultivated at altitudes ranging from 200 to 2,000 meters above sea level, thriving within a temperature range of 10 to 37°C (Cárdenas *et al.* 2021; Kodahl & Sørensen 2021). Traditionally used by indigenous Peruvians for medicinal purposes, its leaves were employed to address rheumatoid issues (Chirinos *et al.* 2013) and as a remedy for burns (Lock *et al.* 2016). Recently, its nutritional value has garnered attention, particularly for its rich protein and lipid content, with seeds comprising approximately 25–30% protein and 35–60% lipids (Chirinos *et al.* 2013). Commercially cultivated primarily for its oil, Sacha inchi serves as a notable source of Polyunsaturated Fatty Acid (PUFA), Alpha Linolenic Acid (ALA), and Linoleic Acid

(LA), as well as monounsaturated fatty acids, particularly Oleic Acid (OA) (Cárdenas *et al.* 2021). The omega-6 to omega-3 ratio in Sacha Inchi Oil (SIO) approximates 1:1.3 (Carrillo *et al.* 2018), aligning closely with the recommended target ratio of 1:1 to 2:1 (Simopoulos 2002).

Recent evidence highlights the potential health benefits of SIO, including its ability to lower blood pressure and improve lipid profiles (Garmendia *et al.* 2011; Huamán Saavedra *et al.* 2012; Gonzales & Gonzales 2014). Studies suggest that ALA found in SIO possesses anti-inflammatory properties by inhibiting pro-inflammatory cytokines such as Interleukin (IL) and Tumor Necrosis Factor-Alpha (TNF- $\alpha$ ), and improving endothelial function (Erdinest *et al.* 2012; Zhao *et al.* 2004; Minami *et al.* 2017). Since endothelial dysfunction is a known marker for Cardiovascular Diseases (CVDs), enhancing endothelial function may help reduce the risk of CVDs (Barthelme *et al.* 2017).

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Most studies on SIO focus on its benefits for Non-communicable Diseases (NCDs), especially Cardiovascular Diseases (CVDs), predominantly in South America, particularly Peru. However, there's a lack of research on SIO's effects in Asia, notably in Malaysia. Understanding SIO's impact on Malaysians is crucial for tailoring interventions considering genetic, cultural, and dietary differences. This study aims to explore how these factors influence SIO's outcomes, recognizing genetic variations' role in nutrient metabolism (Al-Jardli & Elizabeth 2023). Examining SIO within the Malaysian diet can offer insights into integrating it into local cuisines and diets, hence promotes culturally acceptable and sustainable interventions.

A recent health and morbidity survey conducted in Malaysia revealed a high prevalence of NCDs such as hypercholesterolemia, hypertension, diabetes, and metabolic syndrome (WHO 2021). These NCDs are closely associated with abnormal lipid profiles and blood pressure, which can be exacerbated by physical inactivity and an unhealthy diet (WHO 2010). Therefore, nutrition interventions play a critical role in addressing issues related to abnormal blood lipid and blood pressure levels to reduce the risks of NCDs. Currently, there is a lack of research on nutritional interventions for these health challenges in Malaysia. To the best of our knowledge, this is the first nutritional epidemiological study investigating the health effects of SIO in Malaysia, aiming to bridge the research gap within the Asian population.

## METHODS

### Design, location, and time

A non-probability purposive sampling method was applied to select study participants. Recruitment of participants was carried out through 3-month advertisements within a local community by a nutraceutical manufacturer company, none were referred directly by a physician. The company advertised this study of two months SIO supplementation by distributing leaflets through social media including the company's website and Facebook. The target audience would typically include individuals who are interested in health and wellness, dietary supplements, and improving their overall well-being. Online advertising was considered to reduce

face-to-face contact and risks of COVID-19 infection during the COVID-19 pandemic. The leaflet consisted of information about the study objectives, inclusion and exclusion criteria, study period, benefits and risks of SIO supplementation, and contact number of the researcher.

This uncontrolled pre-post study utilized a quasi-experimental design, involving 8 male and 5 female adults aged 35 to 74 years old (n=13). To determine the minimum required sample size, findings from a previous study on the effects of SIO consumption were consulted (Garmendia *et al.* 2011). To detect an effect size of Cohen's  $d=1.73$  with 95% power ( $\alpha=0.01$ , two-tailed), a paired sample t-test calculation using G\*Power software (Faul *et al.* 2007) indicated that a minimum of 10 participants would be necessary. Therefore, considering an estimated dropout rate of 20%, a minimum of 12 participants was deemed appropriate. This intervention was conducted from January to March 2022 in Ipoh, Perak. Research approval was granted by the Human Research Ethics Committee of Universiti Sains Malaysia (JEPeM Code: USM/JEPeM/21060463).

### Materials and tools

Participants completed a self-administered questionnaire designed to gather sociodemographic information. This questionnaire incorporated a mix of closed-ended and open-ended questions to capture data pertaining to various sociodemographic factors, including age, gender, ethnicity, educational attainment, and details regarding smoking and alcohol consumption habits. Participants also provided self-reported measurements for both weight and height, which were subsequently utilized to compute their Body Mass Index (BMI) using the formula:  $(\text{weight in kg})/(\text{height in m})^2$ . Following this calculation, participants were categorized into one of the following BMI groups, consistent with the World Health Organization guidelines (WHO 2010): underweight ( $<18.5$  kg/m<sup>2</sup>), normal weight (18.5 to 24.9 kg/m<sup>2</sup>), overweight (25.0 to 29.9 kg/m<sup>2</sup>), or obese ( $\geq 30.0$  kg/m<sup>2</sup>).

The Diet History Questionnaire (DHQ) was originally developed by Shahar *et al.* (2000) and Suzana *et al.* (2011). It served as the tool for evaluating food and dietary supplement consumption at both the study's commencement

and its conclusion, spanning the 2-month duration. Participants were interviewed via telephone conversations and provided with guidance to recall their weekly food consumption. The data on nutrient intake was subsequently analyzed using Nutritionist Pro software Version 7.9.

International Physical Activity Questionnaire-Short Form (IPAQ-SF) was developed by Craig *et al.* (2003). It is a self-administered questionnaire consisting of 7 items aimed at capturing information regarding the frequency and duration of physical activities across different intensity levels. This questionnaire was administered both at the initiation and conclusion of the 2-month study period. Participants' physical activity levels were subsequently categorized as high, moderate, or low, following the scoring protocol established for the IPAQ-SF.

### **Procedures**

Eligible participants were non-vegetarian adults aged 30 or older, with a BMI ranging from >20 to <35 kg/m<sup>2</sup>. They had to exhibit at least one medical condition diagnosed by Malaysian medical service as borderline high blood lipid profiles or prehypertension. Participants with chronic diseases such as cancer, kidney or liver diseases, psychiatric disorders, severe heart failures, autoimmune diseases, cerebrovascular diseases, uncontrolled hypertension, or pregnant women were excluded from the study.

A total of 13 eligible participants willingly enrolled in this intervention study and provided informed consent. They had successfully adhered to the SIO supplementation for 2 months, resulting in a zero dropout rate. Besides completing the questionnaires, they were assigned to receive daily supplementation with SIO softgels as part of the research procedure, with each softgel containing 530 mg of SIO. Participants were instructed to take one softgel in the morning after breakfast and another softgel at night after dinner, adhering to this regimen for a duration of 2 months. Notably, each softgel consisted of 228 mg of ALA (Omega 3), 170 mg of LA (Omega 6), and 48 mg of OA (Omega 9). The formulation of the softgels was established based on the average specifications of the raw ingredients (Certificate of Analysis #2019004, Agroindustrial Osho SAC) and had received approval from the National Pharmaceutical Regulatory Agency in Malaysia.

To ensure compliance, participants' adherence to the supplementation schedule was closely monitored through regular follow-up calls. Throughout the study, participants were encouraged to maintain their customary dietary habits and level of physical activity to mitigate potential confounding effects on the study's outcomes. Meanwhile, participants were divided into strata based on their medication use to control the confounding effects of medications.

Blood pressure and biochemistry assessments including Total Cholesterol (TC), Low-Density Lipoprotein Cholesterol (LDL-C), High-Density Lipoprotein Cholesterol (HDL-C), and Triglycerides (TG), were obtained through blood tests conducted at both the baseline and the end of the 2-month intervention period. The 13 participants were instructed to visit an established and registered clinical laboratory in Ipoh to undergo these tests and have their blood pressure assessed. A trained technician at the laboratory performed blood draws using venipuncture and measured blood pressure using a sphygmomanometer. Biochemical analysis was carried out using the Atellica<sup>®</sup> CH Analyzer. The results of these clinical assessments were then sent to the researcher via email.

### **Data analysis**

The data obtained were analyzed using IBM Statistical Package for the Social Sciences software (SPSS) Version 26.0. Descriptive statistics were employed to analyze the sociodemographic data, which were presented in terms of frequency (n) and percentage (%). Prior to analysis, DHQ data was processed using Nutritionist Pro software to estimate total energy and macronutrient intake for the participants. To compare the mean differences in physical activity, dietary intake, blood profile, and blood pressure before and after the intervention, paired t-tests were performed. The confidence interval and significance level for the paired t-tests were set at 95% and 0.05, respectively.

## **RESULTS AND DISCUSSION**

### **Demographic and body weight status**

The demographic characteristics of the participants are summarized in Table 1. The mean age of the participants was 55.23±9.23 years, with a higher proportion of males (61.5%) compared

Table 1. Participants' sociodemographic characteristics (n=13)

Characteristic	Mean (SD)/Median (IQR)
Age (years)	55.23 (9.23)
Height (m) <sup>a</sup>	1.61 (0.12)
Weight (kg)	
Baseline	75.89 (22.44)
After 2 month	75.42 (22.26)
BMI (kg/m <sup>2</sup> ) <sup>a</sup>	
Baseline	26.85 (7.58)
After 2 months	26.56 (7.89)

<sup>a</sup> : median and IQR were reported; BMI: Body Mass Index

to females (38.5%). There was no statistically significant difference in BMI observed before (26.85±7.58) and after (26.56±7.89) the intervention (p>0.05).

#### Medication history and lifestyle behaviors

Six participants (46.2%) were taking medications prescribed by doctors. These medications were primarily for high blood pressure (n=6), high blood cholesterol and triglycerides (n=4), gout (n=1), diabetes (n=3), prevention of rejection after kidney transplantation (n=1), and treatment of skin disorders (n=1). Some participants were on multiple types of medications.

Among the 13 participants, there were 2 smokers (15.4%), but none of them consumed alcohol. Throughout the 2-month intervention period, all participants maintained their smoking behavior without any changes. The comparison of energy and macronutrient intake by the participants before and after the intervention revealed no significant differences (p>0.05)

(Table 2). It suggests that participants adhered to the dietary instructions provided. This strengthens the validity of the study results by reducing the likelihood that changes in dietary habits confounded the observed effects of sacha inchi oil on blood pressure and lipid profile. However, it is important to recognize potential limitations, such as self-reporting biases in dietary assessments or unaccounted-for variations in food intake that may still exist despite efforts to control them. Nonetheless, addressing these potential confounders enhances the strength of the study's conclusions.

Additionally, all participants fell into either moderate or low level of physical activity categories, with median values of 531 MET-min/week at baseline and 693 MET-min/week after 2 months. Wilcoxon signed-rank test showed no significant changes in the total energy expended for various activities (total MET-min/week) before and after the 2-month intervention period (Z statistic=0.051, p=0.959).

#### Effect of SIO supplementation on blood lipid profile

The changes in blood lipid profiles (TC, LDL-C, HDL-C, and TG) before and after a 2-month SIO intervention are depicted in Figure 1. Despite the absence of significant changes, the levels of TC and LDL-C showed attenuation by the end of the intervention period, while HDL-C had a slight increase. However, the median TG level remained at 2.00 mmol/L after 2 months of SIO supplementation.

Our findings indicate that a 2-month intervention of SIO supplementation did not have a significant impact on TG levels, aligning with the result of earlier researches (Garmendia *et al.* 2011; Gonzales & Gonzales 2014). However, it contradicts the findings of a quasi-experimental study that reported a significant reduction in

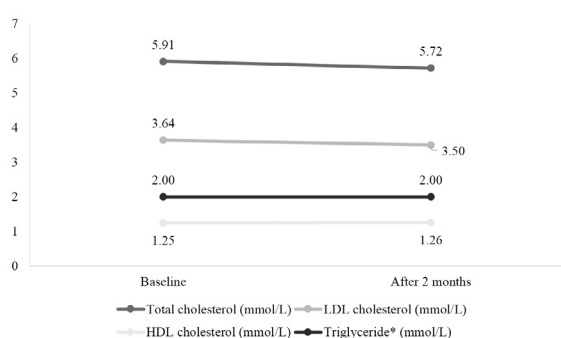
Table 2. Changes of mean energy and macronutrients intake during intervention period (n=13)

Variable	Mean difference (95% CI)	t statistics (df)	p <sup>a</sup>
Energy (kcal)	16.01 (-140.13, 172.14)	0.223 (12)	0.827
CHO (g)	-0.44 (-24.88, 24.01)	-0.039 (12)	0.970
Protein (g)	2.87 (-1.57, 7.30)	1.409 (12)	0.184
Fat (g)	4.65 (-5.55, 6.48)	0.168 (12)	0.869

<sup>a</sup>: Tested using paired t-test

postprandial triglyceridemic levels among 12 young adults who consumed 50 g of sachu inchi (Huamán *et al.* 2008). Similarly, Huamán Saavedra *et al.* (2012) found that a 30 g ingestion of sachu inchi over 6 weeks led to a significant reduction in triglycerides, total cholesterol, and LDL cholesterol levels among 14 young adults. Our findings do not align with several previous studies investigating the effects of SIO on lipid profiles in both animal and human subjects. Those studies typically involved longer intervention periods (3 to 4 months) and supplementation doses of 5, 10, or 20 mL of SIO (Garmendia *et al.* 2011; Gonzales & Gonzales 2014). Therefore, the lack of a significant impact on blood lipid profiles in our study may be attributed to the lower dose of SIO supplementation or the relatively short intervention period.

The hypolipidemic effects of SIO may be attributed to its high content of ALA (alpha-linolenic acid). Several studies have demonstrated the impact of  $\omega$ -3 fatty acids on improving blood lipid profiles (Preston Mason 2019). While the detailed mechanisms are not fully understood,  $\omega$ -3 fatty acids are believed to reduce LDL, LDL-apoprotein-B, Triglyceride (TG) production, and the incorporation of TG into VLDL (very low-density lipoprotein) (Tall & Yvan-Charvet 2015; Backes *et al.* 2016). Furthermore, by reducing the expression of the transcriptional factor SREBPs (sterol regulatory element-binding proteins), ALA is expected to inhibit the cholesterol and fatty acid biosynthesis pathway (Fukumitsu *et al.* 2013).



\*Median values were presented

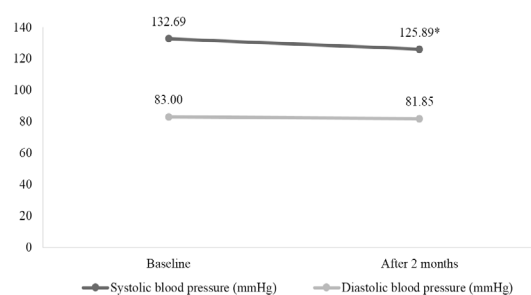
Figure 1. Changes of mean/median blood lipid profile before and after the intervention (n=13)

### Effect of SIO supplementation on blood pressure

Figure 2 shows SBP declined significantly after the 2-month period ( $p < 0.05$ ) but DBP did not show significant change.

This study revealed that SIO supplementation for 2 months significantly reduced SBP, decreasing it from 132.69 mmHg to 125.89 mmHg ( $p < 0.05$ ). These findings are in line with a study by Gonzales and Gonzales (2014), which reported that treatment with 10 or 15 mL of SIO significantly reduced both SBP and DBP during the second month of the intervention period. A similar pattern was also observed in another study involving L-NAME-induced hypertensive Holtzman rats (Gorriti Gutierrez & Quispe 2010), which revealed that SIO at doses of 0.1, 0.5, and 1 mL exerted a hypotensive effect. Doses of 0.5 ml and 1 mL were more effective in reducing SBP, while doses of 0.1 mL and 1 mL showed a similar lowering effect on DBP. The blood pressure-lowering effect of SIO may be attributed to its high content of polyunsaturated fatty acids, primarily ALA and LA, which account for approximately 47.04% and 34.98% of the total fat, respectively (Carrillo *et al.* 2018).

Dietary polyunsaturated fatty acids have been shown to have a positive impact on blood pressure (Grynberg 2005). However, Djoussé *et al.* (2005) suggested in their study that dietary linolenic acid (ALA), but not LA, was associated with a lower incidence of high blood pressure. They concluded that ALA was responsible for significantly reducing SBP but not DBP.



\*SBP decreased significantly after 2-month period [ $t = 2.628$  (12),  $p < 0.05$ ]

Figure 2. Changes of mean blood pressure before and after the intervention (n=13)

Meanwhile, Minami *et al.* (2017) demonstrated in their study that SIO supplementation improved endothelial function by increasing Flow-Mediated Vasodilation (FMD). Several studies have indicated that endothelial function is impaired in animal models of high blood pressure (Tsutsui *et al.* 2010). Moreover it also been suggested that vascular endothelial dysfunction may contribute to the development of high blood pressure (Rajendran *et al.* 2013).

To assess the potential confounding effect of medication, a stratification analysis was conducted. Figure 3 provides evidence that the effect of SIO on SBP was not influenced by the participants' medication status. In fact, a paired sample t-test demonstrated a significant reduction in SBP after the 2-month intervention among the 7 participants who were not taking any medication ( $t=3.440$ ,  $p=0.014$ ). This reduction suggests that SIO independently contributed to lowering SBP in this subgroup. SIO might possess bioactive components that directly influence blood pressure regulation. These components could affect physiological pathways involved in SBP regulation, leading to a reduction in blood pressure levels (Djoussé *et al.* 2005).

While the effect of SIO on SBP was not influenced by medication status overall, it's possible that interactions between SIO and certain medications may have masked or altered its effects in some participants. Overall, these findings suggest that SIO has a beneficial effect on SBP, especially among individuals who are not taking any medication. However, further research is needed to understand the mechanisms underlying this effect and to confirm its generalizability to broader populations.

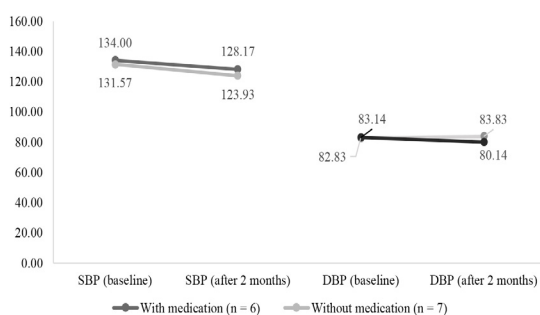


Figure 3. Comparison of mean blood pressure changes in 2 months between participants with and without medication

### Limitation of study

Despite the small sample size and quasi-experimental design utilized, there are reasons supporting these choices. Resource constraints and ethical challenges during the pandemic necessitated this initial investigation to explore the feasibility of conducting further research on SIO in the future. This study serves to refine study protocols based on initial findings and aims to generate preliminary evidence rather than definitive conclusions. However, lacking a control group and limited control over confounding variables result in relatively low levels of evidence. Therefore, caution is advised when interpreting the findings, and their generalizability to other populations or settings may be limited due to differences in patient characteristics.

This study was conducted during the Malaysian Movement Control Order (MCO) in response to the COVID-19 pandemic. Participants self-reported their body height and weight, potentially introducing information bias, although BMI was not the primary outcome. Despite this, further analysis found no significant changes in energy and macronutrient intake, as well as energy expenditure levels during the 2-month intervention period. This helped address the confounding effects. Additionally, stratification analysis showed that participants' medication status did not confound the effect of SIO on SBP.

Despite these limitations, this study offers valuable insights into intervention outcomes, particularly in real-world settings where participant randomization or use of control group may be ethically challenging

### CONCLUSION

The current study indicates that a 2-month daily supplementation of SIO (2 x 530 mg softgel) significantly reduces the Systolic Blood Pressure (SBP) of the participants. While acknowledging the limitations of a small sample size and quasi-experimental design, these findings serve as valuable starting point, providing initial insights that can inform the development of more robust research in the future.

Therefore, it is advisable to plan future studies using a Randomized Controlled Trial (RCT) design with a larger sample size and higher

SIO doses. Additionally, a longer intervention period is clearly necessary to further validate these findings.

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#### DECLARATION OF CONFLICT OF INTERESTS

The authors have no conflict of interest.

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