Effect of 100% Cocoa Powder on Ultraviolet-B Minimal Erythema Dose versus Chocolate Flavored Drink Powder among Filipinos: A Double Blind Study*

Celestine Antoniette A. Apolonio, MD[1]; Elisa Rae L. Coo, MD, FPDS[1]; Ma. May Jasmin R. Yason, MD, FPDS[1]

ABSTRACT

Background: Ultraviolet radiation (UV) imposes significant negative consequences upon excessive exposure. It is a common misconception in darker skin types that there is no need for photoprotection, hence studies have been done on other adjuncts of photoprotection. Cocoa is naturally-occurring antioxidant rich in flavanols that absorbs UV radiation and scavenge reactive oxygen species.

Objective: The study aimed to determine the UVB photoprotective activity through minimal erythema dose determination of 100% cocoa powder versus chocolate flavored powder drink.

Methods: This study was a randomized, double-blind controlled trial, wherein sixty (60) Filipino subjects aged 18 years old to 59 years old with Fitzpatrick skin type IV-IV were equally divided into two groups using computer generated randomization. Group I received 100% cocoa powder, one (1) tablespoon dissolved in hot water daily for 12 weeks, while Group II received chocolate flavored drink powder, one (1) tablespoon dissolved in hot water daily for 12 weeks. Minimal erythema dose (MED) were assessed for both groups at baseline, week 6 and week 12. Laboratory testing for fasting blood sugar (FBS), blood urea nitrogen (BUN), creatinine, SGPT and SGOT was done baseline and at week 12.

Results: In the 100% cocoa powder group, the mean MED increased from baseline to week 6 at an average of 5.5% (p-value 0.64) which were not statistically significant, while from baseline to week 12 an statistically significant increase in mean MED was noted at 21% (p-value < 0.01). These results showed that there is significant photoprotective activity of 100% cocoa powder for intake of 12 weeks as compared to 6 weeks. In the chocolate flavored powder drink, MED remained unchanged. No significant adverse clinical symptoms and laboratory test changes were seen in this study.

Conclusion: Intake of 100% cocoa powder for 12 weeks have significant photoprotective activity compared to baseline among Filipinos with Fitzpatrick skin type IV-V. While chocolate flavored drink powder has no such effect.

Keywords: *Cocoa powder, flavanols, photoprotection, Fitzpatrick skin type IV-V*

INTRODUCTION

Ultraviolet radiation plays a beneficial role in the production of vitamin D, however excessive exposure has negative consequences. These significant negative effects include sunburn, phototoxic and photoallergic reactions, and development of skin cancers[1].

Skin cancer is a preventable disease and a major public health concern[1]. There were 2102 basal cell carcinomas and 614 squamous cell carcinomas from 2011 to 2021 based on the Philippine Dermatological Society Health Information System[2]. Ultraviolet (UV) radiation or sun damage is an established modifiable risk factor for carcinomas of the skin. UV avoidance and photoprotective practices is not commonly done among Filipinos since brown skin has more melanin and many believe it offers greater protection. While the incidence of skin cancer incidence is not as common among Filipinos as it is among Caucasians, it does occur locally, so it is crucial to determine other means of photoprotection.

Cocoa is a naturally-occurring antioxidant with anti-inflammatory molecules that play a role in preventing cutaneous UV damage. It is widely available, inexpensive, and serves as an efficient food supplement that may help with photoprotection. It has a high amount of flavonoids, contributing to the bitterness representing the fundamental aspects of its organoleptic and palatability characteristics[3]. Aside from the photoprotective properties of cocoa, it contains methylxanthines such as theobromine and caffeine, which have beneficial effects on the vascular and central nervous system.[4]

Few studies on photoprotection have been conducted in non-tropical countries with participants of Fitzpatrick Skin Types I to II. However, to our knowledge, no studies have been done on low- and middle-income countries, such as the Philippines, wherein frequent sun exposure is often common in daily life, and most occupations.[5] This further emphasizes the significance of this study since the Philippines is a tropical country and Filipinos are more predisposed to sun exposure.

Disclosures: *The author has formally acknowledged and signed a disclosure affirming the absence of any financial or other relationships (including personal connections), intellectual biases, political or religious affiliations, and institutional ties that could potentially result in a conflict of interest.*

[1]Department of Dermatology, Valenzuela Medical Center, Valenzuela City, Philippines

This study highlights the importance of providing other means of photoprotection for Filipino patients. Dermatologists have been educating patients regarding sun protection through the use of topical/oral sunscreens, physical barriers and avoidance of prolonged sun exposure. However, due to the Philippines being a low-income country, photoprotection has not been a priority among Filipinos. This study will help our patients prevent skin cancers brought by UV radiation and promote our own economy with the use of cocoa freshly made in our country.

The goal of this randomized clinical trial is to determine and compare the photoprotective properties of cocoa powder and chocolate flavored powder drink. No measurements were done on quantifying the flavanol content of the powder drinks. Measurement of ultraviolet B (UVB) protection was done through Minimal Erythema Dose.

Sun Damage

Ultraviolet (UV) radiation is one of the most critical risk factors for skin cancer. The most frequently exposed are outside workers, those who work outdoors for at least three hours between 9 am to 3 pm most days of the week.[6] Limited studies have been done in the Philippines, particularly since skin cancers are not as common among Filipinos. In a local study among Filipino traffic enforcers, researchers concluded that they have adequate knowledge and a good attitude towards sun exposure but are not applied to practice.[6] Thus, proper education among occupational workers and other possible sources of photoprotection may be of aid to Filipinos.

The sun's UV rays between 10 am in the morning and 4 pm in the afternoon release the highest UVA and UVB radiation. In studies, direct exposure to the sun during these hours amounting to 30 to 50 minutes may induce sunburn for skin types Fitzpatrick III and IV. One of the major factors for non-melanoma skin cancer is exposure to UVB, which promotes inflammation, oxidative stress, DNA mutation, and damage. This in turn leads to the evolution of non-melanoma skin cancers.[14]

Cocoa and Photoprotection

Cocoa, from the tree *Theobroma cacao*, has many potential benefits. It contains methylxanthines such as theobromine and caffeine.[4] Theobromine was found to have strong inhibitory effects on the activity of nuclear enzyme poly (ADP-ribose) polymerase-1 (PARP-1), involved in inflammatory diseases such as stroke, diabetes, and chronic obstructive pulmonary disease[7]. While caffeine is a compound that is associated with enhanced cognition[8] and enhances the vascular and central nervous system.[4]

Cocoa beans fresh from trees are exceptionally rich in flavanols, but their high antioxidant capacity may be greatly reduced during the manufacturing process. Regular consumption of chocolate rich in flavanol confers significant photoprotection and can thus be effective at protecting human skin from harmful UV effects but low-flavanol conventional chocolate has no such effect. It was mentioned that in human subjects, flavanol-rich chocolate improved cardiovascular risk factors including total and LDL cholesterol, blood pressure, and insulin sensitivity after 12 weeks of ingestion of high flavanol chocolate droplet snack. A study was done on the impacts on endothelial function with sugar free and sugar-sweetened cocoa consumption and found no significant difference.[19]

Carotenoids have gained momentum in photoprotective properties prior to cocoa. A comparative experimental study was done between low-flavanol cocoa and high-flavanol cocoa, with the determination of minimal erythema dose (MED) using a blue solar simulator. MED is a measurement tool used to examine skin tolerance to ultraviolet radiation and defined as the lowest dose that produces erythema in which the values vary per individual. It measures an individual's tendency to burn, with low MED values associated with increased photosensitivity[21]. Carotenoids and products containing high-flavanol cocoa have comparable photoprotective effects[10]. However, in another study, no statistical difference was noted between low-flavanol cocoa and high-flavanol cocoa particularly due to changes in weather season, wherein participants started the study during winter and ended in spring, and lack of compliance. Researchers found out that there was an increase in MED at week 6 than at weeks 9 and 12 compared to baseline, indicating patients' maximum compliance with the protocol at 6 weeks[11].

A longer trial period of 24 weeks to also assess improvement in skin wrinkles as high flavanol is also believed to have anti-photoaging effects. It was emphasized that the consumption of dietary antioxidants is considered to be a good strategy against photo-aging and in moderately photo-aged women, regular cocoa flavanol consumption had positive effects on facial wrinkles and elasticity. Aside from photoprotection, cocoa flavanol supplementation may contribute to the prevention and progression of photoaging[12].

Safety Profile of Cocoa

Cocoa extract has photoprotective effects from prolonged oral administration of high flavanols which was proven by in vitro and in vivo studies. A short period of one week of administration of cocoa powder demonstrated photoprotective activity, measured by an increase in MED. Volunteers did not report any adverse effects. Researchers have concluded an increase in subjects' adherence to the protocol with the short duration of the study and that cocoa could supplement topical sunscreens for photoprotection[13].

Effects of Cocoa Powder on Glucose, Liver and Kidney

Long-term ingestion of cocoa was well tolerated in one study, wherein adverse effects were evaluated at the 12th and 24th week of treatment. Laboratory tests such as aspartate aminotransferase, alanine transaminase, glucose, blood urea nitrogen, creatinine, and hemoglobin and hematocrit concentrations were measured. Participants reported no subjective adverse effects and no laboratory abnormalities were noted after the 24th week of treatment, indicating a wide margin of the safety profile of cocoa[12]. In another study, cocoa consumption showed a reduction in total cholesterol, fasting blood glucose and in systolic and diastolic blood pressure[20].

Safety Profile of Narrowband UVB Phototherapy

UVB phototherapy is used to treat a variety of skin disorders. A review of literature was done on several studies using UVB phototherapy which resulted in no increased risk for non-melanoma skin cancers within a long follow-up period. These studies were done on Caucasian skin, and would even indicate safer for darker skinned individuals.[15] Narrowband UVB (NB UVB) phototherapy is reported to be safe, but short term erythema, pruritus and xerosis may last for up to two days. UVB Phototherapy may be discontinued in the case of prolonged erythema, pruritus and xerosis existing for more than two days.[17]

METHODOLOGY

STUDY DESIGN AND SETTING

This study was a randomized double-blind study. Patients were randomly allocated using a computer-generated software into two groups: group I (100% Cocoa powder) and group II (Chocolate flavor powder). Patients in group I received a supply of Cocoa powder on day 1 of study and on the 6th week of treatment, while group II received a supply of Chocolate flavored powder drink on day 1 of study and on the 6th week of treatment. The allocation was kept unknown to the participants and the assessor.

All participants were subjected to screening by the primary investigator at Valenzuela Medical Center Dermatology Out-Patient Department. The study was presented to the Hospital Institutional Review Board (IRB) before conducting the process.

SAMPLING DESIGN AND RANDOMIZATION

The study made use of purposive sampling where only those who have satisfied the inclusion and exclusion criteria joined part of the research. Participants were randomized through block sampling (in 1:1 ratio using blocks of four) into group I (100% Cocoa powder) and group II (Chocolate flavor powder).

The primary investigator was blinded on the group assignments of the participants. Research assistant or staff assigned participants to either control group or experimental group while the researcher determined the minimal erythema dose of the patients. List of patients assigned to either group was kept by the research assistant only.

PARTICIPANTS

The study included adult participants seen in the Valenzuela Medical Center Department of Dermatology.

INCLUSION CRITERIA

- Ages 18 years to 59 years old
- Fitzpatrick Skin Types IV to V

EXCLUSION CRITERIA

- History of severe liver, kidney diseases or uncontrolled diabetes
- Immunocompromised patients
- History of allergies against any component of trial food
- Pregnancy or lactation
- Chemical dependency or alcoholism
- Therapy with drugs with known phototoxic activities
- Any dermatological disease in the treatment area, and prolonged UV exposure

WITHDRAWAL CRITERIA

- Unable to undergo blood laboratory tests for safety monitoring
- Unable to have scheduled follow-up during the course of study
- Failure to consume powder drink in at least 80% of the expected number of days within the 12-eek study

- Induction of polymorphous light eruption, appearance of blisters, photoconjunctivitis and photokeratitis. Erythema, xerosis, and pruritus are minor expected side effects of phototherapy occurring within 24 hours, which may last up to 48 hours.
- Patients with any signs of allergies or serious adverse reactions to any of the experimental exposures
- Participants who request to withdraw at any point in time in the course of study

SAMPLE SIZE CALCULATION

Sample size for this study was computed using the online sample size calculator from powerandsamplesize.com/Calculators with the assumption that the mean value of the outcome of cocoa is 0.223 MED.[9] Estimation was done for the study to detect a 0.114 difference in outcome values between cocoa and chocolate. In comparison of two means carried out at <5% level of significance, a sample size of 28 per group (total of 56 participants) is needed for the study to have 80% power of rejecting the null hypothesis if the alternative holds.

MATERIALS

The cocoa powder used is made up of 100% cocoa (Family's choice Pure Cocoa Powder), FDA registered, made from the Philippines while the chocolate flavor drink (Milo Powdered Choco Malt Milk Drink) is made up of cocoa, sugar, milk, and malt extract. The appearance and color were similar in both groups. Both 100% cocoa and chocolate flavor drink were repackaged by a research assistant or staff into identical small opaque plastic canisters (Figure 1).

Subjects in the control group were given a chocolate flavored powder drink while the treatment group was given a 100% cocoa drink.

FLOW OF THE STUDY AND RESEARCH INSTRUMENT

The participants eligible for the study after the screening were divided into two groups, group I (Cocoa) and group II (Chocolate). Prior initiation of the study, informed consent was given and signed by the participant. They were instructed to consume 15 g/day (one tablespoon) dissolved in 100-200mL of hot water for ingestion in the morning after breakfast. They may add up to one teaspoon of sweeteners such as sugar to their drink. Both groups were given small plastic canisters filled with either 100% cocoa powder or chocolate flavored powder, and refilled on the 6th week of treatment.

All participants had blood sampling for liver function tests, kidney function tests and fasting blood sugar and was evaluated at baseline and on the 12th week of treatment for safety and possible side effects such as generalized urticaria, generalized erythema and generalized morbilliform eruption. In the event that the participant will experience any of the mentioned side effects, prolonged short term adverse effects of erythema, xerosis and pruritus, and laboratory test abnormalities, participants will be assessed, managed and referred to the appropriate specialists accordingly based on current clinical practice.

Participants underwent baseline photo testing to determine Minimal Erythema Dose (MED) with the use of NB-UVB (Medisun Psori-Kamm UVB311) by exposing six (6) 1 x 1 cm untanned skin on the back to solar simulation with an initial dose of 200 mJ/cm2 and increasing intervals of 200 mJ/cm2. Upon completion of the UV exposure, adequate skin markings using a permanent marker was made prior to the removal of the MED test patch, in order to more easily identify the exposed areas after 24 hours. Participants were reminded to not wash off the markings until after the skin had been examined for the MED reading. The participants followed up after 24 hours to determine MED. This was done on baseline, on the 6th and 12th week of treatment. Topical sunscreen was allowed for application except on the back. Stopping guidelines were induction of polymorphous light eruption, appearance of blisters, photo-conjunctivitis and photokeratitis. Erythema, xerosis, and pruritus are minor expected side effects of phototherapy occurring within 24 hours, which may last up to 48 hours. [17] If symptoms persist beyond 48 hours, patients will be reassessed for other possible causes and if there are none, phototherapy will be discontinued.

DATA MANAGEMENT, STORAGE, PROCESSING AND ANALYSIS

In data management, it is paramount to protect the patients' privacy and confidentiality. Therefore, to ensure that the results of the study will not be linked directly with their personal information and any identifiable features, each of the patients were assigned with a unique patient code for the study. A database of patient records and their equivalent patient code were kept. During the recording of the study results, patient code was shown instead.

Two types of data that were generated, one is the hard data from the data collection form and one soft copy. The hard copies were stored safely in a secured cabinet and kept for five years until; they are disposed of via shredding. The data were encoded in Google Sheet database accessible only to the researcher and the

statistician of the study. The Google Sheet contains safety features that help in preventing unauthorized access and downloading of the data. The database will be securely deleted after the analyses based on approved objectives and until an ethics protocol closure certificate is issued.

For the study, several statistical tests were performed. For the patients' demographic profile, descriptive statistics were used such as mean and standard deviation for continuous data and frequency and Chi-square test for the categorical data.

To determine and compare the overall minimal erythema dose at baseline, 8th week and 12th week for 100% cocoa powder group and chocolate flavored powder drink group, Repeated Measures Analysis of Variance were used. Pairwise comparisons for baseline to week 6 and to week 12 will be analyzed with Tukey's Multiple Comparison test.

To identify and compare the rate of adverse effects in terms of clinical symptoms, generalized urticaria, generalized pruritus, and generalized morbilliform eruption at 8th week and 12th week, use of t-test for two proportions were done. For the laboratory tests in terms of fasting blood sugar, AST, ALT, BUN, and Creatinine were expressed in terms of mean and standard deviation and compared using Repeated Measures ANOVA.

RESULTS AND DISCUSSION

RESULTS

Table 1. Demographic and Clinical Profiles of participants

Demographic Profile	Cocoa Powder n=28	Chocolate Powder n=28	P-value
Age (years), mean ± SD	33.36 ± 0.32	33.08 ± 0.45	0.006 (NS)
Sex			
Male	4(14.3%)	6(21.4%)	0.4852 (NS)
Female	24(85.7%)	22(78.6%)	
Fitzpatrick Skin Type			
IV	21(75%)	16(57.1%)	0.1582 (NS)
V	7(25%)	12(42.9%)	
Comorbidities			
WITH	6(21.4%)	5(17.9%)	0.7366 (NS)
Endometriosis	2(7.1%)	0(0%)	
Bronchial asthma	2(7.1%)	4(16.7%)	
Hyperthyroidism	2(7.1%)	0(0%)	
Polycystic Ovarian Syndrome	0(0%)	1(4.2%)	
WITHOUT	22(78.7%)	23(82.1%)	
Medications			
WITH	7(25%)	8(28.6%)	0.7628 (NS)
Methimazole	2(7.2%)	0(0%)	
Terbutaline sulfate	1	0	
Budesonide/ Formoterol inhaler	0	1	
Multivitamins	5	7	
WITHOUT	21(75%)	20(71.4%)	

NS: Not significant, SD: Standard deviation

Table 1 revealed notable characteristics in the demographic profile, skin type, comorbidities, and medications of participants consuming cocoa powder and chocolate powder. Overall, no significant statistical difference between both groups were noted meaning both groups were the same at baseline.

Table 2. Comparative Analysis on the Level of Mean Minimal Erythema Dose Between 100% Cocoa Powder and Chocolate Flavored Powder Drink

Treatment Group	Mean ± SD			P-value
	Baseline	Week 6	Week 12	
Group I (Cocoa Powder)	**778.57 ± 152.58**	**821.43 ± 175.03**	**942.86 ± 198.80**	***< 0.001 (S)***
Group II (Chocolate Powder)	800 ± 133.33	800 ± 133.33	800± 133.33	1.0 (NS)

S: Significant, NS: Not significant, SD: Standard deviation

Greenhouse-Geisser 29.037
Linear <0.01
Quadratic = 0.193

The results of the Repeated Measures ANOVA analysis revealed significant variations in erythema dose across different time points for cocoa powder group. Among cocoa powder users, the minimal erythema dose showed a gradual increase from a baseline mean of 778.57 (± 152.58) to 821.43 (± 175.03) at week 6, and further to 942.86 (± 198.80) at week 12. This progressive rise was statistically significant, as indicated by a Greenhouse-Geisser correction value of 29.037 with $p<0.001$. The increase followed a linear trend, with the per protocol analysis yielding a significant linear effect ($p<0.01$). However, the quadratic trend did not reach statistical significance ($p=0.193$), suggesting that the changes over time did not follow a curvilinear pattern.

In contrast, the chocolate powder group displayed no changes in mean and standard deviation at any point.

Table 3. Percentage Change of Minimal Erythema Dose for group I (100% Cocoa Powder) between baseline to week 6 and to week 12

Group I Cocoa Powder	Difference in percentage change (95% CI)	P-value
Baseline to Week 6	42.86 (-69.76, 155)	0.64 (NS)
Baseline to Week 12	**164.29 (51.67, 276.90)**	***<0.01 (S)***

NS: Not significant, S: Significant, CI: Confidence interval

Table 3 shows notable changes in the impact of cocoa powder on minimal erythema doses over time. Minimal erythema dose increase was noted from baseline to week 6 which was not statistically significant.

Meanwhile, significant statistical differences were demonstrated between mean differences from baseline to week 12. No mean differences were noted on chocolate powder group, hence pairwise comparison testing was no longer done.

Table 4. Adverse Effects of Clinical symptoms at baseline, week 6 and week 12 Between 100% Cocoa Powder and Chocolate Flavored Powder Drink

Treatment Group	Baseline			Week 6			Week 12		
	Group I	Group II	P	Group I	Group II	P	Group I	Group II	P
Localized Pruritus (<2 days)	1(3.6%)	2(8.3%)	0.462 (NS)	0(0%)	0(0%)	-	0(0%)	0(0%)	-
Stinging sensation (<2 days)	0(0%)	1(4.2%)	0.275 (NS)	0(0%)	0(0%)	-	0(0%)	0(0%)	-
Generalized Urticaria	(0%)	0(0%)	-	0(0%)	0(0%)	-	0(0%)	0(0%)	-
Generalized Pruritus	(0%)	0(0%)	-	0(0%)	0(0%)	-	0(0%)	0(0%)	-
Generalized Morbiliform Eruption	(0%)	0(0%)	-	0(0%)	0(0%)	-	0(0%)	0(0%)	-

NS: Not significant, Group I: Cocoa powder, Group II: Chocolate powder, P: p-value

Table 4 highlights observations regarding localized pruritus and stinging sensation in the cocoa powder and chocolate powder groups. At baseline, localized pruritus lasting less than two days was reported in 1 subject (3.6%) of cocoa powder users and 2 subjects (8.3%) of chocolate powder users, with a p-value of 0.462, indicating no statistically significant difference. By week 6 and week 12, no occurrences of localized pruritus were recorded in either group, and thus, no p-values were calculated for those time points. For stinging sensation lasting less than two days, no cases were reported in the cocoa powder group at baseline, while 1 subject (4.2%) in the chocolate powder group experienced this symptom (p=0.275). Similar to localized pruritus, no instances of stinging sensation were reported in either group during the 6th and 12th weeks, eliminating the need for further p-value comparisons at those time points.

Table 5. Comparative Analysis on the Laboratory Tests Between 100% Cocoa Powder and Chocolate Flavored Powder Drink

Treatment Group	Baseline			Week 12		
	Cocoa Powder	Chocolate Powder	P-value	Cocoa Powder	Chocolate Powder	P-value
FBS	5.03 ± 0.32	5.1 ± 0.45	0.447 (NS)	4.92 ± 0.48	5.11 ± 0.38	0.126 (NS)
BUN	3.92 ± 1.31	4.4 ± 1.07	0.086 (NS)	3.9 ± 1.08	4.48 ± 0.94	0.07 (NS)
Creatinine	68.38 ± 11.95	71.9 ± 12.61	0.288 (NS)	64.31 ± 11.99	62.05 ± 12.17	0.487 (NS)
SGPT	37.79 ± 29.02	36.63 ± 28.19	0.88 (NS)	43.43 ± 24.93	35.58 ± 20.27	0.202 (NS)
SGOT	26.93 ± 10.66	29.24 ± 15.86	0.525 (NS)	31.74 ± 22.1	30.71 ± 22.91	0.865 (NS)

NS: Not significant

The results of the t-test for two means reveal variations in laboratory parameters between the cocoa powder and chocolate powder groups at baseline and week 12. However, these changes were noted to be not statistically significant. At baseline, the fasting blood sugar (FBS) levels were 5.03 ± 0.32 mmol/L in the cocoa powder group and 5.11 ± 0.45 mmol/L in the chocolate powder group, with a p-value of 0.447, indicating no significant difference. However, by the 12th week, the FBS levels showed a slight decrease with the cocoa powder group reporting at 4.92 ± 0.48 mmol/L and a minimal increase in the chocolate powder group at 4.89 ± 0.38 mmol/L. Kidney function tests and liver function tests also showed not statistically significant results.

DISCUSSION

Ultraviolet radiation is a component present in sunlight and may also come from artificial sources such as halogen, fluorescent and incandescent lamps. Ultraviolet B is high in energy that induces erythema and accounts for approximately 5% to 10% of the UV light that reaches the surface of the earth while Ultraviolet A is low in energy and more likely to cause pigmentation and accounts for 95% of the UV that reaches the earth's surface[28]. Both UVA and UVB contribute to oncogenesis, however, UVB has the higher propensity as they cause direct DNA damage causing mutations[22]. Several means of photoprotection has been the mainstay of prevention to excessive UV exposure such as wearing sun protective clothing, application of a broad-spectrum sunscreen with at least sun protection factor 30, usage of umbrellas, wide brimmed hats or sunglasses, as well as behavioral practices such as seeking shade when outdoors and minimized sun exposure especially during the peak of UV radiation between 10:00 am to 4:00 pm[9]. A higher amount of melanin is found in the upper layers of the epidermis in those with darker skin colors, therefore giving protection to the basal keratinocytes and the dermis[24]. This concept often misleads the general public to think that photoprotection is not a concern in those with darker skin color.

Study Participant and Demographic Profile

Most of the population of the Philippines have Fitzpatrick skin types III to V[23]. Studies on the photoprotective properties of cocoa have been done on lighter skin groups and non-Asian countries [9 10 11 12 13]. In this study, 35 subjects with Fitzpatrick skin type IV and 19 subjects were Fitzpatrick skin type V were not statistically significant. No statistical significant differences were noted on the age, sex, presence and absence of

comorbidities and medications between the two groups making both groups comparable. Demonstrated in Figure 1, 30 subjects who received Cocoa powder and another 30 subjects who received Chocolate powder were included. Seven subjects were excluded due to diabetes mellitus and refusal to participate. A total of 2 participants (7.1%) dropped out of the Cocoa powder group and 2 participants (7.1%) out of the Chocolate powder group. Reasons for dropout included being unable to undergo MED testing (n=2), non-tolerability of taste (n=1) and withdrawal of consent (n=1). This however, did not affect the overall outcome of this study as intention to treat analysis results still showed statistically significant results on the 12th week mean MED compared to baseline for the cocoa powder group.

Minimal Erythema Dose

Overall, the data highlighted distinct trajectories in minimal erythema dose changes between the groups, with the cocoa powder group demonstrating a consistent and substantial increase over the 12-week period (Figure 2-3). Both linear and time-dependent trends were evident, emphasizing a statistically significant progression in erythema dose. This implies that with the continuous intake of cocoa powder, photoprotective properties were observed through the increase of mean minimal erythema dose with an average of 5.5% increase from baseline to week 6 and an even greater increase of 21% from baseline to week 12. Upon further comparison analysis, MED results from baseline to week 6 showed no statistical significant results as compared from baseline to week 12. This demonstrates a minimum duration of intake of 12 weeks of cocoa powder for photoprotective effects. In contrast to other studies, increased photoprotective activity of cocoa was demonstrated at an even shorter duration of just one week administration due to a high flavanol and high amount of polyphenols[13]. The chocolate powder group demonstrated no changes in minimal erythema dose therefore giving no photoprotective activity(Figure 4). Similar results were observed in a study by William, et al. (2009), wherein intake of high flavanol chocolate or those fresh from cocoa beans for 12 weeks conferred significant photoprotection through assessment of minimal erythema dose with subjects with Fitzpatrick skin types II and III[25].

Adverse Effects

In this study, adverse events documented were localized pruritus and stinging sensation not lasting more than 2 days on the irradiated site. These were noted at baseline before the introduction of the cocoa powder and chocolate powder, and were from the minimal erythema dose testing. These findings were not statistically significant and did not affect the overall outcome of the study. Similar adverse effects are also noted in other studies with minimal erythema dose testing and are transient[26]. Changes on the mean values of laboratory parameters from baseline were identified at week 12. A decline in laboratory values were noted on fasting blood sugar, blood urea nitrogen and creatinine tests among the cocoa powder group, however, these were deemed to be not statistically significant. Most studies on cocoa showed a beneficial decrease in fasting blood sugar due to its positive effects on insulin sensitivity [27] [28]. This study showed no statistically significant changes on the laboratory parameters for both groups therefore not signifying any harmful or beneficial effects. These were consistent with a similar study with an even longer course of intake of cocoa for 24 weeks proving its safety[12].

CONCLUSION AND RECOMMENDATION

CONCLUSION

This randomized controlled trial demonstrated the significant benefits of cocoa powder on photoprotection among patients with Fitzpatrick skin type IV to V. Results showed that intake of cocoa powder increases the minimal erythema dose over 12 weeks signifying photoprotection. This study can contribute to local data on photoprotective properties of cocoa powder on darker skin types as an adjunct to the basic principles of photoprotection.

RECOMMENDATION

The authors of this study recommend the use of total flavonoid content assay for the powder groups for better quantification of its contents. This test was however unavailable locally at the time of the study. A longer follow-up to assess its long term effects is also recommended. Minimal erythema dose testing for UVA is advocated as well.

DISCLOSURE AND CONFLICT OF INTEREST

All authors declared that there are no conflicts of interest.

ACHIEVEMENTS

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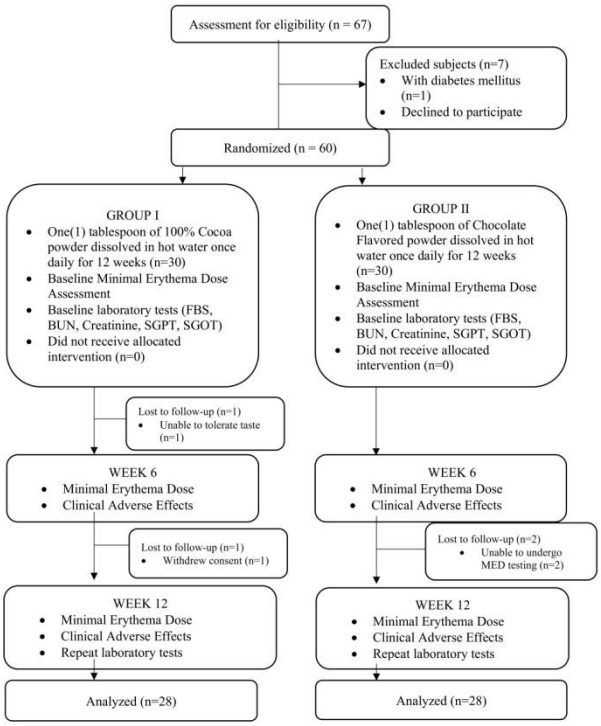
APPENDIX

Appendix 1. Flow diagram of methodology



Appendix 2. Figures

Figure 1. Canister containers used for group I (100% cocoa powder) and group II (chocolate flavored powder drink

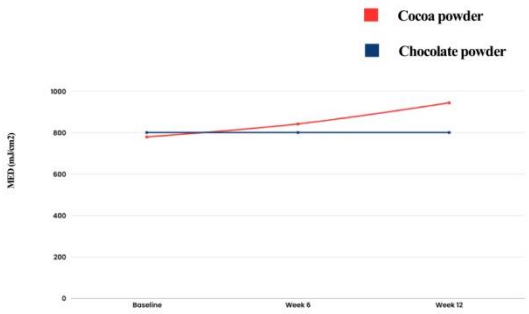


Figure 2. Mean MED increase between cocoa powder and chocolate flavored powder drink

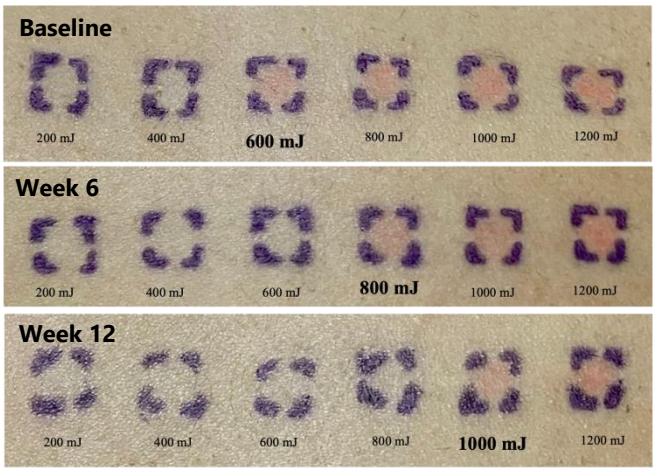


Figure 3. Increase in minimal erythema dose from baseline to week 12 as seen in participant in cocoa powder group

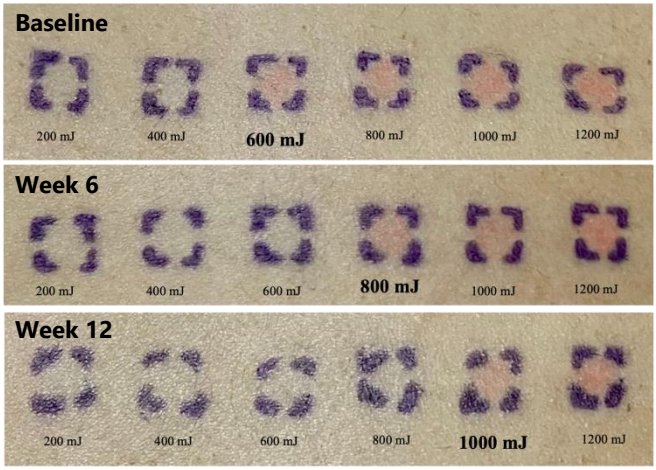


Figure 4. No increase in minimal erythema dose from baseline to week 12 seen in chocolate powder group