A DOUBLE-BLIND RANDOMIZED CONTROLLED TRIAL ON THE PHOTOPROTECTIVE EFFECT OF CUCUMBER (*Cucumis sativus)* SEED EXTRACT VS PLACEBO IN TERMS OF MINIMAL ERYTHEMA DOSE AMONG FILIPINO ADULTS

A RESEARCH PROPOSAL

DEPARTMENT OF DERMATOLOGY AND VENEREOLOGY

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Abstract

Exposure to solar ultraviolet (UV) radiation for a long time causes a variety of skin damage such as sunburn, skin pigmentation, premature aging, and photocarcinogenesis. The main mechanism of skin damage by UV radiation is the formation of reactive oxygen species (ROS) that interact with proteins and lipids and subsequently alter them. Thus, the incorporation of antioxidants in addition to UV filters in formulations of sunscreens can improve the performance of sunscreens in the prevention of skin cancer and photoaging.

Studies have shown that cucumber seed oil has good UV absorption effect because it is rich in an unsaturated functional group structure. Cucumbers also contain triterpenes that offer important cytoprotective capabilities, among other benefits, that may preserve cutaneous barrier function and cellular immunity. Cucumbers also contain rutin and ascorbic acid oxidase, which function as free radical scavengers, just one mechanistic property that helps to protect against skin damage. Some research has indicated that cucumbers have known photoprotective activities and provide an SPF value of 0.2 by itself. In another study, the SPF value of cucumber seed sunscreen at 100 and 200 mcg/ml were found to be 0.39 ± 0.039 and 0.67 ± 0.54 respectively. Another study on the aqueous extract of herbs found cucumber extract to have an SPF of 1.45±0.35. However, most of these studies have been done in vitro. To address this gap, the current investigation aims to further understand the potential skin photoprotective effects of topical administration of *Cucumis sativus* seed extract applied on the skin through a clinical assessment of the Minimal Erythema Dose (MED) which is the smallest UV dose that results in uniform well-defined erythema over the entire exposed area after 24 hours of exposure as a means to evaluate photoprotection.

This monocentric study spanning 3 months will employ a randomized, split-body, double-blind, controlled trial design. Each participant volunteer will receive 2%, 4% cucumber seed extract and a placebo. Test sites will be placed on the lower back and the assignments of which test sites will receive a specific treatment will be randomized. All test sites will be exposed to doses of NB-UVB radiation and minimal erythema response evaluated after 24 hours to determine if there is a significant increase in the MED of 2% and 4% Cucumis seed extract compared with placebo.

I. Introduction

The human skin, the body's largest organ, holds a strategic position at the interface between the external and internal environments. The skin, being directly exposed, is the organ most susceptible to damage from UV light. Sun exposure results in acute and chronic changes to the skin, leading to various forms of photodamage which include sunburn, photoimmune suppression, photodermatoses, depigmentation, photoaging, and cutaneous malignancy (Amaro-Ortiz et al., 2014; Al Jamal et al., 2014; Scott et al., 2017).

The skin has evolved an innate adaptive tanning response using melanin as a chromophore to shield itself from further UV insult. Activation of cellular damage response prompts melanocytes to produce melanin, which is then deposited in keratinocytes, leading to heightened skin pigmentation (Amaro-Ortiz et al., 2014; Al-Jamal et al., 2014). Despite the protective role of skin pigmentation in mitigating the damaging effects of UV exposure, melanin doesn't offer complete protection against UV rays. Skin sensitivity to UV light varies among individuals. To objectively determine the skin sensitivity to ultraviolet radiation in the clinical setting, the Minimal Erythema Dose (MED) is usually evaluated by inducing minimal skin erythema within a few hours following exposure to ultraviolet B (UVB) or ultraviolet A (UVA) with UVB (Yang et al., 2023).

Recognizing the harmful effects of UV exposure, providing additional protection to the skin becomes crucial. In addition to UV filters and physical photoprotective agents, antioxidants emerge as promising candidates to alleviate UV-mediated damage and prevent the health consequences of UV exposure.

Cucumber (Cucumis sativus L.), a vegetable crop belonging to the Cucurbitaceae family, is commercially cultivated and has its origins in India, where it grows wild in the Himalayas from Kumaun to Sikkim (Kirkbride, 1993). The extract from cucumber pulp and peel has been identified to contain lactic acid (7–8% w/w) with antioxidant properties (Moskwa et al., 2023). A study conducted by Gill et al. in 2009 demonstrated that the methanol extract solution of cucumber seeds, in comparison to chloroform, ethyl acetate, and methanol extracts, exhibited antioxidant and photoprotective potential (Gill et al., 2009). Because cucumber seed oil contains a high concentration of unsaturated functional groups, it has a good UV absorption effect. Cucumber seed oil contains

plant sterol, which has a high permeability toward the skin and increases skin metabolism while reducing inflammation. Plant sterols possess an antioxidant effect because their β-sitosterol can effectively shield low-density lipoprotein peroxide. Cucumber's triterpenes may provide significant cytoprotective properties in addition to other advantages that may maintain cellular immunity and the integrity of the cutaneous barrier. As scavengers of free radicals, rutin and ascorbic acid oxidase are two mechanistic characteristics of cucumbers that contribute to their ability to prevent skin damage (Wang et al., 2022). Some research has indicated that cucumbers have known photoprotective activities and provide an SPF value of 0.2 by itself (Katiyar et al., 2015). Another study on the aqueous extract of herbs found cucumber extract to have an SPF of 1.45 (Iuliana et al., 2020). The assessment by the Cosmetic Ingredient Review Expert Panel found that cosmetic ingredients derived from the cucumber plant were safe and non-irritating for use in skincare products.

However, most of these studies on the photoprotective effects of cucumber have been done in vitro. To address this gap, the current investigation aims to further understand the potential skin photoprotective effects of topical administration of *Cucumis sativus* seed extract applied on the skin through a clinical assessment of the Minimal Erythema Dose (MED) as a means to evaluate photoprotection.

II. Objectives

General Objective: To compare the photoprotective effect of Cucumis sativus seed extract vs placebo among Filipino adults

Specific objectives:

1. To determine the Minimal Erythema Dose (MED) after application of 2%, 4% Cucumis sativus seed extract and placebo after 24 hours
2. To determine if there is a significant increase in the MED of 2% and 4% Cucumis seed extract compared with baseline
3. To determine if there is a significant difference between the MED of 2% and 4% Cucumis seed extract and placebo
4. To determine the incidence of adverse effects to *Cucumis sativus* seed extract among patients

III. Review of Related Literature

Cucumis sativus, belonging to the Cucurbitaceae family, is commonly recognized as a long, dark green, and smooth-skinned vegetable. Cucumbers exhibit a rich nutritional profile. The fruits, in particular, contain an array of beneficial compounds such as erepsin, Vitamin B1, Vitamin C, ascorbic acid, proteolytic enzyme, rutin, oxidase, succinic and maleic dehydrogenases, among others. The seeds contribute α- and β-amyrin, sitosterols, and cucurbitasides, while the leaves contain free cucurbitasides B and C, along with ferredoxin (Swamy, 2023). Among the notable phytonutrients in cucumbers are cucurbitacins, lignans, and flavonoids. These compounds play pivotal roles in offering antioxidant, anti-inflammatory, and anti-cancer benefits. Cucurbitacins, for instance, provide valuable antioxidant and anti-inflammatory properties, while lignans contribute to anti-cancer benefits. The flavonoids present in cucumbers further enhance the overall health benefits, making them a valuable addition to a balanced diet (Swamy, 2023).

Medical Applications of *Cucumis sativus*

Considerable research has focused on sustainable botanical ingredients for their potential in nutraceuticals and cosmeceuticals (Lopes et al., 2007; Beluga et al., 2016). In this context, cucumber has a history in folk medicine, where it has been utilized for treating various conditions such as diarrhea, gonorrhea, diabetes, and hypertension. Additionally, it has been employed for detoxification, acting as an anti-inflammatory agent, regulating serum lipids, and exhibiting antioxidant and analgesic properties (Abu-Reidah et al., 2012). While some of these applications await further confirmation, ongoing research suggests that cucumber's phytochemicals may serve as promising chemopreventive and anticancer agents (Lee et al., 2010; Rios et al., 2009; Thoennissen et al., 2009; Murad et al., 2016).

Potential Cytoprotective and Photoprotective Effects of *Cucumis sativus*

Scientific literature suggests that specific phytochemicals found in cucumbers, such as triterpenes, may impart crucial cytoprotective capabilities, alongside other benefits that contribute to the preservation of cutaneous barrier function and cellular immunity (Rios et al., 2010; Murad et al., 2008; Murad et al., 2016). Beyond mere hydration, cucumbers offer elements essential for fortifying and regenerating the body. Notably, researchers

have identified rutin and ascorbic acid oxidase in cucumbers, acting as free radical scavengers—a mechanistic property that aids in shielding the skin against damage (Katiyar et al., 2014).

Moreover, studies indicate that cucumbers exhibit photoprotective activities, possessing an inherent Sun Protection Factor (SPF) value of 0.2 (Katiyar et al., 2015). Recent investigations have delved into the effects of topical creams containing cucumber extract, revealing a significant reduction in melanin and skin sebum levels. This outcome translates to skin whitening and anti-acne effects (Aktar et al., 2011). Although the precise mechanisms by which cucumbers achieve these effects remain not fully understood, ongoing research into their uses and components promises to unveil the intricate workings of these beneficial properties. The multifaceted nature of cucumber's impact on skin health suggests a complex interplay of various compounds, necessitating further exploration for a comprehensive understanding of its mechanisms.

Studies on photoprotective effects of Cucumis sativus

The scarcity of studies on the photoprotective effects of Cucumis sativus is evident from the limited available literature. While some research has explored the photoprotective properties of natural sources, such as vegetables and plant-derived compounds, the specific focus on Cucumis sativus is lacking. One study investigated the photoprotective properties of a supplement formula containing lutein, zeaxanthin, and rosemary, highlighting the potential of natural compounds in skin protection (Heidari et al., 2016). This article mentioned the addition of cucumber extracts (Cucumis sativus) but did not provide specific data on their correlation with photoprotection.

The existing literature primarily focuses on the use of cucumber-derived ingredients in cosmetics and their potential UV photoprotective activity (Khan et al., 2022). A study noted that the incorporation of cucumber extracts (Cucumis sativus) does not show any correlation with an increase in the Sun Protection Factor (SPF) value, as indicated by scientific data (Solano et al., 2020).

Some research has indicated that cucumbers have known photoprotective activities and provide an SPF value of 0.2 by itself (Katiyar et al., 2015). Another study on the aqueous extract of herbs found cucumber extract to have an SPF of 1.45 (Iuliana et al., 2020).

The limited number of studies directly addressing the photoprotective effects of Cucumis sativus suggests a knowledge gap in this area. Further research is needed to explore the specific mechanisms and compounds in Cucumis sativus that may contribute to its photoprotective properties. Additionally, studies evaluating the use of Cucumis sativus extracts or components in skincare and photoprotection could provide valuable insights into its potential benefits.

Cucumis sativus, commonly known as cucumber, has been suggested for its protective effects in oxidative and carbonyl stress models, which are related to diabetes and its complications (Hediari et al., 2016). Studies have shown that cucumber can prevent oxidative stress and carbonyl stress markers in isolated hepatocytes (Hediari et al., 2016). However, there is limited information on the photoprotective effects of cucumber.

One study investigated the protective mechanisms of Cucumis sativus in diabetes-related models of oxidative stress and carbonyl stress (Hediari et al., 2016). The aqueous extract of C. sativus fruit was found to prevent cytotoxicity markers in both oxidative and carbonyl stress models, including cell lysis, ROS formation, membrane lipid peroxidation, depletion of glutathione, mitochondrial membrane potential decline, lysosomal labialization, and proteolysis (Hediari et al., 2016). The extract also protected hepatocytes from protein carbonylation induced by glyoxal, a reactive carbonyl species (Hediari et al., 2016).

Another study mentioned the potential photoprotective effects of cucumber-derived ingredients, such as caffeic acid, which have been reported to penetrate the skin and provide UV photoprotective activity (Fiume et al., 2014). However, this study did not specifically focus on the photoprotective effects of Cucumis sativus itself. In conclusion, while there is evidence suggesting that Cucumis sativus has protective effects against oxidative and carbonyl stress, as well as potential photoprotective effects through its derived ingredients, more research is needed to fully understand the photoprotective properties of cucumber.

Safety of Cucumber as an Ingredient in Skin Care Products

Assessment done by the Cosmetic Ingredient Review (CIR) Expert Panel which examined the safety of six cosmetic ingredients derived from Cucumis sativus (cucumber) plant for use in skincare products showed that

the ingredients were non-aggressive, non-irritating, and non-sensitizing to the skin in various tests and clinical trials (Fiume et al., 2014). One study reviewed in the assessment even demonstrated that exposure to cucumber extract delayed tumorigenesis and reduced tumor incidence in mice (Fiume et al., 2014). Cosmetic formulations containing 0.5% to 2.5% cucumber extract did not irritate the skin for 24 hours. In another study with 21-day administration of 1% cucumber fruit extract ophthalmic emulsion and 28-day application of a 5% cucumber fruit extract ophthalmic gel, no skin irritation was reported among the study participants (Fiume et al., 2014). A clinical phototoxicity study with 9 patients showed that formulation containing 5% C sativus (cucumber) fruit extract was not phototoxic (Fiume et al., 2014).

IV. Research Design

The study will employ a randomized, split-body, double-blind, controlled trial design. Each participant volunteer will receive 2%, 4% cucumber seed extract and a placebo. Test sites will be placed on the lower back and the assignments of which test sites will receive a specific treatment will be randomized using a random wheel. All test sites will be exposed to doses of NB-UVB ultraviolet (UV) radiation and erythema response evaluated after 24 hours. Patient will also be asked to follow up after 48 hours to monitor for adverse reactions. This research will be a monocentric study spanning 3 months.

Operational Definitions

- Minimum Erythema Dose (MED) – The smallest UV dose that results in uniform well-defined erythema over the entire exposed area after 24 hours of exposure to the NB-UVB light source, which will also classify as E2 on the Visual Erythema Scale.
- Placebo – Treatment containing the ingredients for the gel vehicle such as distilled water, glycerin, carbopol and triethanolamine but does not have the active ingredient which is the Cucumis sativus seed extract
- Adverse Effects – Any unpleasant or unintended responses to the study drug at any dose such as but not limited to pruritus, pain, stinging, blistering, xerosis, etc
- Fitzpatrick Skin Type – A way to classify the skin by its reaction to exposure to sunlight

- Type 1 – Always burns, never tans
- Type 2 – Burns easily, tans poorly
- Type 3 – Hardly burns, tans easily
- Type 4 – Burns minimally, tans easily
- Type 5 – Rarely burns, tans darkly easily

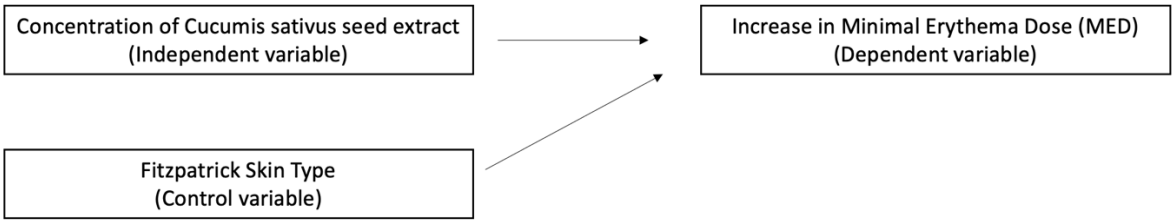


Figure 1. Conceptual Framework

V. Methodology

A. Preparation and extraction of Cucumis sativus seed concentrate

The cucumber seed oil was extracted using the Soxhlet method by Viwil Cosmetics and Skin Care Product Trading, an FDA-registered pharmaceutical company. In the initial process, cucumber seeds and aluminum hydroxide are prepared into a mixture that will undergo triple pulverization followed by passing through a 60-mesh sieve to eliminate particles. The pulverized mixture will be wrapped in filtered paper and placed in a Soxhlet extractor. To initiate the extraction, the system will be heated to maintain a constant solvent reflux at a temperature of 68.5℃. After completion, anhydrous sodium sulfate will be judiciously added to the extracted solution to facilitate dehydration until precipitation occurs. The subsequent step involves the distillation of the solvent at atmospheric pressure. The cucumber seed oil derived from this process was then compounded into 2% and 4% cucumber seed gel formulations under sterile conditions by the same company.

B. Recruitment Process

The recruitment will be carried out in a tertiary hospital in Manila for 3 months. Study participants will be patients aged 18 to 59 years old, Filipino with skin types III to V who will meet the eligibility criteria and with no

criteria for exclusion will be included in the study. Respondents will be provided an informed consent form which will include the option for the respondent to decline participation in the study. Participants who are willing to participate will be recruited by the primary researcher face to face to explain the nature of the study, the consent form, and any additional information as requested by the participant.

C. Randomization and Application of Cucumis sativus cream and Placebo cream

Each participant volunteer will receive three treatments in the form of 2%, 4% cucumber seed extract and a placebo. Study treatments will be randomly assigned to 3 test sites delineated on the skin of the participant's lower back area. The assignments of application of the study treatments will be randomized using a computer-generated randomization by a research assistant. Another assistant researcher will apply the sequentially numbered gels with the amount of 2 mg/cm2 on three test sites measuring 35 cm2 on the lower back of each patient. The gels will be identical in color, consistency, and smell. The administration of the topical gels will follow a double-blind approach, ensuring that the participant and the evaluator is unaware of whether the cream applied is the active or placebo variant on the lower back. All of the three test sites will be exposed to doses of ultraviolet (UV) radiation using a handheld NB-UVB light source and minimal erythema dose (MED) evaluated 24 hours later. Allocation concealment is done by sealed safekeeping data logbooks by the assistant until the end of the research period.

VI. Study Subjects

A. Inclusion Criteria

Participants will need to be between 18 to 59 years old, Filipino with skin types III to V.

B. Exclusion Criteria

- Individuals who are pregnant or breastfeeding
- Those with a past history of phototoxic, photoallergic, or abnormal responses to sunlight
- Subjects with allergies or sensitivity to cosmetic products, toiletries, sunscreens, topical drugs, cucumber, or any compounds of the administered products
- Individuals with pre-existing or dormant dermatologic conditions on the back

- Subjects with sunburn, suntan, scars, active dermal lesions, or uneven tones on the lower back area
- Those patients taking medications that cause hyperpigmentation such as minocycline, clofazimine, amiodarone, antimalarials, and chemotherapeutic drugs
- Individuals who have undergone systemic treatment that may modify the cutaneous state within 15 days from the inclusion visit or during the month preceding the inclusion visit
- Individuals who have had sun exposure on the lower back area for at least four weeks prior to study inclusion
- Individuals who have taken a whitening dietary supplement such as glutathione in the last month

Withdrawal and Stopping Guidelines

The study will be discontinued if a suspected anaphylactic reaction or if there are serious adverse events on the MED test square such as pain and formation of blisters during its administration or if the patient participation consent is withdrawn. Since healthy subjects will be recruited in the study, if ever side effects occur in the form of blisters, pain, edema, or bright red erythema after irradiation, the research subjects will be treated by the primary investigator who will act as attending physician. The research subjects will be treated with normal saline compresses for 15 minutes twice a day. The compresses can be continued with topical corticosteroids twice a day after bathing. Research subjects who experienced serious adverse effects will be considered as dropped out as their MED will not be recorded in the study, but their development will continue to be followed until they recover.

VII. Assessment Instruments

Minimal Erythema Dose (MED) is defined as the amount of UV radiation that will produce erythema of an individual's skin within a few hours post-exposure (Heckman et al., 2023) MED will be measured 24 hours after exposure. The magnitude of erythema will be assessed through visual observation by a blinded and trained evaluator on the skin test sites.

A handheld NB-UVB device will be used as radiation source whose UV light will range from 290-320 nanometers which corresponds to UVB. To measure the value of MED, six skin test areas on each of the three test sites measuring 1 cm2 will be exposed to NB-UVB at increasing intervals of 200 mJ/cm2. At the start of the exposure, only one square of the MED test patch will be open, after which an additional square will be opened and exposed for every increase in dose exposure. The timer is part of the phototherapy device, which automatically turns the NBUVB lamps off after the desired dose has been reached.

Erythema will be measured post-UV exposure using a visual scoring on each of the test sites, read at 24 hours post-exposure.

Score	Erythema Observation	Edema Observation
0	No erythema	No edema
1	Very slight erythema (barely perceptible)	Very slight edema (barely perceptible)
2	Well-defined erythema	Well-defined edema (edges of area well-defined by definite raising)
3	Moderate-to-severe erythema	Moderate edema (raised approximately 1 mm)
4	Severe erythema (beet redness) to slight eschar formation (injuries in depth)	Severe edema (raised >1 mm and extending beyond area of exposure)

Table 1. Draize's Erythema visual scoring (Doughty et al., 2016)

The MED to be measured will be the first UV dose in which a visual score of 2 was observed described as having well-defined erythema. The higher the MED value, the higher the UV dose required to produce erythema with a visual score of 2, thus, the higher the MED, the higher is the photoprotective effect.

Other outcome measures that will be assessed are the participants' subjective assessment of the exposure in terms of pruritus, pain or tenderness using a visual analog scale, and other adverse events. These will be recorded and attended to immediately after the MED testing and after 24 hours exposure to the UV light source.

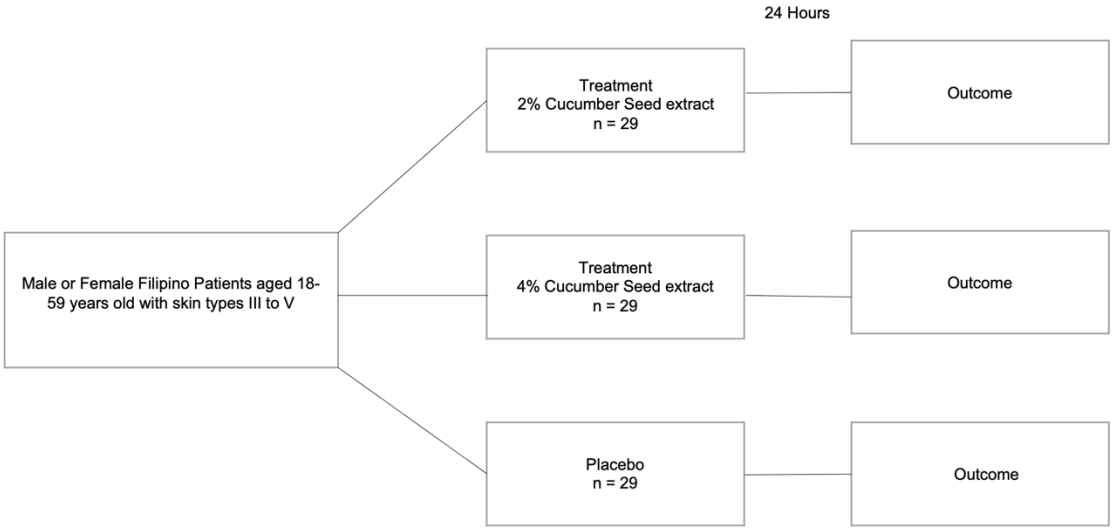


Figure 2. Study Flow

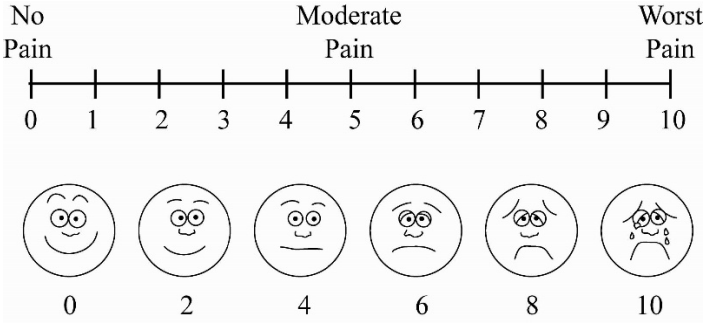


Figure 3. Visual Analog Scale

VIII. Data Collection

The investigator will explain to the participants how MED testing is done, and that the participant has to come back to the center for 2 consecutive days for the MED testing and the MED reading. Demographic profile, and the following data: allergies, comorbidities, occupation, ancestry, daily duration of sun exposure, and Fitzpatrick skin type will be taken, and recorded by the primary investigator using a survey form. A baseline MED will be recorded.

The Daavlin® MED test patch will be attached to a sun-protected region of the body by the research assistant, which will be on the lower back. The assistant researcher will apply the creams at a rate of 2 mg/cm2 on three test sites measuring 35 cm2. The six squares of the MED test patch will be exposed to NBUVB at increasing intervals of 200 mJ/cm2. At the start of the exposure, only one square of the MED test patch will be open, after which an additional square will be opened and exposed for every increase in dose exposure. Upon completion of the UV exposure, adequate skin markings using a permanent marker will be made prior to the removal of the MED test patch, in order to more easily identify the exposed areas after 24 hours. Participants will be reminded to not wash off the markings until after the skin had been examined for the MED reading.

The participants will have two follow-ups with the principal investigator, which is after 24 and 48 hours of the MED testing. After 24 hours, the investigator will examine the exposed areas of skin. Well-defined erythematous skin exposed to the shortest duration of NB-UVB will be defined as the minimal erythema dose (MED), which will also classify as E2 on the Visual Erythema Scale. Participants will also be assessed regarding any experience of any adverse events such as but not limited to pruritus, pain, tenderness, irregular pigmentation, etc immediately after and then 24 and 48 hours after application of creams.

IX. Statistical Data Analysis Plan

Statistical analysis will involve both descriptive and inferential methods.

Sample Size Calculation

With mean (SD) MED for NB-UVB of 946 (276) for Fitzpatrick skin type IV based on the study by Valbuena et al., and assuming that intervention will increase MED by at least 25%, the computed sample size is at least 29 subjects. Computation is done allowing for 5% alpha error and 90% power.

Data Analysis

Descriptive statistics will be done using frequency and proportion for qualitative and categorical data. Means and standard deviation will be done for normally distributed ratio, quantitative data. Otherwise, median, interquartile range, and range will be used.

To compare the mean MED among 2%, 4% cucumber seed extract and placebo, repeated measures analysis of variance (ANOVA) will be used. To compare the mean MED at baseline and after application of 2% and 4%, paired t test will be used. Normality of data will be checked using Shapiro Wilk test. Level of significance will be set at p values <0.05. All statistical analyses will be done using Stata version 14.

X. Limitations of the Study

Since the study will only involve adult patients aged 18-59 years old, the results of the study cannot be used to generalize among individuals belonging to the pediatric and elderly population. Additionally, the study's single-center design, conducted exclusively at Tondo Medical Center, may limit the generalizability of the findings to a wider demographic and geographic context. Different populations and healthcare settings may exhibit varying treatment responses and safety profiles. Therefore, caution should be exercised when extrapolating the results to populations outside the study's specific setting.

XI. Disclosures

This study has nothing to disclose.

XII. Ethical Considerations

Institutional Review Board (IRB)

Ethical oversight is conferred through the critical involvement of the Institutional Review Board (IRB) or Ethics Committee of Tondo Medical Center. The IRB rigorously scrutinizes the study's ethical and methodological facets, encompassing the research protocol, participant recruitment techniques, informed consent procedures, and data management mechanisms. The objective is to ascertain compliance with ethical tenets and to uphold the principles of beneficence and non-maleficence. IRB approval serves as an unwavering ethical compass, anchoring the study's ethical framework.

Good Clinical Practice (GCP) Adherence

This study shall comply with Good Clinical Practice (GCP) to ensure that study is designed, conducted, implemented, recorded, analyzed, and reported scientifically and ethically and at the same time also protecting study participants' rights, integrity, and confidentiality. This study will be conducted only after approval by the

Research Ethics Review Committee. Informed consent will be secured and tailored to inform the subject of rights, risks, and benefits when participating in this study. The Principal Investigator is accountable to explain the informed consent and determine that the subject has understood the information clearly and given his/her voluntary approval for participating in this study.

In the course of the study, the names of the participants will never be revealed. Any identifying information from the data set should be removed by data controllers before further usage and analysis. The data (both variables and their values) may be coded into alpha-numeric format for concealment with few designated persons having the coding key. It will be ensured that data, especially in electronic format, are accessible to authorized personnel only, and appropriately archived or deleted. These files will be limited to the researcher's access will not be released for other purposes except for this study only. This study will be done in accordance with ICH-GCP Guidelines. The results generated from the study will remain confidential, but these can be used for academic purposes only.

Conflict of Interest

There will be no conflict of interest in this study. The participants recruited in the study are healthy subjects. Participants will be provided with an informed consent form, which includes the option for the participant to decline participation in the study. Consequently, participants will be oriented about the nature of the study, the consent form and additional details as requested by participants by the primary researcher.

Funding, Sponsorship and Collaboration

This study is self-funded by the principal investigator. There will be no collaborative partnership with any other group of institutions.

Privacy and Confidentiality

Data de-identification codes will be assigned to patients involved in the study. They will be assigned numbers (01, 02, 03, and so forth) for their privacy. All data gathered will be placed in an envelope which is only accessible to the principal investigator. Data will be disposed via a shredder after the publication of the study.

Tabulations of the data gather will be stored only in the private computer of the principal investigator, which is password-protected. It will then be passed only to the statistician for computation of data.

All records will be kept in a locked file cabinet. Human subject's names will be kept on a password protected database and will be linked only with a study identification number for this research. There will be no patient identifiers. All computer entry and networking programs will be done using study identification only. All data will be entered into a computer that is password protected. Clinical information will not be released without written permission of the subject, except as necessary for monitoring by IRB. Data will be stored in a locked office of the investigators and maintained for a minimum of three years after the completion of the study.

Informed Consent

The study adheres to meticulously structured informed consent protocols. Each eligible participant is presented with a comprehensive patient information sheet and an informed consent form, available in both English and Tagalog. These documents elucidate the study's scientific objectives, experimental procedures, potential risks, and anticipated benefits. Participants are afforded the necessary time for comprehensive review, during which they may raise inquiries and seek clarifications. Informed consent is ultimately obtained in written form, unequivocally affirming participants' voluntary engagement in the study.

Incentives

There will be no monetary compensation for participation in the study. After participating in the study, the subjects will be given appropriate monetary compensation for their travel expenses for participating in the study.

Benefits of the Study

The information gained from the study can be used for further studies on exploring plant and fruit extracts as potential sunscreen agents and their other potential benefits in the hope of providing locally available, efficacious and safe alternative sources for sun protection.

Risks Involved in the Conduct of Study

The paramount concern in this study is the safety and well-being of participants. The study bears inherent risks, encompassing potential adverse events such as pain, erythema, or hyperpigmentation. To mitigate these

risks, a vigilant safety regimen is enacted. Participants are subject to close monitoring throughout the study's duration, with any encountered adverse events duly documented and judiciously managed, all in accordance with prevailing ethical principles.

The study will be discontinued if a suspected anaphylactic reaction or if there are serious adverse events on the MED test square such as pain and formation of blisters during its administration or if the patient participation consent is withdrawn. If side effects occur in the form of blisters, pain, edema, or bright red erythema after irradiation, the research subjects will be treated with normal saline compresses for 15 minutes twice a day. The compresses can be continued with topical corticosteroids twice a day after bathing. Research subjects who experienced serious adverse effects will be considered as dropped out as their MED will not be recorded in the study, but their development will continue to be followed until they recover.

Plan for Disposing Data

All electronic data will be deleted permanently three years after completion of the study. When data is destroyed it must be irreversible with no chance of recovery. Digital data may be destroyed by deleting or overwriting information or destroying the physical media (e.g. CD-ROMS).

Investigator's Responsibility

The investigator will explain the purpose of the study, provide the consent form, collect the demographic, and baseline data, and administer the treatments. The investigator will be responsible for identifying, documenting and reporting all the data and adverse events. She will also serve as the attending physician who will manage any adverse reactions that may occur during or after participation in the study.

Voluntariness

The decision of participants in this study is entirely voluntary. If in case a participant feels uncomfortable in the process of the study, he or she may inform the researcher for his/her decision to discontinue his/her participation. Such a decision will not affect the medical care or services provided to the patient.

Authorship and Contributorship

The main proponent of the study is the researcher and main author of the study. The consultant's guidance and support will be provided by the consultant from the Department of Dermatology and Venereology of Tondo Medical Center.

Questions and Concerns Regarding the Study

The participants will be asked and encouraged to voice out their concerns regarding the study and the possible outcome of the study.

Publication

The research will be submitted to national and/or international publications groups. Participants and their guardians will be informed of this prior to signing the informed consent. In all portions of the paper, the author and co-authors will be duly acknowledged. REC approval is a requirement for publication.

XIII. Budget Proposal

Item	Cost
Bond Paper/Ink	1,000
Sunscreen Development	10,000
Daavlin UV Test Patches (Pack of 100) x 2	14, 000
Travel Expenses	5,000
TOTAL	Php 30,000

XIV. Schedule of Activities/Gantt Chart

RESEARCH PHASE	SPECIFIC ACTIVITIES	EXPECTED OUTPUT	DURATION BY MONTH											
			1	2	3	4	5	6	7	8	9	10	11	12
Phase 1	Obtaining approval from ethics	Approved research by ethics												

	review board	review board												
	Seeking consent from authorities and participants	Signed informed consent form from respective authorities and participants												
Phase 2	Data collection and experimentation phase	Accomplished dummy tables for mean MED values for the 2 groups												
	Summarize and encode data	Summarized Excel sheet of pertinent data												
Phase 3	Data analysis	Statistical outputs												
Phase 4	Interpretation of results	Interpret statistical data and note of significant findings												
	Compare results with RRL	Findings compared with existing research through literature review												
	Technical report writing	Complete research paper from Chapters 1-5												

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XVI. Appendices

A. Appendices

1. APPENDIX A. Database and Data Collection Form

Table 2. Demographic Profile of Study Participants

Characteristics	Values
Mean age +/- SD, years	
Sex (%)	
Male	
Female	
Allergies, frequency (%)	

Comorbidity, frequency (%)	
Occupation, frequency (%)	
Ancestry, frequency (%)	
Pure Filipino	
Mixed ancestry	
Fitzpatrick Skin Type, frequency (%)	
Type III	
Type IV	
Type V	
Daily Duration of Sun Exposure, frequency (%)	
Minimal (less than 10 minutes)	
Moderate (more than 10 minutes, but less than 1 hour)	
Severe (more than 1 hour)	

Table 3. Dummy table for MED measurements of Baseline, Placebo, 2% and 4% Cucumber seed extract

	MED (Mean +/- SD)	p-value
Baseline		
Placebo		
Cucumber seed extract cream 2%		
Cucumber seed extract cream 4%		

Table 4. Dummy Table for Comparison on the Increase of Mean Minimal Erythema Dose between Placebo, 2% and 4% Cucumber seed extract

	Amount of Increase of MED from Baseline (Mean +/- SD)	p-value
Placebo		

Cucumber seed extract cream 2%		
Cucumber seed extract cream 4%		

Table 5. Dummy Table for Subjective Assessment of Pain and Pruritus using Visual Analog Scale During and 24 Hours After MED Testing

	Immediately After MED Testing	24 Hours After MED Testing
Pruritus		
0		
1		
2		
3		
Pain or Tenderness		
0		
1		
2		
3		

Table 6. Dummy Table for Subjective Assessment of Adverse Effects

	Frequency (%)
Burning Sensation	
0 None	
1 Awareness of symptoms but easily tolerated	
2 Enough discomfort to cause interference with daily activities	
3 Incapacitating with inability to do	

work	
Blistering	
0 None	
1 Awareness of symptoms but easily tolerated	
2 Enough discomfort to cause interference with daily activities	
3 Incapacitating with inability to do work	
Irregular Pigmentation	
0 None	
1 Awareness of symptoms but easily tolerated	
2 Enough discomfort to cause interference with daily activities	
3 Incapacitating with inability to do work	

2. APPENDIX B. Informed Consent and Patient Information Sheet (English and Tagalog)

APPENDIX B1. Informed Consent and Patient Information Sheet (English)

TONDO MEDICAL CENTER
Honorio Lopez Boulevard, Balut, Tondo, Manila

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

CLINICAL TRIAL/CLINICAL RESEARCH

A DOUBLE-BLIND RANDOMIZED CONTROLLED TRIAL ON THE PHOTOPROTECTIVE EFFECT OF CUCUMBER (*Cucumis sativus)* SEED EXTRACT VS PLACEBO IN TERMS OF MINIMAL ERYTHEMA DOSE AMONG FILIPINO ADULTS

Invitation
You are invited to participate in a research study comparing the minimal erythema dose of cucumber seed extract vs placebo.

A DOUBLE-BLIND RANDOMIZED CONTROLLED TRIAL ON THE PHOTOPROTECTIVE EFFECT OF CUCUMBER (*Cucumis sativus)* SEED EXTRACT VS PLACEBO IN TERMS OF MINIMAL ERYTHEMA DOSE AMONG FILIPINO ADULTS

The study is being conducted by Claudine Kay M. Fernandez, a third year resident in the Department of Dermatology and Venereology.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. What is the purpose of this study?

The purpose is to compare the potential skin photoprotective effects of 2% and 4% cucumber (*Cucumis sativus)* seed extract vs placebo in terms of minimal erythema dose which is the lowest UV dose that results in uniform well-defined redness over the entire exposed area after 24 hours of exposure to the NB-UVB light source.

2. Why have I been invited to participate in this study?

You are eligible to participate in this study because participants will need to be between 18 to 50 years old. Individuals must be healthy. Participants are required to be Filipino with skin types III and IV. Participants should have a uniform skin color on the lower back. Subjects will be instructed not to take any drugs, dietary supplements, or topical products.

3. What if I don't want to take part in this study, or if I want to withdraw later?

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

New information about the treatment being studied may become available during the course of the study. You will be kept informed of any significant new findings that may affect your willingness to continue in the study.

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

4. What does this study involve?

If you agree to participate in this study, you will be asked to sign the Participant Consent Form.

This study will be conducted over a period of 3 months. There will be 29 participants. If you agree to participate in this trial, you will then be asked to come for 2 days. On day one, three skin applications at the lower back of a formulated 2% and 4% cucumber extract cream and a placebo which will be exposed to UV radiation using an NB-UVB handheld device will be done. On day two, the treatment sites will be observed and recorded after 24 hours of application.

'Randomised trial': Sometimes doctors don't know the best way of treating patients with a particular condition so comparisons need to be made between different treatments. To do this, study participants are given different treatments, and the results are compared to see whether one treatment is better. To ensure the treatments are similar to start with, a computer allocates each treatment to three areas on the lower back randomly. Neither the doctor nor the study participant can decide which treatment the participant receives.

'Blind trial': In a "blind trial" the study participants do not know which treatment they are receving.

'Placebo': A placebo is a treatment that looks like the cucumber sunscreen but contains no active ingredient.

5. **What is my responsibility as participant?**
   The participant has the responsibility to respect the investigators, personnel related to the study and other participants, to read thoroughly the consent form and other documents related, to ask clarifications and questions if need be, to inform the staff if you would like to withdraw from the study and to keep the staff informed of any changes on the contact number or address. The participant should also comply with follow up schedules and instructions while participating in the study.

6. **Are there risks to me in taking part in this study?**
   All medical procedures involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. In spite of all reasonable precautions, you might develop medical complications from participating in this study. The known risks of this study are: allergic reactions or skin discomfort, pain, blistering, and irregular pigmentation.

7. **What happens if I suffer injury or complications as a result of the study?**
   If you suffer any injuries or complications as a result of this study, you should contact the study doctor as soon as possible, who will assist you in arranging appropriate medical treatment.

8. **Are there foreseeable circumstances in which my participation in the study will be stopped or withdrawn?**
   Participation in the study will be discontinued if a suspected anaphylactic reaction or if there are serious adverse events on the MED test square such as severe pain and formation of blisters during its administration or if the patient participation consent is withdrawn. Research subjects who experienced serious adverse effects will be considered as dropped out as their MED will not be recorded in the study, but their development will continue to be followed until they recover.

9. **Will I benefit from the study?**
   This study aims to further medical knowledge and may improve future sun protection practices however it may not directly benefit you.

10. **Will taking part in this study cost me anything, and will I be paid?**
    Participation in this study will not cost you anything. You will be reimbursed for your time and reasonable travel expenses.

11. **What if I want access to the study drug after the study?**
    Patients who participate in the study may have continued access to the investigational cucumber sunscreen after trial completion free of charge if the patient has a life-threatening or severe medical condition and his/her well-being requires use of the investigational product and if there are no other appropriate alternative treatments available to the patient.

12. **How will my confidentiality be protected?**
    Of the people treating you, only study investigators will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researchers named above will have access to your details and results. The REC and regulatory authorities will be granted direct access to participant's medical records for purposes only of verification of clinical trial procedures and data.

13. What will happen to my data or records after participating in the study?

All electronic data will be deleted permanently three years after completion of the study. When data is destroyed it will be irreversible with no chance of recovery. Digital data may be destroyed by deleting or overwriting information or destroying the physical media (e.g. CD-ROMS).

14. What happens with the results?

The participant or the participant's legal representative will be informed right away if any information from the study becomes available that may affect his or her participation in the study.The knowledge we will get from this research will be shared with you at the end of the study period. Confidential information, however, will not be shared. Subsequently, the results may be presented in conferences or published in journals so that other interested people may learn from this study. In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be readily provided to you, if you wish.

15. Do I have access to my records while participating in this study?

All information gathered from the study will not be divulged without the permission of the participants. The participant's study record may be obtained if it affects the provision, coordination, or management of healthcare for the participant.

16. Funding, Sponsorship and Collaboration

This study is self-funded by the principal investigator. There will be no collaborative partnership with any other group of institutions.

17. Investigator's Responsibility

The investigator will explain the purpose of the study, provide the consent form, collect the demographic, and baseline data, and administer the treatments. The investigator will be responsible for identifying, documenting and reporting all the data and adverse events. She will also serve as the attending physician who will manage any adverse reactions that may occur during or after participation in the study.

18. What should I do if I want to discuss this study further before I decide?

If you have any questions regarding the study, you may ask now or anytime during the course of the study. If you have any questions that might occur later in the study you may contact Tondo Medical Center Department of Dermatology and Venereology through (8865-9000 local 1093) and the investigator's contact number (09173197044). For grievances and complaints as well as information on the rights of study participants you may reach through the Research Ethics Committee of Tondo Medical Center:

Paul John L. Ablaza, MD, FPCP, FPCC, FPSE
Chair, Research Ethics Committee
Tondo Medical Center
plablaza@ust.edu.ph
09328488082
8865-9000 loc 1069

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

A DOUBLE-BLIND RANDOMIZED CONTROLLED TRIAL ON THE PHOTOPROTECTIVE EFFECT OF CUCUMBER (*Cucumis sativus)* SEED EXTRACT VS PLACEBO IN TERMS OF MINIMAL ERYTHEMA DOSE AMONG FILIPINO ADULTS

TONDO MEDICAL CENTER
Honorio Lopez Boulevard, Balut, Tondo, Manila

CONSENT FORM
[To be used in conjunction with a Participant Information Sheet]

A DOUBLE-BLIND RANDOMIZED CONTROLLED TRIAL ON THE PHOTOPROTECTIVE EFFECT OF CUCUMBER (*Cucumis sativus)* SEED EXTRACT VS PLACEBO IN TERMS OF MINIMAL ERYTHEMA DOSE AMONG FILIPINO ADULTS

1. I,.....
of.....
agree to participate in the study described in the participant information statement set out above ***(or: attached to this form).***

2. I acknowledge that I have read the participant information statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.

3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.

4. I understand that I can withdraw from the study at any time without prejudice to my relationship to Tondo Medical Center.

5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

6. I understand that if I have any questions relating to my participation in this research, I may contact Dr Claudine Kay M. Fernandez at 09173197044, who will be happy to answer them.

7. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.

Signature of participant	**Please PRINT name [*or person responsible]***	**Date**
_____	_____	_____
Signature of witness	**Please PRINT name**	**Date**
_____	_____	_____

Signature of investigator	Please PRINT name	Date
_____	_____	_____

A DOUBLE-BLIND RANDOMIZED CONTROLLED TRIAL ON THE PHOTOPROTECTIVE EFFECT OF CUCUMBER (*Cucumis sativus)* SEED EXTRACT VS PLACEBO IN TERMS OF MINIMAL ERYTHEMA DOSE AMONG FILIPINO ADULTS

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A DOUBLE-BLIND RANDOMIZED CONTROLLED TRIAL ON THE PHOTOPROTECTIVE EFFECT OF CUCUMBER (*Cucumis sativus)* SEED EXTRACT VS PLACEBO IN TERMS OF MINIMAL ERYTHEMA DOSE

WITHDRAWAL OF CONSENT

I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with Tondo Medical Center.

Signature of participant [*or person responsible]*	**Please PRINT name**	**Date**
_____	_____	_____

The section for Revocation of Consent should be forwarded to **Claudine Kay M. Fernandez, Dermatology II Subspecialty Clinic, Tondo Medical Center.**

APPENDIX B2. Informed Consent and Patient Information Sheet (Tagalog)

TONDO MEDICAL CENTER
Honorio Lopez Boulevard, Balut, Tondo, Manila

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

CLINICAL TRIAL/CLINICAL RESEARCH

A DOUBLE-BLIND RANDOMIZED CONTROLLED TRIAL ON THE PHOTOPROTECTIVE EFFECT OF CUCUMBER (*Cucumis sativus)* SEED EXTRACT VS PLACEBO IN TERMS OF MINIMAL ERYTHEMA DOSE AMONG FILIPINO ADULTS

Paanyaya
Iniimbitahan ka na makilahok sa isang pananaliksik hinggil sa paghambing ng potensyal na epekto ng seed extract ng cucumber (Cucumis sativus) sa balat kumpara sa placebo para sa proteksiyon sa araw.

Ang pag-aaral ay isinasagawa ni Claudine Kay M. Fernandez, isang residente sa Department of Dermatology and Venereology sa Tondo Medical Center.

Bago ka magpasya kung nais mo o hindi sumali sa pag-aaral na ito, mahalaga na maunawaan mo kung bakit isinasagawa ang pananaliksik at ano ang magiging bahagi mo rito. Mangyaring basahin ng maayos ang sumusunod na impormasyon at talakayin ito sa iba kung gusto mo.

1. **Ano ang layunin ng pag-aaral na ito?**

Ang layunin ng pag-aaral na ito ay para ihambing ang potensyal na epekto ng 2% at 4% seed extract ng cucumber (Cucumis sativus) sa balat kumpara sa placebo para sa proteksiyon sa araw.base sa minimal erythema dose o and pinkamababang level ng UV dose na nagdudulot ng pantay na pagpula sa buong balat na na-exposse sa ilaw mula sa NB-UVB matapos and 24 oras.

2. Bakit ako inimbitahan na sumali sa pag-aaral na ito?

Maaring sumali sa pag-aaral na ito ang mga indibidwal na may edad na 18 hanggang 50 taon. Kailangang malusog ang mga kalahok. Dapat na Filipino ang mga lalahok at may skin types III at IV. Dapat din pantay ang kulay ng balat sa likuran. Ang mga kalahok ay dapat na hindi uminom o nagpahid ng anumang gamot, dietary supplements, o topical products.

3. Ano kung ayaw kong sumali sa pag-aaral, o kung gusto kong umatras mamaya?

Ang pagsali sa pag-aaral na ito ay boluntaryo. Nasa iyo kung gusto mo o hindi sumali. Kung hindi ka sasali, hindi ito magiging hadlang sa pagtanggap mo ng anumang paggamot na nararapat ngayon o sa hinaharap. Anuman ang iyong desisyon, hindi ito makakaapekto sa iyong relasyon sa mga taong nagaalaga sa iyo.

Maaaring magkaruon ng panibagong impormasyon hinggil sa gamot na pinagaaralan habang isinasagawa ang pag-aaral. Ikaw ay pagbibigyang-alam sa anumang makabuluhang bagong natuklasan na maaaring makaapekto sa iyong kagustuhan na magpatuloy sa pag-aaral.

Kung gusto mong umatras mula sa pag-aaral pagkatapos ito magsimula, maaari mong gawin ito anumang oras nang walang kailangang magbigay ng dahilan.

4. Ano ang kinabibilangan ng pag-aaral na ito?

Kung sumasang-ayon kang lumahok sa pag-aaral na ito, hihilingin na iyong lagdaan ang Form ng Pahintulot ng Kalahok.

Ang pag-aaral na ito ay isasagawa sa loob ng 3 buwan. Magkakaroon ng 29 na kalahok. Kung sumasang-ayon kang lumahok sa pagsubok na ito, hihilingin sa iyo na pumunta sa loob ng 2 araw. Sa unang araw, ipapahid sa balat sa ibabang bahagi ng likod ang formulated na 2% at 4% na cucumber extract cream at isang placebo (walang cucumber extract) na i-eexpose sa UV radiation gamit ang isang NB-UVB na handheld device. Sa ikalawang araw, ang mga lugar na pinahiran ng mga sunscreen ay obserbahan at itatala pagkatapos ng 24 na oras ng aplikasyon.

'Randomised trial': Minsan hindi alam ng mga doktor ang pinakamahusay na paraan ng paggamot sa mga pasyente na may partikular na kondisyon kaya kailangang gumawa ng mga paghahambing sa pagitan ng iba't ibang paggamot. Upang gawin ito, ang mga kalahok sa pag-aaral ay binibigyan ng iba't ibang gamot, at ang mga resulta ay inihambing upang makita kung ang isang gamot ay mas mahusay. Upang matiyak na ang mga paggamot ay katulad sa simula, ang isang computer ay random na naglalaan ng pagpapahiran ng bawat gamot sa tatlong bahagi sa ibabang bahagi ng likod. Hindi maaaring magpasya ang doktor o ang kalahok sa pag-aaral kung aling paggamot ang matatanggap ng kalahok.

Blind trial': Sa isang "blind trial" hindi alam ng mga kalahok sa pag-aaral kung aling paggamot ang kanilang tinatanggap.

'Placebo': Ang placebo ay isang paggamot na kamukha ng cucumber sunscreen ngunit walang aktibong sangkap.

5. Ano ang aking responsibilidad bilang kalahok?

Ang kalahok ay may responsibilidad na igalang ang mga investigator, mga tauhan na may kaugnayan sa pag-aaral at iba pang mga kalahok, na basahin nang maigi ang form ng pahintulot at iba pang mga dokumentong nauugnay, upang humingi ng mga paglilinaw at mga katanungan kung kinakailangan, upang ipaalam sa mga investigator kung gusto mong umalis mula sa ang pag-aaral at upang magsabi sa mga researcher ng anumang mga pagbabago sa contact number o address. Ang kalahok ay dapat ding sumunod sa mga follow up na iskedyul at mga tagubilin habang nakikilahok sa pag-aaral.

6. Mayroon bang panganib para sa akin sa pagsali sa pag-aaral na ito?

Lahat ng medikal na pamamaraan ay may kaakibat na panganib ng pinsala. Bukod dito, maaaring may mga panganib na kaakibat ang pag-aaral na ito na kasalukuyang hindi alam o hindi maipipredict. Sa kabila ng lahat ng makatwiran na pag-iingat, maaaring magkaruon ka ng mga komplikasyon mula sa pag-aaral na ito. Ang mga kilalang panganib ng pag-aaral na ito ay: allergic reactions o skin discomfort, kirot, o pangingitim ng balat.

7. Ano ang mangyayari kung magkaruon ako ng pinsala o komplikasyon bilang resulta ng pag-aaral?

Kung ikaw ay magkaruon ng anumang pinsala o komplikasyon dahil sa pag-aaral na ito, dapat kang makipag-ugnayan sa doktor ng pag-aaral sa lalong madaling panahon, na tutulong sa iyo sa pag-ayos ng angkop na medikal na paggamot.

8. Mayroon bang nakikitang mga pangyayari kung saan ang aking paglahok sa pag-aaral ay itigil o aalisin?

Ang paglahok sa pag-aaral ay ihihinto kung ang isang pinaghihinalaang anaphylactic na reaksyon o kung may malubhang masamang epekto sa MED test square tulad ng matinding pananakit at pagbuo ng mga paltos habang isinasagawa ang pagpapahid o pagiilaw o kung ang pahintulot ng paglahok ay binawi. Ang mga kalahok na nakaranas ng malubhang masamang epekto ay ituturing na drop out dahil ang kanilang MED ay hindi itatala sa pag-aaral, ngunit ang kanilang paggaling ay patuloy na susundan hanggang sa sila ay gumaling.

9. Makikinabang ba ako sa pag-aaral?

Ang layunin ng pag-aaral na ito ay makapagdagdag sa kaalaman sa medisina at mapabuti ang proteksyon ng balat mula sa araw bagaman ito ay maaaring hindi direktang makakabigay ng benepisyo sa iyo.

10. Magkano ang magagastos ko sa pagsali sa pag-aaral, at may bayad ba ako?

Ang pagsali sa pag-aaral na ito ay hindi magkakaroon ng bayad sa iyo. Ikaw ay irereimburse para sa iyong oras at makatarungan na gastos sa paglalakbay.

11. Paano kung gusto kong makakuha ng gamot sa pag-aaral pagkatapos ng pag-aaral?

Ang mga pasyente na lumahok sa pag-aaral ay maaaring magkaroon ng patuloy na pag-access sa investigational cucumber sunscreen pagkatapos makumpleto ang pag-aaral nang walang bayad kung ang pasyente ay may banta sa buhay o malubhang kondisyong medikal at ang kanyang kapakanan ay nakasalalay sa paggamit ng mga pinagaaralang gamot at kung walang alternatibong gamot na magagamit sa pasyente.

12. Paano protektahan ang aking confidentiality?

Sa mga taong gumagamot sa iyo, ang mga investigator lang sa pag-aaral ang makakaalam kung kasali ka o hindi sa pag-aaral na ito. Ang anumang makikilalang impormasyon na nakolekta tungkol sa iyo kaugnay ng pag-aaral na ito ay mananatiling kumpidensyal at ibubunyag lamang sa iyong pahintulot, o maliban kung kinakailangan ng batas. Tanging ang mga mananaliksik na pinangalanan sa itaas ang

magkakaroon ng access sa iyong mga detalye at resulta. Ang REC at mga awtoridad sa regulasyon ay bibigyan ng direktang access sa mga medikal na rekord ng kalahok para sa mga layunin lamang ng pagpapatunay ng mga pamamaraan at data ng pag-aaral.

13. Ano ang mangyayari sa aking data o mga talaan pagkatapos makilahok sa pag-aaral?

Ang lahat ng elektronikong data ay permanenteng ibubura tatlong taon pagkatapos makumpleto ang pag-aaral. Kapag ang data ay nawasak ito ay hindi maibabalik nang walang pagkakataong mabawi. Maaaring sirain ang digital data sa pamamagitan ng pagtanggal o pag-overwrite ng impormasyon o pagsira sa pisikal na media (hal. CD-ROMS).

14. Ano ang mangyayari sa mga resulta?

Ang kalahok o ang legal na kinatawan ng kalahok ay aabisuhan kaagad kung ang anumang impormasyon mula sa pag-aaral ay makukuha na maaaring makaapekto sa kanyang pakikilahok sa pag-aaral. Ang kaalaman na aming makukuha mula sa pananaliksik na ito ay ibabahagi sa iyo sa pagtatapos ng panahon ng pag-aaral. Gayunpaman, hindi ibabahagi ang kumpidensyal na impormasyon. Kasunod nito, ang mga resulta ay maaaring iharap sa mga kumperensya o mailathala sa mga journal upang ang ibang mga interesado ay matuto mula sa pag-aaral na ito. Sa anumang publikasyon, ibibigay ang impormasyon sa paraang hindi ka makikilala. Ang mga resulta ng pag-aaral ay madaling ibibigay sa iyo, kung nais mo.

15. Mayroon ba akong access sa aking mga tala habang nakikilahok sa pag-aaral na ito?

Ang lahat ng impormasyong nakalap mula sa pag-aaral ay hindi ibubunyag nang walang pahintulot ng mga kalahok. Maaaring makuha ang rekord ng pag-aaral ng kalahok kung makakaapekto ito sa probisyon, koordinasyon, o pamamahala ng paggagamot para sa kalahok.

16. Pagpopondo, Sponsorship at Pakikipagtulungan

Ang pag-aaral na ito ay pinondohan ng sarili ng punong imbestigador. Hindi magkakaroon ng collaborative partnership sa anumang iba pang grupo o institusyon.

17. Pananagutan ng Imbestigador

Ipapaliwanag ng investigator ang layunin ng pag-aaral, ibibigay ang form ng pahintulot, kokolektahin ang demograpiko, at baseline na data, at pangasiwaan ang mga paggamot. Pananagutan ng imbestigador ang pagtukoy, pagdodokumento at pag-uulat ng lahat ng data at masamang kaganapan. Siya rin ay magsisilbing manggagamot na mamamahala sa anumang masamang reaksyon na maaaring mangyari sa panahon o pagkatapos ng paglahok sa pag-aaral.

18. Ano ang dapat kong gawin kung gusto kong pag-usapan ang pag-aaral na ito ng mas mabuti bago magdesisyon?

Kung mayroon kang anumang mga katanungan tungkol sa pag-aaral, maaari kang magtanong ngayon o anumang oras sa kurso ng pag-aaral. Kung mayroon kang anumang mga katanungan na maaaring mangyari mamaya sa pag-aaral maaari kang makipag-ugnayan sa Tondo Medical Center Department of Dermatology and Venereology sa pamamagitan ng (8865-9000 local 1093) at ang contact number ng imbestigador (09173197044). Para sa mga hinaing at reklamo pati na rin ang impormasyon sa mga karapatan ng mga kalahok sa pag-aaral na maaari mong maabot sa pamamagitan ng Research Ethics Committee ng Tondo Medical Center:

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09328488082
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Salamat sa paglaan ng oras para isaalang-alang ang pag-aaral na ito. Kung nais mong sumali, mangyaring pirmahan ang kasamang consent form. Ang impormasyong ito ay para sa iyo na itago.