RANDOMIZED DOUBLE BLIND PLACEBO-CONTROLLED CLINICAL ON THE EFFICACY AND SAFETY OF *MORINGA OLEIFERA (MALUNGGAY)* 1% CREAM IN THE TREATMENT OF TINEA CORPORIS: A PILOT STUDY

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BACKGROUND: All parts of the Moringa tree are edible and have long been consumed by humans. Moringa preparations have been cited in the scientific literature as having antibiotic, antitrypanosomal, hypotensive, antispasmodic, antiulcer, anti-inflammatory, hypocholesterolemic, and hypoglycemic activities as well as having considerable efficacy in water purification.

Tinea corporis is one of the top 10 new cases seen in the Department of Dermatology, outpatient department of East Avenue Medical Center. Tinea corporis refers to dermatophyte infections of the trunk, legs, arms, and/or neck, excluding feet, hands and groin. It is commonly caused by Trichophyton rubrum, T. mentagrophytes and Microsporum canis. There has been no reported or published clinical trial on the efficacy of either antimicrobial or anti-fungal properties of Moringa oleifera. This prompted the investigator to pursue this study.

OBJECTIVE: To determine the efficacy and safety of *Moringa oleifera* (Malunggay) in the treatment of tinea corporis infection among patients at East Avenue Medical Center Department of Dermatology.

METHODOLOGY: A total of 40 patients were randomly assigned to 2 groups, Group A (placebo group) had 20 patients and Group B (Moringa) had 20 patients. Thirty-four patients completed the study period, 16 for placebo group and 18 for Moringa group. Clinical parameters (erythema, pruritus and scaling) were followed-up in terms of improvement. Mycologic cure in terms of KOH smear was also noted at the end of the study. Adverse reactions were noted as well.

RESULTS: There was no significant clinical improvement in terms of erythema, pruritus and scaling observed at the end of the study. Mycological cure rates showed 37.5% for the placebo group and 72.2% in the Moringa group. Among groups, mycologic cure rates using KOH smear showed no significant difference. Minimal pruritus at week one was observed which spontaneously improved at the end of the treatment.

CONCLUSION: Moringa oleifera cream at 1% is not effective in the treatment of tinea corporis

INTRODUCTION

Moringa oleifera, or the horseradish tree, is a pan-tropical species that is known by such regional names as benzolive, drumstick tree, kelor, marango, mlonge, mulangay, nebeday, saijhan, and sajna. It is the most widely cultivated species of a monogeneric family, the Moringaceae, that is native to the sub-Himalayan tracts of India, Pakistan, Bangladesh and Afghanistan. This rapidly-growing tree was utilized by the ancient Romans, Greeks and Egyptians; it is now widely cultivated and has become naturalized in many locations in the tropics. It is a perennial softwood tree with timber of low quality, but which for centuries has been advocated for traditional medicinal and industrial uses. It is already an important crop in India, Ethiopia, the Philippines and the Sudan, and is being grown in West, East and South Africa, tropical Asia, Latin America, the Caribbean, Florida and the Pacific Islands. All parts of the Moringa tree are edible and have long been consumed by humans. The many uses for Moringa include alley cropping (biomass production), animal forage (leaves and treated seed-cake), biogas (from leaves), domestic cleaning agent (crushed leaves), blue dye (wood), fencing (living trees), fertilizer (seed-cake), foliar nutrient (juice expressed from the leaves), green manure (from leaves), gum (from tree trunk), honey-and sugarcane juice-clarifier (powdered seeds), honey (flower nectar), medicine (all plant parts), ornamental plantings, biopesticide (soil incorporation of leaves to prevent seedling damping off), pulp (wood), rope (bark), tannin for tanning hides (bark and gum), water purification (powdered seeds). Moringa seed oil (yield 30-40% by weight), also known as Ben oil, is a sweet non-sticking, non-drying oil that resists rancidity. It has been used in salads, for fine machine lubrication, and in the manufacture of perfume and hair products. This tree has in recent times been advocated as an outstanding indigenous source of highly digestible protein, Ca, Fe, Vitamin C, and carotenoids suitable for utilization in many of the so-called “developing” regions of the world where undernourishment is a major concern.

The benefits for the treatment or prevention of disease or infection that may accrue from either dietary or topical administration of Moringa preparations (extracts, decoctions, poultices, creams, oils, emollients, salves, powders, porridges) are not quite so well known. A plethora of traditional medicine references attest to its curative power, and scientific validation of these popular uses is developing to support at least some of the claims. Moringa preparations have been cited in the scientific literature as having antibiotic, antitrypanosomal, hypotensive, antispasmodic, antiulcer, anti-inflammatory, hypocholesterolemic, and hypoglycemic activities as well as having considerable efficacy in water purification.

An in-vitro study by Chuang PH, MD, et al, in 2007, against antifungal activity of crude extracts and essential oil of Moringa oleifera, showed that ethanol extracts have antifungal activities against dermatophytes such as trichophyton rubrum, T. mentagrophytes, Epidermophyton floccosum, and Microsporum canis.

Another study by Dahot, M.U., MD, et al, in 1998, showed that aqueous extract of M. oleifera leaves posses significant antimicrobial activity against gram positive and negative fungal species.

Tinea corporis is one of the top 10 new cases seen in the Department of Dermatology, out-patient department of East Avenue Medical Center. Tinea corporis refers to dermatophyte infections of the trunk, legs, arms, and/or neck, excluding feet, hands and groin. This may occur at any age, and is more common in warm climates. It is commonly caused by Trichophyton rubrum, T. mentagrophytes and Microsporum canis. As for its transmission, autoinoculation from other parts of the body such as from tinea pedis and tinea capitis may occur. Warmth and humidity favor the growth of the organisms. Contact with infected animals, contaminated soil and fomites can also be sources of infection. This infection is usually asymptomatic but can also be slightly pruritic. Skin lesions usually appear as small, scaling, sharply marginated plaques, with or without pustules or vesicles, usually at margins. Peripheral enlargement and central clearing produces annular configuration with concentric rings or arcuate lesions; fusion of lesions produces gyrate patterns. Single and occasionally multiple lesions may occur. Several treatment options are available in the market. Topical anti-fungal drugs such as ketoconazole, miconazole and clotrimazole and newer generation drugs such as terbinafine and butenafine are being used to treat localized forms of the disease. In choosing the best anti-fungal agent, efficacy, safety and and economics should always be considered by every physician.

There has been no reported or published clinical trial on the efficacy of either antimicrobial or anti-fungal properties of Moringa oleifera. This prompted the investigator to pursue this study.

PROBLEM

To determine the efficacy and safety of *Moringa oleifera* (Malunggay) in the treatment of tinea corporis infection among patients at East Avenue Medical Center Department of Dermatology.

SPECIFIC OBJECTIVES

1. To determine the efficacy of Malunggay cream in the treatment of tinea corporis in comparison with placebo using the following parameters:

    a. Clinical Cure
        i. Erythema
        ii. Pruritus
        iii. Scaling

    b. Microscopic
        i. KOH smear positive
        ii. KOH smear negative

2. To determie the adverse reactions to malunggay cream.

MATERIALS & METHODS

INCLUSION CRITERIA:

- All patients 12 years old to 50 years old seen at the Department of Dermatology, Out-Patient Department, East Avenue Medical Center, between November 2008 and June 2009.

- In good physical health, with no history of systemic diseases.

- No prior treatment.

- Lesions should be erythematous, well-defined, dry, scaly and pruritic plaques with active borders.

- Positive for Potassium hydroxide (KOH) smears.

METHODOLOGY

DESIGN: A double-blind, randomized placebo-controlled clinical trial within patients and between groups in the Department of Dermatology, OPD at East Avenue Medical Center.

PATIENTS/RESPONDENTS: Patients 12 to 50 years old with clinically and microscopically positive tinea corporis.

In the estimation of the sample size, the researcher used an alpha level of 0.05 and statistical power level of 70%, and arrived with a required minimum sample size of 32 and a minimum sample size per group of 16.

STUDY PROCEDURE: Informed written consent from patients and parent/guardian in patients 12-17 years old was obtained. Patients were randomly assigned to 2 groups as they came. Each patient is asked to choose a number between 1-150 from a brown envelop, facilitated by a research assistant. Those who picked an even number will be assigned to group A, while those who picked an odd number will be assigned to group B. Each group was assigned to apply the creams 2 times a day after bath over the lesions with at least one centimeter extension to the normal skin surrounding the lesion. Neither the physician nor patients knew the treatment assignment of each group. Patients were asked to follow-up after 1 week for any adverse effects, and will be re-assessed after 4 weeks of treatment. Clinical assessment parameters are as follows: 1. Erythema; 2. Pruritus; 3. Scaling. Severity grading is as follows: 0- none, 1- mild, 2-moderate and 3- severe.

KOH smear on initial visit and after 4 weeks of treatment will be obtained. Adverse reactions will be noted as well. Photographs of patients on initial visit and after 4 weeks will be gathered as well.

Compounding of Malunggay Cream

Malunggay leaf extract was mixed into cream to make a 1% mixture by a licensed pharmacist and placed into 10g white plastic containers. Placebo (vehicle) will be packaged just the same. Creams will be labeled neither A and B. The color and smell of both creams were indistinguishable.

All patients signed a written consent (parent or guardian for patients 12-17 years old), and filled up a personal data sheet. On initial visit, KOH smear of their lesion was obtained and clinical assessment of their lesions was done by the research assistant. Clinical parameters being presence of erythema, pruritus and scaling and with severity grading from 0-3, none to severe respectively.

Patients were randomly assigned to the experimental group (Malunggay cream) and to the placebo group (vehicle). All creams were placed in similar white containers previously marked. They were instructed to apply the creams 2 times a day after bath over the lesions with at least one centimeter extension to the normal skin surrounding the lesion. Standard verbal instructions were given regarding proper application. Patients were asked to follow-up weekly for 4 weeks. Photographs were taken at baseline and on subsequent follow-ups using a Canon Powershot 5.0 mega pixel digital camera.

At the end of the study period, patients under the vehicle group will be treated accordingly by an antifungal cream, provided by the researcher. Those under the experimental group, who did not improve or was not treated, will be given the same standard antifungal treatment as well. This information is included in the written consent provided at the start of the study period.

Evaluation

Patients were followed-up for assessment and for any adverse reactions for 4 consecutive weeks. The research assistant evaluates improvement using the clinical parameters. At the end of the study period (4th week) a repeat KOH smear was done and evaluated by another research assistant.

Statistical Analysis

The data were compared using the Friedman's Two-way ANOVA and Wilcoxon Rank Signed Test for the clinical parameters and Mc Nemar's Test and chi-square for the KOH smear results.

DATA AND RESULTS

Demographic Profile:

Table 1: Gender Distribution by Group

GENDER	GROUP A (Placebo)	GROUP B (Moringa)
Male	10 (62.5%)	11 (61.11%)
Female	6 (37.5%)	7 (38.88%)
Total	16	18

A total of 40 patients were included in this study. Among this original number, 34 patients completed the treatment period, and 6 patients were dropped from the study (lost to follow-up). In the placebo group (Group A), 16 patients completed the study, 62.5% of whom were males while 37.5% of the total were females. In the Moringa group (Group B), 18 patients finished the treatment period. Among the participants, 61.11% were males while the remaining 38.88% were females.

Table 2. Age Distribution of Patients By Group

AGE DISTRIBUTION	GROUP A (Placebo)	GROUP B (Moringa)
12-20	3 (18.75%)	2 (11.11%)
21-30	4 (25%)	3 (16.67%)
31-40	4 (25%)	7 (38.89%)
41-50	5 (31.25%)	6 (33.33%)
Total	16	18

In this table, it shows that in the placebo group, majority of the patients (31.25%) belong to the 41-50 age group, while 18.75% came from the 12-20 age group. In the Moringa group, majority of the patients (38.89%) belong to the 31-40 age group, while only 11.11% came from the 12-20 age group.

Response to treatment:

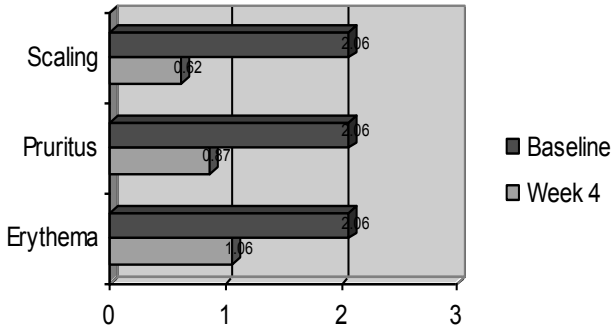


Figure 1. Mean Scores of Improvement of Clinical Parameters (Placebo Group)

This figure shows that among the 3 parameters, all mean scores decreased from baseline to week 4. Scaling showed to have decreased markedly, while erythema decreased the least among the clinical parameters.

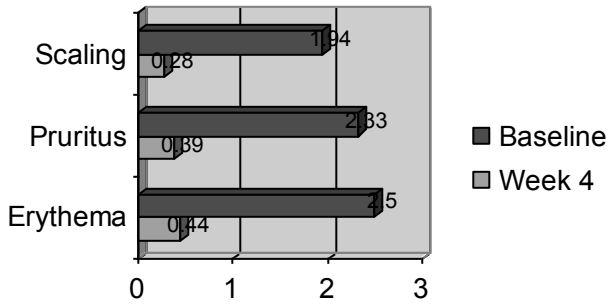


Figure 2. Mean Scores of Improvement of Clinical Parameters (Moringa Group)

This figure shows that in the Moringa group, all 3 parameters improved markedly from baseline to the end of treatment. Scaling improved the most, while erythema showed least improvement compared to pruritus and scaling.

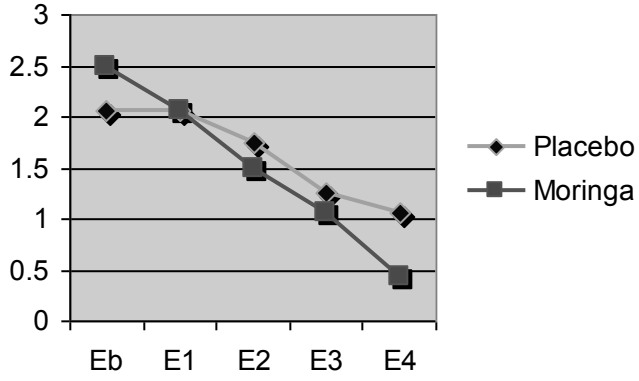


Figure 3. Comparison of Mean Score in Erythema Between Groups

This figure shows that between groups, mean score of improvement was comparable at week 1. During week 2 until end of treatment, improvement in erythema was observed more in the moringa group.

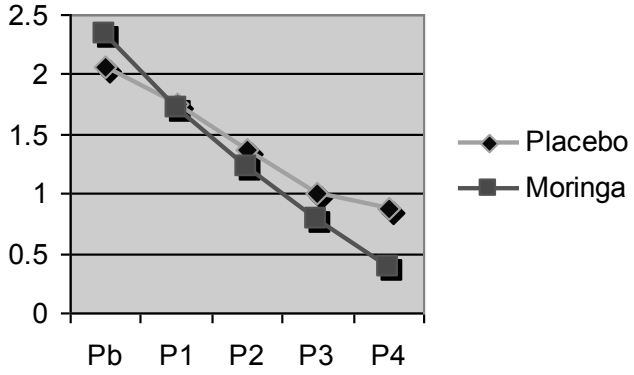


Figure 4. Comparison of Mean Score in Pruritus Between Groups

Both groups showed improvement in terms of pruritus from baseline to week 4. Between the groups, patients under Moringa group showed more improvement from baseline until end of study period.

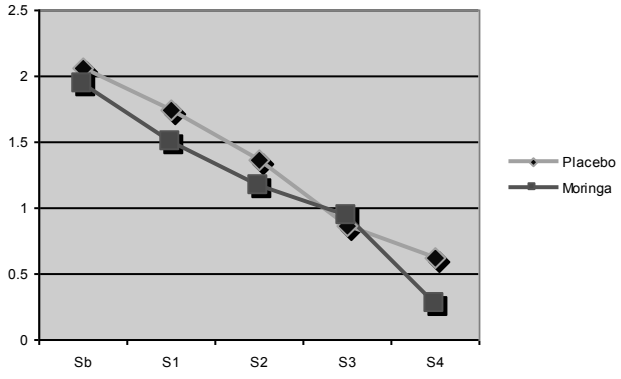


Figure 5. Comparison of Mean Score in Scaling Between Groups

Both groups showed improvement in terms of scaling, from baseline to week 4. Marked improvement was observed in Moringa group from week 3 of study period until end of study.

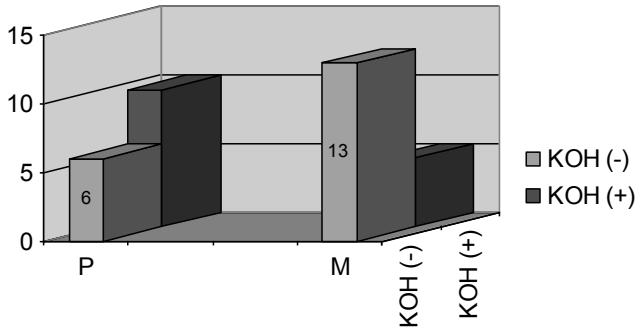


Figure 6. KOH Smear Results at Week 4 Between Groups

This figure shows that at the end of the study period, more patients in the Moringa group showed negative KOH smears at the end of the study.

Analytical Statistics

Table 3: Results of Friedman's Two-way ANOVA on Clinical Parameters (Placebo Group)

Friedman Statistic	p value	Decision
154.5625	26.30	Not statistically significant

Table 4: Results of Friedman's Two-way ANOVA on Clinical Parameters (Moringa Group)

Friedman Statistic	p value	Decision
86.9444	28.869	Not statistically significant

Table 3 & 4 show that among groups, improvement in the clinical parameters (erythema, pruritus & scaling) are not statistically significant.

Table 5: Results of Wilcoxon Rank Signed Test on clinical parameters between Baseline scores & Week 4 scores (Placebo Group)

PARAMETERS	t value	Decision
Erythema	9.405	No significant difference
Pruritus	36.600	No significant difference
Scaling	8.73	No significant difference

Critical t value: 2.131

Table 6: Results of Wilcoxon Rank Signed Test on clinical parameters between Baseline scores & Week 4 scores (Moringa Group)

PARAMETERS	t value	Decision
Erythema	9.380	No significant difference
Pruritus	9.977	No significant difference
Scaling	9.775	No significant difference

Critical t value: 2.11

Table 5 & 6 show that at the end of the study, improvement in clinical parameters between baseline & week 4 among groups, are not statistically significant.

Table 7: KOH results at Week 4 (End of Treatment Period)

	KOH (+)	KOH (-)	TOTAL
Placebo Group	10	6	16
Moringa Group	5	13	18
Total	15	19	34

McNemars Test

$X^2 = (B-C)^2 / B + C$

$= (6-5)^2 / 6 + 5$

$= 1/11$

$X=0.090909$

Critical Value = 3.841

$0.090909 < 3.841$

Therefore: accept null hypothesis, meaning the "drug" has NO impact on the KOH results.

Table 8. Results of chi-square test on the KOH smears

Parameter	Value	df	p value
KOH smear	4.14	1	0.04

KOH smear was used at the start of the study as part of the inclusion criteria. All patients with positive smears were included. At the end of the study the placebo group showed a cure rate of 37.5% while the Moringa group had a cure rate of 72.2% (Figure 6). Results showed that there was a significant difference between the cure rates of placebo group and Moringa group using the chi-square test.

Adverse Reactions

Throughout the study period, only 3 patients from the moringa group complained of increase in pruritus during the first week of treatment, which eventually improved as the study progressed.

DISCUSSION

In the early years, M. oleifera has been planted in large areas in Asia especially in Taiwan and main land China. Most people in these countries have been using the seeds of Moringa as an herbal treatment for athlete's foot and tinea, and discovered that they were effective treatments.[1] An in vitro study, identified 41 compounds in the Moringa crude extracts. In general, heneicosane (17.41%), E-phytol (7.66%) and 1-[2,3,6-trimethyl-phenyl] -2 butanone (3.44%) were the major components of the essential oil of Moringa leaf. Interestingly, there had been no single compound identified to have antifungal activity acting alone. Both benzaldehyde and indole likely might possess antifungal activities, they are also materials nontoxic to human.[1]

A study of the morphological change of the cell, to study the cell lysis mechanism was done. In this study, crude extracts was used to study the shape change of Trichophyton rubrum cells using Transmission electron microscopy (TEM). Fungal cells were treated with crude extracts of Moringa oleifera for 24 hours. Results show that the cytoplasmic membrane of the fungal cell was ruptured and the intracellular components were seriously damaged after treatment. This might indicate that extract compounds interact with the lipid bilayers in membranes leading to subsequent separation of the two membranes, water traverses then cell swells leading to death. [1]

Another study showed that aqueous extract of M. oleifera leaves possess significant antimicrobial activity against positive and negative fungal species. [2]

There were also studies done to evaluate the therapeutic properties of the seeds and leaves of M. oleifera as herbal medicines. Ethanol extracts showed anti-fungal activities in vitro against dermatophytes such as Trichophyton rubrum, Trichophyton mentagrophytes, Epidermophyton floccosum, and Microsporum canis. [4] Recent studies showed that a total of 44 compounds from the recently reported 41 compounds, were isolated from the extracts, which can be utilized in the future in the development of anti-skin disease treatment.[4] Crude extracts showed different MICs (Minimum inhibition concentration) in different fungi, 1.6 mg/ml for Trichophyton rubrum, 0.8 mg/ml Trichophyton mentagrophytes, 0.4 mg/ml Microsporum canis, 0.2mg/ml for Epidermophyton floccossum.[1]

A study which purports to evaluate the safety of the aqueous extract of the leaves of M. oleifera in rats concluded that the plant is relatively safe both for nutritional and medicinal uses. [3]

Tinea corporis refers to dermatophyte infections of the trunk, legs, arms and neck. Most commonly caused by Trichophyton rubrum, M. canis and T. tonsurans. Infection may be through autoinoculation from other parts of the body like from tinea pedis and tinea capitis. Contact with animals or contaminated soil may also be sources of infection. Definite diagnosis may be through KOH smear and culture. Topical antifungal preparations

may be effective in the treatment of dermatophytoses of the skin. Preparations are applied 2 times a day to the involved area optimally for 4 weeks including at least 1 week after lesions have cleared. The topical medications are comparable and are differentiated only by cost, base, vehicle and antifungal activity. Among the treatment options are the imidazoles, allylamines and naphthionates.[4]

CONCLUSION

This study showed that Moringa oleifera could be an effective treatment of tinea corporis. Although it showed improvement in the mean scores of the clinical parameters namely erythema, pruritus and scaling from baseline until end of study period, statistics showed that there was no significant difference among groups. Mycologic cure in terms of KOH smear, showed superior results in the Moringa group compared to placebo group, although appeared to be not statistically significant.

RECOMMENDATIONS

1. Studies using extracts of seeds and roots of Moringa oleifera may also be used in the future to know their antifungal activity in vivo.

2. Different concentrations of the extracts may be used and compared as well, to know the most effective concentrations that may give the highest cure rates.

3. Follow-up of patients after the 4-week treatment period should also be done to assess recurrence rates.

4. A larger study population using a randomized clinical trial is also recommended.

5. A randomized clinical trial comparing Moringa oleifera with a standard treatment is also recommended.

REFERENCES

1. Chen, H. & Chuang, P. Moringa crude extracts and their derived fractions with antifungal activities. Bioresour Technol 2007; 98:232-6.

2. Dahot, M. Antimicrobial Activity of small protein of Moringa oleifera leaves. Journal of Islamic Academy of Sciences 11:1, 27-32, 1998.

3. Adedapo, A. et al. Safety of the Aqueous Extract of the Leaves of Moringa oleifera in rats. Journal of Medicinal Plants Research Vol. 3(8) 586-591, 2009.

4. Wolff, K., et al. Dermatology in General Medicine, 2007.

5. Jabeen, R., et al. Microscopic Evaluation of the Antimicrobial Activity of Seed Extracts of Moringa oleifera. Pak J. Bot., 40(4): 1349-1358, 2008.

6. Fahey, J. Moringa oleifera: A review of the Medical Evidence for Its Nutritional, Therapeutic, and Prophylactic Properties. Trees for Life Journal, 1:5, 2005.

APPENDICES

Clinical Parameters:

Clinical Severity Score

0 – None

1 – Mild

2 – Moderate

3 – Severe

A. Comparison of Baseline and Treatment by Group (At baseline to Week 4)

ERYTHEMA: GROUP A

Patient	*Age*	*Gender*	*Eb*	*E1*	*E2*	*E3*	*E4*
P.L.	19	Male	2	2	2	2	2
T.M.	26	Male	1	2	1	1	1
E.D.	38	Male	1	1	1	0	0
R.R.	49	Male	2	2	2	1	1
C.G.	34	Female	3	3	2	2	2
D.G.	42	Female	2	2	2	1	1
J.R.	24	Male	2	2	2	1	1
D.J.	33	Female	3	3	2	2	2
K.S.	44	Female	2	2	2	1	1
D.F.	18	Male	2	2	2	1	1
E.T.	20	Female	3	3	3	2	2
J.D.	29	Male	1	1	1	0	0
C.S.	21	Male	1	1	1	1	0
R.G.	39	Female	3	2	2	2	1
A.B.	47	Male	2	2	1	1	1
D.R.	42	Male	3	3	2	2	1

ERYTHEMA: GROUP B

Patient	*Age*	*Gender*	*Eb*	*E1*	*E2*	*E3*	*E4*
D.M.	20	Male	3	2	2	1	0
A.B	29	Male	2	2	2	1	1
B.N.	31	Male	3	3	2	1	0
T.Y.	36	Female	2	2	1	1	1
G.T.	44	Female	2	2	1	1	0
R.H.	33	Male	3	2	2	2	1
J.F.	48	Male	2	2	1	1	0
P.R.	50	Female	3	2	2	1	1
P.T.	34	Male	2	2	1	1	0
R.S.	39	Female	3	2	2	2	1
P.C.	33	Female	2	2	1	1	0
M.E.	47	Female	3	2	2	1	1
C.B.	42	Male	2	2	1	1	0
R.T.	49	Male	3	3	2	1	1
A.M.	24	Female	3	2	2	1	1
G.M.	38	Male	2	2	1	1	0
T.P.	29	Male	3	2	1	1	0
N.R.	22	Male	2	1	1	0	0

PRURITUS: GROUP A

Patient	*Age*	*Gender*	*Pb*	*P1*	*P2*	*P3*	*P4*
P.L.	19	Male	2	1	1	1	1
T.M.	26	Male	1	1	1	0	0
E.D.	38	Male	1	1	1	0	0
R.R.	49	Male	2	2	1	1	1
C.G.	34	Female	3	2	2	1	1
D.G.	42	Female	2	2	1	1	1
J.R.	24	Male	2	2	1	1	1
D.J.	33	Female	3	2	2	1	1
K.S.	44	Female	2	2	1	1	1
D.F.	18	Male	2	1	1	1	1
E.T.	20	Female	3	3	3	2	2
J.D.	29	Male	1	1	1	0	0
C.S.	21	Male	1	1	1	1	0
R.G.	39	Female	3	2	2	2	1
A.B.	47	Male	2	2	1	1	1
D.R.	42	Male	3	3	2	2	2

PRURITUS: GROUP B

Patient	*Age*	*Gender*	*Pb*	*P1*	*P2*	*P3*	*P4*
D.M.	20	Male	2	2	1	1	0
A.B	29	Male	2	1	1	0	0
B.N.	31	Male	3	2	2	1	0
T.Y.	36	Female	2	2	1	1	0
G.T.	44	Female	2	1	1	1	0
R.H.	33	Male	3	2	1	1	1
J.F.	48	Male	2	1	1	1	0
P.R.	50	Female	2	2	1	1	1
P.T.	34	Male	2	1	1	1	0
R.S.	39	Female	3	2	1	1	1
P.C.	33	Female	2	1	1	1	0
M.E.	47	Female	2	2	1	1	1
C.B.	42	Male	2	2	2	1	1
R.T.	49	Male	3	3	2	1	1
A.M.	24	Female	3	2	2	1	1
G.M.	38	Male	2	2	1	0	0
T.P.	29	Male	3	2	1	0	0
N.R.	22	Male	2	1	1	0	0

SCALING: GROUP A

Patient	*Age*	*Gender*	*Sb*	*S1*	*S2*	*S3*	*S4*
P.L.	19	Male	2	1	1	1	1
T.M.	26	Male	1	1	1	0	0
E.D.	38	Male	1	1	1	0	0
R.R.	49	Male	2	2	1	1	1
C.G.	34	Female	3	2	2	1	1
D.G.	42	Female	2	2	1	1	1
J.R.	24	Male	2	2	1	1	1
D.J.	33	Female	3	2	2	1	1
K.S.	44	Female	2	2	1	1	1
D.F.	18	Male	2	1	1	1	1
E.T.	20	Female	3	3	3	2	2
J.D.	29	Male	1	1	1	0	0
C.S.	21	Male	1	1	1	1	0
R.G.	39	Female	3	2	2	1	0
A.B.	47	Male	2	2	1	1	0
D.R.	42	Male	3	3	2	1	0

SCALING: GROUP B

Patient	*Age*	*Gender*	*Sb*	*S1*	*S2*	*S3*	*S4*
D.M.	20	Male	1	1	1	1	0
A.B	29	Male	2	1	1	1	1
B.N.	31	Male	2	1	1	1	0
T.Y.	36	Female	2	2	1	1	0
G.T.	44	Female	1	1	1	1	0
R.H.	33	Male	2	2	1	1	0
J.F.	48	Male	2	1	1	1	0
P.R.	50	Female	2	1	1	1	0
P.T.	34	Male	1	1	1	1	0
R.S.	39	Female	2	2	1	1	0
P.C.	33	Male	2	1	1	1	0
M.E.	47	Female	2	1	1	1	0
C.B.	42	Male	2	2	2	1	1
R.T.	49	Male	3	3	2	1	1
A.M.	24	Female	3	2	2	1	1
G.M.	38	Male	2	2	1	1	0
T.P.	29	Male	2	2	1	0	1
N.R.	22	Male	2	1	1	1	0

B. Comparison of Baseline and Treatment Values by Group

Group A (n=16)

Clinical Parameters		None	Mild	Moderate	Severe
Erythema	Baseline	0	4	7	5
	Week 4	3	9	4	0
Pruritus	Baseline	0	4	7	5
	Week 4	4	10	2	0
Scaling	Baseline	0	4	7	5
	Week 4	7	8	1	0

Group B (n=18)

Clinical Parameters		None	Mild	Moderate	Severe
Erythema	Baseline	0	0	9	7
	Week 4	10	8	0	0
Pruritus	Baseline	0	0	12	6
	Week 4	11	7	0	0
Scaling	Baseline	0	3	13	2
	Week 4	13	5	0	0

C. KOH smear Baseline and Week 4

Group A

Patient	*Age*	*Gender*	*Baseline KOH*	*KOH at Week 4*
P.L.	19	Male	(+)	(+)
T.M.	26	Male	(+)	(-)
E.D.	38	Male	(+)	(-)
R.R.	49	Male	(+)	(+)
C.G.	34	Female	(+)	(+)
D.G.	42	Female	(+)	(+)
J.R.	24	Male	(+)	(+)
D.J.	33	Female	(+)	(+)
K.S.	44	Female	(+)	(+)
D.F.	18	Male	(+)	(-)
E.T.	20	Female	(+)	(+)
J.D.	29	Male	(+)	(-)
C.S.	21	Male	(+)	(-)
R.G.	39	Female	(+)	(+)
A.B.	47	Male	(+)	(-)
D.R.	42	Male	(+)	(+)

Group B

Patient	*Age*	*Gender*	*Baseline KOH*	*KOH at Week 4*
D.M.	20	Male	(+)	(-)
A.B	29	Male	(+)	(+)
B.N.	31	Male	(+)	(-)
T.Y.	36	Female	(+)	(-)
G.T.	44	Female	(+)	(-)
R.H.	33	Male	(+)	(-)
J.F.	48	Male	(+)	(-)
P.R.	50	Female	(+)	(-)
P.T.	34	Male	(+)	(+)
R.S.	39	Female	(+)	(-)
P.C.	33	Female	(+)	(-)
M.E.	47	Female	(+)	(+)
C.B.	42	Male	(+)	(-)
R.T.	49	Male	(+)	(+)
A.M.	24	Female	(+)	(+)
G.M.	38	Male	(+)	(-)
T.P.	29	Male	(+)	(-)
N.R.	22	Male	(+)	(-)

WRITTEN INFORMED CONSENT

Pahintulot ng Pasyente

Name *(Pangalan):*
Age *(Edad):*
Gender *(Kasarian):*
Occupation *(Trabaho):*

I have been informed of the nature of the study, and the potential benefits and hazards of the intervention/ treatment.
Naipagbigay alam sa akin ang uri ng pag-aaral na ito, pati na ang mga kabutihan at mga panganib na maaaring idulot ng interbensyon/gamutan.

I hereby voluntarily give my consent to undergo this clinical investigation under the supervision of Dr. Charo F. De Guzman and her co-researchers.
Kusang loob kong ibinibigay ang aking pahintulot na sumailalim sa pananaliksik na ito sa pamamahala ni Dr. Charo F. De Guzman at ng kaniyang mga kasamang mananaliksik.

I have been informed that I may withdraw from this clinical investigation anytime without prejudice against me.
Ipinagbigay alam sa akin na maaari kong bawiin ang aking partisipasyon sa pag-aaral na ito anumang oras na naisin ko, na hindi mamasamain ng mga doctor na namamahala sa pananaliksik na ito.

I have been given the chance to ask questions about the use of the intervention and understand and accept the answers provided.
Ako ay binigyan ng pagkakataon ng makapagtanong tungkol sa interbensyon na gagawin at aking naintindihan at tinanggap ang tugon ukol dito.

I was informed that at the end of the study period (4 weeks), if my condition worsened or persisted, I will be treated accordingly.
Ipinagbigay alam sa akin na sa pagtatapos ng pag-aaral na ito (4 na linggo), kung ang aking kundisyon ay grumabe o nanatili, ako ay bibigyan ng karampatang gamutan.

Signature of Patient/*Lagda ng Pasyente:* _____
Date: _____

I being the physician, confirm that I have fully explained to the patient the nature, purpose and risks of the interventions being used in this study.

Ako, bilang manggagamot, ay nagpapatotoo na ganap na naipaliwanag sa pasyente and uri, layunin at maaaring maging epekto na dulot ng interbensyong ginamit sa pag-aaral na ito.

Charo Fionna F. De Guzman-Castro, M.D.
Date: _____

Clinical Assessment

0 – None 1 – Mild 2 – Moderate 3 – Severe

Patient's Name: _____ Group: _____ Week Number: _____
A. Erythema _____
B. Pruritus _____
C. Scaling _____

KOH ( )

Adverse effects: _____

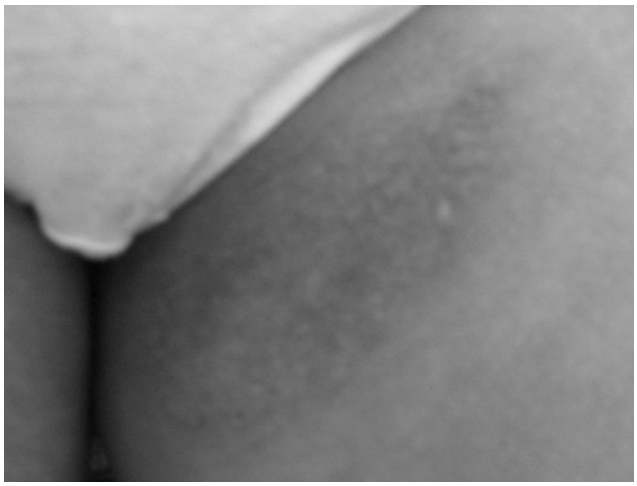
Improvement Score

0 – None (Wala) 1 – Mild (Bahagya) 2 – Moderate (Katamtaman) 3 – Severe (Sobra)

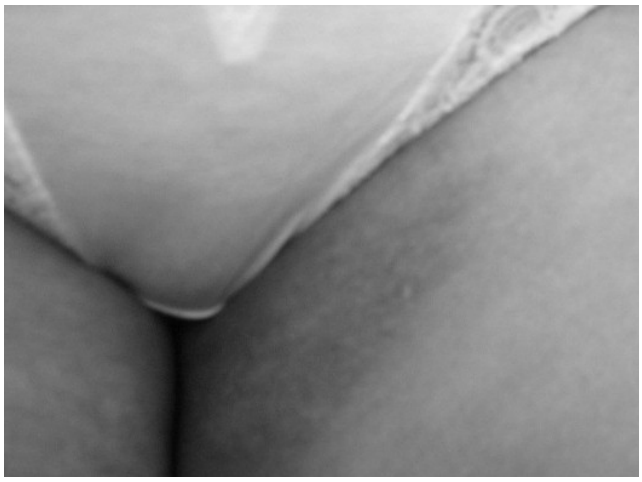
Patient's Name: _____ Group: _____ Week Number: _____

D. Erythema (Pamumula) _____
E. Pruritus (Pangangati) _____
F. Scaling (Kaliskis) _____

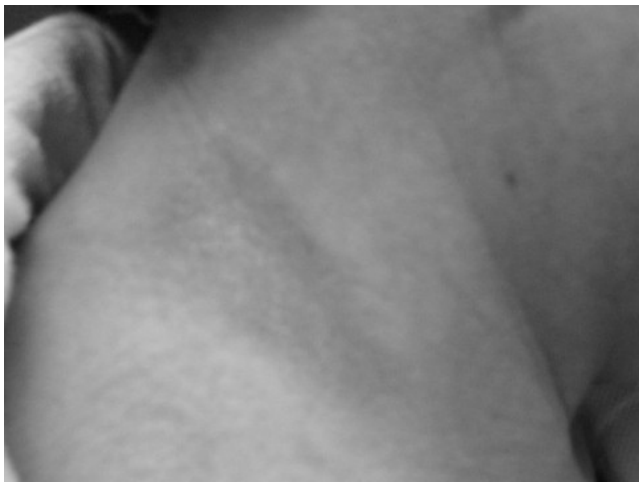
GROUP A: PLACEBO



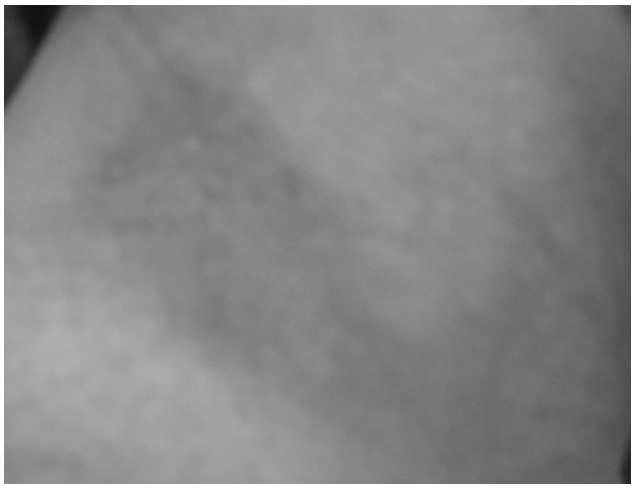
C.G. Baseline



C.G. Week 4

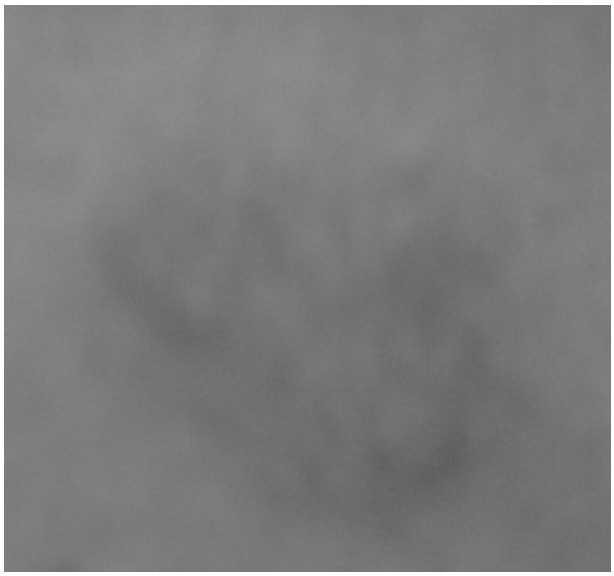


P.L. Baseline

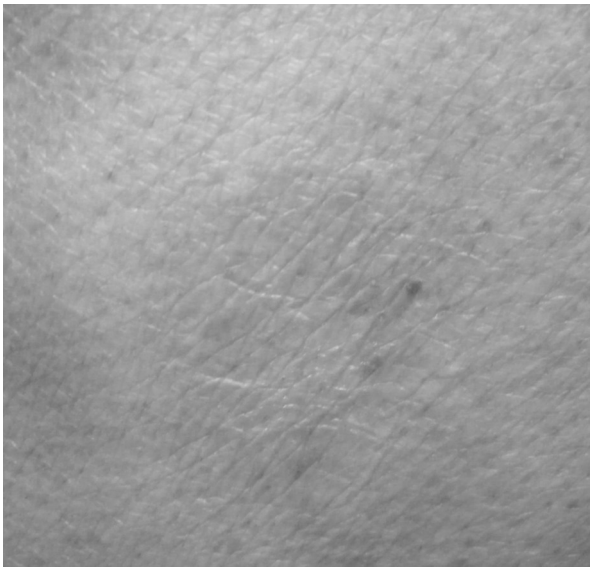


P.L. Week 4

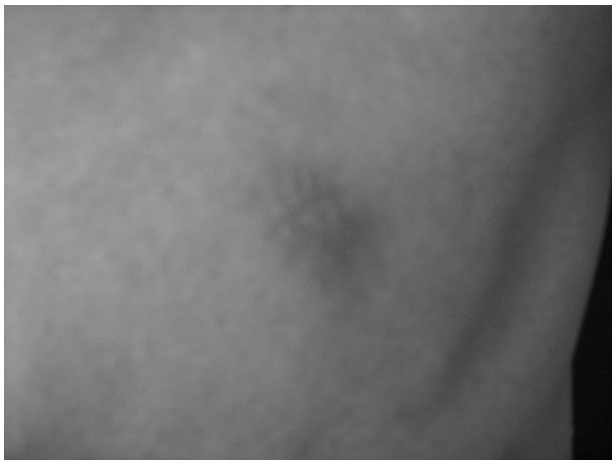
GROUP B: MORINGA



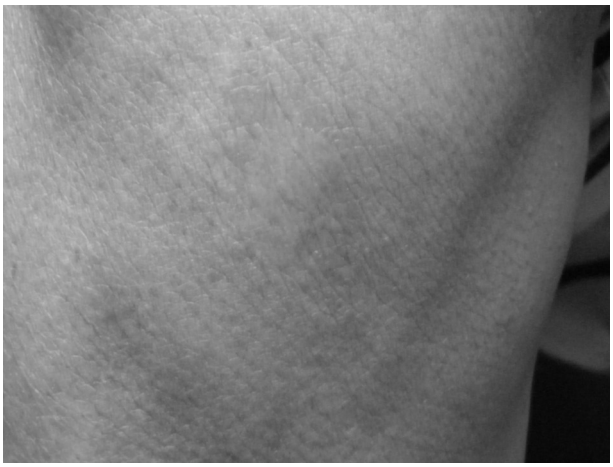
D.M. Baseline



D.M. Week 4



T.Y. Baseline



T.Y. Week 4