

The Effects of Malunggay (*Moringa oleifera*) Leaves Capsule Supplements on High Specificity C-Reactive Protein and Hemoglobin A1c Levels of Diabetic Patients in Ospital ng Maynila Medical Center: A Prospective Cohort Study

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Abstract

Introduction: Current evidence supports a central role of inflammation in the pathogenesis of atherosclerosis and diabetes. Diabetes Mellitus (DM) type 2 is an inflammatory atherothrombotic condition associated with high prevalence of thrombotic cardiovascular disease. In patients with DM, this inflammation is reflected by elevated plasma C-reactive protein (CRP) levels. High specificity (hsCRP) is considered as a strong predictive of cardiovascular risks and death. Some evidence showed that CRP may represent an active participant in atherogenesis.

Among the DM risk factors (like hypertension, atherogenic dyslipidemia, insulin resistance, impaired fibrinolysis, inflammatory profile), inflammation is the neglected one.

Moringa oleifera (*M. oleifera*) has been suggested to exert anti-inflammatory and hypoglycemic property.

Objective: To determine the effect of *M. oleifera* leaves supplementation on the hsCRP, and HgbA1c levels of diabetics of Ospital ng Maynila Medical Center DM clinic

Methods: We performed a prospective quasi experimental study on 56 adult diabetics who were given 12-weeks supplementation of *M. oleifera*. Plasma hsCRP and serum HgbA1c were compared before and after treatment with *M. oleifera*.

Results: The over all population mean prehsCRP is 3.38 mg/dl (95% CI 2.77-3.99). Supplementation of *M. oleifera* decreased significantly ($p < 0.0001$) the posthsCRP to 1.69 mg/dl (95% CI 1.28-2.09). The mean pre-HgbA1c of 6.96% (95% CI 6.64-7.09) was reduced post-HgbA1c to 6.06% (95% CI 5.88-6.24). The mean reduction of 0.6% in HgbA1c was significant (p -value < 0.0001).

Conclusion: Our study confirms that diabetics may have additional benefit from intake of *M. oleifera* leaves by reducing hsCRP and by improving blood sugar control as evidenced by the reduction of HgbA1c.

Keywords: *moringa oleifera*, malunggay leaves

Introduction

Hyperglycemia is the most obvious abnormality in Diabetes Mellitus (DM). However it is only the tip of the 'metabolic syndrome iceberg'. Among the abnormalities in DM like hypertension, atherogenic dyslipidemia, insulin resistance, impaired fibrinolysis, generalized inflammation is the most neglected.

The understanding of the pivotal role of inflammation in the pathogenesis of atherosclerosis has opened the opportunities for a better future for management of DM and prevention of its complications. So risk assessment, prediction of cardiovascular events in DM and prevention of inflammation by add-on therapy are the needs of the present day.¹

C-reactive protein (CRP), an acute-phase reactant

produced by liver, is an extreme sensitive marker of systemic inflammation.²

In healthy young adult volunteer blood donors, the median concentration of CRP is 0.8 mg/l, the 90th percentile is 3.0 mg/l, and the 99th centile is 10 mg/l,³ but, following an acute-phase stimulus, values may increase from less than 50 µg/l to more than 500 mg/l, that is, 10,000-fold.

The attention focused on CRP reflects in part the fact that it is an exceptionally stable analyte in serum or plasma and those immunoassays for it are robust, well standardized, reproducible, and readily available.⁴

HsCRP determination should be performed in a metabolically stable individual without obvious inflammatory or infectious conditions in order to reduce within-individual variability.

Interpreting CRP results is straightforward (Figure 1). If a level of >10 mg/L is identified, there should be a search initiated for an obvious source of infection or inflammation, which could obscure any prediction of coronary risk that might be attributed to the elevated level. That result of more than 10 mg/L should be then discarded and the hsCRP be

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measured again after two weeks.⁶

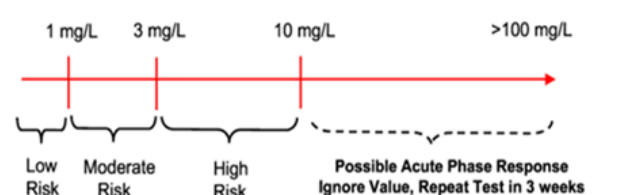


Figure 1: Clinical interpretation of hsCRP for cardiovascular risk prediction⁷

Several factors have been identified as being associated with increased or decreased levels of hsCRP (Table I).

It is perceived that chronic low-grade inflammation as shown by elevated CRP might potentially be a cause underlying the etiology and disease progression of DM, although the exact mechanisms are still not well understood.⁸

It was found out that CRP levels were higher in diabetics than non-diabetics.⁸ In addition, CRP was noted to be a strong and better independent predictor of thrombotic cardiovascular events and death in DM than traditional risk factors^{4,6,9-18} or parameters of metabolic control in DM at high risk for cardiovascular endpoints.¹⁹

Table I: Patient characteristics and conditions associated with increased or decreased levels of hsCRP

Increased Levels	Decreased Levels
Elevated Blood Pressure	Moderate alcohol consumption
Elevated Body Mass Index	Increased activity/ endurance exercise
Cigarette Smoking	Weight loss
Metabolic syndrome/ DM	Medications: Statins, Fibrates, Niacin
Low HDL/High Triglycerides	
Estrogen/Progesterone hormone use	
Chronic Infections (gingivitis, bronchitis)	
Chronic Inflammation (rheumatoid arthritis)	

Besides its predictive role in determining thrombotic cardiovascular risk, there is some evidence that CRP may represent an active participant in atherogenesis.²⁰⁻²²

Moringa oleifera (*M. oleifera*) (of the family Moringaceae and synonymous with *Moringa pterygosperma*²³) is a drought-resistant wispy tree. "Ounce-for-ounce, *M. oleifera* leaves contain more Vitamin A than carrots, more calcium than milk, more iron than spinach, more Vitamin C than oranges, and more potassium than bananas,"²⁴

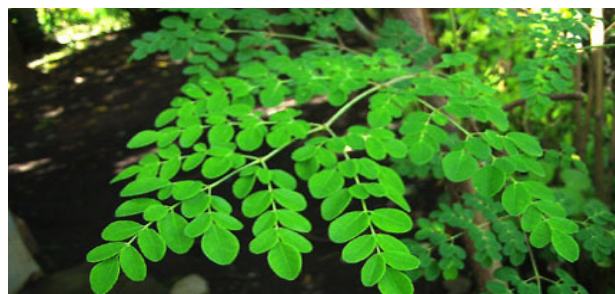


Figure 2: Moringa oleifera

Moringa family is rich in compounds containing the simple sugar, rhamnose, and in a fairly unique group of compounds called glucosinolates and isothiocyanates.^{25,26} In an analysis, it was noted that the leaf extracts appear to have the most level of all bioactives of interest which supports its usage.²⁷⁻²⁸

HgbA1c is a very sensitive index for glycemic control in DM.²⁹ It was noted in studies that every 1.0% drop in HgbA1c reduces the risk of microvascular complications by 40%, and death by 21%.³⁰⁻³¹ Reviews on *M. oleifera* where supplementation of the leaf powder daily noted significant reductions in fasting glucose (28%) and postprandial glucose (26%) relative to baseline.^{32,29,33-34}

Methods

A. Study Participants

A.1 Inclusion Criteria

1. Male or female participants aged between 19 and 65 years of age.
2. Previously diagnosed by a physician as having Diabetes Mellitus using the criteria stated by American Diabetes Association (ADA).

The participant should present with one or more of the following:

- FPG of more than or equal to 126 mg/dl (7.0 mmol/L). Fasting is defined as no caloric intake for at least eight hours. OR
- 2-h plasma glucose more than or equal to 200 mg/dl (11.1 mmol/L) during an OGTT. The test should be performed as described by the WHO, using glucose load containing the equivalent of 75g anhydrous glucose dissolved in water OR
- In patients with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose of more than or equal to 200 mg/dl (11.1 mmol/L)

3. Should be willing to have their blood extracted for hsCRP and HgbA1c measurement before and

- after 12 weeks supplementation of *M. oleifera*.
- Have available treatment partner.
 - Should be willing to stay in Metro Manila together with their treatment partner during the course of the trial, and must be easily contacted by phone.

Treatment partners were relatives of the participants who are living with them and are able to monitor participants' intake of supplements, maintenance medications and activities (smoking, alcohol intake, exercise).

Treatment partners are contacted every week for monitoring of any morbidity to any medical condition, mortality and presumed adverse effects of *M. oleifera*. They monitor the compliance of the participants to supplementation and their maintenance medications. All participants and treatment partners were advised to notify the investigator for any additional drugs that will be taken or prescribed by any physicians. At home, treatment partners were given the responsibility to advise the participants to abstain from smoking, alcoholic beverage intake and endurance exercise a day before the blood extractions.

A.2 Exclusion Criteria

- Subjects who were suspected to have psychiatric disorders and mentally challenged.
- Subjects who were not medically stable or those confirmed to be afflicted with communicable or life threatening diseases such as but not limited to the following:
 - ongoing infection (Pulmonary Tuberculosis, DM foot infection, cellulitis, pneumonia, Urinary Tract Infections, ear infections or dental/gum Infections)
 - decompensated heart failure (CHF III-IV)
 - chronic liver disease in decompensated state
 - stroke in evolution,
 - acute coronary syndrome within six months,
 - systemic or pulmonary inflammatory condition (including rheumatoid arthritis, systemic lupus erythematosus,
 - chronic obstructive pulmonary disease in exacerbation,
 - bronchial asthma in exacerbation,
 - history of renal or other organ transplant and/or
 - immunocompromised state
- Subjects with anemia (hemoglobin value of less than 13.0 g/dl in males; 12.0 g/dl in females)
- Subjects with ongoing *M. oleifera*, fish oil or any vitamins or multivitamins supplementation within the past eight weeks.
- Subjects using estrogen/progesterone hormone.

- Subjects with plan or anticipated by their physicians to be initiated with renal replacement therapy (dialysis) during the study.
- Subjects who are pregnant or plan to be pregnant.
- Subjects with known or suspected allergy to *M. oleifera* or any other component to the drug preparation.

All eligible subjects signed a consent form and agreed with aforementioned conditions.

A.3 Withdrawal

Participants were considered withdrawn if they were lost to follow-up after attempts to contact them through the principal investigator's best effort.

B. *Moringa oleifera* powdered leaves capsule supplementation

M. oleifera powdered leaves capsule contains 500mg of pure malunggay leaves encapsulated in vegetable capsule. These capsules were manufactured for Atienza Naturale by Greenplus Corporation under FDA registration number 17069452532. Manufacturing process was approved by the Department of Science and Technology (DOST).

The capsules used in this study were manufactured last June 2014 with expiration date of June 2016. The capsules were taken by every participants, one capsule thrice a day for 12 weeks.

C. Determination of High Specific C-Reactive Protein (hsCRP) level

High Specificity CRP (hsCRP) was measured by licensed medical technologist at Asia Pacific Laboratory via an automated high-sensitivity immune-nephelometric assay in COBAS INTEGRA 400 Analyzer developed in Germany by ROCHE diagnostics. The equipment is calibrated every six months.

D. Determination of Hemoglobin A1c (HgbA1c) level

Hemoglobin A1c (HgbA1c) serum level was also measured by licensed medical technologist at Asia Pacific Laboratory using Quo-test HgbA1c analyser. All anemic participants as defined by the exclusion criteria will be eliminated. The equipment is calibrated every six months.

E. Setting

The study was administered to participants of a single DM clinic in a single university tertiary hospital in Manila, Philippines. All participants had plasma hsCRP and HgbA1c initial measurement. After taking up *M. oleifera* powdered leaves capsule, one capsule thrice a day, participants were followed up for 12 weeks for post treatment measurement of plasma CRP and

HgbA1c.

F. Intervention

All screened participants had plasma hsCRP and HgbA1c initial measurement. Participants were instructed to take a capsule of powdered *M. oleifera* leaves thrice a day for 12 weeks. After which, participants were required to come back for post treatment measurement of plasma hsCRP and HgbA1c. Initial and final body weight measurements were noted.

Reminders were given to the participants to avoid taking any multivitamins, smoking and alcoholic beverages. Avoidance of endurance exercise a day prior to blood extractions was advised. All participants and treatment partners were advised to notify the investigator for any additional drugs that will be taken or prescribed by any physicians.

G. Assessment & Follow-up

Phone calls were done every week to treatment partners by the investigator to monitor the compliance of the participants to their supplementation and other maintenance medications.

Besides weekly phone calls to treatment partners, participants with their treatment partners were seen monthly by the clinical investigator were done to assess participants. Patients were assessed for any adverse reactions to the supplements.

After taking a capsule of *M. oleifera* thrice a day for 12 weeks, the participants were instructed to have their follow-up visit for repeat measurement of plasma hsCRP and HgbA1c.

Ethical Considerations

A. Securing permits to undergo the study at the required institution

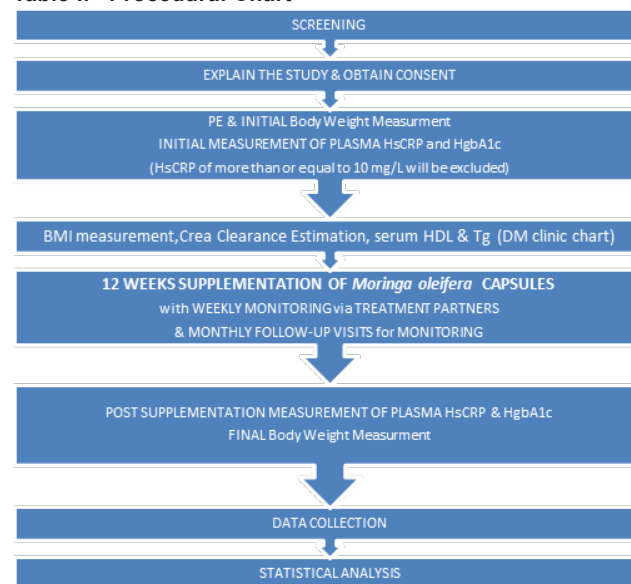
This study was approved by the Ospital ng Maynila Medical Center Medical Education and Research Committee and Ospital ng Maynila Medical Center Department of Internal Medicine Research Committee.

B. Disclosure of research objectives and informed consent

Participants were informed of the research objective both verbally and in writing in a language they can understand before they underwent informed consent process.

Participants were informed of the details of the study and provided a copy of "Talaan ng Impormasyon Para sa Pasyente" (Appendix A).

Table I. Procedural Chart



Statistical Analysis

All statistical analyses were performed on a personal computer running Stata 12.0 on a Microsoft window version 7 operating system. Mean and percentages were computed. Wilcoxon signed-Rank test was used to analyze the difference between pre and post mean plasma hsCRP and HgbA1c values.

Results

All patients of the DM clinic during the period of the study were recruited. From the total of 73 patients enrolled, 60 met the inclusion criteria for this study. Of the 60 patients who met the inclusion criteria, four participants were excluded because three patients did not complete their screening requirements one was hospitalized due to pneumonia and exacerbation of chronic obstructive pulmonary disease a week after the screening period (before the supplementation started).

Majority of participants were female (80%). The mean age of the study population is 61.21 ± 8.01 years. The mean BMI is 20 ± 1.96 .

All participants are noted to have controlled hypertension. No participant was noted to be a smoker.

In their list of maintenance medications, it was noted that all participants were taking simvastatin 40mg once a day. No intake of niacin and fibrates were noted.

Two participants were observed to have weight loss of 0.5kg.

The over all population mean pre hsCRP is 3.38 mg/L (95% CI 2.77-3.99) while the post hsCRP is 1.69 mg/L (95% CI 1.28-2.09). Reduction in mean plasma hsCRP was significant ($p < 0.0001$). (Table II)

Table II: Measurement of mean hsCRP and HgbA1c before and after supplementation of *M. oleifera* (n=56)

	Mean Pretreatment	Mean Posttreatment	Difference	p-value
hsCRP	3.38 mg/l	1.69 mg/l	1.69	<0.0001
HgbA1c	6.69 %	6.06%	0.63	<0.0001

In the measurement of HgbA1c, it was noted that mean pre-HgbA1c is 6.96% (95% CI 6.64-7.09) and was reduced to 6.06% (95% CI 5.88-6.24) post-HgbA1c. The mean reduction of 0.6% was noted to be significant at p-value less than 0.0001.

Controlling the HgbA1c, weight and age, multilinear regression was utilized showing the mean pre hsCRP is 1.5 times (95% CI 0.68-2.35) elevated compared to mean post hsCRP.

Discussion

In this study, the overall population mean plasma pre-hsCRP is 3.38 mg/L (95% CI 2.77-3.99) falling to the high risk category. Treatment of the *M. oleifera* capsules after 12 weeks led to the mean plasma post hsCRP of 1.69 mg/L (95% CI 1.28-2.09) falling to the moderate risk category. The reduction in mean plasma hsCRP was noted to be significant ($p < 0.0001$).

Since hsCRP reduction was noted in all participants, the possible effects of other factors causing elevated hsCRP specifically the presence of elevated blood pressure, elevated BMI, cigarette smoking, low HDL, high triglycerides, were not analyzed.

Another consideration to be made is on the potential contribution of other factors that can decrease hsCRP level. These factors were moderate alcohol consumption, increased activity/endurance exercise, weight loss and medications like statins, fibrates and niacin. Since participants with their treatment partners were advised to abstain from alcohol intake and endurance exercise prior to extractions, focus was turned to presence of weight loss and medications. However, it was noted that all participants took simvastatin 40 mg per capsule once a day as part of their maintenance medications. No noted intake on niacin and fibrates. Weight loss of 0.5 kg was noted in only two participants.

HgA1c is the measure of glycemic control. In our study, the mean pre-HgbA1c of the overall population is 6.96% (95% CI 6.64-7.09). Treatment of the *M. oleifera* capsules after 12 weeks led to the mean post-HgbA1c of 6.06% (95% CI 5.88-6.24). The noted mean reduction of 0.6% in hemoglobin A1c was significant ($p < 0.0001$).

This study showed that 12 weeks supplementation of *M. oleifera* can bring significant reduction in hsCRP and HgbA1c.

The reduction in hsCRP was possibly due to the components of *M. oleifera* that have anti-inflammatory effect. As reported by Lee Y.M., et al., Benzyl isothiocyanate found in *M. oleifera* leaves exhibits anti-inflammatory effects⁴⁰ while benzylisothiocyanate inhibits inflammatory mediator production by lipopolysaccharide-stimulated RAW 264.7 murine macrophage cell lines.⁴¹ Park E.J. et al., reported 4-((2'-O-acetyl- α -L rhamnosyloxy)benzyl) isothiocyanate from *M. oleifera* or RIBT causes inhibition of lipopolysaccharide-induced cyclooxygenase-2 and inducible nitric oxide synthase expression.⁴²

The reduction in HgbA1c was associated with the antioxidants found in *M. oleifera*, namely: the carotenoids, flavonoids, and vitamins C and E, found in *M. oleifera*. These substances were noted to facilitate improvement in reducing blood glucose of the diabetics by improving glucose metabolism and decreasing insulin resistance.⁹³ It was stated that the antioxidants and flavonoids control the glycation process, so that decrease in glycated hemoglobin was observed.¹⁰¹ This was supported by the study done by Gidhari et al.,⁹³ in which administration of *M. Oleifera* leaves powder twice daily for 90 days in 60 patients with type 2 diabetes causes a significant mean reduction of 0.41% ($p < 0.0076$) in HgbA1c.

Several studies have shown that reduction of HgbA1c and weight loss can cause a potential decrease in hsCRP. To eliminate the possible effects of reduction of HgbA1c and weight to the hsCRP reduction, multilinear regression was utilized. Controlling the other variables particularly HgbA1c, age and weight it showed that the mean pre hsCRP is 1.5 times (95% CI 0.68-2.35) elevated compared to mean post hsCRP.

This study emphasized that even if an individual has a good glycemic control as shown by the having HgbA1c less than 7.0%, they can still be at high risks to develop CV events due to high level of inflammation as shown by elevated initial hsCRP of our participants.

This study showed that in diabetic patients taking *M. oleifera* supplementation for 12 weeks in addition to their maintenance medications may still give additional benefit in terms of sugar control and reduction of inflammation.

Conclusion

Our study confirms that diabetic patients may have additional benefits from intake of *M. oleifera* leaves by significantly reducing inflammation as shown by decrease in hsCRP and by substantially improving blood sugar control as evidenced by the reduction of HgbA1c.

Limitations and Recommendations

Limitations inherent to cohort study designs apply to this particular study. Due to absence of randomization and blinding, biases with regards to patients selected for intervention are not controlled. The possibility of bias cannot be excluded since patients gathered were from a DM clinic which may not represent DM patient in general population.

Furthermore, it is also perceived that the result of this study will be more valid if the type of anti-hyperglycemic agents correlated with the outcome, that can be included on subsequent studies.

Randomized-control studies with bigger population size should be undertaken to further elucidate the effect of malunggay capsules to hsCRP and HgbA1c. Study with longer duration of supplementation can also be done to further determine the effect of the malunggay capsule.

A biochemical study of the specific substance of *M. oleifera* that causes the decrease in HgbA1c or blood glucose may be of great focus in the future.

Conflicts of Interest

The principal author and co-author are not affiliated or connected in any way to Greenplus Corporation or Atienza Naturale at the time the study was conducted. No honorarium or remuneration of any sort were received during the study.

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Appendix A

TALAN NG IMPORMASYON PARA SA PASYENTE

1. Titulo ng Pag-aaral

"The Effects of Malunggay (*Moringa oleifera*) leaves

capsule supplements on High Specificity C-Reactive Protein (hsCRP) and HgbA1c levels of Diabetic Patients in (hospital) Medical Center Internal Medicine Department Diabetic Clinic: A Prospective Cohort Study"

Pangunahing tagapagsuri:

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2. Layunin ng Pag-aaral

Kayo ay inaanyayahang sumali sa pag-aaral na ito. Maaari po lamang na basahin ninyo ang impormasyong nakasaad dito. Ang pag-aaral na ito ay ipapaliwanag din ng personal sa inyo kung saan kayo ay bibigyan din ng pagkakataong magtanong. Kung naiintindihan ninyo at nais ninyong lumahok, maaari lang pong pakipirmahan ang 2 kopya ng katibayan ng paghihintulot na nasa dulong pahina ng talaang ito.

Ang "Diabetes Mellitus (DM)" o dyabetis ay isang mahalagang sanhi sa pagkakaroon ng "cardiovascular disease" o atake sa puso o utak. Bagaman maraming pag-aaral na ang naisagawa upang malaman ang mga gamot upang maiwasan ang mga ito, ang mga komplikasyon buhat sa pagkakaroon ng DM ay nangunguna pa rin sa listahan ng sanhi ng "morbidity and mortality" sa buong mundo. Ilan sa listahan ng "DM risk factors" ay ang mataas na "blood pressure", "atherogenic dyslipidemia", "insulin resistance", "impaired fibrinolysis", at "inflammatory profile". Sa mga "DM risks factors" na ito ang "inflammation" ang isa sa hindi pa gaanong nabibigyan pansin. Kaya naman, kailangan nating humanap ng paraan upang matutukan at maibsan ito. Ang "inflammation" ay ipinakaita ng mataas na lebel ng "C-reactive protein" o "CRP" sa dugo.

Buhat sa maraming pag-aaral, ang *Moringa oleifera* o malunggay ay napag-alamang may "anti-inflammatory effects". Ang dahon ng halamang ito kapag ginamit ay maaaring makapagpapababa ang "CRP levels" at "HgbA1c". Sa pagbaba ng "hsCRP at HgbA1c levels" ay maaaring lumiit din ang posibilidad ng pagkakasakit o pagkamatay buhat sa atake sa puso o utak ang pasyenteng may DM. Ang layunin ng pagaaral na ito ay upang malaman kung ang pag-inom ba malunggay capsule ay nakapagpapababa ng "HsCRP, HgbA1c levels" at "clinical outcome" sa mga pasyenteng may DM.

Ang pag-aaral na ito ay gaganapin sa loob ng 12 lingo. Kahit sino na may edad 19 taong hanggang 65 taong gulang at marunong magbasa at sumagot sa wikang Ingles, na nasuring may DM ng "Internal Medicine Resident" o ng isang doctor sa pamamagitan ng "criteria" na nirekomenda ng American Diabetes Association Guideline ay posibleng kandidato para sa nasabing pag-aaral.

Ang pag-diagnose ng pagkakaroon ng diabetes mellitus o DM (Mula sa American Diabetes Association Guideline) ay ang pagkakaroon ng isa o higit pa sa mga sumusunod:

- FPG >126 mg/dl (7.0 mmol/L)
Fasting ay ang hindi pagkain ng higit sa 8 oras
- 2-h plasma glucose >200 mg.dl (11.1 mmol/L)
OGTT
- Sa isang pasyenteng may mga sintomas ng

"hyperglycemia or hyperglycemic crisis",

- random plasma glucose > 200 mg/dl (11.1 mmol/L)

Maaari kang di pasalihin kung ikaw ay may kundisyon ng katulad sa mga sumusunod:

1. Kung ikaw ay babae at may potensyal na maging buntis, hindi ka dapat nagdadalang tao sa pagsimula ng pag-aaral at maaari kang hingan ng pregnancy test ng mga pangunahing tagapagsuri para ito ay kumpirmahin; Kung ikaw ay may "psychiatric disorder" o problema sa pag-iisip.
2. Kung ikaw ay may sakit na katulad sa mga sumusunod:
 - a. Patuloy impeksyon (Pulmonary tuberculosis, DM foot infection, cellulitis, pulmunya, UTI, infection sa tenga, infection sa ngipin/gilagid)
 - b. Patuloy na pagpalya ng puso o heart failure
 - c. Patuloy na pagpalya ng atay
 - d. pasimulang stroke
 - e. atake sa puso sa loob ng 6 na buwan,
 - f. "systemic or pulmonary inflammatory condition" (katulad ng "rheumatoid arthritis", "systemic lupus erythematosus",
 - g. Kasalukuyan atake ng "chronic obstructive pulmonary disease",
 - h. Kasalukuyan atake ng hika,
 - i. May "history" ng renal or ibang organ transplant
 - j. "immunocompromised state"
3. Kung ikaw ay may anemia (hemoglobin value ay mas mababa 13.0 g/dl sa lalake; 12.0 g/dl sa babae)
4. Kung ikaw ay may kasalukuyang umuinom Moringa oleifera, fish oil o kahit anung vitamins o multivitamins sa loob ng 8 lingo ay hindi kasali sa pag-aaral.
5. Kung ikaw ay umiinom ng hormone tulad ng estrogen o progesterone.
6. Kung ikaw ay may hsCRP > 10mg/dl.
7. Kung ikaw ay pinagpaplanuhan na isailalaim sa dialysis.

Ikaw ay maaaring i-disqualify ng "author" o ng "screening doctor" sa mga kadahilanang hindi nakasaad sa listahan sa taas.

3. Pamamaraan ng Pag-aaral:

Kung kayo ay papayag na sumali:

- a. Kayo ay tatanungin ng mga datos tulad ng inyong pangalan, edad, antas ng edukasyon, at kung saan kayo ay maaaring matawagan.
- b. Kayo ay sasailalim sa "physical examination" ng "screening doctor"; Ang inyong chart at mga resulta ng "laboratory" ay sususuriin din.
- c. Ikaw ay kukuhaan ng dugo para alamin ang inyong "hsCRP at HgbA1c level"
- d. Ikaw ay aatasan na uminom ng malunggay capsule, 1 capsule tatlong beses kada araw sa loob ng tatlong buwan. Ikaw ay inaasahan ipagpatuloy inumin ang inyong mga "maintenance" na mga gamot.

e. Ikaw ay hindi dapat manigarilyo, uminom ng alak o gumawa ng "endurance exercise" isang araw bago ang pagkuha ng dugo.

f. Pagkalipas ng tatlong buwan, ikaw ay aatasan upang bumalik para sa mulaing pagkuha ng dugo at pagsusuri ng inyong "hsCRP at HgbA1c level"

4. Mga posibleng panganib at di-inaasahang epekto

Ayon sa mga nakaraang pagsubok pangklinikal, wala pang naiulat na panganib o negatibong side-effect ang pag-inom ng malunggay capsule. Gayunpaman, mayroong posibilidad na makakaranas ka ng pagbibilis ng pagdudumi na maaaring humantong sa diarrhea sa pag-inom ng Malunggay capsule. Ang mga epektong ito ay pansamantalang at karaniwan ay mawawala agad. Kung sa pagganap ng mga pagsasanay na nakatakda sa pagsusuri nito ay magbibigay ng anumang mga negatibong epekto sa iyo, ang mga pangunahing tagapagsuri ay pagaaralan ito at magbibigay sa inyo ng tulong upang malutas ito. Ang mga sumusunod ay maaaring maisama sa tulong na ito: Maaaring sagutin ng pangunahing tagapagsuri ang bayad na konsultasyon sa Out Patient Department o Emergency Room ng (hospital) Medical Center lamang. Para sa konsultasyong out-patient at emergency room, ang pangunahing tagapag-suri ay hindi sasagot sa mga pangangailangang pangiksamen, pagagamot, o panterapeutika. Gayunpaman, ang pangunahing tagapagsuri ay maaaring bimbini ang kompensasyon para sa mga kalagayang naisulat dito kung matiyakan niya na ang mga kaganapan na nagdulot ng pagospital o kamatayan ay hindi direktang may kinalaman sa mga pagsasanay na ipinapagawa sa pagsusuring ito. May mga kaganapan na hindi maisaalang-alang bilang sanhi ng mga pagsasanay na itinuturo sa pagsusuring ito. Ang mga kaganapan na kasama dito, ngunit hindi limitado lamang sa mga ito, ay mga aksidente na nagaganap sa panahon ng transportasyon papunta o mula sa lugar ng pagsusuri, mga kaganapan dulot ng sakunang natural tulad ng ngunit hindi limitado sa baha, lindol, o tsunamis, side effect at di kanais-nais na reaksiyon sa iba pang mga paggamot na hindi bahagi ng pagsusuring ito, o mga kaganapan na ginawa ng tao tulad ng mga nakawan, o pananakit. Kung ikaw ay lalahok sa pag-aaral na ito, sumasang-ayon ka na ang mga tagapagsuri, ang kanyang mga kawani, ang (hospital) Medical Center, ang kanyang mga administrador, mga nars, mga doktor, mga mag-aaral at iba pang mga tauhan nito ay hindi maaaring managot sa mga epektong hindi kanais-nais na maaari mong maranasan.

5. Benepisyo sa mga paglahok sa pag-aaral

Ang mga kalahok sa pag-aaral na ito ay maaaring makakuha ng mga benepisyo mula sa libreng pagpapakuha ng hsCRP at HgbA1c levels. Ang levels ng inyong CRP ay makakatulong sa inyong doktor sa aspeto ng pag-"predict" ng inyong "risk" sa atake sa puso o stroke sa utak. Samantalang ang pagkuha ng HgbA1c ay makakatulong upang malaman kung sapat na ang controling inyong iniinom na gamot sa inyong sugar.

6. Pagkapribado ng Impormasyon

Ang mga datos na inyong binigay sa amin katulad ng inyong pangalan, edad, contact number, o email address ay hindi ipapakita o ibibigay kanino man. Ito rin ay hindi babanggitin sa huling report na ilalabas ng pagaaral na ito. Sa paglagda sa katibayan ng pagpapahayag, kayo ay pumapayag na tawagan kayo ng may-akda, ng mga taong tumutulong sa kanya sa contact number na inyong binigay upang ipaalala o iabiso sa inyo ang mga susunod na hakbang kailangang ninyong gawin sa pagaaral na ito.

7. Pagpapahayag sa pagsali sa pagaaral na ito

Kung kayo ay sumasang-ayon sa pagsali sa pag-aaral na ito. Maaari lamang isulat ang inyong pangalan sa blanko na nasa katibayan ng pagpapahayag at lagyan ng inyong lagda sa itaas ng inyong pangalan. Pakipirmahan lamang ang 2 kopya para maitago ninyo ang isang kopya. Maaari rin kayong tumanggi sa pagaaral na ito at hindi na ninyo kailangan lagdahan ang katibayan na iyon.

8. Mga probisyon na magpatigil sa inyong paglahok sa pagaaral na ito

Ang inyong paglahok sa pagaaral na nito ay matitigil kapag hindi kayo makapupunta sa follow-up sa katapusan ng pag-aaral. Maaari rin kayong matanggal kung napatunayan na hindi totoo ang inyong mga sinasagot o mga datos na inyong binigay sa amin. Kung sakaling kayo ay matanggal mula sa pagaaral, ang mga benepisyo na maaari rin ninyong matanggap mula sa pagsali sa pagsusuri na ito ay hindi ibibigay sa inyo. Ang mga pangunahing imbestigador ng pagaaral na ito ay may karapatan na tanggalin o idisqualify ang kahit sinong kasapi sa pagsusuring ito dahil sa mga dahilan na hindi nabanggit dito.

9. Pabuya

Sa paglahok sa pagsusuring ito, ikaw ay sumasang-ayon na ipagtatanggol, at protektahan laban sa pinsala ang (hospital) Medical Center, ang mga tagapangasiwa nito, mga doktor, at tauhan ng walang pinsala mula sa at laban sa anumang paghahabol, paghahabla, paglilitis o pagdedemanda, kabilang ang, nang walang limitasyon, aksyong legal o bayaring pangaccounting, na magmumula o nagresulta mula sa iyong paglahok sa pagsusuri na ito. Ang pangunahing tagapagsuri ay magbibigay ng abiso sa iyo ng anumang paghahabol, paghahabla, paglilitis o pagdedemanda at siya rin ay tutulong sa iyo, sa iyong sariling pananagutan, sa pagtatanggol ng anumang naturang paghahabol, paghahabla, paglilitis o pagdedemanda. Ang pangunahing tagapagsuri ay may karapatan na akuin ang eksklusibong depensa at kontrol ng anumang bagay na sumasailalim sa mga pabuya sa ilalim ng seksyon na ito. Sa ganoong kaso, sumasang-ayon ka na ikaw ay makikipagtulungan sa anumang mga makatwirang kahilingan sa pagtatanggol sa pangunahing tagapagsuri ng mga naturang bagay na ito.

10. Pagtatatuwa ng mga garantiya at Limitasyon ng Pananagutan

Ang pangunahing tagapagsuri, ang kanyang mga kaakibat,

at kanilang kaukulang mga opisyal, direktor, empleyado, ahente, mga tagapagtustos, o mga tagapaglisensya ay hindi gumagawa ng garantiya tungkol sa nilalaman ng mga materyales na ibibigay para sa pagsusuri, kabilang ngunit hindi limitado sa kanilang katumpakan, pagiging maaasahan, pagkakumpleto, pagiging maagap, o pagiging akma sa panahon o oras.

Wala sa alinman sa mga pangunahing tagapag-usig, ang kanyang mga kaakibat, at kanilang kaukulang mga opisyal, direktor, empleyado, ahente, mga tagapagtustos, o mga tagapaglisensya ang dapat managot para sa katotohanan, o pagkakumpleto ng anumang impormasyon na lumitis sa mga kalahok ng pagsusuri na ito para sa mga pagkakamali, kakulangan o para sa anumang pagkaantala o pagkagambala ng oras o impormasyon mula sa kahit anong dahilan. Ikaw ay sumasangayon na ang paggamit ng mga materyales na ibinigay at ang kanilang mga nilalaman ay sa iyong sariling peligro.

Ang pangunahing tagapagsuri, ang kanyang mga kaakibat, at kanilang kaukulang mga opisyal, direktor, empleyado, ahente, mga tagapagtustos, o mga tagapaglisensya ay nagbibigay ng mga serbisyo para sa iyo na matutunan, masanay, masukat, masubaybayan, at mangasiwaan ang mga ipinanukalang mga pagsasanay sa pagsusuring ito. Ang mga serbisyong ito ay hindi naglalaman o bumubuo, at hindi dapat na mapapakahulugang payo o opinyong medikal. Ang inyong paglahok sa pagsusuri, at ang inyong mga pakikipag-ugnayan sa mga pangunahing tagapagsuri, ang kanyang mga kaakibat, at kanilang mga kaukulang mga opisyal, direktor, empleyado, ahente, mga tagapagtustos, o mga tagapaglisensya ay hindi lumilikha ng isang relasyong pangdoktor at pasyente sa pagitan mo at ng pangunahing tagapagsuri, ang kanyang mga kaakibat, at kanilang kaukulang mga opisyal, direktor, empleyado, ahente, mga supplier, o mga tagapaglisensya.

11. Mga ipinagbabawal na aktibidad

Sa paglahok sa pagsusuring ito, sumasangayon ka na hindi ka gagawa o sasali sa anumang mga gawaing ipinagbabawal katulad ng mga sumusunod:

- Ibenta ang mga ipinamigay na libreng malungay capsules
- Gamitin ang serbisyo para sa anumang mga komersyal na layunin o sa benepisyo ng sinumang ikatlong partido, kung ito ay walang pahintulot ng pangunahing tagapagsuri o sa kahit anong paraan na hindi pinahihintulutan ng aming mga tuntunin.
- Magpanggap o magsinungaling tungkol sa pakikipagtulungan ninyo sa kahit sinumang tao o entidad
- Iumabag sa anumang nalalapat na batas o regulasyon
- Hikayatin o paganahin ang sinuman na gawin ang anuman sa mga gawaing ipinagbabawal sa mga tuntunin na ito.

12. Pagtatatuwa ng mga garantiya at Limitasyon ng Pananagutan

Ang pangunahing tagapagsuri, ang kanyang mga kaakibat, at kanilang kaukulang mga opisyal, direktor, empleyado,

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13. Pagpopondo

Ang pondo na gagamitin sa pag-aaral na ito ay mula sa pangunahing tagapagsuri ng pag-aaral. Ang ibang pondo ay mula sa Philippine College of Physicians- Manila Chapter

14. Pagkontak sa Pangunahing Tagapagsuri

Para sa iba pang katanungan, maaari niyo pong tawagan ang pangunahing tagapagsuri ng pag-aaral:

Rainier Nery Mozo, M.D,
Contact No: 0932-8449951
email: rainiermozomd@yahoo.com

15. Pag-apruba sa pag-aaral

Ang par-aaral na ito ay sinuri at sinang-ayunan ng (hospital) Medical Center Ethics Committee. Kung may katanungan tungkol sa inyong karapatan o mayroon reklamo ukol sa pag-aaral na ito maaari nyong ipagbigay alam sa sumusunod.