Herbal Formula in the Management of Type 2 Diabetes Mellitus: A Three-Arm, Open-Label, Non-Inferiority Randomized Controlled Trial

(Version 1, 17th of February, 2025)

INFORMATION SHEET

I am Dr M.D.E.P. Gunathilaka, attached to the Faculty of Graduate studies, University of Colombo. My current designation is Ayurveda Doctor. I would like to invite you to take part in the research study on *Herbal Formula in the Management of Type 2 Diabetes Mellitus: A Three-Arm, Open-Label, Non-Inferiority Randomized Controlled Trial*, conducted by Professor Pathirage Kamal Perera, Professor Prasad Katulanda and Dr Jeevani Dahanayake with Dr M.D.E.P. Gunathilaka at National Ayurveda Teaching Hospital, Borella.

1. Purpose of the study

The purpose of this research is to investigate a *Herbal Formula in the Management of Type 2 Diabetes Mellitus compared to two different types of herbal formulas with standard medication used in allopathic medicine over 12 weeks' time.*

2. Voluntary participation

Your participation in this study is voluntary. You are free to not participate at all or to withdraw from the study at any time despite consenting to take part earlier. There will be no loss of medical care or any other available treatment for your illness or condition to which you are otherwise entitled. If you decide not to participate or withdraw from the study you may do so at any time.

3. Duration, procedures of the study and participant's responsibilities

This study will be conducted over 12 weeks. If you volunteer to participate in this study, we will ask you to do the following:

a) We will ask you to visit the clinic once a month over the course of a total of about 3 times.

b) You will need to collect your monthly supply of medicine and we will be taking your

4. Potential benefits

Participation in this study may benefit you and others by:

a) Improved Blood Sugar Control – Potential reduction in fasting glucose and HbA1c levels.
b) Reduced Medication Dependency – Possible alternative or complementary therapy for T2DM.
c) Metabolic Health Benefits – Potential improvements in lipid profile and insulin sensitivity.
d) Personalized Health Insights – Regular monitoring and feedback on diabetes management.
e) Scientific Contribution – Expanding knowledge on GS for evidence-based care.
f) Public Health Impact – A natural, cost-effective option for diabetes management.

5. Risks, hazards and discomforts

a) Allergic Reactions – Rare hypersensitivity reactions, such as skin rashes or itching, may occur.
b) Altered Taste Perception – Temporary changes in the ability to taste sweetness have been reported with GS consumption.

c) Blood Sample Collection Discomfort – Minor pain, bruising, or dizziness may occur from routine blood draws.

6. Reimbursements

You will not be paid any sum of money for participating in this study

7. Confidentiality

Confidentiality of all records is guaranteed and no information by which you can be identified will be released or published. These data will never be used in such a way that you could be identified in any way in any public presentation or publication without your express permission.

8. Termination of study participation

You may stop participating in this study at any time with no penalty or effect on medical care or loss of benefits. Please notify the investigator as soon as you decide to withdraw your consent.

9. Clarifications

If you have questions about any of the tests/procedures or information please feel free to ask any of the persons listed below.

Dr. M.D. Erandi Gunathilaka

Phone: 0719288545

Email: erandi.md1@gmail.com

This project has been approved by the Ethics Review Committee, Faculty of Indigenous Medicine, University of Colombo.

You may contact the committee if you wish to seek clarifications, record any concerns or make complaints about the study by calling 0112695300 extension 240 (between 9am and 4pm) or by sending an email to info.ethics@med.cmb.ac.lk

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CONSENT FORM

Part A - To be filled by the participant

The participant should complete the whole of this sheet herself.

1. Have you read the information sheet? (Please keep a copy for yourself) YES/NO
2. Have you had an opportunity to discuss this study and ask any questions? YES/NO
3. Have you had satisfactory answers to all your questions? YES/NO
4. Have you received enough information about the study? YES/NO
5. Who explained the study to you? ……..
6. Do you understand that you are free to withdraw from the study at any time, without having to give a reason and without affecting your future medical care? YES/NO
7. Information held by the investigators relating to your participation in this study may be examined by other research assistants. All personal details will be treated as STRICTLY CONFIDENTIAL. Do you give your permission for these individuals to have access to your records? YES/NO
8. Have you had sufficient time to come to your decision? YES/NO
9. Do you agree to take part in this study? YES/NO

Participant's signature: ……..…… Date:…….

Name (BLOCK CAPITALS):

……

Part B - To be filled by the investigator

I have explained the study to the above volunteer and he/she has indicated her willingness to take part.

Signature of investigator: …….. Date: ……

DR. M.D.E.P. Gunathilaka