Institutional Review Board

STI Myanmar University, Yangon

Republic of the Union of Myanmar

Informed Consent Form for Clinical Studies

Informed Consent Form (English Version):

This informed consent form is for women aged 18–49 living in Hlaing Tharyar Township who are invited to participate in the research project titled "Waitlist-controlled trial of microgreen powder supplementation among women of reproductive age in Yangon, Myanmar to assess changes in nutrition-related symptoms".

Name of Principal Investigator: Daniel Israel Samuelsen

Name of Organization: Good Seed Myanmar

Name of Funding Organization: Pears Foundation

Title of the Study: "Waitlist-controlled trial of microgreen powder supplementation among women of reproductive age in Yangon, Myanmar to assess changes in nutrition-related symptoms".

1. Introduction

I am Daniel Israel Samuelsen and a Project Development and Research Officer. You are being invited to participate in a research study conducted by Eden Myanmar and partners. The objective of the study is to assess changes in nutrition-related symptoms on microgreen powder supplementation among women of reproductive age in Yangon, Myanmar. Before you decide to participate it is important for you to understand why the research is being done and what procedures and activities will involve. Please take your time to read the following information carefully and discuss with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part in this study. If you have questions later, you can ask them of me, or of another researcher of our team.

2. Purpose of the Study

Malnutrition can affect energy levels, skin, hair, and overall health. This study will test whether a daily 10g supplement of nutrient-rich microgreen powder over 60 days can help reduce symptoms of malnutrition in women aged 18–49 living in Hlaing Tharyar Township..

3. Type of Research Intervention

This study will be conducted as a waitlist-controlled trial. If you agree to participate, you may either receive the powder daily for 60 days from the 1st of September, 2025 or all of the powder on the 31st October, 2025. When you receive the powder daily you will consume it immediately in the center. It will be mixed in water in a cup. Those who participate in this research will be interviewed with questionnaires concerning their background characteristics, weight and height for BMI assessment, acceptability of the supplement and symptoms related to malnutrition.

4. Participant Selection

You have been selected because you are a woman aged 18–49 living in a peri-urban area of Hlaing Thatryar Township, Yangon and may be at risk of malnutrition.

5. Voluntary Participation

Your participation in this study is completely voluntary. You may refuse to participate or withdraw at any time without affecting your access to any services. You may change your mind later and stop participating even if you agreed earlier.

6. Procedures and Protocol

You will be randomly assigned to one of two groups:

- Group A: You will come to the community center every day for 60 days starting on September 1st, 2025 to receive a 10g serving of microgreen powder from nurses at the community center.
- Group B: You will not take the powder for the first 60 days but will receive the full 60-day supply when you come in on the 31st October, 2025.

At the beginning and end of the 60 days, all participants will:

- Be weighed and measured for your height.
- Answer questions on symptoms you are experiencing.
- Receive nutrition education pamphlets and stipends.

Group A will also:

- Report daily for powder administration.
- Answer some questions about your satisfaction with the powder at the end.

7. Duration

The total duration of a 10g serving of microgreen powder supplementation is 60 days.

Coming in for supplement administration and recording your attendance will take 5 minutes.

Both groups will attend the start and end of the study which will take about 25 minutes in

total. During that time, it will take about 20 minutes to answer questions and about 5 minutes for weight and height measurement.

8. Risks and Discomforts

The microgreen powder is plant-based and FDA approved. However, some may experience mild digestive discomfort. If you experience any issues, please speak to us at the community center. Moreover, there is no serious risk for your participation. You do not have to answer any question if you feel the question(s) are too personal or if talking about them makes you uncomfortable.

9. Benefits

You can know your nutrition status at the baseline, and whether your nutritional status is improved or not by the effect of microgreen powder supplementation. However, your participation is valuable in helping us learn how to support women's nutrition better.

10. Incentives

Participants in Group A will receive a daily stipend to compensate for transport and time. All participants will receive a stipend for attending the start and end of the study to compensate for transport and time. No additional compensation will be provided.

11. Confidentiality

All your information will be kept strictly confidential. We will not tell other people of your participation in this research and we will not share your data to anyone who does not work in the research study. Your responses will be coded and no names will be used in any publications. Only the researchers will know what your code number is and we will store it safely. Results of this study may be published, but any data included will not be linked to any specific participant. Your anonymity will be preserved.

12. Sharing the Results

Confidential information of an individual participant will not be shared. We will share study findings with participants and local communities. The results may also be published in journals and presented at conferences.

13. Right to Refuse or Withdraw

You can withdraw at any time without any negative consequences.

14. Who to Contact

If you have questions or concerns, please contact one of the research team members or the primary investigator (Daniel Samuelsen; israel@edenmyanmar.org; +959694466755)

This study has been reviewed and approved by the STI Myanmar University Institutional Review Board. For further questions, you may contact the IRB at STI Myanmar University, Building 10, G Floor, MICT Park, Hlaing Township, Yangon. Phone: 09-955123446 / 09-955123447 / 01-377988

PART II: CERTIFICATE OF CONSENT

I have been invited to participate in a research study that involves taking a nutritional powder daily for 60 days or waiting to receive the powder and coming back after 60 days. I understand that I may need to come to the community center daily or only on the 1st of September 2025 and 31st of October 2025 to receive the powder, and that I will be compensated for transport and lost wages. I also understand that I will attend the start and end of the study on the 1st of September 2025 and 31st of October 2025 where I will also receive a stipend to compensate for transport and time. I have been informed that the risks are minimal and that I may or may not benefit directly.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research and understand that I have the right to withdraw from the research at any time without in any way affecting my medical care.

Name of participant _____

Signature of participant _____

Date _____

(Day/ month/year)

If illiterate

Thumb print of participant

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness _____

Signature of witness_____

Date _____

(Day/ month/year)

I have accurately read or witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of researcher _____

Signature of researcher _____

Date _____

(Day/ month/year)

A copy of this Informed Consent Form has been provided to the participant

_____(initialed by researcher/assistant)