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Evaluating the effects of daily microgreen powder supplementation over 60 days on fatigue and nutrition-related symptoms among women of reproductive age in Yangon, Myanmar

Submission date 17/07/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 18/07/2025	**Overall study status** Completed	
Last Edited 03/10/2025	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims

Many women in Myanmar struggle to get the nutrients they need due to rising food prices and limited access to healthy food. This often leads to fatigue, weakened immunity, and other symptoms of malnutrition. This study will test whether taking a small daily amount of microgreen powder, made from nutritious young plants like sunflower sprouts, over 60 days can help improve women's health outcomes, especially by reducing fatigue and malnutrition and strengthening their bodies.

Who can participate?

Women aged 18 to 49 years who live in Yangon, are not pregnant, and are not already taking any supplements. Participants must also be at risk of poor nutrition, which we will assess using a short screening tool.

What does the study involve?

Women who join the study will be randomly placed into one of two groups. One group will take 10 grams of microgreen powder at the community centre each day for 60 days, while the other group will wait and receive the powder after the study ends. Everyone will come to a local community centre twice, once at the beginning and once at the end, for simple measurements of height and weight and to answer a few questions about their wellbeing. Nurses will support participants daily and check in on how they are doing.

What are the possible benefits and risks of participation?

Participants may feel more energetic and notice improvements in other health symptoms, like appetite or skin condition. There are no known serious risks, as the powder is made from natural, plant-based ingredients. Some people might feel mild stomach discomfort, but nurses will be on hand to help if needed.

Where is the study run from?
The study will take place at community centres in Yangon, Myanmar.

When is the study starting and how long is it expected to run for?
November 2024 to October 2025

Who is funding the study?
This research is funded by the Pears IMPH Alumni Seed Grant Program to Promote Public Health Research, which is the result of a continuing partnership between the Braun School of Public Health, Hebrew University of Jerusalem Hadassah and Pears Foundation.

Who is the main contact?
Daniel Israel Samuelsen, israel@edenmyanmar.org

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
STI IRB/21/25

Study information

Scientific Title

A waitlist-controlled trial evaluating the effects of daily supplementation with 10 g of microgreen powder over 60 days on malnutrition-related symptoms among women of reproductive age in Yangon, Myanmar

Acronym
MICRO-WELL

Study objectives
Hypotheses:
1. Daily supplementation with 10g of microgreen powder will significantly reduce fatigue (measured via Fatigue Severity Scale) among women of reproductive age over 60 days compared to a waitlist-control group.
2. Supplementation will improve BMI and malnutrition-related symptoms over 60 days in the intervention group.
3. Acceptability and satisfaction of the microgreen powder will be moderate to high.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/07/2025, STI Myanmar University, Yangon; Institutional Review Board (Block 10, Phase 3 MICT Park, Hlaing Campus, Yangon, 10-3, Myanmar; +95 (0)1507048; info@stiedu.net), ref: STI IRB/21/25

Study design
Waitlist-controlled single-centre interventional trial using block randomisation with blinded outcome assessors

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Dietary micronutrient deficiency

Interventions
Group A (intervention): Receives 10 g of microgreen powder daily, made from an equal blend of sunflower, mung bean and mustard seed, administered with water under nurse supervision at a community centre for 60 days.

Group B (waitlist-control): Receives no intervention during the study but is given a 60-day supply of microgreen powder at study completion.

Randomisation: Stratified block randomisation by malnutrition risk category (medium/high). The block order (4, 6, 8) was randomised using a computer-generated sequence in R software.

Intervention Type
Supplement

Primary outcome(s)
1. Fatigue severity measured using the Fatigue Severity Scale (FSS) at baseline (T0) and day 60 (T1)
2. Body Mass Index (BMI) calculated from weight and height measurements using standard stadiometers and digital scales at baseline (T0) and day 60 (T1)
3. Malnutrition-related symptom severity measured using a structured Malnutrition Symptom Survey (Likert-scale) at baseline (T0) and day 60 (T1)

Key secondary outcome(s))
Acceptability and satisfaction with supplementation measured using a structured post-intervention questionnaire at day 60 (T1)

Completion date
31/10/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 03/10/2025:

1. Women aged 18-49 years
2. Resident of Yangon, Myanmar
3. Malnutrition Universal Screening Tool score indicating medium or high malnutrition risk
4. Not currently pregnant
5. Not taking any other nutritional supplements
6. Able and willing to provide informed consent

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Previous inclusion criteria:

1. Women aged 18-49 years
2. Resident of Hlaing Tharyar township
3. Malnutrition Universal Screening Tool score indicating medium or high malnutrition risk
4. Not currently pregnant
5. Not taking any other nutritional supplements
6. Able and willing to provide informed consent

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
49 years

Sex
Female

Total final enrolment
213

Key exclusion criteria
1. Low malnutrition risk score using the Malnutrition Universal Screening Tool
2. Severe acute/chronic illness or allergy to supplement ingredients
3. Having chronic diarrhoea for more than 2 weeks in the past 1-3 months or having known malabsorption disorders
4. Currently in another study or trial

Date of first enrolment
20/08/2025

Date of final enrolment
31/08/2025

Locations

Countries of recruitment
Myanmar

Study participating centre
New Hope Myanmar Local NGO
New Hope NGO Community Center
Insein Township
Yangon
Myanmar
10-15

Study participating centre
New Hope Myanmar Local NGO
New Hope NGO Community Center
Kyi Min Daing Township
Yangon
Myanmar
11101

Study participating centre

New Hope Myanmar Local NGO
New Hope NGO Community Center
Shwe Pyi Thar Township
Yangon
Myanmar
11411

Sponsor information

Organisation
Hebrew University of Jerusalem

ROR
https://ror.org/03qxff017

Funder(s)

Funder type
Charity

Funder Name
Pears Foundation

Alternative Name(s)
Pears Family Charitable Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Good Seed Myanmar

Results and Publications

Individual participant data (IPD) sharing plan

The de-identified dataset will be securely stored on password-protected computers and a private Dropbox repository accessible only to authorised research team members. The data will be retained indefinitely for potential secondary analyses and to allow verification of study findings. Any data sharing will be strictly controlled, available only upon reasonable request to the Principal Investigator (Daniel Israel Samuelsen; israel@edenmyanmar.org) for ethically approved research purposes.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.2		18/07/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes