

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

The effectiveness of pulse-based food supplements for undernourished pregnant mothers to improve maternal and birth outcomes: a cluster randomized controlled trial

Protocol summary

Study aim

This study aims to assess whether balanced energy protein from pulse food supplement (PFS) combined with MMS has the same effect as the government food supplements (GFS) program in Indonesia

Design

This is a two-arm, cluster-randomized controlled trial, parallel-group, single-blind study.

Settings and conduct

The study will take place in the Tahunan Public Health Center (PHC) area of Jepara District, and the Windusari PHC area of Magelang District, Central Java Province, Indonesia from December 2022 to August 2023. Based on the District Health Office Report Year 2021, about 1000 women are pregnant each year, with antenatal care coverage of 95%, and all births being attended by skilled birth attendants.

Participants/Inclusion and exclusion criteria

The inclusion criteria: pregnant mothers who visit village midwives for antenatal care, with single pregnancies, gestational age at less than 28 weeks, have MUAC <23.5 cm, have no intention of moving from the area for at least 6 months and agree to sign the consent form. We will exclude mothers who have experienced previous stillbirths or miscarriages to avoid having the follow-up disrupted.

Intervention groups

The intervention group will receive legumes food supplements in the form of cookies which contain minimally 300kcal energy and 7 grams of protein combined with multiple micronutrients of UNIMMAP from Vitamin Angel. The control group will receive usual care from the government, namely the GFS and iron folic acid (IFA) supplements. The GFS contains 300 kcal energy and 5 grams of protein per day.

Main outcome variables

The main outcome variables are maternal outcomes

(gestational weight gain and maternal MUAC) and birth outcomes (birth weight, birth length, type of delivery, preterm birth)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221125056601N1**

Registration date: **2022-12-28, 1401/10/07**

Registration timing: **prospective**

Last update: **2022-12-28, 1401/10/07**

Update count: **0**

Registration date

2022-12-28, 1401/10/07

Registrant information

Name

Kun Susiloretni

Name of organization / entity

Semarang Health Polytechnic - Poltekkes Kemenkes Semarang

Country

Indonesia

Phone

+62 813-2532-5911

Email address

kun@poltekkes-smg.ac.id

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-02, 1401/10/12

Expected recruitment end date

2023-06-20, 1402/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of pulse-based food supplements for undernourished pregnant mothers to improve maternal and birth outcomes: a cluster randomized controlled trial

Public title

Pulse-based food supplements for undernourished pregnant mothers

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

pregnant women with mid-upper arm circumference (MUAC) <23.5 cm gestational age at less than 28 weeks single pregnancy had no intention of moving from the area for at least 6 months had visited village midwives for antenatal care

Exclusion criteria:

pregnant women had experienced previous stillbirth or miscarriage

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **120**

More than 1 sample in each individual

Number of samples in each individual: **60**

There will be 60 participants in intervention and control group.

Randomization (investigator's opinion)

Randomized

Randomization description

This will be cluster randomization with a village as a unit of assignment. We will use the random number formula in an Excel spreadsheet. In order to have a balanced number of pregnant women in the intervention and control group, stratified randomization will be used based on the number of undernourished pregnant mothers in the village (3-6, and ≥ 7). A statistician will perform randomization of the 20 villages for the intervention and control group, and then the field researcher will execute the result.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants will be blinded. The nature of the dietary intervention study is impractical to blind the cooks, dietitians and the study staff responsible for preparing the foods and taking all measurements of the diets. An

effort will be made to blind the study participants in the intervention assignment, including 1. The participants will not be told of their group assignment 2. The study will employ a cluster randomized controlled trial, with a village as a unit of assignment. Therefore, the two groups will consume their food supplement in separate villages and presumably will not meet each other. 3. Both groups will receive food and nutrient supplements using similar nutrient content. The intervention group will receive 'pulse cookies' as food supplements combined with multiple micronutrients and the one for control will receive fortified food supplements as the government program. 4. Both groups will receive nutrition education in different classes, places, and schedules.

Placebo

Used

Assignment

Parallel

Other design features

The sample size was calculated using STATA 15 command of "clustersampsi, binomial power p1(0.55) p2(0.12) m(4) k(10) rho(0.01) size_cv(0.9) base_correl(0)~" resulting 60 participants per group.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

HEALTH RESEARCH ETHICS COMMITTEE POLTEKKES KEMENKES SEMARANG

Street address

Jl. Tirto Agung, Pedalangan, Banyumanik, Semarang

City

Semarang

Postal code

50268

Approval date

2022-04-25, 1401/02/05

Ethics committee reference number

0313/EA/KEPK/2022

Health conditions studied**1****Description of health condition studied**

Pregnant mothers with mid-upper arm circumference (MUAC) <23.5cm

ICD-10 code

O25.11

ICD-10 code description

Malnutrition in pregnancy, first trimester

Primary outcomes

1

Description

Birth length of the baby born by the mother

Timepoint

1-3 days after birth

Method of measurement

Measured by baby length board of SECA

2

Description

Birthweight

Timepoint

1-3 days after birth

Method of measurement

Measured by SECA baby's digital scale

3

Description

Mode of delivery

Timepoint

1-3 days after birth

Method of measurement

Hospital/PHC record

4

Description

Maternal MUAC

Timepoint

after 90 days of intervention

Method of measurement

Measured on the non-dominant arm without sleeved garment using non-stretch tape made of fibreglass.

5

Description

Gestational weight gain

Timepoint

after 90 days of intervention

Method of measurement

Measured by SECA digital scale

Secondary outcomes

1

Description

Birthweight

Timepoint

1-3 days after birth

Method of measurement

Measured with digital scale of SECA Brand

Intervention groups

1

Description

Intervention group. The intervention group will receive

firstly, 'Pulse based cookies' as local food supplements (PFS), approximately 80-85 grams cookies that contain 400-450 kcal energy, 10-13 grams protein, and 22-30 grams fat. PBC consist of 8 types of cookies, each cookie is made from pulses (i.e. soybean, green bean, red bean, or brown bean), vegetable oil, white sugar, egg, instant yeast, guar gum, skim milk, peanut or coconut, and salt. Secondly, Multiple micronutrition supplementation (MMS) as UNIMMAP that contain Vitamin A (as palmitate or acetate) 800 µg RE (2667 IU), Vitamin C (Ascorbic acid) 70 mg, Vitamin D (as 5 µg Cholecalciferol) 5 µg (200 IU), Vitamin E (10 mgα-TE) (as dl-alpha tocopheryl acetate) 15 IU, Vitamin B1 (Thiamine mononitrate) 1.4 mg, Vitamin B2 (Riboflavin) 1.4 mg, Vitamin B3 (Niacinamide) 18 mg, Vitamin B6 (Pyridoxine HCl) 1.9 mg, Folate (from Folic Acid) 680 µg DFE (400 µg Folic Acid), Vitamin B12 (Cyanocobalamin) 2.6 µg, Iron (Ferrous Fumarate) 30 mg, Iodine (Potassium Iodide) 150 µg, Zinc (Zinc Sulphate) 15 mg, Selenium (Sodium Selenite) 65 µg, Copper (Copper Citrate) 2 mg. Third, a 1-day class training on maternal health and early life nutrition. The trainers will be from PHCs and the researchers. The trainers will be provided with PowerPoint presentation slides, while participants will receive two booklets of the slides. The supplements (PFS and MMS) will be given for 90 days duration, and a package of 30 days' supplements will be given at the training and another 60 days' package will be delivered at week four and eight.

Category

Treatment - Other

2

Description

Control group. The control group will receive firstly, the Government food supplements (GFS), approximately 60 grams cookies that contain 300 kcal energy, 3 grams protein, and 22-30 grams fat. The GFS is fortified with multiple micronutrition, namely energy 300 Kcal, Total fat 15.6 g, Protein 3 g, Carbohydrate 34.8 g, Natrium 141 mg, Vitamin A 275.22 RE, Vitamin D 7.5 mcg, Vitamin E 7.08 mg, Vitamin B1 0.48 mg, Vitamin B2 0.48 mg, Vitamin B3 5.34 mg, Vitamin B5 1.8 mg, Vitamin B6 0.54 mg, Vitamin B9 198 mcg, Vitamin B12 0.84 mcg, Vitamin C 28.2 mg, Calcium 261.6 mg, Phosphor 194.4 mg, iron 6.96 mg, Iodium 51.6 mg, Zink 4.2 mg, Selenium 19.2 mcg, Fluor 0.18 mg, water 1.764 g. Secondly, a 1-day class training on maternal health and early life nutrition. The trainers will be from PHCs and the researchers. The trainers will be provided with PowerPoint presentation slides, while participants will receive two booklets of the slides. The GFS will be given for 90 days duration, and a package of 30 days' supplements will be given at the training and another 60 days' package will be delivered at week four and eight.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tahunan Public Health Center

Full name of responsible person

Novi Musannadah

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2

Recruitment center

Name of recruitment center

Windusari Public Health Center

Full name of responsible person

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District, Central Java Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semarang Health Polytechnic

Full name of responsible person

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Web page address

<https://poltekkes-smg.ac.id/>

Grant name

DIPA Poltekkes

Grant code / Reference number

DIPA-024.12.2.632242/2021

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Semarang Health Polytechnic

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Semarang Health Polytechnic

Full name of responsible person

Kun A Susiloretni

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Kun A Susiloretni

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Pulse food supplementation Indonesia - PulseIndonesia01

When the data will become available and for how long

Data will be available upon request with the agreement

To whom data/document is available

Scientist

Under which criteria data/document could be used

For academic purposes

From where data/document is obtainable

Principal Investigator by email at kun@poltekkes-smg.ac.id

What processes are involved for a request to access data/document

Depending on the applicant's purposes. We will check their purposes and possibility to use the data.

Comments