

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Effect of Intensive Nutrition Education and Counselling Package on Nutritional Status of Pregnant Women Attending Antenatal Care Clinic. A Clustered Randomized Controlled Trial.

Protocol summary

Study aim

To assess the effect of intensive nutrition education and counseling package on nutritional status during pregnancy

Design

Clustered randomized control trial will be used and the study will be carried out in East Shoa Zone, Ethiopia. A total of 150 pregnant women will be assigned to each arm. It is a multi-center study conducted in six health centers.

Settings and conduct

The study will be conducted in East Shewa Zone in Oromia regional state, Central Ethiopia. The study will take place in 6 health centers of East Shoa Zone, central Ethiopia. The study participants and the outcome assessors will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria - All pregnant women attending antenatal care clinic at the selected health centers
Exclusion criteria - Pregnant women who have preexisting medical illnesses.

Intervention groups

The intervention given for the intervention group is Intensive Nutrition Education and Counseling Package (INECP) which has 4 components that aimed at improving the nutritional status of pregnant mothers attending antenatal care service at intervention arm health facilities.

Main outcome variables

Nutritional status and hemoglobin level of pregnant women.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220508054783N1**

Registration date: **2022-05-29, 1401/03/08**

Registration timing: **retrospective**

Last update: **2022-05-29, 1401/03/08**

Update count: **0**

Registration date

2022-05-29, 1401/03/08

Registrant information

Name

Ermias Wakwoya

Name of organization / entity

Jimma University

Country

Ethiopia

Phone

+251 91 207 0148

Email address

ermi3577@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-20, 1401/02/30

Expected recruitment end date

2022-05-27, 1401/03/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Intensive Nutrition Education and Counselling Package on Nutritional Status of Pregnant Women

Attending Antenatal Care Clinic. A Clustered Randomized Controlled Trial.

Public title

Effect of Intensive Nutrition Counselling on Nutritional Status of Pregnant Women

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnant women attending antenatal care clinic in selected health institutions in East Shoa zone, Central Ethiopia.

Exclusion criteria:

Pregnant women who had known medical illnesses

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Randomized

Randomization description

Unit of randomization will be health center. Health centers will be randomly allocated to intervention and control arms. From the total of 6 health centers, 3 are allocated to intervention groups and the rest 3 health centers are allocated to control groups. Randomization will be done after a public container ballot by a person who is not a member of this study. Cluster randomization will be used to prevent message contamination because women in the same cluster have a high probability of communicating and discussing the intervention messages. To avoid this, all eligible pregnant women in one cluster will be enrolled in the same arm (either in the intervention or control arms). Moreover, buffer zones (health center with non-adjacent catchment area) will be left between the intervention and control clusters to prevent information contamination.

Blinding (investigator's opinion)

Double blinded

Blinding description

The health facilities will be invited to participate prior to randomization without disclosure of allocation status. Participants will not be informed about allocation to intervention or control arm. Outcome assessors who have no information about the experiment will be deployed to measure the outcome of the intervention.

Placebo

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Institutional Review Board, Institute of Health, Jimma University

Street address

Institute of Health, Jimma University, Jimma

City

Jimma

Postal code

378, Jimma University

Approval date

2021-07-24, 1400/05/02

Ethics committee reference number

212021

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

Not applicable

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The primary outcome of the study is nutritional status of pregnant women. The nutritional status of the pregnant women will be assessed by using mid upper arm circumference measurement method. The measurement will be made before and after the intervention.

Timepoint

12 weeks after intervention

Method of measurement

The nutritional status of pregnant women will be measured by using Mid Upper Arm Circumference (MUAC)

Secondary outcomes**1****Description**

Hemoglobin level

Timepoint

12 weeks after intervention

Method of measurement

Heamocue machine

Intervention groups

1

Description

The intervention group will receive the intensive nutrition education and counseling package (INECP). The intervention package contains intensive counselling by trained health care providers on promoting a healthy diet, adequate weight gain, consistent use of micro-nutrient supplements, counseling about healthy eating and deworming. Leaflets will be given and regular short message service will be sent to pregnant mothers on their mobile phones.

Category

Prevention

2

Description

Control group: The control group will continue to receive the usual care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Fentale Health center

Full name of responsible person

Temam Haji Bedaso

Street address

Fentale Health center

City

Mata Hara

Postal code

04, Meta Hara, Ethio

Phone

+251 91 077 0811

Email

matiblessed@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jimma University

Full name of responsible person

Melese Niguse

Street address

Jimma University

City

Jimma

Postal code

378, Jimma Universit

Phone

+251 91 710 5735

Email

meleseniguse@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Jimma University

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

Jimma University

Full name of responsible person

Ermias Bekele Wakwoya

Position

PhD Candidate

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Jimma University

Full name of responsible person

Ermias Bekele Wakwoya

Position

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Nutritional status of pregnant women

When the data will become available and for how long

January 2024

To whom data/document is available

will be shared for people working in academic institutions

Under which criteria data/document could be used

The data could be used for academicians, researchers and policy makers

From where data/document is obtainable

Data can be obtained from Mr. Ermias Bekele Wakwoya, email: ermi3577@gmail.com

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

Making request through email

Comments