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Sistem Informasi Nutrisi Ibu Hamil (Nutrition information system for Pregnant Women)

Submission date
21/10/2019

Recruitment status
No longer recruiting

Registration date
22/10/2019

Overall study status
Completed

Last Edited
31/01/2023

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Sistem Informasi Nutrisi Ibu Hamil (Nutrition information system for Pregnant Women) (SISFORNUTRIMIL) is an app to help expectant mothers to monitor their dietary intake, especially in pregnancy periods that have higher risks of inadequate nutrition.
The aims of this randomised controlled trial (RCT) is to examine the impact of SISFORNUTRIMIL application on maternal eating behaviour and associated maternal factors such as weight gain, blood pressure, biochemical measurement (haemoglobin and blood glucose level), and pregnancy outcome (neonatal birth weight). The pregnant women and family may not have the necessary knowledge and skills to estimate nutrient value in food in line with dietary targets and the guidelines, i.e. they do not know whether or not they are consuming the right amount of nutrition needed during pregnancy. The overall aim of SISFORNUTRIMIL application is to help expectant mothers to monitor their dietary intake, especially in pregnancy periods that have higher risks of inadequate nutrition.

Who can participate?
Pregnant women aged 19 years or above, between 13-26 gestation

What does the study involve?
Participants will be randomised to use the SISFORNUTRIMIL app for 12-weeks or read a leaflet about diet in pregnancy. Participants will need to record their food intake for three days each week during the 12-weeks.

What are the possible benefits and risks of participating?
Through this research, pregnant women will get additional information about nutritional needs during pregnancy and could be self-monitored of nutrition intake to meet pregnancy requirement. In addition, the women will receive health monitoring through the measurements of maternal weight, blood pressure, HB and blood glucose.
There will be no serious risks associated with the participation of pregnant women in this study because there are no actions or treatments that can be endangered or threaten the safety of the mother and baby. There is no supplementation should be consumed by the women. They only consume her daily food, and if the following of food choice as recommendations for alternative consume, the food list based on the Ministry of Health guidelines and is suitable for

pregnant women.
The only potential risk, when collecting data, maybe that participant feel the process of antenatal care visits takes longer. However, the researcher will ensure that the questions asked to pregnant women will focus on the related information need, which is not accessible on their medical record. If the participant is tired, the data collection will be stopped temporally and offered the participant to take a rest.
If in collection data show any type potentially concern about unwanted health problems, the researcher will refer the women to health care professionals.

Where is the study run from?
1. Puskesmas Garuda, Indonesia
2. Puskesmas Ibrahim Adjie, Indonesia

When is the study starting and how long is it expected to run for?
December 2019 to April 2020

Who is funding the study?
Universitas Padjadjaran, Indonesia

Who is the main contact?
Mira Trisyani Koeryaman
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A Randomized Controlled Trial of Maternal Eating Behaviour by using Nutrition Information System for Pregnant Women (SISFORNUTRIMIL) Application at Bandung City, Indonesia

Acronym
SISFORNUTRIMIL

Study objectives
1. The SISFORNUITRIMIL will reduce imbalance nutrition and binge eating by standard criteria of dietary reference intake for Indonesia pregnant women at three months in a group of web-based application user, thereby improving their proper eating
2. The average level of anthropometric, clinical, and biochemical assessment (pregnancy weight gain, haemoglobin, blood pressure, blood glucose and birth weight) will be within normal limits as a nutritional biomarker and a positive pregnancy outcome

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/10/2019, Universitas Padjadjaran Research Ethics Committee (Jl. Prof. Eyckman No. 38 Bandung 40161, West Java, Indonesia; +62 22 2038697; kepk.fk.unpad@gmail.com), ref: 1227/UN6.KEP/EC/2019 (registration number: 0619060938)

Study design
Single-centre two-armed randomized control trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Healthy pregnant women

Interventions
The allocation of participants is 1:1 to the SISFORNUTRIMIL application user and non-user application. The matched pair criteria determined by two groups' similarity such as maternal age based on age range (19 to 29 years and 30 to 49 years), gestational age (trimester 1 and 2), parity (primipara and multipara), education level (secondary and higher education), and social-economic status represented by monthly household income (under and over on minimum wages in West Java). The allocation between intervention and control groups was done using the free online randomizer "QuickCalcs by GraphPad"

Intervention group:
1. The participants who recruited into intervention group will open the SISFORNUTRIMIL application through http://www.sisfornutrimil.com
2. Participants were asked and instructed to record all meals, snacks and drinks had they eat for three days per week during 12 weeks by selecting food on the application. The food list has been grouped into seven food groups. They had to select two weekdays (on Monday and Friday) and one weekend (Sunday) when the women were eating and drink normally. It will be made more accessible for women to remember the day.
3. The women must pay attention to food and drinks size, if the food they had eaten is not in the list, they should input the name of food or drink in “other choices”.
4. The women are asked to access "food intake suggestions" and choose a list of foods with portion size as alternative food choices for consumption

Control group:
1. Participants will be given the leaflet about general information of pregnancy and diet, and paper-based food record (the material used is a standard property that has been provided by a health centre)
2. The participants are asked to record everything had eaten and drunk for three days each week by filing in the "Food record" form (paper-based). They had to select two weekdays and one weekend when the women were regularly eating and drink for 12 weeks.

Participants will get clinical assessment measurements three times: The first measurement (baseline assessment) will be done a week before the mother uses the application includes measurements of maternal weight, blood pressure, HB examination and blood glucose. The second measurement includes measurements of maternal body weight, blood pressure, HB and blood glucose tests that will be performed after 12 weeks. The blood as much as 3 cc drawn by local laboratory staff and it is free of charge. In addition, in the first and second measurement, all participants will fill in eating habit questionnaires.

Intervention Type
Behavioural

Primary outcome(s)
Maternal eating behaviour measured using self-report three times per week for 12 weeks

Key secondary outcome(s))
1. Clinical and biochemical effects of diet measured using MDD-W and biochemical sample at baseline and three months
2. Neonatal birth weight

Completion date
30/04/2020

Eligibility

Key inclusion criteria
1. Pregnant women aged at least 19 years
2. Gestational age between 13-26 weeks
3. Outpatients in the maternal and child health clinic of PUSKESMAS and received regular antenatal care

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
102

Key exclusion criteria
1. Pregnant women with serious medical condition such as food allergy, bulimia and chronic illness
2. Diagnosed with a mental illness patient
3. Non-permanent patients of PUSKESMAS
4. Do not have any devices
5. Participants who fall in the inclusion criteria but do not give or lack the capacity to give consent

Date of first enrolment
02/12/2019

Date of final enrolment
18/01/2020

Locations

Countries of recruitment
Indonesia

Study participating centre
Puskesmas Garuda
Jalan Dadali No. 81
Garuda
Andir
Kota Bandung
West Java
Bandung City
Indonesia
40184

Study participating centre

Puskesmas Ibrahim Adjie
Adjie. Jalan Ibrahim Adjie No.88
Kebonwaru
Batununggal
Kota Bandung
West Java
Bandung City
Indonesia
40272

Sponsor information

Organisation
Padjadjaran University

ROR
https://ror.org/00xqf8t64

Organisation
University of Portsmouth

Funder(s)

Funder type
University/education

Funder Name
Universitas Padjadjaran

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/01/2023	31/01/2023	Yes	No

Protocol (preprint)	version v1	17/06/2021	03/09/2021	No	No
Protocol file			08/11/2019	No	No