Research Article

Nutrition Information System (SISFORNUTRIMIL) Application with Food Record Online for Indonesia Pregnant Women: Protocol for Randomized Controlled Trial

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Abstract

Background

The pregnant women and family may not have the necessary knowledge and skills to estimate nutrient value 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 aims of this randomized controlled trial (RCT) is to examine the effectiveness of SISFORNUTRIMIL application on maternal eating behaviour and clinical indicators such as weight gain, blood pressure, biochemical measurement, and pregnancy outcome.

Methods

The study recruits 109 participants with eligible criteria during November 3rd 2019, and mid-January 2020. The allocation of participants is 1:1 to the SISFORNUTRIMIL application user (56 participants) and non-user application (53

participants), with criteria: singleton pregnancy (22-26 weeks), mother age between 19-30 years old), have monthly income and literate. The participants in the intervention group received a face-to-face visit and standardised prenatal care and diet advice from healthcare professionals which the intervention group used a web-based app for 12 weeks to follow food choices and input their dietary intake on the dietary record that had synchronised total calorie estimation. At the same time, the control group received the usual care and paper-based method only.

Discussion

This is the first randomized controlled trial to examine the effectiveness of the SISFORNUTIMIL application. Additionally, the researcher's personal efforts to reduce morbidity and mortality rates caused by poor nutrition. The frameworks have focused on nutrition self-monitoring interventions concerning calorie intake and food diversity consumed. The application's interface comprises records of dietary intake, food advice, and information on adequate nutrition that follow national guidelines.

Trial registration: ISRCTN Registry: ISRCTN42690828. Date of registration: 22 October 2019.

Key words: Eating behavior; Nutrition; Pregnancy; Information system; Sisfornutrimil

1. Introduction

1.1 Background and rationale

Since 2004, the World Health Organization (WHO) has tried to achieve the challenges of the global strategy on a diet, physical activity and health that focused on maternal health and nutrition before and during pregnancy. During pregnancy, women must set optimal birth outcomes through sound nutrition practices [1]. Proper nutrition during pregnancy is necessary for mother and infant outcomes and, indeed, for later life [2]. However, for pregnant women, a healthy diet and dietary intake are often insufficient to meet these needs; there likely are multiple nutritional deficiencies, particularly in low and middle-income countries [3]. The South-East Asia region is one of the regions that contribute to highly prevalent maternal undernutrition [3]. Lack of nutritional food during pregnancy, unattended prenatal care, belief taboos that prevent uptake of nutritious food during pregnancy, and binge eating, are more likely to be associated with maternal morbidity and mortality prevalence. Key driving factors, such as cultural practices, poverty and weaknesses in nutrition governance, can contribute to maternal and child undernutrition. According to the nutrition profile in Indonesia, approximately 9.2 million (37%) of 24.5 million children under five years of age are stunted, and 24-27% in some regions is low birth weight. Indonesia is one of the countries with a significant contributor to maternal mortality rate (MMR) worldwide, particularly in South-East Asia [3]. Maternal morbidity in Indonesia mainly occurs during labour due to other reasons 53.4%, including hypertension, prematurity, the breech position of the foetus and swelling. The second-highest morbidity during pregnancy was bleeding 25.0%, premature rupture of membrane 21.1%, and convulsion 2.3%. While the neonatal mortality caused by prematurity was 35.5%, birth asphyxia and trauma 21.6%, congenital anomalies 17.1%, sepsis 13%, and other 5.4% [4]. These could profoundly be influenced by inadequate nutrition during pregnancy. The prevalence of imbalance of nutrition requirements has significantly increased in developed countries over recent decades, with an estimated 52%

getting anaemia high-risk and 25.8% having diabetes [5]. In particular, the stunting prevalence rate in West Java was 29.2 percent in 2017, identified as being caused by maternal factors. The current study is motivated by a personal desire to tackle this growing problem, derived from Indonesia's nutrition profile and personal experience as a researcher and thesis supervisor in nutrition pregnancy topics. Despite extensive research in this field, there is no effective solutions/intervention currently available to address this problem. The insufficiency intervention is due to a lack of measurement of maternal dietary consumption and suboptimal counselling by health-provided services focused on maternal diet and weight gain. Therefore, to the author's knowledge, this study proposes solutions to the absence of integrated individual interventions between information systems and food records; the authors devised a group-based intervention to develop a self-monitoring dietary assessment method.

2. Methods

2.1 Overview

This study used the randomised control trial (RCTs) method to attain the study objectives. In order to avoid selection bias in determining maternal eating behaviour and associated maternal assessment, the theory of self-monitoring and randomisation technique should be considered. This study's framework model sets out the theory of self-monitoring for a healthy diet. Eligible participants have randomised to either the intervention or control group in a 1:1 allocation ratio via stratified block randomisation by maternal age (19-24 years and 25-29 years) and education level (primary and secondary level). To allocate between intervention and control groups, the researcher used an online tool (List Randomizer □ - Randomise Any List or Sequence

(gigacalculator.com) as a computer-based tool for random number generator. The guideline intervention refers to Consolidated Standards of Research Trials (CONSORT) items-in, particular for non-pharmacologic treatment [6], and in conjunction with CONSORT 2010 as the latest version. This protocol describes a two-armed randomised control trial (RCTs) for 12 weeks to determine maternal eating behaviour and associated maternal. The recruitment of participants was screened to use inclusion and exclusion criteria. Firstly, the women were recruited into four strata: as permanent patients of PUSKESMAS or private clinic, between 19 to 30 years, gestational age 22-26 weeks and a singleton pregnancy, and necessary ability to use any devices. Blood samples (haemoglobin and blood glucose) will be drawn to confirm eligibility based on clinical laboratory parameters. Then, informed consent will be obtained before any study-related procedures are performed, including the discontinuation of the current study.

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2.2 Recruitment

The principal researcher approaches pregnant women as a recruitment strategy with support from study site staff. The recruitment process is carried out at maternal and child health clinics at the Community Health centre (PUSKESMAS) and private clinics. Pregnant women will be identified based on arrival and registered for regular antenatal care. Researchers have access to data information in identifying potential participants through medical records and register books. Besides, the principal researcher will inform the health professional of the eligibility criteria for potential study participants. These professionals will be provided with information packs (demography questionnaire and participants' information sheets) to identify whether pregnant

women met the study's eligibility criteria. In some cases, health professionals review patient records to identify women suitable as subject participants and then inform the Principal Investigator to follow up. Pregnant women interested in participating in the study were asked for their contact details to obtain further information. No personal data was provided to the researcher without the women's consent. During the first stage, pregnant women were asked for information about their age, gestational age, and smartphone ability, along with information on any medical condition, with the intention of pre-screening pregnant women who did not meet the inclusion criteria. Pregnant women were not invited for baseline measurements if they did not meet the inclusion and exclusion criteria (e.g., outside the age range and have medical problems). It was politely explained to them that they were not eligible. Those who met the criteria were obtained (MDD-W) and ABEQ questionnaire. If the Investigator found the consent was invalid, there has been a substantial change to the research or the subject condition since the original consent was signed. The Investigator will contact the participants in person by phone, explain the need for re-consent, and allow participants to ask questions. In addition, investigators ask the participants to sign a document affirming their willingness to continue to participate in the research study.

2.3 Study population and enrollment

The population of this study were all pregnant women of restricted age between 19-30 years and gestational age between 22-26 weeks who were outpatients in the maternal and child health clinic of PUSKESMAS or private clinic and received regular antenatal care. All women who were eligible for the criteria were asked to read the information sheet and

ask them to participate in the study. A participants' information sheet was translated into the local language detailing all the information about the study covering objectives, length period, outcomes and post-study. The participants are given adequate time to read and understand the information sheet before committing to the study (min 72 hours). Participants were allowed to ask the researcher any questions they may have before and during the interview. Informed consent was obtained before any study-related procedures, including blood samples. The following inclusion and exclusion criteria were applied to select participants in the trial.

Inclusion criteria

1. Permanent patient of Puskesmas
2. Age between 19-30 years old,
3. Primigravida and singleton pregnancy,
4. Gestational age 22-26 weeks
5. Educated
6. Have monthly income
7. Women who are able to use any electronic devices

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 electronic devices, and
5. Participants who fall in the inclusion criteria but do not give or lack the capacity to give consent.

2.4 Sample size

The researcher estimated the sample size based on the previous intervention study, which investigated

the correlation of the maternal factors with neonatal weight birth at Garuda public health centre in 2010 (Budiman, 2017). The initial sample size for within groups n (50) is computed as a function of power level 1-b (0.90), significance level a (0.05), and the effect size d (0.66) by G*Power using a priory type of power analysis for t-test of means different between two independent means (two groups) based on the birth weight infant means prediction (control: 2974.0 ± 417.2 g and intervention: 3250.0 ± 417.2 g). With assumption drop-out level (10%), the sample size within each group (n*) is 56, making 112 for total participants.

2.5 Blinding

Blinding the participant was impossible due to the nature of the intervention. Blinding was impossibly involved in all stages from recruitment, randomisation, follow-up and data analysis as long as the researcher was a data collector. Although it was not feasible to blind participants to their intervention, this study could ensure blinding efforts. The PHC staff responsible for clinical measurements such as weighing, blood pressure checking and blood testing of participants were different at baseline, within, and after 12 weeks, so they were blinded to the intervention; the participant had been allocated to the intervention and control group. Since the start of the study, none of the Puskesmas staff knew which participants were in the intervention or control groups. In addition, the participants in the intervention and control groups were not separated from other patients when receiving antenatal care - Puskesmas staff only knew that research participants were asked to check blood samples by the research assistant.

3. Description of interventions

3.1 Intervention group

The participants recruited into the intervention group were allowed to open the SISFORUTRIMIL application through **http://www.sisfornutrimil.com**. Pregnant women can access this website address, which is automatically matched with the screen size of the device used, such as computer, notebook, tablet, or smartphone. The application feature includes the form of food choice as nutrition intake suggestion, food record or food log history. The food choice form shows the suggestion of nutritional intake that pregnant women could consume at each mealtime. The information provided the nutritional value of each recommended food and the total nutrition obtained. The reference data were based on dietary recommendations for Indonesian population and those published by the health ministry of Republic Indonesia. Energy estimates for each food and drink were calculated based on food groups and subgroups. Standard measuring equipment on common various size containers (e.g. plates, cups, bowls, spoons and glasses) is used to assist in quantifying portion sizes. There are 321 types, divided into seven main food source groups, including carbohydrates, protein, vegetables, fruits, light meals, fast food, and beverages. The food record or food log history page can record all food consumed within one day.

3.2 Comparator group

A *comparator* is a control group that does not have access to the SISFORNUTRIMIL application and only received standard prenatal care. The data were carried out at baseline and every antenatal care visit after baseline. Participants in the control arm received standard prenatal care from health professionals at a maternal and child health clinic,

PUSKESMAS, and souvenirs prepared as gifts (such as a hand towel/meals box). Generally, the standard prenatal care and tests may include checking blood pressure and weight, baby's heart rate, measuring women's abdomen, haemoglobin levels, and blood glucose. The group control will be asked to read information about nutrition during pregnancy through the leaflets. Also, they received an explanation about filling in the food record form for 12 weeks. Then both groups measure birth weight on the day of birth. In addition, the women who have completed food records online or offline are allowed transportation fees. Later, the participants can be entered into a draw to win a gift equal to £10 or 200.000 IDR if they can complete the intervention.

3.3 Criteria for discontinuing or modifying allocated interventions

There is no prohibition intervention. The study may be discontinued at any time by the research committee or other government agencies as part of their duties to ensure that research participants are protected. However, the researcher removed the women from this study if participants did not have a complete data such as missed baseline and after baseline measurement, moved out cities, and miscarriages or Intra Uterine Foetal Death (IUFD) between periods access to the SISFORNUTRIMIL application (in 12 weeks' intervention periods). There are no concomitant interventions and harmful actions where participants received standard antenatal care from health professional including laboratories test as standard assessments. The data collector monitored the evaluation of the intervention process, including laboratory tests, in the antenatal care schedule. The data collector sends text messages every weekend reminding all participants to input their food intake records. The researcher reminds the woman to record

the food via telephone at least once a week and ensure they have no difficulty accessing and using the App.

3.4 Withdrawal procedure

An investigator with a team of data collectors determined a standard withdrawal procedure. The withdrawal participants had health problems, premature birth, missed their follow-up measurements without information or lost contact, and moved from Bandung city. Participants were informed that they were entitled to remain in the study intervention until the end even if they did not feel happy to record their intake frequently; we asked the reason and gave a solution.

3.5 Outcomes and measurements

The primary outcome was identifying women's eating behaviour, including diet quality such as appetitive traits behaviour, dietary diversity, and daily intake. The secondary outcomes will identify the optimal pregnancy experience at twelve weeks after baseline measurements such as maternal weight, biomarkers test, and birth weight measurement at the end of pregnancy- the behaviour of the appetitive trait measured by the Adult Eating Behaviour Questionnaire (AEBQ). The AEBQ define eight appetitive traits: Hunger (H), Food Responsiveness (FR), Emotional Over-Eating (EOA), Enjoyment of food (EF), Satiety Responsiveness (SR), Emotional Under-eating (EUE), Food Fussiness (FF) and Slowness in Eating (SE). Each item's responses were recorded on a 5-point Likert scale ranging from 'Strongly Disagree' to 'Strongly Agree'. Mean scores were calculated for each subscale. Dietary diversity scores were measured using the Minimum Dietary Diversity for Women of reproductive age (MDD-W) for women aged 15-49 years who have consumed at

least five out of ten defined food groups in the previous day or night [7]. The MDD-W describes a critical dimension of women's diet quality, including micronutrient adequacy, summarised across 11 micronutrients. The food diversity indicators can be measured using a list-based method. Using dietary records to derive information on energy intake, researcher used the Indonesian Recommend Dietary Allowance (RDA) to reference diet quality. Food records assessed food intake and food patterns. The food intake estimates and classifies subjects according to usual energy and nutrient intake [8]. The criteria of sufficient nutrients per kilocalorie of energy intake are categorised divided into four groups according to the Institute of Medicine (2005): Good (>80% RDA), modest (70-79% RDA), poor (60-69% RDA), and deficit (<60% RDA). Food frequency questionnaires are commonly assumed to provide accurate estimates of habitual energy intake. Three-day food records will be selected as the method for assessing dietary intake in the RCT. Pregnant women were asked to maintain a 3-day (2 days on a work day and one day on the weekend) record of all the foods and drinks. The data was stored in MySQL database as a structure query language in Entity Relationships Diagram form (ERD). Meanwhile, clinical equipment such as weight scales, mercury sphygmomanometer, electronic blood glucose meter, and the oxy-haemoglobin method was used to measure the secondary outcomes. Gestational weight gain measurements can be determined by weight, height, and gestational age [9]. Measurement of weight (kg) and height (cm) is determined based on the nearest 0.05 kg for weight and 0.1 cm for height. The indicators of maternal weight gain are divided into three categories: less, normal and excess than total weight gain in each trimester. Whereas the rate of

weight gain, according to Committee ONSDP, Institute, OM [9] divided at a different stage of pregnancy as follow:

- 13 to 20 weeks, usually about 0.15 to 0.69 kg (0.3 to 1.5 lb) per week
- 20 to 30 weeks about 0.31 to 0.65 kg (0.7 to 1.4 lb)
- 30 to 36 weeks, about 0.18 to 0.61 kg (0.4 to 1.3 lb) per week

Blood pressure was assessed for gestational hypertension prevention [10]. Blood pressure is measured at each prenatal visit using calibrated equipment according to international guidelines (mmHg) [11]. Women's blood was measured from the right arm using a standard mercury sphygmomanometer after 5 min of rest with the subject sitting. *Hypertension* was defined as systolic blood pressure $\geq$ 140 mmHg or diastolic blood pressure $\geq$ 90 mmHg by using the 2007 European Society of Hypertension (ESH)-European Society of Cardiology (ESC) Guidelines for the management of arterial hypertension. Other clinical indicators assessment was measured using a blood sample test. It screens for pregnancy complications and includes anaemia and gestational diabetes mellitus (GDM). Standard procedures are used for biochemical analyses such as haemoglobin (Hb) and blood glucose test [1]. According to the World Health Organization, anaemia is diagnosed when a blood test shows of haemoglobin level of less than 110 g/L in pregnant women [12]. Additionally, the GDM diagnostic criteria for non-fasting glucose test followed the World Health Organization (1999) and America Diabetes Association (2003) are categories non-diabetes mellitus (<140 mg/dL), impaired glucose tolerance (140 mg/dL - < 200 mg/dL), and diabetes mellitus (>200mg/dL). Finally, pregnancy

outcomes measurement was taken at the end of pregnancy. The infant is weighted on a calibrated scale with minimum clothing, namely only a vest and without a nappy, and recorded to the nearest 5 g [1]. The categories of neonatal birth weight measured according to Chan *et al.* are divided into three groups: very low birth weight (<1.500g), low birth weight (<2.500g), and normal birth weight (2.500 or more).

3.6 Participant timeline

Baseline [T1]: One week after the screening procedure, the participant performed to fill in standardised characteristic information to describe the socio-economic status of the Indonesian population. At baseline measurements, maternal diet quality will be assessed by the MDD-W and ABEQ.

Follow-up [T2]: The primary measurements such as an appetitive traits questionnaire, dietary diversity scores, and daily dietary intake are measured after 12 weeks, including maternal weight gain, blood

pressure and blood test. There was a follow-up sheet for recording clinical conditions.

Post-intervention [T3]: The neonatal birth weight was measured at the end of pregnancy (birth).

Each week the Principal Investigator collected data from the team's research to be input into the computer. Those activities aimed to prevent recording errors and other problems with the data which may become apparent at that stage. The spreadsheet software (excel) was used to save data. Besides the monthly meetings, collector data teams were encouraged to discuss their experiences and findings regularly. This activity highlighted essential points and sometimes showed where recruitment and data collection methods should be modified. Also, the data collector at each PHC inputs all data measurements, including the nutrition intake for each food source, into the calculation of nutritional intake estimation software. At the end of the 12th week of the intervention, all participants had completed the outcomes measurement.

Study Measurement		Study Phases			
	Methods of sample used	Screening	Baseline Assessment	Intervention	Follow-up
Study Days			1 week after screening	12 weeks after baseline assessment	End of pregnancy (birth)
Informed Consent/Assent		√			
Review Inclusion/Exclusion Criteria		√			
Participant allocation			√		
Socio-Demographic data/Characteristics history	Questionnaire	√			
Maternal anthropometrics					
Weight gain during study (kg)	Digital scale		√	√	
Height (cm)	Digital scale		√	√	
Other					
Blood pressure	Mercury sphygmomanometer		√	√	

Biochemical Test					
Blood glucose	Serum sample		√	√	
Haemoglobin	Serum sample		√	√	
Pregnancy outcomes					
Birth weight					√
Dietary					
Food intake**	Food records online		√	√	
	MDD-W questionnaire		√	√	
	ABEQ questionnaire		√	√	

Table 1: List of study measurement

3.7 Data collection procedure

Characteristics of participants and outcomes measurement data such as appetitive traits, dietary intake, anthropometric, blood pressure, haemoglobin and blood glucose levels were collected at baseline (7 days before intervention start) and follow-up (within 12 weeks). Then, the neonatal birth weight data were collected 7-14 days after the intervention ended in the postpartum care room at the study worksite. Participants were asked to fill in the food record from the day preceding data collection until after their antenatal care visit. Participants were also asked to take part in every laboratory test on the day of data collection to monitor their clinical levels and eat any food before their measurement session.

The only potential risk when collecting data may be that participants 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 that is not accessible on their medical records. If the participant is tired, the data collection will be stopped temporally and offered to the participant to take a rest.

If data collection shows any concern about unwanted health problems, the researcher will refer the women to health care professionals.

3.8 Data management and confidentiality

The data were stored on Google drive and securely uploaded through a password-protected computer (laptop) to security-protected data 'cloud' storage. At the same time, food record data will be stored in a MySQL database. The application will store data in MySQL database as a structure query language in Entity Relationships Diagram form (ERD). Confidentiality was assured at all stages of this research. The information sheet and signed consent forms were scanned and uploaded to the security-protected 'cloud' storage, and the original documents were stored in a password-protected briefcase. Names of the participants will not be attached to the dataset: only the participants' medical record numbers and the participants' codes were attached to the document. The Principal Investigator stored all data on a secure cloud during analysis and destroyed it at the earliest convenience. Confidential information such as personal data, written or online, including laboratory notes, field notes, questionnaires, signed consent forms, and subsequent electronic files, will be

destroyed and disposed of securely after ten years. While the data and essential documents related to the health status of participants will be kept in an archive of health care services (PUSKESMAS) and can be found in patients' medical records until the study is published (a maximum of 10 years' period will be assured).

3.9 Statistical methods

Overall, data processing and statistical analysis will be analysed using the SPSS statistical software package version 25. Descriptive statistics will be used to display the study population's baseline characteristics and the mean value of outcome measures. Data will be analysed to determine whether there are any statistically significant differences between the groups. Statistical analysis included descriptive statistics, chi-square test, and independent t-test. At the same time, the Nonparametric Test was used, Mann Whitney, for non-normally distributed outcomes. Data will be analysed prospectively to examine the differences between two groups by using simple linear regression. The statistical significance will set to 5%, where a p-value of <0.05 is statistically significant.

4. Discussion

The primary objective of this study is to determine if maternal eating behaviour effects after three months were at standard criteria of Indonesia pregnant women compare with non-users SISFORNUTRIMIL application. The secondary objectives are (1) to determine if clinical and biochemical assessment effects after three months were at an average level, compare with non-user SISFORNUTRIMIL application; (2) to identify the effect of SISFORNUTRIMIL application toward neonatal birth weight, compare with non-user

SISFORNUTRIMIL application; and (3) to compare intra-participant effects in primary and secondary objectives for determining whether individual changes were sustained at three months from baseline assessment. The information system application is expected to assist pregnant women to provide information about the amount of nutrition by suggesting alternatives of types of food that need to be consumed daily (along with the nutrient description). Therefore, pregnant women can manage their diet and maintain their nutrition intake. Before any evidence-based dietary assessment methods can be effectively adapted and adopted to increase awareness of pregnant women in the improved nutrition quality, the feasibility testing of a mobile technology intervention that influence on maternal eating behaviour and associated maternal is needed. The comprehensive evaluation of this study will be showed by quantitative analyses and will indicate whether SISFORNUTRIMIL application is a feasible application in complication prevention of pregnant women.

Trial status

The protocol trial registration: ISRCTN Registry: ISRCTN42690828. Date of registration: 22 October 2019. The data recruitment begins at November 2019 to January 2020.

Abbreviations

SISFORNUTRIMIL: *Sistem Informasi Nutrisi Ibu Hamil*

Declarations

Acknowledgements

Authors' contributions

Mira Trisyani (MT) conceived and design the research project, also was a major contributor in writing the manuscript. Saseendran Palikadavath (SP) co-writer of the manuscript and supervised the work Mira Trisyani who guided the entire write-up of the manuscript. Isobel Ryder (IR) performed the critical revision of the manuscript. Ngianga Kandala (NK) determined the data analysis for this study

Funding

Availability of data and materials

The University of Portsmouth Data Management will have access to the final trial dataset according to the The University of Portsmouth Data Management policy.

Ethics approval and consent to participate

Ethics approval was obtained from the Universitas Padjadjaran Research Ethics Committee, with a reference letter number: 1227/UN6.KEP/EC/2019. The information sheet and a copy of signed consent form will be given to participate for keep. Furthermore, all signed consent forms will be securely stored in a password-protected briefcase accessible only by the researcher.

Competing interests

The authors declare that there are no conflicts of interest regarding the publication of this paper.

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