STUDY PROTOCOL

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

By:

Mira Trisyani Koeryaman
Student No: 872169

School of Health Sciences and Social Work
University of Portsmouth

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Supervisor:
Prof. Saseendran Pallikadavath
Dr. Isobel Ryder
Dr. Ngianga II Kandala

Abstract

Background: The nutrition intervention as well as the direct impact of pregnancy outcomes. This study will help pregnant women to access information about alternative food choices that include food presentation calculations, and they can record their daily food intake on Nutritional Information System application (SISFORNUTRIMIL). This paper describes the protocol of randomised controlled trial aimed at examining the difference on maternal eating behaviour and associated maternal between women who used the nutrition information system (SISFORNUTRIMIL) application and non-user.

Objectives: The proposed study aims to investigate maternal eating behaviour, pregnancy experience and pregnancy outcomes. Does pregnant women who used SISFORNUTRIMIL application more likely to eat proper nutrition to avoid being exposed to pregnancy complications?

Study design: To address the research objectives by extension, answer the research question, this study will be based on the experimental study involves the experimenter controls by randomised control trial (RCTs).

Setting/Participants: The population of this study were all pregnant women of restricted as outpatients in the maternal and child health clinic of PUSKESMAS and received regular antenatal care. Approximately 122 potential participants will be screened using protocol inclusion and exclusion criteria. The participants will be recruited into four strata: as a permanent patient of PUSKESMAS, the age at least 19 years, gestational age 13-26 weeks and a singleton pregnancy, and necessary ability use any devices.

Study Interventions and Measures: The SISFORNUTRIMIL application as health information system for pregnant women, aimed to direct the development of eating behaviour and managing healthy pregnancy. The protocol describes at two-armed RCTs to evaluate the feasibility of web-based and mobile interventions to determine eating behaviour includes food choice and food intake, blood pressure, weight gain, biochemical assessment (pregnancy experience) in pregnancy periods who have a risk of inadequate nutrition intake and to examine the birth weight (pregnancy outcome).

1. Aims and Study Objectives

This aims of this randomised controlled trial (RCT) is to examine the impact of SISFORNUTRIMIL application on maternal eating behaviour and associated maternal with maternal weight gain, blood pressure, biochemical measurements, and pregnancy outcomes.

The pregnant women and family are difficult to estimate nutrient intake in line with dietary targets and guidelines and nutrient reference value. The essential functions of this application are to manage dietary intake monitoring systems for expectant mothers, especially in pregnancy periods that have a risk of inadequate nutrition. Moreover, pregnant women can eat proper nutrition and lead to improved overall diet quality and optimal pregnancy outcomes.

1.1 Primary Objectives

To determine if maternal eating behaviour effects of the SISFORNUTRIMIL application user after three months were at standard criteria of Indonesia pregnant women, compare with non-user groups.

1.2 Secondary Objectives

a. To determine if clinical and biochemical assessment effects of the SISFORNUTRIMIL application user after three months were at an average level, compare with non-user groups.
b. To identify the effect of SISFORNUTRIMIL application toward neonatal birth weight, compare with non-user groups.
c. To compare intra-participant effects in primary and secondary objectives for determining whether individual changes were sustained at three months from baseline assessment.

2. Background and Rationale

2.1 Background

Proper nutrition is necessary for mother and infant outcomes and has an association with eaten food, health and wellbeing of the mother and the infant properly and indeed for later life (Scott, 2007). The world health organisation (WHO) to achieve the challenges of the global strategy on a diet, physical activity and health

since 2004 that focused on maternal health and nutrition before and during pregnancy. In order to nutritional requirement met for mothers and babies, the dietary intake must ensure from diverse sources. One of the challenges to set the optimal birth outcomes, maternal health and offspring development by consumption pattern in the practice of pregnant women (Symington, 2018). Evidence states that risk factors that related among infant mortality and low birth prevalence related to nutrition problems and behaviour (committee review, 2016).

The pregnancy Nutrition Surveillance System (PNSS), organize by the U.S. Centre for Disease Control and Prevention (CDC), conceive to monitor the incidence of nutrition-related issues and behaviour risk factors that related to infant mortality and low birth among high-risk prenatal populations. The populations and individuals recommended achieving in energy balance and a healthy weigh. Besides, limit energy intake from total fats and shift fat consumption away from saturated fats to unsaturated fats and towards the elimination of trans fatty acids; increase consumption of fruits and vegetables, and legumes, whole grains and nuts; limit the intake of free sugars; limit salt (sodium) consumption from all sources and ensure that salt contain iodised (WHO, 2004). In principle, nutritional monitoring is an essential activity for any government serious in response to the increase in citizen's health. National dietary and nutrition survey has a vital function.

The prevalence of imbalance of nutrition requirement has significantly increase in developed countries over recent decades, with an estimated 52% to get anaemia high-risk and 25.8% to have diabetes (WHO, 2014; Yuan, 2016). In particular, at present, the stunting prevalence rate in West Java is 29.2 per cent in 2017, which identified from maternal factors (Beal *et.al* 2017). In order to pregnancy complication prevention, the Food and Agriculture Organization recommends pregnant women to increase their energy intake respectively by 85, 285 and 475 kcal/day during the pregnancy.

Nowadays, smartphones become an integral part of modern telecommunication facilities. Which like smartphones are easy to use and familiar devices that enable quick communication. Smartphones and their apps appear to offer great potential to assist professionals in their work by providing access to online information at anytime, anywhere (Morrison, 2014). Health care interventions via phone text messaging and

smartphone application are beneficial to promote healthy education for public health. It can be a way to disseminate information about proper diet and nutrition to improve health behaviours among the general population. This 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. To avoid the possibility of scattered documents required recording that does not require paper, which generally uses a computer-based information system. Where this application will store data related to the organisation involved, the system will store data and display information needed by parties or activists who need it, information systems the good ones also need feedback to evaluate and improve the system (Anggadini, 2013).

2.2 Study Rationale

There are a lot of studies about ubiquity variety of apps uses to provide healthy eating, self-monitoring of energy and nutrient intake, weight tracking, and tested in order to determined their effectiveness in promoting health, but most do not include evidence-based features such as reinforcement of health behaviour change and evidence-based recommendations for diet and nutrition (Coughlin *et al*, 2015).

No studies are addressing to record food intake that could be calculation and estimation the nutrient needs in Indonesia. Most of the studies to evaluate the feasibility intervention to promote healthy nutrition, physical activity and weight gain in pregnant women who are overweight or obese. This possibility disregards the ability of pregnant women to consider balance diet in fulfilling the nutritional needs. Some women may have difficulty distinguishing adequate versus binge eating during pregnancy. They not knowing which foods need to be eaten and how much of them, to meet dietary requirements (Malek, 2017). While, women must provide her diet to meet foetal nutritional demands and their own needs during the pregnancy period (Forbes, 2018). 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. Therefore, the application of SISFORNUTRIMIL is one way to help pregnant women select a

healthy diet, and then the extent to which women change their diets to meet pregnancy-related guidelines will be known.

3. Study Design

3.1 General schema of study design

According to basic generic theory of change, which to articulate what is being evaluated the outcomes and impacts of interest, several studies are available to assess different types of interventions, and randomisation should be considered to avoid selection bias (Rogers, 2018). To address the research objectives by extension, answer the research question this study will be based randomized control trial (RCTs) method to assess maternal eating behaviour and associated maternal in SISFORNUTRIMIL application user. This RCT will design to assess the feasibility of 12 weeks intervention, compared to control group. The intervention will be delivered to pregnant women by researcher with no previous experience of delivery. All eligible participants will be assessed at baseline and randomly to allocate between intervention and control groups.

The Nutrition Information System for Pregnant Women (SISFORNUTRIMIL) or "*Sistem Informasi Nutrisi Ibu Hamil*" in Bahasa had created in 2017. This application created to help pregnant women select and record a food intake to meet nutrition requirements based on recommendations dietary allowances (RDA) (Ardiansah & Koeryaman, 2018). The SISFORNUTRIMIL application as health information system for pregnant women, aimed to direct the development of eating behaviour and managing healthy pregnancy. The user will be able to registration and open access at http://www.sisfornutrimil.com. In addition to being accessible through a browser on a computer or notebook, this application can also be opened via tablet or smartphone and the application size will automatically match the screen size of the device used.

This study will provide a critical appraisal of the relevant maternal eating behaviour literature and describes how the SISFORNUTRIMIL application was developed, evaluated in the form of a feasibility RCT, and subsequently implemented in diverse communities in Indonesia.

The guideline intervention referring to Consolidated Standards of Research Trials (CONSORT) items-in particular for non-pharmacologic treatment (Boutron, 2008).

This guidance in conjunction with CONSORT 2010 as the latest version (Schultz *et al*, 2010). The protocol describes at two-armed randomised control trial (RCTs) to evaluate the feasibility of web-based and mobile interventions to determine eating behaviour includes food choice and food intake, blood pressure, weight gain, biochemical assessment (pregnancy experience) in pregnancy periods who have a risk of inadequate nutrition intake and to examine the birth weight (pregnancy outcome).

Measurement will be performed at baseline, 12 weeks after baseline and the end of pregnancy. It is important to note that baseline assessment and 12 weeks after baseline measurement will be performed before and after both groups.

4. Selection and Enrolment of Participant

The population of this study were all pregnant women of restricted age at least 19 years and gestational age between 13-26 weeks who were outpatients in the maternal and child health clinic of PUSKESMAS and received regular antenatal care. The following inclusion and exclusion criteria were applied to select participants in the trial.

4.1 Inclusion criteria

1. These people who are involved in research studies are permanent patient of PUSKESMAS,
2. Age at least 19 years old,
3. Gestational age 13-26 weeks, a singleton pregnancy,
4. Women who necessary ability use any devices

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

4.3 Study Enrolment Procedure

The recruitment of participants in accordance with ethical principles. The first stage to approach the participant recruitment at community based is processing the recommendation letter from researcher workplace and study place to require the permission letter. The researcher submit all documents to *BADAN KESATUAN BANGSA DAN POLITIK* (BKBP) or an Agency for National and Political Unit, Bandung city district. To be known that BKBN is an institution that has legalisation to give permission for researcher with community setting. The recruitment process will be done at multiple sites of public health centre (PUSKESMAS) of Bandung city, which provide basic emergency obstetric and new-born care (BEmONC).

Participants who are eligible criteria in the study will have the information sheet to read and asked they wish to participate. A participants' information sheet, detailing all the information about the. Covering objectives, length, outcomes and post study use will be prepared, translated into the local language and disseminated research aim through the local staff of PUSKESMAS. The participants will have adequate time to read and understand the information sheet before committing to the study. Participants will also be given the opportunity to ask the researcher any questions they may have at any time before and during the interview.

Informed consent will be obtained prior to any study related procedures being performed, including blood samples. All signed consent forms will be securely stored in a password-protected briefcase accessible only by researcher.

5. Study Intervention

5.1 Interventions, Administration, and Duration

Data were collected at baseline assessment and 12 weeks after baseline assessment by principal researcher assisted by two or three senior students as research assistant. All measurement at each site will observed or checked by the principal investigator.

5.2 Handling of Study Interventions

Participants in both groups received the same antenatal care. Clinical assessment measurement will be conducted three times during the mid and end-pregnancy visits. In mid pregnancy were obtained in between 13-26 weeks of gestation will be measure of baseline assessment included blood pressure, weight gain, non-fasting blood samples, haemoglobin levels and collected the dietary diversity survey. Further, in 12 weeks after baseline assessment, both of groups will be assessed blood pressure, weight gain, non-fasting blood samples, and haemoglobin levels, and they answered the ABEQ questions. In the end of the pregnancy, the neonatal birth weight will be follow up.

The participants recruited into 'SISFORNUTRIMIL' application group will be provide access to **http://www.sisfornutrimil.com**. This website address can be access by pregnant women through a computer or notebook, also can be opened via tablet or smartphone, which the application size will automatically match the screen size of the device used. This application also comes with some content about pregnancy that contains material as additional information for pregnant women. When accessing as a member on this website, pregnant women will see the content, which contains basic knowledge about pregnancy and variety of food sources for consumed and also can calculate the amount of energy needed in foods. The references 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) used to assist in quantifying portion sizes. There are 321 types of food which are divided into 7 main food source groups including carbohydrates, protein, vegetables, fruits, light meals, fast food, and beverages. To document of food intake, the woman must open the food log feature and choose any food they have been eating and saved. While, the control arm will be asked to read information about nutrition in pregnancy through leaflets researcher has given that, and they received an explanation about how to fill in the food record form during 12 weeks.

The procedure below was followed to instruct the user and non-user SISFORNUTRIMIL application on how to complete the food record.

The SISFORNUTRIMIL app user	Non-user
1. Participants were asked to record everything had eaten and drunk for three days. They had to select two weekdays and one weekend when the women was eating and drink normally. The researchers suggest choosing the day on Monday, Friday and Sunday. It will be made more accessible for women to remember the day. Food diary record on food log history in the App.	1. Participants were asked to record everything had eaten and drunk for three days. They had to select two weekdays and one weekend when the women was eating and drink normally. The researchers suggest choosing the day on Monday, Friday and Sunday. It will be made more accessible for women to remember the day. Food diary record on 7-Day Food Diary paper-based.
2. The importance of accuracy for food record was explained, and women declare "willingness" for the three days per week, whereby the women will encourage recording all food and drink consumed over this period without any repercussion.	
3. The women will allocation Whereby for App user just select and click on seven food groups list.	3. The women will instruct to record all meals, snacks and drinks for 3 days per week during 12 weeks. Whereby for non-user App completed example day was used to demonstrate how to record foods and drinks, as well as the amounts offered food list on leaflet.
4. The women must pay attention on food and drinks size, if there no available food they had eaten, they should input the food in "other choices"	4. The women were asked to weight all foods and drinks use household measure to describe quantities. A diagram of food list with household measures was provide on leaflet.
5. The women asked to follow the health professional recommendations in dietary, besides access "food intake suggestion" and choice the list of food with nutrition recommendations on App as alternative food consumption.	5. The women asked to follow the health professional recommendations in dietary.

5.3 Concomitant Interventions

There are not concomitant interventions and harmful action. The women will receive standard antenatal care from health professional including laboratories test as standard assessment. The researcher will remind the woman to record the food via telephone at least once a week and ensure they ensure they have no difficulty accessing and using the App.

5.3.1 Allowed Intervention

For user App, the women allowed accessing SISFORNUTRIMIL to get general information about nutritional requirements during pregnancy and food pattern. While the non-user App, they allowed read leaflets about nutrition information.

5.3.2 Required Intervention

The woman should record their food has been consumed each day (two days in weekdays and 1 weekend day) for 12 weeks.

5.3.3 Prohibit Interventions

There is no prohibits intervention, however the researcher will remove the women from this study if participant do not have a completely data such as missed of baseline and after baseline measurement, moved out cities, and miscarriages or Intra Uterine Foetal Death (IUFD) between periods on access the SISFORNUTRIMIL application (in 12 weeks' intervention periods).

5.4 Adherence Assessment

Adherence of study will measure by completed data baseline assessment and after baseline measurement. Any data obtained from the withdrawn partly will be grouped into two: complete dataset or incomplete dataset. Complete dataset will be determined by stage at which participant withdrew. With consent, completed collected dataset will be used in analysis.

6. Study Procedures

The Evaluation Schedule in section 6.1 explains the evaluations listed on the table and the order in which they are to be carried out. Clinical assessment measurement will be conducted three times during the mid and end-pregnancy visits. In mid pregnancy were obtained in between 13-26 weeks of gestation will be measure of baseline assessment included blood pressure, weight gain, non-fasting blood samples, haemoglobin levels and collected the dietary diversity survey. Further, in 12 weeks after baseline assessment, both of groups will be assessed blood pressure,

weight gain, non-fasting blood samples, and haemoglobin levels, and they answered the ABEQ questions. In the end of the pregnancy, the neonatal birth weight will be follow up. The clear explanation for each steps showed at next section.

6.1 Schedule of Evaluation

Study Measurement	Methods of sample used	Study Phases			
		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					
Address and phone number	Questionnaire	√			
Age (years)	Questionnaire	√			
Gestational age (weeks)	Questionnaire	√			
Ethnic group	Questionnaire	√			
Education attainment	Questionnaire	√			
Occupation	Questionnaire	√			
Household income*	Questionnaire	√			
Number of children	Questionnaire	√			
Number of pregnancy	Questionnaire	√			
Degree of physical activity	Questionnaire	√			
Medication history	Questionnaire	√			
Maternal anthropometrics					
Weight gain during study	Digital scale		√	√	
(kg)	Digital scale		√	√	
Height (cm)					
Other					
Fundal height	Tape measure	√		√	
Blood pressure	Mercury sphygmomanometer		√	√	

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

* Indonesia standard income per month

** Intervention group by SISFORNUTRIMIL database/online, control group by paper based

6.2 Description of Evaluations

6.2.1 Screening Evaluation

Screening for eligibility and obtaining consent. The recruitment process will be done at multiple sites of public health centre (PUSKESMAS) of Bandung city, which provide basic emergency obstetric and new-born care (BEmONC). The women will be screened using the protocol inclusion and exclusion criteria. The participants will be recruited into four strata: outpatient as a permanent patient of PUSKESMAS, the age at least 19 years, gestational age 13-26 weeks and a singleton pregnancy, and necessary ability use any devices. Informed consent will be obtained prior to any study related procedures being performed, including discontinuation of current study. Blood samples (haemoglobin and blood glucose) will be drawn to confirm eligibility based on clinical laboratory parameter. This study aims 51 participants in intervention group and 51 participants in control group (approximately 125 participants will recruit on this study);

6.2.2 Enrolment, Baseline and Randomisation

Recruitment

Based on the feasibility trial (Olah C., M., 2019), the study required a minimum of 51 participants per group and a maximum of 70 per group to ensure a power between 80% and 90% or power (1-β err prob) between 0.80 and 0.90, and a significant level of 0.05 for each group. Assuming 5% significant and 80% power, 51 participants needed to be recruited to each group. Considering 20% dropout, 61 pregnant women per group were required, making total of 122.

The recruitment process is carried out at maternal and child health clinics at Community Health centres (PUSKESMAS) following the letter permit from the health office of Bandung city and the approval of the same place health professional. Pregnant women will be identified based on arrival and register for regular antenatal care. The principal researcher will approach pregnant women as a recruitment strategy with support from study sites staff. Researchers have access to data information in identifying potential participants through medical records and

register books. Besides, the health professional will be informed of the eligibility criteria for potential study participants by the principal researcher. These professionals will be provided with information packs (demography questionnaire and participants' information sheets) to identify pregnant women were meeting the eligibility criteria of the study. In some cases, health professionals review patient records to identify women who are suitable as a subject participant and then informed the principal investigator to be followed up.

Pregnant women who interested in participating 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 information about the 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. If the pregnant women did not meet the inclusion and exclusion criteria (e.g., outside the age range and have medical problem), they were not invited for baseline measurements. It was politely explained to them that they not eligible. Those who meet the criteria were obtained Minimum Dietary Diversity for Women of reproductive age (MDD-W) questionnaire and ask them to answer and carry it one week later on baseline measurements.

Baseline Assessment

Participants in both groups received the same antenatal care. One week after screening procedure, the participant will be performed to fill the participants provided standardized of characteristic information on 19 items to describe the socio-economic status of the Indonesia population. At the time of baseline measurements, maternal diet quality will be assessed by the 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 (Martin-Prevel, et al (2015) in FAO, 2016). The MDD-W to describe one important dimension of women's diet quality include micronutrient adequacy, summarised across 11 micronutrients. The food diversity indicators can be measured using list-based method (FAO, 2016).

Randomisation

Before participants were randomized using the free online randomizer "QuickCalcs by GraphPad, they were first identified by matching pair criteria. 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 principal researcher notified all pregnant women that they had the opportunity to access the SISFORNUTRIMIL application; however, the randomizer will choose one of them.

6.2.3 Allocation Participants

The study used a matched pair randomization helps to ensure balance and reduces the required sample size (White *et al.,* 2018). The selecting control group pregnant women who were similar to the intervention group pregnant women based on five similar characteristics, such as maternal age, gestational age, income, education level, and parity. To allocate between intervention and control groups the researcher will use free online randomizer "QuickCalcs by GraphPad allow a researcher to specify the number of participants and number of groups, and quickly return a list showing which participant go to which groups (White *at a*l., 2018).

6.2.4 Follow-up Visit

Maternal Eating Behaviour

Measure for eating behaviour at 12 weeks after baseline assessment. In addition to completing the 47 items 'Adult Eating Behaviour Questionnaire' (AEBQ) and gestational weight gain measurement were obtained for weight gain calculation.

Gestational weight gain measurements can be determined by weight, height, and gestational age (Committee, O. N. S. D. P., & Institute, O. M., 1990). Measurement of weight (kg) and height (cm) is determined based on the nearest 0.05 kg for weight, and 0.1 cm for height (Symington, 2018). Detailed description of the standard operating procedure (SOP) for weight and height measurement are provide

in appendices. The indicators of maternal weight gain are divided into 3 categories: less, normal and excess than total weight gain in each trimester (Scott. 2007). Whereas, the rate of weight gains according to Committee, O. N. S. D. P., & Institute, O. M., (1990) divide at 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); and 30 to 36 weeks about 0.18 to 0.61 kg (0.4 to 1.3 lb) per week.

Eating behaviour was measured by adult eating behaviour questionnaire (ABEQ) (Hunot, 2016). Score on an ABEQ can also be used to inform individuals at risk of inappropriate weight gain. The measured define into 8 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).

Food intake and food pattern was assessed by food record. The food intake to estimation and classify subject correctly according to a usual energy and nutrient intake (Pereira, 2010). The criteria of sufficient nutrient per kilocalorie of energy intake categorized divided into 4 groups according to Institute of Medicine (2005): Good (>80% RDA), modest (70-79% RDA), poor (60-69% RDA), and deficit (<60% RDA). Food frequency questionnaire (Shim, 2014), are commonly assumed to provide accurate estimates of habitual energy intake. Three days food records will selected as the method for assessing dietary intake in the RCT. Pregnant women will asked to maintain a 3-day (2 days in work day and 1 day in week end) record all the foods and drinks they had consumed through a day and night for three days. Pregnant women will show how to complete the diary by principal researcher.

Blood pressure and biochemical measurement

Blood pressure will be assessing for gestational hypertension prevention (Grosvenor, 2006). Blood pressure is measured at each prenatal visit and using calibrated equipment according to international guidelines (mmHg) (Weber, 2014). Women blood pressure will be measure from the right arm using a standard mercury sphygmomanometer after 5 min of rest with the subject in the sitting position. Hypertension was defined as systolic blood pressure ≥ 140 mmHg

or diastolic blood pressure ≥ 90 mmHg by using 2007 European Society of Hypertension (ESH)-European Society of Cardiology (ESC) Guidelines for the management of arterial hypertension (Mansia et *al*., 2007 cited by Yuan 2016).

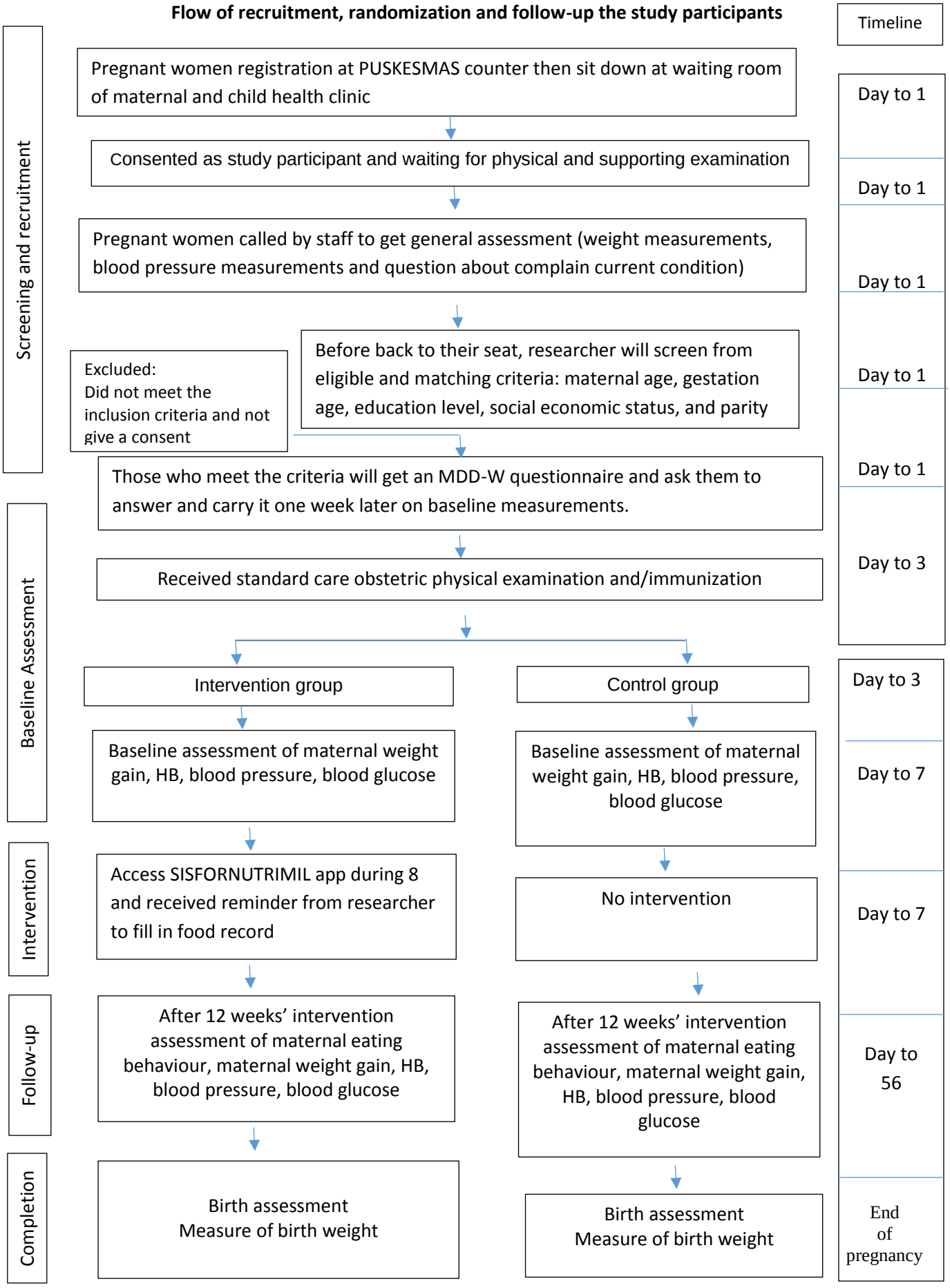
Pregnancy experience assessment will be measured using blood sample test. It screens pregnancy complication includes anaemia and gestational diabetes mellitus (GDM). Standard procedures are used for biochemical analyses such as haemoglobin (Hb) and blood glucose test (Symington, 2018). According to the World Health Organization, anaemia is diagnosed when a blood test shows of haemoglobin level less than 110 g/L in pregnant women (Wang, 2018). 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).

6.2.5 Completion/Final Evaluation

Pregnancy Outcomes

Pregnancy outcomes measurement will be take in the end of pregnancy. The infant is weighted on a calibrated scale with minimum of clothing, namely only a vest, and without nappy, and recorded to the nearest 5 g (Symington, 2018). The categories neonatal birth weight measured according to Chan, *et al* (2011) are divide into three groups: very low birthweight (<1.500g), low birthweight (<2.500g), and normal birthweight (2.500 or more).

6.3 Study Diagram



7. Safety Assessments

7.1 Specification of Safety Parameters

There will be no serious risk associated with participating in this study. 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 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. If during study the principle researcher found eating disorder or abnormal biochemical measurement levels among pregnant women, will decide to further investigation and refer the participant to appropriate health professionals.

8. Intervention Discontinuous

As a volunteer, the participants can stop any test at any time, or withdraw from the study at any time before finishing all study, without giving a reason if they do not wish to. The intervention will stop if they missed of baseline and after baseline measurement, moved out cities, and miscarriages or Intra Uterine Foetal Death (IUFD) during 12 weeks intervention periods.

9. Statistical Consideration

All variables will assess for normality using statistically.

Baseline data will be collected using a structure questionnaire, administered on sample size of 122 (61 each group). The data will analyse using the SPSS statistical software package version 25.

To determine whether there are any statistically significant differences between the groups. Collected data will be analysed in the appropriate parametric or non-parametric test such as two independent simple t-test or Mann u Whitney test, and ANOVA test will be used for continuous data dependent of the distribution.

To examine the relationship between variables and maternal characteristic we will use simple linear regression and multiple linear regression. Chi-square test will be used for categorical variables.

Mean (SD) or median (IQR) will be reported for continuous data. Number and proportions will be reported for categorical data. The statistical significance will be set to 5%, where a p-value of <0.05 is statistically significant.

10. Data handling and stored

Dietary intake will be stored on MySQL database. Where application will store data in MySQL database as structure query language in Entity Relationships Diagram form (ERD). Eating behaviour, information sheet and signed consent forms, will be scanned and uploaded to the security protected 'cloud' storage and the original documents will be stored in a password-protected briefcase and in a locked cupboard in a lockable office space. The researcher will only know the access passwords, who will directly supervise the security protected 'cloud' storage and the briefcase at all times.

11. Participants Rights and Confidentiality

11.1 Ethical Approval

Standing committee the research ethics committee Universitas Padjadjaran, Bandung Indonesia, granted an ethical approval. Appropriate permissions will be gotten from persons in charge of premises where participants will be protected to take part in the study.

11.2 Informed Consent Form

Obtaining consent process will conduct in this study: Offer to participate will be ask to the eligible women in the recruitment venues including registration and waiting room area. Participants who are eligible criteria in the study will have the information sheet to read and asked they wish to participate. A participants' information sheet, detailing all the information about the study. Covering objectives, length, outcomes and post study use will be prepared, translated into the local language and disseminated research aim through the local staff of PUSKESMAS. The participants will have adequate time to read and understand the information sheet before committing to the study. Participants will also be given the opportunity to ask the researcher any questions they may have at any time before and during the interview.

11.3 Participant Confidentiality

To ensure confidentiality, all data collection will be anonymous. The participant code and medical record number will write the questionnaire, which does not carry personal credentials.

11.4 Study Discontinuation

The study may be discontinued at any time by the research committe, or other government agencies as part of their duties to ensure that research participants are protected.

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