Appendices 1.

KEMENTERIAN RISET, TEKNOLOGI DAN PENDIDIKAN TINGGI
UNIVERSITAS PADJADJARAN
KOMISI ETIK PENELITIAN
RESEARCH ETHICS COMMITTEE
Jl. Prof. Eyckman No. 38 Bandung 40161
Telp. & Fax. 022-2038697 email: kepk.fk.unpad@gmail.com, website : kepk.fk.unpad.ac.id

No. Reg.: 0619060938

PERSETUJUAN ETIK
ETHICAL APPROVAL

Nomor: 1227 /UN6.KEP/EC/2019

Komisi Etik Penelitian Universitas Padjadjaran Bandung, dalam upaya melindungi hak asasi dan kesejahteraan subjek penelitian serta menjamin bahwa penelitian yang menggunakan formulir survei/registrasi/surveilens/ Epidemiologi/Humaniora/Sosial Budaya/Bahan Biologi Tersimpan/Sel Punca dan non klinis lainnya berjalan dengan memperhatikan implikasi etik, hukum, sosial dan non klinis lainnya yang berlaku, telah mengkaji dengan teliti proposal penelitian berjudul:

The Research Ethics Committee Universitas Padjadjaran Bandung, in order to protect the rights and welfare of the research subject, and to guaranty that the research using survey questionnaire/registry/surveillance/ epidemiology/humaniora/social-cultural/archived biological materials/stem cell/other non clinical materials, will carried out according to ethical, legal, social implications and other applicable regulations, has been throughly reviewed the proposal entitled:

"*A RANDOMIZED CONTROLLED TRIAL OF MATERNAL EATING BEHAVIOUR BY USING NUTRITION INFORMATION SYSTEM (SISFORNUTRIMIL) APPLICATION AT BANDUNG CITY, INDONESIA*"

Nama Peneliti Utama *Principal Researcher*	:	Mira Trisyani Koeryaman
Pembimbing/Peneliti Lain *Supervisor/Other Researcher*	:	Saseendran Palikadavath Isobel Ryder Ngianga II Kandala
Nama Institusi *Institution*	:	University of Portsmouth United Kingdom

proposal tersebut dapat disetujui pelaksanaannya.
hereby declare that the proposal is approved.

Ditetapkan di : Bandung
Issued in
Tanggal : 04-10-2019
Date

Ketua
Chairman

Dr. Meita Dhamayanti, dr., SpAK., M.Kes
NIP. 19630519 198712 2 001

Keterangan/*notes*:
Persetujuan etik ini berlaku selama satu tahun sejak tanggal ditetapkan.
This ethical clearance is effective for one year from the due date.
Pada akhir penelitian, laporan pelaksanaan penelitian harus diserahkan ke Komisi Etik Penelitian.
In the end of the research, progress and final summary report should be submitted to the Research Ethics Committee.
Jika ada perubahan atau penyimpangan protokol dan/atau perpanjangan penelitian, harus mengajukan kembali permohonan kajian etik penelitian.
If there be any protocol modification or deviation and/or extension of the study, the Principal Investigator is required to resubmit the protocol for approval.
Jika ada kejadian serius yang tidak diinginkan (KTD) harus segera dilaporkan ke Komisi Etik Penelitian.
If there are Serious Adverse Events (SAE) should be immediately reported to the Research Ethics Committee

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PARTICIPANT INFORMATION SHEET

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Supervisor : Prof. Saseendran Pallikadavath
Dr. Isobel Ryder, PhD.SFHEA

STUDY TITLE: A Randomized Controlled Trial of Maternal Eating Behaviour by using Nutrition Information System (SISFORNUTRIMIL) Application at Bandung City, Indonesia.

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please ask us if there is anything that is not clear. We are looking to recruit participants who are at between 20-30 years of age who are pregnant and undergo routine antenatal care in this PUSKESMAS.

What is the purpose of the study?

The purpose of this study is to examine the difference of maternal eating behaviour and pregnancy outcomes between women who use the nutrition information system (SISFORNUTRIMIL) application and those who do not use the application.

Why have I been invited?

You may have been invited for a number of reasons and because you meet the eligibility criteria for this study.

Do I have to take part?

No, taking part in this research is entirely voluntary. It is up to you to decide if you want to volunteer for the study. We will describe the study in this information sheet. If you agree to take part, we will then ask you to sign the attached consent form.

What will happen to me if I take part?

The researcher will randomize participants to assign them into the intervention group or the control group using a computer-generated randomization system:

1) Intervention group: Pregnant women who receive standard prenatal care plus the SISFORNUTRIMIL app to record their daily consumption.
2) Control group: pregnant women who receive standard prenatal care.

Intervention arm Protocol

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 22-26 weeks of gestation will be measurement of blood pressure, weight gain, non-fasting blood samples, haemoglobin levels and dietary diversity survey. Further in 12 weeks after baseline assessment, both of groups will be determined the same assessment except dietary diversity survey and in the end of pregnancy period, the birth weight will be measured.

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.

The woman should record their food has been consumed each day (two days in weekdays and 1 weekend day) until 12 weeks. Also, the investigator will remind the woman to record the food they have consumed every week and ensure they have no difficulty accessing and using the application. Participants will be given telephone support at least once a week during the intervention period also to determine the overall effectiveness of interventions.

Participants will compensate by souvenirs which have been prepared as gifts (such as hand towel/meals box). The rewards will be given at PUSKESMAS on out of schedule of regular antenatal care. Then, for women who have completed food records at SISFORNUTRIMIL, they will be allowed to gift voucher for chance to be entered into a draw to win a gift equal with £10 or 200.000 IDR, if women are able to complete the intervention.

Control arm

The data will be carried out in baseline and every antenatal care visits after baseline. Participants in the control arm will receive standard prenatal care at maternal and child health

clinic, PUSKESMAS from health professionals, plus souvenirs which have been prepared as gifts (such as hand towel/meals box). In general, the standard prenatal care and tests may include checking blood pressure and weight; baby's heart rate; measuring women abdomen; measurement of haemoglobin levels, blood glucose. The group control will be asked to read information about nutrition in pregnancy through leaflets that have been given by researcher, and also they received an explanation about how to fill in the food record form during 12 weeks. Then, for women who have completed food records at SISFORNUTRIMIL, they will be allowed to receive transportation fees. The rewards will be given at PUSKESMAS when they are visiting for baseline measurement. In addition, participants will be entered into a draw to win a gift equal with £10 or 200.000 IDR, if women are able to complete the intervention.

Expenses and payments

Participants will be given the opportunity to choose souvenirs (such as hand towels, food boxes, etc.) as gifts because they are willing to participate in this study. Then, for women who have completed food records at SISFORNUTRIMIL, they will be given transportation fees. The rewards will be given at PUSKESMAS when they are visiting for baseline measurement. In addition, participants will be entered into a draw to win a gift equal with £10 or 200.000 IDR, if women are able to complete the intervention.

What measurements will be taken (or data collected)?

There will be times during the study when you will be antenatal care. We will check your weight gain, height, blood pressure, uteri fundal height. We will also check laboratory test such as haemoglobin, protein urine and blood glucose as standard assessment in pregnancy.

What are the possible disadvantages and risks of taking part?

The data collection process there is no harmful action. You will receive standard antenatal care from health professional including laboratories test as standard assessment. While accessing SISFORNUTRIMIL, beside as a tool for food record, also pregnant women will get content that contains basic information about pregnancy and influence of nutrition pregnancy.

What are the possible benefits of taking part?

You will receive intensive monitoring maternal health care including health information and could potentially win a prize as well.

Will my taking part in the study be kept confidential?

The raw data, which identifies you, will be kept securely by the Principal Investigator. Your questionnaire data will be anonymous with your consent form. This means that whilst your raw data (only identifiable by participant number) will be kept separate from your consent forms (which will have your name and participant number). The exception to this will be any legal authority that may have the legal right to access the data for the purposes of conducting an investigation in exceptional cases. The raw data will be retained for up to 10 years, and your consent will also be retained for 10 years. When it is no longer required, the data will be disposed of securely (e.g. electronic media and paper records / images) destroyed.

The data, when made anonymous, may be presented to others at scientific meetings, or published as a project report, academic dissertation or scientific paper or book. It could also be made available to any sponsor of the research. Anonymous data, which does not identify you, may be used in future research studies approved by an Appropriate Research Ethics Committee.

What will happen if I don't want to carry on with the study?

As a volunteer, you can stop any test at any time, or withdraw from the study at any time before finishing all study, without giving a reason if you do not wish to.

What if there is a problem?

If you have a query, concern or complaint about any aspect of this study, in the first instance you should contact the Principal Investigator (PI) if appropriate.

What will participants be dropped out?

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) during 12 weeks intervention periods.

Thank you

Thank you for taking time to read this information sheet and for considering volunteering for this study. If you do volunteer for this study your consent will be sought on the following page. You will then be given a copy of this information sheet and your signed consent form, for you to keep.

Sincerely,

Mira Trisyani Koeryaman

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CONSENT FORM

STUDY TITLE: A Randomized Controlled Trial of Maternal Eating Behaviour by using Nutrition Information System (SISFORNUTRIMIL) Application at Bandung City, Indonesia.

	Please initial each box if content	
1	I confirm that I have read and understood the attached information sheet for the above. I confirm that I have had opportunity to consider the information, ask questions and that these that been answered satisfactorily.	
2	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.	
3	I understand that the results of this may be published and/or presented at meetings. I give my permission for my anonymous data, which does not identify me, to be disseminated in this way.	
4	Data collected during this study could be requested by regulatory authorities. I give my permission to any such regulatory with legal authority to review the study to have access to my data, which may identify me.	
5	I agree to the data I contribute being retained for any future research that has been approved by the Science Faculty Ethic Consideration.	
6	I agree to take laboratory test for HB, blood glucose and urinary examination	
7	I agree to take part in this study.	
8	I agree that I could be referred to appropriate health professionals, if appropriate.	

Name of Participant : Date: Signature:

Name of Person taking Consent: Date: Signature:

Appendices 2.

BioMed Central

Consent form

I .....Mira Tisyani Koeryaman.....[Name]....give...my....consent for information about myself/my child or ward/my relative (circle as appropriate) to be published in TRIALS, manuscript number is TRLS-D-19-01138 . Corresponding author: Nursing Faculty of Universitas Padjadjaran.....

[Name of journal, manuscript number and corresponding author].

I understand that the information will be published without my/my child or ward's/my relative's (circle as appropriate) name attached, but that full anonymity cannot be guaranteed.

I understand that the text and any pictures or videos published in the article will be freely available on the internet and may be seen by the general public. The pictures, videos and text may also appear on other websites or in print, may be translated into other languages or used for commercial purposes.

I have been offered the opportunity to read the manuscript.

Signing this consent form does not remove my rights to privacy.

Name : Mira Trisyani Koeryaman

Date: 19 November 2019

Signed.....

Author name: Mira Trisyani Koeryaman.

Date:: 19 November 2019

Signed.....

Please keep this consent form in the patient's case files. The manuscript reporting this patient's details should state that 'Written informed consent for publication of their clinical details and/or clinical images was obtained from the patient/parent/guardian/ relative of the patient. A copy of the consent form is available for review by the Editor of this journal.