Virtual Antenatal Intervention for improved Diet and Iron intake (VALID) Trial

Participant Information Sheet for Pregnant Women

Introduction

Namaste! My name is _____. I have come from HERD International located in Thapathali, Kathmandu. HERD International is a national level research organization. This organization has been conducting various programmes and research upon health, environment and social development. Currently, HERD International, in partnership with University College London, is conducting a study that aims to reduce anaemia in pregnant women in Kapilbastu. I would like to invite you to be a part of this study.

Before you decide whether to participate, it is important for you to understand why this research is being done and what participation will involve. I will read what is written in this information sheet aloud to you. You can ask me if there is anything that you do not understand or if you want more information. You will be given a copy of this information sheet. Take your time to decide whether or not you want to take part in the study or not. Thank you for reading this/listening to me.

Details of the study

HERD International, in partnership with University College London, is conducting a study with an aim to reduce anaemia in pregnant women. The Medical Research Council (UK) is funding this research.

Anaemia is a condition when there is decreased haemoglobin in blood, and this is caused by various factors. In Nepal, lack of iron is the most common cause of anaemia in pregnancy. It is important to reduce anaemia in pregnancy because low iron levels are associated with illness and complications during pregnancy and childbirth. Pregnant women who are anaemic are much more likely to die during childbirth than those women who are not and their infants are more likely to be born small for gestational age.

In Nepal, Kapilbastu is one of the districts where anaemia is highly prevalent. Hence, we have chosen 54 clusters (103 old-wards) within 9 pallikas of Kapilbastu for this study. The government of Nepal recommends minimum 4 ANC visits during pregnancy and consumption of 180 tablets of iron and folic acid starting from 20 week's gestation. However, compliance to these recommendations is low, increasing the risk of anemia during pregnancy. The situation has become worse since March 2020 with ongoing COVID-19 imposed travel restrictions and lockdowns, which have made health care less accessible. The health and nutrition status of pregnant women has deteriorated as women are afraid to visit health facilities to seek care.

Objective:

The VALID trial is designed to assess if providing antenatal virtual counselling on a tablet increases compliance to intake of the required dosage of IFA tablets, and improves dietary diversity and dietary practices, compared with women who have access to routine antenatal care (ANC) only (control).

This trial is being implemented in 9 pallikas of Kapilvastu district among 13 to 49 years old married pregnant women. Around 300 pregnant women will be enrolled and allocated to either of the 2 trial arms.

In the intervention arm, in addition to routine pregnancy care, 150 pregnant women will be provided with electronic tablets (like large Smart Phones) which are fitted with sim cards to receive virtual counselling sessions. A female member of HERD staff who is qualified as an ANM (a "nutrition assistant") will visit you in your home to lend you a tablet to provide virtual counselling session. After this she will provide you with two virtual counselling sessions: one between 12 to 28 week's gestation

and another two weeks after the first session. At each session she will discuss with you and your family members about your diet and health in pregnancy and give you advice based on what you are already eating / doing. She will encourage you to discuss and develop an action plan to improve your diet, consume iron tablets and antenatal care to minimize the risk of anaemia during pregnancy.
In the control arm, 150 pregnant women will be encouraged to go for routine pregnancy related services provided by the government of Nepal that includes antenatal care and iron and folic acid tablets.

Who are we inviting to participate?

You can take part in this research if you are a pregnant woman or girl aged 13 to 49 years, less than 28 weeks of gestation, planning to live in ,and/or seek services from the health facilities in, the study area and are able to respond to the survey questions. Pregnant women will be enrolled with the help of the health workers or female community health volunteers in these communities. If you are interested to take part in the trial, we will give you this trial information sheet to read or have others read to you. Once you have listened-to (or read) and understood the information sheet we will ask you to give us sign the consent form agreeing to participating in the trial. The risk or danger of participating in the trial is minimal. Participation in this trial is voluntary. If for any reason you want to withdraw your consent you can do so at any time.

What will happen if you agree to take part in this study?

If you decide to take part and give your consent (by signing or thumb-printing a consent form), first I will give you a unique identification number. On a tablet, I will record some personal details about you such as your age, education, household details, obstetric history, eating habits, iron supplements, physical activity and antenatal care. After responding to these questions, you will be assigned randomly to one of the two arms of the trial (intervention or control). It will take around 90 minutes to answer the questions and to randomly assign you to the trial arm.

Regardless of which arm you are assigned to, I will visit you again in about one month to enquire about your eating habits, iron and folic acid consumptions, antenatal care during pregnancy. This will take additional 90 minutes or so.

But if you are assigned to the intervention arm (virtual counselling) we will provide you a tablet with sim card to use during the intervention. You will receive two virtual counselling sessions 2 to 3 weeks apart and each session will last around 90 to 120 minutes. During these sessions we will discuss with you and your family members the importance of eating iron rich food during pregnancy, identify problems or barriers to eating iron rich food, identify solutions and develop action plans to implement them.

Therefore, if you are assigned to the intervention group, overall, you will need to provide around 5 hours' time, whereas if you fall in the control group (routine care) group you will need to provide 3 hours' minutes to the trial.
At the end of data collection, we will transfer 200 rupees' worth of mobile top up to your cell phone number or to a number of a person of your choice if you do not have your own cell phone.

Are there any risks if you participate?

We do not think that any harm will come to you, but it is possible that you might find sharing information about your pregnancy uncomfortable or upsetting. You don't have to continue to take part if you don't feel like it. If you would like to talk to someone about the feelings generated by the questions, please contact a member of HERD staff.

Are there any benefits if you participate?

There is no direct benefit of participating in this study, however you might enjoy interacting with the counsellor on the tablet. If found effective and feasible, the results of this trial will provide evidence that counselling can be provided virtually to improve health and nutrition of pregnant women from excluded communities in Kapilbastu and rest of Nepal.

Will my taking part in this project be kept confidential?

All the information that we collect about you during the course of the research will be kept strictly confidential. Only researchers directly associated with this project, who are involved in finding you to interview you, will have access to your name and address. All other researchers who look at the information you share with us will not be able to identify you as your name and address will be removed. You will be allocated a unique number, which will be used as a code to identify you instead of your name. You will not be able to be identified in any ensuing reports or publications.

If you consent to take part in this study, the records obtained while you are in this study (age, ethnicity, religion, education and so on) will remain strictly confidential at all times. The information will be held securely on either paper or electronically at HERD International and in University College London in the UK under the provisions the local Data Protection laws. Your name will not be passed to anyone else outside the research team who is not involved in the trial. Your records will be available to people authorized to work on the trial and those responsible for ensuring that the study is carried out correctly. By signing the consent form you agree to this access for the current study. Further research might involve other researchers using the information you give us, but without your name attached to it. Alternatively, we or other researchers might seek to find you in the future to undertake further research with you.

If you withdraw consent from further study, unless you object, your data and samples will remain on file and will be included in the final study analysis.

Ethical approval

This study has been approved by the Nepal Health Research Council Approval ID number 570/2021.

Agreeing to take part

Your participation is voluntary. If you don't want to take part, you can refuse without giving a reason. If you decide to take part in the study, you will be given this information sheet to keep and be asked to sign or thumb print the consent. If you agree to participate and then change your mind at any time, please tell us and we will stop visiting you or telephoning you. We will take a photo of the consent form with your signature which will be filed in your records. You can have more time to think this over if you are at all unsure.

Data safety procedure

All participants will need to provide information two times during the trial, once at enrolment ≤ 28 weeks' gestation and another at 16 to 33 weeks' gestation. Depending on the COVID-19 situation, the information will be collected either over the phone or in person. Data assistants will assess eligibility to confirm pregnancy and gestational age, and take written consent before collecting data. The collected data will be kept confidential, stored in protected servers that can be assessed by authorised personnel only.

Expected outcome of the Trial"

This study is expected to help understand how the virtual nutrition counselling intervention can improve consumption of iron and-folic acid, intake and absorption of iron rich food and antenatal visits among pregnant women. As a result of this trial, pregnant women will be encouraged to go for antenatal check-up, deliver babies in health facilities and contribute in reducing the burden of anaemia during pregnancy.

Use of the trial results:

The evidence generated by the trial can guide government and other stakeholders in development of plans and programs for maternal nutrition and to reduce the burden of anaemia during pregnancy.

Contact for further information

You are encouraged to ask any questions you wish, before, during or after getting involved. If you have any questions about the study, please speak to the HERD International researchers who visit you, who will be able to provide you with up to date information about the trial. If you require any further information or have any concerns while taking part in the study you can contact:

Trial Manager, HERD International, Prasuti Griha Marg, Thapathali, Kathmandu. Tel 01-4238045

Or

Dr Naomi Saville, Senior Research Associate, University College London Institute for Global Health and Technical advisor to HERD, Kathmandu Nepal. Tel: 01-4238045

HERD International District Office, Taulihawa, Kapilbastu. Tel: number: 076-590090

Thank you for listening to / reading this information sheet and for considering whether to take part in this research study.