

## **Research protocol**

### **1. Project title:**

Effect of nutrition education on pregnancy specific nutrition knowledge and practice among pregnant women in Asmara, Eritrea in the year 2018, a quasi-experimental study

### **2. Project summary:**

Nutrition is a central and fundamental pillar of human life that is required for health and development throughout the entire life span in general and during pregnancy in particular. A pregnancy diet which is sufficient in energy, with a variety of nutrients, minerals, and vitamins, and the mother's avoidance of toxins and contaminants is important to ensure health for the mother and the growing fetus. In addition to that, poor quality diet during pregnancy has been found to be associated with unhealthy maternal weight gain, preterm birth, anemia and low birth weight babies which grow and develop less well and have poorer chance of survival than normal birth weight babies. The World Health Organization (WHO) recognized the impact of nutrition in pregnancy and recommends that Antenatal Care providers should provide adequate, specific and acceptable nutrition related advice to their clients during every visit of antepartum. The antenatal period appears to be the ideal time and setting to institute the intervention which could motivate mothers to make changes that could maximize their outcome and that of the baby because it is the period with opportunities for regular contact with health professionals. Protein energy under nutrition and micronutrient deficiency has been associated with infant and maternal mortality and Eritrea is no different from the many countries suffering from infant and maternal mortality. Eritrean Demographic Health Survey (EDHS) of 2002 came up with 2% of women who are shorter than 145cm, the cutoff point below which a woman is said to be at risk of giving birth to a low birth weight baby. It also indicates that 37% of women aged 15-49 have a low body mass index indicating chronic energy deficiency. Despite that fact, it is not uncommon to observe women to eat less during pregnancy to avoid fatty baby and so to prevent difficult delivery. A section from Eritrean Population Health Survey (EPHS) 2002 also showed that only 4 in 10 mothers received iron tablets but almost all took the tablets for less than 60 days despite a 55% prevalence of anemia among pregnant women although the 2010 EPHS showed a 57.3% rate of iron consumption among pregnant women with in their last birth. Such observation was also witnessed in several other

countries where men are given more food than women due to a belief that men need more food because they work harder. Moreover it is true that misconceptions and food taboos governing pregnancy still exist. This was due to the belief that certain food items will be plastered on the fetal head, fear of abortion, fatty baby and still birth. Thus planned interventions can result in the attainment of satisfactory knowledge and practice regarding nutrition during pregnancy ultimately resulting in adequate maternal diet, optimal maternal weight gain and positive infant outcomes such as satisfactory birth weight. This is a quasi-experimental study that aims to assess the effect of nutrition education on the appropriate nutritional knowledge and practice of pregnant women. It also seeks to identify the change in pregnancy-specific dietary knowledge and practice of pregnant women across the categories of demographic variables after the educational intervention. This study involves single group whose knowledge and practice level will be assessed prior to and after educational intervention by a predesigned questionnaire. Data will then be analyzed according to the statistical plan.

### **3. Project description:**

#### ***Rationale***

Every two minutes around the world there is a maternal death and one woman dies every seven minutes from PPH, the single most common cause of maternal mortality (Mirsanjari et al., 2012). This proves right the need to synthesize evidence about the effects of interventions to prevent maternal deaths and reduce maternal morbidities. Health education and counseling instituted correctly is the core of all preventive and control measures. There are strong evidences that show nutrition counseling during pregnancy has significant impact on dietary habit of pregnant women, maternal and birth outcome of pregnancy. But these facts have not been proven to be true in our country especially in the study area.

Pregnant women are one of the vulnerable populations to develop iron deficiency anemia. Severe Anemia (Hb<7.0 g/dl) which worsens with pregnancy in a study sample was found to be 6.4% after which when an intervention was implemented, no subject was found to be severely anemic (Garg & Kashyap, 2006). This gives a picture that the role of nutrition counseling at ANC visit is indisputably crucial to stop the intergenerational cycle of malnutrition.

This study intends to provide insight on the effect of nutrition counseling on knowledge and practice of pregnant women. This study is also important in filling the gap in knowledge of dietary practice among ANC providers and pregnant women. It will serve as a baseline for studies and programs working on interventions to improve national and global nutrition status of pregnant women. The intervention of this study, training and nutrition education at the ANC, materials used can also be duplicated to cover the gap of nutrition education in the area and the country as a whole.

### ***Objectives***

To assess the effect of nutrition education on the appropriate nutritional knowledge and practice of pregnant women in health facilities providing antenatal care in Asmara.

### ***Methodology***

**Research design:** Facility based single group pre-post quasi experimental study design will be employed.

**Research subjects or participants:** Pregnant women who are on their first and second trimester of pregnancy and willing to participate will be included in the study. However, pregnant women who are sick at the time of the study and those who cannot communicate verbally will be excluded from the study.

**Sample size:** Sample size of pregnant women will be calculated using a G-power Version 3 calculator using a test family of t-test. Difference between two dependent means (matched pairs) technique will be used with an effect size of 0.2, which is ideal for this study, with actual power and level of significance of 0.80 and 0.05 respectively. The sample size calculated is 199. Considering 10% dropout from follow-up, a final sample of 220 is determined. This number will then be proportionally allocated to the health facilities.

**Nutrition education counseling:** The nutrition education contains introductory messages and focuses on meanings of healthy diet, eating a variety of food, sources of the main food groups and micronutrients, eating well with the locally available food, hazards of maternal malnutrition, important supplements to be taken during pregnancy, harmful substances to be avoided, gestational weight gain and measures of alleviating common discomforts associated with nutrition during

pregnancy. The training program will be carried out in the form of counseling using printed materials and flip charts for pictorial representation. Self-reading of leaflets containing the core messages for every topic prepared in the native language of the participants will also be employed as the women in the study had one each.

**Data management and analysis:** Data quality will be warranted through trained data supervisors. Close supervision and daily information exchange will be done by the principal investigator in person or by telephone as a means to correct any problems in the course of the data collection. Data uniformity and completeness will be checked throughout the data collection period and will be cleaned.

The cleaned data will be coded and entered in to SPSS version 22.0. Normality of the entered data will be checked with Kolmogorov-Smirnov test and Fisher's measures of skewness and kurtosis. Descriptive analysis of the socio-demographic and other covariates will be done using frequencies (percentages), mean (SD) and median (IQR) as appropriate. In order to make comparison of the overall practice scores at two time points, paired t-test will be used. Comparison of knowledge scores at three time points will be performed using repeated measures ANOVA followed by Bonferroni post-hoc test. Mixed between within effect model will be used to determine effectiveness of health education on nutrition knowledge and practice during pregnancy through categories of socio-demographic variables. Finally the results will be presented using tables and graphs. A statistical significance will be considered at  $p$ -value of less than 0.05 except for the Box M  $p$ -value of less than 0.001.

**Ethical consideration:** Ethical clearance and support letter for the study will be obtained from the ethical and scientific committee of ACHS then the researcher will visit the head of the branch of MOH of Zoba Maekel for further permission. Moreover the head nurses and medical directors of each study site will be approached with full explanation of the general purpose and nature of the study. Informed written and signed consent will be taken from the participants after the purpose of the study is thoroughly explained to them beforehand. Above all, the participants' information will be handled with great confidentiality. Pregnant women will also be informed that their participation is voluntary and that they could withdraw from the study at any time during the research. Ethical supporting letter obtained from Asmara College of Health Sciences is annexed.

## ANNEX

  
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 كلية اسمره للعلوم الصحية  
**ASMARA COLLEGE OF HEALTH SCIENCES**  
 Research Ethical Clearance Committee  
 Documentation of Review and Ethical Approval of Research Project

Project Title: EFFECT OF PREGNANCY SPECIFIC NUTRITIONAL EDUCATION BY HEALTH PROFESSIONALS ON KNOWLEDGE AND PRACTICE OF PREGNANT WOMEN IN HEALTH FACILITIES PROVIDING ANC IN THE YEAR 2018

School/Department: SCHOOL OF NURSING, DEPARTMENT OF MIDWIFERY

Investigator(s): LIRIA GUHEMAL, B.Sc.M.Sc. Candidate

As the signature below testifies, the principal investigator obliged to conform to the following:  
 In case my investigation pertains to human subjects, I acknowledge protecting the rights and welfare of the participants involved. I also acknowledge my responsibility as an investigator to secure the informed consent of the participants by explaining the procedure, as far as possible, and by describing the risk as weighed against the potential benefits of the investigation. I assure the committee that all procedures performed under the project will be conducted in accordance with those federal regulations and College policies which govern research involving human subjects.  
 Any deviation from the project (e.g. change in the principal investigator, research methodology, subject recruitments procedure etc.) will be submitted to the committee in the form of a change of protocol for its approval prior to implementation. P.I. agrees to report all protocol deviations or adverse events immediately to the Research Ethical committee. In case of research involves animals, the investigator(s) has to report the type of animals, number of animals required, N<sup>o</sup> of animals to be sacrificed and whether the research work require sacrifice of animals or blood samples are needed from the research animals. The investigator is also supposed to ensure that he/she will adopt the standard procedure for the research to be conducted.

Principal Investigator(s): LIRIA GUHEMAL Name [Signature] Signature 21/05/2018 Date

Faculty advisor: PROF. ZEMENEFES TSIIOE Name [Signature] Signature 29/05/2018 Date  
 (For Committee Use)

The proposal with the aforementioned title has been reviewed by ACHS-RECC and gave the following decision.

**REVIEW STATUS:**  
 Exempted  Approved  Not Approved

**Members, ACHS-RECC:**

1. Name: <u>Oliver B Achils</u>	Signature: <u>[Signature]</u>	Date: <u>5/6/2018</u>
2. Name: <u>S. ANNALASHIMMY</u>	Signature: <u>[Signature]</u>	Date: <u>8/6/2018</u>
3. Name: <u>Prof. Indemnet Singh Asand</u>	Signature: <u>[Signature]</u>	Date: <u>5/6/2018</u>

**Chair, ACHS-RECC**  
 Name: Abumjer Fessalaye Signature: [Signature] Date: 8/6/2018

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## Informed Consent Sheet for ANC clients

### Consent explanation

Good day to you madam, my name is \_\_\_\_\_ and I am working as a data collector for a study whose aim is to assess the effect of nutrition education by health professionals on the knowledge and practice of appropriate nutrition during pregnancy among pregnant women. This knowledge will help us in providing proper nutritional counseling for pregnant women in the future and will help in shaping the ANC care of the facilities for the better. We would appreciate your participation in this survey very much. Should you agree to participate, I will ask you questions about basic information of you and your pregnancy, your basic knowledge of nutrition during pregnancy and your dietary practices during your current pregnancy. You will be asked this questions now, after the education and six weeks after receiving counseling by ANC provider on the subject. For the interview part, there is no right or wrong answer to each question.

Whatever information you provide will be kept strictly confidential by using codes and will not be shown to other individuals. Your contact information like phone number will be taken as a follow up for your second interview.

Your participation is voluntary, and you can choose not to participate now or at any time during our interview. However, I hope that you will actively participate in this study since the insights and data we get from you are very important.

The interview will take only about 20-30 minutes of your time. You will not have any direct incentives by participating and your decision to participate in the study will not affect the service you will get from your ANC clinic.

If you have any questions, you can contact the Principal Investigator (Lidia Ghirmai: 07447480).

At this time, do you want to ask me anything about the survey? (If yes answer her questions politely) May I begin the interview now? (Circle) 1 = Yes 2 = No (Thank her for her time and end the interview)

Signature of participant: \_\_\_\_\_ Date: \_\_\_\_\_

Name & Signature of interviewer: \_\_\_\_\_ Date: \_\_\_\_\_

Name & Signature of Supervisor: \_\_\_\_\_ Date: \_\_\_\_\_