Effect of preconception pictured-based health education and counseling on adherence to iron-folic acid supplementation to improve maternal pregnancy and birth outcome among women who plan to pregnant: “Randomized Control Trial”

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S U M M A R Y

Background: The practice of antenatal care does not address the preconception health of future parents and should not be viewed as an isolated activity rather as a continuum of care. There is a need to develop a promotion and prevention strategy to promote optimal maternal health and future generation. Pre-conception care is a promising new preventive strategy for improving maternal and fetal health through a primary prevention approach. Although there are many ways to conduct interventions for a healthy pregnancy, pre-conception care is rarely used in Ethiopia. The aim of the proposed study is to identify the effect of pre-conceptual picture-based health education and counseling on adherence to iron-folic acid supplementation and the effect of iron-folic acid supplementation on birth outcomes.

Methods: A two-arm, parallel randomized controlled community trial will be conducted among 244 women with spontaneous abortion and women planning to pregnant in Dire Dawa City Administration. Both arms receive iron-folic acid supplementation for three months, while only the intervention arm receives a treatment which is a preconception picture-based health education and counseling. Using multivariable logistic regression analyzes, the independent effect of picture-based health education and counseling on the outcome variables will be determined using

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both intention-to-treatment and per-protocol analyzes. Both arms will evaluate the result after one year. The primary outcome of the study is adherence to iron folic acid supplementation. This study will assess the effectiveness of preconception care counseling with iron-folic acid supplementation to increase adherence of IFAS and to avert the risk of neonates developing a neural tube defect and other adverse pregnancy and birth outcome among planned mothers to pregnant in eastern Ethiopia. This trial was registered under Clinical Trials.gov with identifier number PACTR202104543567379. The trial was registered before starting enrolment of the first case.

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1. Background

According to the annual estimates of World Health Organization (WHO), approximately 810 women die every day from preventable causes related to pregnancy and childbirth in the world [1] with neonatal deaths being 6,700 [2]. The majority of these deaths were almost 20 times higher in low income countries compared to high-income countries [1] and 10 times more in sub-Saharan Africa in the first month. Significant proportions of maternal, fetal, and newborn deaths are preventable [2]. Micronutrients are play a central part in reducing the morbidity and mortality [3]. Of these micronutrients, iron and folate are two essential nutrients that serve as coenzymes or cofactors for enzymatic reactions and are essential for the synthesis, replication and repair deoxyribonucleotides (DNA) [4–6]. Iron and folic acid deficiencies often occur at the same time. Preconception folic acid supplementation play a great role on reducing the risk for neural tube [7–12]. Also adequate iron plays an important role in neural tube development and successful neural tube closure, and that iron deficiency can cause some cases of NTDs [13–15]. Adherence to iron-folic acid supplement (IFAS) is an important tool in reducing the risk of adverse pregnancy outcomes [16,17]. Pregnant women had receiving different interventions to improve maternal and perinatal outcomes and minimizing risk factors during the antenatal period [18]. However, this service neglects the first gestational weeks and could be inadequate for improving pregnancy and birth outcomes. Pregnancy outcomes are influenced by different factors including pre-pregnancy health status, lifestyle, and personal and family history [19]. It is, therefore, pertinent to identify, modify or avoid those preconception health risks that may be encumbrance to good obstetric outcomes. The rates of unintended pregnancy have declined worldwide, with increasing access to and use of contraception including in Ethiopia [31]. However, in Ethiopia, the rate of contraceptive discontinuation is increasing with remarkable figures (35%) with only 6% of the women switched to another method [32] and most of womens is desired for pregnancy [33]. As a result these women need an intervention program to avert the risk of neonates developing NTDs and other adverse pregnancy and birth outcome in the established health system. Preconception care helps fill the gap in the existing continuum of maternal and child health care [20] and it includes nutritional conditions, mental health, environmental health, vaccination, glycaemic control, infection prevention and treatment, smoking cessation, avoidance of alcohol and substance abuse and control of obesity [21]. In Ethiopia, there is a gap in the integration of persons intending to conceive into the formal IFAS distribution program. Healthcare professionals are not in constant contact with the women and can therefore conduct regular and consistent follow-up examinations and improve IFAS compliance during pregnancy. Therefore, the aim of this study is to determine the effect of pre-conceptual picture-based health education and counseling in health care facilities on IFAS compliance and to identify the effect of IFAS on birth outcomes, including NTDs. The results of these studies will have a
significant impact on the prevention of NTDs and other pregnancy and birth outcomes by providing a simple and inexpensive prevention strategy with the existing health care system. In addition, the novelty of pre-conceptual care services in the study area will make the valuable intervention in improving maternal and neonate health and close the knowledge gap of health care providers, thus providing evidence of the establishment and integration of functional multidisciplinary pre-conceptual care services with iron-folic supplement in the routine family planning services and gynecology department. Also it is important to achieve the sustainable development program which is related to women and child health (Fig. 1 and Table 1).

2. Method and materials

2.1. Study area

The study will be conducted in Dire Dawa City Administration, eastern Ethiopia. The city is located in the eastern part of Ethiopia, 515 km from the capital city, Addis Ababa. It is subdivided into nine urban kebeles and 38 rural kebeles.

2.2. Trial design

A two arm parallel randomized controlled community trial with two arms will be employed.
2.3. Participants

An individually randomized controlled trial will be carried out among women with spontaneous abortion who refused to take a contraceptive and have a plan to be pregnant (a women requested to interrupt contraception because of their plan to be pregnant). A women between the age of 18–45 years who has an intention to have pregnancy (plans to have children), and spontaneous aborted women who refused to take a contraceptive that has an intention to pregnancy (plans to have children), currently living in the study area (women who are usual residents and live or intend to live in the area for 6 or more months) and gives consent to participate. However, women who are currently pregnant, taking contraceptive after spontaneously abortion or those who delivered a neonate with neural tube defect who died after birth or terminated the pregnancy due to neural tube defect, taking contraceptive (i.e. who have not plan to be pregnant), regularly consuming IFAS or micro mineral supplements in the past two months, non-Ethiopian subjects and participants who are mentally/physically challenged to provide consent will be excluded from the study. The study will be carried out in accordance with the Declaration of Helsinki and the requirement of good clinical practice [22].

2.4. Sample size

A two arm randomized controlled community trial using a parallel design; the sample size is be calculated using Gpower using the following assumptions: an effect size of 0.3, power of 80%, number of groups 2, and margin of error 0.05. The calculated sample size is 111 plus 10% contingency. The final sample size for a single arm will be 122. Then, we will have two arms (one intervention and one control arm). The total sample size will be 244.

2.5. Intervention

Healthcare professionals are recruited prior to the start of the intervention. The recruitment criteria are having a good experience and work in gynecology and family planning clinics, good performance in health extension packages and good communication with women. Researcher will give training on the overall study procedure and treatment for selected healthcare.
Study participants will be enrolled when they come for contraceptive removal due to their planned pregnancy and elective termination of the fetus. The trained service providers will receive the necessary information from the study participants including their full address, mobile phone numbers with their partner and a unique ID number. Lists of ID numbers are created by trained health workers and sent to the researcher on a weekly basis. Eligible mothers are assigned to one of the arms based on individual randomization using the ENA for SMART software. Before the data is collected, a declaration of consent is obtained from each participant. In the non-intervention arm, only consent to participate in the data collection is obtained. All consent forms are translated into the national language for better understanding. Details of the consent forms (purpose of the study, activities, risk, benefit, confidentiality, anonymity, future use of information, right to participate) are read out to the study participants and explained to them by the data collectors before they give their consent. Those who have agreed to participate in the study will sign the informed consent form. Baseline data are collected from study participants in both arms. The basic data are collected on socio-demographic status, birth history and knowledge. Trained health professionals will offer the assigned women in the intervention group individual picture-based health education and counseling advice with one-page booklet that shows a picture of a newborn baby with a neural tube defect.

Women in both arms are given one iron folic acid tablet daily. According to WHO guidelines, every woman is given 60 mg of elemental iron and 400 g (0.4 mg) of folic acid for three months from the day the contraceptive was removed, the pregnancy terminated or the day of stillbirth [23]. Women are instructed to swallow one tablet a day, preferably on an empty stomach and at a similar time of the day to minimize side effects. The intervention arm will receive ongoing picture-based health education and counseling. In accordance with the recommendations of the World Health Organization (WHO), individual guided counseling was developed using the guidelines for pre-conceptional care. The training is carried out using three modalities such as conventional face-to-face advice, brochures and text messaging. Counseling is carried out using a prepared brochure, and after the counseling session is over, a question-and-answer session is held to ensure that participants understand or pay attention to the counseling. The consultation lasts 10–15 minutes. The counseling is carried out in three sessions that take place once a month when the mothers come to take IFAS.

The key text SMS contains information and warnings about what women should and should not do before pregnancy and after childbirth, and includes taking iron-folic acid supplementation, lifestyle, diet, using iodized salt, reducing heavy workload, ingestion Day rest, use of mosquito nets, avoidance of medication before and after pregnancy, risk factors for NTDs and other pregnancy and childbirth outcomes, and health services. Two SMS messages (one-way communication) are sent to the women by mobile phone on Mondays and Thursdays during the day in order to avoid disruptions. Everyone in the home or neighborhood who can read is recommended to read the leaflet for a woman who cannot read. Every month their partners will be contacted and the topics on pre-conception care will be discussed. This contact is important to reduce drop-outs and to support participants with any questions that may arise and to strengthen the partner’s involvement in reproductive health.

The take-away message brochure is also provided to aid understanding after the training. This brochure contains key messages and is prepared with images and text. The local language is used in the provision of educational packages. The acceptance of interventions is reinforced by continuous follow-up visits. The home visit is used to review the general situation and IFAS compliance using an observation checklist with monthly count of the remaining IFA pills. Personal health education and counseling is provided in their home for 10–15 minutes with each monthly visit over a period of three months. Criteria are developed for investigators to assess the fidelity of the intervention. Similar health education will be given to the control group upon completion of the study. After one year, the necessary outcome data will be taken from both arms.

2.6. Outcomes

The primary outcome is adherence to iron-folic acid supplementation, whereas the secondary outcome is pregnant and birth outcomes such as birth defects, (NTDs), maternal anemia, infants’ birth weight, birth length and gestational age), and infant’s hemoglobin status (Hb) at birth.
2.6.1. Operational definition

**Adherence to iron-folic supplement or treatment**: is defined as woman should be taken if they took 80% or more of the supplement, equivalent to taking the supplement at least 4 days a week in three months consecutively starting from treatment or supplement [24–28].

**Maternal anemia**: is defined as Hb value <12 g/dL for baseline and postpartum, and <11 g/dL during pregnancy. Maternal high Hb concentrations at any time during pregnancy will be defined as Hb >13 g/dL. Maternal high Hb concentrations at any time during pregnancy will be defined as Hb >13 g/dL) [29].

**Infants anemia**: is defined as hemoglobin (Hb) at birth <11 g/dL. **Infant birth weight**: is defined as the first weight recorded after birth, ideally measured within the first hours after birth, before significant postnatal weight loss has occurred [29].

**Low birth weight (LBW)**: is defined as a birth weight of less than 2500 g (up to and including 2499 g), as per the World Health Organization (WHO) [30].

2.6.2. Measurement of potential confounders

**Demographic Data** will be collected by using validated questionnaire that include questions about demographic background, ethnicity, occupation and family situation. These data will be collected by trained field workers who will interview women.

**Socioeconomic status** will be measured using wealth index based on the ownership of fixed assets.

**Health and reproductive history** will be assessed through guided self-reporting interviewer administered questionnaire. Women will be asked about their reproductive history such as number of pregnancies, live births and abortions, and previous pregnancy complications like: hypertension, convulsions and bleeding. Women will be asked questions about nervous sickness, depression, psychiatric disorders, and addictions like smoking, drug and alcohol use.

**Maternal pre-pregnant nutritional status**: Pre-pregnant weight and height will be measured at baseline. Weight will be measured using an electronic scale (UNISCALE) that is accurate to 100 g and height will be measured to the nearest 0.1 cm using a stadiometer.

**Dietary intakes** will be collected at baseline using a 7 days Food Frequency Questionnaire (FFQ). The administration of this instrument takes approximately 30 minutes.

2.7. Data collection schedule

The data will be collected by the trained health workers.

2.8. Randomization

The sample is drawn at random from the eligible population and divided between two arms. Intervention arm (these (n = 22) will be exposed to nutrition and lifestyle-based training and counseling, and the control arm (n = 122) will not be exposed to any intervention. The arm is assigned using the ENA Smart software. The study population is from health care institutions (Department of Family planning and gynecology). Study participants, data collectors and research assistants are blinded to group classification.

2.9. Statistical methods

Preliminary descriptive analyzes will be performed to examine the distribution of the data and check for outliers. The assumptions of normality are assessed using graphs and normality tests. The effects of the interventions on birth outcomes and maternal and infant health are assessed using the Per Protocol approach. The effectiveness of randomization is assessed by comparing key baseline features across two experimental groups using an independent sample t-test for continuous variables or a chi-square test for categorical variables. Multivariable logistic and linear regression models will be used to evaluate the association between dependent and independent variables. Standard regression diagnostics are performed with all analyzes to assess model assumptions, including examining distributions, performing any required transformations, and examining the overall fit, residuals, and
leverage. Statistical analyses will be performed with the SPSS version 25 statistical package. All statistical tests will be two-tailed and $P$ values $< 0.05$ will be considered statistically significant.

3. Quality control

Several procedures will be performed to ensure data quality, which is a major concern. There will be extensive training of the team of interviewers, and supervision during data collection and data entry. Supervisors will verify all forms for accuracy and completeness on a routine basis before data entry at the server and import to SPSS. Incorrect or incomplete entries will be corrected during data collection. This will be done using an ongoing interactive system. Monthly reports of all data collection activities will be generated and sent to the principal investigator.

4. Study timeline

Activities related to the development of the protocol, pre-testing and finalizing questionnaires, hiring and training of all study staff will be carried out in the first 1 month. Screening and recruitment of study subjects for the intervention will be completed in 1–2 months and will assign individual randomization using ENA for SMART software to one of the arms. The daily supplementation will begin as subjects are recruited. Sample size calculations were made based on an assumption that women will receive at least 3 months of intervention during the pre-pregnancy period. Women who get pregnant within less than 3 months of pre-pregnancy supplementation will be followed up. The total duration of data collection will be completed in eight months. All data entry and cleaning will be carried out in an on-going fashion. Data analysis will be conducted in one month and the preparation and submission of manuscripts for publication will be undertaken in one month. The finding of this intervention will be analyzed and disseminated through journal articles, policy reports, and presentations at national, regional, and international conferences and meetings.

4.1. Data safety monitoring plan (DSMP)

We assume that there is no risk of interference. The validity and integrity of the data is ensured through a suitable research design, the use of previously tested and validated instruments for data collection and quality assurance.

4.2. Data confidentiality and archiving

Data protection, anonymity and confidentiality of the data will be strictly observed. To protect the safety of the participants, all study-related information will be treated confidentially and stored securely. An encrypted identification will be used to anonymize and anonymize the data. Access to the data will be restricted to a small number of people, including the investigators, statisticians, the quality control team, and the audit.

References
