INFORMED CONSENT FORM

A Randomized Controlled Trial in Lombok: Assessing Factors Influencing Adherence to Multiple Micronutrient Supplementation (MMS) Using Digital Tools

SUMMIT INSTITUTE FOR DEVELOPMENT (SUMMIT)

Jl. Sultan Hasanuddin No 137B
Lingkungan Karang Jero, Kelurahan Karang Taliwang, Kota Mataram, Nusa Tenggara Barat, Indonesia

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Please read the following information carefully, or ask someone to read it to you if necessary. You will receive a copy of this form for your records. Before deciding whether to participate in this program, you are encouraged to discuss your participation with someone you trust. Please feel free to ask the program team if there is any part you do not understand; the team will be happy to provide clarification. If you agree to participate in this program, you will be asked to sign the Informed Consent Form.

1. Background

The Yayasan Institut Pengembangan Suara Mitra, more widely known as the Summit Institute for Development (SUMMIT), is a non-profit research organization working in the fields of health, education, and human resource development. SUMMIT is currently implementing a cluster randomized controlled trial entitled "Assessment of Factors Influencing Adherence to Multiple Micronutrient Supplementation (MMS)."

Multiple Micronutrient Supplementation (MMS) is particularly important for pregnant women, as it contains essential micronutrients required to support maternal health and fetal development during pregnancy. MMS contributes to improved maternal health and supports optimal child growth and long-term cognitive development. Furthermore, MMS has been shown to prevent micronutrient deficiencies that may lead to adverse outcomes such as anemia, low birth weight, and an increased risk of stunting.

MMS has been adopted as part of a national program promoted by the Ministry of Health of the Republic of Indonesia to improve maternal nutrition and child development, with the goal of fostering a healthier and more productive future generation. In addition, calcium supplementation, as part of the MMS intervention, plays an important role in supporting maternal health and reducing the risk of pregnancy-related complications such as preeclampsia and impaired fetal growth. However, insufficient monitoring and evaluation of MMS and calcium consumption among pregnant women may lead to suboptimal adherence.

Pregnant women are encouraged to maintain adherence to MMS and calcium supplementation to ensure adequate nutritional intake for both mother and fetus, prevent low birth weight (LBW), reduce the risk of hemorrhage associated with anemia, prevent preeclampsia, and support the future cognitive development of the child. Therefore, this program aims to strengthen the monitoring of supplementation to improve adherence among pregnant women. Through this information, we would like to invite you to participate in this program.

2. Objective

The objective of this program is to assess the factors influencing adherence to MMS and calcium supplementation. The findings from this program are expected to contribute

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to improving maternal and child health services, particularly through the use of digital technologies to support the provision and monitoring of MMS and calcium supplementation among pregnant women.

3. Duration and Procedures

Data collection for this program will be conducted from the time a pregnant woman agrees to participate until at least one month postpartum. Program activities include anamnesis/interviews, data collection during pregnancy and up to one month after delivery, provision of MMS and calcium supplementation, and monitoring of their consumption. The data collected will include information related to healthcare services, such as pregnancy data, antenatal care visits, delivery data, postnatal care visits, and monitoring data on MMS and calcium consumption. The duration of each data collection session per participant will align with routine healthcare services provided by health workers, typically ranging from 10 to 15 minutes. Routine home visits will be conducted to monitor pregnancy, postpartum conditions, and supplementation adherence, as well as to collect the required data.

4. Manfaat Potensial

Participation in this program may provide several benefits, particularly related to maternal, postpartum, and breastfeeding health. These include improved quality and frequency of antenatal care (ANC) services during pregnancy; access to MMS and calcium supplementation; and enhanced monitoring of maternal health.

MMS has been shown to support adequate nutritional intake, reduce the risk of maternal undernutrition, lower the likelihood of low birth weight (LBW), decrease the risk of preterm birth, and enhance the cognitive development of the child. Calcium supplementation is essential for bone health and plays a significant role in reducing the risk of preeclampsia, a condition characterized by high blood pressure that may lead to seizures and impaired liver or kidney function.

Through this program, SUMMIT will also support regular monitoring of MMS and calcium consumption. Participants will have the opportunity to receive free health consultations and health education through direct visits. In addition, participants will be ensured access to primary healthcare services in accordance with established health standards. After delivery, postnatal care (PNC) monitoring will be conducted, and in the event of any health concerns affecting the mother or baby, appropriate referrals and assistance to healthcare facilities will be provided.

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5. Potensi Efek Samping

This program will provide MMS supplementation to participants assigned to the intervention group. MMS contains iron and folic acid in amounts similar to those found in iron and folic acid (IFA) tablets; however, MMS includes a broader range of micronutrients, making it more comprehensive than IFA supplementation.

MMS contains 15 essential micronutrients that are beneficial for maternal and fetal health, as outlined in the table below:

No.	Komposisi	Spesifikasi MMS standar UNIMMAP
1	Vitamin A	800 mcg RE
2	Vitamin C	70 mg
3	Vitamin D	5 mcg (200 IU)
4	Vitamin E	10 mcg a-TE (tocopherol equivalents)
5	Vitamin B1 (Thiamine)	1.4 mg
6	Vitamin B2 (Riboflavin)	1.4 mg
7	Vitamin B3 (Niacinamide)	18 mg
8	Vitamin B6 (Pyridoxine)	1.9 mg
9	Folic Acid	400 mcg
10	Vitamin B12	2.6 mcg
11	Iron	30 mg
12	Iodine	150 mcg
13	Zinc	15 mg
14	Selenium	65 mcg
15	Copper	2 mg

In addition, as part of this program, pregnant participants will receive calcium tablets (calcium carbonate) for consumption. During pregnancy, symptoms such as nausea, vomiting, constipation, or changes in stool color are common and may be influenced by various factors, including hormonal changes and the consumption of iron-containing supplements. The potential side effects that may be experienced are similar to those associated with iron and folic acid (IFA) tablets.

These effects are not directly attributable to the administration of MMS, but rather represent common physiological responses frequently observed among pregnant women. Although rare, sensitivity or allergic reactions to one or more micronutrient components may occur. Therefore, participants are advised to promptly contact the program team or a healthcare provider if they experience any unusual or bothersome symptoms, so that appropriate evaluation and management

can be undertaken.

In the event that allergic reactions or adverse effects are identified, the following procedures will be implemented:

1. Participants may report any suspected allergic reactions or side effects through the following contact channels:
   SUMMIT Call Center: +62 21 3000 6100
2. SUMMIT WhatsApp: +62 859 7413 2010
3. Upon receiving a report, SUMMIT will coordinate with the nearest primary healthcare facility (puskesmas), midwife, or clinic to ensure prompt and appropriate management.
4. SUMMIT will deploy a trained staff member (Community Health Promoter) in the participant's vicinity to provide assistance and facilitate referral to the nearest healthcare facility, if necessary.
5. All cases will be documented and reported by SUMMIT through a digital data recording system.
6. Adverse events related to health supplements will also be reported to the Indonesian Food and Drug Authority (BPOM) through established reporting mechanisms, including electronic reporting systems, email, written correspondence, telephone, or mobile applications. BPOM provides an online platform, E-MESO (https://e-meso.pom.go.id/), which can be used to report adverse effects associated with medications and health supplements.

6. Voluntary Participation

Your participation in this implementation study is important; however, it is entirely voluntary. If you agree to participate, you have the right to change your decision or withdraw from the study at any time without any penalty or consequences.

7. Confidentiality

We will not disclose any information about you or your baby to anyone outside the program team. All information collected during this study will be treated with strict confidentiality. Any data related to you will be identified using a unique code rather than your name. Personal information about you or your baby will not be shared with any parties outside the program team. Any information presented in publications or reports will consist only of aggregated program findings and will not include any personally identifiable information. All collected data will be securely stored in digital formats and maintained with appropriate safeguards to ensure confidentiality. These data may be used to support the development of health program policies.

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8. Informasi Lain

This program has received ethical approval. Should there be any additional information related to the program, participants will be promptly informed. If at any time you require further information or clarification, you may contact:

Summit Institute for Development (SUMMIT)

Telephone	: +62 21 3000 6100
WhatsApp	: +62 859 7413 2010
Address	: Jl. Sultan Hasanuddin No. 137 B, Lingkungan Karang Jero, Karang Taliwang Subdistrict, Mataram City
Program Contact Person	**:** Nurmalita Hartiyana Kusuma Wardani
Mobile	: +62 851 7989 2736

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PERSETUJUAN SETELAH PENJELASAN (PSP)

Bagian yang diisi oleh responden/wali
Responden mengisi bagian ini sendiri

No.	Pernyataan	Persetujuan	
1	Have you read the information sheet? (Please retain a copy for your records.)	Yes	No
2	Have you been given the opportunity to discuss this MMS program and ask questions?	Yes	No
3	Have you received satisfactory answers to all of your questions (if any)?	Yes	No
4	Have you received sufficient information regarding this MMS program?	Yes	No
5	Do you understand that you have the right to refuse or not participate in this program (participation is voluntary)?	Yes	No
6	Do you understand that you may withdraw from the program at any time without any penalty?	Yes	No
7	Do you agree to participate in this study?	Yes	No
8	Do you agree to commit to taking MMS and calcium supplements regularly as recommended?	Yes	No
9	Do you agree to have your health status and your MMS and calcium consumption monitored throughout your pregnancy?	Yes	No
10	Do you agree to be contacted via telephone and WhatsApp and to receive home visits?	Yes	No

ID CHP		ID pregnant women	

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CONSENT STATEMENT: PREGNANT WOMAN RESPONDENT:

I, the undersigned:

Id Pregnant Women	
Name	
Husband Name	
Address	Posyandu:_____ Hamlet:_____ Village:_____ PHC:_____
Birth Date	
Gestational Age (GA) Based on USG 1st Trimester	GA (TM 1) : _____ Week/ Delivery Date USG:_____ Last Menstrual Date: _____
Phone Number	

I hereby confirm that all explanations regarding the Multiple Micronutrient Supplementation (MMS) and calcium program entitled "Assessment of Factors Influencing Adherence to Multiple Micronutrient Supplementation (MMS)" have been clearly provided to me, and that all of my questions have been satisfactorily answered by the program team. By signing this form, I voluntarily agree to participate in this program and, where applicable, to allow my child/ward to participate, without any coercion or undue influence from any party.

Responden	Witness (Midwive)
_____,_____/_____/ _____	_____,_____/_____/ _____
(_____)	(_____)
Full Name	Full Name

Witness (Family Member)
_____,_____/_____/ _____
(_____)
Full Name

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1. Background

The Yayasan Institut Pengembangan Suara Mitra, more widely known as the Summit Institute for Development (SUMMIT), is a non-profit research organization engaged in the fields of health, education, and human resource development. Currently, SUMMIT is implementing a cluster randomized controlled trial entitled "Assessment of Factors Influencing Adherence to Multiple Micronutrient Supplementation (MMS)."

Multiple Micronutrient Supplementation (MMS) is particularly important for pregnant women, as it contains essential micronutrients required to support maternal health and fetal development during pregnancy. MMS contributes to improving maternal health and supports optimal child growth and long-term cognitive development. Furthermore, MMS has been shown to prevent micronutrient deficiencies that may lead to adverse outcomes such as anemia, low birth weight, and an increased risk of stunting.

At present, MMS has been adopted as part of a national program promoted by the Ministry of Health of the Republic of Indonesia to improve maternal nutrition and child development. This program is expected to contribute to the development of a healthier and more productive future generation. However, limited monitoring and evaluation of MMS consumption among pregnant women may result in suboptimal adherence.

Pregnant women are encouraged to adhere to MMS consumption to ensure adequate nutritional intake for both mother and fetus, prevent low birth weight, reduce the risk of hemorrhage associated with anemia, and enhance the future cognitive development of the child. Therefore, this program aims to strengthen the monitoring of MMS consumption in order to improve adherence among pregnant women. Through this information, we would like to invite you to participate in this program.

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2. Objective

The objective of this program is to assess the factors influencing adherence to MMS consumption. The findings from this program are expected to contribute to improving maternal and child health services, particularly through the use of digital technologies to support the provision and monitoring of MMS among pregnant women.

3. Duration and Procedures

Data collection for this program will be conducted from the time a pregnant woman agrees to participate until at least one month postpartum. Program activities include anamnesis/interviews, data collection during pregnancy and up to one month after delivery, provision of MMS supplementation, and monitoring of its consumption.

The data collected will include information related to healthcare services, such as pregnancy data, antenatal care visits, delivery data, postnatal care visits, and MMS consumption monitoring data. The duration of each data collection session per participant will align with routine healthcare services provided by health workers, typically ranging from 10 to 15 minutes.

Routine home visits will be conducted to monitor pregnancy, postpartum conditions, and MMS consumption, as well as to collect the required data.

4. Potential Benefits

Participation in this program may provide several benefits, particularly related to maternal health. These include improved quality and frequency of antenatal care (ANC) services during pregnancy; access to MMS supplementation, which has been shown to support adequate nutritional intake, reduce the risk of maternal undernutrition, lower the likelihood of low birth weight and preterm birth, and enhance the cognitive development of the child.

Participants will also have the opportunity to receive free health consultations and health education through direct visits. In addition, participants will be ensured access to primary healthcare services in accordance with established health standards. After delivery, postnatal care (PNC) monitoring will be conducted, and in the event of any health concerns affecting the mother or baby, appropriate referrals and assistance to healthcare facilities will be provided.

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5. Potential Risks and Side Effects

This program will provide Multiple Micronutrient Supplementation (MMS) to participants assigned to the intervention group. MMS has a composition similar to iron and folic acid (IFA) tablets; however, MMS contains a broader range of micronutrients. Specifically, MMS includes 15 essential micronutrients that are beneficial for maternal and fetal health.

No.	Komposisi	Spesifikasi UNIMMAP
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These effects are not directly attributable to the MMS intervention in this study, but

rather represent common physiological responses frequently observed among pregnant women. Although rare, sensitivity or allergic reactions to one or more micronutrient components may occur.

Therefore, pregnant participants are advised to promptly contact the program team or a healthcare provider if they experience any unusual or bothersome symptoms, so that appropriate evaluation and management can be undertaken.

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6. Voluntary Participation

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7. Confidentiality

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Personal information about you or your baby will not be shared with any parties

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8. Ethical Approval and Contact Information

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Statement of Informed Consent Following Explanation

Section to be Completed by the Participant
This section is to be completed by the participant (or their legal guardian).

No.	Pernyataan	Persetujuan	
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Responden	Witness (Midwive)
_____,_____/_____/ _____	_____,_____/_____/ _____
(_____)	(_____)
Full Name	Full Name

Witness (Family Member)
_____,_____/_____/ _____
(_____)
Full Name

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