

Design and evaluation of a targeted behavior change communication program for a healthy pregnancy and delivery

Submission date 10/11/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/11/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 19/11/2025	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

In many communities of Bangladesh, the utilization of maternal health services is low and subsequently, maternal health outcomes are poor. Other key issues potentially related to poor maternal health outcomes in Bangladesh are high adolescent pregnancy rates and early marriage in the context of patriarchal culture. One of the social and behavioral change communication (SBCC) approaches to encourage maternal health service utilization is a courtyard session facilitated by trained community health workers (CHWs). In a courtyard session, participants are invited to engage in a dialogue and gain information about the importance of antenatal care visits, facility delivery, or postnatal and neonatal care. Despite its potential, little empirical evidence exists that can inform the implementation of SBCC strategy in a broader context. Furthermore, these courtyard sessions deliver general messages not specifically targeted for pregnant adults or adolescents, their husbands or mothers-in-law who are likely to have different perspectives, lived experiences and information needs within a family dynamic. To address these gaps, this study aims to recruit 750 pregnant women in addition to their husbands and mothers-in-law for separate targeted courtyard sessions involving 5-month curriculum. This targeted SBCC intervention is designed, implemented, and evaluated as part of the official development assistance (ODA) program funded by Korea International Cooperation Agency (KOICA). By assessing effectiveness and implementation outcomes of the targeted SBCC intervention compared to a standard ODA practice and a control group without direct support from the ODA, this study seeks to provide insights into the scale-up efforts and policy adoption. If proven effective and feasible, the targeted SBCC can increase demands for maternal health services and improve maternal health outcomes in Bangladesh, and potentially other similar contexts.

Who can participate?

Pregnant women with a gestational age of 16 weeks or less in Rangpur and Lalmonirhat districts in Rangpur Division, Bangladesh. (If their union of residence is selected for targeted SBCC intervention, their mothers-in-law and husbands will be invited to courtyard sessions.)

What does the study involve?

From the community health workers' household lists, women who are pregnant for 16 weeks or less are identified. Then, the pregnant women are asked to complete an online questionnaire with the assistance of an enumerator who visits the household. During the survey, pregnant women from the randomly selected unions are invited to participate in separate courtyard sessions for the next 5 months. The sessions for adult pregnant women (aged above 18) and pregnant adolescents (aged 18 or below) are scheduled for the 2nd and 3rd weeks for 5 months respectively, with a total of 5 sessions for each group. In the 4th week during those 5 months, the first and second sessions are held privately with their mothers-in-law, and the rest of the 3 sessions are held for husbands. If the participating pregnant women are not from these randomly selected unions, they are only asked to participate in another survey after 6 to 7 months. Some of the participants and their mothers-in-law and husbands are planned to be invited for a group discussion about a year after the first survey.

What are the possible benefits and risks of participating?

There will be no immediate direct benefit to the participants, although those who attend the awareness-raising courtyard sessions will learn about the importance of antenatal care visits, facility delivery, postnatal care, and neonatal care. Additionally, findings from the study will be shared with the relevant local government authorities in Bangladesh to improve how pregnant women and their families access important information related to healthy pregnancy and childbirth. There is no known risk or potential harm expected from participation in this study.

Where is the study run from?

The targeted SBCC study is being run by Save the Children in Bangladesh with RDRS Bangladesh as the implementing partner and takes place in Rangpur and Lalmonirhat districts of Rangpur Division, Bangladesh.

When is the study starting and how long is it expected to run for?

December 2023 to October 2026

Who is funding the study?

Korea International Cooperation Agency (KOICA) under the Ministry of Foreign Affairs, South Korea

Who is the main contact?

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Targeted social and behavior change communication (SBCC) for improved maternal health service utilization in a high adolescent pregnancy setting of Bangladesh: a cluster-randomized study engaging key family members

Study objectives

This study aims to conduct a formative assessment for the design of targeted social and behavior change communication (SBCC) intervention, and to conduct a mixed-method impact evaluation of this intervention through hybrid effectiveness-implementation type II cluster-randomized study. The study hypothesis is as follows:

Targeted SBCC improves maternal and neonatal health service utilization more than non-targeted, generic messaging approaches.

Ethics approval required

Ethics approval required

Ethics approval(s)

1. approved 15/04/2025, Save The Children Ethics & Evidence Generation Team (St Vincent House, 30 Orange Street, London, WC2H 7HH, United Kingdom; +44 (0)20 3272 0300; jenny.cotton@savethechildren.org), ref: SC-EEG-FY2024-328

2. approved 30/04/2025, University of Dhaka, Institutional Review Board (University of Dhaka Arts Building (4th Floor), Dhaka, 1000, Bangladesh; +88-09666911463; director.ihe@du.ac.bd), ref: IHE/IRB/DU/16/2025/Final

Study design

Hybrid effectiveness-implementation type II cluster-randomized study

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Improvement of maternal and neonatal health service utilization in pregnant adolescents and adults

Interventions

This is a hybrid effectiveness-implementation type II cluster-randomized study to assess the effectiveness and implementation outcomes in Rangpur and Lalmonirhat districts of Rangpur Division in Bangladesh, where 40 unions were strategically selected for support through Korea International Cooperation Agency (KOICA)'s official development assistance (ODA) program. Of these, 20 unions were randomly selected to receive the targeted SBCC intervention, and the remaining 20 unions will continue to receive the routine ODA support without participating in the targeted SBCC intervention. In addition, another 20 unions were randomly selected outside the 40 ODA-supported unions to serve as a control group. Blinding was not implemented due to the practical constraints of conducting a community-based intervention.

Randomization was conducted by the lead researcher using R software's `sample()` function. Among 140 facilities from the master list, 40 facilities supported by the ODA project across 17 unions in Lalmonirhat and 23 unions in Rangpur districts were assigned for randomization process of arms 1 or 2. Using R's `sample()` function, simple random sampling without replacement was performed to randomly select 20 unions from the 40 unions. Considering that the difference in the number of supported unions between the two districts (Lalmonirhat and Rangpur) is not significant, with 17 and 23 unions respectively, all 40 unions were assigned an equal probability for selection.

To randomly select another 20 unions outside these 40 unions, 100 facilities located across 23 unions in Lalmonirhat and 50 unions in Rangpur districts were considered. Among these 73 unions, 7 unions had facilities that received ODA support. Therefore, 66 unions (22 in Lalmonirhat and 44 in Rangpur) were assigned for randomization process for arm 3. Because the total number of unions in Rangpur is twice as that in Lalmonirhat, different probabilities were assigned as follows:

Probability of selecting Lalmonirhat: $22/66=1/3=0.333$

Probability of selecting Ranpur: $44/66=2/3=0.6667$

Using R's sample() function, simple random sampling without replacement was performed to randomly select 20 unions from the 66 unions not supported by ODA project.

The targeted SBCC intervention invites four groups of key family members separately, including (1) pregnant women aged over 18 years, (2) pregnant adolescents aged 18 or below, (3) mothers-in-law, and (4) husbands or male partners. The five-month curriculum is designed to cover topics such as antenatal care, safe delivery, postnatal care, and neonatal care with tailored messages for each group. Four sets of flip charts with images and targeted message transcripts will be used by the community health workers who will lead the group-based interactive community courtyard sessions. The sessions for adult pregnant women (aged over 18 years) and pregnant adolescents (aged 18 years and below) are scheduled for the 2nd and 3rd weeks for 5 months respectively, with a total of 5 sessions for each group. In the 4th week during those 5 months, the first and second sessions will be held privately with mothers-in-law, and the rest of the 3 sessions will be held for husbands. For the standard of practice arm (arm 2), general support through ODA will still be provided, including routine awareness-raising sessions without targeted messages. The participants for the control arm (arm 3) will be recruited from another 20 unions outside the 40 ODA-supported unions.

Intervention Type

Behavioural

Primary outcome(s)

The following primary outcomes (%) will be measured using a questionnaire at 6-7 months after the baseline:

1. Mothers who received 4 or more ANC services
2. Births attended by skilled health professionals
3. Facility delivery
4. Mothers who received postnatal care (PNC) within 48 hours after delivery
5. Neonates who received neonatal care within 48 hours after birth

Key secondary outcome(s)

1. Changes in perceived appropriate age for marriage measured using questionnaires at baseline and endline (6-7 months after baseline)
2. Changes in perceptions on maternal health-seeking behavior and its motivation measured using questionnaires at baseline and endline (6-7 months after baseline), supported by endline Focus Group Discussion (7-10 months after baseline).
3. Changes in perceived support from family members measured using questionnaires at baseline and endline (6-7 months after baseline), supported by endline Focus Group Discussion (7-10 months after baseline).
4. Changes in perceptions on women's empowerment represented by the involvement in decision making measured using questionnaires at baseline and endline (6-7 months after baseline), supported by endline Focus Group Discussion (7-10 months after baseline).
5. Level of satisfaction with the information gained from the targeted SBCC intervention measured using questionnaires at baseline and endline (6-7 months after baseline), supported by endline Focus Group Discussion (7-10 months after baseline).

Completion date

31/10/2026

Eligibility

Key inclusion criteria

Pregnant women:

1. A gestational age of 16 weeks or less
 2. For the intervention arm only: willingness and availability to participate in the courtyard sessions held at randomly selected unions for the intervention arm
 3. Agreed to provide their own names, husbands' names, and contact information for follow-up
- *For the intervention arm only: Their husbands and mothers-in-law are invited to participate in the respective sessions, but they will not be participating in the baseline and endline surveys.

Participant type(s)

Population

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

15 years

Upper age limit

65 years

Sex

All

Total final enrolment

786

Key exclusion criteria

Those who are unable to understand or communicate in Bengali

Date of first enrolment

06/05/2025

Date of final enrolment

15/05/2025

Locations**Countries of recruitment**

Bangladesh

Study participating centre

Save the Children International Bangladesh (SCiBD) Rangpur Project Office

House 272, G L Roy Road, Purba Kamal Kachna
Rangpur

Bangladesh
5400

Sponsor information

Organisation

Save the Children

ROR

<https://ror.org/032e5zb24>

Organisation

Save the Children Korea

Organisation

Yonsei University Mirae Campus

ROR

<https://ror.org/0160gc229>

Funder(s)

Funder type

Government

Funder Name

Korea International Cooperation Agency

Alternative Name(s)

KOICA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Korea, South

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository. For the survey, Kobo Toolbox platform will be used and can be accessed via <https://www.kobotoolbox.org/>. However, the raw datasets that contain personally identifiable information to match baseline and endline participants will only be shared within the research team to maintain confidentiality.

The qualitative datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality and privacy of the focus group discussion participants.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes