# Title: Impact of TARANG, a group-based life skills and health empowerment for married women to avoid unintended pregnancies in Rajasthan, India

**Tarang Study Protocol**

NCT06320964

Initial IRB approval: 10/02/2022 and final approval: 10/02/2023

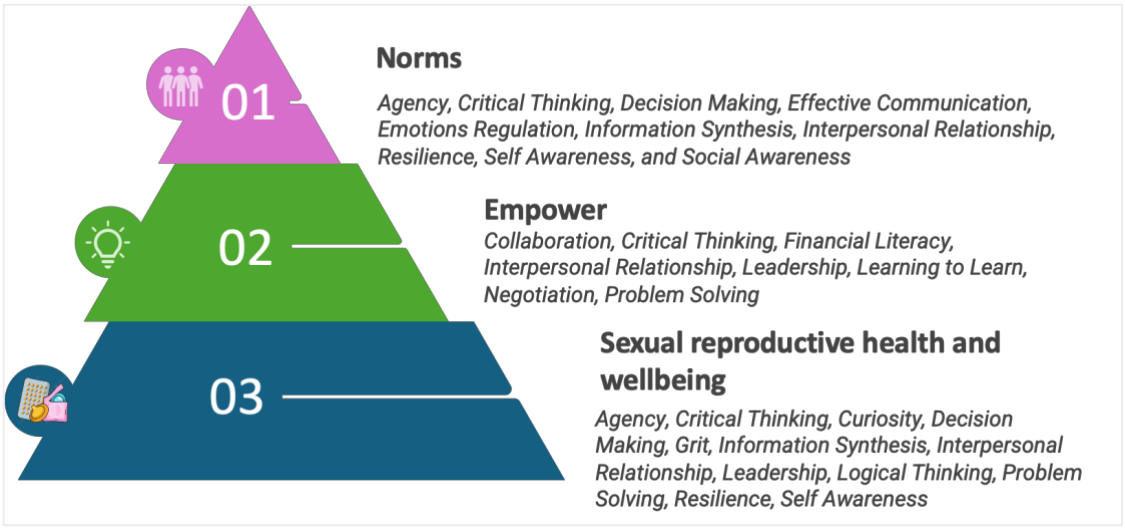
### 1.1 Development of the TARANG intervention for and with newly married women

The TARANG intervention was developed and tailored to address the needs of young, newly married women in Rajasthan. The final curriculum for the intervention was rooted in the principles of adult and experiential learning with a rights-based framework, covering 19 specific life skills under three overarching thematic areas—Empower, Norms, and Sexual Reproductive Health and Wellbeing (Figure 1). We prioritized these three thematic areas together in a series of consultations with our implementing non-governmental organization (NGO) partner, Vikalp Sansthan (referred to as NGO staff henceforth), based on their decades of field experience with newly married women to ensure it was directly applicable to young women's lives. The curriculum, built on the rights-based framework, adopts a 'spiral-curriculum approach', wherein various aspects and topics are interconnected throughout the curriculum, serving to reinforce the message and deepen participants' understanding of the interconnectedness among the key concepts outlined.

The curriculum development was led by the Orange Tree Foundation, an organization based in Jodhpur, Rajasthan, with contextual knowledge and extensive experience in working with young people and promoting youth-friendly educational programs. Given that this curriculum targets neo-literate participants residing in rural and tribal areas of Southern Rajasthan, the team from the Orange Tree Foundation meticulously designed the sessions to be interactive and activity-driven, with audiovisual aids and self-explanatory illustrated visuals. The content was developed directly in vernacular Hindi, tailored to the specific context of Southern Rajasthan, where our study is based, encompassing character names, illustrations, case studies, and cultural nuances pertinent to the region. To enhance the learning process, the TARANG toolkit,

comprising of tools, posters, activity charts, link to audio-video resources and other relevant resource materials, was developed to serve as a resource compendium for moderators and participants. The toolkit also includes additional reading materials for the trainers that supplement in-session delivery.

*Figure 1: Life skills integrated into the TARANG intervention for newly married women*




During the developmental phase spanning from February to May 2023, we conducted iterative user testing with 38 newly married women in selected villages in Udaipur district of Southern Rajasthan, one of our primary study locations. Drawing insights from this pilot phase, final curriculum was developed by incorporating cultural adaptations and ensuring the curriculum's linguistic suitability and appropriateness for the target audience.

### 1.2 Overview of the TARANG intervention

TARANG (Transforming Actions for Reaching and Nurturing Gender Equity and Empowerment) meaning, 'cascading waves', in Hindi, and was chosen because, through this curriculum, we hypothesized that young women would feel empowered through a ‘wave’ of agency to make informed choices about their bodies as well as family planning. The TARANG intervention was implemented by our NGO staff based in Udaipur, Rajasthan.

*Moderators and groups*: The Orange Tree Foundation team trained NGO staff and two female moderators in two phases, over a period of seven days, on the intervention curriculum in May and October 2023. Four intervention groups were run in four villages, with convenient timings for the groups set by each group individually. Moderators also continued to receive regular supervision from the NGO team.

The TARANG intervention started with an introductory rapport-building session, followed by 16 group sessions facilitated by the moderators over six months. Using practical skill-building activities, the intervention aimed to empower participants by enhancing their understanding of fundamental topics such as menstruation, conception, and contraception. Additionally, the curriculum was designed to strengthen participants' sense of agency and their ability to make informed decisions regarding family planning and the timing of their first childbirth. Finally, the curriculum was designed to bring awareness to inequitable gender norms and their rights. The 16 sessions are summarized below:

*Table 1: TARANG intervention sessions and objectives*

| Session # | Name of the session | Objectives |
|---|---|---|
| **Session 0** | Kickstart | Building rapport, fostering a culture of learning |
| **Session 1** | My health, my priority | Prioritizing health and understanding its four pillars: mind, body, heart, and soul |

| | | |
|---|---|---|
| **Session 2** | Know your body | Understanding menstruation, menstrual health management and conception |
| **Session 3** | Science behind conception | Engaging in activities to comprehend sex determination of the fetus and addressing norms related to son preference |
| **Session 4** | Contraception | Exploring various contraceptive methods tailored to individual needs and life circumstances. |
| **Session 5** | Love has no space for violence | Developing a support system chart and recognizing different forms of violence, including physical, sexual, economic, and emotional |
| **Session 6** | My identity | Reflecting on personal identity and self-awareness |
| **Session 7** | Responsible sexual behavior | Addressing issues such as hygiene, sexually transmitted infections, and reproductive tract illnesses |
| **Session 8** | My consent is important | Exploring the concept of consent, emphasizing voluntary and informed decision-making, and understanding the right to withdraw consent |
| **Session 9** | How to choose family planning methods | Understanding that family planning is a shared responsibility and should be a personal decision |
| **Session 10** | Negotiate your way | Examining healthy and unhealthy relationship dynamics and developing negotiation skills |
| **Session 11** | Language of money | Learning to create a family budget and strategies for saving money |
| **Session 12** | Preparing for a digital world | Understanding essential digital tools such as Gmail, phone apps, and utilizing search engines effectively |
| **Session 13** | My five year plan | Engaging in a workshop to make decisions for the next five years, including considerations for family planning |
| **Session 14** | Conception and abortion | Exploring topics related to abortion, sex-selective abortion, and relevant laws |
| **Session 15** | Safe maternity, healthy life | Understanding conception, pregnancy, antenatal care, and newborn care |
| **Session 16** | Managing emotions and stress | Learning coping mechanisms to manage stress effectively |

The TARANG intervention also included separate, light-touch interventions for important household-level stakeholders, namely husbands and mothers-in-law, to create a supportive environment at home for the newly married women. The feasibility and acceptability of this part of the intervention for husbands and mothers-in-law will be published elsewhere.

### 1.3 Aims:

The pilot study aims to evaluate the acceptability, feasibility, and implementation challenges of the TARANG intervention in villages in rural/tribal Rajasthan to inform the study design and operational details for a larger cluster-randomized controlled trial.

Our specific objectives include:

a) To qualitatively understand the participants' acceptability, feasibility of the TARANG intervention delivery, content, modules, etc.
b) To impact of the TARANG intervention using feasibility, acceptability, and usefulness measures.
c) To understand operational challenges of delivery from participants and moderators delivering the intervention.

### 1.4 Study design and setting

Mixed methods research designs integrate quantitative and qualitative data to harness the complementary strengths of both datasets and have a more comprehensive evaluation of intervention feasibility than would be attainable from either dataset alone. This convergent mixed methods study consisted of a one group design with pre- and post-intervention data collection to examine the feasibility and acceptability of the intervention.

The study was conducted across four villages in Kumbhalgarh block of Rajsamand district of Southern Rajasthan in India from July 2023 through January 2024, with the intervention for women spanning six months. Kumbhalgarh block was chosen by the NGO partner based on their area of operations and cultural competency to work in these areas. While block level estimates are not available, Rajsamand district lags the state's family planning indicators—only one in two women use any modern contraceptive method. Further, in Rajsamand district, female

sterilization is the dominant method adopted by women, which is a limiting family planning method, highlighting significant gaps in adoption of reversible short/long-acting contraceptive methods such as condoms, intrauterine devices, pills, among others.

The sample size was based on feasibility given this was a pilot study. The eligibility criteria for the study included: married women between the ages of 18 and 25 who had been living in their husband's home at least for the past six months, cohabiting with mother-in-law, and had been married within the last one year. Individual private consent was sought from newly married women. All participants who were approached agreed to participate but three participants did not meet eligibility criteria at baseline. A total of 45 potentially eligible households were approached and 42 newly married women (also called participants henceforth) were enrolled in the study at baseline (Figure 2). Three households could not be enrolled because two were migrants and one participant was a minor (below 18 years of age). All participants provided audio-recorded verbal informed consent before all rounds of data collection.

### 1.5 Data collection

#### *Quantitative surveys*

We collected quantitative data through close-ended surveys with participants before the launch of the intervention (baseline) and after the end of the intervention (endline). Sex matched trained enumerators conducted surveys (~60-70 minutes) using structured computer-assisted personal interviews.

#### *Qualitative data*

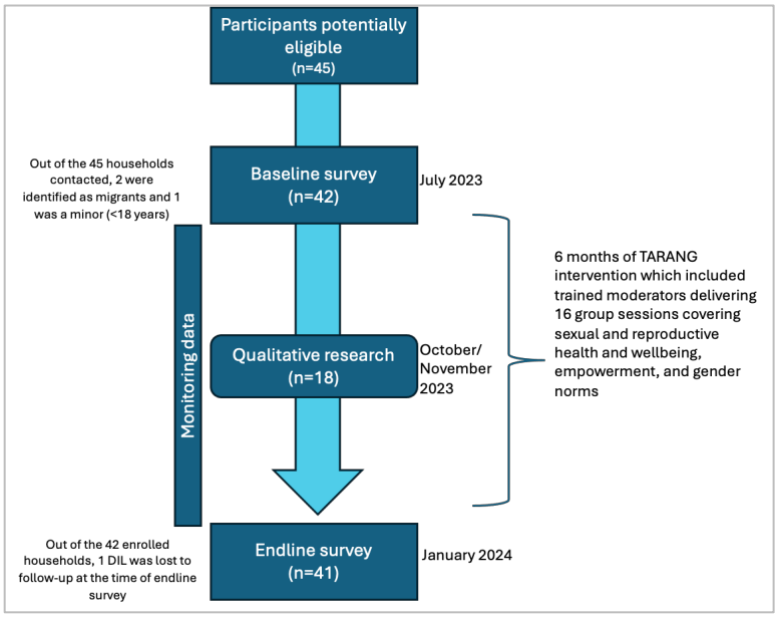
From the study participants enrolled in the study, we purposively selected 12 participants for in-depth interviews (IDIs) and 6 NGO staff implementing and managing the intervention. We attempted to interview participants who had less than 25% attendance as well as those with greater than 50% attendance to understand a diversity of perspectives and experiences. In October 2023, at the middle of the intervention period, in-depth interviews were led by UCSF personnel in participant's preferred language (Hindi), using an interview guide in a private setting at the participants' homes. We sought separate verbal consent from participants before conducting interviews. The average length of the interviews was ~35 minutes. Interviews were audio recorded and transcribed.

***Monitoring data***

Throughout the period of the intervention, we also collected monitoring data through a mobile application form that was completed after every session by moderators. The form captured the attendance and reasons for missing the intervention sessions.

The intervention timing and data collection are shown in Figure 1 below.

*Figure 2:Timeline of TARANG intervention sessions and different modes of data collection*




### *Ethical approvals*

Study protocols were reviewed and approved by institutional review boards at the University of California, San Francisco (IRB number: 22-37173), and the India-based Center for Media Studies (IRB00006230).

**Title: Impact of TARANG, a group-based life skills and health empowerment for married women to avoid unintended pregnancies in Rajasthan, India**

**TARANG pilot-statistical analysis plan**

Clinical trial registration: NCT06320964

**Quantitative measures**

Prior to initiating the TARANG pilot intervention, we established *a priori* definitions for the primary outcomes, focusing on feasibility and acceptability to allow us to provide critical information for planning a larger randomized controlled trial.

1) Feasibility (proportion of participants who attended at least 50% intervention sessions)
2) Acceptability (proportion completely satisfied/somewhat satisfied with TARANG intervention)
3) Usefulness (proportion who found TARANG intervention useful/somewhat useful)

Retention rates were defined as women enrolled at baseline through the end of the study and are presented as percentages. Quantitative data were summarized as proportions using Stata 15.

**Qualitative themes and analysis**

We analyzed in-depth interview transcripts line-by-line using a codebook. We developed a coding framework, deductively based on the interview guide, was iteratively refined with the addition of inductive codes following coding of initial transcripts. A team of three researchers initially double-coded at least 10% of the transcripts using the codebook in Dedoose version 9.0.107. We analyzed the code reports and developed themes along with illustrative quotes using a thematic analysis.

**Mixed methods integration**

We employed a convergent mixed-methods approach, with the interview guide to complement and elucidate the quantitative results.

**Title: Impact of TARANG, a group-based life skills and health empowerment for married women to avoid unintended pregnancies in Rajasthan, India**

**TARANG pilot study: Informed consent forms**

NCT06320964

Initial IRB approval: 10/02/2022 and final approval: 10/02/2023

# The impact of group-based life skills and health empowerment for young, married, women to avoid unintended pregnancies in India.

## Consent form for Participation in Qualitative Research (married women of age 18-25 years, husbands, mother-in-law)

**Introduction**:
Hello! My name is _____. I have come to your home to conduct interviews on behalf of Dr. Sumeet Patil at NEERMAN, Dr. Nadia Diamond-Smith at University of California, San Francisco, and *Vikalp Sansthan* which is an NGO serving women in rural communities. The study is funded by the United States National Institute of Health.

**Study Purpose**:
The aim of this study is to understand if providing newly married women with knowledge on reproductive health, family planning and life skills such as communication, decision-making, and leadership skills can empower women and improve contraceptive usage. We are interviewing married woman, her husband and her mother-in-law and other persons in this community.

**What are we requesting you to do?**
You are being asked to take part in these interviews because [you or your wife or your son's wife] got married recently into this village, and you/your wife/your son's wife's inputs will inform our intervention. We will conduct discussion with you on topics related to health behaviors, communication with husband, decision-making at the household, woman's mobility outside the house, questions on gender role attitudes, pregnancy, family planning, health of children, etc. This discussion will take 45-60 minutes. I will audio record this discussion and also take notes during our discussions. We will also be interviewing some community influencers like Sarpanch, ASHA worker, teacher etc.

**The benefits of participating**
By participating in this study, you will not receive any money or other direct benefits. While not a benefit or payment, in appreciation of the time you will invest in the study, we will give you a small gift during every interview round. But please remember that the information you give, and your time is much more valuable than this small gift.

**The risks and costs of participation**
You do not have any additional risk (loss) by participating in this study or interview. But you will need to invest your precious time to participate in the discussions.

Some of our questions are personal, so you may feel hesitant (shy) to answer them. You also may not want to give us some private or sensitive information. However, please note that you have right to refuse answering any questions as discussed next. But if you still feel sad or stressed by answering a few questions, we can refer you to ASHA or ANM in this village who can connect you with a counsellor.

**Data Confidentiality:**

We would like to assure you that in this interview all your information will be kept safe and confidential as follows.

- We will not audio-record your name to the extent possible. When we make notes from this recording, we will give you a fake name and a ID. The audio recorded files will be deleted once we prepare detailed notes.
- We will collect your name, address, location and phone number only to contact you again and to correct any errors in the data we collect. However, this information is available only to me, my managers and my data team, and we will not share this information with anyone else. After the study is completed, we will delete all this contact information.

- Once the formative study is completed using your information, we may use the information collected for future research studies or share it with other researchers so they can use it for other studies in the future. We will not share your name or any other personal information. We cannot guarantee that this will prevent future researchers from determining who you are. We will not ask you for additional permission to share this de-identified information.
- Authorized representatives from the U.S. National Institutes of Health, the U.S. Office of Human Research Protections (OHRP), and the University of California may review your research data to monitor or manage the conduct of the study.

**Rights as Study Participants:**
You have the following rights.

- You have the right to decide whether you want to participate in this formative study or not. I can only request you to oblige us by giving your valuable time to this important formative study.
- Even if you agree to participate in the study, you can refuse to answer any questions and even stop the interview at any time without any loss to you.

***COVID protocol:*** Each member of our research team is checked for any symptoms of COVID-19 before starting the work every day. To protect you, our research team members will maintain one meter of distance, wear a mask, and wash or sanitize hands before and after the interview. Please tell us if you have experienced any COVID-19 related symptoms today, so that we can take extra care.

**Do you have any questions about this study?**
If you have any questions related to the study which I cannot answer, then you can contact XXXXXX. If you want to go to higher authority about additional information or answers, then call XXXXXX at following.

For any information with regards to the rights of the participants in India, you may contact CMS-IRB.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. The National Clinical Trial (NCT) number for this study is not yet assigned.

**Verbal Consent**
If you want to give permission for participation in this study, then verbally say "yes". And let me record you saying "I give my consent for participation in this study

Interviewer's signature: _____ Date: _____ / _____ / _____
DAY MONTH YEAR

# The impact of group-based life skills and health empowerment for young, married, women to avoid unintended pregnancies in India.

## Consent form for Listing Survey and Recruitment of Study Participants

**Introduction**: Hello! My name is _____. I have come to your home to conduct a short survey on behalf *Vikalp Sansthan* which is an NGO serving women in rural communities.

**Study Purpose**: The aim of this survey is to assess if your household is eligible for participation in a project cum research study that will be conducted in this village by Vikalp Sansthan.

**What are we requesting you to do?**
To identify households eligible for the study, we have to contact 100-200 households in this village and conduct a short survey. We will collect information on basic socio-economic status of the household, number of people staying in the house, and presence of newly married couple or impending wedding. If the household has or will have a newly married woman aged 18-25 years, then this household may be eligible for participation in this study. In this case, I will ask additional questions to assess eligibility and recruit household in the study.

**The benefits and Risks of participating**
By participating in this short 10-minute survey, you will not receive any money or other direct benefits. You also do not have any additional risk (loss) by participating in this survey. Your data and information will be kept confidential. Your name, address, location and phone number to contact you again will be available only to me and my managers, and it will be deleted if the household is not eligible for the study or refuses participation. You have a right not to participate in this survey and give me any data.

**Verbal Consent**
Do you agree for participation in this listing survey? Yes / No

Interviewer's signature: _____ Date: _____ / _____ / _____
DAY MONTH YEAR

# The impact of group-based life skills and health empowerment for young, married, women to avoid unintended pregnancies in India.

## Consent from Husband / Mother-in-Law for Participation in the Study

**Introduction**: Hello! My name is _____. I have come to your home to conduct interviews on behalf of Dr. Sumeet Patil at NEERMAN, Dr. Nadia Diamond-Smith at University of California, San Francisco, and *Vikalp Sansthan* which is an NGO serving women in rural communities. The study is funded by the United States National Institute of Health.

**Study Purpose**: The aim of this study is to understand if providing newly married women with knowledge on reproductive health, family planning and life skills such as communication, decision-making, and leadership skills can empower women and improve family's contraceptive usage. We are conducting this study with approximated 2000 women from 80 villages in Udaipur districts.

**What are we requesting you to do?**
Since you have agreed to participation of your [wife/daughter-in-law] in this study, we would also like to recruit you as a study participant. Today, we request your time to complete an interview which will take 60 minutes of your time. In this survey, we will ask you questions about the social and economic status of your family, your plans and aspirations about career, house management and children, health and nutrition behaviors, communication and decision making within the household, services from the government, [*and your family planning needs – to be asked only to husband*].

In future, our study team will visit you 2-3 times over next two years and conduct follow-up interviews with you. Theses interviews will ask questions on family planning, your role in household activities and decision making, your knowledge on issues related to women's health, and other questions similar to the initial survey we are doing today. The follow-up interviews will take approx. 60 minutes of your time. In case you in-person survey is not possible due to your travel or other reasons, then we will conduct the follow-up interviews over phone.

**[Only in treatment villages:** A local NGO – Vikalp Sansthan – will be conducting few information and training program for you over next year on topics such as communication and decision making, relationships, leaderships, financial planning, etc. You will be requested to participate in 4-5 sessions for a period of one-year.**]**

**The benefits of participating**
By participating in this study, you will not receive any money or other direct benefits. However, your wife/daughter-in-law will be gaining knowledge or skills on how to settle into a family that may benefit the entire household. [Only in treatment villages: You will be provided skills training which can help you in decision making, time management, financial planning, communications etc which can help you in all aspects of life]

While not a benefit or payment, in appreciation of the time you will invest in the study, we will give you a small gift during every survey round; we expect to visit you five times including this time over next 2 years. But please remember that the information you give, and your time is much more valuable than this small gift.

**The risks and costs of participation**
You do not have any additional risk (loss) by participating in this study or survey. There is also no monetary cost or fees to you for participating in this study. But you will need to invest your precious time to participate in the study.

Some of our questions are personal, so you may feel hesitant (shy) to answer them. You also may not want to give us some private or sensitive information. However, please note that you have right to refuse answering any questions as discussed next. But if you still feel sad or stressed by answering a few questions, we can refer you to ASHA or ANM in this village who can connect you with a counsellor.

**Data Confidentiality:**
We would like to assure you that in this survey all your information will be kept safe and confidential as follows. The information given to us will be collected in the form of numbers only and aggregated to the entire state level. Therefore, it will be highly unlikely that anyone can trace your responses or answers back to you, and everything you tell us remains confidential. The researchers will use your information to conduct this study. Once the study is done using your information, we may use the information collected for future research studies or share it with other researchers so they can use it for other studies in the future. We will not share your name or any other personal information. We cannot guarantee that this will prevent future researchers from determining who you are. We will not ask you for additional permission to share this de-identified information.

We will collect your name, address, location and phone number to contact you again and to correct any errors in the data we collect. However, this information is available only to me, my managers and my data team, and we will not share this information with anyone else. After the study is completed, we will delete all this contact information. The survey data will remain only as numbers and will be kept secure on a computer with a password. We may keep this data for 25 years.

Authorized representatives from the U.S. National Institutes of Health, the U.S. Office of Human Research Protections (OHRP), and the University of California may review your research data to monitor or manage the conduct of the study. India based Medical Council and IRBs may also provide oversight to the study as per rules and regulation of the country.

**Rights as Study Participants:**
You have the following rights.

- You have the right to decide whether you want to participate in this study or not. I can only request you to oblige us by giving your valuable time to this important study.
- Even if you agree to participate in the study, you can refuse to answer any questions and even stop the interview at any time without any loss to you.
- You have a right to take a break during the interview and request the interviewer to come at another convenient time. However, please note that interviewers are in the village for a limited time and we will request your support in scheduling a mutually convenient time for a revisit.
- You have a right to refuse participation in the interview or survey in future rounds even if you consent for the participation in this round of interviews.

***COVID protocol:***
Each member of our survey team is checked for any symptoms of COVID-19 before starting the work every day. To protect you, our survey team members will maintain one meter of distance, wear a mask, and wash or sanitize hands before and after the interview. Please tell us if you have experienced any COVID-19 related symptoms today, so that we can take extra care.

**Do you have any questions about this study?**
If you have any questions related to the study which I cannot answer, then you can contact XXXX. If you want to go to higher authority about additional information or answers, then call XXXXX at following.

For any information with regards to the rights of the participants in India, you may contact CMS-IRB at +91-11-26851660.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. The study will be registered on Clinical Trial Registry of India (CTRI) as well.

**Verbal Consent**

If you want to give permission for participation in this study, then verbally say "yes". And let me record you saying "I give my consent for participation in this study

Interviewer's signature: _____ Date: _____ / _____ / _____

DAY MONTH YEAR

# The impact of group-based life skills and health empowerment for young, married, women to avoid unintended pregnancies in India.

## Consent form for Study Participants (married women of age 18-25 years)

**Introduction**: Hello! My name is _____. I have come to your home to conduct interviews on behalf of Dr. Sumeet Patil at NEERMAN, Dr. Nadia Diamond-Smith at University of California, San Francisco, and *Vikalp Sansthan* which is an NGO serving women in rural communities. The study is funded by the United States National Institute of Health.

**Study Purpose**: The aim of this study is to understand if providing newly married women with knowledge on reproductive health, family planning and life skills such as communication, decision-making, and leadership skills can empower women and improve contraceptive usage. We are conducting this study in 80 villages in Udaipur districts.

**What are we requesting you to do?**
You have been selected in this survey because you got married recently into this village. There will be many recently married women like you in this village, but your selection has happened through a lottery process and hence only a coincidence. If you decide to participate in this study, you will be requested to participate in the following:

(1) **Short Interview:** we request your time to complete a short questionnaire will take maximum 30 minutes of your time. In this survey, we will ask you questions about the social and economic status of your family and your pregnancy status and family planning needs. During this interview, we will request that you take a home-based urine pregnancy test to make sure you are not pregnant. If the test shows you are pregnant at this stage, you will not be able to continue in the study. Once it is confirmed that you are not expecting, we will request your participation in the next steps.

(2) **Long Interview:** Once you are found eligible to participate and consent to participating in the surveys and the study, we will invite you to participate in the longer duration (90 minutes) interviews – once at baseline and then later after 24 months at endline surveys). This interview will consist of questions on health and nutrition behaviors, communication with husband, decision-making at the household, woman's mobility outside the house, questions on gender role attitudes, pregnancy, health of children, services from the government, etc. Additionally, your height and weight will be measured. If you deliver a child during this study period, then height and length of the child will also be measured at the time of the survey including follow-up surveys or endline survey as the case maybe.

(3) **[to be read in the intervention villages] Participation in Training and Education Sessions for woman:** In your village, a local non-governmental organization (NGO) is conducting a training and education program for newly married women. The organization will provide two sessions every month for one year; a total of 24 sessions of 2-hours each to a small group of women on topics such as family planning, women empowerment, relationships, leadership, etc. You will be requested to participate in these sessions for a period of one-year.

(4) **[to be read in the control villages] Participation in Training and Education Sessions for woman:** In your village, local ASHA and Anganwadi workers may provide counselling to recently married women and pregnant women on topics such as family planning, women empowerment, relationships, leadership, etc. You are encouraged to participate in the sessions conducted by them such as *mamta diwas* or their home visits.

(5) **Follow-up surveys:** Our study team will visit you for 4 times over next two years; approximately every 6 months and conduct a follow-up interview with you. This interview will ask questions on family planning, your role in household activities and decision making, your knowledge on issues related to women's health, and other questions similar to the initial survey we are doing today. The follow-up interview will take approx. 60-70 minutes of your time. In case you in-person survey is not possible due to your travel or other reasons, then we will conduct the follow-up interviews over phone.

**The benefits of participating**

By participating in this study, you will not receive any money or other direct benefits. However, if you are given training or information by NGOs, ASHA or Anganwadi workers, then you can gain some knowledge or skills on how to settle into your new marriage, family planning, and how to feel empowered in your own life.

While not a benefit or payment, in appreciation of the time you will invest in the study, we will give you a small gift during every survey round; we expect to visit you five times including this time over next 2 years. But please remember that the information you give, and your time is much more valuable than this small gift.

**The risks and costs of participation**

You do not have any additional risk (loss) by participating in this study or survey. There is also no monetary cost or fees to you for participating in this study. But you will need to invest your precious time to participate in the surveys and to attend training / education session conducted by local non-governmental organizations, ASHA, Anganwadi workers etc.

Some of our questions are personal, so you may feel hesitant (shy) to answer them. If you have a child <24 months, then we will be measuring the weight and length of your child, and some babies may be uncomfortable during such measurements. You also may not want to give us some private or sensitive information. However, please note that you have right to refuse answering any questions as discussed next. But if you still feel sad or stressed by answering a few questions, we can refer you to ASHA or ANM in this village who can connect you with a counsellor.

Some women may be concerned whether their family will support them in participating in the surveys or attending training sessions. We have taken consent of your family members (husband and/or/ mother-in-law) Already and they have agreed to support you.

Because we request you to conduct a pregnancy test at home, there is a possibility that a small fraction of the woman find out that they are pregnant when they did not intend to. Please note that study team does not disclose any data or answers to any one so this finding will be strictly confidential. If you request us, we will provide you information on your family planning options and refer you to ANM for further services. Also, when we measure height or weight of women or children, we may find that some of them are too weak or obese. In this situation,. We will inform you of the same and refer you to the ANM or ASHA to get counselling on proper nutrition. Please note that above findings of unintended pregnancy or weakness/obesity are not because of study participation but they would have anyway happened. Participation in the study only helps you find out and manage these risks.

**Data Confidentiality:**

We would like to assure you that in this survey all your information will be kept safe and confidential as follows. The information given to us will be collected in the form of numbers only and aggregated to the entire state level. Therefore, it will be highly unlikely that anyone can trace your responses or answers back to you, and everything you tell us remains confidential. The researchers will use your information to conduct this study. Once the study is done using your information, we may use the information collected for future research studies or share it with other researchers so they can use it for other studies in the future. We will not share your name or any other personal information. We cannot guarantee that this will prevent future researchers from determining who you are. We will not ask you for additional permission to share this de-identified information.

We will collect your name, address, location and phone number to contact you again and to correct any errors in the data we collect. However, this information is available only to me, my managers and my data team, and we will not share this information with anyone else. After the study is completed, we will delete all this contact information. The survey data will remain only as numbers and will be kept secure on a computer with a password. We may keep this data for 25 years.

Authorized representatives from the U.S. National Institutes of Health, the U.S. Office of Human Research Protections (OHRP), and the University of California may review your research data to monitor or manage the conduct of the study. India based Medical Council and IRBs may also provide oversight to the study as per rules and regulation of the country.

**Rights as Study Participants:**
You have the following rights.

- You have the right to decide whether you want to participate in this study or not. I can only request you to oblige us by giving your valuable time to this important study.
- Even if you agree to participate in the study, you can refuse to answer any questions and even stop the interview at any time without any loss to you. For example, even if you refuse answers to any questions, you can still access training and education sessions by the NGOs.
- You have a right to take a break during the interview and request the interviewer to come at another convenient time. However, please note that interviewers are in the village for a limited time and we will request your support in scheduling a mutually convenient time for a revisit.
- Even if you have agreed to participate in the sessions by local NGO, you cannot be compelled to attend these. You have a right to discontinue the training or not attend any sessions or leave half-way. However, not completing or attending the trainings can compromise the extent of knowledge or skills you could gain.
- You have a right to refuse participation in the interview or survey in future rounds even if you consent for the participation in this round of interviews.

***COVID protocol:***

Each member of our survey team is checked for any symptoms of COVID-19 before starting the work every day. To protect you, our survey team members will maintain one meter of distance, wear a mask, and wash or sanitize hands before and after the interview. Please tell us if you have experienced any COVID-19 related symptoms today, so that we can take extra care.

**Do you have any questions about this study?**
If you have any questions related to the study which I cannot answer, then you can contact XXXX. If you want to go to higher authority about additional information or answers, then call XXXXX at following.

For any information with regards to the rights of the participants in India, you may contact CMS-IRB at +91-11-26851660.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. The study will be registered on Clinical Trial Registry of India (CTRI) as well.

**Verbal Consent**

If you want to give permission for participation in this study, then verbally say "yes". And let me record you saying "I give my consent for participation in this study

Interviewer's signature: _____ Date: _____ / _____ / _____

DAY MONTH YEAR

# The impact of group-based life skills and health empowerment for young, married, women to avoid unintended pregnancies in India.

## Consent form for Participation in Qualitative Research (married women of age 18-25 years, husbands, mother-in-law)

**Introduction**:
Hello! My name is _____. I have come to your home to conduct interviews on behalf of Dr. Sumeet Patil at NEERMAN, Dr. Nadia Diamond-Smith at University of California, San Francisco, and *Vikalp Sansthan* which is an NGO serving women in rural communities. The study is funded by the United States National Institute of Health.

**Study Purpose**:
The aim of this study is to understand if providing newly married women with knowledge on reproductive health, family planning and life skills such as communication, decision-making, and leadership skills can empower women and improve contraceptive usage. We are interviewing 10 sets of a married woman, her husband and her mother-in-law in this study to collect information through discussions.

**What are we requesting you to do?**
We will conduct these interviews only if all three of you agree to participate in the interviews (you're your son, your wife, and your mother-in-law). We will conduct discussion with you on topics related to health and nutrition behaviors, communication with husband, decision-making at the household, woman's mobility outside the house, questions on gender role attitudes, pregnancy, family planning, health of children, services from the government, etc. I will audio record this discussion and also take notes during our discussions. [Read only for the first round: Over the next two years, I will contact you three times for similar interviews].

Please note that I am also interviewing your [husband/mother-in-law/wife/daughter-in-law] along with you because I want to get information from all three of you.

**The benefits of participating**
By participating in this study, you will not receive any money or other direct benefits. While not a benefit or payment, in appreciation of the time you will invest in the study, we will give you a small gift during every interview round. But please remember that the information you give, and your time is much more valuable than this small gift.

**The risks and costs of participation**
You do not have any additional risk (loss) by participating in this study or interview. But you will need to invest your precious time to participate in the discussions.

Some of our questions are personal, so you may feel hesitant (shy) to answer them. You also may not want to give us some private or sensitive information. However, please note that you have right to refuse answering any questions as discussed next. But if you still feel sad or stressed by answering a few questions, we can refer you to ASHA or ANM in this village who can connect you with a counsellor.

**Data Confidentiality:**

We would like to assure you that in this interview all your information will be kept safe and confidential as follows.

- We will not audio-record your name to the extent possible. When we make notes from this recording, we will give you a fake name and a ID. The audio recorded files will be deleted once we prepare detailed notes.
- We will collect your name, address, location and phone number only to contact you again and to correct any errors in the data we collect. However, this information is available only to me, my managers and my

data team, and we will not share this information with anyone else. After the study is completed, we will delete all this contact information.

- Once the study is done using your information, we may use the information collected for future research studies or share it with other researchers so they can use it for other studies in the future. We will not share your name or any other personal information. We cannot guarantee that this will prevent future researchers from determining who you are. We will not ask you for additional permission to share this de-identified information.
- Authorized representatives from the U.S. National Institutes of Health, the U.S. Office of Human Research Protections (OHRP), and the University of California may review your research data to monitor or manage the conduct of the study. India based Medical Council and IRBs may also provide oversight to the study as per rules and regulation of the country.
- Please note that even though we are interviewing all three of you, none of the information any of you share will be shared with others in this household.

**Rights as Study Participants:**

You have the following rights.

- You have the right to decide whether you want to participate in this study or not. I can only request you to oblige us by giving your valuable time to this important study.
- Even if you agree to participate in the study, you can refuse to answer any questions and even stop the interview at any time without any loss to you.

***COVID protocol:*** Each member of our research team is checked for any symptoms of COVID-19 before starting the work every day. To protect you, our research team members will maintain one meter of distance, wear a mask, and wash or sanitize hands before and after the interview. Please tell us if you have experienced any COVID-19 related symptoms today, so that we can take extra care.

**Do you have any questions about this study?**
If you have any questions related to the study which I cannot answer, then you can contact XXX

For any information with regards to the rights of the participants in India, you may contact CMS-IRB at +91-11-26851660.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. The study will be registered on Clinical Trial Registry of India (CTRI) as well.

**Verbal Consent**
If you want to give permission for participation in this study, then answer "yes". And let me record you saying “I give my consent for participation in this study

Interviewer’s signature: _____ Date: _____ / _____ / _____

# The impact of group-based life skills and health empowerment for young, married, women to avoid unintended pregnancies in India.

## Consent from Husband / Mother-in-Law/Father-in-law for Participation in the Follow-Up Quantitative Survey

**Introduction**: Hello! My name is _____. I have come to your home to conduct interviews on behalf of Dr. Sumeet Patil at NEERMAN, Dr. Nadia Diamond-Smith at University of California, San Francisco, and *Vikalp Sansthan* which is an NGO serving women in rural communities. The study is funded by the United States National Institute of Health.

**Study Purpose**: We had already contacted you regarding this study approx. XX months ago. As you may recall, the aim of this study is to understand if providing newly married women with knowledge on reproductive health, family planning and life skills such as communication, decision-making, and leadership skills can empower women and improve family's contraceptive usage. We are conducting this study with approximated 2000 women from 80 villages in Udaipur districts.

**What are we requesting you to do?**
Today, we request your time to complete a follow-up interview which will take 60 minutes of your time. In this survey, we will ask you questions about your interaction with government or Vikalp Sansthan community workers, your interactions with your [WIFE/daughter-in-Law], recent health and nutrition related decisions and practices, , your knowledge related to women's health, [*and your family planning needs – to be asked only to husband*].

**The benefits of participating**
By participating in this study, you will not receive any money or other direct benefits. [Only in treatment villages: However, you are invited to participate in the training sessions conducted by Vikalp Sansthan which can help you in decision making, time management, financial planning, communications etc]

While not a benefit or payment, in appreciation of the time you will invest in the study, we will give you a small gift. But please remember that the information you give, and your time is much more valuable than this small gift.

**The risks and costs of participation**
You do not have any additional risk (loss) by participating in this survey. There is also no monetary cost or fees to you for participating in this survey..

Some of our questions are personal, so you may feel hesitant (shy) to answer them. You also may not want to give us some private or sensitive information. However, please note that you have right to refuse answering any questions as discussed next. But if you still feel sad or stressed by answering a few questions, we can refer you to ASHA or ANM in this village who can connect you with a counsellor.

**Data Confidentiality:**
We would like to assure you that in this survey all your information will be kept safe and confidential as follows. The information given to us will be collected in the form of numbers only and aggregated to the entire state level. Therefore, it will be highly unlikely that anyone can trace your responses or answers back to you, and everything you tell us remains confidential. The researchers will use your information to conduct this study. Once the study is done using your information, we may use the information collected for future research studies or share it with other researchers so they can use it for other studies in the future. We will not share your name or any other personal information. We cannot guarantee that this will prevent future researchers from determining who you are. We will not ask you for additional permission to share this de-identified information.

We will confirm your name, address, location and phone number to correct any errors in the data we collect. However, this information is available only to me, my managers and my data team, and we will not share this information with anyone else. After the study is completed, we will delete all this contact information. The survey data will remain only as numbers and will be kept secure on a computer with a password. We may keep this data for 25 years.

Authorized representatives from the U.S. National Institutes of Health, the U.S. Office of Human Research Protections (OHRP), and the University of California may review your research data to monitor or manage the conduct of the study. India based Medical Council and IRBs may also provide oversight to the study as per rules and regulation of the country.

**Rights as Study Participants:**
You have the following rights.

- You have the right to decide whether you want to participate in this study or not. I can only request you to oblige us by giving your valuable time to this important study.
- Even if you agree to participate in the study, you can refuse to answer any questions and even stop the interview at any time without any loss to you.
- You have a right to take a break during the interview and request the interviewer to come at another convenient time. However, please note that interviewers are in the village for a limited time and we will request your support in scheduling a mutually convenient time for a revisit.
- You have a right to refuse participation in the interview or survey in future rounds even if you consent for the participation in this round of interviews.

***COVID protocol:***
Each member of our survey team is checked for any symptoms of COVID-19 before starting the work every day. To protect you, our survey team members will maintain one meter of distance, wear a mask, and wash or sanitize hands before and after the interview. Please tell us if you have experienced any COVID-19 related symptoms today, so that we can take extra care.

**Do you have any questions about this study?**
If you have any questions related to the study which I cannot answer, then you can contact XXXXX. If you want to go to higher authority about additional information or answers, then call XXXX at following.

For any information with regards to the rights of the participants in India, you may contact CMS-IRB at +91-11-26851660.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. The study will be registered on Clinical Trial Registry of India (CTRI) as well.

**Verbal Consent**
If you want to give permission for participation in this survey, then verbally say "yes". And let me record you saying “I give my consent for participation in this survey”

Interviewer's signature: _____ Date: _____ / _____ / _____
DAY MONTH YEAR

# The impact of group-based life skills and health empowerment for young, married, women to avoid unintended pregnancies in India.

## Consent form for Study Participants (married women of age 18-25 years) for follow-up quantitative survey

**Introduction**: Hello! My name is _____. I have come to your home to conduct interviews on behalf of Dr. Sumeet Patil at NEERMAN, Dr. Nadia Diamond-Smith at University of California, San Francisco, and *Vikalp Sansthan* which is an NGO serving women in rural communities. The study is funded by the United States National Institute of Health.

**Study Purpose**: We had already contacted you regarding this study approx. XX months ago. As you may recall, the aim of this study is to understand if providing newly married women with knowledge on reproductive health, family planning and life skills such as communication, decision-making, and leadership skills can empower women and improve contraceptive usage. We are conducting this study in 80 villages in Udaipur districts.

**What are we requesting you to do?**
Today, we request your time to complete a follow-up interview which will take 60 minutes of your time. This interview will ask questions on family planning, your role in household activities and decision making, your knowledge on issues related to women's health, [Only in treatment villages: your participation in trainings organized by Vikalp Sansthan], and other questions.

**The benefits of participating**
By participating in this study, you will not receive any money or other direct benefits. While not a benefit or payment, in appreciation of the time you will invest in the study, we will give you a small gift. But please remember that the information you give, and your time is much more valuable than this small gift.

**The risks and costs of participation**
You do not have any additional risk (loss) by participating in this survey. There is also no monetary cost or fees to you for participating in this survey.

Some of our questions are personal, so you may feel hesitant (shy) to answer them. If you have a child <24 months, then we will be measuring the weight and length of your child, and some babies may be uncomfortable during such measurements. You also may not want to give us some private or sensitive information. However, please note that you have right to refuse answering any questions as discussed next. But if you still feel sad or stressed by answering a few questions, we can refer you to ASHA or ANM in this village who can connect you with a counsellor.

**Data Confidentiality:**
We would like to assure you that in this survey all your information will be kept safe and confidential as follows. The information given to us will be collected in the form of numbers only and aggregated to the entire state level. Therefore, it will be highly unlikely that anyone can trace your responses or answers back to you, and everything you tell us remains confidential. The researchers will use your information to conduct this study. Once the study is done using your information, we may use the information collected for future research studies or share it with other researchers so they can use it for other studies in the future. We will not share your name or any other personal information. We cannot guarantee that this will prevent future researchers from determining who you are. We will not ask you for additional permission to share this de-identified information.

We will confirm your name, address, location and phone number to correct any errors in the data we collect. However, this information is available only to me, my managers and my data team, and we will not share this information with anyone else. After the study is completed, we will delete all this contact information. The survey

data will remain only as numbers and will be kept secure on a computer with a password. We may keep this data for 25 years.

Authorized representatives from the U.S. National Institutes of Health, the U.S. Office of Human Research Protections (OHRP), and the University of California may review your research data to monitor or manage the conduct of the study. India based Medical Council and IRBs may also provide oversight to the study as per rules and regulation of the country.

**Rights as Study Participants:**
You have the following rights.

- You have the right to decide whether you want to participate in this study or not. I can only request you to oblige us by giving your valuable time to this important study.
- Even if you agree to participate in the study, you can refuse to answer any questions and even stop the interview at any time without any loss to you. For example, even if you refuse answers to any questions, you can still access training and education sessions by the NGOs.
- You have a right to take a break during the interview and request the interviewer to come at another convenient time. However, please note that interviewers are in the village for a limited time and we will request your support in scheduling a mutually convenient time for a revisit.
- Even if you have agreed to participate in the sessions by local NGO, you cannot be compelled to attend these. You have a right to discontinue the training or not attend any sessions or leave half-way. However, not completing or attending the trainings can compromise the extent of knowledge or skills you could gain.
- You have a right to refuse participation in the interview or survey in future rounds even if you consent for the participation in this round of interviews.

***COVID protocol:***

Each member of our survey team is checked for any symptoms of COVID-19 before starting the work every day. To protect you, our survey team members will maintain one meter of distance, wear a mask, and wash or sanitize hands before and after the interview. Please tell us if you have experienced any COVID-19 related symptoms today, so that we can take extra care.

**Do you have any questions about this study?**
If you have any questions related to the study which I cannot answer, then you can contact XXXX. If you want to go to higher authority about additional information or answers, then call Dr. Sumeet Patil at following.

For any information with regards to the rights of the participants in India, you may contact CMS-IRB at +91-11-26851660.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. The study will be registered on Clinical Trial Registry of India (CTRI) as well.

**Verbal Consent**

If you want to give permission for participation in this study, then verbally say "yes". And let me record you saying "I give my consent for participation in this survey".

Interviewer's signature: _____ Date: _____ / _____ / _____
DAY MONTH YEAR

# The impact of group-based life skills and health empowerment for young, married, women to avoid unintended pregnancies in India.

## Consent form for Study Participants (married women of age 18-25 years)/ Consent from Husband / Mother-in-Law for Participation in the Follow-Up Quantitative Survey

**Introduction**: Hello! My name is _____. I have come to your home to conduct interviews on behalf of Dr. Sumeet Patil at NEERMAN, Dr. Nadia Diamond-Smith at University of California, San Francisco, and *Vikalp Sansthan* which is an NGO serving women in rural communities. The study is funded by the United States National Institute of Health.

**Study Purpose**: We had already contacted you regarding this study approx. XX months ago. As you may recall, the aim of this study is to understand if providing newly married women with knowledge on reproductive health, family planning and life skills such as communication, decision-making, and leadership skills can empower women and improve contraceptive usage. We are conducting this study in 80 villages in Udaipur districts.

**What are we requesting you to do?**
Today, we request your time to complete a follow-up interview which will take 60 minutes of your time. This interview will ask questions on family planning, your role in household activities and decision making, your knowledge on issues related to women's health, [Only in treatment villages: your participation in trainings organized by Vikalp Sansthan], and other questions.

**The benefits of participating**
By participating in this study, you will not receive any money or other direct benefits. While not a benefit or payment, in appreciation of the time you will invest in the study, we will give you a small gift. But please remember that the information you give, and your time is much more valuable than this small gift.

**The risks and costs of participation**
You do not have any additional risk (loss) by participating in this survey. There is also no monetary cost or fees to you for participating in this survey.

Some of our questions are personal, so you may feel hesitant (shy) to answer them. If you have a child <24 months, then we will be measuring the weight and length of your child, and some babies may be uncomfortable during such measurements. You also may not want to give us some private or sensitive information. However, please note that you have right to refuse answering any questions as discussed next. But if you still feel sad or stressed by answering a few questions, we can refer you to ASHA or ANM in this village who can connect you with a counsellor.

**Data Confidentiality:**
We would like to assure you that in this survey all your information will be kept safe and confidential as follows. The information given to us will be collected in the form of numbers only and aggregated to the entire state level. Therefore, it will be highly unlikely that anyone can trace your responses or answers back to you, and everything you tell us remains confidential. The researchers will use your information to conduct this study. Once the study is done using your information, we may use the information collected for future research studies or share it with other researchers so they can use it for other studies in the future. We will not share your name or any other personal information. We cannot guarantee that this will prevent future researchers from determining who you are. We will not ask you for additional permission to share this de-identified information.

We will confirm your name, address, location and phone number to correct any errors in the data we collect. However, this information is available only to me, my managers and my data team, and we will not share this information with anyone else. After the study is completed, we will delete all this contact information. The survey

data will remain only as numbers and will be kept secure on a computer with a password. We may keep this data for 25 years.

Authorized representatives from the U.S. National Institutes of Health, the U.S. Office of Human Research Protections (OHRP), and the University of California may review your research data to monitor or manage the conduct of the study. India based Medical Council and IRBs may also provide oversight to the study as per rules and regulation of the country.

**Rights as Study Participants:**
You have the following rights.

- You have the right to decide whether you want to participate in this study or not. I can only request you to oblige us by giving your valuable time to this important study.
- Even if you agree to participate in the study, you can refuse to answer any questions and even stop the interview at any time without any loss to you. For example, even if you refuse answers to any questions, you can still access training and education sessions by the NGOs.
- You have a right to take a break during the interview and request the interviewer to come at another convenient time. However, please note that interviewers are in the village for a limited time and we will request your support in scheduling a mutually convenient time for a revisit.
- Even if you have agreed to participate in the sessions by local NGO, you cannot be compelled to attend these. You have a right to discontinue the training or not attend any sessions or leave half-way. However, not completing or attending the trainings can compromise the extent of knowledge or skills you could gain.
- You have a right to refuse participation in the interview or survey in future rounds even if you consent for the participation in this round of interviews.

***COVID protocol:***

Each member of our survey team is checked for any symptoms of COVID-19 before starting the work every day. To protect you, our survey team members will maintain one meter of distance, wear a mask, and wash or sanitize hands before and after the interview. Please tell us if you have experienced any COVID-19 related symptoms today, so that we can take extra care.

**Do you have any questions about this study?**
If you have any questions related to the study which I cannot answer, then you can contact XXXX. If you want to go to higher authority about additional information or answers, then call XXXX at following.

For any information with regards to the rights of the participants in India, you may contact CMS-IRB at +91-11-26851660.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. The study will be registered on Clinical Trial Registry of India (CTRI) as well.

**Verbal Consent**

If you want to give permission for participation in this study, then verbally say "yes". And let me record you saying "I give my consent for participation in this survey".

Interviewer's signature: _____ Date: _____ / _____ / _____
DAY MONTH YEAR

# The impact of group-based life skills and health empowerment for young, married, women to avoid unintended pregnancies in India.

## Consent form for Study Participants (married women of age 18-25 years)/ Consent from Husband / Mother-in-Law for Participation in the Study [TO BE USED FOR QUANTITATIVE BASELINE SURVEY]

**Introduction**: Hello! My name is _____. I have come to your home to conduct interviews on behalf of Dr. Sumeet Patil at NEERMAN, Dr. Nadia Diamond-Smith at University of California, San Francisco, and *Vikalp Sansthan* which is an NGO serving women in rural communities. The study is funded by the United States National Institute of Health.

**Study Purpose**: The aim of this study is to understand if providing newly married women with knowledge on reproductive health, family planning and life skills such as communication, decision-making, and leadership skills can empower women and improve contraceptive usage. We are conducting this study in 80 villages in Udaipur districts.

**What are we requesting you to do?**
You have been selected in this survey because you got married recently into this village. There will be many recently married women like you in this village, but your selection has happened through a lottery process and hence only a coincidence. If you decide to participate in this study, you will be requested to participate in the following:

(1) **Short Interview:** we request your time to complete a short questionnaire will take maximum 30 minutes of your time. In this survey, we will ask you questions about the social and economic status of your family and your pregnancy status and family planning needs. During this interview, we will request that you take a home-based urine pregnancy test to make sure you are not pregnant. If the test shows you are pregnant at this stage, you will not be able to continue in the study. Once it is confirmed that you are not expecting, we will request your participation in the next steps.

(2) **Long Interview:** Once you are found eligible to participate and consent to participating in the surveys and the study, we will invite you to participate in the longer duration (90 minutes) interviews – once at baseline and then later after 24 months at endline surveys). This interview will consist of questions on health and nutrition behaviors, communication with husband, decision-making at the household, woman's mobility outside the house, questions on gender role attitudes, pregnancy, health of children, services from the government, etc. Additionally, your height and weight will be measured. If you deliver a child during this study period, then height and length of the child will also be measured at the time of the survey including follow-up surveys or endline survey as the case maybe.

(3) **[to be read in the intervention villages] Participation in Training and Education Sessions for woman:** In your village, a local non-governmental organization (NGO) is conducting a training and education program for newly married women. The organization will provide two sessions every month for one year; a total of 24 sessions of 2-hours each to a small group of women on topics such as family planning, women empowerment, relationships, leadership, etc. You will be requested to participate in these sessions for a period of one-year. [**For husband and MIL**: You will be requested to participate in 4-5 sessions for a period of one-year].

(4) **[to be read in the control villages] Participation in Training and Education Sessions for woman:** In your village, local ASHA and Anganwadi workers may provide counselling to recently married women and pregnant women on topics such as family planning, women empowerment, relationships, leadership, etc. You are encouraged to participate in the sessions conducted by them such as *mamta diwas* or their home visits.

(5) **Follow-up surveys:** Our study team will visit you for 4 times over next two years; approximately every 6 months and conduct a follow-up interview with you. This interview will ask questions on family planning, your role in household activities and decision making, your knowledge on issues related to women's health, and other questions similar to the initial survey we are doing today. The follow-up interview will take approx. 60-70 minutes of your time. In case you in-person survey is not possible due to your travel or other reasons, then we will conduct the follow-up interviews over phone.

**The benefits of participating**

By participating in this study, you will not receive any money or other direct benefits. However, if you are given training or information by NGOs, ASHA or Anganwadi workers, then you can gain some knowledge or skills on how to settle into your new marriage, family planning, and how to feel empowered in your own life.

While not a benefit or payment, in appreciation of the time you will invest in the study, we will give you a small gift during every survey round; we expect to visit you five times including this time over next 2 years. But please remember that the information you give, and your time is much more valuable than this small gift.

**The risks and costs of participation**

You do not have any additional risk (loss) by participating in this study or survey. There is also no monetary cost or fees to you for participating in this study. But you will need to invest your precious time to participate in the surveys and to attend training / education session conducted by local non-governmental organizations, ASHA, Anganwadi workers etc.

Some of our questions are personal, so you may feel hesitant (shy) to answer them. If you have a child <24 months, then we will be measuring the weight and length of your child, and some babies may be uncomfortable during such measurements. You also may not want to give us some private or sensitive information. However, please note that you have right to refuse answering any questions as discussed next. But if you still feel sad or stressed by answering a few questions, we can refer you to ASHA or ANM in this village who can connect you with a counsellor.

Some women may be concerned whether their family will support them in participating in the surveys or attending training sessions. We have taken consent of your family members (husband and/or/ mother-in-law) Already and they have agreed to support you.

Because we request you to conduct a pregnancy test at home, there is a possibility that a small fraction of the woman find out that they are pregnant when they did not intend to. Please note that study team does not disclose any data or answers to any one so this finding will be strictly confidential. If you request us, we will provide you information on your family planning options and refer you to ANM for further services. Also, when we measure height or weight of women or children, we may find that some of them are too weak or obese. In this situation,. We will inform you of the same and refer you to the ANM or ASHA to get counselling on proper nutrition. Please note that above findings of unintended pregnancy or weakness/obesity are not because of study participation but they would have anyway happened. Participation in the study only helps you find out and manage these risks.

**Data Confidentiality:**

We would like to assure you that in this survey all your information will be kept safe and confidential as follows. The information given to us will be collected in the form of numbers only and aggregated to the entire state level. Therefore, it will be highly unlikely that anyone can trace your responses or answers back to you, and everything you tell us remains confidential. The researchers will use your information to conduct this study. Once the study is done using your information, we may use the information collected for future research studies or share it with other researchers so they can use it for other studies in the future. We will not share your name or any other personal information. We cannot guarantee that this will prevent future researchers from determining who you are. We will not ask you for additional permission to share this de-identified information.

We will collect your name, address, location and phone number to contact you again and to correct any errors in the data we collect. However, this information is available only to me, my managers and my data team, and we will not share this information with anyone else. After the study is completed, we will delete all this contact information. The survey data will remain only as numbers and will be kept secure on a computer with a password. We may keep this data for 25 years.

Authorized representatives from the U.S. National Institutes of Health, the U.S. Office of Human Research Protections (OHRP), and the University of California may review your research data to monitor or manage the conduct of the study. India based Medical Council and IRBs may also provide oversight to the study as per rules and regulation of the country.

**Rights as Study Participants:**
You have the following rights.

- You have the right to decide whether you want to participate in this study or not. I can only request you to oblige us by giving your valuable time to this important study.
- Even if you agree to participate in the study, you can refuse to answer any questions and even stop the interview at any time without any loss to you. For example, even if you refuse answers to any questions, you can still access training and education sessions by the NGOs.
- You have a right to take a break during the interview and request the interviewer to come at another convenient time. However, please note that interviewers are in the village for a limited time and we will request your support in scheduling a mutually convenient time for a revisit.
- Even if you have agreed to participate in the sessions by local NGO, you cannot be compelled to attend these. You have a right to discontinue the training or not attend any sessions or leave half-way. However, not completing or attending the trainings can compromise the extent of knowledge or skills you could gain.
- You have a right to refuse participation in the interview or survey in future rounds even if you consent for the participation in this round of interviews.

***COVID protocol:***

Each member of our survey team is checked for any symptoms of COVID-19 before starting the work every day. To protect you, our survey team members will maintain one meter of distance, wear a mask, and wash or sanitize hands before and after the interview. Please tell us if you have experienced any COVID-19 related symptoms today, so that we can take extra care.

**Do you have any questions about this study?**
If you have any questions related to the study which I cannot answer, then you can contact XXXX. If you want to go to higher authority about additional information or answers, then call XXXX at following.

For any information with regards to the rights of the participants in India, you may contact CMS-IRB at +91-11-26851660.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. The study will be registered on Clinical Trial Registry of India (CTRI) as well.

**Verbal Consent**

If you want to give permission for participation in this study, then verbally say "yes". And let me record you saying "I give my consent for participation in this study

Interviewer's signature: _____ Date: _____ / _____ / _____

DAY MONTH YEAR

# The impact of group-based life skills and health empowerment for young, married, women to avoid unintended pregnancies in India.

## Consent form for Participation in Qualitative Research (married women of age 18-25 years, husbands, mother-in-law)

**Introduction**:
Hello! My name is _____. I have come to your home to conduct interviews on behalf of Dr. Sumeet Patil at NEERMAN, Dr. Nadia Diamond-Smith at University of California, San Francisco, and *Vikalp Sansthan* which is an NGO serving women in rural communities. The study is funded by the United States National Institute of Health.

**Study Purpose**:
The aim of this study is to understand if providing newly married women with knowledge on reproductive health, family planning and life skills such as communication, decision-making, and leadership skills can empower women and improve contraceptive usage. We are interviewing 10 sets of a married woman, her husband and her mother-in-law in this study to collect information through discussions.

**What are we requesting you to do?**
We will conduct these interviews only if all three of you agree to participate in the interviews (you're your son, your wife, and your mother-in-law). We will conduct discussion with you on topics related to health and nutrition behaviors, communication with husband, decision-making at the household, woman's mobility outside the house, questions on gender role attitudes, pregnancy, family planning, health of children, services from the government, etc. I will audio record this discussion and also take notes during our discussions. [Read only for the first round: Over the next two years, I will contact you three times for similar interviews].

Please note that I am also interviewing your [husband/mother-in-law/wife/daughter-in-law] along with you because I want to get information from all three of you.

**The benefits of participating**
By participating in this study, you will not receive any money or other direct benefits. While not a benefit or payment, in appreciation of the time you will invest in the study, we will give you a small gift during every interview round. But please remember that the information you give, and your time is much more valuable than this small gift.

**The risks and costs of participation**
You do not have any additional risk (loss) by participating in this study or interview. But you will need to invest your precious time to participate in the discussions.

Some of our questions are personal, so you may feel hesitant (shy) to answer them. You also may not want to give us some private or sensitive information. However, please note that you have right to refuse answering any questions as discussed next. But if you still feel sad or stressed by answering a few questions, we can refer you to ASHA or ANM in this village who can connect you with a counsellor.

**Data Confidentiality:**

We would like to assure you that in this interview all your information will be kept safe and confidential as follows.

- We will not audio-record your name to the extent possible. When we make notes from this recording, we will give you a fake name and a ID. The audio recorded files will be deleted once we prepare detailed notes.
- We will collect your name, address, location and phone number only to contact you again and to correct any errors in the data we collect. However, this information is available only to me, my managers and my

data team, and we will not share this information with anyone else. After the study is completed, we will delete all this contact information.

- Once the study is done using your information, we may use the information collected for future research studies or share it with other researchers so they can use it for other studies in the future. We will not share your name or any other personal information. We cannot guarantee that this will prevent future researchers from determining who you are. We will not ask you for additional permission to share this de-identified information.
- Authorized representatives from the U.S. National Institutes of Health, the U.S. Office of Human Research Protections (OHRP), and the University of California may review your research data to monitor or manage the conduct of the study. India based Medical Council and IRBs may also provide oversight to the study as per rules and regulation of the country.
- Please note that even though we are interviewing all three of you, none of the information any of you share will be shared with others in this household.

**Rights as Study Participants:**

You have the following rights.

- You have the right to decide whether you want to participate in this study or not. I can only request you to oblige us by giving your valuable time to this important study.
- Even if you agree to participate in the study, you can refuse to answer any questions and even stop the interview at any time without any loss to you.

***COVID protocol:*** Each member of our research team is checked for any symptoms of COVID-19 before starting the work every day. To protect you, our research team members will maintain one meter of distance, wear a mask, and wash or sanitize hands before and after the interview. Please tell us if you have experienced any COVID-19 related symptoms today, so that we can take extra care.

**Do you have any questions about this study?**
If you have any questions related to the study which I cannot answer, then you can contact XXXX.
For any information with regards to the rights of the participants in India, you may contact CMS-IRB at +91-11-26851660.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. The study will be registered on Clinical Trial Registry of India (CTRI) as well.

**Verbal Consent**
If you want to give permission for participation in this study, then answer "yes". And let me record you saying “I give my consent for participation in this study

Interviewer’s signature: _____ Date: _____ / _____ /