## Title

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## Journal

BMJ Open, 14(4)

## ISSN

2044-6055

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## Publication Date

2024-04-01

## DOI

10.1136/bmjopen-2024-086778

Peer reviewed

BMJ Open

# Life skills and reproductive health empowerment intervention for newly married women and their families to reduce unintended pregnancy in India: protocol for the TARANG cluster randomised controlled trial

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**To cite:** Diamond-Smith N, Gopalakrishnan L, Leslie H, *et al*. Life skills and reproductive health empowerment intervention for newly married women and their families to reduce unintended pregnancy in India: protocol for the TARANG cluster randomised controlled trial. *BMJ Open* 2024;**14**:e086778. doi:10.1136/bmjopen-2024-086778

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (https://doi.org/10.1136/bmjopen-2024-086778).

Received 22 March 2024
Accepted 12 April 2024



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## ABSTRACT

**Introduction** In South Asia, younger women have high rates of unmet need for family planning and low empowerment. Life skills interventions can equip young women with agency, but the effectiveness of these interventions in reproductive and sexual autonomy and contraception has not been examined.

**Methods and analysis** A two-arm, parallel, cluster randomised controlled trial will evaluate the impact of TARANG (Transforming Actions for Reaching and Nurturing Gender Equity and Empowerment), a life skills and reproductive health empowerment group-based intervention for newly married women, compared with usual services in the community in rural and tribal Rajasthan, India. TARANG will also provide light-touch sessions to husbands and mothers-in-law of newly married women. We will test the impact of TARANG in 80 village clusters among 800 eligible households comprising newly married women aged 18–25 years who are at risk of pregnancy but do not want a pregnancy within 1 year at the time of enrolment, their husbands and mothers-in-law who consent to participate. Women in the intervention villages will receive 14 sessions over a 6-month period, while husbands and mothers-in-law will receive 1 and 4 sessions (respectively) each. Three rounds of surveys will be collected over 18 months. Control villages will receive the intervention after the endline surveys. Primary outcomes include rate of unintended pregnancy and modern contraceptive use. We plan to start recruitment of participants and data collection in April 2024. We will estimate unadjusted and adjusted intention-to-treat effects using survival analysis and mixed models.

**Ethics and dissemination** Study protocols have been reviewed and approved by the human subjects review boards at the University of California, San Francisco, and the Centre for Media Studies, India (IRB00006230) and ACE Independent Ethics Committee, Bangalore (NET0062022). Results will be disseminated in international peer-reviewed journals and conferences, to stakeholders including local government and non-governmental organisations, and directly to the communities and individuals that participated in the intervention.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study will use a cluster randomised controlled design to test the impact of a group empowerment and reproductive health intervention on young women's ability to time their pregnancies, adding to the evidence on the impact of empowerment interventions on measurable health outcomes.
⇒ This intervention is novel in that it engages newly married husbands and mothers-in-laws, as well as newly married women, providing evidence on successful approaches to engage other household members.
⇒ The study follows women longitudinally for 18 months to collect data on the longer-term impact of the intervention on pregnancy.
⇒ This study is limited in that it will be implemented in two districts of one state in India, reducing generalisability.

**Trial registration number** NCT06024616.

## INTRODUCTION

Despite significant progress, maternal and infant mortality and morbidity remain stubbornly high in South Asia.[1] In India, a host of gendered risk factors, such as low women autonomy, early age at marriage, pressure to prove fertility early in marriage and preference for a male child, contribute to adverse maternal and neonatal health outcomes, including lower levels of perinatal care utilisation and preterm birth, low birth weight, neonatal complications and infant death, as well as maternal complications and mortality.[2–9] These gendered risk factors also have long-term impact on women's health and human capital development and

empowerment, such as schooling and labour force participation.[10 11] One pathway through which women's status in society impacts health outcomes is unintended pregnancy, where women are less able to negotiate for, obtain or use family planning to time and plan their births. Previous evidence has found that women who have an unintended pregnancy are more likely to receive inadequate prenatal care, deliver without a skilled birth attendant, and have children with fewer childhood vaccinations and increased risk of neonatal and infant mortality.[12 13]

About 58% of women under age 25 in India were married before age 18, and 68% of women under 25 had given birth by age 20.[14] Childbearing begins soon after marriage—about 60% of women under 25 are pregnant within 1 year of marriage.[14] In India, it is estimated that there are 70 unintended pregnancies per 1000 women aged 15–49, about half of all pregnancies in the country.[15 16] Rates of unintended pregnancy are much higher among young women, estimated at 67% of all pregnancies in those under 25.[17]

It has long been believed that societal and family pressure to prove childbearing in South Asia is so strong that contraception programmes should focus on delaying the age at marriage or on spacing and stopping practices.[18] Indeed, contraceptive use is virtually non-existent (2%) among currently married nulliparous women, and most use less effective traditional methods such as rhythm or withdrawal.[14 19–21] Use of effective and reversible contraceptives is also low in India in general, with most women adopting sterilisation after two or three births.[22]

While it has been assumed that much of the early childbearing and low family planning use among young, newly married women were desired, recent research from South Asia suggests that there is a high demand for delaying the first childbirth and increasing spacing between two children. National data suggest that younger women in India have high rates of unmet need for family planning, with about 22% of women aged 15–24 having an unmet need (compared with 8% or less in women over 35).[23] A multistate study in India found that 51% of recently married women wanted to postpone the first pregnancy, although only 10% of those wishing to delay were using contraception.[18] Another recent study in India similarly found that while almost half of young married women wanted to delay birth by more than 2 years, few (13%) were using contraception, with their husband's/family members' opposition the primary perceived barrier.[24] Another study on nulliparous newly married women and their households in rural Nepal, in a district adjoining India, found that 67% wanted to wait at least 2 years before having a baby, yet 71% were pregnant or had given birth within 1 year of marriage.[17] Respondents cited factors such as lack of access to and knowledge about contraception leading to low use. However, the primary reason was the (mis)perception of pressure from the family due to lack of communication, as well as women's low status in the household—key factors that could be modifiable by increasing women's empowerment. Importantly, newly married women and their families also expressed a desire for women to gain some vocational and life skills, especially before beginning childbearing. Therefore, empowering recently married women and providing them life skills such as communications can perhaps help them negotiate their family planning objectives and access family planning methods to delay or space pregnancies.

Past evidence shows that women's empowerment is associated with more healthcare seeking, better maternal and child nutrition, higher immunisation rates, longer birth intervals, lower unintended pregnancy, lower fertility overall, increased contraceptive use, and lower stunting and infant mortality in South Asia.[12 25–32] However, women in South Asia, including India, have lower levels of empowerment than women in any other region globally, which is contributing to their poor health outcomes.[25] Young women in India also have less economic empowerment compared with men and older women, including low labour force participation and decision-making power about household purchases or healthcare.[14 23 33] Young, nulliparous, married women in South Asia are particularly disempowered by customs such as eating last, not leaving the house unchaperoned, not speaking in front of household elders and having decisions about their lives made by mothers-in-law or other household members.[34 35] Young women who have not yet given birth, or not yet given birth to a boy, are often not allowed to leave their homes, restricting their ability to seek healthcare. Therefore, increasing young women's empowerment can be critical to improving their health outcomes.

While there is a long history of 'empowerment and life skills' interventions in South Asia, the evidence regarding the impact of such interventions, excluding self-help groups, livelihood and microfinance-related interventions, on family planning and pregnancy outcomes is limited, with mixed results and of low-quality.[36–38] A recent review of life skills interventions on sexual and reproductive health (SRH) noted specifically that few interventions had measured biological (health) outcomes, rather most measured behavioural outcomes.[39] This review also noted the lack of life skills evaluations in Asia with an SRH focus. A few group-based intervention models have been shown to be successful at increasing reproductive and other health knowledge, as well as empowerment, but have not measured pregnancy-related outcomes, especially in newly married women.[40–42] A 2015 systematic review found only eight interventions that focused on young, newly married women, with five conducted in India and two in neighbouring Nepal.[43] However, none of these studies measured the impact on unintended pregnancy, although six studies examined contraceptive usage.

Prior evidence has recognised the role of husbands and mothers-in-law as significant influencers in family planning decision-making and contraception uptake.[7 44–47] Restrictive attitudes of husbands and in-laws against family planning and their pronatal norms against delaying the first pregnancy can prevent uptake of family planning.[48–50] Further, decisions such as

contraception and timing of pregnancy are couple-level choices and cannot be made alone, nor can women be expected to change and fight against entrenched gender norms on their own. Despite this recognition, there remains a notable gap in the literature. While a handful of studies have addressed the involvement of key household members, such as mothers-in-law and husbands, in efforts to enhance contraception uptake and promote women's empowerment,[51–53] such interventions are scarce, particularly in the context of South Asia. This highlights a significant gap in the current research landscape, as more comprehensive approaches involving these influential household members are essential for effectively addressing barriers to family planning and advancing women's reproductive health and empowerment in the region.

Overall, women's empowerment and life skills are potentially promising interventions that can target the root cause of early unintended pregnancies, such as misinformation, misperception and lack of knowledge regarding why and how to plan a family, which methods to use and where to access them. However, current empowerment and life skill interventions have not assessed these outcomes especially in the context of newly married young women, who are most vulnerable to unwanted early pregnancies.

To address this evidence gap, this study will measure the impact of a group-based life skills and reproductive health empowerment intervention for young married women who do not intend to get pregnant in the first year of the marriage on unintended pregnancy and use of modern contraception. The key objectives of this study include the following:

- Objective 1: to quantify the causal impact of the TARANG intervention on the rate of unintended pregnancy and on the likelihood of modern contraceptive use (primary outcomes) over the control group with usual activities.
  - Hypothesis 1.1. Women in the TARANG intervention group will have a lower relative hazard of unintended pregnancy compared with control participants.
  - Hypothesis 1.2. Women in the TARANG intervention will be more likely to use modern contraceptive methods compared with control participants.
- Objective 2: to characterise the mechanisms of impact and assess the effect of TARANG on secondary outcomes, including time to childbirth, desire to avoid pregnancy, SRH empowerment and attitudes towards intimate partner violence (IPV).
  - We will examine if the intervention impacts secondary outcomes as per the expected pathways to impact and explore if intermediate variables such as empowerment mediate the effect of the intervention on the primary outcomes.
  - Hypothesis. We hypothesise that the TARANG intervention will improve above secondary outcomes, and that women with higher impact on mediating intermediate outcomes will have larger impact of TARANG on the primary outcomes.
- Objective 3: to conduct a process evaluation and cost-effectiveness analysis of the TARANG intervention to inform scale-up.
  - We will explore factors leading to success and the barriers to implementation, scale-up, and inform integration within existing community programmes. We will conduct cost-effectiveness analysis to examine the cost per unintended pregnancy avoided and compare across study arms.

## METHODS

The main aim of this study is to evaluate the additive impact of a life skills and reproductive health empowerment intervention (TARANG) compared with usual services (control group) on the rate of unintended pregnancy and rate of modern contraceptive use (primary outcomes). To do this, we will conduct a two-arm, parallel, cluster randomised controlled trial with nulliparous newly married women aged 18–25 years who do not want to get pregnant within 12 months (1 year) from the time of recruitment and who state that they currently are not pregnant. We will recruit their husbands and mothers-in-law for the intervention and the survey because the intervention also seeks to create enabling environment in the marital home.

The control group will receive the usual services in this setting, which include government SRH programmes that provide counselling on contraception, birth planning and spacing, and other SRH issues (sexually transmitted infections) to all women, including newly married couples, through community health workers such as accredited social health activists (ASHAs), auxiliary nurse midwife, Anganwadi workers and linkages to public health facilities. There can also be other social and community-based organisations conducting programmes in the communities under private initiatives. Such public and private standard of care is expected to be available in both arms.

### Study setting

The study will be conducted in Udaipur and Rajsamand districts of Rajasthan, India. The rate of use of any modern contraceptive methods among rural women in Rajasthan is 62% and only 17% among women with no children. Among women aged 20–24, only 34% currently use any modern contraceptive methods. In Rajasthan, the unmet need for contraception is at 8%—highest among those aged 15–19 (19%) and 20–24 (15%)—and these age groups have the lowest per cent of demand satisfied by modern methods (62%, compared with 92% or more for women over age 30).[20] Contraceptive methods are available free of cost through local CHWs (Community Health Workers) and public health facilities, and lack of access is not a primary barrier to use.[20] Knowledge of contraceptive methods among married women is nearly universal,[22] highlighting that empowerment/agency of women might be a probable reason for low contraceptive uptake.

Compared with older women, younger women in Rajasthan are less likely to be part of decision-making about resources, to have freedom of mobility, to seek healthcare and to have access to money, and are less likely to have a bank account or own household assets.[20] 35% of women justified violence from husbands for one or more reasons, including if women disrespected their in-laws, argued with their husbands or neglected the husband or children. Further, 31% of men also justified violence towards their wives, especially if the wife showed disrespect for in-laws or if there is a suspicion that the wife was unfaithful and if she argues with him, highlighting the need to address harmful gender norms and to involve men in interventions to improve gender equality and change attitudes towards IPV.[22]

## TARANG intervention

Our intervention—called TARANG (Transforming Actions for Reaching and Nurturing Gender Equity and Empowerment), which means 'cascading waves' in Hindi—is grounded on the theory of planned behaviour (TPB).[54] The TPB postulates that behaviour is dependent on one's intention to perform the behaviour. Intention is determined by an individual's attitudes (such as gender attitudes and attitudes towards IPV) and subjective norms (beliefs about what others think the person should do, or general social pressure such as gender and social norms). Behaviours are then determined by an individual's perceived behavioural control, defined by their self-efficacy, to perform those behaviours as hypothesised in our conceptual model (figure 1). TARANG seeks to provide newly married women the knowledge, skills, agency and self-efficacy to improve their contraceptive usage and avoid unintended pregnancy.

Recognising that the decision to use family planning or challenge existing restrictive gender norms cannot be accomplished by women alone, the TARANG intervention also seeks to intervene on husbands and mothers-in-law of the women to create a supportive and enabling environment for the women within the families.

TARANG will be implemented by our non-governmental organisation (NGO) partner Vikalp Sansthan. Vikalp Sansthan is a registered non-profit women's organisation dedicated to promoting women's rights with a feminist approach in Rajasthan.

The TARANG intervention for newly married women will include 14 group sessions (2 rapport-building sessions and 12 content sessions) covering three overarching themes (online supplemental appendix 1). Each group session will be facilitated by female trained moderators from Vikalp following a structured curriculum providing detailed guidance for each lesson. Sessions will be participatory and interactive, and include information, small group activities, group discussions and take-home assignments to practise the skills. The sessions are expected to be delivered over a period of 5–6 months such that two to four sessions will be conducted every month depending on the availability and convenience of the study participants. It is expected that using life skills such as decision-making, spousal communication, healthy relationships with in-laws and negotiation skills, newly married women will be better equipped to deal with navigating newly formed relationships with their husband and in-laws in their marital household.

Recognising that the decision to use family planning or the ability to challenge existing gender norms cannot be accomplished by the woman alone, TARANG will also include light-touch sensitisation sessions for the mothers-in-law and husbands. As mentioned previously, these sessions are designed to encourage support and an enabling environment at home for the newly married women participants, but also to help mothers-in-law and husbands with their own health information, better

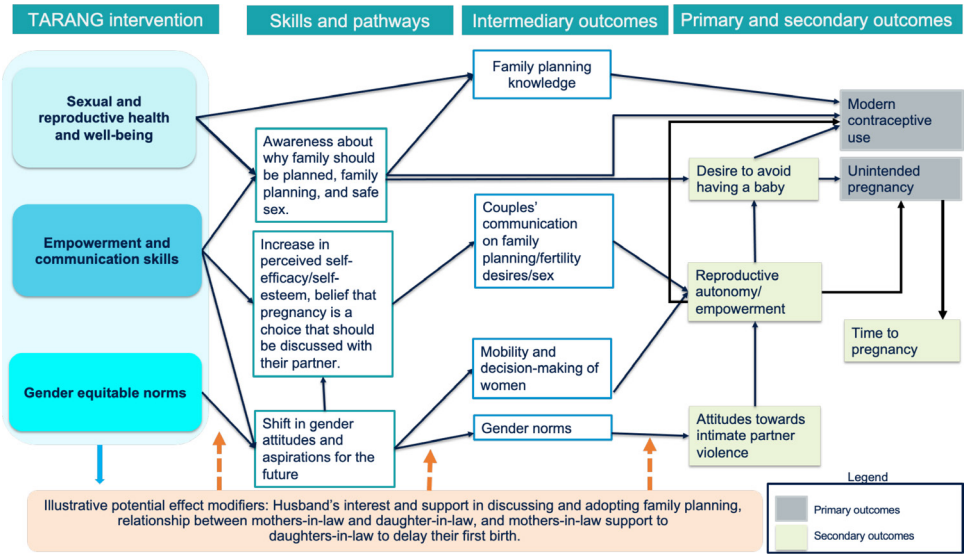


**Figure 1** Conceptual model for the TARANG intervention to avoid unintended pregnancies in young married women. TARANG, Transforming Actions for Reaching and Nurturing Gender Equity and Empowerment.

awareness about gender norms and navigating relationships with newly married women.

For mothers-in-law, TARANG will include a total of four sessions, including one rapport-building session and three group content sessions to be conducted by a female moderator over 1–2 months as per the convenience of the group participants in each intervention village.

For husbands, TARANG will include one 2-hour group session within the first month of the intervention, followed by regular and moderated content delivery in the form of videos and take-home exercises over WhatsApp groups of husbands on topics complementary to the women's sessions (online supplemental appendix 2).

## Impact estimation strategy

### Randomisation

A cluster randomised design will be used since participants will receive the intervention in a group format and to avoid spillover effects. We will randomise a total of 40 villages into the intervention arm (TARANG) and 40 villages into the control arm. We will test the impact of the TARANG intervention in 80 villages (40 intervention and 40 control villages) with intention-to-treat estimator. The study will be implemented in two phases, each consisting of 40 villages (20 treatment and 20 control) and separated in time by 12 months for operational reasons. In each phase, the randomisation procedure (1:1 ratio) will be carried out using a random number generator in Stata V.15[55] with a reproducible seed. The Vikalp team will be blind to the allocation status at the time of assessing suitability of a village for the study and then during listing and identification of the study participants. Randomisation will be revealed to the Vikalp team only after the baseline survey is completed. Survey teams responsible for identifying, obtaining consent and recruiting trial participants will be also blind to the allocation status. This will help minimise postrandomisation recruitment bias.

### Impact parameters

The primary impact parameter will be intention-to-treat HR for pregnancy and relative risk for current contraceptive use. We will also estimate the local average treatment effect (LATE) on those with strong participation in the intervention as a treatment on the treated parameter.

### Participant eligibility criteria

The eligibility criteria for the newly married women and their justification are summarised in table 1.

The husband and mother-in-law of the recruited woman will also be study participants because (1) they will be invited to participate in TARANG sessions designed for husbands and mothers-in-law; and (2) baseline and two follow-up surveys will be conducted with them to collect data on factors that can be used in the analysis as effect modifiers or covariates for subgroup analysis. All husbands and mothers-in-law related to eligible women will be eligible to participate, assuming they are 18 years old.

### Recruitment of study participants

#### *Identification and randomisation of study villages*

40 villages in each phase will be selected based on the following criteria: (1) adequate population size and (2) practical viability of the programme implementation. First, the largest 40 villages as per 2011 Census population will be identified, and a rapid viability assessment of these villages will be done by Vikalp. Some of the selected villages may not be viable for the intervention due to reasons such as poor possibility of finding adequate number of eligible newly married women, caste discrimination issues preventing the formation of groups of young women, absence of ASHA, difficult/unsafe terrain that can hamper regular attendance of women at TARANG intervention sessions and safety concerns for the study team. If any village is not found viable, it will be replaced with the next village from the population-ordered list of villages, and the process will be continued until 40 villages are finalised for phase 1. The 40 finalised villages will then be randomised into a treatment or a control arm. The same process will be followed in phase 2 selection of villages after 12 months.

In each selected village, the implementing NGO will list all households where a newly married woman has started cohabitation since the start of the most recent marriage season (October of each year) and the household is willing to let her participate in TARANG group sessions. If a household has a newly married woman who has moved in the recent wedding season and of age 18–25 years, then the listing team will collect more detailed information to determine 'potential' eligibility as per the criteria listed in table 1. Note that women who are not eligible but want to attend TARANG sessions will be allowed to do so, but no data shall be collected from them except basic socioeconomic and eligibility-related questions at baseline. During the listing phase, the description of the TARANG intervention provided by Vikalp will be the same in both treatment and control villages since Vikalp will be blind to the assignment at the time of listing. The script to be used by Vikalp during the listing will clarify that the TARANG intervention may not be implemented in their village immediately and that it could take up to 2.5 years for the programme to reach the village.

Within a week of listing the households, the survey team (from NEERMAN) will visit all potentially eligible households, administer consent, and if consented administer a screening module consisting of basic socioeconomic and demographic questions and following set of eligibility questions: (1) pregnancy status (self-reported yes/no), (2) sterilisation status (self-reported yes/no), (3) intention to migrate during the intervention delivery period in the next 6 months (self-reported yes/no), (4) confirm all the information captured during the listing and (5) pregnancy intention (self-reported response to pregnancy intention question with response options of: (a) 'Not in one year', (b) 'Right away', (c) 'Don't know' or (d) 'When god wants'. If a woman is pregnant, sterilised or wants to get pregnant 'right away', or if it has been

Table 1 Inclusion criteria for recently married women

| Women | |
|---|---|
| Self-reported age ≥18 and <25 years at the time of recruitment. | This age range was selected because 18 is the legal age of consent and marriage for women in India and sterilisation rates increase rapidly after age 25.[14] |
| Married women have permanently moved in their husband's home in the most recent wedding season (recruitment month going backwards up to October of the previous year). | Wedding and moving to the husband's house can be two different events in this setting. There is a cultural practice called 'gauna', where women sometimes are married (only ritually but the marriage is not consummated immediately) and they do not move into their husband's home for months or even years. Sometimes, even after the wedding, a woman moves only at an auspicious time after several weeks. More than two-thirds of pregnancies occur in the first year of cohabiting.[18] Therefore, women need to be recruited as soon as possible after the initiation of cohabitation so that the intervention has an opportunity to make a difference. Considering the practicality of finding adequate number of women, this criterion was set. |
| Not wanting to get pregnant within 1 year from recruitment/enrolment. | Since our goal is to enable women from avoiding unintended pregnancy, we will include women who do not want to have a baby within the next 12 months (1 year) from the time of enrolment. |
| Have not had a live birth previously and not currently pregnant. | After delivering their first child, women experience less societal pressure to prove their fertility, and counselling on family planning options often begins during pregnancy and after delivery. Consequently, this group of women who have never given birth and not currently pregnant is particularly vulnerable to unintended pregnancies. |
| Women not planning to migrate out of the area for the period of the intervention. | To reduce attrition because the intervention is being delivered over a period of approximately 6 months. |
| Has a living husband who is willing to consent and participate in the study in person or remotely (over phone). | As explained previously, engaging husbands as enablers and stakeholders in family planning. |
| Has a living, coresiding mother-in-law type of person* who is willing to consent and participate in the study in person. | Mothers-in-law are expected to be coresiding in the same household as the women through the intervention period. |

*A mother-in-law type of person should be staying in the same household for the period of the intervention and has consented to participate in the study. Mother-in-law is defined as any senior woman (from a previous generation of the daughter-in-law) who is responsible for their daughter-in-law and cohabiting in the same household as their daughter-in-law (note: household would mean a family unit that shares the same kitchen). This will usually be the biological mother of the husband, but it can be the stepmother, grandmother, aunt, etc.

more than 8 months since her cohabitation at the time of enrolment, or if she plans to migrate during the intervention, she will not be enrolled. The final recruitment of the household by survey team will occur when the eligible woman, her husband and her mother-in-law all privately consent to participate in the study.

After enrolment, trained gender-matched enumerators from NEERMAN will administer a detailed baseline survey to all three participants (woman, mother-in-law and husband). The baseline surveys for all study participants will cover the following broad topic areas: sociodemographic characteristics, knowledge about family planning and reproductive health, social/gender norms related to family planning/gender, norms related to IPV, fertility preferences, intentions related to having a family, use of contraceptives, communication with partners, sexual behaviour and future aspirations. The midline and endline surveys will ask similar questions to assess changes in these constructs over the 6-month and 18-month study period, respectively (figure 2). If the husband is a migrant worker and/or is travelling and not in the village, then a shorter telephonic survey will be administered by a gender-matched enumerator from NEERMAN. Baseline and follow-up surveys will be captured electronically using computer-assisted personal interviews (CAPI) on ODK, a secure and user-friendly survey software platform. Quantitative surveys will be first drafted in English, then professionally translated and back-translated to and from Hindi for CAPI programming. In addition, intervention monitoring data will be collected from Vikalp. All data will be remotely uploaded to a secure data server in India with de-identified data accessible to the core research team in India and the USA. All files will be compliant with good clinical practices (including a date and time stamp of original data entry and with an audit trail to document any subsequent changes).

## Blinding

The implementing NGO will be blinded to the treatment assignment at the time of assessment of suitability of a village for the study and then during listing and identification of the study participants. The treatment assignment

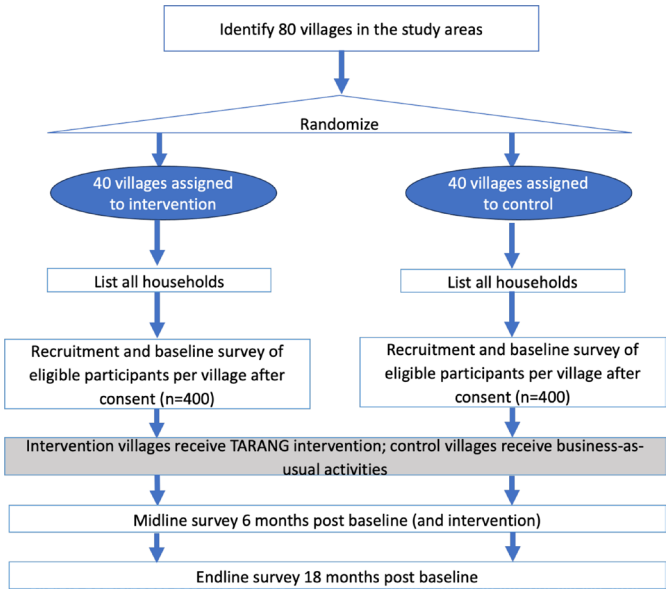


**Figure 2** Flow of participants in the intervention and control arms. TARANG, Transforming Actions for Reaching and Nurturing Gender Equity and Empowerment.

will be disclosed only after the baseline survey. Owing to the nature of the intervention, the study participants, the implementing NGOs, the survey staff and the researchers cannot be blinded to the treatment status after the baseline survey because they can learn the status of the intervention during the routine study procedures anyway.

### Retention plan and potential for attrition

The assent of heads of selected households and enlisting husbands and mothers-in-law as study participant are the key strategies to ensure their continued support for the newly married women. Our survey procedures will allow for phone surveys if the respondent is not available for inperson follow-up surveys.

### Potential contamination of the control with similar interventions

Other NGOs that provide a wide range of SRH services are active in the study setting. While none of them currently provides group-based reproductive health empowerment intervention to women or specifically target young married women, we cannot preclude the possibility of other interventions being implemented in the control group.

### Sample size/power calculations

We expect to recruit 800 households (~400 in each arm) into the study. We anticipate 70% retention accounting for attrition from the intervention and from the follow-up survey by 18 months, providing 560 participants for primary analyses. We used NCSS PASS V.20[56] to compute the minimum detectable effect sizes for the primary outcomes. Assuming a power of 0.80, intracluster correlation coefficients (ICC) ranging from 0.01 to 0.10, an overall event (pregnancy) rate of 67% and a multiple correlation of 0.30 among covariates in multivariable Cox proportional hazard models, the minimum detectable adjusted HR for the primary outcome of pregnancy ranges from 0.68 to 0.73. These minimum detectable adjusted HRs are between small and medium effect size thresholds,[57 58] which we should expect from an intensive intervention such as TARANG.

For the outcome of contraceptive use, data will include month-by-month usage of modern contraception; these data will be modelled as repeated measures of month within person. The study sample would have 0.80 power to detect a relative risk of 1.35–1.87 between intervention and control, assuming a control group level of 17% (0.17) across the range of ICC as above and within-person correlations among repeated observations from 0.30 to 0.70.

### Measurement of outcomes

#### Primary outcomes

##### *Rate of unintended pregnancy*

Data for analysis consist of time 'at risk'—active in the study and not known to be pregnant already—and the binary outcome of 'unintended' pregnancy. The binary outcome of pregnancy will be as per self-reported answers on the Demographic Health Survey-style monthly calendar on whether the woman was pregnant at any time during the month and whether the pregnancy was planned/wanted. Since eligibility is based on participants stating that they wanted to wait at least a year to get pregnant, that it was 'up to god' or they did not know, our primary outcome will assume that all pregnancies were unintended. We will do additional sensitivity analyses with a second definition of 'unintended pregnancy', where we allow intention to change over time, so only pregnancies where respondents said they wanted to delay in the prior round will be counted as unintended.

##### *Modern contraceptive use*

This will be calculated at the endline (18 months post-survey) based on women's self-reported data through a detailed set of questions modelled on the Demographic Health Survey's contraceptive calendar question. For each month of the study/follow-up period, women will be asked whether they used any contraceptive method, and if yes which type(s). A binary indicator of modern contraceptive use by month will be constructed. Modern contraceptive methods will include copper-T (intrauterine device), injectables (Antara), emergency contraception, contraceptive pills, male and female condoms, male and female sterilisation, lactational amenorrhoea method, foam/jelly, diaphragm, and standard-days method, as defined by the Demographic Health Survey in India.[22] Person-months during pregnancy and immediate post partum will be censored for this analysis.

#### Secondary outcomes

##### *Desire to avoid pregnancy*

This is an indicator that measures the intensity of the desire to avoid childbirth immediately. This is measured

using the Desire to Avoid Pregnancy scale,[59] a nine-item scale that measures self-assessed preferences for having a baby and on thoughts and feelings about the idea of having a baby in the next 1 year, which has been adapted to our population and context. The items include the following:

1. You want to have a baby in the next year.
2. If you had a baby in the next year, it would be bad for your life.
3. It would be a positive addition to your life to have a baby in the next year.
4. It would be the end of the world for you to have a baby in the next year.
5. Thinking about having a baby within the next year makes you smile.
6. Thinking about having a baby within the next year makes you feel stressed out.
7. You would feel a loss of freedom if you had a baby in the next year.
8. If you had a baby in the next year, it would be hard for you to manage raising the child.
9. You would worry that having a baby in the next year would make it harder for you to achieve other things in my life.

Each item is scored from 0 to 4, with higher scores indicating greater preference to avoid pregnancy/childbirth.

### *Individual attitudes towards IPV*

This is a seven-item index that measures attitudes towards IPV against women.[60] This is measured using the question 'In your opinion, is a husband justified in hitting or beating his wife in the following situations', with responses noted as either yes or no.

1. If she goes out without telling him?
2. If she neglects the house or the children?
3. If she argues with him?
4. If she refuses to have sex with him?
5. If she doesn't cook food properly?
6. If he suspects her of being unfaithful?
7. If she shows disrespect for in-laws?

To construct the index, items are summed to create a score ranging from 0 to 7.

### *Reproductive autonomy/empowerment*

This indicator will be measured using the Women's and Girls' Sexual and Reproductive Health Empowerment Index.[61] This SRH index was adapted to have 26 relevant items for existence of choice (autonomy) subscales and exercise of choice (self-efficacy, decision-making, negotiation) subscales. Few example items include the following: you can decide when to get pregnant; you can decide to have a gap between pregnancies (such as time between your first and second child); if you refuse sex with your husband, he will be upset with you, etc.

To construct the index, summary scores for each domain and outcome are computed by averaging the scores for relevant items. Three outcome-specific empowerment scores (sexual empowerment, contraceptive empowerment and pregnancy empowerment) can be computed by adding the relevant summary scores for the existence of choice and exercise of choice domains. Finally, to examine the contribution of empowerment across the three SRH dimensions, a multidimensional SRH additive index comprising all items included in the three empowerment subscales will be computed.

### *Time to pregnancy*

This will be calculated as time elapsed in months between the date of study enrolment and the date of last missed period constructed ono basis of documentary records or recall. We will construct this indicator for intended/unintended, terminated/aborted and full-term pregnancies as reported by the woman.

Other measures are included in table 2.

## Statistical analyses

The quantitative analysis will be done using Stata V.15 following the Consolidated Standards of Reporting Trials guidelines for cluster randomised trials. Descriptive statistics will characterise the sample. Balance by intervention group will be assessed; if the groups differ significantly, we will use causal inference methods to obtain estimates under the counterfactual assumption of balanced groups.[62–66] We will address incomplete data via direct maximum likelihood estimation or multiple imputation.[67 68]

The main analysis will include all observed data through the second follow-up, but sensitivity analysis will focus on the 6 months of the TARANG intervention. Type I error or alpha ($\alpha$) will be set at 0.05 with two-sided test for all analyses. We will cluster by community and specify robust SE.

We will analyse the impact on the primary outcomes as follows:

- Rate of unintended pregnancy (survival analysis). We hypothesise that nulliparous women assigned to TARANG (arm 1) will have a lower relative hazard of a pregnancy compared with control participants (arm 2). We will generate Kaplan-Meier curves for the pregnancy outcome to describe the unadjusted survival function. We will then fit Cox proportional hazard regression models comparing the TARANG intervention (arm 1) versus control (arm 2) to test the hypothesis.
- Modern contraceptive use. We hypothesise that women assigned to TARANG (arm 1) will have higher contraceptive use than the control group (arm 2). We will employ log-linear mixed models with a random effect per person to estimate the relative risk of contraceptive use between intervention and control arms.

For both primary outcomes, baseline individual-level (eg, age, education, work status, caste, religion, time since marriage) and community-level (eg, community size) covariates will also be included to maximise statistical efficiency. We will estimate the LATE using instrumental variable analysis by quantifying intervention participation

Table 2 Other measures in the analysis

| | Description and source |
|---|---|
| Domains | |
| Knowledge | Knowledge of contraceptive methods, source, side effects, myths and health-seeking, validated in the NFHS. |
| | Knowledge about pregnancy, nutrition, maternal and child health, and women's health (anaemia, menstruation, fertility, etc), validated in India. |
| Fertility preference | Preference for ideal family size, number of children and timing of children. |
| Aspirations | Questions on aspirations for higher education, employment and hope. |
| Couples' communication | Couples' communication about sex scale. |
| Women's household decision-making | Household decision-making questions, validated in the NFHS. |
| Self-efficacy, self-esteem | Generalised Self-Efficacy Scale and Rosenberg's Self-Esteem Scale. |
| Mobility and control | Questions about women's freedom of movement and independence, previously used in India. |
| Gender norms | Questions about son preference and the GNORM Scale. |
| Intimate partner violence | Physical, sexual, emotional and financial intimate partner violence, validated in India. |
| Maternal, newborn and child health outcomes | Pregnancy outcome and neonatal health outcomes (self-reported birth weight, gestational age and infant death), pregnancy and delivery complications, and breast feeding, validated in the NFHS. |
| Mental health | PHQ-9, a validated scale for women in many settings. |
| Sociodemographics | Age, education, household wealth, household structure, caste and religion. Socioeconomic information about the husband and the head of the household, validated in the NFHS. |
| Cost-effectiveness | |
| Intervention financial costs: Vikalp Sansthan | Per capita budget allocated to Vikalp Sansthan inclusive of administrative overheads (excludes profit as Vikalp is an NGO). |
| Private financial costs: households | Expenditure on purchase of family planning methods.<br>Expenditure on travel to obtain family planning methods.<br>Travel expenditure on attending TARANG session (if any). |
| Private opportunity costs: households | Economic value of time invested in accessing family planning methods.<br>Economic value time invested in attending and travelling to TARANG sessions, home visits by community health workers and attending events/sessions by the government or other organisations. |

Gender-Norm Scale (G-NORM); PATIENT HEALTH QUESTIONNAIRE (PHQ-9)
NFHS, National Family Health Survey; NGO, non-governmental organisation; TARANG, Transforming Actions for Reaching and Nurturing Gender Equity and Empowerment.

as the proportion of TARANG group sessions attended or by binary variable of whether the minimum required number of sessions are attended.

We will also do a sensitivity analysis where we only include women who explicitly stated that they wanted to delay, excluding women who stated 'up to god' and 'don't know' in their response to the intention question. We expect the effect to be stronger among women who were more certain in their desire to delay pregnancy for 12 months. Exploratory analyses will assess whether the secondary outcomes at husband and/or mother-in-law levels or other covariates moderate the effect of TARANG on the rate of unintended pregnancy and modern contraceptive use by including interaction terms between intervention assignment and the potential effect modifiers. Additional exploratory analyses will investigate the impact of TARANG on secondary outcomes.

## Data monitoring plan

Adverse events will be defined as self-reported IPV resulting from participation in the study. Each week, intervention moderators will fill out a computer programmed monitoring form with attendance, participation, etc. Within the weekly monitoring form, we will include the following question:

> If anyone in this group has faced any trouble in attending TARANG session or faced any physical harm or mental trouble because you attend TARANG sessions or because you have tried to use some skills or knowledge you have gained in these sessions, then

please let me know. If you do not want to speak up in this group, you can always contact me over phone or some other time.

Within the response for each participant, the moderator will fill out the following question: 'Did [–NAME–] report any physical harm or mental trouble that was associated to TARANG?' If yes, select all that apply (IPV options and some others). Data will be constantly monitored by the study team and the principal investigator (PI).

Adverse events will be tracked, referred and followed up. An adverse event form will be used to record each incident, actions taken, supervisor notes and follow-up steps.

## Other research components

### Qualitative assessment

We will conduct indepth longitudinal qualitative interviews (LQIs) with purposively sampled women who participated in the intervention, their husbands and mothers-in-law (intact triads) using a grounded theory approach.[69] LQIs will be used to understand mechanisms for intervention impacts as well as to document challenges for participants in attending the intervention sessions. We aim to interview roughly 10 intact triads (n=30) at three timepoints in the first phase of the roll-out of the study: before the start of the intervention, 6 months postintervention and at 18-month follow-up (1 year postintervention). LQIs will be conducted in local language (Hindi or Mewadi) per the convenience of the participant. All interviews will be audio-recorded, transcribed and translated into English. Additionally, we will also interview all Vikalp moderators to understand their feedback on intervention delivery and acceptability of the intervention content. The data analysis will be conducted using Dedoose by a team consisting of trained researchers.[70] We will use a grounded theory approach to analyse these data.[69]

### Process evaluation

We will conduct a process evaluation to understand the degree to which essential elements were delivered (implementation fidelity) and to understand the barriers and facilitators for potential scale-up of the TARANG intervention. We will first develop a monitoring app on ODK to help the Vikalp team enter routine data throughout the 6 months of intervention delivery on implementation outcomes, such as the total number of intervention sessions planned and delivered, participants attending each session, feedback forms from moderators on each session, facility in which the session was conducted, time taken for each session, dropouts, etc. Data will be entered in this app after each intervention session delivery by Vikalp moderators and other external observers who may visit the sessions for monitoring. Periodic observation of TARANG sessions by a senior person from Vikalp and provision of immediate feedback to moderators will also be part of the monitoring and process evaluation. Periodic debrief sessions will also be conducted with moderators, involving the Vikalp team and research team. These sessions aim to discuss challenging situations and identify ways to address issues that may arise during programme implementation. These process evaluation and monitoring data will be analysed periodically to identify gaps in the implementation. We will also triangulate information from the surveys, longitudinal qualitative data of Vikalp moderators and process evaluation to understand barriers and facilitators for participants to attend such sessions and to plan future scale-up of the intervention. This longitudinal, multistakeholder analysis combined with quantitative data will provide more insight into what worked and how and if that changed over time.

### Cost-effectiveness

If TARANG demonstrates effectiveness in accordance with our hypotheses, we will conduct a cost-effectiveness analysis. An Indian co-PI and a health economist (SRP) will oversee this aspect of the study. We will collect the costs of the intervention prospectively, including capital costs (rent) and recurrent inputs (eg, salary of moderators, training, etc). We will evaluate the relative cost-effectiveness of the TARANG intervention compared with usual services provided; we will also compare it with available data on other interventions aimed to reduce unintended pregnancy in this setting. Our cost-effectiveness assessment will have three major components: intervention cost, health effects and the cost-effectiveness ratio. Costs to be considered are summarised in table 3.

Next, we will quantify effectiveness for key outcomes of interest. These outcomes can include (but not limited to) the number of unintended pregnancies averted, increase in proportion of women whose contraceptive needs are met, change in number of women exceeding a critical value in the indices for empowerment, relationship quality and IPV. These outcomes will be those which are used in other published research to enable comparison of cost-effectiveness estimates. The cost-effectiveness ratios will be estimated in terms of money required to achieve a unit of change in the outcome of interest. These ratios will be estimated from the perspectives of the following:

- Only household financial.
- Only intervention financial cost.
- Household financial+intervention financial.
- Full economic cost=household financial+intervention financial+household opportunity costs.

Uncertainty ranges will be computed using standard Monte Carlo methods for full probabilistic sensitivity analysis for assumptions. Finally, we will also conduct a hypothetical cost estimation for a scale-up in non-research setting to 1000 villages by assuming scale of economies in reducing the cost of the intervention, but also reduced effectiveness. This analysis will be based on similar assessments of other interventions in low-income and middle-income countries.

## Ethics and dissemination

This study has received ethical approval from the University of California, San Francisco, and the Institutional

**Table 3** Schedule of enrolment and assessments according to the Standard Protocol Items: Recommendations for Interventional Trials

| | Study period | | | | | |
|---|---|---|---|---|---|---|
| | Pre-enrolment | Enrolment and baseline | Allocation | Postallocation | | |
| | $t_{-1}$ | $t_0$ | | $t_1$ | $t_2$ | $t_3$ |
| Timepoint | ~2 weeks prior to the enrolment | Month 0 and baseline survey | Allocation | Start of intervention (month 1) | Postcompletion of intervention: midline at end of month 7 | Endline survey at end of month 18 |
| Enrolment | | | | | | |
| Listing all households | X | | | | | |
| Permission from the head of the household | X | | | | | |
| Informed consent/screen for final recruitment of eligible women into the study | | X | | X | | |
| Randomisation (immediately after baseline survey) | | | X | | | |
| Interventions | | | | | | |
| TARANG villages | | | | ← | → | |
| Control villages | | | | ← | → | |
| Assessments§ | | | | | | |
| Basic sociodemographic variables* | X | | | | | |
| Screener questions† | | X | | | | |
| Comprehensive sociodemographic variables‡ | | X | | | X | X |
| Self-report pregnancy status (last menstrual period and/or estimated due date) | | X | | | X | X |
| Knowledge of contraceptive methods | | X | | | X | X |
| Fertility preferences and decision-making | | X | | | X | X |
| Use of contraceptive methods using the calendar approach | | X | | | X | X |
| Women's empowerment measures (freedom of movement) | | X | | | X | X |
| Relationship quality with spouse and mother-in-law | | X | | | X | X |
| Beliefs and gender/social norms | | X | | | X | X |
| Anxiety and depression | | X | | | X | X |
| Time use | | X | | | X | X |
| Process evaluation | | ← | | | → | |
| Intervention financial costs: Vikalp Sansthan | | X | | | X | X |
| Private financial costs: households | | X | | | | X |
| Private opportunity costs: households | | X | | | | X |

*Basic sociodemographic variables such as number of participants, husband's occupation, woman's duration of stay in the marital household and presence of mother-in-law (or equivalent senior person).
†Screener questions include age of the participant, husband's occupation, presence of mother-in-law, wedding date, date she moved into marital household and intention to get pregnant (immediately want to have a child or not).
‡Detailed sociodemographic variables such as age, education, household wealth, household structure, caste, religion and economic/occupation of the husband.
§Assessments on mother-in-law and husbands will be shorter surveys composed of similar questions.
TARANG, Transforming Actions for Reaching and Nurturing Gender Equity and Empowerment.

Review Board (IRB) at the Centre for Media Studies, New Delhi (IRB00006230). It has received clinical trials approval from both India and the USA (ClinicalTrials.gov NCT06024616; submission date: 28 August 2023). It has received Health Ministry Screening Committee approval from the Department of Health Research under the Ministry of Health and Family Welfare, Government of India. Results will be disseminated in international peer-reviewed journals and conferences, to stakeholders including local government and NGOs,

and directly to the communities and individuals that participated in the intervention, through a series of village-level workshops. The focal community will also be involved in planning the dissemination process.

All PIs and coinvestigators have up-to-date ethical training certifications (or similar incountry relevant trainings), which will remain up-to-date throughout the study.

Main enforcement of ethics will be through consent and ensuring data security and privacy.

At the time of listing, Vikalp Sansthan will seek permission of the head of the household or other responsible elders to the women's participation in TARANG sessions and potential participation in three rounds of the survey to be conducted by an external survey team. The consent for study participation will be administered by the external survey team to the women, husbands and mothers-in-law before collecting data from them. Consent will also be administered before each of the follow-up surveys. Given widespread illiteracy and fear of signing documents, the consent will be administered electronically by audio-recording the verbal consent on tablets used for administering the questionnaires. A paper copy of the consent form will be offered to the participant with contacts of the study team, local and US PI, and IRBs. The consent and surveys will be carried out by NEERMAN research staff who have previous experience collecting survey data. All enumerators will receive training in ethics and questionnaires prior to each round of data collection.

The data protection as per the ethics guidelines and the Information Technology Act of India shall be followed. All data will be collected, transmitted and stored with electronic encryption, stored in the servers in India, and de-identified by the data processing team before sharing with the research team. Only de-identified and anonymised data will be shared with international researchers.

After the completion of the second follow-up survey, Vikalp will implement similar intervention such as TARANG in the control group villages. The recruited women for the survey will be at least 2 years into their marriage and thus not eligible for an intervention exactly like TARANG, which is for newly married, nulliparous women. However, most of the sessions are still relevant to the recruited study participants and other women like them in the control villages. The study will fund such programmatic activities in the control villages through Vikalp Sansthan.

### Patient and public involvement

This programme was based on programming by a local NGO, and then adapted with them, in partnership with another local NGO (also based in Rajasthan) that focused on educational content for women's empowerment, and the research team. The design process included a formative phase with qualitative and quantitative feedback from participants (newly married women, their husbands and mothers-in-law) and other community stakeholders.

### Study implementation timeline

The study will be conducted in two phases, 1 year apart, with 40 villages recruited in each phase. An overview of the enrolment and assessment procedure is shown in table 3.

Timepoint $t_{-1}$ corresponds to the time the Vikalp team will visit and the listing of each household as explained previously. At this time, they will collect basic sociodemographic variables from all households. At timepoint $t_0$, the research team led by NEERMAN will visit the eligible listed households, ascertain final eligibility and administer consent to each household member individually (privately) followed by baseline surveys. Following this, randomisation sequence generation and allocation will be conducted. Following the baseline survey, at timepoint $t_1$, intervention villages will initiate the intervention sessions. Timepoint $t_2$ corresponds to the midline survey roughly at the end of 6 months after the completion of intervention delivery and baseline survey; at this time, all variables will be measured on all participants—inperson survey with women and mothers-in-law, and phone surveys with husbands. Timepoint $t_3$ corresponds to the endline surveys and 18 months after timepoint $t_1$, at which point all variables will be measured. After timepoint $t_3$, the intervention will be rolled out to waitlist control villages. Following this, for the next phase of 40 villages, the same schedule of enrolment, interventions and assessments will be carried out.

## DISCUSSION

This study uses a cluster randomised controlled study design to rigorously test the effectiveness of a multifaceted life skills and reproductive health empowerment intervention on women's health outcomes, specifically women's ability to avoid an unintended pregnancy. Few of the existing evaluations of life skills or reproductive health empowerment interventions have been randomised controlled trials and most have had a limited focus on economic or empowerment outcomes, with less rigorous research on the impact on health outcomes, like avoiding unintended pregnancy.[39] The impact on health is especially challenging to ascertain in non-randomised research designs because of secular changes that often occur in these populations independent of the interventions. Furthermore, existing life skills and empowerment interventions have almost exclusively focused on unmarried adolescents; young, newly married women have been neglected despite low status, high need and a desire for these resources.[71 72] For example, a life skills programme in Rajasthan, India (PAnKH, or Promoting Adolescent Engagement, Knowledge and Health) that focused on adolescents but also tried to reach newly married women stated in its executive report that it was 'remarkably unsuccessful at reaching married girls'.[72]

In this study, we will rigorously test the effectiveness and provide evidence for scale-up of a life skills and health empowerment intervention on avoiding an unintended

pregnancy. Most evaluations of life skills or economic empowerment interventions, including those that layer on health, do not actually measure the impact on health outcomes. Avoiding unintended pregnancy has not been studied. If shown to be successful at helping women achieve their desired timing of pregnancy, this community-driven and developed intervention, with locally demonstrated feasibility and acceptability, has high potential for broader acceptance, impact and sustainability in this and other low-resource contexts. This model could easily be integrated into existing programmes, such as self-help groups.

We will measure the impact of this intervention among young, recently married women, which has important implications for maternal and child health, as well as women's long-term empowerment-related outcomes. Young, newly married women have been forgotten in most public health interventions, and we are extending research to this understudied population with critical needs. Intervening with young married women may also represent a unique opportunity where targeted empowerment interventions could have relatively large pay-offs both in terms of health as well as longer-term empowerment and opportunity. This study will provide evidence for a community-developed model to improve women's health and life skills-related empowerment. It also presents evidence for an approach to reduce rates of unintended pregnancy.

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**Funding** This study is funded by a grant from the National Institutes of Health (1R01HD108252-01) to the University of California, San Francisco (PI: ND-S).

**Disclaimer** The funder reviewed and approved the design of this study but will not have any role during its execution, analyses, interpretation of the data or decision to submit the results.

**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

**Patient consent for publication** Not required.

**Provenance and peer review** Not commissioned; peer reviewed for ethical and funding approval prior to submission.



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